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The Effectiveness of Foetal Membranes Stripping at 40 Completed Weeks of Gestation on the Prevalence of Late-Term Pregnancies

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Abstract

Background: Post-term pregnancy is a high-risk pregnancy. **Objectives:** This study evaluated the effectiveness and safety of foetal membranes stripping at 40 completed weeks of gestation on the prevalence of late-term pregnancies at the Yaounde Gynaecology-Obstetrics and Paediatrics Hospital (YGOPH). **Materials and Methods:** Our study is a prospective hospital-based cohort study, conducted over a period of 06 months from February 2023 to July 2023. Three hundred and eighty-eight pregnant women at 40 completed weeks of gestation were enrolled into two groups with: exposed group (those with foetal membranes stripping) and unexposed group (those without foetal membranes stripping). Stripping of foetal membranes was done just once. Participants were followed-up till delivery or attainment of 41 completed weeks of gestation. **Results:** Post term delivery was significantly lower in the membrane stripping group compared with the unexposed group (12% vs. 43%; $P < 0.001$). There was a significantly lower mean-time interval from recruitment to spontaneous labour-onset among the membranes stripping group (2.51 ± 0.98 days) compared with the unexposed group (4.33 ± 1.18; $P < 0.001$). Onset of spontaneous labour in the exposed group was 171 (88%) compared to the unexposed group that had 111 (57%) ($P < 0.001$). There was no statistically significant difference in the incidence of premature rupture of membranes and perinatal outcomes.

Conclusion: Stripping of the foetal membranes appears to be an effective and safe procedure in reducing the incidence of late-term pregnancies and duration of pregnancy at term in low-risk population.

Keywords

Foetal, Membranes, Stripping, Prevalence, Late-Term, Pregnancy, Induction, Labour

1. Background

According to the American College of Obstetricians and Gynaecologists (ACOG 2013), Term pregnancy which is defined as pregnancy from 37 completed weeks to 41 weeks + 6 days gestation can be sub-divided into 03 groups: Early term; is pregnancy from 37 completed weeks to 38 weeks + 6 days gestation, Full term; is pregnancy from 39 completed weeks to 40 weeks + 6 days gestation and Late term; is pregnancy from 41 completed weeks to 41 weeks + 6 days gestation. Post-term pregnancy is defined as a pregnancy that continues beyond 42 weeks (294 days) from the day of the last menstrual period (LMP) or 14 days beyond the best obstetric estimate of the date of delivery [1]. Stripping of foetal membranes is one of the oldest but least understood methods to prevent post-maturity [2]. Stripping of the membranes entails the digital separation of the amniotic-chorionic membranes from the lower uterine segment. It causes an increase in prostaglandin metabolites in the maternal circulation as well as local prostaglandin production [3]-[6]. Membrane stripping is cheap, easy to use, and its safety has been confirmed in almost all studies [2] [7] [8]. It has been used either to induce labour or to shorten the length of pregnancy. However, some of these studies were not randomized and had selection bias, and as a result, there is still controversy on the clinical utility of membrane stripping [2].

The prevalence of post-term pregnancy depends on the particular patient population, including factors such as the percentage of primigravid women, the prevalence of obesity, proportion of women with pregnancy complications, the prevalence of ultrasound assessment of gestational age, and the frequency of spontaneous preterm birth. Local practice pattern such as the rates of scheduled cesarean delivery and routine labor induction, also affect the overall prevalence of prolonged pregnancy, particularly as induction of labour before 42 weeks of gestation has increased in recent years [1]. In the United States in 2005, the prevalence of post-term pregnancy was 6% [9]. This was lower than the 10% observed in 1998 [10]. In Wales, the prevalence dropped from 4.6% in 1990 to 2.8% in 1996 [11]. The decline in the prevalence of post-term pregnancy was associated with increasing rates of induction of labour [1] [12]. In Sub-Saharan Africa, including Cameroon, the prevalence of post-term pregnancy is quoted as 8% - 10% of all pregnancies [13]. However, it has been shown that accurate dating in early pregnancy and elective induction of labour at 41 weeks of gestation can reduce the prevalence

to as low as 1% [1] [5] [14] [15]. Our study tries to evaluate the effectiveness and safety of foetal membranes stripping at 40 completed weeks of gestation on the prevalence of late-term pregnancy in the Cameroonian context, with goal to inform clinicians and policy makers.

