



Preconception laparoscopic cervical cerclage for prevention of mid-trimester pregnancy loss and preterm birth: A 6-year study

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ABSTRACT

Objective: To evaluate surgical results and pregnancy outcomes of preconception laparoscopic cervical cerclage (LCC) in women with cervical insufficiency.

Study design: We conducted an observational study in consecutive women who had preconception LCC. Data was prospectively collected from 55 women at high risk of second trimester miscarriage and extreme preterm delivery due to cervical insufficiency who underwent pre-conception LCC between January 2017 – December 2021. This included patient demographics and relevant obstetric & gynaecological history, previous cervical cerclage, operative complications and subsequent pregnancy outcomes. All women included in study had at least one previous unsuccessful transvaginal cervical cerclage. The surgeries were conducted in private tertiary hospital in Hyderabad, India. The follow-up was until December 2022. The primary outcome was neonatal survival. Surgical morbidity and complications were also recorded.

Results: There were 49 pregnancies of which 46 progressed beyond first trimester. 4.34 % (2/46) were delivered between 28 and 33 weeks due to preterm premature rupture of membranes (PPROM). 13.04 % (6/46) including 5 women with pregnancy complications and one with unicornuate uterus needed delivery between 34 and 36 weeks. 82.60 % (38/46) women were delivered at or beyond 37 weeks of pregnancy. In those who carried pregnancy beyond first trimester, live-birth rate and neonatal survival rate were 100 %. All neonates had favourable outcome with no long-term morbidity. There were no intraoperative or immediate postoperative complications. Two women had long-term complication in the form of tape erosion needing further surgery.

Conclusions: This study provides evidence that LCC improves pregnancy outcomes significantly in those with cervical weakness, without increasing the safety risk.

1. Introduction

There are many causes of mid-trimester pregnancy loss including abnormal placentation, immunological interactions, thrombophilia, cervical insufficiency and upper genital tract anomalies to name a few. The overwhelming majority of cases are associated with ascending infection from the lower genital tract [1]. Cervical incompetence contributes to approximately 1 % of women with history of recurrent mid-trimester loss [2].

Cervical incompetence should be described in two main categories: mechanical and functional. Mechanical incompetence implies that the cervical components do not have the strength to maintain the structure of cervix through gestation. Functional incompetence is the premature triggering of the cervical ripening process that occurs at term [3]. Each

risk factor describes a pro-inflammatory environment that promotes cervical ripening for which a cervical cerclage will be effective.

Cervical cerclage is aimed at providing mechanical support to the cervix and keep it closed during pregnancy. Although stitches are normally inserted via vaginal route, transabdominal cerclage has also been proposed in a sub-group of women who either have failed TVC previously or have short cervix due to iatrogenic reasons or because of developmental anomaly. First described in 1965 [4], transabdominal cervical cerclage (TAC) remains a valuable approach in prevention of mid-trimester miscarriage and extreme preterm birth. Potential advantages of TAC include higher placement relative to the level of the internal os (Fig. 1), decreased incidence of slippage, and the ability to leave the stitch in place between pregnancies [5].

Some experts believe that the benefits of TAC extend beyond the

Abbreviations: LCC, Laparoscopic cervical cerclage; PPRM, Preterm prelabour rupture of membranes, TVC - Transvaginal cervical cerclage.

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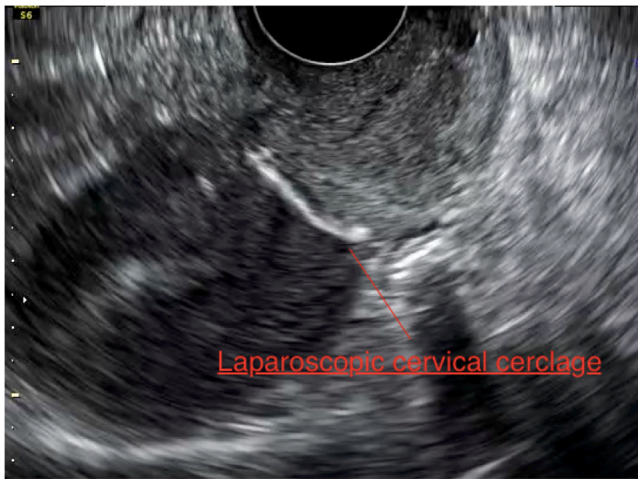


Fig. 1. Ultrasound image of the inserted cervical cerclage.

