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Review

Cervical lacerations in planned versus labor cerclage removal: a systematic review

Giuliana Simonazzi^a, Alessandra Curti^a, Maria Bisulli^a, Viola Seravalli^b, Gabriele Saccone^c, Vincenzo Berghella^{d,*}^a Department of Medical Surgical Sciences, Division of Obstetrics and Prenatal Medicine, St. Orsola Malpighi Hospital, University of Bologna, Bologna, Italy^b Department of Gynecology and Obstetrics, The Johns Hopkins Hospital, Baltimore, MD, USA^c Department of Neuroscience, Reproductive Sciences and Dentistry, School of Medicine, University of Naples Federico II, Naples, Italy^d Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Sidney Kimmel Medical College of Thomas Jefferson University, Philadelphia, PA, USA

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ABSTRACT

Objective: The aim of this study was to evaluate the incidence of cervical lacerations with cerclage removal planned before labor compared to after the onset of labor by a systematic review of published studies.**Study design:** Searches were performed in electronic databases from inception of each database to November 2014. We identified all studies reporting the rate of cervical lacerations and the timing of cerclage removal (either before or after the onset of labor). The primary outcome was the incidence of spontaneous and clinically significant intrapartum cervical lacerations (i.e. lacerations requiring suturing).**Results:** Six studies, which met the inclusion criteria, were included in the analysis. The overall incidence of cervical lacerations was 8.9% (32/359). There were 23/280 (6.4%) cervical lacerations in the planned removal group, and 9/79 (11.4%) in the removal after labor group (odds ratio 0.70, 95% confidence interval 0.31–1.57).**Conclusions:** In summary, planned removal of cerclage before labor was not shown to be associated with statistically significant reduction in the incidence of cervical lacerations. However, since that our data probably did not reach statistical significance because of a type II error, further studies are needed.

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Introduction

Evidence suggests that cervical cerclage is effective in reducing the incidence of preterm birth in singleton pregnancies at risk of recurrent preterm birth [1,2]. Although it is a relatively easy procedure to perform, it is associated with pregnancy complications. In particular, women with a cerclage in place can have

* Corresponding author at: Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Thomas Jefferson University, 833 Chestnut Street, Philadelphia, PA 19107, USA. Tel.: +1 215 955 7996; fax: +1 215 955 5041.

E-mail address: Vincenzo.berghella@jefferson.edu (V. Berghella).

cervical injuries during labor [3]. The suture may tear through the cervix during the shortening and dilatation which occur in particular with uterine contractions.

Because of this concern, cerclage removal has been recommended by many as a planned out-patient procedure once the patient reaches 36–37 weeks [4–6]. Others have instead reported favorable outcomes when allowing women to retain cerclage until the onset of labor even at term [7]. Moreover, the mean interval between elective cerclage removal and spontaneous delivery is 14 days and women with cerclage who achieved 36–37 weeks had a chance of spontaneous delivery within 48 h of only 11% [8].

There are no randomized studies and limited literature comparing cerclage removal before (planned) versus after the onset of labor.

The aim of this study was to evaluate the incidence of cervical lacerations with cerclage removal planned before labor compared to after the onset of labor by review of published studies.

Materials and methods

Searches were performed in MEDLINE, OVID, Scopus, Clinical-Trials.gov, the PROSPERO International Prospective Register of Systematic Reviews, EMBASE, ScienceDirect.com, MEDSCAPE and the Cochrane Central Register of Controlled Trials with the use of a combination of text words related to “cerclage,” “preterm birth” and “cervical lacerations” from inception of each database to November 2014. No restrictions for language or geographic location were applied. In addition, the references of all the included studies were screened for any potentially relevant studies.

We identified observational studies (either cohort and case-control studies) reporting the rate of cervical lacerations and the timing of cerclage removal (either before or after the onset of labor). All studies evaluating patients with cervical cerclage who delivered vaginally and reporting on cervical lacerations and on timing of cerclage removal were included in the review. Only women who reached 36 weeks of gestational age and could have cerclage removal either planned at 36–37 weeks or in labor were included. We compared the incidence of cervical laceration in cerclage removal planned before labor with cerclage removal after the onset of labor.

The following criteria were used to exclude studies: (1) case reports, reviews, guidelines, letters to the editor and reports without a comparison group; (2) studies which reported the outcome of interest for cerclage in multiple gestations; (3) studies which reported the outcome of interest for Lash or Mann procedures; (4) studies which reported the outcome of interest for open or laparoscopic transabdominal cerclage; (5) studies which reported cervical occlusion as an outcome of interest.

Two reviewers (AC, GS) independently assessed the quality of the included studies via the Methodological Index for Non-Randomized Studies (MINORS) [9].

The primary outcome was the incidence of spontaneous and clinically significant intrapartum cervical lacerations (i.e. lacerations requiring suturing). These cervical lacerations were defined as lacerations associated with bleeding or that required cervical suturing. Authors were contacted for missing data.

