Published in final edited form as:

J Matern Fetal Neonatal Med. 2012 November ; 25(11): 2287–2290. doi:10.3109/14767058.2012.688081.

Suture type and ultrasound-indicated cerclage efficacy

VINCENZO BERGHELLA¹, JEFF M. SZYCHOWSKI², JOHN OWEN³, GARY HANKINS⁴, JAY D. IAMS⁵, JEANNE S. SHEFFIELD⁶, ANNETTE PEREZ-DELBOY⁷, DEBORAH A. WING⁸, and EDWIN R. GUZMAN⁹ for the Vaginal Ultrasound Trial Consortium

¹Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Thomas Jefferson University, Philadelphia (PA)

²Department of Biostatistics, University of Alabama, Birmingham (AL)

³Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, University of Alabama, Birmingham (AL)

⁴Department of Obstetrics and Gynecology, University of Texas Medical Branch, Galveston (TX)

⁵Department of Obstetrics and Gynecology, The Ohio State University Medical Center, Columbus (OH)

⁶Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, Dallas (TX)

⁷Department of Obstetrics and Gynecology, College of Physicians and Surgeons, Columbia University, New York, (NY)

⁸Department of Obstetrics and Gynecology, University of California, Irvine, Irvine (CA)

⁹Department of Obstetrics and Gynecology, Saint Peter's University Hospital, New Brunswick (NJ)

Abstract

OBJECTIVE—To assess whether type of suture material affects cerclage efficacy for preterm birth (PTB) prevention.

METHODS—Secondary analysis of a multicenter trial of ultrasound-indicated cerclage for short cervical length (CL), in which women with prior spontaneous PTB at 16–33 6/7 weeks, a singleton gestation and CL<25mm between 16–22 6/7 weeks, were randomized to McDonald cerclage or no cerclage. Outcomes of women who underwent cerclage were analyzed by type of

---

Correspondence: Vincenzo Berghella, MD, Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Jefferson Medical College of Thomas Jefferson University, 834 Chestnut Street, Suite 400, Philadelphia, PA 19107, Tel: (215) 955-7996, Fax: (215) 955-5041, vincenzo.berghella@jefferson.edu.

Disclosure of interest: None to declare

Contribution to authorship: All authors were the principal investigators in this NIH-sponsored prospective trials, with this secondary analysis proposed before the beginning of the study by VB, and approved by Dr. Owen and all others. Each author contributed to approval of the protocol, data collection and analyses. VB wrote the manuscript, with major help from JS (also statistical help) and JO, and all authors edited and contributed to the final version of the manuscript.

Ethics approval: Each of the centers obtained Institutional Review Board approval, and each woman signed informed consent at entry into the randomized study.

suture material, comparing polyester braided thread (Mersilene™ or Ethibond™) to Mersilene tape™. Primary outcome was PTB<35weeks.

RESULTS—138 women underwent McDonald cerclage: 84 (61%) received polyester braided thread and 46 (33%) Mersilene tape™. Eight (6%) received monofilament suture and were excluded from analysis. Rates of PTB < 35 weeks were similar, 35% for polyester braided thread vs 24% for Mersilene tape™ (p=0.24). Birth gestational age was also similar among the 2 groups (p=0.18).

CONCLUSION—Type of suture material may not affect ultrasound-indicated cerclage efficacy in high-risk women with short CL, but further study is needed. Polyester braided thread (Mersilene™ or Ethibond™) and polyester braided Mersilene tape™ seem to have similar efficacy.

Keywords

Cerclage suture; preterm birth prevention; short cervical length

Introduction

Cervical cerclage in pregnancy for prevention of recurrent early preterm birth (PTB) was first described in 1955 [1]. Several different surgical techniques have been described, of which the most commonly utilized is the McDonald procedure [2,3]. Cerclage efficacy has been shown to depend on several factors, including the target population (e.g. singleton vs twins), and the indication (history- vs ultrasound- vs physical exam-indicated cerclage). Its efficacy in singleton gestations with a short cervical length (CL) by transvaginal ultrasound (TVU) has been evaluated now in 5 randomized controlled trials. In pregnancies with a prior preterm birth, a singleton gestation, and short CL < 25mm before 24 weeks, cerclage has been associated with a significant 30% reduction in preterm birth < 35 weeks, and significant 36% reduction in perinatal mortality and morbidity [4].

Given these recent data confirming the benefit of cerclage in selected populations, other more detailed technical aspects of cerclage should be investigated for their possible effect on PTB prevention. There is very limited, and non-randomized, data assessing effect of suture type on cerclage efficacy only on physical-exam indicated cerclage [5–7]. Our objective was to estimate the effect of different types of suture material on ultrasound-indicated cerclage efficacy for PTB prevention in women at high risk for recurrent PTB.

