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Original Research

Cervical Pessary and Vaginal Progesterone in Twin Pregnancies With a Short Cervix

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OBJECTIVE: To evaluate cervical pessary as an intervention to prevent preterm birth in twin pregnancies with a short cervix.

METHODS: This was a retrospective cohort study of twin pregnancies managed by a single maternal-fetal medicine practice from 2005 to 2015. We included patients at 28 weeks of gestation or less who were diagnosed with a cervical length less than 20 mm. At the time of diagnosis, all patients were prescribed vaginal progesterone. Starting in 2013, they were also offered pessary placement in addition to vaginal progesterone. We compared outcomes between patients who received a pessary and matched women in a control group in a one-to-three ratio. Women in the control group were matched to women in the case group according to cervical length and gestational age (within 5 mm and 1 week, respectively, of the case patient at the time of pessary placement). We excluded patients with cerclage, monochorionic–monoamniotic placentation, major fetal congenital anomalies discovered before or after birth, patients with twin-twin transfusion syndrome, and patients for whom there were no appropriate controls. Chi-square, Fisher exact, and Student's *t* tests were used, as appropriate. Regression analysis was performed to control for significant differences at baseline.

RESULTS: Twenty-one patients received a cervical pessary, and they were compared with 63 matched women in the control group. As expected (as a result of matching), baseline gestational age (25.7±2.1 compared with 25.9±2.1 weeks of gestation, *P*=.671) and cervical length (10.9±3.6 mm compared with 11.9±4.5 mm, *P*=.327) were similar between the groups. Patients with a pessary had a significantly lower incidence of delivery at less than 32 weeks of gestation (1/21 [4.8%] compared with 18/63 [28.6%], adjusted *P*=.05), longer interval to delivery (65.2±16.8 compared with 52.1±24.3 days, adjusted *P*=.025), and a lower incidence of severe neonatal morbidity (2/21 [9.5%] compared with 22/63 [34.9%], adjusted *P*=.04).

CONCLUSION: For twin pregnancies with a short cervix, the addition of a cervical pessary to vaginal progesterone is associated with prolonged pregnancy and reduced risk of adverse neonatal outcomes. A large randomized trial should be performed to verify these retrospective findings.

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Twin births now account for 3.4% of all live births in the United States.[1] Compared with singleton pregnancies, twins have a disproportionate risk of neonatal morbidity and mortality, principally as a result of the increased risk of prematurity. In the United States in 2011, 57.3% of twins delivered at less than 37 weeks of gestation and 11.3% delivered before 32 weeks of gestation.[2] Multiple studies and meta-analyses have demonstrated that a short cervical length on transvaginal ultrasonography is associated with an increased risk of preterm birth in women with twin pregnancies.[3–6] However, despite our ability to predict preterm birth in twins, our ability to prevent it has thus far been disappointing. Interventions designed to

reduce the risk of preterm birth in high-risk twins such as bedrest, cerclage, and tocolysis have mostly been shown to be ineffective.[7–9] Some evidence suggests that vaginal progesterone may be effective for women with twin pregnancies and a short cervix.[10]

Evidence from singleton pregnancies suggests that in women with a short cervix, a cervical pessary may reduce the risk of preterm birth.[11] The ProTWIN trial demonstrated that, in unselected twin pregnancies, a cervical pessary does not appear to prolong pessary or reduce the risk of preterm birth.[12] However, a subgroup analysis in this trial suggested that a cervical pessary may be effective for women with twin pregnancies and a short cervix. Before publication we had offered all twins with a short cervix vaginal progesterone. Since the ProTWIN results were published in 2013 and based on the subgroup analysis, we have been offering cervical pessary for patients with twin pregnancies and a short cervical length on transvaginal ultrasonography. Our hypothesis for this study was that a cervical pessary would reduce the risk of preterm birth and prolong gestation in these patients, thereby reducing neonatal morbidity. The objective of this study was to study the effect of a cervical pessary in twin pregnancies with a short cervix when the mother was also treated with vaginal progesterone.

