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Decrease in the incidence of threatened preterm labor after implementation of transvaginal ultrasound cervical length universal screening

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ABSTRACT

Background: It is unknown if universal second-trimester transvaginal ultrasound (TVU) cervical length (CL) screening in asymptomatic women with singleton gestations and no prior spontaneous preterm birth (SPTB) affects the incidence of symptoms of preterm labor (PTL) later in pregnancy.

Objective: To evaluate the incidence of threatened PTL before and after the implementation of universal second trimester TVU CL screening.

Study design: This was a retrospective cohort study of all consecutive singleton gestations without prior SPTB presenting to obstetric triage for threatened PTL between 23 0/7 and 33 6/7 week in 2011 (1 January–31 December), and in 2014 (1 January–31 December) at Thomas Jefferson University Hospital (TJU) (Philadelphia, PA). These 2 years were chosen as a new protocol for universal TVU CL screening was started on 1 January 2012. This protocol involved one measurement of TVU CL in all singleton gestations without a prior SPTB at 18 0/7 – 23 6/7 week, the time of the "anatomy" scan. Women with prior SPTB were excluded from this study. The primary outcome included the incidence of threatened PTL, defined as the number of women with singleton gestations without prior SPTB who presented with threatened PTL to our labor and delivery (L&D) triage unit annually, divided by the total number of annual deliveries of women with singleton gestation without prior SPTB. Secondary outcomes were the incidence of PTL, defined as the number of women with singleton gestations without prior SPTB admitted for PTL annually divided by the total number of annual deliveries of women with singleton gestation and without prior SPTB; and length of stay in the hospital. We aimed to compare primary and secondary outcome in the "2011" versus the "2014" group.

Results: In 2011, there were a total of 1745 deliveries at TJU, of which 1550 (88.8%) were singletons without prior SPTB. In 2014, there were a total of 1924 deliveries at TJU, 1751 (91.0%) were singletons without prior SPTB who were offered universal TVU CL screening. One hundred and seventy-two women with singletons without prior SPTB presented in L&D triage unit in 2011; and 118 women with singletons without prior SPTB presented in L&D triage unit in 2014. There were significant decreases in the incidence of threatened PTL from 11.1% (172/1550) in 2011 to 6.7% (118/1751) in 2014 ($p < .001$), as well as in the rate of admission for PTL from 2.3% (35/1550) to 1.4% (24/1751), respectively ($p = .04$). Length of stay was not significantly different between the two groups.

Conclusion: The introduction of a universal TVU CL screening program in women with singleton gestations without a history of SPTB is associated with a reduction in the frequency of threatened PTL and admission for PTL.

KEY MESSAGE

- The introduction of a second trimester universal transvaginal ultrasound (TVU) cervical length (CL) screening program in women without a history of spontaneous preterm birth (SPTB) is associated with a reduction in the incidence of threatened preterm labor (PTL) and admission for PTL.

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KEYWORDS

Preterm delivery; preterm birth; pessary; progesterone; cerclage

Introduction

Preterm birth (PTB) is the leading cause of perinatal morbidity and mortality [1]. Worldwide, about 15 million babies are born too soon every year, causing 1.1 million deaths [2].

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Different strategies have been adopted for the prevention of PTB. The evidence supports the use of vaginal progesterone in singleton gestations without prior spontaneous PTB (SPTB) who develop short transvaginal ultrasound (TVU) cervical length (CL) before 24 weeks [3,4]. Based on this evidence, universal TVU CL screening at around 18–23 6/7 week has been proposed for all singleton gestations without prior SPTB, with one TVU CL measurement at the time of the anatomy scan at about 18 0/7 – 23 6/7 week [3–11].

It is unknown if second-trimester TVU CL screening in asymptomatic women affects the incidence of symptoms of preterm labor (PTL) later in pregnancy. Indeed, early identification and treatment of women at risk of SPTB, such as women with asymptomatic short TVU CL, may decrease the risk of these women later having symptoms of PTL, or PTL, in addition to decreasing the risk of subsequent SPTB [8]. PTL is one of the common indication for admission in the second and third trimester, thus the importance of any intervention that may decrease this frequent reason for hospital evaluation and admission cannot be underestimated.

