

**Cervical Incompetence: Pregnancy outcomes according to the cervical
state and the presence of labor**

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Short title: Elective, urgent, and emergency cerclage outcomes

ABSTRACT

OBJECTIVE: We conducted this study to classify patients undergoing cervical cerclage for incompetent cervix according to the state of the cervix before the procedure and to evaluate the outcomes of pregnancies in such patients.

METHODS: This is a retrospective analysis of all cases of cervical cerclage procedures done at The Brooklyn Hospital Center from January 1997 to January 2000 on singleton gestations. The patients were classified in three groups (elective-A, urgent-B, and emergency-C) according to the state of the cervix and the urgency of the procedure.

Outcomes assessed included: mode of delivery, perinatal mortality, preterm labor, use of tocolysis, prolongation of pregnancy, birth weight, delivery prior to 34 weeks, and delivery prior to 37 weeks.

RESULTS: Within the group of 107 patients, 54 (50.5%) patients delivered before 37 weeks and 36 (33.6 %) delivered before 34 weeks gestation. The overall survival (groups A, B, and C combined) was 88 %, and 10 % of patients delivered at or before 23 weeks gestation. Forty-six of the pregnancies (43 %) were complicated by labor and 58.8 % required some form of tocolysis before delivery. Forty-seven women (43.9 %) were nulliparous. The overall mean gestational age at delivery was 33.8 weeks and the mean birth-weight 2387.56 grams. There exist significant differences among the three groups in regards to gestational age at delivery, birth weight, pregnancy prolongation and delivery prior to 37 weeks ($p < 0.001$). Survival, birth weight and gestational age at delivery were

similar in groups A and B but significantly poorer in group C. Survival in groups A and B was 92.7% and 97.6 % respectively and in group C was only 62.5 %.

CONCLUSIONS: Patients undergoing elective cerclage due to history of incompetent cervix have outcomes similar to patients without history of incompetence but with second trimester ultrasound findings suggestive of cervical incompetence. In contrast, patients with advanced cervical changes and / or labor at the time of diagnosis do poorly in comparison to the previous two groups but still with a significant survival worth pursuing.

Key words: cervix, cerclage, pregnancy, cervical incompetence

Introduction

Cervical incompetence has been defined as recurrent second trimester pregnancy loss in the absence of labor.¹ The introduction of ultrasound has added a new dimension in the definition of cervical incompetence.² A number of surgical techniques³⁻⁵ were developed for the cure of cervical incompetence. Cervical cerclage is the treatment of choice for patients with incompetent cervix, despite the fact that the subject remains controversial and several studies have failed to prove any benefit from cerclage placement in patients with history suggestive of incompetent cervix⁴⁻⁶.

The addition of ultrasound⁷⁻¹² in the diagnosis and management of patients with known or suspected incompetent cervix has improved our understanding of the relationship of cervical physiology and preterm delivery. Incompetent cervix usually coexists with preterm labor and it has been proposed that the two are part of one entity.¹³ Patients undergoing cervical cerclage after cervical changes diagnosed by ultrasound may do as well as patients undergoing cerclage based on strong history of pregnancy loss because of cervical incompetence.^{14,15}

This retrospective study was designed to assess and compare outcomes in patients undergoing cervical cerclage at various levels of severity and with the presence of labor in an inner-city institution.

Methods

We performed a retrospective analysis of all patients who underwent cervical cerclage for incompetent cervix at The Brooklyn Hospital Center, Brooklyn, New York from January 1 1997 to January 1 2000. The study was approved by the hospital's IRB. We identified the patients by means of electronic search of our ultrasound-reporting database for all patients with the diagnosis of incompetent cervix (ICD-9 code 654.53) exclusive of multiple gestations. All patients undergoing cervical cerclage at our institution underwent transvaginal sonography for cervical evaluation before and after the procedure. The list of names was then matched with the list produced from the discharge diagnosis database from the medical record computer system. One hundred and fifteen patients were identified. We reviewed all hospital records and recorded demographic, clinical, and ultrasound parameters. Eight patients were excluded, three moved elsewhere and pregnancy outcomes were not available, and 5 were diagnosed with preterm labor and treated accordingly. We divided the patients in three groups based on the state of the cervix and the presence or absence of labor as follows:

Group A (elective): consists of patients undergoing elective cerclage with intact cervix and cervical length > 25 mm (n=41, 38.3 %). All patients in this group had history of previous pregnancy loss consistent with cervical incompetence. These patients attended private practices and HMO managed clinics and were managed privately with various management schemes deemed appropriate by private attendings.

