A Novel Technique of Emergency Cerclage for Mid Trimester Cervical Dilatation

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Abstract

Objective: Introducing a novel method of dealing with bulging fetal membranes in the mid trimester using Mersilene tape with favorable obstetric and neonatal outcome in terms of prolongation of pregnancy, fetal viability and neonatal survival.

Material and Methods: Analysis of twenty-four pregnancies complicated by bulging membranes in mid-trimester during 26-year study period including 14 singleton, 8 twin and 2 triple pregnancies. All cases of cervical dilatation and bulging of membranes were diagnosed by ultrasound scan and speculum examination. Patients have received perioperative antibiotic, Indomethacin and Progesterone. Emergency cervical cerclage was accomplished using Mersilene 5 mm tape after pulling the margins of the dilated cervix over the bulging fetal membranes without having to touch or push the membranes and without doing amnioreduction. The exclusion criteria were rupture of membranes, uterine contractions, bleeding, chorioamnionitis and fetal anomalies.

Results: Emergency cervical cerclage on 24 patients with bulging membranes in mid-trimester. The pregnancies were prolonged by 9.4 ± 5.6 weeks in the singleton group, 8 ± 5.6 weeks in the twin group, and 8 ± 4 weeks in the triplet group. Fetal viability was achieved in 20 patients (83.3%), and the neonatal survival was 96.6%.

Conclusions: Favorable obstetric outcome can be achieved with bulging membranes in mid-trimester pregnancies using the novel method. There is no need to push the bulging membranes.

Keywords: Novel method; Emergency cerclage; Cervical incompetence; Multiple pregnancy; Bulging fetal membranes

Introduction

The human cervix is composed of an extracellular connective tissue matrix covered by a thin cellular layer of smooth muscle and fibroblasts that penetrate the connective tissue matrix. Approximately 10% to 15% of the cervix is comprised of smooth muscle and 85% to 90% is connective tissue matrix as pregnancy progresses [1], the collagen fibres become less dense with thinner more loosely packed fibres and loss of cervical tensile strength.

Thousands of second trimester miscarriages and neonatal deaths are a result of cervical incompetence [2]. In 1658, Riverius was the first to label the term “cervical incompetence” [3], the dilatation in an incompetent cervix is silent, painless and accompanied by a feeling of pressure on the perineum with mucoid pinkish discharge as shown in Figure 1.

The current methods of treating bulging membranes in mid-trimester are many, but they have the common concept of mechanical reduction, manipulation, and challenging the bulging membranes before insertion the emergency cervical cerclage [4,5].

Wong et al. [4] reported a retrospective review of the outcome of emergency cervical cerclage with bulging membranes in 1993. The prolapsed membranes were reduced with a Foley catheter or wet sponge and ovum forceps, followed by application of McDonald or Shirodkar sutures.

Ogwa et al. [5] published an article in 1999 that described a modified cervical cerclage application in pregnant women with advanced bulging membranes with the patient in the knee-chest position. A standard examination was performed prior to the surgical procedure to evaluate chorioamnionitis or to decompress the bulging membranes by transabdominal amniocentesis. The patient was placed in the knee-chest position and a metreuretery with a bulb was inserted and inflated with warm saline solution. After the membranes were reduced inside the uterine cavity, a
modified McDonald suture was placed. The patient was then placed into the dorsal lithotomy position and a modified Shirodkar suture was used.

Makino et al. [6] conducted a prospective cohort study in 2004 on pregnancies with bulging membranes, which were either filling the vagina or protruding beyond the vaginal inlet. The patients were divided into two groups; one group underwent Amnioreduction via Bulging Membranes (AVBM) and cerclage, and the other group had cerclage without AVBM. The overall prolongation of pregnancy was 5 weeks. However, the prolongation of pregnancy in the AVBM group was 4.7 weeks compared to 5.2 weeks in patients without AVBM.

