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Diagnostic accuracy of posterior cervical angle and cervical length in the prediction of successful induction of labor

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Keywords: Bishop score; Cervical length; Failure of induction; Induction of labor; Posterior cervical angle; Transvaginal ultrasonography.

Synopsis: The posterior cervical angle was a better measure for predicting the success of induction of labor than the cervical length and the traditional Bishop score.

Abstract

Objective: To determine the accuracy of the posterior cervical angle (PCA) compared with the cervical length and the Bishop score in predicting the outcome of induction of labor (IOL).

Methods: The present prospective observational study included IOL candidates who had their PCA and cervical length assessed by transvaginal ultrasonography and the Bishop score at the Obstetrics and Gynecology Department, Kasr El-Aini Hospital, Cairo University, Cairo, Egypt, between April 1 and July 31, 2017. The accuracy of these tests in predicting successful IOL (defined as vaginal delivery) was compared.

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Results: The analysis included 49 women with successful IOL and 21 women with unsuccessful IOL. The suggested cutoffs for the prediction of successful IOL were a PCA of more than 99.5°, a cervical length of less than 34 mm, and a Bishop score of more than 5. The areas under the receiver operating characteristics curves for these three measures were not significantly different. However, a PCA of more than 99.5° had the best sensitivity (91.84%), specificity (90.48), positive predictive value (95.7%), negative predictive value (82.6%), positive likelihood ratio (9.64), and negative likelihood ratio (0.09) compared with the other two predictors.

Conclusion: A PCA of more than 99.5° yielded the best accuracy in predicting successful IOL compared with the cervical length and the Bishop score.

ClinicalTrials.gov: [NCT03113227](https://clinicaltrials.gov/ct2/show/study/NCT03113227).

1 INTRODUCTION

Induction of labor (IOL) represents a common procedure in everyday obstetric practice: it is used in 30–40% of women in labor [1,2]. However, IOL may lead to various maternal and fetal hazards [3]. Moreover, failure of IOL is not uncommon (approximately 30%) [4]. Therefore, the proper selection of candidates for successful IOL represents a demanding issue in obstetric practice [2].

The Bishop score, first described in 1964, has been the mainstay for the assessment of cervical readiness prior to IOL [5]. However, some investigators have raised concerns about the value of the Bishop score in predicting the IOL outcome because it is a subjective measure with great intra- and inter-observer variability, affected by a physician's clinical experience and the imprecise nature of the assessment of cervical length and direction [6].

Given these limitations, it is necessary to find a better alternative [7]. Transvaginal sonography appears promising because of its availability, reproducibility, and ability to provide images for accurate documentation [8]. Several ultrasonography parameters have been suggested as substitutes to the traditional Bishop score [7, 9, 10]. In particular, investigators have looked at the role of the cervical length [9, 11, 12] and the cervical stiffness [4] determined by transvaginal ultrasonography prior to IOL, but only a few studies [13,14] have focused on the posterior cervical angle (PCA). The results are conflicting. Therefore, more research is required to evaluate the sonographic cervical changes prior to IOL and to identify reliable predictors of IOL success.

The aim of the present study was to evaluate the value of the PCA and the cervical length, both measured by ultrasonography, compared with the Bishop score in the prediction of the IOL outcome.

2 MATERIALS AND METHODS

The present prospective validation study was conducted at the Obstetrics and Gynecology Department, Kasr El-Aini Hospital, Cairo University, Cairo, Egypt, from April 1 to July 31, 2017. The local ethics committee approved the study. The ethics principles of the Declaration of Helsinki were followed and informed consent was taken from all participants.

The study included candidates for IOL aged 18–37 years who had a single live fetus in cephalic presentation and pregnancy duration of 35–42 weeks. The exclusion criteria were fetal anomalies, amniotic fluid disorders, placenta previa, prepartum hemorrhage, cephalopelvic disproportion, prior cervical procedure (cerclage, cauterization, or conization), previous cesarean delivery, morbid obesity (body mass index of more than 40, calculated as weight in kilograms divided by the square of height in meters), fetal macrosomia (fetal weight of 4 kg or more measured by ultrasonography), and active labor on admission.

MedCalc version 15.8 (MedCalc Software, Ostend, Belgium) was used to calculate the minimum sample size needed to achieve an area under the curve (AUC) of at least 0.75 as a measure of diagnostic accuracy for the PCA in predicting a positive IOL outcome. The type I error was set at 0.01, the power at 80%, and the ratio of positive to negative IOL outcome (when using prostaglandin and/or oxytocin) at two to one [4]. Accordingly, it was estimated that 70 IOL candidates were needed. The sampling was consecutive.

