SYSTEMATIC REVIEW

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Pre-conceptional laparoscopic cerclage for prevention of preterm birth: a systematic review

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ABSTRACT

Background: Cervical cerclage is used to prevent preterm delivery caused by cervical insufficiency, thereby reducing neonatal morbidity and mortality rates. Transabdominal cerclage is usually performed in women who previously underwent transvaginal cerclage that failed to prevent pregnancy loss, or in those with a short cervix where transvaginal cerclage was not feasible.

Objectives: To estimate the efficacy of pre-conceptional laparoscopic cerclage in facilitating term delivery and live birth.

Methods: A systematic review was conducted according to the PRISMA 2020 guidelines. This study was registered in PROSPERO (CRD42024545316). A search was conducted up to the 15th of April 2024, in the PubMed and Cochrane databases, using a combination of terms "laparoscopy", "transabdominal" and "cerclage". Original studies investigating the role of pre-conceptional laparoscopic cerclage on pregnancy outcomes after follow-up were eligible for inclusion in this review.

Main Outcomes Measures: Prevalence of deliveries after 37 weeks of gestation and live birth rates.

Results: Ten studies involving 1060 patients were included. The pooled prevalence of deliveries after 37 weeks of pregnancy was 70% [95% confidence interval (CI) 60%-79%, 7 studies, 515 pregnancies, I^2: 85%] and the pooled prevalence of live birth was 92% (95% CI 86%-95%, 10 studies, 713 pregnancies, I^2: 69%). Significantly higher rates of delivery after 37 weeks of pregnancy were associated with the use of mersilene tape compared to conventional sutures [odds ratio (OR): 2.98, 95% 1.95-4.56] and the use of an anterior knot compared to a posterior knot (OR: 2.26, 95% CI: 1.50-3.40).

Conclusions: Pre-conceptional laparoscopic cerclage achieved high rates of live birth after 37 weeks in women considered at high risk of preterm delivery. Comparative research is needed to better understand the efficacy of pre-conceptional laparoscopic cerclage as well as refine the indications for this procedure, optimise surgical techniques, and determine the best timing for cerclage placement.

What is New? Pre-conceptional laparoscopic cerclage may prevent future preterm births and second-trimester pregnancy losses.

Keywords: Cervical cerclage, laparoscopy, preterm birth, miscarriage, live birth

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Introduction

Cervical cerclage is used to prevent preterm delivery due to cervical insufficiency, thereby reducing neonatal morbidity and mortality rates.[1] There are three major indications for the cervical cerclage: (1) women with risk factors for a preterm birth, (2) cervical shortening on ultrasound and (3) where the cervix is already open and the foetal membranes are exposed (rescue cerclage).[1]

A synthetic suture or tape is used to mechanically maintain the structural integrity of the cervix, thereby prolonging gestation.[2] Four different surgical approaches have been used to date: the transvaginal, transabdominal with laparotomy, laparoscopic and robotic transabdominal cerclage.[1,3] The two most common transvaginal techniques for cerclage were described by McDonald and Shirodkar. The Shirodkar cerclage is placed as close as possible to the internal os, while the McDonald technique is applied closer to the external os.[4]

Most guidelines suggest that prophylactic cerclage can be placed before or after conception in women with a history of three or more previous preterm deliveries and/or second-trimester pregnancy losses.[5] To reduce perioperative risk during pregnancy, pre-conceptional transabdominal cerclage was first proposed in 1998 and has been increasingly utilised since.[6,7] Transabdominal cerclage is usually performed in women who have had a previous transvaginal cerclage that failed to prevent pregnancy loss, or in women with a short cervix, where transvaginal cerclage is not possible.[8] Laparoscopic approaches to transabdominal pre-conceptual cervical cerclage are now commonly used.[9]

We conducted a systematic review to determine the efficacy of pre-conceptional laparoscopic cerclage by calculating the pooled prevalences of delivery after 37 weeks of pregnancy and live birth following this procedure.

