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Robot-assisted transabdominal cerclage for the prevention of preterm birth: A multicenter experience

Paul Tyan[a], Jamal Mourad[b], Brian Wright[c], Marc Winter[d], Devon Garza[e], Rachael Smith[f], Janel Brink[f], Chapman Wei[g], Gaby Moawad[h,*]

[a] University of North Carolina School of Medicine, Department of Obstetrics and Gynecology, Division of Minimally Invasive Gynecologic Surgery, Chapel Hill, NC, United States
[b] University of Arizona College of Medicine, Department of Obstetrics and Gynecology, Division of Minimally Invasive Gynecologic Surgery, Phoenix, AZ, United States
[c] George Washington University, Columbian College of Arts and Sciences, Washington, DC, United States
[d] Orange Coast Women's Medical Group, Laguna Hills, CA, United States
[e] Renaissance Women's Group, Austin, TX, United States
[f] University of Arizona College of Medicine, Department of Obstetrics and Gynecology, Phoenix, AZ, United States
[g] George Washington University School of Medicine and Health Sciences, Washington, DC, United States
[h] George Washington University, Department of Obstetrics and Gynecology, Division of Minimally Invasive Gynecologic Surgery, Washington, DC, United States

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ABSTRACT

Objective: High-risk pregnancy stratification and the use of Progesterone and prophylactic cerclage based on prior obstetrical outcomes and cervical length screening have been successful in curbing the impact of preterm birth. However, a large number of women will still suffer from preterm delivery even with optimal management. Experts agree that a transabdominal cerclage is the next best option for women who fail a transvaginal cerclage in a prior pregnancy. Our primary objective with this study is to assess the obstetric benefits and feasibility of robotic-assisted transabdominal cerclage in high-risk women projected to have poor obstetric outcomes.
Study design: A multicenter retrospective cohort analysis of consecutive patients undergoing a robotic-assisted transabdominal cerclage (RA-TAC) for obstetric indications at two urban teaching university hospital and one academically affiliated community hospital. High-volume gynecologic surgeons performed all transabdominal cerclage procedures (N = 68). To assess whether the transabdominal cerclage had any effect on subsequent pregnancies, we categorized gestational age into ordinal variables and used a two-proportion z-test to compare pregnancy outcomes and neonatal survival pre (n = 200) and post (n = 59) abdominal cerclage placement.
Results: A total of 68 consecutive patients undergoing a RA-TAC for obstetric indications were selected. We compared 200 pregnancies pre-robot-assisted cerclage to 59 pregnancies post-robot-assisted cerclage. The odds of delivering after 34 and 37 weeks gestational age was 4.0 and 3.6 times greater post-robot-assisted cerclage, respectively ($P < 0.001$). The RA-TAC also had a significant effect on neonatal survival. The odds of neonatal survival was 12.6 times greater after RA-TAC placement when compared to prior pregnancy outcomes. Surgical outcomes were also favorable with no conversions to laparotomy or perioperative pregnancy loss.
Conclusion: The RA-TAC influences an increase in gestational age and improves neonatal survival in women projected to have poor pregnancy outcomes. The robot-assisted transabdominal cerclages provide excellent obstetric outcomes without the morbidity of a laparotomy or the technical challenges associated with a conventional straight-stick laparoscopy. This procedure is not intended to replace any other minimally invasive modality for cerclage placement but rather increase awareness of a less technically challenging option for transabdominal cerclage placement to help propagate the procedure to more patients.

* Corresponding author at: 900 23rd St NW, Washington, DC 20037, United States.
E-mail address: GNMoawad@gmail.com (G. Moawad).

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Introduction

A History Indicated Cerclage is usually placed between 12 and 14 weeks gestational age (GA), after the prenatal screening window, based solely on prior adverse obstetric outcomes. Although first described more than century ago, the first scientific evidence supporting the benefit of TransVaginal (TV) cerclage placement in high-risk women with three or more preterm births was published in 1993 [1–4]. Given the morbidity associated with multiple preterm deliveries, substantial efforts were made to incorporate ultrasound technology to identify women at highest risk earlier in their obstetric history.

