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Research Paper

Concomitant Use of Misoprostol and Transcervical Foley Catheter Versus Misoprostol Used Singly For Induction Of Labour: A Randomized Controlled Trial.

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Abstract
Background: *Induction of labour is an obstetric intervention resorted to when it is expedient that delivery is undertaken when indicated. The use of low dose intravaginal misoprostol used singly or in combination with intracervical extra- amniotic Foley Catheter for induction is safe and effective.* ***Objective:*** *The study set out to determine and compare, the effectiveness of combining intracervical extra amniotic Foley catheter and low dose vaginal misoprostol with vaginal misoprostol alone for induction of labour among parturients with an unfavourable cervix.* ***Methodology:*** *172 eligible parturients admitted for cervical ripening were randomized such that one group received 25µg of intravaginal misoprostol and intracervical Foley catheter concurrently and the other group received 25µg of intravaginal misoprostol alone. The primary outcome was time expended to deliver. All data obtained were analysed using SPSS version 22 and statistical significance was set as $p < 0.05$.* ***Result;*** *There were no differences between the groups concerning gestational age, parity, Bishop score, duration of augmentation of labour, birth weight, or indication for induction, foetal distress caesarean delivery and neonatal outcomes. There was a significant difference in the time of onset of uterine contraction, tachysystole and active phase labour. The induction-delivery interval was significantly shorter in the combined misoprostol-Foley group: compared to the misoprostol-only group (15.0 ± 3.5 vs. 19.1 ± 5.0h, P=.001).* ***Conclusion:*** *The use of misoprostol in combination with transcervical Foley catheter has a shorter induction delivery interval, a shorter period to ripen the cervix and initiate uterine contractions when compared with misoprostol alone.*
Keywords: *Induction of labour, misoprostol, Foley catheter, induction-delivery interval*

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I. INTRODUCTION

Induction of labour (IOL) is the artificial initiation of uterine contractions after the gestational age of foetal viability and before the spontaneous onset of contractions, for the purpose of achieving vaginal delivery of the product of conception.[1] It is a frequently undertaken intervention in obstetric practice when the risks of continuing pregnancy prevail over the benefits.[1,2]

The frequency of labour induction varies from location and institution.[1, 3] Sri Lanka has the highest rate of induction of labour in the world which is about 37.5%.[3] The lowest incidence of IOL was reported in Africa: Niger Republic about 1.4%.[4, 5.] Generally, induction of labour is higher in developed countries than developing countries. [1-3, 6] In Africa, it is underutilized with a rate of 4.4%, and unmet need of 66. 0–80. 2%. [2, 3] It accounts for 6.3% of deliveries in Nigeria [1,6,7.]

The aim of inducing labour is to achieve vaginal delivery, where this does not occur, it is termed failed induction and there is recourse to abdominal delivery. Induction of labour is indicated in medical, obstetric and foetal conditions among which are: pregnancy-induced hypertensive disorders, diabetes, post-term pregnancy,

thrombophilia, intrauterine foetal growth restriction, oligohydramnios and intrauterine foetal death[8,9]. Prevention of post term pregnancy seems to be the most common indication of labour induction[8,10].

The success of induction of labour is determined majorly by the state of the cervix at the point of commencement of induction. Conducting induction of labour with an unfavourable cervix may result in prolonged labour, a higher rate of failed induction and increased abdominal deliveries[11]. Induction of labour undertaken for women with favourable cervix escalates the prospect for vaginal delivery[1-8].

In contemporary obstetric practice induction of labour is frequently effected using either mechanical, pharmacological or surgical means or a combination of both[12-15]. These methods are used to ripen and dilate the cervix and successfully induce labour. The mechanical methods are among the oldest methods, used for decades before the discovery of pharmacological agents[16]. Pharmacologically the use of prostaglandins for induction of labour gained popularity in the past few decades and currently enjoys significant patronage by many obstetricians[8, 9, 13.17-19].

