

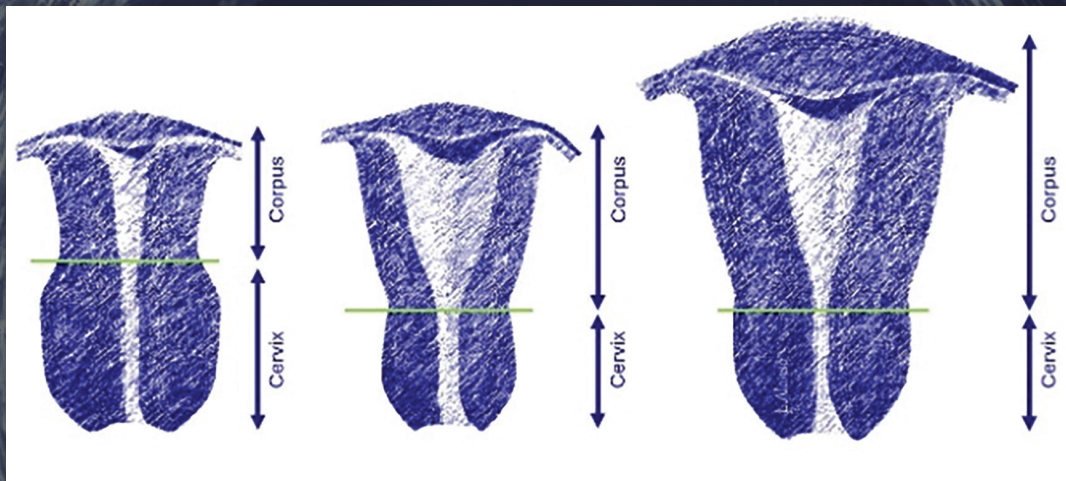
ISSN (PRINT): 2032-0418 ISSN (ELECTRONIC): 2684-4230

# FACTS, VIEWS & VISION

Journal of the European Society for Gynaecological Endoscopy (ESGE)

VOLUME: 17 | ISSUE: 1 | MARCH 2025

in ObGyn



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Facts, Views and Vision in ObGyn is indexed in the PubMed, PMC, Emerging Sources Citation Index and CNKI.

The journal is published online.

**Owner:** The European Society for Gynaecological Endoscopy

**Responsible Manager:** T. Justin Clark

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## In memoriam: Giovanni Scambia (1959-2025)

***Fagotti A, on behalf of the Gynecologic Oncology Unit at Policlinico Gemelli and his many mentees spread throughout the world\****

It is with huge sorrow that we announce that Professor Giovanni Scambia passed away on February 20<sup>th</sup>, 2025, leaving an indelible mark on the global gynaecological endoscopy and gynaecological oncology communities. He was the head of the Gynecologic Oncology Unit at Policlinico Agostino Gemelli IRCCS in Rome. He played a pivotal role in the institution becoming a recognised “scientific hospital” by the Italian Ministry of Health and subsequently served as the scientific director of the hospital. Professor Scambia was President of the European Society for Gynaecological Endoscopy (ESGE) from 2020-2022 and became the Chair of the ESGE Board of Directors. He was also the past president of the Italian Society of Obstetrics and Gynecology (SIGO). Professor Scambia's other notable contributions to women's health include being one of the funders of the Multicenter Italian Trials in Ovarian Cancer and Gynaecological Malignancies (MITO) cooperative group of the European Network of Gynaecological Oncological Trials (ENGOT), and a consultant for the Superior Health Institute in Italy. With over 2,000 peer-reviewed articles in the most prestigious scientific journals, his contribution to scientific advancements in gynaecological oncology, endoscopy and wider gynaecological practice, was immense.

Professor Scambia devoted his life to treating patients with gynaecological cancers and benign

gynaecological conditions, while also tirelessly training and mentoring the next generation of specialists. His presence in the operating room, research laboratory, not to mention countless early morning or late-night meetings was a model of dedication and excellence. His door was always open, and his words of encouragement brightened the lives of many.

A gifted surgeon, compassionate healer, and visionary leader, Professor Scambia set the standard for excellence in patient care, modernisation, and advancing research. With his vision, he was able to predict and anticipate the future of science, pushing innovations such as artificial intelligence and translational research in gynaecological oncology.

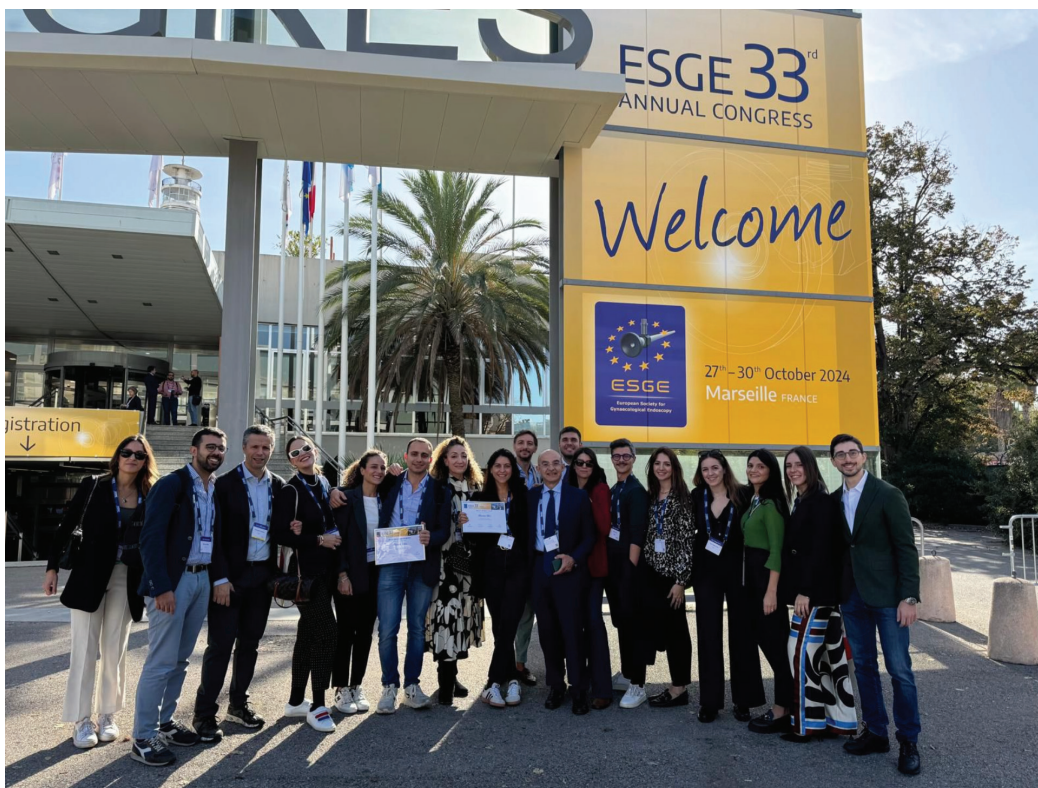
In the irreplaceable void of his loss, Giovanni Scambia leaves the most precious asset: his school, his legacy to society. Everything he has built will grow and flourish as he designed. A network of dedicated doctors, nurses, midwives, biologists and other professionals who will continue his work and vision. His intellectual honesty, passion, wisdom, generosity and humanity will continue to guide and inspire future generations.

He taught us to have faith in justice and merit, never to shy away from challenges, and to embrace diversity and collaboration. He encouraged us to dream of a better world and to pursue those dreams relentlessly.

In one of his final messages to the community, he said: *“There is one last message I want to leave to the young trainees who will build the future: it is to be astonished by progress and achievements, just as I am*

*still astonished today by how far we have come. When I started, I never thought I would be able to tell a woman with cancer that, after recovery, she could have a pregnancy. Yet, today, this is the reality. For those who will write our history, my wish is for them to experience many more discoveries and victories, perhaps with a wonderful team like ours, made of talent, passion, the ability to work together, and to take care of the women."*

Professor Scambia's memory will live on in our hearts and guide us throughout our careers. We will continue to honour his legacy in our work, knowing he continues to oversee us.



# Is it time to re-evaluate how we speak to women with endometriosis about their risk of ovarian cancer

 Thomas Edward Ind

Head of Department of Gynaecological Oncology, Royal Marsden Hospital, London, United Kingdom

**Keywords:** Endometriosis, endometriomas, ovarian cancer

The lifetime risk of all ovarian cancers in women is about 1.3% (1 in 77), with that reported in women with endometriosis to be 1.8% (1 in 56).<sup>1</sup> A more recent meta-analysis confirmed the association, with the strongest relationship occurring with type 1 histological subtypes.<sup>2</sup> There is a 160% increased risk of cardiovascular disease if a woman is menopausal, accompanied by the risks of surgery, most authors feel that the increased risk of ovarian cancer secondary to endometriosis does not warrant surgical intervention. Recent ESHRE guidelines state that "... clinicians reassure women with endometriosis with regards to their cancer risk...".<sup>3</sup>

However, the same guideline states that "... there is epidemiological data, mostly on ovarian endometriosis, showing that complete excision of visible endometriosis may reduce the risk of ovarian cancer...".<sup>3</sup>

The association between endometriosis and ovarian cancer is greater than the proportion of cases that fulfil the Sampson criteria<sup>4</sup> for Endometriosis Associated Ovarian Cancer (EAOC) and is thought to be related to combinations of inflammation, oxidative stress, oestrogens, and genomic alteration via the KRAS,

P13K pathways with alteration in ARID1A and PTEN. For this reason, we more commonly associate EAOC with clear cell, endometrioid, and low-grade serous types of cancers (type 1) with odds ratios previously being reported as high as 3.73, 2.32, and 2.02, respectively.<sup>5</sup>

A more recent study has looked at the 'typology' of endometriosis and the ovarian cancer risk by assessing 78,476 women with endometriosis on the Utah Population Database matched against those women without endometriosis on a 1 to 5 ratio.<sup>6</sup> In this later study, the median follow-up in women with endometriosis was 8 years and 14 years for women without endometriosis. The adjusted hazard ratio for any endometriosis and the development of epithelial ovarian cancer was 4.20 [confidence interval (CI): 3.59-4.91].

However, women with deep infiltrative endometriosis and endometriomas had the highest hazard ratios for epithelial ovarian cancer of 9.66 (CI: 7.77-12.00). This increased risk involved all epithelial ovarian cancers, including high-grade serous carcinomas, which have previously not been associated with endometriosis. The adjusted hazard ratio for type 1 ovarian cancers was 18.96 (CI: 13.78-26.08).

**Corresponding Author:** Thomas Edward Ind, MD, Head of Department of Gynaecological Oncology, Royal Marsden Hospital, London, United Kingdom

**E-mail:** ThomasInd@mac.com **ORCID ID:** [orcid.org/0000-0001-5260-199X](https://orcid.org/0000-0001-5260-199X)

**Received:** 31.07.2024 **Accepted:** 15.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Ind TE. Is it time to re-evaluate how we speak to women with endometriosis about their risk of ovarian cancer. Facts Views Vis Obgyn. 2025;17(1):3-4



As with other registry-based studies, the Utah Study's strength lies in the large number of patients.<sup>6</sup> However, the diagnosis of endometriosis itself is not a rigorous one, with some patients diagnosed on symptoms alone, others by laparoscopic interpretation and others by histology. Histologically proven endometriosis can be in a number of different sites and can be superficial or deep, or it can be in the form of endometriomas. Registry-based clinical studies are not without their own intrinsic failings.

They often lack in data quality and are variable in detail. Furthermore, there are often failings in active follow-up.<sup>7</sup> In this subject, known confounding factors such as contraceptive pill usage and tubal ligation are not accounted for.

The significance of any new data lies in how practice could change as a result. With type 1 ovarian cancers accounting for about 20% of all cases and therefore occurring in about 1 in 400 women, even with a hazard ratio of nearly 20, any intervention could result in at best 20 people receiving treatment to prevent one case. Either way, this could be presented in plain language to a patient wishing to make an informed decision and balanced along with symptoms, fertility wishes and risks of surgery. There is some evidence that excision of endometriosis (especially endometriomas) may be protective against the risk of EAOc.<sup>8,9</sup> However, the extent of protection is controversial and does not take into account other environmental factors and hormone usage that may also influence malignant transformation.

This study will no doubt prompt analyses of other large patient cohorts. If these figures are confirmed, then we will have to rethink how we counsel women with a history of deep infiltrative endometriosis and endometriomas. This is especially in those women who are nearing the end of their menstrual life and who have completed their

family. Furthermore, an understanding of the molecular differences between women with endometriosis that eventually do lead to EAOc and those that do not might help us understand which patients to offer prophylactic surgery to.

**Acknowledgements:** None.

#### Footnotes

**Financial Disclosure:** The author declared that this study received no financial support.

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# Infantile uterus and uterine hypoplasia: a comprehensive overview to explore possible managements amidst limited scientific certainties

✉ Luis Alonso Pacheco<sup>1</sup>, ✉ José Carugno<sup>2</sup>, ✉ Juan Luis Alcázar<sup>1</sup>, ✉ Miguel Caballero<sup>3</sup>, ✉ María Carrera Roig<sup>4</sup>,  
✉ Liliana Mereu<sup>5</sup>, ✉ José Antonio Domínguez<sup>6</sup>, ✉ Enrique Moratalla<sup>6</sup>, ✉ Stefania Saponara<sup>8</sup>,  
✉ Salvatore Giovanni Vitale<sup>8</sup>, ✉ Federico Pérez Millán<sup>3</sup>

<sup>1</sup>Quirónsalud Hospital, Málaga, Spain

<sup>2</sup>Department of Obstetrics, Gynecology and Reproductive Sciences, Miami University Faculty of Medicine, Florida, USA

<sup>3</sup>Gregorio Marañón General University Hospital, Madrid, Spain

<sup>4</sup>12 de Octubre University Hospital, Madrid, Spain

<sup>5</sup>Department of Obstetrics and Gynecology, University Hospital Company Polyclinic "G. Rodolico - San Marco" - Catania, Catania, Italy

<sup>6</sup>Assisted Reproduction Institute of Extremadura, Badajoz, Spain

<sup>7</sup>Ramón y Cajal University Hospital, Madrid, Spain

<sup>8</sup>Department of Surgical Sciences, Division of Gynecology and Obstetrics, Cagliari University Faculty of Medicine, Cagliari, Italy

## ABSTRACT

**Background:** The uterus, a complex organ, performs crucial functions including fertilisation, embryonic implantation, and supporting fetal development. Infantile uterus, resembling a prepubescent girl's uterus, and uterine hypoplasia, characterised by a smaller than normal size but with a normal body/cervix ratio, present significant reproductive challenges.

**Objectives:** This study aims to critically review the existing literature on the infantile uterus and uterine hypoplasia, focusing on the aetiology, clinical features, diagnosis and treatment options.

**Methods:** A comprehensive narrative review was conducted based on a thorough database search in PubMed, Google Scholar, Scopus, and Web of Science, complemented by cross-referencing relevant articles. Inclusion criteria included studies on the aetiology, clinical features, diagnosis, and treatment of infantile uterus and uterine hypoplasia.

**Main Outcome Measures:** Diagnostic criteria based on measurements and therapeutic options.

**Results:** The review revealed distinct characteristics of infantile uterus and uterine hypoplasia. The infantile uterus has a body/cervix ratio of 1:1 or 1:2, resembling that of a prepubescent girl, while uterine hypoplasia maintains a normal body/cervix ratio of 2:1 but is smaller in size. Diagnostic criteria include a total uterine length of less than 6 cm and specific ultrasound features such as reduced intercornual distance. Therapeutic options include hormonal therapy, particularly oestrogen administration, and surgical interventions aimed at expanding the uterine cavity. Hormonal treatments showed variable effectiveness, primarily beneficial in cases of oestrogen deficiency, while surgical approaches demonstrated some success in enhancing fertility outcomes in women with a hypoplastic uterus.

**Conclusions:** Infantile uterus and uterine hypoplasia remain poorly understood, with no consensus on their aetiology. Accurate diagnosis relies on specific measurements and body/cervix ratios. Treatment options, including hormonal and surgical interventions, show limited success, indicating a need for further research to optimise management strategies.

**Corresponding Author:** Jose Carugno, MD, FACOG, Department of Obstetrics, Gynecology and Reproductive Sciences, Miami University Faculty of Medicine, Florida, USA

**E-mail:** jac209@med.miami.edu **ORCID ID:** orcid.org/0000-0002-5716-4933

**Received:** 28.05.2024 **Accepted:** 17.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Pacheco LA, Carugno J, Alcázar JL, Caballero M, Roig MC, et al. Infantile uterus and uterine hypoplasia: a comprehensive overview to explore possible managements amidst limited scientific certainties. Facts Views Vis Obgyn. 2025;17(1):5-14



## ABSTRACT

**What is New?** This review highlights the diagnostic challenges and the limited efficacy of current treatments for infantile uterus and uterine hypoplasia, emphasising the need for standardised diagnostic criteria and further research aiming to elucidate more effective therapeutic approaches.

**Keywords:** Infantile uterus, uterine hypoplasia, congenital uterine anomalies, Mullerian anomalies, infertility

## Introduction

The uterus an extremely complex organ, performs crucial functions including facilitating fertilisation, enabling embryonic implantation and hosting the developing product of conception until it reaches a viable state capable of survival in the outside environment. During the normal development of the uterus, significant changes occur in the Müllerian ducts, giving rise to the upper third of the vagina, the cervix, the uterine body, and the Fallopian tubes. However, in certain conditions these changes are incomplete or abnormal, leading to Müllerian malformations that represent a significant category of congenital anomalies of the female reproductive tract, which can substantially impact fertility.<sup>1</sup> These malformations arise from abnormalities in the development of the Müllerian ducts and can range from minor structural defects to significant deformities that severely compromise uterine function.<sup>2</sup> Uterine malformations can impede conception and increase the risk of miscarriage, preterm birth, and other pregnancy complications.<sup>1</sup> Evaluating these anomalies typically involves a combination of imaging techniques, including ultrasound, magnetic resonance imaging, and hysterosalpingography (HSG).<sup>3</sup> Among these, hysteroscopy stands out as a minimally invasive procedure that allows for direct visualisation and treatment of intrauterine abnormalities.<sup>4,5</sup> It not only aids in the accurate diagnosis and classification of uterine malformations but also offers therapeutic interventions that can enhance fertility outcomes.<sup>6,7</sup>

The term "infantile uterus" refers to a uterus resembling the uterus of a pre-menarche girl, exhibiting an absence of changes that occur during pubertal development. Conversely, a hypoplastic uterus has a body/cervix proportion of 2:1, similar to a normal reproductive-aged uterus but overall smaller.<sup>8,9</sup> This narrative review critically analyses the available literature on these enigmatic uterine conditions, exploring their aetiology, clinical features, diagnosis, and therapeutic options.

## Methods

This narrative review was conducted through a comprehensive search of multiple databases, including PubMed, Google Scholar, Scopus, Web of Science, and research registers such as Clinicaltrials.gov. The search was complemented by cross-referencing the reference lists of relevant articles. We adhered to the quality standards for narrative reviews as defined and quantified by the Scale for the Assessment of Narrative Review Articles.<sup>10</sup> Keywords used in the search included "infantile uterus", "congenital uterine anomalies", "uterine hypoplasia", and "infertility". The inclusion criteria encompassed original research articles, reviews, and case studies that focused on the aetiology, clinical features, diagnostic criteria, and treatment options for infantile uterus and uterine hypoplasia. Articles lacking a clear focus on these conditions were excluded from the review. Data were meticulously synthesised to provide a comprehensive overview of the current understanding and management of infantile uterus and uterine hypoplasia.

## Uterine Development

Understanding the pathogenesis of genital malformations requires considering the embryological origin of various elements of the genitourinary system. During the early stages of embryonic development, significant changes occur in the Müllerian ducts, which differentiate, migrate, fuse, and canalise to form the upper third of the vagina, the cervix, the uterine body, and the Fallopian tubes.<sup>11</sup> By the sixth week of embryonic development, the paramesonephric or Müllerian ducts form, located laterally to the gonadal ridge and the mesonephric ducts. These ducts arise from longitudinal invaginations of the superficial coelomic epithelium, which eventually closes. By the end of the sixth week, both pairs of genital ducts, Wolffian and Müllerian, are present, making the male and female genital systems indistinguishable. The undifferentiated phase of genital development concludes at this point.<sup>12</sup> In the cranial region, the paramesonephric duct presents an open funnel shape, opening into the abdominal cavity. In the caudal

region, it initially moves laterally with the mesonephric duct, crosses it ventrally, and grows in the caudomedially until it meets the opposite paramesonephric duct. Although a septum initially separates these ducts, this septum is subsequently reabsorbed, with the most accepted theory suggesting a cranial direction of reabsorption.<sup>13</sup> An alternative theory, the bidirectional Müllerian theory, suggests bidirectional reabsorption, both cranially and caudally, simultaneously.<sup>14</sup> The caudal tips of the Müllerian ducts project towards the posterior wall of the urogenital sinus, forming a small protrusion called the Müllerian tubercle, which later gives rise to the upper third of the vagina. Each duct consists of three parts: a cranial vertical part opening into the abdominal cavity, a horizontal part crossing the mesonephric duct, and a caudal vertical part that merges with its counterpart on the opposite side. After the descent of the ovaries, the upper two-thirds transform into the Fallopian tubes, while the caudal third fuse to form the uterine cavity, which occurs between weeks 10-12.<sup>15</sup> Following the fusion in the midline of the ducts, a broad transverse pelvic fold, known as the broad ligament of the uterus, forms and extends from the lateral sides of the fused paramesonephric ducts to the pelvic wall. Later, the solid tip of the paramesonephric ducts meets the urogenital sinus.<sup>16</sup> Two theories regarding uterine development are noteworthy. Leyendecker's theory suggests that only the endometrial-subendometrial region and the innermost layer of the uterine body, formed by circular fibres, derive from the Müllerian ducts, referred to as the "Archimetra". The term "neometra" describes the outer layers of the myometrium, which are thought to have a mesenchymal rather than a Müllerian origin.<sup>17</sup> Additionally, experts challenge the classic theory regarding vaginal formation, arguing that the Müllerian ducts do not reach the urogenital sinus. Therefore, the upper third of the vagina does not have a Müllerian origin.<sup>16</sup>

Little is known about the characteristics of the uterus during the early stages of embryonic life. According to O'Rahilly<sup>18</sup>, the uterus is indistinguishable as an organ until the 9<sup>th</sup> week of gestation, and it is only after the 17<sup>th</sup> week of gestational age that the isthmus, cervix, and the different layers of the uterus can be identified. Novak<sup>19</sup> observed that the fetal uterus in the early stages of development is a tubular structure with a uniform calibre, where marked anteversion or retroversion cannot be appreciated, although a moderate anterior curvature is observed. Additionally, it is almost impossible to identify the uterine body and cervix during early development. The uterus is

located above the pubic symphysis, at the abdominal level and above the pelvis.<sup>19</sup> From the 18<sup>th</sup> week of gestational age, the uterus undergoes linear growth, primarily of the cervix, stimulated by hormones, reaching its maximum development at the end of gestation.<sup>20</sup> Soriano's et al.<sup>21</sup> studies on 140 fetuses showed that the uterus could be measured by ultrasound from the 19<sup>th</sup> week, with linear continuing until the birth. They determined the width and uterine circumference at different gestational ages, finding that the mean  $\pm$  standard deviation (SD) of the width and uterine circumference was  $12.9 \pm 4.1$  mm [95% confidence interval (CI) 12.1-13.7] and  $40.2 \pm 12.5$  mm (95% CI 37.9-42.5), respectively. They also established the regression equation for uterine width as a function of gestational age, which was  $y = 12.9 + 0.73 \times \text{gestational age (weeks)}$ , where "y" represents fetal uterine width (in mm). For uterine circumference, the regression equation was  $y = 40.2 + 2.13 \times \text{gestational age (weeks)}$ , where "y" represents fetal uterine circumference (in mm).<sup>21</sup>

Interestingly, after birth, both the size and volume of the uterus undergo a sudden shrinkage, particularly at the cervix level, due to the hormonal decline experienced by the newborn upon leaving the maternal womb.<sup>22,23</sup> During the infantile phase, the uterus goes through a quiescent stage, with no activity or function, and the body portion of the uterus increases in size, resulting in a 1:1 ratio between the body and cervix. The endometrium is not visible during this stage, although a central echogenic line can be observed on ultrasound.<sup>22,23</sup> During puberty, increased hormone levels lead to significant growth of the uterine body size compared to the cervix, resulting in the typical adult 2:1 body/cervix ratio. There is also an increase in uterine and the organ takes on its characteristic pear-shaped form. The endometrial line becomes visible, and its appearance varies during the menstrual cycle.<sup>22,23</sup>

Researchers have observed variations in uterine size due to physiological and pathological factors. Physiologically, uterine size increases with age and parity, reaching an average length of 7.5 cm by age 40, in the absence of pathologies such as fibroids or adenomyosis. From then on, there is usually a sharp decrease in size starting from menopause due to the decline in hormonal levels until reaching 3 cm again at 90 years of age.<sup>24</sup> Some authors have observed to have a progressive increase in the thickness of the uterine fundus and the interostial distance with age.<sup>25</sup> The uterus is a dynamic organ subject to changes throughout a woman's life, and its size is influenced by factors such as age, parity, and hormonal status. In

some cases, the uterus does not reach its maximum development or decrease in size compared to the expected age growth curves.<sup>24</sup> These abnormal changes lead to the formation of uteri that are smaller than expected, referred to as hypoplastic uterus and infantile uterus.

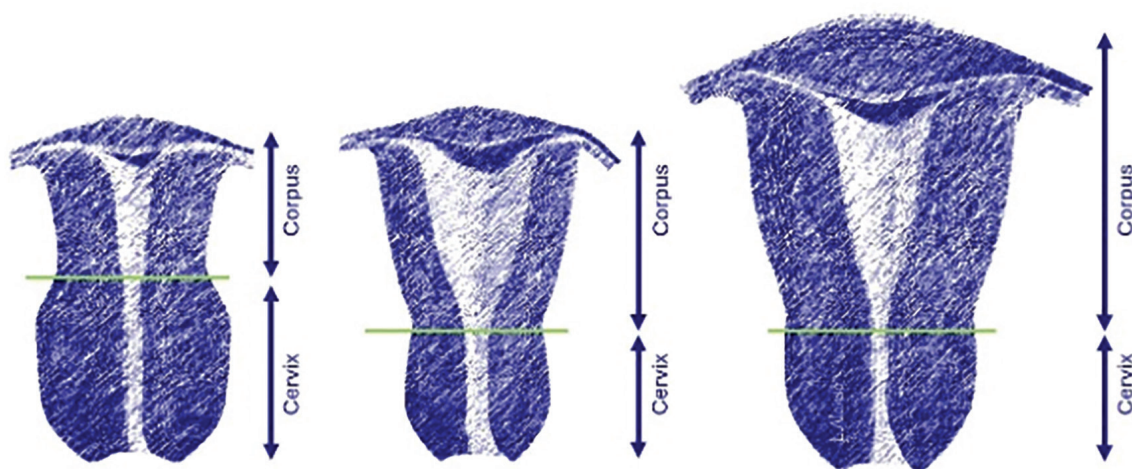
### Definition

In 1930, Menge and von Oettingen<sup>8</sup> defined hypoplastic uterus and infantile uterus as two distinct conditions characterised by unique morphological and dimensional differences from a normal uterus. These variations are evident in the uterine cavity's size and morphology. The term "infantile uterus" refers to a uterus that resembles that of a pre-menarche woman, exhibiting an absence of the developmental changes that typically occur during puberty. This condition is characterised by a body/cervix proportion of 1:1 or 1:2, resembling that of a prepubescent girl (Figure 1).<sup>8</sup> Conversely, the term "hypoplasia" is derived from the Greek words "hypo", meaning under, and "plasia", meaning formation, defining a uterus that has not reached sufficient development. The hypoplastic uterus has a body/cervix proportion of 2:1, similar to the normal uterus of a woman of reproductive age but is smaller overall (Figure 1).<sup>8</sup> Hegar<sup>26</sup> further refined these definitions by observing uteri of normal size but with an inverted body/cervix proportion. He categorised the infantile uterus into two subtypes: the non-hypoplastic infantile uterus with normal size but an inverted body-to-cervix proportion and the hypoplastic infantile uterus with reduced size along with an inverted body-to-cervix proportion.

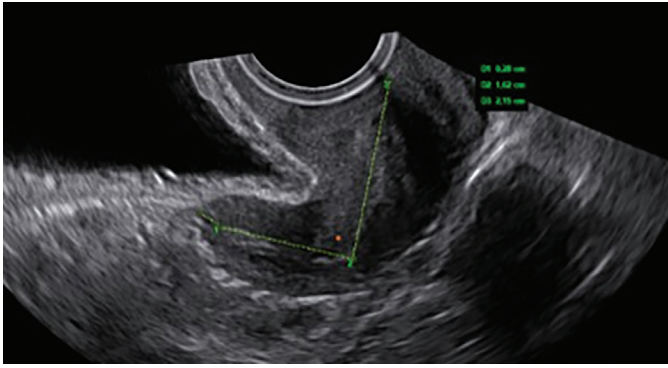
To facilitate the diagnosis and classification of different uterine types, Meaker<sup>27</sup> in 1927 introduced the "uterine index". This index determines the proportion between the body and the cervix using a modified and scaled probe. The formula used is  $1/2 (U-C/C)$ , where U is the total length of the body plus the cervix, and C is only the cervix measurement. The result for a normal adult uterus is 0.75, while the infantile uterus yields a result of 0.25. Intermediate Values were considered variations of uterine types, with values below 0.60 indicating a degree of hypoplasia.

In 1945, Jeffcoate and Lerer<sup>28</sup> conducted a study involving 120 patients with suspected hypoplastic uteri who underwent uterine length measurement by sound of the cavity under anaesthesia. A uterus measuring over 2 1/2 inches (6.25 cm) was considered normal, while those with a total length below this limit were classified as hypoplastic.<sup>28</sup> In 2002, Barranger et al.<sup>29</sup> defined a hypoplastic uterus as having a reduced cavity size on HSG and a total uterine length not exceeding 6 cm on transvaginal ultrasound in sagittal view (Figure 2).

Currently, there is no consensus on the exact definitions of infantile and hypoplastic uterus. These definitions involve a combination of size and proportions between the uterine body and cervix. Based primarily on Hegar's<sup>26</sup> definitions, a hypoplastic uterus is identified as having a total length of less than 6 cm, whereas an infantile uterus is characterised by a body/cervix proportion of 1:2 or 1:1.



**Figure 1.** Infantile uterus, hypoplastic uterus, and normal uterus (from left to right). The hypoplastic uterus (centre) displays a body/cervix ratio of 2:1, comparable to that of a normal uterus of a reproductive-age woman (right). In contrast, the infantile uterus (left) has a body/cervix ratio of 1:1 or 1:2, resembling that of a prepubescent girl.



**Figure 2.** 2D ultrasound view of a hypoplastic uterus. The total uterine length is 4.05 cm, significantly smaller than the normal length of 6 cm.

### Aetiology

The aetiology of the infantile uterus and uterine hypoplasia remains largely unknown. Although it is challenging to establish the precise cause of these uterine developmental defects in most cases, it is generally accepted that endocrine failures affecting normal development during adolescence and conditions leading to a deficit in female sex hormones result in delayed uterine development.

In an initial attempt to determine the causes of this condition, Meaker<sup>30</sup> studied a group of 103 women aged 16 to 19 with delayed menarche and genital hypoplasia. Among them, 61 (59.2%) had pituitary insufficiency, 11 had thyroid failure (10.6%), and the remaining 31 (30.2%) had non-endocrine pathologies, with severe anaemia being the most frequent. Subsequently, Jeffcoate and Lerer<sup>28</sup> examined 86 women diagnosed with uterine hypoplasia, defined as having a small uterus with the uterine cavity measuring less than 1 ½ inches. Among these, 21 cases (24.4%) showed no response to oestrogen, as indicated by the absence of bleeding upon oestrogen withdrawal. Another 23 cases (26.7%) had various endocrine dysfunction, including primary hypopituitarism, primary ovarian failure, thyroid dysfunction, and adrenal dysfunction. Additionally, 12 cases (13.9%) combined the two aforementioned causes, while the remaining 10 cases (11.6%) were associated with different diseases such as tuberculosis, severe anaemia, or anorexia nervosa.

It is noteworthy that J. Künzig pointed out a relationship between the presence of a hypoplastic uterus and long-term use of oral contraceptives. To differentiate it from the infantile and hypoplastic uterus, he defined it as a secondary small uterus or "pill uterus".<sup>31</sup> Among well-documented causes, Barranger et al.<sup>29</sup> highlighted in-utero exposure to diethylstilbestrol (DES) as a known

cause of hypoplastic uterus. DES, a synthetic oestrogen used to prevent spontaneous abortions, was withdrawn from the market in the 1970s due to health risks, including reproductive tract anomalies in female offspring of exposed mothers. In a series of 29 women diagnosed with hypoplastic uterus, with a uterine length measured by ultrasound less than 6 cm and hysteroscopy revealing a tubular cavity, Barranger et al.<sup>29</sup> reported that 23 (79.3 %) had been exposed in utero to DES.

Turner syndrome (TS) is caused by a total or partial absence of an X chromosome. Characteristics in affected women include short stature, lymphoedema, cervical malformations, and difficulties in sexual character development leading to primary amenorrhoea.<sup>32</sup> According to karyotype, the following types can be observed: 45,X, the most common karyotype, accounting for almost 80% of cases; 45,X/46,XX, a less frequent variant; 45,X/46,iXq; and 45,X/46,XY. According to a study by Doerr et al.<sup>32</sup> of 75 women with TS, only those with TS and a karyotype of 45,X/46,XX had normal uterine sizes, while 26% of those with TS and a karyotype of 45,X had a uterine length <-2 SDS (SD scores), and 18% had a volume <-2 SDS.

Women with Swyer syndrome or 46,XY pure gonadal dysgenesis have a feminine external appearance despite having male sex chromosomes. There is abnormal testicular development associated with a deficiency in the production of male sex hormones. Patients generally have an underdeveloped uterus and fallopian tubes and typically present with primary amenorrhea.<sup>33</sup>

Mayer-Rokitansky-Küster-Hauser syndrome (MRKH) is characterised by typically female secondary sexual characteristics with normal breast development. However, there is a congenital absence of the vagina associated with uterine hypoplasia or aplasia. MRKH affects 1 in 5000 women and is the second most common cause of primary amenorrhea.<sup>34</sup> MRKH is classified into type I (isolated Müllerian defect) and type II when it presents with other associated congenital anomalies such as renal dysplasia, cardiac defects, skeletal system abnormalities, and deafness.<sup>35</sup>

A mutation in the FSH receptor located on chromosome 2p21 (follicle-stimulating hormone receptor) is a rare cause of delayed puberty, amenorrhea, and hypergonadotropic hypogonadism, sometimes associated with the hypoplastic uterus. A case was described of a 19-year-old patient with this mutation, presenting with primary amenorrhea, a hypoplastic uterus, and a very thin endometrial line.<sup>36</sup>

Hyperprolactinemia is a known cause of hypogonadism. When it occurs in adult women, it typically presents with amenorrhea/galactorrhoea. However, when it occurs in pubescent girls, delayed development of secondary sexual characteristics and primary amenorrhea can be observed. It has been documented that the presence of hyperprolactinemia before complete genital development can lead to uterine hypoplasia.<sup>37</sup>

Perrault syndrome is an autosomal recessive disorder characterised by neurosensory hearing loss and ovarian dysgenesis. To date, mutations in six different genes have been associated with this rare disease. Affected women have a normal karyotype (46XX), hypergonadotropic hypogonadism, and typically present with amenorrhea, uterine hypoplasia, and small ovaries.<sup>38</sup>

### **Clinical Features**

Clinical data on the symptoms presented by patients with a small uterus, whether hypoplastic or infantile, are limited. As affirmed by Novak<sup>19</sup> in 1918, the two main functions of the uterus, menstruation and reproduction, are significantly affected by various forms of uterine hypoplasia. Calatroni and Ruiz<sup>39</sup> extensively studied the symptomatology of patients with uterine hypoplasia. They described alterations in vaginal discharge, dyspareunia, menstrual irregularities, infertility, and high rates of pregnancy loss among patients diagnosed with infantile uterus.

Alterations in vaginal discharge can be categorised into two groups: those with normal vaginal discharge and those with scanty discharge, the latter often

associated with a deficiency in female sex hormones.<sup>39</sup> Dyspareunia in these patients may be linked to a short or underdeveloped vagina which is smaller than normal, as well as cases of vaginal tightness or a significant decrease in menstrual flow. Regarding menstrual patterns, patients usually experience a decrease in menstrual flow, reaching amenorrhea in severe cases. This reduction in flow may be related to various endocrinopathies or simply because of a smaller endometrial surface area (Figure 3).<sup>39</sup>

Infertility is common among these patients due to a combination of several factors, including possible associated endocrine alterations that cause uterine hypoplasia, as well as the presence of a nonfunctional endometrium, especially in patients with hypomenorrhoea.<sup>40</sup> Garbin et al.<sup>41</sup> presented a series of 24 women with hypoplastic uterus diagnosed by HSG, of whom 15 had been exposed in utero to DES. Of these, 15 had previous pregnancies with one patient experiencing secondary infertility after a previous full-term pregnancy, and the remaining 14 had a total of 32 pregnancies with no live births. The remaining 9 patients had primary infertility. Subsequently, Barranger et al.<sup>29</sup> presented a study on 29 women with hypoplastic uterus, defined as having a uterine cavity length of less than 6 cm and a tubular-shaped cavity at HSG. Of these patients, 23 had been exposed in utero to DES. Regarding reproductive outcomes, 14 had primary infertility, and the remaining 15 had a total of 26 previous pregnancies, with only one live birth resulting from a premature delivery at 29 weeks of gestation.

Another clinically referred symptom traditionally associated with this type of uterus is spasmodic dysmenorrhoea. Meaker's<sup>30</sup> theory is noteworthy for explaining this phenomenon. Meaker observed that the hypoplastic uterus, similar to the uterus in infancy, contained only 50% of muscle fibres compared to the 90% found in a fully developed adult uterus, with the remaining portion being connective fibrous tissue). This disproportion between muscle fibre and connective tissue is responsible for the presence of irregular and uncoordinated contractions that cause spasmodic dysmenorrhoea.

### **Diagnosis and Classification**

Diagnosing infantile uterus and uterine hypoplasia can be challenging in daily clinical practice due to the limited and often descriptive nature of current classification systems. Among the two most commonly used classifications of uterine malformations, the American Society for



**Figure 3.** Hysteroscopic view of a hypoplastic uterus showing a significantly reduced cavity size and an exceptionally thin endometrium.

