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Can transvaginal ultrasonographic evaluation of the endocervical glandular area predict preterm labor among patients who received tocolytic therapy for threatened labor: a cross-sectional study

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Abstract

Objective: Increased neonatal morbidity and mortality rates resulting from preterm delivery (PTD) remain as a problem despite increasing evidence about the physiology of uterine contractility process. More predictive signs of preterm labor detected on prenatal ultrasonography like the presence of cervical gland area (CGA) on transvaginal ultrasonography can be a reassuring finding among patients with threatened labor risk.

Methods: In this prospective study, 85 pregnant patients at 24–34 weeks of gestation who attended to our high risk pregnancy clinic for threatened labor between March 2011 and March 2012 have been examined by transvaginal ultrasonography to evaluate CGA located around the endocervical canal. Following discharge, the gestational week at birth, birth weight and birth route of patients have been recorded.

Results: Among patients with a cervical length (CL) <30 mm and ≥ 30 mm measured by transvaginal ultrasonography on admission, 82.4% of the patients with a short cervix exhibiting echolucent endocervical glandular area and 42.3% of the patients with short cervix exhibiting echogen endocervical glandular area on sonography delivered at term ($p = 0.013$).

Conclusion: The presence of CGA detected on transvaginal ultrasonography especially when combined with the evaluation of CL during the management of patients with threatened labor can be a reassuring sign for actual probability of PTD.

Keywords

Cervical gland area, echogenicity, echolucency, preterm labor

History

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Introduction

Almost half of the preterm births result from preterm labor. Neonatal morbidity and mortality rates of preterm delivery (PTD) are extremely increased when compared with term ones. Despite improvements in detection of preterm labor, preterm birth rates remain unchanged because of the lack of therapeutic measures to furnish uterine quiescence when a true labor commences. Predicting spontaneous labor is a major challenge for clinicians to determine patients who should precisely receive therapeutic measures and who should not. Although clinical, ultrasonographic, biological and biochemical diagnostic methods have previously been applied to detect preterm labor more definitely tests with greater sensitivity and specificity are needed. Transvaginal ultrasonographic evaluation of cervical length (CL) and vaginal determination of fetal fibronectin have high specificity and low sensitivity rates that reflect the ability of these tests to detect patients who will not deliver imminently but not the ones who will deliver at preterm gestational weeks probably. The limit of the CL representative of risk for PTD is controversial with many studies suggesting lengths that vary from 15 to 35 mm that makes the sensitivity and the positive predictive value of this method unsatisfactory [1–9]. Among the different transvaginal sonographic morphological markers used in the prediction of preterm labor risk, funneling of the internal cervical orifice is one of the most widely used markers for prediction of PTD despite some publications reporting significant associations, while others not observing any significant associations between the occurence of funneling and preterm labor risk [10,11]. Not only the length but also the consistency and ability of the cervix to maintain the pregnancy until the term period deserves investigation to understand the spontaneous preterm labor. Recently, cervical gland area (CGA) was described as a new sonomorphological parameter for predicting preterm labor by Fukami et al., Sekiya et al., Yoshimatsu et al. and other authors [12–18]. According to these authors, the sonographic disappearance of CGA that demonstrates accelerated cervical maturation could be used as an additional sonographic screening test for the prediction of PTD in low-risk population. Whether the presence of the CGA qualitatively

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Figure 1. Transvaginal ultrasonographic view of the cervix demonstrating endocervical glandular area as an echolucent region.

defined as ''all or nothing'' phenomenon and/or the size of the CGA quantitatively predicts preterm labor or not among threatened labor patients needs to be investigated for the detection of patients with high preterm labor risk. The aim of this study was to evaluate the presence of CGA on transvaginal ultrasonography as an echolucent area around the endocervical canal among patients with a diagnosis of threatened labor by investigating the predictive value of the absence of CGA for subsequent genuine preterm labor occurance.

