

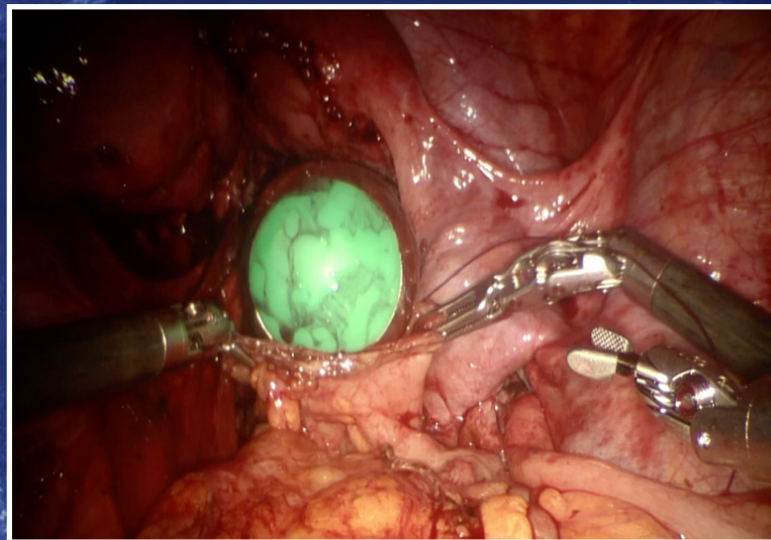
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Stephan Gordts (1947-2026)



With deep respect and sadness, we bid farewell to Dr. Stephan Gordts, honorary member of the European Society for Gynaecological Endoscopy (ESGE), who passed away on May 22, 2026.

Dr. Gordts was a pioneer in reproductive medicine and surgery, and one of the founders of modern fertility care in Belgium. He played a key role in the birth of the first *in vitro* fertilization (IVF) baby in Belgium in 1983 and founded the Leuven Institute for Fertility & Embryology (LIFE) in 1984, where he remained Scientific Director until his death.

Throughout his impressive career, he combined medical excellence with innovation and humanity. He gained international recognition for his work in minimally invasive fertility surgery and for the development of transvaginal hydrolaparoscopy—a technique that was applied and studied worldwide. With this technique, he was the first one to visualise and record the beauty of the normal ovulatory process.

In addition to being a physician, he was also a mentor, researcher, and inspirator. The courses in microsurgery he organised at the Centre of Surgical Technology in Leuven, Belgium, in the late seventies were legendary. Afterwards, Stephan opened a private IVF centre under the umbrella of the LIFE institution. Science and innovation have always guided him to push the boundaries and improve his clinical practice and patient care. Training and education, transferring his knowledge without any hesitation and with patience and kindness, were the engines for the numerous courses and congresses he organised in the field of reproductive medicine and minimal invasive surgery. He was given the most prestigious Honorary Membership of the ESGE in 2024.

With more than one hundred scientific publications and decades of dedication within international associations, he left a lasting impact on generations of doctors and on thousands of families who were able to experience hope and happiness thanks to his work.

Those who knew him remember him not only for his exceptional expertise but also for his drive, vision, and warm commitment to patients and colleagues.

His legacy lives on in the science he helped shape, in the lives he helped create, and in the people he inspired. Our community has lost its Gentleman and a Gentle Man.

Stephan will be missed, and his passing affects us deeply, but the richness and value we gained from those intense moments shared with Stephan will remain priceless.

With love, Rudi

Dr. Rudi Campo

Member of the Board of Directors, European Society for Gynaecological Endoscopy

Following the NOSE: when surgical evolution outpaces the evidence

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Keywords: Anastomosis, colorectal, endometriosis, laparoscopy, minimally invasive surgery, pain

Surgery for endometriosis has always been defined by a dual ambition: to remove disease thoroughly while preserving normal anatomy and function. Unlike oncological surgery, where radicality is often justified by survival endpoints, endometriosis surgery demands a more nuanced balance. Pain relief, fertility, bowel, bladder and sexual function all sit alongside technical completeness as measures of success. Progress in this field has therefore been evolutionary rather than revolutionary, shaped by refinement, shared experience and a willingness to question established practice.

The introduction of minimally invasive surgery represented the most transformative advance in endometriosis care. Laparoscopy fundamentally changed what was possible, allowing precise dissection within distorted pelvic anatomy while reducing collateral damage. Subsequent developments focused not only on the extent of excision but on how surgery is performed: fewer ports, nerve-sparing dissection, tailored bowel resections, enhanced recovery program and an increasing emphasis on functional outcomes. In this context, the question is

no longer whether surgery can be less invasive, but whether it can be less traumatic.

Nowhere has this evolution been more apparent than in colorectal endometriosis. Segmental bowel resection, once performed with generous margins and accompanied by routines such as ileostomy and ligation of the inferior mesenteric artery borrowed from cancer surgery, has progressively become more conservative as experience has accumulated. Alongside this, principles of conservative mesenteric dissection and blood vessel sparing—long established in inflammatory bowel disease surgery—have increasingly informed practice in endometriosis, further reducing unnecessary surgical trauma. Shaving and discoid excision emerged as deliberate alternatives where full segmental resection was unnecessary, and techniques such as transanal discoid excision were largely developed within the gynaecological community before being adopted more widely.¹ This exchange of ideas across specialties has been a defining feature of progress in endometriosis surgery.

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Natural orifice specimen extraction (NOSE) represents a continuation of this trajectory, albeit with the direction of knowledge transfer reversed. Developed within colorectal surgery, largely in the oncological setting, NOSE has been increasingly adopted in benign disease as surgeons have questioned the necessity of an abdominal extraction incision. Importantly, NOSE does not alter the principles of disease excision or anastomotic construction. It modifies only the completion phase of the operation by asking whether specimen retrieval can be achieved with less collateral trauma.

At this point in the evolution of technique, it is worth remembering that many meaningful advances in endometriosis surgery have arisen not from new instruments, but from structured approaches that reduce variability and unnecessary trauma. Frameworks such as SOSURE, which emphasise systematic exposure, anatomical normalisation and disciplined progression through operative steps, illustrate how technique can evolve without fundamentally changing the operation itself.^{2,3} Viewed in this light, NOSE should be understood as a refinement of an already optimised procedure rather than a novel concept.

Viewed in this light, NOSE represents not a departure from established practice, but a refinement of the final phase of an already optimised procedure. Variations in execution—including configuration of the anastomosis (for example side-to-end vs. end-to-end), methods of anvil introduction such as transanal piercing or hand-sewn purse-string closure, and the choice of stapling devices—largely reflect surgeon experience and preference rather than competing surgical philosophies.

The paper published in this of Facts, Views and Vision in ObGyn (FVVO) by Popov et al.⁴ should be interpreted within this context. It does not describe a new operation, nor does it claim to redefine colorectal endometriosis surgery. Instead, it adds further data on outcomes associated with NOSE compared with conventional laparoscopic specimen extraction, contributing to a growing body of literature that seeks to evaluate incremental refinements rather than wholesale change.

Concerns surrounding intracorporeal bowel opening are legitimate and should not be dismissed. Exposure of the bowel lumen raises questions around microbial contamination, inflammatory response and potential downstream effects that may be difficult to measure, particularly in a young population where fertility preservation is often paramount. What is encouraging

is that such questions are now being addressed directly rather than assumed. The inclusion of microbiological assessment in the study published in this issue of FVVO reflects a welcome shift toward examining biological consequences alongside surgical outcomes. However, the current evidence remains incomplete, and further work will be required to determine whether subtle or longer-term effects exist.

Much of the available evidence for NOSE initially came from observational series and single-centre experiences, several of which reported favourable perioperative and functional outcomes and contributed to increasing uptake in high-volume centres.^{5,6} Importantly, this has now been supplemented by randomised data. A prospective randomised controlled trial comparing NOSE with conventional laparoscopic colorectal resection demonstrated non-inferiority in terms of safety and functional outcomes, supporting the view that NOSE can be performed without compromising patient recovery when undertaken by experienced teams.⁷

Taken together, these data suggest that NOSE has moved beyond an experimental technique and is now routinely used in several large centres by surgeons with expertise in advanced endometriosis surgery. This does not imply that it should be universally adopted, nor that unanswered questions no longer matter. Rather, it reflects a pattern familiar in surgical progress: accumulating experience, cautious validation and gradual incorporation into practice where appropriate.

The broader question raised by NOSE is therefore not whether it represents progress, but how much evidence is required before surgeons feel justified in abandoning a step that is already known to cause harm. Surgery offers many examples where plausible reasoning proved misleading, reminding us that intuition alone is insufficient. At the same time, an excessive reliance on formal trial evidence can slow progress in technically evolving fields where randomised studies are difficult to design and interpret.

Following the NOSE should not be understood as privileging instinct over evidence. Rather, it reflects recognition of a direction of travel that has consistently characterised progress in endometriosis surgery: questioning unnecessary trauma, refining technique and allowing practice and evidence to evolve together. The study published in this issue of FVVO adds to that body of evidence without claiming to settle the debate, and it should be interpreted accordingly.

Surgical progress is rarely linear, and certainty is often retrospective. The responsibility of the surgeon is to remain both open-minded and sceptical—willing to innovate, while continuing to measure, question and refine. NOSE may yet reveal limitations that are not fully understood. For now, it appears to represent another thoughtful step along a path endometriosis surgeons have been walking for decades.

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Research and audit are essential for improving women's experience of outpatient hysteroscopy

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Keywords: Audit, hysteroscopy, pain, research

Outpatient hysteroscopy is one of the most common procedures in contemporary gynaecology. The convenient setting and avoidance of general anaesthesia or sedation¹ allow for quicker recovery and avoids hospital admission.² Most patients consider the degree of discomfort experienced as acceptable. However, up to a third of patients experience severe pain.³ This means abandoning the procedure in 5-10% of all patients undergoing the procedure and subsequent rescheduling to an operating theatre for a general anaesthetic.²

Severe pain is the biggest driver of poor patient experience and a wider negative perception of outpatient hysteroscopy among some women. In the United Kingdom (UK), the Women's Health Strategy for England,⁴ has prioritised the need to ensure that women do not endure painful procedures. Evidence-based guidelines have been published⁵ outlining the evidence for interventions that minimise pain and recommendations for implementation. The guidance identified the need to find and evaluate novel interventions in outpatient hysteroscopy, and gynaecology more broadly, to reduce pain and improve the patient experience.

In this issue of Facts, Views and Vision in ObGyn (FVVO), a group in Italy has conducted a randomised controlled trial (RCT) comparing the use of intraoperative music or oral analgesia premedication for pain control during outpatient hysteroscopy.⁶ Neither intervention was found to reduce pain compared to their standard approach, where no additional pain control measures were used. This negative finding probably reflects their routine use of evidence-based technical aspects⁵ such as adoption of a vaginoscopic technique and the use of small-diameter hysteroscopes, as well as limiting procedures to diagnostic or minor operative interventions. Methodologically, the study has limitations that limit clinical inferences. These include failure to define a minimally important magnitude of pain reduction to power the study and restriction of patient-reported outcomes to pain scores. Other measures of experience, such as acceptability and willingness to undergo the procedure again, would have provided more granularity. This RCT was conducted in a single centre by the same expert gynaecologist, potentially limiting generalisability. Outpatient hysteroscopy may be performed by clinicians with differing levels of expertise, including residents and nurse

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hysteroscopists, and operator experience may influence procedural outcomes and patient experience. Future studies should therefore consider including multiple operators across different centres and reporting operator experience (e.g., procedural volume rather than operator grade or type) to better reflect real-world practice. Nevertheless, the authors should be congratulated for completing an RCT in this much-needed area.

An international consensus paper¹ has defined pain control options in the outpatient setting according to three levels: Level 1- no medication or the use of oral non-sedative medication; Level 2- Local anaesthetic to the genital tract and Level 3 (a)- Oral or inhalational medications with a sedative effect. The RCT published in this issue of FVVO⁶ has evaluated Level 1 pain relief interventions. More such trials are needed to evaluate pain relief options for outpatient hysteroscopy across all levels, whether used in isolation or in combination. To this end, we have recently been funded to conduct a large multi-centre RCT in the UK, to evaluate the use of Pentrox as a mobile, handheld device that allows patients to self-administer a rapidly acting analgesic medication with a mild sedative effect, methoxyflurane, by breathing in and out of the mouthpiece [equating to pain relief Level 3(a)]. The technology is widely used for the relief of trauma-associated pain, often in emergency settings, but has shown promise for elective interventions, including outpatient hysteroscopic procedures.^{7,8} We will compare Pentrox against nitrous oxide and include diagnostic and operative hysteroscopic and other intrauterine procedures, including endometrial ablation. We hope that this RCT will allow us to better understand the relative roles of inhalational analgesia and which patients and which procedures, if any, will benefit from the use of Pentrox.

We also propose developing a core outcome set, using established methodology, for measurement and reporting in all outpatient hysteroscopy trials.⁹ These outcomes will include measures of safety, effectiveness and patient experience. Our proposal will involve all relevant stakeholders and an international collaboration of clinicians. Standardising outcomes will aid interpretation of trials, like the one published in this issue of FVVO,⁶ enhancing evidence-based decision-making and the quality of research in outpatient hysteroscopy.

Outside of research aimed at discovering the best ways of conducting outpatient hysteroscopy, it is also important that we quality assure our practice to

ensure we are actually implementing these optimal practice interventions and achieving expected levels of performance. The British Society of Gynaecological Endoscopy (BSGE) has developed a patient reported outcome measure; the OutPatient Hysteroscopy-Patient Satisfaction Survey (OPH-PSS).^{3,10} Moreover, the recent joint Royal College of Obstetricians and Gynaecologists/BSGE evidence-based guidelines for outpatient hysteroscopy⁵ includes an audit tool covering procedural aspects, such as success, vasovagal reactions, uterine trauma, infection, and hospital admissions, for clinicians to complete and evaluate against published standards. We are planning to use this audit tool alongside the OPH-PSS to conduct a national UK audit across National Health Service hysteroscopy units over a 3-6 month period. This will allow us to collect an electronic dataset for thousands of consecutive women undergoing outpatient hysteroscopic procedures to understand what the real world performance and experience of outpatient hysteroscopy is. In this way we hope to improve care by identifying themes, disseminating good practice and examining the causes and potential solutions for areas of deficiency.

Outpatient hysteroscopy remains one of the most common and useful diagnostic and therapeutic interventions in modern gynaecology. Our patients deserve high quality care. To this end we must develop and participate in research to improve clinical outcomes, including patient experience. Furthermore, we must effectively implement best practices and reassure ourselves and our patients that we are delivering high quality, evidence-based care. This mandates regular audit of our services.

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Competing interests: TJC has received honoraria for lectures and educational courses from medical device companies that manufacture hysteroscopes and related technologies. TJC and PDS set up the BSGE Ambulatory Care Network dedicated to improving the practice of outpatient hysteroscopy and related ambulatory interventions. 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.

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Buddy operating in gynaecological endoscopy: what should this model of surgical practice look like?

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ABSTRACT

"Buddy operating" is a subtype of dual operating described in the Clark model, where two surgeons of comparable proficiency collaborate during complex procedures. Potential benefits include improved surgical efficacy and safety, shared intraoperative decision making, enhanced skill development, and improved surgeon wellbeing. However, implementation must be justified given resource constraints and potential impacts on surgical training. We propose that buddy operating should be selectively applied to clearly defined complex cases, supported by governance frameworks, structured protocols, and outcome monitoring. Importantly, buddy operating must be distinguished from supervisory training. Future research should evaluate its effects on clinical outcomes, cost-effectiveness, surgeon health, and access to training opportunities.

Keywords: Gynaecology, laparoscopic surgery, mentorship, patient safety, surgical training, workforce resilience

Introduction

We have made the case for dual operating in our previous editorial in Facts, Views and Vision in ObGyn.¹ Whether supervisory (surgical trainer to surgical trainee), buddy (surgeons of similar proficiency within a specialty) or inter-specialty (surgical collaboration across specialities) as defined in the Clark model of dual operating. This model defines three subtypes based on the relationship between surgeons and the purpose of their collaboration: (1) supervisory operating, where a more experienced surgeon supports and guides a less experienced colleague within a training paradigm; (2) buddy operating, referring to collaboration between surgeons of equivalent proficiency within the same specialty, typically undertaken for complex cases; (3) inter-specialty operating, involving surgeons from different specialties working together in procedures

requiring multi-disciplinary expertise, each surgeon typically undertaking distinct components of the same procedure. It is hoped that using this framework will enable a clearer distinction between training, collaborative practice, and procedural task sharing within dual operating.

In this follow-on editorial we will concentrate upon the dual operating subtype of buddy operating. Potential benefits of operating with a colleague of equivalent competency include improved clinical outcomes, namely efficacy and safety, development of surgical skills and enhanced surgeon wellbeing where assistance is more precise and intraoperative decision making is shared. However, can health services afford this "luxury" of two senior surgeons operating in tandem and what happens to the access and quality of surgical training for junior doctors?

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So we need to utilise the educational and safety benefits of buddy consultant operating but implementation must have a clear rationale. The place of dual inter-speciality operating is clear for the most part e.g. advanced laparoscopic surgery for endometriosis with bowel, urinary tract or thoracic involvement.² In the United Kingdom, the British Society for Gynaecological Endoscopy (BSGE) have established BSGE Endometriosis Centres,³ and a mandated requirement of these centres is to have named bowel and urological surgeons who provide the necessary inter-speciality surgical support. However, no structures to realise “buddy operating” are well defined. It seems sensible to avoid a “one size fits all” approach but rather to tailor implementation to local needs and available resources such as theatre operating capacity, workforce availability and funding.

One approach is to identify and define surgical cases that are complex. For example, total laparoscopic hysterectomy (TLH) is a common operation within the proficiencies of most gynaecologists with an interest in endoscopic surgery. However, cases of TLH can be more challenging due to patient factors such as previous abdominal surgery, past infection and obesity. Thus, it seems that a framework to recommend when buddy operating should be considered could be helpful. We have proposed operations that should be considered complex and be aided by operating with a “buddy” (Tables 1 and 2). We should aim to establish consensus across our surgical discipline. This would reassure those managing scarce resources within health services that the expense of allowing two trained senior surgeons to operate is justified, restricted and is cost-saving through safer and more expeditious surgery; better efficacy minimising the need for re-intervention and enhanced safety, reducing morbidity and costs from prolonged use of health services, re-interventions and legal ramifications.

Defining the operations necessitating operating with a buddy is one thing, but we must also recognise that a serious complication can affect a surgeon’s confidence and performance. Buddy operating can be an invaluable resource after a serious surgical complication, especially when the same surgical procedure is to be undertaken. Even the most seasoned surgeon’s surgical “flow” can be affected; stress can lead to uncharacteristically tentative surgical dissection leading to imprecise identification of surgical planes and resultant bleeding. Our usual surgical performance is compromised when our brains are “scrambled”. Operating with a trusted colleague, where

responsibility is shared, helps restore confidence while maintaining patient safety. Having two surgeons of similar proficiency allows double-checking of critical surgical steps thereby reducing the likelihood of technical errors and poor intraoperative decision making. Discussing adjustments in technique may allow for safer approaches in future cases. The main reason for advocating buddy operating after a surgical complication is for peer support but it can also be useful from a clinical governance perspective; individually demonstrating reflective practice and proactive risk reduction and institutionally following case reviews and liaison with patients’ and their families.

In some centres, typically high volume, tertiary centres or other better funded surgical units, structured buddy operating may be adopted more liberally facilitating mentorship, skill transfer, and shared intraoperative decision making. In contrast, other, maybe smaller units, may implement buddy operating more selectively for specified high-risk cases (Tables 1 and 2). It is likely that successful implementation will necessitate flexibility that aligns with local service demands while maintaining the goals of buddy operating in terms surgical safety, and training.

It is important however, to recognise the inadequacies of current surgical training, especially the limited access and exposure to surgery. The wider acceptance of buddy operating will further deprive doctors in training (“junior doctors”/“residents”) of experience, albeit trainee surgeons can still acquire valuable educational experience from observing the interactions between buddy surgeons. It is thus, of paramount importance that the defined Clark models of dual operating are adhered to. Buddy operating is not “supervisory” where one surgeon (the trainee) is less proficient than the other (the trainer) in the same specialty.¹ It is peer to peer operating of equally proficient surgeons within the same speciality for complex cases defined by the local surgical team, with reference to the suggest framework (Tables 1 and 2). Most examples provided are drawn from minimally invasive benign gynaecological surgery, where variability in complexity is common; however, the conceptual framework is not limited to this domain. During surgical training (Clark model: “supervisory”) then it doesn’t matter whether it is the conventional senior: junior training or the increasingly prevalent situation of peer: peer training that has been necessitated by inadequate surgical exposure during “junior/resident” training years.

Table 1. Complex gynaecological operating justifying buddy operating as defined by the Clark model.¹

Reason	Pathology
Significant adhesions/distorted anatomy anticipated	Deep endometriosis Large fibroid uterus Previous peritonitis (including pelvic abscess) Previous midline laparotomies Significant previous abdominal surgeries Congenital pelvic anomalies Other
Surgery that requires access to the retroperitoneal pelvic spaces	Lymph node dissection Deep endometriosis ¹ Other
Hysterectomy for large uterus	Adenomyosis/fibroids
Myomectomy for complex fibroids	Cervical/broad ligament/multiple fibroids/posterior location
BMI>35 ²	Obesity
Other (e.g., medical co-morbidities, repeat after failed surgery/revision surgery)	Anticoagulation, cardio-respiratory, mesh removal etc.
After a prior serious surgical complication ³	Not applicable

¹Clark model "inter-speciality"-surgeons with proficiency in different surgical specialties may be required.
²Laparoscopic.
³Especially if this has affected confidence but it should be recognised that some surgeons may lack insight and so impacts on "confidence" should not be the main driver to recommend buddy operating.
 BMI: Body mass index.

Table 2. Complex obstetrical operating justifying buddy operating as defined by the Clark model.¹

Reason	Pathology
Significant adhesions/distorted anatomy anticipated	Three previous Caesarean sections Deep endometriosis Large fibroid uterus Previous peritonitis (including pelvic abscess) Previous midline laparotomies Significant previous abdominal surgeries Congenital pelvic anomalies Other
Anticipated peri-operative bleeding +/- other complications including need for hysterectomy	Placenta accreta spectrum
BMI >40	Morbid obesity
Fibroids distorting uterine anatomy and anticipated access/closure	Significant fibroids in lower segment
Other (e.g., medical co-morbidities; surgical complexities)	Anticoagulation, cardio-respiratory, previous complications at CS etc.
After a prior serious surgical complication ¹	Not applicable

¹Especially if this has affected confidence but it should be recognised that some surgeons may lack insight and so impacts on "confidence" should not be the main driver to recommend buddy operating.
 BMI: Body mass index.

This is training time regardless of the stage of a surgeons career and should not be confused with true “buddy operating”.

We need robust quality assurance for the successful implementation of buddy operating in gynaecological surgery. Clear governance structures, defined roles for each surgeon, specification of operations meeting the thresholds for buddy operating, and documentation are essential to ensure accountability and maintain high standards of patient care. Institutions endorsing buddy operating should adopt protocols to ensure appropriate case selection, team briefing and postoperative outcome monitoring. Regular audit of operative time, complication rates, and training outcomes can help determine whether buddy operating delivers measurable benefits for patients and surgeons.

In our previous editorial on dual operating, we raised the concern that the boundaries of responsibility between surgeons may lack clarity.¹ Transparency regarding clinical responsibility is necessary and this should probably be decided locally so that it is appropriate for specific regional and national healthcare systems. We envisage that for most settings, buddy operating would involve joint operating where the surgeons not only share technical tasks and decision-making, but also intra-operative responsibility. Outside of the operation, the indication for surgery, acquisition of adequate informed consent and responsibility for post-operative management should reside with the named senior clinician who the patient is under, unless a team model of care is routinely adopted.

Research is needed to better define the clinical and educational value of buddy operating in gynaecology. Prospective studies comparing buddy vs. single operating across different procedure types and levels of complexity would provide important evidence regarding outcomes such as complication rates, surgical efficiency, learning curves, cost-effectiveness and surgeon physical as well as mental health. Differential uptake, implementation and impacts of buddy operating according to mode of surgery; open, laparoscopic and robotic, should be evaluated. Research should also explore the impact on

surgical training, particularly in minimally invasive and advanced pelvic surgery, where collaborative operating may accelerate skill acquisition. However, the potential detrimental effects of buddy operating, particularly around restrictions on exposure and capacity of those in training grades, need to be evaluated.

As minimally invasive gynaecology evolves, embedding a buddy operating model into contemporary gynaecological surgical practice may improve outcomes and workforce resilience. However, how best to do this needs to be determined. We call upon professional bodies to promote collaborative surgery, as defined within the Clark model, as a standard of care and contribute to developing consensus about how best to optimise the use of buddy operating.

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Racial disparities and risk factors for blood transfusion in patients undergoing myomectomy for uterine fibroids: insights from a national surgical database

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ABSTRACT

Background: Uterine fibroids are common among reproductive-aged women, with notable racial disparities in disease burden and outcomes. Myomectomy is a fertility-sparing surgical treatment associated with variable transfusion risk.

Objectives: To evaluate racial disparities and identify risk factors for blood transfusion in patients undergoing myomectomy, and to develop a predictive model for high-risk patients.

Methods: This retrospective cohort study used the American College of Surgeons National Surgical Quality Improvement Project (2018–2022) to identify women aged 18–55 years who underwent myomectomy. Patients with malignancy or bleeding disorders were excluded. Multivariable logistic regression was used to assess transfusion predictors and racial disparities.

Main Outcome Measures: Incidence and predictors of perioperative blood transfusion; model performance for transfusion prediction.

Results: Among 6,154 patients, 604 (9.8%) required transfusion. Non-Hispanic Black patients accounted for 74.3% of transfusion cases (vs. 52.0%, $P < 0.001$) and had over twice the adjusted odds of transfusion compared to Non-Hispanic White patients [adjusted odds ratio (aOR): 2.1, 95% confidence interval: 1.6–2.7]. Preoperative anaemia (aOR: 8.5), abdominal approach (aOR: 4.7), and fibroid burden (>250 grams) (aOR: 2.0) were also significant. The predictive model demonstrated excellent discrimination (area under the receiver operating characteristic curve: 0.79).

Conclusions: Non-Hispanic Black patients face higher transfusion risks during myomectomy, even after adjusting for clinical factors. Interventions targeting anaemia and prioritising minimally invasive approaches may reduce these disparities.

What is New? This study explores recent racial disparities in blood transfusion among myomectomy patients and assesses how these patterns have evolved in recent years using a nationally representative surgical dataset.

Keywords: Myomectomy, uterine fibroids, blood transfusion, minimally invasive surgery

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Introduction

Uterine leiomyomas, commonly known as fibroids, are the most prevalent benign tumours in women of reproductive age, affecting approximately 20-25% of this population.¹ The cumulative incidence rises dramatically with age, with up to 70% of White women and over 80% of Black women developing fibroids by age 50.² Symptoms are diverse, including heavy menstrual bleeding, pelvic pain, and pressure-related issues, all of which can significantly impair quality of life. Management of fibroids ranges from medical to surgical options, tailored to symptom severity and patient preferences.¹

Larger fibroids or refractory symptoms often require surgery.³ While hysterectomy is definitive, myomectomy is preferred for those desiring fertility or uterine preservation, with minimally invasive laparoscopic techniques offering faster recovery and fewer complications than open surgery.⁴

Despite these advantages, data from the American College of Surgeons National Surgical Quality Improvement Project (ACS-NSQIP) reveal that only 42% of myomectomies are performed minimally invasively.⁵ Furthermore, Black women are disproportionately more likely to undergo both abdominal myomectomies and hysterectomies compared to White women, with relative risks of 2.4 and 6.8, respectively.⁶ Myomectomy procedures, particularly when performed abdominally, present unique challenges, including increased intraoperative bleeding due to tumour-related neovascularization and anatomical distortion.^{7,8} The size, number, and location of fibroids, as well as the surgical approach, are critical factors influencing the risk of excessive bleeding and subsequent blood transfusion.⁹

Previous studies reported variable transfusion rates for abdominal myomectomies, ranging from 8% to 28%, reflecting outdated practices from two decades ago.¹⁰⁻¹³ More recent data from a tertiary centre reported an overall transfusion rate of 4.7%, with rates of 6.4% for abdominal and 2.2% for laparoscopic myomectomies.¹⁴ Disparities in the burden and clinical outcomes of fibroids are evident, with Black women presenting with larger, more numerous, and rapidly growing leiomyomas at younger ages, contributing to greater perioperative morbidity and higher transfusion rates.¹⁵

Our study evaluates risk factors for blood transfusion during myomectomy and examines the impact of evolving health policies on reducing racial disparities. Additionally, we developed a predictive model to identify

high-risk patients, supporting clinicians in optimising perioperative management and improving outcomes.