Methods

A systematic review was conducted following the PRISMA 2020 guidelines. This study was registered in PROSPERO (CRD42024545316). A search was carried out up to April 15, 2024, in the Medline and Cochrane databases. The search strategy included a combination of terms "laparoscopy", "cerclage", "transabdominal" ((cerclage) AND ((transabdominal) OR (laparoscopy [MeSH Terms]))). Citation tracking was also performed. Studies published in English, German or French were assessed for eligibility. Original studies investigating the role of pre-conceptional laparoscopic cerclage on pregnancy outcomes were eligible for inclusion. The primary outcome of this review was the rate of delivery after 37 weeks of gestation, and the live birth rate was a secondary outcome. Studies were excluded if the groups were mixed with pre- and post-conceptional laparoscopic cerclage or pre-conceptional laparoscopic and pre-conceptional cerclage placed via laparotomy, in order to reduce heterogeneity between studies caused by different procedures. Conference papers were omitted from the review due to their restricted data availability, lack of peer review and potential for duplicating published research.

The search was conducted by two investigators (D.R.K., I.M.), with any discrepancies resolved through consultation with a third investigator (K.C.), who was not part of the initial process. Data extraction from each study was conducted independently by two reviewers using a standardised data extraction form in Excel. This included study characteristics (author, year of publication, country, study design, number of patients, follow-up time), clinical characteristics of the patients (age, body mass index, indication), information about surgical techniques of cerclage in every study (type of tape used, type of knot, manipulator used and number of surgeons conducted the procedure, hysteroscopy conducted after the placement of the cerclage) and requested outcomes (rate of delivery after 37 weeks of gestation, live birth rate and complications). In cases of missing data, the corresponding authors were contacted.

Each study underwent a quality assessment using a modified Newcastle-Ottawa quality assessment scale, evaluating the domains representativeness of the sample, sample size, non-respondents, ascertainment of exposure, assessment of outcome and statistical test with a maximum possible score of 8. Studies were classified according to the score in poor (0-2), fair (3-5) and good quality (6-8).[10]

The pooled prevalence and 95% confidence interval (CI) were estimated using a random-effects model via the Metaprop command in STATA (Stata Statistical Software: Release 16. StataCorp LLC, College Station, TX). Odds ratios (OR) with 95% CI and chi-square tests for the analysis of delivery rates after 37 weeks and live birth rates between the subgroups were calculated. Statistical significance was set at *P*-values <0.05 and 95% CI that did not include 1, were considered statistically significant. OR with 95% CI and chi-square tests were calculated using SPSS version 10.

Results

Ten studies involving 1060 patients were included in this systematic review (PRISMA Flowchart, Figure 1). All studies were cohort studies with follow-up; five of them were retrospective,[9,11-14], and the remaining five were prospective.[15-19] The studies were conducted across nine different countries, with three of them conducted in China. The number of participants with pre-conceptional laparoscopic cerclage in the included studies ranged from 18 to 250. The duration of follow-up was not clearly reported in the majority of the studies. The indications across most studies were failed or impossible vaginal cerclage, typically after history of cervical surgery and previous adverse obstetrical outcomes. Delivery rates after 37 weeks of pregnancy were reported in 7 out of 10 studies, while live birth rates were reported in all of the included studies. The characteristics of the included studies are summarised in Table 1.

The methodological quality of studies is presented in Table 2. All studies had a high risk of selection bias due to the absence of random sampling and control groups. A sensitivity analysis based on study quality was not performed as all the included studies were classified as fair and good.

The rates of delivery after 37 weeks of pregnancy varied across the studies from 52% to 82%. Four of the included studies reported a delivery rate after 37 weeks of pregnancy of more than 75%,[13,16,18,19] while three studies reported a prevalence between 52% and 61%.[9,12,17] A multicentre study reported that 90% (94/104) of deliveries were after 34 weeks of pregnancy,[14] while another study found 73.3% (33/45) delivery rates after 36 weeks of pregnancy.[15]

