Nigerian Medical Journal
NIGERIA MEDICAL ASSOCIATION
Print ISSN 0300-1652, E-ISSN 2229-774X

Original Research

Cervicovaginal fetal Fibronectin in Predicting Success of Induced Labour among Nulliparous Women.

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Abstract

Background: Induction of labour is a routine and common obstetric intervention which aims at achieving successful vaginal delivery. Over the years, attempts have been made to find a pre-induction test that can predict the success of induced labour, which may also serve as a selection criterion for determining which women should undergo labour induction. The study aims to determine whether the presence of fetal fibronectin in the cervicovaginal secretion can predict the success of induced labour.

Methodology: This was a cohort study involving 137 nulliparous women at term undergoing induction of labour. The presence of fetal fibronectin in the cervicovaginal secretion was determined using a fetal fibronectin rapid immunoassay kit. Induction of labour was done using misoprostol.

Results: Data obtained were analysed using statistical product and service solutions (IBM-SPSS) version 20.0. Data obtained were tested for normality of distribution and compared by Chi square, Students' t-test, or Mann-Whitney U as appropriate. A p-value of less than 0.05 was regarded as significant. The rate of vaginal delivery was not significantly different between fetal fibronectin positive and negative women (65% vs. 66.7%, p value—0.839). Women who were positive for fibronectin had a significantly shorter mean duration of induction (22.8±6.1 hours versus 30.1 ± 11.1 hours, P value of 0.015), had higher bishop's scores, and required fewer doses of misoprostol. Regression analysis did not find fetal fibronectin to be predictive of vaginal delivery.

Conclusion: The Presence of fetal fibronectin was not predictive of successful labour induction. Its presence may possibly be associated with a relatively shorter duration of induction.

Keywords: Fetal Fibronectin; Induction of Labour; Misoprostol; Bishop's Score.

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How to cite: Archibong MS, Sangolana MO, Olomola OV, Amuda M, Ugwu OT, Adetunji LN, Ojo OD, Ubom AE, Ayegbusi EO, Orji EO. Cervicovaginal fetal fibronectin in predicting success of induced labour among nulliparous women. Niger Med J 2025; 66 (3):904-914.https://doi.org/10.71480/nmj.v66i3.593.

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Introduction

Induction of labour is the artificial initiation of labour after the age of fetal viability for the purpose of achieving vaginal delivery. It is one of the most performed obstetric interventions, which has been on the increase over the years, and it is indicated when the interest of the mother or baby or both is better served by delivery than allowing the pregnancy to continue. [1,2,3]

Successful vaginal delivery is the desired end point of induced labour; therefore, the chance of success is a principal consideration when a decision to induce labour is reached.[4,5,6]There appears to be a need for reliable and clinically usable pre-induction characteristics/markers that can predict labour induction success or failure that will permit informative counselling for a maternal decision to either delay induction or opt for Caesarean delivery if the chance of induction failure is high.[7,8]

Currently, there is no strong evidence to suggest the most dependable method for predicting successful vaginal delivery in women undergoing induction of labour.[9] If such evidence becomes available, clinicians will be guided appropriately in the selection criteria for patients. Over the years, it has been established that pre-induction cervical status is one of the most important factors for successful vaginal delivery; as such, information about cervical ripeness is important when induction of labour is considered. The bishop's score is the most common method in use to assist the clinician in assessing the "ripeness" of the cervix. Despite the different modifications, the bishop's score remains the most popular way of assessing the cervix for ripeness, but its objectivity and ability to predict vaginal delivery have been contested.[10-15]A reliable and better-tolerated method of pre-induction assessment than the bishop's score would be a helpful tool in the assessment and counselling of women planned for cervical ripening and labour induction.