MATERIALS AND METHODS

This was a retrospective cohort of twin pregnancies with a short cervical length (less than 20 mm) on ultrasonography comparing outcomes between women who did and did not receive a cervical pessary. After Biomedical Research Alliance of New York institutional review board approval was obtained, we reviewed the charts of all patients with twin pregnancies managed or comanaged in our practice from June 2005 (when our electronic database was created) to June 2015. In our practice, patients with twin pregnancies routinely undergo serial ultrasonographic cervical length screening every 2–4 weeks.[4] Measurements of cervical length were performed using a 4- to 8-MHz transvaginal probe with an empty bladder according to criteria established by Iams et al.[13] The shortest functional cervical length was used because this has been found to be the most reproducible measurement (Fig. 1).[14] Over the entire course of the study period, patients at 28 weeks of gestation or less with a cervical length less than 20 mm were prescribed 200 mg vaginal progesterone daily at the time of diagnosis.[10] Since 2013, in addition to prescribing vaginal progesterone, these patients were also counseled about the potential benefits of a cervical pessary and were offered pessary placement. Patients undergoing cervical pessary received an Arabin pessary size 3 or 4. It was placed by a physician in the manner described by Goya et al[11] with the pessary around the cervix and the larger diameter facing the pelvic floor. After verifying that the patient was able to sit and stand comfortably, the pessary was left in place until labor, rupture of membranes, indicated delivery, or 36 weeks of gestation, whichever came first. It was not routinely removed for cleaning or repositioning unless the patient had specific concerns or complaints.

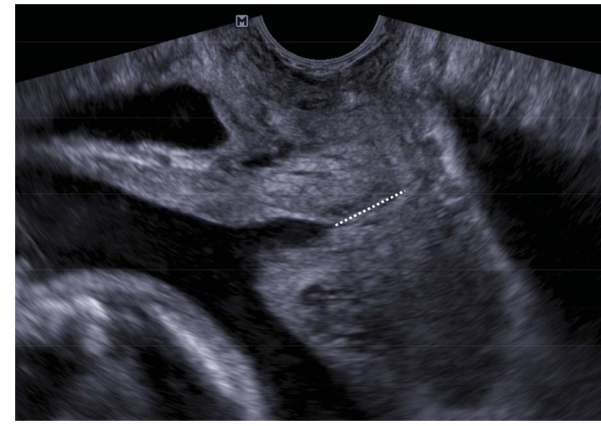

Fig. 1. Shortest functional cervical length measurement. *Dashed line* indicates cervical length.

Fox. Pessary for Short Cervix in Twins. Obstet Gynecol 2016.

The study group included all patients who underwent cervical pessary placement. For every case we selected three women for a control group. Women in the control group were matched to women in the case group according to cervical length and gestational age (within 5 mm and 1 week, respectively, of the case patient at time of pessary placement). We excluded patients with a cerclage, monochorionic–monoamniotic placentation, major fetal congenital anomalies discovered before or after birth, patients with twin-twin transfusion syndrome, and patients for whom there were no appropriate women in the control group. Baseline characteristics and pregnancy outcomes were obtained from our computerized medical records. Gestational age was determined by last menstrual period and confirmed by ultrasonography in all patients. The pregnancy was redated if there was a greater than 5-day discrepancy up to 14 weeks of gestation or a greater than 7-day discrepancy after 14 weeks of gestation. If the pregnancy was the result of in vitro fertilization (IVF), gestational age was determined from IVF dating.

Patients in our practice with twin pregnancies and a cervical length less than 20 mm are managed similarly regardless of whether a pessary is in place or not and aside from the addition of a cervical pessary as an option in 2013, our protocol for twin pregnancy management did not change over the course of the study period. Patients with twin pregnancies and a short cervix are not routinely admitted to the hospital nor are they prescribed bedrest. However, they are advised not to have intercourse. Patients are followed up in the office every 1–2 weeks or sooner if the patient has specific concerns or symptoms of preterm labor. At 36 weeks of gestation, vaginal progesterone is discontinued and, if the patient has a pessary, it is removed as well. Uncomplicated dichorionic twin pregnancies are typically delivered at 38 weeks of gestation and uncomplicated monochorionic pregnancies are delivered at 37 weeks of gestation. Management and follow-up did not differ for patients who were managed or comanaged by us.

