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Diagnostic accuracy of PremaQuick in detection of preterm labor in symptomatic women

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ABSTRACT

Objectives: Failure to identify women at risk of preterm labor (PTL) leads to failure to implement standard measures. This study designed to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with threatened preterm labor (TPTL).

Material and methods: One hundred and twenty-two (122) pregnant women, singleton pregnancy, < 37 weeks, admitted with TPTL included in this study, and were compared to 122 controls.
After thorough evaluation, participants were examined using sterile vaginal speculum for cervico-vaginal fluid (CVF) sampling, and PremaQuick test. The CVF sampling was followed by trans-vaginal sonographic (TVS) assessment of cervical length (CL). Participants were managed according to hospitals policy thorough their admission, and after discharge in the ante-natal clinics till delivery. After delivery, the delivery data were compared by the recorded participants` data on admission.

Results: The PremaQuick test had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value, 95.2% negative predictive value, and 96.3% accuracy in detection of PTL. The PremaQuick had significantly higher true negative rate, specificity, positive predictive value, and overall accuracy in detection of PTL compared to CL < 25 mm ($p = 0.005, 0.005, 0.01, 0.002$; respectively).

Conclusions: The PremaQuick is an accurate bedside test in detection of PTL in women presented with TPTL. It had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value, 95.2% negative predictive value, and 96.3% overall accuracy in detection of PTL. The PremaQuick had significantly higher true negative rate, specificity, positive predictive value, and overall accuracy in detection of PTL compared to CL < 25 mm.

Key words: diagnostic accuracy; PremaQuick; preterm labor

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INTRODUCTION

Preterm labor (PTL) is an important cause of perinatal deaths, and neonatal morbidity [1–4]. PTL occurs after excessive uterine stretch (twin or triplet pregnancies), amniotic fluid infection, or chorio-decidual hemorrhage [5, 6].

The fetal fibronectin and cervical length (CL) measured by trans-vaginal sonography (TVS) are the main diagnostic tools currently used to detect PTL [7].

The CL, and fetal fibronectin have low positive predictive value, and limited accuracy to detect PTL [8, 9].

The fetal fibronectin, and insulin growth factor binding protein-1 (IGFBP-1) are amniotic fluid markers used for prediction of PTL [10].

The fetal fibronectin test has high negative predictive value (NPV) in diagnosing PTL [11, 12]. While amniotic fluid contamination, bleeding, and unprotected intercourse are associated with false fetal fibronectin results [4].

Failure to identify women at risk of PTL leads to failure to implement standard measures with subsequent increase in perinatal deaths, and neonatal morbidity. While the false

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positive diagnosis of PTL exposes women to unnecessarily admission, tocolysis, and corticosteroids.

The IGFBP-1 released into the cervico-vaginal fluid (CVF) during the process of chorio-decidual disruption of PTL [13–15]. The IGFBP-1 is a good negative predictor of PTL [16]. The interlukein-6 (IL-6) is a marker of sub-clinical chorioamnionitis associated with PTL [17, 18].

It is crucial to have a reliable diagnostic tool rather than the currently available tests to identify women at risk of PTL [10]. PremaQuick is a bedside test containing antibodies against three amniotic fluid markers (Native, and total IGFBP-1, and IL-6).

Objectives

This study designed to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with threatened preterm labor (TPTL).

MATERIAL AND METHODS

This prospective comparative study was conducted over 15 months (June 2019 to August 2020); after ethical committees approval (approval number OB_0403_19), and registration as clinical trial (ACTRN12618001472268) [19].

One hundred and twenty-two (122) pregnant women between 20–40 years` old, singleton pregnancy, < 37 weeks` gestation, admitted with TPTL were included in this study, and compared to 122 controls, after informed consent in accordance with the Declaration of Helsinki to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with TPTL.

Women without medical disorders, with pregnancy, and intact fetal membranes, between 24–36^{+6} weeks` gestation, presented with uterine contractions (3–4 contractions/30 minutes), each contraction lasting for ≥ 30 seconds with ≤ 50% cervical effacement, and < 3 cm dilated cervix were included in TPTL group.