To find an objective and reliable predictor of successful induction of labour in women planned for labour induction, different biophysical and biochemical methods have since been proposed to predict the likelihood of vaginal delivery in patients undergoing induction of labour. [16,17]

Fetal fibronectin (fFN) is a basement membrane glycoprotein produced by fetal and placental tissues. When delivery is imminent, fFNenters cervical and vaginal secretions, and therefore may become detectable. It has been reported to be an indicator for premature delivery and can be used as a complementary test to confirm the clinical diagnosis of premature rupture of fetal membranes.[18-22]Therefore, it has been hypothesized that in those patients undergoing cervical ripening and induction of labour at term with evidence of fFN in the cervicovaginal secretions, it could be easier to induce labour as a result of these changes.

This study aimed at assessing the usefulness of fFN in predicting successful vaginal birth in women undergoing induction of labour.

Materials and Methods

This cohort study was conducted between April 2019 and December 2020. Research approval with protocol number: ERC/2019/04/13 was obtained from the Institutional Ethics and Research Committee. The study population was nulliparous women who presented for induction of labour during the period of study. Inclusion criteria were women with singleton fetuses and intact fetal membranes, gestational age between 37 weeks and 42 weeks. Exclusion criteria were women with Preterm fetuses, multiple gestation, ruptured membranes and or vaginal bleeding, women who had vaginal examination or sexual intercourse in the preceding 24 hours and women planned for induction with another method aside misoprostol.

A purpose-designed proforma was used to obtain information on sociodemographic, obstetric, and other variables. Their antenatal records were reviewed to determine the indication for induction and confirm the gestational age.

The sample size was determined using the formula for comparison of proportions [23]

$$\mathbf{N}= \frac{2(Z_a + Z_b)^2 P(1-P)}{(P1-P2)^2}$$

Where N is the sample size,
Z_a is the desired level of statistical significance (typically 1.96 for a 0.05 significant level)
$Z_b$is 0.842 from the statistical (z) table at 80% power

P1 is the proportion of women who are fFN positive and did not achieve vaginal delivery, from a previous study by Droulez et al, this was reported to be 21.85%.

P2 is proportion of women who are fFN positive and are expected not to achieve vaginal delivery from the proposed study. This will be set at 70% reduction of P1, giving a P2 value of 6.55%.
P is P1 plus P2

Substituting the values, $N= 2 \frac{(1.96 + 0.842)^2 (0.284) (1-0.284)}{(0.1535)^2} = 135$

Allowing for an attrition rate of 10%, N will be (10% of 135) + 135= 14+135= 149

Fetal Fibronectin Testing: This was done before the digital assessment of the cervix. A sterile disposable Cusco's speculum was gently introduced into the vagina to expose the cervix and the posterior vaginal fornix. The sample was obtained from the patients using a Dacron polyester-tipped swab. The vagina was not cleaned with any antiseptic agent before introducing the tipped swab as this may interfere with the result. The swab was gently introduced into the vagina up to the cervical canal and gently rotated after which the swab was placed in the posterior vaginal fornix to ensure proper saturation with the cervicovaginal secretions. The swab was then taken to the side lab to test for the presence of fetal fibronectin.

The presence of fetal fibronectin in the cervical vaginal secretion was determined using a rapid chromatographic immunoassay test kit. The **Encode Zhuhai kit (medical engineering China FFN502 CE/ ISO9001/ ISO13485**) was used for this study. The test kit detects fetal fibronectin at a concentration of at least 50ng/ml. This test adopts the principle of the double antibody sandwich method and colloidal gold immune chromatography. Specimens are combined with an antihuman fibronectin-gold colloid conjugate and passed through a membrane containing the monoclonal antibody, which is specific to fetal fibronectin. If the fFN is positive, anti-fibronectin complex binds to the membrane, forming a visible line. This test was interpreted as positive if both the test and control lines were visibly coloured; if only the control line was coloured, the test was interpreted as negative. If only the test line was coloured or no line was coloured, the test was interpreted as invalid.