Misoprostol and catheter are very useful agents in a low resource setting, they are available, affordable, and heat stable[9,14,29]. For induction of labour, intra-vaginal misoprostol and intracervical extra amniotic Foley Catheter have been reported to have similar effectiveness and similar risk of caesarean section when used singly, though the risk of tachysystole is reduced with the use of intracervical extra amniotic Foley Catheter[14,21-24].

The synergistic effects of concurrent use of Foley intracervical catheter and low-dose misoprostol for induction of labour are documented and well utilized in most African institutions[2,8,25-27]. This synergy effect has also been reported to be more effective in hastening the induction process and reducing induction failure rate compared to when either is used singly[26-30].

Despite the wide acceptance of misoprostol and catheter singly or in combination for induction of labour, the study was undertaken to access the response of our parturients and also the findings will add to the body of literature

II. MATERIALS AND METHOD

The study was carried out at the Department of Obstetrics and Gynaecology, Federal Medical Centre, Yenagoa, Bayelsa State, Nigeria, from 1st of September 2018 to 31st of August 2019. All eligible patients were enrolled after they were adequately counselled and written consent was obtained. The patients were randomized into two groups; Group A represent parturients with intracervical extra amniotic Foley catheter and synchronous intermittent low dose 25µg misoprostol while Group B represents parturients with misoprostol alone. At presentation, the history of the index pregnancy was noted, the gestational age was determined via early ultrasound scan or the certain last menstrual period. Foetal weight estimation was determined by ultrasound scan, a non-stress test was done. The pre-induction Bishop's score (modified) was determined.

The participants in group A; had a Foley catheter No 16 inserted through the cervix under sterile technique and the balloon was inflated with 30ml of sterile water. Additionally, they received 25 µg of misoprostol passed concurrently into the posterior vaginal fornix. This was repeated every 6 hours for 24 hour period to a maximum of 4 doses. The Intracervical extra amniotic Foley catheter and cervical parameters were assessed every 6 hours and the Bishop's score was documented. When the catheter fell off, the time of spontaneous expulsion was recorded and the cervix is assessed. If no spontaneous expulsion of the catheter occurred at 12 hours post-insertion, the catheter was deflated, removed and the cervix re-assessed.

Low dose intravaginal misoprostol was continued until patients received four doses for 24 hours, or had met the criteria to exit the study. Patients exited from this group; after receiving the four doses of misoprostol, bishop's scores are favourable > 6, in active phase labour and after 24 hours of administration of induction agent. When the cervix was favourable or in active phase labour, further management of labour was as per departmental protocol.

Those randomized to group B (misoprostol alone group) received 25µg of misoprostol inserted into the posterior vaginal fornix 6 hourly for 24 hours, to a maximum of four doses, unless adequate contractions ensued, Bishop's score of ≥ 6, cervical dilatation of ≥ 4cm, or spontaneous rupture of membranes occurred. When the cervix was favourable or in active phase of labour, further management of labour was as per protocol.

Amniotomy was performed at cervical dilatation of ≥ 4 cm. Labour was monitored using continuous cardiotocograph. Any abnormality detected in labour was documented and appropriate intervention was instituted. Abnormal foetal heart rates were noted and documented. Occurrence of abnormal uterine contractions such as tachysystole (at least six contractions in 10 minutes for two consecutive 10 min periods), hypertonus (single contraction of > 90 seconds) and hyperstimulation syndrome (tachysystole or hypertonus associated with foetal heart tachycardia or late decelerations) was documented. The time of delivery and the induction-delivery interval was documented. The APGAR scores at 1 minute and 5 minutes were assessed and documented as well as the need for and outcome of neonatal admissions. All perinatal and maternal morbidity were recorded.

Failure to achieve a favourable cervical status by any arm of the study, after 24 h of initiation of treatment, was referred to as failed induction. This may necessitate an emergency caesarean section as deemed appropriate.