Methods

This retrospective analysis of a publicly available database did not require institutional ethical approval or patient consent. The ACS-NSQIP serves as a nationally validated database aimed at assessing and enhancing surgical outcomes across various specialties. This programme collects preoperative, intraoperative, and 30-day postoperative data directly from patient medical records, with specially trained personnel overseeing the abstraction process at more than 600 participating hospitals nationwide.¹⁶

Data were collected from 6154 premenopausal women between the age of 18 to 55 years from 2018 to 2022 who underwent myomectomy procedure. The study period (2018-2022) was selected to capture contemporary surgical practices following the widespread adoption of minimally invasive techniques and to reflect current health policy environments. This timeframe represents the most recent complete data available at the time of analysis whilst providing sufficient sample size for robust statistical modelling. The primary outcome was perioperative blood transfusion, defined as any allogeneic red blood cell transfusion occurring intraoperatively or within 72 hours postoperatively (NSQIP variable). Blood transfusion was selected as the primary outcome due to its clinical significance as both an indicator of surgical complexity and a modifiable target for quality improvement. Transfusion represents a common, measurable complication with direct implications for patient safety, cost, and disparities in surgical care. Preoperative transfusions were analysed as an independent predictor variable but were not included in the primary outcome count.

Preoperative Anaemia Definition

Preoperative anaemia was defined using the NSQIP variable for preoperative haematocrit <30%, consistent with moderate anaemia thresholds used in surgical risk assessment. This represents a clinically significant degree of anaemia associated with increased perioperative transfusion risk.

Myomectomy procedure was identified using one of the following current procedure terminology (CPT) codes: 58140,¹⁷ 58146, 58545, and 58546. Women with underlying malignancy or bleeding disorders were excluded.

(CPT) codes 58545 and 58140 were considered low fibroid burden (one to four fibroids or total weight 250 g or less), and 58146 and 58546 were considered high fibroid burden (more than five fibroids or fibroid weight greater than 250 g).

Statistical Analysis

Unadjusted analysis of categorical baseline characteristics, surgical approach, medical comorbidities by patients' race and ethnicity using chi-square test. Age and body mass index (BMI) were evaluated for normality and compared using two-sample t-tests. Patients with missing data on race and ethnicity or blood transfusion were excluded from the analysis to ensure the integrity and completeness of the dataset. Adjusted odds ratios (aORs) and 95% confidence intervals (CIs) were calculated using multivariable logistic regression. A multivariable model adjusted for age, BMI, preoperative anaemia, preoperative blood transfusion, hypertension, surgical approach, fibroids burden was used to examine the race and ethnicity association with postoperative blood transfusion.

The goodness-of-fit for the logistic regression model was evaluated using the Hosmer-Lemeshow test. The data were grouped into 10 quantiles based on predicted probabilities, and observed versus expected frequencies of the outcome were compared across these groups. A *P* value greater than 0.05 was considered indicative of adequate model fit.

Model selection was guided by information criteria, specifically the Akaike Information Criterion (AIC) and Bayesian Information Criterion (BIC). After comparing models, the model with the better fit, based on lower AIC and BIC values, was selected for the final analysis. Similarly, we evaluated all predictors for their contribution to model performance and parsimony. The variables for diabetes and smoking status were excluded from the final model due to lack of improvement in model fit as determined by AIC and BIC criteria. To enhance clinical interpretability, absolute transfusion rates were calculated and presented as descriptive statistics stratified by race and ethnicity, surgical approach, fibroid burden, and their combinations. These unadjusted rates were provided to complement the multivariable regression analyses.

Then the discriminative ability of the logistic regression model was assessed using the area under the receiver operating characteristic (ROC) curve (AUC). To assess the robustness of model discrimination and ensure that

predictive performance was not disproportionately influenced by patients who received preoperative transfusion, a sensitivity analysis was performed excluding these individuals. The multivariable logistic regression model was re-estimated in the restricted cohort, and model discrimination was reassessed using the ROC-AUC. All analyses were completed using STATA 14.2 with two-sided *P* values of <0.05 considered statistically significant.

Results

Patient Characteristics and Blood Transfusion Incidence

Of the 6,154 patients included in the study, 604 (9.8%) required a blood transfusion. The mean age was similar between the two groups, at 37 years (*P*=0.2). However, significant differences were observed in race and ethnicity distribution (*P*<0.001). Non-Hispanic Black patients comprised the majority of those requiring transfusions (74.3%), compared to 52.0% in the non-transfusion group (Table 1). Figure 1 illustrates the annual incidence of blood transfusions by race and ethnicity between 2018 and 2022, with Non-Hispanic Black patients consistently exhibiting the highest rates of transfusion compared to Non-Hispanic White and Hispanic patients throughout the study time.

Preoperative and Surgical Characteristics

Preoperative anaemia (*P*<0.001) and preoperative transfusion (*P*<0.001) were significantly more frequent among those who required a transfusion. A higher proportion of patients in the transfusion group had fibroid weight greater than 250 grams (59.8% vs. 38.8%, *P*<0.001). Furthermore, the surgical approach differed significantly between the groups (*P*<0.001). Abdominal approach was predominant in the transfusion group (80.3%), while laparoscopic and vaginal approaches were more frequent in the non-transfusion group (Table 1).

Association of Demographic, Preoperative, and Surgical Factors with Blood Transfusion

After adjusting for clinically significant variables—including age, BMI, hypertension, preoperative anaemia, preoperative transfusion, surgical approach, and fibroid burden—Non-Hispanic Black race remained strongly associated with increased odds of requiring a blood transfusion (aOR: 2.1, 95% CI: 1.6–2.7, *P*<0.001). Notably, the association between Hispanic ethnicity and

Table 1. Demographics, medical, and surgical characteristics of the study cohort stratified by blood transfusion status.

	Transfusion (n=604)	No transfusion (n=5550)	P value
Age	37±5.7	37±5.9	0.2
Race/ethnicity			<0.001
Non-Hispanic White	85 (14.07%)	1746 (31.46%)	
Non-Hispanics Black	449 (74.34%)	2888 (52.04%)	
Hispanics	70 (11.59%)	916 (16.50%)	
Smoking	45 (7.45%)	431 (7.77%)	0.7
BMI			0.9
Underweight	2 (0.33%)	30 (0.54%)	
Normal	138 (22.85%)	1211 (21.82%)	
Overweight	172 (28.48)	1589 (28.63%)	
Obese	211 (34.93%)	1966 (35.42%)	
Morbidly obese	69 (11.42%)	637 (11.48%)	
HTN	57 (9.44%)	615 (11.08%)	0.2
DM	19 (3.15%)	204 (3.68%)	0.5
Preoperative transfusion	45 (7.45%)	64 (1.15%)	<0.001
Anemia	163 (26.99%)	231 (4.16%)	<0.001
Fibroid burden			<0.001
≤250 grams	243 (40.23%)	3394 (61.15%)	
>250 grams	361 (59.77%)	2156 (38.85%)	
Surgical approach			<0.001
Laparoscopic	79 (13.08%)	2587 (46.61%)	
Abdominal	485 (80.30%)	2640 (47.57%)	
Vaginal	40 (6.62%)	323 (5.82%)	
Prolonged operative time (>180 minutes)	268 (44.37%)	1393 (25.10%)	<0.001

BMI: Body mass index, HTN: Hypertension, DM: Diabetes mellitus.

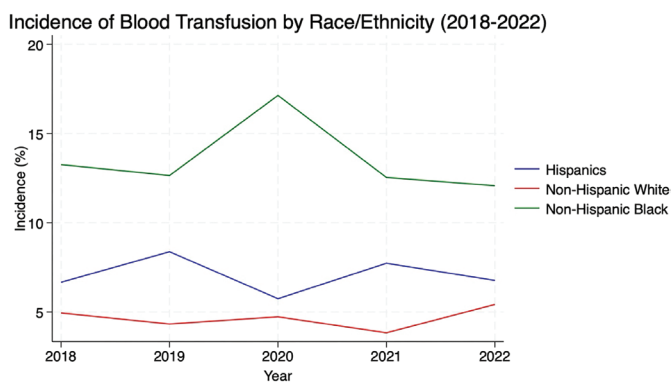


Figure 1. Shows the incidence rate of blood transfusion among myomectomy patients by race/ethnicity during the study period.

transfusion was attenuated and no longer significant in the adjusted model (aOR: 1.1, 95% CI: 0.7–1.6, $P=0.5$).

Preoperative transfusion was independently associated with a higher likelihood of requiring a transfusion (aOR: 2.4, 95% CI: 1.3–3.9, $P=0.001$). Fibroid burden, defined as fibroid weight greater than 250 grams, also showed a strong association with transfusion risk (aOR: 2.0, 95% CI: 1.9–2.7, $P<0.001$). Among surgical approaches, abdominal surgery had the strongest independent association with transfusion (aOR: 4.7, 95% CI: 3.6–6.1, $P<0.001$), while vaginal surgery remained significantly associated with transfusion, though to a lesser degree (aOR: 1.7, 95% CI: 1.0–2.9, $P=0.04$). The presence of preoperative anaemia was the strongest independent predictor of transfusion, with an aOR of 8.5 (95% CI: 6.4–11.1, $P<0.001$) (Table 2).

Additionally, absolute transfusion rates stratified by race and ethnicity, surgical approach, and fibroid burden are presented in Supplementary Table 1.

Overall transfusion rates were highest among Non-Hispanic Black patients (13.46%) compared with Hispanic (7.10%) and Non-Hispanic White patients (4.64%). Within surgical approaches, abdominal myomectomy was associated with the highest transfusion rates across all racial/ethnic groups; however, disparities persisted within each approach. For example, among laparoscopic procedures, transfusion occurred in 4.63% of Non-Hispanic Black patients compared with 1.72% of Non-Hispanic White patients. Similar patterns were observed for abdominal and vaginal approaches, demonstrating that racial disparities were present even within comparable surgical techniques.

Model Performance and Goodness of Fit

The final model was evaluated for goodness of fit using the Hosmer-Lemeshow test, which indicated no evidence of poor fit ($P=0.34$), suggesting that the model adequately represents the data. The predictive performance of the model was assessed using the AUC-ROC, which yielded a value of 0.79, indicating excellent discrimination (Figure 2). Additionally, a sensitivity analysis was conducted excluding patients who received preoperative transfusion to assess the robustness of model discrimination. In the restricted cohort ($n=5,576$), the model demonstrated similar performance, with an AUC of 0.79 (0.7937).

Table 2. Factors associated with blood transfusion among patients undergoing myomectomy: racial disparities and other predictors.

	Univariate analysis			Multivariable analysis		
	Odds ratio	Confidence interval 95%	P value	Odds ratio	Confidence interval 95%	P value
Race/ethnicity						
Non-Hispanic Whites	-	-	-	-	-	-
Non-Hispanic Blacks	3.1	2.5-4	<0.001	2.1	1.6-2.7	<0.001
Hispanics	1.5	1.1-2.1	0.007	1.1	0.7-1.6	0.5
BMI						
Normal	-	-	-	-	-	-
Underweight	0.5	0.1-2.4	0.4	0.4	0.07-2.4	0.3
Obese	0.9	0.7-1.2	0.6	0.8	0.6-1	0.1
Overweight	0.9	0.7-1.1	0.6	0.7	0.5-0.9	0.02
Morbidly Obese	0.9	0.7-1.2	0.7	0.7	0.5-1.1	0.1
HTN						
No	-	-	-	-	-	-
Yes	0.8	0.6-1.1	0.2	0.7	0.5-1	0.06
Preoperative transfusion						
No	-	-	-	-	-	-
Yes	6.9	4.6-10.2	<0.001	2.4	1.3-3.9	0.001
Fibroid burden						
Fibroids ≤250g	-	-	-	-	-	-
Fibroids >250g	2.3	1.9-2.7	<0.001	2	1.9-2.7	<0.001
Surgical approach						
Laparoscopic	-	-	-	-	-	-
Abdominal	1.7	1.5-2	<0.001	4.7	3.6-6.1	<0.001
Vaginal	1.4	1-1.7	<0.001	1.7	1-2.9	0.04
Prolonged operative time						
<180 min	-	-	-	-	-	-
≥180 min	2.3	2-2.8	<0.001	3.6	2.9-4.5	<0.001
Anemia						
Hct <30	-	-	-	-	-	-
Hct ≥30	8.2	6.5-10.2	<0.001	8.5	6.4-11.1	<0.001

BMI: Body mass index, HTN: Hypertension, Hct: Hematocrit, min: Minutes.

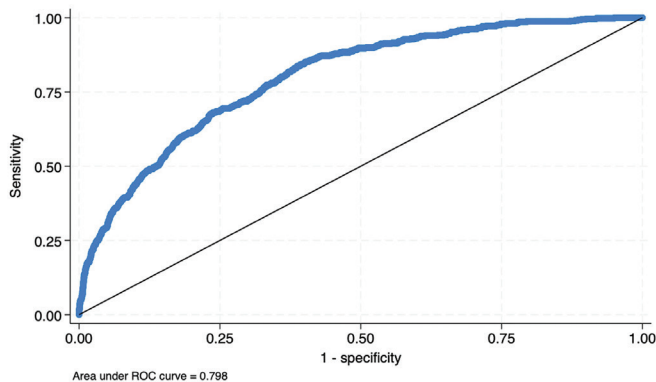


Figure 2. Receiver operating characteristic (ROC) curve for predicting blood transfusion among myomectomy patients.

These findings suggest that the predictive ability of the model was not substantially influenced by the inclusion of patients who received preoperative transfusion. The corresponding receiver operating characteristic curve is presented in Supplementary Figure 1.

Discussion

Main Findings

Our study revealed that approximately 1 in 10 patients undergoing myomectomy for uterine fibroids required a postoperative blood transfusion. We developed a predictive model incorporating clinical and demographic variables, including race and ethnicity, BMI, preoperative anaemia, surgical approach, and fibroid burden, which demonstrated excellent discrimination (AUC-ROC: 0.79). Notably, racial disparities in transfusion rates were persistent and pronounced: Non-Hispanic Black patients had over twice the odds of receiving a transfusion compared to Non-Hispanic White patients, even after adjusting for clinical risk factors. This underscores the multifactorial and systemic nature of racial inequities in surgical outcomes.

Our findings highlight both modifiable and structural risk factors that contribute to transfusion risk and racial disparities. Modifiable factors amenable to clinical intervention include preoperative anaemia (aOR: 8.5), which can be addressed through iron supplementation or gonadotropin-releasing hormone (GnRH) agonist therapy; surgical approach (abdominal aOR: 4.7 vs. laparoscopic), which can be mitigated through expanded access to minimally invasive techniques; and fibroid burden >250g (aOR: 2.0), potentially reducible through preoperative medical management.¹⁸ Structural factors beyond individual patient optimisation include race and ethnicity (Non-Hispanic Black aOR: 2.1), which likely

reflects systemic inequities in access to high-volume surgical centres, experienced minimally invasive surgeons, and timely specialist referral—variables not captured in NSQIP but known to influence outcomes. Effective reduction of transfusion disparities requires simultaneous intervention at both levels: optimising individual patient factors through standardised preoperative protocols whilst addressing system-level barriers through policy initiatives that ensure equitable access to advanced surgical care and subspecialty expertise.

Study Limitations

A major strength of this study is its use of a large, contemporary, and nationally representative surgical dataset (ACS-NSQIP), enhancing the generalisability of our findings. We applied rigorous model-building and statistical approaches, including AIC/BIC criteria and the Hosmer-Lemeshow test, to ensure robustness and model fit.

However, the study has limitations. As with all retrospective analyses using administrative databases, unmeasured confounders may exist. The ACS-NSQIP does not capture details on intraoperative blood loss, use of hemostatic agents, or preoperative medical optimisation strategies (e.g., GnRH agonists), which could affect transfusion risk. Additionally, although fibroid burden was categorized using CPT codes, this may not fully reflect fibroid complexity (e.g., location or vascularity). Several factors may limit the generalisability of our findings. The ACS-NSQIP database does not capture important confounders including surgeon experience, hospital volume, insurance status, or access to subspecialty care—all of which may mediate the observed racial disparities. The nature of the US insurance-based healthcare system, with its documented access barriers and fragmented care delivery, may amplify racial inequities compared to universal healthcare systems such as those in Europe. Additionally, provider-level factors (e.g., implicit bias, differential referral patterns) and patient-level factors (e.g., health literacy, medical mistrust) that contribute to disparities cannot be fully adjusted for in this analysis. Additionally, the NSQIP database does not distinguish between intraoperative and postoperative transfusions. This limitation prevents analysis of whether racial disparities are driven primarily by intraoperative bleeding versus postoperative anaemia management. Understanding this timing distinction could inform targeted interventions. Lastly, causality cannot be established due to the observational nature of the study.

Strengths and Limitations Compared to Other Studies

Our findings are consistent with prior studies reporting increased perioperative risks for patients with larger fibroids. For instance, Casarin et al.²⁰ and Vargas et al.¹⁹ linked greater fibroid burden to higher complication rates during myomectomy. Our data extend these findings by confirming that fibroid weight greater than 250 g is an independent risk factor for transfusion. Furthermore, our findings also showed that Non-Hispanic Blacks and Hispanic patients were disproportionately more likely to require blood transfusions. These disparities are consistent with older studies, including an analysis by Stentz et al.²¹ of 8,438 myomectomy patients from 2012 to 2015, which found that African American women had a 50% higher likelihood of morbidity following abdominal myomectomy, while no significant differences in morbidity were observed among Hispanic patients.

Compared to earlier work by Stentz et al.²¹ and Kim et al.²² which highlighted disparities and transfusion-related morbidity, our study reflects more recent surgical practice patterns and includes predictive modelling. Unlike some previous studies limited to single centres or older data, our study uses a national dataset from 2018 to 2022, capturing evolving surgical practices and racial trends.

Our predictive model builds upon and improves prior tools by integrating both modifiable (e.g., anaemia, surgical approach) and non-modifiable (e.g., race) risk factors. This holistic approach enhances its clinical utility for perioperative risk stratification.

Clinical and Policy Implications

Our findings have immediate clinical relevance. The strong association between preoperative anaemia and transfusion risk (aOR: 8.5) supports the need for early screening and optimisation prior to elective myomectomy. Interventions such as iron supplementation or hormonal suppression (e.g., GnRH agonists) could significantly reduce transfusion needs, particularly in high-risk populations. From a surgical standpoint, the abdominal approach was associated with a nearly five-fold increased transfusion risk. Where feasible, prioritising minimally invasive methods may reduce complications and improve recovery. Potential applications include preoperative risk calculators integrated into electronic health record systems, standardised protocols for identifying and optimising high-risk patients, and decision support for surgical planning and resource allocation (e.g., cross-match requirements, postoperative monitoring intensity).

Future work should focus on external validation of the model in diverse practice settings, development of user-friendly clinical tools (such as web-based calculators or mobile applications), and prospective evaluation of whether model-guided risk stratification and targeted interventions improve patient outcomes and reduce racial and ethnic disparities in transfusion rates.

The observed racial disparities reflect deeper systemic issues. Structural inequities—such as differential access to high-resource hospitals, experienced surgeons, and minimally invasive technologies—likely contribute to worse outcomes for minority patients. Policy efforts should focus on improving access to advanced surgical care, addressing institutional biases, and implementing protocols that promote equity in preoperative optimisation and referral patterns.

Unanswered Questions and Future Research

Our study raises several important questions. Why do racial and ethnic disparities persist even after adjustment for clinical risk factors? Our findings demonstrate that Non-Hispanic Black patients have over twice the odds of requiring transfusion (aOR: 2.1, 95% CI: 1.6-2.7) even after controlling for preoperative anaemia, fibroid burden, surgical approach, and other measurable clinical factors. This persistent disparity suggests that traditional risk adjustment may not fully capture the complexity of racial inequities in surgical outcomes.

One important alternative perspective to consider is whether fibroid disease itself differs fundamentally across racial and ethnic groups. As noted by recent research, uterine fibroid disease may represent fundamentally different pathophysiological entities across racial and ethnic groups. Beyond epidemiological differences in tumour size, number, and age at presentation, emerging evidence demonstrates distinct molecular and genetic profiles.^{17,23,24} Black women show higher prevalence of certain fibroid molecular subtypes, different patterns of genetic variants, and potentially divergent pathways involving vitamin D metabolism and environmental exposures. These biological differences—including variations in molecular characteristics, growth kinetics, and recurrence patterns—may partly explain the persistent racial disparities observed in our study even after adjustment for clinical factors. Future research should prioritise investigation of the underlying mechanisms driving these disparities, including genetic, epigenetic, hormonal, and environmental contributors, to

develop targeted therapeutic interventions that address root biological causes rather than merely documenting outcome inequalities.

Beyond biological mechanisms, future studies should investigate patient-level, provider-level, and hospital-level contributors to inequities in myomectomy outcomes. Prospective studies are also needed to assess the impact of targeted interventions—such as standardised anaemia screening protocols or referral to high-volume minimally invasive surgeons—on reducing transfusion rates and promoting equitable surgical care.

Additionally, refinement and external validation of our predictive model in diverse populations and practice settings are warranted. Incorporating additional variables, such as intraoperative estimated blood loss, surgical skill level, and postoperative haemoglobin levels, could enhance its accuracy and clinical application.

Conclusion

This study highlights persistent racial disparities in transfusion risk during myomectomy, particularly affecting Non-Hispanic Black women. By identifying key clinical and demographic predictors, we developed a robust risk stratification model with high predictive accuracy. These findings underscore the urgent need for targeted interventions—such as anaemia optimisation and broader access to minimally invasive surgery—to promote equitable surgical outcomes in reproductive health.

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Data sharing: The datasets used and analysed during the current study are available from the corresponding author upon reasonable request.

Transparency: The authors affirm that this manuscript is an accurate, and transparent account of the study being reported; no important aspects have been omitted.

Supplementary Table: <https://d2v96fxpocvxx.cloudfront.net/580eb5e7-1480-44a6-9404-b8b7446acbc/c/content-images/5691e298-2780-4661-a412-cff1aa2563be.pdf>

Supplementary Figure: <https://d2v96fxpocvxx.cloudfront.net/cf9d60d6-523c-458a-a2e6-78728d3ffb0/content-images/4e25b601-7757-4375-98f8-31ec61221294.pdf>

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Postoperative and long-term outcomes of nerve-sparing segmental rectal resection and complete nodular resection of rectal endometriosis

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ABSTRACT

Background: Rectal endometriosis is a severe form of deep endometriosis affecting up to 12% of patients, causing significant pain and bowel dysfunction. The optimal surgical approach can be individually tailored based on lesion size and localization as assessed by preoperative imaging.

Objectives: To compare the postoperative and long-term clinical results of two alternative surgical approaches to symptomatic rectal endometriosis.

Methods: A retrospective single-centre study of 115 patients who had surgical resection of rectal endometriosis either by complete nodular resection (CNR) (n=55) or segmental rectal resection (SRR) (n=60). The surgical approach was indicated based on #Enzian related presurgical transvaginal sonography. #Enzian C1-2 lesions were planned for CNR, and #Enzian C3 lesion for SRR. Postoperative pain and satisfaction data were collected.

Main Outcome Measures: Satisfaction and change in pre-operative and post-operative pain symptoms and overall improvement in symptoms, urinary and bowel dysfunction measured at follow-up and complications following surgery.

Results: 68/115 (59%) women provided follow up data. There were significant reductions in dysmenorrhoea, dyspareunia and dyschezia following surgical resection compared to pre-operative levels in both groups ($P \leq 0.001$). Patients treated with CNR had significantly lower postoperative defecation dysfunction compared to SRR (12.1% vs. 42.9%, $P = 0.007$) and lower postoperative C-reactive protein (CRP) levels ($P < 0.001$), but satisfaction and complication rates were comparable between the two surgical approaches. One case of leakage occurred following SRR and no cases of fistulisation or bowel stenosis were observed.

Conclusions: CNR and SRR are both safe and effective in treating symptomatic rectal endometriosis. CNR may be associated with lower postoperative defecation dysfunction rates and lower postoperative CRP levels.

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ABSTRACT

What is New? Complete nodular mucosa-sparing resection of rectal endometriosis seems to be feasible and potentially efficacious in lesions up to 3 cm. Compared to SRR, CNR may be associated with less post-operative defecation dysfunction.

Keywords: Endometriosis, rectum, defecation, rectal surgical procedures, transvaginal ultrasonography, laparoscopy

Introduction

Intestinal endometriosis is a less common form of deep endometriosis, as it affects 8-12% of patients with deep disease.¹ Intestinal endometriosis is only diagnosed when the muscularis layer of the bowel wall is invaded by the endometriotic lesions.² Rectal endometriosis can cause dyschezia, defecation dysfunction and a variety of symptoms including diarrhea, obstipation, bloating and nausea. Medical treatment might be able to control these symptoms and in some patients rectal endometriosis can be asymptomatic.³ In such cases, surgical resection can be avoided and imaging can be used to follow-up the lesions.^{4,5} Persistence of symptoms under medical treatment, bowel dysfunction or infertility despite reproductive treatments are indications for the surgical removal of rectal endometriosis. Three different surgical techniques have been reported: rectal shaving, discoid excision, and segmental rectal resection (SRR).⁶

The preoperative assessment of disease complexity can be performed by transvaginal ultrasonography (TVUS) and/or magnetic resonance imaging (MRI).⁷ Nonetheless, the final treatment decision is confirmed intraoperatively. A meta-analysis of seventeen studies including 2,861 patients showed that SRR is related to a lower recurrence rate when compared to rectal shaving, while shaving is related to a lower risk of stoma formation and rectal stenosis. The comparison of discoid excision and colorectal resection showed no difference in recurrence rates, complications and functional outcomes.⁸ The term “rectal shaving” has been widely adopted in the literature. An international consensus-based terminology considered shaving as a partial thickness excision, without entering the lumen but requiring suture of the bowel. Lesions located on the peritoneal surface of the rectum are considered peritoneal endometriosis and not rectal endometriosis.⁹ However, different types of excision on the rectal wall are referred to as “shaving” in published literature. For this reason, we prefer to use the term “Complete Nodular Resection (CNR)” instead. We aim with this work to present our single-center experience in indicating either CNR or SRR for symptomatic rectal endometriosis in accordance with lesion size based on

presurgical imaging and to evaluate the postoperative and long-term outcomes of both techniques.

Methods**Study Design**

This is a single-centre retrospective cohort study that aims to investigate the outcomes of the surgical management of rectal endometriosis. The study included endometriosis patients who were admitted to and operated on at the Department of Obstetrics, Gynecology and Gynecological Oncology of Bethesda Hospital (Duisburg, Germany) between 2020 and 2022.

Ethical Considerations

This study adheres to the guidelines of the Committee on Publications Ethics and conforms with the ethical standards of the Declaration of Helsinki (2013). All included participants granted written patient consent regarding the study's procedures and the use of their anonymized medical data for research purposes. The study protocol was reviewed and approved by an Independent Ethical Review Board of Bethesda Hospital Duisburg and Evangelic Hospital Duisburg Niederrhein the 19th of June 2023 under the number IR-12-2023.

Patient Characteristics

We included in this study all patients with imaging-based and histologically proven diagnosis of rectal endometriosis. Twenty-seven patients were diagnosed by TVUS or MRI with rectal endometriosis but were treated conservatively. To better characterize the presentation of rectal endometriosis, their data were pooled with the entire cohort for the general descriptive analysis but excluded from the main analysis. The main analysis included all patients who were managed surgically by means of CNR or SRR. The decision about the specific surgical procedure was based on the lesion size according to the #Enzian C1-C3 classification in imaging and made before the intervention. In case of lesions larger than 3 cm and multiple lesions, we opted for SRR. In case of intraoperative additional findings, the pre-operative plan was adopted accordingly. The goal of all

surgeries was the complete excision of the lesions. Rectal endometriosis was defined by disease infiltration of the muscularis layer. Discoid excision of rectal endometriosis was not performed in this cohort as we opted for CNR instead of disc excision. We excluded from the main analysis: 1) patients with rectal endometriosis diagnosed by imaging who were treated medically, 2) patients with rectal endometriosis who were operated on for deep endometriosis but declined bowel surgery and 3) patients without a histologically evident endometriotic invasion of the bowel musculature.

Surgical Management

All patients were managed with comparable surgical strategies, either CNR or SRR, by a multidisciplinary team with more than 10 years of experience in the management of colorectal endometriosis. All the surgical procedures have been carried out laparoscopically under general anesthesia with the patients in the dorsal lithotomy position. Endometriosis is classified surgically according to the #Enzian classification. The distance of the nodules from the anal verge was >7 cm in all included cases.