All women underwent ultrasonography examination by two ultrasonography-experienced researchers (AH and AHS), who used a SonoAce X4 (Medison, Seoul, South Korea) ultrasonography machine with a 3.5-MHz abdominal probe and a 7.5-MHz vaginal probe; ultrasonography examinations were supervised by a third researcher (EFO). Transabdominal ultrasonography was done first to check the fetal number, viability, presentation, adequacy of amniotic fluid, and placental site. Then, after bladder emptying and placement of the patient in the lithotomy position, the vaginal probe was gently inserted into the vagina until it reached the posterior fornix. Undue pressure was avoided. A sagittal plane of the cervix was obtained that ensured visualization of the entire length of the cervical canal. Once the view was optimal, the depth was increased so that the image occupied approximately two-thirds of the screen (Figure S1). For the cervical length measurement, the calipers were

placed in a line between the internal and external cervical orifices [15]. The PCA was measured with the software for measuring angle in an ultrasonography image taken in the sagittal plane at the level of the internal cervical os; the PCA was defined as the angle between the line used for the cervical length measurement and the posterior uterine wall (Figure S2)

Afterward, two researchers (DSB and SMS), who were masked to the ultrasonography data, performed a digital examination to calculate the Bishop score [16].

The protocol for IOL followed the local university hospital protocol. Women with a closed or firm cervix were initially given a cervical ripening agent in the form of a vaginal tablet containing 25 µg misoprostol (Vagiprost, Adwia, Cairo, Egypt). The cervix was reassessed 6 hours after the initial dose to decide whether to repeat the dose or to start oxytocin infusion [17]. If no cervical ripening was achieved after four doses of misoprostol (at 6-hour intervals), the outcome was considered to be failed IOL and the infant was delivered by cesarean delivery (in accordance with the hospital's policy for IOL). Women with a soft cervix and those who progressed after misoprostol administration received an intravenous infusion of oxytocin (Syntocinon, Novartis, Basel, Switzerland). The starting dose was 5 units (in 500 mL Ringer solution) at a rate 12 drops/minute. The dose was doubled every 30 minutes until efficient contractions were achieved; the maximum dose was 96 drops/minute.

A successful outcome of IOL was defined as an uncomplicated vaginal delivery, whereas unsuccessful IOL was defined as cesarean delivery because of failed progress of labor. Women who had a cesarean delivery for reasons other than failed IOL, such as prepartum hemorrhage, fetal distress, and cephalopelvic disproportion, were excluded from the data analysis.

The statistical analysis was conducted with SPSS version 23 (IBM, Amonk, NY, USA). Differences between the groups were evaluated using the Student *t*, Mann–Whitney *U*, χ^2 , and Fisher exact tests. Univariate logistic regression analyses were conducted to test the association between demographic, clinical, and ultrasonography parameters (age, body mass index, parity, neonatal birth weight, Bishop score, PCA, cervical length, pregnancy duration, and indication of IOL) with successful IOL; odds ratios (ORs) with 95% confidence intervals (CIs) were calculated. Subsequently, multivariate regression analysis was conducted on the variables that were significantly correlated ($P < 0.05$) with successful IOL in

the univariate analyses to assess the independence of each variable in affecting the outcome. Receiver operating characteristics curve analyses were done to test and compare the accuracy of the three index cervical measures (PCA, cervical length, and Bishop score) in predicting the IOL outcome. The AUCs for the cervical tests were compared. In addition, the diagnostic accuracy measures of sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio were calculated. $P < 0.05$ was considered statistically significant.

3 RESULTS

In total, 90 candidates for IOL were screened for eligibility (Figure 1). After exclusions, 70 women were included in the final data analysis; IOL was successful in 49 (70%) women and unsuccessful in 21 (30%).

The maternal age, body mass index, parity, and neonatal weight did not differ significantly between the two groups (Table 1). However, the pregnancy duration was significantly longer in the group with successful IOL than in the group with unsuccessful IOL ($P = 0.002$). The indication for IOL was classified into two categories: passed due date ($n = 28$) and “other indications” ($n = 42$), which included rupture of membranes and maternal medical disorders such as gestational diabetes and gestational hypertension. A passed due date was more prevalent in the successful IOL group ($P = 0.009$).

The two groups differed significantly in each of three cervical measures (Table 1): the Bishop score was higher, the cervical length was shorter, and the PCA was larger in the group with successful IOL.

Logistic regression analysis revealed that the pregnancy duration, IOL indication, Bishop score, cervical length, and PCA were significantly correlated with the IOL outcome (Table S1). In the multivariate regression analysis including these five factors, the correlation between the IOL outcome and the pregnancy duration or IOL indication was no longer significant; only the three cervical measures (PCA, cervical length, and Bishop score) remained independent factors affecting the IOL outcome (Table 2).