Induction of labour: Women who met the inclusion criteria had labour induced with Misoprostol (Cytotec®, Pfizer pharmaceuticals, PL 00057/0956)**.** Prior to induction, the lie and presentation of the fetus were confirmed, and a cardiotocogram was done for all patients to ascertain fetal status.
The cervix was assessed digitally to determine the Modified Bishop's score. After the cervical assessment, 25 micrograms of misoprostol were inserted into the posterior vaginal fornix. This was repeated every 6 hours until labour was established or till a maximum of 4 doses. Women in established

labour did not have further doses of misoprostol. Women in the active phase of labour were assessed for adequacy of contractions; those not having up to 3 to 5 contractions lasting between 40-60 seconds had their labour augmented. Augmentation of labour was done with 5 international units of oxytocin (Syntocinon®, Novartis pharmaceuticals, UK, PL 00101/0960) in 500mls of 0.9% normal saline and commenced at 10 drops per minute with incremental dose and interval of 10 drops and 30 minutes respectively till adequate contractions were reached or a maximum of 60 drops per minute. Partographic monitoring of labour was ensured for all patients.

Data Analysis: Data obtained was analysed using the statistical product and service solutions (IBM-SPSS) version 20.0. Data obtained were tested for normality of distribution and compared by Students' t-test or Mann Whitney U as appropriate. Regression analysis was done to find out if fetal fibronectin was an independent predictor of successful vaginal delivery.

Results

Over the study period, a total of 137 women who met the inclusion criteria were recruited. Cervicovaginal secretion was positive for fetal fibronectin in Eighty (58.4%) of the participants, while fifty-seven (41.6%) of the participants had a negative test result for fetal fibronectin.

There was no significant difference with respect to mean age, weight, height, and gestational age between women who were fibronectin positive and those who were negative. The sociodemographic and antenatal characteristics are depicted in Table 1

Table 1: Sociodemographic and Antenatal Characteristics.

Variables	**fFN Positive n= 80**	**fFN Negative n=57**	**P Value**
Mean Age (Years)	30.65 ± 6.31	29.81 ± 6.50	0.99
Mean Weight (Kg)			
Mean Height (Cm)	72.92 ± 11.80	77.58 ± 12.02	0.69
Mean Gestational Age (Weeks)			
Indication For Induction (%)	159.04 ± 6.59	159.85 ± 6.56	0.79
Postdated pregnancy			
Hypertension	39.03 ± 1.89	38.79 ± 4.31	0.38
Diabetes			
Fetal growth restriction			
Fetal death	33.8	33.3	
Others			
	15.0	22.8	
	13.6	8.8	0.59
	16.3	10.5	
	11.3	8.8	
	10.0	15.8	

Rate of vaginal delivery

Ninety (65.7%) of the total participants achieved vaginal delivery while forty-seven (34.3%) had caesarean section. Of the ninety who achieved vaginal delivery, rate of vaginal delivery was not significantly different between participants who were fetal fibronectin positive and those who were fetal fibronectin negative (65% vs. 66.7%, p value—0.839). It was, however, noted that non-reassuring fetal heart rate accounted for 13.8% of caesarean sections among fibronectin-positive women, whereas among fibronectin-negative women, non-reassuring fetal heart rate accounted for 22.8% of caesarean sections.

Induction delivery interval

Mean induction to delivery interval in fibronectin-positive women was 22.8 $\pm$ 6.1 hours, while that of fibronectin-negative women was 30.1 $\pm$ 11.1 hours. This difference was statistically significant with a p-value of 0. 015.The mean induction to active phase interval was also observed to be significantly shorter in women who were positive for fibronectin. (13.9 $\pm$ 4.3 hours versus 20.8 $\pm$ 9.1, P value-- 0.01). Comparison of delivery characteristics is depicted in Table 2.