Complete Nodular Resection

The rectal nodule is mapped based on the preoperative imaging and intraoperative palpation with atraumatic graspers. The laparoscopic excision of the nodule is performed by using cold scissors and monopolar energy using the laparoscopic high-frequency needle (KARL STORZ, Tuttlingen, Germany). The muscular layer of the anterior rectal wall is dissected gradually and carefully until macroscopically healthy endometriosis-free margins are reached, and the mucosa is exposed underneath. The nodule is then separated from the mucosa. When necessary, haemostasis is achieved with punctual bipolar energy using short activation. The integrity of the rectal mucosa is examined through air leak test. The healthy intact mucosa bulges through the iatrogenic defect of the rectal musculature forming the "bubble-like sign". Finally, the rectal wall is closed by a transversal single layer suture using absorbable 3-0 barbed suture (V-Loc, Medtronic, Germany) (Figures 1-3). In case of accidental opening of the mucosa, a separate mucosal suture with a 5-0 PDS suture is necessary. To ensure the consistency of the rectal wall, the air leak test is repeated after filling the posterior cul-de-sac with normal saline. It is noteworthy that this technique is applicable in cases with more than one lesion if the distance between bowel lesions is at least >3 cm.

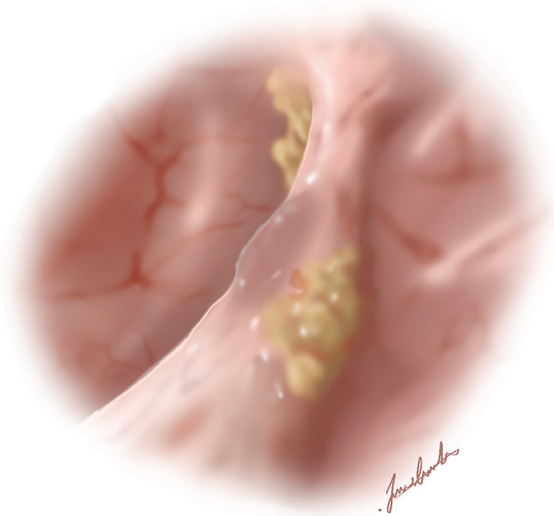


Figure 1. #Enzian C2 lesion of the anterior rectal wall; design Johan S. Krentel.

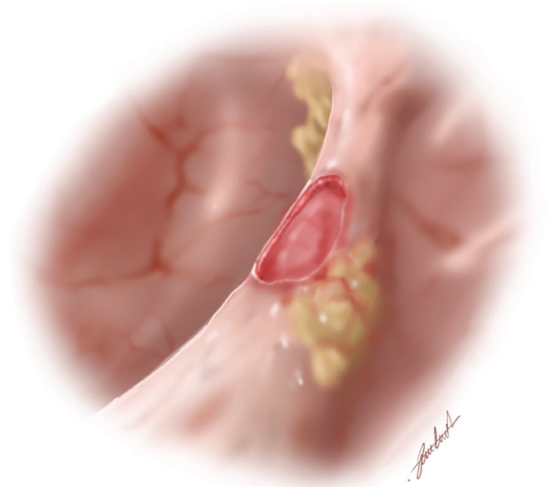


Figure 2. Rectum after mucosa-sparing excision of the endometriotic nodule, design Johan S. Krentel.

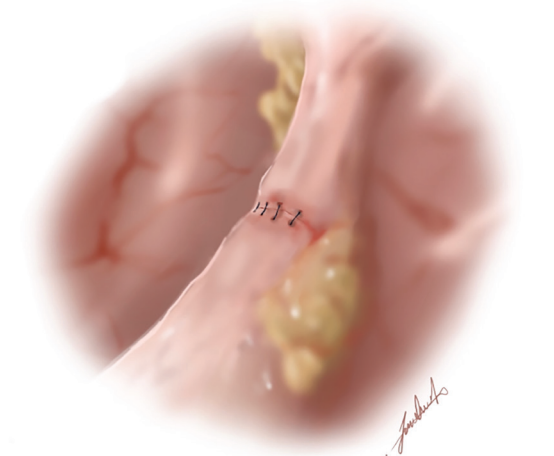


Figure 3. Rectum after transversal continuous suturing of musculature and serosa, design Johan S. Krentel.

Segmental Rectal Resection

In all cases of SRR, we mobilised the inferior part of the descending colon, the sigmoid colon, and the rectum by accessing the pararectal spaces. The neurovascular structures were carefully preserved by tubular preparation, and the blood supply of the rectum was skeletonized and coagulated according to the anatomical position and length of the resected rectal segment. All segments were resected as short as possible in accordance to the lesions. After laparoscopic stapling the tissue extraction and insertion of anvil were performed via suprapubic minilaparotomy in all cases of this cohort. After anastomosis with circular stapler the integrity was checked via rigid rectal endoscopy and air leak test as a standard procedure of the colorectal surgeons.

Data Collection and Follow-up

The electronic medical records of the included patients were retrospectively reviewed and data regarding their demographics, medical, and surgical history were extracted. All patients were followed up via phone calls and asked to complete a questionnaire regarding their pre- and postoperative symptomatology, and their overall satisfaction. Time to follow-up was 27.2 ± 11.4 month (CNR) and 28.7 ± 10.9 month (SRR). To assess overall improvement in the patient's postoperative symptoms and quality of life, the Patient Global Impression of Improvement (PGI-I) index was implemented. Urinary and bowel dysfunction were defined as impairment of function compared to the preoperative situation and included missing sensation of bladder filling, incomplete voiding or loss of voiding function, and diarrhoea, constipation and defecation frequency.

Statistical Analysis

Descriptive statistics were used. The distribution of continuous data was assessed using the Shapiro-Wilk test. Normally distributed data were expressed as means \pm standard deviation while non-normally distributed data were expressed as medians with interquartile ranges. Categorical data were presented as frequencies and valid percentages. The paired Student's t-test and Wilcoxon signed-rank test were used to compare means and medians of paired samples. Student's t-test and Mann-Whitney U test were used to compare the means and medians of normally and non-normally distributed data, respectively. Chi-square test and Fisher's exact test were used to compare categorical data, as appropriate. The level of significance was set at $P < 0.05$. All analyses

were carried out using the Statistical Package for Social Sciences (SPSS) software, version 25.0 (SPSS, Chicago, IL, USA).

Results

General Characteristics

A total of 1,226 endometriosis patients were admitted to our department between during the study period. Out of these, 142 patients were diagnosed with rectal endometriosis, making its prevalence 11.5% at our centre. Twenty-seven patients (19%) were not operated on due to being either asymptomatic or unwilling to undergo major bowel surgery and thus were excluded from the main analysis.

In all included patients we performed a complete excision of peritoneal and deep endometriosis. The overall Clavien-Dindo grade III-IV complication rate was 7%. We did not perform any preventive stoma in this cohort. It is noteworthy that more than half of the patients, regardless of their surgical management, underwent at least one previous endometriosis surgery.

Complete Nodular Resection vs. Segmental Rectal Resection

Out of 115 patients who underwent surgery for colorectal endometriosis, 60 patients were managed with SRR (52.2%) and 55 patients were managed with CNR (47.8%). The mean age at presentation of the SRR group and CNR group was comparable. The infertility rate was higher among patients who underwent SRR compared to patients who underwent CNR (71.7% vs. 52.9%, $P = 0.048$). Otherwise, both groups were comparable in terms of their demographics, obstetric, and surgical history.

Patients who underwent SRR and CNR presented with similar symptomatology, with dysmenorrhea being the most common complaint in both groups. However, dyschezia was significantly more frequent in the SRR group than the CNR group (60.0% vs. 30.9%, $P = 0.002$). Table 1 presents patients' general characteristics, symptomatology, surgical findings and a detailed comparison between both study groups in terms of their characteristics, symptoms, and laboratory values.

In accordance with the presurgical indication based on lesion size, the #Enzian classification C3 was significantly more prevalent in the SRR group (73.3% vs. 1.8%), and #Enzian C1-C2 lesions were more common in the CNR group (98.2% vs. 26.7%, $P < 0.001$). Our data revealed

a significant association between large endometriotic nodules of the rectovaginal septum/vagina and the rectum. Patients with #Enzian classification C3 were more frequently diagnosed with large rectovaginal nodules (#Enzian A3) in comparison with patients with smaller rectal nodules who had smaller nodules of the rectovaginal septum as well (65.9% vs. 33.8%, $P=0.001$). The rate of additional bowel endometriosis in non-rectal bowel localisations (appendix, sigmoid colon, coecum, small bowel; #Enzian FI) was significantly higher in the segmental resection group than in the CNR group (33.3% vs. 12.9%, $P=0.009$).

The postoperative CRP levels at day 1 (3.64 vs. 1.22 mg/dL, $P<0.001$), day 2 (3.95 vs. 1.01 mg/dL, $P<0.001$) and day 3 (2.43 vs. 1.02 mg/dL, $P=0.001$) were significantly higher in patients with SRR than those with CNR. The

Clavien-Dindo grade I-II (13.3% vs. 14.5%) complication rates were comparable between both groups. The Clavien-Dindo grade III-IV complication rates reached 13,3% in the segmental resection group and 3.6% in the CNR group. However, this was not a statistically significant finding. Most of the grade III complications were related to hematoma and local infection of the vaginal cuff when simultaneous hysterectomy was performed. The detailed complications are listed in Supplementary Table 1. It is noteworthy that out of 115 patients who underwent surgery for rectal endometriosis, only 1 case of leakage was documented (0.87%) in the SRR group, while fistulisation or stenosis of the anastomosis did not occur at all. In only 1 case of CNR an accidental opening of the mucosa occurred (1.8%), that was treated with a separate mucosal suture.

Table 1. The general characteristics, symptomatology and surgical findings of patients who underwent complete nodular resection or segmental rectal resection for deep endometriosis.

	CNR (n=55)	SRR (n=60)	P
General characteristics (n=115)			
Age (years)	35.7±7.6	33.5±5.9	0.09
Previous gynecologic operation (%)	29 (48.3%)	37 (69.8%)	0.109
Abortions (%)	8 (16.7%)	4 (7.1%)	0.13
Infertility (%)	27 (52.9%)	38 (71.7%)	0.048
Preoperative symptomatology			
Constipation (%)	7 (12.7%)	11 (18.3%)	0.409
Hematochezia (%)	3 (5.5%)	8 (13.3%)	0.151
Surgical findings			
#Enzian P (%)	47 (85.5%)	59 (98.3%)	0.013
#Enzian O (left) (%)	19 (34.5%)	14 (23.7%)	0.203
#Enzian O (right) (%)	18 (32.7%)	19 (31.7%)	0.9
#Enzian T (left) (%)	14 (25.9%)	24 (42.1%)	0.07
#Enzian T (right) (%)	14 (25.9%)	18 (31%)	0.55
#Enzian A (%)	45 (81.8%)	56 (93.3%)	0.059
#Enzian A1-2	32 (71.1%)	21 (37.5%)	0.001
#Enzian A3	13 (28.9%)	35 (62.5%)	
#Enzian B (left) (%)	46 (83.6%)	55 (91.7%)	0.18
#Enzian B (right) (%)	36 (65.5%)	47 (78.3%)	0.12
#Enzian C (%)			
#Enzian C1-2	54 (98.2%)	16 (26.7%)	<0.001
#Enzian C3	1 (1.8%)	44 (73.3%)	
#Enzian FI (%)	7 (12.7%)	20 (33.3%)	0.009
#Enzian FU (%)	0 (0%)	2 (3.3%)	0.49
#Enzian FA (%)	27 (51.9%)	28 (47.5%)	0.63

Continuous data is presented as means ± standard deviations or medians with interquartile ranges, as appropriate. Categorical data is presented as frequencies and percentages. CNR: Complete nodular resection, SRR: Segmental rectal resection.

Outcomes

We managed to gain contact with 68 patients for the follow-up, which makes the follow-up rate 59.1%. The median duration of follow-up is 24.5 months. Neither the follow-up rates nor the durations of follow-up were different between both study groups (Table 2).

The postoperative NRS scores for dysmenorrhea, dyspareunia, and dyschezia were significantly reduced among the entire cohort as well as within each study group (Table 3). The median reduction in NRS in dysmenorrhea, dyspareunia and dyschezia was numerically higher in the CNR group, without reaching statistical significance.

Table 2. Clinical outcomes for 68/115 women who were operated for rectal endometriosis and provided follow up data.

	Total (n=68)	CNR (n=33)	SRR (n=35)	P value
Follow-up overview				
Follow-up rate (%)	68 (59.1%)	33 (60.0%)	35 (58.3%)	1.000
Duration of follow-up (months)	24.5 (17)	27.2±11.4	28.7±10.9	0.590
Postoperative pain [NRS, median (IQR)]				
Dysmenorrhea NRS	1 (4.75)	0 (3.5)	2 (5)	0.230
Dyspareunia NRS	1 (4)	0.5 (4)	1 (4.5)	0.520
Dyschezia NRS	0 (2)	0 (2)	1 (2)	0.300
Postoperative urinary dysfunction				
Urinary dysfunction (%)	11 (16.2%)	4 (12.1%)	7 (20.0%)	0.510
Temporary	10 (90.9%)	4 (100%)	6 (85.7%)	1.000
Permanent	1 (9.1%)	0 (0%)	1 (14.3%)	
Postoperative defecation dysfunction				
Defecation dysfunction (%)	19 (27.9%)	4 (12.1%)	15 (42.9%)	0.007
Temporary	6 (31.6%)	4 (100%)	2 (13.3%)	0.004
Permanent	13 (68.4%)	0 (0%)	13 (86.7%)	
Additional outcomes				
Postoperative hormonal therapy (%)	38 (55.9%)	22 (66.7%)	16 (45.7%)	0.820
Rate recommending surgery (%)	65 (95.6%)	31 (93.9%)	34 (97.1%)	0.600
Patient Global Impression of Improvement (PGI-I)				
Very much better	27 (39.7%)	12 (36.4%)	15 (42.9%)	0.900
Much better	22 (32.4%)	11 (33.3%)	11 (31.4%)	
Slightly better	14 (20.6%)	7 (21.2%)	7 (20.0%)	
No change	4 (5.9%)	2 (6.1%)	2 (5.7%)	
Slightly worse	0 (0%)	0 (0%)	0 (0%)	
Much worse	1 (1.5%)	1 (3.0%)	0 (0%)	
Very much worse	0 (0%)	0 (0%)	0 (0%)	
		CNR (n=55)	SRR (n=60)	P value
Perioperative outcomes				
Clavien-Dindo grade I-II complications (%)		8 (14.5%)	8 (13.3%)	0.851
Clavien-Dindo grade III complications (%)		2 (3.6%)	8 (13.3%)	0.097
Postoperative day 1 CRP (mg/dL)		1.22 (1.8)	3.64 (3.11)	<0.001
Postoperative day 2 CRP (mg/dL)		1.01 (1.86)	3.95 (4.56)	<0.001
Postoperative day 3 CRP (mg/dL)		1.02 (1.4)	2.43 (3.41)	0.001

Continuous data is presented as means ± standard deviations or medians with interquartile ranges, as appropriate. Categorical data is presented as frequencies and percentages. CNR: Complete nodular resection, SRR: Segmental rectal resection, NRS: Numeric rating scale, IQR: Interquartile range, CRP: C-reactive protein.

Table 3. A comparison between the pre- and postoperative pain levels among patients who were operated on for rectal endometriosis. The data is presented as medians with interquartile ranges.

The entire cohort (n=68)			
Symptom	Preoperative NRS score	Postoperative NRS score	P value
Dysmenorrhea	9 (2.75)	1 (4.75)	<0.001
Dyspareunia	6 (7.25)	1 (4)	<0.001
Dyschezia	5 (8)	0 (2)	<0.001
Complete nodular resection (n=33)			
Dysmenorrhea	8 (2.5)	0 (3.5)	<0.001
Dyspareunia	6 (8)	0.5 (4)	0.001
Dyschezia	5 (7)	0 (2)	0.001
Segmental rectal resection (n=35)			
Dysmenorrhea	9 (2)	2 (5)	<0.001
Dyspareunia	5 (6.25)	1 (4.5)	0.001
Dyschezia	5 (7)	1 (2)	<0.001

Continuous data are presented as means ± standard deviations or medians with interquartile ranges, as appropriate. Categorical data is presented as frequencies and percentages. NRS: Numerical rating scale.

Most patients reported significant improvement in their symptoms postoperatively, while four patients (5.9%) reported no change and one patient (1.5%) reported worsening of the symptoms. More than half of the patients used postoperative hormonal therapy (55.9%). It is noteworthy that the postoperative pain scores for all three symptoms were not significantly different between patients with and without postoperative hormonal therapy (data not shown). The postoperative urinary and defecation dysfunction rates are 16.2% and 27.9%, respectively. The postoperative defecation dysfunction rate was significantly higher among patients who received SRR in comparison to those with CNR (42.9% vs. 12.1%, $P=0.007$). Otherwise, the follow-up outcomes and satisfaction rates were comparable among both study groups (Table 1).

A total of 19 patients reported to have a negative postsurgical change in defecation and bowel function. Fifteen of these patients underwent segmental resection for large rectal nodules. Six patients reported a temporary dysfunction. The other 13 patients reported either a higher defecation frequency or constipation. Out of 11 patients who reported postoperative urinary dysfunction, 1 patient had a urinary infection that was successfully treated with antibiotics and 9 patients reported a temporary dysfunction that completely disappeared after a period of 3 weeks up to a maximum of 6-month. One patient reported a permanent difficulty to completely empty the bladder without the need of self-catheterisation.

The analysis revealed that the main factor affecting the occurrence of defecation dysfunction is the size of the rectal nodule and the respective choice of surgical approach. Patients with #Enzian classification C3 nodules are 8 times more likely to develop postoperative defecation dysfunction (odds ratio: 8.66, confidence interval: 1.36–55.22, $P=0.022$).

Discussion

Rectal endometriosis represents one of the most severe forms of deep endometriosis due to its possible intense symptomatology and thus negative effect on patients' quality of life.¹⁰ Our results confirm previous findings that the surgical management of rectal endometriosis leads to a significant decrease in pain levels regardless of the used technique. While in the available literature, the term "rectal shaving" refers to different surgical procedures from simply isolating the rectum from rectovaginal endometriosis to full-thickness resection.¹¹ CNR indicates the complete mucosa-sparing excision of the endometriotic nodule from the rectal wall. This is in line with the definition by Roman et al.¹² and the international consensus terminology,⁹ and excludes incomplete excision and distinguishes rectal shaving clearly from disc excision and segmental colorectal resection. We limited the indication for CNR to nodules of a maximum size of approximately 3 cm, as the approximation of the muscular rectal layer by a single transversal suture might be difficult and related to complications in larger

distances. However, this limitation is a non-evidence based expert opinion and should be analysed in future trials. In some cases, when CNR was not feasible due to additional bowel lesions only diagnosed during surgery, a tubular SRR has been carried out. Our data demonstrated that CNR for #Enzian C1-2 nodules and SRR for #Enzian C3 nodules are both feasible and related to a relief of symptoms and increasing patients' satisfaction. Although our data remains unable to draw definitive conclusions regarding the indication of each technique, it provides a substantial basis for standardising the surgical approach for colorectal endometriosis based on presurgical imaging by transvaginal ultrasound and/or MR imaging using the #Enzian classification.^{13,14} This approach does not only allow for the choice of resection technique before surgery, but also for a detailed counselling of the patient including risk-stratification and precise preparation regarding complexity of the procedure. Avoiding intrasurgical surprises seems to be a relevant factor in decreasing complication rates. Our data contributes to the body of evidence regarding the safety of CNR and confirms the safety of SRR for rectal endometriosis. The overall Clavien-Dindo grade III/IV complication rate was 7%. We did not face any case of postoperative fistulisation or stenosis, while anastomosis leakage requiring stoma occurred in one patient of the SRR group only, which is lower than what has been previously reported.¹⁵ One meta-analysis has shown that the rectovaginal fistula and anastomosis leakage rates are 1.5% and 1.2%, respectively.¹⁶ Another systematic review has shown that the fistulisation and leakage rates are comparable in patients undergoing nerve-sparing segmental resection, nerve- and artery-sparing segmental resection, and conventional segmental resection.¹⁷ Our analysis demonstrated that rectal nodule's size influences the postoperative occurrence of defecation dysfunction. SRR can be considered more invasive compared to CNR as healthy tissue along with endometriosis is resected. Large rectal nodules more frequently require SRR, which is related to higher complexity and radicality and thus to higher postoperative defecation dysfunction when compared to CNR. If feasible, the more conservative CNR could be considered as treatment of first choice in order to decrease the rate of segmental resection and thus decrease the rate of postsurgical complications and defecation dysfunction.

Our data shows that the presence of #Enzian C3 lesions is not only related to a higher rate of dyschezia, but also to a higher rate of additional large rectovaginal

and vaginal lesions (#Enzian A3). The available literature describes the posterior nodules as rectovaginal lesions and the infiltration of rectum and vagina as two sides of the same nodule.^{18,19} The significant correlation between lesion size in #Enzian compartment C and A in our study is a new aspect in the understanding of rectovaginal endometriosis. Our data also showed that #Enzian C3 lesions are related to a higher rate of additional intestinal lesions of appendix, coecum, sigmoid or small bowel (#Enzian FI). This could be relevant in light of the three mechanisms of bowel-related pain and dysfunction in patients with colorectal endometriosis: rectal lateral or anterior fixation, rectal stenosis, and cyclic inflammation.²⁰ While surgery can restore the normal anatomy and remove the mechanical barrier imposed by the rectal nodule, it remains unable to revoke the prolonged effect of cyclic inflammation and the resulting bowel hypersensitivity.²¹ However, the meticulous intrasurgical examination of the appendix, coecum, sigmoid and small bowel is of importance, as occult lesions might contribute to ongoing postsurgical bowel symptoms.²² In contrast to our results, Pashkunova et al.²³ reported significantly improved low anterior resection syndrome (LARS) symptoms in patients treated with SRR and full-thickness discoid excision. However, patients with preoperative LARS-like symptoms of the full-thickness discoid excision group exhibited aggravated LARS scores during their postoperative follow-up.²³ Alternatively, Roman et al.²⁴ indicated that the risk of defecation dysfunction in endometriosis patients undergoing rectal surgery is as high as 40%. In another study, the same group demonstrated that the surgical management of rectal endometriosis does not mandatorily relieve the digestive complaints,²⁵ but that the improvement of other endometriosis-related pain symptoms outweighed the persistence of bowel symptoms, which was also evident in our study.

Although we did not use protective stoma in this cohort, the leakage rate was 0.87% and there was no case of fistulisation. Similarly, Collinet et al.²⁶ in their recent study reported a complication rate of 14% among 97 patients who were operated for colorectal endometriosis without preventive stoma, with 1 case of fistulisation and 2 cases of anastomosis dehiscence. This strongly indicates that a protective stoma should not be performed on a standard basis. On the contrary, protective stomas for rectal endometriosis could be considered as "over-treatment" as they may lead to increased morbidity and higher costs of endometriosis management.

In their systematic review, Bendifallah et al.²⁷ demonstrated that the recurrence rate of rectal endometriosis was higher among patients who underwent conservative bowel surgery in comparison to those who underwent SRR and discoid excision. On the other hand, the recurrence did not differ significantly between SRR and discoid excision. Our study did not assess the histologically proven recurrence rate, but we hypothesize that CNR technique shares the same principle of the complete disease removal and thus comparable recurrence rates as discoid excision. A prospective randomized trial comparing CNR and disc excision could analyse possible differences.

Study Limitations

Our study has several limitations. This is a non-randomised retrospective single-center study, which makes it prone to selection bias. We followed up with the patients through phone calls using an unvalidated questionnaire. This might limit the strength of long-term functional outcome conclusions for bowel and urinary dysfunction. Although it is useful, the application of the PGI-I scale could be problematic since, to the best of our knowledge, it has not been applied in the field of rectal endometriosis. The follow-up rate is relatively low, and the number of followed patients in each study group is low, which makes it harder to detect significant differences between the groups. Urinary and defecation dysfunction were defined as impairment compared to the preoperative situation. However, we did not access presurgical bladder and bowel dysfunction in detail. Thus, we are not able to completely differentiate between already existing dysfunction from surgery-related dysfunction. Important anatomical variables such as number of nodules, exact distance of endometriosis nodules from the anal verge and circumferential bowel involvement are missing, although these parameters might influence the choice of surgical approach. A more detailed prospective data analysis including disc resection should include these parameters in a future trial.

Conclusion

CNR and SRR are safe, equally effective in improving pain symptoms of deep rectal endometriosis, and associated with high postoperative satisfaction rates. CNR seems to be a feasible mucosa-sparing approach in lesions up to 3 cm, related to lower postoperative defecation dysfunction rates and CRP levels when compared to segmental resection. Large rectal nodules are related to a higher rate of additional intestinal deep endometriosis.

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Informed consent: All patients gave informed consent to the respective surgery and to the anonymous use of their data.

Data sharing: All the data are available from the corresponding author on a reasonable request.

Transparency: The authors affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Supplementary Table: <https://d2v96fxpocvxx.cloudfront.net/bfe6b059-1982-481c-8e2f-073cbc0b054a/content-images/0b1e1a56-4be5-46e0-a767-2b6abe012c39.pdf>

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Conventional laparoscopic segmental bowel resection with mini-laparotomy specimen extraction compared with Natural Orifice Specimen Extraction (NOSE) procedures in patients with colorectal endometriosis

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ABSTRACT

Background: In patients with colorectal endometriosis the optimal surgical approach for excising disease remains unknown.

Objectives: To compare the safety and efficacy of classic colorectal resection with mini-laparotomy and extracorporeal specimen removal and anastomosis formation (CLS) and colorectal resection with natural orifice specimen (bowel segment) extraction (NOSE), which is performed entirely in the abdominal cavity.

Methods: This is a single centre, retrospective observational study of 161 cases of colorectal endometriosis. Women underwent laparoscopic excision of deep endometriosis with segmental bowel resection between 2015 and 2023.

Main Outcome Measures: Hospital stay, complication rate, infectious issues, pain measured on a 10 cm visual analogue scale (VAS) and quality of life [derived from Knowles-Eccersley-Scott-Symptom (KESS)] questionnaire were the outcomes of interest.

Results: No differences in post-operative pain or bowel quality of life at 3 months were observed between CLS and NOSE surgical treatment of colorectal endometriosis (mean VAS score 2 vs. 1, ($P=0.62$) and mean KESS score 12.3 vs. 10.7 ($P=0.28$). No clinically significant differences between techniques for intra-abdominal sepsis were seen as judged by C-reactive protein elevation and bacterial contamination from peri-operative cultures.

Conclusions: NOSE and CLS procedures appear comparable in safety and efficacy for removing colorectal endometriosis. Randomised trials are needed to compare these techniques.

What is New? The NOSE technique for removing colorectal endometriosis is not associated with poorer safety, inflammatory, infective or efficacy outcomes compared to the classical CLS approach. Randomised controlled trials are needed to compare these techniques.

Keywords: Anastomosis, colorectal, endometriosis, laparoscopic, surgery, quality of life

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Introduction

Endometriosis is a chronic disease with a prevalence 10-15% in reproductive- age women.¹⁻³

Deep colorectal endometriosis (DE) is the most aggressive type of endometriosis which occurs in 5-12% of women with endometriosis.³⁻¹⁰ In such patients, characteristic intestinal symptoms may appear during the perimenstrual period—diarrhea, dyschezia, flatulence, tenesmus, ribbon—like stools, difficulty defecating, and the presence of blood in the stool, which significantly affects daily life.¹¹⁻³⁸

Despite its relevance, the question of choosing the optimal treatment method for colorectal endometriosis remains a significant problem.³⁹⁻⁴¹ Conservative medication (non-steroidal anti-inflammatory drugs, combined oral contraceptives, progestins, gonadotropin-releasing hormone agonists) is a first line treatment, especially for asymptomatic patients. It can reduce symptoms, still, it does not provide long-term control after medication is stopped and cannot halt the progression of endometriosis.¹²⁻¹⁵ Therefore, surgical treatment is often required to remove affected tissues to alleviate the symptoms of endometriosis.¹⁶ Endometriosis with involvement of a large bowel is challenging.

Surgical treatment of colorectal endometriosis includes shaving technique (superficial removal of infiltrates without opening its lumen), discoid resection of the intestine (excision of an endometriotic infiltrate on anterior wall, opening its lumen and subsequent suturing), and segmental bowel resection with consequent formation of anastomosis.^{17,18}

Currently, colorectal resection is performed with minimally invasive approaches, either laparoscopically or robot-assisted. One of them, that proved its safety and efficacy, is conventional laparoscopic segmental bowel resection with mini-laparotomy specimen extraction (CLS). However, there is still a need to search for alternative techniques to reduce surgical trauma and its complications. Thus, a new direction emerged—transluminal surgical interventions. Natural Orifice Specimen Extraction (NOSE) refer to surgical procedures performed through natural anatomical openings—the vagina or rectum.^{16,17,19}

The NOSE technique has become particularly widespread among gynaecological surgeons who operate on colorectal endometriosis, utilising intracorporeal end-to-end anastomosis.²⁰⁻²²

A 2021 study by Dobó et al.²⁴ demonstrated that NOSE is an acceptable surgical treatment method for patients with rectal endometriosis. However long-term data on gastrointestinal well-being after segmental bowel resection for DE in a large cohort of patients are sparse which limits robust conclusions.²³⁻²⁵

Therefore, the development of an algorithm for selecting the optimal surgical treatment method for colorectal endometriosis remains an ongoing issue. This retrospective single centre study compares CLS and NOSE bowel resection techniques and its outcomes in patients with colorectal DE in a long-term follow-up.