Before data extraction, the review was registered with the PROSPERO International Prospective Register of Systematic Reviews (registration No.: CRD42014015201). The review was reported following the Preferred Reporting Item for Systematic Reviews and Meta-analyses (PRISMA) statement.

The data analysis was completed independently by authors (GS, AC) using Review Manager 5.3 (Copenhagen: The Nordic Cochrane Centre, Cochrane Collaboration, 2014). The analyses were then compared, and any difference was resolved with review of the entire data. Statistical heterogeneity between studies was assessed

using Higgins I^2 statistics. The summary measures were reported as odds ratio (OR) with 95% confidence interval (CI).

Results

Six studies, which met the inclusion criteria, were included in the analysis (Fig. 1) [4–7,10–13]. All included studies had good methodological quality (Fig. 2). Original database of one study were obtained from the primary authors [13].

The characteristics and results of each study are shown in Table 1. All included studies were retrospective cohort studies. A total of 427 cerclages were included, with the majority being McDonald. Of the 359 women who had vaginal delivery, 280 (78%) had planned removal at 36–37 weeks, while 79 (22%) had removal after the onset of spontaneous labor at 36 weeks or after. Three studies included only history-indicated cerclage [4,7,12]; one study included both ultrasound-indicated and history-indicated cerclage [13], while the other two included ultrasound- and history- and physical exam-indicated cerclage [10,11].

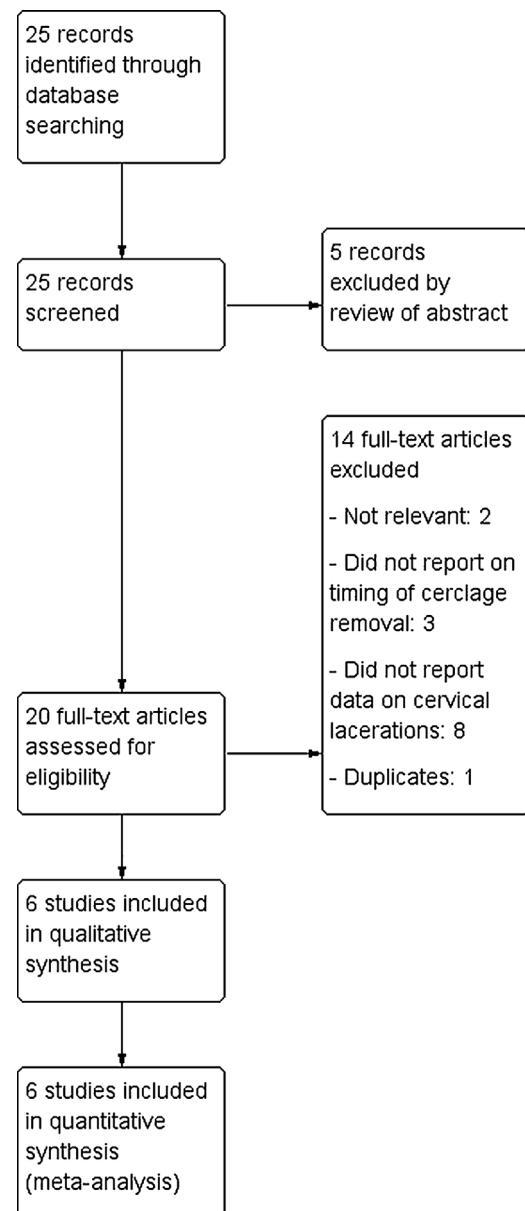


Fig. 1. Flow diagram of studies identified in the systematic review.

