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Prediction of preterm birth by estimating ultrasonographic cervical changes

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□ ABSTRACT □

The study is carried on 65 pregnant patients attending the outpatient clinics and inpatient department of Obstetrics and Gynecology of Al Assad University Hospital from February- 2013 until February- 2014. They were divided to three groups. The first is preterm labor with intact membranes (25 patients). The second is PROM (20 patients). The third one is control group (20 patients). All of them were submitted to ultrasonography to find cervical changes (cervical canal length and diameter of internal os in order to predict preterm delivery. Cervical canal length has a sensitivity of 91.43%, a specificity of 100%, a positive predictive value of 100%, a negative predictive value of 76.92%, and a relative risk (95% CI) of 4.33 (1.61-11.69) among patients with short cervical canal length and those with normal cervix.

Diameter of internal os as a predictor of preterm delivery has a sensitivity of 60%, a specificity of 60%, a positive predictive value of 84%, a negative predictive value of 30%, and a relative risk (95% CI) of 1.2 (0.86–1.68)

key words: (pretermlabour, prediction, preterm birth, ultrasound, cervical length, cervical internal os diameter

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التنبؤ بالولادة المبكرة بقياس تبدلات عنق الرحم بواسطة الأمواج ما فوق الصوتية

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(تاريخ الإيداع 23 / 7 / 2014. قُبِل للنشر في 16 / 2 /2015)

□ ملخّص □

تم إجراء الدراسة على65 سيدة من النساء الحوامل المترددات على العيادات الخارجية والداخلية في قسم النساء والتوليد في مستشفى الأسدالجامعي خلال الفترة الممتدة من شباط 2013 حتى شباط 2014. و تم تقسيمهم الى ثلاث مجموعات الأولى خمس و عشرون مريضة لديهن مخاض باكر مع أغشية سالمة والثانية عشرون مريضة لديهن انبثاق اغشية باكر، والمجموعة الثالثة عشرون مريضة للمقارنة.

كل المريضات سوف تخضعن للكشف بالموجات ما فوق الصوتية لتقييم التغيرات الطارئة على عنق الرحم (طول عنق الرحم وقطر الفوهة الباطنة) بغرض التنبؤ بالولادة المبكرة

ان طول عنق الرحم كمشعر للتنبؤ بالولادة المبكرة ذو حساسية عالية وصلت حتى 91.43% و ذو نوعية أعلى وصلت حتى 100% وذو قيمة تنبؤية موجبة عالية وصلت حتى 100% و ذو قيمة تنبؤية سلبية 76.92%.

إن خطر الولادة في المريضات اللواتي لديهن عنق رحم قصير(اقل أو يساوي 25 مم) هو 4.33 ضعف أولئك اللواتي لديهن عنق رحم طبيعي (اكثر من 25 مم).

إن قطر الفوهة الباطنة لعنق الرحم كمشعر للتنبؤ بالولادة المبكرة ذو حساسية وصلت حتى 60% و ذو نوعية وصلت حتى 60% وذو قيمة تنبئية موجبة وصلت حتى 84% و ذو قيمة تنبئية سلبية وصلت حتى 30%.

الكلمات المفتاحية: المخاض الباكر – الولادة المبكرة – التنبؤ–الامواج ما فوق الصوتية – طول عنق الرحم – قطر الفوهة الباطنة لعنق الرحم.

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Introduction:

Premature birth is the single largest cause of perinatal mortality and morbidity in infants without anomalies in developed nations. To prevent preterm delivery, one must first correctly select women at the greatest risk for preterm delivery. For many decades, the gold standard for the diagnosis of preterm labor was the documentation of cervical change by digital examination. This method proved to be neither diagnostic nor predictive and has caused investigators to develop newer methods of determining which women are at risk for preterm delivery . Concurrently, investigators rediscovered the cervix as a predictor for preterm birth using newer technologies such as ultrasound. [1]