Methods

This is a planned secondary analysis of a multicenter US randomized trial [8]. Women with prior spontaneous PTB 16–33 6/7 weeks and a singleton gestation were screened with serial transvaginal ultrasonographic assessment of CL beginning no earlier than 16 weeks; sonographic screening ended by 22 6/7 weeks. Women found to have a CL < 25mm between 16–22 6/7weeks were randomized to cerclage or no cerclage. McDonald cerclage was the recommended type of cerclage. Pregnancy outcomes of the women who received a McDonald cerclage for short CL were analyzed in this planned secondary analysis according to the type of suture material used for the procedure. The selection of suture type was left to the discretion of the operating obstetrician, but all used a non-absorbable material. Suture

types compared were braided polyester thread (Mersilene™ or Ethibond™) versus Mersilene 5 mm tape™. Non-absorbable monofilament sutures (e.g. Prolene™) were excluded given the small sample size. All these types of sutures or the tape are made by Ethicon, Somerville, NJ. We also considered the number of sutures placed during the procedure. The primary outcome for the parent trial and for this secondary analysis was PTB < 35 weeks.

Patient characteristics and primary outcomes were compared across the two suture type groups (braided polyester thread and Mersilene 5mm tape™) with Pearson chi-square tests for categorical measures and Student t-tests for continuous measures. Fisher's exact and Wilcoxon rank-sum tests were used as appropriate. Multivariable logistic regression was used to examine observed differences in the presence of multiple covariates. SAS 9.2 (SAS Institute, Cary, NC) was used for all statistical analyses. A level of 0.05 was selected to indicate statistical significance and all tests were 2-sided.

Results

A total of 152 women received cerclage in the trial: 138 randomized to cerclage, and 14 randomized to non-cerclage [8]. Of these, 142 received ultrasound-indicated cerclage for CL < 25mm, while 10 were excluded as they received physical-exam indicated cerclage placed after randomization for manually-detected cervical changes. Four (3%) of the 142 women received Shirodkar cerclage and were excluded. Of the 138 with McDonald, ultrasound-indicated cerclage, 84 (61%) received braided polyester thread (59 Mersilene thread™, 25 Ethibond™), 46 (33%) Mersilene tape™, and 8 (6%) monofilament suture (4 Prolene™, 4 non-specified monofilament suture).

Selected characteristics of the study population are shown in Table I. There was no difference in gestational age at cerclage placement ($p=0.81$) or at removal ($p=0.08$) between the braided polyester thread and Mersilene tape™ groups, and other characteristics were also similarly distributed, except that significant differences were observed for maternal age, race/ethnicity, marital status, cigarette use, and the use of multiple stitches (Table I).

PTB < 35 weeks did not differ significantly among suture type groups ($p=0.24$), while PTB < 37 weeks was significantly lower with Mersilene tape™ ($p=0.03$) (Table II). However, this effect became null ($p=0.55$) in a multivariable logistic regression model controlling for those covariates imbalanced in the 2 groups: maternal age, race/ethnicity, marital status, body mass index (BMI), cigarette use, and multiple sutures. There was no difference in gestational age at delivery among the 2 groups (Table II).

The number of women receiving multiple stitches was 4 (9%) for Mersilene tape™, but 60 (71%) for braided polyester thread (Table I). The use of multiple (2 or more) stitches of braided polyester thread at placement of ultrasound-indicated cerclage for short CL was not associated with any effect on outcomes when compared to placement of just a single stitch (Table III).

Discussion

Polyester braided thread (Mersilene™ or Ethibond™) and polyester braided Mersilene (5 mm) tape™ appear to have similar efficacy in prolonging pregnancy following ultrasound-indicated McDonald cerclage for short CL < 25mm. Although other types of suture materials have been utilized for transvaginal cerclage, we believe that many obstetricians utilize one of these permanent materials which provide continued mechanical support until the stitch is removed at term or for other indications. This disparity in choice of suture material likely reflects physician training or other bias and is not evidence-based.

Several materials have been utilized for cerclage. These include human fascia lata [1], sutures such as Mersilene™ (Ethicon, NJ) (2), silk, Prolene™ (Ethicon, NJ), Tevdek™ (Teleflex, PA), metal wire, as well as Mersilene tape™ (Ethicon, NJ), and others [5–7,9]. Today, most commonly used ones are Mersilene 5mm tape™ (Thicon RS-21 or D-8113; Ethicon, NJ) [8,10–13] and large nonabsorbable monofilament (e.g. Prolene™) [14].

