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Title: Pessary vs. Cerclage vs. Expectant Management for Cervical Dilation with Visible Membranes in the Second Trimester

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Abstract Objective: We evaluated pessary for dilated cervix and exposed membranes for prolonging pregnancy compared to cerclage or expectant management.

Methods: Multicenter retrospective cohort study of women, 15-24 weeks, singleton pregnancies, dilated cervix ≥ 2 cm and exposed membranes. Women received pessary, cerclage or expectant management. Primary outcome was gestational age at delivery. Secondary outcomes were time until delivery, preterm premature rupture of membranes (PPROM) and neonatal survival.

Results: 112 women met study criteria; 9- pessary, 85- cerclage and 18- expectant management. Mean gestational age at delivery was 22.9 ± 4.5 weeks with pessary, 29.2 ± 7.5 weeks with cerclage and 25.6 ± 6.7 weeks with expectant management ($p=0.015$). Time until delivery was 16.1 ± 18.9 days in the pessary group, 61.7 ± 48.2 days in the cerclage group and 26.8 ± 33.4 days in the expectant group ($p < 0.001$). PPRM occurred less frequently and neonatal survival increased in women with cerclage. There was a significant difference in all perinatal outcomes with cerclage compared with either pessary or expectant management.

Conclusions: Perinatal outcomes with pessary were not superior to expectant management in women with dilated cervix with exposed membranes in the second trimester in this small retrospective cohort.

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Introduction

Preterm birth (PTB) occurs in 11.38% of pregnancies in the United States and is the principal cause of perinatal morbidity and mortality [1].

Women with singleton pregnancy, dilated cervix and exposed membranes during the second trimester have a 90% rate of preterm birth (PTB) [2-6]. These women represent a treatment challenge. Current management options are limited and include expectant management, physical exam indicated cerclage (PEIC) or pessary placement if there is no contraindication for continuing pregnancy.

There is no known proven benefit in prolongation of pregnancy with bed rest, and it is known to increase the risks of DVT and PE; maternal deconditioning also increases the risk of preterm birth [7].

PEIC performed usually between 14 to 24 weeks has instead been associated with decreased PTB <28 and <32 weeks by 70% and 64% respectively, decreased neonatal morbidity and improved neonatal survival, when compared with expectant management.^{3-6, 8} The risk of PEIC placement includes: rupture of membranes (4% -19%), bleeding from cervical laceration and intrauterine infection [8-13].

Pessaries have been used to prevent preterm birth for over 50 years and have been evaluated for treatment of short cervix [14-17]. Mechanically, the pessary is thought to change the angle between the cervical canal and the uterus to help displace the uterine weight and block the internal os. There are no data yet regarding the efficacy of pessary in women with second trimester cervical dilatation on physical exam. Our objective was to evaluate whether insertion of a pessary in women with dilated cervix \geq 2 centimeters provides better outcomes compared to PEIC or expectant management.

Materials and Methods

This is a retrospective cohort of all pregnancies identified with dilated cervix ≥ 2 centimeters and visible membranes in the second trimester of pregnancy managed between September 1994 and June 2014 at North Shore University Hospital, Long Island Jewish Medical Center and Thomas Jefferson University Hospital. The Institutional Review Board of both participating centers approved the study protocol. Patients were identified by ultrasound records, hospital records and delivery records. Both centers have extensive experience with the management of advanced cervical dilation early in pregnancy and have a level three neonatal intensive care unit (NICU) associated with their antepartum unit. In all cases, exposed membranes were diagnosed on speculum exam. This study was exempt from the Institutional Review Board.

Inclusion criteria were asymptomatic women between 15-24 weeks, with singleton pregnancies and a dilated cervix ≥ 2 cm and ≤ 4 cm with exposed membranes.

Exclusion criteria were fetal anatomical or genetic anomaly, bleeding, clinical chorioamnionitis, medically indicated preterm delivery or evidence of progressive preterm labor or miscarriage. Cervical length screening and progesterone (vaginal or intramuscular) were not routinely used during the entire study time period and thus were not incorporated in the inclusion or exclusion criteria. Demographic information was recorded for each patient. Matching neonatal records were reviewed. Women received either pessary, PEIC or expectant management as determined by their primary

obstetric provider. The Bioteque cup # 3 pessary was used in the pessary group. Pessaries were only used at one center, Thomas Jefferson University Hospital. Physical exam indicated cerclage was done with a # 5 mersiline suture or a 5mm mersiline tape in a McDonald technique. Expectant management was on either inpatient or outpatient depending on provider. Maternal activity, antibiotics, tocolysis and progesterone were given at the discretion of the primary obstetrician.