Material and methods

In this prospective study, we evaluated 85 pregnant patients at 24–34 weeks of gestation who attended to our high risk pregnancy clinic for threatened labor between March 2011 and March 2012. Threatened labor has been defined as regular contractions (at least three within 10 min) on nonstress test with closed cervix whether funneling on transvaginal ultrasonography exists or not. Patients with cervical dilatation revealing an established situation of preterm labor have not been included in the study. Urinary infection and/or any other comorbid conditions that pose potential risk to induce uterine contractions have also been excluded for selecting only the patients with spontaneous preterm labor risk. All patients were categorized into two socioeconomical status of fair and worse based on the classification including several criteriae that consider income, occupation, housing or neighborhood, education and transportation defined by Samar et al. [19]. Fair socioeconomic status was defined as upper and middle class, worse socioeconomic class was defined as lower class according to these criteriae. Before tocolytic therapy, all patients have been examined by using transvaginal sonography with a 7-MHz transducer with an angle of 160° (model 6117, Aloka 5500, ALOKA Co. Ltd., Tokyo, Japan) that operated at a constant output power of 0 dB and at a 65 dB gain setting for determining CL and evaluating CGA qualitatively and quantitatively by the same clinician (Figure 1). CL was measured with electronic calipers as the linear distance between the external cervical os and the internal cervical os along a closed endocervical canal. The echolucency surrounding the endocervical canal that corresponds to the presence of histologic CGA that was measured under a 90° angle from the endocervical canal, as a linear distance from the outer boundary of the deepest existence of cervical glands was defined as ''echolucent endocervical glandular area''. The presence of an echogen area around the endocervical canal on transvaginal ultrasonography was assumed as ''echogen endocervical glandular area'' that corresponds to the absence of cervical glands. Each patient was scanned only once at admission to the ward for threatened labor and cervical examination was performed over a period of 5 min to detect spontaneous dynamic changes resulting from uterine contractions. During the ultrasonographic examination at least three measurements were made for each patient and the lowest values were recorded for further interpretation.

Tocolytic therapy including intravenous hydration with normal saline combined with diazepam 10 mg and oral nifedipine 20 mg capsule four times per 20 min within 60 min proceeding with 20 mg per 6 h as maintenance till uterine contractions cease have been administered to all patients. Two doses of 12 mg betamethasone intramuscularly 24 h apart has also been administered to all patients as antenatal corticosteroid therapy to induce fetal lung maturity prophylactically. Patients were discharged from hospital after the uterine contractions have ceased following tocolytic therapy. Thereafter, the gestational week at birth, birth weight and birth route of patients have been recorded. Statistical analysis was performed by using IBM SPSS Statistics Software (19.0, SPSS Inc., Chicago, IL). Normal distribution of values were tested by using Kolmogorov- Smirnov test. The results were presented as means ± standard deviation values and compared by using the Independent Samples Test and Paired Samples Test for parametric values that distribute normally and by Mann–Whitney *U* test for parametric values without normal distribution and for nonparametrik values. The comparison of categorical data was accomplished by using the Pearson chi-square test and Fisher's exact test. p Values < 0.05 were considered statistically significant.

Results

The demographic and clinical characteristics of the patients who have delivered preterm and term were demonstrated in Tables 1 and 2. Thirtyseven percent (N:32) of the patients delivered before 37 weeks of gestation and 63% (N:53) of the patients delivered at term. Forty percent (N:13) of patients who have delivered at preterm and 55% (N:29) of patients who have delivered at term exhibited echolucent cervical glanduler area on transvaginal ultrasonographic scan before the tocolytic therapy intervention. Mean CL measurements of patients who have delivered at preterm and who have delivered at term was 24 and 29 mm, respectively ($p = 0.01$). Mean endocervical echolucent thickness measured from endocervical canal to the border of CGA on one lip of the cervix was 4.9 and 5.3 mm for patients who delivered at preterm and term period ($p = 0.43$) (Table 3). Endocervical glanduler area has been detected as echogen on transvaginal ultrasonography for 59.4% of 32 patients who have delivered at preterm and 45.3% of 53 patients who have delivered at term. When patients who have delivered before 37 weeks

Table 1. Demographic and clinical characteristics of patients according to the gestational week at delivery ($n = 85$).

	Preterm† ($n = 32$) (24–33^{+6} weeks)		Nonpreterm† ($n = 53$) (34–42 weeks)		
Parameter	N	%‡	N	%‡	*p* Value*
Gestational week at admission					
24–28 week	0	0	5	9.4	0.19
28–32 week	15	46.9	21	39.6	
32–37 week	17	53.1	27	51	
Parity					
Nulliparous	22	68.7	33	62.3	0.54
Multiparous	10	31.3	20	37.7	
BMI					
18.5–24.9	14	43.8	29	54.7	0.61
25–29.9	14	43.8	19	35.8	
>30	4	12.4	5	9.5	
Socioeconomical Status					
Fair	26	81.2	32	60.4	0.04
Worse	6	18.8	21	39.6	
Endocervical echogenicity					
Echolucent	13	40.6	29	54.7	0.20
Echogen	19	59.4	24	45.3	
Endocervical length					
<30 mm	18	56.2	25	47.1	0.12
≥30 mm	14	43.8	28	52.9	
Endocervical length					
<20 mm	13	40.6	13	24.5	0.11
≥20 mm	19	59.4	40	75.5	
Birth route					
Normal vaginal	26	81.3	38	71.7	0.32
Cesarean sectio	6	18.7	15	28.3	
Gender of newborn					
Male	19	59.4	32	60.4	0.92
Female	13	40.6	21	39.6	