The primary outcome of this study was a change in Bishop score and induction-to-delivery interval. Secondary outcomes were the use of oxytocin augmentation, mode of delivery, intrapartum complications, Apgar score at 1 and 5 minutes, the need for SCBU admission and maternal outcome; postpartum haemorrhage, uterine rupture and maternal satisfaction.

Inclusion criteria were; pregnant women admitted for induction of labour with no contraindication for vaginal delivery, reactive pre-induction cardiotocograph, singleton foetus in longitudinal lie, cephalic presentation, gestational age between 37 weeks and below 41 weeks and 6 days, Bishop score of less than 6 and an estimated foetal weight of ≥ 2.5kg to ≤ 4kg.

All data collected from this study were analysed using the statistical package for social sciences (SPSS) computer software version 22 for Windows. Categorical variables were expressed as absolute numbers and percentages and a significant difference were determined using the chi-square test and Mann-Whitney test, while continuous variables were expressed as means with standard deviations and a significant difference was determined by the student's t-test. The level of statistical significance was set as $p < 0.05$.

III. RESULTS

A total of 174 pregnant women were recruited for this study, with 87 participants in each arm, however, two women from the 'Misoprostol + Catheter' group opted out after randomization. A total number of 172 participants received intervention with 87 participants (50.5%) in the Misoprostol alone group and 85 participants (49.5%) in the 'Misoprostol + Catheter group. The mean age for the study population was 31.5 ± 4.4 years. The misoprostol alone group and the Misoprostol + catheter group had mean ages of 32.3 ± 4.2 years and 30.7 ± 4.4 years respectively

Table 1: Sociodemographic Characteristics of Study Participants

Characteristics	Total Freq = 172 (%)	Misoprostol + Catheter Freq = 85 (%)	Misoprostol Only Freq = 87 (%)
Age group (yrs)			
< 25	14 (8.1)	9 (10.6)	5 (5.7)
26 - 30	65 (37.8)	38 (44.7)	27 (31.0)
31 - 35	50 (29.1)	22 (25.9)	28 (32.2)
36 - 40	43 (25.0)	16 (18.8)	27 (31.0)
Marital Status			
Single	16 (9.3)	10 (11.8)	6 (6.9)
Married	158 (90.7)	75 (88.2)	81 (93.1)
Religion			
Islam	12 (7.5)	7 (9.0)	5 (5.7)
Christian	160 (92.5)	78 (91.0)	82 (94.3)
Level of Education			
Primary	6 (3.5)	5 (5.9)	1 (1.1)
Secondary	54 (34.5)	24 (28.2)	30 (34.5)
Tertiary	112 (65.1)	56 (65.9)	56 (64.4)
Parity			
Nulliparous	29 (16.9)	18(21.2)	11 (12.6)
Primigravida	58 (33.7)	23 (27.1)	35 (40.2)
≥ 2	85 (49.4)	44 (51.8)	41 (47.1)

Table 1: shows that majority of the parturients were multiparous (49.4%) and married (90.7%). The area of study was in urban settlement, expectedly most participants had tertiary education as their highest educational attainment (65.1%) and none of the participants had no formal education.

Table 2: Mean Values of obstetric variables, Induction and delivery parameters in the misoprostol + Catheter and Misoprostol only groups.

Characteristics	Total	Group: Misoprostol + Catheter	Group: Misoprostol Only			
	Mean (SD)	Mean (SD)	Mean (SD)	t	df	*p*-value
Estimated gestational age	39.7 (1.5)	39.8 (1.5)	39.7 (1.6)	0.62	170	0.611
Interval to achieve favourable BS (hours)	10.6 (5.1)	8.0 (2.8)	13.1 (5.5)	7.69	170	0.001*

Duration of onset of uterine contractions (hours)	7.5 (3.9)	5.8 (2.2)	9.2 (4.5)	6.41	170	0.001*
Duration to achieve the active stage of labour (hours)	11.5 (5.1)	8.9 (3.0)	14.3 (5.4)	7.98	166	0.001*
Induction-delivery interval (hours)	16.8 (4.7)	15.0 (3.5)	19.1 (5.0)	5.71	141	0.001*
Duration to decide induction failure (CS) – (hours)	24.4 (6.8)	23.0 (2.2)	24.8 (7.4)	0.52	27	0.608
Duration for Augmentation (hours)	5.9 (1.8)	6.2 (1.9)	5.7 (1.8)	1.34	76	0.184