2. Materials and Methods

2.1. Study Design

We carried out a prospective cohort study.

2.2. Study Duration

The study was conducted within a period of 06 months from February 2023 to July 2023.

2.3. Study Setting

The study was carried out in the Obstetrics and Gynaecology unit of the Yaounde Gynaecology-Obstetrics and Paediatrics Hospital (YGOPH). This is a tertiary hospital, located in Ngousso in Yaoundé, Cameroon. It is well equipped to ensure proper antenatal consultations and proper management of pregnancies.

Created on September 24, 2001 and inaugurated on March 28, 2002 by the President of the Republic H.E. Paul Biya, the YGOPH is the result of the Sino-Cameroonian cooperation. It is a public administrative establishment whose mission is first the improvement of the quality of health care for women, mothers and children in Cameroon.

The Obstetrics and Gynaecology unit of YGOPH has three parts: the maternity ward, the hospitalization wards and the out-patient sub-unit. It has a team of 11 (eleven) Obstetricians-Gynaecologists including: 1 professor, 2 Associate Professors; residents and interns in Obstetrics and Gynaecology; nurses; medical and nursing students; paramedical staff.

On average, about 200 to 250 deliveries are being conducted at the maternity of YGOPH monthly.

This hospital was chosen for this study because of the high attendance rates, materialized by a considerable number of births (on average 200 per month at the YGOPH), and this was in order to reach an acceptable sample size within the set deadlines.

2.4. Study Population

The study population was all pregnant women at term receiving antenatal care at the YGOPH. To be eligible, they conformed to the following inclusion criteria.

2.5. Inclusion Criteria

- Be at 40 completed weeks of gestation (singleton foetus, longitudinal lie, and cephalic presentation).

- Had no contra-indication for vaginal delivery.
- Accepted freely to participate in the study.

a) Exposed group

- With foetal membranes stripping done following their consent for the intervention.

b) Unexposed group

- Women who refused foetal membranes stripping, but consented to be recruited as a control group.

2.6. Exclusion Criteria

- Non-consenting pregnant women.
- All pregnant women with closed cervical os at 40 completed weeks of gestation.
- Pregnancies with scarred uteri.
- Multiple gestation pregnancies.
- Pregnancies programmed for elective surgery.
- Cases with complications of pregnancy.
- All pregnant women who were unsure of their last normal menstrual period and did not have an ultrasound scan dating before 16 weeks of gestation.

The sample population was all pregnant women at 40 completed weeks of gestation receiving antenatal care, with no contraindication to vaginal delivery and whose pregnancy was being adjudged as low-risk pregnancy (singleton foetus, longitudinal lie, and cephalic presentation).

Recruitment gestational age of 40 completed weeks was chosen because participants will be curious and motivated to comply to follow-up care since their pregnancies were already at their expected date of delivery (EDD) hence prevented loss-to follow-up.

At 40 weeks and above will be a fairer representation of the population of pregnant women likely to experience prolonged pregnancy and subsequently induction of labour. Recruitment as from 38 weeks and above may not be a true representation of the proportion of pregnant women likely to go beyond their EDDs because there is a possibility that pregnant women could experience spontaneous onset of labour on or before their EDD.

2.7. Sample Size Estimation

The minimum sample size in each arm was calculated using the formula below;

$$n = \frac{1}{(1-f)} \times \left[\frac{2*(Z\alpha + Z\beta)^2 * p*(1-p)}{(p0-p1)^2} \right]$$

where,

n = The required minimum sample size in each of the study arm.

f = The proportion of study subjects who are expected to leave the study for reasons other than the outcome under investigation = 0.