Methods

In this single-centre, retrospective study we investigated two surgical scenarios of deep colorectal endometriosis. It is a comparative analysis of data from 161 patients who underwent surgical treatment for DE in the gynaecological department of Krasnopolski Moscow Regional Research Center of Obstetrics and Gynecology from 2015 to 2023. All patients provided informed consent to participate in the study. This study was approved by the Local Ethics Committee of the Moscow Regional Research Institute of Obstetrics and Gynaecology (IRB number: 060004245) on 8th September 2016 and approval number: 715.

In all cases, patients underwent colorectal resection due to the symptomatic form of bowel endometriosis with the following nodule characteristics: length—3 cm or more, depth of invasion—7 mm or more, and the involvement of 40% or more of the bowel circumference, as well as the narrowing of the bowel lumen up to 50% according to colonoscopy in asymptomatic patients with diagnosed colorectal endometriosis. In the classic technique (CLS), after ureterolysis and opening of the pararectal space, the surgeon mobilizes the affected bowel segment. The unaffected distal part of the colon is separated from the mesorectum over a length of 10-20 mm and is cut-off using a linear stapler. Next, the affected proximal section of the intestine is removed through a suprapubic mini-laparotomy incision in the abdominal wall (up to 4 cm long), where it is resected proximally to the infiltrate with a distance of 5-10 mm. Extracorporeally, the anvil of the circular stapler is fixed to the intestinal tube with a purse-string suture and immersed back into the abdominal cavity, the anterior abdominal wall is sutured in layers. The intestinal anastomosis is performed using a transanal circular stapling device (end-to-end or side-to-end).

After the anastomosis is performed, a Michelin gas test is performed to determine the integrity of the suture. The CLS was routinely used from 2015-2020 in our centre.

A second method to compare was NOSE. Krasnopolski Moscow Regional Research Center of Obstetrics and Gynecology developed an algorithm optimising surgical treatment of patients with colorectal endometriosis using transluminal technology, particularly NOSE. The advantage of this method is that it can be performed using a single access port –laparoscopic or robotic. The NOSE technique was introduced as an alternative technique to CLS in our centre from 2020.

Technical Features of the Operation

After restoring the physiological anatomy of the pelvis, the intestine is mobilized. The affected bowel (sigmoid colon, rectosigmoid junction) is mobilized from the promontory level under visual control of the ureters and hypogastric nerves in an avascular space. Dissection continues towards the uterosacral ligaments and rectovaginal fascia as close as possible to the mesentery of the bowel, opening the presacral space. This step is carried out in the embryonic layers, which are limited by presacral and mesocolon fascias.

This stage of the operation helps to approach intact areas of the bowel below the nodule. The uterus is then brought to a position of maximum anteflexion using a manipulator, thus opening the posterior pelvis. Adhesions between the posterior uterine wall and the colon are separated. Simultaneously, the assistant pushes the posterior fornix using the rectal probe placed into the vagina, and the bowel with the nodule is separated from the cervix, uterosacral ligaments, and the posterior fornix of the vagina. The rectal probe is then inserted into the rectum. Along the lower margin of the nodule within healthy areas, the bowel is cleared of visceral fatty tissue under the probe control using the “shaving” method. The primary goal that is being pursued here is to increase the distance between the anus and the lower border of the nodule, thereby allowing for cutting off the affected part of the colon as high as possible from the anus. The rectal probe is then removed.

The colon wall is then cleared of visceral fatty tissue in the cranial direction over 1.5-2.0 cm from the upper margin of the nodule. The affected area of the colon is crossed within the intended boundaries. Using ovarian forceps, the fragment is removed through the anus (Figures 1, 2).

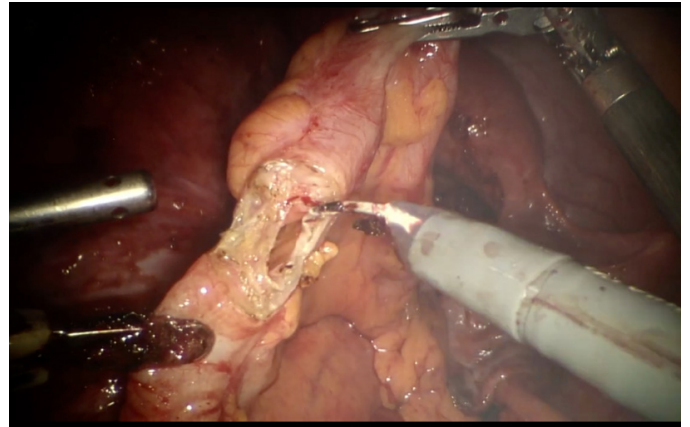


Figure 1. Cutting off the fragment of the colon affected by endometrioid infiltrate within healthy tissue.

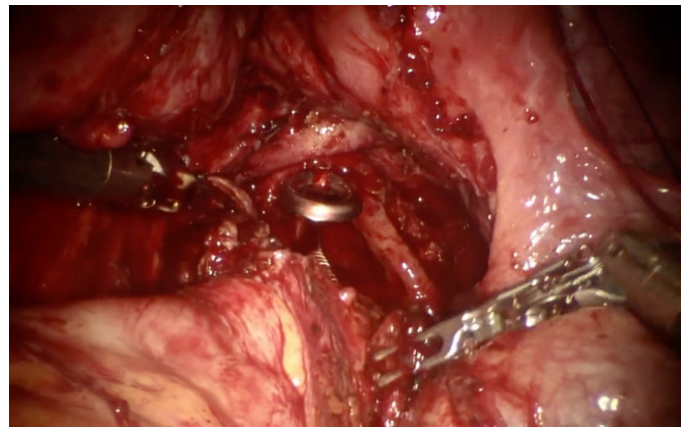


Figure 2. Transanal extraction of histological material.

Purse string sutures are placed through all layers of the colon wall with 2-0 monofilament at the proximal and distal edges of the colon resection. The sutures are not tightened.

The circular stapler with a diameter of 28.5 or 31.5 mm is inserted into the anus, depending on the diameter of the resected section of the bowel (Figure 3). The device is inserted into the abdomen in the “close” state, then its anvil is brought out to the “open” position. The proximal and distal resection margins are immersed in the anvil and proximal part of the circular stapler, and the purse-string sutures are tightened. Next, stapling and suturing of the proximal and distal parts of the rectum are performed to form an end-to-end anastomosis (Figure 4). The final stage involves the rectal air leak (Michelin) test for anastomosis integrity.

As with any new technique, NOSE technology requires some additions to the traditional patient management.

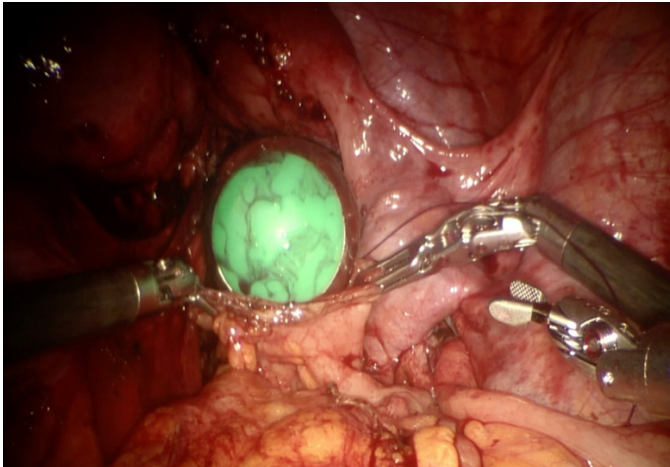


Figure 3. Introducing of the head of the stapler into the lumen of the proximal resection margin.

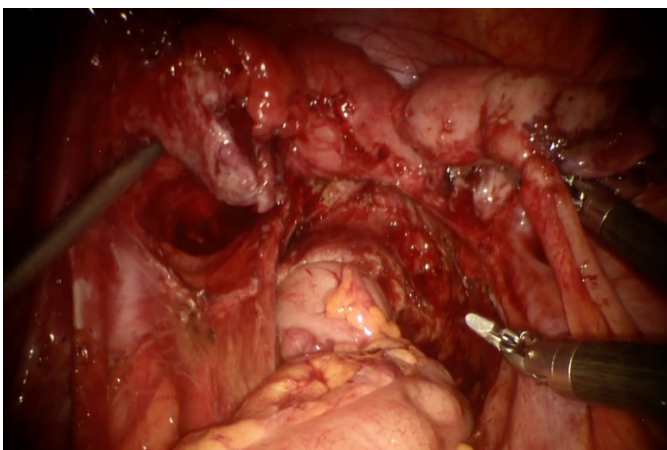
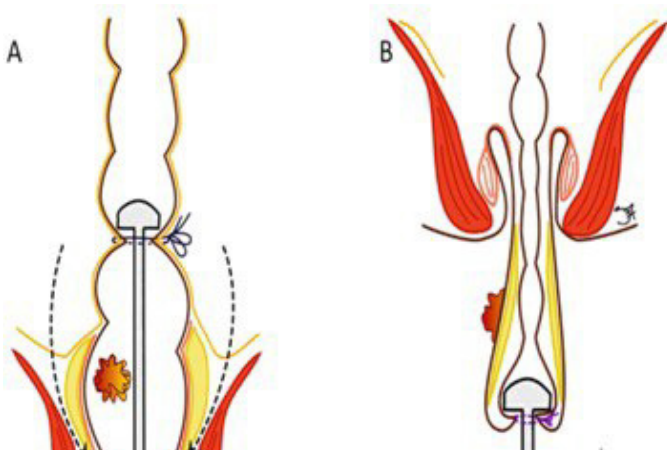


Figure 4. Final view of the end-to-end stapled anastomosis.

In all cases of intracorporeal opening of the intestinal lumen, additional antibiotic prophylaxis was used by irrigating the pelvic cavity with 20.0 hydroxymethylquinoxaline dioxide saline solution. After that, an anastomosis is performed. Finally, a 50 mL syringe is inserted into the rectum and air is injected (the bubble test).

In the current study, a comparative bacterial analysis of two techniques was conducted –classical colorectal resection and resection using NOSE technology. For preoperative preparation, we recommend that the patient’s last meal be taken before 2 p.m. on the day before the operation, and fluids were allowed no later than 6 a.m. on the day of the operation. Two to three hours after the last meal, the patients began bowel preparation with a laxative according to the schedule.

In our study, preoperative bowel preparation was performed by following a low residue diet for 72 hours, taking a laxative 24 hours before the operation, and administering antibiotic prophylaxis 30 minutes before the operation commenced. Patients were given a leaflet with dietary recommendations. The preoperational preparation also included IV antibiotic prophylaxis: tinidazole 600 mg and ciprofloxacin 500 mg twice daily for 48 hours, or rifaximin 400 mg twice daily 72 hours before the operation date.

Additionally, patients were divided into two slightly uneven groups. The first group consisted of 56 patients who underwent NOSE surgery, of whom 33 underwent traditional laparoscopic surgery and 23 underwent robot-assisted surgery. The second group included 105 patients who underwent colorectal resection using the classic method (CLS) with mini-laparotomy. Laparoscopic access (laparoscopic surgery) was used in 66 patients, and robotic access in 39 patients. Recognising limitations of retrospective design, we merged robot-assisted procedures with laparoscopic. We found this feasible and reasonable regarding studies suggesting no significant difference between two types of procedures for colon resection.^{42,43} Patient reported outcomes were assessed at baseline and 3 days (visual analogue pain scale only) and 3 months after surgery. These measures included pain measured using a 10cm VAS and the Knowles-Eccersley-Scott-Symptom questionnaire (KESS) to assess the frequency and severity of constipation. This is a structured scoring system that evaluates the impact of constipation on quality of life; a higher KESS score is associated with everyday life worsening. Symptoms evaluated include duration of constipation, laxative use, frequency of bowel movement, unsuccessful evacuatory attempts, feeling incomplete evacuation, abdominal pain, bloating, use of enemas/digitation, time taken in minutes in the lavatory per attempt, difficulty evacuating (with painful effort) and stool consistency without laxatives.

Statistical Analysis

Statistical analysis of the research results was performed using the IBM SPSS Statistics v26 program. With a normal distribution, the data were described using the mean and range. For distributions other than normal when assessing differences between groups, the nonparametric Mann-Whitney U-test was used; for evaluating dynamic changes, the Wilcoxon test was used. In the analysis, the nominal data were obtained as absolute results, and the percentage (%) was determined using the Pearson χ^2 test with Yates's correction.

Results

Baseline demographic and clinical data can be seen in Table 1. No differences in the severity of bowel symptoms

associated with DE were found before or after surgery between CLS and NOSE groups according to mean visual analogue scale (VAS) pain scores and mean KESS scale values (Table 1). Median blood loss as well as mean hospital stay were similar in both groups (Table 2).

As shown by mean C-reactive protein (Table 3) the use of intracorporeal opening of the intestinal lumen is not associated with higher levels of this inflammatory marker. Moreover, as is seen from Table 4 bacterial flora found in pelvic cavity probes remained uniform for both procedures. The rate of operative complications was low (6/161, 4%). A description of complications in both groups is presented in Table 5.

Table 1. Baseline and post-operative pain and constipation quality of life data.

Mean value	NOSE n=56	CLS n=105	P value
Mean age (years)	36 (30-45)	35 (32-41)	0.07
Mean BMI (kg/m ²)	22.3 (18.5-23.7)	22.7 (22.1-23.3)	0.09
Mean (range) VAS pain score before surgery	7 (5-10)	7 (5-10)	0.87
Mean (range) VAS pain score at day 3 day post-surgery	3 (0-4)	6 (2-5)	0.34
Mean (range) VAS pain score at 3 months post-surgery	1 (0-2)	2 (0-4)	0.62
Mean KESS scale score before surgery	30.3	25.7	0.12
Mean KESS scale score at 3 months post-surgery	10.7	12.3	0.28

P values were calculated using the Mann-Whitney U-test. BMI: Body mass index, KESS: Knowles-Eccersley-Scott symptom, CLS: Conventional laparoscopic surgery, NOSE: Natural orifice specimen extraction, VAS: Visual analogue scale.

Table 2. Perioperative data.

	NOSE (laparoscopic) n=33	NOSE (robotic) n=23	CLS n=105
Mean (range) blood loss (mL)	100 (75-100)	120 (100-150)	128 (100-150)
Median (range) operation duration (minutes)	90 (80-150)	130 (100-160)	209 (150-270)
Mean (range) length of hospitalisation, days	4 (4-7)	4 (4-6)	4 (4-5)

CLS: Conventional laparoscopic surgery, NOSE: Natural orifice specimen extraction.

Table 3. C-reactive protein mean values during the first four days postoperatively.

C-reactive protein	Day 1	Day 2	Day 3	Day 4
NOSE (laparoscopic) n=33	65.7	74.1	67.2	44.7
NOSE (robotic) n=23	69.1	85.6	64.9	33.8
CLS n=105	46.2	60.4	47.1	36.6

C-reactive protein normal range = 0-20 mg/dL.

CLS: Conventional laparoscopic surgery, NOSE: Natural orifice specimen extraction.

Table 4. Abdominal culture data.

Pathogen	Sample taken before anastomosis		Sample taken after anastomosis	
	NOSE n=17	CLS n=10	NOSE n=17	CLS n=10
<i>Staphylococcus epidermidis</i>	2 (11.8%)	0	1 (5.8 %)	1 (10%)
<i>Staphylococcus haemolyticus</i>	1 (5.8%)	0	0	0
<i>Staphylococcus warneri</i>	1 (5.8%)	1 (10%)	0	0
<i>Staphylococcus faecalis</i>	1 (5.8%)	2 (20%)	0	1 (10%)
<i>Enterococcus durans/hirae</i>	0	1 (10%)	2 (11.8%)	0
<i>Pseudomonas aeruginosa</i>	0	0	1 (5.8 %)	1 (10%)

CLS: Conventional laparoscopic surgery, NOSE: Natural orifice specimen extraction.

Table 5. Complications and its description according to Clavien-Dindo scale.

	CD I	CD II	CD IIIb
NOSE	Three patients with microperforations of bowel detected that resolved with conservative treatment	-	One patient with a sigmoid colon injury that led to peritonitis and required anastomosis. Initially made anastomosis was intact
CLS	-	One patient with initial anastomosis stenosis. Bougienage was indicated but anecdotal resolution of stenosis was found after anaesthesia (probably due to bowel relaxation and functional nature of stenosis)	One patient with a small bowel anastomosis failure. Combined procedure was initially performed. Re-laparotomy was required to fix anastomosis failure

CD: Clavien-Dindo.

Discussion

Main Findings

The NOSE technique for excising colorectal endometriosis appears to be as safe and efficacious as the conventional CLS approach. Moreover, the procedure time is shorter. Inflammatory markers and bacterial cultures did not suggest a higher risk of intra-abdominal septic complications.

Strengths and Limitations

Our study has some limitations including its retrospective and observational design, that introduces the risks of recall and selection bias. Moreover, the NOSE technique was introduced to our centre later than CLS, raising the possibility of proficiency bias. Procedures were dispersed in time which could cause bias due to surgeon’s skills evolution and changes in the operating team experience. Generalisability is an issue also as all procedures were performed by a single surgeon in a single centre.

Strengths and Limitations Compared to Other Studies

Our results are consistent with previous studies that show that outcomes of colorectal endometriosis surgical treatment might be associated with technique used. A retrospective cohort study³⁴ comparing two methods of specimen extraction during colorectal resection for endometriosis: transvaginal removal and suprapubic removal showed that there were no statistically significant differences in the incidence of postoperative complications including rectovaginal fistulas between the groups. Another Russian retrospective single centre study showed no differences between two types of procedures, although there were some better pain outcomes (according to VAS scale) and cosmetic abdominal wall appearance after NOSE procedure.³⁵ It is consistent with the results of some other studies.³⁶

Other authors have previously demonstrated the efficacy and safety of NOSE (transvaginal and transrectal) in DE patients.^{37,38} These findings are also confirmed by a more recent study.³⁹ Our study showed

the same rate of intra- and postoperative complications when using classic mini-laparotomy access and NOSE. Relatively small difference in long-term outcomes was also previously shown³⁷ as well as in the duration of the procedure and hospital stay. Our study showed the same mean procedure time but slightly prolonged hospital stay in NOSE group. This implies that NOSE, being a novel technique, can attain comparable results with well-established CLS.

Clinical and Policy Implications

The NOSE technique should be considered for excision of colorectal endometriosis. The CLS technique also has disadvantages: histological material (bowel segment) is extracted extracorporeally which in turn increases the risk of infectious complications and, as above-mentioned severe pain in the postoperative period, requiring more frequent use of analgesics and narcotics. Hernia formation should also be considered as it is a well-known complication of compromising the abdominal wall integrity. There are also risks of anastomosis failure due to the T-shaped line in the area of the circular suture. Still, in our work, we did not encounter such complications. However, duration of recovery period and the physical promotion of patients were longer in the CLS group compared to NOSE, and more postoperative analgesia was required for pain relief, especially after mobilisation of patients. The absence of greater skin incision also eliminates some instruments and suturing, along with no need for stapler use. All the above suggests better cost effect provided by NOSE technique, making this potentially useful in less well-resourced centres.

Unanswered Questions and Future Research

The NOSE technique for colorectal endometriosis surgical treatment has two obvious advantages –no need for mini-laparotomy and hence shorter procedure duration. When performed mini laparotomy inevitably takes more operative time in OR and is associated with wound issues, longer recovery and need for suture integrity control. Although we didn't find any significant differences in complication rate and pain dynamics, it only proves comparability of NOSE with well-established conventional laparoscopic surgery.

The technique can be proposed as an efficient method for surgical treatment in patients with colorectal endometriosis. This may be one of the directions of further research and development of surgical techniques

in such patients. Larger, randomised, blinded studies are necessary to provide evidence to be more affirmative about the method.

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Informed consent: Retrospective design doesn't suggest informed consent to use patient's data for specific research, although routine consent to process any personal data before surgery was taken.

Data sharing: Data does not compromise any ethical standards or legal requirements and has no restrictions for access but intended to be shared solely with Facts, View and Vision in ObGyn journal.

Transparency: The manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Music and oral premedication for pain management during outpatient hysteroscopy: results from a randomised controlled trial

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ABSTRACT

Background: Outpatient hysteroscopy is a common procedure, but pain can lead to failure and poor patient experience, especially in women without previous vaginal delivery and postmenopausal women.

Objectives: To compare the use of music during outpatient hysteroscopy with oral pre-procedural analgesia or no pain control intervention on perioperative and postoperative pain.

Methods: A randomised controlled trial was conducted at the outpatient hysteroscopy service of the University of Cagliari between December 2024 and June 2025. Women undergoing outpatient hysteroscopy were allocated to a music group (pre-defined instrumental relaxing music without lyrics, delivered through a Bluetooth speaker throughout the procedure), an oral premedication analgesia group (ibuprofen 200 mg + paracetamol 1000 mg, 90 min pre-procedure), or a control group (no pre-pharmacological or music-based analgesic support). A 5-mm hysteroscope and standardised vaginoscopic "no-touch" technique were used.

Main Outcome Measures: The primary outcome was maximum pain on a 0–10 visual analogue scale (VAS) intraoperatively (T0) and 30 minutes post-procedure (T1). Secondary outcomes included operative time, successful procedural completion, and complications. A pre-specified subgroup analysis was performed to explore potential treatment-by-previous vaginal delivery status (no previous vaginal delivery vs. women with a previous vaginal delivery) and menopausal status (reproductive age vs. menopause) interactions.

Results: Two hundred sixty-four women were randomised; 88 to intra-procedural music, 89 to pre-operative analgesia, and 87 to no pain control intervention. Peak intraoperative pain did not differ across groups (VAS mean \pm standard deviation: 3.4 ± 1.0 in the music group, 3.5 ± 1.45 in the oral premedication group, and 3.6 ± 0.9 in the control group; $P=0.35$). Post-procedural pain at 30 minutes was also similar across groups (1.5 ± 1.4 , 1.5 ± 1.5 , and 1.7 ± 1.1 , respectively; $P=0.24$). Operative time was comparable across groups (mean: 3.2, 3.1, and 3.2 minutes; $P=0.13$). Procedure completion rates did not differ between groups ($P=0.62$), and no complication rates or drug-related adverse events were observed. In exploratory analyses across the overall cohort, women with no previous vaginal delivery ($n=82$) reported higher intra-procedural pain scores than women with a previous vaginal delivery ($n=182$) (VAS 4.1 ± 0.9 vs 3.2 ± 0.9 ; $P=0.032$). Similarly, postmenopausal women ($n=76$) reported higher pain scores than women of reproductive age ($n=188$) (VAS 4.0 ± 0.9 vs 3.4 ± 0.9 ; $P=0.023$).

Conclusions: The use of intraoperative music or pre-procedural analgesia with oral ibuprofen-paracetamol does not reduce pain compared with standard outpatient hysteroscopy.

What is New? Intraoperative music and oral analgesia during outpatient hysteroscopy are not more effective than standard hysteroscopy for reducing pain associated with outpatient hysteroscopy.

Keywords: Hysteroscopy, outpatient, pain, music therapy, patient experience, premedication

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Introduction

Outpatient hysteroscopy is the gold standard for diagnosing and treating intracavitary uterine pathology, combining feasibility and reproducibility, with a low complication rate.¹⁻³ Avoiding general anaesthesia enables faster recovery, earlier return to daily activities, improved patient satisfaction, and is cost-effective.⁴ Nevertheless, pain during and after the procedure remains a barrier and is associated with incomplete procedures.⁵

Pain perception during outpatient hysteroscopy is multifactorial. The most relevant risk factors include lack of previous vaginal delivery, menopause, cervical synechiae, and prolonged operative time, whereas women with at least one prior vaginal delivery generally tolerate the procedure better.⁶ From a pathophysiological standpoint, intraoperative pain is attributed to uterine contractions triggered by distension of the uterine cavity with saline, while postoperative pain is thought to be related to increased prostaglandin production.⁷

Beyond these biological contributors, psychological factors are clinically relevant: anxiety can reduce pain thresholds and amplify pain perception, which is not purely sensory but also shaped by emotional and cognitive components. Thus, anxiety represents a meaningful patient-related variable that may adversely affect tolerance and overall procedural success.^{8,9}

With the adoption of the vaginoscopic “no touch” technique and the introduction of smaller-caliber hysteroscopes, multiple pharmacological and non-pharmacological interventions have been investigated to mitigate pain during outpatient hysteroscopy. Pharmacological strategies have included opioids (e.g., tramadol), local anaesthetics (e.g., ropivacaine or intrauterine lidocaine), antispasmodics, cervical priming agents (misoprostol or dinoprostone), and non-steroidal anti-inflammatory drugs (NSAIDs).^{10,11} However, a recent Cochrane meta-analysis of 32 randomised controlled trials (RCTs) did not identify a clearly superior pharmacological approach.¹² Non-pharmacological methods have also gained attention, including the vocal–local approach, grounded in empathetic communication and continuous support, as well as stretching, hypnosis, heat application, music, and transcutaneous electrical nerve stimulation.¹³ Nevertheless, the most commonly used approach is vocal local. During the procedure, a nurse, midwife, or resident doctor should provide emotional support to the woman to further reduce the level of anxiety and distract them

from the procedure.¹⁴ In parallel, interest in music as an adjunct has increased, based on its potential to reduce anxiety and modulate pain; its routine use is encouraged in several gynaecological and obstetric settings.^{15,16}

Eventually, evidence remains conflicting, and there is currently no consensus on an optimal pain management strategy for office hysteroscopy (OH). Given the limited comparative literature, we conducted this study to evaluate whether music or oral pre-procedural analgesia provides superior pain control compared with standard care during OH.

Methods

Study Design

A prospective, triple-arm, RCT was conducted at the Hysteroscopy Unit of the University Hospital in Cagliari between December 2024 and June 2025. The study was approved by the Regional Ethics Committee on 25.11.2024 (protocol number: 31891) and conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained for each participant. Women referred for outpatient diagnostic or operative hysteroscopy during the study period were consecutively enrolled in this series and were allocated after baseline data collection. Participants were randomly allocated to the three study groups using a computer-generated randomisation list in Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). The randomisation sequence was generated before patient enrolment and maintained by the study investigators. No block randomisation or stratification was applied. The research coordinators regularly performed data quality control, management, and verification of protocol compliance. Due to the nature of the intervention, blinding participants, care providers, and outcome assessors was not possible.

The patients were randomly allocated to three groups based on the pain-relief method used: the music group, the oral premedication group, and the control group. Oral premedication consisted of ibuprofen 200 mg + paracetamol 1000 mg administered 90 minutes before hysteroscopy. In contrast, women allocated to the music group listened to the same pre-defined instrumental relaxing playlist, without lyrics, delivered through a Bluetooth speaker (JBL GO 3, Harman International Industries, Stamford, CT, USA) placed approximately 1 metre from the examination table, with the volume adjusted to a comfortable level, allowing communication

with the operator during the procedure performed. Patients in the control group did not receive any pharmacological or music-based analgesic support.

All procedures were performed in an outpatient setting using a vaginoscopic “no-touch” technique.³ The same expert gynaecologist performed all hysteroscopies in a dedicated room. A Bettocchi hysteroscope (Karl Storz, Tuttlingen, Germany) with a 30-degree lens and a 5-mm external diameter, featuring an oval profile, was used following the “no touch” approach via vaginoscopy, without the use of a speculum or cervical hook. This system is routinely adopted in our unit because it allows both diagnostic evaluation and minor operative procedures during the same outpatient session while maintaining good optical quality. In reproductive-age patients, procedures were scheduled in the early proliferative phase. Standard saline solution was used as the distension medium, maintaining intrauterine pressure below 80 mmHg and a flow rate of 150 mL/min via a mechanical irrigation system (Endomat, Karl Storz, Tuttlingen, Germany). Before starting the procedure, the following data were recorded and entered into our electronic database: age, body mass index, previous vaginal delivery, menopausal status, past medical and surgical history, ongoing medical treatments, allergies, indication for outpatient hysteroscopy, and ultrasound findings. Diagnostic hysteroscopy was defined as a visual assessment alone without additional intervention. For data analysis, procedures requiring an endometrial biopsy for diagnostic indications were classified as operative hysteroscopies.

Primary outcomes were intraoperative pain (T0) and post-procedural pain (T1), measured using a 0–10 visual analogue scale (VAS). Intraoperative pain (T0) was recorded immediately after completion of the hysteroscopic procedure, while post-procedural pain (T1) was assessed 30 minutes after completion. VAS scores were collected in the presence of the investigators, who provided standardised instructions without influencing patient responses. Secondary outcomes included operative time, procedure completion rate, and complication rate. We considered the operative time from the entry of the hysteroscope into the external cervical orifice till its exit from the cervix. The procedure was recorded as “failed” when it was impossible to complete because of the pain due to severe cervical canal stenosis requiring mechanical dilatation under general anaesthesia. These patients were excluded from statistical analysis.