In a case reported by Tsapanos et al. [7] in 2005 PelvicolTM sterile cellular porcine implant followed by a McDonald cerclage in a 24-week twin gestation was used. The prolongation of pregnancy was 14 weeks and the gestational age at the time of delivery was 38 weeks.

Debby et al. [8] reported in 2007 on the use of a Foley catheter filled with normal saline for reducing prolapsed membranes before placement of a McDonald suture. The report included 24 singleton pregnancies.

Levin et al. [9] in 2012 conducted a retrospective study in which the outcomes of mid-trimester emergency cerclage in twins were analysed. Only four patients presented with bulging of membranes beyond the external os. In that group, the prolapsed membranes were reduced using a Foley catheter inflated balloon and then a McDonald suture was placed.

Maerjio et al. [10] reported a case series of 12 twin and 2 triplet gestations with painless cervical dilation and exposed fetal membranes that underwent emergency cerclage placement prior to 24 weeks gestation, patients were admitted and received perioperative antibiotic and Indomethacin, a McDonald-type rescue cerclage was placed in all cases, and distention of the urinary bladder and/or a Foley balloon was used when necessary to replace the fetal membranes into the uterine cavity.

The aim of this study is to introduce a novel technique in dealing with cervical incompetence at mid trimester bulging membranes. Unlike the currently used methods, this novel technique is distinguished by application of emergency cervical cerclage without the need to touch or push the membranes and without the need to do amnioreduction. Obstetric and neonatal outcomes were analysed for a group of pregnant women, including singleton, twin, and triplet pregnancies who underwent an emergency second trimester cerclage.

**Materials and Methods**

This is a retrospective study of 24 pregnant patients who underwent an emergency second trimester cerclage after reducing the bulging membranes following the novel technique. Data were collected over 26 years (1987-2013) at Farah, which is a tertiary obstetrics hospital in Amman, Jordan. Singleton, twin, and triplet pregnancies presented with bulging membranes were included in this study.

Patients in this series were identified as candidates for an emergency cerclage by their presentation with subjective complaints of increased pelvic pressure or mucoid vaginal discharge. All patients subsequently had speculum and ultrasound examination to identify cervical dilatation with exposed fetal membranes. Patients in whom the membranes were easily visualized through a dilated internal cervical os were only included in the analysis as well as two patients who presented with prolapsed membranes beyond the vaginal introitus. Patients with rupture of membranes, uterine contractions, bleeding, chorioamnionitis and those with lethal fetal anomalies were excluded from the study.

All patients were admitted preoperatively for evaluation of uterine activity and signs of chorioamnionitis. During this evaluation, they received pre-operative Indomethacin 10 mg rectally, antibiotics (Ceftizoxime & Clindamycin) and Progesterone (Progesterone depot 250 mg) for a period of 12 to 24 hours prior to cerclage insertion.

Pre-operative laboratory investigations include: CBC, ABO and RH blood group, high vaginal swab, urine microscopy and urine culture, genetic thrombophilia and antiphospholipid syndrome screening were done for 17 patients, fifteen out of them have positive thrombophilia screen (88.2%).
The procedure is performed under general anaesthesia with the patient in the lithotomy position (Figure 2). The urinary bladder was catheterized and emptied. After Sims speculum is placed in the posterior vaginal wall and another narrow speculum is placed on the anterior vaginal wall (Figure 1). The edges of the cervix were grasped with ovum forceps and pulled down over the bulging membranes either de novo or after dissecting the urinary bladder (Figure 3). A Mersilene tape 5 mm (Cervix-Set B/Braun; Aesculap, Tuttlingen, Germany) was placed around the cervix after dissecting the urinary bladder when possible as shown in Figure 4. Once placement of the cervical cerclage is completed, the membranes are noted to be intact and bulging (Figure 5). The free ends of the tape are approximated and then the bulging membranes will recede easily and gently above the internal os. There is no need to touch or push the membranes inside the uterine corpus (Figure 6). The tape is tied in several knots thus minimizing the risk of rupture of membranes and infection (Figure 7).

