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Original Research Article

Investigation on Utilisation of Biomechanical Measurements of the Cervix for Labor Prediction

Priyanka Kumari[1], Rahul Ranjan[2], Krishna Sinha[3]

[1]Senior Resident, Department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India,
[2]Senior Resident, Department of General Surgery, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India,
[3]Associate Professor, Department of Obstetrics and Gynaecology, Jawaharlal Nehru Medical College & Hospital, Bhagalpur, Bihar, India,

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Corresponding Author: Krishna Sinha
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Abstract

Objective: The induction of labor is a frequently performed procedure in the field of obstetrics. The capacity to anticipate the length of labor has the potential to enhance both planning processes and patient happiness. The main objective of this research was to assess the efficacy of a novel biomechanical assessment approach for the cervix, using the aspiration method, in predicting the length of labor subsequent to induction.

Study design: The study used a prospective single-center design. The inclusion criteria for this study consisted of nulliparous pregnant women with an unfavourable cervix who required induction of labour. The study included the use of digital assessment (Bishop score), sonographic evaluation (cervical length and cervical consistency index (CCI)), and aspiration measures (closure pressure) of the cervix. These measurements were then compared to the duration of labour. The study investigated the technical feasibility and acceptability of the measures.

Findings: The sonographic and aspiration measures did not exhibit any technical problems. The measurement of the Bishop score has been documented as the most uncomfortable evaluation. There exists a substantial correlation between the duration of the active phase of labor as well as the time to delivery and the Bishop score, whereas no such correlation is seen with respect to cervical length, cervical collagen content index (CCI), or cervical closure pressure.

Conclusion: In conclusion, the use of the aspiration approach for biomechanical evaluation of the cervix has been shown to be both technically possible and well-received. No significant connection was seen among our limited sample between closure pressure and the length of labour.

Introduction

Methods that are effective, accurate, and repeatable may be used to quantitatively evaluate the biomechanical features of the uterine cervix. These assessments have the potential to predict the outcome of labour induction or determine the heightened likelihood of spontaneous preterm birth. The presence of a rigid cervix may suggest unsuccessful induction of labour, whereas a pliable cervix may be associated with an increased likelihood of premature birth. In the latter scenario, it is essential to identify patients who are at risk as a fundamental need in order to implement preventative measures or promptly mitigate its repercussions. The risk of preterm birth may be determined by considering many indicators such as cervical length, maternal characteristics (e.g., age, height, and obstetric history), and biomarkers (specifically, foetal fibronectin) [1-7]. The use of biomechanical cervical evaluation for this objective is still an emerging approach without established consensus.

The induction of labour is a frequently performed procedure within the field of obstetrics. Approximately 25% of infants in wealthy nations are delivered by induced labor at full term [1]. Induction may be recommended for several medical disorders. The objective is to achieve a successful vaginal birth of a newborn in good health [2]. The capacity to anticipate the effective initiation of labour and its duration has the potential to enhance pregnancy outcomes and enhance women's contentment with their childbirth encounter [2–5]. The cervix assumes a pivotal function in the initiation of labour induction. The

tissue in question is a biochemically active entity that undergoes a remodelling process throughout pregnancy, hence modifying its biomechanical properties in anticipation of childbirth [6]. Throughout the course of pregnancy, the cervix plays a crucial role in the biological process of retaining the developing embryo or foetus inside the confines of the uterus. Subsequently, at an opportune juncture, a significant shift occurs: the cervix undergoes a process of softening, shortening, and dilation, facilitating the expulsion of the developing organism [7,8]. The capacity of the cervix is influenced by many critical mechanical parameters, including cervical mechanical characteristics, cervical geometry, foetal membrane properties and adhesion, static loading, and uterine contractions (8). The changes in biomechanical properties that occur during pregnancy are associated with modifications in the cross-linking, organisation, and distribution of collagen fibres, as well as the glycosaminoglycans and their water content [8,9].

The clinical research under investigation examines the use of the aspiration method as a methodology. The methodology used in this study is rooted in the pipette aspiration technique and was first developed at Eidgenössische Technische Hochschule [22]. The method of pipette aspiration has been effectively used in clinical investigations involving the liver and uterine cervix [6, 23, 24]. Cervical stiffness may be assessed by the application of strain on the cervical epithelium and underlying stroma. There exists a positive correlation between tissue stiffness and the amount of tension necessary to achieve a certain degree of deformation. The findings from the measurements conducted on pregnant individuals indicate a consistent progression of cervical softening during the first two trimesters. However, during the third trimester, the cervix tends to reach a relatively stable condition with a reduced degree of rigidity, hence facilitating the maintenance of the pregnancy. The softness of the cervix is anticipated to undergo a notable change during delivery in contrast to its condition throughout the third trimester. However, there is currently a lack of empirical evidence to support this assertion [9,23]. The objective of this clinical investigation is to assess the viability and reception of a novel methodology for forecasting the length of labour subsequent to induction, among a limited sample of nulliparous pregnant women at term.