Inclusion and Exclusion Criteria

We considered the following inclusion criteria: patients over 18 years old; traditional indications for outpatient hysteroscopy (abnormal uterine bleeding, infertility, suspected intrauterine pathologies, endometrial thickness over 4 mm on sonographic evaluation in postmenopausal women); ability to make a voluntary decision to participate; and ability to sign consent after being properly informed. The patient’s exclusion criteria were allergy or other contraindications to administering analgesic drugs used in the study, any contraceptive (oral, vaginal, intrauterine, dermal, or subcutaneous) because they would confound the study, the use of any analgesic for other pathologies and presenting any disease or disability that may intervene in the aim of this study (any auditory or sensory deficits, diseases or mental syndromes that could make the study difficult or impossible to complete). Before the procedure, all participants were specifically asked whether they had taken any analgesic medication prior to attending the appointment.

Subgroup Analysis

A prespecified subgroup analysis was performed to explore differences in pain by previous vaginal delivery status (women without previous vaginal delivery vs. women with a previous vaginal delivery) and menopausal status (reproductive age vs. menopause). Previous vaginal delivery was defined as at least one previous vaginal birth of a viable pregnancy, while menopausal status was determined clinically and by medical history. Intra-procedural pain scores (VAS at T0) were compared between subgroups across the overall cohort. Because no formal sample size calculation was performed and the trial was not powered for subgroup comparisons, these analyses are exploratory and are reported as mean \pm standard deviation with unadjusted *P* values.

Statistical Analysis

The independent-samples t-test was used to assess statistical significance, along with Fisher’s exact test and the chi-square test when appropriate. A Kruskal-Wallis test was performed to compare the three groups. $P < 0.05$ was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics (version 29.0; IBM Corp., Armonk, NY, USA). This exploratory randomised trial was conducted on a convenience sample of consecutive eligible women during the study period; no formal sample size calculation was performed.

Results

During the study period, 293 women of Caucasian ethnicity underwent hysteroscopy at our outpatient hysteroscopy service of the University of Cagliari and were considered eligible for enrollment. After applying exclusion criteria, only 264 patients were included in the analysis. They were divided as follows: control group (n=87), oral premedication group (n=89), and music group (n=88), as shown in Figure 1. None reported the use of additional analgesics on the day of the procedure.

Demographic characteristics were comparable among the three groups, and no differences were observed for the type of surgery (diagnostic or operative) ($P>0.05$) (Table 1).

The most common hysteroscopy indication was the suspicion of intrauterine lesions at ultrasound examination (143/264; 54%), followed by evaluation for abnormal uterine bleeding (70/264; 27%), infertility work-up (48/264; 18%), and intrauterine device displacement (3/264; 1%).

Endometrial polyps were treated in 18 patients (music n=8, oral premedication n=5, control n=5), with a mean polyp size of 19 ± 5.1 mm. Endometrial biopsies were performed in 56 patients (music n=17, oral

premedication n=20, control n=19). The remaining 10 operative procedures consisted of minor targeted interventions (removal of small intracavitary lesions and adhesiolysis) and were similarly distributed among the groups. The distribution of operative procedures was comparable across groups. None of the women enrolled in the study suffered intraoperative complications or experienced vasovagal reactions, and no women in the oral premedication group suffered from medication-related side effects (nausea, rash, tachycardia, or hypotension). The overall mean operative time was 3.2 minutes, with no differences among groups ($P>0.05$). No statistically significant differences were found in the procedure success rate by pain-relieving method ($P=0.62$), with pain being the most common cause of failure, followed by severe stenosis of the cervical canal requiring mechanical dilation under general anaesthesia. Primary and secondary outcomes by treatment group are summarised in Table 2. There were no between-group differences in operative time, complication rate, or mean pain scores at either time point (T0 and T1), consistent with the overall analyses (T0 $P=0.35$; T1 $P=0.24$). The three groups showed similar results for the primary outcome of the study, with no statistically significant differences in mean pain scores during the

Table 1. Baseline characteristics of participants.

	Music group (n=88)	Oral premedication group (n=89)	Control group (n=87)	P-value
Age (years)	45.21±7.5	42.96±7.1	43.38±7.6	$P=0.10$
BMI	26.3±1.1	26.5±1.3	26.6±1.3	$P=0.26$
Reproductive status				$P=0.61$
Premenopausal	62/88 (70%)	67/89 (75%)	59/87 (68%)	
Postmenopausal	26/88 (30%)	22/89 (25%)	28/87 (32%)	
Previous vaginal delivery status				$P=0.69$
No previous vaginal delivery	30/88 (34%)	25/89 (28%)	27/87 (31%)	
Previous vaginal delivery	58/88 (66%)	64/89 (72%)	60/87 (69%)	
Indication for outpatient hysteroscopy (%)				$P=0.76$
Intrauterine lesion	52%	57%	55%	
AUB	29%	24%	30%	
Infertility	18%	17%	15%	
IUD displacement	1%	2%	0%	
Type of procedure (%)				$P=0.65$
Diagnostic	57/88 (65%)	61/89 (69%)	62/87 (71%)	
Operative	31/88 (35%)	28/89 (31%)	25/87 (29%)	

AUB: Abnormal uterine bleeding, BMI: body mass index, IUD: Intrauterine device.

procedure and 30 minutes after completion (T0 $P=0.35$; T1 $P=0.24$, respectively), despite the mean pain score being consistently slightly higher in the control group. The VAS score was also comparable between the three groups at stratification for both diagnostic and operative procedures ($P=0.31$ and $P=0.43$, respectively).

Among the 264 women included, the proportion of premenopausal participants did not differ across arms: 70% in the music group arm (62/88), 75% in the oral premedication group arm (67/89), and 68% in the control group arm (59/87). Accordingly, postmenopausal women represented 30%, 25%, and 32% of each group, respectively.

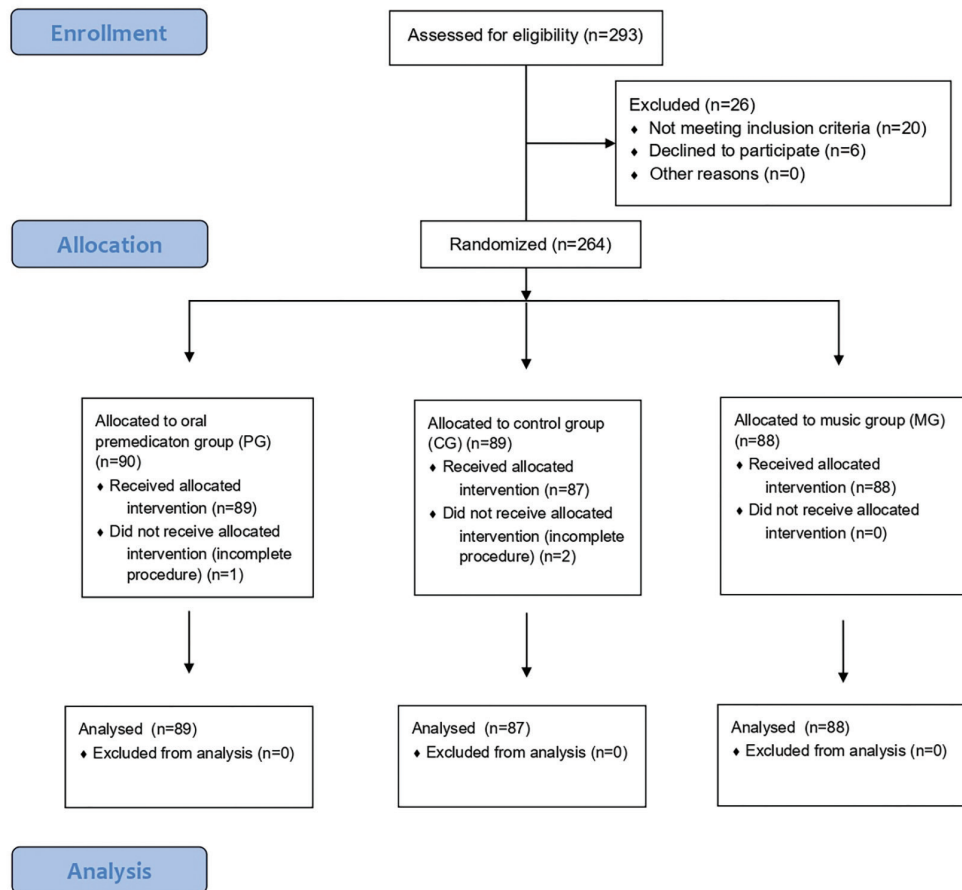


Figure 1. Patient study enrollment, allocation, and analysis.

Table 2. Primary and secondary outcomes.

	Music group (n=88)	Oral premedication group (n=89)	Control group (n=87)	P-value
Operative time (min)	3.2±0.3	3.1±0.5	3.2±0.3	$P=0.13$
Complication rate	0/88 (0%)	0/89 (0%)	0/87 (0%)	$P=1.0$
Mean pain score (VAS)				
T0	3.4±1.0	3.5±1.45	3.6±0.9	$P=0.35$
T1	1.5±1.4	1.5±1.5	1.7±1.1	$P=0.24$
Mean pain score (VAS)				
diagnostic	3.3±1.4	3.4±1.3	3.2±1.3	$P=0.31$
operative	3.6±1.6	3.6±1.6	3.8±1.5	$P=0.43$

VAS: Visual analogue scale, min: Minute.

Women without previous vaginal delivery ranged from 28% to 34% across groups, while the majority had a previous vaginal delivery (66-72%). No statistically significant differences were observed in these baseline characteristics among the three study arms. Across the overall cohort, women without previous vaginal delivery experienced significantly more pain during outpatient hysteroscopy than women with a previous vaginal delivery (VAS score 4.1 ± 0.9 vs. 3.2 ± 0.9 , respectively; $P=0.032$), as illustrated in Figure 2A. This difference was not observed

30 minutes after the procedure, when pain scores were comparable between the two groups (VAS score 1.5 ± 1.2 vs. 1.4 ± 1.1 ; $P>0.05$; Figure 2B). Regarding reproductive status, Figure 2C shows that postmenopausal women reported moderately higher intra-procedural pain scores than those of reproductive age (VAS score 4.0 ± 0.9 vs. 3.4 ± 0.9 , respectively; $P=0.023$), while Figure 2D shows a similar trend at 30 minutes post-procedure, although the difference was not statistically significant.

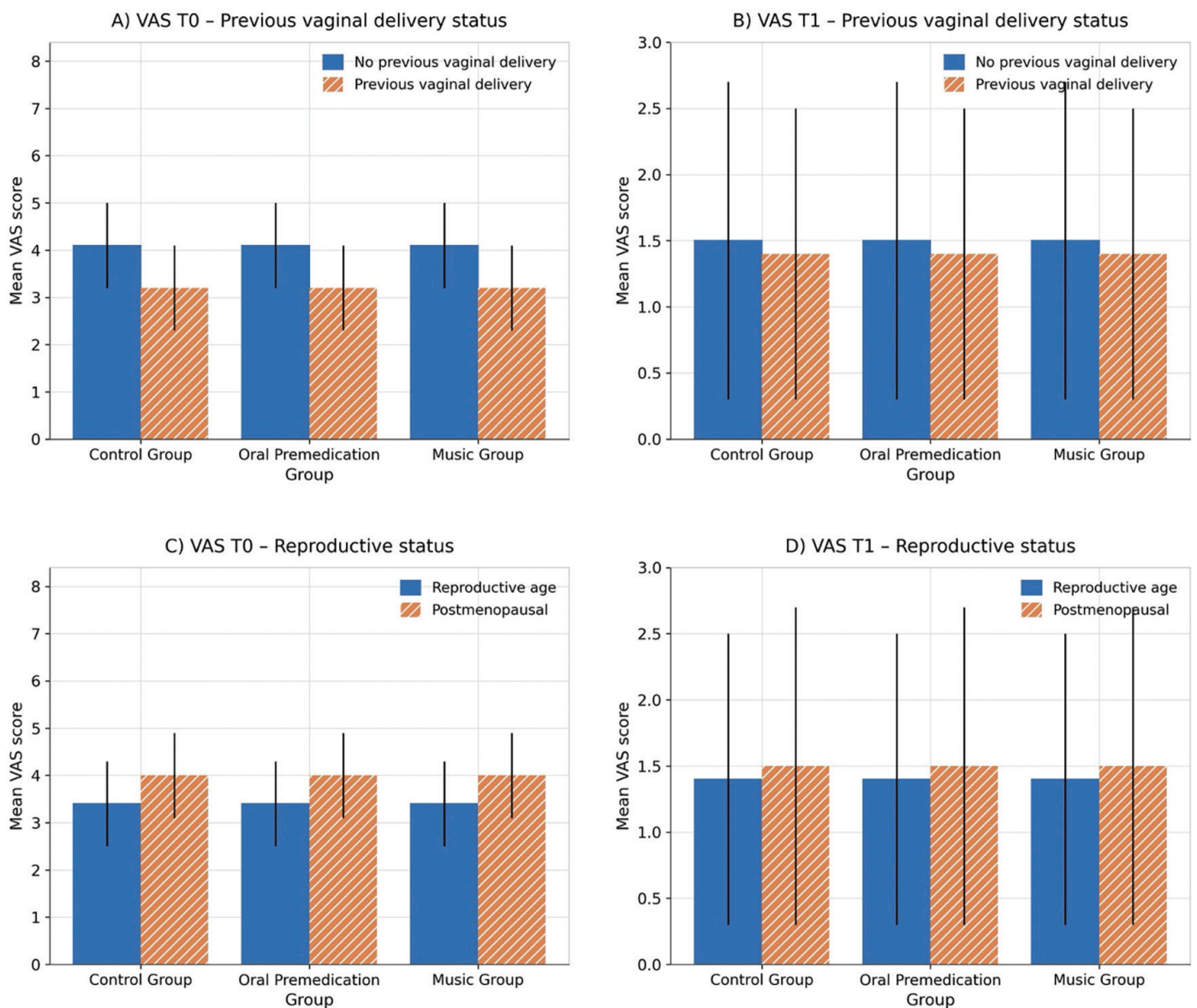


Figure 2. Pain scores (VAS) at T0 (intra-procedural) and T1 (30 minutes post-procedure) by subgroup, across the overall cohort, and independently of treatment allocation. A, B) Women without previous vaginal delivery reported higher pain scores than women with a previous vaginal delivery during the procedure (T0), with no difference 30 minutes after the procedure (T1). C, D) Postmenopausal women reported moderately higher intra-procedural pain scores than women of reproductive age (T0), with a comparable, non-significant trend at 30 minutes (T1). Error bars represent standard deviation.

VAS: Visual analog scale.

Discussion

Main Findings

In this RCT, neither intraoperative music nor oral pre-procedural ibuprofen–paracetamol premedication reduced pain during or after outpatient hysteroscopy when compared with standard care performed using a vaginoscopic technique. Pain scores were low across all groups, and no differences were observed in operative time, complication rates, or procedure completion. Independently of treatment allocation, patient-related factors such as absence of previous vaginal delivery and postmenopausal status were associated with higher intra-procedural pain scores, but no difference in pain scores was observed between purely diagnostic and operative hysteroscopic procedures. The diagnostic and operative approach to the most common intrauterine anomalies has undergone significant changes since the widespread adoption of outpatient hysteroscopy in general gynaecological practice, leading to less invasive procedures. The outpatient setting allows for the management of up to 60–65% of hysteroscopies, with consequent advantages for both clinicians and patients.¹⁷ Despite this technique being considered well tolerated by most women, the pain is still responsible for variable completion rates ranging from 77% to 97%, with conflicting results about the most effective pain-relieving method.¹⁸

For prior oral analgesic medication, we chose ibuprofen and paracetamol because their use, particularly NSAIDs, is recommended by the Royal College of Obstetricians and Gynaecologists.¹⁹ In addition, when compared to other pharmacological drugs such as opioids or local anaesthetics, these molecules are less associated with adverse events, do not require anaesthetic supervision, and are a cheap, non-invasive, and readily available measure. The combined use (or co-administration) of NSAIDs and paracetamol is also reported in the literature, as the latter can exert a synergistic effect in preventing prostaglandin production through a different mechanism of action.²⁰ On the other hand, the effectiveness of music in reducing pain perception has been demonstrated in both postoperative and chronic pain management.^{21,22} More recently, the same results have been observed and proven during outpatient hysteroscopy.^{16,23}

Strengths and Limitations

To our knowledge, this is the first randomised controlled study to directly compare the effects of music and oral

premedication on reducing pain during outpatient hysteroscopy. The study design, a prospective, triple-arm, RCT, provides more data than previous research, which did not directly compare music with prior analgesic medication. Strengths include standardisation of diagnostic and operative procedural approaches across groups and completeness of follow-up. The main limitation of this study relates to the adequacy of the sample, as we did not perform a power calculation. This limits the strength of any clinical recommendations and raises the risk of type II errors, in which negative results are falsely declared. Another limitation is the trial's non-blinded design. This relates to the pain-relieving methods we tested, as they enable patients to identify which group they belong to, which may influence their pain evaluation. Another limitation of this study is that pain intensity measured by the VAS was the only patient-reported outcome collected. Although VAS remains the most widely used measure of procedural pain in outpatient hysteroscopy trials, it does not fully capture the overall patient experience.²⁴ Measures of acceptability, satisfaction, and willingness to undergo repeat hysteroscopy may provide a more comprehensive assessment of procedural tolerance. Future studies should incorporate broader patient-reported outcome measures to better evaluate the overall experience of women undergoing outpatient hysteroscopy. An additional potential limitation concerns the diameter of the hysteroscope used. All procedures were performed with a 5-mm Bettocchi hysteroscope, but smaller-diameter hysteroscopes are increasingly available and may be associated with lower pain perception, particularly in women without previous vaginal delivery and postmenopausal women. Finally, the generalisability of our findings is limited, as all procedures were performed by a single experienced surgeon.

Strengths and Limitations Compared to Other Studies

Our findings regarding the effectiveness of prior oral medication were similar to those reported by Teran-Alonso et al.,²⁵ who found that women who received prior oral analgesia experienced a significant reduction in the occurrence of non-painful hysteroscopic side effects, without any difference in intraoperative or postoperative pain. Regarding postoperative pain evaluation, we hypothesised that the T1-VAS score in the oral premedication group might have been statistically significantly lower, as prostaglandin release and its peak have been associated with delayed pain.

We found no difference among the three groups regarding postoperative pain, and the timing of drug administration could not explain this, as the same results also emerged for administration at 60 and 120 minutes before the procedure.^{25,26}

Conversely, our results for the music group contrast with those reported in the literature. In the study by Law et al.,²³ listening to music during outpatient hysteroscopy was associated with significantly less pain than the standard procedure. The technique used during outpatient hysteroscopy could explain the discrepancies between these results. In the current study, the procedure was performed in all patients using standardised vaginoscopy, providing the least invasive approach possible. At the same time, in the other study, a speculum and tenaculum were used at the surgeon's preference, without stating whether there was any statistically significant difference between the two groups with respect to this variable.

On the contrary, the significantly higher VAS score in the women without a previous vaginal delivery and menopausal subgroup compared to women with a previous vaginal delivery and reproductive age women mirrored the results of several previous published studies.²⁷⁻²⁹ Indeed, our subgroup analysis is consistent with the absence of previous vaginal delivery as a determinant of procedural pain during outpatient hysteroscopy, with women without previous vaginal delivery consistently reporting higher pain levels than women with a previous vaginal delivery. Importantly, these differences emerged across the overall cohort and independently of treatment allocation, since neither music nor premedication reduced pain in the primary analysis. These findings, although exploratory, may inform the design of future trials specifically powered to detect clinically relevant differences within these subgroups.

Clinical and Policy Implications

Our data do not suggest that investment in resources such as music systems or routine use of prior oral administration of ibuprofen and paracetamol is justified to reduce intra- and postoperative pain experienced during outpatient hysteroscopy. However, adoption of recommended approaches to conducting outpatient hysteroscopy, such as the routine use of small-diameter instruments and vaginoscopy, should be encouraged.

Unanswered Questions and Future Research

Further RCTs are needed to evaluate novel pain-controlling interventions to minimize the pain associated

with outpatient hysteroscopy and improve patient experience, with particular attention to higher-risk subgroups such as women without previous vaginal delivery and postmenopausal women.

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Informed consent: Written informed consent was obtained for each participant.

Data sharing: The datasets generated and analyzed during the current study are available from the corresponding author upon reasonable request.

Transparency: The manuscript is an honest, accurate, and transparent account of the study being reported; no important aspects of the study have been omitted; and any discrepancies from the study as planned have been explained.

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“Pocket sign” on hysterosalpingography: an adjunctive imaging finding suggestive of caesarean isthmocele

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ABSTRACT

Caesarean scar defects, known as isthmocele, are increasingly recognized in women with secondary infertility, yet hysterosalpingographic (HSG) criteria remain poorly defined. We describe a reproducible HSG feature, the “pocket sign,” observed in seven women with prior caesarean delivery. This finding appears as contrast pooling in the anterior lower uterine segment near the internal cervical os. In all cases, it correlated with transvaginal ultrasound and hysteroscopic findings. Although non-specific and not diagnostic, the pocket sign may serve as an adjunctive indicator prompting further evaluation. Given anatomical variability and intrinsic limitations of HSG, multimodal imaging remains essential.

Keywords: Caesarean scar defect, isthmocele, hysterosalpingography, uterine niche, infertility, imaging

Introduction

Caesarean scar defects (CSD), also termed isthmocele or uterine niche, are increasingly recognised in women presenting with secondary infertility, postmenstrual spotting, and abnormal uterine bleeding.¹ Transvaginal ultrasound (TVUS), particularly when combined with saline infusion sonohysterography (SIS), is considered the first-line imaging modality due to its accessibility and diagnostic performance.² Hysteroscopy allows direct visualisation and is commonly used for confirmation.³ Hysterosalpingography (HSG), although widely used in infertility work-up, is not a primary diagnostic tool for CSD, and standardised radiographic criteria are lacking. Nevertheless, suggestive radiographic patterns have been described, including variable shapes and locations of contrast pooling within CSDs, albeit without consistent terminology or validation.⁴ In this report, we describe a reproducible HSG feature,

termed the “pocket sign,” and demonstrate its concordance with TVUS and hysteroscopic findings, suggesting a potential adjunctive role in clinical practice.

Methods

This technical report includes data from 7 patients at Centrum Clinic IVF Center, Ankara-Turkey. All had a history of caesarean delivery and underwent HSG during the early follicular phase as part of infertility evaluation. Images were independently reviewed by two experienced observers for the presence of a contrast pooling pattern defined as the “pocket sign.”

HSG was performed using a balloon catheter and water-soluble contrast medium. Fluoroscopic images were obtained during injection and, when feasible, after catheter removal, when contrast retention was more clearly visualised. All patients subsequently underwent TVUS and diagnostic hysteroscopy. Findings were

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compared across modalities to assess concordance. Patients with postmenstrual spotting underwent niche scar revision with a 5-mm mini-resectoscope or a 9-mm standard resectoscope, depending on niche size.

Results

All seven patients presented with secondary infertility; five reported postmenstrual spotting. On HSG, a consistent pattern of contrast pooling was observed in the anterior lower uterine segment, at or around the level of the internal cervical os and in some cases extending

below it into the endocervical canal. This appeared as a shallow recess with bilateral or mildly asymmetric distribution, consistent with the “pocket sign” (Figure 1).

TVUS demonstrated a hypoechoic niche ≥ 2 mm at the caesarean scar site in all cases. Hysteroscopy confirmed a corresponding pouch-like defect in the anterior uterine wall in all patients. Schematic illustration (A) and correlation between imaging modalities, including vaginal sonography (B) and hysteroscopy (C), is shown in Figure 2.

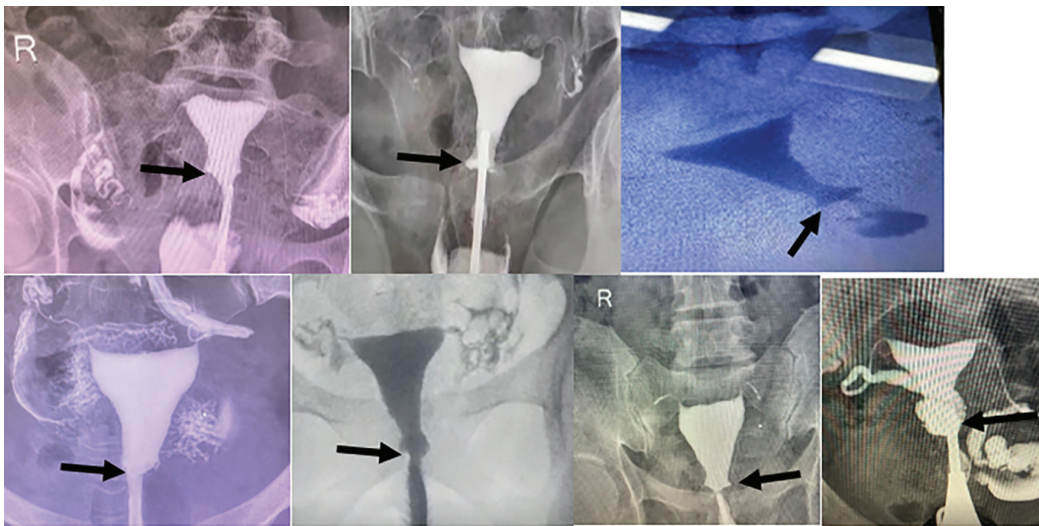


Figure 1. Representative hysterosalpingographic images from seven patients: demonstrating the “pocket sign” (black arrows), characterised by asymmetric contrast pooling in the anterior lower uterine segment at or near the level of the internal cervical os.

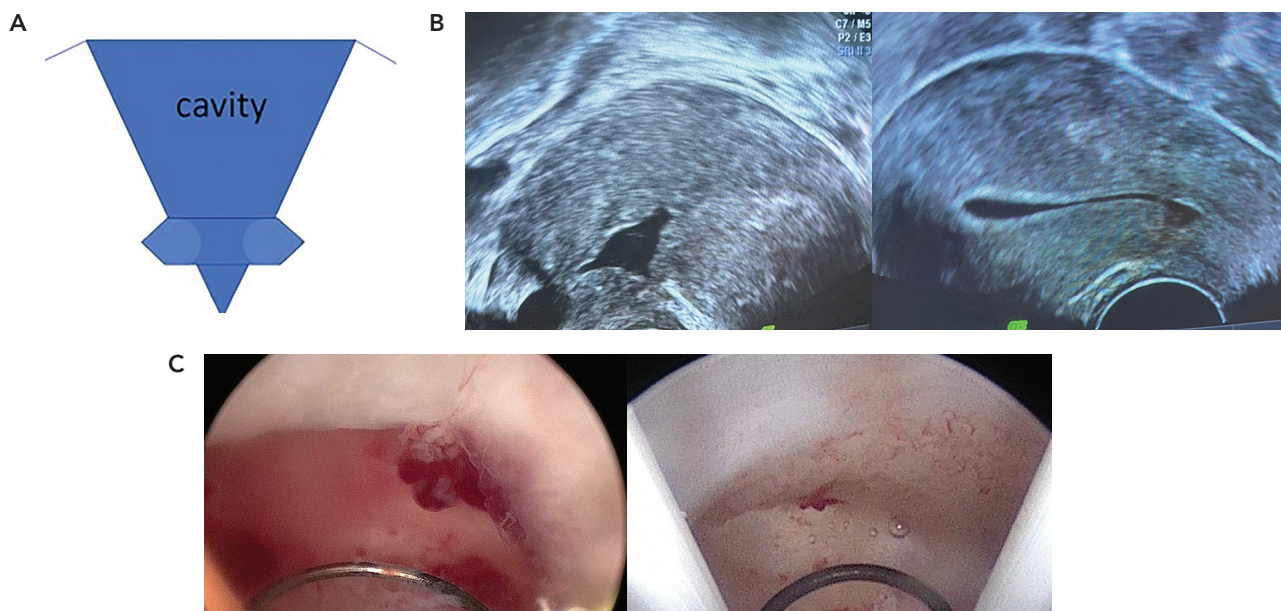


Figure 2. Multimodal correlation of the “pocket sign”: A) Schematic illustration of contrast pooling on hysterosalpingography in the anterior lower uterine segment, at or near the level of the internal cervical os. B) Transvaginal ultrasound images showing a hypoechoic niche. C) Hysteroscopic views demonstrating a pouch-like caesarean scar defect.

Discussion

The “pocket sign” represents a pragmatic HSG feature that may raise suspicion of CSDs during infertility evaluation. Although similar contrast pooling patterns have been previously described,⁴ our findings demonstrate consistent concordance with TVUS and hysteroscopy.

In current clinical practice, TVUS—particularly when combined with SIS—remains the first-line imaging modality due to its superior ability to delineate niche morphology.² SIS has been shown to improve both detection rates and morphological characterisation of CSDs and should be considered when initial imaging findings are inconclusive or suspicious. Within this context, HSG findings should be regarded as adjunctive observations that may prompt further targeted evaluation rather than as primary diagnostic criteria.