*p Value (Pearson chi-square test).
†PTD has been assumed as delivery between 24 and 33^{+6} weeks of gestation that necessitates aggresive tocolytic therapy and non-PTD has been assumed as delivery between 34 and 42 weeks of gestation that does not necessitate aggresive tocolysis.
‡Percentages are calculated for columns.

Table 2. Prenatal and postnatal clinical characteristics of all patients ($n = 85$).

	N	Minimum	Maximum	Mean	Std. Deviation
Age (years)	85	17	40	25	4
Gestational week during at admission to the ward	85	26	34	31	2
Body mass index (BMI)	85	19	34	25	3
CL (mm)	85	7	50	31	8
Endocervical echolucent thickness (mm)	85	2.3	8.0	5.3	1.4
Birthweight (grams)	85	1590	3960	2933	507
Gestational week at delivery	85	30	41	37.19	2.24

were categorized into two groups according to their CL <30 mm and ≥30 mm, 17.6% of the patients with short cervix exhibiting echolucent endocervical glandular area and 57.7% of the patients with short cervix exhibiting echogen endocervical glandular area delivered before 37 weeks. When patients who have delivered at term were categorized into two groups according to their CL <30 mm and ≥30 mm, 82.4% of the patients with short cervix exhibiting echolucent endocervical glandular area and 42.3% of the patients with short cervix exhibiting echogen endocervical glandular area delivered at term ($p = 0.013$). Gestational week of birth among patients with long cervix (CL ≥ 30 mm) regardless of the presence or absence of their endocervical glandular area were found similar ($p = 0.38$) (Table 4). When patients who have delivered at preterm were categorized into two groups according to their CL <20 mm and ≥20 mm, 22.2% of the patients with short cervix exhibiting echolucent endocervical glandular area and 64.7% of the patients with short cervix exhibiting echogen endocervical glandular area delivered at preterm. When patients who have delivered at term were categorized into two groups according to their CL <20 mm and ≥20 mm, 77.8% of the patients with short cervix exhibiting echolucent endocervical glandular area and 35.3% of the patients with short cervix exhibiting echogen endocervical glandular area delivered at term ($p = 0.09$). Gestational week at birth among patients with long cervix

Table 3. Mean clinical values of the patients according to the gestational week at delivery ($n = 85$).

Parameter	Preterm† (Mean)	Term† (Mean)	p Value
Age (years)	27	24	0.09*
Gestational week during at admission to the ward	32	31	0.90*
Body mass index (BMI)	25	25	0.67*
Gestational week at delivery	34	38	<0.001*
CL (mm)	24	29	0.014**
Endocervical echolucent thickness (mm)	4.9	5.3	0.43**
Birthweight (grams)	2384	3191	<0.001**

*Mann–Whitney U test.
**Independent Samples t test.
†PTD was assumed as 24–36^{+6} weeks of gestation and term delivery was assumed as 37–42 weeks of gestation.

therapy is generally not recommended beyond 34 weeks, due to the potential maternal complications. Between 24 and 33 weeks' gestation, benefits of tocolytic therapy are generally accepted to outweigh the risk of maternal and/or fetal complications. Although aggressive tocolysis is not typically used beyond 34 weeks' gestation, clinicians are advised not to deliver patients at this gestation without indication because of a higher risk of neonatal morbidity in infants born at 34–36 weeks' gestation compared with deliveries at 37–40 weeks' gestation. In this study, the demographic and clinical characteristics of two group of patients who have delivered at 24–33^{+6} weeks of gestation and 34–42 weeks of gestation regarding aggresive tocolysis necessity were found to be similar except socioeconomic status. When we grouped patients into two groups according to gestational week at delivery, preterm (24–36^{+6} weeks) patients' mean CL

Table 4. Transvaginal ultrasonographic endo CL and echogenicity of the patients according to the gestational week at delivery ($n = 85$).