The primary outcome was preterm birth at less than 32 weeks of gestation. Secondary outcomes included preterm birth at less than 34 weeks of gestation, gestational age at delivery, and time to delivery (from the diagnosis of short cervical length to delivery in both groups, which was also the same day as pessary placement in the study group). We also examined neonatal outcomes including birthweight, neonatal intensive care unit admission, length of stay, and a composite of severe adverse outcomes (death, respiratory distress syndrome, intraventricular hemorrhage, necrotizing enterocolitis, patent ductus arteriosus, sepsis, mechanical ventilation, retinopathy of prematurity, and chronic lung disease) as diagnosed by the treating neonatologists. As a result of the relationship between outcomes in twins born to the same mother, we compared the incidence of an adverse neonatal outcome per pregnancy and not per child.

χ^2, Fisher exact, and Student's *t* test were used, as appropriate (IBM SPSS for Windows 22.0). A *P* value of ≤.05 was considered significant. A planned regression analysis was performed in a backward stepwise fashion, including variables with significant ($P \leq .05$) differences at baseline.

RESULTS

Over the course of the study period, there were 23 patients with twin pregnancies with a cervical length less than 20 mm who underwent cervical pessary placement. Two patients received the pessary at 18 weeks of gestation and there were no appropriate women in the control group for comparison, because the majority of patients with a cervical length less than 20 mm at less than 20 weeks of gestation eventually underwent cerclage placement, which was also offered during the study period to select women with a very short cervix (less than 15 mm at less than 24 weeks of gestation). Therefore, these two patients were excluded from analysis, leaving 21 women in the case group. The details for the two excluded participants are as follows: one patient had a cervical length of 13 mm at 18 5/7 weeks of gestation, underwent pessary placement, and delivered 32 days later at 23 2/7 weeks of gestation (neither twin survived). The other patient had a cervical length of 18 mm at 18 weeks of gestation, underwent pessary placement, and delivered 113 days later at 34 1/7 weeks of gestation (both twins are doing well at 18 months of life).

The remaining 21 cases of twins with a cervical length less than 20 mm who underwent cervical pessary were compared with 63 women in the control group with twin pregnancies and a cervical length less than 20 mm who did not have a cervical pessary placed. All patients received vaginal progesterone. As expected (as a result of matching), the baseline cervical lengths (10.9±3.6 mm compared with 11.9±4.5 mm, $P=.327$) and gestational ages (25.7±2.1 compared with 25.9±2.1 weeks of gestation, $P=.671$) were similar between the groups. Other baseline characteristics between the groups are described in Table 1. The pessary group had a higher proportion of monochorionic twin pregnancies and a lower proportion of IVF pregnancies.

Table 1. Baseline Characteristics of the Population

Characteristic	Pessary (n=21)	No Pessary (n=63)	*P*
Gestational age at cervical length measurement (wk)	25.7±2.1	25.9±2.1	.671
Cervical length (mm)	10.9±3.6	11.9±4.5	.327
Maternal age (y)	32.2±6.9	33.2±6.4	.531
Prior preterm birth	4 (19.0)	5 (7.9)	.154
Prior term birth	1 (4.8)	9 (14.3)	.439
Prior LEEP or cone biopsy	2 (9.5)	3 (4.8)	.595
Chorionicity			.032
Dichorionic	14 (66.7)	55 (87.3)	
Monochorionic	7 (33.3)	8 (12.7)	
In vitro fertilization	7 (33.3)	42 (66.7)	.007
Multifetal pregnancy reduction	0 (0.0)	6 (9.5)	.329
White race	17 (81.0)	48 (76.2)	.651
Uterine anomaly	0 (0.0)	2 (3.2)	.999

LEEP, loop electrosurgical excision procedure.
Data are mean±standard deviation or n (%) unless otherwise specified.

Table 2. Pregnancy Outcomes in Twin Pregnancies With a Short Cervical Length Based on the Placement or Not of a Cervical Pessary

Pregnancy Outcome	Pessary (n=21)	No Pessary (n=63)	*P*	Adjusted *P**
Preterm birth at less than 32 wk of gestation	1 (4.8)	18 (28.6)	.033	.05
Preterm birth at less than 34 wk of gestation	5 (23.8)	28 (44.4)	.094	.100
Days to delivery (mean)	65.2±16.8	52.1±24.3	.008	.025
Gestational age at delivery (wk; mean)	35.0±2.6	33.3±3.9	.032	.074

Data are n (%) or mean±standard deviation unless otherwise specified.
* Regression analysis controlling for in vitro fertilization and chorionicity.