	Median (Range)	**Median (Range)**	**Median (Range)**	**Mann-Whitney U**	***p*-value**
Parity – Median (range)	1 (0 – 5)	1 (1 – 4)	1 (1 – 5)	3544.0	0.627
FHR at commencement of IOL	140 (128 – 154)	140 (130 – 154)	140 (128 – 150)	3513.0	0.568
BS at commencement of IOL	4 (2 – 5)	4 2 – 5)	4 (2 – 5)	3313.5	0.202
Number of doses of misoprostol administered	2 (1 – 4)	1 (1 – 3)	2 (1 – 4)	1702.5	0.001*

*Statistically significant, BS Bishop score.

There was no significant difference in the bishop score of the two arms at the commencement of cervical ripening (p > 0.202). The concurrent use of the misoprostol + catheter performed better than misoprostol used singly in terms of; duration to achieve a favourable Bishop score, the onset of uterine contractions, achieving active phase labour and induction delivery interval and all these were statistically significant. However, there was a shorter duration of augmentation of labour for misoprostol used singly compared to the misoprostol + catheter, though it was not statically significant.

The number of doses of misoprostol for the misoprostol and catheter group was 1 (1-3) and the misoprostol alone group was 2 (1-4) (Mann-Whitney U = 1702.5 p – 0.001). The difference was found to be significant. More women in the combined group needed fewer doses of misoprostol to achieve cervical ripening.

Table 3: Relationship between Conditions in labour and methods of cervical ripening

Characteristics	**Total**	**Misoprostol + Catheter**	**Misoprostol**
	Freq. = 172 (%)	**Freq. = 85 (%)**	**Freq. = 87 (%)**
Indication for Induction			
Prolonged Pregnancy	89 (51.7)	50 (58.8)	39 (44.8)
PIH/PET	70 (40.7)	30 (35.3)	40 (46.0)
GDM/DM in pregnancy	13 (7.6)	5 (5.9)	8 (9.2)
		X^2 = 3.46; df - 2; p - 0.177	
Bishop Score at commencement			
< 3	77 (44.8)	35 (41.2)	42 (48.3)
4 ─ 5	95 (55.2)	50 (58.8)	45 (51.7)
		X^2 = 0.89; df – 1; p – 0.349	
Side effect	**N = 75**	**N = 27**	**N = 48**
Fever	14 (18.7)	7 (25.9)	7 (14.6)
Chills and Rigor	53 (70.7)	14 (51.9)	39 (81.3)
Nausea	8 (10.7)	6 (22.2)	2 (4.2)
		X^2 = 8.59; df – 2; p – 0.014*	
Time duration to achieve Favourable bishop score			
<12 hours	133 (77.3)	82 (96.5)	51 (58.6)
12–24 hours	36 (20.9)	3 (3.5)	33 (37.9)
>24 hours	3 (1.7)	0 (0.0)	3 (3.4)
		X^2 = 35.21; df – 2; p < 0.001*	
Time duration to achieve Uterine contraction			
< 4 hours	53 (30.8)	34 (40.0)	19 (21.8)
4 – 8 hours	70 (40.7)	43 (50.6)	27 (31.0)
9 – 12 hours	25 (14.5)	7 (8.2)	18 (20.7)
> 12 hours	24 (14.0)	1 (1.2)	23 (26.4)
		X^2 = 32.89; df – 3; p < 0.001*	
Augmentation with Oxytocin			
Augmentation	75 (43.6)	32 (37.6)	43 (49.4)
No Augmentation	97 (56.4)	53 (62.4)	44 (63.2)