$Z\alpha$ = The level of significance at 5% (0.05) = 1.96.

$Z\beta$ = Correspond to the statistical power of 90% (0.90) = 1.28.

$p0$ = The proportion of the participants in the unexposed group who are expected to exhibit the outcome of interest (post-term pregnancy) = 10% (0.1).

$p1$ = The proportion of the participants in the exposed group that are expected to exhibit the outcome of interest (post-term pregnancy) = 1% (0.01).

$$p = \frac{p0 + p1}{2}$$

Thus,

$$n = \frac{2(1.96 + 1.28)^2 * 0.055(1 - 0.055)}{(0.1 - 0.01)^2} = 135$$

n = 135.

Each group was allocated at least 135 participants.

The minimum sample size altogether ($2n$) = 270.

Therefore, a total sample size of at least 270 participants was needed for this study. But in order to improve the power of our study, all the low-risk pregnant women at 40 completed weeks of gestation who met the inclusion criteria and provided informed consent (388) were included in the study.

2.8. Ethical Consideration

Ethical approval was obtained from the Institutional Review Board of the Faculty of Medicine and Biomedical Sciences, University of Yaounde 1 (0192/UY1/FMSB/VDRC/DAASR/CSD). Administrative approval was obtained from the YGOPH (392/CIERSH/DM/2023)

2.9. Data Collection

In the antenatal clinic, under aseptic conditions and with participants in decubitus dorsal position, a vaginal examination was carried out on all the individuals by their attending obstetricians. The middle and index fingers of the gloved hand were passed into the vagina; the position, consistency, effacement, cervical os dilatation in centimetres, and the station of the presenting part were determined; and the bishop's score was recorded for all participants. However, for the participants in the exposed group, after assessment of the bishop's score with the examining digits still in the vagina, the middle finger was then passed through the cervical os into the lower portion of the lower uterine segment. Stripping of the foetal membranes was then performed by separating approximately 2 - 3 cm of chorionic membranes from the lower uterine segment using two circumferential movements of the middle finger. Stripping of membranes was done once.

The participants were observed for at least 30 min in the antenatal clinic after membranes stripping, after which they were discharged home with no complications and were advised to come for twice-weekly cardiotocography and were also informed about the possibility of passage of "show." They were instructed to come

to the labour ward if they experienced decreased foetal movement, rupture of the membranes, excessive vaginal bleeding, or onset of labour. Clinical data for each participant were collected and recorded on a Structured questionnaire.

The primary outcome was to determine the proportion of pregnancies reaching an estimated gestational age of 41 weeks and 0 day between the exposed and unexposed groups. The secondary outcome was to compare the time interval between stripping of membranes and labour onset between the two groups for those women who went spontaneously into labour before 41 completed weeks of gestation, as well as to compare pregnancy outcome between the exposed and unexposed group. Intervention in both groups occurred when the study participants did not go into spontaneous labour beyond 41 weeks and 0-day gestation.

2.10. Data Management and Data Analysis

The data collected were entered into Microsoft Excel 2013 and then later transferred to the statistical software EPI INFO version 7, which was used for analysis.

- **Inferential statistics**

The data were presented using a simple frequency table. Statistical analysis of categorical data was performed by the chi-square test. Statistical significance was established at $p < 0.05$. Relative risk (RR) was calculated. Logistic regression to identify independent predictors was done.

3. Results

3.1. Characteristics of the Study Population

A total of 388 women were recruited into two groups with 194 women each, as follows: those who had foetal membranes stripping at 40 completed weeks of gestation (exposed group). The unexposed group was women who had vaginal examination at 40 weeks to assess Bishop's score, without stripping of foetal membranes (Figure 1).

