

Predicting Labour Duration Based on Biomechanical Measurements of the Cervix

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Abstract:

Background: Predicting the timing and process of childbirth in pregnant women has long posed a challenge for healthcare professionals. Unfortunately, there has been limited advancement in preventing adverse outcomes associated with either premature or overdue deliveries. According to the perspective of the author, who specializes in maternal-fetal medicine, there is potential promise in approaching labor from a biomechanical perspective and treating it as an engineering problem. This novel approach may hold the key to unraveling the complexities of the labor process.

Method and Objective: The labor induction is a routine approach in obstetrics. Having a way to predict the duration of labor would greatly assist in planning and enhance patient satisfaction. The main objective of this research was to assess the effectiveness of a novel biomechanical measurement method for the cervix, which utilizes the “aspiration technique”, in predicting the length of labor following induction.

Results: No technical issues were encountered during the aspiration or sonographic assessment. Amongst various examinations, the assessment of the “Bishop score” was consistently recorded as the majority uncomfortable for patients. It's important to note that both the duration until reaching the dynamic phase of labor and the period until parturition demonstrated significant correlations with the “Bishop score”, while there were no notable correlations with cervical length, CCI (cervical compliance index), or termination pressure.

Conclusion: The application of the innovative biomechanical cervix measurement technique using the aspiration method has proven to be both technically feasible and positively received. Within our small study cohort, we did not identify any apparent link between termination pressure and time period of pain of labor.

Keywords: Preterm Birth, Short Cervix, Cervix Length, Labor Induction, Bishop Score.

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Introduction

The “labor induction” is a commonly performed approach in the field of obstetrics. In developed nations, nearly one in four babies is delivered following labor induction at term [1]. Induction may be recommended for various medical reasons, with the ultimate goal being a safe natural childbirth resulting in the delivery of a healthy baby through the birth canal [2]. Capacity to foresee a successful induction and its timeline can enhance outcomes of pregnancy and contribute to increased satisfaction among expectant mothers during the childbirth process.

The role of cervix

Presently, a brief cervix identified in 2nd trimester is the most reliable indicator of spontaneous preterm

birth (sPTB). However, the treatment approach for a short cervix remains a subject of debate, even with over six hundred articles in the past two decades examining the connection amongst sPTB, a short cervix, and potential interventions [1]. According to a meta-analysis, cerclage is not beneficial for a cervix measuring less than or equal to 25.0 mm in nonselected population [2]. Nevertheless, if there is a history of sPTB, cerclage does reduce the risk of sPTB by 30% [3].

The crucial part in the initiation of labor and is a dynamically active tissue which undergoes both biochemical and biomechanical transformations during pregnancy to prepare for childbirth is played by cervix [4]. Throughout gestation, the cervix's primary biological function is to retain the fetus

within the uterus. However, when the time is right, its role undergoes a complete shift: the cervix becomes softer, shorter, and more dilated to facilitate the fetus's delivery [5, 6]. Numerous mechanical factors influence the cervix's ability to carry out this function, encompassing its mechanical properties, geometric features, the properties and adhesion of fetal membranes, uterine contractions, and static loading [7]. The changes in cervix's bio-mechanical characteristics in the period of pregnancy are linked to alterations in collagen fiber cross-links, their organization and distribution, variations in "glycosaminoglycans" and "water content".

A widely accepted method for assessing the cervix and predicting its readiness for labor induction is through a manual vaginal examination to calculate the Bishop score [8-10]. In most randomized trials, a cervix is considered unfavorable if it has a Bishop score of 6 or lower. According to the "American College of Obstetrics and Gynecology", if the count surpasses 8, the likelihood of successfully having a vaginal delivery following labor induction is comparable to that of spontaneous, natural labor [11]. However, a notable limitation of the Bishop score is its subjective nature, which results in significant variability in assessments both within and between different healthcare providers.