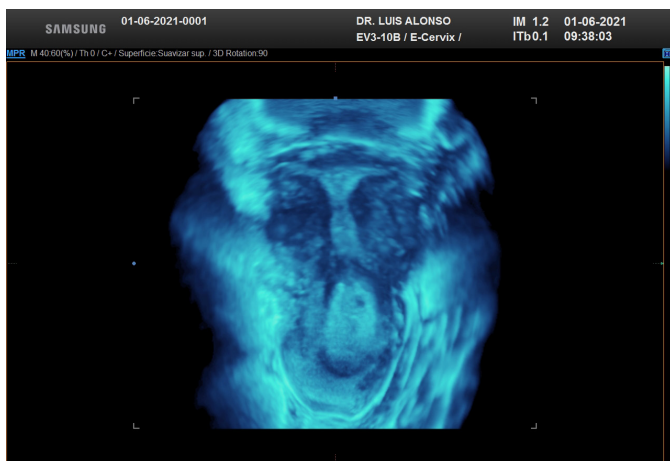
Reproductive Medicine 2021<sup>42</sup> and the European Society for Gynaecological Endoscopy/European Society of Human Reproduction and Embryology (ESGE/ESHRE) 2013, only the latter makes specific reference to the infantile uterus.<sup>43</sup> In the ESGE/ESHRE classification, the infantile uterus is classified as U1b, defined as a uterus characterised by having a narrow cavity, normal thickness of the lateral walls, and an inverted body/cervix correlation, with 2/3 of the total length corresponds to the cervix and 1/3 to the uterine body (Figure 4).

To establish a diagnosis, a high degree of clinical suspicion is essential. Generally, women with delayed menarche, hypo- or amenorrhoea, and reproductive problems such as infertility or recurrent miscarriages should raise suspicion of having a small uterus.<sup>3</sup>

According to Jeffcoate and Lerer<sup>28</sup>, the best method to diagnose the presence of a hypoplastic uterus is by measuring its size. However, older diagnostic procedures such as measuring uterine length by bimanual examination or the length of the uterine cavity using a hysterometer, have fallen out of use.

HSG has been frequently used for the diagnosis of these uterine anomalies, yet there are no universally accepted criteria. Hypoplastic or infantile uteri are generally defined as those appearing small on a hysterosalpingogram and often have uterine cavities with T- or Y-shaped morphology.<sup>3</sup>

Hysteroscopy is a minimally invasive technique that allows for the evaluation of the cervical canal and endometrial cavity, aiding in the differential diagnosis of the T-shaped and infantile uterus (Figure 3).<sup>44</sup>



**Figure 4.** 3D coronal view of an Infantile uterus showing a narrow cavity with normal thickness of the lateral walls and an inverted body/cervix correlation, where 2/3 of the total length corresponds to the cervix and 1/3 to the uterine body.

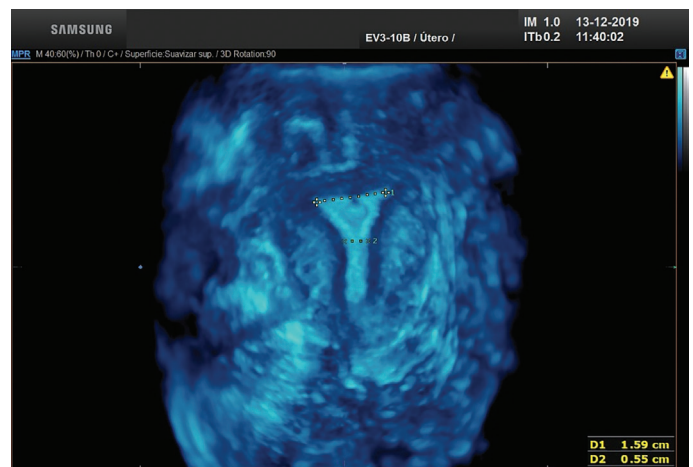
Using ultrasound criteria, Bonilla-Musoles et al.<sup>45</sup> defined a uterus as hypoplastic or infantile when the measurement from the external cervical os to the fundus of the uterine cavity is less than 6 cm or when the measurement from the external cervical os to the uterine fundus of the uterus (total uterine length) is less than 6.5 cm. Carvalho et al.<sup>46</sup> further attempts to establish more objective criteria, suggesting that a uterus should be considered hypoplastic if the intercornual distance is less than 2 cm or if the distance from the internal cervical os to the uterine fundus is less than 3 to 5 cm (Figure 5). Additional characteristics often present in these uteri include a small cervix, altered uterine anatomy, thickening of the junctional zone, significantly reduced uterine cavity size, and changed uterine blood perfusion diagnosed using Doppler ultrasound.<sup>45</sup>

Currently, there are no universally accepted criteria, but two key criteria are essential for diagnosis: a total uterine length measured from the external cervical os to the uterine fundus of less than 6 cm, as established by different authors over the years based on Jeffcoate's and Lerer<sup>28</sup> clinical results; the body/cervix ratio to differentiate between hypoplasia and infantilism. A ratio of 1:2 or 1:1 identifies an infantile, whereas a hypoplastic uterus maintains a normal ratio of 2:1.

## Treatment

### Hormonal Therapy

Several treatments have been proposed for patients diagnosed with hypoplastic or infantile uterus. The type of hypoplasia is crucial when choosing the appropriate treatment, necessitating a comprehensive evaluation of



**Figure 5.** 3D coronal ultrasound view of a hypoplastic uterus, demonstrating a reduced interstitial distance of 1.59 cm.

the patient, including hormonal level determination, to ensure an accurate diagnosis and proper treatment.

Given the role of oestrogen in uterine development during puberty, the administration of systemic oestrogens was among the first treatment options explored. In 1934, Clauberg demonstrated increased uterine size through radiological studies, although the effects were temporary.<sup>28</sup> Later, Lardaro<sup>47</sup> presented a series of 30 patients diagnosed with a hypoplastic uterus who received intramuscular stilbestrol, a synthetic oestrogen, at the dose of 5 mg, three times a week for 14 weeks. Uterine growth was observed in only 5 patients; except for two, the growth was temporary. These findings indicate that the effectiveness of oestrogen therapy depends on the uterus's ability to respond, being beneficial primarily in cases where hypoplasia is due to oestrogen deficiency. Local oestrogen injections into the cervix were also explored for many years. In 1955, Field-Richards<sup>48</sup> reported on a preliminary series of 30 patients with hypoplastic uterus treated with cervical injection of oestrogens. Ten milligrams of oestradiol benzoate were injected laterally into the cervical canal, with an average of 4 injections per patient. Uterine growths between 0.4 and 2.2 cm were achieved, with an average increase of 0.94 cm per patient, indicating significant uterine growth in most patients.

De la Puente Lanfranco<sup>49</sup> conducted a notable study on infertile women with uterine hypoplasia diagnosed through HSG. The treatment involved ten injections of 10 mg of oestradiol benzoate to the anterior lip of the cervix, administered over 2 or 3 menstrual cycles. Follow up HSG showed that of the 66 patients who completed the treatment and underwent follow-up, 19 became pregnant (28.7%), 18 normalised the uterine size (27.3%), and 16 showed partial improvement (19.6%), with therapy failing in only 16 cases (24.4%). The authors concluded that this therapy is effective in treating uterine hypoplasia, particularly in cases of primary infertility, minimal uterine hypoplasia, and younger patients.

In 1956, Kaiser<sup>50</sup> proposed creating a pseudo-pregnancy state by pharmacologically prolonging the secretory phase. This therapy, based on oxyprogesterone and oestradiol valerate, was administered to 6 women diagnosed with hypoplastic uterus and dysmenorrhoea. The treatment aimed to extend the secretory phase for two or three weeks and was recommended for cases with a hypoplastic uterus and dysmenorrhoea as well as patients with associated infertility. In 1960, a therapy

called "pseudo-pregnancy" was further developed.<sup>51</sup> This approach suggested that similar to the uterus growth observed during pregnancy due to progesterone stimulation, inducing a pseudo-pregnancy state with hormonal therapy could also stimulate uterine growth. The treatment involved an initial dose of estradiol followed by increasing doses of 6-alpha-methyl-17-alfa-hydroxyprogesterone acetate over 4 weeks. The treatment resulted in a measurable increase in uterine size, as evidenced by hysteroscopy and HSG.

### *Surgical Interventions*

Surgical treatment has been documented as an option for patients with hypoplastic or infantile uterus, particularly those experiencing infertility or recurrent miscarriages. Barranger's et al.<sup>29</sup> study highlights the efficacy of such interventions. The surgical technique involves creating two lateral incisions on the uterine walls using a resectoscope loop, approximately 5-7 mm deep, to expand the uterine cavity. Following the surgery, patients received oestrogen-progestagen therapy for two months, followed by a control hysteroscopy. Of the 26 women seeking pregnancy after surgery, 13 (50%) became pregnant, with 9 conceiving spontaneously. These results suggest that expansion surgery, due to its simplicity and minimal post-surgical complications, may be an effective intervention for women with a hypoplastic uterus and a history of recurrent miscarriages and infertility.

### **Conclusion**

Infertile women diagnosed with infantile uterus and uterine hypoplasia represent a significant clinical challenge. Despite extensive research over the past few decades, the aetiology of these conditions remains poorly understood, with various theories proposed but no consensus on the underlying causes. Currently, there are no universally accepted diagnostic criteria. Two critical criteria are important for the diagnosis: a total uterine length measured from the external cervical os to the uterine fundus of less than 6 cm, and the body/cervix ratio, identifying an infantile uterus with a ratio of 1:2 or 1:1, and a hypoplastic uterus with a normal ratio of 2:1. Both medical and surgical treatment have shown limited success, indicating the need for further research to determine the most effective diagnostic and therapeutic approaches for successfully treating female infertility associated with infantile uterus and uterine hypoplasia.

**Acknowledgements:** None.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: L.A., J.L.A., Concept: L.A., J.C., Design: M.C., M.C.R., Data Collection or Processing: L.M., J.A.D., E.M., S.S., Analysis or Interpretation: S.G.V., F.P.M., Literature Search: S.G.V., S.S., M.C.R., Writing: L.A., J.C., J.L.A., E.M., F.P.M.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Impact of Enhanced Recovery After Surgery (ERAS) guidelines implementation in deep infiltrating endometriosis surgery. A systematic review and meta-analysis

Ⓐ Athanasios Douligeris<sup>1</sup>, Ⓐ Nikolaos Kathopoulos<sup>1</sup>, Ⓐ Christina Karasmani<sup>1</sup>, Ⓐ Konstantinos Kypriotis<sup>1</sup>,  
Ⓐ Dimitrios Zacharakis<sup>2</sup>, Ⓐ Anastasia Mortaki<sup>1</sup>, Ⓐ Anastasia Prodromidou<sup>2</sup>, Ⓐ Ioannis K. Chatzipapas<sup>1</sup>,  
Ⓐ Themis Grigoriadis<sup>2</sup>, Ⓐ Athanasios Protopapas<sup>1</sup>

<sup>1st</sup> Department of Obstetrics and Gynecology, Endoscopic Surgery Unit, "Alexandra" Hospital, National and Kapodistrian University of Athens, Athens, Greece

<sup>2nd</sup> Department of Obstetrics and Gynecology, Urogynaecology Unit, "Alexandra" Hospital, National and Kapodistrian University of Athens, Athens, Greece

## ABSTRACT

**Background:** The complexity of surgical management in women with deep infiltrating endometriosis (DIE) demands the optimisation of perioperative care protocols to ensure optimal postoperative outcomes.

**Objectives:** This meta-analysis evaluates the effectiveness of Enhanced Recovery After Surgery (ERAS) protocols compared to conventional perioperative care in patients undergoing surgery for DIE.

**Methods:** A systematic literature search was conducted in Medline, Scopus, Google Scholar, Cochrane CENTRAL, and ClinicalTrials.gov databases from inception till August 2024. Meta-analysis was performed with RevMan 5.4 software (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2020), with mean differences (MDs), pooled risk ratios (RR) and random-effects model. Quality assessment was performed using the Risk of Bias in Non-randomised Studies of Interventions and Risk of Bias tools.

**Main Outcome Measures:** Primary outcomes assessed were postoperative length of hospital stay and readmission rates. Secondary outcomes included Clavien-Dindo grade I-II and grade III or higher complication rates.

**Results:** Four comparative studies were included, encompassing a total of 1,662 patients. ERAS protocols significantly reduced the mean length of hospital stay [MD: -2.88 days; 95% confidence interval (CI): -5.34 to -0.41;  $P=0.02$ ] without increasing readmission rates (RR: 1.13; 95% CI: 0.75-1.73;  $P=0.55$ ). No significant differences were observed in Clavien-Dindo grade I-II complications (RR: 0.75; 95% CI: 0.49-1.16;  $P=0.20$ ) or grade III or higher complications rates (RR: 0.60; 95% CI: 0.27-1.33;  $P=0.21$ ).

**Conclusions:** ERAS protocols appear to reduce the length of hospital stay without increasing complications or readmissions in DIE surgery. However, further large-scale randomised studies still needed to be conducted to confirm these findings.

**What is New?** The application of ERAS protocols is associated with better postoperative outcomes in patients undergoing major surgeries for DIE.

**Keywords:** Endometriosis, deep infiltrating endometriosis, Enhanced Recovery After Surgery, ERAS, perioperative care, postoperative outcomes

**Corresponding Author:** Athanasios Douligeris, MD, <sup>1st</sup> Department of Obstetrics and Gynecology, Endoscopic Surgery Unit, "Alexandra" Hospital, National and Kapodistrian University of Athens, Athens, Greece

**E-mail:** thanosdouligeris92@gmail.com **ORCID ID:** orcid.org/0000-0001-8823-882X

**Received:** 05.08.2024 **Accepted:** 17.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Douligeris A, Kathopoulos N, Karasmani C, Kypriotis K, Zacharakis D, Mortaki A, et al. Impact of Enhanced Recovery After Surgery (ERAS) guidelines implementation in deep infiltrating endometriosis surgery. A systematic review and meta-analysis. Facts Views Vis Obgyn. 2025;17(1):15-29



## Introduction

Deep infiltrating endometriosis (DIE) affects approximately 1-2% of women of reproductive age. It is characterised by the presence of endometrial-like tissue infiltrating more than 5 mm beneath the peritoneal surface, often involving multiple structures of the posterior compartment of the pelvis such as the ureters, nerves, the rectovaginal septum, the uterosacral ligaments and the rectosigmoid colon.<sup>1</sup> DIE is associated with severe pelvic pain, dysmenorrhoea, dyspareunia, dyschezia, and can significantly impair the quality of life and fertility of affected women. As a result, it demands comprehensive and individualised management strategies.<sup>2</sup>

The surgical management of DIE is often complex due to the extent and severity of the disease, frequently necessitating advanced laparoscopic techniques to achieve meticulous dissection and excision of endometriotic nodules.<sup>3</sup> This approach aims to alleviate the pain, restore pelvic anatomy, improve fertility, and enhance the quality of life of patients. However, the invasive nature of these procedures and the involvement of multiple organs underscore the importance of optimising perioperative care.<sup>4</sup>

To reduce the risks associated with surgeries and improve recovery, Enhanced Recovery After Surgery (ERAS) protocols have been developed. ERAS protocols form a multidisciplinary approach aiming to optimise the perioperative management by integrating evidence-based practices designed to decrease surgical stress, maintain postoperative physiological function, and ensure a fast-track recovery.<sup>5</sup> These protocols have been widely adopted across various surgical specialties, including minimally invasive gynaecology and gynaecological oncology.<sup>6,7</sup> Integrating ERAS protocols into the complex and highly morbid surgical treatment of DIE can potentially enhance patient outcomes. However, studies investigating the impact of ERAS protocols in patients undergoing surgery for DIE are scarce.

The aim of the present meta-analysis is to evaluate the effectiveness of ERAS compared to conventional perioperative care protocols in patients undergoing surgery for DIE.

## Methods

### **Search Strategy, Eligibility of Studies and Protocol Registration**

The present meta-analysis was performed in accordance with the guidelines for Preferred Reporting Items for

Systematic Reviews and Meta-Analysis (PRISMA) based on the authors' predetermined inclusion criteria.<sup>8</sup> Since all the studies were extracted from previously published data, institutional review board approval was not requested. Selection of abstracts was conducted by two authors (A.D., C.K.) who independently searched the literature. Only studies published in languages using the Latin alphabet were included. The inclusion of studies was based on pre-established eligibility criteria. All observational comparative studies that evaluated postoperative outcomes between patients treated for DIE within an ERAS protocol and those treated for the same disease using conventional perioperative care protocols were included. Case reports, small case series, letters to the editor, animal studies, and review articles were not included. Conference proceedings and abstracts were also planned to be excluded, as they lack important information that is necessary for the assessment of study limitations and quality of evidence.

The PICO criteria that were used to develop our search strategy were as follows:

- **Population:** Women undergoing surgery for DIE, encompassing all cases of deep endometriosis regardless of the site and stage of the disease.
- **Intervention:** The application of an ERAS perioperative protocol.
- **Comparator:** Conventional perioperative care protocols.
- **Outcomes:** Perioperative outcomes (readmission rate, length of hospital stay, operative time, major and minor postoperative complications rate).

The study's protocol was published in the International Prospective Register of systematic reviews prior to the conduct of this review (registration number: CRD42024572905).

### **Literature Search and Data Extraction**

We used the Medline (1966-2023), Scopus (2004-2023), Google Scholar (2004-2023), Cochrane Central Register of Controlled Trials and ClinicalTrials.gov databases in our primary search, along with the reference lists of electronically retrieved full-text papers (snowballing). The date of last search was set at August 1<sup>st</sup>, 2024. The search strategy included a combination of the following search terms words: "deep endometriosis"[MeSH Terms] OR "deep endometriosis"[All Fields] OR "endometriosis"[All Fields] OR "deep"[All Fields] OR "deep infiltrating endometriosis"[All Fields] OR "endometriosis"[All

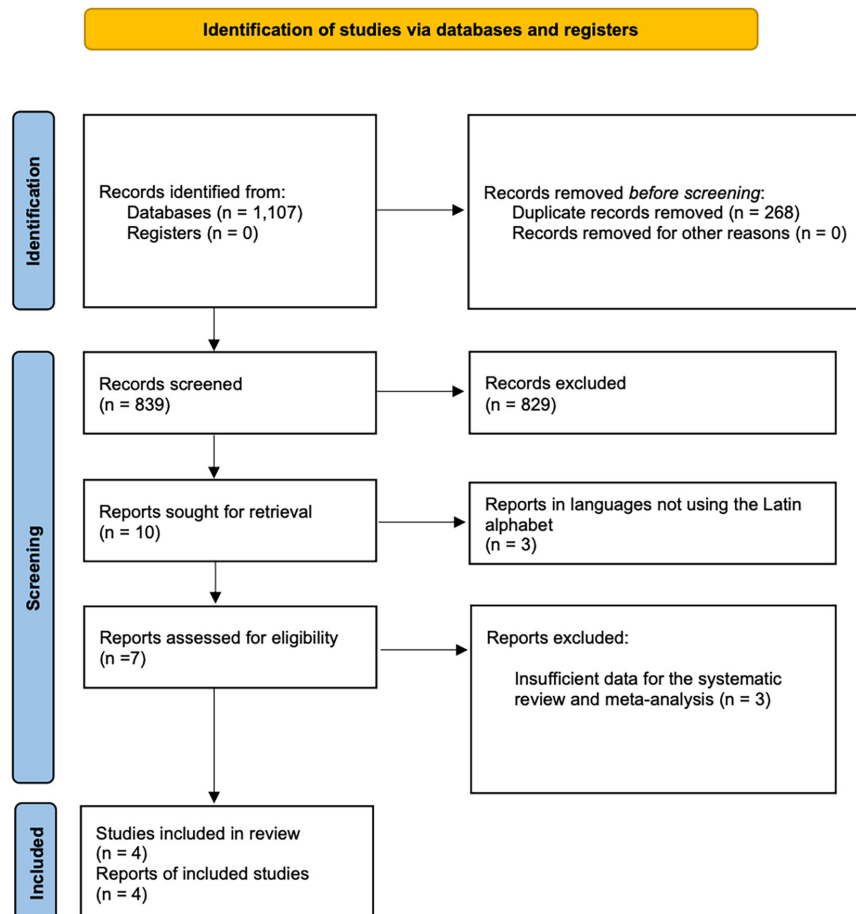
Fields] OR "deep infiltrating"[All Fields] OR "bowel endometriosis"[All Fields] OR "non-hysterectomy"[All Fields]) AND ("enhanced recovery after surgery"[MeSH Terms] OR "enhanced recovery after surgery"[All Fields] OR "ERAS"[All Fields] OR "recovery protocol"[All Fields] OR "enhanced recovery"[All Fields] OR ("fast-track surgery"[All Fields] OR "fast-track recovery"[All Fields] OR "fast track surgery"[All Fields] OR "fast track recovery"[All Fields] OR "fast track care"[All Fields])).

The initial selection of studies was conducted based on the titles, followed by an assessment of abstracts when eligibility was uncertain. After eliminating duplicates, the studies were evaluated according to the predefined inclusion and exclusion criteria. Articles that met or appeared to meet these criteria were retrieved for further analysis. Two authors (A.D. and C.K.) independently conducted a comprehensive literature search, resolved redundancies, and organised the selected indices in structured forms. Any discrepancies among the authors were discussed collectively until a consensus

was achieved. The PRISMA flow diagram schematically presents the stages of article selection (Figure 1).

### Definitions and Predetermined Outcomes

Readmission rate was defined as the ratio of patients readmitted to the hospital to the total number of patients who underwent surgery for deep infiltrative endometriosis. Readmission must have occurred within the first 45 days post-surgery due to a minor or major complication or a symptom related to the surgery. Postoperative complications were categorised using the Clavien-Dindo classification system. Classes I and II were considered minor complications, while classes III, IV, and V were considered major complications.<sup>9</sup> If the rate of minor complications was not separately reported, it was derived by subtracting the number of major complications from the total. Additionally, in cases where complications were not reported according to the Clavien-Dindo classification, our research team classified them accordingly.



**Figure 1.** Flow diagram of the detailed process of selection of articles for inclusion in the systematic review and meta-analysis.

Primary outcomes that were assessed in our study were the postoperative length of hospital stay and the readmission rate. Secondary outcomes were determined following data extraction that was performed using a modified data form based on Cochranes' data collection form for intervention reviews for randomised controlled trials (RCTs) and non-RCTs. These included the Clavien-Dindo grade I-II and grade III or higher postoperative complication rates, as these were considered outcomes indirectly influenced by the enhanced perioperative care promoted by the ERAS protocols.

### Quality Assessment

The Risk of Bias in Non-randomised Studies of Interventions (ROBINS-I) tool was employed to assess the quality of non-randomised studies.<sup>10</sup> RCTs were evaluated using the Risk of Bias (RoB-2) tool.<sup>11</sup> The ROBINS-I tool examines seven domains of bias in non-randomised studies: confounders, participant selection, intervention classification, intervention deviations, missing data, outcome measurement, and result reporting. It classifies studies into four levels of bias: low, moderate, serious, and critical. The RoB-2 tool for randomised studies evaluates five domains: the randomisation process, intervention deviations, missing outcome data, outcome measurement, and result reporting, categorising studies into three levels of bias: low risk, some concern, and high risk. Two authors (A.D. and A.M.) independently conducted the quality assessments, with any disagreements resolved by a third author (N.K.).

### Statistical Analysis

This systematic review and meta-analysis were conducted in accordance with the recommendations of the Cochrane Collaboration, as outlined in the Cochrane Handbook for Systematic Reviews of Interventions and following the Preferred Reporting Items for PRISMA guidelines.<sup>12,13</sup> Statistical meta-analysis was performed using the RevMan 5.4 Software.<sup>14</sup> Two authors (A.D. and A.M.) independently conducted all analyses, with any disagreements resolved by a third author (A.P.). For dichotomous outcomes, risk ratios (RR) with 95% confidence intervals (CI) were used to compare pooled results. For continuous outcomes, mean differences (MD) with 95% CI were employed. For studies reporting results in formats other than (mean  $\pm$  standard deviation), conversions were applied, and skewness detection was conducted. Heterogeneity was assessed using Cochran's Q test and  $I^2$  statistics, considered

significant if  $P < 0.10$  or  $I^2 > 25\%$ , respectively. Given the anticipated high heterogeneity in the methodological characteristics of included studies, the DerSimonian-Laird random-effects model was utilised for all comparisons. In estimating weight, the generic inverse-variance method was employed. This method incorporates the standard error and the intervention effect, aggregating data across all studies to provide an estimate. It assumes that variability in effect sizes across studies is due to both sampling errors and inherent differences in effect sizes among studies.<sup>15</sup> For studies reporting median values and ranges, the formula proposed by Hozo et al.<sup>16</sup> in 2005 was used to estimate the mean and variance (standard deviation). The cut-off for statistical significance was set at  $P < 0.05$ .

The trial sequential analysis (TSA), which was used for the evaluation of the information size, allows investigation of the type I error in the accumulated result of meta-analyses performed for all outcomes that were predetermined in the present meta-analysis. At least a number of three studies were considered suitable in order to perform the analysis. In meta-analyses, repeated significance testing raises the danger of type I error, but TSA can use the O'Brien-Fleming  $\alpha$ -spending function to re-adjust the target significance threshold. As a result, TSA sequential interim analyses allow researchers to investigate the impact of each study on the meta-analysis's overall conclusions. The risk for type I errors was set at 5% and for type II errors at 20%. The TSA analysis was calculated using the TSA v. 0.9.5.10 Beta software (<http://www.ctu.dk/tsa/>) (TSA) [Computer program] Version 0.9.5.10 Beta, The Copenhagen Trial Unit).

## Results

### Study Selection and Characteristics

Our search strategy, depicted in Figure 1, resulted in 1,107 abstracts/manuscripts. Among these, 268 were identified as duplicates across databases, and 832 were excluded based on title and abstract analysis due to irrelevance. A detailed review of 7 studies was performed by two authors (A.D. and C.K.), resulting in the exclusion of 3 studies.<sup>17-19</sup> Among them, the study by Peters et al.<sup>19</sup> was excluded from the present meta-analysis because, although it compares patients receiving ERAS with those receiving conventional perioperative care, it includes data on mixed gynaecological conditions requiring minimally invasive surgery, rather than focusing solely on patients with DIE, which is the specific population of interest.

Another study was also excluded because it did not focus on fast-track perioperative care protocols for patients undergoing surgery for deep endometriosis. Instead, it compared surgical techniques for the treatment of intestinal endometriosis, specifically the radical approach (segmental resection) with more conservative approaches (rectal shaving or discoid excision), which they referred to as fast-track surgery.<sup>18</sup> Finally, the study by Falcone et al.<sup>17</sup> was excluded because it was a survey-based investigation focusing on the implementation of ERAS protocols across different hospitals for endometriosis patients, rather than providing comparative data on ERAS versus conventional perioperative care specifically for patients with deep endometriosis.

Ultimately, four comparative studies (one RCT and three retrospective cohort studies) met all the inclusion criteria and were incorporated into the study.<sup>20-23</sup> These studies, conducted in France and Italy, encompassed a total of 1,662 patients, with 569 patients (34.2%) receiving ERAS and the remainder receiving non-ERAS perioperative care. The methodological characteristics of the included studies are briefly presented in Table 1. Accordingly, we used the RECOVER checklist, in order to evaluate all the studies included in our meta-analysis.<sup>24</sup> Table 2 qualitatively represents the comprehensive set of characteristics each study meets according to the RECOVER checklist. Additionally, it displays the overall compliance percentage of each study with all 20 items outlined in this tool for ERAS-related studies.

**Table 1.** Methodological characteristics of the included studies.

Year; author	Study design	Country	Study period	Number of patients	Inclusion criteria	Exclusion criteria
ERAS vs. non-ERAS						
<b>2017; Scioscia et al.<sup>23</sup></b>	Randomised controlled trial	Italy	January-December 2015	62 vs. 165	Age >18 years; preoperative evidence of bowel endometriosis (ultrasound, MRI, double contrast barium enema); primary laparoscopic approach; informed consent.	Surgery for reasons other than endometriosis, laparotomy, or vaginal approach; patients with endometriosis without bowel involvement; no consent for intestinal surgery.
<b>2022; Pivano et al.<sup>22</sup></b>	Retrospective observational study	France	January-December 2015 and March-November 2019	191 vs. 573	Women with a hospital stay for a DIE surgical procedure; The hospital stay had to include the ICD-10 code corresponding to the primary diagnosis of endometriosis (N80) and a CCAM code corresponding to a DIE surgical procedure.	All patients with hospital stay with an associated diagnosis of cancer (C*) or a history of a previous year's stay with a cancer code.
<b>2024; Arena et al.<sup>20</sup></b>	Retrospective cohort observational study	Italy	February 2017-February 2023	263 vs. 316	All women aged between 18 and 50 years who underwent surgery for rectosigmoid endometriosis.	History of concomitant pelvic inflammatory disease; malignancy; laparotomic conversion; women whose charts contained missing data about the perioperative period.
<b>2024; Djemouai et al.<sup>21</sup></b>	Retrospective observational study	France	April 2014-January 2018 and February 2018-March 2020	53 vs. 39	All patients presenting an indication for deep pelvic endometriosis surgery validated in an endometriosis meeting.	Initial or conversion laparotomy surgery.

MRI: Magnetic resonance imaging, DIE: Deep infiltrating endometriosis, ICD-10: International Classification of Diseases, 10<sup>th</sup> Revision, CCAM: Classification Commune des Actes Médicaux.

**Table 2.** Reporting on ERAS compliance, outcomes, and elements research (RECOVER) checklist among the included studies.

Item	Recommendation	2017; Scioscia et al. <sup>23</sup>	2022; Pivano et al. <sup>22</sup>	2024; Arena et al. <sup>20</sup>	2024; Djemouai et al. <sup>21</sup>
<b>Title</b>					
1	Indicate that this is an enhanced recovery study in the title	-	+	+	+
<b>Introduction</b>					
2	Explain the area of uncertainty that the study seeks to address	+	+	+	+
3	If a published set of enhanced recovery guidelines exists for this procedure, include a reference to the guidelines	-	+	+	+
4	Define the primary outcome and any key prespecified secondary outcomes for the study	+	+	+	+
<b>Methods</b>					
5	Give the Institutional Review Board/Ethics Committee name and approval number. If permission was not required, reasons should be stated	+	+	+	+
6	Indicate what type of study is presented (randomised controlled trial, cohort, cross-sectional, etc.) The individual guidelines for the type of should be followed (e.g., CONSORT for randomised controlled trials, STROBE for cohort studies, etc.)	+	+	+	+
7	Describe whether this is a single or multicentre study, the type of practice (academic vs. community, tertiary vs. primary), and the providers (limited group or all providers on a service)	+	+	+	+
8	Describe periods of recruitment, time points at which outcomes are assessed, and follow-up	+	+	+	+
9	Define study inclusion and exclusion criteria	+	+	+	+
10	Describe when the enhanced recovery protocol was implemented relative to the study period	-	+	+	+
11	Provide a flow diagram or table through the continuum of care detailing the enhanced recovery protocol, including the following elements: (a) Preadmission patient education regarding the protocol (b) Preadmission screening and optimisation as indicated for nutritional deficiency, frailty, anaemia, HbA1c, tobacco cessation, and ethanol use (c) Fasting and carbohydrate loading guidelines (d) Pre-emptive analgesia (dose, route, timing) (e) Anti-emetic prophylaxis (dose, route, timing) (f) Intraoperative fluid management strategy (g) Types, doses, and routes of anaesthetics administered (h) Patient warming strategy (i) Management of postoperative fluids (j) Postoperative analgesia and anti-emetic plans (k) Plan for opioid minimisation (l) Drain and line management (m) Early mobilisation strategy (n) Postoperative diet and bowel regimen management (o) Criteria for discharge (p) Tracking of post-discharge outcomes	-	+	+	+

**Table 2.** Continued

Item	Recommendation	2017; Scioscia et al. <sup>23</sup>	2022; Pivano et al. <sup>22</sup>	2024; Arena et al. <sup>20</sup>	2024; Djemouai et al. <sup>21</sup>
12	Describe the audit system for compliance with the enhanced recovery protocol and how compliance data are measured.	-	-	-	-
13	(a) Explain the criteria for assessing primary and secondary outcomes (b) Distinguish among clinical, functional, administrative, and quality of life outcome measures	+	+	+	+
14	If patient questionnaires are used, provide references to validation of these study instruments	+	Not used	Not used	Not used
<b>Results</b>					
15	(a) Use a flow diagram to explain the derivation of the study population (b) Provide Table 1 with the key demographic and clinical features of the study population (c) Indicate number of participants with missing data for each variable of interest	+	+	+	+
16	Provide Table 2 with average compliance for each enhanced recovery protocol element and present a comparison of the variation in enhanced recovery compliance among the study groups	-	-	-	-
17	Perform logistic regression to correlate the change in primary outcome with the study intervention	-	-	+	-
<b>Discussion</b>					
18	Explain what the study adds to the body of knowledge regarding the study intervention within the context of enhanced recovery after surgery care	+	+	+	+
19	Discuss the limitations of the study and how these might temper the findings	+	+	+	+
<b>Other information</b>					
20	Document all sources of funding and potential conflicts of interest for the study authors	+	+	+	+
<b>Total (%)</b>		<b>13/20 (65%)</b>	<b>17/20 (85%)</b>	<b>18/20 (90%)</b>	<b>17/20 (85%)</b>

Baseline patients' and perioperative characteristics that were preestablished as essential for inclusion in the present meta-analysis were underreported among the included studies. Available data revealed minimal differences between patients who were treated for deep endometriosis according to the ERAS protocol and those treated for the same condition with conventional perioperative care. Similarly, differences were identified in the ERAS parameters applied across the four studies, and there was an overall underreporting of the ERAS parameters implemented in each respective study. The analysed indices were tabulated in two structured tables, as follows: patients' and surgical characteristics (Table 3)

and principal components of ERAS programs, employed across the included studies (Table 4).

The RCT included in this systematic review and meta-analysis demonstrated a low RoB-2. All three retrospective studies included in the present study exhibited a moderate RoB-2 in the confounding, deviation from intended interventions, and measurement of outcomes domains. Assessment of the methodological heterogeneity with the RoB 2 and ROBINS-I tools revealed that the overall quality of analysed evidence was moderate-high. The detailed assessment of each included study is shown in Table 5.

## Outcomes

The primary outcomes of the meta-analysis were the length of hospital stay and readmission rates. The analysis for the length of hospital stay included one RCT and three non-RCT studies. The RCT by Scioscia et al.<sup>23</sup> reported a significant reduction in the mean length of hospital

stay for patients treated with ERAS compared to those with conventional care (MD: -7.55 days, 95% CI: -8.51 to -6.59;  $P<0.00001$ ). Similarly, the pooled analysis of the three non-RCT studies also demonstrated a significantly shorter length of hospital stay for the ERAS group (MD: -1.26 days, 95% CI: -1.74 to -0.78;  $P<0.00001$ ). Overall, the total pooled effect indicated a significant reduction in

**Table 3.** Patients' and surgical characteristics.

Year; author	Age (years)	BMI (kg/m <sup>2</sup> )	Smoking status	Previous abdominal surgery	History of endometriosis	Type of surgical procedure
ERAS vs. non-ERAS						
<b>2017; Scioscia et al.<sup>23</sup></b>	35.2 ± 4.4 vs. 35.5 ± 5.8 <sup>a</sup>	22.1 ± 3.9 vs. 21.6 ± 3.2 <sup>a</sup>	No data available	33/62 (53.2%) vs. 92/165 (55.8%)	No data available	Segmental bowel resection: 54/62 (87.1%) vs. 141/165 (85.5%) Ileostomy: 9/62 (14.5%) vs. 27/16 (16.4%) Ureterocystoneostomy: 5/62 (8.1%) vs. 9/165 (5.5%) Full-thickness excision of VW: 9/62 (14.5%) vs. 40/165 (24.2%)
<b>2022; Pivano et al.<sup>22</sup></b>	38.26 ± 7.74 vs. 37.9 ± 7.32 <sup>a</sup>	No data available	No data available	No data available	No data available	*Radical surgery: 74/191 (38.7%) vs. 222/573 (38.7%) **Conservative surgery: 117/191(61.3%) vs. 351/573 (61.3%)
<b>2024; Arena et al.<sup>20</sup></b>	36.5 ± 6.7 vs. 36.5 ± 6.3 <sup>a</sup>	23.4 ± 4.3 vs. 23.9 ± 4.7 <sup>a</sup>	No data available	63/263 (24%) vs. 79/316 (25%)	83/263 (31.6%) vs. 119/316 (37.7%)	Shaving: 121/263 (46%) vs. 196/316 (62%) Full thickness anterior resection: 35/263 (13.3%) vs. 28/316 (8.9%) Segmental bowel resection: 107/263 (40.7%) vs. 92/316 (29.1%) Hysterectomy: 31/263 (11.8%) vs. 37/316 (11.7%) Cystectomy of endometrioma: 133/263 (50.6%) vs. 176/316 (55.7%) Bilateral SO: 7/263 (2.7%) vs. 9/316 (2.8%) Monolateral SO: 13/263 (4.9%) vs. 16/316 (5.1%) Removal of bladder endometriosis: 29/263 (11%) vs. 25/316 (7.9%) Removal of parametrial endometriosis: 60/263 (22.8%) vs. 89/316 (28.2%)
<b>2024; Djemouai et al.<sup>21</sup></b>	33.3 ± 8.2 vs. 34.2 ± 6.8 <sup>a</sup>	23.6 ± 4.7 vs. 24.7 ± 6.2 <sup>a</sup>	13/53 (24.5%) vs. 3/39 (7.7%)	No data available	17/53 (32.1%) vs. 17/39 (43.6%)	Segmental bowel resection: 1/53 (1.9%) vs. 0/39 (0%) Segmental bowel resection + ileostomy: 11/53 (20.7%) vs. 7/39 (17.9%) Shaving: 23/53 (43.4%) vs. 22/39 (56.4%) Urinary endometriosis surgery: 2/53 (3.8%) vs. 1/39 (2.6%) Rectovaginal septum surgery: 8/53 (15.1%) vs. 4/39 (10.3%) Other mixed procedures: 8/53 (15.1%) vs. 5/39 (12.8%)

<sup>a</sup>mean + standard deviation, \*Radical surgery: Bowel resection procedures for deep endometriosis, \*\*Conservative surgery: Procedures without bowel resection for deep endometriosis, SO: Salpingoophorectomy, BMI: Body mass index, ERAS: Enhanced Recovery After Surgery.

