EFFICACY OF CERVICAL CERCLAGE IN SONOGRAPHICALLY SHORTENED CERVIX IN WOMEN AT MODERATE RISK OF PRETERM DELIVERY

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ABSTRACT

Objective: To compare the efficacy and safety of cervical cerclage following objective shortening of cervix by endovaginal ultrasound with elective cerclage in women at high risk of midtrimester miscarriage or preterm delivery.

Study design: Quasi experimental.

Place and Duration of study: Military Hospital Rawalpind., January 2005 to July 2008.

Material and Methods: Cases of elective cerclage were matched for maternal age, previous history of single mid trimester loss or preterm delivery or preterm rupture of membranes before 34 weeks with women who had selective cerclage if cervical length became < 25mm. All patients were followed up till delivery and outcomes in the two groups were assessed in terms of duration of gestation and neonatal survival.

Results: 23 cases of elective cerclage were matched to 24 cases of selective cerclage. Transvaginal ultrasound indicated cerclage was performed in 50% of the control group due to decrease in cervical length. There was no significant difference in the number delivering before 25 weeks 2(8.6 %) versus 3(12.4%), those delivering at gestation>35 weeks 17 (73%) versus 16(66.6%)(p=0.94) . Neonatal survival was also similar 18(78%) versus 19(79%) p=0.96.

Conclusion: Cervical length as measured by TVS is the best available technique for predicting preterm labour. In women deemed moderately high risk on the basis of history, sonographic cervical length indicated cerclage appears to reduce cerclage rates without comprising pregnancy outcome

Key words: Cerclage. Cervical length. Cervical weakness.

INTRODUCTION

A history of 2nd or early 3rd trimester fetal loss after painless dilatation of cervix, prolapse or rupture of membranes and expulsion of alive fetus despite minimal uterine activity is characteristic of cervical insufficiency. In such cases the risk of recurrence is high and a policy of prophylactic cerclage may be safer than one of serial cervical length measurement followed by cerclage. In the absence of classic recurrence of painless midtrimester miscarriages it is not justified to use the term cervical weakness in connection with a short cervix[1] . The diagnosis of cervical weakness is elusive because of lack of diagnostic criteria. There are few publications specifically addressing the causes of miscarriage in the 2nd trimester[2]. 'Cervical competence' was first proposed by Lash and Lash in 1950[3] in a report on reconstruction of non-pregnant cervix . Shirodkar described this technique in 1955[4] and Mcdonald described the simpler technique in 1957[5]. Both originally described the technique in an emergency situation when the cervix was already opening. The differing indications for cervical cerclage were highlighted by Medical research Council/Royal College of Obstetricians and Gynaecologists Working Party 1993[6]. Between pregnancies the passage of size 8 Hegar dilator with ease (Lash and Lash 1950[3]) , hysterosalpingogram(Jeffcoate and Wilson 1956[7]), the foley catheter traction technique (Bergman and Svenerund 1957[8]) and cervivcal resistance studies have been used . These tests are inaccurate , inconvenient and/or unproven. There is substantial evidence that a short cervix is a risk factor for preterm delivery with the risk being inversely proportional to cervical length. Cervical incompetence has traditionally been viewed as an "all or nothing phenomenon"1. Recent evidence shows that the risk of preterm

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birth increases as the cervical length shortens, making cervical length a continuous variable[9].

METHODS

This was a prospective study comparing two methods of management in patients at high risk of cervical incompetence with previous one delivery between 13-34weeks. One arm was managed by elective cerclage between 13-18weeks in all the patients with viable pregnancy. The 2nd arm was managed by serial transvaginal ultrasound (TVS) between 11-13 weeks and again between 14-18 weeks. In the 2nd arm cerclage was performed selectively only if cervical length became less than 2.5 cm on these serial scans.

Inclusion criteria:

Women with previous one:

Midtrimester miscarriage of well formed fetus documented alive till the time of miscarriage or

Previous spontaneous preterm delivery between 26-34 weeks of morphologically normal fetus or

Previous preterm rupture of membranes <34 weeks.

Exclusion criteria:

Very high risk women with 2 or more of the risk factors mentioned above.

Previous 1st trimester miscarriage or missed abortion.

Patients reporting after 17 weeks complete of pregnancy.

Patients with evidence of prolapsed membranes in cervical os or those undergoing emergency cerclage.