Table 2: Delivery Characteristics of Participants

Variables	**fFN Positive**	**fFN Negative**	**P-value**
Vaginal Delivery (%)	65	66.7	0.839
Mean Induction to Active Phase Interval in Hours	13.9 $\pm$ 4.3	20.8 $\pm$ 9.1	0.02
Mean Induction to Delivery Interval in Hours	22.8 $\pm$ 6.1	30.1 $\pm$ 11.1	0.02
Vaginal Delivery Within 24 Hours (%)			
Caesarean Section (%)	42.5	26.3	0.02
Indication For Caesarean Section (%)	35	33.3	0.839
Failure to progress			
Non reassuring fetal heart status	21.2	10.5	
	13.8	22.8	0.411

Kaplan-Meier curve (Figure 1) was plotted to know the percentage of women who remained undelivered at each desired time, and it was observed that vaginal delivery was achieved within 24 hours in 42.5 % of those who were fibronectin positive compared to 26.3% of those who were fibronectin negative and this difference was statistically significant (p value = <0.001). Women who were positive for fetal fibronectin were also noted to have a significantly lower oxytocin requirement. The Bar chart (Figure 2) illustrates the Misoprostol requirement.

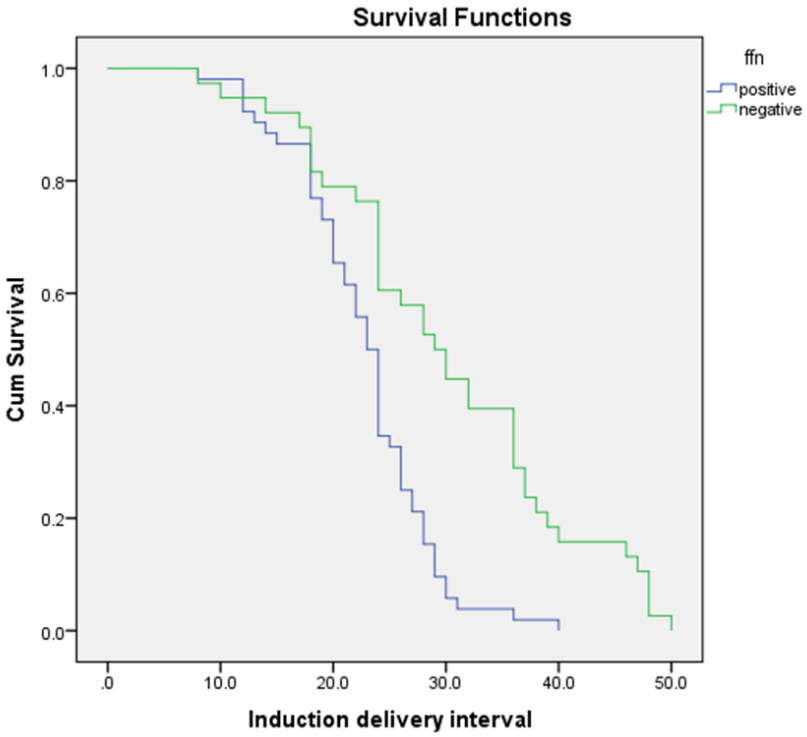

Figure 1: Kaplan Meier curve for Induction delivery interval

Comparison of Doses of Misoprostol

Participants who were positive for fetal fibronectin required fewer doses of misoprostol compared to those who were negative, and this difference was statistically significant (p value-0.002).

For participants who were fibronectin positive, 50% required one dose, and none required a fourth dose. On the other hand, 17.5% of participants who were fibronectin negative required one dose, and 17.5% required 4 doses.