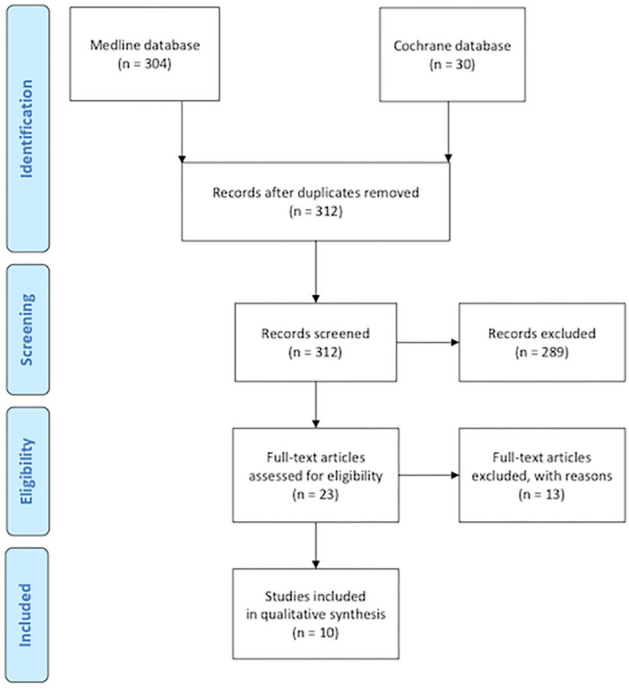

Figure 1. Flowchart diagram.

The pooled prevalence of deliveries after 37 weeks of pregnancy was 70% (95% CI: 60-79%, 7 studies, 515 pregnancies, I^2: 85%) (Figure 2). A subgroup analysis based on knot localisation showed that the anterior knot was associated with significantly higher delivery rate after 37 weeks in comparison to the posterior knot (OR: 2.26, 95% CI: 1.50-3.40, P<0.05). Comparison of suture types showed that women who underwent pre-conceptional laparoscopic cerclage with Mersilene tape had a higher delivery rate after 37 weeks than those with conventional suture (OR: 2.98, 95% 1.95-4.56, P<0.05). Additionally, women who did not undergo hysteroscopy after cerclage placement had a significantly higher delivery rate after 37 weeks of pregnancy (OR: 1.61, 95% CI: 1.02-2.56, P=0.04).

Live birth rates were high across the included cohort studies, ranging from 78 to 100%. The majority of the studies reported live birth rates exceeding 90%.[11,16-19] Demirel et al.[12] found that 84% of pregnancies reached the stage of viability, with 5 out of 25 women over 29 weeks pregnant at the time of publication. Another study reported live birth rates below 80%.[9] The pooled prevalence of live birth was 92% (95% CI: 86-95%, 10 studies, 713 pregnancies, I^2: 69%) (Figure 3). The comparison between the subgroups according to the knot localisation showed that the posterior knot was associated with higher live birth rates (OR: 2.26, 95% CI: 1.50-3.40, P=0.01). The conventional suture was also associated with higher live birth rates in comparison to Mersilene tape (OR: 2.98, 95% 1.95-4.56, P<0.05). Subgroup analysis also indicated that patients who did not undergo hysteroscopy after cerclage placement had significantly higher live birth rates (OR: 5.03, 2.65-9.54, P<0.05). Additionally, cohorts with a single surgeon for the laparoscopic cerclage had significantly higher pooled live birth rate in comparison to cohorts with more than one surgeon (OR: 2.70, 95% CI: 1.27-5.74, P<0.05).

Discussion

Main Findings

The pooled prevalence of delivery after 37 weeks of pregnancy in this systematic review was 70% among women who underwent preconception laparoscopic cerclage, with an even higher live birth rate of 92%. These findings demonstrate the efficacy of this intervention in a high-risk population for second-trimester pregnancy loss or preterm birth.

Table 1. Characteristics of studies included in systematic review.