The Maternal-Fetal Medicine United Network in 1996 (preterm prediction trial) confirmed that there is an inverse relation between the transvaginal cervical length and the frequency of preterm birth[2]. Taipale and Hiilesmaa in 1998 found that when the cervical length was 29 mm or less at 18 to 22 weeks gestation, the relative risk for delivery before 35 weeks was 8 (95% confidence interval [CI]; 3,19) [3]. In addition the authors found that if the patient was noted to have dilatation of the internal cervical os > 5 mm with a cervical length of 29 mm or less, the relative risk for delivery before 35 weeks gestation was 28 (95% CI; 12,67) [3] . Unfortunately, these findings were only shown to have a sensitivity of 29% in predicting preterm delivery before 35 weeks. [3]

In summary, a cervical length less than 25 mm at 24 weeks gestation or the presence of a funnel that accounts for 50% of the cervical length predict an increased risk for preterm delivery.. In a patient with preterm contractions, the absence of a funnel at the internal cervical os and a cervical length of 30 mm or greater suggests that the patient is not at increased-risk for preterm birth. These observations could prevent unnecessary tocolysis and intervention.[1]

The risk for preterm delivery increases with an earlier gestational age of the previous delivery and a shorter cervical length in the current pregnancy[1]. One should also note that the term delivery in a previous pregnancy suggest a significantly lower risk for preterm delivery even if the cervical length is less than 25 mm (10th percentile) [2]. The authors found a relationship between preterm delivery and the ultrasound findings of cervical changes, but not the digital examination findings.[4]

Iams et al (1994) indicated that the strong negative predictive value of a cervical length greater than 30 mm measured by ultrasound can essentially rule out the diagnosis of preterm labor. [1]

Timor-Tritsch et al.(1996) suggested that the presence of a cervical length > 30 mm by ultrasound essentially ruled out preterm labor. Of interest, the presence of cervical funneling was noted in 100% of patients who delivered preterm and was present in only 26% of patients who delivered at term.[1]

OBJECTIVE OF THE STUDY

The aim of this study is to estimate the cervical changes(cervical length and diameter of internal oss) in order to predict preterm delivery.

PATIENTS AND METHODS

This study is performed on (65) pregnant women attending the outpatient clinics and inpatient department of Obstetrics and Gynecology of Al Assad University Hospital. The main complaint of the study group is suspected preterm labor or watery vaginal discharge while the control group attending the outpatient clinics for antenatal care with normal non complicated pregnancy.

Inclusion criteria: For the control group:Age (25-35) years, singleton pregnancy, no medical complications, gestational age (24-36) weeks gestation.

-For the study group: as mentioned above plus: Criteria of suspected preterm labor (menstrual like cramps, backache, pelvic heaviness, increased vaginal secretions), previous history of preterm labor, watery vaginal discharge in some patients denoting to premature rupture of membranes(PROM).

Exclusion criteria: Age below 25 and above 35 years, multiple gestations, presence of medical complication such as: Heart, liver, or kidney diseases, diabetes, hypertension, hyperthyroidism, intrauterine fetal death, lethal congenital fetal anomalies, placenta praevia or abruptio placenta, cervical dilation more than 3 cm, gestational age below 24 weeks or above 36 weeks gestation, cervical cerclage, previous cesarean section, in cases of PROM chorioamnionitis must be excluded.

The patients involved in this study were divided into three groups:

Group I-G1 Twenty five patients with preterm labor pains and intact membranes

Group II- G2 Twenty Patients with premature rupture of membranes (PROM).

Group III- Control group which includes twenty patients with normal pregnancy.

All patients were submitted to :

1. Complete history taking including: Personal history, menstrual history, obstetrical history, past history (history of preterm labor), family history, present history (symptomatic regular uterine contractions with intact membranes or watery vaginal discharge or without any complaint).
2. Thorough general examination
3. Obstetrical examination: including abdominal and pelvic examination.

- **Pelvic examination** in the form of :

a) Sterile speculum examination:

a. Patient in lithotomy position.
b. Sterile Cusco's speculum was inserted.
c. State of the cervix was observed as regard dilatation and effacement.
d. Fetal membrane may be visualized through the cervical canal.
e. A watery discharge escaping from the cervix.

b) Digital vaginal examination:

Vaginal examination under aseptic conditions is performed to evaluate the following:

- Cervical characteristics including:
  - Cervical dilatation.
  - Cervical effacement (length of the cervix)
  - Consistency of the cervix
  - Position of the cervix
  - Position of the presenting part.
- Intact or ruptured membranes.
- Presentation: cephalic, breech or transverse.