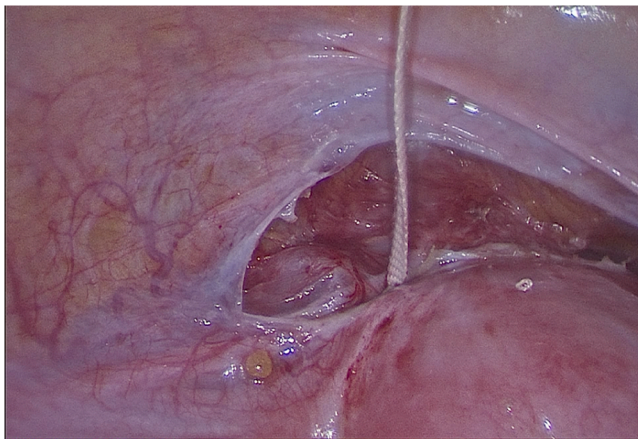


Fig. 2. Tape medial to left uterine artery.

mechanical support that it provides. One hypothesis suggests that sterile placement of TAC mitigates the risk of infection by avoiding placement of a foreign object in the vagina [6].

Advances in the field of minimal access surgery has made it possible to insert cerclage laparoscopically thus providing with the proven benefits including less blood loss, quick recovery, less need for analgesia and less postoperative adhesions [7].

The aim of present study was to evaluate surgical results and pregnancy outcomes after LCC performed as interval procedure in women with cervical insufficiency.

2. Materials and methods

Consecutive series of all women who had interval LCC between January 2017 – December 2021 with follow up until December 2022 were included in this study. All surgeries were performed by single surgeon (NY). Data were collected from patient medical records. The primary outcome was neonatal survival. Surgical morbidity and complications were also noted.

Laparoscopic abdominal cerclage was carried out pre-conception. Surgery was performed under general anaesthesia. After placing the patient in Lloyd Davies position, 4-port laparoscopy was performed. 30⁰ Laparoscope was introduced thru 10 mm umbilical port while three accessory ports were placed in both lower quadrants and left upper quadrant. After completing initial survey of abdomen and pelvic cavity, utero-vesical fold of peritoneum was opened in the midline. This was

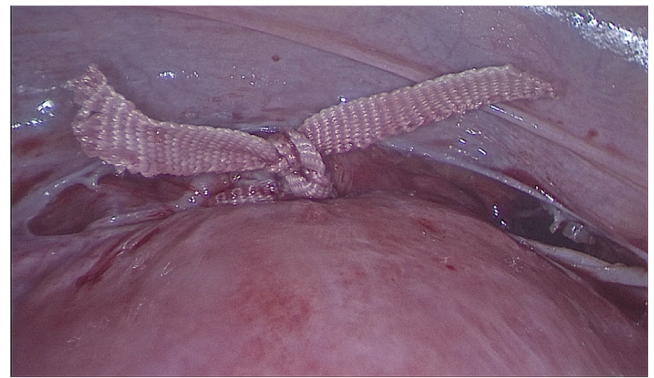


Fig. 3. LCC anterior knot.

extended laterally on both sides to expose the uterine artery. Posteriorly, with a monopolar diathermy hook, incisions were made approximately 1 cm above the uterosacral ligament attachment to the uterus. These were the points of entry or exit of the mersilene tape based on whether the knot was placed anteriorly or posteriorly respectively. The decision in this regard was taken based on the prominence of uterine arteries visible and the depth of space available posteriorly for safe negotiation of the needle without injuring the rectum. Curved needles on mersilene tape were straightened prior to introducing the tape thru 5 mm trocar. Needles were then passed medial to uterine vessels at the level of isthmus and tape was pulled to tie the knot (Fig. 2 & 3). Uterine manipulator in the form of No 6 Hegar dilator was used during the procedure and was removed after securing the knot. This not only helps in manipulating the uterus but also ensures that the endocervical canal remained open.

