SCIENTIFIC PAPER JSLS

Robot-Assisted Abdominal Cerclage During Pregnancy

Burak Zeybek, MD, Amanda Hill, MD, Gulden Menderes, MD, Mostafa A. Borahay, MD, Masoud Azodi, MD, Gokhan Sami Kilic, MD

ABSTRACT

Background and Objectives: Cervical insufficiency is a difficult condition to diagnose and can lead to preterm birth, miscarriage, or perinatal infant morbidity and mortality. We conducted this retrospective case study and literature review to evaluate the safety and efficacy of robot-assisted abdominal cerclage during pregnancy.

Methods: We conducted a case series and a systematic review that included patients who underwent robot-assisted abdominal cerclage during pregnancy from January 2010 through March 2016.

Results: Six patients met the criteria for the case series. Median age was 34 years (range, 28–37) at the time of the procedure. In 5 cases, the indication for transabdominal cerclage was a failed vaginal cerclage in a previous pregnancy, whereas a scarred and shortened cervix caused by a previous dilatation and curettage–induced cervical laceration was the indication in the remaining case. Median operating time was 159.5 minutes (range, 124–204), and median estimated blood loss was 25 mL (range, 10–25). No surgeries were converted to laparotomies; all patients were discharged on postoperative day 1. The median gestational age at delivery was 37.5 weeks (range, 22–39). Five patients delivered between 36 and 39 weeks. No patients had chorioamnionitis or preterm premature rupture of membranes. One patient went into preterm labor at 22 weeks, and the cerclage was removed via minilaparotomy. Eight articles met the criteria for systematic review. Sixteen patients underwent robot-assisted abdominal cerclage during pregnancy. Median age was 31.5 years (range, 25–37). The major indication in most articles was previous failed transvaginal cerclage. The median gestational ages at time of procedure and delivery were 12 weeks (range, 10–15) and 37 weeks (range, 33–39), respectively.

Conclusion: Robot-assisted abdominal cerclage is safe and effective during pregnancy.

Key Words: Abdominal cerclage, Cervical insufficiency, Preterm birth, Robotic.

INTRODUCTION

Cervical insufficiency is one of the leading causes of perinatal infant morbidity and mortality, with an incidence of 0.1–1.0% of all pregnancies.[1,2] It is characterized by painless dilation of the cervix, usually followed by bulging and premature rupture of membranes, which leads to miscarriage or preterm birth. The diagnosis is challenging because of the absence of clear diagnostic criteria, and it is generally made retrospectively, based on obstetric history. The American College of Obstetrics and Gynecology (ACOG) currently recommends the placement of cerclage in patients with a current singleton pregnancy, prior spontaneous preterm birth at fewer than 34 weeks' gestation, and short cervical length (less than 25 mm) before 24 weeks' gestation.[3] The traditional procedure is transvaginal; however, a transabdominal approach is preferred in selected cases, such as in patients in whom transvaginal cerclage failed and resulted in second-trimester pregnancy loss or in those with scarred, physically disabled, or absent cervix.

The success rate of abdominal cerclage is reported to be 85–90% in the literature; however, when performed as an open procedure, it is associated with higher morbidity than the vaginal approach.[4,5] Laparoscopic abdominal cerclage during pregnancy has been shown to be advantageous over laparotomy when comparing success rates and recognizing the well-known benefits of minimally invasive surgery, such as decreased blood loss, shorter hospital stay, decreased pain, and faster recovery

Department of Obstetrics and Gynecology, The University of Texas Medical Branch at Galveston, Texas, USA (Drs Zeybek, Borahay, and Kilic).

Department of Obstetrics and Gynecology, Bridgeport Hospital, Bridgeport, Connecticut, USA (Dr Hill).

Department of Obstetrics, Gynecology, and Reproductive Sciences, Yale School of Medicine, New Haven, Connecticut, USA (Drs Menderes and Azodi).

Disclosures: none.

Address correspondence to: Gokhan Sami Kilic, MD, 301 University Boulevard, Galveston, TX 77555-0587. Telephone: 409-747-4980, Fax: 409-747-0366. E-mail: gokilic@utmb.edu

DOI: 10.4293/JSLS.2016.00072

time.[6,7] Robot-assisted abdominal cerclage is a relatively new minimally invasive technique that facilitates less invasive procedures when compared to the open approach, and it has the advantages of 3-dimensional visualization and endowristed instrumentation when compared to traditional laparoscopy. Since the da Vinci surgical system (Intuitive Surgical, Sunnyvale, California, USA) was approved by the U. S. Food and Drug Administration (FDA) for gynecologic procedures in 2005, there have been only a few robotic abdominal cerclages performed during pregnancy; the first was reported in 2008.[8]

The objective of our case series and review of the literature was to evaluate the safety, efficacy, and feasibility of the robot-assisted abdominal cerclage procedure during pregnancy.