In each patient the cervix was $\leq$ 3 cm dilated and $\leq$ 80% effaced.

4. Investigations

I- Routine laboratory investigations: Complete blood count(CBC), Blood glucose level, Urea and creatinine, Complete urine analysis.

II- Special laboratory investigations:

a. C-reactive protein (CRP) to discover chorioamnionitis in premature ruptured membranes and the presence of subclinical infection in preterm labor pain with intact membranes.

III-Ultarasonography to show: Data about the fetus (e.g. excluding fetal congenital anomalies), and Cervical changes including diameter of internal os, cervical canal length. To obtain a clear picture of the cervix by transabdominal ultrasound, the urinary bladder had to be full. This often had an unpredictable effect on the length of the cervical canal. Transvaginal ultrasound is performed in some cases.

Results

Table (1):

Shows the clinical characteristics of patients in group I, and group II in comparison to control group. Maternal age in group I is ranged from 25–35 years, with a mean of 27.44 and standard deviation of 3.19. In group II, the maternal age ranged from 25–35 and a mean of 27.60 and SD of 3.63. In the control group the range of maternal age is 25–33 years, the mean is 28.25, and the SD is 2.71. There is no statistically significant difference between the three groups (P = 0.683).

The parity in group I is ranged from 0–4 with a mean of 0.92 and SD of 0.95. In group II the range of parity is 0-6 and the mean is 1.30 and SD of 1.63. In group III the range is 0-2 and the mean is of 1.00 and S.D of 0.92. No statistically significant difference is present between the three groups (P = 0.550).

Table (1): Comparison of clinical data in the three studied groups

Clinical data	Group I (n=25)			Group II (n=20)			Group III (n=20)			F	p
	Range	Mean	S.D.	Range	Mean	S.D.	Range	Mean	S.D.		
Age in years	25-35	27.44	3.19	25-35	27.60	3.63	25-33	28.25	2.71	0.383	0.683
Parity	0-4	0.92	0.95	0-6	1.30	1.63	0-2	1.00	0.92	0.603	0.550

Table (2):

Shows classification of patients according to gestational age at studying In group I, there is four patients (16%) with gestational age less than 30 weeks and 14 patients (56%) with gestational age between 30 and 34 weeks gestation. Seven patients (28%) has gestational age more than 34 weeks gestation. In group II, there is seven patients (35%) with gestational age less than 30 weeks and 7 patients (35%) with gestational age between 30 and 34 weeks gestation. Six patients (30%) has gestational age more than 34 weeks gestation. In group III, there is four patients (20%) with gestational age less than 30 weeks and 14 patients (70%) with gestational age between 30 and 34 weeks gestation. Two patients (10%) has gestational age more than 34 weeks gestation.

Table (2) Classification of patients according to gestational age at studying

Gestational age at studying/weeks	group I N = 25		group II N = 20		group III N = 20	
	N	%	N	%	N	%
< 30 weeks	4	16%	7	35%	4	20%
30 - 34	14	56%	7	35%	14	70%
> 34	7	28%	6	30%	2	10%

Table (3):

Shows classification of patients according to mode of delivery. In group I, 22 patients delivered by normal vaginal delivery (NVD), it accounts for 88% of group I. Caesarian section occurred only in three patients (12%) of cases. In group II, 15 patients delivered by normal vaginal delivery (NVD), it accounts for 75% of group II. Caesarian section occurred only in five patients (25%) of cases. In group III, 19 patients delivered by normal vaginal delivery (NVD), it accounts for 95% of group I. Caesarian section (CS) occurred only in one patient (5%) of cases. Most patients of the three groups delivered by normal vaginal delivery. The higher rate of CS is encountered in group II.