Our objective was to evaluate the incidence of threatened PTL before and after the implementation of universal second trimester TVU CL screening.

Materials and methods

Study design

We conducted a retrospective cohort study of all consecutive singleton gestations without prior SPTB presenting to obstetric triage for threatened PTL between 23 0/7 and 33 6/7 week in 2011 (1 January – 31 December), and in 2014 (1 January – 31 December) at Thomas Jefferson University Hospital (TJU) (Philadelphia, PA). Multiple gestations and women with prior SPTB were excluded. These 2 years were chosen as a new protocol for universal TVU CL screening was started on 1 January 2012 [6]. This protocol involved one TVU CL screen of all singleton gestations without a prior SPTB at 18 0/7 – 23 6/7 week, the time of the “anatomy” scan (Figure 1). The CL was measured by operators with certification of competence in the technique (CLEAR). The length of the cervix was measured with a transvaginal real-time ultrasound probe placed in the anterior fornix of the vaginal. Endocervical canal length was measured as the distance between the internal and external os, by using a straight line with calipers placed at the notches made by the internal os and external os. Three anatomic landmarks defined the appropriate sagittal view: the internal os, the external os and the endocervical canal.

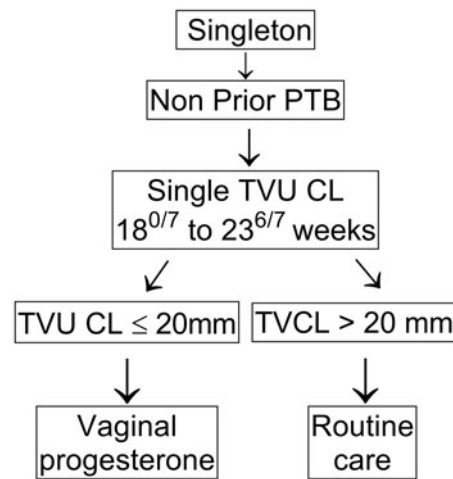


Figure 1. Clinical management algorithm for the universal cervical length screening program for asymptomatic singleton gestations.

The image was enlarged while visualizing the three landmarks simultaneously. This procedure was repeated three times. After a baseline CL was measured, the fundal pressure was applied for 30 s as a provocative maneuver. CL was measured during and after the fundal pressure. Only the shortest CL measurement was recorded. Each examination was performed during a minimum of 5 min.

Women without prior SPTB identified to have a TVU CL ≤ 20 mm were offered daily 90 mg vaginal progesterone gel, or if the vaginal gel could not be obtained from the patient’s insurance company, daily 200 mg micronized natural progesterone gel capsules were offered (Figure 1).

Women who presented to obstetric triage for threatened PTL were identified through labor and delivery (L&D) records (our triage book), medical records, and billing records. Threatened PTL was defined as any symptoms of possible uterine contractions, including abdominal cramps, low back pain, pelvic pressure, or bloody show, for which the woman presented to our L&D triage unit. Women with threatened PTL were evaluated according to an approved clinical guideline [12] (Figure 2). PTL was defined as threatened PTL with short TVU CL ≤ 20 mm, or TVU CL 21–29 mm and positive fetal fibronectin (FFN). This guideline recommends intervention for PTL (i.e. admission, tocolysis, and steroids) for women with TVU CL ≤ 20 mm and for those with TVU CL 21–29 mm and a positive FFN, and discharge for women with threatened PTL but with TVU CL ≥ 30 mm [12] (Figure 2). This protocol was started on November 2013, while before this date the decision for admission and interventions for women with threatened PTL was at physician’s discretion based on serial digital exams.

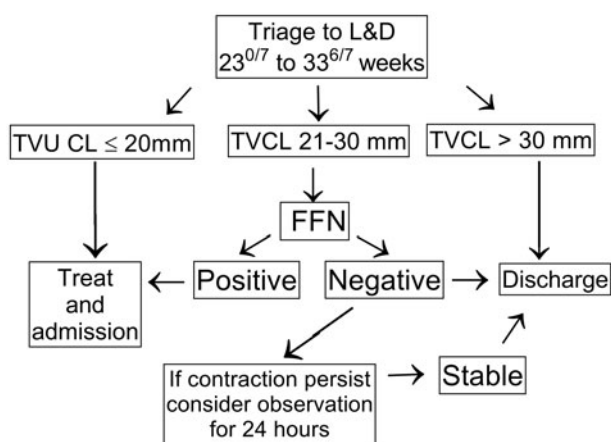


Figure 2. Clinical management algorithm for women with threatened preterm labor presenting in triage. TVU CL: transvaginal ultrasound cervical length; FFN: fetal fibronectin.