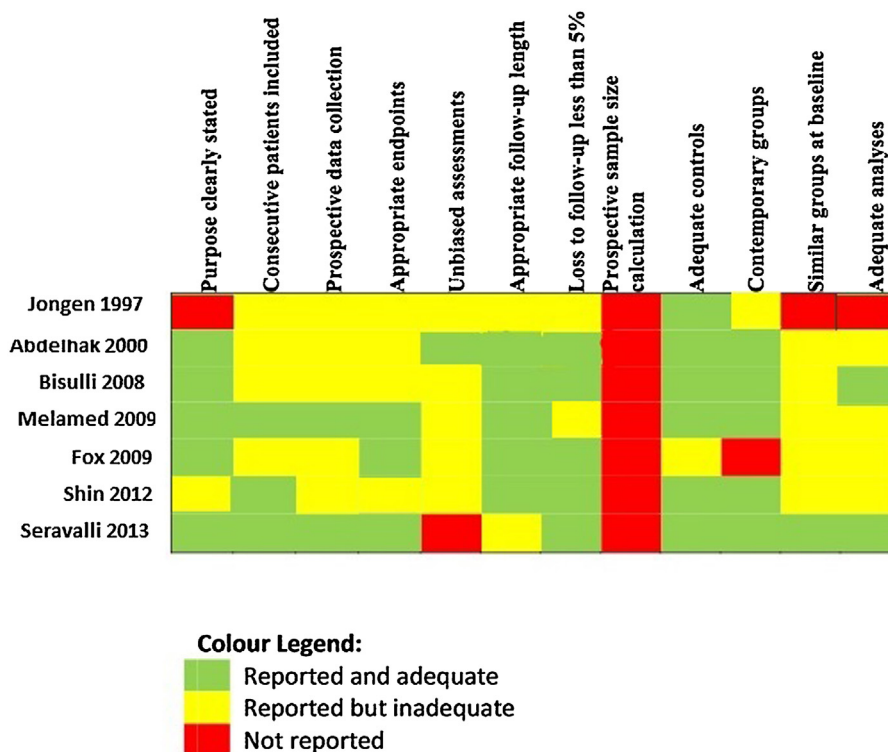


Fig. 2. Assessment of risk of bias. Overall MINORS scoring [9].

Table 1
Data of included studies.

| | Jongen [4] | Abdelhak [7] | Melamed [10] | Fox [11] | Shin [12] | Seravalli [13] | Total |
|--|--|--------------------|--------------|--------------|--|--|---------------|
| Suture (N) | 20 | 96 | 18 | 69 | 127 | 97 | 427 |
| Type of cerclage | N/R | Modified Shirodkar | N/R | Shirodkar | McDonald | McDonald | – |
| Vaginal delivery | 16 | 62 | 18 | 55 | 111 | 97 | 359/427 |
| Planned removal | 5/16 (31%) | 0/62 | 18/18 (100%) | 55/55 (100%) | 111/111 (100%) | 91/97 (94%) | 280/359 (78%) |
| Labor removal | 11/16 (69%) | 62/62 (100%) | 0/18 | 0/55 | 0/111 | 6/97 (6%) | 79/359 (22%) |
| GA at planned removal (weeks) | 36 (36 ⁰ –36 ⁶) | N/R | N/R | 36.0 ± 2.2 | 35 (36 ⁰ –38 ⁶) | 36.5 (36 ⁰ –37 ⁶) | 36 |
| GA at delivery (weeks) | N/R | 37.2 ± 4.0 | N/R | 37.3 ± 3.2 | 37.6 ± 3.3 | 36.5 ± 5.5 | 37 |
| Total cervical laceration | 4/16 (25%) | 5/62 (8%) | 7/18 (39%) | 3/55 (5%) | 12/111 (11%) | 1/97 (1%) | 32/359 (8.9%) |
| Cervical laceration in planned removal group | 0/5 | 0/0 | 7/18 (39%) | 3/55 (5%) | 12/111 (11%) | 1/91 (1%) | 23/280 (6.4%) |
| Cervical laceration in labor removal group | 4/11 (36%) | 5/62 (8%) | 0/0 | 0/0 | 0/0 | 0/6 | 9/79 (11.4%) |

N/R: not reported; GA: gestational age. Data about GA are presented as means ± standard deviation or as median (range).

The overall incidence of cervical lacerations was 8.9% (32/359) (Table 1). There were 23/280 (6.4%) cervical lacerations in the planned removal group, and 9/79 (11.4%) in the removal after labor group (OR 0.70, 95% CI 0.31–1.57).

Comment

Based on the present review, planned removal of cervical cerclage before the onset of labor was not associated with statistically significant reduction in the incidence of cervical lacerations. However, while non-significant there were 11.4% lacerations in after labor group, and 6.4% in the planned removal group (30% non-significant reduction). Based on these data, probably limited by a type II error, we continue to remove cerclage around 36 weeks, before the onset of labor.

One of the strengths of our study is the inclusion of all published studies evaluating patients with cervical cerclage who delivered vaginally and reporting data about cervical lacerations and about timing of cerclage removal. All the included studies had good

methodological quality [9]. So far, there is no prior meta-analysis on this subject. No similar systematic reviews were found during the search process. Original database of one study were obtained [13].

Limitations of our study are inherent to the limitations of the included studies. None of the studies included were clinical trials and none of them were prospective. It is not known if Shirodkar cerclages have a different risk for laceration than McDonald. The individual studies included reported a wide range of cervical laceration rate (1% to 39%). None of the included studies aimed primarily at comparing removal of the cerclage before or after the onset of labor, and only two studies had cervical laceration as the primary outcome, which indicates that the topic is not properly studied [10,13]. For this reason, an adjusted analysis was not feasible and assessing the results in a forest plot was not possible. While authors were contacted for missing data, only one provided additional data [13]. Moreover, it is still unclear when cervical lacerations associated with cerclage occur, e.g. at time of removal, and/or during labor. The differences between data obtained by

different studies showed that probably there were other factors that are not controlled in non-prospective studies. Since that our data probably did not reach statistical significance because of a type II error, further studies are needed. A power analysis suggested a total sample size of 716 women to achieve 80% to power (with an α of 0.05) to detect a 28% decrease of cervical laceration. Large and well-designed randomized trials are needed.

Conflicts of interest

The authors report no conflict of interest.

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