The peritoneum over vesicouterine fold was closed with polyglactin 2-0 suture regardless of whether the knot is anterior or posterior. Trocars were withdrawn and wounds closed after ensuring hemostasis. All women were discharged within 24 h of surgery.

The purpose of inserting tape medial to uterine artery is to preserve the blood supply to uterus. We did not have a situation where we were unable to pass the tape in desired area between cervix and uterine artery either by blunt dissection or with the needle that the tape comes loaded on. It is not our usual practice to perform doppler following interval LCC. All women have ultrasound scan at follow-up visit in a week to confirm correct placement of tape. Those who have LCC inserted during pregnancy have doppler flow the following day. This group of women however were not part of this study.

All women were counselled and informed consent taken prior to surgery regarding the long-term risk of tape erosion in adjacent pelvic organs along with other potential surgical risks.

3. Results

There were total of 170 pregnancies in the study population prior to

Table 1
Demographics of study population.

Age - Mean (Range)	34 (28–42)
BMI - Mean (Range)	29.64 (21–42)
Gravidity	2–6
Total pregnancies	170
First trimester miscarriage	10
Mid-trimester miscarriage (12 ⁺⁰ - 23 ⁺⁶ weeks)	147
Extreme preterm delivery (24 ⁺⁰ - 26 ⁺⁶ weeks)	13
Prior cerclages	1–4
Living children	None
Blood loss at surgery	<50 ml
Operating time	35–75 mins
Hospital stay	<24 h

LCC. Past vaginal cerclages were based on both clinical findings as well as scan indications. They were all performed by skilled personnel via McDonald technique.

No operative or postoperative complications were observed at the LCC procedures, and all patients were discharged on the day of operation or the next morning. Operating time ranged from 35 to 75 min. Estimated blood loss did not exceed 50 ml in any case.

3.1. Study population

Fifty-five women underwent LCC between the study period. Table 1 shows historical data of our study population. At the time of surgery mean age of the women was 34 years (range 28–42) and mean BMI 29.64 (range 21–42). All women had previously been pregnant (range gravida 2–6). There were 10 first trimester miscarriages, 147 mid-trimester miscarriages and 13 extreme preterm (24^{+0} – 26^{+6} weeks) births between them. In this group, there were 3 live-born babies between 25^{+0} – 26^{+6} weeks but they did not survive. All women had previous failed TVC and had no living children.

3.2. Surgical outcome

All procedures were performed by the same surgeon (NY). Operating time ranged from 35 to 75 min. Estimated blood loss did not exceed 50 ml in any case. Anterior and posterior knot was placed in 32 and 23 women respectively. There were no intraoperative or postoperative complications. All patients were discharged within 24 h. There were two instances of tape erosion. One woman who had knot tied posteriorly developed rectovaginal fistula while the other with anterior knot had tape erosion in the uterine cavity. Both presented with symptoms at least three years post-laparoscopic cerclage and two years following term caesarean section.

3.3. Postoperative obstetric outcome

Follow up was available for all 55 women. 49 women achieved pregnancy at different times after the surgery giving a fertility rate of 89 %. Six out of 55 women had not conceived at the time the manuscript was submitted. Two women were delaying pregnancy for social reasons while four were trying for pregnancy. Of the 49 who achieved pregnancy, 3 women had first trimester miscarriage. They underwent evacuation of products of conception surgically with cerclage-in-situ. Forty-six pregnancies progressed beyond first trimester. 4.34 % (2/46) had premature prelabor rupture of membranes between at 28^{+0} and 29^{+6} weeks. Both needed delivery at 31^{+2} and 32^{+4} weeks respectively because of onset of labour pains. 13.04 % (6/46) women needed delivery between 34^{+0} and 36^{+6} weeks because of mullerian anomaly in one woman and medical conditions complicating pregnancy in five. This included one with Unicornuate uterus, four with severe pre-eclampsia and one with uncontrolled gestational diabetes.