**Table 4.** ERAS pathway elements across included studies.

	2017; Scioscia et al. <sup>23</sup>	2022; Pivano et al. <sup>22</sup>	2024; Arena et al. <sup>20</sup>	2024; Djemouai et al. <sup>21</sup>
<b>Preoperative phase</b>				
<b>Preadmission information, education, and counselling</b> (including alcohol/smoking cessation and physical exercise/prehabilitation programs)	NR	Implemented	Implemented	Implemented
<b>Management of anemia (Hb &lt;12 g/dL): needed for screening and treatment</b>	NR	NR	Implemented	Implemented
<b>Nutritional Screening</b> (supplementation if needed)	NR	NR	Implemented	Implemented
<b>Preoperative fasting</b> (light meal until 6 h, clear fluids including oral carbohydrate drinks until 2 h)	NR	NR	Implemented	Implemented
<b>Thromboprophylaxis</b> (mechanical + low molecular weight heparin)	NR	NR	Implemented	NR
<b>No mechanical bowel preparation</b> (+ oral antibiotic)	Implemented	NR	Not Implemented	NR
<b>Prevention of nausea and vomiting</b>	NR	Implemented	Implemented	NR
<b>Avoidance of preanesthetic medication</b> (Sedative/ anxiolytics)	NR	Implemented	Implemented	NR
<b>Intraoperative phase</b>				
<b>Prophylactic antibiotics</b>	Implemented	Implemented	Implemented	NR
<b>Skin preparation by chlorhexidine</b>	NR	NR	NR	NR
<b>Anesthetic protocol</b> <ul style="list-style-type: none"> <li>• Cerebral function monitoring</li> <li>• Neuromuscular monitoring</li> <li>• Deep neuromuscular block and reversal by specific antagonists</li> <li>• Lung-protective ventilation</li> </ul>	NR	NR	Implemented	Implemented
<b>Prevention of intraoperative hypothermia</b>	NR	Implemented	Implemented	NR
<b>Intraoperative glycemic control</b>	NR		NR	NR
<b>Advanced hemodynamic monitoring to guide fluid therapy</b>	NR	Implemented	Implemented	NR
<b>Multimodal analgesia</b>	NR	Implemented	Implemented	Implemented
<b>Minimally invasive surgery</b> (in 100% of patients)	NR	Implemented	Implemented	Implemented
<b>No Prophylactic abdominal drains</b>	NR	Implemented	Implemented	Implemented
<b>Postoperative phase</b>				
<b>No use of prophylactic nasogastric drainage</b>	Implemented	Implemented	Implemented	Implemented
<b>Early removal of urinary catheter</b> (within the first 24 h after surgery)	NR	NR	Implemented	Implemented
<b>Early oral intake resumption</b> (clear liquids on the day of surgery, solid food from postoperative day 1)	Implemented	Implemented	Implemented	Implemented
<b>Mobilisation as early as the day of surgery</b> (out of bed)	Implemented	Implemented	Implemented	Implemented
<b>Pharmacological thromboprophylaxis until 4 weeks after surgery</b>	NR	Implemented	Implemented	NR
<b>Patient education before discharge</b> (including nutritional counselling, instruction on feeding and return to work and sport)	NR	NR	Implemented	NR
<b>Collection and documentation of patient-reported outcomes</b>	Implemented	Implemented	Implemented	Implemented
<b>Use ERAS auditing tools</b>	NR	Implemented	NR	NR

NR: Not reported, ERAS: Enhanced Recovery After Surgery, Hb: Haemoglobin.

**Table 5.** Risk of bias of the included studies (risk of bias summary).

Study	Type	Tool	Bias arising from the randomisation process	Bias in selection of participants into the study	Bias in classification of Interventions	Bias due to confounding	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias
<b>2017; Scioscia et al.<sup>23</sup></b>	RCT	RoB-2	Low Risk	X	X	X	Low risk	Low risk	Low risk	Low risk	Low
<b>2022; Pivano et al.<sup>22</sup></b>	Non-RCT	ROBINS-I	X	Low risk	Low risk	Moderate risk	Moderate risk	Low risk	Moderate risk	Low risk	Moderate
<b>2024; Arena et al.<sup>20</sup></b>	Non-RCT	ROBINS-I	X	Low risk	Low risk	Moderate risk	Moderate risk	Low risk	Moderate risk	Low risk	Moderate
<b>2024; Djemouai et al.<sup>21</sup></b>	Non-RCT	ROBINS-I	X	Low risk	Low risk	Moderate risk	Moderate risk	Low risk	Moderate risk	Low risk	Moderate

RCT: Randomised controlled trial, RoB-2: Risk of Bias 2.

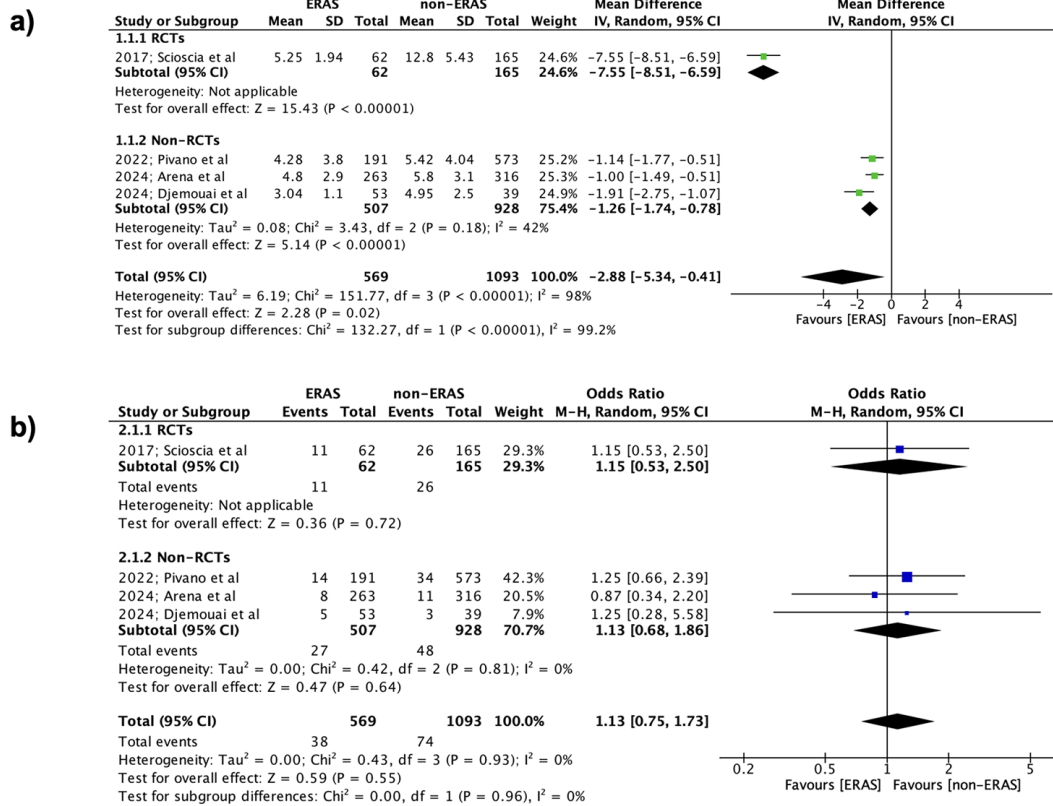
hospital stay for the ERAS group (MD: -2.88, 95% CI: -5.34 to -0.41;  $P=0.02$ ) (Figure 2a).

For readmission rates, the meta-analysis included one RCT and three non-RCT studies. The RCT by Scioscia et al.<sup>23</sup> showed no significant difference in readmission rates between the ERAS and non-ERAS groups (RR: 1.15, 95% CI: 0.53 to 2.50;  $P=0.72$ ). Likewise, the pooled analysis of the three non-RCT studies also indicated no significant difference in readmission rates (RR: 1.13, 95% CI: 0.68 to 1.86;  $P=0.64$ ). Consequently, there was no significant difference in readmission rates between the ERAS and non-ERAS groups overall (RR: 1.13, 95% CI: 0.75 to 1.73;  $P=0.55$ ) (Figure 2b).

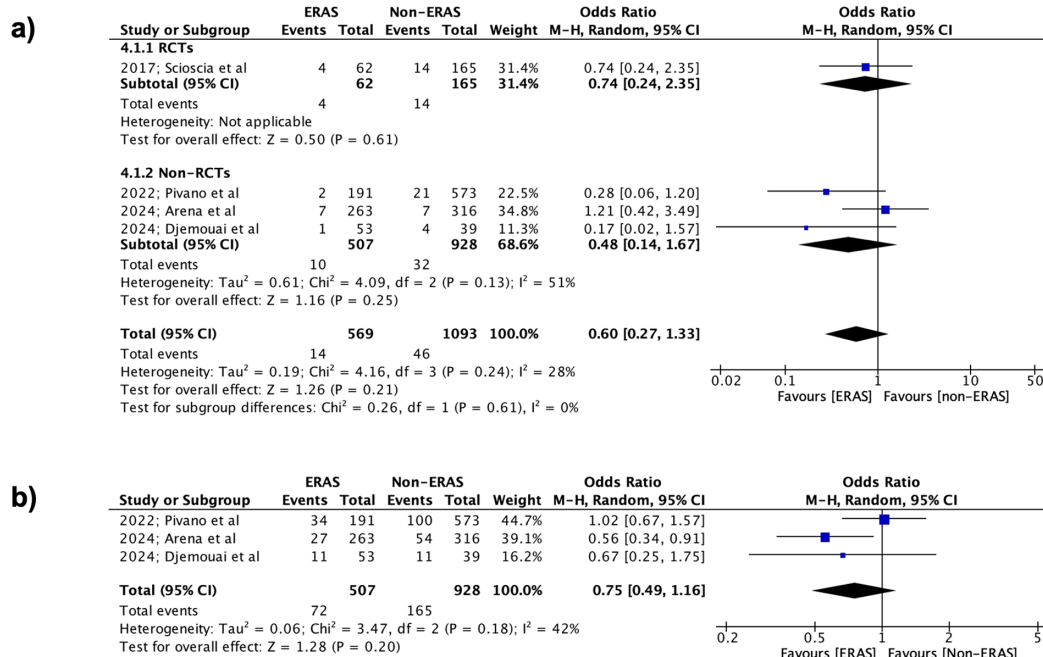
The secondary outcomes included the Clavien-Dindo grade I-II and the Clavien-Dindo grade III or higher complication rates. Regarding Clavien-Dindo grade III or higher complication rate, the meta-analysis included one RCT and three non-RCT studies. The RCT by Scioscia et al.<sup>23</sup> showed no significant difference in higher grade complications between the ERAS and non-ERAS groups (RR: 0.74, 95% CI: 0.24 to 2.35;  $P=0.61$ ). Similarly, the pooled analysis of the three non-RCT studies also showed no significant difference in higher grade complications (RR: 0.48, 95% CI: 0.14 to 1.67;  $P=0.25$ ). Thus, there was no significant difference in Clavien-Dindo grade III or higher complications between the ERAS and non-ERAS groups overall (RR: 0.60, 95% CI: 0.27 to 1.33;  $P=0.21$ ) (Figure 3a).

On the other hand, the meta-analysis for Clavien-Dindo grade I-II complication rates included only three non-RCT studies. The pooled analysis indicated no significant difference in grade I-II complications between the ERAS and conventional perioperative care groups (RR: 0.75, 95% CI: 0.49 to 1.16,  $P=0.20$ ) (Figure 3b).

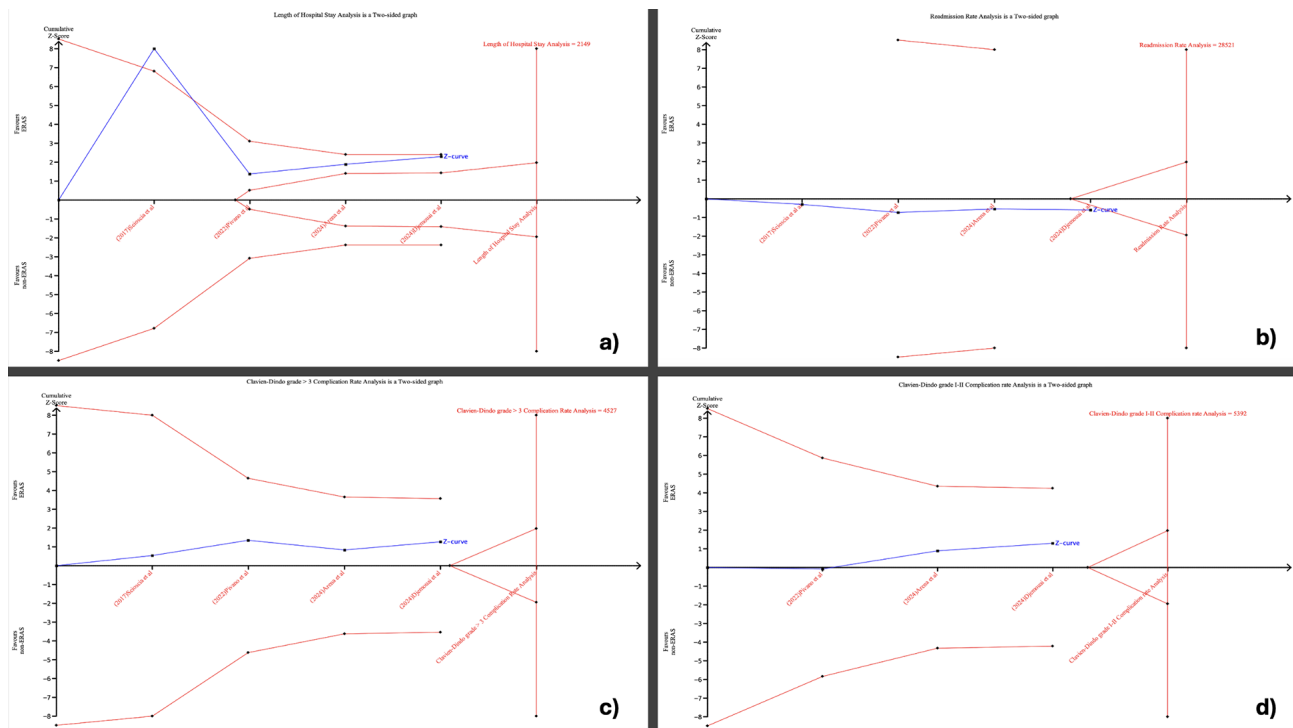
Finally, the TSA for all outcomes did not reach the required information sizes, and the Z-curves did not consistently cross the traditional boundaries. This indicates that, although there are indications of benefits associated with ERAS, the current evidence is not yet definitive (Figure 4). Further research with larger sample sizes is required to provide conclusive evidence on the effectiveness of ERAS protocols in patients operated for DIE.



**Figure 2.** Forest plots describing the contrast between the ERAS group and conventional perioperative care group. a) length of hospital stay, b) readmission rate (Vertical line = "no difference" point between the two groups. Blue squares = risk ratios; Green squares = mean differences; Diamonds = pooled mean differences/risk ratios and 95% confidence intervals for all studies; Horizontal lines = 95% confidence interval).



**Figure 3.** Forest plots describing the contrast between the ERAS group and conventional perioperative care group. a) Clavien-Dindo grade III or higher complication rate, b) Clavien-Dindo grade I-II complication rate (vertical line = "no difference" point between the two groups. Blue squares = risk ratios; diamonds = pooled risk ratios and 95% confidence intervals for all studies; horizontal lines = 95% confidence interval).



**Figure 4.** Trial sequential analysis for primary and secondary outcomes. a) Length of hospital stay, b) readmission rate, c) Clavien-Dindo grade III or higher complication rate, d) Clavien-Dindo grade I-II complication rate.

## Discussion

### Principal Findings

Based on the results of the present meta-analysis, it is demonstrated that the implementation of ERAS protocols in patients undergoing surgery for DIE is associated with a statistically significant reduction in the length of the postoperative hospital stay. This reduction is achieved without a concurrent increase in the rates of postoperative complications and readmissions due to complications, compared to conventional perioperative care protocols.

### Comparison with Existing Literature

ERAS recommendations for gynaecological/oncology surgeries, initially proposed in 2016 and revised in 2019, provide the foundation for studies examining the impact of these protocols on various gynaecological procedures. ERAS protocols have consistently demonstrated clinical benefits for patients and reduced healthcare costs across procedures such as hysterectomies, urogynaecological surgeries, caesarean sections, and gynaecological oncology surgeries.<sup>6,25-27</sup>

Given these proven benefits, similar positive outcomes are anticipated when ERAS protocols are applied to DIE

surgeries. However, current literature on ERAS in DIE is scarce. Two nationwide studies highlight low compliance rates: the Italian Society of Gynaecological Endoscopy reported an overall compliance rate of 56.5%, with preoperative, intraoperative, and postoperative rates at 40.4%, 64.4%, and 62.6%, respectively.<sup>17</sup> Similarly, a French study by Pivano et al.<sup>22</sup> found that only 8.1% of patients with posterior DIE were managed using an enhanced recovery pathway, suggesting an even lower compliance rate.

Despite limited data and low compliance, DIE patients are ideal candidates for ERAS protocols due to their unique clinical characteristics. Prehabilitation programs, a core ERAS component, may alleviate distress and anxiety in DIE patients, improving surgical outcomes.<sup>28</sup> Kalogera et al.<sup>29</sup> demonstrated improved recovery outcomes in minimally invasive gynaecological surgeries involving bowel procedures, relevant to DIE surgeries. Additionally, DIE patients typically have lower postoperative pain thresholds and higher analgesic requirements, necessitating multimodal analgesia strategies inherent in ERAS.<sup>30-32</sup> This necessitates multimodal analgesia strategies, such as those advocated by ERAS pathways, to possibly manage their postoperative pain more effectively. Lastly, ERAS can mitigate the high direct and

indirect costs associated with endometriosis surgeries by reducing complications and hospital stays.<sup>33</sup>

### **Clinical Implication**

Despite the efforts made by the AAGL ERAS Task Force and the ERAS Society to establish specific ERAS protocols for minimally invasive gynaecological and gynaecological oncology surgeries, a primary challenge remains the lack of standardisation.<sup>7,34</sup> This challenge is particularly significant for patients with DIE. The multidisciplinary nature of ERAS protocols, involving the coordinated efforts of surgeons, anaesthesiologists, ERAS nurses, and postoperative care teams, makes adherence and consistent application challenging. The inclusion of multidisciplinary team meetings, as highlighted in the consensus by the European Endometriosis League, can play a pivotal role in aligning practices, fostering collaboration among specialties such as visceral surgeons and urologists, and facilitating the implementation of standardised care pathways.<sup>35</sup> Furthermore, the variability in surgical and anaesthetic practices, as well as economic constraints, add to the difficulty of establishing a standardised protocol.<sup>7</sup>

The clinical implications of the findings from this meta-analysis highlight the need for larger and more comprehensive studies to clearly demonstrate the value of ERAS protocols in DIE surgery. Additionally, these findings should prompt consideration for the development of specific ERAS protocols tailored for patients with DIE. Given the intricate and multisystemic nature of endometriosis, and the distinct characteristics of this patient cohort, standardised ERAS protocols could significantly improve both immediate postoperative outcomes and long-term quality of life, including reproductive health. Establishing such protocols could ensure optimal perioperative care, leading to enhanced surgical outcomes and better overall patient management.

### **Strengths and Limitations of the Study**

This study represents the first comprehensive systematic review and meta-analysis evaluating the implementation of ERAS protocols in DIE surgery. A notable strength is the inclusion of studies without date restrictions, enabling a broad and thorough data collection process. Multiple databases were extensively searched, and records were independently reviewed by multiple assessors, ensuring methodological rigor and enhancing the reliability of

our findings. While preliminary, this study provides valuable insights into the impact of ERAS guidelines on perioperative outcomes in DIE surgery.

However, several limitations must be acknowledged. The small number of included studies, coupled with TSA indicating insufficient sample size for all outcomes, suggests that our results should be interpreted with caution. Most studies were retrospective, increasing the potential for selection bias. Additionally, significant heterogeneity was observed, particularly in the types of surgical interventions and the specific ERAS protocol components applied. This heterogeneity underscores the need for standardised ERAS protocols tailored to DIE surgery, as large-scale randomised trials alone may not address these inconsistencies. Another limitation is the narrow scope of reported outcomes. Important parameters such as postoperative nausea and vomiting, analgesic use, time to return to normal activities, and hospitalisation costs were not assessed. Finally, while the included studies demonstrated substantial compliance with the RECOVER Checklist, none reported adherence to individual ERAS protocol components, limiting our ability to evaluate the protocols' consistency and comprehensive implementation.

Despite these limitations, our findings highlight the potential benefits of ERAS protocols in DIE surgery and underscore the need for further research to validate these results in larger, more homogenous cohorts.

### **Conclusion**

Our study concluded that implementing ERAS perioperative care protocols in DIE surgery can significantly reduce hospital stay, without adversely affecting complication and readmission rates. These findings are particularly relevant given the rising incidence of DIE and increasing surgical volumes, underscoring the need for integrating ERAS protocols to enhance surgical outcomes and reduce healthcare costs. Nevertheless, the limitations of this study, as previously noted, pose challenges in drawing definitive conclusions. Therefore, more extensive and robust scientific evidence is essential, particularly from studies with larger sample sizes and more controlled application of specific ERAS guidelines. Such research is necessary to accurately determine the impact of ERAS protocols on postoperative outcomes in DIE surgery.

## Footnotes

**Acknowledgements:** None.

## Authorship Contributions

Concept: A.D., A.P., Design: A.D., I.K.C., T.G., Data Collection or Processing: A.D., C.K., K.K., Analysis or Interpretation: A.D., N.K., A.M., Literature Search: A.D., C.K., An.P., Writing: A.D., N.K., C.K., D.Z.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Laparoscopic pectopexy for the treatment of pelvic organ prolapse (POP): how, why, when: a narrative review of the literature

Anna Pitsillidi<sup>1</sup>, Athanasios Protopapas<sup>2</sup>, Fani Gkrozou<sup>3</sup>, Angelos Daniilidis<sup>4</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Rheinland Klinikum Dormagen, Dormagen, Germany

<sup>2</sup>Department of Obstetrics and Gynecology, University of Athens, "Alexandra" Hospital, Athens, Greece

<sup>3</sup>Department of Obstetrics and Gynecology, University of Ioannina Faculty of Medicine, School of Health Sciences, Ioannina, Greece

<sup>4</sup>Department of Obstetrics and Gynecology, Papageorgiou General Hospital Faculty of Medicine, School of Health Sciences, Aristotle University of Thessaloniki, Thessaloniki, Greece

## ABSTRACT

**Background:** Pelvic organ prolapse (POP) is a common gynaecological condition that can have an adverse impact on women's quality of life. Apical prolapse refers to the descending of the vaginal apex, uterus or cervix. Nowadays, laparoscopic sacropexy (LS) is the gold standard surgical method for the treatment of apical prolapse. However, defecation and urinary problems are often detected in patients who underwent LS. Laparoscopic pectopexy (LP) is a newer procedure for apical prolapse correction that uses the iliopectineal ligaments as fixation point for the surgical mesh.

**Objectives:** To review the current evidence of the effectiveness and safety of LP and compare outcomes with other commonly used techniques for apical prolapse treatment.

**Methods:** A literature search was carried out in MEDLINE, PubMed and ClinicalTrials.gov databases. The search was restricted to humans, female patients and currently used surgical procedures.

**Main Outcome Measures:** The current recommendations from leading global scientific associations and prevailing trends in accepted clinical protocols.

**Results:** LP was found to have shorter learning curve and operating times, better improvement in quality of life scores including sexual function and low complication rates.

**Conclusions:** LP appears to be a viable alternative to LS. However, further prospective, comparative studies are necessary to evaluate its long-term effectiveness and morbidity.

**What is New?** This review summarises the evidence and current role of LP in the treatment of POP.

**Keywords:** Apical prolapse, laparoscopic pectopexy, laparoscopic sacropexy, pelvic organ prolapse, pelvic organ prolapse treatment, pelvic organ prolapse surgery, hysteropexy, sacrospinous ligament fixation

**Corresponding Author:** Anna Pitsillidi, MD, Department of Obstetrics and Gynecology, Rheinland Klinikum Dormagen, Dormagen, Germany

**E-mail:** anna.pitsillidi@gmail.com **ORCID ID:** orcid.org/0009-0003-5363-352222

**Received:** 04.06.2024 **Accepted:** 17.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Pitsillidi A, Protopapas A, Gkrozou F, Daniilidis A. Laparoscopic pectopexy for the treatment of pelvic organ prolapse (POP): how, why, when: a narrative review of the literature. Facts Views Vis Obgyn. 2025;17(1):30-38



## Introduction

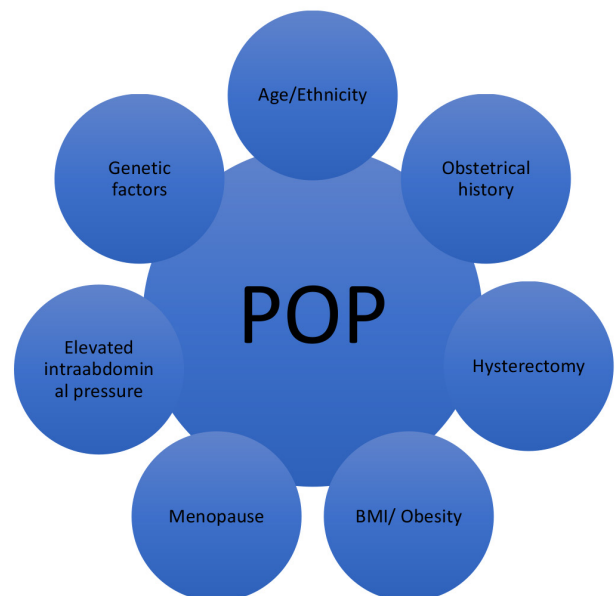
Pelvic organ prolapse (POP) is a very common medical condition and is defined as the protrusion or herniation of the pelvic organs through the vaginal walls and pelvic floor, a condition that affects many women and their quality of life worldwide.<sup>1,2</sup> The prevalence of POP based on the existence of symptoms appears to be 3-6% and up to 50% when based on vaginal examination results, which refer only to the anatomical changes and not the symptoms or severity of the prolapse.<sup>3</sup> According to the compartment which is involved in POP, it can be divided into POP of the anterior, posterior or apical vaginal compartment, with the first one being the most common. However, it must be noticed that POP is caused due to a global pelvic floor dysfunction which affects all three compartments.<sup>4,5</sup>

There are several risk factors which weaken the pelvic floor connective tissue. Increased age is strongly associated with higher prevalence rates of pelvic floor disorders. The proportion of women who suffer from POP is significantly increasing from 6.3% in women aged 20-29 years to 31.6% in those aged 50-59 years and to 52.7% for women 80 and older.<sup>6</sup> Furthermore, parity and the mode of delivery seem to be very important predisposing factors to POP. Multiparous women show an increased likelihood of developing POP compared with nulliparous women.<sup>7</sup> Although parity is an established risk factor for POP, it does not influence the development of recurrence.<sup>8</sup> Regarding delivery mode, it has been shown that vaginal delivery and mostly the first and second delivery can lead to damage of the pelvic floor and POP.<sup>9</sup> On the other hand, caesarean section appears to be protective in the absence of prior vaginal delivery.<sup>10</sup> Increased risk for POP is also reported in women with instrumental delivery, especially with forceps delivery.<sup>11</sup> Other childbirth-related factors for POP are high infant weight, prolonged second stage of labour and maternal age less than 25 years at the first delivery.<sup>12</sup> Furthermore, patients who underwent hysterectomy show an increased risk of expressing pelvic floor prolapse, especially of the central compartment, compared with those with *in situ* uterus.<sup>13</sup> High body mass index (BMI), comorbidities which increase the intraabdominal pressure and menopause due to the low levels of systemic oestrogens and their effect on the collagen of pelvic floor predispose to POP.<sup>14-18</sup> Nevertheless, it is widely recognised that a genetic predisposition to POP does exist. A history of POP in the family leads to an 2.5-fold increased prevalence of POP in comparison with the general population (Figure 1).<sup>19,20</sup>

The pelvic organ prolapse quantification system (POP-Q) and Baden-Waker scoring system are used worldwide for the evaluation of the degree of POP, with the first being recommended by the leading societies.<sup>21</sup>

## Treatment of Pelvic Organ Prolapse

Treatment of POP includes non-surgical and surgical options. The conservative management of POP consists of lifestyle modifications, application of topical oestrogen, pelvic floor physiotherapy and utilisation of mechanical devices (pessaries).<sup>22-24</sup> Surgical management of POP is mainly suggested to symptomatic women who decline non-surgical treatments or no improvement with these strategies. Important aspects which must be considered before deciding the optimal type and route of surgery are the following: the location and the severity of the defect, frequency and severity of symptoms, patient's health condition and comorbidities, patient's preference, desire to have children, coexisting incontinence and of course surgeon's expertise.<sup>25</sup> Patients with prolapse extending beyond the hymen appear to lack adequate support of the vaginal apex, making its surgical repair of great importance in the treatment of women with severe prolapse.<sup>26,27</sup> Apical support in general seems to be the foundation of pelvic floor support. Elliott et al.<sup>28</sup> demonstrated that as the severity of cystocele increases, the likelihood of apical prolapse also increases. Therefore, patients who underwent anterior and/or posterior vaginal wall repair require rarely a POP reoperation.



**Figure 1.** Risk factors for POP.

There are many different procedures for apical suspension which can be mainly divided into restorative and obliterative. Obliterative procedures such as colpocleisis are usually applied to women who are elderly, with many comorbidities and are no longer sexually active. The restorative procedures can be approached transvaginally and transabdominally. Sacrospinous ligament fixation (SSLF) is one of the most commonly performed native tissue transvaginal procedures for the treatment of apical prolapse. However, sacrocolpopexy is the gold standard procedure for correction of apical defects and can nowadays be performed using laparoscopic or even robotic-assisted techniques. In addition to sacrocolpopexy, pectopexy is another type of procedure which has been widely used in the treatment of apical prolapse.

### **Laparoscopic Pectopexy**

Banerjee and Noé<sup>29</sup>, presented, a new laparoscopic technique for prolapse surgery, called pectopexy. This new method was at first designed especially for obese patients and for situations where access to the sacrum, to the longitudinal ligament, or the lesser pelvis was limited. In this difficult surgical field setting, pectopexy seems to be an easier and more safe therapeutic option. In pectopexy, the bilateral mesh fixation points of the prolapsed structures are the lateral parts of the iliopectineal ligament.<sup>29</sup>

### **Technique**

Ten patients with prolapse and obesity (BMI >30 kg/m<sup>2</sup>) and two with past diverticulitis underwent pectopexy.<sup>29</sup> The method was indicated in patients with a POP-Q stage higher than I with a difficult surgical field. Preoperative bowel preparation was not undertaken. The steps of the procedure were:

#### **• Step one: preparation of the patient**

The preferred position for the procedure was the dorsal lithotomy position with the patient's arms placed by her side. A 16-F urinary catheter with continuous drainage system was used. All procedures were carried out under general anaesthesia.

#### **• Step two: insertion of the endoscope**

A 12-mm access port was used to introduce the laparoscope after performing an incision of the inferior margin of the umbilicus. Then follows the insufflation of the abdomen with CO<sub>2</sub> up to 12 mmHg intraabdominal pressure. Three further access ports were used during

pectopexy; two 5 mm ones placed 2-4 cm medial and inferior to the anterior iliac spines and one 5 mm access port placed 2-3 cm superior to the symphysis.

#### **• Step three: intraperitoneal survey and preparation of the iliopectineal ligaments**

During this step, the round ligaments of the uterus were identified. These structures provided the anatomic landmark for a 4 cm<sup>2</sup> region, concluding the iliopectineal ligament and defined by the iliac vessels (cranial/ventral) and the obturator nerve (dorso-caudal). The iliopectineal ligaments were prepared by incising superficially the peritoneum next to the round ligament. A blunt dissection of the soft tissue of pelvic floor followed until the iliopectineal ligaments were visualised taking care of the iliac vessels during dissection, which was extended up to the area of the obturator nerve on both sides.

#### **• Step four: peritoneal and vaginal apex/cervical stump preparation**

Superficial extension of the peritoneal incisions on both sides by blunt dissection using a bipolar clamp and a blunt forceps was conducted. This extension followed an imaginative line between the physiological axis of the pectineal line and the cervical stump or the vaginal apex, remaining superficial during the dissection in order to avoid an accidental injury of deeper nerves and vessels. The insertion of the central part of the mesh depends on the existing structures. In the first presentation of the method, Banerjee and Noé<sup>29</sup> preferred a fixation on the cervical stump accompanying pectopexy with a laparoscopic supracervical hysterectomy (LASH). In patients with a past history of complete hysterectomy the mesh was fixed directly on the vaginal apex after dissecting the peritoneum. This step ends with the lower insertion area corresponding to the peritoneal incisions.

#### **• Step five: mesh fixation**

A polyvinylidene fluoride (PVDF) monofilament mesh (e.g. DynaMesh® PVDF, 3x15 cm) and a suture (non-absorbable suture, 2-0 with attached needle) is inserted via the 12 mm access port. The one small end of the mesh was fixed with two simple interrupted sutures to the left and right iliopectineal ligaments. A biomechanical analysis by Sauerwald et al.<sup>30</sup>, has demonstrated that placement of a single suture was not inferior to a bilateral approach although there are no randomised trials comparing one versus two sutures. The needle was then removed and a new suture (in the case of vaginal apex fixation with polydioxanone suture PDS®, in the case of cervical stump

fixation with a non-absorbable suture, 2-0 with attached needle) was inserted. After elevating the cervical stump or vaginal apex to the expected tension free position it was fixed with 2-4 stitches (simple interrupted or continuously) to the central part of the mesh.

#### • Step six: closure of the peritoneum

The peritoneum was sutured with a 2-0 absorbable suture 35 cm long with attached needle. At the end of this step the needles were removed via the 12 mm access port. The urinary catheter was removed. Insertion of pelvic drainage was not considered obligatory.

### **Surgical Anatomy of Pectineal Ligaments During Pectopexy**

An in-depth understanding of the iliopectineal ligament and the anatomic structure near this ligament is of key importance towards improving the outcomes and minimising the complications of pectopexy. The iliopectineal ligament, also known as the Cooper ligament, is located on the lateral part of the prevesical and paravaginal space, defining the posterior border of the femoral canal and has a great proximity with the external iliac vessels (Figure 2).<sup>31</sup> Furthermore, the pubic vein or the anastomosis between the inferior epigastric artery and obturator artery (corona mortis) is close to the ligament. The obturator area, consisting of obturator nerve, obturator vessels and many anastomoses, is found on the inferolateral side of pectineal ligament.

Familiarity with these landmarks is vital for surgeons conducting pectopexy in order to prevent complications. Pulatoğlu et al.<sup>32</sup> investigated the proximity of these important anatomical structures to the pectineal ligament in seven fresh female cadavers and demonstrated that the nearest anatomic structure on both sides was the external

iliac vein. Corona mortis was shown to be also in close distance with pectineal ligament suturing point, making this anastomotic vessel an important anatomic landmark during accession to the retroperitoneum through the pelvic cavity.

In summary, an understanding of the anatomy and a careful surgical approach while suturing the mesh onto the pectineal ligament during pectopexy is of great importance to avoid inadvertent injury to the external iliac vein.<sup>32</sup>

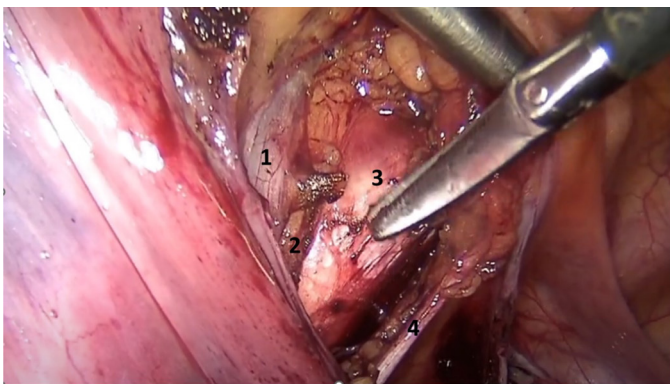
### **Biomechanical Analysis of Laparoscopic Pectopexy**

Due to the high potential benefit of this alternative surgical method of apical prolapse treatment, it is important to optimise the technique by testing its functional stability.<sup>30</sup> Lamers et al.<sup>33</sup> investigated, in an *in vitro* cadaver study, the use of a single suture/mesh iliopectineal ligament fixation as an alternative option to the most commonly used continuous suturing. This study showed that a single 'interrupted' suture, bearing an ultimate load of 35N, was not inferior to a continuous suture and it could be an adequate option for mesh fixation during pectopexy. Nevertheless, the usage of two single sutures may result in an improvement of the ligamentous fixation. However, suturing in general appears to have no important influence on the overall stability, as the surgical mesh remains the limiting factor.<sup>33</sup> After this in *in vitro* cadaver study Sauerwald et al.<sup>30</sup> proceeded to a dynamic *in vitro* analysis of pectopexy in order to evaluate the time needed until function stability was reached and showed that there was no need for fear of global fixation failure while remaining within the load envelope of below 25N.

### **Comparative Analysis of Laparoscopic Pectopexy and Laparoscopic Sacropexy**

#### *Complications*

Sacropexy was first described by Lane<sup>34</sup> in 1962. This technique has been considered to be the gold standard for the treatment of apical prolapse. Sacropexy can be performed both transabdominally and laparoscopically. Abdominal sacropexy has been shown to be associated with long operating-, recovery times and high costs.<sup>35</sup> These disadvantages, in addition to its higher morbidity, have led to the development of new, minimally invasive, approaches (laparoscopic and robotic-assisted sacropexy) with better outcomes and shorter hospitalisation time. In the early 1990s, the first laparoscopic sacropexy (LS) was reported by Nezhat et al.<sup>36</sup>



**Figure 2.** The anatomical landmarks for the exposure of the iliopectineal ligament. 1) External iliac vein, 2) psoas muscle, 3) iliopectineal ligament, 4) obliterated umbilical ligament.

There have been numerous studies which have tried to investigate the differences in perioperative complications and outcomes of pectopexy versus the gold standard method of sacropexy. In sacropexy the anchoring point for the mesh is the longitudinal ligament at the height of the second vertebra (S2), while many surgeons have modified this technique by using the promontory as fixing point in order to avoid the difficult surgical field of the ventral side of the sacrum. This modification leads to changing the direction of the abdominal wall at the vaginal axis.<sup>37,38</sup> Many studies have reported high *de novo* stress incontinence rates (SUI) after sacropexy,<sup>39,40</sup> while others, favouring the classical fixation point (S2 level), reported extremely lower rates of SUI. Classic anchor point usage is recommended in order to avoid traction at the urethral entrance of the bladder. *De novo* SUI and urgency rates seem to have no significant difference between patients who underwent sacropexy (classical fixation point) and those who underwent pectopexy according to Noé et al.<sup>41</sup> The same seems to apply for the axis deviation.<sup>41</sup> On the other hand, Yang et al.<sup>42</sup> showed in a prospective cohort study that urinary symptoms recurrence rate is higher after pectopexy.

The placement of the mesh between the sacrum and the vagina/cervix leads to space restriction of the pelvis which has been shown to cause defecation disorders, expressed mostly in form of constipation. This pelvic cavity narrowing may also lead to post-inflammatory changes of the sigmoid. Furthermore, during the preparation of the anterior sacral bone, there is a great risk of injuring the hypogastric nerves. On the other hand, in pectopexy there are no such disorders to be expected as the mesh follows natural structures (round and broad ligaments) and it is positioned in an organ-free area, without influencing the pelvic space or interfering with the ureter, the bowel or the autonomous nerves. Due to its fixation point, it has been proven to contribute in preserving the natural vaginal axis. Cosson et al.<sup>43</sup> demonstrated that pectineal ligament is statistically significantly stronger than the sacrospinous ligament and the arcus tendineus of the pelvic fascia.

### Recurrence

Noé et al.<sup>41</sup> have shown, in a prospective, randomised, comparative clinical trial with a long follow-up (21.8 months for pectopexy and 19.5 months for sacropexy) that there are no *de novo* lateral defects in pectopexy, compared to sacropexy (12.5%). There was no significant difference in recurrence rates of apical prolapse, *de novo* central-

or lateral- defect cystocele and *de novo* rectocele for both groups. Furthermore, regarding *de novo* defecation disorders, a great difference was demonstrated between the two groups (0% in the pectopexy vs 19.5% in the sacropexy group). The two methods revealed similar anatomic outcomes, intraoperative blood loss and hospitalisation duration, while operation time in pectopexy is proven to be shorter.

