MERIT RESEARCH JOURNALS
www.meritresearchjournals.org
Merit Research Journal of Medicine and Medical Sciences (ISSN: 2354-323X) Vol. 7(12) pp. 478-482, December, 2019
Available online http://www.meritresearchjournals.org/mms/index.htm

Original Research Article

Emergency cervical cerclage and pregnancy outcomes; a prospective clinical trial

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Abstract

Cervical incompetence is an important contributor to preterm birth and second trimester pregnancy loss.The aim of this study was to evaluate the effectiveness and safety of emergency cervical cerclage in women with advanced cervical dilatation and bulging of fetal membranes. The study included 363 women who underwent emergency cervical cerclage because of cervix dilatation and protruding membranes in mid-trimester at Prince Meshari Bin Saud General Hospital in Baljurashi, Al-Baha area, Saudi Arabia. Pregnancy outcomes were analyzed, and revealed that the placement of emergency cerclage led to the delivery of live infants with a success rate of 84.49%. The mean interval between cerclage and delivery was 92.16±26.62 days, with a mean gestation at delivery of 35.3±4.7 weeks and a mean birth weight of 2134.69±370.37 g. No severe maternal complications such as maternal death, hematosepsis, and hysterorrhexis occurred after the operation. There were significant correlations between the pregnancy outcome and risk factors, including any presenting symptoms, cervical dilatation and post-operative white blood cell count. Emergency cervical cerclage is effective in prolonging pregnancy and improving neonatal outcome in women with cervical incompetence. It should be considered a viable option for women with a dilated cervix in mid-trimester.

Keywords: Bulging fetal membranes, Cervical dilatation, Cervical incompetence, Emergency cervical cerclage, Prolonging pregnancy

INTRODUCTION

Cervical incompetence is an important contributor to preterm birth and second trimester pregnancy loss. It is defined as the inability to support a full-term pregnancy because of a functional or structural defect of the cervix (American College of Obstetricians and Gynecologists, 2003). The typical symptoms of cervical incompetence include history of recurrent mid-trimester losses or pre-term birth and painless cervical dilatation in the absence of contractions or intrauterine infections. Labor is often short and the premature fetus is born alive. It is reported that the rate of cervical incompetence is between 0.1% and 2%, and is estimated to account for 15% of the recurrent pregnancy losses between 16 and 28 weeks (Debbs and Chen, 2009). In cases with cervical incompetence, mechanical support of a weak cervix is thought to be the main factor required to prolong the pregnancy. Cervical cerclage has been used to treat cervical incompetence for more than 50 years, since it was first described by Shirodkar (Shirodkar, 1955) and later modified by McDonald (McDonald, 1957). That is insertion of sutures around cervix in three stitches, and the most commonly used suture material is the

Mersilene tape (McDonald, 1957; Israfil-Bayli et al., 2015).

Emergency cervical cerclage (ECC) has been used as a salvage procedure in women with cervical dilatation and bulging fetal membranes in mid-trimester, in an attempt to prolong the pregnancy to a viable gestation. However, emergency cervical cerclage is likely to increase the risk of infection, due to increased exposure of the fetal membranes to vaginal bacteria, and its effectiveness and safety remain controversial (Alfirevic et al., 2013; Rand and Norwitz, 2003; Seravalli et al., 2013).

This study reports the neonatal outcomes and safety of ECC placement in women with advanced cervical dilatation and bulging of fetal membranes in Baljurashi, Saudi Arabia. The aim of this study was to evaluate the feasibility of emergency cervical cerclage.

MATERIAL AND METHODS

This is a prospective study conducted in Prince Meshari Bin Saud General Hospital (PMH) in Baljurashi, Al-Baha area, Saudi Arabia. The ethics committee of PMH approved this study. This study was conducted during the period of 01 January 2016 to 01 November 2019. Inclusion criteria included cervix dilatation and intactfetal membranes protruding beyond the external cervicalos in mid-trimester and agreed to follow up and delivery in the hospital. Exclusion criteria included planning to deliver in another hospital, refusal to sign consent to join the study, intact membranes, presence of chronic medical disease (Hypertension, Diabetes Mellitus, Heart disease, etc.) and presence of fetal congenital anomalies.

Diagnosis of cervix dilatation and membrane protruding was made by physical examination and both abdominal and vaginal ultra sound as patients complained about pelvic pressure sensation, bloody vaginal discharge or accidentally discovered during routine follow up. The criteria for cerclage were that there must be no significant contractions, rupture of the membranes, no heavy bleeding and no evidence of infection. Pre-operative microbiological analyses and drugs sensitivity done by vaginal swabs, fetal anomalies were excluded by obstetric ultrasounds before the cerclage procedure.