All of the preterm births at less than 32 weeks of gestation were spontaneous preterm births (from preterm labor or preterm premature rupture of membranes). There were two indicated preterm births between 32 and 34 weeks of gestation, one in the pessary group (for severe fetal growth restriction) and one in the control group (for oligohydramnios with abnormal fetal testing). Pregnancy outcomes are described in Table 2. Cervical pessary was associated with a decreased likelihood of preterm birth at less than 32 weeks of gestation (4.8% compared with 28.6%, *P*=.033). On regression analysis controlling for the differences at baseline, a cervical pessary remained independently associated with a reduced risk of preterm birth at less than 32 weeks of gestation (adjusted odds ratio 0.125, 95% confidence interval 0.016–1.00, *P*=.05). The use of a cervical pessary was also associated with a longer interval until delivery (65.2±16.8 compared with 52.1±24.3 days, *P*=.008) and a later gestational age at delivery (35.0±2.6 compared with 33.3±3.9 weeks of gestation, *P*=.032). On regression analysis controlling for the differences at baseline, the cervical pessary remained independently associated with prolonged gestation (adjusted *P*=.025), but not gestational age at delivery (adjusted *P*=.074). There were no pessary-specific complications reported in the pessary group nor were any pessaries removed prematurely for patient discomfort or infection.

Neonatal outcomes are listed in Table 3. Cervical pessary was associated with larger birth weights. The mean length of stay was significantly longer by approximately 14 days on unadjusted analysis, but this association was not significant on adjusted analysis. The use of a cervical pessary was associated with a lower risk of the composite adverse neonatal

Table 3. Neonatal Outcomes in Twin Pregnancies With a Short Cervical Length Based on the Placement or Not of a Cervical Pessary

Neonatal Outcome	Pessary (n=21)	No Pessary (n=63)	*P*	Adjusted *P**
Birth weight (g)				
Larger twin	2,323±503	2,061±652	.062	.097
Smaller twin	2,102±442	1,791±565	.013	.024
NICU admission†	47.6	69.8	.066	.069
5-min Apgar score less than 7†	0	4.8	.570	NA
Length of stay (d)‡	12.4±16.4	27.1±33.5	.010	.175
Composite outcome†	9.5	34.9	.028	.040
Death	0	6.3	.568	NA
Respiratory distress syndrome	0	19.7	.031	NA
Intraventricular hemorrhage	0	9.8	.330	NA
Necrotizing enterocolitis	4.8	4.9	.999	.945
Patent ductus arteriosis	0	9.8	.330	NA
Sepsis	4.8	14.5	.439	.332
Mechanical ventilation	4.8	14.3	.439	.345
Retinopathy of prematurity	0	3.3	.999	NA
Chronic lung disease	0	4.9	.566	NA

NICU, neonatal intensive care unit; NA, not applicable.
Data are mean±standard deviation or n (%) unless otherwise specified.
* Regression analysis controlling for in vitro fertilization and chorionicity.
† In either twin.
‡ The surviving twin with the longest length of stay.

outcome (9.5% compared with 34.9%, adjusted $P=.040$).

Post hoc power analysis demonstrated that we had 80% power to detect a difference in preterm birth at less than 32 weeks of gestation from 33%[4] to 10%.