After the surgical procedure, patients were continued on the Indomethacin, prophylactic oral antibiotics Cefitoxime & Clindamycin for a total of 5 days, weekly 250 mg. 17 hydroxy Progesterone caproate 100 mg rectally for a total of 4 doses and anticoagulation LMWH (Clexane 40 mg). All patients were observed in the ward until discharge, the hospital stay was limited to a mean of 2.6 days for singleton, 4 days for twins, and 35 days for triplets postoperatively.

The first course of steroids for lung maturity was given at 26 weeks and some patients received a rescue course if needed. The patients were instructed to have adequate rest, to avoid intercourse and to stay well-hydrated. The patients were followed in the clinic every two to three weeks with a vaginal ultrasound to assess the cervix. A vaginal swab was also obtained.

Consent was only obtained after the patient was given risks and benefits of the procedure a realistic knowledge of the risks and benefits of the procedure and told that there is no guarantee of achieving a full-term pregnancy. The immediate and late hazards of the procedure were thoroughly discussed.

The neonatal outcome was assessed in the 29 newborns who survived from the 24 pregnancies included in the study. The parameters examined included the following: single or multiple gestation, gestational age at the time of delivery, birth weight, admission to the Neonatal Intensive Care Unit (NICU) or nursery, duration of stay in the hospital, development of Respiratory Distress Syndrome (RDS), early onset sepsis and clinical or laboratory findings, including blood culture results and inflammatory mediator levels or both and neonatal survival. The data of the neonates delivered at Farah Hospital were obtained by reviewing the records of the NICU and normal nursery. Farah Hospital NICU is a tertiary consultant neonatologist led unit. Of the 29 newborns, one set of twins was delivered outside Jordan, and another two sets of twins and one infant were born in another hospital within Jordan. The data were collected by direct telephone contact with the parents or from the attending neonatologist.

Our primary outcome using the new method is prolongation of pregnancy and improving neonatal survival. Secondary outcome is reducing the risk of chorioamnionitis and intraoperative rupture of membranes.
**Statistical Analysis**

The statistical analysis was performed using SPSS package version 17.0 (SPSS Inc., Chicago, IL, USA).

**Results**

This study included 24 patients who underwent an emergency second trimester cervical cerclage using a novel technique to treat a dilated cervix (17 to 27 weeks gestation) over a period of 26 years (1987 to 2013). The patients were between 20 and 42 years of age mean was 30.5 ± 5.5 years. Eighteen women (75%) were primiparous, 10 (41.7%) had a history of a miscarriage, and 10 (41.7%) had multiple pregnancies. The maternal and clinical characteristics are shown in Table 1.

The operation was performed between 17 and 27 weeks gestation (mean ± SD of 21.9 ± 2.8 weeks). The mean gestational age at delivery was 30.6 ± 5.8 weeks (range, 19 weeks to 38 weeks). The pregnancies were prolonged after the procedure by a mean of 8.8 ± 5.4 weeks (range, 0.1 to 20.0 weeks). The singleton pregnancies were prolonged for a greater length of time than multiple pregnancies (9.4 vs. 8 weeks). The difference was not statistically significant (P=0.553). The women stayed in the hospital for a mean of 2.6 ± 1.7 days (singleton gestation), 4 ± 1.6 days (twin gestation) and 35 ± 2.8 days (triplet gestation) after the procedure.

Thus, series included eight cases of twin gestations and the mean prolongation of pregnancy in that group was 8 ± 5.6 weeks. The average gestational age of delivery in this group was 29±5 weeks (range, 19 weeks to 36±5 weeks), and the neonatal survival was 93.8%. This is one of the largest reports regarding twins undergoing emergency cerclage [9,10]. The two cases with triplet gestations were included with a prolongation of pregnancy of 5+1 weeks for the first case and 10+6 weeks for the second case. The first patient went into labor at 29+1 weeks, and the second patient delivered at 32+4 weeks because of severe pre-eclampsia with worrisome symptoms. The neonatal survival in triplets was 100%.