Group B (urgent): consists of patients undergoing urgent cerclage due to cervical shortening (cervical length ≤ 22 mm) diagnosed by transvaginal ultrasound during a routine pregnancy evaluation or due to suspicious history of cervical incompetence

obtained during the ultrasound exam. There was neither labor nor cervical dilatation in any of these patients (n=42, 39.2 %).

Group C (emergency): consists of patients presenting to the ultrasound unit for routine ultrasound or to the obstetrical emergency room. These patients were found to have no measurable cervix with or without external cervical os dilatation (n=24, 22.4 %).

All staff members of the perinatal ultrasound unit (ultrasound technicians, nurses, and perinatologists) were trained to obtain pertinent history for previous poor pregnancy outcomes and pregnancy loss. The information was utilized for further enhancement of the ultrasound examination. We routinely attempted to assess the cervix on all patients prior to 24 weeks transabdominally and if not possible, transvaginally.

All patients in group A underwent cerclage on an outpatient basis performed by private obstetricians. Neither antibiotics nor tocolytics were used in these patients intra-operatively. Patients in groups B and C were admitted for uterine monitoring and preparation for cerclage. Patients in group B received only perioperative tocolysis with either MgSO₄ or Indomethacin based on the attending's preference. All patients in group C received tocolysis by means of MgSO₄ (4gm IVPB/20 minutes followed by a continuous infusion of 3gm/hour) and Indomethacin (50-100 mg rectally followed by 25 mg every 6 hours for a total of 48 hours). We obtained cultures only if the cervix was dilated or there were clinical signs and/or symptoms suggestive of lower genital infection. All patients in group B and C received prophylactic perioperative antibiotics for 24 to 48 hours. Follow up management after discharge was done by weekly cervical assessment by transvaginal sonography and if stable, by same means every two weeks until delivery. After discharge from the hospital, we instituted oral tocolysis (Terbutaline

5 mg po q4h) until 37 weeks gestation. We removed the cerclage at the time of delivery for those patients who delivered before 37 weeks gestation and at 37 completed weeks for the patients who reached term.

We obtained cervical evaluation and measurements by means of endovaginal sonography. We obtained a clear sagittal view of the cervix extending from the external cervical os to the lower uterine segment and we assessed the length and shape of the cervical canal. We considered cervical length less than 22 mm with or without funneling abnormal and the patient underwent cerclage.

Cerclage procedure: In group A, patients underwent McDonald cerclage by means of two size #2 (5.0 metric) Mersilene sutures (Ethicon, Bridgewater, New Jersey). The needles that come attached to the suture are removed and the suture is threaded through a ½ tapered, size #4 Mayo needle. The procedure was performed under spinal anesthesia and the patient was discharged home the same day. In group B, patients underwent the above described cerclage procedure after the amniotic membranes were pushed away from the cervix with the help of Foley catheter (30 ml balloon) insertion into the endocervix. In group C, we applied the same procedure as in group B and the membranes were replaced back above the internal os level. The cutoff gestational age is 27-28 weeks. All patients that were evaluated for emergency cerclage with intact membranes underwent the procedure. There were two patients with hourglass forming membranes. In these two patients, it became necessary to perform transabdominal amnioreduction followed by the combination of endocervical Foley catheter balloon inflation and urinary bladder filling with sterile normal saline.