A meta-analysis of four trials published in 2005 reinforced the benefits of cerclage placement in women found to have a short cervix and had endured one prior Preterm Delivery (PD) or Second-Trimester Loss (STL) [5]. Ensuing studies in the field aimed at evaluating the optimal cervical length at which a cerclage was deemed beneficial [6–8]. Another meta-analysis published in 2011 reinforced the benefits of cerclage placement for singleton pregnancies in women with prior STL or PD and a cervical length of less than 25 mm or less [9]. In addition to the critical research done in the field of surgical prevention of preterm birth and risk stratification, comparable work had been made in the pharmacologic prevention of preterm birth. Progesterone therapy was associated with a significant reduction in PD before 34 weeks and a reduction in perinatal mortality in high-risk women [10,11].

With optimal management by early identification of high-risk women, cervical length screening and monitoring, progesterone therapy, and by ultrasound or history-indicated transvaginal cerclage placement we are preventing a large number of preterm birth. The rate of preterm delivery has been steadily decreasing over the past decade and has reached a nadir in 2015. Preterm births dropped from 12.6% of all deliveries in 2006 to 9.6% in 2015 [12,13]. However, preterm birth remains the leading cause of neonatal morbidity and mortality, and we still lack a clear consensus on the next best management option for patients with the highest risk.

Experts suggest that a transabdominal cerclage is warranted in women with a prior failed transvaginal cerclage and those with cervical or anatomical issues precluding a transvaginal cerclage placement [14,15]. First successfully described in the mid-1960s, the transabdominal cerclage has failed to gain popularity [16]. With the advent of minimally invasive surgery, we have seen a surge of articles describing pregnancy outcomes with a laparoscopic-assisted transabdominal cerclage placement. A metanalysis of laparoscopically placed transabdominal cerclages published in 2018 showed a clear obstetric benefit with 82.7% of patients delivering after 34 weeks and a small benefit over transabdominal cerclages placed through laparotomy [15]. Given the technical challenges associated with placing a cerclage via conventional laparoscopy we conducted this study to analyze the obstetric benefit and delineate the surgical safety profile of the Robotic-Assisted Transabdominal Cerclage (RA-TAC).

Material and methods

The focus of this research work was to test the effectiveness of a robot-assisted cerclage placement in preventing preterm delivery. In doing so, data was gathered on pregnancy outcomes of patients both before and after the procedure was completed. Various pregnancy outcome variables were then used to determine if a statistically significant change can be measured. This study involved retrospective data collection from three institutions. Institutional Review Boards (IRB) approval was obtained at all referenced centers in 2017. The institutions included two urban teaching university hospitals and an academically affiliated community hospital in California, Washington D.C., and Arizona. High-volume minimally invasive gynecologic surgeons, each with more than 300 robot-assisted completed cases, performed all the procedures. Data was collected between 10/2011 and 10/2017. At least three months were allowed from the last cerclage placement to initiation of data collection. Consecutive cases were collected at each institution, and no cases were allowed to be omitted. Data collection was capped at different times at different institutions as cited in their respective IRB documents. Seven patients were still pregnant at the time the data was collected. One of the authors' techniques for placement of a pre and postconceptional RA-TAC is detailed in a separate publication [17].

Preoperative, intraoperative, postoperative, and obstetric data were obtained for all patients. Pregnancy outcomes after cerclage placement were gathered through the electronic medical record as most patients subsequently delivered at the center where the cerclage was placed. All patients were contacted by telephone to confirm obstetric outcomes after the cerclage placement. Eight patients were lost to follow up and had no subsequent electronic record information after the RA-TAC. Two of those eight patients had a post-conceptional transabdominal cerclage placement. A multi-disciplinary team made the clinical decision for a RA-TAC placement for each patient. At two of the three institutions, the surgeon was not involved in that decision.