Mode of Delivery			
SVD	143 (83.1)	80 (94.1)	63 (72.4)
CS	29 (16.9)	5 (5.9)	24 (27.6)
		$X2$ = 14.45; df – 1; p <0.001*	
Induction and SVD Interval	**N = 143**	**N = 80**	**N = 63**
< 24 hours	133 (93.0)	79 (98.8)	54 (85.7)
≥ 24 hours	10 (7.0)	1 (1.2)	9 (14.3)
		X^2 = 9.20; df – 1; p – 0.002*	
Induction and caesarean section Interval (Induction Failure)	**N = 29**	***N = 5***	**N =24**
< 24 hours	15 (51.7)	4 (80.0)	11 (45.8)
≥ 24 hours	14 (48.3)	1 (20.0)	13 (54.2)
		X^2 = 0.012; df – 1; p – 0.911	

Table 3 shows the commonest indication for induction of labour was prolonged pregnancy (51.7%) and this was more in the Misoprostol+ Catheter group of the study (58.8%) than the misoprostol alone group (44.8%). The highest bishop score at the commencement of induction of labour was between 4 and five. The distribution of indication for induction and Bishop score at commencement of study was not significantly different in the two study groups (p> 0.05). 77.3% of participants achieved favourable cervix within 12 hours of commencement of cervical ripening while for parturients in the misoprostol + catheter group and misoprostol only group it was 96.5% and 41.3% respectively.

In the study population, 43.6% required augmentation with oxytocin to achieve optimum uterine contraction. There was less augmentation with oxytocin misoprostol + catheter group (37.6%) compared to the Misoprostol alone group (49.4%) but this was not statistically significant (p-Value = 0.119).

Whilst 83.1% of the study population had spontaneous vaginal delivery, 94.1% and 98.8% of those in the misoprostol + catheter group and misoprostol group respectively, achieved the same within 24 hours. Chills and rigour which is the commonest side effect of the induction agent was significantly higher among the misoprostol alone group compared to the misoprostol + catheter group (81.3% vs 51.9% X^2=8.59: P=0.014).

Table 4: Indication for CS among study participants

Characteristics	**Total**	**Misoprostol + Catheter**	**Misoprostol alone**
	Freq. = 29 (%)	**Freq. = 5 (%)**	**Freq. = 24 (%)**
Intrapartum haemorrhage	5 (17.2)	0 (0.0)	5 (20.8)
Cord Presentation	3 (10.3)	0 (0.0)	3 (12.5)
Cervical dystocia	6(20.7)	1 (20.0)	5 (20.8)
Severe Pre-eclampsia	2 (6.9)	0 (0.0)	2 (8.3)
Cephalopelvic disproportion	5 (17.2)	1 (20.0)	4 (16.7)
Suspected foetal Distress	8 (27.6)	3 (60.0)	5 (20.8)
		$X2$ = 4.41; df – 5; p – 0.492	

Of the 172 participants in the study, about 29 participants (16.9%) delivered their foetuses through a caesarean section (Table 3). The commonest indication is for foetal distress.

Table 4: shows that the most common indications for Caesarean section were suspected foetal distress (27.6%), cervical dystocia (20.7%), significant intrapartum haemorrhage (17.2%) and cephalopelvic disproportion (17.2%). All these conditions were more common in the misoprostol only group, however, the difference in proportions was not statistically significant (x^2 = 4.41:p = 0.492).

Table 5: Relationship between Maternal and Foetal outcome and the methods of cervical ripening

Characteristics	**Total**	**Misoprostol + Catheter**	**Misoprostol Only**
	Freq. = 172 (%)	**Freq. = 85 (%)**	**Freq. = 87 (%)**
Maternal outcome			
Tachysystole			
Yes	14 (8.1)	2(2.4)	12(13.8)
No	158 (91.9)	83 (97.6)	75(86.2)
		X^2 = 7.538; df - 1; p - 0.014*	
Postpartum haemorrhage			
Yes	4 (2.3)	4 (4.7)	0(0.0)
No	168 (97.7)	81 (95.3)	87 (100.0)
		X^2 = 4.19; df – 1; p – 0.041	
Foetal outcome			
Foetal heart irregularity			
Yes	3 (1.7)	1(1.2)	2 (2.3)
No	169 (98.3)	84(98.8)	85(97.7)
		X^2 = 0.316; df – 1; p – 0.574	