The post-operative obstetric complications are shown in Table 2. The incidence of placenta abruption was 8.3%. The incidence of chorioamnionitis was 8.3% of the 24 pregnancies, four (16.7%) aborted spontaneously and one (4.2%) ended in a neonatal death at 25 weeks gestation. There were nineteen (79.2%) mothers that achieved neonatal survival. Overall, 96.6% of newborns survived, 27.6% had RDS, 79.3% were admitted to the NICU, and 31% developed early onset sepsis (Table 3). The majority of newborns (82.8%) had a birth weight <2,500 g. The newborns were admitted to the hospital for a mean of 21.4 days.

**Discussion**

Cervical incompetence is a known risk factor of preterm birth [11], it is responsible for 5% of extremely premature deliveries with significant association between cervical insufficiencies [12], and gestational age at delivery and combined neonatal morbidity with severe neonatal sequel and neonatal mortality [13].

Although the data from the literature are few, the insertion of emergency cervical cerclage was proved to improve pregnancy outcome in addition [14], the majority of data concerning the effectiveness of emergency cervical cerclage came from retrospective analysis [15,16].

According to our results 75% of patients diagnosed with cervical incompetence and bulging membranes who required insertion of emergency cervical cerclage are primiparous with no ascertainable risk factor, this is congruent with the data presented in the literature [16].

The primary clinical outcomes of emergency cervical cerclage using our new method were comparable with those previously published by other authors. The emergency cervical cerclage was inserted on mean of 21.9 weeks of gestation, similarly to procedures discussed in the literature [4-10]. According to the literature the mean gestational age at delivery after emergency cervical cerclage insertion ranged from 24 to 30 weeks [4,7,8]. Most authors reported the mean prolongation of pregnancy between 1 to 9.3 weeks [4,7,8].

**Table 1: Maternal and clinical characteristics for 24 patients who underwent the method followed by cervical cerclage.**

<table>
<thead>
<tr>
<th>Age (year), mean ± SD; range</th>
<th>N=24</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>30.25 ± 5.5; 20-42</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-30</td>
<td>13</td>
<td>54.2</td>
</tr>
<tr>
<td>31-42</td>
<td>11</td>
<td>45.8</td>
</tr>
<tr>
<td><strong>Parity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primiparous</td>
<td>18</td>
<td>75%</td>
</tr>
<tr>
<td>Multiparous</td>
<td>6</td>
<td>25</td>
</tr>
<tr>
<td><strong>Miscarriage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No miscarriage</td>
<td>14</td>
<td>58.3</td>
</tr>
<tr>
<td>One miscarriage</td>
<td>4</td>
<td>16.7</td>
</tr>
<tr>
<td>2-3 miscarriage</td>
<td>6</td>
<td>20.8</td>
</tr>
<tr>
<td><strong>Mode of conception</strong></td>
<td></td>
<td></td>
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<tr>
<td>Intracytoplasmic sperm injection</td>
<td>11</td>
<td>45.8</td>
</tr>
<tr>
<td>Intrauterine insemination</td>
<td>3</td>
<td>12.5</td>
</tr>
<tr>
<td>Spontaneous</td>
<td>10</td>
<td>41.7</td>
</tr>
<tr>
<td><strong>Number of fetuses</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton</td>
<td>14</td>
<td>58.3</td>
</tr>
<tr>
<td>Twins</td>
<td>8</td>
<td>33.3</td>
</tr>
<tr>
<td>Triplets</td>
<td>2</td>
<td>8.3</td>
</tr>
<tr>
<td><strong>Previous treatment with cerclage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>8.3</td>
</tr>
<tr>
<td>No</td>
<td>22</td>
<td>91.7</td>
</tr>
<tr>
<td><strong>High vaginal swab culture before onset of cerclage</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not done</td>
<td>2</td>
<td>8.4</td>
</tr>
<tr>
<td>Positive (Candida)</td>
<td>5</td>
<td>20.8</td>
</tr>
<tr>
<td>Negative</td>
<td>17</td>
<td>70.8</td>
</tr>
</tbody>
</table>