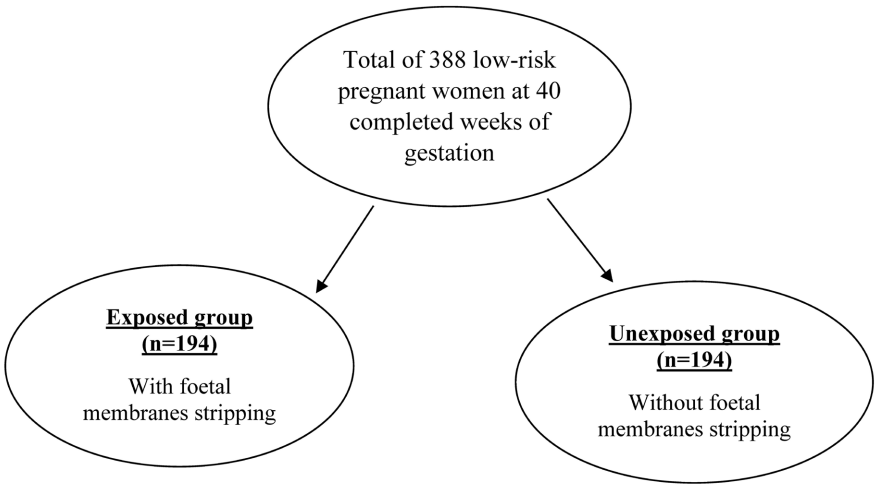

Figure 1. Flow chart of study population.

3.2. Socio-Demographic Characteristics at Recruitment

Most of the pregnant women were of the protestant faith (62% in exposed group and 41% in unexposed group) and had received tertiary education (46% in exposed group and 62% in unexposed group) (Table 1).

Table 1. Socio-demographic characteristics at recruitment.

Characteristic	Exposed group (n = 194)	Unexposed group (n = 194)
Residence		
Rural	20 (10%)	9 (4.6%)
Urban	174 (90%)	185 (95%)
Religion		
Muslim	28 (14%)	37 (19%)
Catholic	31 (16%)	75 (39%)
Protestant	121 (62%)	80 (41%)
None	14 (8%)	2 (1%)
Marital status		
Married	92 (47%)	123 (63%)
Single	49 (25%)	40 (21%)
Others (widowed/divorced/cohabitation)	53 (27%)	31 (16%)
Educational Status		
No formal education	7 (3.6%)	1 (0.5%)
Primary	13 (6.7%)	9 (4.6%)
Secondary	84 (43%)	63 (32%)
Tertiary (High school/University)	90 (46%)	121 (62%)
Occupational status		
Student	23 (12%)	29 (15%)
Housewife	71 (37%)	66 (34%)
Civil servants	33 (17%)	38 (20%)
Formal private sector worker	40 (21%)	39 (20%)
Informal private sector worker	27 (14%)	22 (11%)

3.3. Obstetrical Characteristics at Recruitment

The obstetrical characteristics at the onset of the study were comparable between the two groups. There were no statistically significant differences between the two groups regarding maternal age, parity, body mass index and initial Bishop's score assessment (Table 2).

3.4. Obstetrical Characteristics on Admission

The incidence of delivery at late-term gestation after induction of labour was sig-

nificantly lower in the membranes stripping group compared with the unexposed group (12% vs. 43%; P < 0.001). There was a significant lower mean-time interval from recruitment to spontaneous labour-onset among the membranes stripping group (2.51 ± 0.98 days) compared with the unexposed group (4.33 ± 1.18; P < 0.001). The proportion of those that had spontaneous labour in the exposed group was 171 (88%) compared to the unexposed group that had 111 (57%). This was statistically significant with P-value < 0.001 (Table 3).

Table 2. Obstetrical characteristics at recruitment.