Postoperative descriptive data were collected to study the safety and efficacy of the RA-TAC in preventing PD and STL. We also collected conception rates and time to conception in months for preconceptional RA-TAC cases. Surgical complications rates, estimated blood loss, same day discharge rates, and perioperative miscarriages for interval cerclages were also obtained. Neonatal morbidity and mortality outcomes were collected including survival rates and Neonatal Intensive Care Unit (NICU) admissions. Cesarean delivery metrics were also collected for all the cases.

In adherence with the vast majority of preterm birth prevention literature, the primary endpoint was delivery at 34 weeks GA or greater. Secondary endpoints included delivery at less than 34 weeks GA. Those were categorized as early miscarriage (GA < 12.6 weeks), second-trimester loss (GA 13–23.6 weeks), and preterm delivery. Preterm delivery was further classified into three groups (GA 24–28.6 weeks, GA 29–34.6 weeks, and GA 35–36.6 weeks). We compared pregnancy outcomes before and after cerclage placement similarly to previously published cerclage data. The primary variables are described in Tables 1 and 2. Pregnancy outcomes were treated as a factor level variable composed of the six categories of possible outcomes.

In comparing pre and post RA-TAC data, a substantial increase in the percentage of full-term pregnancies was observed after cerclage placement. The effect of RA-TAC on pregnancy outcomes was analyzed using two proportions z-test to determine if significant differences are present. The null hypothesis is that no differences between the proportions are present or $P1 - P2 = 0$ with the alternative hypothesis being the differences between proportions are present or $P1 - P2 \neq 0$.

This analysis was completed for each one of the pregnancy outcome categories with emphasis placed on the differences between pregnancy rates past 34 weeks and past 37 weeks GA. A 95 percent confidence level was used for the analysis. Statistical significance was defined when the p-value was less than .05. The statistical computing language R version 3.5 was used to complete the analysis.

Results

We retrospectively analyzed data from 68 patients, 45 (66.1%) patients had a preconceptional RA-TAC, and 23 (33.8%) had a postconceptional RA-TAC. The average gestational age at postconceptional RA-TAC placement was 11.6 weeks. For the

Table 1
Descriptive Data of Pregnancy Outcomes Pre and Post RA-TAC Placement.

	n		Mean		Mode		Std Dev		Max	
	Pre-RA-TAC	Post-RA-TAC	Pre-RA-TAC	Post-RA-TAC	Pre-RA-TAC	Post-RA-TAC	Pre-RA-TAC	Post-RA-TAC	Pre-RA-TAC	Post-RA-TAC
Total Number of Pregnancies	200	59	2.94	0.98	3	1	1.64	0.65	7	3
Total Number of Live Births	41	45	0.6	1.02	0	1	0.94	0.54	5	3
Early Miscarriage (0–12 weeks GA)	57	5	0.83	0.08	0	0	1.14	0.42	4	3
Second Trimester Loss (13–23 weeks GA)	95	2	1.39	0.03	1	0	0.99	0.18	3	1
Preterm Delivery (24–28 weeks GA)	18	0	0.26	0	0	0	0.477	0	2	0
Preterm Delivery (29–34 weeks GA)	8	5	0.12	0.09	0	0	0.325	0.295	1	1
Preterm Delivery (35–36 weeks GA)	2	9	0.02	0.167	0	0	0.17	0.37	1	1
Term Deliveryc(>37 weeks GA)	20	32	0.29	0.57	0	1	0.82	0.56	5	2

Table 2
Outcomes of Interest Pre and Post RA-TAC Placement.

	Pre-RA-TAC	Post-RA-TAC
Number of live births	41	45
Number of pregnancies[a]	143	54

[a] Excluding first early miscarriage.

preconceptional RA-TAC cohort, 70.2% of patients were able to conceive after an average of 9.0 months. Before the RA-TAC placement, 89.3% of patients had experienced at least one preterm delivery or late miscarriage between 13 and 36 weeks gestational age. Prior placement of a transvaginal cerclage was also common among our patient cohort as 68 patients had a total of 60 TV cerclages, 51 of which failed and resulted in a preterm delivery before 34 weeks. 63.2% of all patients experienced at least one prior failed transvaginal cerclage. Also, 23.5% had experienced at least one cervical surgical procedure. One patient had a cervical laceration as a result of birth trauma, and two patients had congenital anomalies at the uterine level, but none had congenital cervical anomalies.