We performed statistical analysis by means of JMP Statistical Discovery Software for personal computers (SAS Institute Inc., SAS Campus Drive, Cary, NC 27513), and analyzed the data by t-test, one-way analysis of variance and χ^2 -test when appropriate. We used simple regression analysis to assess the relationships between various clinical and outcome parameters. Statistical significance was set at $p < 0.05$. Power analysis revealed that the study sample is enough to provide 80% power in identifying the following differences with an alpha < 0.05 : one week difference in gestational age, 150 Gm difference in birth weight, and 5% difference in the frequency of the outcomes analyzed.

Results

A total of 115 patients were identified but only 107 records were included in the study. Five patients were treated with tocolysis and bed rest and did not require cerclage. In these patients, cervical length remained at > 22 mm and preterm labor treatment was sufficient. Three of these patients delivered between 32 and 34 weeks and two after 34 weeks. We excluded these patients from the analysis. Three patients delivered elsewhere and outcomes were not available for analysis. Private obstetricians performed only elective procedures. A perinatologist performed or supervised all urgent and emergency procedures (groups B and C) and supervised the management until delivery. We performed 41 (38.3 %) elective, 42 (39.3 %) urgent and 24 (22.4 %) emergency procedures. The ethnic mix of our patients is 64.2 % African American, 25.3 % Hispanic, and 10.5 % Caucasian. This mix is representative of the population in this inner city hospital. Most of the patients (65 %) are cared for by house-staff, 20 % by HMO based group practice and 15 % by private obstetricians. The ethnic distribution was similar in the three insurance groups. Table 1 compares various clinical parameters among the three groups. Significant differences were found between at least the two of the three groups in each category compared.

Patients in groups B and C were more likely to experience labor that required tocolysis between the time of cerclage placement and the time of delivery (Likelihood Ratio = 41.3, $p < 0.0001$ and Pearson's $r = 0.36$, $p < 0.0001$). In group A, only 14 % of the patients had funneling in comparison to 95 % of patients in group B and 100 % in group C ($p < 0.0001$). In group C, 29 % of the patients delivered prior to viability (< 24 weeks gestation) compared to 4.8 % in group A and 0 % in group B, $p < 0.002$). Total cesarean

section rate was 30.5 %, 43 %, and 20 % in groups A, B, and C respectively ($p < 0.002$). Total cesarean section rate at our institution for the same period ranged from 18 to 20 %. In group C only 62.5 % of neonates were discharged home alive in comparison to 92.7 % and 97.6 % in groups A and B respectively.

In group A, 14.6 % of patients delivered prior to 34 weeks gestation. In contrast, 87.5 % of patients in group C delivered before 34 weeks ($p < 0.0001$). In group B, 21.4% of patients delivered prior to 34 weeks but this was not statistically different from group A. When we compared the incidence of prematurity (delivery before 37 weeks gestation) group A and group B were not statistically different (31.7 and 40.5 % respectively). In contrast, all patients in group C delivered before 37 weeks gestation. The number of previous abortions (elective and spontaneous combined) was similar in all groups (1.9 ± 0.25 , 1.75 ± 0.33 and 1.6 ± 0.25 respectively for groups A, B, and C, $p = 0.69$).

Discussion

Previous studies^{5,6} found no benefit from cerclage in women with a history of preterm birth. In patients with previous pregnancy loss of undefined etiology, cerclage was marginally beneficial.¹⁶ It seems that the selection criteria for the necessity of cerclage in addition to other factors may be important in the outcomes of these patients. In a recent report, Guzman et al¹⁴ compared outcomes in patients at risk for pregnancy loss who received elective cerclage with patients at similar risk who did not receive cerclage and instead were followed by ultrasound for cervical changes. In this later group, all patients with cervical shortening documented by transvaginal cervical sonography received cerclage. These authors found that serial follow-up with vaginal sonography, is a medically acceptable alternative to the use of elective cerclage. This has significant implications since a significant number of patients have histories that are not clear as to the etiology of the pregnancy loss. In a different study, Kurup et al¹⁵ found that patients undergoing urgent cerclage due to cervical changes documented by sonography had outcomes similar to patients undergoing elective cerclage.