The effectiveness of the suture may vary according to the indication for cerclage. In women undergoing *history-indicated* or *ultrasound-indicated* cerclage, there is no published data comparing suture types. Among several different sutures used, Mersilene tape™ was the most commonly utilized in women included in randomized trials whose meta-analysis showed benefit from cerclage in singleton gestations with prior PTB and short CL < 25mm [4,12,13]. Given these data and the results of our study, it appears reasonable to use Mersilene braided tape™ for cerclage placed for short CL. The purported (but unproven) advantage of the tape as compared to the suture is that it spreads the tension better in tissue. Given our results, polyester braided thread and tape seem to have similar efficacy and are alternatives.

In women undergoing *physical exam-indicated cerclage*, one small retrospective study compared Mersilene tape™, Tevdek™ and Prolene™ sutures in the McDonald cerclage [5]. The rates of PTB were similar in the three groups [5]. Another small retrospective study found braided suture to be associated with decreased PTB < 28weeks and improved neonatal survival compared to Mersilene tape™ [6]. In a small study which included women undergoing either *history- or physical exam-indicated* McDonald cerclage, gestational age at delivery and interval from cerclage to birth were similar in women who received a Mersilene tape™ vs those who received a Prolene™ suture [7].

Other aspects related to suture material for cerclage have not been studied. Some surgeons soak the mersilene band in either gel or betadine for easier treading through cervical tissue, but this aspect has not been evaluated in any study. We are also unaware of data to support a recommendation regarding the numbers of knots, or the placement of the knot anterior or posterior.

Some investigators have advocated placing additional stitches (total of 2 or more) for cerclage. Originally the 2nd stitch was placed to support the posterior (i.e. at 6 o'clock) suture and to prevent its displacement [15]. More recently an additional goal is to place a 2nd stitch superiorly to the 1st, closer to the internal os [16]. Placing more than 1 braided polyester stitch at the time of ultrasound-indicated cerclage was not associated with benefits

in our population of singleton gestations with prior spontaneous PTB, short CL < 25mm, and McDonald cerclage (Table III). Another study has evaluated the efficacy of cerclage with either placement of 1 or 2 stitches [16]. Women with both history- and ultrasound-indicated, as well as both McDonald and Shirodkar cerclages, were included and reported together, making external validity in any of these 4 groups limited. Type of suture used was not reported. There were no statistically significant differences in PTB outcomes and complications in women who received 2 or 1 stitch [16]. We suggest placing a second stitch at the time of initial cerclage only if the initial stitch is evaluated to be 'too low' in the cervix, and gentle pulling on this first stitch may allow placing a second stitch much closer to the internal os, at least 2cm above the external os, just below the bladder reflection.

Placing a second stitch at the external os, aiming to keep the mucus plug in place, has been termed 'cervical occlusion'. While there is yet no RCT to evaluate the safety and effectiveness of this intervention, a RCT is currently on-going [17].

Strengths of our study include the fact that data was obtained from a prospective randomized trial. The population was homogeneous, as it consisted of women with singleton gestations, prior PTB, and CL < 25mm before 23weeks. We could locate no other reports on efficacy of suture type for ultrasound-indicated cerclage. Weaknesses are that it is not a randomized study comparing directly suture types. Not all suture types ever used for cerclage could be investigated, but the most common ones were. The monofilament group had a small sample size (n=8), and was therefore excluded from analysis. Additionally, as there were trends for benefit of Mersilene tape™ for preterm births at < 35 and < 37 weeks as well as gestational age at birth (Table 2), we cannot exclude the possibility of a type II error. In fact, it should be noted that our observed sample size provides less than 20% power to observe a 30% reduction in the PTB < 35 week rate, assuming a baseline rate of 35% in the braided polyester thread group. Thus, if such a difference does exist between the 2 groups, our study is underpowered to observe it.

In the absence of data suggesting the superiority of one suture type, the choice of suture for cerclage should be investigated further, and currently left to the operators' preference.

Acknowledgments

We wish to acknowledge other members of the Vaginal Ultrasound Trial Consortium: Susan Ramin, MD, Mark Tomlinson, MD, Eric Knudson, MD, Robert Egerman, MD, Richard Silver, MD, Helen How, MD, Mike Gordon, MD.

Source of funding: The Eunice Kennedy Shriver National Institute of Child Health and Development provided funding via grant U01 HD039939; from the same agency, Dr. Owen also received support via grant 5K24 HD43314-5.