High risk patients meeting the inclusion criteria were randomized into two arms. Patient demography was noted at booking. Her weight, age was recorded. Mc Donald suture was applied using standard technique using, Silk-1 on round boy needle. Four bites were taken circumferentially around cervix at cervico vaginal junction4 under General anaesthesia. All patients were admitted with overnight stay after suture application. All were discharged with advice for light activity only. Bed rest was not prescribed. Cases were followed up until delivery. Suture was removed at 37-38 weeks electively to allow spontaneous labour, earlier if patient went into labour or presented with leaking membranes or at the time of elective LSCS whichever was applicable. All patients were followed until delivery. The duration of gestation was noted to assess the efficacy of suture. Depending on gestation 4 groups were identified in each arm<25 weeks, between 26-32weeks +6 days, 32-34weeks +6 days and >or equal to 35 weeks.

RESULTS

Patient demography is shown in Table 1. The mean age and weight were comparable hence the two groups were similar .Table 2 shows the previous adverse event in obstetric history in both groups . There was almost equal distribution of previous midtrimester miscarriage, preterm leaking and preterm labour <35 weeks.

In elective cerclage group all patients underwent Mc Donald suture, majority between 14-16weeks + 6 days (65%). In group B only about half as many required a suture (50%). Majority of sutures were applied late after 15 weeks when cervical shortening was objectively observed (Table-3).

Pregnancy outcome is given in table-4.

DISCUSSION

Cervical insufficiency is the leading contributor to the pool of preterm births. Accordingly, it is of utmost importance to gain insight into management of cervical insufficiency[9]. The diagnosis of cervical weakness in pregnant women may be based upon historical, clinical, or sonographic criteria. None have been validated in well designed studies[10]. The reason for paucity of studies may be because it is difficult to randomize high risk patients into non intervention group. Studies of cervical cerclage have not been performed on truly high risk patients as such patients may not give consent for randomization[6]. Most studies quote a high viable delivery rate following cerclage. These studies are flawed as patients are used as their own historic controls[10] . The

Table 1: Demographic features

	Elective cerclage N=23	Selective cerclage n=24	P value
Age	30±0.83	31±3.2	0.55
Weight at booking	62±6.3	64±6.7	0.53

Table-2: Previous adverse event.

	Midtrimester miscarriage	Preterm labour<34 weeks	Preterm leaking
Elective cerclage n=23	12(52%)	6(26%)	59(22%)
Selective cerclage n=24	10(41%)	8(33%)	6(26%)

Table-3: Gestation at Cerclage.

	12-14 weeks +6days	15-18 weeks	Total	P value
Elective n=23cerclage	15 (65 %)	8 (35%)	23 (100%)	0.001
Selective cerclage n=24	4 (17%)	8 (33%)	12 (50 %)	

Table-4: Pregnancy outcome.

Gestation at delivery	Elective Cerclage N=23	Selective cerclage n=24	P value
<25 weeks	2(8.6%)	3(12.5%)	0.94
26-31 weeks +6 days	1(4.3%)	0	
32-34 weeks +6 days	3(13%)	5(20%)	
> 35 weeks	17(74%)	16(67.5%)	
Neonatal survival	19(82%)	20(83%)	0.96

success rate in concurrent untreated randomly assigned population appears to be much higher[11]. Cerclage placement for cervical insufficiency is a heavily debated issue. The assumption that cerclage may prevent preterm birth in women with asymptomatic ultrasonic cervical shortening has recently been tested by randomized control trials. In 1995 a large multicentric trial measured cervical lengths between 24-26 weeks transvaginally and linked this to preterm delivery. The authors concluded that the risk of preterm labour increased as the cervical length decreased but without historical factors the risk was small. We chose cervical length as a screening test in women at high risk of cervical weakness because the earliest changes in cervical length and cervical os can only be detected by TVS reliably[12], with low inter and intra observer variability. We did not choose digital exam in predicting cervical weakness as it is subjective with inter observer variability. Sonographic cervical length measurements are on the average 11 mm longer than the manual estimation. We chose 25mm as the cutoff for shortening as it is the 10th percentile .The optimum threshold for cervical length was <25mm according to the largest blinded study on high risk women by Owen et al[13] . Serial scans were performed at gestations 16-24 weeks. In our study serial scans were performed at gestations 13-16 weeks only and sutures were applied by 18 weeks. Sensitivity in this study was 69%. Similar results were duplicated in some smaller studies. In women at high risk of cervical insufficiency the utility of TVS ha been suggested by several, mostly small, unblinded observational studies. Our study had a control group but we did not find it possible to blind this study.