The best cutoff values for the prediction of successful IOL were a PCA of more than 99.5° , a cervical length of less than 34 mm, and a Bishop score of more than 5 (Table 3). There was no significant difference between the PCA, cervical length, and Bishop test as regards the

overall accuracy, as evidenced by comparison of the AUC values (0.94 versus 0.87 versus 0.82) (Figure 2, Table S2). However, a PCA of more than 99.5° had the best sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio in comparison with the cervical length and the Bishop score (Table 3).

4 DISCUSSION

The present study investigated the value of the PCA, the cervical length, and the traditionally used Bishop score in the prediction of successful IOL. Multivariate regression analysis proved the validity of these three cervical measures in predicting the outcome of IOL because each parameter was an independent factor affecting the outcome of IOL. However, the PCA had a higher specificity, positive predictive value, and negative predictive value than did cervical length measurement; the Bishop score had the least predictive value. The positive likelihood ratio for a PCA of more than 99.5° was close to 10 (the cutoff above which positive likelihood ratios are considered to be indicating good predictive capacity) and the negative likelihood ratio was less than 0.1. This means that a PCA of more than 99.5° is observed 10 times as frequently in women with successful IOL as in women with unsuccessful IOL, and a PCA of less than 99.5° is observed one-tenth as frequently in women with successful IOL as in women with unsuccessful IOL. The results imply that the predictive power of the PCA is considerably greater than that of the other two cervical tests [18].

Concern over the poor predictive value of the Bishop score has already been raised by previous authors. In a review of 40 studies reporting on 13 757 women, Kolkman et al. [6] concluded that there is no solid evidence validating the current use of the Bishop score in obstetric practice even though it has been used for more than 40 years to assess cervical ripeness and predict the outcome of IOL. By contrast, a meta-analysis that included 59 studies [5] confirmed a positive correlation between IOL outcome and Bishop score.

Several studies have investigated the role of ultrasonography cervical length measurement in the prediction of IOL outcome. Hatfield et al. [11] concluded in a review of 20 trials that the cervical length measured by ultrasonography is not effective in predicting the IOL outcome and does not provide additional beneficial information over the Bishop score. Papillon-Smith and Abenhaim [9] took a different view in an analysis of 32 observational studies: they established the superiority of ultrasonography cervical length assessment over traditional digital examination in predicting the IOL outcome.

Few studies to date have evaluated the role of PCA measurement in predicting the outcome of IOL. Paterson-Brown et al. [19] reported that the PCA was more accurate than the Bishop score in predicting a vaginal delivery. A PCA of more than 70° together with a Bishop score of more than 5 had the best accuracy for predicting a successful IOL outcome. Rane et al. [20] reported that a PCA of more than 120° was associated with a positive response to IOL within 24 hours. Gokturk et al. [13] found that a PCA of 120° or more had the best predictive value for successful IOL, but this finding was not statistically significant in a multiple regression analysis.

The identification of different PCA cutoffs is most likely attributable to the large variability in methodology among these studies. The present study was conducted prospectively by skilled obstetricians, with the ultrasonography examinations performed by two researchers, and the digital examinations performed by two different researchers who were masked to the ultrasonography data; this minimized inter-observer variability. The induction protocol was restricted to two methods only (administration of a cervical ripening agent and oxytocin infusion) to nullify the effects of different induction agents on the induction outcome. The need for administration of a cervical ripening agent was established not by applying the Bishop scoring system but based on the initial cervical effacement and dilatation state, to overcome any potential bias and to be able to evaluate the independent influence of the Bishop score on IOL outcome. Moreover, women with a cesarean delivery for indications other than failure of progress were excluded from the data analysis because these indications were not relevant to assessment of the cervical status as a predictor of IOL outcome. These are all strengths of the present study.

The present study also had limitations. The sample size was determined to enable evaluation of the diagnostic accuracy of the PCA test and not the diagnostic accuracy of other possible factors associated with successful IOL. The wide range of pregnancy durations (35–42 weeks) may also be considered as a limitation. Rozenberg et al. [21] proposed that cervical ripening is a dynamic process, with cervical changes occurring progressively during the third trimester; therefore, sonographic cervical features may differ depending on the pregnancy duration. The multiple logistic regression analysis was adjusted for the pregnancy duration to overcome this limitation.

In conclusion, a PCA of more than 99.5° yielded the best accuracy in predicting IOL success. Thus, we recommend the routine use of sonographic cervical measurements, in particular measurement of the PCA, in the assessment of IOL candidates to achieve a better outcome. Further research is needed to verify the present findings and to validate the benefit of sonographic cervical measurements—especially PCA—in everyday obstetric practice.