Utilizing ultrasound examination for cervix evaluation offers a more objective approach. Through transvaginal ultrasound examination, it becomes possible to objectively assess crucial factors as cervical length, internal anatomy, and post Cervical angle. The cervical consistency index (CCI) is a measurement that involves calculating ratio between ant-post length of the cervix prior to and after application of pressure using a "transvaginal transducer". Parra-Saavedra and his team observed a progressive softening of the cervix as pregnancy advanced, demonstrating a steady linear decline in the CCI.

The approach investigated in this clinical study is referred to as the aspiration method. This technique is rooted in the principles of pipette aspiration, and its origins can be traced back to its development at the organization [12]. The method called "pipette aspiration" has proven effective in clinical research involving various organs, such as the liver and the uterine cervix [13]. This evaluates the rigorosity of the cervical tissue by applying tensility to both the cervix epithelium and the underlying stroma. The greater the tissue's rigorosity, the greater the tensility crucial to achieve the pre-defined extent of distorts.

Measurements conducted on women pregnant have revealed that the cervix undergoes continuous softening during the initial two trimesters. However, it tends to equilibrate in 3rd trimester, maintaining a lower extent of rigorosity to support the preg-

nancy. It is anticipated that the cervix will significantly soften at the time of delivery compared to its state in the third trimester. However, objective data regarding this softening process at delivery remains currently unavailable.

The main goal of this study is to evaluate the effectiveness along with acceptability of a new method for predicting the length of labor after induction. This assessment is carried out in a specific group of patients, which includes pregnant women who are at term and have not previously given birth (nulliparous women).

Materials and Methods

The present prospective study was conducted at Anugrah Narayan Magadh Medical College and Hospital Gaya(Bihar) for three months. Throughout this duration, all cases scheduled for labor induction were extended an invitation to engage in research prior to the induction process were initiated. We ensured that formal descriptive consent was obtained from patients who chose to engage. The inclusion criteria encompassed nulliparous women with pregnancies at term (with a gestational age exceeding 37 weeks), convey one fetus in a cephalic presentation, and possessing an unfavorable cervix (Bishop score equal to or less than 6). On the other hand, exclusion criteria comprised difficulties in communication, any worrisome signs of fetal distress upon admission, planned caesarean section, spontaneous labor with more than 2 contractions per 10 minutes, and technical ineligibility for aspiration measurements.

The main goals of this research included evaluating the period of every measurement and assessing the level of pain experienced during these evaluations. Secondary objectives encompassed examining the connections between these measurements and the time required for labor induction to progress into the active phase of labor and ultimately result in delivery, the method of delivery, the overall health of the newborn. The active phase of labor was defined as the onset of regular, painful uterine contractions that led to cervical dilation beyond 3 cm. An induction was considered unsuccessful if a patient did not progress to the active phase of labor within 71 hours of "cervical ripening". New-born well-being was assessed using the 5-minute Apgar score and the need for admission to the neonatal care unit.

Measurement

Aspiration Measurement

After inserting a speculum to widen the vaginal cavity, the tube's opening was positioned vertically on the front edge of the cervix at the 12 o'clock position. As vacuum pressure increased, the tissue of cervix was drawn into tube, taking on a round cup shape. The negative pressure required to distort

the tissue to a depth of 4 millimeters was termed the closure pressure, which was the primary report measure for this assessment. We performed three rounds of aspiration at the same selected point, with a brief pause of a few seconds between each round. For the analysis of rigorosity of cervix, we exclusively relied on data obtained from the first round, as it provided the most accurate representation of the tissue's physiological condition.

Measurements of Sonography

Ultrasound assessments were carried out utilizing a Voluson1 mobile ultrasound machine. The measurements of cervical length consistently utilized a transvaginal probe with a frequency range of 6–9 MHz. Cervical length was defined as the direct measurement from the internal to the external cervical os, excluding the endocervical funnel.

Digital Measurements

The Bishop score, following description provided as per Bishop [14], was assessed by a seasoned obstetrician immediately before the initiation of labor induction. It's important to note that the managing obstetrician was unaware of the outcomes obtained from the measurements mentioned earlier.