Apgar score in 5 minutes			
4 - 5	7(4.1)	2(2.4)	5(5.7)
6	5 (2.9)	3 (3.5)	2 (2.3)
7 - 10	160(93.0)	80 (94.1)	80 (92.0)
		X^2 = 1.46; df – 2; p < 0.481	
Characteristics of the Liquor			
Clear	164 (95.3)	80 (94.1)	84 (96.6)
Fresh meconium-stained	2 (1.2)	1(1.2)	1(1.1)
Stale meconium-stained	6(3.5)	4 (4.7)	2(2.3)
		X^2 = 0.74; df – 2; p – 0.690	
Admission to SCBU			
Yes	12 (7.0)	3 (3.5)	9 (10.3)
No	160 (93.0)	82 (96.5)	78 (89.7)
		X^2 = 3.08; df – 1; p – 0.079	

The maternal complications reported in the study include primary postpartum haemorrhage and tachysystole which occurred in 2.3% and 8.1% of the study population respectively (Table 5). All cases of postpartum haemorrhage occurred in the Misoprostol + catheter group. Table 5 also shows that the relationship between the occurrence of postpartum haemorrhage and the cervical ripening method happens to be significant statistically (X2 = 4.19; df 1; p – 0.041).

Foetal heart irregularity occurred in the foetuses of 3 parturients. While 1 (1.2%) foetus, occurred in Misoprostol and +catheter group, 2 (2.3%) occurred in the misoprostol alone group. APGAR score at 5 minutes, less than 7, was reported in 12 neonates in the study (7.0%). The same proportions of neonates were admitted into the special care baby unit (SCBU) in this study. More children in the 'Misoprostol alone group were admitted into the special care baby unit (10.3%). However, despite having a higher proportion of neonates in the Misoprostol alone group being admitted into the special care baby unit, the relationship between the methods of cervical ripening and admission of neonates into the special baby care unit was not significant statistically (X2= 3.03; p – 0.079) in this study (Table 5).

IV. DISCUSSION

Misoprostol used singly or in combination with intracervical extra amniotic Foley catheter for ripening of the cervix and induction of labour is safe and have comparable effectiveness[16, 31]. As reported by other researchers, [26,27,32,33] the study revealed that the combined use of misoprostol + catheter (at 8.0 ± 2.8 hours) achieved favourable Bishop sooner than misoprostol used singly (at 13.1 ± 5.5 hours) and this is expectedly due to the synergistic consequence of the combined method. However, this contrasts with the findings by other authors[30, 34].

The faster rate to achieve favourable Bishop score for the misoprostol + catheter group also mirrors an earlier onset of uterine contraction compared to misoprostol used alone. By the 8th hour of commencement of induction, 9 out of every 10 parturients in the combined group had initiated uterine contraction as compared to 5 out every 10 in the misoprostol alone group. This reflects the synergistic effect of combing misoprostol and catheter.

In this study, 83.1% of all the participants had vaginal delivery. However, 94% of the women in the combine group of misoprostol and Foleys catheter had vaginal delivery as compared to 72.4% of the women that received only misoprostol. Failed induction of labour using the combined method is less likely when compared to misoprostol used singly.

The average time from the commencement of the induction process to vaginal delivery (induction-delivery interval) in this study was 16 hours. The parturients who had misoprostol alone had an induction-delivery interval of 19 hours compared to 15 hours for the combine group. This is a follow up on the shorter duration to achieve favourable cervical parameters and the early onset of uterine contraction, established in the combine group. The shorter induction-to-delivery interval could be due to the impact arising from the effect of prostaglandin on the cervix and the Foley's catheter causing dilation of the cervix coupled with local release of additional prostaglandins.

