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Short-Term Perioperative Outcomes of a Needle-Free Versus Conventional Laparoscopic Abdominal Cerclage: A Prospective Comparative Study

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ABSTRACT

Background & Objective: Cervical incompetence significantly contributes to mid-trimester pregnancy loss and preterm birth before 28 weeks. Transabdominal cerclage is indicated for high-risk patients when vaginal cerclage fails or anatomy prevents its use. Laparoscopy reduces morbidity compared to laparotomy. A novel needle-free laparoscopic pericervical technique aims to simplify suture placement and reduce tissue trauma. The present study was conducted with aim to compare short-term perioperative outcomes of a needle-free versus conventional laparoscopic abdominal cerclage.

Materials & Methods: This prospective study was conducted on 100 women undergoing preconception abdominal cerclage at Arash Women's Hospital, Tehran (March 2025-2026). Fifty patients received needle-free Laparoscopic Pericervical Abdominal Cerclage (LPAC) and 50 received conventional Laparoscopic Intracervical Cerclage (L-CIC). Allocation was performed by surgeon preference. Operative time, complications, conversion rates, and postoperative outcomes were recorded. Data were analyzed using SPSS (version 26). $P<0.05$ was considered statistically significant.

Results: Two groups had comparable baseline characteristics. Mean operative time was significantly shorter in the LPAC group than in the L-CIC group (42.3±8.1 vs. 61.7±10.4 minutes; $P<0.001$). In the LPAC group, there was lower intraoperative bleeding (4% vs. 14%, $P=0.081$) and laparotomy conversion (2% vs. 6%, $P=0.31$), but the difference was not statistically significant. There were no significant differences between the two groups in uterine perforation, visceral injury, fever>38°C, hospital stay, wound infection, or pelvic hematoma.

Conclusion: Needle-free LPAC appears feasible and safe with shorter operative time and comparable perioperative outcomes. Given the non-randomized design and limited sample, larger randomized trials with obstetric follow-up are needed to confirm the clinical effectiveness of this method.

Keywords: Transabdominal cerclage, Cervical insufficiency, Laparoscopic cerclage, Preterm birth

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1. Introduction

Prematurity constitutes a predominant factor in perinatal morbidity and mortality across global populations. Deliveries prior to 28 weeks of gestation carry substantial risks for adverse neurodevelopmental trajectories, pulmonary compromise, and enduring functional impairment. Cervical incompetence represents a potentially modifiable contributor to second-trimester pregnancy wastage and premature delivery **(1-4)**.

Cervical insufficiency is clinically characterized by progressive, painless cervical effacement and dilatation during the second trimester in the absence of demonstrable uterine contractile activity, predisposing to membrane herniation, preterm premature rupture of membranes, and subsequent pregnancy loss. Predisposing factors encompass previous cervical surgical interventions, repetitive cervical instrumentation, cone biopsy procedures, cervical amputation, congenital structural anomalies, and obstetric histories suggestive of inherent cervical structural compromise **(5-7)**.

Surgical cervical cerclage constitutes the principal therapeutic modality for mitigating recurrent second-trimester fetal loss and early prematurity. Transvaginal cerclage techniques including the McDonald and Shirodkar procedures represent first-line approaches but demonstrate limited efficacy in women with pronounced cervical shortening, distorted

cervicovaginal anatomy, or prior cerclage failure. These clinical scenarios typically warrant transabdominal cerclage placement **(8,9)**.

Historically performed through laparotomy, transabdominal cerclage has undergone progressive transition toward laparoscopic execution, offering advantages including diminished postoperative discomfort, abbreviated hospitalization, accelerated functional recovery, and enhanced surgical visualization. Nevertheless, conventional laparoscopic cerclage presents substantial technical challenges attributable to the requirement for meticulous dissection and precise needle manipulation in proximity to the uterine vasculature **(10-12)**.

A needle-free laparoscopic pericervical method has recently emerged as an alternative strategy. This approach involves circumferential passage of suture material around the cervix through anatomically avascular planes, obviating the need for needle penetration through cervical tissue and potentially attenuating iatrogenic injury to adjacent vascular structures. However, comparative evidence regarding its safety and clinical effectiveness remains sparse **(13-16)**. Therefore, the present study was conducted with aim to compare immediate perioperative metrics between needle-free laparoscopic pericervical cerclage and traditional laparoscopic intracervical cerclage among women requiring preconception abdominal cerclage placement.