Parameters	Exposed group (n = 194)	Unexposed group (n = 194)	P-value
Mean maternal age (±SD) in years	31.0 (±4.1)	30.5 (±4.7)	0.4
Parity, n (%)			
• Nulliparity	52 (27%)	57 (29%)	0.9
• Primiparity	45 (23%)	43 (22%)	
• Multiparity	97 (50%)	94 (48%)	
Initial Bishop's score category, n (%)			
• ≤7	189 (96.9%)	191 (98.5%)	0.032
• 8 - 13	5 (3.1%)	3 (1.5%)	
Body mass index category, n (%)			
• 18.4 - 24.9	133 (69%)	118 (61%)	0.019
• 25 - 29.9	46 (24%)	69 (36%)	
• 30 - 34.9	13 (6.7%)	7 (3.6%)	
• ≥35	2 (1.0%)	0 (0%)	

Table 3. Obstetrical characteristics on admission compared between the two groups.

Parameters	Exposed group (n = 194)	Unexposed group (n = 194)	P-value
Reasons for admission, n (%)			
• Spontaneous labour onset before 41 completed weeks.	171 (88%)	111 (57%)	<0.001
• Induction of labour for late-term gestation.	23 (12%)	83 (43%)	
Mean gestational age (±SD) of spontaneous labour onset before 41 completed weeks in weeks.	40.25 (±0.10)	40.43 (±0.12)	<0.001
Mean recruitment to spontaneous labour-onset time interval (±SD) in days.	2.51 (±0.98)	4.33 (±1.18)	<0.001

The initial Bishop's scores at recruitment showed no significant difference between the two groups (P = 0.032). However, the pre-induction Bishop's scores at admission for those who finally had induction of labour for late-term pregnancy revealed a statistically significant difference between the two groups (P < 0.001) (Table 4).

Table 4. Comparing pre-induction Bishop's scores between the two groups among those who finally had induction of labour.

Parameter	Exposed group (n = 23)	Unexposed group (n = 83)	P-value
Pre-induction Bishop's score category, n (%)			
• ≤7	4 (17.4%)	82 (98.8%)	<0.001
• 8 - 13	19 (82.6%)	1 (1.2%)	

3.5. Pregnancy Outcomes

The successful rate of vaginal delivery had no statistically significant difference between the two groups. Although caesarean delivery occurred less frequently in the membranes stripping group, the difference was not statistically significant (P = 0.013) (Table 5).

Table 5. Pregnancy outcomes.

Parameters	Exposed group (n = 194)	Unexposed group (n = 194)	P-value
Type of delivery, n (%)			
• Vaginal delivery	175 (90%)	158 (81%)	0.013
• Caesarean section	19 (9.8%)	36 (19%)	

3.6. Maternal and Fetal Complications

Overall, the maternal and foetal complications were similar between the two groups (Table 6 and Table 7). Although maternal discomfort during vaginal examinations was significantly higher in the membranes stripping group (32.0% vs. 8.8%; P < 0.001) (Table 6), the discomfort was not severe enough to require medication in any of the women and was acceptable to the patients. There was no statistically significant difference in the cases of inadvertent spontaneous premature rupture of membranes (PROM) between the two groups (8.2% vs. 5.7%; P = 0.069) (Table 7).

Table 6. Maternal complications.

Parameters	Exposed group (n = 194)	Unexposed group (n = 194)	RR (95% CI)	P-value
PROM	16 (8.2%)	11 (5.7%)	0.47 (0.21 - 1.05)	0.069
Pelvic Discomfort	62 (32%)	17 (8.8%)	0.18 (0.09 - 0.31)	<0.001
Per vaginal bleeding	2 (1.0%)	0 (0%)	0.00	>0.9

Neonatal outcomes were similar in both groups (Table 7). Five neonates in the membranes stripping group and seven in the unexposed group had Apgar score of <7 at 5 min (P = 0.6). There were nine neonatal intensive care unit (ICU) admissions in the membranes stripping group and eleven in the unexposed group (P = 0.6). There were no neonatal deaths in both study groups.