Primary outcome was gestational age (GA) at delivery. Secondary outcomes were interval between intervention and delivery, rate of preterm premature rupture of membranes (PPROM) and neonatal survival at discharge. Data analysis was conducted using GraphPad for Windows 8.0. The three groups were compared using the Analysis of Variance (ANOVA) test or the Student t-test for continuous variables and Fischer Exact test for categorical data. A Kaplan-Meier curve was used to evaluate gestational age at delivery.

Results

Overall, 112 pregnancies were identified for retrospective analysis. The pessary group included 9 women. Eighteen women were expectantly managed and 85 women underwent physical exam indicated cerclage. 46 women were from North Shore University Hospital, Long Island Jewish Medical Center and 66 women were from Thomas Jefferson University Hospital. Maternal demographics were not significantly different between the three hospitals or among treatment groups (Table I).

The mean gestational age at delivery was 22.9 ± 4.5 weeks with pessary, 29.2 ± 7.5 weeks with cerclage and 25.6 ± 6.7 weeks with expectant management, $p= 0.015$ (Table II). Perinatal outcomes were not significantly different between pessary and expectant management (Table II).

The risk of preterm birth between the three groups was assessed by Kaplan-Meier survival analysis (Figure 1). There was a significant difference in gestational age at delivery with cerclage compared with either pessary or expectant management (Figure 1).

PEIC significantly improved perinatal outcomes of PPRM ($p < 0.001$) and neonatal survival on discharge ($P= 0.03$) when compared with expectant management or

nessary. Additionally, the latency period between diagnosis of exposed membranes and delivery was significantly prolonged in the PEIC group ($p = <0.001$) (Table II).

Comment

The management of women with a dilated cervix and visible membranes in the early second trimester is a clinical challenge. We sought to evaluate pessary as an alternative method to PEIC. Perinatal outcome of women treated with pessary was not significantly different than expectant management. PEIC remains the best therapeutic choice for these women.

It is suspected that a dilated cervix and visible membranes in the early second trimester is the terminal phase of the spectrum of cervical insufficiency, with a short cervix being a leading clinical sign of this process. We wanted to evaluate whether a cervical pessary, which has shown promise in women with a short cervix, could be beneficial to women with the more concerning diagnosis of advanced cervical dilation[15-17].

For women with advanced cervical dilation, evidence of treatment options is limited and mostly retrospective, as in our study. The only randomized control trial of PEIC was performed by Althuisius et al⁶. Women with membranes at or beyond the cervical os before 27 weeks of gestation were treated with PEIC and antibiotics or bed rest. Both the PEIC group and controls were placed on strict bed rest until 30 weeks gestational age. Twenty three women (16 singleton and 7 twins) were randomized to cerclage with indomethacin, or bed rest only. PTB <34 weeks and composite neonatal morbidity, were significantly lower in the cerclage and indomethacin group as compared to the control group. Several retrospective observational series, mostly with no controls, also have

claimed benefit of PEIC [5]. The largest cohort study was published in 2007 by Pereira et al [8]. They evaluated women with a dilated cervix who underwent expectant management vs PEIC. They reported a 92% reduction in PTB < 28 weeks, a greater than 10-fold increase in neonatal survival, higher birth weight and a prolongation of pregnancy by 10 weeks with PEIC, compared with no cerclage, in singletons with ≥ 1 cm of cervical dilatation by digital examination between 14 0/7- 25 6/7 weeks. There is some evidence that PEIC may be beneficial in reducing PTB, but larger well designed randomized trials are needed to confirm the benefit of this intervention. Despite this evidence, there are many providers who do not perform PEIC as they feel the risk may exceed the benefit [18].

In this small retrospective cohort, we again confirmed the benefit of PEIC in women with dilated cervix and visible membranes in the early second trimester. Vaginal pessary, however, did not prove to be better at prolonging the pregnancy interval compared to expectant management. Some of the weaknesses of this study was that it was a small study over a long time period and that the data was retrospective. Provider and selection bias may have played a role as to why certain patients received different treatments. For example, the assessment of uterine activity prior to intervention was up to the provider, and the diagnosis of chorioamnionitis was not uniformly made on amniocentesis, as this was a retrospective study. Women who were contracting or who had hard evidence of amniocentesis are more likely to have been placed in the expectant group. Additionally, data on tocolytics, antibiotics and progesterone were not available for all patients. Although the cervical dilation and demographics and risk

factors were similar amongst the groups, there may have been other factors involved in the pessary group that made them higher risk for delivery. Lastly, it is important to note that the time criterion of this study was prolonged, and the clinical decision making has changed over this period.

Physical exam indicated cerclage remains the best treatment in prolonging pregnancy in women with singleton pregnancies with exposed membranes in the second trimester. In regards to perinatal outcomes, pessary was not superior to expectant management in this small retrospective analysis.

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