

## Value of Transvaginal Cervical Ultrasonographic Assessment and Bacterial Vaginosis in Prediction of Preterm Birth

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**Abstract: Objective:** To determine the diagnostic value of cervical length measurement, in the second trimester of pregnancy and impact of bacterial vaginosis as preterm labour (PTL) predictor. **Background:** Preterm birth is the leading direct cause of neonatal death and morbidity and imposes large costs to the health care system. Early detection of pregnant women at risk of PTL will help to reduce the occurrence of prematurity-related mortality and morbidity. Cervical insufficiency and bacterial vaginosis are two items that recently known play an essential role in preterm delivery. They can be diagnosed using safe, simple and reliable methods. **Patients and Methods:** This a prospective cohort study included 580 pregnant women uncomplicated singleton pregnancy between 22 and 24 weeks of gestation to assess cervical length which was measured by transvaginal probe immediately after collecting vaginal swab for diagnosis of bacterial vaginosis by Amsel's criteria. Cervical length (CL) < 30mm was considered short cervix and suggest cervical insufficiency. The vaginal swab had 3 out of 4 Amsel's criteria was considered positive for bacterial vaginosis. Patients were followed until delivery. **Results:** Our final analysis was based on results for 500 participants. The incidence of PTL was 100/500 (20 %). The incidence of PTL had bacterial vaginosis (BV) were 52/100 (52%) which is statistically significant. The incidence of PTL in cases with short CL  $\leq$  30mm were 39/100 (39%) while short cervix cases in full term were 3/400 (0.8%) which is statistically significant. The incidence of PTL were (16%) for cases had BV and short CL while no cases for full term labour which is statistically significant ( $P < 0.001$ ). **Conclusion:** The assessment of cervical length by transvaginal ultrasound and detection of bacterial vaginosis during pregnancy have significant value in prediction of PTL.

[Mohamed M. Fahmy, Sherief M.S. Abd El Salam, Mohamed A. Emarah, Abeer A. ElSobky. **Value of Transvaginal Cervical Ultrasonographic Assessment and Bacterial Vaginosis in Prediction of Preterm Birth.** *Life Sci J* 2015;12(7):35-40]. (ISSN:1097-8135). <http://www.lifesciencesite.com>. 6

**Key Words:** Bacterial vaginosis, cervical length measurement, Preterm birth, Second trimester.

### 1. Introduction

Preterm labour is defined as the onset of labour at a gestational age between 20 and 37 completed weeks of pregnancy. The incidence of preterm birth had gradually increased over the last few decades (8.9% in 1980 to 12% in 2002). Preterm premature rupture of the membranes (PPROM) is antecedent to approximately one third of these births<sup>(1)</sup>.

Cervical insufficiency and bacterial vaginosis are two items that recently known play an essential role in preterm delivery. They can be diagnosed using safe, simple and reliable methods. These problems are also potentially treatable<sup>(2)</sup>.

An increasing risk of preterm birth as cervical length decreases has been consistently observed in all populations, Short cervical length at 16 to 28 weeks is the cervical change best related to the risk of preterm birth, with a particularly strong relationship when it occurs before 24 weeks or in women with a prior preterm birth, especially before 32 weeks<sup>(3)</sup>. Reproducible measurement of cervical length becomes possible at about 14 weeks of gestation, when the cervix normally becomes distinct from the lower uterine segment, The protocol for initiating cervical length measurements is based on the patient's

prior obstetrical history, Women with no prior preterm birth are screened between 18 and 23 weeks of gestation; women with a prior preterm birth are screened beginning at 14 to 16 weeks of gestation<sup>(4)</sup>.

Bacterial vaginosis (BV) represents a complex change in the vaginal flora characterized by a reduction in concentration of the normally dominant hydrogen-peroxide producing lactobacilli and an increase in concentration of other organisms, especially anaerobic gram negative rods<sup>(5)</sup>. Pregnant women with bacterial vaginosis (BV) are at higher risk of preterm delivery<sup>(6)</sup>. The increased risk of preterm birth attributable to BV appears to be linked to preterm labor due to chorio-amnionitis, Spontaneous preterm labor is mostly found approximately 30-50% and bacterial vaginosis is one of the many causes of preterm labor. Pregnancy with bacterial vaginosis is a higher risk for preterm delivery<sup>(7)</sup>. There is an inverse relationship between cervical length by ultrasound and gestational age at delivery, a high Bishop or cervical score on digital examination is also associated with increased odds of preterm birth<sup>(8)</sup>.

Early detection of pregnant women at risk of premature labor (PTL) will help to reduce the

occurrence of prematurity- related mortality and morbidity<sup>(9)</sup>.