### Quality of Life

Several studies have investigated the influence of pectopexy on the quality of women's life (QOL) compared with sacropexy. QOL has been evaluated by using the Pelvic Floor Distress Inventory (PFDI-20) and the Incontinence QOL (I-QOL) questionnaires pre- and post-operatively. Both techniques resulted in a significant improvement in QOL, with pectopexy having a greater impact on QOL than sacropexy.<sup>44</sup> Pectopexy also had also a statistically significant positive influence on sexual life of the patients.<sup>45</sup>

### Learning Curve

The learning curve is also an important aspect of both techniques, being in the center of many researchers' interests. Chuang et al.<sup>45</sup> used cumulative analysis to evaluate the learning curve of laparoscopic pectopexy (LP) and compare it with LS. This study demonstrated that the learning curve of LP, according to the duration of the operation, had a turning point at the 12<sup>th</sup> case. The fewer cases needed for reaching this turning point in LP compared to LS may be a result of the anatomical differences in the surgical field. In LP the most important anatomical landmarks while dissecting the pectineal ligament, as already mentioned, are only the external iliac vessels, the obturator nerve and the corona mortis. However, the obturator nerve is not so close to the pectineal ligament and corona mortis can be easily cauterised if this seems important for the unobstructed mesh fixation. Only the external iliac vessels appear to have a great proximity to the dissection area, but are easily detectable due to their obvious colour and pulsation. LP is shown to have a steep learning curve, which in the case of LS appears to be really challenging for a novice.<sup>46</sup> Furthermore, LS seems to be an operation of great difficulty in obese patients due to the challenging retroperitoneal dissection and identification of the important anatomical structures. High BMI also causes problems in achieving an adequate surgical field while balancing sufficient abdominal pressure and ventilation.

On the contrary, LP's surgical field is not directly influenced in obese patients because it's limited in the anterior pelvis.<sup>46,47</sup>

### **Comparative Analysis of Laparoscopic Pectopexy and Vaginal Sacrospinous Ligament Fixation**

SSLF was first described by Amreich in 1950. In 1968, Richter modified the technique. SSLF has been commonly used for the treatment of apical prolapse, due to its high cure rates.<sup>48,49</sup>

Cosson et al.<sup>43</sup> demonstrated that the sacrospinous ligament and the arcus tendineus of the pelvic fascia seem to be statistically weaker than the Cooper ligament. Brasoveanu et al.<sup>50</sup> compared SSLF and LP in relation to their treatment rates and complications. The cure rates of both procedures were similar high with also similar anatomical results. Astepe et al.<sup>51</sup> showed in their study that there was no statistically significant difference in apical regression rates for both techniques, although patients who underwent SSLF seem to have a greater risk of *de novo* cystocele compared to those who underwent LP. This result may be understood by the fact that in SSLF the vaginal axis appears to have a deviation to the right and posterior side of the pelvis and the body's centre of gravity is also anteriorly shifted, which leads to the placement of greater weight on the anterior compartment. On the other hand, no differences in the rates of *de novo* rectocele have been mentioned. The laparoscopic technique seemed to have a better impact on the post-operative sexual function. This may be due to the presence of vaginal scar after a vaginal procedure. According to Vitale et al.<sup>52</sup> the postoperative sexual life of women could be improved by performing a bilateral sacrospinous fixation.

Both techniques (SSLF and LP) seem to be safe and effective in the treatment of apical prolapse providing a high satisfactory rate. SSLF preserves its role in apical prolapse treatment due to the increasing importance of native tissue repair after the reclassification of surgical mesh for transvaginal usage in the treatment of POP by Food and Drug Administration. In general, LP is a very promising procedure in the field of POP therapy. However, more multicentre studies appear to be still needed in order to investigate the long-term outcomes of the procedure.<sup>51,53</sup>

### **Combined Laparoscopic Pectopexy with Native Tissue Repair**

Nowadays, there seems to be a great deal of concern regarding the use of vaginal meshes, leading to an

increased interest in native tissue repair. Although, native tissue repair has been thought to be an insufficient treatment for POP in the past, there are many publications which suggest that this kind of repair seems to be associated with better long-term outcomes, compared with meshes. In a prospective international multicentre pelvic floor study, Noé et al.<sup>54</sup> investigated the efficacy of sufficient apical support through LP or LS combined with the traditional native tissue repair. This study demonstrated that the procedure, including apical repair with LP with a PVDF mesh (PVDF PRP 3x15 Dynamesh), was associated with very high overall success (96.9%), accompanied by almost total reduction of pelvic pressure and pain, as long as no procedure-related major or minor adverse events. The patients also expressed a very high rate of satisfaction, estimated by pre-designed questionnaires. In a sub-analysis of the forementioned trial, the investigators compared laparoscopic versus vaginal native tissue repair combined with LP and demonstrated that both therapeutic options showed satisfactorily comparable results and concluded that both surgical alternatives could be utilised by surgeons, depended on their skills, expertise and preference. What's interesting is that the only difference reported between the two comparison arms is the presence of vaginal scar, which should be further evaluated in future randomised trials.<sup>55</sup>

Yu and Liu<sup>56</sup>, conducted a study that enrolled 49 patients with POP stage III or IV who underwent a LP with combined vaginal native tissue repair and evaluated the efficacy of this procedure, regarding POP stage and symptom's severity regression. According to the investigators, the primary outcome of the study was the anatomical cure, defined as less than stage I, as scored by POP-Q system and secondary outcomes were symptom severity and quality of life estimates by the PFDI-20, and Pelvic Floor Impact Questionnaire (PFIQ-7) scores. At 3-month follow up period, POP stage showed statistically significant improvement at all point measurements and both questionnaires elucidated also statistically significant improvement (the median value of the preoperative PFDI-20 score was  $79.62 \pm 35.69$ , and the post-operative score was  $9.97 \pm 10.73$ ,  $P < 0.001$ , and preoperative and postoperative median PFIQ-7 scores were  $89.69 \pm 60.05$  and  $11.7 \pm 10.16$ , respectively,  $P < 0.001$ ).

### **Hysteropexy - Laparoscopic Pectopexy with Uterine Preservation**

Hysterectomy has been a part of the procedures performed for the treatment of POP for many decades,

as it appears to have a low rate of risk. In the early 1960s, Heidenreich et al.<sup>57</sup> revised the indications for hysterectomy, so that only a 24.3% of the patients who underwent a surgical treatment for POP, had simultaneously also a hysterectomy. As it was shown, there was no important advantage in the long-term success in the POP procedures. In 1992, DeLancey<sup>58</sup> had already understood the important role of paracervical structures in the prevention of cystocele and rectocele. However, no disadvantages were reported when the uterus was conserved.

Experts should always considerate the patient's desire to preserve her uterus. Korbly et al.<sup>59</sup> had investigated this patient's preference for uterus preservation and showed that only 20% of them also desired a simultaneous hysterectomy. Jefferis et al.<sup>60</sup> evaluated the outcomes of 507 patients who underwent hysteropexy in a period of 10 years. An extremely low complication occurrence (1.8%), the absence of mesh erosion and the very high rate of patient's satisfaction with the POP outcome postoperatively are the most important aspects of this study.<sup>61</sup> Concomitant hysterectomy does not improve the outcome of POP procedures and appears to be rather disadvantageous, as longer operating times and higher rates of mesh exposure, especially in total hysterectomy, have been reported.<sup>61</sup> Thus, hysterectomy should only be performed if there is a clinical indication.

Noé et al.<sup>61</sup> first described the combination of LP with a hysterectomy. However, hysteropexy can also be performed in this technique. The typical mesh (DynaMesh PRP 3 × 15) used in LP can also be used in hysteropexy for the fixation of the uterus (anteriorly). The fixation can also be done with PVDF thread without peritonealisation as the thread and mesh are of the same material, which prevents the provocation of adhesions. The lateral arms of the mesh are passed through a small window in the broad ligament and then typically fixed laterally. On the other hand, an extended mesh (DynaMesh PRP 3 × 18) should be used when the uterus is larger (fixation dorsally for preventing retroflexion).

## Conclusion

LP appears to be a safe technique with comparable anatomic success to sacropexy, lower complication and morbidity rates, and possibly better improvement in QOL, including sexual life. It provides a steady, tension-free replacement of the descended apical compartment,

as the iliopectineal ligament is a more stable structure than the sacrospinous ligament, especially in patients with a difficult operating field and limited access to lesser pelvis and anterior longitudinal ligament due to obesity or adhesions. LP seem to have a shorter learning curve and operating times. It is important to note that there are also some other alternatives to pectopexy methods in the literature, such as the Mulayim and Sendag<sup>62</sup> technique and unilateral pectineal suspension, that also need to be evaluated in clinical trials' setting.<sup>63</sup> In conclusion, LP appears to be a very good alternative to the LS. However, further prospective comparative studies as well as long-term follow-up data are necessary towards evaluating the long-term safety and efficacy of the method.

## Footnotes

**Acknowledgements:** None.

## Authorship Contributions

Surgical and Medical Practices: A.P., A.D., Concept: A.P., A.D., F.G., A.P., Design: A.D., A.P., Data Collection or Processing: A.P., F.G., Analysis or Interpretation: A.P., A.D., Literature Search: A.P., F.G., Writing: A.P., A.D., A.P.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.









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# Diagnosis, management and outcomes of incarceration or intussusception of Fallopian tubes following uterine perforation after vacuum aspiration or dilatation and curettage of the uterine cavity: a systematic review of the literature

 Guglielmo Stabile<sup>1</sup>,  Chiara Ripepi<sup>2</sup>,  Giuseppe Ricci<sup>1,2</sup>,  Luigi Nappi<sup>3</sup>,  Giulia Oletto<sup>4</sup>,  Manuela Ludovisi<sup>5</sup>,  Giovanni Scambia<sup>6,7</sup>,  Matteo Bruno<sup>6</sup>

<sup>1</sup>Institute for Maternal and Child Health IRCCS “Burlo Garofolo”, Trieste, Italy

<sup>2</sup>Department of Medicine, Surgery and Health Sciences, University of Trieste, UOC Clinica Ostetrica e Ginecologica, Trieste, Italy

<sup>3</sup>Department of Medical and Surgical Sciences, Institute of Obstetrics and Gynecology, University of Foggia, Foggia, Italy

<sup>4</sup>Department of Obstetrics and Gynecology, Center for Fetal Care and High-Risk Pregnancy, University of Chieti, Chieti, Italy

<sup>5</sup>Department of Life, Health and Environmental Sciences, University of L'Aquila, L'Aquila, Italy

<sup>6</sup>Dipartimento per la Salute della Donna, del Bambino e di Sanità Pubblica, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, UOC Ginecologia Oncologica, Rome, Italy

<sup>7</sup>Università Cattolica del Sacro Cuore, Rome, Italy

## ABSTRACT

**Background:** Dilation and curettage and vacuum aspiration are frequently performed gynaecological procedures used to treat uterine pathology. This procedure carries a risk of uterine perforation, which can lead to injury of abdominal organs and, rarely, to fallopian tubes.

**Objectives:** To evaluate symptoms and diagnostic signs and to propose the most appropriate management for the intussusception and incarceration of fallopian tubes following uterine aspiration and curettage.

**Methods:** We screened three major databases (Medline, Scopus, Google Scholar) from 2000 to May 2024. Our review examined tubal incarceration, causes, management, symptoms, parity, diagnosis timelines, visceral injury, and surgical complications. The methodological quality of the included studies was assessed using the JBI Critical Appraisal Checklist for case reports.

**Main Outcome Measures:** Diagnostic methods, complications and management of tubal incarceration following uterine perforation.

**Results:** We identified 24 papers, all of which were case reports or case series. In our analysis, tubal incarceration was observed in 25 of 26 cases (96.2%) and in 2 of which (7.7%) it was associated with the entrapment of the infundibulopelvic ligament. In 1 of 26 cases (3.8%) intussusception of the fallopian tube was observed. The most frequently manifested symptoms were abdominopelvic pain, vaginal bleeding, vaginal discharge and amenorrhoea. The mean time to diagnosis was 15.4 months, with transvaginal ultrasound being the primary diagnostic tool, followed by hysteroscopy and diagnostic laparoscopy.

**Conclusions:** Diagnosing this condition should involve a detailed medical history, a comprehensive clinical examination, and imaging evaluations. If instrumental investigations are negative but suspicion remains, hysteroscopy and/or laparoscopy may be necessary.

**What is New?** Tubal incarceration complicating uterine perforation can be managed using hysteroscopy and laparoscopy.

**Keywords:** Fallopian tubes incarceration, intussusception, aspiration, curettage, uterine perforation, systematic review

**Corresponding Author:** Guglielmo Stabile, MD, Institute for Maternal and Child Health IRCCS “Burlo Garofolo”, Trieste, Italy

**E-mail:** guglielmost@gmail.com **ORCID ID:** orcid.org/0000-0001-9266-3896

**Received:** 06.01.2024 **Accepted:** 17.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Stabile G, Ripepi C, Ricci G, Nappi L, Oletto G, Ludovisi M, et al. Diagnosis, management and outcomes of incarceration or intussusception of Fallopian tubes following uterine perforation after vacuum aspiration or dilatation and curettage of the uterine cavity: a systematic review of the literature. Facts Views Vis Obgyn. 2025;17(1):39-49



## Introduction

The risk of perforation during gynaecological procedures ranges from 0.1% to 4%. The highest risk is associated with postpartum procedures (4%), followed by operative hysteroscopies (1%), and the lowest risk is seen in diagnostic hysteroscopies or procedures involving premenopausal patients (0.1%-0.5%).<sup>1</sup> Hysteroscopic procedures generally present a lower risk of perforation and accidental organ damage compared to dilation and curettage (D&C) procedures, due to the greater control provided by direct vision.<sup>1</sup>

D&C is one of the most common gynaecological procedures for the investigation of abnormal uterine bleeding, which nowadays has been replaced with procedures that are more accurate. Nevertheless, vacuum evacuation and curettage remains the standard to remove pregnancy tissue during a first-trimester abortion or miscarriage or post-partum retention of material, despite its highly invasive nature.<sup>2</sup> In contrast, for heavy menstrual bleeding or abnormal uterine bleeding, a hysteroscopic approach, whether "office" or operative, is currently recommended to identify the underlying cause, as it offers superior diagnostic and therapeutic accuracy compared to "blind" procedures like D&C.<sup>3</sup>

It is well-known that any intrauterine procedure, from a simple aspiration to a more complex curettage, carries a risk of uterine perforation.<sup>1</sup> While most perforations can be managed without additional interventions and typically do not result in significant morbidity, serious complications can occur. These include sepsis, haemorrhage, poor reproductive and obstetric outcomes, or injuries to the small intestines, bladder, rectum, appendix, and, rarely, the fallopian tubes, potentially leading to death.<sup>1,4</sup>

In this literature review, we have collected all cases published since inception concerning fallopian tube incarceration following intrauterine procedures. Our goal is to highlight suspicious symptoms and diagnostic signs and to propose the most appropriate management strategies. We have defined tubal incarcerations as cases in which the tube, or a portion of it, become trapped inside the uterus through a breach created by D&C or suction with a cannula during vacuum aspiration. Additionally, we have included cases of tubal intussusception, where one segment of the tube slips inside another, leading to its entrapment.

## Methods

This research was approved by the Institutional Review Board of the Institute for Maternal and Child Health IRCCS Burlo Garofolo (RC 08/2022). A literature search was conducted in May 2024 using various combinations of the following terms: "Tubal incarceration," "Tubal incarceration and uterine perforation," and "Tubal incarceration after vacuum aspiration dilatation and curettage." All cases published in the literature in any language until May 2024 were sourced from Google Scholar, PUBMED, and Scopus.

In our review, we evaluated cases of tubal incarceration, including their causes, management, symptoms, parity, diagnosis timelines, visceral injuries, previous gynaecological surgeries, and complications. Articles that were not relevant to the topic were excluded. All identified studies were examined for year, citation, title, authors, abstract, and full text. Duplicates were identified through manual screening performed by two researchers (C.R. and G.S.) and subsequently removed. The review followed PRISMA guidelines.<sup>5</sup>

The PRISMA flow diagram illustrating the selection process is provided in Figure 1. For the eligibility process, two authors (C.R. and G.S.) independently screened the titles and abstracts of all non-duplicated papers and excluded those not pertinent to the topic. The same two authors independently reviewed the full texts of papers that passed the initial screening and identified those to be included in the review. Discrepancies were resolved by consensus.

Due to the rarity of this condition, the included studies are all case reports. Consequently, we present the data in a descriptive manner. The methodological quality of the included studies was assessed using the JBI Critical Appraisal Checklist for case reports (Supplementary Table 1).

## Results

After the literature search, we identified 24 articles comprising 26 cases (Table 1).<sup>6-36</sup> Most of the cases occurred after vacuum aspiration (11/26, 42.3%), 7 of 26 cases (27%) after D&C, 3 of 26 cases (11.5%) after curettage only, 3 of 26 (11.5%) cases after the combination of vacuum aspiration and curettage and, finally, 2 of 26 (7.7%) cases after combination of dilatation and curettage and vacuum aspiration. In 25 of 26 cases (96.2%), incarceration of the distal part of either the right or left

fallopian tube was observed, of which in 2 cases (7.7%) tubal incarceration was associated with entrapment of the infundibulopelvic ligament, and in one of these two cases, the ipsilateral ovary was also involved. In 2 of 26 cases (7.7%) the avulsion of fimbrial part or distal part of the tube occurred, and the rest remained entrapped. In 1 of 26 cases (3.8%) a tubal intussusception was observed. No concurrent injuries to other visceral organs, such as the bowel, sigmoid colon, or omentum, were reported in any of the screened cases.

The most common indication for the surgeries that led to tubal incarceration, avulsion or intussusception was surgical evacuation of the uterine cavity, either after a miscarriage (AS) or for voluntary termination of pregnancy (TOP) (73%). This was followed by removal of retained placenta after delivery or an incomplete afterbirth phase (23.2%). In one case (3.8%), the removal of an intrauterine device using Pean's forceps led to tubal incarceration. The symptoms most frequently reported by patients included non-specific abdomino-pelvic pain (14/26, 54%), abnormal vaginal bleeding (8/26, 30.8%), vaginal discharge (5/26, 19.2%), secondary amenorrhoea (3/26 11.5%), secondary infertility (4/26, 15.4%) and postpartum haemorrhage (1/26, 3.8%). Two of 26 patients (7.7%) were completely asymptomatic (Table 2).

In our analysis, the mean time to diagnosis was 15.4 months, with a range from a few hours post-procedure to 5 years. In most cases, the suspected diagnosis was made using transvaginal ultrasound, followed by hysteroscopy and diagnostic laparoscopy. Magnetic resonance imaging (MRI) was used in 4 of 26 cases (15.3%) to complete the instrumental investigations, and computed tomography (CT) was used in 2 of 26 cases (7.7%).

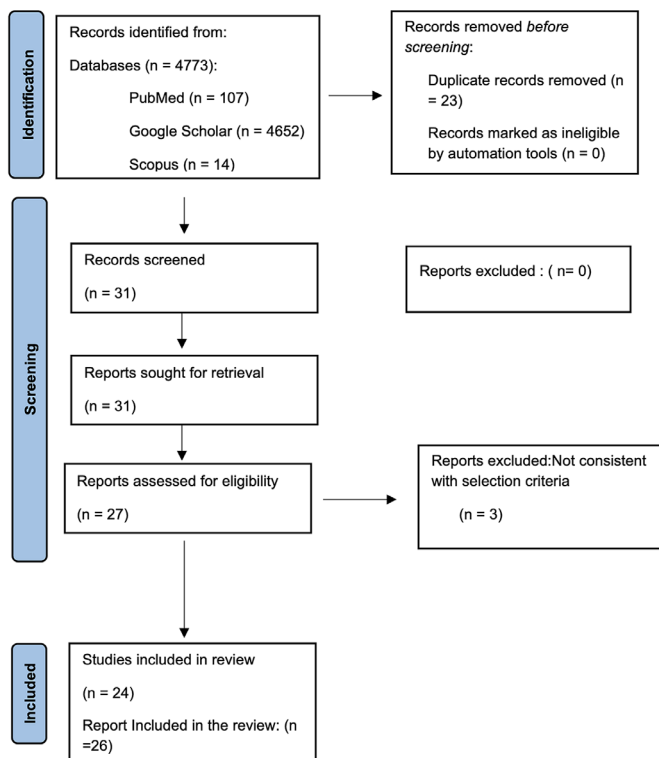
Except for eight cases, laparoscopy was the approach of choice. In four cases (15.3%), the tube was extracted from the myometrium, which was subsequently sutured. In most cases (12 of 26, 46.1%), salpingectomy was necessary. In three cases, diagnostic hysteroscopy was performed concomitantly with laparoscopy. Except for one case of infection treated with antibiotics, there were no post-operative complications. Only one case presented with a life-threatening situation due to a postpartum haemorrhage of 2000 mL, which required the transfusion of 4 units of blood and fresh plasma, with no post-operative complications.

Two patients successfully delivered via caesarean section after laparoscopic correction of the tubal incarceration, and one patient was still pregnant without any related complications in the second trimester.

## Discussion

Our review compiles cases of tubal damage following uterine perforation due to dilatation & curettage or vacuum aspiration. The analysis of the various cases reveals that the procedure most frequently associated with tubal damage is vacuum aspiration and the surgical indication is termination of pregnancy. Moreover, in most cases, the tube itself, entrapped in the myometrium, acts as a haemostatic agent, contributing to a delayed diagnosis, as the most common symptom is non-specific pelvic pain. Furthermore, as reported in our results, the incarceration of the tube is not accompanied by the incarceration of other abdominal organs, further reducing the presence of other suspicious signs or symptoms. The three most frequent symptoms are abdomino-pelvic pain (54%), abnormal vaginal bleeding (30.8%), vaginal discharge (19.2%) and they are aspecific and not directly related to a tubal pathology, leading to a mean time for the diagnosis of 15.4 months and to the low incidence reported in the literature.<sup>22</sup>

The data suggested the most significant risk factor for uterine perforation, accounting for approximately 95.6% of cases, was the surgeon's inexperience, especially when



**Figure 1.** The PRISMA flow diagram of the selection process.

**Table 1.** Reports of the literature.

Article/article type	Procedure	Tubal incarceration	Cause	Management	Visceral injury	Delayed diagnosis/ immediate diagnosis	Complication	Symptoms	Parity/uterine anomalies/ previous gynaecological surgeries
Steigrad and Margin <sup>6</sup> , 1978	Vacuum aspiration and curettage	Yes, presented as uterine polyp extruded through the cervix	Postpartum haemorrhage after delivery	Twisted away from the vagina and after histological examination, LPT	No	After 10 months	No	Abnormal vaginal discharge, vaginal bleeding	G3P3, sterilised
Lapas and Todorov <sup>7</sup> , 1987 Abstract	Dilatation and curettage + vacuum aspiration	Avulsion of right fallopian tube	Therapeutic abortion presence due to Rubeola antibodies in the serum	Emergency LPT, right horn suture with 3 haemostatic sutures	Round ligament	Immediately	No	Examination of vacuum-curettage specimen fragments of an abdominal suspected appendix	G1
Thomas <sup>8</sup> , 2003	Vacuum aspiration	Yes	8-week gestation missed abortion	Hysteroscopy (resected as a polyp)	No	6 months	No	Secondary dysmenorrhea menometrorrhagia and lower back pain	G2P0, D&C for abortion 15 mo before
Deffieux et al. <sup>9</sup> , 2007 Case report	Vacuum aspiration	Fallopian tube	Voluntary interruption of a first-trimester pregnancy	LPS: salpingectomy	No	5 years after vacuum aspiration/ US, MRI, laparoscopy, hysteroscopy (utero setto)	No	Intermittent abdominal pain	G1P0 (1 TOP)
Alanbay et al. <sup>10</sup> , 2009 Case report	Dilatation and curettage	Tubal and distal part of the infundibulopelvic ligament herniation	First trimester due to early fetal loss	LPS, minilaparotomy: gentle traction of the tubal complex. Hydroperitubation of the tubes (bilateral passage)	No	2 years after curettage/ hysterosalpingography, diagnostic laparoscopy along with a diagnostic hysteroscopy	No	Secondary infertility	1G0P (1 AS)
Trio et al. <sup>11</sup> , 2010 Case report	Vacuum aspiration	Incarceration of the left fallopian tube	Pregnancy termination (9 w)	LPS: during surgery, the tube was extracted from the uterine wall and the myometrial lesion was repaired using coagulation	No	Few days later/US, diagnostic laparoscopy	No	Pelvic pain and minimal vaginal bleeding	G1P0 (1 AS)
Ceccaldi et al. <sup>35</sup> , 2011 Case report	Vacuum aspiration	Right fallopian tube	First-trimester surgical abortion	LPS: tube was extracted from the posterior wall of the uterus and repaired by neosalpingostomy	No	18 months after a surgical abortion/ hysterosalpingography, hysteroscopy, LPS	No	Secondary infertility	G5P2

**Table 1.** Continued

Article/article type	Procedure	Tubal incarceration	Cause	Management	Visceral injury	Delayed diagnosis/ immediate diagnosis	Complication	Symptoms	Parity/uterine anomalies/ previous gynaecological surgeries
Bharathan et al. <sup>12</sup> , 2011 Case report	Vacuum aspiration	Fimbrial end of the right fallopian tube	Surgical termination of pregnancy at 6 w	Laparoscopy under hysteroscopic guidance	No	Three weeks following first procedure/US, followed by hysteroscopy and diagnostic laparoscopy	No	Persistent spasmodic pelvic pain	Multiparous
Damiani et al. <sup>36</sup> , 2011 Case report, 2 cases	Vacuum aspiration	Tubal prolapse	Voluntary interruption of first-trimester pregnancy	Removed using a Pozzi Palmer forceps after insertion of a speculum	No	18 months after procedure/US, hysteroscopic (myoma misdiagnosed), histological examination	No	Secondary oligomenorrhea, lower abdominal pain and discomfort. Cramping abdominal pain, reflex pain in the right iliac fossa, deep dyspareunia, nausea and vomiting, diarrhoea, intermittent vaginal bleeding, vaginal discharge with an abnormal foul smell and colour that was either watery or bloody; and occasional febrile episodes	G5P2 (2 TOP, 1 AS, performed by dilation and suction curettage)
Nkwabong et al. <sup>4</sup> , 2011 Case report	Vacuum aspiration and curettage	Incarcerated distal part of the right fallopian tube	Post-partum retained material	LPS: salpingectomy + myometrium repaired	No	3 months after the delivery/US, hysteroscopic examination, biopsy, laparoscopic examination		Metrorrhagia on day 13 of puerperium, amenorrhea	G1P1
	Vacuum aspiration	Incarceration of the distal part of the fallopian tube	Early foetal loss at 7 weeks 3 days	Emergency laparotomy: a left total salpingectomy (left fimbria and part of the ampulla were necrosed). The uterine cavity was curetted and the perforations closed with vicryl	No	Immediately	No	Painful aspiration and persistent pelvic pain, slight vaginal bleeding	G7P4 (4 PS 2 TOP)

**Table 1.** Continued

Article/article type	Procedure	Tubal incarceration	Cause	Management	Visceral injury	Delayed diagnosis/ immediate diagnosis	Complication	Symptoms	Parity/uterine anomalies/ previous gynaecological surgeries
Cremieu et al. <sup>13</sup> , 2012	Dilatation and curettage	Right fallopian tube (posterior wall)	First trimester early foetal loss	Hysteroscopy 1 <sup>st</sup> step (normal) and LPS 2 <sup>nd</sup> step, salpingoscopy with blue, myometrial suture with monocrystal	No	Unspecified, diagnostic sonosolpingography	No	Secondary infertility	G2P1, spontaneous pregnancy 3 months after, caesarean section 39 wks due to placenta accreta)
Kondo et al. <sup>29</sup> , 2013 Case report	Curettage	Right fallopian tube	Post-partum retained placenta	LPS: right salpingectomy + uterine repair	No	11 months after uterus curettage/US, MRI, diagnostic laparoscopy	No	Pelvic pain (intermittent) and amenorrhea since vaginal delivery	G2P2
Guzel et al. <sup>14</sup> , 2014	Dilatation and curettage	Yes	First-trimester Pregnancy loss	Hysteroscopy and LPS (preserved)	No	3 years	No	Secondary infertility	G3P1, previous caesarean section at 37 ws
Lin et al. <sup>15</sup> , 2015 Case report	Dilatation and curettage	Fallopian tube	First-trimester pregnancy loss	Laparoscopy: salpingectomy with adhesiolysis + uterus repair (histopathological examinations of the resected specimens demonstrated an ectopic pregnancy in the ampulla of the fallopian tube)	No	5 years/US, laparoscopy, hysteroscopy	No	5-year history of irregular menstruation and vaginal bleeding	G2P1 (1 TOP)
Chung and Cheung <sup>16</sup> , 2015	Vacuum aspiration	Fimbrial part of right fallopian tube avulsed	Voluntary interruption of a 9 + 0 wk pregnancy	Repeat suction evacuation and laparoscopy. 1 cm perforation on caesarean scar	No	After 5 days	No	fallopian tube tissue shown on histological examination	G4P2, previous caesarean section
Camus et al. <sup>33</sup> , 2017 Case report- video article	Dilatation and curettage	Fallopian tube incarceration	Non-evolving pregnancy at 8 w	LPS: tube extracted out of the uterine defect + uterus repair. Positive tubal patency test	No	9 months later/US, MRI, laparoscopy, hysteroscopy	No	abnormal vaginal discharge	G1P0 (1AS)

**Table 1.** Continued

Article/article type	Procedure	Tubal incarceration	Cause	Management	Visceral injury	Delayed diagnosis/ immediate diagnosis	Complication	Symptoms	Parity/uterine anomalies/ previous gynaecological surgeries
Dean et al. <sup>23</sup> , 2017 Case report	Vacuum aspiration and curettage	Prolapse of the left fallopian tube and ovary into the uterine cavity and avulsion of the infundibulopelvic ligament	Elective surgical termination of pregnancy (TOP) at 19 w, followed by PPH (1500 cc)	Emergency LPS	No	Immediate diagnosis after PPH. Manual examination and ultrasound	Haemorrhagic Shock (2000 mL) with 4 units of blood transfusion and fresh frozen plasma	Postpartum haemorrhage	G5P2 (2 TOP), vaginal delivery, no previous PPH
Boujenah et al. <sup>17</sup> , 2017 Letter to Editor	Vacuum aspiration	Intrauterine intussusception of the fallopian tube	Postpartum retained placenta 15 days after delivery	LPS: salpingectomy (because of severe ampullary damages) + uterus repair	No	9 months after vacuum aspiration/US (3D+ Doppler), MRI, hysteroscopy, LPS	No	Abdominal pain, spotting and amenorrhea	
Linton et al. <sup>18</sup> , 2019 Case report	Dilatation and curettage + vacuum aspiration (7-mm rigid suction cannula)	Left fallopian tube	Voluntary pregnancy termination at 6 w + 5 d	Laparoscopy, using a standard entry, performed under general anaesthesia. Left salpingectomy, uterus repair and gentle suction curettage under direct laparoscopic visualization	No	In few hours/US	No	Increasing pain in her lower abdomen, nausea	G5P1 (1VB, 1CS, 2 ABS D&C)
Liu and Chi <sup>19</sup> , 2021 Case report	Curettage	Right fallopian tube partly incarcerated in the uterine fundus	4 weeks postpartum after delivery for removal of retained placental membranes	LPS: neosalpingostomy and hysterothoraphy	No	3 years later curettage/diagnostic hysteroscopy (severe IUA), US (hydrosalpinx), hysteroscopy combined with laparoscopy	No	Amenorrhea and watery leucorrhoea	G2P1
Sedrafi et al. <sup>20</sup> , 2021	Dilatation and curettage	Yes	First-trimester pregnancy loss	Hysteroscopy and LPS (salpingectomy)	No	6 months	No	Pelvic pain	G1P0

**Table 1. Continued**

Article/article type	Procedure	Tubal incarceration	Cause	Management	Visceral injury	Delayed diagnosis/ immediate diagnosis	Complication	Symptoms	Parity/uterine anomalies/ previous gynaecological surgeries
Zhou et al. <sup>26</sup> , 2021 2 case reports	Vacuum aspiration	A small part of the right ovary and most of the fallopian tube	Voluntary interruption of first trimester pregnancy	Bedside ultrasound (clinical suspicious if uterine rupture and surrounding tissue incarceration), extemporaneous histological examination of the tissue in vagina, exploratory LPT à chronic rupture in the anterior wall close to the fundus. Repair of rupture + right salpingectomy	No	2 years later after the delivery of 2 <sup>nd</sup> child	No	A dark red growth approximately 7 mm x 2 mm x 2 cm in size, with moderate texture, was palpated in the vagina after the after-birth phase. Then, postpartum pain in the lower right abdomen, with noticeable tenderness and rebound pain	G3P2 (1AS with D&C)
	Vacuum aspiration	Fallopian tube	Voluntary interruption of first trimester pregnancy	Hysteroscopy with mass removal, no sign of perforation, placement of IUD à histological examination: fallopian tube		1 year		Severe dysmenorrhea, moderate vaginal discharge	G4P2 (2AS), IUD after 2 <sup>nd</sup> AS removed for displacement after a year
Shu et al. <sup>21</sup> , 2022	Curettage	Yes	Retained placenta after delivery	Hysteroscopy and LPS (salpingectomy)	No	2 months	No	Pelvic pain	G1P0
Wang et al. <sup>31</sup> , 2022 Case report	Dilation and curettage	Fallopian tube incarceration	One month after term delivery due to space-occupying lesions	LPS: salpingectomy and oophorectomy (left ovarian mass concomitant) + repair of the uterus and ovary	No	3 years later/US (ovarian endometriosis cyst and endometrial polyps in the cavity misdiagnosed), hysteroscopy, LPS	No	Slight lower left abdominal pain	G1P0

LPT: Laparoscopic tubal surgery, LPS: Laparoscopic surgery, US: Ultrasound, MRI: Magnetic resonance imaging, D&C: Dilation and curettage, TOP: Termination of pregnancy, PPH: Postpartum haemorrhage, IUD: Intrauterine device, IUA: Intrauterine adhesions.

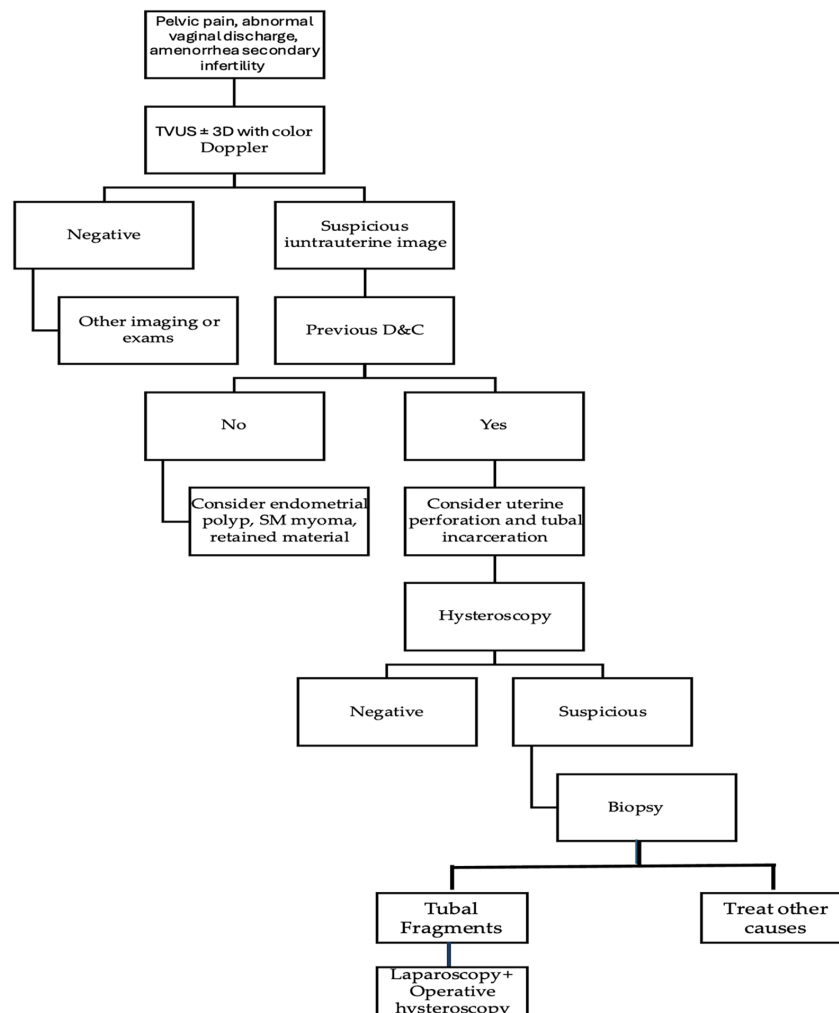
surgery (vacuum aspiration or dilatation and curettage) is performed after a miscarriage or for voluntary termination of pregnancy when the uterus is less resistant.<sup>4,22-26</sup>

**Table 2.** Frequency of symptoms.

Complaint	Number of cases	% of presentation
Abdominal/pelvic pain (non-specific)	14/26	54%
Abnormal vaginal bleeding (spotting, metrorrhagia, menorrhagia)	8/26	30.8%
Vaginal discharge	5/26	19.2%
Secondary infertility	4/26	15.4%
Secondary amenorrhoea	3/26	11.5%
Asymptomatic	2/26	7.7%
Post-partum hemorrhage	1/26	3.8%

Transvaginal ultrasound is the first-line instrumental exam, with findings of a hyperechoic tubular structure in the myometrium or endometrial cavity, possibly associated with intra-pelvic free fluid, which is often misdiagnosed as an endometrial polyp, submucous myoma, or intrauterine adhesion.<sup>27</sup> 3D transvaginal ultrasound and color Doppler can assist in differential diagnosis.<sup>28</sup>

CT can be used in acute patients while, MRI can aid in challenging cases in stable patients where ultrasound and CT are not informative.<sup>29,30</sup> However, according to the data from our analysis, it may be quicker and less stressful for the patient to proceed directly with a diagnostic hysteroscopy, as suggested by Wang et al.<sup>31</sup> in order to obtain a bioptic diagnosis. Moreover, Boughizane et al.<sup>32</sup> and Camus et al.<sup>33</sup> recommended a combined approach with laparoscopy for the double diagnostic and therapeutic value of laparoscopy in these cases and for optimal tubal preservation.



**Figure 2.** Diagnostic-therapeutic algorithm.

D&C: Dilation and curettage.