Surgical metrics for robot-assisted cerclage procedures were collected. The average estimated blood loss was 40.4 cc, and 92.3% of patients were discharged on the same day. No intraoperative organ injuries, conversion to laparotomy, post-discharge readmissions, or post-discharge reoperations occurred. For the post-conceptional RA-TAC cohort, none of the patients experienced a perioperative miscarriage within 48 h of cerclage placement. 4.4% of patients experienced incisional cellulitis. Cesarean delivery complications after RA-TAC were also reviewed. None of the patients had a placenta previa. One patient had an undiagnosed placenta accreta resulting in an intraoperative hemorrhage and a cesarean hysterectomy. Out of the 54 pregnancies carried after 23 weeks, 45 neonates survived, yielding a neonatal survival rate of 83.3%. Fifteen (28.3%) of the 53 pregnancies carried after 23 weeks were admitted to the NICU.

Detailed descriptive outcomes of prior pregnancies are listed in Tables 1 and 2. The results of the outcomes of interest analysis by GA category are seen in Tables 3 and 4. The RA-TAC resulted in a significant decrease in the proportion of second trimester losses 66.4% vs 4.1% ($p < 0.001$). The odds of delivering after 34 and 37 weeks gestational age was 4.0 and 3.6 times greater post-robot-assisted cerclage, respectively ($P < 0.001$). The RA-TAC also had a significant effect on neonatal survival. The odds of neonatal survival was 12.7 times greater after RA-TAC placement when compared to prior pregnancy outcomes.

Table 3
Results of Two Proportions Z-Test for Pregnancy Outcomes.

	Pre-RA-TAC Rate (%)[a]	Post-RA-TAC Rate (%)[a,b]	95% CI for mean difference	p-value
Second Trimester Loss (13–23 weeks GA)	95/143 (66.43%)	2/48 (4.16%)	0.746, 0.938	<0.001
Preterm Delivery (24–28 weeks GA)	18/143 (12.58%)	0	–	1
Preterm Delivery (29–34 weeks GA)	8/143 (5.59 %)	5/48 (10.42%)	−0.133, 0.154	0.883
Preterm Delivery (35–36 weeks GA)	2/143 (1.39%)	9/48 (18.75%)	−0.242, −0.038	0.012
Term Delivery (>37 weeks GA)	20/143 (13.98%)	32/48 (66.67%)	−0.471, −0.145	p<0.001

[a] Excluding first early miscarriage.
[b] Excluding current pregnancies.

Table 4
Results of Two Proportions Z-Test for Delivery After 34 and 37 weeks and Neonatal Survival.

Successful Cerclage	Pre-RA-TAC[a]	Post-RA-TAC[a,b]		
	Rate (%)	Rate (%)	95% CI for mean difference	p-value
Delivery > 34 weeks GA	22/143 (15.38%)	41/47 (85.23%)	−0.328, −0.118	< 0.001
Delivery > 37 weeks GA	20/143 (13.98%)	32/47 (68.08%)	−0.471, −0.145	< 0.001
Neonatal Survival				
	Rate (%)	Rate (%)[a,b]	95% CI for mean difference	p-value
	41/143 (28.67%)	45/47 (97.88%)	−0.801, −0.562	<0.001

[a] Excluding first early miscarriage.
[b] Excluding current pregnancies.

Comments

Robot-assisted transabdominal cerclage leads to favorable pregnancy outcomes in a cohort of patients projected to have poor obstetric results based on history-related risk stratification [18]. Our obstetric results are in line with prior open and laparoscopic transabdominal cerclage studies [16,19]. When excluding first trimester losses, the vast majority of our patients delivered in the third trimester and our neonatal survival rate was 83.3%. Our detailed surgical metrics also suggest that the RA-TAC is a safe procedure given that no major intraoperative, postoperative, or pregnancy-related adverse outcomes occurred in all cases. Also, based on our data, we can suggest that a cesarean delivery after robotic-assisted cerclage is safe. One patient had abnormal placentation with subsequent complications at the time of delivery.

