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**OBSTETRICS** 

### Operative complications and fetal morbidity encountered in 300 prophylactic transabdominal cervical cerclage procedures by one obstetric surgeon

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This retrospective cohort study identifies complications associated with transabdominal cerclage (TAC). In 300 procedures performed over a 24 year time span, 11 (3.7%) surgical complications were encountered. Fetal loss (prior to 20 weeks) occurred in 4.1% of pregnancies. The median estimated blood loss among patients was 100 ml, with blood loss sufficient to require transfusion only once. Considering patients with classical indications, the gestational age at delivery was greater (37 weeks) after TAC than in the latest pre-TAC pregnancy (24 weeks) (p < 0.001). Lower uterine dehiscence in four patients and uterine rupture in one, underscore the advisability of early term delivery after fetal lung maturity is assured. A survival rate of 98.0% was calculated among infants that were delivered at >24 weeks' gestation. Our results demonstrate that complications encountered in placing a TAC were unusual and generally manageable. This communication may assist the surgeon to balance risks in individual clinical circumstances more adequately.

**Keywords:** Cervical insufficiency, pregnancy, surgical complications, transabdominal cervical cerclage

#### Introduction

Pre-term delivery, particularly when it occurs prior to 28 weeks, is one of the greatest challenges in obstetrics. Although cervical closure is maintained until near term in the large majority of pregnancies, individual cervical structural differences, combined with pregnancy factors such as multiple fetuses can lead to extremely early softening and dilatation, leading to pre-term delivery (Iams et al. 1995).

Cervical insufficiency (CI) occurring in the 2nd or early 3rd trimester may recur in subsequent pregnancies, leading to a sequence of pre-term deliveries (Daskalakis 2009; Debbs and Chen 2009). The incidence of CI has been reported in 0.1-1% of all pregnancies and is an important cause of 2nd trimester loss (Al-Fadhli and Tulandi 2004; Wolfe et al. 2008). Diagnosis is usually from history, based on recurrent 2nd or early 3rd trimester pregnancy losses following relatively silent cervical dilation (Harger 1983). Numerous studies have shown that some women may benefit from the placement of an encircling cervical suture (cerclage) in subsequent pregnancies; however, appropriate candidates and the use of cerclage as a treatment remain a matter of debate (Daskalakis 2009; Knudtson et al. 2010).

In 1955, Shirodkar proposed a transvaginal cerclage (TVC) for the treatment of cervical insufficiency. MacDonald later simplified the procedure in 1957, and the MacDonald technique is now the most commonly used. Transabdominal cerclage (TAC) was introduced in 1965 by Benson and Durfee, as a procedure reserved for patients with either a poor obstetric history, patients who experience a failed prophylactic TVC or in whom a TVC is not technically possible. In most instances, the TAC procedure is conducted between 10 and 16 weeks' gestation, as a prophylactic measure. During the TAC procedure, a band is placed circumferentially around the cervix via an abdominal approach, at the level of the junction of the uterine body and the cervix and medial to the uterine arteries. This band bolsters cervical strength against the expansion of the uterus (Benson and Durfee 1965; Simcox and Shennan 2007). Conventionally, the procedure is performed by laparotomy, although the cerclage can also be placed laparoscopically with and without robotic-assistance (Debbs and Chen 2009; Umstad et al. 2010). With the abdominal approach, a band at the level of the internal os avoids slippage of the suture caudally, maintained in place by the uterosacral ligaments and, possibly, by the attachment of the bladder. If the patient is considering future pregnancies, the TAC suture may be left *in situ* (Debbs and Chen 2009).