Method

The present investigation was undertaken at gynecology department of Jawaharlal Nehru Medical College & Hospital, in Bhagalpur, Bihar, India, after the approval of our local Ethics Committee. During this specific time frame, all individuals seeking labor induction were given an invitation to participate in this research endeavour prior to the commencement of the induction process. Subsequently, the participating patients were provided with formal informed consent. The inclusion criteria for this study consisted of the following: participants who were nulliparous, had a term pregnancy with a gestational age more than 37 weeks, had a singleton foetus with cephalic presentation, and had an unfavourable cervix as indicated by a Bishop score of less than 6. The exclusion criteria for this study encompassed several factors. These factors included difficulties with communication, a planned Caesarean section, any indication of foetal distress upon admission, spontaneous labour with contractions occurring more frequently than 2 per 10 minutes, and technical limitations for aspiration measurements such as active bleeding, severe genital infections, known carriers of HIV, Hepatitis B or C, individuals not receiving treatment for pre-malignant or malignant changes on the cervix, and rupture of the membranes.

The main findings of this research were the time of each measurement and the level of pain reported during the measurements. The assessment of pain was conducted using the Visual Analogue Scale (VAS) scoring system, which ranged from 0 to 10. The secondary goals of this study included the examination of the relationship between these measures and the length of time required for induction until the active phase of labour and till delivery, the method of delivery, and the well-being of the foetus. The active phase of labour is characterised by the onset of regular and painful uterine contractions, resulting in progressive cervical dilation after reaching a dilatation of 3 cm. The decision was made to proceed with a failed induction in the case when a patient did not progress to the active phase of labour during a 72-hour period of cervical ripening. The assessment of foetal well-being was conducted using the Apgar score at five minutes postpartum, as well as the need for admission to the neonatal care unit.

The topic of interest pertains to measurements.

Sonographic measurements were conducted utilising a Voluson1 mobile ultrasound equipment for all ultrasonographical examinations. The measurement of cervical length and CCI consistently used a transvaginal probe operating at a frequency range of 6-9 MHz. The measurement of cervical length was obtained by calculating the linear distance between the internal and external cervical os, while eliminating the endocervical funnel [25]. The approach used to assess the CCI was based on the methodology outlined by Parra-Saavedra et al. (2018) [18].

Measurement of aspirations: The aspiration apparatus developed by Badir et al. [23] was used

in our study. Following the use of a speculum to expand the vaginal canal, the tube's aperture was positioned perpendicularly on the anterior lip of the cervix, namely at the 12 o'clock position. As the vacuum pressure increased, the cervical tissue underwent suction and conformed to the shape of a spherical cup inside the tube. The pressure required to induce a deformation of up to four millimetres in the tissue is referred to as the closure pressure (Pcl), which is the resultant value obtained from this measurement. The experiment included doing three iterations of aspiration at a consistent, predetermined site. The temporal duration between each cycle was a matter of seconds. The examination of cervical stiffness was conducted only using data obtained from the first cycle, since it accurately reflects the physiological condition of the tissue.

The topic of interest pertains to digital measurements.

The Bishop score, as delineated by Bishop (10), was assessed by a proficient obstetrician just before to the initiation of labour induction. The obstetrician responsible for providing medical care was unaware of the outcomes of the aforementioned measures.

The process of initiating labor artificially

The process of inducing labor included the administration of prostaglandins, namely Prostin E21 or Propess1, in order to alter the cervical favorability. In this case, a cervix that had been partially erased was seen, with a minimum dilation of 3 cm. Subsequently, an amniotomy procedure was conducted. In order to enhance labor efficiency, the administration of oxytocin was used, with dosage levels gradually increased in accordance with the local protocol, until the desired level of uterine contractility was attained.

The field of statistics is concerned with the collection, analysis, interpretation, presentation, and organisation

In instances when the distribution of continuous data is skewed, the descriptive statistics used are the median and interquartile range. Conversely, in cases where the distribution is symmetric, the mean and standard deviation are utilised. The frequencies and percentages were shown for categorical variables. Linear regression was used to assess the linear relationship between the measures and the duration of the active phase of labour, as well as the duration till vaginal delivery. Patients who did not progress to the active phase of labour were eliminated from the first study, whereas patients who had a caesarean section were excluded from the subsequent analysis. The statistical significance of the results was determined using a p-value threshold of less than 0.05.