MATERIALS AND METHODS

The study was approved by the University of Texas Medical Branch Institutional Review Board Ethics Committee, and formal informed consent was obtained from all patients.

Case Series

We conducted a retrospective study, including 6 cases from 2 institutions (The University of Texas Medical Branch, Galveston, Texas, and Yale School of Medicine, New Haven, Connecticut), evaluating the safety and efficacy of robot-assisted abdominal cerclage during pregnancy and obstetric outcomes after the procedure. Patients were referred to the Obstetrics and Gynecology Departments of the 2 institutions from January 2010 to March 2016 and were offered the procedure if abdominal cerclage was indicated per ACOG guidelines.[3] All options, risks, benefits, and outcomes were discussed with each patient; informed consent was obtained; and a thorough physical examination was performed before the procedure. Fetal viability and gestational age were confirmed with pelvic ultrasonography. Routine first-trimester screening was obtained to rule out aneuploidies. All patients who underwent robot-assisted abdominal cerclage while pregnant during the study period were included in the analysis. The technique used has been described in previous reports.[9,10]

Systematic Review

Search Strategy

We conducted a systematic literature search of the following databases: PubMed, EMBASE, Ovid Medline, Web of Science, and Cochrane Systematic Reviews. The following medical subject heading (MESH) terms, keywords, and their combinations were used: "robotic," "cervical cerclage," and "cervicoisthmic cerclage." We collected data from all robot-assisted abdominal cerclage procedures during pregnancy. The search was limited to articles published in English up to March 2016. In addition, we manually searched the reference lists of all reports. Two of the investigators reviewed the articles independently (BZ and GSK). Data extracted from the studies included study design, number of patients, and surgical and obstetric outcomes.

Inclusion and Exclusion Criteria

Articles regarding robotic cerclage in nonpregnant patients and traditional laparoscopic cerclage were excluded, and only robotic procedures during pregnancy were included.

Outcome Measures

The primary outcome measure was defined as delivery of a viable infant at 34 weeks' gestational age or more. Secondary outcome measures were gestational age at delivery, preterm labor, premature rupture of membranes, neonatal survival after the procedure, failed abdominal cerclage, and surgical complications. Failure was defined as second trimester or any perioperative pregnancy loss within 2 weeks of the procedure.

Data Analysis

Descriptive statistics were used to report continuous variables.

RESULTS

Case Series

From January 2010 to March 2016, 6 patients met the criteria for inclusion. The median age was 34 y (range, 28–37) at the time of the procedure. In 5 cases, the indication for transabdominal cerclage was failed vaginal cerclage in a previous pregnancy; in the remaining case, a scarred and shortened cervix was the indication, caused by a cervical laceration in a dilatation and curettage. Median operating time was 159.5 minutes (range, 124–204) and median estimated blood loss (EBL) was 25 mL (range, 10–25 mL). None of the surgeries was converted to laparotomy, and all patients were discharged on postoperative day 1. The median gestational age at delivery was 37.5 weeks (range, 22–39). Five patients

delivered at between 36 and 39 weeks. None of the patients had chorioamnionitis or preterm premature rupture of membranes. One patient went into preterm labor at 22 weeks and underwent cerclage removal via minilaparotomy. The patient was found to have a ~1-cm uterine rupture close to the right uterine artery under the cerclage suture. The cerclage suture was removed, and the rupture site was repaired without the need for a hysterectomy. The patient gave birth vaginally to a 500-g female infant 3 h after the procedure. Unfortunately, the infant did not survive because of cardiorespiratory failure. The clinical characteristics of the patients as well as the operative and obstetric outcomes are summarized in **Table 1**.

Systematic Review

Of 27 reports in the initial search, 8 were included. All were either case reports or case series. In total, 16 patients underwent robot-assisted abdominal cerclage during pregnancy. The median age was 31.5 years (range, 25–37). The major indication in most of the published articles was previous failed transvaginal cerclage. Median gestational age at the time of the procedure and delivery was 12 weeks (range, 10–15) and 37 weeks (range, 33–39), respectively. The characteristics of the patients and the surgical and obstetric outcomes are summarized in **Table 2**.