Table 7. Neonatal complications.

Parameters	Exposed group (n = 194)	Unexposed group (n = 194)	RR (95% CI)	P-value
Mean birth weight (±SD) in grams	3.133 (±267)	3.135 (±248)	/	0.5
Apgar score < 7 at 1st min, n (%)	9 (4.6%)	15 (7.7%)	0.11 (0.01 - 0.78)	0.2
Apgar score < 7 at 5th min, n (%)	5 (2.6%)	7 (3.6%)	1.03 (0.14 - 7.51)	0.6
Neonatal ICU admissions	9 (4.6%)	11 (5.7%)	6.80 (0.52 - 187)	0.6

4. Discussion

Stripping of foetal membranes is one method whose efficacy has mainly been assessed as a method of inducing labour. The procedure is safe, easy to perform, and inexpensive. In this study, membrane stripping was used to evaluate its effectiveness in preventing late-term pregnancies, in low-risk pregnant women.

All pregnant women with closed cervices were excluded from the study firstly because an open cervix is a requirement to conduct membranes stripping, given the fact that you have go through the cervix with the examining gloves to get access to the foetal membranes. Secondly cervical massage which as an alternative to membranes stripping in the presence of a closed cervix seems to be highly subjective, although there have been several studies that adopted cervical massage as an alternative to stripping of the membranes [5] [16]. However, this could still be a subject for further studies, given the fact that a closed or an open cervix at term is a reflection of the dynamic nature of the physiological changes of pregnancy and labour onset [17]. The implication is that a woman with an open cervix at term will likely benefit from an objective method of preventing post term pregnancy, rather than a subjective method being used on a closed cervix.

During the conduct of this study, there were no dropouts of participants given the short interval from eventual delivery of less than two weeks. This could also be attributed to the fact that participants were highly motivated more so that their pregnancies were already beyond their EDDs. The exposed group women were therefore curious and readily welcomed the intervention. A dedicated telephone number given to all participants in addition to collecting their telephone numbers for prompt communication might also have contributed to the "no dropout" as they were all reminded the night before their hospital visits. However, this was not

the case in similar studies conducted elsewhere. The study done in Ile-Ife, Nigeria [2], had nine participants that were lost to follow-up and another study done in Istanbul, Türkiye [5] had five "drop-out" of participants; perhaps this was so in these studies because both studies recruited women at term that were yet to reach their EDDs (*i.e.*, at 38-week gestation). This earlier recruitment might have contributed to some of the participants feeling that perhaps there was no danger to their pregnancies and that there was still more time to go and eventually they were lost to follow-up. In another study done in Washington DC [18], there were five dropouts; four of the women dropped out because of the desire to be induced before 41 weeks of gestation, which was their endpoint. The fifth woman dropped out due to the discomfort of membranes stripping, which in their study was done twice weekly. In our study, this was not the case as membrane stripping was done once at 40 completed weeks of gestation for the exposed group.

Stripping of foetal membranes effectively reduced the incidence of late-term pregnancies. The incidence of delivery at late-term gestation after induction of labour was significantly lower in the membranes stripping group compared with the unexposed group (12% vs. 43%; $P < 0.001$). The proportion of those that had spontaneous labour in the exposed group was 171 (88%) compared to the unexposed group that had 111 (57%). This was statistically significant with $P < 0.001$ (**Table 5**). Several studies have shown that fewer women eventually need induction for pregnancy beyond 41 weeks if membrane stripping is performed during antenatal clinic [2] [19]-[21]. All the women who had induction of labour as from 41 completed weeks according to our departmental protocol had late-term pregnancy. Likewise, in the Ile-Ife study [2], one of their primary outcome measures was the proportion of women whose gestation exceeded 41 weeks. Therefore, they carried out induction of labour at 41-week gestation with indication being late-term pregnancy. Studies in Saudi Arabia and in Washington DC also carried out induction of labour at 41-week gestation with indication being late-term pregnancy [18] [21].