To our knowledge, there are no randomized controlled trials that compare any method of transabdominal cerclage to optimal management by cervical length monitoring, Progesterone administration, and TV cerclage placement. Many studies report favorable obstetric outcomes after laparoscopic-assisted transabdominal cerclage placement, a finding that was reinforced by a meta-analysis of 728 that published an 82.9% rate of delivery at GA > 34 weeks [16]. Evidence supporting robotic-assisted transabdominal cerclage is limited to case reports and case series [20,21].

Preterm delivery is the result of a multifactorial process. Given the severe implications caused by preterm delivery on the newborn, affected family, society, and healthcare, remarkable efforts have been implemented to prevent such outcomes. Apart from the initial NICU admission, children born at less than 28 weeks GA have a 130% increase in inpatient hospital admission and a 443% increase in healthcare related costs over ten years when compared to children born at term [22]. Over the past two decades, we have been very successful at identifying and remedying this major healthcare issue as evidenced by a steady decrease in preterm births that coincides with the vast collective research effort in the field [13]. However, we still have close to 382 000 children born preterm in the United States alone each year. The annual economic burden per preterm newborn is estimated at USD 51 600 in a report published in 2007 by the National Academy of Health with an incurring national healthcare cost of at least USD 26 billion [23]. Although significant breakthrough has been made, a substantial number of newborns and their families are still affected. Based on a large number of published case series, retrospective studies, and meta-analyses, we believe that a transabdominal cerclage is reasonable for affected patients who still deliver preterm despite best efforts.

Many issues limit the routine use of transabdominal cerclage placement. The most pressing issue is the lack of level I evidence demonstrating the superiority of the transabdominal cerclage in a specific patient population. Second, TAC commits the patient to future cesarean deliveries. Third, a transabdominal cerclage placed via laparotomy entails a major surgical procedure done for prophylactic indications and another short interval laparotomy for a CD. The laparoscopic transabdominal cerclage resolves the latter issue, however, creates its own set of drawbacks. The laparoscopic approach is a technically challenging procedure that requires vertical plane dissection and knot tying which might be made technically more accessible with a robotic-assisted approach.

Our study has a number of limitations. The primary limitation is the retrospective study design that precludes controlling for some variables. Also, the indication for cerclage placement varies widely among patients. Even though all patients experienced either a preterm delivery, failed cerclage, or cervical surgery we could not control for the number of times each indication occurred. Although the decision for cerclage was made independently of this study, given the multicenter approach we could account for measures taken in addition to cerclage placement at each institution. The strength of this study is the relatively large number of patients for an emerging procedure and the holistic approach in which data had been collected. The multicenter approach makes our results more generalizable among high volume gynecologic surgeons.

Future research could include conditional mean testing for categories of patients that have experienced multiple preterm pregnancies which could be done by creating categories of patients that experience high, medium, or low levels of preterm births. In doing so, it would be possible to measure the impact that RA-TAC procedure on various risk levels to ascertain which category of patients would benefit the most from this surgical procedure. Greater sample size would be needed for such statistical work.

The RA-TAC technique is not intended to replace or prove to be superior to the laparoscopic-assisted transabdominal cerclage but rather add another safe and minimally invasive modality for transabdominal cerclage placement. Describing another less technically challenging method for abdominal cerclage placement will hopefully result in more widespread use, with the ultimate goal of building a backbone for a randomized clinical trial.

Disclosures

Dr. Moawad is speaker for Intuitive Surgical. Dr. Garza is a preceptor for Intuitive Surgical. Dr. Winter is speaker for Intuitive Surgical, Applied Medical, Haylard, and Acessa Health. All other authors have nothing to disclose.

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