Despite these advantages, the TAC has not replaced the conventional McDonald cerclage in popularity. Customarily, most patients undergoing a TAC will have it done by laparotomy, which means the patient must have two laparotomies during pregnancy. Transabdominal cerclage has been associated with serious operative complications compared with a TVC (Zaveri et al. 2002; Witt et al. 2009). Although Mahran (2000) reported a significant incidence of later pregnancy complications, these complications may well reflect the healthcare available to them or accessed by them, rather than the surgeon's experience or the surgery itself. Reported complications include significant blood loss, chorioamnionitis, and premature rupture of membranes (PROM). In addition, some studies report similar effectiveness between the TVC and TAC procedures in prolonging the pregnancy (Golfier et al. 2001; Hole et al. 2003; Rand and Norwitz 2003; Witt, et al. 2009), while others have shown that TAC is associated with fewer recurrent pre-term births and improved neonatal survival compared with previous pregnancies or failed TVC used as controls (Novy 1991; Craig and Fliegner 1997; Turnquest et al. 1999; Lotgering et al. 2006). Compared with placement of TVC repeatedly in the face of prior failure, TAC produces fewer recurrent pre-term births and improved neonatal survival (Zaveri et al. 2002; Debbs and Chen 2009). Other studies have also found improved survival rates of infants born to patients that had a TAC, ranging from 79% to 93% (Novy 1991; Golfier et al. 2001; Lotgering et al. 2006; Fick



Although this paper supports previous studies that show the efficacy of the TAC procedure, it focuses specifically on the risks that might be encountered with TAC. Obstetric surgeons may shy from undertaking this procedure for fear of imposing undue risks on the pregnancy and the mother. Since the complications we encountered seemed lower than expected, or manageable, we hope this communication might allow the obstetric surgeon to balance patient risks more adequately against the potential gain. This study reviews the surgical complications and fetal/neonatal outcomes of patients who underwent a TAC procedure by one maternal fetal specialist over a 24-year period.

#### Methods

#### Study design

This is a retrospective cohort study of all TAC procedures performed by one of the authors (JES) from 1987 to 2011. The study was approved by the hospital's Institutional Review Board. Patients came to this practice only through physician referral and were offered TAC if the clinical history, findings and situation warranted. All TAC procedures were performed between 10.0 and 20.6 weeks' gestation and were completed by laparotomy or by robotic-assisted laparoscopy (da Vinci standard surgical system, Intuitive Surgical, Inc, Sunnyvale, CA). In all cases, blood loss was estimated by the anaesthesiologist.

Recommendation for a TAC included classical indications: history typical of CI in a prior pregnancy with either: (1) failure of a prophylactically placed vaginal cerclage in a prior pregnancy; (2) a deep cervical laceration or (3) remarkable shortening of the exocervix making the forniceal recesses either shallow or non-existent. Particularly in recent years, a TAC was offered to some patients with a history indicative of only CI, as well as patients without a history of CI if one of the following were present: extreme cervical shortening, uterine anomaly or deep cervical laceration. Starting in 2002, prophylactic TAC was offered to higher order multiples as an option, based on the observation of positive outcomes in patients who had undergone TAC for classical indications and on the observation that risk of loss prior to 28 weeks was 13% in these pregnancies. (A detailed discussion of reduction of risk with TAC in triplet pregnancies can be found in Sumners et al. 2011.)

Some patients were offered a TAC when presenting with cervical hypoplasia and a uterine unification defect (UUD). Ultrasound, historical findings and vaginal speculum examination were used to identify the extent of the uterocervical malformation. Cervical hypoplasia was assessed by vaginal speculum examination and involved extremely shallow or non-existent forniceal recesses in addition to small cervical stromal volume, as appreciated by transvaginal ultrasound imaging.

#### Definitions

Gestational age was assessed by late 1st trimester or early 2nd trimester ultrasound. Patients who had a prior singleton pregnancy (excluding 1st trimester loss) functioned as their own control in order to determine whether there was an increase in gestational age at delivery post-TAC. Therefore, eligible controls were defined within each patient's most immediate, singleton pregnancy, prior to the TAC pregnancy.

A failed TVC (in a prior pregnancy) was defined as a cerclage that either did not prolong the gestational age at delivery or did not result in a viable neonate.

#### Evolution of surgical technique

The majority of laparotomy procedures were performed under spinal anaesthesia and all robotic-assisted procedures under general anaesthesia. Surgical technique and perioperative care has evolved over the years, as surgeons' experience accumulated, as noted below.