2. Materials and Methods

This prospective comparative study was conducted at the Department of Gynecologic Laparoscopy, Arash Women's Hospital, Tehran University of Medical Sciences, Tehran, Iran, from March 2025 to March 2026. A total of 100 women candidates for preconception abdominal cerclage were enrolled.

Patients were allocated into two equal groups based on surgeon preference and operating room scheduling. During the study period, two attending surgeons performed the procedures: one surgeon routinely performed the needle-free LPAC technique, while the other routinely performed the conventional L-CIC technique. Patients were assigned to the technique corresponding to the surgeon scheduled for their procedure.

Patients were included if they met at least one of the following criteria:

1. Anatomical conditions preventing vaginal cerclage (e.g., cervical agenesis, amputation, severe hypoplasia).

2. History of failed prophylactic cerclage with subsequent preterm delivery before 28 weeks in women desiring future pregnancy.

Patients with prior abdominal surgery, severe pelvic adhesions, uterine anomalies, or major medical comorbidities were excluded.

All procedures were performed under general anesthesia by one of two experienced laparoscopic surgeons, each with over 50 prior cases of their respective technique. This was done to minimize the impact of the learning curve on the outcomes. Both surgeons had comparable levels of overall laparoscopic experience (over 10 years each). Procedures were performed during the same study period to minimize temporal confounding.

After bladder catheterization, a 10-mm umbilical port, one 10-mm suprapubic port, and two 5-mm lateral ports were placed. A uterine manipulator was used. The uterine arteries were identified. The peritoneum at the internal cervical os was incised. Bilateral avascular windows were created at the cervico-isthmic junction, medial and inferior to the uterine vessels, without routine vessel skeletonization.

In the LPAC group, a Mersilene tape without a needle was introduced. Using graspers, the tape was passed around the cervix through the avascular spaces (anterior to the rectum, lateral to the ureters, and medial to the uterine vessels) at the level of the internal os. The anatomical plane was precisely identified as the avascular areolar tissue between the uterine vessels and the cervical wall, with careful lateral retraction of the ureters to avoid injury. The tape was secured anteriorly with a knot after confirming proper positioning.

In the L-CIC group, the conventional laparoscopic cerclage was performed using needle-mounted Mersilene tape, passed through cervical tissue at the cervico-isthmic junction and tied securely. The needle was passed from anterior to posterior through the cervical stroma, avoiding the uterine vessels.

Primary outcomes were operative time and intraoperative complications.

Operative time was defined as the duration from skin incision to skin closure (minutes), measured by the circulating nurse using a standardized timer.

Intraoperative complications included uterine perforation (identified by direct visualization or hysteroscopy if performed), bladder injury (identified by visible defect, dye test, or cystoscopy), and bowel injury (identified by direct visualization).

Secondary outcomes were intraoperative bleeding, conversion to laparotomy, postoperative fever, hospital stay, wound infection, and pelvic hematoma.

Intraoperative bleeding was defined as estimated blood loss >500 mL or hemoglobin drop >2 g/dL from preoperative to 24-hour postoperative measurement.

Conversion to laparotomy was defined as any unplanned conversion from laparoscopic to open abdominal approach.

Postoperative fever was defined as temperature ≥38°C within 48 hours of surgery, measured by axillary thermometer.

Hospital stay was defined as the number of days from surgery to hospital discharge.

Wound infection was defined as presence of purulent drainage, cellulitis, or wound dehiscence requiring antibiotic therapy or surgical intervention within 30 days postoperatively.

Pelvic hematoma was defined as a fluid collection in the pelvic cavity confirmed by pelvic ultrasound when clinically suspected (e.g., pelvic pain, unexplained hemoglobin drop, or hemodynamic instability).

Data were analyzed using SPSS (version 26) (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean±standard deviation. Normality of data was assessed using Shapiro-Wilk test. For normally distributed continuous variables, the independent t-test was used; for non-normally distributed variables, the Mann-Whitney U test was applied. Categorical variables were presented as frequencies and percentages and compared using the chi-square test or Fisher's exact test (when expected cell counts were <5). P<0.05 was considered significant. All tests were two sided.