	Preterm‡		Term‡		Total		
Transvaginal ultrasonographic endocervical view	N	%***	N	%***	N	%	p Value
Cervix short + echolucency†	3	17.6	14	82.4	17	20	0.013*
Cervix short + echogenicity†	15	57.7	11	42.3	26	30.5	
Cervix long + echolucency†	10	40	15	60	25	29.4	0.38**
Cervix long + echogenicity†	4	26.3	13	73.7	17	20.1	
Total	32	100	53	100	85	100	0.031**

†Short-long cervix; endocervical canal length <30 mm has been accepted as short and ≥30 mm has been accepted as long cervix. Echolucency is defined as presence of cervical glandular area and echogenicity is defined as absence of cervical glandular area on transvaginal ultrasonography.
‡PTD was assumed as 24–36^{+6} weeks of gestation and term delivery was assumed as 37–42 weeks of gestation.
*Fisher's exact test.
**Pearson chi-square test.
***Percentages are calculated for rows.

Table 5. Transvaginal ultrasonographic endo CL and echogenicity of the patients according to the gestational week at delivery ($n = 85$).

	Preterm‡		Term‡		Total		
Transvaginal ultrasonographic endocervical view	n	%***	n	%***	n	%	p Value
Cervix short + echolucency†	2	22.2	7	77.8	9	10.6	0.09*
Cervix short + echogenicity†	11	64.7	6	35.3	17	38.8	
Cervix long + echolucency†	11	33.3	22	66.7	33	20	0.83**
Cervix long + echogenicity†	8	30.8	18	69.2	26	30.6	
Total	32	100	53	100	85	100	0.072**

†Short-long cervix; endocervical canal length <20 mm has been accepted as short and ≥20 mm has been accepted as long cervix. Echolucency is defined as presence of cervical glandular area and echogenicity is defined as absence of cervical glandular area on transvaginal ultrasonography.
‡PTD was assumed as 24–36^{+6} weeks of gestation and term delivery was assumed as 37–42 weeks of gestation.
*Fisher's exact test.
**Pearson chi-square test.
***Percentages are calculated for rows.

(≥20 mm) regardless of the presence or absence of their endocervical glandular area were found similar ($p = 0.83$) (Table 5).

Discussion

The risk of neonatal mortality and morbidity is low after 34 completed weeks of gestation and aggressive tocolytic

and birthweight measurements were significantly lower than term (37–42 weeks) patients. This result confirmed the previously determined statement that implies high predictive value of shortened CL which was accepted as the best predictive clinical sign for preterm labor. When we compared the patients with short cervix (<30 mm) exhibiting echolucent endocervical glandular area during initial admission to the ward for tocolytic therapy with patients with short

cervix exhibiting echogen endocervical glandular area, term delivery rates were significantly higher in the echolucent group (Table 4). Patients with normal CL ($\geq$30 mm) measurements either exhibiting echolucent or echogen endocervical glanduler area had similar term delivery rates. The predictive value of the presence of CGA on transvaginal ultrasonography seems to be higher when a shortened CL accompanies to echolucent endocervical glandular area. Although statistically nonsignificant, when we compared the patients with a shortened cervix (<20 mm) exhibiting echolucent endocervical glandular area during initial admission to the ward for tocolytic therapy with patients exhibiting echogen endocervical glandular area, term delivery rates were also higher among patients with shortened cervix (<20 mm) exhibiting echolucent endocervical glandular area. Studies with higher patient numbers will probably achieve statistically significant results for these group of patients. The results of this study demonstrated that the presence of CGA on transvaginal ultrasonography is a reassuring sign for preterm labor probability when accompanied with a shortened CL. The predictive value of CGA detection on sonography for the gestational age at delivery has been found to be lower in patients with threatened labor either having CL measurements of $\geq$20 mm or $\geq$30 mm at admission. Shortening process within the microenvironment of cervix during preterm labor initiation pathogenesis is closely related to the disappearance of CGA visualisation on transvaginal ultrasonography.