Induction of Labor

Labor induction was initiated employing prostaglandins to enhance favorability of cervix. Once the cervix exhibited effacement with a minimum dilation of three centimeters, amniotomy was conducted. In case of necessity to enhance labor progress,

oxytocin was administered incrementally in accordance with the local protocol until achieving optimum uterine contractions.

Statistical Assessment

In our analysis of continuous variables, we presented “descriptive statistics” as the mean and interquartile range for variables with a skewed distribution, while for those with a symmetric distribution, we provided mean and standard deviation. For categorical variables, we recorded percentages and frequencies.

To assess the continuous impact of the measurements on the duration up till the labor in its active phase and the period until vaginal delivery, we utilized linear regression. Cases that did not progress to the active phase of labor were excluded from the first assessment, and patients who underwent a cesarean section were excluded from the second assessment. We considered reports statistically significant when the “p-value” was less than 0.05.

Results

Throughout the duration, a total count of 56 cases was enrolled to partake in this course prior the commencement of labor induction. Twelve of these women (21%) were excluded due to not meeting the inclusion criteria, and six (11%) declined to participate. Consequently, our analysis was carried out with data from the remaining thirty-eight women (68%). The demographic features and the reasons for labor induction are detailed in Table 1.

Table 1: Demographical data

Characteristics	Variables (mean)	Range
Maternal age(yrs)	31	21-38
Gestational age(Days)	268	257- 291
Maternal BMI (kg/m ²)	24.09	21.20- 38.68
Birth weight, (Gms)	3501	2260- 4108

The cause for labor induction was attributable to both maternal factors (38%) and fetal factors (62%). In all cases, prostaglandins were employed to enhance cervical favorability, followed by either amniotomy, oxytocin administration, or both. Out of the thirty-eight women included in the analysis,

29 (76.31%) experienced an optimal induction of labor that culminated in a vaginal delivery. Among the remaining nine women (19%), three required “caesarean section” due to unsuccessful induction due to cephalopelvic disproportion and caused by non-reassurance of fetal heart rate.

Table 2: Indication for labor induction

Maternal characteristics	Percentage indication
Pregnancy- induced hypertension	16
Hydrnephrosis	17.6
Pre existing disease	4.4
Fetal	-
Growth restriction	14
Post-term pregnancy	8
Fetal malformation	12
Macrosomia	13
Isoimmunisation	15

The duration from the initiation of labor induction until the onset of the active labor phase ranged

from 5 hours and 10 minutes to 65 hours. Similarly, the duration from the start of labor induction to

delivery varied between 8 hrs and 56 mins to 73 hrs and 18 mins. In the majority of cases (89%), 5-minute “Apgar score” was either 9 or 10. However, 9 cases (19%), enrollment to the neonatal care unit was required due to various reasons such as p^rerinatal asphyxia, low birth weight, congenital heart defects, and hyperbilirubinemia “.

Sonographical Assessment

The sonographical assessments encompassed measurements of the length of cervix and the CCI. “Cervical length” ranged from nine millimeters to forty-three millimeters, with a median cervical length of twenty two millimeters. As for the CCI, it spanned from forty seven percent to eighty percent.

The average count period of the sonographical measurements lasted around 3 minutes. Remarkably, none of the cases experienced any pain during these assessments, as indicated by VAS-scores ranging from 0 to 3, along with mean score of 0. Furthermore, there were no technical complications reported.

Aspiration Measurements

During the cervical aspiration assessments, 3 consecutive cycles were carried out on same point, with a brief interval of a few seconds between each cycle. In the initial cycle, the closure pressures ranged from 12 mbar to 82 mbar, with a median closure pressure of 37.02 mbar.

The complete assessment process involving all three aspiration cycles had an average period of 3:59 minutes. Notably, no patients were reported with any pain in the period of assessment, as indicated by VAS-scores ranging from 0 to 4, with a median score of 1. After the measurements, there were no observations of trauma, bleeding, or severe technical issues. Digital measurements

During cervical aspiration assessment, 3 consecutive cycles were carried out at the same location, with a brief interval of a few seconds between each cycle. In the initial cycle, the closure pressures ranged from 12 mbar to 80 mbar, with a median closure pressure of 36.5 mbar.