3. Results

A total of 100 women were included (50 per group). No patients were lost to follow-up during the perioperative period.

Baseline demographic and clinical characteristics were comparable between the two groups (Table 1), with no statistically significant differences between the two groups in age, BMI, history of abortions, preterm birth, failed cerclage, or previous cesarean section. This supports the comparability of the two groups despite the non-randomized allocation.

Operative outcomes are shown in Table 2. The LPAC group had a significantly shorter operative time compared with the L-CIC group (42.3±8.1 vs. 61.7±10.4 minutes; mean difference 19.4 minutes, 95% CI 15.8 to 23.0; P<0.001).

Intraoperative bleeding occurred in 2 patients (4%) in the LPAC group and 7 patients (14%) in the L-CIC group, but this difference was not statistically significant (P=0.081). Conversion to laparotomy was required in 1 patient (2%) in the LPAC group and 3 patients (6%) in the L-CIC group (P=0.31). No uterine perforations, bladder injuries, bowel injuries, or wound infections occurred in either group. Pelvic hematoma was observed in 1 patient (2%) in the L-CIC group (P=0.32). Postoperative fever >38°C occurred in 2 patients (4%) in the L-CIC group and none in the LPAC group (P=0.15). Hospital stay was similar between the two groups of LPAC and L-CIC (1.2±0.4 vs. 1.4±0.6 days; P=0.09).

No major visceral injuries occurred. Postoperative outcomes were similar between groups, with no statistically significant differences in any secondary outcome measures.

Table 1. Baseline demographic and clinical characteristics of the patients in two groups

Variables	LPAC (n=50)	L-CIC (n=50)	P-value
Age (years, mean±SD)	31.2±5.4	30.8±6.1	0.73†
BMI (kg/m², mean±SD)	26.1±4.2	25.7±4.8	0.65†
History of ≥2 abortions (n, %)	28(56%)	26(52%)	0.69‡
History of preterm birth (n, %)	35(70%)	33(66%)	0.67‡
Previous failed cerclage (n, %)	12(24%)	14(28%)	0.64‡
Previous cesarean section (n, %)	18(36%)	16(32%)	0.67‡

† Independent t-test; ‡ Chi-square test

Table 2. **Intraoperative and postoperative outcomes in the LPAC and L-CIC groups**

Outcome	LPAC (n=50)	L-CIC (n=50)	P-value
Operative time (min, mean±SD)	42.3±8.1	61.7±10.4	<0.001*
Intraoperative bleeding (n, %)	2(4%)	7(14%)	0.081**
Conversion to laparotomy (n, %)	1(2%)	3(6%)	0.31**
Uterine perforation (n, %)	0	0	NA
Bladder injury (n, %)	0	0	NA
Bowel injury (n, %)	0	0	NA
Pelvic hematoma (n, %)	0	1(2%)	0.32**
Fever >38°C (n, %)	0	2(4%)	0.15**
Wound infection (n, %)	0	0	NA
Hospital stay (days, mean±SD)	1.2±0.4	1.4±0.6	0.09†

* Independent t-test; ** Fisher's exact test; NA: Not Applicable (test not performed due to zero events in both groups)

4. Discussion

The purpose of the present study was to compare immediate perioperative metrics associated with needle-free laparoscopic pericervical cerclage versus conventional laparoscopic intracervical cerclage. There was a substantial reduction in surgical duration approximately 20 minutes with the needle-free approach, while maintaining a comparable safety profile. This time savings carries potential implications for operating room throughput and anesthetic exposure **(17,18)**.

The two study cohorts demonstrated balanced baseline characteristics, supporting the validity of between-group comparisons. Although the observed reductions in hemorrhagic events and conversion rates among LPAC recipients did not achieve statistical significance, the magnitude of these differences (10% absolute reduction in bleeding, 4% reduction in conversions) suggests clinically meaningful trends worthy of investigation in adequately powered future trials **(18,19)**.