CSDs are anatomically heterogeneous and are not confined to the classical isthmic region. They may extend into the endocervical canal, and their variable location, size, and depth can influence their radiographic appearance on HSG. In addition, HSG is inherently limited by its two-dimensional projection and its inability to accurately assess myometrial thickness or defect volume.⁵ Accordingly, the “pocket sign” should not be interpreted as a standalone diagnostic finding.

The clinical relevance of imaging-detected CSDs, particularly in asymptomatic individuals, remains uncertain. Imaging findings alone—especially those from HSG—should not dictate management decisions; instead, management should be individualised based on clinical presentation and reproductive goals.⁶

Finally, given the small sample size and the absence of diagnostic accuracy analysis, the clinical utility and reproducibility of the “pocket sign” require confirmation in larger, prospective studies.

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Transparency: Lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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The Four-Clamp Technique for primary laparoscopic access in morbidly obese patients: a retrospective cohort study

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ABSTRACT

This retrospective, single-centre cohort study evaluated the Four-Clamp Technique for primary laparoscopic access in 45 morbidly obese women (body mass index ≥ 40 kg/m²) undergoing gynaecological procedures at a tertiary centre between January 2015 and August 2025. The technique utilised four symmetrically positioned towel clamps to allow omnidirectional traction to achieve stable abdominal wall elevation before direct trocar insertion. First-attempt success was achieved in 39 (86.7%) of patients, with overall success in 42 (93.3%) women. No major vascular or visceral injuries occurred. Ten (22.2%) minor complications occurred: trocar-site or clamp-site bleeding (4, 8.9%), minor omental injury (3, 6.6%), subcutaneous emphysema (2, 4.4%), and extraperitoneal insufflation (1, 2.2%). Mean time to intraperitoneal access was 74±18 seconds. Target intra-abdominal pressure was maintained at 12–14 mmHg. The Four-Clamp Technique may represent a feasible and reproducible method for primary laparoscopic access in morbidly obese patients in this single-centre cohort; however, prospective comparative studies are warranted to confirm these preliminary findings.

Keywords: Abdominal wall traction, intraoperative complications, laparoscopy, morbid obesity, trocar

Introduction

Safe primary access to the peritoneal cavity represents the most critical step in laparoscopic surgery, yet entry-related complications continue to contribute disproportionately to laparoscopic morbidity. Entry-related injuries occur in 0.02% to 0.64% of procedures but account for up to 17% of perioperative deaths.¹ The 2019 Cochrane systematic review by Ahmad et al.,² analysing 57 randomised controlled trials involving 9,865 participants, concluded that insufficient evidence exists to recommend one entry technique over another, noting that more than 50% of laparoscopic injuries occur during primary access.

These challenges are substantially magnified in morbidly obese patients [body mass index (BMI ≥ 40 kg/m²), who present unique anatomical difficulties fundamentally altering the risk profile of laparoscopic entry. Thick, mobile panniculus obscures anatomical landmarks, substantially increases skin-to-peritoneum distance (often exceeding 10–15 cm vs. 2–4 cm in normal-weight individuals), and diminishes tactile feedback during trocar insertion.³ The considerable weight of redundant abdominal wall compromises effective counter-traction, essential for safe entry in standard-weight patients.⁴

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Traditional access approaches—Veress needle (closed), Hasson (open), and direct trocar insertion (DTI)—each present distinct limitations in obese populations. The Veress needle method relies on blind entry with inherent risk of major vessel or visceral injury. Moreover, traditional confirmation tests for correct needle placement, including the hanging-drop test, saline aspiration-injection test, and opening intra-abdominal pressure measurement, have reduced sensitivity in morbidly obese patients because preperitoneal fat may mimic free peritoneal space, the weight of the panniculus elevates baseline intra-abdominal pressure, and the characteristic tactile feedback is attenuated by thick subcutaneous tissue.⁵ The Hasson approach, whilst providing direct visualisation, is time-consuming and technically challenging due to thick subcutaneous tissue requiring extensive dissection.⁶ Standard DTI avoids pre-insufflation but frequently lacks sufficient control in patients with substantially thickened, mobile abdominal walls.⁷ Optical-access trocar systems offer the theoretical advantage of continuous visualisation during trocar advancement through abdominal wall layers; however, their higher cost limits availability in resource-constrained settings, and adequately powered comparative trials demonstrating consistent superiority over standard DTI in morbidly obese populations are lacking.^{8,9}

Comparative studies have not demonstrated consistent superiority of one method over others, particularly within obese populations, where study enrolment is often limited or excluded entirely.² The paucity of standardised techniques specifically designed for morbidly obese patients represents a critical unmet clinical need.

We developed the Four-Clamp Technique, a standardised DTI modification employing omnidirectional traction via four symmetrically placed towel clamps. This configuration enhances abdominal wall stability and vertical elevation through symmetrical force distribution, maximising the distance between peritoneum and underlying retroperitoneal vascular structures and intraperitoneal viscera whilst mitigating risks of uncontrolled lateral displacement or oblique trocar advancement. We hypothesised that the Four-Clamp Technique would achieve a high rate of successful primary peritoneal access with an acceptable safety profile in morbidly obese patients (BMI ≥ 40 kg/m²), defined as an overall success rate exceeding 90% with no major entry-related vascular or visceral injuries. This study comprehensively evaluates the safety, efficacy, and reproducibility of the Four-Clamp Technique in morbidly obese patients.

Methods

Study Design and Setting

This retrospective cohort study analysed prospectively maintained surgical data from a tertiary academic centre in İstanbul, Turkey, specialising in gynaecological oncology and advanced laparoscopic surgery. The study period extended from January 2015 to August 2025. All procedures were performed by a single surgical team comprising a board-certified gynaecological oncologist with laparoscopic experience. Ethics committee approval was obtained from the Scientific Research Ethics Committee of, University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital prior to data collection (approval number: 2025/010.99/22/34, date: 26.11.2025). All patients gave written consent to the collection of data and surgical data from their operations to be stored in the database and used subsequently for research and publication.

Patient Selection

The study included 45 consecutive morbidly obese women (BMI ≥ 40 kg/m²) who underwent laparoscopic gynaecological procedures using the Four-Clamp Technique for primary peritoneal access. Inclusion criteria comprised women aged ≥ 18 years, BMI ≥ 40 kg/m², American Society of Anaesthesiologists (ASA) physical status I–III, and who underwent laparoscopic gynaecological surgery.

Exclusion criteria included dense periumbilical adhesions from prior midline laparotomy, history of extensive open pelvic operations (≥ 2 previous laparotomies with known intraperitoneal adhesions), previous ventral or incisional hernias at the proposed entry site, coagulopathy (international normalised ratio >1.5 or platelet count $<50,000/\mu\text{L}$), and emergency surgical indications. Patients with prior lower-segment caesarean delivery or prior laparoscopic surgery without clinical or radiological suspicion of periumbilical adhesions were not excluded, as lower transverse incisions typically do not produce significant periumbilical adhesion formation.

The Four-Clamp Technique

Following induction of general anaesthesia with endotracheal intubation and neuromuscular blockade, patients were positioned supine in the dorsal lithotomy position with arms tucked. A urinary catheter was inserted for bladder decompression, and an orogastric or nasogastric tube was placed for gastric decompression.

Abdominal skin was prepared using povidone-iodine solution. A 10–12 mm transverse skin incision was made at either the umbilical or supraumbilical (Lee-Huang point) midline location, selected according to uterine size, panniculus distribution, and estimated abdominal wall thickness. The incision was carried through the skin and subcutaneous tissue. The technique employs omnidirectional traction via four symmetrically positioned towel clamps to achieve stable abdominal wall elevation before DTI. Clamps grasped the full-thickness abdominal wall, creating a square configuration around the entry site at approximately 3–4 cm from the incision in each cardinal direction (Figure 1). The surgical assistant and the surgeon simultaneously and forcefully elevated four clamps perpendicular (90 degrees) to the operating table surface. This manoeuvre was performed with a sustained, strong upward force to achieve maximal tissue tension and maximal distance between the peritoneum and the underlying viscera. Elevation was maintained consistently throughout trocar insertion.

Whilst maintaining maximum upward traction, a 10 mm or 12 mm sharp, non-optical, disposable trocar with a pyramidal tip was inserted with perpendicular pressure to the elevated abdominal wall using a single,

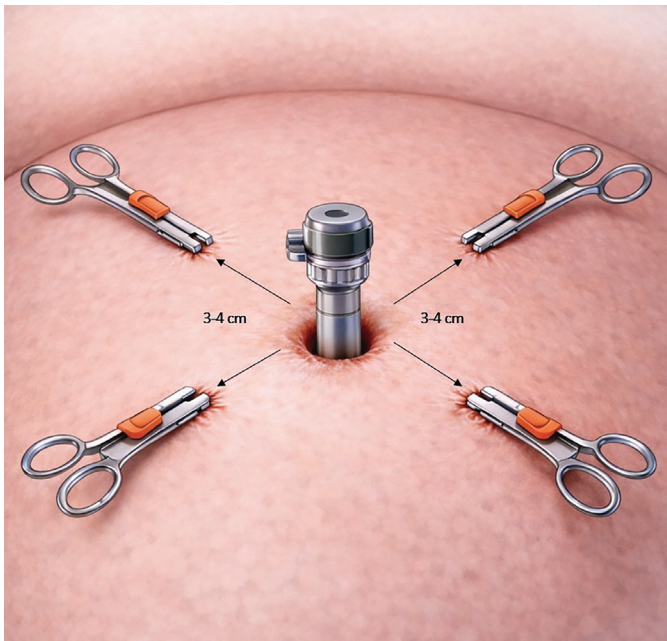


Figure 1. Schematic illustration of the Four-Clamp Technique. Four towel clamps are placed in a square configuration at approximately 3–4 cm from the entry incision in each cardinal direction, grasping the full-thickness abdominal wall. Omnidirectional traction vectors (arrows) demonstrating simultaneous perpendicular elevation by the surgeon and assistant. Perpendicular trocar insertion through the elevated, taut abdominal wall with a stable tissue platform.

controlled, by rotating left and right motion. The surgeon maintained continuous tactile feedback throughout insertion, assessing a composite of indicators including a perceptible reduction in tissue resistance, the presence of fascial or peritoneal penetration sensation (the characteristic “two-pop” representing sequential breach of rectus fascia and peritoneum), and the depth of trocar insertion relative to the estimated abdominal wall thickness.

Upon the surgeon’s assessment that peritoneal entry had likely occurred—based on the composite tactile indicators described above—trocar advancement was halted, the trocar obturator was removed, and a 10 mm 30-degree rigid laparoscope was inserted through the trocar sleeve for direct visual confirmation of intraperitoneal placement. The correct position was confirmed by direct visualisation of intra-abdominal viscera (omentum, bowel serosa, or uterine fundus). If preperitoneal or extraperitoneal placement was identified, the trocar was either advanced cautiously under direct vision or redirected. The laparoscopic camera was swept through 360 degrees to inspect for immediate complications. Only after direct visual confirmation was pneumoperitoneum established using CO₂ insufflation at an initial flow rate of 1–2 L/min, gradually increased to 4–6 L/min to achieve the target intra-abdominal pressure of 12–14 mmHg (Video 1).

Ancillary Port Placement

All subsequent trocars were placed under direct laparoscopic visualisation. A standard triangular configuration was employed, consisting of two lateral 5 mm ports placed in the bilateral lower quadrants at or lateral to the inferior epigastric vessels. When dictated by surgical complexity, an additional 5 mm or 10–12 mm port was placed in the suprapubic midline or contralateral upper quadrant. Port-site selection was adjusted intraoperatively to accommodate panniculus position and ensure optimal instrument triangulation, particularly in the presence of a thick, overhanging panniculus.

Outcome Measures

Primary Outcomes

1. First-attempt success rate: Successful intraperitoneal access achieved on initial trocar insertion with direct laparoscopic confirmation.
2. Overall success rate: Successful access achieved within two attempts using the Four-Clamp Technique

Conversion to alternative entry technique: abandonment of the technique after two unsuccessful attempts.

3. Major complications: Major vascular injury (aorta, inferior vena cava, iliac vessels, requiring repair) or visceral injury (bowel perforation, liver laceration, splenic injury requiring intervention).

Secondary Outcomes

1. Time to intraperitoneal access: Measured from skin incision to achievement of direct visual confirmation of intraperitoneal placement.
2. Minor complications: Trocar-site bleeding not requiring intervention beyond local pressure or cautery, subcutaneous emphysema, extraperitoneal insufflation, minor omental injury, localised clamp-site haematoma.
3. Postoperative entry-site complications within 30 days: Wound infection, fascial dehiscence, incisional hernia.

All complications were classified using the Clavien-Dindo system, with major complications defined as grade III or higher.¹⁰

Data Collection and Statistical Analysis

Data were extracted from electronic health records. Statistical analyses were performed using IBM SPSS Statistics version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables with normal distribution were presented as mean \pm standard deviation, whilst non-normally distributed variables were presented as median (interquartile range). Normality was assessed using the Shapiro-Wilk test and visual inspection of histograms. Categorical variables were presented as absolute counts and percentages. Success rates and complication rates were calculated with 95% confidence intervals (CIs) using the Wilson score method. Stratified analyses by BMI subcategory and prior surgical history were performed using Fisher's exact test, given the small, expected cell counts. A two-sided *P* value <0.05 was considered statistically significant.

Results

Patient Characteristics

Forty-five morbidly obese women underwent laparoscopic gynaecological procedures using the Four-Clamp Technique between January 2015 and August 2025. Mean age was 46.8 ± 9.2 years, and mean BMI was

43.9 ± 3.8 kg/m². The majority (84.4%) had class III obesity (BMI: 40.0–49.9 kg/m²), 13.3% had super obesity (BMI: 50.0–59.9 kg/m²), and 2.2% had super-super obesity (BMI ≥ 60.0 kg/m²). Fourteen patients (31.1%) had previous abdominal surgery, including eight with prior caesarean section. Sixty per cent presented with at least one medical comorbidity, most commonly hypertension (35.6%) and type 2 diabetes mellitus (24.4%). ASA classification was II in 62.2% and III in 37.8%. Surgical indications comprised benign gynaecological disease in 68.9% and malignant disease in 31.1%. The primary entry site was umbilical in 28 patients (62.2%) and supraumbilical (Lee-Huang point) in 17 patients (37.8%). Baseline, demographic and clinical features characteristics are provided in Table 1.

Specific surgical indications comprised total laparoscopic hysterectomy with or without bilateral salpingo-oophorectomy for leiomyoma or abnormal uterine bleeding ($n=14$, 31.1%), laparoscopic bilateral salpingo-oophorectomy for adnexal masses ($n=7$, 15.6%), laparoscopic hysterectomy for endometrial hyperplasia ($n=5$, 11.1%), laparoscopic surgery for endometriosis ($n=3$, 6.7%), diagnostic laparoscopy ($n=2$, 4.4%), comprehensive surgical staging for endometrial cancer ($n=10$, 22.2%), laparoscopic staging or interval debulking for ovarian malignancy ($n=3$, 6.7%), and laparoscopic radical hysterectomy for cervical cancer ($n=1$, 2.2%) (Table 1).

Primary Outcomes

First-attempt success was achieved in 39 of 45 patients (86.7%; 95% CI: 73.2–94.5%). Among the six patients where the initial attempt was unsuccessful, contributing factors included extreme supraumbilical adiposity with difficulty achieving adequate tissue tension ($n=3$), thick fibrotic subcutaneous tissue impeding clamp placement ($n=2$), and technical difficulty with assistant coordination ($n=1$). Three of these six patients (50%) achieved successful access on the second attempt, yielding an overall cumulative success rate of 93.3% (42/45; 95% CI: 81.7–98.1%). Primary outcome measures specifications are provided in Table 2. The two-pop sensation was not uniformly perceptible; among successful cases, a clearly discernible two-pop was reported in 71.4%, an attenuated or single-pop sensation in 19.0%, and absent or equivocal tactile feedback in 9.5%. Mean trocar insertion depth from skin surface to peritoneal entry was 9.4 ± 2.8 cm, reflecting the substantially increased skin-to-peritoneum distance characteristic of morbid obesity.

Table 1. Baseline demographic and clinical characteristics (n=45).

Characteristic	Value
Age (years), mean ± SD	46.8±9.2
BMI (kg/m²), mean ± SD	43.9±3.8
BMI category, n (%)	
Class III obesity (BMI: 40.0-49.9)	38 (84.4)
Super obesity (BMI: 50.0-59.9)	6 (13.3)
Super-super obesity (BMI ≥60.0)	1 (2.2)
Parity, median (range)	2 (0-5)
Previous abdominal surgery, n (%)	
Previous caesarean section only	8 (17.8)
Previous benign gynaecologic surgery	4 (8.9)
Previous laparoscopy	2 (4.4)
Comorbidities, n (%)	
Any comorbidity	27 (60.0)
Hypertension	16 (35.6)
Type 2 diabetes mellitus	11 (24.4)
Cardiovascular disease	4 (8.9)
Chronic pulmonary disease	3 (6.7)
Multiple comorbidities (≥2)	9 (20.0)
ASA classification, n (%)	
ASA II	28 (62.2)
ASA III	17 (37.8)
Primary entry site, n (%)	
Umbilical	28 (62.2)
Supraumbilical (Lee-Huang point)	17 (37.8)
Surgical indication, n (%)	
Benign gynaecologic disease	31 (68.9)
TLH ± BSO for leiomyoma/AUB	14 (31.1)
Laparoscopic BSO for adnexal mass	7 (15.6)
Laparoscopic hysterectomy for endometrial hyperplasia	5 (11.1)
Laparoscopic surgery for endometriosis	3 (6.7)
Diagnostic laparoscopy	2 (4.4)
Malignant disease (staging/cytoreduction)	14 (31.1)
Surgical staging for endometrial cancer	10 (22.2)
Staging/debulking for ovarian malignancy	3 (6.7)
Radical hysterectomy for cervical cancer	1 (2.2)
Haemoglobin (g/dL), mean ± SD	12.4±1.6

SD: Standard deviation, BMI: Body mass index, ASA: American Society of Anaesthesiologists, TLH: Total laparoscopic hysterectomy, BSO: Bilateral salpingo-oophorectomy, AUB: Abnormal uterine bleeding.

Table 2. Primary outcome measures (n=45).

Outcome	n (%)	95% CI
First-attempt success	39 (86.7)	73.2-94.5
Second-attempt success*	3/6 (50.0)	18.8-81.2
Overall success (≤2 attempts)	42 (93.3)	81.7-98.1
Conversion to an alternative technique	3 (6.7)	1.9-18.3

*Among the 6 patients who had an unsuccessful first attempt. CI: Confidence interval.

Three patients (6.7%; 95% CI: 1.9–18.3%) required conversion to alternative entry methods following two unsuccessful attempts. In two patients, conversion to the left upper quadrant Palmer’s point using the Veress needle technique was successfully performed. In one patient with extreme central adiposity and redundant panniculus, conversion to the open Hasson technique at the same umbilical site entry was utilised. All three conversions ultimately achieved safe peritoneal access without complications.

Stratified Analysis

When stratified by obesity subclass, first-attempt success was 89.5% (34/38) among patients with Class III obesity (BMI: 40.0–49.9 kg/m²), 66.7% (4/6) among patients with super obesity (BMI: 50.0–59.9 kg/m²), and 100% (1/1) in the single patient with super-super obesity (BMI ≥60 kg/m²). Overall success rates were 94.7% (36/38), 83.3% (5/6), and 100% (1/1), respectively. When stratified by prior abdominal surgical history, patients without prior surgery (n=31) demonstrated first-attempt and overall success rates of 90.3% (28/31) and 96.8% (30/31), respectively, compared with 78.6% (11/14) and 85.7% (12/14) among patients with prior surgery (n=14). These differences did not reach statistical significance (Fisher’s exact test, P=0.35 for first-attempt success; P=0.20 for overall success), consistent with the limited statistical power of the study (Table 3).

Safety Outcomes

No major vascular injuries occurred throughout the study period, including injuries to the aorta, inferior vena cava, common iliac vessels, or external iliac vessels. No visceral injuries were observed, including bowel perforations or solid organ injuries. No patients experienced gas embolism, and there were no perioperative deaths.

Minor complications were limited to localised bleeding at clamp sites or trocar sites, occurring in four patients (8.9%; 95% CI: 3.5–20.7%). Two cases of subcutaneous

Table 3. Stratified analysis of outcomes by BMI category and prior surgical history.

Subgroup	n	First-attempt success, n (%)	Overall success, n (%)	Conversion, n (%)
BMI category				
Class III obesity (40.0–49.9 kg/m ²)	38	34 (89.5)	36 (94.7)	2 (5.3)
Super obesity (50.0–59.9 kg/m ²)	6	4 (66.7)	5 (83.3)	1 (16.7)
Super-super obesity (≥60.0 kg/m ²)	1	1 (100)	1 (100)	0 (0)
P value (Fisher’s exact)		0.32	0.47	
Prior abdominal surgery				
No prior surgery	31	28 (90.3)	30 (96.8)	1 (3.2)
Prior surgery	14	11 (78.6)	12 (85.7)	2 (14.3)
P value (Fisher’s exact)		0.35	0.20	

BMI: Body mass index.

emphysema, one case of extraperitoneal insufflation and three cases of clinically insignificant omental injury were documented. The total minor complication rate was 22.2% (10/45). Within a 30-day follow-up, two cases of wound infections occurred, but there were no reported fascial dehiscence, or incisional hernias (Table 4).

Procedural Efficiency

Among the 42 patients who achieved successful entry with the Four-Clamp Technique, the mean time from skin incision to direct visual confirmation of intraperitoneal placement was 74±18 seconds (median 72 seconds; range: 52–121 seconds). The majority (88%) achieved intraperitoneal access within 90 seconds. Time to intraperitoneal access did not significantly correlate with BMI (P=0.26).

All 45 patients successfully proceeded with the intended definitive laparoscopic procedures after achieving

Table 4. Complication profile (n=45).

Complication category	n (%)
Minor complications	10 (22)
Trocar-site/clamp-site bleeding	4 (8.9)
Subcutaneous emphysema	2 (4.4)
Extraperitoneal insufflation	1 (2.2)
Omental injury (minor)	3 (6.6)
Postoperative entry-site complications (30 days)	2 (4.4)
Wound infection	2 (4.4)
Fascial dehiscence	0 (0)
Incisional hernia	0 (0)

Major complications were defined as major vascular injury (aorta, vena cava, or iliac vessels), visceral injury (bowel), solid organ injury (liver or spleen), gas embolism, or mortality. No major complications occurred in this study.

peritoneal access. Mean total operative time was 118±34 minutes, mean estimated blood loss was 145±78 mL, and mean length of hospital stay was 2.1±0.8 days.

Postoperative Histopathological Findings

Postoperative histopathological diagnoses are detailed in Table 5. Among malignant cases (n=14), the most common diagnosis was endometrioid adenocarcinoma of the endometrium (n=9, comprising International Federation of Gynaecology and Obstetrics (FIGO)

Table 5. Postoperative histopathological diagnoses (n=45).

Diagnosis	n (%)
Benign (n=31)	
Uterine leiomyoma	12 (26.7)
Endometrial hyperplasia without atypia	3 (6.7)
Endometrial hyperplasia with atypia	2 (4.4)
Mature cystic teratoma	3 (6.7)
Serous cystadenoma	2 (4.4)
Mucinous cystadenoma	2 (4.4)
Endometrioma	3 (6.7)
Chronic salpingitis	2 (4.4)
Normal pelvic findings	2 (4.4)
Malignant (n=14)	
Endometrioid adenocarcinoma, FIGO Grade 1	4 (8.9)
Endometrioid adenocarcinoma, FIGO Grade 2	3 (6.7)
Endometrioid adenocarcinoma, FIGO Grade 3	2 (4.4)
Uterine serous carcinoma	1 (2.2)
High-grade serous ovarian carcinoma	2 (4.4)
Borderline mucinous ovarian tumour	1 (2.2)
Squamous cell carcinoma of the cervix	1 (2.2)

FIGO: International Federation of Gynaecology and Obstetrics.

Grade 1 in four, FIGO Grade 2 in three, and FIGO Grade 3 in two patients), followed by uterine serous carcinoma (n=1), high-grade serous ovarian carcinoma (n=2), borderline mucinous ovarian tumour (n=1), and squamous cell carcinoma of the cervix (n=1). The predominance of endometrial carcinoma in this cohort is consistent with the well-established epidemiological association between morbid obesity and endometrial malignancy. Among benign cases (n=31), the most common pathological findings were uterine leiomyomata (n=12), endometrial hyperplasia without atypia (n=3) or with atypia (n=2), benign ovarian cysts including mature cystic teratoma (n=3), serous cystadenoma (n=2), and mucinous cystadenoma (n=2), endometriomas (n=3), chronic salpingitis (n=2), and normal pelvic findings at diagnostic laparoscopy (n=2).

Discussion

This study presents a single-centre experience with a standardised modification of DTI tailored for morbidly obese patients undergoing laparoscopic surgery. The Four-Clamp Technique achieved a 93.3% overall success rate without major entry-related complications, providing clinically relevant descriptive data supporting the feasibility of a modified DTI approach in this high-risk population. However, due to the retrospective design and absence of a concurrent control group, these findings should be interpreted as observational benchmarks rather than evidence of superiority.

The abdominal wall in morbidly obese patients presents complex biomechanical challenges beyond increased thickness alone. These include excessive subcutaneous adipose tissue, a mobile and redundant panniculus obscuring anatomical landmarks, distortion of normal tissue planes, and reduced effective counter-traction due to tissue mobility.¹¹ Collectively, these factors limit control during trocar advancement and may reduce the safety margin between the advancing trocar tip and intra-abdominal or retroperitoneal structures.

A recent systematic review emphasised the limited evidence available for laparoscopic entry in high-BMI patients, noting that most studies excluded this population.² The review concluded that current data are insufficient to determine differences in rates of vascular injury, visceral injury, or failed entry between techniques, with overall evidence graded as very low quality.

The Four-Clamp Technique was designed to help mitigate these biomechanical limitations through balanced,

omnidirectional traction using four-point fixation. In contrast to single- or dual-clamp approaches,¹² which provide limited directional lift and may allow lateral tissue displacement, the four-clamp configuration stabilises the abdominal wall by distributing tension across quadrants. This creates a taut operative field, increases the perpendicular skin-to-peritoneum distance, constrains lateral movement, facilitates a controlled perpendicular trocar trajectory, and distributes mechanical stress more evenly.

The observed first-attempt success rate (86.7%) and overall success rate (93.3%) are consistent with previously reported outcomes for DTI in obese populations. Ikechebelu et al.¹³ demonstrated comparable success rates between direct trocar and Veress needle entry techniques in obese patients (BMI >30 kg/m²), with no statistically significant difference between the two methods. Notably, our cohort represents a higher-risk population (BMI ≥40 kg/m²). Similarly, Turgay et al.¹⁴ demonstrated that obesity and prior abdominal surgery do not adversely affect laparoscopic outcomes when appropriate technical adaptations are employed, consistent with our findings.

Raimondo et al.,¹⁵ in a systematic review and meta-analysis of randomized controlled trials, reported that direct trocar entry was associated with lower rates of failed entry compared with Veress needle and open techniques. However, differences in major complications remained inconclusive due to their low incidence. These findings support the role of DTI when appropriately modified for patient-specific anatomical conditions.

Alternative entry strategies remain important in selected cases. Palmer's point has been advocated in patients with prior midline surgery, suspected adhesions, or significant umbilical adiposity. Varghese et al.¹⁶ reported no entry-related complications in 47 morbidly obese patients using left upper quadrant access. While this approach benefits from thinner subcutaneous tissue and reliable anatomical landmarks, it carries risks such as gastric or splenic injury and may necessitate additional ports to maintain optimal triangulation. In our series, Palmer's point was successfully utilised in one conversion case, supporting its role as a complementary strategy.

Optical trocars provide real-time visualisation during entry and may facilitate identification of tissue planes. Favourable outcomes have been reported in obese populations.^{8,9,17,18} However, their use in morbid obesity is limited by restricted visualisation through thick adipose tissue, increased cost, limited availability, and the lack of

robust comparative evidence demonstrating superiority. In contrast, the Four-Clamp Technique utilises standard instruments and is immediately applicable without additional resource requirements. However, we do not position the Four-Clamp Technique as a replacement for optical entry systems; rather, it may serve as a cost-effective and immediately applicable alternative in settings where optical trocars are unavailable or impractical.

Pre-insufflation with a Veress needle increases the distance between the abdominal wall and retroperitoneal structures, theoretically enhancing safety. However, in morbidly obese patients, increased skin-to-peritoneum distance, reduced reliability of traditional confirmation tests, and the risk of preperitoneal insufflation limit its effectiveness.² The Four-Clamp Technique aims to achieve a similar increase in working distance through mechanical elevation while maintaining tissue stability during trocar insertion. Hybrid approaches combining mechanical elevation with insufflation may warrant further investigation, particularly in super-obese patients. Accordingly, the choice between mechanical elevation and pre-insufflation should be individualised based on patient anatomy, surgeon experience, and available resources, rather than interpreted as mutually exclusive strategies.