Under general anesthesia, five zero Mersilene tape was used to suture thecervix, while a sterile foley catheter was used with gentle pressureto replace the membranes into the uterus and to push themembranes to allow suturing. All participants given prophylactic Indomethacin rectal suppositories 100mg twice daily for 3 days, Progesterone Vaginal suppositories 400mg twice daily for 7 days, prophylactic broad-spectrum antibiotics before the cerclage and Long acting Penicillin 1.2mu post-operative and then once monthly until delivery. Postoperative management included bed rest for one week, abstinence from intercourse for two weeks and ultrasonographic assessment of the cervix every 3 weeks until 37 weeks. The sutures removed in all women who labored, ruptured their membranes, developed clear evidence of infection, or on reaching 37 weeks of gestation. Failure of emergency cerclage defined as delivery before 37 completed weeks of pregnancy.

The following data were gathered: clinical and demographic data, gestational age, cervical dilatation at time of cerclage, cerclage-delivery interval, gestational age at time of delivery, mode of delivery, fetal survival rate, neonatal birthweight, Failure of emergency cerclage and maternal complications. Analyzed data are represented either as simple statistics (number, percentage or mean ± standard deviation). The statistical analyses involved two-sample testand chi-squared test, as appropriate. P value of <0.05 was considered significant.

RESULTS

Total number of 381 patients had ECC during the period of the study. 18 women were excluded because they refused to consent for the study or planned to deliver elsewhere rather than PMH. 363 women join the study.

At the time of cerclage, the mean maternal age was 29.18±3.52 years (range: 23–37 years), the mean gestational age was 18.45±2.23 weeks (range: 17–27 weeks), and the cervical dilatation was 2.79±1.38 cm (range: 1–5 cm). The clinical and demographic data displayed in (Table 1).

Neonatal outcomes presented in Table 2. Emergency cerclage led to term delivery (beyond 37 complete weeks) in 84.49% of participants. The mean interval between cerclage and delivery was 92.16±26.62 days (range: 45–125 days) with a mean gestation at delivery of 35.3±4.7 weeks (range: 33–39.6 weeks) and a mean birth weight of 2134.69±370.37 g (range: 1580–3350 g). There were no severe maternal complications such as maternal death, hematosepsis, endometritis and hysterorrhexis. 67 women (18.46%) suffer from recurrent vaginal infection. 289 women (79.61%) delivered vaginally and the rest delivered by LSCS.

DISCUSSION

In the last several decades, a number of studies have attempted to evaluate the advantages and disadvantages of ECC (Cavus et al., 2014; Celen et al., 2011; Debby et al., 2007; Gundabattula et al., 2013). However, only a very few informative randomized controlled trials (RCT) with large sample size have been conducted for evaluating the use of ECC (Keeler et al., 2009), and the effectiveness and safety remain controversial.

There is a believe that once cervical dilatation has occurred, infections, uterine contractions, or rupture of

Table 1. Clinical and demographic data.

Data	Mean ± standard	Range
Maternal age	29.18±3.52	23–37
History of live birth	0.52±0.31	0–1
Number of previous miscarriages	1.63±0.87	0–3
Gestation at cerclage (weeks)	18.45±2.23	17–27
Cervical dilatation (cm)	2.79±1.38	1–5

Table 2. Neonatal outcomes of emergency cerclage.

Outcome	Mean ± standard/rate	Range
Suture to delivery interval (days)	92.16±26.62	45–125
Gestation at delivery (weeks)	35.3±4.7 weeks	30–39.6
<24 weeks (%)	00% (0/363)	
24–27+6 weeks (%)	0.55% (2/363)	
28–31+6 weeks (%)	12.12% (44/363)	
32–36+6 weeks (%)	17.08% (62/363)	
≥37 weeks (%)	54.75% (199/363)	
Survival (%)	84.49% (307/363)	
Birth weight (g)	2134.69±370.37	1580–3350

the membranes often follow, leading to a poor outcome after ECC (Lisonkova et al., 2014; Treadwell et al., 1991). In some developed countries, it is not recommended to perform ECC beyond the limit of fetal viability (24 weeks), because the potential for harm probably outweighs the potential benefit (American College of Obstetricians and Gynecologists, 2003). Although the treatment of neonates in Saudi Arabia had improved dramatically over the past few years (Chen and Zhang, 2013), infants born before 28 weeks of gestation may have a survival rate of <50%, and more than half of the surviving infants are moderately to severely handicapped (Chen et al., 2014; Jiang and Chen, 2014; Owen et al., 2009; Shennan and Jones, 2004). In the urgent situation of bulging membranes, ECC may be the only hope for prolonging gestation until fetal viability is reached.