**Table 2: Post-operative Obstetric complications in patients who underwent the new method followed by cervical cerclage.**

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Premature rupture of membranes</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Chorioamnionitis</td>
<td>2</td>
<td>8.3</td>
</tr>
<tr>
<td>Placental abruption</td>
<td>2</td>
<td>8.3</td>
</tr>
<tr>
<td>Positive high vaginal swab culture</td>
<td>10</td>
<td>42</td>
</tr>
<tr>
<td>Positive urine culture</td>
<td>1</td>
<td>4.2</td>
</tr>
<tr>
<td>Pre-eclampsia</td>
<td>1</td>
<td>4.2</td>
</tr>
</tbody>
</table>
The incidence of chorioamnionitis ranges from 17% to 60% and the incidence of rupture of membranes ranges from 0-15, 7% [4-6,8]. The above-mentioned differences were probably due to the diversity of studied groups of patients and a different methodology.

All of the previously mentioned techniques [4-10], except the bed rest preference, require repositioning of the herniating membranes by pushing them back with or without amnioreduction. They have the negative aspects of the procedure which endanger the pregnancy and reduce the success rate. These practiced methods carry the risk of rupturing the membranes and might require many attempts to push the bulging membranes behind the internal os. Thus, there is a danger of infection and release of prostaglandins due to prolonged manipulation. In our opinion, abdominal amniocentesis and amniocentesis via bulging membranes increases the risk of infection and premature labor. Bed rest has a very poor outcome and is notably inconvenient and costly. This approach is physically and mentally exhausting to the patient, and the probability of neonatal survival remains uncertain and poor [14].

In addition to singleton pregnancy, few case series have proposed the beneficial effect of emergency cervical cerclage in multiple pregnancy with mean prolongation of pregnancy range from 7 to 8 weeks in twin and 11 weeks in triplet pregnancies [9,10]. The mean gestational age at delivery ranges from 28.7 to 29 weeks in twin and 31.9 weeks in triplet pregnancies. Neonatal survival was achieved in 62.5% to 70% in twin [9,10], and 100% in triplet pregnancies [10]. The incidence of chorioamnionitis was 21% to 25% and the incidence of rupture of membranes was 0% to 25% [9,10].

Our new method was performed by the same surgeon at the same center and it is distinguished by being simple, quick and easy to perform, to teach and to learn. The membranes are not touched of rupturing the membranes and might require many attempts to push the bulging membranes behind the internal os. Thus, there is a danger of infection and release of prostaglandins due to prolonged manipulation. In our opinion, abdominal amniocentesis and amniocentesis via bulging membranes increases the risk of infection and premature labor. Bed rest has a very poor outcome and is notably inconvenient and costly. This approach is physically and mentally exhausting to the patient, and the probability of neonatal survival remains uncertain and poor [14].
or pushed. Instead, the stretchable cervix is pulled down and sutured using the McDonald or Shirodkar techniques. This approach minimizes the risk of infection and vanishes the risk of membranes rupture, which did not occur in any of our patients. The duration of the operation is a few minutes.

The new method requires only one surgeon, one assistant, and one staff nurse. Wong et al. [4] recommended that patients with bulging membranes in the mid-trimester should be referred to a specialized center and attributed their poor results to the number of surgeons (n=21) performing the procedure. Using the new method, there is no need to transfer the patient for a simple procedure because it takes a few minutes and it can be performed by any experienced obstetrician. Most of our patients underwent a McDonald cervical cerclage, which is easier and quicker than the Shirodkar technique.