DISCUSSION

In this study we found that for patients with twin pregnancies and a short cervical length (less than 20 mm), placement of a cervical pessary was significantly associated with prolonged gestation and improved neonatal outcomes. We did not observe any complications related to pessary placement. This suggests that for women with twin pregnancies and a short cervix, there may be an intervention that is effective in reducing the risk of preterm birth and improving overall outcomes. Cervical pessary has been studied prospectively in singleton pregnancies with a short cervix with mixed results. A multicenter randomized trial of pessary compared with no pessary in 385 women with a singleton pregnancy and cervical length 25 mm or less at 18–22 weeks of gestation showed a significant reduction in the incidence of spontaneous preterm birth at less than 28 weeks of gestation (2% compared with 8%, $P<.006$) and less than 34 weeks of gestation (6% compared with 27%, $P<.001$).[11] However, a subsequent randomized trial of 203 women with a cervical length less than 25 mm at 20–24 weeks of gestation did not show a difference in the incidence of delivery at less than 28 weeks of gestation (3.8% compared with 5.5%, $P=1.00$) or less than 34 weeks of gestation (9.4% compared with 5.5%, $P=.46$).[15] In twin pregnancies, there have been two large randomized trials of pessary compared with no pessary, but both were in unselected twins (ie, not specifically twins with a short cervix).[12,16] Both studies demonstrated that pessary placement in all patients with twin pregnancies is not associated with a reduced risk of preterm birth. However, in each study a secondary analysis was performed to examine the effect of a pessary in a subset of patients with twin pregnancies and a short cervix. In the ProTWIN trial, a subanalysis of patients with twin pregnancies and a cervical length in the bottom 25th percentile at 16–20 weeks of gestation (38 mm or less) showed that pessary placement was significantly associated with later gestational ages at delivery (36.4 compared with 35.0 weeks of gestation), a reduced incidence of preterm birth at less than 28 weeks of gestation and less than 32 weeks of gestation as well as improved neonatal outcomes.[12] The more recent second trial also performed a subanalysis of 214 women with twin pregnancies and a cervical length 25 mm or less but did not find pessary to be associated with a reduced risk of preterm birth at less than 34 weeks of gestation (31.1% compared with 25.9%).[16] Based on these two secondary analyses of large trials, it is uncertain whether a pessary improves outcomes in patients with twin pregnancies and a short cervix. Our study addresses the same question and we found pessary placement to be associated with improved outcomes. One difference between our retrospective study and the two larger secondary analyses was that in our study, the cervical lengths were shorter with a mean length of 10–11 mm at a mean gestational age of approximately 25 weeks. It is possible that this represents a different population than those studied in the two larger trials. Based on the differing results from these retrospective and secondary analyses, a prospective trial is warranted to specifically answer the question of whether a cervical pessary is associated with improved outcomes in patients with twin pregnancies and a short cervical length. Given the findings in our study, it would be necessary to ensure that there is at least a large subgroup with a very short cervical length such as less than 15 mm, because it is possible that patients with twins and a cervical length 15–25 mm do not have the same benefit from cervical pessary as do those with a cervical length less than 15 mm.

If well-designed trials demonstrate that a pessary improves outcomes in twins with a short cervix, it could potentially improve outcomes for a large number of twins given the high incidence of a short cervix and preterm birth in this population. It is relatively inexpensive and without known associated adverse outcomes. The Arabin pessary is readily available and can be purchased online through several vendors. It could also affect the routine management of twin pregnancies, increasing support for routine cervical length screening in this population. Currently, the available treatments include cerclage and progesterone. Although cerclage is not a standard treatment for patients with twin pregnancies and a short cervix in the second trimester, there are data to suggest that it is beneficial in twin pregnancies with either a very short cervix (less than 15 mm)[8] or a dilated cervix.[17,18] A recent meta-analysis suggests that progesterone supplementation is associated with improved outcomes in twins with a short cervix.[10]

The strengths of our study include uniform management of twin pregnancies regardless of pessary placement as well as our ability to match women in the case group to women in a control group according to gestational age and cervical length. However, our study is not without limitations. Because it was a relatively small retrospective study, the positive

results, although statistically significant, must be interpreted with caution, and we did not have enough power to detect differences in rare outcomes. Although we controlled for the most clinically relevant factors, cervical length, and gestational age, the decision to place a pessary or not could have been influenced by other unknown factors including patient preference or physician intuition, and unrecorded baseline characteristics could have differed between the groups as well. The differences in chorionicity and IVF between the groups did not appear to affect the results, but the regression analysis is limited by the small number of cases and outcomes. Also, we did not have proper women in a control group for two so they had to be excluded. Therefore, our study does not address whether a pessary is beneficial for women with twin pregnancies and a short cervix at earlier gestational ages. Our cohort was relatively homogenous, and it is unknown whether our results could be extrapolated to other populations. Finally, because all of our patients also received vaginal progesterone, we do not know the benefit of cervical pessary without concurrent vaginal progesterone nor do we know which of the two interventions is more effective or whether patients should receive both or either of them.

In conclusion, our study suggests that for twin pregnancies with a short cervix, cervical pessary is associated with a prolonged gestation and reduced risk of adverse neonatal outcomes. A large randomized trial should be performed to verify these retrospective findings.

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