This study illustrated that emergency cerclage can lead to the delivery of a live infant with a success rate of 84.49%. The mean procedure-to-delivery interval was 92.16±26.62days. That achievement of 84.49% live births can be considered a good result for mid-trimester emergency cerclage in the presence of protruding membranes. These results are mostly in agreement with previous reports. Recently, some studies found that ECC was a favorable approach to cervical dilatation in the mid-trimester and can lead to delivery of a more viable infant (Gundabattula et al., 2013; Hashim et al., 2014; Güdücü et al., 2013; Karau et al., 2013). Another study compared the role of bed rest with ECC (Aoki et al., 2014). There results indicate significant increase in median duration of pregnancy prolongation (44 days vs. 12.5 days, $P<0.01$). The numbers of deliveries after 28 and 32 weeks were also significantly higher in the cerclage group than in the bed rest group ($P<0.05$) (Aoki et al., 2014). Evidence shows a significant increase in live birth rate (72% vs. 25%) in the emergency cervical cerclage group (Stupin et al., 2008). On top of that, two studies reported a significant increase in pregnancy duration at the time of delivery and neonatal birth weight in women with emergency cervical cerclage after 20 weeks (Stupin et al., 2008; Abo-Yaqoub et al., 2012; Althuisius et al., 2003). They also suggested that the significant reduction in neonatal morbidity is an added benefit of emergency cervical cerclage (Althuisius et al., 2003).

Exposure of the fetal membranes to vaginal bacteria may increase the risk of chorioamnionitis, intra-amniotic infection, hematosepsis of mother, or even maternal death because of severe infection. In this study, no severe maternal complications such as hematosepsis or maternal death occurred after ECC. Prophylactic broad-spectrum antibiotics given before the cerclage and Long acting Penicillin 1.2 mu post-operative and then once monthly until delivery may reduce the incidence of infection.

Bulging membranes into the cervix, avoiding inadequate placement of the cerclage in a superficial portion of the cervix, and the risk of iatrogenic rupture of the membranes during the operative procedure make ECC difficult for surgeons and poses challenges such as uterine contraction, laceration of the cervix, or even hysterorrhexis after cerclage.

Deep venous thrombosis (DVT), a blood clot forming in a deep vein, is another maternal complication after emergency cerclage. In this study, no such complication occurred because women were advised to return to their normal daily activity from day two of the procedure. That is not to advise them of bed rest but to avoid it.

Previous study (Fortner et al., 2012; Gupta et al., 2010) reported that women who receive an emergency cerclage are more likely to deliver at an earlier gestational age when the cervical dilation is >2 cm at the time of procedure. This may be due to the increased exposure of fetal membranes to vaginal bacteria and because women with bulging membranes are more susceptible to infection. Moreover, the procedure is associated with more challenges as the degree of cervical dilation becomes greater. It is reported that women with cervical dilation of >2 cm at cerclage placement were more likely to have an intracervical Foley balloon catheter utilized for membrane reduction during the procedure. Present study revealed that patients with cervical dilation ≥4 cm tend to have longer operation duration, and may need extra one day in hospital after the operation. Neonatal outcomes were better in patients with cervical dilation <4 cm.

Pregnancy is unlikely to be prolonged in the presence of infection. Although none of the women in our current study had any evidence of infection before the operation, none of them developed post-operative infection. In this trial, women without evidence of infection at the time of the procedure, thought that, may have subsequently developed chorioamnionitis, which usually results from infection by microorganisms. This was rolled out during hospital stay and follow up with the monitoring of white blood cells (WBC's)

It has been reported that in women with emergency cerclage, delivery <32 weeks was significantly more common in women with symptoms (vaginal bleeding, discharge, or pelvic pressure sensation) (Tezcan et al., 2012). This study, also indicate that pregnancy outcome of the women without symptoms are better than in women with any presenting symptoms.

However, the study is limited by only included women followed-up and giving birth in our setting after the operations and had no data about those who were not followed-up.

CONCLUSIONS

This study demonstrates a favorable prolongation of pregnancy and neonatal outcome in emergency cerclage placement in women with advanced cervical dilatation and bulging of fetal membranes. In addition, these results indicate that several factors, including the degree of cervical dilatation, postoperative WBC's count, and any clinical symptoms, are closely related to the pregnancy outcomes.

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