82.60 % (38/46) women were delivered beyond 37^{+0} weeks of pregnancy. No operative complication happened during delivery. All women who went beyond first trimester had live births and took baby home. Neonatal survival rate calculated in relation to number of pregnancies excluding first trimester miscarriage was 100 % with no long-term morbidity.

Removing mersilene tape at caesarean section would be very difficult in view of significant fibrosis that occurs around it. Also increased vascularity to uterus during pregnancy will mean that any attempt to remove the tape may be associated with laceration of uterine vessels that are in proximity. Leaving tape in-situ also helps planning subsequent pregnancy.

Three women in our study group got pregnant for the second time post LCC and had successful outcome. However, this study included only the outcome of first pregnancy that followed laparoscopic cerclage and not the subsequent ones.

4. Discussion

Originally reported by Scibetta et al. [8], modifications have been suggested by several authors to the technique of performing LCC [9–12]. Two important surgical steps involved in LCC are dissection and reflection of the bladder away from isthmus part of the uterus to be able to visualise the uterine vessels and placing the tape medial to vessels ensuring they are not injured. Most complications arising from LCC can be related to these two steps.

Laparoscopic approach to abdominal cerclage offers the potential to reduce morbidity associated with laparotomy. Although there is clear obstetrical advantage of abdominal cerclage over TVC in high-risk populations [13], abdominal cerclage has not been widely practised. This could be due to the need for two surgical procedures; the first is to perform cerclage and the second is for caesarean delivery. As the morbidities are formidable, abdominal cerclage is typically reserved for one of the two groups. The first group is women who have suffered a recurrence of miscarriage despite a TVC. This is the group that is at highest risk of premature birth [14]. The second group would be those women who have a congenitally or surgically inadequate cervix to allow for the vaginal technique [13]. These indications make this procedure relatively rare, and published data on outcomes is limited.

We report prospective experience of LCC over a period of 6 years performed in a tertiary centre for laparoscopic surgery with follow up of at least 12 months after the last surgery. The strength of this study is performance of all surgeries by single surgeon and the stringent patient selection to include women with cervical incompetence who previously underwent TVC ranging from 1 to 4 cerclages and had no surviving neonate. We collected relevant data on past obstetric & gynecological history and monitored the outcome of subsequent pregnancies following LCC for at least up to one year. One woman in our group had complete loss of structural integrity of the cervix due to trauma sustained at repeated miscarriages with in-situ transvaginal cerclage.

Placement of the cerclage medial to uterine arteries ensures that the blood flow to uterus is not compromised. We believe that mersilene tape being made from polyester fiber, tying knot is easier and more secure compared to polypropylene monofilament mesh which is commonly used in laparoscopic suspension procedures. One other added advantage is that the mersilene tape comes preloaded with needles at both ends which may be of use when the avascular window is too narrow to negotiate with atraumatic graspers.

This study has few limitations. Outcome of cerclage was limited to only one subsequent pregnancy although there were women who got pregnant more than once. They were not included in this study. Our group was relatively homogenous and included women with previous cervical cerclage and pregnancy losses. These factors may make it difficult to draw firm conclusions regarding effectiveness in other group of women such as the ones included by other authors [10,15,16]. All procedures were performed by the same surgeon, which might limit the ability to generalize results.

Vaginal birth is not possible following laparoscopic cervical cerclage because of the occlusion of cervix at the level of isthmus thereby making caesarean section the only option for delivery. Thirty eight women (77.5 %) women had elective caesarean section at term. The neonatal survival rate in our cohort was 100 % in pregnancy lasting beyond first trimester with a mean gestational age of 37.4 weeks. Forty-four women (89.7 %) delivered at 34 weeks or beyond.