- 1. The uterocervical junction is obvious by the early 2nd trimester, and the uterine arteries may be located by a combination of palpation and visualisation, after dissection of the bladder from the anterior cervix.
- 2. A 5 mm Mersilene tape (Ethicon Inc, Somerville, NJ) is passed posteriorly to anteriorly on either side of the cervix at the uterocervical junction medial to the uterine arteries, with the knot tied anteriorly to secure the tape tightly around the cervix. In the initial cases of this series, the tape was passed bluntly using the large, swedged needle provided with the tape. After significant, rapid haemorrhage was encountered in the second case, this blunt passage was abandoned in favour of a meticulous dissection of a fenestration among the uterine venous plexus medial to the uterine arteries and drawing opposite ends of the Mersilene band through the fenestration with a blunt grasping instrument.
- 3. Control of venous bleeding was with titanium clips and, on occasion, with mass ligation of the venous structures (securing them against the lateral cervical wall, usually above the level of the band). Except in a few cases, ligation of the entire vascular bundle (including the artery) has been avoided to limit alteration of arterial flow to the uterus.
- 4. Loupe magnification and a headlamp have been used since
- 5. Perioperative indomethacin treatment (2 days) and antibiotic prophylaxis has been used routinely since 1999.
- 6. In more recent cases, the density of the uterine venous plexus provoked dissection of the uterine artery free from surrounding venous and connective tissue to allow passage of the tape through a less venous-engorged area of the posterior leaf of the broad ligament and under the uterine artery, excluding it from compression by the tape.
- 7. In some cases, and depending on the pelvic geometry, the cervix and lower uterus was elevated into the field by inflation of a balloon, placed in the posterior cul-de-sac, to 300-400 ml.
- 8. In laparoscopic cases, the tape has been passed, held in a grasping instrument, from posterior to anterior medial to the uterine artery. In some of the cases, dissection of the uterine artery free, as noted in number 6 above, was accomplished.

#### Statistical analysis

Statistical analysis was conducted using SPSS 18.0 for Windows (SPSS Inc, Chicago, IL). For continuous variables with normal distribution, the mean and standard deviation are reported. For continuous variables not normally distributed, the median and inter-quartile range (IQR) are reported. A Wilcoxon matchedpair signed-rank test was used to compare prior pregnancy gestational age at delivery with post-TAC gestational age at delivery. A p value of < 0.05 was considered statistically significant.

#### Results

A total of 300 TAC procedures were performed between 1987 and 2011. Of these, 157 (52.3%) were done for classical indications; 74 (24.7%) for multifetal pregnancies and 69 (23.0%) for other indications (Figure 1). The majority of patients were Caucasian (n = 245, 81.7%) and most procedures were performed by laparotomy (n = 281, 93.7%). Additional patient demographics are found in Table I.

The median age of patients at the time of TAC placement was 30.9 years (range 17.8-43.3 years). The majority of procedures (n = 254, 89.8%) were performed prior to 15 weeks' gestation.



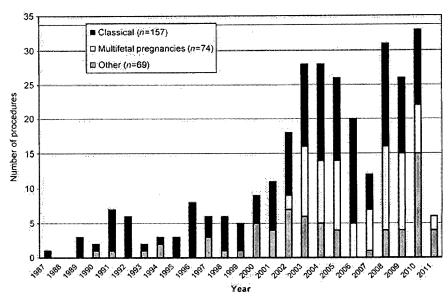


Figure 1. Transabdominal cervical cerclage (TAC) procedures completed from 1987 to 2011.

There was no statistical difference in gestational age at the time of the procedure between singleton and multiple pregnancies (median age: 13.0 and 13.3 weeks, respectively; p = 0.101). Of the 283 pregnant patients, 270 (95.4%) had delivered by the time of analysis. Looking at prior pregnancies in the entire collection of sampled patients, slightly under half (n = 142, 47.3%) had at least one spontaneous loss (prior to 20 weeks' gestation); 154 (51.3%) had a prior pre-term birth and 137 (45.7%) had at least one living child at the time of the procedure. When considering only those patients with classical indications of CI (n = 144), the gestational age significantly increased from the latest pre-TAC pregnancy (24.0 weeks) to the TAC pregnancy (37.0 weeks) (p < 0.001).

Of the patients, 12 (4.3%) had TAC for UUD (Table II). Of these, five had a unicornuate uterus and seven a duplex uterine

Table I. Maternal characteristics at transabdominal cervical cerclage (TAC).