The needle-free technique streamlines the surgical workflow by enabling suture passage through naturally occurring avascular tissue planes, thereby circumventing needle traversal through cervical stroma and potentially mitigating vascular injury risk **(20)**. The fact that all procedures were performed by experienced surgeons during the same period minimizes confounding by learning curve or temporal changes in practice **(21-23)**. However, it is important to acknowledge that the two techniques were performed by different surgeons, and although both had comparable overall experience, subtle differences in surgical skill or technique may have influenced the outcomes. The operative time difference may partly reflect differences in surgeon technique or efficiency rather than the inherent advantage of the needle-free approach **(24)**.

Our findings are consistent with previous reports suggesting that needle-free laparoscopic cerclage is technically feasible and may reduce operative time compared with conventional techniques **(14)**. The operative time of 42.3 minutes in the LPAC group compares favorably with published series of laparoscopic cerclage, which typically report operative times ranging from 45 to 90 minutes **(1,2,9)**. The safety profile observed in our study aligns with the low complication rates reported in systematic reviews of laparoscopic cerclage **(9,19)**. The absence of major visceral injuries in both groups of the p0resent study underscores the safety of laparoscopic approaches when performed by experienced surgeons.

The reduction in operative time with the needle-free technique may translate into several clinical benefits, including reduced anesthesia exposure, improved operating room efficiency, and potentially lower costs. The simplified technique may also facilitate adoption by surgeons with less experience in laparoscopic cerclage, although formal training and proctoring would still be recommended. However, the lack of long-term obstetric outcome data indicates that the clinical effectiveness of the needle-free technique in terms of preventing preterm birth and improving neonatal outcomes remains unproven.

Future multicenter randomized controlled trials with larger samples and long-term follow-up are needed to confirm these findings and evaluate reproductive outcomes. Such trials should assess gestational age at delivery, live birth rates, neonatal morbidity and mortality, and maternal quality of life. Cost-effectiveness analyses would be also valuable to inform healthcare resource allocation. Additionally, studies should explore whether the benefits of the needle-free technique are consistent across different populations and surgeon experience levels.

This study has several strengths, including its prospective design, clear definition of outcome measures, and standardized surgical techniques performed by experienced surgeons. The comparison of two contemporary techniques during the same period minimizes temporal confounding. The inclusion of consecutive eligible patients and complete follow-up enhances internal validity.

However, this study has important limitations. The non-randomized, surgeon-based allocation introduces potential selection bias, as patients were not randomly assigned to treatment groups. The allocation method may have introduced confounding by indication or surgeon factors. The sample size may be insufficient to detect differences in uncommon complications, as evidenced by the wide confidence intervals for rare events. Long-term obstetric outcomes (gestational age at delivery, live birth rate, neonatal outcomes) were not assessed in this study that limits the ability to draw conclusions about clinical effectiveness beyond the perioperative period. The single-center design limits generalizability to other settings and populations. Additionally, the lack of blinding (surgeons and patients were aware of the technique used) may have introduced performance or detection bias, although objective outcome measures such as operative time and major complications are less susceptible to such bias.

5. Conclusion

Needle-free laparoscopic pericervical abdominal cerclage appears to be a feasible and safe technique for selected women requiring abdominal cerclage. It is associated with a significantly shorter operative time and comparable short-term perioperative outcomes compared with conventional laparoscopic intracervical cerclage. However, given the non-randomized design, surgeon-based allocation, and limited sample size, the findings of the present study should be interpreted cautiously. The shorter operative time may offer practical advantages, but the clinical effectiveness in terms of pregnancy outcomes remains to be established. Larger randomized studies with long-term obstetric follow-up are warranted before widespread adoption can be recommended.

6. Declarations

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Ethical Considerations

The protocol was approved by the Ethics Committee of Tehran University of Medical Sciences (ethical code: IR.TUMS.MEDICINE.REC.1404.035). Written informed consent was obtained from all participants. Participation was voluntary, and confidentiality was maintained. The study was conducted in accordance with the Declaration of Helsinki.

Authors' Contributions

RH, ZA, ZJ: Concept and study design.

YP, ZJ: Literature search and study screening.

RH, ZA: Data extraction and analysis.

RH, ZA,ZJ,YP: Manuscript preparation.

All authors

Reviewed and approved the final version

Conflict of Interest

The authors declare no conflict of interest.

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