The conversion rate of 6.7% is clinically acceptable in this high-risk cohort. Importantly, all failed initial entries were successfully managed using alternative techniques without complications, indicating that unsuccessful initial access did not compromise overall procedural safety.

Major entry-related complications, although rare, carry significant morbidity. Alkatout¹⁹ reported bowel injury rates of 0.04% and major vascular injury rates of 0.02–0.04%, with over 50% occurring during initial entry. A substantial proportion of these injuries remain unrecognised intraoperatively, contributing to increased morbidity and mortality. In this context, the absence of major complications in our cohort is reassuring, although the sample size precludes definitive conclusions regarding comparative risk reduction.

The optimal entry technique in morbidly obese patients remains uncertain. Veress needle entry is limited by the reduced reliability of confirmation methods in thick abdominal walls,² while the Hasson technique can be technically demanding and time-consuming.²⁰ Optical systems offer visualisation advantages but are constrained

by cost and availability, and lack consistent evidence of superiority.^{8,21} Within this context, the Four-Clamp Technique offers a simplified, reproducible, and cost-neutral alternative using universally available equipment.

In our practice, selection of entry technique in patients with prior abdominal surgery was individualised based on surgical history, suspected adhesions, and available imaging. Patients with limited prior lower-segment or laparoscopic surgery were considered suitable for Four-Clamp entry, whereas those with prior midline laparotomy, multiple surgeries, or suspected dense adhesions were managed using alternative approaches such as Palmer's point or open Hasson entry. This stratified approach reflects the need to tailor the entry technique to patient-specific anatomical risk.

Study Limitations

Several limitations should be acknowledged. First, the retrospective single-centre design introduces potential selection bias. The exclusion of patients with dense periumbilical adhesions, known hernias, coagulopathy, or emergency indications resulted in a cohort with relatively favourable anatomy, limiting generalizability to higher-risk populations. Second, the sample size of 45 patients is insufficient to detect statistically meaningful differences in rare but serious complications. Given baseline rates of major complications ranging from 0.1% to 0.5%, substantially larger cohorts would be required to demonstrate meaningful risk differences with adequate statistical power. Accordingly, the absence of major complications in this study should not be interpreted as evidence of superiority. Third, the absence of a concurrent control group precludes direct comparative analysis with alternative entry techniques. Although randomised controlled trials would provide higher-level evidence, such studies are challenging due to the rarity of major outcomes, ethical considerations in high-risk populations, and the logistical demands of multicentre recruitment. Fourth, all procedures were performed by a single experienced surgical team at a tertiary academic centre. While this ensures technical consistency, it limits generalizability to other settings and to surgeons with varying levels of experience.

Finally, subgroup analyses based on BMI category and prior surgical history were limited by small sample sizes. Observed trends, including potentially lower success rates in patients with super-obesity or prior surgery, should therefore be interpreted as exploratory. Prospective,

multicentre studies with adequate power, standardised outcome definitions, and inclusion of health economic analyses are required to further evaluate this technique.

Conclusion

In this single-centre retrospective cohort, the Four-Clamp Technique demonstrated feasibility, reproducibility, and an acceptable safety profile for primary laparoscopic access in morbidly obese patients. The combination of high success rates, absence of major entry-related complications, and use of universally available equipment supports its consideration as a practical option in selected patients. However, definitive clinical recommendations cannot be made on the basis of these findings alone. These findings should be interpreted within the context of a selected patient population and an experienced surgical team. Prospective, multicentre comparative studies are required to determine its relative efficacy and safety compared with established entry techniques. Future studies incorporating comparative designs and multi-surgeon settings will be essential to validate external applicability.

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Data sharing: The datasets used for this study are not available publicly due to legal and confidentiality reasons. However, the data analysis can be requested from the author.

Transparency: We affirm that the manuscript is an honest, accurate and transparent account of the study and no important aspects have been omitted. There are no discrepancies from the study as planned.

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Video 1. <https://youtu.be/nJDVVEilHPY>

High-resolution, unedited video demonstrating the Four-Clamp Technique for direct trocar entry in a representative morbidly obese patient (BMI 45.26 kg/m², height 156 cm, weight 110 kg). The video demonstrates clamp placement, omnidirectional traction, controlled trocar insertion, and laparoscopic confirmation of intraperitoneal position.

Retained intrauterine devices and abdominal actinomycosis, diagnostic challenges from a case series

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ABSTRACT

Abdominal actinomycosis is an uncommon infection that may mimic malignancy or inflammatory bowel disease, leading to delayed diagnosis. Retained intrauterine devices (IUDs) have been associated with pelvic and abdominal actinomycosis. We report four women with prolonged IUD use presenting with non-specific abdominal symptoms and varied radiological findings, including abdominal wall, pelvic and hepatic abscesses. Diagnosis was supported by microbiological and/or histopathological findings. Management included IUD removal, prolonged antibiotic therapy and, in one case, surgery. These cases highlight the diagnostic challenges of abdominal actinomycosis and the importance of considering the diagnosis in women with long-term IUD use.

Keywords: Actinomycosis, intrauterine devices, intra-abdominal infections, liver abscess, delayed diagnosis, case reports

Introduction

Actinomycosis is a rare, chronic granulomatous infection caused by *Actinomyces israelii*, a filamentous, anaerobic Gram-positive bacterium that forms part of the normal flora of the oral cavity, gastrointestinal tract and female genital tract.^{1,2} Infection typically occurs following mucosal disruption, resulting in a slow progressing, locally invasive disease characterised by abscess formation and fibrosis.

Cervicofacial disease accounts for approximately 60% of cases, with abdominal involvement reported in 20-30%.^{1,2} Abdominal actinomycosis often presents insidiously and may mimic more common conditions such as diverticulitis, malignancy, tuberculosis or inflammatory bowel disease, contributing to delayed diagnosis.²

Intrauterine devices (IUDs) have been identified as a potential risk factor, particularly when retained beyond the recommended duration.³⁻⁵ Although the mechanism remains unclear, prolonged foreign body presence may facilitate mucosal disruption and microbial proliferation.^{4,6} The incidence of actinomycosis in IUD users is not well defined; however, a systematic review by Manterola et al.⁷ identified IUD use in 14.3% of abdominal cases, and García-García et al.⁸ reported a frequent association in pelvic disease.⁹

Despite increasing recognition, abdominal actinomycosis remains under-recognised and frequently requires microbiological or histopathological confirmation. It may be mistaken for advanced malignancy, leading to unnecessary surgical intervention.¹⁰⁻¹² With appropriate diagnosis, however, most cases respond well to prolonged antibiotic therapy and IUD removal.^{4,5}

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We present a case series of four women with abdominal actinomycosis associated with retained IUDs, highlighting the variability in presentation and the diagnostic challenges encountered.

Methods

This study was conducted as a retrospective case series at Whittington Hospital. Medical records, including both paper and electronic, were reviewed over a 10-year period to identify female patients presenting with non-specific acute or chronic abdominal or pelvic symptoms and a history of long-term IUD use. Long-term or retained IUD use was defined as device retention beyond the recommended duration, or where the device had remained *in situ* for several years without documented follow-up or removal.

Cases were included if abdominal actinomycosis was confirmed by histopathological examination or microbiological culture and sensitivity testing from surgical specimens, aspirates or IUD samples. Abdominal actinomycosis was defined by a combination of compatible clinical presentation and radiological findings, supported by microbiological or histopathological evidence.

Isolation of *Actinomyces* species from sterile sites, such as intra-abdominal collections or surgical specimens, was considered diagnostic. Detection from IUD samples alone was interpreted with caution and was not considered sufficient in isolation, but rather supportive when consistent with clinical and radiological features of invasive infection. This approach was used to distinguish true infection from colonisation or contamination.

Antibiotic choice and duration were determined according to clinical presentation, disease severity and microbiological findings, in keeping with standard clinical practice.

All identified patients were contacted and provided informed written consent for publication of their clinical data, imaging and diagnostic results.

Case 1

A 68-year-old woman presented with a six-week history of progressively worsening right lower quadrant abdominal pain, associated with unintentional weight loss over the preceding three months. On examination, a firm, tender mass was palpable in the right lower quadrant.

Computed tomography (CT) imaging (Figure 1) demonstrated a 2.3 × 4.4 cm fluid collection within the

anterior abdominal wall musculature with surrounding fat stranding, consistent with a chronic inflammatory process. A long-retained IUD was also identified. The patient reported insertion of a copper IUD approximately 30 years earlier, which had not been removed (Figures 1 and 2).

Image-guided drainage of the collection was performed. Microbiological analysis identified *Actinomyces* species, and histopathological examination confirmed actinomycosis. The IUD was subsequently removed.

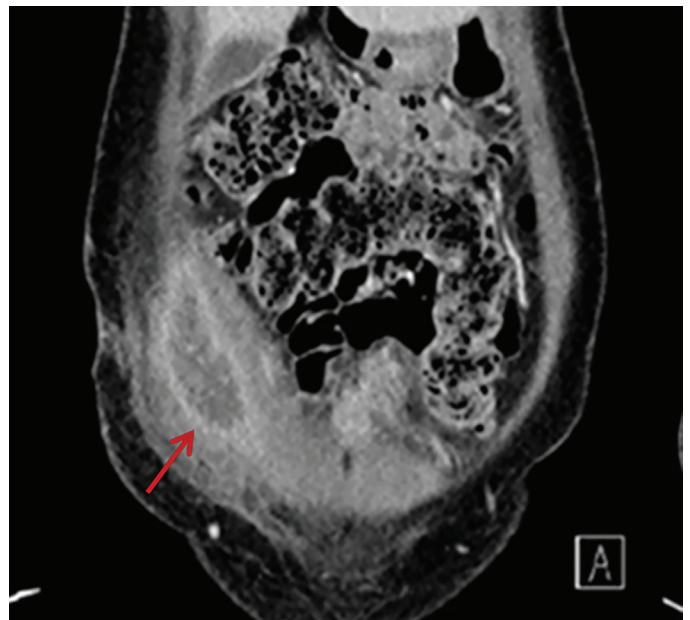


Figure 1. Coronal computed tomography abdomen and pelvis demonstrating a collection within the right abdominal wall musculature (right rectus and oblique muscles), measuring approximately 4.4 × 2.3 cm, with adjacent fat stranding.

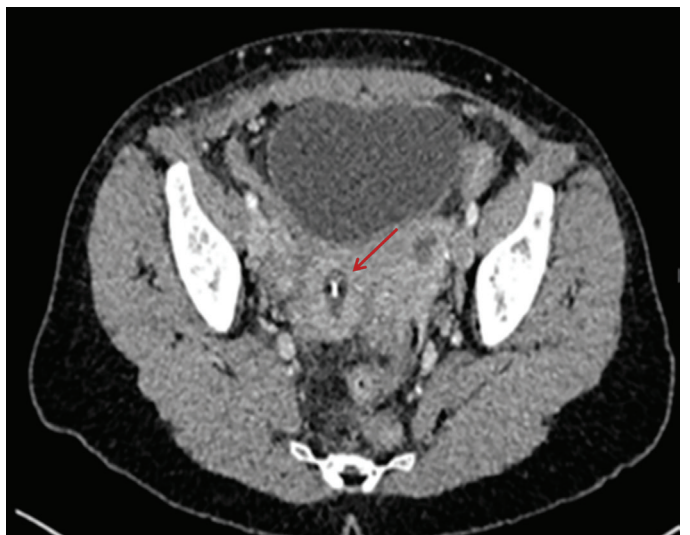


Figure 2. Axial computed tomography abdomen and pelvis showing an intrauterine device *in situ*.

She was treated with intravenous co-amoxiclav (1.2 g three times daily for 10 days) during admission, followed by oral amoxicillin (1 g four times daily) with a planned six-month course and monthly outpatient follow-up. She made a full clinical recovery, with complete resolution of symptoms and no evidence of recurrence at follow-up.

Case 2

A 50-year-old woman with no known comorbidities presented with a two-week history of diffuse abdominal pain, diarrhoea, vomiting and fever. Blood tests demonstrated markedly elevated inflammatory markers.

CT imaging (Figure 3) revealed multiloculated cystic lesions involving both adnexa, moderate ascites and peritoneal thickening, raising concern for disseminated pelvic infection, peritoneal tuberculosis or adnexal malignancy. A retained IUD was identified, reported to have been inserted several years earlier.

She was clinically septic with signs of generalised peritonitis and underwent emergency laparotomy. Intraoperatively, purulent fluid was present in all four quadrants, with a dense pelvic abscess involving the right adnexa, uterus and sigmoid colon. A right salpingectomy, left-sided abscess drainage and Hartmann's procedure were performed.

Cultures from intra-abdominal pus and the removed IUD grew *Actinomyces* species. Postoperatively, she required CT-guided drainage of residual collections. Antibiotic

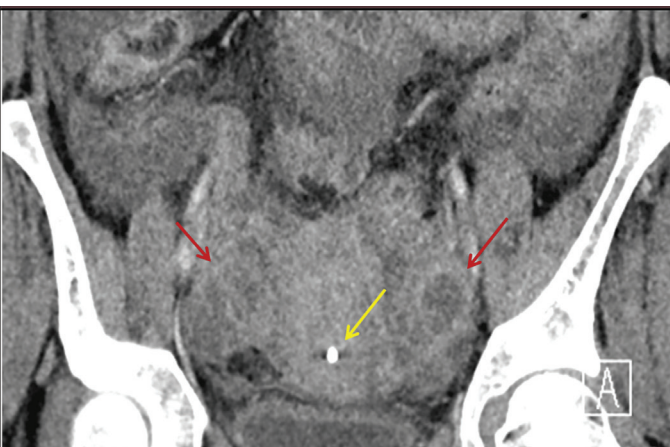


Figure 3. Coronal computed tomography abdomen and pelvis demonstrating multiloculated cysts in both adnexa and an intrauterine device within the uterus.

therapy was escalated to intravenous meropenem (1 g three times daily for 7 days) and oral doxycycline (100 mg twice daily for 7 days), followed by a six-month course of oral doxycycline (100 mg twice daily). She completed a six-month course of oral antibiotics, with complete recovery. Her colostomy was successfully reversed at seven months.

Case 3

A 30-year-old woman presented with a 19-day history of abdominal pain, intermittent fever, and mucous rectal discharge with associated vaginal discharge. CT imaging (Figure 4) demonstrated features suggestive of segmental colitis involving the rectum and sigmoid colon, alongside a complex multiseptated cystic lesion in the left adnexa. A retained IUD was identified, which the patient confirmed had been *in situ* for several years.

Magnetic resonance imaging (MRI) confirmed a left-sided tubo-ovarian abscess with associated pyosalpinx. The IUD was removed, and microbiological culture of the device confirmed *Actinomyces* species.

Image-guided drainage was not feasible due to the deep pelvic location of the collection. She was therefore managed conservatively with oral co-amoxiclav (625 mg three times daily for 6 months). Her symptoms gradually resolved, and she was discharged with outpatient follow-up for 6 months. She made a full clinical recovery with no evidence of progression on follow-up imaging (Figure 4).

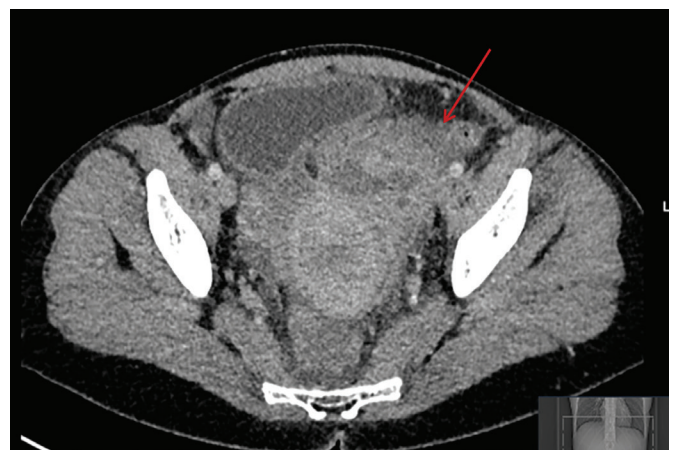


Figure 4. Axial computed tomography of the abdomen and pelvis demonstrating a complex collection within the left pelvis, located between the uterus and the left ovary posteriorly.

Case 4

A 62-year-old woman presented with a prolonged history of low-grade fever, weight loss and non-specific abdominal symptoms. She also reported recurrent abdominal wall abscesses and cutaneous boils affecting the thighs and gluteal region.

She had a prior diagnosis of abdominal actinomycosis confirmed by microbiological culture from an intra-abdominal abscess, which grew *Actinomyces* species. At that time, she was treated at an external institution with prolonged outpatient intravenous amoxicillin (1 g, four times daily) for 3 months, and a long-retained IUDs, *in situ* for over 22 years, was removed. The device itself also cultured *Actinomyces* species.

Two months later, she re-presented with upper abdominal pain and fever. CT imaging (Figure 5) demonstrated multiple complex septated hypodense lesions in the liver with peripheral enhancement, consistent with hepatic abscesses secondary to actinomycosis (Figure 5).

The liver abscesses were drained under radiological guidance, and microbiological analysis again confirmed *Actinomyces* species. She was restarted on intravenous antibiotics (amoxicillin 1 g four times daily) for 7 days, followed by prolonged oral therapy (amoxicillin 1 g four times daily orally for 6 months).

She improved clinically with resolution of symptoms, normalisation of inflammatory markers, and radiological regression of hepatic lesions on 6-month follow-up.

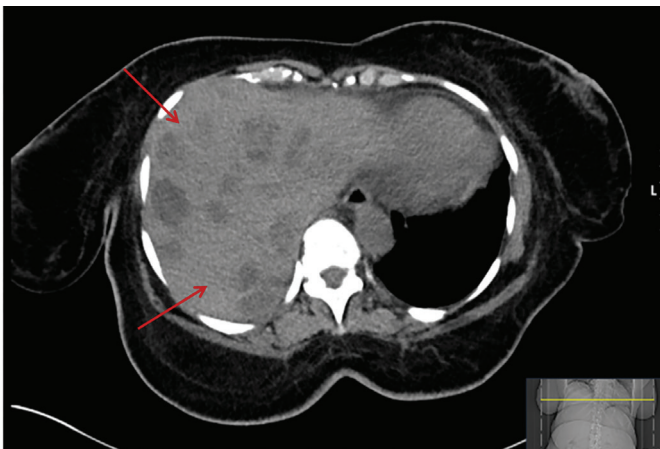


Figure 5. Axial computed tomography of the abdomen and pelvis demonstrating multiple complex, septated cystic lesions in the liver, consistent with multiple abscesses.

Patient Perspective

Due to the retrospective nature of this case series and the prolonged interval between the original clinical presentations and manuscript preparation, formal patient perspectives were not obtainable. Written informed consent for publication of clinical details and imaging was obtained from all patients.

Discussion

Abdominal and pelvic actinomycosis remains a diagnostic challenge.⁸ Although an association with IUD use is observed, a causal relationship cannot be confirmed from this case series. *Actinomyces* species are commensals of the female genital tract, and IUD colonisation does not necessarily indicate invasive infection. Disease development is likely multifactorial, involving mucosal disruption, prolonged foreign body exposure and host factors.

The condition is frequently under-recognised due to its ability to mimic gastrointestinal, gynaecological and malignant disease.^{2,10,11} Unlike typical pelvic inflammatory disease, actinomycosis often follows an indolent course with fibrosis, abscess formation and delayed diagnosis.^{2,8,13}

Previous series, including Fiorino's¹⁴ review of 92 cases and García-García et al.'s⁸ systematic review of 63 cases, highlight its association with pelvic disease but focus mainly on tubo-ovarian presentations. In contrast, our cases demonstrate a broader spectrum, including abdominal wall infection, hepatic abscesses and presentations mimicking colitis or malignancy, reflecting its protean nature.^{2,10,12}

Imaging is often non-specific. CT and MRI may demonstrate abscesses or inflammatory masses that are frequently misinterpreted as malignancy or peritoneal carcinomatosis.^{2,11} In our series, this contributed to major surgical intervention in one case and concern for metastatic disease in another. Definitive diagnosis therefore relies on microbiological or histopathological confirmation where possible.^{11,14}

Microbiological confirmation was not uniform. Isolation of *Actinomyces* from IUDs alone may represent colonisation rather than infection, whereas isolates from sterile sites carry greater diagnostic weight. Where tissue confirmation was unavailable, diagnosis was supported by clinical features, imaging findings and response to therapy.

All patients had long-term IUD use, ranging from several years to over 30 years. While colonisation is relatively common and often asymptomatic, invasive disease appears associated with prolonged exposure and mucosal disruption.^{3-6,15} Detection on cervical or device cultures alone has limited predictive value and should be interpreted in context.

Management typically involves prolonged antibiotic therapy, with penicillin-based regimens as first line, and surgery reserved for complications or diagnostic uncertainty.^{5,7} In our series, antibiotic regimens varied according to severity and initial uncertainty, with broader-spectrum antibiotics used in septic patients or where alternative diagnoses were considered, and subsequently rationalised based on microbiology and clinical response.

Treatment duration was individualised based on clinical response, inflammatory markers and radiological resolution, reflecting current practice.

Early recognition remains essential. Actinomycosis should be considered in women with prolonged IUD use and unexplained abdominal or pelvic masses, including extra-pelvic presentations such as hepatic or abdominal wall disease.

Management of IUDs should be individualised. Removal is recommended in suspected infection, while incidental colonisation alone does not mandate removal. Sampling from sterile sites is preferred, and a multidisciplinary approach is important to avoid misdiagnosis.

This series demonstrates that IUD-associated actinomycosis is not limited to tubo-ovarian disease but may involve multiple abdominal sites with varied presentations (Table 1).

Table 1. Clinical overview of cases: symptoms, IUD duration, imaging findings, microbiology, management and outcomes.

Case	Age	Symptoms	IUD duration	Imaging findings	Microbiology	Management	Outcome	Antibiotic regimen	Follow-up
1	68	Abdominal pain, weight loss (3 months)	30 years	2 × 1.5 cm anterior abdominal wall collection (Figure 1)	IUD and aspirate positive for <i>Actinomyces</i>	IUD removal, antibiotics	Full recovery	IV Co-amoxiclav 1.2 g TDS for 10 days, followed with Amoxicillin 1 g QDS oral for 6 months	6 months
2	50	Abdominal pain, vomiting, fever, diarrhoea	10+ years	Bilateral adnexal cysts, ascites, peritoneal thickening (Figure 3)	IUD and pus positive for <i>Actinomyces</i>	Surgery (Hartmann's), abscess drainage, antibiotics	Recovery: stoma reversed at 7 months	IV meropenem 1 g TDS for 7 days + oral doxycycline 100 mg BD for 7 days → 6 months oral doxycycline 100 mg BD	OP follow up for 6 months → Stoma reversal at 7 months
3	30	Abdominal pain, fever, mucus PR, vaginal discharge	Several years	Colitis, left tubo-ovarian abscess, pyosalpinx (Figure 4)	IUD culture positive for <i>Actinomyces</i>	IUD removal, conservative antibiotics	Complete recovery with follow-up	Oral co-amoxiclav 625 mg TDS for 6 months	6 months
4	62	Weight loss, low-grade fever, abdominal wall abscesses, skin boils	22 years	Multiple complex liver abscesses (Figure 5)	IUD and liver aspirate positive for <i>Actinomyces</i>	IUD removal, IR drainage, long-term antibiotics	Improved on long-term antibiotics	IV amoxicillin 1 g QDS for 7 days → 6-month oral amoxicillin 1 g QDS	6 months

IUD: Intrauterine device, IV: Intravenous, TDS: Three times daily, QDS: Four times daily, BD: Twice daily, IR: Interventional radiology, OP: Outpatient.

Study Limitations

This study has several limitations. It is a small, retrospective case series from a single centre, which limits generalisability. There is potential for selection bias, as only clinically significant or atypical cases are likely to have been identified. Microbiological confirmation was not uniform across all cases, and no comparator group of long-term IUD users without actinomycosis was available. These factors should be considered when interpreting the findings.

Conclusion

Abdominal actinomycosis remains an important but often under-recognised differential diagnosis in women with long-standing IUD use. While an association is observed, a direct causal relationship cannot be established from this series. The condition may present with a wide spectrum of clinical features, including non-gynaecological manifestations, contributing to diagnostic uncertainty. Recognition relies on careful clinical evaluation, appropriate imaging, and microbiological confirmation where feasible. Management with IUD removal and antibiotic therapy appears effective in selected cases, although treatment should be individualised. Further studies are required to better define the relationship between IUD use and invasive actinomycosis and to guide optimal management strategies.

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Ethical approval: Not applicable.

Informed consent: All identified patients were contacted and provided informed written consent for publication of their clinical data, imaging and diagnostic results.

Data sharing: The data supporting this study will be made available in a public repository. There are no ethical or legal restrictions preventing data sharing.

Transparency: I, as the lead author, affirm that this manuscript is an honest, accurate, and transparent account of the study being reported.

I confirm that no important aspects of the study have been omitted and that any discrepancies from the study as planned (and, if relevant, registered) have been fully explained.

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Intra-uterine use of a Foley balloon catheter to tamponade an actively bleeding post-traumatic uterine arteriovenous shunt

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ABSTRACT

Arteriovenous shunts (AV-shunts) whilst rare, can complicate intrauterine surgical procedures leading to severe vaginal bleeding. We present the case of a 29-year-old woman who experienced sudden, torrential vaginal bleeding 10 days following a hysteroscopic resection and curettage of a placental remnant after vaginal delivery. Ultrasonographic evaluation with power doppler demonstrated a post-traumatic AV-shunt. Tamponading the shunt for 36 hours utilising an intra-uterine inflated Foley catheter successfully controlled the bleeding and led to complete resolution of the AV-shunt. Accurately differentiating an AV-shunt from other hyper vascular entities, such as enhanced myometrial vascularity or arteriovenous malformations, is essential, due to the important differences in therapeutic management strategies.

Keywords: Arteriovenous malformations, surgical arteriovenous shunt, enhanced myometrial vascularity, uterine artery embolisation

Introduction

Uterine hypervascularity can be present in different physiological and pathological entities such as enhanced myometrial vascularity (EMV), post-traumatic arteriovenous shunts (AV-shunts), gestational trophoblastic disease, uterine malignancy, uterine ectopic pregnancies or rare congenital uterine arteriovenous malformations (AVM).¹⁻³

Post-traumatic AV-shunt has been reported following various obstetric and gynaecologic procedures such as dilation and curettage (D&C), caesarean section, hysteroscopy, myomectomy and manual removal of the placenta.⁴⁻⁶ It is a rare condition. Abnormal uterine bleeding is the most common presenting symptom of post-traumatic AV-shunts.^{4,6} Differentiating acquired

AV-shunts from other hyper vascular entities is important to provide optimal treatment.^{1,2} We report a case of a post traumatic AV-shunt, where the use of an intra-uterine Foley catheter controlled the uterine haemorrhage and resulted in a complete disappearance of the AV-shunt. Written informed consent was obtained from the patient after approving the final version of the manuscript.

Case Report

A 29-year-old woman, G1P1, with an unremarkable medical history was diagnosed with an asymptomatic hematometra and placental remnant of 22x19x7mm located on the anterior uterine wall 8 weeks after a vaginal delivery. Three months postnatally, the shared

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decision was made to perform a cold loop hysteroscopic resection of the retained placental tissue. Complete resection could not be achieved hysteroscopically, necessitating conversion to ultrasound-guided curettage during the same procedure. Intraoperative ultrasonography and hysteroscopy confirmed complete evacuation of the retained placental tissue. The patient was discharged from hospital the same day without any adverse events. Histopathological review of the tissue confirmed placental remnants with associated chronic endometritis.

Ten days following hysteroscopy and curettage, the patient presented to the emergency department

with acute onset of severe vaginal bleeding. Clinical examination confirmed active bleeding originating from the cervical ostium. The patient was haemodynamically stable. There were no clinical nor biochemical signs of infection: white blood cell count was 6300/ μ L, C-reactive protein 2.6 mg/L and haemoglobin 10.6 g/dL. Transvaginal ultrasound demonstrated a hematometra without persistent retained placental tissue. Within the posterior myometrium an anechoic structure was detected (Figure 1). Power Doppler imaging revealed a high velocity (30 cm/s) and low resistance blood flow exhibiting a whirlpool flow-pattern within the anechoic lumen, suggestive of an AV-shunt (Figure 2).