	. n	(%)
Age (n, median years, IQR)	300	30.9 (7.
Gestation age (n, median weeks, IQR)	283	13.1 (1.5
Nulliparous	99	33.0
Gravida 1	66	22
Indications	•	
Classical	157	52.3
Failed TVC	68	22.6
SC with CI	74	24.7
DCL with CI	15	5.0
Non-classical	69	23.0
SC without CI	42	14.0
DCL without CI	5	1.7
UA without CI	1	0.3
CI only	21	7.0
Multifetal pregnancy	74	24.7
Fetal number at TAC		
Non-pregnant	17	5.7
Singleton	179	59.7
Twin	19	6.3
Triplet	72	24.0
Quadruplet	9	3.0
Quintuplet	3	1.0
Septuplet	1	0.3

IQR, interquartile range; TVC, transvaginal cervical cerclage, SC, short cervix, DCL, deep cervical laceration; UA, uterine anomaly; CI, cervical insufficiency.

system (two unicornuate uterine bodies with two cervical structures connected by intervening connective tissue, or a complete uterine septum in a single uterine body with two cervixes). Diagnosis was made indirectly using sonohysterography and/or hysterosalpingogram for three patients, and directly with laparotomy/ laparoscopy on nine patients. The gestational ages at delivery of UUD patients are presented in Figure 2.

#### Surgical complications

There were 11 (3.7%) total surgical complications with few of these being intra- or early postoperative. Table III lists the number and type of complications encountered. Blood loss (EBL) was modest with a median loss of 100 ml (100.0 IQR), with only four patients losing 500 ml or more. No UUD patients required blood transfusion. Pulling of the tape through the cervical wall, associated with labour late in pregnancy, occurred with one UUD patient and another experienced uterine rupture necessitating a hysterectomy. The patient who experienced the uterine rupture was a singleton pregnancy with two prior extremely pre-term deliveries (one resulting in a neonatal demise). Her cerclage was placed at 13.71 weeks' gestation and until the time of her presentation at an outlying hospital, had not experienced any complications. Pre-term labour was stabilised on intravenous Mg++infusion and expediently transferred by ambulance to our hospital. The patient arrived with a ruptured uterus and fetal demise at 30 weeks' gestation.

#### Fetal/neonatal outcomes

At the time of cerclage, 491 fetuses were present among 283 pregnancies, but at the time of analysis, the outcome of 25 neonates (13 non-delivered pregnancies) had yet to be determined. Out of 270 pregnancies, 25 experienced a fetal and/or neonatal loss

Table II. Characteristics of transabdominal cerclage (TAC) patients with cervical hypoplasia and uterine unification defect (n = 12).

Median	Interquartile range
27.5	10.5
13.9	1.5
35.6	6.3
n	(%)
8	66.7
10	83.3
	27.5 13.9 35.6 n 8



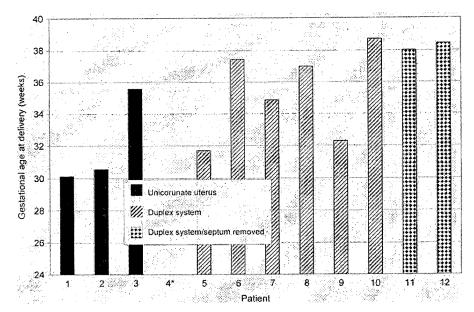


Figure 2. Gestational age at delivery of patients with uterine unification defect and cervical hypoplasia. \*Patient 4 (unicornuate) was not pregnant.

(9.3%). Table IV examines the fetal/neonatal losses in the cohort of 466 fetuses and 440 infants. There were 14 (3.2% of total fetuses) fetal losses prior to 20 weeks and 12 (2.7% of total fetuses) fetal demises occurred after 20 weeks' gestational age. A total of 440 infants were born after 24 weeks. The survival rate for liveborn infants in this series is 98.0% (431 infants). Therefore, out of 466 fetuses, 431 (92.5%) survived to livebirth and infant hospital discharge.