In most of our review cases, salpingectomy was performed after extracting the tube from the myometrium; if tubal preservation is affordable, it could be useful to perform chromo-salpingoscopy in order to verify tubal function. Dysfunction of the fallopian tubes is a leading cause of tubal infertility, with proximal tubal blockage accounting for about 26% of all infertility cases.<sup>34</sup> In addition, with a view to future pregnancies, suturing the myometrial breach is advisable even if it represents an area of minor resistance and tissue alteration, which may be susceptible to placentation issues or complications during manual placenta removal (2.7%).<sup>4</sup>

There are no specific guidelines on how to complete childbirth in these cases, with decisions made by the gynaecologist in consultation with the patient. Elective C-sections were performed in the cases described in this review. Ceccaldi et al.<sup>35</sup> suggested that large fundal myometrial defects and thin fibrosis may favour elective caesarean delivery. However, there is no absolute contraindication to vaginal delivery, though labour and delivery should be closely monitored to prevent uterine rupture.

Preventive strategies for uterine perforation include careful preoperative evaluation, appropriate instrumentation and techniques, and adequate training and experience of the surgeon.<sup>23</sup> Ultrasound guidance during surgical termination is supported to reduce procedure-related morbidity.<sup>22</sup> Damiani et al.<sup>36</sup> recommends using negative pressure not exceeding 500 mmHg (or 0.07 bar) during vacuum aspiration to reduce the risk of adjacent organ suction in case of uterine perforation.

The strength of this manuscript lies in the extensive literature review period, with the largest number of cases considered. All studies selected during the eligibility phase were manually compared to avoid overlapping cases. The methodological quality of the included studies was assessed using the JBI Critical Appraisal Checklist for case reports. Conversely, the main limitation is the inclusion of only case reports due to the rarity of this complication. For this reason, we aimed to gather data in order to provide clinical suspicion signs based on the patient's history, along with a diagnostic and management algorithm (Figure 2).

## Conclusion

A thorough diagnosis of uterine perforation with secondary tubal damage requires a detailed medical history, a comprehensive clinical examination, and imaging

evaluation. If instrumental investigations are negative but clinical suspicion remains, direct visualisation tools such as hysteroscopy and/or diagnostic laparoscopy may be necessary.

Given the rarity of this condition, there are no specific guidelines on how to manage this complication, considering that the majority of cases involve women of reproductive age, it is essential to preserve their reproductive function by assessing tubal integrity and function and preserving the myometrium as much as possible.

## Footnotes

**Acknowledgements:** This work was supported by the Ministry of Health, Rome-Italy, in collaboration with the Institute for Maternal and Child Health IRCCS Burlo Garofolo, Trieste-Italy.

## Authorship Contributions

Conceptualization: G.S., G.R., M.B., Methodology: G.S., C.R., G.O., G.R., Software: C.R., G.O., Validation: G.S., L.N., M.L., G.Sca, Formal Analysis: G.S., C.R., M.B., Investigation: G.S., M.B., C.R., Data Curation: C.R., G.O., Writing-Original Draft Preparation: G.S., C.R., M.B., G.O., Writing-Review and Editing: G.S., M.B., G.R., Visualization: G.Sca, L.N., M.L., Supervision: G.R., G.Sca, Project Administration: G.S., G.R.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Unveiling the real benefits of robot-assisted surgery in gynaecology: from telesurgery to image-guided surgery and artificial intelligence

✉ Matteo Pavone<sup>1,4</sup>, ✉ Marta Goglia<sup>1,2,5</sup>, ✉ Andrea Rosati<sup>3</sup>, ✉ Chiara Innocenzi<sup>3</sup>, ✉ Nicolò Bizzarri<sup>3</sup>,  
✉ Barbara Seeliger<sup>1,2,4,6</sup>, ✉ Pietro Mascagni<sup>2,8</sup>, ✉ Filippo Alberto Ferrari<sup>9</sup>, ✉ Antonello Forgione<sup>1</sup>,  
✉ Antonia Carla Testa<sup>3,10</sup>, ✉ Anna Fagotti<sup>3,10</sup>, ✉ Francesco Fanfani<sup>3,10</sup>, ✉ Denis Querleu<sup>3,10</sup>, ✉ Giovanni Scambia<sup>3,10</sup>,  
✉ Cherif Akladios<sup>7</sup>, ✉ Jacques Marescaux<sup>1</sup>, ✉ Lise Lecointre<sup>2,4,7</sup>

<sup>1</sup>IRCAD France Research Institute Against Digestive Cancer, Strasbourg, France

<sup>2</sup>Institute of Image-Guided Surgery, IHU Strasbourg, Strasbourg, France

<sup>3</sup>Dipartimento di Scienze per la salute della Donna e del Bambino e di Sanità Pubblica, Fondazione Policlinico Universitario A. Gemelli, UOC Ginecologia Oncologica, Rome, Italy

<sup>4</sup>ICube, Laboratory of Engineering, Computer Science and Imaging, Department of Robotics, Imaging, Teledetection and Healthcare Technologies, University of Strasbourg, Strasbourg, France

<sup>5</sup>Department of Medical and Surgical Sciences and Translational Medicine, Faculty of Medicine and Psychology, Sapienza University of Rome, Rome, Italy

<sup>6</sup>Department of Digestive and Endocrine Surgery, University Hospitals of Strasbourg, Strasbourg, France

<sup>7</sup>Department of Gynecologic Surgery, University Hospitals of Strasbourg, Strasbourg, France

<sup>8</sup>Fondazione Policlinico Universitario A. Gemelli, Rome, Italy

<sup>9</sup>Department of Obstetrics and Gynecology, AOUI Verona, University of Verona, Verona, Italy

<sup>10</sup>Università Cattolica del Sacro Cuore, Rome, Italy

## ABSTRACT

**Background:** Several new robotic platforms are being commercialised, with different features in terms of types of consoles, numbers of arms, and targeting transabdominal or natural orifice approaches. The benefits of robotic surgery over laparoscopy have yet to be conclusively demonstrated in gynaecology, as several studies comparing perioperative and postoperative patient outcomes have reported no significant differences, leading to a lack of precise recommendations in surgical guidelines for both gynaecologic oncology and benign gynaecology. In addition, these outcomes must be balanced against the high costs of robotic surgery, in particular when considering building an infrastructure for safe telesurgery to democratise access to telementoring and remote interventions.

**Objectives:** Drawing from the expertise gained at the IRCAD Research and Training Center in Strasbourg, France, this article aims to provide an overview of the unveiled benefits of robotic-assisted surgery in gynaecology, investigating the role of digital surgery integration.

**Methods:** The objective of this narrative review is to provide an overview of the latest advancement in digital robotic-assisted surgery in gynaecology and illustrate the benefits of this approach related to the easiest integration with new technologies. To illustrate such evidence, PubMed, Google Scholar, and Scopus databases were searched.

**Corresponding Author:** Marta Goglia, MD, IRCAD France Research Institute Against Digestive Cancer; Institute of Image-Guided Surgery, IHU Strasbourg, Strasbourg, France; Department of Medical and Surgical Sciences and Translational Medicine, Faculty of Medicine and Psychology, Sapienza University of Rome, Rome, Italy

**E-mail:** marta.goglia@uniroma1.it **ORCID ID:** orcid.org/0000-0002-3763-8847

**Received:** 15.07.2024 **Accepted:** 19.11.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Pavone M, Goglia M, Rosati A, Innocenzi C, Bizzarri N, Seeliger B, et al. Unveiling the real benefits of robot-assisted surgery in gynaecology: from telesurgery to image-guided surgery and artificial intelligence. Facts Views Vis Obgyn. 2025;17(1):50-60



## ABSTRACT

**Main Outcome Measures:** In the era of surgical innovation and digital surgery, the potential of robotic surgery becomes apparent through the capacity to integrate new technologies. Image-guided surgery techniques, including the analysis of preoperative and intraoperative images, 3D reconstructions and their use for virtual and augmented reality, and the availability of drop-in robotic ultrasound probes, can help to enhance the quality, efficacy and safety of surgical procedures.

**Results:** The integration of artificial intelligence, particularly computer vision analysis of surgical workflows, is put forward to further reduce complications, enhance safety, and improve operating room efficiency. Additionally, new large language models can assist during procedures by providing patient history and aiding in decision-making. The education and training of young surgeons will undergo radical transformations with robotic surgery, with telementoring and shared procedures in the side-by-side double-console setup.

**Conclusions:** Robotic systems play a fundamental role in the transition towards digital surgery, aiming to improve patient care through integration of such new technologies.

**What is New?** While the advantages of robotic surgery in terms of perioperative outcomes have yet to be demonstrated, the benefits of its easiest integration with new technologies are evident.

**Keywords:** Robotic-assisted surgery, image-guided surgery, artificial intelligence, telesurgery, training, minimally invasive surgery

## Introduction

The integration of robotic surgery into clinical practice is becoming increasingly widespread and currently one robotic surgical procedure is performed every 16.8 seconds worldwide using the da Vinci system by Intuitive Surgical, the main actor among robotic companies in the last 25 years.<sup>1</sup> Given the increasing amount of robotics companies created annually, and the numerous new platforms with diverse features (multi-port, single port, flexible) under development and reaching market clearance, the current and expected growth rate is between 15-25%.<sup>1,2</sup> In oncologic gynaecology, only three randomised trials are present in the literature with small sample size.<sup>3-5</sup> A French multicentre trial the ROBO-GYN-1004 demonstrates no differences in terms of severe morbidity, conversion rate to open surgery and longer operating time for robotic surgery.<sup>6</sup> To date robotic surgery is indicated for obese patients with endometrial cancer<sup>7</sup> and in selected cases of ovarian cancer<sup>8</sup>, while its adoption in cervical cancer surgery is still under investigation.<sup>9-11</sup> The robotic single-port approach is a feasible option in endometrial cancer comparable to the multiport procedure in terms of intraoperative and postoperative findings, and has an advantage in terms of shorter surgical times and aesthetic outcomes.<sup>12-14</sup> In benign gynaecologic surgery, robotic platforms are used in challenging cases of deep endometriosis or complex urogynaecological conditions<sup>15</sup> and as a possible option in reconstructive pelvic surgery.<sup>16</sup> A prospective multicentre randomised trial (LAROSE trial) enrolling 73 patients with suspicion of pelvic endometriosis, showed a similar OT between RAS and LPS (mean  $\pm$  standard deviation, 107  $\pm$  48 min vs. 102  $\pm$  63 min) when adjusted to the stage of disease.<sup>17</sup>

Several studies have been published to compare robotic surgery with laparoscopy in terms of objective outcomes such as length of hospital stay, estimated blood loss, operative time, and postoperative pain.<sup>11,18,19</sup> However, significant differences have yet to be consistently demonstrated, and prospective clinical trials are still ongoing<sup>10,17,20</sup> without any guidelines recommending the robotic approach as the first choice. Additionally, and in contrast to other fields of abdominal surgery, in gynaecology a significant number of procedures, including hysterectomies and sacrocolpopexies, are carried out via the transvaginal route.<sup>21</sup> The number of reported robotic transvaginal procedures (R-vNOTES) is still low, but has been successfully demonstrated and compared with the traditional transvaginal approach. Robotic platforms designed to enhance transvaginal approaches, such as the Anovo™ Surgical System (Momentis Surgical, Israel) approved for benign disease, or a future inclusion of robotically steerable uterine manipulators into existing multi-arm systems, provide new opportunities for increased dexterity and instrument control in a restricted space.<sup>21</sup>

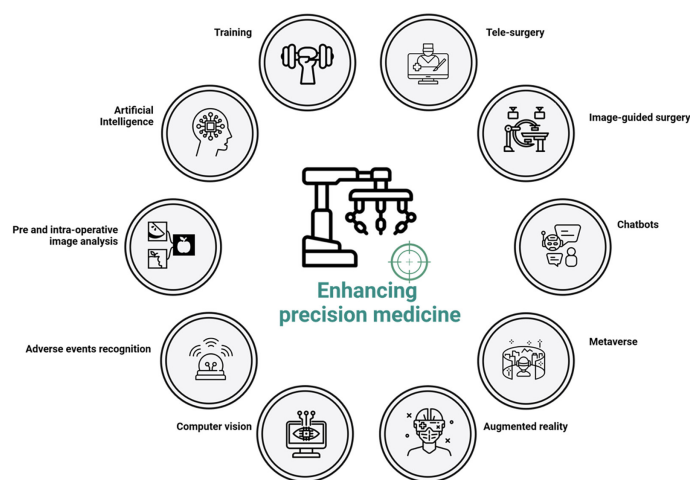
With rapid technological evolution and robust evidence supporting the benefits of minimally invasive surgery (MIS) over conventional laparotomy, the focus has shifted beyond telemanipulation of surgical instruments to exploring additional advantages offered by robotic systems.<sup>19</sup> In the research setting of clinical studies, the informatics interfaces of robotic platforms facilitate integration of emerging technologies. Combined with improved ergonomics for surgeons, these features are key to the potential benefits of these platforms.<sup>22</sup>

Modern surgical practices are evolving similarly to the transition from driving 1980s manual transmission cars with crank windows to using contemporary vehicles equipped with assisted driving/autopilot features, parking sensors, lane-keeping systems, and advanced safety mechanisms. These advancements have the potential to reduce patient risks and complications while also enhancing the quality of work for surgeons.

Drawing from the expertise gained at the IRCAD Research and Training Center in Strasbourg, France, where theoretical and hands-on robotic courses are conducted across various surgical disciplines in collaboration with robotic industrial partners, this article aims to provide an overview of the unveiled benefits of robotic surgery in gynaecology. This includes new approaches to education and training, communication between platforms and cutting-edge technologies in surgery, overcoming distances with telesurgery and telementoring, and the integration of image-guided surgery and artificial intelligence analyses into clinical practice (Figure 1).

## Methods

The objective of this narrative review is to provide an overview of the latest advancement in digital robotic-assisted surgery in gynaecology and illustrate the benefits of this approach related to the easiest integration with new technologies. To illustrate such evidence, PubMed, Google Scholar, and Scopus databases were searched using the terms “artificial intelligence”, “image-guided surgery”, “digital surgery”, “artificial intelligence” and “telesurgery” to retrieve relevant articles.



**Figure 1.** Potential benefits of robotic surgery: integration with new technologies.

## Telesurgery

Telesurgery, which allows surgeons to operate on patients from remote locations, holds promise for transforming surgical practice and expanding the reach of healthcare services.<sup>23</sup> Since the advent of robotic surgery, the idea of performing operations over vast distances has captivated researchers and innovators.<sup>24</sup> In the latter part of the twentieth century, organisations such as NASA and the United States military invested heavily in developing technologies to facilitate remote surgical operations, thereby protecting surgeons from hazardous environments<sup>24</sup>.

The potential of telesurgery to democratise access to advanced medical care is particularly significant in underserved rural areas of developed countries and in developing nations.<sup>25</sup> The World Health Organisation report states that 5 billion people lack access to surgery due to a paucity of trained workforce.<sup>26</sup> High-speed internet connections could make it possible for patients in remote or resource-limited settings to receive the same high-quality surgical care available in urban centres. Additionally, the ability to perform surgeries remotely transcends geographical barriers, enabling critical surgical interventions in otherwise inaccessible situations, such as during space missions or in disaster-stricken areas.<sup>27,28</sup> This was evident during the coronavirus disease-2019 pandemic, when telemedicine gained a pivotal role in *safe setting* patients' assessment.<sup>29</sup>

In regions facing a shortage of experienced surgeons, remote assistance can be especially beneficial. It allows expert surgeons to provide real-time guidance and support to less experienced practitioners, thereby enhancing both patient care and the outcomes of complex procedures, as well as the surgical training.<sup>30</sup>

Despite its transformative potential, the widespread adoption of telesurgery has encountered several obstacles since its introduction in the early 2000s.<sup>31</sup> Challenges such as limited access to reliable remote connections with low latency, the associated high costs, and the availability and medicolegal liability considerations for remote surgical practice across – and sometimes within – national borders, but also unclear liability and incentives for surgeons telementoring have hindered its implementation.<sup>32</sup> However, recent advancements in surgical robotics and telecommunication technologies are expanding the possibilities for telesurgery<sup>25</sup> and overcoming long-standing barriers, paving the way for remote surgical procedures to be integrated in clinical

practice. This progress holds the potential to deliver high-quality surgical care to patients regardless of their location, potentially transforming global healthcare delivery.<sup>30,32</sup> Additionally, recent evidence shows that centralising care, particularly in gynaecologic oncology, improves patient outcomes. This underscores the benefits of telesurgery, which allows patients in peripheral hospitals to be operated on by expert surgeons.

### **Current Reports of Telerobotic Surgery**

The early strides in telesurgery began in 1998 when Bauer et al.<sup>33</sup> documented a pioneering percutaneous urological procedure. In this case, a surgeon at the Johns Hopkins Hospital in Baltimore, USA, remotely controlled the positioning and advancement of a needle on a patient over 7,000 km away in Rome, Italy, using a PAKY (percutaneous access of the kidney) robot connected via a plain old telephone system line. The team achieved percutaneous access to the collecting system via two attempts in less than 20 minutes.<sup>33</sup> After this remote control of a single instrument, Marescaux et al.<sup>31</sup>, achieved the first transatlantic robot-assisted laparoscopic cholecystectomy in 2001, known as "Operation Lindbergh", with remote control of a robotic system comprising a laparoscope and two instruments. This procedure connected the console of a ZEUS robotic system (Computer Motion Inc., California) with its bedside units over a high-speed terrestrial fibreoptic network (France Télécom/Equant) spanning a signal round-trip of 14,000 km, and the gallbladder dissection was completed in 54 minutes without complications.<sup>31</sup>

Advancements continued with Anvari et al.<sup>34,35</sup> who conducted 21 telerobotic laparoscopic operations between 2003 and 2005 between McMaster University in Hamilton, Ontario, and North Bay General Hospital in Northern Ontario, Canada, using the ZEUS TS micro joint system connected via an Internet Protocol Virtual Private Network. They experienced overall round-trip delays of 135 to 140 ms and no significant complications.<sup>34,35</sup> The team reported 22 total cases conducted on the same network, noting that an increased latency above 200 ms requires the surgeon to slow down to avoid overshooting.<sup>34</sup> Tian et al.<sup>36</sup> expanded the scope to stereotactic neurosurgery, performing 10 procedures between Beijing and Yan'an in late 2005 with the CAS-BH5 frameless robotic system.<sup>36</sup>

In 2019, Patel et al.<sup>37</sup> explored long-distance telerobotic surgery in cardiology by performing 5 tele-robotic-assisted percutaneous coronary artery interventions over

32 km using the CorPath GRX robotic system (Corindus Vascular Robotics, Waltham, MA, USA), with an observed delay of 53 ms and no complications. Later, Tian et al.<sup>36</sup> conducted 12 spinal surgeries using the TiRobot system connected to a 5G network (China Telecom and Huawei Technologies Co. Ltd.), with no network delays or adverse events. Acemoglu et al.<sup>38</sup> further advanced the field by performing a laser microsurgical procedure on a cadaver with a novel surgical robot connected to a 5G Radio Access Network, experiencing a maximum round-trip latency of 280 ms over 15 km.

From March to October 2021, the Micro Hand S robotic system was adopted to perform robot-assisted laparoscopic radical nephrectomies on 29 patients across eight hospitals, demonstrating the potential of 5G technology and surgical robots for treating renal tumours with a median distance of 187 km and a round-trip delay of 26 ms.<sup>39</sup> In 2022, the Hinotori Surgical Robot System, developed by Medcaroid Inc., was successfully used to perform telesurgical gastrectomies, establishing a basis for short-distance telesurgical procedures using high-speed optic-fibre communication.<sup>40</sup> To date no telesurgical cases have been reported on gynaecology globally.

### **Robotic Platforms for Pelvic Surgery Designed for Telesurgery**

In recent years, several new robotic surgical systems have entered the marketplace, promising to reduce surgical costs and increase the accessibility of robotic procedures. Many of these platforms come equipped with built-in capabilities for remote connections, leveraging advancements in telecommunication and cellular networks from 1G to 6G (Table 1).<sup>41,42</sup> This progress has enabled the development of fully digital and connected systems, crucial for the practice of telesurgery. The time lag between a surgeon's actions and the robot's response remains a critical issue, as significant delays can compromise precision and safety during surgery.<sup>43</sup> An experimental study using the dV-Trainer simulator concluded that latencies under 200 ms are ideal for telesurgery, with up to 300 ms still being acceptable. Higher latencies require compensatory mechanisms to maintain performance.<sup>44</sup> Among the new systems, the Hinotori Surgical Robot System from Medcaroid Inc. stands out. Hinotori features a multi-port setup with an immersive console and manoeuvrable surgeon cockpit. Initially approved for urology in Japan in 2020, its use has expanded to gynaecology and general

surgery in 2022. Medcaroid Europe is now pursuing CE marking compliance, aiming to introduce Hinotori to the European market.<sup>42</sup> Another significant player is the Edge Medical Telesurgery System from Shenzen Edge Medical Company. The Multiport 1000 and Single Port SP1000 platforms, approved for various surgeries including gynaecology, come with high-performance communication modules and low-latency control systems designed for remote operations.<sup>42</sup> The KangDuo Surgical Robot System, developed in China, offers a versatile setup with multiple arm configurations and compatibility with various endoscopes and accessory equipment. It integrates advanced features like fluorescence imaging and augmented reality (AR) surgical navigation. The system supports multiple consoles, enhancing the safety and flexibility of telesurgery by allowing local surgeons to manage cases if technical difficulties arise.<sup>42</sup> MicroPort MedBot Robotic Systems, also from China, include the Toumai laparoscopic surgical system. Compatible with 5G networks and capable of dual-console operation, the Toumai system has successfully performed ultra-long-distance surgeries, demonstrating the feasibility and reliability of telesurgery across vast distances. These advancements underscore the potential of new robotic platforms to revolutionise telesurgery, enhancing the performance of telecommunication and bringing high surgical quality worldwide (Table 1).<sup>42</sup>

**Ethical Issue in Telerobotic Surgery**

Maintaining the integrity of the surgeon-patient relationship in telesurgery is complex due to varying levels of remote involvement, from verbal guidance to full control of procedures, raising concerns about

dehumanisation and patient objectification.<sup>30</sup> Patient vulnerability is significant, requiring full disclosure of local surgeons’ skill limitations and the necessity of remote experts, with risks of overstating capabilities for financial gain. Telesurgery introduces physical and emotional distance between the surgeon and patient, which can reduce trust and connection. The lack of in-person interactions may undermine patients’ confidence and make the relationship feel transactional, as surgeons have limited ability to convey empathy and emotional support. Communication may suffer due to technical issues and the absence of face-to-face discussions, potentially leading to misunderstandings and diminished trust.<sup>37</sup> Additionally, telesurgery often involves multiple surgeons across different locations, which can disrupt continuity of care, making it difficult for patients to experience a consistent and personalised treatment journey. Clear communication about remote involvement and a novel approach to informed consent are essential, along with a defined accountability chain for errors.<sup>45</sup> Informed consent requires thoroughly informing patients about the procedure, including its remote nature, reasons for choosing telesurgery over local surgery, and potential risks and complications. Patients may worry about the ability of the on-site surgeon to handle emergencies, so contingency plans must be clearly outlined. The process also defines the responsibilities of both the remote and local surgical teams, as well as any technical parties involved. Virtual consultations can help patients ask questions, voice concerns, and build trust with both teams.<sup>46</sup> Balancing medical appropriateness with cost effectiveness and improved access to advanced surgical care is crucial, despite the unclear financial responsibility

Table 1. Summary of robotic platforms for pelvic surgery equipped with built-in capabilities for remote connections. <sup>42</sup>					
Model	Characteristics	Application	Connection	Average delay	Maximum distance
Hinotori Medcaroid, Japan	Single boom, multiport	Animal, lab cadaver	Dedicated network, 5G, guaranteed-type line	-	-
MPI000 Edge Medical System, China	Single boom, multiport	Human	Dedicated line, China Telecom	<200 ms	3000 km
SP 1000 Kangduo Robotics, China	Single boom, single port	Human	5G, wired networks	-	3000 km
Toumai Micropprt, Medbot, China	Immersive console, multiport	Human	5G, dedicated network, Internet	24-41 ms at 200 km; 52 ms at 1,000-2,000 km; up to 159 ms at 5,000 km	5000 km

for tele-surgical infrastructure. Moreover, nations may lack the necessary social and legal infrastructure to support telesurgery, facing international governance challenges.<sup>30</sup>

### **Image-guided Robotic Surgery**

The next major advancements in minimally invasive precision surgery lie in the development of specialised software which facilitates the creation of 3D models from preoperative and intraoperative imaging.<sup>47</sup> Image-guided surgery is central to ongoing improvements in robotic surgery, offering much more than just sensors, actuators, and telemanipulation.<sup>48</sup> Enhanced visualisation and critical guidance for complex procedures are achieved through integrated imaging technologies.<sup>49</sup>

Computer-assisted intraoperative data collection, information processing, and decision support systems hold significant promise. Technologies such as virtual reality (VR), AR are becoming increasingly prevalent in daily life and are gradually being incorporated into MIS.<sup>50,51</sup> Advanced imaging systems can significantly enhance a surgeon's vision beyond natural capabilities, overcoming current limitations in tactile feedback and force sensing. This allows surgeons to visualise tissue consistency and resistance during manipulation.<sup>52</sup>

Recent research has been propelled by the successes of deep learning in automatic image analysis and interpretation. AR systems have already been reported to identify sentinel lymph nodes in endometrial cancer<sup>53</sup> and to intraoperatively assess bowel infiltration by endometriosis.<sup>54</sup> One challenge in AR is achieving precise registration in enhanced views, especially with soft tissues which continuously undergoes modifications due to respiratory movements, intraperitoneal insufflation, or surgical manipulation. The retroperitoneum is comparatively stable, making accurate overlays easier than with other intra-abdominal organs.<sup>55,56</sup>

Hybrid operating rooms, equipped with integrated intraoperative imaging systems like computed tomography, magnetic resonance imaging, ultrasonography, and fluoroscopy, offer additional support during surgeries in advanced settings.<sup>57</sup> Ideally, *in vivo* 3D tissue analysis would guide surgical procedures in real time. Some robotic platforms come equipped with integrated software that can display images in a dual view within the console (such as da Vinci's TilePro™), facilitating integration with image-guided surgery tools.<sup>58</sup>

Beyond 3D macroscopic guidance, there is an increasing need for real-time intraoperative tissue analysis, especially to tailor the extent of resection in oncological surgeries.<sup>59</sup> Various intraoperative optical imaging techniques are currently being evaluated to complement or enhance extemporaneous histopathological analysis.<sup>52,60</sup> For *in vivo* tissue, 3D high-resolution ultrasound is a major advancement in intraoperative analysis, supporting decisions such as the necessity of resection in cases like lymph node metastasis.<sup>61</sup> Intraoperative ultrasound application, through drop-in probes connected by flexible cables which can be easily manoeuvred with robotic graspers, is being increasingly adopted across different robotic platforms due to their adaptability. Robotic probes with frequencies of 7-13 MHz can be inserted through 10-12 mm trocars, and their flexibility and manoeuvrability, surpassing the rotational capability of robotic instruments, allow them to reach anatomical locations otherwise inaccessible with traditional laparoscopic ultrasound probes.<sup>62</sup> A recent systematic review highlighted the applications of ultrasound-guided robotic procedures in surgery, particularly emphasising its potential in gynaecologic oncology.<sup>52</sup>

Fluorescence imaging, using fluorescent tracers, enables visualisation beyond the visible surface, allowing for the evaluation of organ perfusion, the definition of specific segments within organs, and highlighting critical anatomical structures essential for various procedures.<sup>63</sup> Its integration into robotic systems like the da Vinci Firefly® enhances its utility. Advances in computer-assisted signal analysis and artificial intelligence algorithms are poised to provide additional insights and intraoperative guidance.<sup>64</sup> Combining fluorescence image-guided surgery with 3D VR/AR models offers enhanced intraoperative support.<sup>65</sup> Quantitative fluorescence imaging and artificial intelligence-driven analysis of fluorescence signal dynamics support perfusion assessment and tissue classification, promoting the broader adoption of fluorescence image-guided surgery.<sup>66</sup>

The next steps aim to introduce experimental techniques in robotic surgery, which enable intraoperative microscopic visualisation, ideally detecting low-volume metastasis and improving the sensitivity of frozen sections in gynaecologic oncology.<sup>62</sup> This includes the introduction of high-frequency (up to 70 MHz) and ultra-high-frequency (up to 100 MHz) ultrasound

probes as drop-in for robotic surgery, which can achieve resolutions of 30  $\mu\text{m}$ .<sup>67</sup> Additionally, integrating full-field optical coherence tomography (FF-OCT) offers an immediate ex vivo imaging system which does not require dedicated sample preparation and has a quick learning curve with tissue section analysis similar to traditional histopathology.<sup>60,68</sup> This innovative technique can be useful for real-time assessment of lymph nodal status, especially in cervical cancer, where the presence of metastatic nodes guides the intraoperative decision making.<sup>69</sup> For resected specimens, whole-slide imaging can digitally reconstruct a 3D volume, preventing missed lesions due to skipped depth slides.<sup>70</sup> In the era of digital surgery, robotic platforms can serve as computer interfaces capable of integrating multiple modalities of real-time image data analysis.

### **Integration of Artificial Intelligence in Robotic Surgery**

The digital interface of robotic platforms facilitates communication with artificial intelligence systems more effectively than it is possible with other types of MIS, such as endoscopy or laparoscopy.

### **Surgical Workflow Analysis**

Surgery workflow analysis relies on artificial intelligence models to automatically monitor and assess the progression of surgical procedures.<sup>71</sup> This field has undergone significant evolution over the past decade, with advanced algorithms now integrated into the software of robotic platforms like Medtronic's Surgery, Johnson & Johnson's C-SATS, and Intuitive Surgical's Orpheus.<sup>72</sup> A primary objective of surgery workflow analysis is the automatic identification of the major steps or phases during an operation. This task is fundamental in surgical artificial intelligence and heavily relies on deep learning techniques applied to high-quality, annotated surgical video data. These systems not only recognise current steps, but also measure the time spent in each step, which may be an indicator of difficulties and potential complications.<sup>73</sup> Prolonged durations in certain steps can trigger alerts, predicting complication risks or notifying senior surgeons of resident difficulties. Deviations from standardised workflows can be flagged, ensuring adherence to best practices.<sup>74</sup> Additionally, performance analytics derived from workflow analysis provides insights into surgical proficiency. The time taken to complete surgical steps serves as a benchmark for assessing technical competency, enabling the evaluation of learning curves and peer performance

comparisons. Moreover, recognising when a procedure is nearing completion can enhance operating room efficiency.<sup>75</sup> Automated notifications can alert wards to prepare for the next patient and prompt cleaning staff, thereby reducing turnaround times and hospital costs.<sup>76</sup> As artificial intelligence continues to advance, the integration of comprehensive workflow analysis into surgical practice promises to refine procedural standards, enhance training, and optimise efficiency.<sup>77</sup>

Human errors significantly contribute to surgical complications and negative outcomes. Many studies use deep learning to automatically validate safety procedures visually.<sup>78</sup> For instance, laparoscopic cholecystectomy can lead to bile duct injuries, occurring in about 3 out of every 1,000 surgeries. To mitigate these risks, the Critical View of Safety (CVS) was devised in 1995 to ensure correct identification of the cystic duct and cystic artery, and it's now being automatically assessed by artificial intelligence.<sup>79,80</sup> Researchers have recently used deep learning to verify adherence to the CVS, acting as a warning system. Systems to automatically identify safe and unsafe areas during surgery, using instrument tracking to establish a safety alert system, are under development.<sup>57,79,81</sup> The Rome-Strasbourg gynaecologic oncology team is conducting computer vision studies aimed at reducing complications and enhancing surgical safety for sentinel node dissection in uterine cancers (LYSE study).

### **ChatBots**

Robotic consoles are also well-suited for easy communication with new large language models capable of providing computational outputs based on specific inputs.<sup>82</sup> Studies assessing the validity of these systems' responses are ongoing, with prospects of surgeons engaging with these machines in decision-making during complex procedures.<sup>83</sup> Decision-making in the operating room requires a collaborative team effort, and today, artificial intelligence is increasingly aiding in this process. Surgery is just one step in the entire continuum of patient care, and the concept of having a chatbot powered by deep learning systems which can provide precise patient information is emerging as a valuable tool. Such a chatbot can deliver real-time intraoperative information as well as comprehensive details about the patient's medical history, including anamnesis, comorbidities, and consultations with other specialists. This integration of chatbots into the surgical workflow may enhance the ability to make informed decisions, ultimately improving patient outcomes.<sup>82</sup>

### **Education and Training in Robotic Surgery**

Robotic platforms are fundamentally reshaping the landscape of training for both residents and young surgeons.<sup>84</sup> Unlike traditional open or laparoscopic surgeries, the integration of virtual simulators with consoles akin to those used in real patient scenarios presents undeniable advantages for education.<sup>85</sup> Through these platforms, learners can engage in immersive experiences which closely mimic actual surgical procedures, allowing for hands-on practice without harming patients. Furthermore, VR systems equipped with progressively complex tasks enable learners to undergo training in a gradual manner, progressively advancing through objectives of increasing difficulty.<sup>86</sup>

One notable feature offered by several companies is the dual-console mode, which provides a unique opportunity for experienced surgeons to mentor and guide younger colleagues in real time. This collaborative approach not only fosters skill development but also promotes knowledge sharing and professional growth within the surgical team.<sup>87</sup>

As the demand for specialised training in robotic surgery continues to rise, various scientific societies are taking steps to establish their own training curriculum programs such as Gynaecological Endoscopic Surgical Education and Assessment (GESEA) robotics program endorsed by the European Society for Gynaecological Endoscopy (ESGE) or the Robotic courses provided by the European Network of Young Gynae Oncologist (ENYGO) and European Society of Gynaecologic Oncology (ESGO).<sup>88</sup> This initiative is particularly significant given that not all residency programs currently offer dedicated paths. However, with the proliferation of robotic platforms in the market and ongoing development efforts, the challenge lies in ensuring that training courses expose learners to a diverse range of platforms.<sup>89</sup>

In response to this challenge, dedicated training centres represent essential hubs for providing comprehensive instruction across various robotic platforms. These centres serve as focal points for collaboration between industry experts, academic institutions, and healthcare organisations, facilitating the exchange of knowledge and best practices in robotic surgery training.<sup>72</sup>

The integration of robotic platforms into surgical training represents a paradigm shift in medical education. By leveraging virtual simulators, VR systems, and collaborative learning opportunities, these platforms

empower aspiring surgeons to acquire the skills and expertise needed to excel in the rapidly evolving field of robotic surgery.<sup>85</sup>

### **Study Limitations**

The high costs associated with robotic surgical systems create a significant barrier, as these technologies require substantial initial investments, ongoing maintenance, and specialised training, all of which impose financial strain on healthcare providers and patients.<sup>72</sup> The expense of robotic systems often necessitates advanced operating rooms and specialised staff, limiting their availability in less affluent areas and contributing to disparities in access.<sup>27</sup> Additionally, the infrastructure required for robotic surgery, such as reliable telecommunication networks for telesurgery, is not universally available, which further restricts its application in resource-limited settings. These factors highlight the complexity of adopting robotic surgery on a larger scale, emphasising the need for a balanced view that considers both the significant potential and the notable challenges.<sup>84</sup>

### **Future Direction**

Robotic surgery serves as a bridge between laparoscopy and digital surgery, thanks to its seamless integration with digital interfaces. Image-guided surgery, enhanced by deep learning applications, opens up unprecedented intraoperative diagnostic possibilities. Future studies should explore more the use of FF-OCT, photoacoustic imaging, HFUS, and drop-in robotic probes in the assessment of cancer/no cancer tissue status in gynaecological oncology.<sup>90</sup> Computer vision could further aid in enhancing the assessment of quality and effectiveness in robotic procedures through image analysis. In the near future, telesurgery is expected to help overcome physical boundaries, paving the way for the democratisation of healthcare access.

### **Conclusion**

The adoption of robotic platforms is increasing across all surgical fields. Retrospective studies and meta-analyses have not yet demonstrated significant benefits over standard laparoscopy in gynaecology. While prospective studies are ongoing and scientific evidences still lacking, the real advantages of robotic surgery are likely to be found in its superior integration with new technologies. Future prospective studies should focus on the potential for integrating robotic platforms with artificial intelligence systems, image-guided surgery, and overcoming physical limitations through telerobotic surgery.

## Footnotes

**Acknowledgements:** The authors are grateful to Camille Goustiaux and Guy Temporal for their assistance in revising the English language of this manuscript.

## Authorship Contributions

Concept: M.P., M.G., L.L., Design: M.P., M.G., Data Collection or Processing: M.P., C.I., Analysis or Interpretation: M.P., M.G., Literature Search: M.P., M.G., N.B., A.R., Writing: M.P., M.G., C.I., F.A.F., N.B., B.S., P.M., A.F., A.C.T., A.F., F.F., D.Q., G.S., C.A., J.M., L.L.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Do we need a preventive stoma in surgery for colorectal endometriosis? A retrospective series of 97 patients treated at an expert centre

 Pierre Collinet<sup>1</sup>,  Margherita Renso<sup>1</sup>,  Nicolas Briez<sup>2</sup>

<sup>1</sup>Departement of Gynecological Surgery, Hôpital Privé Le Bois, Lille, France

<sup>2</sup>Departement of Digestive Surgery, Hôpital Privé Le Bois, Lille, France

## ABSTRACT

**Background:** Various surgical techniques for the treatment of colorectal endometriosis have been described, and the benefit of a preventive stoma remains unclear.

**Objectives:** The aim of our study is to evaluate the risk of complications in patients who underwent surgery for colorectal endometriosis without a policy of preventive stoma.

**Methods:** Retrospective cohort study of 97 consecutive patients treated for colorectal endometriosis in an expert centre from January 2022 to January 2024.

**Main Outcome Measures:** Complications after colorectal endometriosis surgery in patients without preventive stoma.

**Results:** Forty-three patients were managed by segmental resection, 20 patients by single-disc excision, 5 patients by double-disc excision and 29 patients by rectal shaving. 48 patients required vaginal suturing. We found complications in 14% of patients. Severe complications (Clavien-Dindo  $\geq 3$ ) were encountered in 8.24% of patients. 3.09% developed a rectovaginal fistula. Patients with a colorectal endometriosis nodule larger than 3 cm had more complications than patients with smaller nodules (57.1% vs. 42.9% of total complications), with a *P*-value close to the statistical significance.

**Conclusions:** Surgery for colorectal endometriosis performed in high-volume centres by expert surgeons leads to a reduction in the risk of postoperative complications. In our study, we did not perform routine preventive stoma formation, and we did not find an increase in postoperative complications compared to the literature.

**What is New?** This study provides data on the risk of postoperative complications in patients undergoing surgery for colorectal endometriosis without a preventive stoma policy.

**Keywords:** Colorectal endometriosis, endometriosis surgery, preventive stoma

## Introduction

Endometriosis is a benign disorder in women, which is defined as the presence of endometrial-like tissue outside the uterus, inducing a chronic inflammatory reaction. The exact number of women suffering

from endometriosis is unknown because some are asymptomatic, but it is estimated that up to 15% of all women of reproductive age have endometriosis.<sup>1</sup> The estimated incidence of colorectal endometriosis in patients with deep endometriosis (DE) varies between 5.3% and 12%.<sup>2</sup>

**Corresponding Author:** Margherita Renso, MD, Departement of Gynecological Surgery, Hôpital Privé Le Bois, Lille, France

**E-mail:** [margherita.renso@gmail.com](mailto:margherita.renso@gmail.com) **ORCID ID:** [orcid.org/0009-0004-1469-9905](https://orcid.org/0009-0004-1469-9905)

**Received:** 23.07.2024 **Accepted:** 18.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Collinet P, Renso M, Briez N. Do we need a preventive stoma in surgery for colorectal endometriosis? A retrospective series of 97 patients treated at an expert centre. Facts Views Vis Obgyn. 2025;17(1):61-67



Surgical management of colorectal endometriosis is an option after failure of medical treatment.<sup>3</sup>

Several laparoscopic surgical techniques have been presented for treating colorectal endometriosis, including rectal shaving, disc excision, and segmental resection.