Primary and secondary outcomes

The primary outcome included the incidence of threatened PTL in singleton gestations without prior SPTB, defined as the number of women with singleton gestations without prior SPTB who presented with threatened PTL to our L&D triage unit annually, divided by the total number of annual deliveries in singletons without prior SPTB at our institution. Secondary outcomes were the incidence of PTL in women with singleton gestation without prior SPTB (admitted for PTL annually), divided by the total number of annual deliveries in singletons without prior SPTB at our institution. We aimed to compare the primary and the secondary outcome in the “2011” versus the “2014” group.

Statistical analysis

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) v 19.0 (IBM Inc., Armonk, NY). Differences between groups were analyzed using chi-square test and Fisher’s exact test for categorical variables and Student’s *t*-test or Mann–Whitney test for normally and non-normally distributed continuous variables, respectively. A two-tailed *p* value of .05 or less was considered significant. This study was approved by the Thomas Jefferson University Institutional Review Board Control #15D.221 JeffTrial # 7737.

Results

In 2011, there were a total of 1745 deliveries at TJU, of which 1709 (97.9%) were singletons, and 1550 (88.8%) were singletons without prior SPTB. In 2014, there

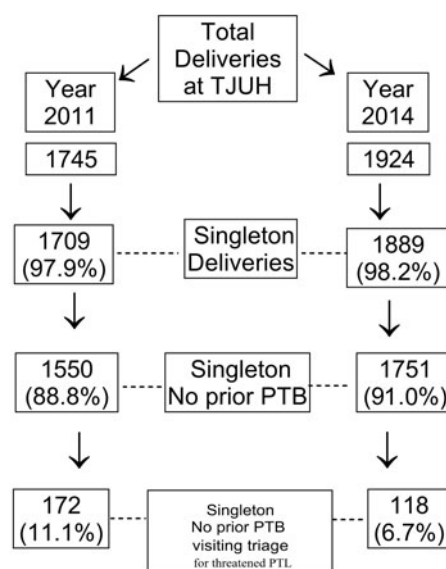


Figure 3. Study flowchart. PTL: preterm labor; PTB: preterm birth.

were a total of 1924 deliveries at TJU, of which 1889 (98.2%) were singletons, and 1751 (91.0%) were singletons without prior SPTB.

In 2011, 172 women with singletons gestations without prior SPTB presented in L&D triage unit for a total of 178 visits; while 118 women with singleton gestations without prior SPTB presented in L&D triage unit in 2014 for a total of 121 visits (Figure 3).

Table 1 shows the characteristics of the women with threatened PTL. There were no significant differences in maternal age, parity, and the race between the 2011 and 2014 groups of women who presented with threatened PTL.

There were significant decreases in the incidence of threatened PTL from 11.1% (172/1550) in 2011 to 6.7% (118/1751) in 2014 ($p < .001$), as well as in the rate of admission for PTL from 2.3% (35/1550) to 1.4% (24/1751), respectively ($p = .04$). Length of stay was not significantly different between the two groups (Table 2).

Discussion

This study aimed to evaluate the incidence of threatened PTL before and after the implementation of universal second trimester TVU CL screening in singleton gestations without a prior SPTB. We found significant decreases in the incidences of visits to L&D triage due to threatened PTL and of admission to L&D for PTL comparing data at our institution in 2011, before universal TVU CL screening, to 2014, after implementation

Table 1. Characteristics of women with singleton gestations without prior spontaneous preterm birth with threatened preterm labor in 2011 and in 2014.