This study aims to determine the value of transvaginal cervical ultrasonography examination and impact of bacterial vaginosis in prediction of the risk of preterm birth.

## 2. Patients and Methods

### Patients

This prospective cohort study started with 580 pregnant women came to outpatient clinic at Menoufia University Hospital after acceptance of ethical committee, but 80 cases were discontinued, this study started from March 2011 to December 2013.

### Inclusion criteria

1. Primigravida or multigravida.
2. Singleton pregnancy.
3. Gestational age: between (20 and 22) weeks.

### Exclusion criteria

1. Multiple pregnancies
2. Obstetrical or medical complications in the current pregnancy,
  - A- Congenital malformation of the fetus,
  - B- Current or planned cervical cerclage,
  - C- Uterine malformation,
  - D- Ante partum hemorrhage,
  - E- Anemia or diabetes mellitus or hypertension associated with the current pregnancy,
  - F- Symptomatic cases of vaginal discharge or infection.

### Methods

An oral informed consent was taken from all the patients prior to examination. All patients were submitted to the following:

- Full history taking
- General examination
- Obstetric examination

Assessment for both the vaginal swab for bacterial vaginosis and transvaginal ultrasound for cervical length done one time at visit of gestational age from 22 to 24 weeks of gestation for all included patients which done as following.

### Diagnosis of bacterial vaginosis

We adopted the most accepted clinical criteria for diagnosis of bacterial vaginosis "Amsel's criteria" as reported by Neelam S and Sohaili<sup>(10)</sup>. A high posterior vaginal swab was collected using non lubricated sterile vaginal speculum to be examined for "Amsel's criteria". Bacterial vaginosis was diagnosed when three out of four criteria were fulfilled:

- Homogenous thin milk like vaginal discharge

- Positive whiff test
- Presence of clue cells under microscope
- Ph > 4.5 (Normal vaginal pH 3.8 -4.2)

All diagnosed cases positive for bacterial vaginosis as recommended from Ethical committee were treated by metronidazole 250mg three times daily for seven days.

### Examination of Cervical Length

Patient in lithotomy position and empty bladder sonographic examination was performed by endovaginal probe (3.5 MHz with Sonata plus, Mindery china) we followed the guidelines for the performance of TVU of the cervix by Berghella et al.,<sup>(4)</sup>. A cervical length of 30 mm (the threshold for the 5th percentile) or less was considered short and suggestive of cervical insufficiency. In all cases, the measurement was the mean of three different measurements taken in quick succession.

All patients were followed till delivery and hospital records were reviewed to obtain the obstetric information.

### Statistical Analysis:

The clinical and laboratory results obtained are statistically analyzed using SPSS version 19 (Statistical package for social science version 19). Chi-square test and t-test were used for comparing results. *P*-value less than 0.05 was considered statistically significant and *P*-value less than 0.001 was highly statistically significant.

### 3. Results:

This prospective cohort study was conducted at Al Menoufia Hospital, our final analysis was based on results for 500 pregnant women in second trimester at gestational age from 20 to 22 weeks of pregnancy.

Our final results were the incidence of preterm labour (PTL) was 100/500 (20 %). The incidence of PTL had bacterial vaginosis (BV) were 52/100 (52%) while the incidence of early PTL < 34 weeks was 18/100 and the incidence of PTL between 34 to 37 weeks was 34/100 while 49/400 (12.3%) of full term cases had BV as table (1) which is statistically significant. The incidence of PTL in cases with short CL ≤ 30mm were 39/100 (39%) while short cervix cases in full term were 3/400 (0.8%) as table (2) which is statistically significant. The incidence of PTL were (16%) for cases had BV plus short CL while no cases for full term labour as table (3) which is statistically significant (*P* < 0.001). The previous results showed that there is a significant relationship between bacterial vaginosis and cervical length and the incidence of preterm labour.

**Table (1): Relation between B.V and time of delivery/week**

	Time of delivery						p
	Less than 34 (n = 31)		34 to less than 37 (n = 69)		More than or equal 37 (n = 400)		
	No	%	No	%	No	%	
<b>B.V</b>							
Negative	13	41.9	35	50.7	351	87.8	<0.001*
Positive	18	58.1	34	49.3	49	12.3	

p: p value for Chi-square test; \*: Statistically significant at  $p \leq 0.05$ ; \*\*: Highly statistically significant at  $p \leq 0.001$