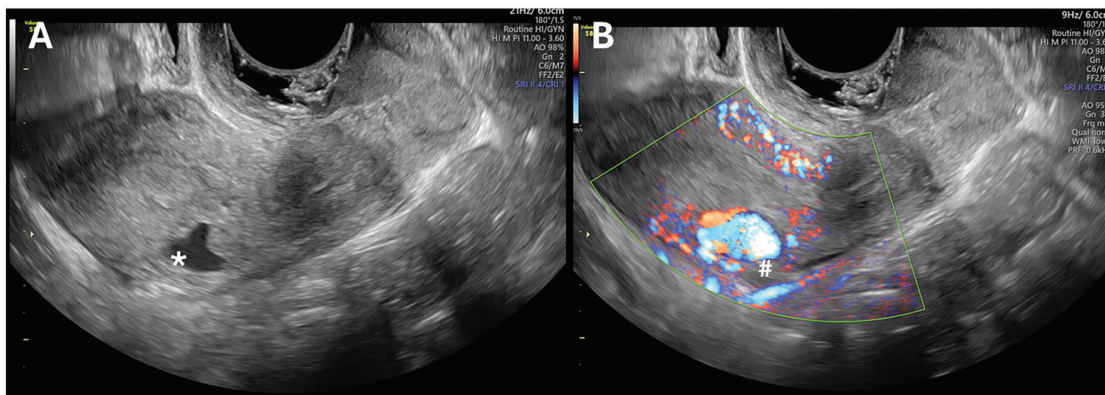


Figure 1. A) Grey scale ultrasound image of an anechoic area in the posterior myometrium (*), corresponding with an AV-shunt. (B) Power Doppler Image of this same image. Pulse Repetition Frequency 0.6 kHz. AV: Arteriovenous.

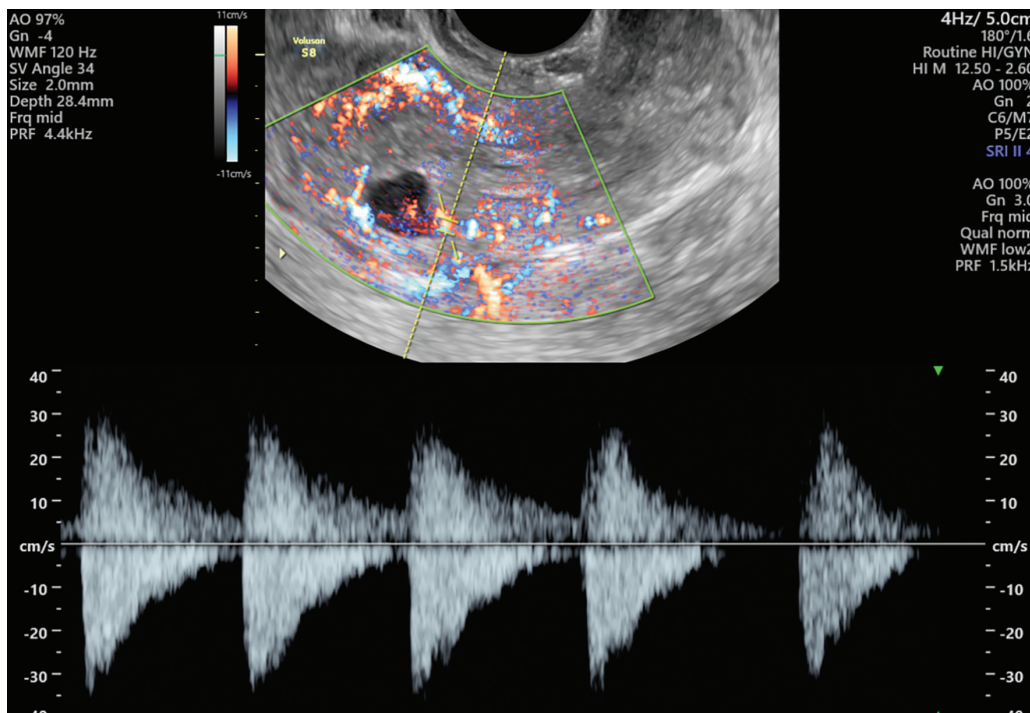


Figure 2. Spectral Doppler demonstrating high velocity arterial flow into the cavity. Pulse repetition frequency 1.5 kHz. Peak systolic velocity 30 cm/s.

Given the clinical context and availability of recent pre-operative imaging without the presence of a vascular lesion, other types of hypervascularity such as congenital AVM could be excluded. An EMV with retained placental tissue was also less likely given hysteroscopy confirmed complete resection after the D&C.

Intervention

During the emergency assessment 1 g of intravenous tranexamic acid was administered. To achieve source control of the active bleeding, a Foley catheter was inserted in the uterine cavity under ultrasound guidance and positioned at the level of the AV-shunt. The balloon was gradually inflated with a normal saline solution until the sonographic image confirmed complete compression of the lesion with the disappearance of the anechoic area and resolution of the Power Doppler signal (Figure 3). In total 10 cc was inserted. This intervention successfully controlled the haemorrhage. Post-procedurally the patient was admitted and intravenous tranexamic acid 1 g three times per day was continued and prophylactic doxycycline initiated.

Outcome

After 36 hours, sonographic assessment confirmed a sustained tamponade of the AV-shunt and the Foley catheter was gradually deflated by 5 cc, followed by an additional 5 cc four hours later. Minimal bleeding was observed throughout the process and patient remained

haemodynamically stable. Catheter removal under sonographic guidance confirmed complete resolution of the AV-shunt. Haemoglobin level was 9.6 g/dL.

The patient was subsequently discharged with oral tranexamic acid 1 gram 3 times daily and doxycycline 100 mg twice a day. Follow-up ultrasound examination at 3 weeks confirmed persistent resolution of the AV-shunt. There was some residual hematometra (Figure 4A). Vaginal bleeding remained minimal and Desogestrel 75 mcg once a day was reinitiated for contraceptive purposes. Ultrasounds 6-months after the procedure demonstrated a normal endometrial lining and homogeneous myometrium (Figure 4B).

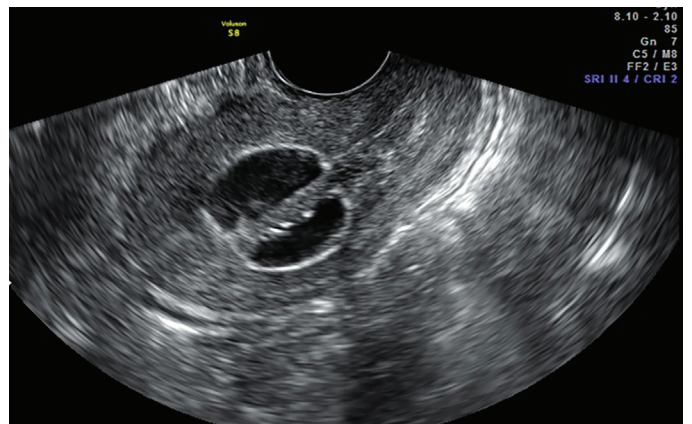


Figure 3. Complete compression of the lesion with disappearance of the anechoic area after Foley catheter insertion.

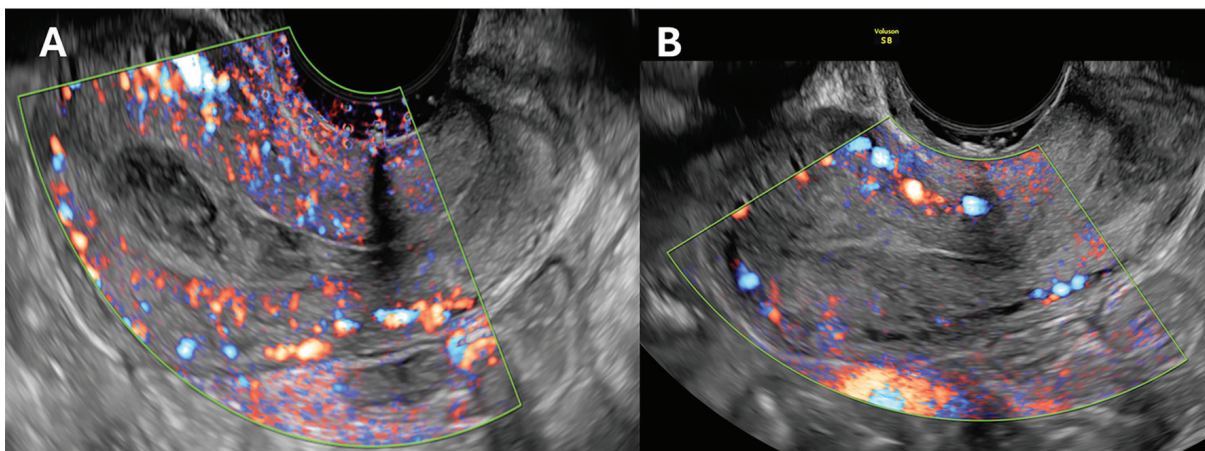


Figure 4. A) Follow-up Doppler ultrasound 3 weeks postoperatively confirmed sustained and complete resolution of the arteriovenous shunt but with a residual hematometra. Pulse repetition frequency 0.3 kHz. (B) Ultrasound 6 months postoperatively demonstrates absence of the hematometra and a sustained resolution of the arteriovenous shunt. Pulse Repetition Frequency 0.3 kHz.

Discussion

In this case we describe the successful minimal invasive haemostatic control of a symptomatic post-traumatic uterine AV-shunt with the intra-uterine placement of a Foley catheter. This intervention led to the complete regression of this rare but potential life-threatening vascular lesion highlighting its potential use as minimal invasive low-cost intervention. We hypothesize that the regression of the traumatic AV-shunt can be explained by the local compression of a non-physiological cavity, allowing for secondary haemostasis with resolution of the traumatic arterio-venous connection. The use of tamponade with a Foley catheter balloon is well-established in the management of postpartum haemorrhage and has demonstrated its efficacy in procedures such as myomectomies, caesarean sections for placenta accreta spectrum and caesarean scar pregnancies.⁷⁻⁹ To our knowledge, the therapeutic application of a Foley catheter for AV-shunts has not been extensively described. Three case reports describe the use of a Foley catheter to control torrential bleeding in case

of a uterine hypervascularity. The case reports describe a uterine AVM or 'uterine artery pseudoaneurysm', but the manuscripts do not allow to differentiate between a true AV-shunt, EMV or congenital AVM.¹⁰⁻¹²

The diagnosis of a post-traumatic AV-shunt can be challenging, as imaging findings alone may be insufficient to reliably distinguish it from an EMV or a rare congenital AVM.⁴ Besides ultrasound findings, clinical context is indispensable for accurate diagnosis (Figure 5). Based on the available literature, the diagnostic process is further complicated by the historically inconsistent and interchangeable use of the terms post-traumatic AV-shunts, AVM (both congenital and acquired) and EMV.^{1,13} However, they represent separate entities that require different management approaches.

A post-traumatic AV-shunt, is characterised by a single arteriovenous communication between one or more branches of the uterine artery and the myometrial venous plexus.⁴ In the literature, post-traumatic AV-shunts have interchangeably been referred to as "arteriovenous fistulas", "traumatic uterine arteriovenous malformations"

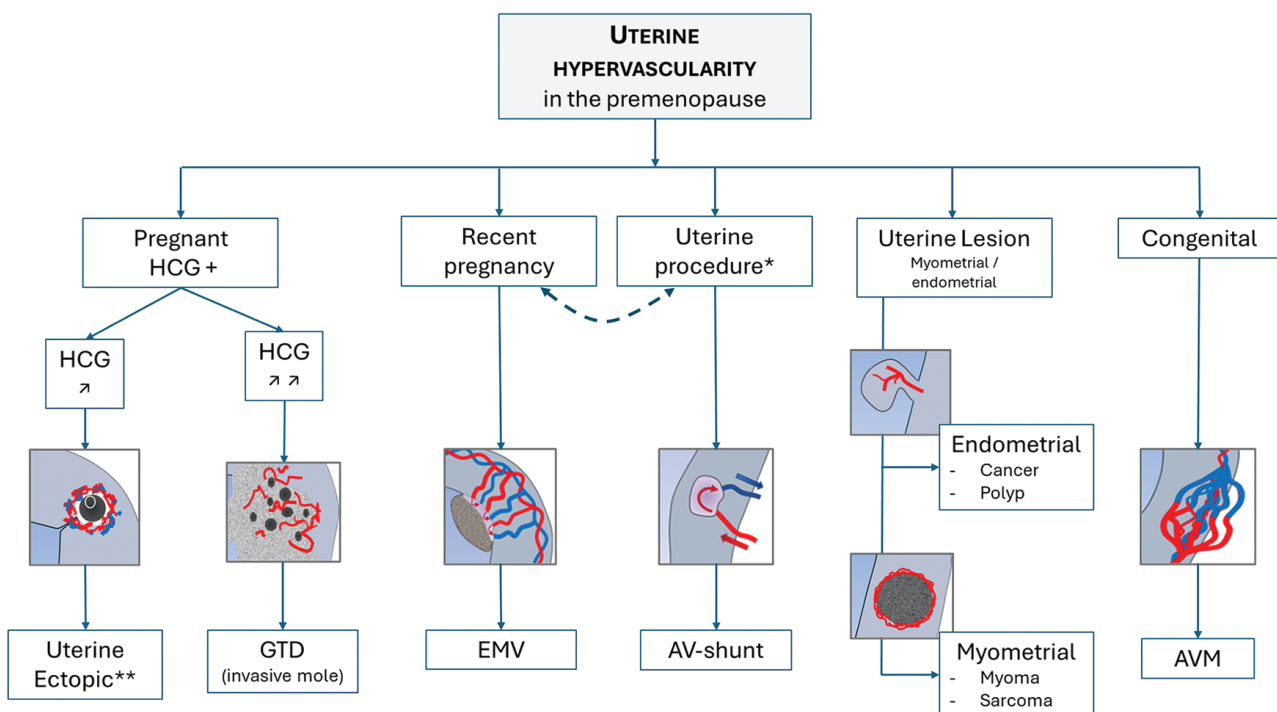


Figure 5. Differential diagnosis of uterine hypervascularity in premenopausal women.

*Uterine procedures with a risk of a myometrial trauma such as (but not limited to) uterine sounding, intra-uterine device placement, curettage, hysteroscopy, myometrial resection for fibroid, adenomyosis, caesarean section.

**Uterine ectopic such as an intra-mural pregnancy, caesarean scar pregnancy, interstitial pregnancy, cervical pregnancy.

HCG: Human chorionic gonadotropin, GTD: Gestational trophoblastic disease, EMV: Enhanced myometrial vascularity, AV-shunt: Arteriovenous shunt, AVM: Arterio-venous malformation.

or “acquired uterine arteriovenous malformations”.¹ In contrast to acquired AV-shunts, congenital AVMs result from embryological maldevelopment and arise from defects in the differentiation of the primitive capillary plexus during foetal angiogenesis. They are characterized by multiple feeding arteries, a central nidus consisting of vessels with characteristics of both arteries and veins and multiple large draining veins.^{6,14,15} A congenital AVM and an acquired (post-traumatic) AV-shunt represent a non-pregnancy related shortcut between an artery and a vein, which does not resolve spontaneously.² EMV is distinct from an AV-shunt because it represents an incomplete regression of physiological vascular changes within the myometrium due to retained pregnancy tissue. It typically resolves once the retained tissue is expelled or surgically removed.^{1,16-18}

Integrating clinical context in the diagnostic process is essential, particularly given the significant differences in management strategies.² Historically, hysterectomy was the standard treatment for post-traumatic AV-shunts.⁴ In recent years, selective uterine artery embolisation (UAE) has become the preferred treatment, being less invasive and fertility-preserving.^{5,6} Although other surgical techniques including laparoscopic occlusion of the internal iliac or uterine artery, hysteroscopic coagulation or surgical removal have been described, UAE remains the most commonly used intervention.^{4,19} However, this radiological treatment may not be available in all hospital settings and alternative management approaches such as the one described in this case report should be considered. Moreover, whilst generally safe, UAE can be associated with pelvic pain and rare complications such as thromboembolic events, puncture site hematoma, non-target embolization, ovarian function disruption, intrauterine adhesions and an increased risk for placental abnormalities (placenta accreta and/or placental insufficiency) in future pregnancies.^{4,16,20-23}

In contrast to treatment of symptomatic AV-shunts, expectant management of EMV is appropriate when symptoms are minimal, as spontaneous resolution usually occurs.¹ Intervention with removal of the retained pregnancy tissue can be indicated in case of heavy or persistent bleeding or if conception is deemed hindered by the retained tissue. Misdiagnosing EMV as a shunt or rare congenital AVM may lead to overtreatment with unnecessary morbidity from interventions such as UAE or hysterectomy. On the other hand, misdiagnosing an AV shunt as EMV may lead to endometrial curettage, which may exacerbate bleeding.^{4,17}

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Data sharing: All data generated or analysed during this study are included in this published article. De-identified data may be available from the corresponding author upon reasonable request and with appropriate ethical approvals.

Transparency: The authors affirm that the manuscript is an honest, accurate, and transparent account of the reported case. No important aspects have been omitted.

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Toumai robotic system in uterine cancer surgery: first report of sentinel lymph node dissection in ten steps

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ABSTRACT

Background: In recent years, robotic surgery has gained traction across multiple disciplines, establishing a new minimally invasive paradigm. After the Da Vinci® (Intuitive, Sunnyvale, California) patent expired, several platforms with increasingly digital interfaces entered the market. Robotic surgery may represent a bridge between laparoscopy and digital surgery through interfaces that enable integration with emerging technologies. Among platforms, the Toumai robotic system (Medbot-Microport, Shanghai, China) features a single-arm cart with four arms, a three-dimensional console, and a split-view "picture-in-picture" function enabling communication with image-guided surgical technologies. This functionality is particularly valuable for indocyanine green (ICG)-guided sentinel lymph node (SLN) mapping in gynaecologic oncology.

Objectives: We present for the first time, a step-by-step video demonstration of SLN dissection for endometrial malignancies using the Toumai robotic system.

Participant: A postmenopausal patient with uterine-confined endometrial carcinoma undergoing total hysterectomy, bilateral salpingo-oophorectomy, and bilateral SLN biopsy.

Intervention: The technique includes: 1) ICG injection; 2) robotic trocar placement; 3) docking; 4) pelvic retroperitoneal access; 5) switch to split-view mode; 6) identification of the SLN critical view of safety by developing pararectal and paravesical spaces; 7) introduction of an ICG-capable camera through an accessory trocar; 8) activation of near-infrared visualisation after switching off the robotic light source; 9) SLN identification and dissection; 10) safe extraction.

Conclusions: The digital interface of the Toumai system integrates adjunctive technologies, illustrating how next-generation robotics expand the feasibility of SLN dissection in endometrial cancers.

What is New? The Toumai platform enables SLN dissection even in the absence of an in-house integrated ICG endoscopic camera.

Keywords: Robotic surgical procedures, sentinel lymph node, indocyanine green, endometrial neoplasms, robotics

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Ethical approval: According to institutional policy, formal ethics committee approval is not required for educational video articles describing a single anonymised clinical case performed as part of routine clinical practice.

Informed consent: Written informed consent for participation and video publication was obtained from the patient.

Data sharing: No additional data are available beyond the material presented in the video.

Transparency: The authors affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.



Video 1. Toumai robotic system in uterine cancer surgery: first report of sentinel lymph node dissection in ten steps: <https://youtu.be/VkxWDYkAHYE>

Laparoscopic cervical cerclage at 10 weeks gestation in a patient with an adverse obstetric history following fertility-sparing surgery for cervical cancer

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ABSTRACT

Background: For women who undergo fertility-sparing treatment for early cervical cancer, transabdominal cerclage (TAC) may be considered to prevent adverse obstetric outcomes due to cervical insufficiency. Laparoscopic-TAC (LPS-TAC) is now preferred over conventional transabdominal approaches because of decreased pain and bleeding, shorter hospitalisation and quicker recovery. However, a systematic, precise approach to performing LPS-TAC during pregnancy is necessary to overcome the lack of uterine manipulation and minimise complications such as bleeding and pregnancy loss.

Objectives: To demonstrate the surgical technique of post-conceptual LPS-TAC.

Participant: A 33-year-old woman with a history of FIGO stage IA1 squamous cervical cancer treated with fertility-sparing surgery. She had suffered a foetal loss after an emergency Caesarean section at 28 weeks because of uterine rupture. In her next pregnancy she presented at 10 weeks gestation with an ultrasound diagnosis of cervical shortening (14 mm).

Intervention: The patient underwent LPS-TAC at a tertiary referral center. The operating time was 51 minutes, and blood loss was minimal. Intraoperative transvaginal ultrasound was used to guide the cerclage placement. No perioperative complications occurred; the hospital stay was two days. Elective C-section was performed at 34+6 weeks with hysterotomy above the tape, which was left *in situ*.

Conclusions: LPS-TAC during pregnancy represents a feasible minimally invasive option for selected patients with cervical insufficiency, particularly those with a history of prior cervical surgery. Intraoperative ultrasound may assist in identifying the internal cervical os, facilitating safe tape placement and minimising the risk of membrane injury during pregnancy.

What is New? Intraoperative ultrasound guidance may support safe identification of the internal cervical os and optimal tape placement when performing LPS-TAC during pregnancy in patients with previous fertility-sparing treatment for cervical cancer.

Keywords: Cervical cancer, cervical cerclage, hysterotomy, laparoscopic, pregnancy, uterine rupture

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Ethical approval: Given the study design (i.e. video presentation of the surgical treatment), IRB approval was not necessary.

Informed consent: Written informed consent for publication of video and images was provided by the patient.

Data sharing: All the video tapes are available at the Division of Gynecology and Human Reproduction Physiopathology, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy. Data will be made available to the editors of the journal for review or query upon request.

Transparency: The lead author affirms that the content of the article is honest, accurate, and transparent.



Video 1. Laparoscopic cervical cerclage at 10 weeks gestation in a patient with an adverse obstetric history following fertility-sparing surgery for cervical cancer: <https://youtu.be/se8ZEwOXheE>

Robotic ureteral reimplantation for endometriosis: the Lich-Gregoir technique. A step-by-step approach

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ABSTRACT

Background: Urinary tract endometriosis affects fewer than 6% of patients with endometriosis, with ureteral involvement representing the second most common site of disease (9–23%). The condition is often asymptomatic, which may result in silent loss of renal function. Surgical intervention is required in cases of ureteral obstruction. Ureteroneocystostomy is indicated for distal ureteral disease, particularly when ureterolysis is insufficient or vascular compromise is present. The Lich-Gregoir technique is an extravesical approach to ureteral reimplantation into the bladder.

Objectives: To present a step-by-step demonstration of robot-assisted ureteral reimplantation using the Lich-Gregoir technique following excision of a parametrial and vaginal endometriosis nodule.

Participant: A 47-year-old nulliparous woman presented with dysuria, deep dyspareunia, and dyschezia. Imaging revealed a left parametrial endometriosis nodule extending to the vagina, causing distal ureteral obstruction and grade III hydronephrosis.

Intervention: This narrated video demonstrates the surgical management of severe ureteral endometriosis, including ureterolysis, safe nodule excision, and ureteral reimplantation using the Lich-Gregoir technique. Reimplantation was preferred to segmental resection or ureterolysis due to distal stenosis, proximity to the bladder, and the depth of disease infiltration. The patient remained asymptomatic at follow-up visits at 1 and 6 months. Retrograde cystography performed 3 weeks postoperatively showed no leakage.

Conclusions: Robot-assisted Lich-Gregoir ureteral reimplantation represents a feasible and reproducible option for distal ureteral endometriosis. The robotic platform may facilitate precise and complex reconstructive procedures.

What is New? The case illustrates the role of robotic surgery in complex pelvic endometriosis, demonstrates the feasibility of integrating ureteroneocystostomy with simultaneous excision of parametrial and vaginal endometriosis.

Keywords: Endometriosis, laparoscopy, reimplantation, robotic surgery, ureter, ureteral obstruction

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Ethical approval: The study obtained approval from the local Ethics Committee of the Azienda Ospedaliero-Universitaria Senese, Siena, Italy (protocol number: 25431, date: 16.10.2023). It was conducted in compliance with the Helsinki Declaration, and patient data were anonymized.

Informed consent: Written informed consent was obtained from the patient for publication of this case report and accompanying images and videos.

Data sharing: The data underlying this article cannot be shared publicly due to the need for privacy of the individual that participated in the study. The data will be shared on reasonable request to the corresponding author.

Transparency: The authors affirm that this manuscript is an honest, accurate, and transparent account of the case being reported; that no important aspects of the case have been omitted; and that any discrepancies from the standard clinical management have been explained.



Video 1. Robotic ureteral reimplantation for endometriosis: the Lich-Gregoir technique. A step-by-step approach: <https://youtu.be/INPxHpfSZtk>

Immediate volume reduction following transvaginal ultrasound-guided thermal ablation (interstitial myolysis) of a symptomatic uterine fibroid

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ABSTRACT

Background: Interstitial thermal ablation represents a uterine-sparing alternative for symptomatic fibroid management. Transvaginal ultrasound-guided myolysis enables precise targeting and real-time monitoring of the ablation zone.

Objectives: To illustrate the feasibility and immediate intraoperative response of transvaginal ultrasound-guided interstitial myolysis for the treatment of uterine fibroids.

Participant: A 36-year-old multiparous woman with persistent abnormal uterine bleeding and pelvic pain related to a known uterine fibroid seeking a uterus-preserving treatment. Previous treatments, including levonorgestrel-releasing intrauterine system and oral therapy with relugolix, estradiol, and norethisterone had failed.

Intervention: Transvaginal ultrasound revealed a retroverted, enlarged uterus with a posterior type 2-5 fibroid measuring 45×37×49 mm (volume: 42.4 cm³). Under conscious sedation, a 16G-27 cm microwave antenna was transvaginally inserted and repositioned within the fibroid under continuous ultrasound guidance. Ablation was delivered in four cycles at 20 W for a total duration of 194 seconds, with a cumulative net energy delivered of 3.3 kJ calculated by the device, while continuously assessing safety margins and tissue response. Immediate ultrasound evaluation showed a 42.7% volume reduction (from 42.4 to 24.3 cm³), loss of fibroid definition, and partial collapse, consistent with effective devascularisation. No complications occurred, and the patient was discharged the same day. At 4-month follow-up, fibroid volume reduction was sustained (41.7%), with complete symptom control under the previously ineffective hormonal therapy.

Conclusions: Transvaginal interstitial myolysis offers a minimally invasive, uterine-sparing treatment option for selected patients with symptomatic fibroids. Real-time ultrasound monitoring enables precise ablation and immediate confirmation of treatment efficacy.

What is New? This video documents the immediate volumetric response of a uterine fibroid following transvaginal ultrasound-guided myolysis.

Keywords: Microwave, relugolix, ultrasound-guided, uterine fibroids

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Informed consent: The patient included in this video gave written informed consent for the publication and online distribution of the video and related materials.

Data sharing: All relevant data are included in the article and the accompanying video. No additional data are available.

Transparency: The authors affirm that this manuscript is an honest, accurate, and transparent account of the case reported, and that no important aspects of the case have been omitted.



Video 1. Immediate volume reduction following transvaginal ultrasound-guided thermal ablation (interstitial myolysis) of a symptomatic uterine fibroid: https://www.youtube.com/watch?v=kRw_VhSMw7w

Inside the obturator canal: robotic ganglion cyst decompression

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ABSTRACT

Background: Obturator nerve compression is an uncommon cause of groin and medial thigh pain. Ganglion cysts extending into the obturator foramen are rare and usually managed via open or orthopaedic approaches. Robotic neuropelvelogy offers high-definition access to pelvic neurovascular structures and may facilitate nerve-preserving excision.

Objectives: To demonstrate a robotic pelvic approach to the obturator foramen for excision of a ganglion cyst inseparable from the obturator nerve, and to highlight multidisciplinary (MDT) planning in atypical neuropathic pelvic pain.

Participant: A 47-year-old woman presented with left groin/medial thigh pain and impaired leg function. MRI showed a 16-mm lobulated ganglion cyst arising from the undersurface of the left hip joint and extending into the left obturator foramen, inseparable from the obturator nerve with neurogenic oedema in obturator externus/adductor muscles.

Intervention: After MDT planning with radiology, neurosurgeon, neuropelvelogy and gynaecology surgeon, a joint robotic procedure was performed. Key steps: develop an avascular pelvic sidewall plane via the lumbosacral space; dissect caudally to the obturator canal with minimal traction; identify the obturator nerve and vein and perform nerve-sparing neurolysis; perform controlled cystotomy and evacuate gelatinous contents for decompression; deroof the ganglion and remove the cyst wall to reduce recurrence.

Conclusions: Robotic access to the obturator foramen can enable minimally invasive, nerve-preserving decompression and excision of selected pelvic nerve compression lesions, supported by MDT planning, with symptomatic and motor improvement.

What is New? A stepwise robotic route to the obturator canal for a ganglion cyst inseparable from the obturator nerve, demonstrating MDT-enabled management of rare neuropathic pelvic pain.

Keywords: Obturator nerve, ganglion cyst, robotic surgery

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Transparency: The lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.



Video 1. Inside the obturator canal: robotic ganglion cyst decompression: <https://youtu.be/-sQwsoSIVAw>