Those who needed iatrogenic preterm delivery between 34 and 36 weeks had reason that was not associated with the cerclage itself: one woman developed gestational diabetes mellitus, four had pre-eclampsia while the remaining one with unicornuate uterus was delivered at 36 weeks considering her demographics and anxieties around presumed delay that would have occurred in her reaching hospital in time. Two women developed preterm premature rupture of membranes (PPROM) at 28 and 29 weeks of gestation. They needed emergency caesarean section delivery at 31 and 32 weeks respectively due to unremitting

Table 2
Outcome of pregnancy among 55 subjects with cervical incompetence prior to and after LCC.

	Prior to surgery	After surgery
Number of subjects	55	55
Pregnancies achieved	170	49
First trimester miscarriage	10	3
Mid-trimester loss (14–23)	147	0
Extreme preterm delivery (24 ⁺⁰ – 26 ⁺⁶)	13	0
24 ⁺⁰ ,24 ⁺⁶	10	0
25 ⁺⁰ ,25 ⁺⁶	2	0
26 ⁺⁰ ,26 ⁺⁶	1	0
27 ⁺⁰ ,27 ⁺⁶	0	0
Preterm delivery (28 ⁺⁰ ,33 ⁺⁰)	0	2
Preterm delivery (34 ⁺⁰ ,36 ⁺⁶)	0	6
Term delivery (>37 ⁺⁰)	0	38
Live birth	3	46
Neonatal survival	0	46

contractions.

Prior to inserting LCC, 160 pregnancies ended in mid-trimester loss or extreme preterm birth with no neonate surviving. Post-surgery live birth rate and neonatal survival was 100 % after excluding early pregnancy failure (Table 2).

These findings are replicated in large observational studies of laparoscopic transabdominal cerclage, with Huang et al. [9] reporting a live birth rate of 96 % and neonatal survival rate of 100 % and Ades et al. [17] reporting perinatal survival rate of 98.4 %.

Success rates of LCC are reported in the range of 80–100 % (Table 3). In the study by Sarodigan et al. [16] including 54 women who underwent LCC in women at high risk of mid-trimester loss and preterm labour, live birth and neonatal survival rates of 92 % and 97 % were

achieved. Their study population included women who had mid-trimester loss or preterm birth (23–34 weeks) despite a TVC and those who had cervical surgery resulting in very short cervix or no visible ectocervix, hence deeming TVC impossible.

Published series of LCC report very low complication rates [16–18] of minor nature such as uterus perforation at the time of surgery or pelvic infection post-operatively. Ades et al. reported bladder injury which was repaired laparoscopically [19]. Mesh erosion is known to occur and has been reported [20]. In our study, there were no intra-operative or immediate postoperative complications. However, two women developed delayed complications with tape erosion. Both had term caesarean section delivery at least 2 years prior to presentation with symptoms. One woman developed rectovaginal fistula (Fig. 4) while the other presented with excessive vaginal discharge. Ultrasound scan showed the tape in uterine cavity. Rectovaginal fistula was repaired laparoscopically and was discharged within 48-hours. In the other woman, tape from uterine cavity was removed under hysteroscopy guidance as day care procedure. She also had LCC reinserted as a concurrent surgery at her request. In the most recent 2 years following the experience of rectovaginal fistula with posterior knot, there has been a shift in our practice in tying the knot anteriorly in most women.

To sum up, in accordance with past studies, our results show significant effectiveness of preconception LCC in improving obstetric outcomes in women with cervical insufficiency. This procedure carries significant technical advantages: the uterus is smaller and less vascularised, and there is also the ability to use a manipulator to mobilize it while placing the tape. The main disadvantage of preconceptual placement is that some women fail to conceive after the cerclage and would have therefore undergone an unnecessary procedure.