Results

During the designated study period, a total of 28 patients were extended invitations to participate in this research endeavour prior to the commencement of the induction of labour process. A total of six women, accounting for 21% of the sample, were eliminated from the study according to the specified exclusion criteria. Additionally, three women, representing 11% of the sample, declined to participate in the study. A total of nineteen women, accounting for 68% of the sample, were subjected to analysis.

The factors contributing to induction included both maternal (37%) and foetal (63%) considerations. In all instances, prostaglandins were used to alter cervical favorability, subsequently accompanied by either an amniotomy procedure and/or the injection of oxytocin. A total of 19 women participated in the study, out of whom 15 individuals, accounting for 81% of the sample, had a successful induction of labour resulting in a vaginal birth. Out of the total sample of 19 women, it was seen that four individuals, constituting about 19% of the group, required a Caesarean section. The reasons for these interventions were identified as failed induction in two cases, non-reassuring foetal heart rate in one case, and cephalopelvic disproportion in another case. The duration from the initiation of induction to the onset of active labour exhibited a range of 4 hours and 45 minutes to 64 hours, with a median duration of 15 hours and 20 minutes.

The duration from the start of induction to the point of delivery exhibited a range of 9 hours and 13 minutes to 72 hours and 16 minutes, with a median duration of 24 hours and 9 minutes. In seventeen instances, the Apgar score at five minutes was recorded as 9 or 10, accounting for 89% of the cases. In four instances, including 19% of the cases, admission to the neonatal care unit was deemed required due to various factors, including perinatal hypoxia, low birth weight, congenital heart problem, and hyperbilirubinemia.

The measurements obtained by the use of sonography

The sonographic measures included the assessment of cervical length and the cervical canal index (CCI). The range of cervical length observed in the study population ranged from 9 mm to 43 mm. The recorded measurement for the cervical length was determined to be 22 mm. The Consumer Confidence Index (CCI) exhibited a range of values spanning from 47% to 80%, with a central tendency indicated by a median CCI value of 63%. The average length of the sonographic measurements was around 3 minutes. All participants in the study did not experience any discomfort throughout the measuring process. The Visual Analogue Scale (VAS) scores ranged from 0

to 3, with a median value of 0. There were no instances of technical problems. A slight association was seen between cervical length and the time interval until the active phase of labour ($r = 0.412$, $p = 0.101$), as well as between cervical length and the time interval till delivery ($r = 0.376$, $p = 0.168$). However, these correlations were not statistically significant. Similar findings were seen for the connection between CCI and the time interval until the active phase of labour ($r = 0.306$, $p = 0.232$) or the time interval until delivery ($r = 0.310$, $p = 0.260$).

Measurement of aspirations

Three cycles of aspiration were conducted at a consistent location. The temporal duration between each cycle was a matter of seconds. The first round of aspiration measurements revealed closure pressures ranging from 11 mbar to 81 mbar, with a median closure pressure of 36.5 mbar.

The average length of the whole process, including three aspiration cycles, was 4 minutes. All individuals in the study did not experience any discomfort while doing the measures. The Visual Analogue Scale (VAS) scores ranged from 0 to 4, with a median value of 1. Upon ocular examination after the measures, there were no indications of trauma or bleeding. The measurements were conducted without encountering any significant technological issues. In two instances, about 11% of the cases, the visibility of the tube placement was challenging owing to the presence of vaginal mucus. In one of these cases, it was necessary to change the probe during the process as it was obstructed by the mucus. There was no statistically significant link seen between the closure pressure and the time interval until the active phase of labour ($r = 0.216$, $p = 0.421$), as well as between the closure pressure and the time interval till delivery ($r = 0.149$, $p = 0.612$).

The topic of interest pertains to digital measurements.

The Bishop score exhibited a range of values from 0 to 6, with a central tendency indicated by a median score of 3. The participants universally reported that this particular test elicited greater levels of discomfort compared to the study assessments. The Visual Analogue Scale (VAS) scores ranged from 1 to 5, with a median value of 3. A significant statistical link was seen between the Bishop score and the time interval until the active phase of labour, with a Pearson correlation coefficient of 0.656 ($p = 0.004$). In comparison to the time interval till delivery, the linear correlation exhibited a much greater relationship, with a correlation coefficient of $r = 0.767$ ($p = 0.001$).