References

1. Shirodkar VN. A new method of operative treatment for habitual abortions in the second trimester of pregnancy. *Antiseptic*. 1955; 52:299–300.
2. McDonald IA. Suture of the cervix for inevitable miscarriage. *J Obstet Gynecol*. 1957; 64:346–350.
3. Shortle, B., Jewelewicz, R. Clinical aspects of cervical incompetence. Chicago: Yearbook Medical Publishers; 1989.

4. Berghella V, Rafael TJ, Szychowski JM, Orion AR, Owen J. Cerclage for Short Cervix on Ultrasound in Singleton Gestations with Prior Preterm Birth: Meta-analysis of Trials. *Obstet Gynecol.* 2011; 117:663–671. [PubMed: 21446209]
5. Pereira L, Levy C, Lewis D, Broth R, Rust O, Berghella V. Effect of suture material on the outcome of emergent cerclage. *Obstet Gynecol.* 2004; 103:s35.
6. Bernard L, Pereira L, Berghella V, et al. Effect of suture material on outcome of cerclage in women with a dilated cervix in the 2nd trimester: results from the expectant management compared to physical exam-indicated cerclage (EM-PEC) international cohort study. *Am J Obstet Gynecol.* 2006;s103.
7. Abdelhak YE, Sheen JJ, Kuczynski E, Bianco A. Comparison of delayed absorbable suture vs nonabsorbable suture for treatment of incompetent cervix. *J Perinat med.* 1999; 27:250–252. [PubMed: 10560075]
8. Owen J, Hankins G, Iams JD, Berghella V, Sheffield JS, Perez-Delboy A, Eggerman RS, Wing DA, Tomlinson M, Sliver R, Ramin SM, Guzman ER, Gordon M, How HY, Knudtson EJ, Szychowski JM, Cliver S, Hauth JC. Multicenter randomized trial of cerclage for preterm birth prevention in high-risk women with shortened midtrimester cervical length. *Am J Obstet Gynecol.* 2009; 201:375e1–8. [PubMed: 19788970]
9. Althuisius SM, Dekker GA, Hummel P, Bekedam DJ, van Geijn HP. Final results of the cervical incompetence prevention randomized cerclage trial (CIPRACT): Therapeutic cerclage with bed rest versus bed rest alone. *Am J Obstet Gynecol.* 2001; 185:1106–1112. [PubMed: 11717642]
10. MRC/RCOG Working Party on Cervical Cerclage. Final report of the Medical Research Council/Royal College of Obstetricians and Gynaecologists multicentre randomized trial of cervical cerclage. *BJOG.* 1993; 100:516–523.
11. Ezechi OC, Kalu BKE, Nwokoro CA. Prophylactic cerclage for the prevention of preterm delivery. *Internat J Gynecol Obstet.* 2004; 85:283–284.
12. Berghella V, Odibo AO, Tolosa JE. Cerclage for prevention of preterm birth in women with a short cervix on transvaginal ultrasound: A randomized trial. *Am J Obstet Gynecol.* 2004; 191:1311–1317. [PubMed: 15507959]
13. To MS, Alfrevic Z, Heath VCF, Cicero S, Cacho AM, Williamson PR, Nicolaides KH. Cervical cerclage for prevention of preterm delivery in women with short cervix: randomized controlled trial. *Lancet.* 2004; 363:1849–1853. [PubMed: 15183621]
14. Rust OA, Atlas RO, Reed J, van Gaalen J, Balducci J. Revisiting the short cervix detected by transvaginal ultrasound in the second trimester: Why cerclage therapy may not help. *Am J Obstet Gynecol.* 2001; 185:1098–1105. [PubMed: 11717641]
15. Hofmeister FJ, Schwartz WR, Vondrak BF, Martens W. Suture reinforcement of the incompetent cervix. *Am J Obstet Gynecol.* 1968; 101:58–65. [PubMed: 4868916]
16. Woensdregt K, Norwitz ER, Cackovic M, Paidas MJ, Illuzzi JL. Effect of 2 stitches vs 1 stitch on the prevention of preterm birth in women with singleton pregnancies who undergo cervical cerclage. *Am J Obstet Gynecol.* 2008; 198:396e1–7. [PubMed: 18177834]
17. Secher NJ, McCormack CD, Weber T, Hein M, Helmig RB. Cervical occlusion in women with cervical insufficiency: protocol for a randomized, controlled trial with cerclage, with and without cervical occlusion. *BJOG.* 2007; 114:649–e6. [PubMed: 17439572]