Table 3
Neonatal survival rate following laparoscopic transabdominal cervical cerclage.

Author	Study design	Subjects	Inclusion criteria	Neonatal survival	Complications
Theusen [21]	Prospective Laparotomy Interval	45	Prior midtrimester delivery	100 %	2/45 - Bleeding Paraesthesia
Knudtson [22]	Retrospective Laparotomy Pregnancy cerclage	15	Prior midtrimester loss and failed cervical cerclage	80 %	1/15 Surgical site infection
Whittle [7]	Prospective Laparoscopy Pregnancy and Interval	65	Cervical incompetence	89 %	10.7 %
Umstad [23]	Prospective Laparotomy Pregnancy and Interval	22	Prior midtrimester loss; Cervical surgery in past	100 %	Bleeding in preg group
Riiskjaer [15]	Retrospective Laparoscopy Interval	52	Prior midtrimester loss;short/amputated cervix	100 %	None
Ades [19]	Observational Laparoscopy Pregnancy and Interval	64	Prior midtrimester loss, cervical surgery Congenital uterine malformations	95.8 % (One neonatal death of twin pregnancy; co-twin survived)	Bladder injury 1/64
Luo [10]	Prospective Laparoscopy Interval	19	Prior midtrimester loss; failed TVC; congenital short cervix	92.3 %	None
Bolla [11]	Retrospective Laparoscopy Pregnancy and Interval	18	Prior failed TVC; extremely short or absent cervix	95 %	None
Huang [9]	Retrospective Laparoscopy Interval	100	Prior midtrimester loss; failed TVC	96.4 %	1/100 Perforation of uterus
Sarodigan [16]	Prospective Laparoscopy Interval	54	Cervical surgery; short cervix; previous failed TVC	97 %	None
Current study	Prospective Laparoscopy Interval	55	Prior midtrimester loss and failed TVC	100 %	None

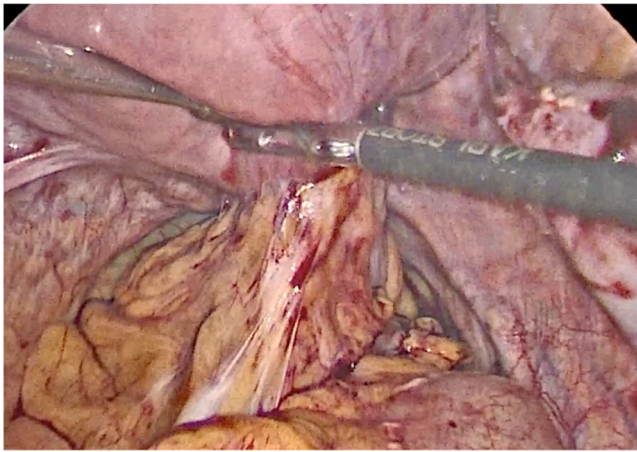


Fig. 4. Mesh erosion – rectovaginal fistula.

5. Conclusions

LCC offers hope to women with recurrent pregnancy loss related to cervical incompetence and in whom TVC has proven to be ineffective, would be difficult or impossible. From a scientific point of view, randomized controlled trials would be needed to define the effectiveness of LCC. Randomized trial however will be unlikely due to the rarity of the procedure and difficulty of finding an appropriate control group. In centres where advanced laparoscopic skills including intra-corporeal suturing is available, this procedure would be considered as relatively simple. Although it has the potential for significant morbidity, in practice, this is unlikely with experienced operators.

Details of ethics approval

This study comes under service evaluation project and does not require ethical review by our organisation ethics committee or management permission. There was therefore no need to submit applications in this regard to seek their approval.

Author contribution statement

NY was the chief operating surgeon. He was responsible for conception, planning and analysing the study. SP did literature review and contributed towards drafting the manuscript.

Declaration of Competing Interest

The authors declare that they have no competing financial interests or personal relationships that could have influenced the work reported in this paper.

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None.

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