DISCUSSION

To the best of our knowledge, this is the first systematic review of robot-assisted abdominal cerclage during pregnancy. Since robotics technology is relatively new, the published reports in the literature are limited to case reports and case series. However, the safety and efficacy of conventional laparoscopy has been reported to have success rates comparable to those of the open technique.[6,7] In the systematic review by Tulandi et al,[6] the rates of third-trimester delivery and live birth via laparoscopy during pregnancy were found to be 70% and 70–100%, respectively, whereas these rates were 77.4% and 85.2–100% via laparotomy. In the report by Burger et al[7] the fetal survival rate (defined as the total number of liveborn infants who survived the first 6 weeks after delivery divided by the total number of all pregnancies) after laparoscopic cerclage during pregnancy was 80.9%, whereas it was 88.4% in the open surgery group, which was not significantly different. The rate of fetal loss was 11.5% in the laparoscopy group ($n = 26$) and all were during the second trimester. The rate of delivery at ≥34 weeks of gestation was 88%, and mean gestational age at delivery was 34.4 weeks. The rate of conversion to laparotomy was 4.4%; however, the reasons for conversion were not mentioned in the study.

Table 1.
Patient Characteristics and Surgical and Obstetric Outcomes

Patient	Age	Gravida	Parity	Indication (History)	Gestational Age (week)	Operative Characteristics			Obstetric Outcome	
						Operative Time (minutes)	Complications	EBL (ml)	Gestational Age at Delivery (weeks)	Neonatal Survival
1	28	6	2	Failed McDonald cerclage	12	150	None	25	38	1/1
2	34	6	1	Failed McDonald cerclage	14	204	None	25	39	1/1
3	28	5	1	Failed McDonald cerclage	13	158	None	25	38	1/1
4	37	2	0	Scarred cervix	12	124	None	25	36	1/1
5	29	3	0	Failed McDonald cerclage	10	161	None	10	37	1/1
6	34	6	1	Failed McDonald cerclage	12	194	None	20	22	0/1

Table 2.
Reports on Robot-Assisted Abdominal Cerclage During Pregnancy

Reports	Cases (n)	Age	Gravida	Parity	Indication	Gestational Age (weeks)	Operative Characteristics			Obstetric Outcome	
							Operative Time (min)	Complications	Technique/ Technological Advancements	Gestational Age at Delivery (weeks)	Neonatal Survival
Zeybek et al[11]	1	35	3	1	Scarred cervix, preterm delivery, cervical shortening	13	130	None	Indocyanine green	35	1/1
Mourad et al[12]	1	26	6	4	Failed McDonald cerclage in a previous pregnancy	NR	60	None	Needleless	NR	NR
Gibbs et al[13]	1	31	6	1	Cervical insufficiency	12	NR	None	Using a Koh cup as a vaginal fornices delineator	Term	1/1
Menderes et al[10]	2	25	4	0	Failed McDonald cerclage in a previous pregnancy	13	NR	None	Needleless TVUS guidance	Term	2/2
		32	6	0	Failed McDonald cerclage in a previous pregnancy	15	150	Uterine artery (ascending branch) injury, fixed with vascular clips	Needleless	Term	
Foster et al[14]	7	NR	NR	NR	Short congenitally deformed cervix	Median, 13	Median, 157	Conversion to laparotomy in 2 cases:	TVUS guidance	Median, 35	5/6
					Deeply lacerated or markedly scarred cervix	Range, 11–15	Range (112–307)	(1) difficulty in accessing lower uterus		Range, 33/39	1 missed abortion 1 day after the procedure
					Failed cerclage in a previous pregnancy			(2) broad ligament laceration			
Walsh et al[9]	1	35	3	2	Scarred cervix, previous abdominal cerclage, cervical shortening	11	120	None	TVUS guidance with TilePro	37	1/1
Fechner et al[15]	1	37	3	1	Preterm delivery and cold knife cone, cervical shortening	12	NR	None	Needleless	37	1/1

Table 2
Continued

Reports	Cases (n)	Age	Gravida	Parity	Indication	Gestational Age (weeks)	Operative Characteristics			Obstetric Outcome	
							Operative Time (min)	Complications	Technique/ Technological Advancements	Gestational Age at Delivery (weeks)	Neonatal Survival
Wolfe et al[8]	2	27	5	0	Failed vaginal cerclage in a previous pregnancy	12	233	None	A Koh cup was sutured to the cervix for manipulation	35	2/2
										Uterine rupture through posterior uterine wall at cerclage site, repaired successfully	
		23	3	2	Failed vaginal cerclage in a previous pregnancy	10	149 min	None	Manual manipulation of cervix	38	

TVUS, transvaginal ultrasonography.