**Table (2): Relation between CL and time of delivery/week**

	Time of delivery						p
	Less than 34 (n = 31)		34 to less than 37 (n = 69)		More than or equal 37 (n = 400)		
	No	%	No	%	No	%	
<b>CL</b>							
Negative less than 30 mm	20	64.5	19	27.5	3	0.8	<0.001**
Positive More than or equal 30 mm	11	35.5	50	72.5	397	99.3	
<b>r<sub>s</sub></b>	0.436* (<0.001)						

p: p value for Chi-square test; r<sub>s</sub>: Spearman coefficient; \*: Statistically significant at  $p \leq 0.05$ ; \*\*: Highly statistically significant at  $p \leq 0.001$

**Table (3): Relation between CL plus B.V and time of delivery per week**

	Time of delivery						p
	Less Than 34 (n = 31)		34 to less than 37 (n = 69)		More than or equal 37 (n = 400)		
	No	%	No	%	No	%	
<b>CL plus B.V</b>							
CL more than or equal 30 mm and B.V is negative	22	71.0	62	89.9	400	100.0	<0.001**
CL less than 30 mm and B.V is positive	9	29.0	7	10.1	0	0.0	

p: p value for Chi-square test; \*: Statistically significant at  $p \leq 0.05$ ; \*\*: Highly statistically significant at  $p \leq 0.001$

#### 4. Discussion:

Preterm birth is the leading direct cause of neonatal death (death in the first 28 days of life). It is responsible for 27 percent of neonatal deaths worldwide, comprising over one million deaths annually. The risk of neonatal mortality decreases as gestational age at birth increases, but the relationship is nonlinear<sup>(1)</sup>. Preterm labor is still the major cause of perinatal morbidity and mortality. Around 30 percent of threatened preterm labor was preterm labor.<sup>(7)</sup>

Cervical assessment by ultrasound has been correlated with the prediction of spontaneous PTB<sup>(4)</sup>. There are three methods of ultrasound cervical assessment: transvaginal, transabdominal, and transperineal (also called translabial). The most objective and effective ultrasound method is transvaginal (TVU)<sup>(12)</sup>.

Bacterial vaginosis (BV) is the most common lower genital tract disorder among women of reproductive age. The condition is not a classical infection caused by a single pathogen but is rather a complex alteration of the vaginal ecosystem where the physiologic lactobacilli-dominant flora is replaced by an overgrowth of mixed flora, with a high concentration of anaerobic bacteria, normally present in the vagina in substantially fewer numbers<sup>(13)</sup>. Pregnant women with bacterial vaginosis (BV) are at higher risk of preterm delivery<sup>(6)</sup>.

It was found in our study that 52% of preterm labour patient had positive bacterial vaginosis while 12.3% was found in full term which is statistically significant these results are in agreement with the study of **Hassan et al.**,<sup>(14)</sup> which done in Basrah maternity & children hospital to assess the association between bacterial vaginosis and preterm labour & to

compare it with those who delivered at term. It was a prospective case control study which was carried out over a nine-month-period. This study has confirmed that Gardnerellavaginalis was the commonest bacterial pathogen isolated from women with preterm labour, it was detected in 17 out of 72 women with preterm labour (23.6%) in comparison to 2 of 107(1.9%) women who delivered at term (P value <0.01). That is why it can be concluded that bacterial vaginosis was detected in a significant number of women with preterm delivery.

Several other authors as **Leitich et al.**,<sup>(15)</sup> a case control study which reported that the percentage of bacterial vaginosis in preterm labor was significantly higher than in term labor.

Also **Klebanoff et al.**,<sup>(6)</sup> found that pregnant women with bacterial vaginosis (BV) are at higher risk of preterm delivery.

Also **Chawanpaiboon and Pimol**,<sup>(7)</sup> found that the prevalence of bacterial vaginosis in all the preterm labor group was higher than the term labor group with statistical significance ( $p < 0.05$ ).

Finally **Kelmaj et al.**,<sup>(16)</sup> his prospective study showed that the diagnosis of BV was made according to Amsel's criteria. The prevalence of BV was 32%, whereas in the control group, the figure was 14.6% ( $\chi^2 = 0.01$ ) which showed a significant correlation between BV and preterm labor.

On the other hand the results of our study disagree with the study of **Figueroa et al.**,<sup>(17)</sup> in the University of Alabama at Birmingham, to estimate whether bacterial vaginosis, as defined by either Nugent score or vaginal pH, predicts gestational age at delivery in women at risk for recurrent preterm birth. The number of studied cases was 768 women between 16 to 22 weeks of gestation. The prevalence of bacterial vaginosis by Nugent score was 11% and by pH was 33% and it was not associated with earlier birth. That is why the study concluded that the presence of bacterial vaginosis at 16-22 weeks of gestation does not predict preterm birth at the group of the study. This disagreement may be due to the lack of knowledge regarding symptomatic bacterial vaginosis treatment, the study design, the selected group of patient the gestational age group and laboratory method of diagnosis.