The benefits in terms of improvement of quality of life and pain management have been widely discussed over the last two decades.<sup>4</sup> A key surgical objective is to minimise complications, particularly that of a rectovaginal fistula, one of the most serious complications affecting both quality of life and fertility. Various surgical techniques have been described to reduce this risk: avoiding opening the vagina, placing the omentum or peritoneum between vaginal and rectal sutures or performing a transitory diverting stoma at the end of the procedure.

In rectal cancer, the literature supports the systematic use of a diverting stoma after low colorectal anastomosis to reduce complications. For colorectal endometriosis surgery, we do not have definitive guidelines, and it is impossible to automatically extrapolate data due to differences between patients managed for endometriosis and for rectal cancer.<sup>5</sup>

Therefore, the benefit of a preventive stoma in colorectal endometriosis surgery remains unclear, due to the lack of comparative studies, and its role has been widely debated over the last ten years. A recent study did not reveal statistically significant differences in the risk of rectovaginal fistula between women with rectovaginal endometriosis managed with a preventive stoma or not.<sup>6</sup>

The aim of our study is to evaluate the risk of complications in patients who underwent surgery for colorectal endometriosis without a policy of routine stoma formation.

## Methods

Patients treated for colorectal endometriosis requiring surgical treatment managed at the Hopital Privé Le Bois, Ramsay Santé in Lille (France) from January 2022 to January 2024 were enrolled consecutively in our retrospective, cohort study.

The study population was treated by the same gynaecologic surgeon (P.C.) and by the same bowel surgeon (N.B.), both of whom are experts in endometriosis surgeons.

A preoperative assessment was performed by radiologists with experience in deep infiltrative endometriosis; all the patients underwent preoperative pelvic magnetic resonance imaging and computed tomography

colonography. This allowed characterisation of the rectal nodules (size, location, whether unifocal or multifocal) as well as the identification of other endometriotic lesions within the pelvis. To perform the rectal nodule excision, we utilised three different techniques (depending on nodules' characteristics and localisation): segmental resection, disc excision or rectal shaving.

The surgical route was exclusively laparoscopic. Rectal shaving was performed by the gynaecologic surgeon alone, either using cold scissors, monopolar scalpel or ultrasonic energy, as deep as possible into the thickness of the rectal wall in order to allow the complete removal of the endometriotic nodule. For full-thickness mural nodules, the rectal muscular layer was repaired through absorbable interrupted sutures. If, at the end of the shaving, the rectal wall was still infiltrated by the deep endometriotic nodule, the visceral surgeon would perform disc excision using an end-to-end circular transanal stapler. The rectal shaving is an absolutely essential prerequisite of disc excision. When multiple nodules were revealed, they were managed with a double disc excision.

Segmental resection was performed, as previously described, by other teams.<sup>7,8</sup> First, a dissection of the recto-vaginal space and mobilisation of the rectum was performed, followed by a section of the mesorectum and mesocolon in contact with the posterior wall of the rectosigmoid. The rectum was distally sectioned using a laparoscopic stapler, then the extraction of the piece was carried out through a small suprapubic transverse incision. The affected section of the digestive tract was resected, and colorectal anastomosis was performed using an end-to-end transanal stapler with a diameter of either 28 mm or 31 mm.

At the end of the surgical procedure an assessment of rectal suture was carried out with a bubble test or by applying betadine solution into the rectum.

The decision to create a stoma, by either ileostomy or colostomy, was not based on preoperative findings. It was based on intraoperative findings after discussion between the gynaecologic and bowel surgeons. The criteria that led to the creation of a stoma were: the close proximity of vaginal and rectal sutures, unsatisfactory bubble test of the colorectal anastomosis or a very low rectal suture.

The vaginal suturing, when necessary, was performed using either a running V-lock 2/0 suture or interrupted Vicryl 2/0 suture(s).

The patients met the bowel surgeon pre-operatively to discuss the procedure, the risk of complications and the possible need of a preventive stoma. Generally, the type of surgical procedure (segmental resection, discoid resection or rectal shaving) was planned preoperatively based on the imaging's findings in a multidisciplinary meeting between the gynaecologist, the bowel surgeon and the radiologist.

All the other endometriotic lesions were treated concomitantly using, where required, ureterolysis, resection of utero-sacral ligament(s), partial colectomy, hysterectomy, treatment of endometrioma and oophorectomy.

The post-operative complications were assessed according to the Clavien-Dindo classification.<sup>9</sup>

### Statistical Analysis

For the statistical analysis, GraphPad Prism 10 software was used. The number of patients and percentages (qualitative variables) were used, as well as median values

and range (continuous variables). A comparison was performed using Fisher's exact test (qualitative variables), and continuous variables were assessed by One-Way ANOVA between groups.  $P < 0.05$  was considered statistically significant.

### Results

A total of 97 consecutive patients were enrolled and treated from January 2022 to January 2024 by the same gynaecologic surgeon and the same bowel surgeon.

Forty-three patients were managed by segmental resection. The remaining fifty-four patients had conservative surgery: 20 treated by single disc excision, 5 by double disc excision and 29 by rectal shaving.

Table 1 shows the baseline characteristics of the study population.

In the whole population, the rectal nodule was most commonly found in the high rectum. The diameter of the largest nodule was greater in the group of patients

**Table 1.** Patient's baseline characteristics.

Parameter	Total of patients (n=97)	Conservative surgery (n=54)	Segmental resection (n=43)
<b>Age (years)</b>	34.9 (20.3-49.3)	35.1	36.2
<b>Previous abdominal surgery</b>	35 (36%)	33 (61.1%)	21 (48.8%)
<b>Preoperative symptoms</b>			
- Dysmenorrhea	68 (70.1%)	34 (62.9%)	33 (76.7%)
- Dyspareunia	33 (34.0%)	16 (29.6%)	16 (37.2%)
- Chronic pelvic pain	44 (45.4%)	17 (31.5%)	27 (62.8%)
- Digestive symptoms	65 (67.0%)	33 (61.1%)	32 (74.4%)
- Urinary symptoms	8 (8.2%)	3 (5.6%)	5 (11.6%)
<b>Preoperative therapy</b>			
- EP	39 (40.2%)	22 (40.7%)	17 (39.5%)
- Progesterone	63 (64.9%)	35 (64.8%)	28 (65.1%)
- IUD	16 (16.5%)	12 (22.2%)	4 (9.3%)
- Analogues	22 (22.7%)	12 (22.2%)	10 (23.3%)
<b>Localisation of deep nodules</b>			
- Low rectum	3 (3.1%)	1 (1.9%)	2 (4.7%)
- Medium rectum	20 (20.6%)	15 (27.8%)	5 (11.6%)
- High rectum	37 (38.1%)	19 (35.2%)	18 (41.9%)
- Sigmoid colon	32 (32.9%)	12 (22.2%)	20 (46.5%)
- Caecum and others	5 (5.2%)	0 (0%)	5 (11.6%)
<b>Height of the lowest nodule (cm from the anal verge)</b>	11.9	13.3	11.5
<b>Diameter of largest rectal nodule (mm)</b>	35 (15-100)	26.8	39.6

EP: Endometriosis, IUD: Intrauterine device.

treated with segmental resection than in the group having conservative surgery.

The intraoperative findings are shown in Table 2.

Only one patient in the segmental resection group, required conversion to open surgery due to the presence of extensive adhesions and multiple uterine fibroids. In the segmental resection group the operative time was statistically longer than in the group that underwent conservative surgery. Most patients had endometriotic lesions in other anatomical locations, which required associated surgical procedures (hysterectomy, partial colectomy, adnexectomy, ureterolysis, management of ovarian endometriomas). More specifically, in the segmental resection group 11 patients had concomitant hysterectomy and 7 patients had concomitant partial

colectomy, while in the conservative group 15 patients had concomitant hysterectomy and 15 patients had concomitant partial colectomy. Thus, a total of 48 patients had vaginal suturing concomitant with the surgical procedure on the digestive tract.

Table 3 presents the post-operative complications. Data on immediate postoperative complications was available in all patients. We did not find any statistical differences in the complications between the two groups, but we found that the segmental resection group had more Clavien Dindo I complications, and the conservative surgery group had more severe Clavien-Dindo IIIB complications. Among the severe complications (Clavien Dindo IIIB) one patient developed a ureteral fistula requiring uretero-vesical reimplantation, two dehiscences of anastomoses, one recto-vaginal fistula and one pelvic abscess.

**Table 2.** Intraoperative findings.

Parameter	Conservative surgery (n=54)	Segmental resection (n=43)	
<b>Operative route</b>			
- Laparoscopic	54 (100%)	42 (97.7%)	
- Laparoscopic converted to open surgery	0 (0%)	1 (2.3%)	
Operative time (min)	103 ( $\pm$ 60.9)	150 ( $\pm$ 48.5)	P=0.039
<b>Procedure on the digestive tract</b>			
- Shaving only	29 (53.7%)	43 (100%)	
- Disc excision	20 (37%)		
- Double disc excision	5 (9.2%)		
- Segmental resection	0 (0%)		
<b>Preventive stoma</b>	1 (1.8%)	1 (2.3%)	P=0.874
<b>Length of colorectal resection (cm)</b>	-	9.09 (3.5-40)	
<b>Associated procedure</b>			
- Hysterectomy	15 (27.8%)	11 (25.6%)	
- Colectomy	15 (27.8%)	7 (16.3%)	
- Ureterolysis	48 (88.9%)	41 (95.3%)	
- Adnexectomy	8 (14.8%)	15 (34.9%)	
- Resection of bladder nodule	1 (1.8%)	1 (2.3%)	
- Management of endometrioma	12 (22.2%)	11 (25.6%)	
- Reimplantation of the ureter	1 (1.8%)	1 (2.3%)	
- Nephrectomy	0 (0%)	1 (2.3%)	
- Appendectomy	1 (1.8%)	2 (4.7%)	

**Table 3.** Post-operative complications.

	Conservative surgery	Segmental resection	
Total complications	8 (14.8%)	6 (13.9%)	P=0.684
Clavien-Dindo	3 (5.6%)	3 (6.9%)	P=0.479
Clavien Dindo	0 (0%)	0 (0%)	-
Clavien Dindo	1 (1.9%)	2 (4.6%)	P=0.429
Clavien Dindo	4 (7.4%)	1 (2.3%)	P=0.261

Table 4 presents the relationship between the complications and some parameters that were chosen for analysis. A rectal nodule  $\geq 30$  mm and the presence of associated vaginal suturing were associated with more complications, although this was not statistically significant.

## Discussion

We reported the results of a complete assessment of intraoperative findings and postoperative complications in 97 consecutive patients with colorectal endometriosis, managed with a policy of no preventive stoma unless strictly necessary by intraoperative findings, in the same centre by the same expert gynaecological surgeon and bowel surgeon.

We analysed both early and late postoperative complications with a mean follow-up of  $49 \pm 15$  months. All patients were followed up to at least 30 days post-operation. Out of all the patients, we found that a total of 14% had complications which is less than that described in literature. Roman et al.<sup>10</sup>, described a total amount of early postoperative complications of 30% in a retrospective series of 168 patients, without any differences in patients treated with preventive stoma or not. More specifically, 8.2% of patients had severe complications (Clavien-Dindo  $\geq 3$ ) and 3.1% developed a rectovaginal fistula. There was no statistical difference between the groups that received segmental resection or conservative surgery. Similarly, in another retrospective study of 364 patients, a postoperative risk of rectovaginal fistula of 3.8% was reported.<sup>11</sup> A French study, including 1,135 patients managed for colorectal endometriosis, reported the risk of fistula and leakage after shaving, disc excision, and segmental resection as 1.3%, 3.6%, and 4.7%, respectively.<sup>12</sup> The largest systematic review and meta-analysis on surgical outcomes after colorectal surgery for endometriosis<sup>13</sup> resection, an overall rate of rectovaginal fistula of 1.5% (0.3%, 2.7%, and 3.3% after shaving, disc excision, and segmental resection

respectively).

Although the difference was not statistically significant, we observed a higher complication rate in the group that underwent conservative surgery (disc excision or rectal shaving), contrary to findings in the literature. This could be explained by the fact that over 50% of our conservative surgery was performed to remove nodules larger than 3 cm which could lead to an increased risk of postoperative complications. However, we believe that conservative surgery helps preserve the rectum and may lead to better functional outcomes, which were not evaluated in this study. Additionally, disc excision and rectal shaving required less operative time ( $P=0.039$ ).

We also analysed the relationship between the postoperative complications and the presence of concomitant vaginal and rectal suturing, so patients in which we had performed concomitant hysterectomy or partial colectomy, and we observed no differences in the risk of complications. Therefore, we believe that these cases no longer indicate the need for preventative stoma formation, as was indicated a few decades ago. Moreover, quite often we forget complications that are related to the stoma. In a series of 163 patients that received a diverting stoma after colorectal surgery for endometriosis, a risk of severe complications Clavien-Dindo IIIb of 8% was found.<sup>14</sup> Thus, this is an argument for limiting the use of preventive stomas to only selected cases, and women should also be informed that the use of a preventive stoma does not completely exclude the risk of recto-vaginal fistula.

Finally, we observed that patients with a colorectal endometriosis nodule larger than 3 cm had more complications than patients managed for smaller nodules (57.1% vs. 42.9% of total complications), with a  $P$ -value close to statistical significance. These findings should be validated by larger prospective studies and ought to be considered in the preoperative assessment to reduce the risk of major complications.

**Table 4.** Relationship between complications and size of nodule, vaginal suture or stoma.

	Complications (n=14)	
Nodule $\geq 30$ mm	8 (57.1%)	$P=0.079$
Nodule $< 30$ mm	6 (42.9%)	
Vaginal suture	8 (57.1%)	$P=0.849$
No vaginal suture	6 (42.9%)	
Stoma	2 (14.3%)	$P=0.197$
No stoma	12 (85.7%)	

## Study Limitations

Our study has three main limitations: the retrospective collection of data, the sample size and the lack of functional outcome assessment.

The limited sample size may be too small to detect statistically significant differences when complication rates are rare. To counter this, we suggest using a larger sample size in future prospective studies to evaluate the incidence of complications and a real need for diverting stomas in patients with colorectal endometriosis. In future research, it would be beneficial to assess differences in functional outcomes in two groups of patients (with and without a stoma).

Our study has two particular strengths. Firstly, women managed with conservative surgery (disk excision or rectal shaving) had endometriotic nodules which significantly infiltrated the digestive wall, not only superficially. Because of this, the rectal shaving was performed as deeply as possible into the thickness of the rectal wall and for the full-thickness nodules, rectal muscular layer was repaired by resorbable separate stitches. Secondly, all the patients were managed by the same gynaecologist and bowel surgeon. This ensured a homogeneous population to allow complication comparison. The surgical procedures were all performed in a centre with a deep expertise in endometriosis management, ensuring a multidisciplinary management that has been demonstrated to be crucial in the postoperative outcomes. The impact of surgeon expertise in colorectal endometriosis on morbidity and postoperative complications has already been demonstrated,<sup>15</sup> so we recommend that, in order to improve patients' quality of life, surgery for deep infiltrative endometriosis is performed in high volume centres.

## Conclusion

Surgery for colorectal endometriosis performed in high volume centres by expert surgeons leads to a reduction in the risk of postoperative complications. In our study, we did not use a routine preventive stoma and we did not find an increase in postoperative complications compared to the literature. Future research should include a prospective study comparing patients with and without stoma with a larger sample size to evaluate the incidence of complications and the true necessity of diverting stomas in colorectal endometriosis surgery.

## Ethics

**Ethics Committee Approval:** No ethical approval was required as the retrospective study used routinely available clinical data only.

**Informed Consent:** Retrospective study.

**Acknowledgements:** None.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: P.C., N.B., Concept: M.R., P.C., N.B., Design: M.R., P.C., Data Collection or Processing: M.R., Analysis or Interpretation: M.R., P.C., Literature Search: M.R., Writing: M.R., P.C.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Sexual quality of life after hysterectomy performed by conventional laparoscopy versus Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) in benign gynaecology

Marie Timmermans<sup>1</sup>, Hripsime Hovsepyan<sup>2</sup>, Panayiotis Tanos<sup>2</sup>, Michelle Nisolle<sup>1</sup>, Stavros Karampelas<sup>2</sup>

<sup>1</sup>Department of Obstetrics and Gynaecology, University of Liège, CHU of Liège-Citadelle site, Liège, Belgium

<sup>2</sup>Department of Obstetrics and Gynaecology, Centre Hospitalier Universitaire Brugmann, Université Libre de Bruxelles, Brussels, Belgium

## ABSTRACT

**Background:** Hysterectomy is a common surgical procedure in gynaecology, performed through abdominal, vaginal, and laparoscopic techniques. The vaginal route is typically preferred for benign conditions like fibroids, adenomyosis, and uterine prolapse due to shorter operative time, faster recovery, reduced pain, and fewer complications. In cases where the uterus is large or vaginal access is restricted, a laparoscopic approach may be necessary. A minimally invasive alternative, Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES), allows hysterectomy via vaginal access using a combination of endoscopic and laparoscopic techniques.

**Objectives:** To evaluate if sexual quality of life (sQoL) is impaired by using vNOTES for hysterectomy compared to conventional laparoscopy in benign gynaecology.

**Methods:** A retrospective monocentric study. One hundred and twenty seven patients were included in the study. Of these, 91 underwent TLH and 36 vNOTES hysterectomies between September 2020 and October 2022 at Brugmann University Hospital.

**Main Outcome Measures:** This study compares sQoL after hysterectomy performed via conventional laparoscopy versus vNOTES for benign gynecological conditions.

**Results:** Regarding surgical characteristics, there were no differences between the two groups in terms of operative time, drop in blood haemoglobin levels and days of hospitalisation. Arousal and Orgasm scores are improved post-operatively in patients suffering from adenomyosis (4.47 vs. 3.91  $P=0.04$  for arousal and 5.07 vs. 4.26,  $P=0.016$  for orgasm).

**Conclusions:** The vNOTES method shows shorter hospital stay and faster re-introduction to sexual life over conventional laparoscopy for total hysterectomy in patients with benign gynaecology.

**What is New:** Our study shows that in patients suffering from adenomyosis, sQoL improved after hysterectomy using the vNOTES approach.

**Keywords:** Adenomyosis, hysterectomy, laparoscopy, vNOTES, sexual quality of life

**Corresponding Author:** Panayiotis Tanos, MD, Department of Obstetrics and Gynecology, Centre Hospitalier Universitaire Brugmann, Université Libre de Bruxelles, Brussels, Belgium

**E-mail:** p.tanos@outlook.com **ORCID ID:** orcid.org/0000-0001-5742-0995

**Received:** 17.09.2024 **Accepted:** 17.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Timmermans M, Hovsepyan H, Tanos P, Nisolle M, Karampelas S. Sexual quality of life after hysterectomy performed by conventional laparoscopy versus Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) in benign gynaecology. Facts Views Vis Obgyn. 2025;17(1):68-74



## Introduction

Hysterectomy is one of the most common surgical procedures in gynaecology, performed through different approaches like abdominal, vaginal, laparoscopic total (TLH) or laparoscopically assisted vaginal hysterectomy.<sup>1</sup> In benign conditions such as leiomyomas, adenomyosis, menometrorrhagia, uterine prolapse or chronic pelvic pain,<sup>2</sup> the vaginal route is preferred as it allows shorter operating time, faster recovery time, reduced pain, number of hernias at surgical site and can have better aesthetic appeal.<sup>3</sup> The laparoscopic approach is necessary in case of large uterus, limited vaginal access, or history of abdomino-pelvic adhesions, and endometriosis. However, this technique increases the risk of injury to the urinary or digestive tracts.<sup>4,5</sup>

The minimally invasive technique Vaginal Natural Orifice Transluminal Endoscopic Surgery (vNOTES) allows hysterectomy to be performed using a combined endoscopic view and laparoscopic instrumentation, with the vagina used as an access route to the peritoneal cavity.<sup>6</sup> Firstly described in 2007 for cholecystectomy,<sup>7</sup> vNOTES feasibility and safety were demonstrated for hysterectomy in 2012.<sup>8</sup> Contraindications include history of pelvic infection disease, previous rectum surgery, endometriosis at the pouch of Douglas, previous multiple pelvic surgeries, pelvic radiotherapy, and severe genital prolapse.

So far, few studies have compared vNOTES with TLH in operative time, length of hospital stay, postoperative pain, and intra- and postoperative complications.<sup>9,10</sup> However, the literature lacks data on dyspareunia, well-being and sexual quality of life (sQoL) in patients undergoing vNOTES. The main objective of this study is to evaluate and compare the quality of sexual life (QSL) of patients undergoing hysterectomy by vNOTES and by TLH. Our secondary objective is to determine if there is improvement in adenomyosis patients as about 40% of the population undergoing hysterectomy present with adenomyosis.<sup>11,12</sup>

## Methods

### Study Design

This is a single-centre retrospective observational study conducted at Brugmann University Hospital in the Gynaecology Department between September 2020 and October 2022. This study was reviewed and approved by the Ethics Committee of the Brugmann University Hospital under reference number B0772022000153, date: 14.02.2023.

We established our database according to the following inclusion criteria: women over 18 years of age, who underwent hysterectomy by laparoscopic or by vNOTES methods for benign indications such as drug-resistant menometrorrhagia, polyfibromatous uterus or adenomyosis. A total of 127 patients underwent hysterectomy for these benign indications.

### Surgical Procedures

All procedures, vNOTES or TLH, were performed by the same team, experienced in laparoscopic surgery. vNOTES was performed under general anaesthetic, with the patient installed in the gynaecological position. After disinfection, placement of sterile drapes and indwelling urinary catheter, peritoneal exposure and opening were performed. A circular pericervical colpotomy was undertaken, then the bladder was dissected down to the vesico-uterine peritoneal fold, giving access to the peritoneal cavity anteriorly. The pouch of Douglas was opened and the uterosacral ligaments of the paracervix were sectioned, ligated and reattached to the vaginal angles. The vNOTES was then installed as follows. After peritoneal rinsing, an Alexis retractor was placed. The uterus was downwardly attracted using Pozzi forceps. A posterior right-angled valve was placed in the pouch of Douglas and a long anterior right-angled valve, anterior to the uterus, was placed in the peritoneal cavity. Afterwards, 2/3 of the inner ring was inserted over the anterior valve before sliding the remaining third against the posterior valve in the Douglas, and the Alexis retractor was tensioned by winding the outer ring 2 turns. An optical trocar and 3 x 5 mm operating trocars were inserted. The trocars were then positioned on the vNOTES platform: 2 operating trocars at 10 and 2 o'clock and the optical trocar and third trocar at 5 and 7 o'clock on the Gel point™ platform. This platform was attached to the outer ring of the Alexis retractor, and insufflation was performed at a low pressure of 8 mmHg. Hysterectomy was performed after peritoneal exploration. After right lateralisation of the uterus, the uterine pedicle was resected after thermo-fusion, and the broad ligament was released. A vascular anastomosis was performed between the uterine pedicle and the utero-ovarian ligament was resected. After left lateralisation of the uterus, the same procedures were repeated on the contralateral side. The uterine pedicles, utero-ovarian and round ligaments were bilaterally resected, and the uterus released. The exsufflation was performed, the Alexis retractor removed, and haemostasis checked. Monocryl 0 was used to close the vagina. The urinary the

catheter was removed. TLH was performed as standard practice by following the validated 10 steps described by the European Society of Gynaecological Endoscopy working group in 2019. After both surgical procedures, paracetamol and non-steroidal anti-inflammatory drugs were prescribed for 48 hours.

### Sexual Life Quality Evaluation

The main objective of this study was to assess the QSL in patients at least 3 months after surgery, and to compare it between the two groups (vNOTES and TLH). The Female Sexual Function Index (FSFI)<sup>13</sup> was completed by patients during telephone interviews after informed consent had been obtained. The questionnaire covers the following six areas: desire, subjective arousal, lubrication, orgasm, satisfaction and pain. A total score is calculated, and a threshold value is predefined (26.55). A score below or equal to this threshold implies female sexual dysfunction.

### Collected Data

Descriptive patient characteristics (age, body mass index, gestational age, parity) and intra- and post- operative data were extracted from medical records. Intra- and post- operative data consisted in operative time, blood loss, change in haemoglobin level, length of hospital stay, pre-operative symptoms, operative complications and duration of postoperative analgesia.

### Statistical Analysis

Data were analysed using R software version 3.6.2 (R Core Team 2014). Continuous variables were expressed as

median (standard deviation), while categorical variables were expressed as numbers (frequencies). The normal distribution of continuous variables was assessed by QQ plots, and the homogeneity of variances by Levene's test. To detect a statistically significant difference between the "laparoscopy" and "vNOTES" groups, the chi-square or Fisher's exact test was used to compare categorical variables. The t-test or Mann-Whitney U test was used to compare continuous variables. A *P*-value <0.05 was considered statistically significant.

## Results

### Patient Characteristics

Initially, 127 patients were included in the study. Of these, 91 underwent TLH and 36 vNOTES hysterectomies. Table 1 shows the different results concerning patient characteristics. There was no significant difference in age or body mass index between the two groups.

Regarding surgical characteristics, there were no differences between the two groups in terms of operative time, drop in blood haemoglobin levels and days of hospitalisation. However, significant differences were observed between TLH and vNOTES regarding to total blood loss (respectively, 166.1 mL vs. 286.4 mL, *P* 0.007) and uterine weight (respectively 445.1 g vs. 305.3 g, *P* 0.022). For the period of postoperative analgesic administration, the mean duration was 8.9 days for the TLH group and 6.7 days for the vNOTES group. This the

**Table 1.** General and surgical characteristics of the general population (n=127) according to type of surgery.

Variables	General population (n=127)		
	TLH (n=91)	vNOTES (n=36)	P-value
Age (years)	46.9 (5.4)	46.6 (4.9)	0.759
BMI (kg/m <sup>2</sup> )	28.5 (5.2)	30.3 (7.2)	0.180
Gestivity	2.3 (1.6)	3.4 (2.0)	0.002*
Parity	1.8 (1.3)	2.8 (1.6)	0.001*
Operative time (min)	174.2 (66.3)	152.6 (60.4)	0.093
Total blood loss (mL)	166.1 (211.5)	286.4 (248.6)	0.007*
Haemoglobin drop (g/dL)	2.3 (3.2)	2.1 (1.1)	0.521
Hospital stay (days)	2.5 (1.1)	2.0 (2.4)	0.243
Analgesic intake (days)	8.9 (10.0)	6.7 (11.1)	0.305
Uterine weight (g)	445.1 (419.3)	305.3 (246.3)	0.022*
Adenomyosis	35 (38.5)	18 (50.0)	0.235
Complications	4 (4.4)	5 (13.9)	0.12

Data is presented as mean (standard deviation) or frequency (%). Complications: hemoperitoneum, infection, bladder injury, ureter injury, bowel injury.

\*Significant difference, BMI: Body mass index, TLH: Total laparoscopic hysterectomy, vNOTES: Vaginal Natural Orifice Transluminal Endoscopic Surgery.

difference was not statistically significant. According to histopathological diagnosis, 38.5% of patients in the TLH group had adenomyosis, compared with 50.0% in the vNOTES group.

### Comparison of sQoL After Hysterectomy by TLH and vNOTES

We aimed to determine if the sQoL was impacted by the surgical technique. We focused on the sexually active population, meaning 66 of the 127 patients who declared themselves sexually active and completed the FSFI questionnaire. This corresponded to 42.9% of the TLH group and 75.0% in the vNOTES group ( $P < 0.01$ ). The general characteristics of this sub-population are summarised in Table 2.

Of these 66 patients, 39 underwent TLH and 27 vNOTES. Patients who underwent vNOTES had significantly more pregnancies and deliveries. Surgically, vNOTES induced greater total blood loss (301.5 mL vs. 176.8 mL,  $P 0.028$ ) with no difference in haemoglobin drop. Despite this, vNOTES patients were discharged earlier (1.8 days vs. 2.6 days,  $P 0.011$ ).

Regarding histopathological diagnosis, in the TLH group, 33.3% of patients had adenomyosis versus 51.8% in the vNOTES group. This difference was not statistically significant. When we focused on postoperative sQoL, according to the type of surgery (Table 3), we observed that patients who benefited from vNOTES had higher scores than those operated on by conventional laparoscopy, which was statistically significant for arousal,

**Table 2.** General and surgical characteristics of the postoperative sexually active population (n=66) according to type of surgery.

Variables	Postoperative sexually active population (n=66)		
	TLH (n=39)	vNOTES (n=27)	P-value
Age (years)	46.6 (0.7)	47.1 (1.0)	0.642
BMI (kg/m <sup>2</sup> )	28.9 (0.9)	30.6 (1.3)	0.272
Gravidity	2.4 (0.3)	3.4 (0.4)	0.017*
Parity	1.9 (0.2)	2.9 (0.3)	0.005*
Operative time (min)	173.4 (7.4)	149.3 (12.3)	0.080
Total blood loss (mL)	176.8 (31.1)	301.5 (49.1)	0.028*
Haemoglobin drop (g/dL)	2.4 (0.4)	1.9 (0.2)	0.350
Hospital stay (days)	2.6 (0.2)	1.8 (0.3)	0.011*
Analgesic intake (days)	9.1 (1.6)	4.7 (1.5)	0.064
Uterine weight (g)	478.3 (78.6)	312.6 (49.7)	0.080
Adenomyosis	13 (33.3)	14 (51.8)	0.132
Complications	4 (10.2)	2 (7.4)	1

Data are presented as mean (standard deviation) or frequency (%). Complications: Hemoperitoneum, infection, bladder injury, ureter injury, bowel injury.

\*Significant difference, BMI: Body mass index, TLH: Total laparoscopic hysterectomy, vNOTES: Vaginal Natural Orifice Transluminal Endoscopic Surgery.

**Table 3.** FSFI results of the sexually active population (n=66) according to type of surgery.

Variables	TLH (n=39)	vNOTES (n=27)	P-value
Desire	3.40 (0.20)	3.82 (0.19)	0.138
Arousal	3.87 (0.20)	4.53 (0.17)	0.014*
Lubrication	4.44 (0.28)	4.91 (0.20)	0.173
Orgasm	4.19 (0.24)	5.15 (0.20)	0.003*
Satisfaction	4.21 (0.23)	5.15 (0.17)	0.002*
Pain	4.87 (0.31)	5.39 (0.25)	0.193
Global score	24.99 (1.04)	28.97 (0.80)	0.003*

Data are presented as mean (standard deviation).

\*Significant difference, FSFI: Female Sexual Function Index, TLH: Total laparoscopic hysterectomy, vNOTES: Vaginal Natural Orifice Transluminal Endoscopic Surgery.

**Table 4.** FSFI results of the sexually active population (n=66) according to presence of adenomyosis.

Variables	No adenomyosis (39)	Adenomyosis (27)	P-value
Desire	3.45 (0.20)	3.76 (0.21)	0.290
Arousal	3.91 (0.21)	4.47 (0.16)	0.040*
Lubrication	4.61 (0.25)	4.66 (0.27)	0.914
Orgasm	4.26 (0.24)	5.07 (0.22)	0.016*
Satisfaction	4.51 (0.23)	4.73 (0.23)	0.517
Pain	4.94 (0.28)	5.23 (0.31)	0.412
Global score	25.69 (1.05)	27.96 (0.91)	0.107

Data are presented as mean (standard deviation).

\*Significant difference, FSFI: Female Sexual Function Index.

**Table 5.** FSFI results of the sexually active population suffering from adenomyosis (n=27) according to type of surgery.

Variables	TLH (n=13)	vNOTES (n=14)	P-value
Desire	3.65 (0.28)	3.86 (0.32)	0.629
Arousal	4.31 (0.20)	4.61 (0.24)	0.365
Lubrication	4.43 (0.43)	4.86 (0.32)	0.433
Orgasm	4.86 (0.30)	5.26 (0.33)	0.387
Satisfaction	4.34 (0.36)	5.08 (0.28)	0.118
Pain	5.35 (0.46)	5.23 (0.43)	0.844
Global score	26.95 (1.34)	28.90 (1.23)	0.292

Data are presented as mean (standard deviation).

\*Significant difference, FSFI: Female Sexual Function Index, TLH: Total laparoscopic hysterectomy, vNOTES: Vaginal Natural Orifice Transluminal Endoscopic Surgery.

orgasm, and overall sexual satisfaction. The total sQoL score in the vNOTES group was significantly better than in the TLH group ( $P 0.003$ ). Their overall score was above the the cut-off of 26.55, indicating satisfaction with sQoL.

When we analysed our results depending on the presence of adenomyosis, we obtained the values described in Table 4. Only arousal and orgasm scores were improved post-operatively in patients suffering from adenomyosis (4.47 vs. 3.91  $P 0.04$  for arousal and 5.07 vs. 4.26,  $P 0.016$  for orgasm). No other results were significantly different. However, the FSFI global score was over the threshold of 26.55 in patients with adenomyosis. If we compared the two techniques inside our adenomyosis population only (Table 5), no difference was observed in FSFI results.

## Discussion

Only a few significant differences were observed between TLH and vNOTES when applied for benign indication. These concerned uterine weight, total blood loss, hospital stay, sexual intercourse continuation and sQoL.

It was previously demonstrated that 30 cases are required to reach a learning curve plateau in vNOTES.<sup>14,15</sup> Our the

surgical team had reached the plateau of this learning curve while demonstrating no impact on patients' post-operative recovery. The vNOTES group experienced significant bleeding in the general population (286.4 vs. 166.1 mL,  $P 0.007$ ) but this was not related to experience. As vaginal access to the peritoneum requires a colpotomy, bleeding often occurs due to the access through a highly vascularised area. Sometimes the cleavage plane is incorrect or the endocervical myometrium is dissected by mistake.<sup>16</sup> Nevertheless, none of the patients had required blood transfusion.

We observed a difference in hospital stay between the two techniques only if we focused on the sexually active group. The vNOTES sexually active group was discharged earlier (1.8 vs. 2.6 days,  $P 0.011$ ) with a trend of shorter analgesic intake duration postoperatively (almost the half). This is in line with the recent study of Kaya et al.<sup>17</sup>, 2021 which showed that the VAS pain score at 6 and 24 hours after surgery was significantly lower in patients operated on with vNOTES. It is important to note that the patients who are discharged earlier feel better earlier and resume intercourse earlier. 75% of women operated with vNOTES, and 42.9% operated by TLH had restarted

sexual activities within 3 months postoperatively ( $P < 0.01$ ). All of them completed the FSFI questionnaire, which is the gold standard for measuring female sexual function for 20 years.<sup>18,19</sup> In the early use of the vNOTES technique, Su et al. (2012) demonstrated good healing of the vaginal scar, as well as the absence of post-coital bleeding, dyspareunia and discomfort during intercourse. In a randomised controlled trial (RCT), Baekelandt et al.<sup>4</sup> did not find any pain during intercourse nor worsening of pre-existing pain 3 and 6 months after the procedure.

Our study stands out for its analysis of patients' sQoL and the identification of a possible sexual dysfunction. Indeed, our results showed that patients who underwent vNOTES surgery had significantly higher scores than those operated on TLH in the areas of arousal, orgasm and satisfaction. The median total score was 28.97 for the vNOTES group and 24.99 for the TLH group ( $P 0.003$ ). The route to perform the vaginal suture and its effect on sexuality is controversial and very few studies exist on the topic. It seems that laparoscopic cuff closure seems to be preferred because of better postoperative vaginal length and no impact woman sexuality.<sup>20,21</sup> This is confirmed by a RCT performed by Bastu et al.<sup>22</sup>, where vaginal versus laparoscopic route for vaginal suture were compared (Bastu et al., 2016). Nevertheless, at 3 months postoperatively, they did not show any difference in FSFI between the two routes of suture. However, in our population, despite vaginal suture, vNOTES gave better results in terms of FSFI global score.

Furthermore, patients suffering from adenomyosis had a better arousal, orgasm and global scores after hysterectomy, independently of the surgical technique used, compared to those not suffering from adenomyosis. We can therefore extrapolate that patients are treated for their adenomyosis while improving their sQoL. However, we cannot demonstrate that vNOTES is better in this case, as no significant difference was observed between the two techniques. Few publications have described the sexual life quality of women suffering from adenomyosis.<sup>23-25</sup> However, by comparison to endometriosis patients, it could be expected that women with adenomyosis also show the negative impact of their pathology on their sexual life.

### Study Limitations

Our study presents limitations due to its retrospective nature from a single centre. The uterine weight in the vNOTES group was smaller (305.3 vs. 445.1 g,  $P 0.022$ )

due to some selection bias, as our team did not wish to propose this technique for larger uterus. Bias due to different number of births and deliveries between the two groups. Lastly, a baseline preoperative FSFI score should also have been collected to determine further differences in sQoL between the two groups pre-operatively. Our results can be validated by prospective randomised multicentric studies. It is important to note that our team's surgical results in vNOTES include their learning curve as the procedure was only very recently adapted by the team. The main operating surgeon was always the same increasing the reliability of our results. Our results further show vNOTES rapid learning in the case of an experienced laparoscopic surgeon.

### Conclusion

vNOTES technique is a plausible operative method for total hysterectomy in patients with benign gynaecological conditions and specifically adenomyosis. vNOTES offers advantages of shorter hospital stay and faster re-introduction to sexual life. In the absence of contraindications, vNOTES can be considered as first-line management option in benign gynaecological surgery.

### Ethics

**Ethics Committee Approval:** This study was reviewed and approved by the Ethics Committee of the Brugmann University Hospital under reference number B0772022000153, date: 14.02.2023.

**Informed Consent:** Informed consent has been obtained.

**Acknowledgements:** None.

### Footnotes

#### Authorship Contributions

Surgical and Medical Practices: M.T., H.H., P.T., M.N., S.K., Concept: M.T., H.H., P.T., M.N., S.K., Design: M.T., H.H., P.T., M.N., S.K., Data Collection or Processing: M.T., H.H., P.T., M.N., S.K., Analysis or Interpretation: M.T., H.H., P.T., M.N., S.K., Literature Search: M.T., H.H., P.T., M.N., S.K., Writing: M.T., H.H., P.T., M.N., S.K.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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# Uptake, views, opinions and practice of same-day discharge following total laparoscopic hysterectomy: a national survey of UK gynaecologists

 Lina Antoun<sup>1</sup>,  T. Justin Clark<sup>1,2</sup>

<sup>1</sup>Department of Gynaecology, Birmingham Women's NHS Foundation Trust, Birmingham, UK

<sup>2</sup>Institute of Metabolism and Systems Research, University of Birmingham, Birmingham, UK

## ABSTRACT

**Background:** Total laparoscopic hysterectomy (TLH) is associated with reduced post-operative pain and enhanced recovery, allowing same-day discharge (SDD). However, adoption of SDD TLH is not established, and practice varies.