Studies included					**Clinical characteristics**			**Surgical technique**				
Study	Country	Design	Year	n	Age	BMI	Indication	Number of surgeons	Manipulator	Tape	Knot	Hysteroscop
Riiskjaer et al.[15], 2012	Denmark	Prospective cohort study	2004-2011	52	n/a	n/a	Obstetrical and surgical indications	Unclear	Manipulator used unclear	Mersilene tape	Anterior	No
Luo et al.[16], 2014	China	Prospective cohort study	2008-2013	19	31 (27-35)*	n/a	Failed previous or impossible vaginal cerclage	1	Manipulator used unclear	Mersilene tape	Posterior	Yes
Bolla et al.[10], 2015	Switzerland	Retrospective cohort study	2008-2014	18	33 (4)	n/a	Failed previous or impossible vaginal cerclage	Unclear	Rumi or Hegar	Mersilene tape	Anterior	No
Huang et al.[9], 2016	China	Retrospective cohort study	2010-2015	100	31.2 (3.9)	n/a	Failed previous vaginal cerclage	Unclear	Cervical cup	Mersilene tape	Anterior	Yes
Ades et al.[17], 2018	Australia	Prospective cohort study	2007-2017	225	33.9 (4.39)	n/a	Obstetrical and surgical indications, failed previous vaginal cerclage	1	Manipulator used unclear	Prolene suture	Posterior	No
Saridogan et al.[18], 2019	England	Prospective case series	2004-2017	54	36 (23-44)*	n/a	Obstetrical and surgical indications	1	Spackman cannula	Mersilene tape	Posterior	No
Li et al.[13], 2021	China	Retrospective cohort study	2015-2017	247	n/a	n/a	Obstetrical and surgical indications	Unclear	Cervical cup	Mersilene tape	Anterior	No
Demirel et al.[12], 2021	Turkey	Retrospective cohort study	2012-2020	40	Range 21-42	n/a	Obstetrical indications	1	Manipulator used unclear	Mersilene tape	Anterior	Yes
Yanamandra and Pooskuru, 2023	India	Prospective case series	2017-2021	55	34 (28-42)*	29.64 (21-42)	Failed previous vaginal cerclage	1	Hegar 6	Mersilene tape	Mixed	No
Abdulrahman et al.[14], 2024	Holland/ USA	Retrospective cohort study	1997-2021	250	34.4 (4.4)	n/a	Failed previous or impossible vaginal cerclage	2	Type of manipulator used unclear	Mersilene/ polyeste	Mixed	Some

All values are presented as mean (standard deviation) unless otherwise indicated. Values marked with * are presented as median (interquartile range). BMI: Body mass index, n/a: Not applicable.

Table 2. Quality assessment of included studies using modified Newcastle-Ottawa quality assessment scale.

Study	Representativeness of the sample	Sample size	Non-respondents	Ascertainment of the exposure	Assessment of outcome	Statistical test	Total score (max 8)	Quality rank
Riiskjaer et al.[15], 2012	*	0	*	*	*	*	5	Fair
Luo et al.[16], 2014	*	0	0	*	**	*	5	Fair
Bolla et al.[11], 2015	*	0	0	*	*	*	4	Fair
Huang et al.[9], 2016	*	0	*	*	*	*	5	Fair
Ades et al.[17], 2018	*	0	*	**	**	*	7	Good
Saridogan et al.[18], 2019	*	0	0	*	*	*	4	Fair
Li et al.[13], 2021	*	0	0	*	*	*	4	Fair
Demirel et al.[12], 2021	*	0	0	*	*	*	4	Fair
Yanamandra and Pooskuru, 2023	*	0	*	**	**	*	7	Good
Abdulrahman et al.[14], 2024	*	0	0	*	*	*	4	Fair

max: Maximum.

Strengths and Limitations

To the best of our knowledge, this is the first systematic review examining the effect of preconception laparoscopic cerclage. The strengths of this study are the large sample size of the included studies with only preconception laparoscopic cerclage and similar outcomes. However, several limitations need to be acknowledged. All the included studies were observational, uncontrolled cohort studies, with the majority being retrospective, carrying a high risk of selection bias due to the inclusion of patients, which is based on pre-existing conditions, the presence of various confounders, and missing data. The cohorts studied were heterogeneous, with variations in maternal age, previous obstetric history, and indications for cerclage. Additionally, the follow-up periods varied across studies, and many did not report follow-up duration. Although subgroup analyses were performed, when possible, to address discrepancies, these limitations may affect the generalisability of the findings.

Strengths and Limitations Compared to Other Studies

The incidence of pregnancy loss between 12 and 24 weeks of gestation ranges from 2% to 3%,[20] while the incidence of preterm birth, defined as delivery before 37 weeks of gestation, varies between 5% and 18% according to the World Health Organization (WHO).[21] The causes for both second trimester pregnancy loss and preterm birth are multifactorial, with cervical insufficiency, infection, congenital anomalies and previous cervical dilatation or cervical lacerations due to traumatic deliveries proposed as the main causes.[22,23]

A poor obstetric history with previous failed transvaginal cerclage and a history of cervical surgery resulting in no visible ectocervix or a short cervix, where transvaginal cerclage was not feasible, were the two most common indications for preconception laparoscopic cerclage in the studies included in this systematic review. Subgroup analysis based on the indication for cerclage was not possible in this review, as most of the included studies did not report outcomes according to the indication. Saridogan et al.[18], found comparable deliveries after 37