Table (3) Classification of patients according to mode of delivery

Mode of delivery	group I N = 25		group II N = 20		group III N = 20	
	N	%	N	%	N	%
NVD	22	88%	15	75%	19	95%
CS	3	12%	5	25%	1	5%

Table (4):

Shows classification of patients according to preterm or full term delivery. Preterm delivery encountered in 17 (68%), 18 (90%), and 0 (0%) patients in group I, II, and III, respectively. Full term delivery encountered in 8 (32%), 2 (10%), and 20 (100%) patients in group I, II, and III, respectively. higher percentage of preterm delivery is founded in group II.

Table (4) Classification of patients according to pregnancy outcome

Pregnancy outcome	group I N = 25		group II N = 20		group III N = 20	
	N	%	N	%	N	%
Preterm	17	68%	18	90%	0	0%
Full term	8	32%	2	10%	20	100%

Table (5):

Comparison of cervical length and diameter of internal os of the three groups.

Mean cervical length in group I is 22.60 mm, and 18.4 mm in group II in comparison to 38.35 mm in group III. There is statistically significant difference between group I & II vs group III (P = 0.0001).

Mean internal os diameter is 11.99 mm in group I, and 12.13 mm in group II in comparison to 4.86 mm in group III. There is statistically significant difference between group I & II vs group III (P = 0.005).

Table(5): Comparison of cervical length and diameter of internal os of the three groups

Clinical data	Group I (n=25)			Group II (n=20)			Group III (n=20)			F	p	Scheffe test
	Range	Mean	S.D.	Range	Mean	S.D.	Range	Mean	S.D.			
Cervical canal length in mm.	5-40	22.60	9.01	5-30	18.4	7.62	30.-45	38.35	4.03	41.413	0.0001*	Group I vs. III Group II vs. III
Internal os diameter in mm.	0-30	11.99	7.88	0-30	12.13	10.90	1-8	4.86	2.37	5.760	0.005*	Group I vs. III Group II vs. III

Table (6):

Sensitivity, specificity, positive and negative predictive value, and relative risk of cervical canal length and diameter of internal os in prediction preterm birth in group I & II together.

Cervical canal length has a sensitivity up to 91.43%, specificity of 100.0%, PPV of 100.0%, and NPV of 76.92%, relative risk of 4.33 with 95%cI (1.61-11.69). Relative risk of cervical canal length is significant.

Diameter of internal os has a sensitivity up to 60.0 %, specificity up to 60.0%, PPV of 84%, and NPV of 30%, and relative risk of 1.20 with 95% CI (0.86-1.68). Relative risk of internal os is not significant.

Table (6): Sensitivity, specificity, negative and positive predictive value, and relative risk of cervical canal length and diameter of internal os in predicting preterm delivery in groups I and group II

	Preterm labor		Full term labor		Total	
	n	%	n	%	n	%
Length of cervical canal:						
≤25mm.	32	91.4	0	0.0	32	71.1
>25mm	3	8.6	10	100.0	13	28.9
Total	35	100.0	10	100.0	45	100.0
Relative risk (95%CI)	4.33 (1.61 – 11.69)*					
Sensitivity	91.43%					
Specificity	100.00%					
Positive predictive value	100.00%					
Negative predictive value	76.92%					
Diameter of internal os :						
<8 mm.	14	40.0	6	60.0	20	44.4
≥8 mm.	21	60.0	4	40.0	25	55.6
Total	35	100.0	10	100.0	45	100.0
Relative risk (95%CI)	1.20 (0.86 – 1.68)					
Sensitivity	60.00%					
Specificity	60.00%					
Positive predictive value	84.00%					
Negative predictive value	30.00%					

***Significant**

DISCUSSION

Clinical characteristics of patients involved in this study including maternal age, parity, and gestational age at studying are not significant between the three groups. This is in agreement with Gary M. J., et al. (1999).[5]

Gestational age at delivery, cervical canal length, diameter of internal os are significant between the studied groups (group I and group II) in comparison to control group (group III).

Iams JD et al. (2001) concluded that cervical ultrasonography have low sensitivity for preterm birth before 35 weeks gestation. This is different from this study in wich cervical length has high sensitivity (91.43). [6]

Floraski J et al. (2001) reported that Cervical length shorter than 20 mm correlates with increased risk of preterm delivery[7] . This is in consistent with this study but the cut-off point of cervical length is 25 mm in the current study.