**Objectives:** To conduct a national survey of UK gynaecologists with an interest in laparoscopic surgery to obtain their views, opinions and experience of SDD TLH.

**Methods:** Members of the British Society for Gynaecological Endoscopy were invited to complete an online questionnaire between January 2023 and January 2024.

**Main Outcome Measures:** The questionnaire consisted of 16 questions about SDD TLH covering three domains: (i) service provision, (ii) prognostic variables and (iii) information giving and education.

**Results:** One hundred and forty-eight clinicians from 148/215 NHS hospitals (69%) responded. One hundred and thirty one (89%) respondents thought that SDD following TLH was beneficial, and 48 (32%) hospitals had an established service. Adequate pain control was considered the most important factor to achieve SDD TLH, followed by control of nausea and vomiting. Seventy-eight (53%) respondents removed the urinary catheter at the end of the procedure. All respondents believed that managing patients' expectations was important to achieve compliance with SDD and 123 (83%) thought that developing an online preadmission patient information resource was needed.

**Conclusions:** One third of UK NHS hospitals have a SDD TLH service but there is variation in availability and protocols (pre-, peri- and post-operative management). These data can help develop health service strategy to promote SDD after TLH and standardise protocols.

**What is New?** The survey quantifies and demonstrates hospital-level variation in uptake and practice of SDD provision after TLH.

**Keywords:** Same-day discharge, laparoscopic hysterectomy, questionnaire, SDD pathway

## Introduction

Total laparoscopic hysterectomy (TLH) is replacing abdominal approach to hysterectomy as the standard of care due to its less invasive nature allowing reduced intra-operative blood loss, post-operative pain and

length of stay.<sup>1,2</sup> Capitalising upon this enhanced recovery, there has been a move to same day discharge after TLH,<sup>3</sup> other types of laparoscopic hysterectomy (LH)<sup>4,5</sup> and vaginal hysterectomy<sup>5</sup> thereby avoiding overnight hospital stay and optimising the use of

**Corresponding Author:** Lina Antoun, MD, Department of Gynaecology, Birmingham Women's NHS Foundation Trust, Birmingham, UK

**E-mail:** antoun.lina@gmail.com **ORCID ID:** orcid.org/0000-0003-4893-0576

**Received:** 21.07.2024 **Accepted:** 08.03.2025 **Publication Date:** 28.03.2025

**Cite this article as:** Antoun L, Clark TJ. Uptake, views, opinions and practice of same-day discharge following total laparoscopic hysterectomy: a national survey of UK gynaecologists. Facts Views Vis Obgyn. 2025;17(1):75-83



scarce healthcare resources. Previous research has shown that day-case TLH does not compromise patient care compared to conventional discharge practices and is associated with an increase in patient satisfaction.<sup>6-8</sup> Patient characteristics contributing to the success of day-case hysterectomy, that is discharge on the same day, include younger age, lower body mass index and reduced co-morbidity scores.<sup>9,10</sup> Surgical factors increasing compliance with same-day discharge (SDD) include greater surgeon experience, reduced operating times and aspects of surgical technique such as using low operating pressures no higher than 8-11 mmHg.<sup>6,7,12</sup> The barriers to SDD identified in the literature include post-operative pain and nausea and vomiting (N&V)<sup>11</sup> and urinary retention, which were more likely with longer operating time, greater blood loss and more intra-operative opioid use.<sup>10</sup>

Thus, in addition to patient selection and surgical proficiency, standardised protocols and pathways for pre-, peri- and postoperative care appear to be important to increase the likelihood of safe and successful SDD. Implementation of such pathways can be relatively quick and successful.<sup>3,13</sup> Nensi et al.<sup>7</sup> reported an increase in their SDD rate from 18% prior to introduction of a SDD pathway, to 79% after implementation of the pathway, without any significant differences in peri-operative complications, readmission rates or patient satisfaction. While the literature seems to support the introduction of SDD TLH pathways, SDD has not yet been adopted as the standard of care in the UK or internationally.<sup>24</sup> In the UK, the National Health Service (NHS) - "Getting It Right First Time (GIRFT)" initiative is promoting SDD for a number of common gynaecological operations, including LH, where SDD rates of 50% have been proposed as achievable across the country.<sup>14</sup>

We, therefore, undertook a national survey to understand the prevalence of established SDD services for TLH in UK NHS hospitals and the proportion of hospitals planning to introduce such services. In addition, we sought UK gynaecologists' views and experiences of SDD for TLH, including key clinical and educational components of SDD pathways, to optimise the success of such pathways and their implementation.

## Methods

We conducted an online survey in the UK of members of the British Society for Gynaecological Endoscopy (BSGE) about SDD TLH services. They were invited to share their

views, opinions and experience of SDD TLH. Access to the survey, a link and/or QR code to the online software provider "SurveyMonkey" was advertised online and through a press release in the BSGE "Scope" newsletter (Issue 21).<sup>15</sup> The survey was open from January 2023 to January 2024. The questionnaire was developed through a literature review to understand the existing practice regarding SDD TLH. The survey was reviewed by a focus group discussion, including doctors who are experts in the field of minimally invasive surgery. The questionnaire was evaluated for relevance and face validity by a team of five experts representing the officers of BSGE and the editor of the BSGE "Scope" newsletter.

The aim was to gain the views, beliefs, opinions and practice of UK gynaecologists with an interest in endoscopic surgery on SDD TLH. The acquired information could then be used to plan and standardise future service development, including SDD pathways with the aim of improving compliance with SDD TLH, patient experience and clinical outcomes.

The survey comprises 16 mandatory questions including exclusive and non-exclusive categorical responses as well as hierarchical responses (scale 1 to 5 in importance). The option of an open "free text" reply was restricted to three questions in order to enhance speed of completion of the survey and thus response. The online survey was split into three domains. The first domain enquired about the SDD *service provision*: prevalence of SDD services, plans to set up such services, availability of specific protocols and infrastructure including use of dedicated SDD units and specialist nursing roles for discharge and follow up. The second domain focused on *prognostic variables*: views and opinions about the relative importance of patient expectations and clinical factors such as pain, N&V, early mobilisation, introduction of diet and timing of urinary catheter removal. Their surgical practice regarding peri-operative insufflation pressures and protocols for post-operative local anaesthesia and analgesia was also asked about in this domain. The third and final domain sought views on *information giving and education*: pre-admission information and potential value of developing bespoke online resources.

While we were interested in the views and experiences of individual clinicians, we recorded the NHS hospitals they worked in to provide an accurate denominator at the hospital level to estimate the rate of SDD services across the UK. If more than one clinician replied from a specific hospital, we selected the first response. All information

collected through the survey was anonymous. A full list of the survey questions is available in Figure 1.

## Results

### Service Provision

One hundred and seventy-one clinicians registered as BSGE members from 148/215 (69%) NHS hospitals in the UK responded to the survey. The full list of responses to the 16 survey questions posed is available in Supplementary Table 1. 131 (89%) of respondents thought that SDD following TLH was beneficial for eligible patients and 48 (32%) of hospitals had already set up an SDD TLH service with a further 53 (36%) in the process of setting up a service. 61/148 (41%) of respondents confirmed they had established a specific protocol for their implemented or proposed SDD TLH service. Fifty-nine/148 (40%) had a dedicated unit or area within their hospital (e.g. Day Surgery Unit) for patients undergoing SDD TLH. 85 (57%) of hospitals had pathways that included nurse-led discharge, i.e. nurses can make the decision that a patient is fit for discharge according to the specified discharge criteria.

The majority of survey respondents (126, 85%) reported provision of phone numbers to patients as a form of contact option within the first few days following discharge from the hospital after an SDD TLH (Table 1).

### Prognostic Variables

All respondents agreed that patients' expectations about their duration of stay on admission to hospital was important, with 134 (91%) feeling that this was very important. We also asked BSGE survey respondents to rank (1 = most important; 5 = least important) the relative importance of the following clinical factors to facilitate SDD after a TLH: control of pain, control of N&V, early mobilisation, early introduction of diet and early removal of the urinary catheter. Adequate control of pain scored the highest ranking amongst all respondents [mean: 4.4; standard deviation (SD): (16.0), followed by adequate control of N&V (mean: 3.14; SD: (19.6)] (Table 2).

Half of the respondents (78, 53%) reported removing the urinary catheter at the end of the procedure to facilitate SDD (Figure 2). The majority of respondents (138, 93%) use a pneumoperitoneal pressure of either 12 mmHg or 15 mmHg to achieve SDD TLH. Cutaneous ports post-incision was the most used local anaesthetic in 94 (64%) to reduce postoperative pain following planned SDD TLH (Figure 3). Non-opioids were the most popular routine post-operative analgesia (112, 76%), followed by opioids in 77 (52%) amongst respondents. Nine (6.1%) respondents used continuous patient-controlled analgesia opioid.

Same Day Discharge (SDD) Total Laparoscopic Hysterectomy (TLH) Quality Improvement Question Initiative Questionnaire	
1. Do you think a SDD TLH service is beneficial for eligible patients?	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
2. Are you currently setting up or planning to set up a SDD TLH service?	<ul style="list-style-type: none"> <li>• Have set up a service already,</li> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
3. Do you have a specific protocol / pathway for the implementation of SDD for TLH in your hospital?	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
4. Do you have a dedicated unit or area within your hospital (e.g. day surgery unit) for patients undergoing SDD TLH?	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
5. Does your hospital's service pathway include nurse-led discharge (i.e. nurses can make the decision that a patient is fit for discharge e.g. based on set criteria)?	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
6. What contact options are patients provided with in the first few days following discharge from hospital after a SDD TLH? (tick all that apply)	<ul style="list-style-type: none"> <li>• Phone numbers</li> <li>• Text (SMS) numbers</li> <li>• On-line contact (e.g. web address)</li> <li>• Pro-active phone call from a member of the clinical team</li> <li>• Pro-active text (SMS) from a member of the clinical team</li> <li>• Pro-active text on-line contact (e.g. email) from a member of the clinical team</li> </ul>
7. To what extent do you think a patient's expectation, about their duration of stay on admission to hospital, is important to achieve SDD TLH procedures	<ul style="list-style-type: none"> <li>• A lot</li> <li>• A little</li> <li>• Not at all</li> </ul>
8. Please rank the relative importance of the following clinical factors to facilitate SDD after a TLH? (1 = most important; 5 = least important)	<ul style="list-style-type: none"> <li>• Adequate control of pain</li> <li>• Adequate control of nausea and vomiting</li> <li>• Early mobilisation</li> <li>• Early introduction of diet (eat and drink)</li> <li>• Early removal of the urinary catheter</li> </ul>
9. When do you ideally take the catheter out following TLH to facilitate SDD?	<ul style="list-style-type: none"> <li>• At the end of the procedure</li> <li>• After 2-4 hours</li> </ul>
	<ul style="list-style-type: none"> <li>• After 6 hours</li> <li>• Patients are sent home with the catheter in situ</li> </ul>
10. What pneumoperitoneal pressures do you routinely target and achieve for the majority of a TLH? (tick all options that apply)	<ul style="list-style-type: none"> <li>• 15 or higher?</li> <li>• 12mm</li> <li>• 10mm</li> <li>• 8mm</li> <li>• 6mm</li> </ul>
11. What type of local anaesthetic do you use routinely to reduce postoperative pain following planned SDD TLH? (tick all options that apply)	<ul style="list-style-type: none"> <li>• Cutaneous ports pre-incision</li> <li>• Cutaneous ports post-incision</li> <li>• Laparoscopic transverse abdominus plane (LTAP) blocks</li> <li>• Regional anaesthetic</li> <li>• I do not use local anaesthetic</li> <li>• Other (please specify) _____</li> </ul>
12. What type of analgesia do you routinely use to reduce postoperative pain following planned a SDD TLH?	<ul style="list-style-type: none"> <li>• Non-opioids</li> <li>• Opioids</li> <li>• Continuous PCA opioid</li> <li>• Other (please specify) _____</li> </ul>
13. Do you think that developing an online pre-admission information resource for patients listed for a TLH could help compliance with SDD for eligible patients?	<ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> <li>• Don't know</li> </ul>
14. If we were to develop an online resource to pilot for patients who are waiting for a SDD TLH, how do you think this should be provided?	<ul style="list-style-type: none"> <li>• A live, structured 'educational class' (e.g. over zoom) that allows the opportunity for attendees to ask questions ('Q&amp;A') run by the local clinical team</li> <li>• A pre-recorded educational class (e.g. over zoom) accessible on demand but without the opportunity for attendees to ask questions (but FAQs with answers provided)</li> <li>• No preference for either suggestion</li> <li>• No need to provide information like this (i.e. you do not consider such resources necessary and / or practical)</li> </ul>
15. If you did not answer 'yes' to the question above, can you explain why? (tick all options that apply)	<ul style="list-style-type: none"> <li>• Not applicable</li> <li>• Lack of resources</li> <li>• Lack of expertise</li> <li>• Lack of support from management</li> <li>• Lack of support from clinicians</li> <li>• Lack of evidence for benefit</li> <li>• Not a clinical priority</li> <li>• Other (please specify) _____</li> </ul>
16. If you agree that a SDD TLH service is important, how helpful do you think, some sort of upliftment tariff or some sort of financial incentive to Trusts would be, in driving the uptake and adoption of a SDD TLH Services across hospitals in the UK?	<ul style="list-style-type: none"> <li>• A lot</li> <li>• A little</li> <li>• Not at all</li> </ul>

**Figure 1.** Same day discharge following total laparoscopic hysterectomy survey (distributed online-SurveyMonkey).

**Table 1.** What contact options are patients provided with in the first few days following discharge from 148 hospitals after an SDD TLH? (more than one response allowed).

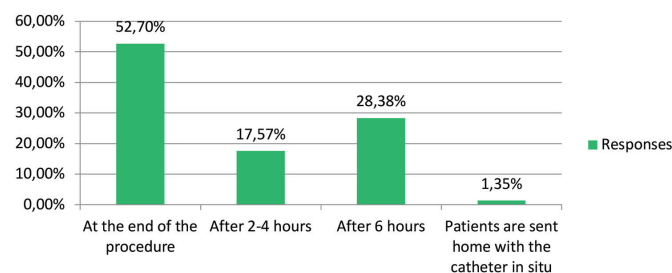
Answer choices	Responses	
Phone numbers	126	85.1%
Text (SMS) numbers	9	6%
online contact (e.g. web address)	20	14%
Pro-active phone call from a member of the clinical team	54	36.5%
Pro-active text (SMS) from a member of the clinical team	6	4.1%
Pro-active on-line contact (e.g. email) from a member of the clinical team	4	2.7%

SDD: Same day discharge, TLH: Total laparoscopic hysterectomy, SMS: Short message service.

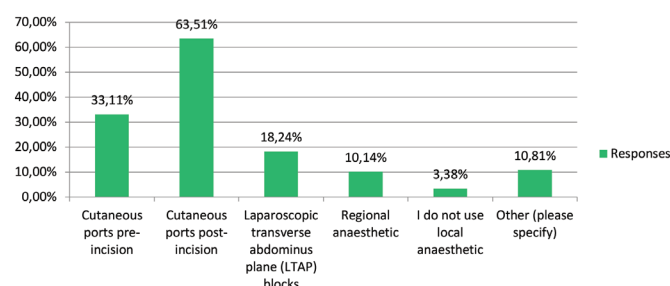
**Table 2.** Ranking of the relative importance of the clinical factors facilitating SDD after a TLH from 148 respondents representing 148 UK hospitals. (1 = most important; 5 = least important).

Answer choices	1	2	3	4	5	Mean score (SD)
Adequate control of pain	105 (70.9%)	18 (12.2%)	10 (6.8%)	9 (6.1%)	6 (4.1%)	4.40 (16.0)
Adequate control of nausea and vomiting	7 (4.7%)	63 (42.6%)	38 (25.7%)	24 (16.2%)	16 (10.8%)	3.14 (19.6)
Early mobilisation	9 (6.1%)	29 (19.6%)	53 (35.8%)	41 (27.7%)	16 (10.8%)	2.82 (16.0)
Early introduction of diet (eat and drink)	9 (6.1%)	8 (5.4%)	18 (12.2%)	46 (31.1%)	67 (45.3%)	1.96 (23.2)
Early removal of the urinary catheter	18 (12.2%)	30 (20.3%)	29 (19.6%)	28 (18.9%)	43 (29.1%)	2.68 (8.0)

SD: Standard deviation, SDD: Same day discharge, TLH: Total laparoscopic hysterectomy, SMS: Short message service.

**Figure 2.** Removal of urinary catheter timing following TLH to facilitate SDD (148 hospital respondents)?

TLH: Total laparoscopic hysterectomy, SDD: Same day discharge.

**Figure 3.** Type of local anaesthetic routinely used to reduce postoperative pain following planned SDD TLH? (148 hospital respondents - more than one response category allowed)

TLH: Total laparoscopic hysterectomy, SDD: Same day discharge.

### Information Giving and Education

The majority of respondents (123, 83%) thought that developing an online pre-admission information resource for patients listed for a TLH could help compliance with SDD in eligible patients. We sought views about preferences and support for the development of an online resource for patients awaiting an SDD TLH (Table 3). Half of the respondents, 75 (51%), believed that a pre-recorded educational class (e.g. video conferencing platforms) accessible on demand, incorporating "frequently asked questions" with answers provided, would be the most

beneficial online resource to pilot for patients who are waiting for a SDD TLH. We also asked respondents to rank reasons why they thought the development of a patient's pre-admission information resource might not be helpful. Ninety-eight (66%) did not think this contention was applicable. Of the 50 respondents providing a response (more than one response category allowed), lack of resources was ranked by 17 (34%) as the main obstacle, followed by lack of support from management (13, 26%), lack of evidence for benefit (11, 22%), non-clinical priority (9, 18%) and lack of resources (17, 34%).

**Table 3.** Views on the development of a proposed online resource for patients awaiting an SDD TLH (148 hospital respondents).

Answer choices	Responses	
A live, structured 'educational class' (e.g. over Zoom) that allows the opportunity for attendees to ask questions ('Q&A') run by the local clinical team	37	25.0%
A pre-recorded educational class (e.g. over zoom) accessible on demand but without the opportunity for attendees to ask questions (but FAQs with answers provided)	75	50.7%
No preference for either suggestions	27	18.2%
No need to provide information like this (i.e. you do not consider such resources necessary and/or practical)	9	6.1%

SDD: Same day discharge, TLH: Total laparoscopic hysterectomy, FAQs: Frequently asked questions.

Overall, 104/148 (70%) of respondents agreed that providing an upliftment in the funding tariff or some sort of financial incentive would be helpful in driving the uptake and adoption of a SDD TLH services across hospitals in the UK.

## Discussion

### Principal Findings

This national survey provides an insight into the opinions, views and beliefs of UK gynaecologists with an interest in endoscopic surgery about service provision, prognostic variables and information/education as well as current implementation and plans for implementation of SDD TLH. If the uptake of LH is expected to follow a similar trajectory to other minimally invasive surgical techniques, it is reasonable to anticipate increased adoption as more evidence supports its benefits, including quicker recovery times and reduced hospital stays. Almost 90% of respondents thought that SDD TLH was beneficial for patients. While the concept of SDD TLH following LH service has been established to be safe and feasible,<sup>3,6,16</sup> we found that it is only implemented by one third of hospitals surveyed, although another third is planning to set up the service. Surprisingly, more than half of hospitals did not have a dedicated unit or area for day-surgery, a deficiency that may be holding back service implementation. As regards prognostic factors to improve the success of SDD TLH, all respondents agreed that patients' expectation about their duration of stay on admission to the hospital was important, implying that patient information and education are a key facet of SDD TLH pathways.

Although most respondents removed the urinary catheter at completion of surgery, used post-operative local anaesthesia to port sites and a mixture of opioid and non-opioid analgesia, it was interesting to note that there

was substantial variation in protocols for management of the bladder and post-operative pain. Follow up protocols varied with only the minority of providers pro-actively contacting patients by phone or SMS at home post-operatively, to support the SDD service. The majority of respondents believed that the development of online patient friendly information/education resources to support SDD TLH could help compliance and satisfaction.

### Strengths and Limitations

Surveys provide evidence on practice, attitudes, and knowledge. To the best of our knowledge, there is no comparable national survey addressing discharge concepts following LH. For the first time, this survey provides data on the opinions, beliefs and practices of SDD TLH services from gynaecologists with an interest in endoscopic surgery across the UK. The survey includes data from 69% of UK hospitals from BSGE-registered gynaecologists in the UK. The response rate and UK hospital representation are good. Non-response bias, which arguably affects the external validity of our findings, is present to some degree, but there is no agreed-upon standard for acceptable response rates.<sup>17</sup> Response rates of between 50% and 75% are generally considered acceptable to be representative and valid.<sup>18-20</sup> While we believe our hospital response rate to be good, at the time of the survey the BSGE had approximately 1400 gynaecologist members. We did receive responses from 171 members, but this equates to only 12% of members who are gynaecologists. Thus, a repeat, wider survey, with a better individual response rate would allow for a more in-depth evaluation of the beliefs and opinions of relevant clinicians.

### Implications for Clinical Practice

Successful discharge post-surgery of any type requires a clinically stable patient capable of managing, with some support, in their home environment. This means the

ability to control pain to allow mobilisation and comfort and to treat N&V, such that an oral diet is possible. Proficient laparoscopic surgery utilising the most effective technologies reduces intra-operative trauma, complications and post-operative pain.<sup>21</sup> However, the conduct of the operation, whilst of fundamental importance, is only one factor that will influence compliance with SDD and patient satisfaction.

Attention needs to be paid to all stages of the patient journey: pre-, peri- and post-operative management. This requires appropriate patient selection, optimisation of health status and education, judicious anaesthetic and surgical management and holistic post-operative care, targeting treatment of pain, N&V and voiding dysfunction, as well as proactive patient follow-up and accessibility. One area of peri-operative practice that our survey revealed was not being implemented was "pressure surgery". Almost all respondents aimed for a pneumoperitoneal pressure of 12 mmHg-15 mmHg despite evidence that low-pressure surgery (6-8 mmHg) facilitated by specialist insufflation systems can reduce post-operative pain and facilitate SDD<sup>22,23</sup> more are important clinical factors to facilitate SDD TLH.

While there is a need for more evidence, there are data identifying pre-, peri- and postoperative factors that can optimise SDD.<sup>24,25</sup> The variation in practice revealed in our national survey shows however, that either the available evidence is being ignored, interpreted differently or is deficient. Surgeons' preference plays a critical role in the implementation of SDD after minimally invasive hysterectomy. While the rehospitalisation rates, postoperative complications and healthcare costs are low in SDD cases,<sup>26,27</sup> concerns about patient safety are preventing its application in over a third of patients.<sup>25</sup> This highlights the need for standardised protocols that outline postoperative monitoring and discharge criteria, ensuring effective communication among healthcare teams and providing comprehensive patient education to prepare patients for discharge and follow up care. It is important to share best practice from all units but especially those hospitals with established and successful units with high rates of SDD TLH, safety and patient satisfaction. In addition, research studies and trials evaluating SDD TLH should be supported so we can better understand the key prognostic components. In the absence of evidence to guide best practice, protocols should be tailored to suit local populations and infrastructure.

While pre- and peri-operative care may vary, it is most likely that it is the post-operative management pathways that dictate the success or failure of SDD TLH. Management of pain, N&V and self-care (mobilisation) are key determinants of suitability for hospital discharge following surgery.<sup>3,5,11,13</sup> Standardisation of post-operative pain control based upon the best evidence is required, and if evidence is lacking to uniform practice then we need to acquire it. It was surprising to see that 10% of units used regional anaesthesia because this impairs early mobilisation and urinary voiding. The use of laparoscopic transverse abdominis plane (LTAP) blocks or local anaesthetics at the port sites has been found to help minimise postoperative pain<sup>3,11</sup> but LTAPs were only routinely used by 18% of respondents.

Opioid and non-opioid analgesia were used post-operatively. We did not ask directly about whether patients were discharged with morphine or other potent opioids. Several publications recommend opioid-free analgesia pathways to facilitate effective implementation of SDD TLH<sup>10,28</sup> and this reflects findings from a meta-analysis<sup>24</sup> that opioid prescribing at surgical discharge does not reduce pain intensity but does increase adverse events. However, other units successfully run SDD TLH services with routine use of opiates as take-home medications<sup>11</sup> and this is commonplace following caesarean section.<sup>29</sup> Observational studies suggest that removing urinary catheters at the end of the surgery help to maximise the chance of successful trial without catheter (TWOC) and subsequent SDD.<sup>3,12,13</sup> However, almost half of the respondents delayed urinary catheter removal. Indeed, few respondents were prepared to send patients home with a urinary catheter if they failed their TWOC. Thus, there are areas to address, evaluate and standardise that may quite quickly increase SDD after TLH rates.

Health service policy needs to help effect change and inevitably this means prioritisation and resourcing. The NHS is working in collaboration with the NHS England GIRFT programme and the British Association of Day Surgery to address the shortage of inpatient beds and expand day-case surgery.<sup>30</sup> Recognising the paramount importance of providing exceptional care for women, 70% of respondents agreed that introducing a national tariff that is structured and priced to incentivise and adequately reimburse care for SDD TLH would be helpful. This will encourage other hospitals to implement SDD TLH pathways and will reflect high quality care and cost effectiveness.

## Implications for Research

Systematic reviews of randomised and non-randomised studies have identified factors predictive of compliance with SDD.<sup>6,24</sup> Pathways should incorporate this evidence base to optimise success. However, given how prevalent hysterectomy is in contemporary gynaecological practice, there remains a relative paucity of large multicentre trials or observational datasets evaluating specific protocols and pathways, and this may explain the observed variation in SDD practices. While individual interventions need evaluating, there needs to be research into overarching protocols inclusive of pre-, peri- and post-operative strategies. In the absence of a core outcome set for hysterectomy, outcomes to assess should include rates of compliance with SDD, safety, satisfaction, patient experience and cost-effectiveness of SDD TLH. Previous studies suggest that patients who are discharged on the same day experience comparable recovery outcomes in terms of physical function when compared to those discharged the following day.<sup>3,25</sup> This supports the viability of SDD as a safe and effective option, allowing patients to return to their daily activities sooner while minimising hospital stay duration.

There have been three RCTs that did not show any significant difference in patients' satisfaction according to length of stay or return to physical function following SDD TLH compared to the traditional 1-to-2 night stay TLH.<sup>25,31,32</sup> However, there appears to be a lack of data regarding the effectiveness of pre-operative patient information, patients' experience and the cost-effectiveness of SDD, and this is of fundamental importance for enhanced recovery post-surgery.<sup>14</sup> Patient-friendly, educational materials pertaining to day-case LH are lacking. Information technology should be utilised. Over 80% of respondents thought that developing online pre-admission information resources, including educational "classes" in preparation for SDD post-TLH from the hospital, could help patients' compliance with the process and improve their experience and satisfaction. Qualitative research to better understand patients' views and motivations across diverse backgrounds is needed to optimise SDD models of care.

## Conclusion

Our survey suggests that there is an increase in the use of SDD following LH. Several factors are associated with SDD, including pre-planning, intraoperative considerations and patients' education and support. Our

survey gives an insight into hospital-level variation uptake and practice relating to SDD after TLH. These data can be used to help develop a health service strategy to promote SDD after TLH and standardise protocols based on best practice. Audits and research projects need to be run alongside this innovation in the model of care to evaluate and improve outcomes after minimally invasive gynaecological surgery.

## Ethics

**Ethics Committee Approval:** The content and dissemination of this survey of the British Society of Gynaecological Endoscopy (BSGE) members was reviewed by the officers and clinical governance committee and approval was given.

**Informed Consent:** All responses were anonymous, so informed consent is not required.

**Acknowledgements:** Thanks to the gynaecologists working in the following 148 UK NHS hospitals for completing the survey on same day discharge after total laparoscopic hysterectomy:

Aberdeen Hospital, Addenbrookes Hospital Cambridge, Altnagelvin Hospital Northern Ireland (NI), Antrim NI, Arrowe Park Hospital Liverpool, Ashford and St Peter's NHS Foundation Trust, Barnet & Chase Farm (RFNHST), Barnsley Hospital, BCUHB, Birmingham Women's and Children's Hospital, Bolton Hospital, Bradford Hospital, Brighton General Hospital, Burnley General Hospital Chelsea & Westminster Hospital, Cheltenham General Hospital, Chesterfield Royal Hospital NHS Foundation Trust, Chichester Churchill hospital, City Hospital Birmingham, Colchester General, Coventry Walsgrave Hospital, Craigavon Hospital, Croydon Hospital, Darlington Memorial Hospital, Derriford Hospital Plymouth, Doncaster Royal Infirmary, Dorset County Hospital, East and North Hertfordshire NHS Foundation Trust, Epsom and St Helier NHS Foundation Trust, Freeman Hospital, Glasgow Royal Infirmary Scotland, Good Hope Hospital Birmingham, Great Western Hospital Swindon, Guildford Hospital, Hampshire Hospitals Foundation Trust, Harrogate Hospital, Heartlands Hospital Birmingham, Hereford Hospital, Hertfordshire Hospital, Hillingdon Hospital Uxbridge, Hinchingsbrooke hospital Cambridge Homerton Hospital London, HSE South East Dublin Ireland Huddersfield Royal Infirmary, James Paget University Hospitals NHS Foundation Trust Great Yarmouth, John Radcliffe Hospital Oxford, Lancashire Teaching Hospital NHS Foundation Trust Preston, Leicester General Hospital, Leicester Royal Infirmary, Lewisham Hospital London, Lister Hospital Stevenage, Liverpool Women's Hospital, London North West University Healthcare NHS Trust, Manchester Royal Infirmary, Mid and South Essex NHS Foundation Trust, Mid Yorkshire NHS Foundation Trust, Milton Keynes Hospital, Musgrove Park Hospital Somerset, North Cumbria Integrated Care NHS Foundation Trust, New Cross Hospital Wolverhampton, North Manchester Hospital, Northampton General Hospital, Northumbria Healthcare NHS Foundation Trust, Ormskirk Hospital, Peterborough City Hospital, Plymouth Hospital, Poole Hospital, Princess Anne Hospital, Southampton, Princess of Wales Hospital Bridgend Wales, Queen Elizabeth Hospital Birmingham, Queen Elizabeth Glasgow Scotland, Queen Elizabeth Hospital, Gateshead Queen Elizabeth Hospital, Woolwich Queen's Hospital Burton, Queen's Medical Centre Nottingham, Royal Cornwall Hospital, Rotherham Hospital, Royal Derby Hospital, Royal Infirmary of Edinburgh Scotland, Royal Hampshire Hospital, Winchester Royal Lancaster Infirmary Royal London Hospital, Royal Oldham Hospital, Royal Stoke University Hospital, Royal Surrey County Hospital, Royal Victoria Infirmary Newcastle, Russel's Hall Hospital, Dudley, Royal Victoria Infirmary Newcastle, Shrewsbury and Telford Hospital Sheffield Teaching Hospital, Singleton Hospital Swansea Wales, Stoke Mandeville Hospital Aylesbury, South Tees NHS Foundation Trust Middlesborough, South West Acute Hospital NI Southampton

University Hospital, Southmead Hospital Bristol, Harpenden Hospital, St Georges Hospital London, St Helens & Knowsley Teaching Hospitals NHS Trust, Whiston Hospital, St James Hospital Dublin Ireland St James Hospital Leeds, St Mary's Hospital Manchester, St Michael's Bristol, St Richard's Hospital Chichester, Stepping Hill Hospital Stockport, South Tyneside and Sunderland Hospital, University College Hospital London, University Hospital Dublin, University Hospital North Midlands Stoke, University Hospital Wales Cardiff, University hospital of North Durham, University Hospitals Bristol and Weston, University Hospitals Leicester, WAHT, Walsall Manor Hospital, Warwick Hospital, Wishaw Hospital Scotland, Worcestershire Royal Hospital Worcester, Wythenshawe Hospital Manchester, York Hospital.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: L.A., T.J.C., Concept: L.A., T.J.C., Design: L.A., T.J.C., Data Collection or Processing: L.A., T.J.C., Analysis or Interpretation: L.A., T.J.C., Literature Search: L.A., T.J.C., Writing: L.A., T.J.C.

**Conflict of Interest:** T. Justin Clark, MD, is Editor-in-Chief of Facts, Views and Vision in ObGyn. He had no involvement in the peer review of this article and had no access to information regarding its peer review. Other authors have nothing to disclose. TJC received an honoraria for participating in a symposium sponsored by Medtronic on Day-case Hysterectomy at the BSGE Annual Scientific Meeting, Belfast 2024.

**Financial Disclosure:** The authors declared that this study received no financial support.

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**Supplementary Table 1.** <https://l24.im/Ef5wL>

# Complete uterine septum, cervical septum and longitudinal vaginal septum: a challenging differential diagnosis with double cervix

Ursula Catena<sup>1</sup>, Federica Bernardini<sup>1</sup>, Eleonora La Fera<sup>1</sup>, Camilla Fedele<sup>1</sup>, Emma Bonetti<sup>2</sup>,  
Federica Pozzati<sup>1</sup>, Giovanni Scambia<sup>1-3</sup>, Grigoris F. Grimbizis<sup>4</sup>

<sup>1</sup>Department of Woman and Child Health and Public Health, Fondazione Policlinico Universitario Agostino Gemelli, IRCCS, Rome, Italy

<sup>2</sup>Department of Clinical and Experimental Sciences, University of Brescia, ASST Spedali Civili, Brescia, Italy

<sup>3</sup>Università Cattolica del Sacro Cuore, Rome, Italy

<sup>4</sup>Department of Obstetrics and Gynecology, Aristotle University of Thessaloniki, Thessaloniki, Greece

## ABSTRACT

**Background:** The presence of complete uterine septum, cervical septum and longitudinal vaginal septum (class U2bC1V1 according European Society of Human Reproduction and Embryology/European Society for Gynaecological Endoscopy classification) is a rare congenital anomaly of the female genital tract. The diagnosis of this anomaly is very challenging, significantly influencing the type of treatment to be performed.

**Objectives:** We propose a one-stop diagnosis through the combined use of 2D-3D ultrasound (US) and hysteroscopy and the minimally invasive endoscopic treatment of this anomaly, emphasising the diagnostic and therapeutic differences compared to U2bC2V1 anomaly.

**Participant:** Stepwise demonstration with video footage of an integrated approach in the management of a patient with a class U2bC1V1 anomaly. The patient was 23 years old and presented with dyspareunia and a previous miscarriage. We performed a one-stop diagnosis through the combined use of diagnostic hysteroscopy and 2D-3D pelvic US and a minimally invasive endoscopic treatment with a 15Fr bipolar miniresectoscope.

**Intervention:** Hysteroscopic control performed 40 days after the procedure showed a regular vagina, a normal single cervix and a normal uterine cavity. No intra- or postoperative complications occurred. The patient was discharged 3 hours after the procedure. The total operation time was 24 minutes.

**Conclusions:** Making an accurate diagnosis of a single cervix with cervical septum and a double cervix is crucial in the management of patients with complex genital anomalies. An accurate diagnosis is possible when combining hysteroscopy and US. Minimally invasive endoscopic treatment of U2bC1V1 anomaly with a 15 Fr bipolar miniresectoscope is an effective and safe procedure, easier when compared to the treatment of U2bC2V1 anomaly.

**What is New?** This video article describes the hysteroscopic criteria for the differential diagnosis between single cervix with cervical septum and double cervix.

**Keywords:** Cervical septum, uterine malformation, ultrasound, hysteroscopy, U2bC1V1

**Corresponding Author:** Federica Bernardini, MD, Department of Woman and Child Health and Public Health, Fondazione Policlinico Universitario Agostino Gemelli, IRCCS, Rome, Italy

**E-mail:** federica.bernardini@guest.policlinicogemelli.it **ORCID ID:** orcid.org/0000-0002-8976-1708

**Received:** 02.09.2024 **Accepted:** 19.11.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Catena U, Bernardini F, La Fera E, Fedele C, Bonetti E, Pozzati F, et al. Complete uterine septum, cervical septum and longitudinal vaginal septum: a challenging differential diagnosis with double cervix. Facts Views Vis Obgyn. 2025;17(1):84-89



## Introduction

The simultaneous finding of complete uterine septum, cervical septum, and non-obstructive longitudinal vaginal septum is a rare anomaly of the female genital tract classified as U2bC1V1 according to the European Society of Human Reproduction and Embryology/European Society for Gynaecological Endoscopy (ESHRE/ESGE) classification.<sup>1</sup> The real incidence of this complex anomaly cannot be estimated because of its rarity and lack of data in the literature.<sup>2,3</sup> The most frequent symptoms are dysmenorrhea and dyspareunia, which are often associated with adverse obstetric outcomes such as infertility, recurrent miscarriages, preterm deliveries, and intrauterine growth restriction. In a yet undetermined proportion of patients, this condition remains entirely asymptomatic.<sup>4-6</sup>

The non-specificity of symptoms, their rarity, and the absence of standardised diagnostic techniques often result in misdiagnosis or diagnostic delay.

Diagnosis can be very challenging and may require the use of different techniques and multiple steps. In the past, diagnosis was obtained through a combination of hysteroscopy and laparoscopy. Due to improved diagnostic techniques, currently the most widely used methods are magnetic resonance, 2D-3D pelvic ultrasound (US), and hysteroscopy.<sup>7</sup>

Crucial aspects in diagnosis involves the study of the external uterine profile and of the cervix or cervices.

The correct assessment of these two parameters allows a differential diagnosis in the first case between septate uterus and bicorporal uterus (U2b vs. U3b); in the second case between the presence of single cervix with cervical septum and double cervix (C1 vs. C2).

While the enormous progress made in 3D US allows for a remarkably accurate investigation of the external uterine profile, the cervix evaluation appears, to date, still controversial and is the main diagnostic challenge in the evaluation of these complex anomalies.<sup>8</sup>

Evaluation of the cervix is particularly complex in patients with intact hymen and/or vaginal congenital anomalies. In these cases, the speculum examination may not be feasible or may be hindered by the vaginal anomaly, not allowing complete and accurate visualisation of the cervix or cervices.

Moreover, even when well visualised, it is not always easy to distinguish between a double cervix and a single

cervix with a cervical septum, due to the lack of clear guidelines providing precise parameters for a differential diagnosis. The techniques that have been found to be most effective in the study of the lower genital tract are vaginoscopy as well as the 3D saline-contrast sonovaginocervicography.<sup>9,10</sup>

The differential diagnosis is fundamental as it results in substantially divergent surgical treatments. In fact, considering the external uterine profile, many studies have shown that removal of the uterine septum improves obstetric outcomes, while there are no surgical indications in cases of bicorporal uterus.<sup>11</sup>

More controversial is the treatment of the cervical anomaly. In the literature, data are scarce and quite contradictory. While it seems, there is no indication to treat double cervix,<sup>12,13</sup> some evidence, although limited, showed that the removal of the cervical septum associated with metroplasty makes the procedure safer, easier, and less complicated.<sup>13-15</sup> Women treated with cervical septum incision have no significant differences in reproductive outcomes compared to patients with preservation of the cervical septum. Moreover, the caesarean section rate is lower after the removal of cervical septum.<sup>14,16</sup>

The aim of our study is to describe the characteristics to make the differential diagnosis between double cervix and single cervix with cervical septum easier. We describe the key differential aspects between single cervix with cervical septum and double cervix, and we share our one-stop<sup>17</sup> minimally invasive approach for the diagnosis and treatment of this anomaly.