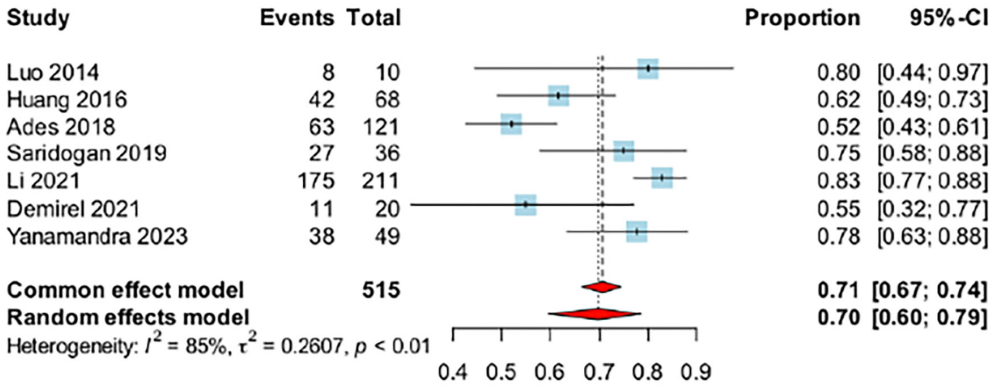

Figure 2. Pooled prevalence of delivery after 37 weeks of pregnancy.

CI: Confidence interval.

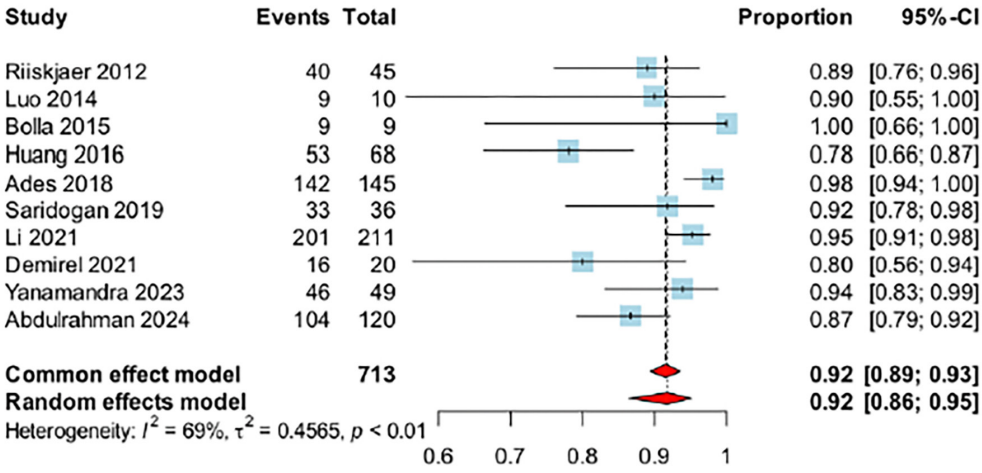

Figure 3. Pooled live birth rate.

CI: Confidence interval.

weeks, live birth rates and neonatal survival rates between the different subgroups according to indication. The authors suggested that cerclage may act as a protective mechanism by preserving cervical mucus, preventing ascending infection and offering mechanical support for the cervix, thereby reducing the risk of preterm birth and second-trimester pregnancy loss.

Regarding different surgical approaches, a multicentre randomised controlled trial (MAVRIC) included women with a history of failed cerclage who underwent both pre- and postconceptional cerclage and showed that transabdominal cerclage was superior to both high and low vaginal cerclage in reducing early preterm birth and foetal loss.[22] In another study, Moawad et al.[24], compared both pre- and postconceptional cerclage performed via laparoscopy versus laparotomy, finding significantly better neonatal survival rates and higher rates of delivery after 34 weeks of gestation for laparoscopy group. Similarly, Tulandi et al.[8], found higher third-trimester delivery and live birth rates with laparoscopic cerclage compared to laparotomy, concluding that laparoscopic cerclage should be considered as the first option, preferably during the pre-conceptional period. Robotic-assisted cerclage, a technique gaining popularity due to enhanced visualisation, precise dissection, and knot-tying capabilities, has also shown promising results.[3] Recent studies have found comparable favourable obstetric outcomes for both pre-conceptional and post-conceptional robotic-assisted cerclage compared to transabdominal cerclage via laparotomy.[3,25]

Pregnancy rates after a pre-conceptional cerclage in the publications included varied from 56%,[17] to 97.2%,[13] with an overall pregnancy rate of 76.3%, however, these studies are heterogeneous in terms of follow-up periods, which ranged from 2 months[11] to more than 18 months[9] and the pregnancies were achieved both spontaneously and through assisted reproductive techniques. As far as the optimal timing for laparoscopic pre-conceptional cerclage,

there is no current evidence indicating the best time before pregnancy to achieve better outcomes. Tulandi et al.[8] found comparable live birth rates between pre-conceptional and post conceptional laparoscopic cerclage.