In patients with symptoms of preterm labor, endovaginal cervical ultrasonography appears to be an effective predictor of preterm delivery[8]. This is in agreement with this study. Leitich H et al. (1999) considered cervical length and diameter of internal os as predictors for preterm delivery. Optimal cut off values for cervical length ranged between 18 and 30 mm. Sensitivity rates were between 68% and 100%, specificity rates were between 44% and 79%, sensitivity of internal os dilatation were 70% to 100%, specificity rates were 54% to 75%[8]. In comparison to this study cervical length cut-off value, cervical length sensitivity, and internal os specificity are comparable to Leitich study.

Transvaginal sonography of cervix between 14 and 24 weeks gestation is a good predictor of preterm delivery[9]. This is consistent with this study but ultrasonography of the cervix is performed between 24 and 36 weeks for the study in hand.

In this study, cervical length sensitivity is consistent with that of Vendittelli F. et al. (2000) who reported a sensitivity from 68% to 100%, but the specificity is different between Vendittelli and this study (30%-78% vs 100%).The best cut-off for cervical length in his study 18 to 30 mm which is consistent with cut-off point of this study which is 25 mm. [10]

Hassan SS et al. (2000) reported that a cervical length of < or = 15 mm had a positive predictive value of 47.6%, NPV of 96.7%, a sensitivity of 8.2%, and a specificity of 99.7% for early preterm delivery. So a short cervix seen on a second trimester was a powerful predictor of early spontaneous preterm delivery < or = 32 weeks gestation. So interventions (e.g. cerclage) in this population are urgently needed. [11]

Vendiltelli F. et al. (2001) in a study performed to examine the relation between cervical length and risk of preterm delivery, found that the cut-off cervical length is < 30 mm and the relative risk was 2.79 (95% CI 1.70 - 4.59) [10]. In comparison between this study and Vendiltelli study, the cut-off is comparable (25 vs 30 mm) and the relative risk is (4.33 vs 2.79). The difference in relative risk may be attributed to presence of additional parameter (presence of funneling at the internal os) in Vendiltelli study.

When comparison is performed between this study and Hincz P et al. (2001) study of the cervical length as a predictor of preterm birth, it can be found that the cut-off value is (25 vs 31 mm), the sensitivity is (91.43% vs 100%), the specificity is (100 vs 47.1%), PPV (100% vs 28.0%), and NPV is (76.92% vs 100%). [12]

So, this study differs from the previous study. Also, patient characteristics are different between this study and Hincz study, number of patients (65 vs 82), gestational ages (24-36 vs 23-34 weeks), mode of ultrasonography (Transabdominal in most cases vs transvaginal).

Naim A et al (2002) reported that cervical length < 3 cm before 16 weeks of gestation is associated strongly with preterm birth, independently of base line length, more rapid shortening of the cervix increase the risk of preterm birth. [13]

Transvaginal cervical sonography identifies women who are at higher risk of spontaneous preterm birth. Threshold cervical length is 25 mm [14]. This is in agreement with this study .

In women presenting with suspected preterm labour, transvaginal sonographic assessment of cervical length may be used to help in determining who is at high risk of preterm delivery and may be helpful in preventing unnecessary intervention[15] . This is in agreement with our study but we use abdominal and vaginal ultrasound.

Only transvaginal ultrasound should be used to evaluate the cervix for prediction of preterm birth (PTB). The shortest cervical length (CL) is the most effective measurement for clinical use.. The risk of PTB increases with ever shorter CL(<25 mm). This is in agreement with our study but we use abdominal and vaginal ultrasound [16].

When a short cervix is suspected by transabdominal sonography before 25 weeks, TVU examination should be performed to obtain the best estimate of cervical length. Transabdominal images of the cervix are less reproducible; thus, they should not be used for clinical management [17].In our study we use abdominal and vaginal ultrasound.

CONCLUSIONS

- The risk of preterm birth is fourfold in patients with short cervix compared with normal cervix.
- Short cervix is more risky for preterm delivery than diameter of internal os.
- Cervical length is a very good predictor of preterm delivery.

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