	No TVU CL universal screening (2011) <i>N</i> = 172	TVU CL universal screening (2014) <i>N</i> = 118	<i>p</i> value
Maternal age	27.3 ± 4.7	27.1 ± 5.1	.67
African American race	100 (58.1%)	70 (59.3%)	.72
Nulliparity	76 (44.2%)	51 (43.2%)	.81
TVU CL ≤20 mm at TVU CL screening	ND	15 (12.7%)	–
Vaginal progesterone	0	15 (12.7%)	–

TVU CL: transvaginal ultrasound cervical length; d: not done.

Table 2. Primary and secondary outcomes.

	2011 <i>N</i> = 1550 ^a	2014 <i>N</i> = 1751 ^a	<i>p</i> value
Threatened PTL	172 (11.1%)	118 (6.7%)	<.001
Admitted for PTL	35 (2.3%)	24 (1.4%)	.04
LOS	4.4 ± 3.7	4.6 ± 4.2	.15

PTL: preterm labor; PTB: preterm birth; LOS: length of stay.

^aOnly singleton gestations without prior spontaneous preterm birth (PTB).

of universal TVU CL screening. These decreases can be, at least partially, explained by the introduction on 1 January 2012 of universal second trimester TVU CL screening in asymptomatic singleton pregnancies without prior SPTB, with treatment with vaginal progesterone for those with short CL. The incidence of short TVU CL, defined as TVU CL ≤20 mm, in the screened women in 2014 was 12.7% among those who developed threatened PTL later in gestation (Table 1).

This study has several limitations. The most important one was the retrospective nonrandomized study design. Because of its retrospective nature, it was not possible to separate the effect of the screening versus other variables, such as other management interventions. However, there were no other changes in management in PTB preventions between 2011 and 2014 in our institution apart from the introduction of universal TVU CL screening, except for the introduction in November 2013 of a protocol using TVU CL (and FFN as necessary) for triaging women presenting for threatened PTL [12,13]. This other new protocol could have decreased further the incidence of PTL, but could not have influenced our primary outcome, i.e. the incidence of threatened PTL. Our study lacks of data regarding important maternal demographics, such as smoking or BMI, and regarding gestational age at delivery, PTB, and neonatal outcomes. We used ≤20 mm as cut-offs for vaginal progesterone, while now in 2017 we have started using ≤25 mm based on new 2017 data [4]. We did not evaluate therapy or management of women with PTL or of those with arrested PTL after threatened PTL. So far, no therapy [14–25], including cerclage [14,19,21,24], progesterone [15,16], or cervical pessary [17,18], as well as diet or antenatal supplementation [20,22,25] have

been shown to be effective in women with PTL or with arrested PTL, neither in singletons nor in twins. We did not evaluate the antenatal lifestyle of the included women. Several studies have been shown that exercise during pregnancy may reduce the risk of PTB [26–28].



Our study has some strength, including the single institution study design, with the unified protocol for the management of universal second trimester TVU CL screening, vaginal progesterone and management in triage guided by a protocol for women with threatened PTB. The main strength of our study is that there is limited information in the literature on the effect of second trimester universal TVU CL screening in asymptomatic women with singletons without a prior SPTB on the incidence of symptoms of PTL later in pregnancy. Several studies [6–11] have evaluated the effect of the introduction of universal TVU CL screening in women without prior SPTB, showing decreases in PTB after implementation [7], but only one study looked at the incidence of PTL. Son et al. in a large cohort of women with singleton gestations without any prior PTB showed that the introduction of a universal TVU CL screening program was associated with a reduction in the incidence of PTB, while the incidence of threatened PTL and PTL were not evaluated [7]. The incidence of threatened PTL and PTL was also not reported on other studies on universal TVU CL screening [6,9–11]. Shaniker et al. is the only prior study which aimed to evaluate the effect of a universal TVU CL screening program on the incidence of PTB and of antepartum intervention, and which reported on PTL. They found that women who had universal TVU CL screening had less PTL admissions (2.3%) compared to women who did not have a CL measurement done (7.4%) [8]. They did not report on the incidence of threatened PTL [8]. Their findings concur with our results.

In summary, based on this retrospective study, following the implementation of universal CL screening with the treatment of short cervix with vaginal progesterone, there was a reduction in the frequency of threatened PTL and admission for PTL.

Disclosure statement

The authors report no conflict of interest.

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