As regarding the cervical length in prediction of preterm labor our study showed the following results: The cervical length (CL) is significantly lower in cases of preterm labor than cases of full term. The cervical length (CL) measurements of threatened preterm labor cases were significantly short. The study showed the validity of CL in prediction of PTB among studied group showed a new cut off point of CL in the studied group was (32.2 mm). our results were in agreement with the study of **Kagan et al.**,<sup>(18)</sup> which

done in King's College Hospital, London, UK, to estimate the value of sonographic measurement of cervical length by Transvaginal ultrasound scanning of cervical length at approximately 20 weeks of gestation in women attending for routine antenatal care is useful for predicting the likelihood of spontaneous early preterm birth. And the study concluded that the transvaginal ultrasound scanning of cervical length is highly reproducible and is acceptable to women. Routine measurement of cervical length at 20-24 weeks of gestation provides a sensitive prediction of preterm birth. The risk of such preterm birth increases exponentially with decreasing cervical length.

Our results were in agreement with the study published by **Celik et al.**,<sup>(19)</sup> which was a prospective observational study done in King's College Hospital, London, UK with Department of Obstetrics and Gynecology, Cambridge University, transvaginal sonographic measurement of cervical length at 20 to 24 weeks of gestation was carried out in 58 807 singleton pregnancies as part of routine antenatal care, the final results conclude that The best prediction of spontaneous preterm birth was provided by cervical length and these was improved by adding obstetric history.

Also our results were in agreement with the studies published by **Visintine et al.**,<sup>(20)</sup> **Crane and Hutchens**,<sup>(3)</sup> concluded that the measurement of cervical length provides prediction of risk for early preterm delivery.

Our study showed the relation between occurrence of preterm labor (PTL) and the presence of both short cervical length (C.L) plus positive bacterial vaginosis (B.V) found that, 15.8% of the PTL had combination of the two factors while no cases found between full term cases which is highly statistically significant ( $P < 0.001$ ).

In agreement with the current results the study done by **Mancuso et al.**,<sup>(21)</sup> and **Matijevic et al.**,<sup>(22)</sup> reported that, a high vaginal pH value and a shortened CL measurement on ultrasound were both significantly correlated with PTL in that low risk population.

There are other studies done to estimate the effect of both cervical length and bacterial vaginosis on the occurrence of preterm birth and they are in agreement with our study in some points and disagree in other points as the study done by **Surbek et al.**,<sup>(23)</sup> in University of Basel, Switzerland It was an observational study in 112 pregnant patients between 24 and 34 weeks of gestation admitted with symptoms of preterm labor measurement of cervical length was done by transvaginal ultrasound and diagnosis of bacterial vaginosis was done by gram stain and treated with systemic metronidazole. The final conclusion of

the study was that cervical change in patients with preterm labor is more pronounced in bacterial vaginosis, but without a concomitant increase in the risk for preterm delivery. Despite this association, the cervical length measured by transvaginal ultrasonography alone is a useful predictor of preterm delivery, independent of the presence or absence of bacterial vaginosis. This difference between the two studies may be due to difference in the study design, the selected group of patient and the gestational age group.

Also the study done by **Donders *et al.***,<sup>(24)</sup> in Femi care vzw, clinical research for women, Tienen, Belgium. The study done to examine 1026 unselected low risk women, the examination done once to detect bacterial vaginosis before 16 weeks of gestation and cervical length (CL) was measured three times by transvaginal ultrasound at (10 to14) ,(20 to 24) and at (30-34) weeks of gestation and gestational age with delivery was recorded. The results of the study concluded that short cervix at 20 to 24 weeks of gestation was predictive for preterm birth while short cervix at 10 to 14 weeks of gestation and bacterial vaginosis could not be proved to predict preterm birth.

On the other hand the results of our study disagree with the study of **Wennerholm *et al.***,<sup>(25)</sup> the aim of the study was to evaluate the predictive values of fetal fibronectin, bacterial vaginosis, endotoxin and cervical length for preterm birth (< 35 and < 37 weeks) and neonatal morbidity in twin pregnancies. The cervical length was measured with transvaginal sonography at the same time intervals. The final results concluded that the predictive value of cervical length determinations was low. Endotoxin and bacterial vaginosis had no predictive power for preterm delivery. This disagreement may be due to the study design, the selected group of patient the gestational age group and laboratory method of diagnosis which resulted in case of bacterial vaginosis the prevalence of bacterial vaginosis at 24 weeks (8%) was much lower than other published studies.

#### **Conclusion:**

From our study we can conclude that assessment of cervical length by transvaginal ultrasound and bacterial vaginosis during pregnancy can help in prediction of preterm labor.

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7/13/2015