Our systematic review showed slightly improved outcomes via the robotic route regarding gestational age at delivery (median, 37 weeks), and the rates of live birth (90%), and third-trimester delivery (90%) when compared to the aforementioned success rates of the laparoscopic approach. However, as mentioned previously, these rates reflect only the outcomes of case reports and small case series. Randomized trials are needed to compare the 2 minimally invasive options to make definitive conclusions.

The outcome that attracted attention is that the reported procedure times are longer with the robotic approach than with laparoscopy. The largest case series of robotic cerclage during pregnancy, reported by Foster et al,[14] included 7 cases for which median procedure time was reported to be 157 minutes, which was similar to the median operative time of 159.5 minutes of our case series. Cho et al[16] reported a mean operative time of 55 minutes in their case series of 20 laparoscopies, which was similar to the reported mean procedure time of 52 minutes in the case series reported by Shin et al.[17] The longer operative time for the robotic procedure may be related to incomplete learning curves and additional docking time for the robot, which may be improved with surgeon experience and application of efficiency strategies in the operating room.[18] The longer procedure time will increase the costs of the robotic procedure at this time. However, appropriate cost comparison studies should be designed in the setting of completed surgeon learning curves before definitive conclusions are drawn.

Most articles in the literature report some challenges during the procedure for both the laparoscopic and robotic routes, such as difficulty accessing the lower uterine segment because of a soft and enlarged uterus, difficulty maneuvering because of lack of a uterine manipulator, and enhanced vascularization during pregnancy, which raises a concern for severe hemorrhage.[10,14] To overcome these challenges, various surgical techniques were described, and some technological tools have been implemented in robotics, which may make the robotic system more beneficial over conventional laparoscopy. One of these tools is the concomitant use of transvaginal ultrasonography during the procedure.[9] The TilePro multiinput, display feature of the da Vinci Surgical system provides simultaneous display of real-time ultrasonography and the operative field, enabling the surgeon to identify the borders of the cervix and the location of the internal cervical ostium. This feature allows the surgeon to pass the needle more precisely through the correct surgi-

cal plane while avoiding the lower uterine segment and membranes.

Increased uterine vascularity has also been addressed as a challenge in different reports.[10,11] Menderes et al[10] described the "needleless" surgical technique, during which a needleless Mersilene tape (Ethicon, Somerville, New Jersey, USA) is passed through a peritoneal window medial to the uterine vessels. In another recent report, Zeybek et al[11] described the concomitant use of indocyanine green (ICG) dye with a near-infrared camera system. ICG is commonly used as a contrast agent to assess microvascular circulation and organ vascularization with excellent tolerability. The near-infrared camera system is a recent innovation that was integrated into the da Vinci Si surgical system in 2010. The combination of both creates 2 relatively opposite (low/high) contrasts, which enables identification of high contrast (ICG) on a relatively low-contrast (near-infrared light) background. The authors concluded that the technique may be beneficial in overcoming the obstacles of visualization of the vascular anatomy.

Another challenge that has been reported is the difficulty of manipulating the gravid uterus.[14] An early report described manual manipulation with an assistant's fingers,[9] and Gibbs et al[13] recently reported use of a vaginal fornices delineator, the Koh cup (Cooper Surgical, Inc, Trumbull, Connecticut, USA), to aid in manipulation and improve cervix visualization during a robot-assisted abdominal cerclage.[13] The Koh cup was first introduced in the mid-1990s by the gynecologic surgeon Charles Koh and has been used since that time to facilitate total laparoscopic hysterectomy. Gibbs et al used it as a manipulator during a cerclage procedure by assembling the tips of 2-ring forceps clamps along the base of the Koh cup, which encircles the cervix without disruption of the cervical canal. It has also been reported to enhance uterine vessel identification by delineating vaginal fornices.