Elective removal of the cervical cerclage was performed on three patients and urgent removal was performed for 20 patients as shown in Table 4. One patient who delivered twins outside the unit was not included in this statistical analysis because the data regarding the timing of cervical stitch removal was not confirmed. There are no studies comparing elective cerclage removal with removal during labor in the absence of established Preterm Labor (PTL). The elective removal of cervical cerclage at 36 to 37 weeks of pregnancy is preferable due to the risk of cervical trauma when spontaneous labor occurs with the suture in place. Alternatively, an elective caesarean delivery can be performed with suture removal [17,18].

Women with Preterm Premature Rupture of Membranes (PPROM) between 24 to 34 weeks of pregnancy and no infection or PTL are advised to delay suture removal for 48 hours. This allows completion of a prophylactic course of steroids for fetal lung maturation. However, we do not recommend delaying the suture removal until the onset of labor to avoid the risk of maternal and neonatal sepsis [19,20].

Possible adjunctive therapy after emergency cervical cerclage discussed in the literature included antibiotics, intrauterine microbiological invasion occurred in about 50% of women with asymptomatic cervical dilatation [21,22]. Moreover, there is some evidence that antibiotics administered after the cerclage may improve perinatal outcome [23]. In many studies antibiotic therapy was also applied [24-26].

Progesterone administration appears to reduce uterine contractions due to its anti-inflammatory mechanisms, Oxytocin inhibition, or improvement of immune function. Adjunctive Progesterone therapy has not yet proved to be effective in emergency cervical cerclage patients, but there are some data suggesting that it may be beneficial Progesterone or 17-OH Progesterone therapy was also conducted in other studies [26,27].

Our study is limited by its retrospective nature, lack of randomization, a small sample size, and selected study group, but this is the largest study dealing with bulging membranes in twin pregnancy and the first dealing with bulging membranes in triplet pregnancy. Although the study has its limitations, the presented results are promising. However, further prospective randomized study is required to prove it.

Conclusion

After thoroughly researching the medical literature and reviewing the practiced methods for treatment of bulging membranes in mid-trimester pregnancies, the conclusion is that the results of the methods excel the previous methods. Most of the previous methods address touching, pushing and challenging the bulging membranes; which in our opinion is not necessary or safe. This new method is distinguished by being quick, safe and is easy to perform, to learn and to teach. It has minimal complications and proved to be effective even in twins and triplet pregnancies. It has a significant prolongation period of pregnancy with an average of 9.4 ± 5.6 weeks in the singleton group, 8 ± 5.6 weeks in the twin group, and 8 ± 4 weeks in the triplet group. It also improved neonatal outcome to 96.6%, which was not documented previously.

Contribution to Authorship

Dr. Zaid Kilani performed the operation and wrote the paper. Dr. Mohanad Hamarsheh analyzed the data and wrote the paper. Dr. Sanad Kilani helped in the operation. Dr. Ziad Rubeia analyzed the data. Dr. Lamia Haj Hassan helped in the operation and helped in writing the paper.

The authors have the permission to use the embedded table.

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Details of Ethics Approval

Ref. No.: 2/4/37/18564

The Institutional Review Board at the Farah Hospital agreed on conducting a retrospective study on Kilani method for emergency cervical cerclage in mid-trimester pregnancies with bulging membranes.

The study plans to introduce a new method for treating an incompetent cervix with bulging membranes in the mid-trimester that yields a high success rate in terms of obstetric and neonatal outcomes.

The study was approved on the 27th of December 2011, by the Institutional Review Board.

Prof. Ghazi Saleh Bakaen Medical - President
Prof. Muataz Al Ramahi Medical- Deputy Chair
Mr. Omar Malkey Lawyer
Dr. Amid Abd Al Nour Scientific Representative
Ms. Sirsa Qursha Society Representative
Dr. Lamia Haj Hassan Medical Representative

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