Table I

Demographic Characteristics

	Braided polyester thread* (n=84)	Mersilene tape™ (n=46)	p value
Maternal age (y)	24 (20–32) [†]	28 (20–35) [†]	0.03 **
Race/ethnicity* - no. (%)			
Black (non-Hispanic)	52 (62%)	15 (33%)	<0.01
White (non-Hispanic)	17 (20%)	7 (15%)	
Hispanic	7 (8%)	17 (37%)	
Other	8 (10%)	7 (15%)	
Marital Status - no. (%)			
Single/never married	56 (67%)	18 (39%)	<0.01
Years of education (n)	11.8 ± 2.5	12.2 ± 3.5	0.47
Body mass index (kg/m ²)	26.6 (21.9–43.0) [†]	27.5 (21.0–40.1) [†]	0.86 **
Cigarette use - no. (%)	20 (23%)	3 (7%)	0.01
Any drug abuse - no. (%)	5 (6%)	0 (0%)	0.16 ^{††}
Cervicovaginal microbiology			
Chlamydia - no. (%)	4 (5%)	0 (0%)	0.30 ^{††}
One or more prior induced abortion - no. (%)	14 (17%)	8 (17%)	0.92
Prior cerclage - no. (%)	4 (5%)	6 (13%)	0.16 ^{††}
Number of prior births (n)	2 (1–4) [†]	2 (1–4) [†]	0.78 **
Gestational age of qualifying birth (wks)	23 (18–31) [†]	23 (18–32) [†]	0.86 **
Weeks of gestation at first vaginal sonogram (wks)	17.0 (16.0–19.1) [†]	17.4 (16.1–18.7) [†]	0.25 **
Cervical length at first vaginal sonogram (mm)	28.9 (16.9–43.0) [†]	27.0 (11.0–39.0) [†]	0.59 **
Weeks of gestation at randomization (wks)	19.1 (16.4–21.7) [†]	19.4 (16.6–22.0) [†]	0.63 **
Cervical length at randomization or last sonogram (mm)	21.0 (10.0–24.0) [†]	20.7 (11.0–24.0) [†]	0.46 **
Total number of vaginal sonograms (N)	2 (1–4) [†]	2 (1–4) [†]	0.95 **
Multiple stitches	60 (71%)	4 (9%)	<0.0001
Gestational age at cerclage placement (wks)	19.6 ± 1.9	19.7 ± 2.0	0.81
Gestational age at cerclage removal [^]	35.7 (26.7–37.1) [†]	36.1 (25.3–37.4) [†]	0.08 **

Plus-minus values are means and one standard deviation.

Race and ethnic group are self-reported

* Mersilene^{TM} or Ethibond^{TM}

** Wilcoxon rank-sum test

[†] Median and interdecile range

^{††} Fisher exact test

[^] indicates that 4 patients had missing date of cerclage removal, 3 in the Mersilene/Ethibond group and 1 in the Mersilene tape^{TM} group.

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Table II

Outcomes

	Braided polyester suture[*] (n=84)	Mersilene tape^{TM} (n=46)	p-value
PTB < 37weeks	43 (51%)	14 (30%)	0.03
PTB < 35weeks	29 (35%)	11 (24%)	0.24
PTB < 28weeks	10 (12%)	7 (15%)	0.79
PTB < 24weeks	3 (4%)	3 (7%)	0.67 ^{††}
GA at birth (weeks) [†]	36.9 (26.7–39.7) [†]	37.9 (24.6–39.9) [†]	0.18 ^{**}
Perinatal death	5 (6%)	5 (11%)	0.32 ^{††}

PTB, preterm birth; GA, gestational age.

^{*} Mersilene^{TM} or Ethibond^{TM} suture.

^{**} Wilcoxon rank-sum test.

[†] Median and interdecile range.

^{††} Fisher exact test

Table III

Outcomes comparing placement of multiple vs single stitches for ultrasound-indicated cerclage in those with braided polyester (Mersilene™ or Ethibond™) suture

Outcome	Multiple stitches n=60	Single stitch n=24	p value
PTB < 37weeks	32 (53%)	11 (46%)	0.53
PTB < 35weeks	21 (35%)	8 (33%)	0.88
PTB < 28weeks	6 (10%)	4 (17%)	0.46 *
PTB < 24weeks	1 (2%)	2 (8%)	0.20 *
Perinatal death	3 (5%)	2 (8%)	0.62 *
GA at delivery (weeks)	36.7 (27.8–39.7) [†]	37.2 (24.6–39.7) [†]	0.93 **

PTB, preterm birth; GA, gestational age.

* Fisher's exact test.

** Wilcoxon rank-sum test.

[†] Median and interdecile range.