The induction-delivery interval difference of 4 hours for both groups was similarly reported by Levine et al [32] whilst, Charaya et al[35] and Santosh[36] reported a difference of 3 hours and 5 hours respectively. The failed induction rate in this study was 16.9%. The majority of the women who had failed induction (27.6%) were parturients that received misoprostol alone for induction of labour compared to 5.9% of women that had combined methods.

The commonest indication for caesarean section in both arms of the study was foetal distress. The subgroup of women in this study, who had the highest caesarean section, had more doses of misoprostol, longer duration to achieve changes in cervical parameters as well as longer duration of labour. These factors may be

responsible for the higher rate of suspected foetal distress and by extension more delivery by caesarean section. The significant difference in the mode of delivery observed in this study has been reported by other authors[27,29].

The use of either the Foley catheter alone or misoprostol alone is capable of stimulating the endogenous release of oxytocin.[37,38] It is expected that combining these two agents will ultimately result in lesser oxytocin requirement in labour than using a single agent. This was demonstrated in this study, about 43.6% of the total participants of this study required oxytocin induction. While 37.6% of women in the combined arm had oxytocin augmentation, 49.4% of the women that had only misoprostol had labour augmented with oxytocin. This finding was reported by other authors.[26,32,39]

The use of misoprostol alone in this study was complicated by a higher risk of foetal heart irregularity than when misoprostol and Foley catheter was used though this was not statistically significant. Similarly, tachysystole occurred more in parturients who received misoprostol alone (13.8%) compared to those who had Foley catheter and misoprostol (2.4%) and this was statistically significant. The difference may be ascribed to the number of doses and consequently the period of exposure to misoprostol in parturients that had misoprostol only. The combined group received statistically significant fewer misoprostol doses compared to the intravaginal misoprostol group. Other authors reported similar findings[33,40,41].

More babies with foetal heart irregularity, birth asphyxia as well as the need for admission into the special care baby unit (SCBU) were found in the group of women that received only misoprostol. In this subgroup (misoprostol alone) more misoprostol was passed and the need for augmentation of labour was more. In regards to safety, there were no significant differences in the rates of adverse maternal and perinatal outcomes or complications in this study. This outcome is similar to findings from prior trials[27, 29,33,41].

The strength of this study is in the fact that the study was conducted in a low resource setting, making its findings generalizable to similar settings in low and middle-income countries. Also the participants of this study had various indications for induction as well as varying parity, making our results more representative and therefore generalizable to all women scheduled for induction of labour at term

V. CONCLUSION

The use of misoprostol alone and in combination with intracervical extra amniotic Foley Catheter for the obstetric purpose of induction of labour is safe and effective. The use of misoprostol and in combination with intracervical Foley has a shorter induction delivery interval, shorter period to ripen the cervix and the initiation of uterine contractions when compared with misoprostol alone. The rate of failed induction is less when misoprostol is combined with Foley catheter compared to misoprostol used alone. Misoprostol alone group had a higher rate of foetal heart rate abnormality compared to when misoprostol was combined with a catheter.

LIMITATION OF THE STUDY

Despite the strength identified above, this study had some limitations. It was not possible to mask the attending obstetrician or the women of the method of labour induction, and we could not exclude the possibility of any bias. The study randomized women with varied Bishop score, women respond differently to cervical ripening agents, the way women with a Bishop score of 3 will respond to the intervention may be different from the response of women with a score of 5. Therefore, it is important to compare women with the same demographic factor to reduce bias and to have a better comparable result. Again women with varied parity were randomized in this study, the response to induction agent may be affected by parity; as women of higher parity respond better than nulliparous women. Therefore, comparing a group of women with varied parity using the same agent may affect the outcome. Oxytocin use in this study may have contributed to foetomaternal outcome which may have affected some of the results. The intravaginal route itself has a larger variation in uptake compared to other routes, which may be another source of variability. There may thus be the need for further studies in this direction.

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