#### Discussion

Our experience indicates the TAC procedure can be efficacious and safe in the right clinical situation in selected patients and when performed by an experienced surgeon using a consistently applied approach. One reason obstetric surgeons are reluctant to use the TAC procedure is the uncertainty and fear of complications. This paper defines the extent of complications with this procedure, as performed by a single surgeon. Few surgical complications and a relatively low risk of fetal loss presented here and in other published reports offer consideration of the TAC procedure. The uterine rupture with fetal loss in a unicornuate, previously scarred uterus underscores the need to manage the pregnancy with caution in such cases. In addition, the erosion of the band through the cervix in four cases here indicates that careful evaluation and management of pre-term labour are appropriate and that elective caesarean in late pregnancy after documentation of fetal lung maturity is a judicious approach.

Cervical hypoplasia, associated with UUD, presents an interesting therapeutic challenge. Risk of CI is expected to be significant, and rescue surgical options may be limited after cervical opening in the late 2nd trimester. Although aggressive tocolytic treatment alone may be successful, our presentation here suggests these patients may benefit from prophylactic TAC. Prior uterine incisions in unicornuate uteri risk uterine rupture in the 3rd trimester, particularly when a cervical obstruction such as TAC is present. Pre-term labour should be aggressively managed in these patients.

We could expect that surgical experience, as technical skills are gained, would be important in decreasing the number of complications - as in all procedures. For instance, in a cohort of 101 patients, most perioperative complications were encountered in the first 20 cases (Lotgering et al. 2006). Use of indomethacin to suppress operative and postoperative uterine activity and meticulous dissection with magnification are logical surgical enhancements. The most common serious maternal risk in previous case reports and this series was haemorrhage, typically due to the marked flow in the fragile paracervical venous plexus (Novy 1991; Lotgering et al. 2006; Debbs et al. 2007).

As we report, complications encountered with the procedure are small; however, they can be very serious and result in significant maternal morbidity and fetal mortality. Therefore, this procedure should not be undertaken by a novice without appropriate training and mentoring. It is recommended that clinicians gain significant experience assisting in this operation before employing its regular application independently.

The relative safety of TAC presented here allows us to contemplate other questions. Does the failure rate of TVC make TAC appropriate to use as a first surgical approach in patients with a clear diagnosis of cervical insufficiency? Our ability to diagnose accurately this syndrome compounds the dilemma. We would suggest that clarification would best arise from a prospective randomised trial of TAC vs TVC in patients selected for the clarity of their cervical insufficiency diagnosis.

#### **Prior presentation**

An abstract and poster of this manuscript were presented at the annual meeting of the Central Association of Obstetricians and Gynecologists, Las Vegas, Nevada, 27-30 October, 2010.

Table III. Surgical complications.

Table 111. oargreat complications.		
Intraoperative and postoperative (2.0%)		
Blood loss requiring transfusion	1 patient	
Uterine artery ligation	2 patients	
Wound infection	2 patients	
Wound haematoma	1 patient	
3rd trimester complications (1.6%)	_	
Uterine rupture/hysterectomy	1 patient*	
Lower uterine dehiscence	4 patients	

<sup>\*</sup>Unicornuate uterus with prior classical incision.



Table IV. Transabdominal cervical cerclage (TAC) and fetal and neonatal

	<20 week loss: 11	ss: 11 pregnancies (4.1%); 14 fetuses (3.2%)	
Gestation	Gestational age at loss (weeks)	Days between TAC and loss	
Triplet	12	1 Two died	
Singleton	13	3	
Singleton	14	9	
Twin	14	5 Both died	
Singleton	15	23	
Singleton	15	26	
Singleton	16	8	
Singleton	16	18	
Twin	19	27 Both died (pre-existing cervical AV malformation	
Triplet	19	45 One died (twin-to-twin transfusion syndrome)	
Triplet	19	52 One died	
	≥20 week loss: 5	pregnancies (1.9%); 12 fetuses (2.7%)	
	Gestational age		
Gestation	at loss (weeks)	Weeks between TAC and loss	
Quintuplet	21	9 One died	
Septuplet	21	9 All died	
Triplet	25	12 Two died	
Singleton	30	17 (Rupture of unicornuate uterus)	
Triplet	33	22 One died	
•	Neonatal demise:	9 infants (2.0%) (98.0% survival rate)	
	Gestational age at delivery		
Gestation	(weeks)	Weeks between TAC and delivery	
Singleton	24	14	
Triplet	24	11 All died	
Triplet	28	16 One died	
Triplet	28	16 One died	
-			

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Quintuplet

Quintuplet

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15 Two died

16 One died

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