Pregnant women without TPTL admitted under observation for fetal wellbeing assessment because of suspected intrauterine growth retardation or for blood sugar or blood pressure monitoring due to suspected diabetes or hypertensive disorders with pregnancy, were included as controls after exclusion of intrauterine growth retardation, diabetes, and hypertensive disorders with pregnancy [15].

Women ≥ 37 weeks`, twin or triplet pregnancies, intrauterine growth retardation, medical disorders with pregnancy (diabetes and/or hypertension), dilated cervix ≥ 3 cm, rupture of membranes (ROM), fetal anomalies or intrauterine fetal death, and/or ante-partum hemorrhage were excluded from this study.

Women delivered preterm iatrogenically due to medical disorders with pregnancy (diabetes, hypertension, or intrahepatic cholestasis) or obstetrics indications [twins, triplets, or premature rupture of fetal membranes (PROM)] [20] were also excluded from this study.

The gestational age was estimated based on the first day of LMP (last menstrual period), and confirmed by ante-natal scan done before 20 weeks` [21–23].

Participants were examined abdominally to evaluate; the fundal height, uterine contractions (frequency and duration), and fetal heart, followed by laboratory investigation according to hospitals protocol.

Participants were also examined using sterile vaginal speculum (without antiseptics or lubricant) for CVF sampling, and PremaQuick test before CL assessment, and digital examination.

The sterile swab of PremaQuick kit (Biosynex, France) was placed in the posterior vagina for 15 seconds for CVF sampling, then placed in the extraction solution provided by manufacture for 10 seconds. Three drops of the extraction solution were dispensed into the wells of test device/cassette, then the test result detected within 10 minutes, and recorded.

The presence of 3C (control) lines is important for PremaQuick test validation, and score ≥ 2 means positive PremaQuick test, while score 0 or ≤ 1 means negative PremaQuick test [15].

PremaQuick test is a bedside test containing antibodies against three amniotic fluid markers: Native, and total IGFBP-1, and IL-6 [15].

The CVF sampling for PremaQuick test was followed by TVS assessment of CL by sonographer blinded to participants' clinical data using the standard guideline (to avoid potential bias) [24], and digital examination for assessment of cervical effacement, and dilatation.

Participants were managed according to hospitals policy (hospitalization, tocolysis, and corticosteroids) based on the PremaQuick test results, CL, and clinical findings.

The participants were followed in the ante-natal clinics weekly after hospital discharge till delivery. After delivery, the delivery data were compared to the recorded participants` data on admission to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with TPTL.

Statistical Analysis

Statistical analysis done using Statistical Package for Social Sciences (SPSS) version 20 (Chicago, IL, USA). The Chi-square test (x^2), and student (t) were used for analysis of qualitative, and quantitative variables, respectively.

The sensitivity, specificity, predictive values, and accuracy of PremaQuick test and CL in dectection of PTL were calculated and compared. The relative risk (RR) of PTL in women with positive PremaQuick test, and CL < 25 mm was also calculated. P-value < 0.05 was considered significant.

RESULTS

One hundred and twenty-two (122) pregnant women, singleton pregnancy, < 37 weeks` gestation, admitted with TPTL were compared to 122 controls in this study to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with TPTL.

There was no significant difference between the TPTL group, and controls regarding the mean maternal age, and gestational age at enrollment (30.7 ± 7.1 years, and 32.4 ± 4.1 weeks vs 33.1 ± 6.3, and 35.2 ± 3.7; respectively) (p = 0.9 and 0.1; respectively).

In TPTL group, the PremaQuick test had higher true positive rate in detection of PTL compared to CL < 25 mm (95.1% (116/122) vs 71.3% (87/122); respectively), but this difference was statistically insignificant (p = 0.1).

In controls, the PremaQuick test had significantly higher true negative rate in detection of PTL compared to CL < 25 mm (97.5% (119/122) vs 56.6% (69/122); respectively) (p = 0.005) (Tab. 1).