However, in most of these studies, the absolute proportion of women that ended up with induction of labour for late-term gestation were lower in both the membranes stripping group and the unexposed group compared to the values from our study. The Ile-Ife study showed that 3% in the membranes stripping group versus 16% in the unexposed group had induction of labour. These lower percentages may be likely due to the fact that recruitment was early (at 38-week gestation), and hence, participants had longer period to go before induction of labour was considered while our study recruited at 40 completed weeks of gestation. Furthermore, there may be a possibility that some of their participants could have experienced spontaneous onset of labour on or before their EDD with or without stripping of the membranes. In other words, there could be a possibility that recruitment at 38 weeks of gestation might not be a true representation of the proportion of women likely to go beyond their EDDs. While, on the other hand, recruitment at 40 completed weeks of gestation might be a fairer representation

of the proportion of women likely to experience late-term pregnancy and subsequently induction of labour.

There was also a significant reduction in the recruitment to spontaneous labour-onset mean-time interval in our study, (2.51 ± 0.98 in exposed group vs. 4.33 ± 1.18 in unexposed group, P < 0.001). Similar observation was made by studies in Ile-Ife Nigeria [2], Abuja Nigeria [22] and Washington DC [18]. These observers found a significant lower mean-time interval from recruitment to spontaneous labour-onset among the stripping group.

It was observed that the Bishop's scores at recruitment were slightly different between the two groups with slightly higher scores in the stripping group compared with the unexposed group, although this was not statistically significant (P = 0.032). This slight difference in Bishop's scores at recruitment between the two groups could have been minimized by stratification of the initial Bishop's scores and the parity. Even though the overall Bishop's scores at recruitment showed no significant difference between the two groups (P = 0.032), this was not the case when the Bishop's scores between the two groups among those who had induction of labour were compared. The pre-induction Bishop's scores assessment at admission revealed a statistically significant difference between the two groups (P < 0.001) with significantly higher Bishop's scores on admission in the membrane stripping group compared with the unexposed group. Similar findings were observed by most researchers [2] [8] [16] [22].

Nineteen women in the membrane stripping group and thirty-six women in the unexposed group had caesarean delivery (9.8% vs. 19%, P = 0.013). This difference was statistically not significant, which was also the discovery made in Abuja Nigeria study [22]. However, a similar study in USA observed a significantly decreased caesarean delivery rate with membrane stripping but due to the limitation of their sample size, they remarked that a larger trial was needed to confirm this finding. Another similar study in England, however, observed an increased risk of caesarean delivery in the stripping group, but the difference did not reach a statistical significance. The effect of membrane stripping on caesarean delivery rate remains inconclusive for now and must await the result of larger trials and more reviews [23] [24].

In our study, stripping of membranes did not significantly alter the mode of vaginal delivery (90.2% vs. 81%; P = 0.013). Most studies made similar observations [5] [22]. No significant differences were observed in maternal and foetal complications in this study. The safety of stripping of membranes is confirmed in almost all studies [2] [5]-[8] [19]. This was the case in our study where it was observed that neonatal outcome including birth weight, Apgar Scores at 5 min, and admission into neonatal ICU were similar between the two groups. Apgar Score <7 at 5 min was considered birth asphyxia. Several studies [2] [21] [22] also adopted Apgar Score <7 as birth asphyxia. It was also observed that participants expressed more satisfaction with birth process despite slightly more initial discomfort after stripping.

5. Conclusion

Stripping of foetal membranes may appear to effectively reduce the incidence of late-term pregnancies, by lowering the mean-time interval from recruitment to spontaneous labour-onset, and also improve the pre-induction Bishop score. The procedure appears safe as it doesn't increase the risk of maternal and neonatal adverse outcomes.

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Conflicts of Interest

There are no conflicts of interest.

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