There are limitations of the current case series and the systematic review. The case series is limited by the absence of a control group for comparison. Although it also includes a systematic review of the literature, the included articles are only case reports and case series. Thus, a meta-analysis cannot be performed at this time. However, our case series and reports to date suggest that robot-assisted abdominal cerclage during pregnancy is safe and effective.

CONCLUSION

We conclude that robot-assisted abdominal cerclage is feasible during pregnancy and the implemented technological advancements in robotics (the TilePro near-infrared camera system) may be beneficial in overcoming the obstacles of visualization during the procedure. Randomized controlled trials with larger samples of patients are needed to make definitive conclusions.

References:

1. Ludmir J. Sonographic detection of cervical incompetence. *Clin Obstet Gynecol.* 1988;31:101–109.

2. Drakeley AJ, Quenby S, Farquharson RG. Mid-trimester loss: appraisal of a screening protocol. *Hum Reprod.* 1998;13:1975–1980.

3. ACOG Practice Bulletin No. 142: Cerclage for the management of cervical insufficiency. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2014;123:372–379.

4. Novy MJ. Transabdominal cervicoisthmic cerclage: a reappraisal 25 years after its introduction. *Am J Obstet Gynecol.* 1991;164:1635–1641.

5. Witt MU, Joy SD, Clark J, Herring A, Bowes WA, Thorp JM. Cervicoisthmic cerclage: transabdominal vs transvaginal approach. *Am J Obstet Gynecol.* 2009;201:105.e1–e4.

6. Tulandi T, Alghanaim N, Hakeem G, Tan X. Pre- and postconceptional abdominal cerclage by laparoscopy or laparotomy. *Minim Invasive Gynecol.* 2014;21:987–993.

7. Burger NB, Brölmann HA, Einarsson JI, Langebrekke A, Huirne JA. Effectiveness of abdominal cerclage placed via laparotomy or laparoscopy: systematic review. *J Minim Invasive Gynecol.* 2011;18:696–704.

8. Wolfe L, DePasquale S, Adair CD, et al. Robotic-assisted laparoscopic placement of transabdominal cerclage during pregnancy. *Am J Perinatol.* 2008;25:653–655.

9. Walsh TM, Borahay MA, Fox KA, Kilic GS. Robotic-assisted, ultrasound-guided abdominal cerclage during pregnancy: overcoming minimally invasive surgery limitations? *J Minim Invasive Gynecol.* 2013;20:398–400.

10. Menderes G, Clark M, Clark-Donat L, Azodi M. Robotic-assisted abdominal cerclage placement during pregnancy and its challenges. *J Minim Invasive Gynecol.* 2015;22:713–714.

11. Zeybek B, Borahay MA, Kilic GS. Overcoming the obstacles of visualization in robotically-assisted abdominal cerclage using indocyanine green. *J Robot Surg.* Published ahead of print April 16, 2016. DOI: 10.1007/s11701-016-0585-9.

12. Mourad J, Burke YZ. Needleless robotic-assisted abdominal cerclage in pregnant and nonpregnant patients. *J Minim Invasive Gynecol.* 2016;23:298–299.

13. Gibbs S, Widelock T, Elkattah R, Depasquale S. Additional uses of a vaginal fornices delineator. *Am J Obstet Gynecol.* 2015;213:433.e1–e3.

14. Foster TL, Addleman RN, Moore ES, Sumners JE. Robotic-assisted prophylactic transabdominal cervical cerclage in singleton pregnancies. *J Obstet Gynaecol.* 2013;33:821–822.

15. Fechner AJ, Alvarez M, Smith DH, Al-Khan A. Robotic-assisted laparoscopic cerclage in a pregnant patient. *Am J Obstet Gynecol.* 2009;200:10–11.

16. Cho CH, Kim TH, Kwon SH, Kim JI, Yoon SD, Cha SD. Laparoscopic transabdominal cervicoisthmic cerclage during pregnancy. *J Am Assoc Gynecol Laparosc* 2003;10:363–366.

17. Shin SJ, Kwon SH, Cha SD, et al. The feasibility of a modified method of laparoscopic transabdominal cervicoisthmic cerclage during pregnancy. *J Laparoendosc Adv Surg Tech A.* 2015;25:651–656.

18. Zeybek B, Oge T, Kılıç CH, Borahay MA, Kılıç GS. A financial analysis of operating room charges for robot-assisted gynaecologic surgery: efficiency strategies in the operating room for reducing the costs. *J Turk Ger Gynecol Assoc.* 2014;15:25–29.