The PremaQuick test had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value (PPV), 95.2% negative predictive value (NPV), and 96.3% overall accuracy in detection of PTL. While the CL < 25 mm had 71.3% sensitivity, 56.6% specificity, 62.1% PPV, 66.3% NPV, and 63.9% overall accuracy in detection of PTL (Tab. 1).

The PremaQuick had significantly higher true negative rate, specificity, PPV, and overall accuracy in detection of PTL compared to CL < 25 mm (p = 0.005, 0.005, 0.01, 0.002; respectively) (Tab. 1).

The relative risk of PTL in women presented with TPTL was higher with positive PremaQuick test (RR 20.3 (95% CI: 9.29–44.36), p = 0.0001) compared to CL < 25 mm (RR 1.85 (95% CI: 1.37–2.49), p = 0.0001). In addition, the number of women delivered preterm after positive PremaQuick test was significantly higher than those delivered preterm after CL < 25 mm (116/119 versus 87/140; p = 0.01) (Tab. 2).

DISCUSSION

Failure to identify women at risk of PTL leads to failure to implement standard measures. The false positive diagnosis of PTL exposes women to unnecessarily admission, tocolysis, and corticosteroids. It is important to have a reliable diagnostic tool rather than the currently available tests to predict women at risk of PTL [10].

Table 1. Accuracy of the PremaQuick test, and cervical length (CL) in detection of Preterm labor

Variables	PremaQuick Number (%)	CL < 25 mm Number (%)	p-value
TPTL group (122 women) True positive (TP) False negative (FN)	 116/122 (95.1%) 6/122 (4.9%)	 87/122 (71.3%) 35/122 (28.7%)	0.1
Controls (122 women) True negative (TN) False positive (FP)	 119/122 (97.5%) 3/122 (2.5%)	 69/122 (56.6%) 53/122 (43.4%)	0.005*
Sensitivity (TP ÷ TP + FN) × 100	116 ÷ (116 + 6) × 100 = (95.1%)	87 ÷ (87 + 35) × 100 = (71.3%)	0.1
Specificity (TN ÷ TN + FP) × 100	119 ÷ (119 + 3) × 100 = (97.5%)	69 ÷ (69 + 53) × 100 = (56.6%)	0.005*
Positive predictive value (PPV) (TP ÷ TP + FP) × 100	116 ÷ (116 + 3) × 100 = (97.5%)	87 ÷ (87 + 53) × 100 = (62.1%)	0.01*
Negative predictive value (NPV) (TN ÷ TN + FN) × 100	119 ÷ (119 + 6) × 100 = (95.2%)	69 ÷ (69 + 35) × 100 = (66.3%)	0.07
Accuracy (TP + TN ÷ TP + TN + FP + FN) × 100	116+119 ÷ (116 + 119 + 3 + 6) × 100 = (96.3%)	87 + 69 ÷ (87 + 69 + 53 + 35) × 100 = (63.9%)	0.002*

* Significant difference; Chi-square test (x^2) used for statistical analysis; TPTL — threatened preterm labor

Table 2. Relative risk of PTL with positive PremaQuick test, and cervical length (CL) < 25 mm

Variables	PTL (bad outcome)	Good outcome (No PTL)	RR (95% confidence interval) p-value
PremaQuick Positive test group (119) Negative test group (225)	 116 6	 3 119	20.3 (9.29–44.36) 0.0001*
CL < 25 mm Positive group (140) Negative group (104)	 87 35	 53 69	1.85 (1.37–2.49) 0.0001*

* Significant difference; CL — cervical length; PTL — preterm labor; RR — relative risk

PremaQuick is a bedside test containing antibodies against three amniotic fluid markers (Native, and total IGFBP-1, and IL-6). Therefore, one hundred and twenty-two (122) pregnant women, < 37 weeks`, admitted with TPTL were compared to 122 controls in this study to evaluate the accuracy of PremaQuick test in detection of PTL in women presented with TPTL.

In this study, the PremaQuick test had significantly higher true negative rate in detection of PTL compared to CL < 25 mm (97.5% (119/122) vs 56.6% (69/122); respectively), (p = 0.005). It also had significantly higher specificity, PPV, and overall accuracy compared to CL < 25 mm (p = 0.005, 0.01, and 0.002; respectively) in detection of PTL.