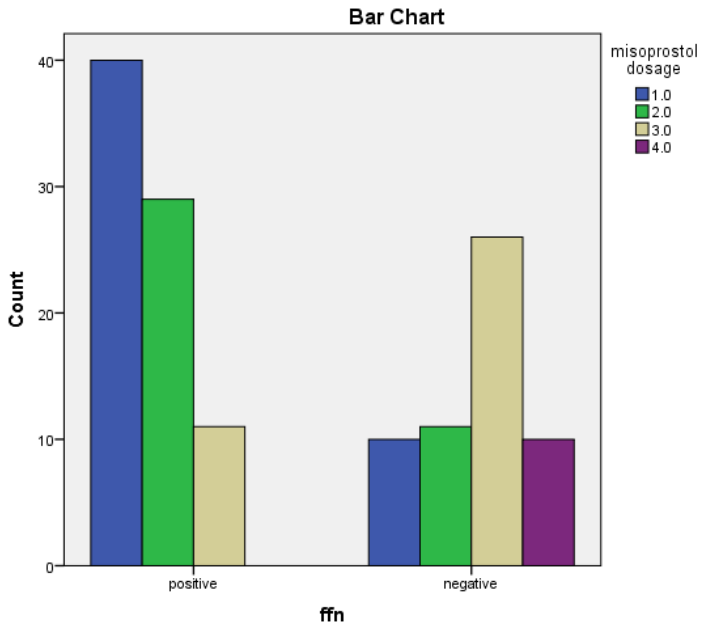

Figure 2: Bar chart for comparison of doses of misoprostol

Regression analysis

This was done using the cox model to determine which of the obstetric variables will be an independent predictor or factor for successful vaginal delivery. Presence of fetal fibronectin was not shown to be a predictor of vaginal delivery as shown in Table 3.

Table 3: Cox Regression Analysis on Prediction of Vaginal Delivery

Variables	Exp (B)	95% confidence Interval	Significance
Age	0.989	0.953-1.027	0.557
Weight	0.998	0.975-1.022	0.865
Height	0.430	0.951-1.022	0.430
Birth Weight	0.863	0.569-1.309	0.487
Bishops Score	1.098	0.930-1.297	0.268
Fetal Fibronectin	0.967	0.879-1.064	0.490

Bishop's Score and Fibronectin

The bishop's score for fetal fibronectin positive women was significantly higher compared to those who were negative (median score of 3, range 0 to 6 versus median score of 2, range 0-5).

The Box plot (Figure 3) compares values for bishop's score.

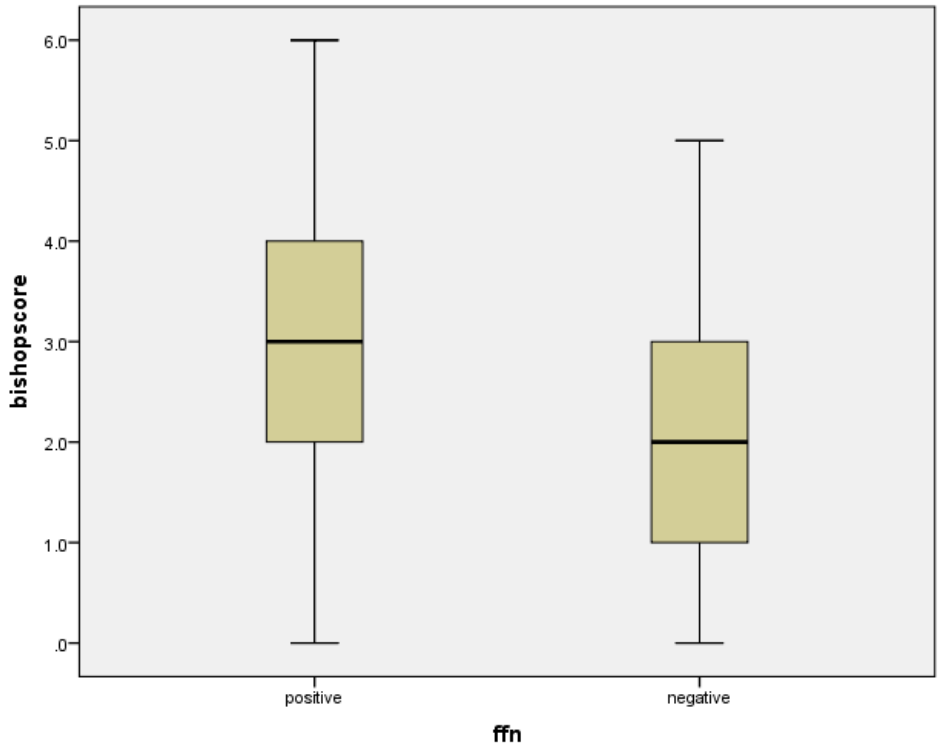

Figure 3: Box Plot comparing the median, upper and lower quartile, minimum and maximum values of the bishop's score between fibronectin positive and fibronectin negative women.

