Elective cerclage vs. ultrasound-indicated cerclage in high-risk pregnancies

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ABSTRACT

Objective To compare pregnancy outcome after elective vs. ultrasound-indicated cervical cerclage in women at high risk of spontaneous mid-trimester loss or early preterm birth.

Methods This was a retrospective study comparing two management strategies in women with singleton pregnancies who had at least one previous spontaneous delivery at 16–33 weeks of gestation. One group was managed by the placement of an elective cerclage at 12–16 weeks and the other group had transvaginal ultrasound examinations of the cervix at 12–15+6, 16–19+6, and 20–23+6 weeks and cervical cerclage was carried out if the cervical length was 25 mm or less.

Results A total of 90 patients were examined, including 47 that were managed expectantly and 43 treated by elective cerclage. In the expectantly managed group, 59.6% (28/47) required a cervical cerclage. We excluded from further analysis three patients who were lost to follow-up and three because of fetal death or iatrogenic preterm delivery. Miscarriage or spontaneous delivery before 34 weeks’ gestation occurred in 14.6% (6/41) of the elective cerclage group, compared with 20.9% (9/43) in the expectantly managed group ($\chi^2 = 0.219$, $P = 0.640$).

Conclusion In women at increased risk of spontaneous mid-trimester or early preterm delivery, a policy of sonographic surveillance followed by cervical cerclage in those with a short cervix reduces the need for surgical intervention without significantly increasing adverse pregnancy outcome.

INTRODUCTION

Women with a history of spontaneous second-trimester miscarriage and preterm delivery have an increased risk of recurrence of a similar event in a subsequent pregnancy. Although several studies have reported that the treatment of such patients by elective cervical cerclage may reduce the risk of adverse pregnancy outcome1, randomized studies have shown that equally good results are achieved with expectant management2–5. This apparent controversy, of increased risk that may not be altered by elective cerclage, could be the consequence of inadequate selection of the high-risk group so that the risks associated with surgical intervention outweigh any potential benefit.

Recent evidence suggests that in patients with a previous history of late miscarriage or early preterm delivery, ultrasonographic assessment of cervical length may provide useful prediction of those at increased risk of recurrence6–8. Consequently, two policies have emerged in the management of such patients: placement of an elective suture early in the second trimester, and serial scans for cervical assessment and placement of a suture only in those patients with cervical changes suggestive of incompetence. One previous study has compared the two policies and suggested pregnancy outcome was similar9. The aim of the present study is to provide further data in the comparison of the two management strategies.

PATIENTS AND METHODS

This was a retrospective study of all patients with singleton pregnancies and a history of one or more spontaneous losses between 16 and 33 weeks, who were managed according to one of two treatment strategies between the years 1995 and 2000. At King’s College Hospital, London, women with a history of one or more mid-trimester miscarriages or early preterm deliveries are managed by elective cervical cerclage at 12–16 weeks (depending on the gestation at presentation for antenatal care) or serial measurements of cervical length by transvaginal ultrasound and the placement of cerclage only in those with cervical length of 25 mm or less. The chosen management is at the discretion of the attending obstetrician and patient choice. In the elective cerclage group, surgery is undertaken after sonographic examination of the fetus to confirm gestational age and exclude major defects. In the second group, transvaginal sonography is performed at 12–15+6, 16–19+6 and 20–23+6 weeks, as described
previously\textsuperscript{10,11}. Patients with a cervical length of more than 25 mm are managed expectantly. This did not include the use of hospitalization, prophylactic tocolytics, home uterine monitoring, or routine antibiotics. Those patients with a cervical length of 25 mm or less (in the absence of symptoms of preterm labor, preterm prelabor rupture of the membranes or chorioamnionitis) are offered cervical cerclage.

In all patients undergoing cerclage the Shirodkar technique was used and prophylactic antibiotics were given intraoperatively. In cases with an open external os, reduction of the membranes was achieved using a Foley catheter with a 30-mL balloon placed transcervically during the procedure. The anesthetic of choice was spinal and patients were discharged from hospital on the first postoperative day. Bed rest and prophylactic tocolysis were not used routinely.

We searched the obstetric ultrasound database and the operating theater register to identify all patients with a history of one or more spontaneous losses between 16 and 33 weeks, who were managed according to one of the two policies. The hospital notes were then examined to obtain details of demographic characteristics, ultrasound findings, operative procedures and pregnancy outcome.

Statistical analysis
To calculate the significance of differences between the two management groups, Mann–Whitney U-test was used for the continuous variables (maternal age, body mass index, gestation at cerclage, gestation at delivery), and chi-squared test was used for categorical variables (ethnic origin, cigarette smoking, obstetric history, percentage delivering before 34 weeks).

RESULTS
Elective cerclage at 12–16 weeks (median 13, mean 13.5, SD 1.0) was carried out in 43 patients. In the serial cervical assessment group, there were 47 patients and 28 (59.6%) of these were found to have a cervix of 0–25 mm (median 17, mean 14.7, SD 8.8) and had cervical cerclage at 12–23 weeks (median 18, mean 17.6, SD 3.0). The two management groups were not significantly different in ethnic origin (Afro-Caribbean 81% compared with 79%), mean body-mass index (29 kg/m\textsuperscript{2} compared with 28 kg/m\textsuperscript{2}), mean maternal age (32 years compared with 30 years), or incidence of cigarette smoking (12% compared with 4%).