Similarly, Abu-Faza et al. [15], found the CL < 25 mm had low specificity, and low positive predictive value in detection of PTL.

Schmitz et al. [25], also, found the CL ≤ 25 had 75% senstivity, 63% specificity, and 24% PPV in detection of PTL.

Nikolova et al. [26], concluded that the PAMG-1 (placental alpha microglobulin-1) is better predictor of imminent PTL when compared with phosphorylated-IGFBP-1 (ph IGFBP-1) alone or in combination with CL.

Melchor et al. [27], found the positive predictive value of PAMG-1 was significantly higher than the phIGFBP-1 or fetal fibronectin in detection of spontaneous PTL within seven days.

The phIGFBP-1 alone as an amniotic fluid marker has limited predictive ability to detect women at risk for PTL [28]. Therefore, the PremaQuick test designed against three amniotic markers (Native, and total IGFBP-1, and IL6) to increase its accuracy in detection of PTL.

In this study, the PremaQuick test had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value, 95.2% negative predictive value, and 96.3% overall accuracy in detection of PTL. The PremaQuick test had significantly higher specificity, positive prtedictive value, and overall accuracy in detection of PTL compared to CL < 25 mm (p = 0.005, 0.01, and 0.002; respectively).

Similarly, Asiegbu et al. [29], found the the PremaQuick test had 96.3% senstivity, 97.6% specificity, 89.7% PPV, 99.2% NPV, and 97.3% accuracy, in detection of PTL within 14 days in women with TPTL between 28–36^{+6} weeks` gestation.

Eleje et al. [30], also found the PremaQuick test had 100.0/87.5% sensitivity, 94.1/96.9% specificity, 70.5/87.5% PPV, 100.0/96.9% NPV and 95.0/95.0% accuracy in detection of PTL within 7/14 days in women with singleton pregnancy presented with TPTL < 35 weeks`, respectively. They concluded that the PremaQuick test is an accurate test in detection of PTL in women with singleton pregnancy presented with TPTL [30].

Abu-Faza et al. [15], also found the PremaQuick test had higher specificity and positive predictive value in diagnosing PTL compared to CL.

In this study, the relative risk of PTL in women presented with TPTL was higher with positive PremaQuick test (RR 20.3 (95% CI: 9.29–44.36), p = 0.0001) compared to CL < 25 mm (RR 1.85 (95% CI: 1.37–2.49), p = 0.0001). In addition, the number of women delivered preterm after positive PremaQuick test was significantly higher than those delivered preterm after CL < 25 mm (116/119 vs 87/140; p = 0.01).

Abu-Faza et al. [15], also found the odds, and relative risk (RR) of PTL within 7–14 days in symptomatic women were significantly higher for PremaQuick (12.9, and 8.4; respectively) compared to CL < 25 mm (1.4, and 1.1; respectively).

This study found the PremaQuick is an accurate bedside test in detection of PTL in symptomatic women presented with TPTL. It had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value, 95.2% negative predictive value, and 96.3% overall accuracy in detection of PTL. Its true negative rate, specificity, PPV, and overall accuracy in detection of PTL were significantly higher than CL < 25 mm.

The current study was the first registered, prospective, comparative, multicenter study conducted to evaluate the accuracy of PremaQuick test in detection of PTL in symptomatic women presented with TPTL.

Women refused to give consent and participate, and shipping of the PremaQuick kits were the limitations faced during this study.

The accuracy of PremaQuick test in detection of PTL should be compared with other amniotic fluid markers as PAMG-1 (AmniSure test) or IGFBP-1 (Actim-PROM test) in future studies.

CONCLUSIONS

The PremaQuick is an accurate bedside test in detection of PTL in women presented with TPTL. It had 95.1% sensitivity, 97.5% specificity, 97.5% positive predictive value, 95.2% negative predictive value, and 96.3% overall accuracy in detection of PTL. The PremaQuick had significantly higher true negative rate, specificity, positive predictive value, and overall accuracy in detection of PTL compared to CL < 25 mm.

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Conflict of interest

No conflict of interests related to this study.

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