Discussion

Over the years, there has been a quest for a reliable marker and predictor of successful induction of labour to guide clinicians appropriately in the selection of patients for induction of labour. Such a marker would be one that is cheap, less subjective, and accurate. Research has also been done into the various possible factors that may influence the success of labour induction. This study examined the presence of fetal fibronectin in the cervico-vaginal secretion as a predictor of successful vaginal delivery.

This study showed that women who were fibronectin positive did not differ significantly from those who were negative in terms of rate of vaginal delivery. (65% vs 66.7%; p value—0.839). Similarly, the difference in rates of vaginal delivery for positive and negative result reported by Scicione et al (55.8% versus 53.3%), Droulez et al (78.15% versus 78.22%), Bailit et al and Ojutiku et al were not statistically significant.[18,25,27,28] Though Droulez et al reported higher rates of vaginal delivery for both positive and negative results, the higher rate of vaginal delivery reported by Droulez et al may in part be attributed to the heterogenous parity of the participants as women with higher parity were also included in the study and regression analysis found parity to be associated with successful induction/vaginal delivery.

In contrast, a statistically significant difference in rates of vaginal delivery between fibronectin positive and fibronectin negative women was reported by Urguh et al (58.3% versus 28%, p-0.014) and Garite et al (85% vs 73%, p=0.05). [24,26]

On regression analysis, fetal fibronectin was not shown to be an independent factor for successful vaginal delivery. This was like the finding of Droulez et al, who found Bishop's score and age to be independent factors for successful delivery.[27] Reis et al, Roman et al, Scicione et al, and Ojutiku et al also did not find fetal fibronectin to be predictive of vaginal delivery.[7,21,24,26]However, Garite et al, Ahner et al, Blanch et al, and Uygur et al found fetal fibronectin to be predictive of successful induction and proposed that fetal fibronectin test should be used as a complementary test to the Bishop's score.[20,22,24,26]

Though the rate of vaginal delivery was not influenced by the presence of fetal fibronectin from our findings, women who were fibronectin positive were observed to have a significantly shorter induction to delivery interval. Furthermore, a significantly higher proportion of women with positive fibronectin results delivered within 24 hours. This is consistent with the findings of Ahner et al, Blanch et al, Uygur et al, and Garite et al. [20,22,24,26] Even for participants who had caesarean section, the time taken to reach the active phase was also observed to be significantly shorter in women who tested positive for fetal fibronectin.

However, Reiss et al, Roman et al, and Droulez et al did not find any significant difference between the two groups in terms of time taken to reach the active phase or total duration of labour.[7,21,28] This contrary finding may be due to the fact that there was no unified/standardized induction protocol in the aforementioned studies.

Another important intrapartum observation was that fibronectin positive women had reduced need for augmentation and required lower doses of augmentation compared to their negative counterparts. This observation was also reported by Scicione et al.[25]The need for higher doses of oxytocin/ need for augmentation in fibronectin negative women may have led to uterine hyperstimulation and diminished blood flow to the placenta with its resultant effect on fetal heart rate pattern which may in part be responsible for most of the indication for caesarean section to be for non-reassuring fetal heart rate pattern in this category of women.