A complete assessment process involving all 3 “aspiration cycles” had an average period of four minutes. Notably, none of the cases recorded any discomfort during the measurements, as indicated by “VAS-scores” ranging from zero to four, with a median score of one. After the measurements, there were no observations of trauma, bleeding, or severe technical issues. In a small subset of cases (11%), there was difficulty in visualizing the tube placement was obstructed by vaginal mucus in one of these instances, necessitating the replacement of the probe during the procedure.

Discussion

Our study was designed to assess the medical utility of a novel “biomechanical cervical measurement”, which relies on the “aspiration technique”, for predicting the duration of labor following induction. It was compared that this innovative measurement with other established methods, including the “Bishop score” and sonographic assessments of cervix length and CCI.

“Aspiration technique” is considered to be a safe and efficient examination, alongside the traditional digital and sonographic examinations. In primary study, we did not observe a significant correlation between the closure pressure and the period of labor after induction. However, it's essential to interpret these findings cautiously because this course of research was not specifically powered to address this particular result parameter.

The relationship amongst cervix tissue, assessed through various methods, and gestational age has been thoroughly examined. Parra-Saavedra et al. documented that cervical os length remains relatively consistent until thirty weeks of pregnancy, followed by gradual compression beyond this gestational age [15]. However, the design of compression observed for the CCI differs from cervical length, as there is a gradual reduction of the CCI with advancing gestational age. In a similar vein, Badir et al. also observed a consistent decline in closure pressure when utilizing the aspiration method during initial 2 trimesters, a subsequent stabilization at lower levels in the third trimester was followed [15, 16]. Both studies highlighted the progressive softening of cervical tissue during gestation, in contrast to cervical length, which primarily decreases in the third trimester [17]. Interestingly, our study's findings fell within the range of measurements made in the 3rd trimester of pregnancy, as reported in the studies mentioned above.

Initial anticipation of ours was that the cervix tissue would become certainly softer in the hours leading up to delivery. However, our findings did not align with this expectation, possibly due to the fact that all the patients in our cohort had unripe cervixes and required induction.

The intensity of study lies in adoption of a novel biomechanical measurement technique known as the aspiration method. While aspiration devices have been tested for over a decade, previous research primarily focused on non-pregnant women or pregnancies at risk of preterm birth [7]. As far as we are aware, none of these studies utilized this technique prior to commencing labor induction.

We extended invitations to 56 women to take part in our study, and only 11% declined participation, citing the extended vaginal assessment prior the induction process as their reason. It's worth noting

that none of the enrolled patients experienced significant pain, defined as a request to halt the approach. The attachment of the speculum was identified as the most uncomfortable aspect of the process. Importantly, we did not encounter any medical or technical complications, except in one instance where a minor technical issue arose due to excessive vaginal mucus, necessitating the replacement of the probe.

In light of these results, we can deduce that the aspiration method proves to be a well-tolerated and secure measurement technique, rendering it viable for practical use in labor induction. This stands as a pivotal prerequisite for forthcoming clinical investigations geared towards assessing the relevance of this measurement in clinical aspect.

We did not observe any noteworthy correlation between closure pressure and the time it took to enter the active phase of labor or the duration of labor after induction in our cohort study. Nevertheless, it is crucial to interpret these findings cautiously, considering the preliminary nature of this study. The number of women included in our research is inadequate for establishing definitive conclusions regarding the connection between cervical stiffness measurements and their quantitative relationship with the duration of labor following induction.

Additionally, this study has certain limitations, including the heterogeneity in the medications used for labor induction and the non-appearance of a rigorous "induction protocol" for test of our subjects. In order to approve findings, a larger population study and a more standardized protocol for induction has to be necessary.

Conclusion

The innovative bio-mechanical assessment of the cervix, using the "aspiration technique", has shown both technical viability and acceptability in the context of labor induction. Among all the measurement approaches utilized in this study, it's noteworthy that the "Bishop score" consistently emerged as the most effective predictor of the duration of labor following induction.

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