## Methods

A 23-year-old woman was referred to our hospital - Fondazione Policlinico Agostino Gemelli IRCCS of Rome, Italy - for a suspicious of complex uterine anomaly. The patient presented with dyspareunia, and in her obstetric history she reported a previous spontaneous miscarriage.

The diagnosis was obtained in our Digital Hysteroscopic Clinic - CLASS Hysteroscopy - through a one-stop office procedure with the integration of 2D-3D pelvic US and hysteroscopy both performed at the same time by an experienced operator (U.C.). Through 2D US, in the transverse scan, the presence of a complete uterine septum was observed. At 3D reconstruction, the external uterine outline showed a convex profile and the presence of a complete uterine septum that reached the internal uterine orifice with the evidence of two distinct, non-

communicating uterine hemicavities. The uterine septum appeared to continue into the cervix, resulting in the presence of two distinct cervical canals. Ultrasonographic evaluation was performed according to the diagnostic criteria of the 2016 ESHRE/ESGE consensus.<sup>7</sup>

Vaginoscopy showed the presence of two hemivaginas and of a non-obstructive complete longitudinal vaginal septum. From the left hemivagina, we entered the left cervical canal, reaching the left uterine hemicavity visualising the ipsilateral tubal ostium. At this point, exiting from the left cervical canal, we noticed that the cervical septum was not in junction with the vaginal septum. So, from the left hemivagina, we directly entered the right cervical canal, overpassing the vaginal septum. Through the right cervical canal, we reached the right uterine hemicavity visualising the ipsilateral tubal ostium.

The two uterine hemicavities appeared completely separated by the presence of a complete uterine septum that continued with the cervical septum without interruption. It was the first time that we found this scenario and we carefully evaluated the cervix. It was single with a single external uterine orifice. The complete cervical septum originated from the external uterine orifice, it was not in continuity with the vaginal septum and the apex of the cervical septum was covered by endocervical glandular epithelium. The ectocervix was covered by squamous epithelium. No intercervical cleft, covered by squamous epithelium, was observed.

The patient was diagnosed as a class U2bC1V1 anomaly according to the ESHRE/ESGE classification and the endoscopic treatment was scheduled after 30 days of progestin hormone therapy.

Table 1 shows the diagnostic criteria for single cervix with cervical septum.

Surgical treatment was performed according to an ambulatory model of care,<sup>18</sup> under general anaesthesia with laryngeal mask. The minimally invasive endoscopic

the technique was performed with a 15 Fr bipolar miniresectoscope, as follows:

1. Vaginoscopic complete incision of the vaginal septum with a Collins loop.
2. Anterograde incision of the cervical septum and of the complete uterine septum up to the interostial line, using a Collins loop.
3. 2D transabdominal coronal US scan, evaluating the fundal myometrial thickness.
4. Resection of the redundant tissue on the anterior and posterior uterine walls, with a 90° angled bipolar cutting loop.

Results

At the end of the procedure, the total fundal myometrial thickness at 2D-3D US, was 10 mm.

No intra- or post-operative complications occurred. The total surgery time was 24 minutes. The patient was discharged in good clinical condition 3 hours after the procedure.

The hysteroscopic office control performed 40 days after the procedure, showed a regular vagina, a normal single cervix and a normal uterine cavity (class U0C0V0 according ESHRE/ESGE classification). Mild fundal cuts were performed with 5 Fr scissors to optimize the surgical result obtained on the fundus. No intrauterine adhesions were observed. At 3D US, the fundal total myometrial thickness was 9 mm.

Discussion

In this video article we presented our integrated approach in the diagnosis and minimally invasive treatment of patients with vaginal septum, single cervix with cervical septum and complete uterine septum, demonstrating the key aspects in the differential diagnosis with double cervix and analysing the differences in the treatment.

Through the integrated use of 2D-3D transvaginal US and hysteroscopy, we obtained a precise and accurate diagnosis at the same time, avoiding multiple diagnostic steps and unnecessary delays. Furthermore, our combined approach makes magnetic resonance not required for diagnosis. This approach, in the hands of an experienced operator, is effective in diagnosing other complex anomalies of the genital tract, as complete uterine septum, double cervix and vaginal septum.<sup>19</sup>

Table 1. Diagnostic criteria for single cervix with cervical septum.
Hysteroscopic diagnostic criteria
- Single cervix covered by squamous epithelium
- No intercervical cleft
- Single external uterine orifice
- Cervical septum apex covered by endocervical glandular epithelium
- Non-continuity between the vaginal septum and the cervical anomaly

Although the cervix can be clinically assessed by the speculum examination, in many cases the presence of concomitant vaginal malformations can make the precise evaluation impossible. Moreover, it cannot be performed in patients with an intact hymen. It is important to emphasise that, even if well visualised, it is not always easy to distinguish between a single cervix with cervical septum and a double cervix. To the best of our knowledge, Ludwin et al.<sup>16</sup> is the only author who described the diagnostic criteria for cervical anomalies. In his experience the absence of a cleft on the ectocervix is the only diagnostic criterion for distinguishing between these two conditions. Vaginoscopy provides a close view of the cervix allowing an accurate assessment. The presence of a single cervix covered by squamous epithelium, the absence of a cervical cleft, a single external uterine orifice with the cervical septum apex covered by endocervical glandular epithelium, the non-continuity between the vaginal septum and the cervical anomaly, are reliable diagnostic parameters that allowed to accurately diagnose the presence of a single cervix with a cervical septum. The non-continuity between the vaginal septum and the cervical anomaly represents a valuable and easily identifiable landmark for the differential diagnosis; our hypothesis is that this absence of communication directly reflects the alteration in the resorption mechanism that determines the U2bC1V1 anomaly. The absence of this feature could, on the contrary, identify a deficit in the fusion mechanism that determines the U2bC2V1 malformation instead.

Table 2 summarises the hysteroscopic criteria for the differential diagnosis between the two conditions.

The two cervical anomalies differ not only in their pathogenetic mechanism (fusion defect in the case of

double cervix versus a reabsorption defect in the case of single cervix with cervical septum) but also for a different incident.<sup>16</sup> In fact, in our experience while double cervix is an uncommon anomaly, single cervix with cervical septum is even rarer, although some authors claim the exact opposite. This is clearly due to a lack of standardised diagnostic criteria.<sup>16</sup>

The two conditions also differ in the treatment. While there are no surgical indications for treating double cervix, the most recent scientific evidence, although based on limited data and accounting for low sample size, has shown that resection of the cervical septum in case of single cervix, seems to be a safe and effective procedure.<sup>13-15</sup> In a multicentre randomised controlled trial, 28 patients diagnosed with complete uterine septum and cervical septum, without vaginal septum, who had a history of miscarriages or infertility underwent surgical treatment of these conditions. Patients were randomised into two groups according to receiving or not cervical septum incision. The results showed that incision of uterine septum associated with removal of the cervical septum makes the procedure safer, easier, and less complicated. No significant differences in the reproductive outcomes were found in the two groups. The caesarean section rate was higher in the group with preservation of the cervical septum.<sup>14</sup> Also in our case, the simultaneous incision of the cervical septum and the complete uterine septum makes the procedure simpler, quicker and safer because the step in which the two hemicavities must be connected is avoided.<sup>19</sup> This step corresponds to the most challenging phase of the procedure performed to treat a complete uterine septum with double cervix, thus, it is possible to create false paths along the myometrium and subsequent uterine perforation.

Regarding surgical technique, while US guidance is essential in the treatment of U2bC2V1 anomaly in order to connect the two uterine haemicavities, in U2bC1V1 patients this guide is not necessary since the incision starts at the vaginal septum apex and continues anterogradely since the uterine fundal interstitial line. The only application of US in this procedure is to assess the post-operative fundal myometrial thickness.

The strength of our technique is the possibility to obtain an accurate diagnosis in a single step by combining hysteroscopy and US. In addition, the use of a 15 Fr miniresectoscope makes our surgical technique safe, effective and minimally invasive, allowing us to discharge the patient 3 hours after the procedure. The limitation of

**Table 2.** Hysteroscopic criteria for the differential diagnosis between single cervix with cervical septum and double cervix.

	Single cervix with cervical septum	Double cervix
Number of external uterine orifices	One	Two
Cervical septum apex covered by endocervical glandular epithelium	Yes	No
Intercervical cleft	No	Yes
Continuity between the vaginal and the cervical septum	No	Yes

our study is the fact that it is a report of a single case. Further studies are needed to evaluate the reproducibility of our technique and to assess the future obstetric outcomes.

## Conclusion

The differential diagnosis between single cervix with cervical septum and double cervix is a crucial moment in the management of patients with complex genital anomalies in order to plan the type of surgical treatment. The combined approach using hysteroscopy and US simultaneously, makes it possible to obtain an accurate diagnosis avoiding diagnostic delays and multiple diagnostic steps.

Minimally invasive endoscopic treatment of a U2bC1V1 anomaly with a 15 Fr bipolar miniresectoscope is an effective and safe procedure, easier if compared to the treatment of U2bC2V1 anomaly, in which US guidance plays a fundamental role. Further studies are needed to evaluate the obstetric outcomes of these patients and to standardise the proposed technique.

## Ethics

**Informed Consent:** Signed informed consent allowing the use of personal data was given by the patient.

**Acknowledgements:** We would like to express our special thanks to Prof. Giovanni Scambia whose memory will live on in our hearts, continuing to inspire and guide us in our commitment to providing the best care for our patients.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: U.C., Concept: U.C., G.S., G.G., Design: U.C., F.B., Data Collection or Processing: E.L.F., E.B., C.F., Analysis or Interpretation: U.C., F.B., G.G., Literature Search: E.L.F., E.B., C.F., Writing: U.C., F.B.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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diagnosis and ultrasound-guided endoscopic treatment. *Facts Views Vis Obgyn*. 2023;15:167-70.



**Video 1.** <https://vimeo.com/1007985390/c15bc447e0?share=copy>

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# Conservative management of caesarean scar pregnancy: tissue removal device hysteroscopic treatment after uterine artery embolisation

Emma Bonetti<sup>1</sup>, Eleonora La Fera<sup>2</sup>, Maria Vittoria Alesi<sup>2</sup>, Silvia D'Ippolito<sup>2,3</sup>, Antonio Lanzone<sup>2,4</sup>, Giovanni Scambia<sup>2,4</sup>, Ursula Catena<sup>2</sup>

<sup>1</sup>Department of Clinical and Experimental Sciences, University of Brescia, ASST Spedali Civili, Brescia, Italy

<sup>2</sup>Department of Woman and Child Health and Public Health, Fondazione Policlinico Universitario A Gemelli, IRCCS, Rome, Italy

<sup>3</sup>Dipartimento di Medicina e Scienze della Salute "Vincenzo Tiberio", University of Molise, Campobasso, Italy

<sup>4</sup>Università Cattolica del Sacro Cuore, Rome, Italy

## ABSTRACT

**Background:** Caesarean scar pregnancy (CSP) is an uncommon complication in women with prior caesarean deliveries. Treatment options include both medical and surgical approaches, but there is no consensus on definitive management.

**Objectives:** We propose a step-by-step video demonstration of a conservative approach for CSP, using hysteroscopic treatment with tissue removal device (TRD) after uterine artery embolisation (UAE).

**Participant:** A 34-year-old woman with two previous caesarean deliveries was diagnosed with a CSP involving an 8-week embryo implanted in the isthmocoele. Initial management consisted of UAE performed at another hospital. The patient was then referred to the Digital Hysteroscopic Clinic, CLASS Hysteroscopy of Policlinico Gemelli in Rome, for hysteroscopic removal of residual trophoblastic tissue.

**Intervention:** Safety and effectiveness of a novel conservative CSP management, involving TRD following UAE. Preoperative assessment, combining transvaginal ultrasound and diagnostic hysteroscopy, revealed trophoblastic remnants inside the uterine niche with an extremely thin myometrial margin. The procedure was performed under general anaesthesia, according to an ambulatory model of care. A TRD with a soft tissue blade was used for the complete removal of the lesion.

**Conclusions:** This video article suggests that TRD hysteroscopic treatment after UAE is a safe and effective approach for CSP. This conservative management minimises the risk of complications such as bleeding and uterine perforation. Additionally, the TRD avoids the use of electrosurgery, potentially reducing the incidence of subsequent intrauterine adhesions. Further studies are needed to confirm these results in the long term.

**What is New?** This is the first reported case of conservative CSP management combining UAE with hysteroscopic resection using a TRD.

**Keywords:** Caesarean scar pregnancy (CSP), uterine artery embolisation (UAE), tissue removal device (TRD), hysteroscopy

## Introduction

Caesarean scar pregnancy (CSP) is a rare but potentially severe complication arising when an embryo is implanted within the uterine scar from previous

caesarean deliveries. Its incidence ranges between 1/1008 and 1/2500 of all caesarean deliveries, with a higher risk among women with multiple caesarean births.<sup>1</sup> Left untreated, CSP can lead to severe

**Corresponding Author:** Emma Bonetti, MD, Department of Clinical and Experimental Sciences, University of Brescia, ASST Spedali Civili, Brescia, Italy

**E-mail:** emmabonetti@outlook.it **ORCID ID:** orcid.org/0009-0005-0836-5260

**Received:** 22.08.2024 **Accepted:** 14.12.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Bonetti E, La Fera E, Alesi MV, D'Ippolito S, Lanzone A, Scambia G, et al. Conservative management of caesarean scar pregnancy: tissue removal device hysteroscopic treatment after uterine artery embolisation. Facts Views Vis Obgyn. 2025;17(1):90-93



complications such as placenta accreta, haemorrhage, uterine rupture, and even maternal death.<sup>2</sup> Currently, there is no consensus on a definitive management strategy for CSP. However, various medical and surgical approaches have been proposed. Hysteroscopy has emerged as a safe and effective treatment option. The first case of hysteroscopic resection of CSP was reported by Wang et al.<sup>3</sup> Following studies have confirmed the effectiveness of this procedure, often combined with complementary techniques such as methotrexate (MTX) injection, intrauterine balloon catheters, or uterine artery embolisation (UAE).<sup>4</sup> Recent advancements in hysteroscopic technology, including the tissue removal device (TRD), have shown promise in treating intrauterine pathologies.<sup>5</sup> Additionally, preoperative UAE has demonstrated efficacy in facilitating subsequent hysteroscopic resection.<sup>6</sup> This video article aims to describe a novel conservative CSP management involving TRD-assisted hysteroscopic resection of residual trophoblastic tissue after UAE. We present a step-by-step video demonstration with narrated video footage of this treatment strategy. We explore the potential advantages of this approach and highlight the need for further research to confirm its long-term impact on fertility.

## Methods

A 34-year-old woman with a history of two previous caesarean deliveries was diagnosed with a CSP involving an 8-week embryo implanted in the anterior isthmic region of the scar site. First, the patient underwent UAE at another institution for termination of pregnancy. Bilateral selective catheterisation of the anterior branches of the hypogastric arteries and superselective catheterisation of the uterine arteries were performed. Then, the patient was referred to our Gynecology Department, at Policlinico Gemelli in Rome, to complete the treatment with the removal of residual trophoblastic tissue. The serum human chorionic gonadotropin (hCG) levels were monitored weekly until negative. The patient was scheduled for a conservative approach consisting of hysteroscopic surgery with TRD, performed by an expert surgeon. The procedure was planned four months after the UAE to allow for hCG levels to normalise and to coordinate the preoperative workup. Informed consent was obtained.

## Results

We performed the procedure at our Digital Hysteroscopic Clinic, CLASS Hysteroscopy of Policlinico Gemelli of

Rome. The procedure was conducted under general anaesthesia with a laryngeal mask, according to an ambulatory model of care.<sup>7</sup> A combined preoperative evaluation, including transvaginal ultrasound (TV-US) and diagnostic hysteroscopy, revealed a 26x29x30 mm avascular trophoblastic remnant within the isthmocoele. Both the tissue and the isthmocoele predominantly involved the right side of the anterior isthmic region. The free myometrial margin measured 1.9 mm. The uterine cavity was significantly left laterodeviated and retroflexed, despite the cervical canal and the isthmic region. Furthermore, minimal residual trophoblastic tissue was also detected in the uterine cavity. The TRD (Truclear Elite Mini, Medtronic) equipped with a soft tissue blade, was used for hysteroscopic resection of the tissue. The removal of the tissue in the niche was carefully performed. The blunt tip of the shaver prevented damage to the apex of the niche, where the myometrial scar thickness was very thin. Using TRD, the intrauterine residual tissue was completely removed as well. The entire procedure lasted 15 minutes and achieved complete removal of the tissue without requiring cervical dilation. The TV-US assessment, performed immediately after hysteroscopy, using saline solution as contrast agent, confirmed the myometrial residual margin of 1.9 mm. The patient was discharged in optimal condition three hours later. No complications occurred during or after the procedure. A follow-up outpatient hysteroscopy, performed three months after the hysteroscopic treatment, revealed no trophoblastic remnants. Six months later, a TV-US demonstrated a normal uterine cavity with an empty isthmocoele. The patient reported regular menstrual cycles and no further pregnancy-related symptoms.

## Discussion

CSP is a rare but potentially life-threatening obstetric complication requiring prompt and effective intervention. The treatment goal is to manage this condition while preserving fertility. Non-surgical options may include local and systemic MTX or UAE. Surgical treatment options may involve laparoscopy, laparotomy, hysteroscopy, curettage or gestational sac suction evacuation.<sup>8</sup> MTX provides a non-invasive, relatively low-cost treatment for patients who wish to preserve fertility, but it has been associated with a 57% failure rate and a complication rate of 62.1%.<sup>9</sup> UAE in combination with other treatment modalities, such as hysteroscopy, has been found to be efficacious with high success rates and low complication rates.<sup>10,11</sup> Preoperative selective UAE induces ischemic necrosis

by hindering blood supply to the gestational sac and surrounding tissue, facilitating subsequent hysteroscopic resection and reducing the bleeding risk during surgery.<sup>6</sup> Notably, successful pregnancies after this procedure have been well documented, without significant morbidity or mortality.<sup>12,13</sup> In 2021, Sorrentino et al.<sup>14</sup> proposed a new combined UAE - hysteroscopic diode laser surgery for CSP treatment in an office setting, with minimal patient discomfort and optimal recovery time. Our hysteroscopic procedure employed TRD, a mechanical instrument enabling simultaneous cutting and removal of tissue from the uterine cavity. To our knowledge, this is the first reported case of TRD hysteroscopic treatment following UAE for conservative CSP management. TRD allows for precise visualisation and targeted removal of trophoblastic remnants without damaging the healthy endometrium, thereby reducing the risk of subsequent intrauterine adhesions. Performing the procedure under direct vision with a blunt shaver helps to prevent potential complications such as perforation and intra- or post-operative bleeding. The absence of electrosurgery, used with traditional resectoscopes, avoids thermal injuries. Indeed, electrocoagulation should be used cautiously in this condition to prevent bladder trauma and subsequent dehiscence. Additionally, TRD reduces the risk of intrauterine adhesions, preserving potential future fertility.<sup>5</sup> Moreover, this hysteroscopic procedure offers short recovery times. Casadio et al.<sup>15</sup> proposed a conservative CSP management strategy involving TRD hysteroscopic resection. In their approach, the procedure, following a hysteroscopic MTX injection into the gestational sac and surrounding myometrial tissue, was performed in an outpatient setting without reported complications. This video article suggests that TRD hysteroscopic treatment following UAE is a safe and effective approach for conservative CSP management, reduces the risk of early complications, such as bleeding and uterine perforation, and late complications, such as intrauterine adhesions. Our combined approach can significantly improve long-term fertility outcomes for women with CSP who desire subsequent pregnancies. By reducing the risk of intrauterine adhesions and other complications, our technique may enhance the likelihood of successful pregnancies. Our study limitations include its single-case design, hindering generalisation of findings, and the absence of long-term follow-up data. Another limitation of our procedure could be the risk of recurrent CSP, as the isthmocele was not excised.

## Conclusion

The use of TRD for precise removal of trophoblastic remnants after UAE offers an effective strategy for conservative CSP management, preserving the uterine structure and the woman reproductive potential. Further research is warranted to confirm the long-term safety and efficacy of this technique and to establish its place in the management of CSP.

## Ethics

**Informed Consent:** Informed consent was obtained.

**Acknowledgments:** None.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: U.C., Concept: U.C., G.S., A.L., Design: U.C., G.S., A.L., Data Collection or Processing: E.B., E.L.F., M.V.A., S.D., Analysis or Interpretation: E.B., Literature Search: E.B., E.L.F., M.V.A., S.D., Writing: E.B., U.C.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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**Video 1.** <https://vimeo.com/1020989980/850d0d60ef?share=copy>

# Leiomyosarcoma of the left external iliac artery: a case report and narrative review of the literature

Anna Pitsillidi<sup>1</sup>, Sergios Ion Karras<sup>1</sup>, Günter Karl Noé<sup>1,2</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Rheinland Klinikum Dormagen, Dormagen, Germany

<sup>2</sup>Department of Obstetrics and Gynecology, University of Witten Herdecke, Witten, Germany

## ABSTRACT

Leiomyosarcomas (LMS) arise from smooth muscle and represents only 6% of all sarcomas. LMS originating from major blood vessels, called vascular LMS, are detected mostly in the inferior vena cava. Arterial LMS are a rarity. We present a 43-year-old patient with a LMS arising from the left external iliac artery. The patient was referred to us with symptoms of left lower abdominal pain extending to the left limb and underwent a contrast computed tomography which suggested a suspicious mass near the left iliac vessels. She underwent laparoscopic excision of the tumour, whose histological examination revealed an LMS G2 arising from the external iliac artery. Immunohistochemically CD34, p53, Desmin, as well as smooth muscle actin, tested positive.

**Keywords:** Leiomyosarcoma, iliac vessels, external iliac artery, laparoscopy

## Introduction

Leiomyosarcomas (LMS) are a rare type of sarcoma, originating from the smooth muscle and represent only 6% of all sarcomas. They can be classified into two types, the cutaneous type, derived from the arrector pili muscles associated with hair follicles and the subcutaneous type, derived from vascular smooth muscle.<sup>1,2</sup> LMS can arise in different areas of the human body such as the retroperitoneum, gastrointestinal tract, urogenital tract and soft tissue. LMS originating from major blood vessels' muscular walls, known as vascular LMS, are exceptionally rare, representing only 2% of all sarcomas.<sup>1,3,4</sup> The inferior vena cava (IVC) is the most commonly involved vessel.<sup>5</sup> Due to their rarity, there is a scarcity of evidence in the field of the diagnosis and treatment of vascular LMS. Our review aims to delve into the laparoscopic, imaging

and immunohistochemical findings of this entity and to raise awareness among experts of this uncommon type of tumour thus improving its early detection and appropriate management.

## Case Report

A 43-year-old patient was referred to our outpatient gynaecology department with a history of chronic left lower abdominal pain, radiating to the left lower limb. The patient had one normal delivery, a normal body mass index, a groin hernia operation, no other previous abdominal surgeries and no relevant family history. Our clinical examination did not reveal any abnormalities. Laboratory examination, including tumour markers (CEA, Ca19-9, Ca125, AFP) documented nothing of note. Transvaginal ultrasound detected a 4.5x4 cm, Doppler positive mass, of high

**Corresponding Author:** Anna Pitsillidi, MD, Department of Obstetrics and Gynecology, Rheinland Klinikum Dormagen, Dormagen, Germany

**E-mail:** anna.pitsillidi@gmail.com **ORCID ID:** orcid.org/0009-0003-5363-3522

**Received:** 10.08.2024 **Accepted:** 13.10.2024 **Publication Date:** 28.03.2025

**Cite this article as:** Pitsillidi A, Karras SI, Noé GK. Leiomyosarcoma of the left external iliac artery: a case report and narrative review of the literature. Facts Views Vis Obgyn. 2025;17(1):94-98



malignancy suspicion in the left lower abdomen near to the left adnexa. The aforementioned finding was verified with further investigation by contrast computed tomography (CT) examination of the abdomen that demonstrated a suspicious mass (4.6x4 cm), near the left iliac vessels (Figure 1).

Based on the high suspicion of malignancy, derived from the CT scan results, an excision of the tumour via laparotomy was suggested to the patient, who did not consent and preferred the laparoscopic approach. Therefore, she was scheduled for a laparoscopic excision of the tumour. An informed, written consent was obtained. The operation was carried out by a gynaecology team with the local vascular surgery team available if needed. Intraoperatively a solid mass was detected lying on the left external iliac artery. The peritoneum was opened, and the tumour was stepwise separated from the left iliac artery (Figure 2). The tumour was then safely placed in a laparoscopic specimen retrieval bag and was extracted through mini-laparotomy in the suprapubic region. At the end of the procedure, no residual tumour was detected. The operation was performed successfully without any peri- or post-operative complications. The patient had an uneventful recovery and was discharged on the first postoperative day. Pathological and immunohistochemical examination of the mass followed, which revealed a leiomyosarcoma G2 according to Fédération Nationale des Centres de Lutte Contre le Cancer (FNCLCC), arising from the external iliac artery.<sup>6</sup>

## Histopathological Findings

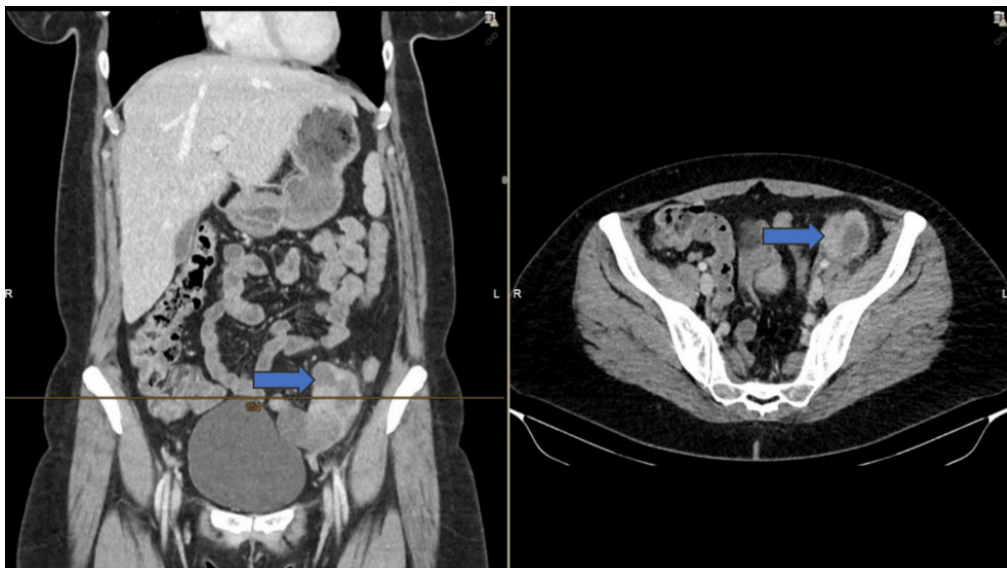
### a. Microscopic Findings

Histologically, there are components of a smooth muscle tumour, consisting of spindle cells in fascicular arrangement with occasional nuclear atypia and necrotic areas (Figure 3). Additionally, occasional mitotic figures are observed (up to four mitoses in 10 high-power fields). These findings align with a diagnosis of LMS with a G2 malignancy grade, according to FNCLCC, indicating an arterial-originated leiomyosarcoma.

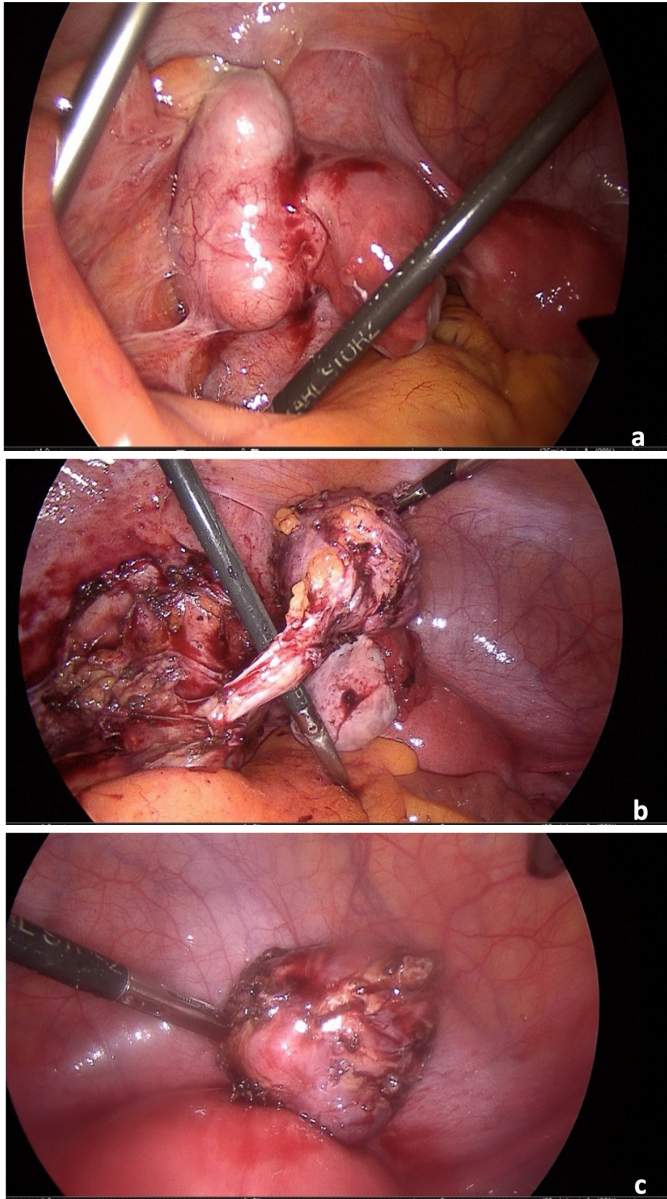
### b. Immunohistochemical Findings

Immunohistochemically, the tumour cells strongly express Desmin, smooth muscle actin (SMA), and predominantly caldesmon. CD34 highlights a dense network of compressed capillaries. There is no evidence of S100 protein. CD68 identifies numerous macrophages within the lesion. There is no convincing expression of MDM2, oestrogen- or progesterone receptor. RB1 shows heterogeneous expression, with some cells being negative, whereas p53 is detected in nearly all tumour cells. The Ki67 index is high, reaching over 20% in the examined paraffin block. A liposarcoma was excluded by using a FISH analysis with MDM2 amplification.

The case was presented to the multidisciplinary tumour board, which advised that the patient should undergo a laparotomy to exclude residual disease. The laparotomy was carried out two weeks later, and it was negative. The patient was discharged and scheduled for a 6-month



**Figure 1.** Abdominal CT scan. CT scan image, showing the left pelvic iliac tumour (see blue arrows). CT: Computed tomography.



**Figure 2.** Laparoscopic tumour excision. a-c) Intraoperative photos of the tumour surrounding the left external iliac artery.

follow-up during the first postoperative year. No chemotherapy or radiotherapy was indicated.

## Discussion

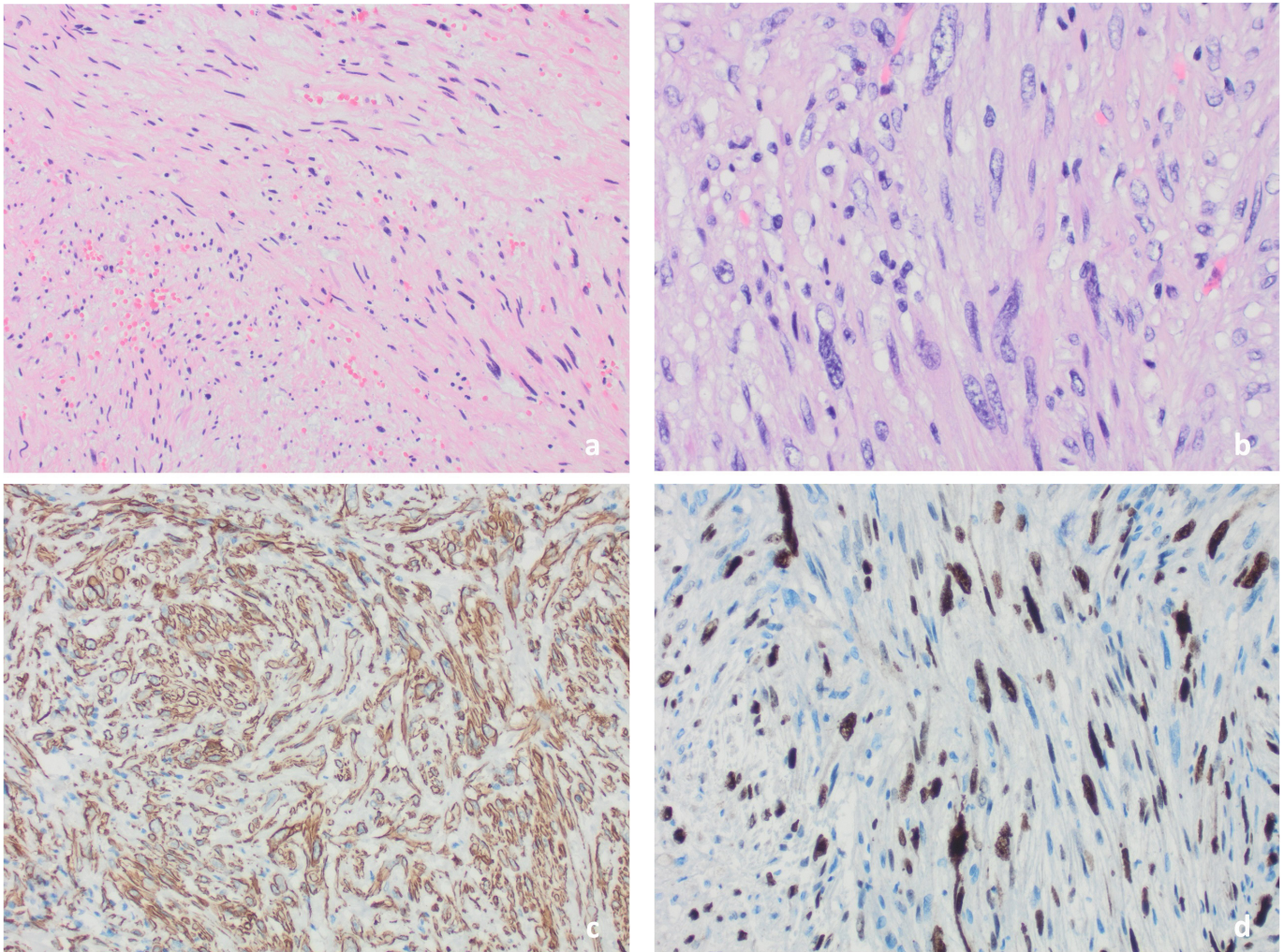
Vascular LMS represent a rarity amongst LMS and tend to originate within the venous vasculature.<sup>7,8</sup> The adult population, especially the female gender, are mostly affected by this type of tumour (commonly between 37-80 years).<sup>9,10</sup> In the 1970s Kevorkian and Cento<sup>11</sup> showed in a cohort of 86 vascular LMS cases, that the majority of the tumours (79%) are associated with venous origin, and most frequently the IVC. On the other hand, LMS

arising from an artery represented only 21% of all cases, with the pulmonary artery being mostly involved. Furthermore, Leeson et al.<sup>12</sup> reported two rare cases of LMS, originating from the aorta and nine cases of the peripheral arteries, including the common iliac artery. In the reported cases where the lumen of the common iliac artery was implicated, the patients developed clinical signs and symptoms of Leriche syndrome.<sup>12</sup>

The clinical presentation of arterial LMS varies and depends on the location of the tumour. LMS involving peripheral arteries can lead to nerve compression, causing neurological symptoms.<sup>13</sup> Multimodality imaging plays a key role in the diagnostic algorithm of LMS, interpreting clinical symptoms and their association with their origin. Magnetic resonance imaging and CT scanning are of great importance in the evaluation of high LMS-suspicion tumours, giving the opportunity to optimally evaluate the tumour's size, its association with neighbouring tissues and structures, as well as providing evidence regarding potential metastases.<sup>14</sup>

Histopathological examination is of great value in the diagnosis and differentiation of LMS. Pathological diagnosis of a vascular LMS demands the use of standard haematoxylin-eosin and can be really challenging. The microscopic histological features of vascular LMS are similar to the other types of LMS, including necrosis, cellular atypia, and mitotic activity.<sup>15</sup> Spindle cells are typically found in these tumour types, mostly combined with subintimal fibrous changes. However, an immunohistochemical staining is essential for the diagnosis. Many biochemical and molecular markers, especially Cyclin-dependent kinases, and their role in diagnosis and prognosis of vascular LMS have been investigated.<sup>16</sup> In our case CD34, p53, Desmin as well as SMA were tested positive. Furthermore, Ki67 index was found to be 20%, while S100 protein was negative in all examined tissues.

The gold-standard treatment of vascular LMS is the surgical resection of the tumour. In most cases of vascular LMS published in the literature, the tumour was excised en bloc with the segment of the affected vessel with or even without reconstruction with a graft.<sup>17</sup> However, it can be challenging to achieve healthy resection margins, as LMS tends to have great proximity to vital anatomical structures. In cases where local tumour control is not possible, radiation could be an option. In our case, the tumour was extraluminal, arising from the surface of tunica media and also invaded tunica adventitia. So, its excision



**Figure 3.** Histopathological findings. a, b) Hematoxylin and eosin stain (a: 200 magnification, b: 400 magnification). Nuclear pleomorphism, cytologic atypia and spindle cells arranged in haphazard fascicles with numerous mitotic figures. c) Caldesmon staining (200 magnification). Tumour cells with strong diffuse expression for caldesmon by immunohistochemistry. d) Ki67 staining (200 magnification). Expression of Ki67 in LMS (Ki67 20%).

was possible without affecting the lumen of the vessel, which remained intact, and no vessel reconstruction was needed.

Furthermore, not only surgical resection but also close follow-up of such patients is of great importance.<sup>18</sup> In our patient, the tumour surrounded the left iliac artery and was uncomplicatedly separated from the vessel. LMS, like other sarcomas, seem to have only a poor sensitivity to chemotherapy.<sup>13,19</sup>

## Conclusion

Vascular and especially arterial LMS are a rarity. Early tumour diagnosis plays an important role in defining patients' prognosis. Due to the vascular origin and proximity of the tumour, general and gynaecology

surgeons should be familiar with both clinical signs and symptoms and imaging features. As literature evidence is scarce, it is noteworthy to add that there is a definite need for multi-centre registries aiming to improve early diagnosis and disease treatment further.

## Ethics

**Informed Consent:** Informed consent was obtained.

**Acknowledgments:** None.

## Footnotes

### Authorship Contributions

Surgical and Medical Practices: A.P., G.K.N., Concept: A.P., S.I.K., Design: A.P., G.K.N., Data Collection or Processing: A.P., S.I.K., Analysis or Interpretation: A.P., S.I.K., G.K.N., Literature Search: A.P., S.I.K., Writing: A.P., S.I.K., G.K.N.

**Conflict of Interest:** No conflict of interest was declared by the authors.

**Financial Disclosure:** The authors declared that this study received no financial support.

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