Excluded from further analysis were three women that were lost to follow-up, one from the elective cerclage group and two from the expectant management group. Two further patients from the surveillance group that suffered an intrauterine death at 14 and 22 weeks were excluded as was one patient from the elective cerclage group who had iatrogenic delivery at 27 weeks because of an abruption. The median gestational age at delivery of those who had elective cerclage was 38 weeks (mean 36.6, SD 4.5, range 16–41) and of those who underwent surveillance was 38.3 weeks (mean 36.2, SD 6.4, range 16–43); these were not significantly different ($P = 0.346$). Spontaneous delivery before 34 weeks of gestation occurred in 14.6% (6/41) of the elective cerclage group and in 20.9% (9/43) of the surveillance group ($\chi^2 = 0.219$, $P = 0.640$). In the 43 who were managed expectantly, there were 17 with a cervical length of more than 25 mm and one (5.9%) of these delivered before 34 weeks (Table 1).

DISCUSSION
The findings of the study suggest that in women at increased risk of mid-trimester miscarriage or early preterm delivery, a policy of sonographic surveillance followed by cervical cerclage in those with a short cervix may reduce the need for surgical intervention without increasing adverse pregnancy outcome. In the expectantly managed group, about 40% did not require the insertion of a suture because the cervix remained above 25 mm.

Support of our findings is provided by preliminary results of a study from Althuisius et al.\textsuperscript{12}, who examined 77 patients with a history suggestive of cervical incompetence that were randomized into elective cerclage ($n = 23$) or surveillance ($n = 44$). In the latter group, 18 (41%) developed a short cervix (less than 25 mm) and these were further randomized into cerclage ($n = 10$) or expectant management ($n = 8$). The rate of delivery before 34 weeks was 13% in those treated with elective cerclage, 10% in those who had a suture because of a short cervix and 63% in those with a short cervix that was managed expectantly\textsuperscript{12,14}. This study not only supports the policy of surveillance by sonographic assessment of the cervix and selective cerclage as an alternative to elective cerclage, but also the concept that if there is appropriate selection of the high-risk group, the risks associated with surgical intervention are outweighed by the benefit of a significant reduction in early preterm birth.

In the study of Althuisius et al.\textsuperscript{12}, only 41% (18/44) developed cervical changes that would have required cerclage in comparison with our study in which 60% (28/47) underwent ultrasound-indicated cerclage. In addition, the rate of

Table 1 Gestation at delivery of the two groups of high-risk pregnancies that were managed by elective cerclage at 12–16 weeks or serial scans and placement of a suture when the cervix became 25 mm or less

<table>
<thead>
<tr>
<th>Gestation at delivery (weeks)</th>
<th>Elective cerclage, N = 41 n (%)</th>
<th>Ultrasound surveillance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total, N = 43 n (%)</td>
<td>Cerclage, N = 26 n (%)</td>
</tr>
<tr>
<td>12–23</td>
<td>1 (2.4)</td>
<td>3 (7.0)</td>
</tr>
<tr>
<td>24–34</td>
<td>5 (12.2)</td>
<td>6 (13.9)</td>
</tr>
<tr>
<td>&gt; 34</td>
<td>35 (85.4)</td>
<td>34 (79.1)</td>
</tr>
<tr>
<td>Total &lt; 34</td>
<td>6 (14.6)</td>
<td>9 (20.9)</td>
</tr>
</tbody>
</table>

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delivery before 34 weeks was more comparable in their elective- and ultrasound-indicated cerclage groups (13 vs. 10%, respectively), whereas in our study there was a trend toward a lower preterm delivery rate in the elective group in comparison with the ultrasound-indicated group (15 vs. 31%). One possible explanation for this may lie in the difference in preoperative cervical length in the two studies. In our patients the mean cervical length at cerclage placement was 14.7 mm (SD 8.8, range 0–25 mm) and included five women with bulging membranes. In Althuisius’ study, those women undergoing ultrasound-indicated cerclage were selected randomly from a group with a mean cervical length of 18.2 mm (SD 5.9, range 0–24 mm). Emergency cerclage, when the membranes are bulging through the cervix, is associated with a high risk of adverse outcome. In our study, the expectantly managed group had scans every 4 weeks, starting from 12 weeks of gestation. Guzman et al. described how an incompetent cervix may shorten at a rate of 4–8 mm per week between 15 and 24 weeks’ gestation. It may therefore be necessary to follow high-risk patients with scans every 2 weeks, allowing for a more timely intervention.

Some further support of the use of ultrasound-indicated cerclage as an alternative to elective cerclage comes from a study by Guzman et al., which reports that the rate of delivery before 37 weeks in 81 high-risk pregnancies treated by prophylactic cerclage at 12–18 weeks (median 13) was identical (46%) to the rate in 57 high-risk pregnancies undergoing cerclage at 16–24 weeks (median 20) as a result of serial scans demonstrating that the cervix had shortened to 20 mm or less. However, interpretation of this study is limited by the lack of data regarding the numbers and outcome of high-risk patients who did not have any sonographic changes in cervical length and hence did not require cerclage.

The findings of our study essentially suggest that a policy of selective cerclage avoids unnecessary surgical intervention without a significant increase in adverse outcome.

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REFERENCES