The present study has similarities with both of the above-mentioned studies. The results were similar in groups A and B. One may question the validity of elective cerclage in the patients in group A. In fact, the data are suggestive of no need for elective cerclage if the patients are compliant and present to the prenatal clinic for proper ultrasound cervical assessment. It is very likely that a number of cerclages would be unnecessary. Some of the patients in groups B and C might have been benefited by serial sonography without cerclage had they been detected at an earlier stage. The reason that many of the patients in groups B and C who underwent urgent/emergency cerclage were not identified

earlier was poor clinic attendance. We saw many of these patients for the first time for dating purposes at the time of the diagnosis of the cervical changes. Approximately 12 % of the patients delivering in our institution have not attended a prenatal clinic or if they did, they did so in a very inconsistent manner in other public clinics. This particular group of patients delivers 25 % of their babies preterm and contributes 20 % of the institution's stillbirths (unpublished data from institutional annual quality assurance statistics). Follow up with cervical sonography instead of cerclage placement was deemed inappropriate in-group B, given our experience with poor clinic attendance by such patients. We believe that the patients in groups B and C are different from the typical non-inner-city patients who attend outpatient clinics in other settings. This is supported by documented poor outcomes far and beyond any other group of patients delivering in our institution as well as national statistics after normalization for socioeconomic and ethnic status (unpublished data from annual quality assurance statistics).

In the past, incompetent cervix and preterm labor were seen as mutually exclusive. However, most recently there has been significant evidence that may dispute this concept.^{13,17,18} Instead, of a dichotomous state, there exists a continuum and it appears that pregnancy loss in the second trimester may not be the result of either "pure" incompetent cervix or "pure" preterm labor. This dichotomy leads to a management duality where labor was a contraindication to placing a cerclage and patients would be treated with either cerclage placement or tocolysis. In fact, in our population, patients in groups B and C were more likely to either be in early labor at the time of diagnosis or develop premature labor and require tocolysis soon after. In our experience, most of the patients identified with premature cervical shortening when properly questioned, reported

vague symptoms (vaginal and rectal pressure, menstrual cramping like pain, wetness in the vagina and low back pain) for several days before the diagnosis. Early recognition of such symptoms should prompt evaluation of the cervix with transvaginal sonography. Failure to act on such symptoms may lead to delayed diagnosis of cervical incompetence and/or preterm labor. Our findings and results might not apply to other populations with different socioeconomic and prenatal care attendance characteristics. In a group of patients that attend prenatal care more consistently, conservative management with serial cervical sonography may be appropriate and equally efficacious. Our experience can only be contrasted to experiences with similar population characteristics that were managed with cerclage or serial cervical sonography.

References

1. Easterday CL, Reid DE. The incompetent cervix in repetitive abortion and premature labor. *N Engl J Med* 1959;260:687-90
2. Feingold M, Brook I, Zakut H. Detection of cervical incompetence by ultrasound. *Acta Obstet Gynecol Scand* 1984;63:407-10.
3. Shirodkar V. A new method of operative treatment for habitual abortion in the second trimester of pregnancy. *Antiseptic* 1955;52:299.
4. McDonald I. Suture of the cervix for inevitable miscarriage. *J Obstet Gynaecol Br Commonw* 1957;64:346.
5. Lazar P, Gueguen S, Dreyfus J, Renaud R, Pontonnier G, Papiernik E. Multicentered controlled trial of cervical cerclage in women at moderate risk of preterm delivery. *Br J Obstet Gynaecol* 1984;91:731-5.
6. Rush R, McPherson K, Jones L, Chalmers K, Grant A. A randomized controlled trial of cervical cerclage in women at high risk of spontaneous preterm delivery. *Br J Obstet Gynaecol* 1984;91:724-30.
7. Final report of the Medical Research Council/Royal College of Obstetricians and Gynaecologists Multicentre Randomized Trial of Cervical Cerclage. *Br J Obstet Gynaecol* 1993;100:516-23.
8. Costantini S, Valenzano M, Venturini PL, Fasce V, Gorlero F, Foglia G, Ragni N. Ultrasonic evaluation of cervical incompetence. *Biol Res Pregnancy Perinatol* 1986;7:11-6.