Most of the included studies used a Mersilene tape. The subgroup analysis revealed significantly higher chances of delivery after 37 weeks of pregnancy in women who had a Mersilene tape compared to those with conventional sutures. However, the live birth rate was significantly higher in the conventional suture group. This discrepancy could be attributed to the small sample size of the conventional suture group, as only Ades et al.[17] used conventional sutures for pre-conceptional laparoscopic cerclage.

A previous systematic review, which included five studies comparing Mersilene tape with conventional sutures in transvaginal cerclage, found a lower incidence of preterm birth before 34 weeks with Mersilene. However, the risk of preterm birth between 34 and 37 weeks was higher with Mersilene compared to conventional sutures, with comparable adverse events such as chorioamnionitis and neonatal death.[26] The authors concluded that the existing evidence is limited and insufficient to definitively support the superiority of Mersilene tape in transvaginal cerclage. A large multicentre randomised controlled trial (C-STICH), which compared two different sutures (monofilament versus braided sutures) in vaginal cerclage, found comparable pregnancy outcomes.[27] However, findings from transvaginal cerclage may not be directly applicable to transabdominal cerclage, as the exposure of the tape and sutures, which could potentially cause infection and pre-term delivery, differs.

According to the studies included in our systematic review, the anterior knot had higher rates of delivery after 37 weeks of pregnancy in comparison to the posterior knot. However, the subgroup with the posterior knot had a significantly higher live birth rate. The anterior knot was used in most of the included studies; thus maybe the above discrepancy could be explained by the small group of women with a posterior knot. In addition, another explanation could be that the anterior wall of the uterus is more accessible for the surgeon, allowing the knots to have better stability and leading to more deliveries after 37 weeks of pregnancy. Anterior knots can be also easily removed via laparoscopy without accessing the posterior cul de sac, while posterior knots have the advantage of potential vaginal removal. A third type of knot, the intravaginal knot, is also proposed by some authors, with the advantage of simplified knot removal.[28]

Hysteroscopy after the placement of cerclage was conducted in three of the included studies.[9,12,16] The subgroup analysis showed significantly fewer deliveries beyond 37 weeks of pregnancy and a lower live birth rate. Limited information was provided about the procedure or the size of the hysteroscope. Luo et al.[16] reported the use of a Hegar 6 dilatator before hysteroscopy, while Demirel et al.[12] reported that patients underwent office hysteroscopy, but did not specify the hysteroscope's diameter. Huang et al.[9], did not detail the method of hysteroscopy. The adverse effects of hysteroscopy on pregnancy outcomes could be attributed to cervical dilation performed before hysteroscopy in some of these studies, following cerclage placement. A hysteroscope less than 5 mm in diameter could potentially allow passage through the cervix after cerclage placement without requiring cervical dilation.[29]

Clinical and Policy Implications

Preconception laparoscopic cerclage seems to be safe because few complications, such as uterine perforation, were reported. Our study found that single-surgeon cohorts had significantly higher live birth rates. Women with poor obstetric histories, including failed transvaginal cerclage, cervical surgery with no visible ectocervix, or a short cervix, should be counselled about the option of pre-conceptional cerclage. This procedure has been shown to be effective, especially when performed by an experienced surgeon, leading to high rates of delivery after 37 weeks.

Unanswered Questions and Future Research

Our review suggests that pre-conceptional laparoscopic cerclage is an effective intervention for women at high risk of preterm delivery, achieving high rates of delivery after 37 weeks and live birth. Comparative research is needed to better understand the efficacy of pre-conceptional laparoscopic cerclage as well as refine the indications for this procedure, optimise surgical techniques, and determine the best timing for cerclage placement before pregnancy.

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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 planned (and, if applicable, registered) study have been explained.

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