These intrapartum observations may have some application to clinical practice as it may help in informative pre-induction counselling in women planned for induction, preparing the minds of the patients (and the obstetricians) for the possibility of a relatively longer duration of induction and likely need for augmentation, particularly, if the fetal fibronectin is negative. This may be beneficial in allaying patients' anxiety and fear. This information could also be useful in making sound clinical judgments with respect to the route of delivery and offering caesarean section to patients who need urgent delivery in circumstances where a longer duration of induction could pose substantial maternal or fetal risk. Furthermore, these observations/findings will be helpful from an administrative standpoint. Women who are positive for fFN may be better candidates for day-case induction pathways or outpatient monitoring, given their higher likelihood of faster cervical response and reduced pharmacologic requirement. This has potential implications for bed management, staffing logistics, and cost-effectiveness, particularly in very busy tertiary centers.

Results from this study also showed that women with positive fetal fibronectin required a significantly smaller number of doses of prostaglandins for the process of induction. This finding was consistent with that of Ahner et al and Garite et al. [22,26] The fewer doses of prostaglandin requirement did not however influence the overall rate of vaginal delivery. Findings from this study also showed that women who were positive for fetal fibronectin had a significantly higher Bishop's score. This finding is like that reported by Ahner et al and Blanch et al. [20,22]

The fewer doses of prostaglandin and higher Bishop's scores associated with presence of fetal fibronectin may therefore be indicative of the remodeling and connective tissue alteration that occurs in the cervix in preparation for delivery and may suggest that women who are positive for fetal fibronectin are perhaps, more physiologically prepared for labour than their negative counterpart; this finding may partly explain the relative ease with which the process of induction was conducted in this category of women viz a viz the shorter induction to active phase interval, shorter induction to delivery interval and significant proportion of delivery within 24 hours observed in them.

Unlike other studies that reported higher Bishop's scores in fetal fibronectin positive women, Ojutiku et al did not observe higher Bishop's scores in fetal fibronectin positive women. This contrary finding by Ojutiku et al may be attributed to the low power of the study, as only 33 women were recruited for the study.[27]

Strengths and Limitations

This study offers valuable information on the role of fetal fibronectin (fFN) in predicting the course of labour induction among nulliparous women. A key strength lies in the homogeneous study population, which excluded multiparas to control for parity as a cofounder. Additionally, the use of a unified induction protocol with vaginal misoprostol ensured standardization in clinical management.

However, some limitations should be acknowledged. As a single-centre study, the findings may not be generalizable to other populations or settings. The study did not adjust for certain unmeasured confounders, such as fetal position or maternal psychological factors, which are known to be associated with prolonged labour, increased need for augmentation, and higher cesarean section rates, and may have influenced induction outcomes independently of cervical readiness or fibronectin status. Although these variables were beyond the scope of this study, their potential influence on labour dynamics is supported by existing literature and should be considered in future research seeking a more holistic predictive model. Furthermore, while fFN testing was objective, Bishop's score assessment remained subjective and prone to inter-observer variability.

Conclusion

This study investigated the role of fetal fibronectin (fFN) in cervicovaginal secretions as a predictor of successful vaginal delivery in nulliparous women undergoing induction of labour. The findings revealed that although the presence of fFN did not significantly predict the overall rate of vaginal delivery or independently influence delivery outcomes on regression analysis, it was associated with several favourable intrapartum parameters. Women who tested positive for fFN demonstrated significantly shorter induction-to-delivery and induction-to-active phase intervals, required fewer doses of misoprostol, and showed reduced need for labour augmentation. Additionally, fFN positivity correlated with higher Bishop's scores, suggesting better baseline cervical readiness. These findings suggest that fFN, while not a predictor of delivery mode, may serve as a useful and complementary tool for anticipating the length of the induction process. It may assist clinicians in stratifying patients, optimizing resource use, and providing more accurate pre-induction counselling regarding expected labour progression. It may complement traditional methods like the Bishop's score and potentially form part of a multivariate model for guiding induction strategies. Further research is recommended to validate these findings in larger, more diverse populations and to explore the integration of fFN with other emerging predictive markers.

Conflict of Interest: The authors declare no competing interests

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