9. Michaels WH, Schreiber FR, Padgett RJ, Ager J, Pieper D. Ultrasound surveillance of the cervix in twin gestations: management of cervical incompetency. *Obstet Gynecol* 1991;78:739-44.
10. Chung TK, Haines CJ, Kong D, Woo WK, Rogers MS. Transvaginal sonography in the diagnosis and management of cervical incompetence. *Gynecol Obstet Invest* 1993;36:59-61.
11. Guzman ER, Vintzileos AM, McLean DA, Martins ME, Benito CW, Hanley ML. The natural history of a positive response to transfundal pressure in women at risk for cervical incompetence [see comments]. *Am J Obstet Gynecol* 1997;176:634-8.
12. Guzman ER, Pisatowski DM, Vintzileos AM, Benito CW, Hanley ML, Ananth CV. A comparison of ultrasonographically detected cervical changes in response to transfundal pressure, coughing, and standing in predicting cervical incompetence. *Am J Obstet Gynecol* 1997;177:660-5.
13. Iams JD, Goldenberg RL, Meis PJ, Mercer BM, Moawad A, Das A, Thom E, McNellis D, Copper RL, Johnson F, Roberts JM. The length of the cervix and the risk of spontaneous premature delivery. National Institute of Child Health and Human Development Maternal Fetal Medicine Unit Network [see comments]. *N Engl J Med* 1996;334:567-72.
14. Guzman ER, Forster JK, Vintzileos AM, Ananth CV, Walters C, Gipson K. Pregnancy outcomes in women treated with elective versus ultrasound- indicated cervical cerclage [see comments]. *Ultrasound Obstet Gynecol* 1998; 12:323-7.
15. Kurup M, Goldkrand JW. Cervical incompetence: elective, emergent, or urgent cerclage. *Am J Obstet Gynecol* 1999; 181:240-6.

16. MRC/RCOG. Working Party on Cervical Cerclage: Final report of the Medical Research Council/Royal College of Obstetricians and Gynaecologists multicentre randomised trial of cervical cerclage. *Br J Obstet Gynaecol* 1993; 100:516.
17. Iams JD, Johnson FF, Sonek J, Sachs L, Gebauer C, Samuels P. Cervical competence as a continuum: A study of ultrasonographic cervical length and obstetric performance. *Am J Obstet Gynecol* 1995;172:1097.
18. Guzman ER, Mellon C, Vintzileos AM, Ananth CV, Walters C, Gipson K. Longitudinal assessment of endocervical canal length between 15 and 24 weeks gestation in women at risk for pregnancy loss or preterm birth. *Obstet Gynecol* 1998;92:31-7.

Table 1. Comparison of clinical parameters and outcomes according to the type of cerclage (one way analysis of variance, Tukey-Kramer post hoc analysis)

Parameter	Group A (Mean \pm SE)	Group B (Mean \pm SE)	Group C (Mean \pm SE)	P value
GA @ cerclage (weeks)	15.4 \pm 0.5	19.7 \pm 0.5	19.4 \pm 0.7	<0.0001
GA @ delivery (weeks)	36 \pm 0.8	35.9 \pm 0.9	26.5 \pm 1.0	<0.0001
Birth weight (grams)	2809.8 \pm 140.6	2689.9 \pm 138.9	1137.2 \pm 183.7	<0.0001
Cerv. length @ cerclage (mm)	38.2 \pm 1.0	16.9 \pm 1.0	6.7 \pm 1.4	<0.0001
Pregnancy prolongation (wks)	20.6 \pm 0.8	16.2 \pm 0.8	7.0 \pm 1.0	<0.0001