In addition to absolute cervical length Zilante et al described an alphabetical progression of cervical effacement which preceeds caudal from internal to external os by letters T,Y , V and then U. As the cervix opens and membranes are exposed through the internal os into the vagina a characteristic "U" appears. Funneling is a significant risk factor for adverse perinatal outcome. Funneling of membranes into cervical canal and funneling > 40% of vaginal length has been described as a criteria[15]. Dilatation of internal os has a sensitivity of 16-25% for predicting preterm

birth. We did not take into account funneling in our study design, though one patient with cervical length 18mm did have funneling and prolapse of membranes through internal os that was noted at the time of cerclage. May be the increased incidence of preterm delivery between 32-34 weeks in non cerclage group could have been avoided if funneling was added to further refine the diagnosis of cervical weakness. While delivery between 32-34 weeks can be well managed in the west, in a developing country like ours appropriate neonatal facilities may not exist leading to escalation in perinatal mortality.

The largest randomized control trial to date on role of cerclage fueled the argument rather than settling it conducted by Medical Research council (MRC) and Royal College of Obstetricians and Gynaecologists(RCOG).The study demonstrated a modest beneficial effect of cerclage its use was associated with increased intervention as judged by admission to hospital, tocolysis, caesarean section and puerpueral pyrexia. For every 25 cerclages one extremely preterm birth was prevented. In the subgroup that had 3 or more midtrimester losses cerclage was beneficial[6]. We did not include very high risk group our study as in the light of the MRC/RCOG trial it seems unethical to leave such a high risk group without cerclage. The type of suture was not specified in this trial. In our trial we used only standard Mc Donald suture in all patients. The trial estimated the risk of puerpueral pyrexia and mode of delivery. This was not in the domain of our small trial a we felt it was underpowered to detect smaller differences.

The largest procerclage randomized control trial to date is the CIPRACT (Cervical Incompetence Prevention Randomized Cerclage Trial)[16]. Here high risk patients with cervical shortening and suggestive history were randomized into prophylactic cerclage plus bed rest versus bed ret alone. Our study resembled the 1st arm of this trial. In the observation arm secondary surgical intervention as needed appeared to be an effective alternative to prophylactic cerclage. Those women who maintained a normal cervical appearance were spared cerclage without any increase in preterm delivery rate . Similar findings were reported in several observational studies[17-19]. We applied cerclage to all high risk ladies with shortened cervix and did not follow cervical appearance with rescue cerclage as in CIPRACT[16] .The authors of this trial concluded that therapeutic cerclage with bed rest was more beneficial than bed rest alone. Similar results have been duplicated by other smaller studies[21,22]. We did not advise for bed rest in either arm, but recommended light activity to both groups to eliminate tha effect of confounding factors.

Screening for shortened cervix does not lead to beneficial intervention in low risk groups[9]. In this trial by To et al> 40,000 patients were evaluated. We also chose a high risk group in view of these findings.

Rust etal from Pennsylvania reported results of randomized control trial of cerclage versus no cerclage for TVS detected dilatation of internal os[23]. They found no benefit of cerclage and declared that the procedure should be considered investigationl at present. A point to note is that all patients received initial 72 hours of bed rest, urogenital cultures ,amniocentesis to evaluate for intra-amniotic infection ,and a medical regimen consisting of indomethacin and antibiotics. This could have accounted for the variance in results compared to other studies. The same group also analyzed their data and found that funnel width, depth and distal cervical length are independent predictors of preterm delivery. We did not analyze such fine data in our study. Some studies have evaluated the role of inflammatory factors by evaluating the combined role of shortened cervix and Interluekin -8[24].

Some studies have matched ethnic group in addition to maternal age[25].We did not take the ethnic group into account. Once the cervical length shortens , indomethacin , progesterone and antibiotics have been studied in addition to cerclage has been studied in randomized trials . We did not study any of these and the study

was dedicated to finding out the role of cerclage in this high risk group[25].

Many studies have followed up patient's cervical lengths following cerclage. We did not recommend this in our study design as no intervention is available to effect the outcome in post cerclage patients[26].

According to Cochrane database analyses of six trials with >2000 patients showed a small reduction in births under 33 weeks[27]. The role of cervical cerclage in women with short cervix remains uncertain as the number of randomized conrtol trials is too few to draw firm conclusions.

CONCLUSION

Cervical length as measured by TVS is the best available technique for predicting preterm labour. This screening tool can be a key test aimed at preventing this complication. The results of this studies demonstrates that in women deemed moderately high risk on the basis of history sonographic cervical length indicated cerclage appears to reduce cerclage rates without comprising pregnancy outcome. Institutions performing cervical cerclage should formulate strict criteria for use of this procedure and collect data prospectively on their outcome. The optimum treatment for these women remains to be determined by large multicentric randomized control trials .

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