Discussion

A research was conducted to assess the clinical use of a novel biomechanical assessment approach for the cervix, using the aspiration method, in predicting the length of labour after induction. In our study, we conducted a comparison between the measurement in question and other established metrics, including the Bishop score, sonographic cervical length, and CCI. The aspiration method is regarded as a secure and well-tolerated diagnostic procedure in addition to digital and sonographic examinations. In our first investigation, we did not see a statistically significant association between closure pressure and the length of labour after induction. However, it is important to interpret these findings cautiously due to the limited statistical power of our research in connection to this particular outcome measure.

Extensive research has previously been conducted to investigate the association between cervical tissue, as assessed by various approaches, and gestational age. In this study, Parra-Saavedra et al. provided a description of cervical length patterns throughout pregnancy. They observed that cervical length remained rather stable up to 30 weeks of gestation, after which it exhibited a gradual reduction. The observed pattern of shortening deviates from that which was reported for the CCI, as a linear decrease of the CCI was noted with increasing gestational age [18]. In a similar vein, Badir et al. observed a consistent decline in closure pressure with the use of the suction technique throughout the first two trimesters, which was then followed by a stabilisation phase characterized by low values in the third trimester [9,23]. Both investigations demonstrated that cervical tissue undergoes a gradual softening process throughout gestation, although cervical length only decreases during the third trimester [19]. The findings of our study align with the measurements reported in the aforementioned research during the third trimester of pregnancy. It is anticipated that the cervical tissue will exhibit a notable decrease in firmness during the hours leading up to birth. This observation did not align with the findings of our investigation, perhaps due to the fact that the cervices of the patients in our group were uniformly unripe, necessitating the use of induction methods.

Prior research has examined the Bishop score and cervical length as potential predictors of effective induction of labor. However, the findings of these studies did not provide definitive conclusions [11,12,16,26,27]. The knowledge on CCI in the context of induction of labor has been limited till recent times. A recent research elucidated the correlation between Cervical Collagen Integrity (CCI) and the likelihood of undergoing a caesarean birth subsequent to a scheduled induction of labour.

No significant correlation was seen between the CCI and the aforementioned risk [28]. Within our limited sample cohort, we did not see a statistically significant association between the Charlson Comorbidity Index (CCI) and the duration of time until delivery after induction.

One notable aspect of this research is the use of a novel biomechanical measurement approach known as the aspiration method. The concept of aspiration has been testing for over a decade. Nevertheless, the aforementioned research have mostly focused on women who are not pregnant or had preterm pregnancies [7,9]. To the best of our current knowledge, none of the individuals had conducted testing on this approach prior to commencing the induction process. A total of 28 female participants were approached for the study. It was observed that 11% of these individuals declined to take part in the research due to their reluctance to undergo an extra vaginal examination prior to the induction process. No considerable discomfort was reported by any of the participating patients, as indicated by their request to cease the operation. The participants indicated that the insertion of the speculum was seen as the most discomforting aspect of the medical process. There were no medical or technical issues observed. One of the instances encountered a minor technical issue due to an abundance of vaginal mucous, resulting in the need to replace the probe. Based on the aforementioned data, it can be inferred that this particular approach has a high level of tolerance and safety as a measurement, so making it a viable option for use in the clinical practice of an induction. The aforementioned condition has utmost significance as a prerequisite for forthcoming clinical investigations aimed at assessing the clinical significance of this particular parameter.

Within our limited sample size, there was no statistically significant link seen between closure pressure and the duration of the active phase of labor or the time until delivery after induction. Given the exploratory nature of this investigation, it is imperative to use significant care when interpreting these findings. The sample size of women included in this research is insufficient to establish definitive correlations between assessments of cervical stiffness and their quantitative association with the length of labor after induction. One further limitation of our research pertains to the variability in the medications used to initiate labor, as well as the lack of a standardised induction regimen for the participants in our study. In order to ensure the validity of our results, it will be necessary to conduct a research with a bigger population size and implement a more rigorous induction process.

Conclusion

The aspiration approach has shown technical feasibility and acceptability for the biomechanical assessment of the cervix in the context of labor induction. Among the several techniques of measurement used in the field. The study found that there is a relationship between the Bishop score and the time interval until the active phase of labor and the time interval until delivery. Specifically, the Bishop score was identified as the most reliable predictor of the duration of labor following induction. In order to ensure the validity of our results, it will be necessary to conduct a research with a bigger population size and implement a more rigorous induction process.

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