Frequently, but not always, a shortened cervix (i.e. generally less than 3.0 cm) and/or a funneling at the internal cervical os on transvaginal ultrasonography increases the likelihood of preterm labor. PTD occurs only in 30–60% of women presenting with preterm contractions [20]. The fetal fibronectin assay which evaluates vaginal fetal fibronectin as a placental glycoprotein that is thought to play a role in implantation and maintenance of choriodecidual attachment throughout pregnancy, is found to be superior to cervical dilatation and contraction frequency determination in predicting PTD. However, the negative predictive value of fetal fibronectin testing is greater than 99% for delivery within 14 d, the positive predictive value is 13–30% [11]. Although, cervical ultrasonography rules out preterm labor when CL is measured >30 mm, a shortened cervix does not necessarily indicate preterm labor besides increased risk of subsequent delivery among patients presenting with premature contractions [5–8,21]. Determining a CL that is accurately predictive of preterm birth is not possible. Combining both CL measurement and vaginal fetal fibronectin testing has an increased negative predictive value than conducting these diagnostic tests alone. In one study, 11.4% of symptomatic patients with CL measurements <30 mm eventually delivered within 7 d when the fetal fibronectin test was negative, and 44.7% delivered when it was positive [11]. A new sonographic morphological marker of the cervix CGA corresponding the sonographically hyperechoic or hypoechoic zone surrounding the cervical canal on transvaginal ultrasonography was first described by Sekiya et al. [14]. Absence of the CGA on vaginal ultrasound was found to be be a predictive sign of spontaneous PTB [13–18]. Not only the absence or presence of CGA, but also the ''gray scale histogram'' (GSH) has also been studied to increase the objectivity of this diagnostic method by demonstrating graphic representation of the quantity and distribution of the ''pixels'' within the cervix on two dimensional ultrasound [17]. Despite increasing studies investigating the clinical utility and usefullness of GSH, the interpretation of this method for diagnostic purposes has not been established yet. In 2003, Tekesin et al. [13] evaluated the quantitative ultrasound tissue characterization of the uterine cervix in patients with threatened labor and when they conducted multiple logistic regression analysis of other variables, the mean gray scale value was the single best predictor of PTD. Following this study, the absence of echolucent endocervical glanduler area on transvaginal ultrasonography has also been found to be predictive for PTD by several authors [16–18,22]. In our study; the mean age, BMI, cerebroplacental doppler ratio, CGA mean echolucent thickness and gestational age during tocolytic therapy of preterm and term delivered patients were similar. Mean CL during admission to the high risk pregnancy unit was lower for patients delivered preterm than patients delivered term that reflects the diagnostic value of CL for preterm labor risk. When we grouped patients according to CL measurement of <30 mm and $\geq$30 mm at admission, 82.4% of patients having shortened cervix a ccompanied with detectable CGA as endocervical echolucent area on transvaginal ultrasonography delivered term. This statistically significant finding has not been found relevant for patients with $\geq$30 mm long cervix whether with or without a detectable CGA on sonography. Combining CL with CGA evaluation can be a more useful test for ruling out preterm labor risk among patients with threatened labor and shortened cervix based on a cutoff value of 30 mm. When we grouped patients according to CL measurement of <20 mm and $\geq$20 mm at admission; despite 77.8% of patients with shortened cervix accompanied with a detectable CGA on sonography have delivered term, we did not establish a significant relationship between CGA evaluation and preterm labor risk. However, it seems that the diagnostic value of CGA evaluation disappeared when the patients were grouped by using a cut off CL value of 20 mm, this statement can be a result of low patient number that needs to be tested with good-designed controlled studies including larger patient numbers. Cheng et al. conducted one of the largest cohorts in the literature that examined perinatal outcomes associated with late preterm births. Consistent with prior studies, they found that deliveries at 34–37 weeks of gestation remain at risk of perinatal morbidity compared to deliveries at 37–40 weeks [23]. Despite increasing studies related to preterm labor, the cost-effectivity of tocolytic therapy regarding fetal and maternal clinical consequences between 34 and 37 weeks of gestation remains as a debate.

In conclusion; despite our sample size is relatively low, we demonstrated the presence of CGA on transvaginal ultrasonography as a reassuring sign for preterm labor among patients with a CL of <30 mm. Although CL measurement remains as the best sonographic screening test regarding the prediction of preterm labor, the qualitative sonographic analysis of CGA seems to have a significant value in addition to CL measurement for the prediction of preterm labor. Based on the results of this study, further studies should be designed and conducted to investigate the pathogenesis of preterm

labor regarding cervical physiology in pregnancy. Among patients with threatened labor, the evaluation of endocervical glandular area echogenicity qualitatively with transvaginal ultrasonography can be a useful marker to predict PTD probability more precisely.

Declaration of interest

We, as authors of this original research study, disclose that we do not have any financial and personal relationships with other people or organisations that could inappropriately influence our work. We, as the authors of this manuscript, report no conflicts of interest also.

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