Author contributions

AMA-A contributed to the study design and the manuscript revision. SMS contributed to the data acquisition and the manuscript revision. DSB contributed to the study design, the literature review, the data acquisition, and the writing of the manuscript. EFO contributed to the literature review, the data acquisition and analysis, and the writing of the manuscript. AH contributed to performing ultrasonography examinations, data analysis, and the manuscript revision. AHS contributed to performing ultrasonography examinations, the data analysis, and the manuscript revision. MMA contributed to the data acquisition and the manuscript revision. AMN contributed to the study design and the writing of the manuscript.

Conflicts of interest

The authors have no conflicts of interest.

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Figure 1 Flow chart of the study population.

Figure 2 Receiver operating characteristic curves for the three index cervical measures (posterior cervical angle, cervical length, and Bishop score).

Table S1 Univariate logistic regression analysis of predictors of successful induction (defined as vaginal delivery).

Table S2 Pairwise comparison of the areas under the receiver operating characteristics curves of the three index cervical tests.

Figure S1 Cervical length measured by transvaginal ultrasonography.

Figure S2 Posterior cervical angle measured by transvaginal ultrasonography.

Table 1 Demographic, clinical, and ultrasonography characteristics of the study groups. ^a

Characteristic	Successful IOL (n=49)	Unsuccessful IOL (n=21)	Difference between groups (95% CI)	<i>P</i> value
Age, y	26.0±4.1	26.8±4.2	-0.71 (-2.84 to 1.43)	0.510
Body mass index ^b	27.3±3.8	26.1±2.3	1.2 (-0.59 to 3.0)	0.190
Parity				
Nulliparous	24 (49)	5 (24)	1.5 (-0.7 to 4)	0.060
Multiparous	25 (51)	16 (76)		
Neonatal weight, g	3097.7±449.1	3026.1±464.2	72 (-172 to 316)	0.550
Pregnancy duration, wk	39 (36–42)	38 (35–42)	1 (1–2)	0.002
Indication for IOL				
Passed due date	25 (51)	3 (14)	37 (16–57) ^c	0.009
Other	24 (49)	18 (86)		
Bishop score	6 (0–10)	5 (0–8)	2 (1–3)	<0.001
Cervical length, mm	27.9±5.0	36.7±5.6	-8.77 (-5.88 to - 11.7)	<0.001
Posterior cervical angle, °	125 (75–150)	89 (70–130)	33.3 (28.3–40.7)	<0.001

Abbreviation: IOL, induction of labor; NS, non-significant.

^a Values are given as mean±SD, median (range), or number (percentage), unless indicated otherwise.

^b Calculated as weight in kilograms divided by the square of height in meters.

^c Difference in percentage of women with a passed-due-date indication.

Table 2 Multivariate logistic regression analysis of predictors of successful induction of labor (defined as vaginal delivery).

Variable	OR (95% CI)	<i>P</i> value
Posterior cervical angle	1.14 (1.07–1.22)	<0.001
Bishop score	3.20 (1.20–8.60)	0.002
Cervical length	0.80 (0.68–0.90)	0.040
Pregnancy duration	1.30 (0.60–2.50)	0.540
Indication for induction	1.57 (0.04–7.90)	0.680

Abbreviations: OR, odds ratio; CI, confidence interval.

Table 3 Receiver operating characteristics curve analysis of the accuracy of three cervical tests in predicting successful induction of labor. ^a

Parameter	Posterior cervical angle	Cervical length	Bishop score
AUC (95% CI)	0.939 (0.855–0.982)	0.872 (0.771–0.940)	0.821 (0.711–0.903)
<i>P</i> value for AUC	<0.001	<0.001	<0.001
Suggested cutoff value	>99.5°	<34 mm	>5
Sensitivity (95% CI), % ^b	91.84 (80.4–97.7)	91.84 (80.4–97.7)	73.47 (58.9–85.1)
Specificity (95% CI), % ^b	90.48 (69.6–98.8)	80.95 (58.1–94.6)	80.95 (58.1–94.6)
+ve LR (95% CI) ^b	9.64 (2.6–36.1)	4.82 (2.0–11.7)	3.86 (1.6–9.5)
-ve LR (95% CI) ^b	0.09 (0.03–0.2)	0.10 (0.04–0.3)	0.33 (0.2–0.5)
PPV (95% CI), % ^b	95.70 (85.5–99.5)	91.80 (80.4–97.7)	90.00 (76.3–97.2)
NPV (95% CI), % ^b	82.60 (61.2–95.0)	81.00 (58.1–94.6)	56.70 (37.4–74.5)

Abbreviations: +ve LR, positive likelihood ratio; -ve LR, negative likelihood ratio; AUC, area under curve; NPV, negative predictive value; PPV, positive predictive value.

^a Reference: actual induction outcome.

^b Accuracy measure for the suggested cutoff value.



