Scholars Journal of Applied Medical Sciences
Abbreviated Key Title: Sch J App Med Sci
ISSN 2347-954X (Print) | ISSN 2320-6691 (Online)
Journal homepage: https://saspublishers.com/sjams/

OPEN ACCESS

Gynaecology & Obstetrics

"Effectiveness of Intravaginal Foley's Catheter & Intravaginal Misoprostol Use on Cervical Ripening in Term Pregnancy: A randomized comparative study in a tertiary hospital of Bangladesh"

Shamima Begum[1*], Mst. Mahmuda Begum[2], Marzia Mehbin[3], Mst. Marzina Khatun[4], Prof. Hasina Akhter[5]

[1]Junior Consultant (Gynaecology & Obstetrics), Upazilla Health Complex, Sadullapur, Gaibandha, Bangladesh
[2]Medical Officer, Upazilla Health Complex, Palashbari, Gaibandha, Bangladesh
[3]Indoor medical officer, Dept. of Gynaecology & Obstetrics, Dhaka Medical College Hospital, Dhaka, Bangladesh
[4]Medical Officer, Upazilla Health Complex, Mohonpur, Rajshahi, Bangladesh
[5]Ex-Professor & Head of department, Dept. of Gynaecology & Obstetrics, Rajshahi Medical College Hospital, Bangladesh

DOI: 10.36347/sjams.2020.v08i02.034 | **Received:** 07.02.2020 | **Accepted:** 14.02.2020 | **Published:** 16.02.2020

***Corresponding author:** Dr. Shamima Begum

Abstract **Original Research Article**

Introduction: Induction of labour is widely carried over the world in cases where continuation of pregnancy is hazardous to mother or fetus. Varieties of techniques are available for induction of labour. Although there are many proper methods for cervical ripening, there exists no agreement on the choice of best and most proper method of labour induction in cases with unripe cervix. Among these methods cervical foley catheter and vaginal misoprostol (PGE_1) are more commonly used for labour induction and cervical ripening. The efficacy and safety of low dose misoprostol as a ripening agent compared to the widely used balloon catheter in developing countries is undetermined. So, this study was carried out to see the safety and efficacy of intravaginal misoprostol and intra cervical Foley's catheter for cervical ripening. ***Material & Methods:*** This randomized clinical trial was performed on 100 primigravida women who were admitted in department of obstetrics and gynaecology unit of Rajshahi medical college and hospital during a time period of July 2012 to December 2012 with various indication for induction of labour volunteering to participate were included in the study. These women were randomly divided in to two groups. Misoprostol group (including 50 patients) and Foley's catheter group (including 50 patients). For the first group 25 microgram vaginal misoprostol tablet was administered every 4 hours up to maximum of 6 doses. For the second group Foley's catheter 18F, inflated with 50cc distilled water was placed through the internal os of the cervix. ***Results:*** In this study 50 patients where intravaginal misoprostol tablet was used for cervical ripening where compared with 50 patients were cervical ripening was done by using intracervical and extra-amniotic Foley's catheter. Two groups were similar in the view of demographic characteristics, indication for labour induction, caesarian indications, maternal and fetal outcomes. Out of 100 patients 41(82%) women in misoprostol group and 42(82%) in Foley's catheter group were delivered vaginally. Augmentation by oxytocin drip was required in 9(18%) and 9(18%) case in two groups. Artificial rupture membrane required 18(36%) and 19(38%) cases and both oxytocin drip and ARM required in 13(26%) and 11(22%) cases in misoprostol and Foley's catheter group respectively. Comparison of mean differences of induction-labour pain interval, induction-full dilatation interval, induction-delivery interval between the groups showed no significant difference, but the relationship between Bishop's score and induction-full dilatation interval of the cervix showed a negative (r= -0.963, -0.879 respectively and highly significant p <0.008, <0.050 in both groups). That is increase in Bishop's score reduce the induction-full dilatation interval. The mean difference of Apgar score at 1 minute was significantly significant (P<0.05) between two groups but at 5 minutes was not statistically significant (P >0.05). ***Conclusion:*** From this study it was found that the safety and efficacy of Foley's catheter is comparable to misoprostol. In addition, Foley's catheter is free from side effects of misoprostol like vomiting and hyperstimulation. Therefore, we feel that Foley's catheter can be used instead of misoprostol safely and effectively for cervical ripening especially in the developing countries.

Keywords: Pregnancy, Gynaecology, Intravaginal misoprostol, Cervical, Misoprostol.

INTRODUCTION

Induction of labour is common in obstetric practice. In the absence of a ripe or favorable cervix a successful vaginal birth is less likely [1]. Induction of labor is widely carried where continuation of pregnancy is hazardous to mother, fetus or both. Induction of labor in ripen cervix is not difficult but complication can increase significantly when cervix is unripe [2]. Therefore, cervical ripening for induction should be assessed before a regimen is selected. Assessment is accomplished by calculating a Bishop's score. When the Bishop's score is less than 6 it is recommended that a cervical ripening agent should be used before labour induction [1]. A score of 5 or less suggests that labour is unlikely to start without induction. A score of 9 or more indicates that labour will most likely commence spontaneously [3]. A low Bishop's score often indicates that induction is unlikely to be successful [4]. Some sources indicate that only a score of 8 or greater is reliably predictive of successful induction. According to the modified Bishop's pre induction cervical scoring system, effacement has been replaced by cervical length in cm, with scores as follows-0 > 3cm, 1> 2cm, 2 > 1cm, 3 > 0cm [5]. Cervical ripening can be accomplished mechanically or medically using hormones and thus increase the success rate of induction of labour. These include: a. oxytocin b. intravaginal, intracervical or extra-amniotic application of prostaglandins, c. intravaginal administration of estradiol, d. intracervical placement of osmotic dilators, e. stripping the membrane and amnitomy[6]. Although there are many proper methods of cervical ripening, there exists no agreement on the choice of best and most proper labour induction of cases with unripe cervix. Among these methods cervical foley's catheter and vaginal misoprostol (PGE_1) are most commonly used for labour induction and cervical ripening [7-9]. The use of prostaglandins for cervical ripening administered by any route has been reported to improve the rate of vaginal delivery and decrease the rate of caesarean section & instrument deliveries [10, 11]. Adeniji *et al*. performed a study in 2006 to compare vaginal misoprostol & Foley's catheter for cervical ripening. They reported that vaginal misoprostol was more effective to improve the scores of cervical length & consistencies, while foley catheter was better to improve the cervical os dilatation score during the pre-induction cervical ripening [12]. Foleys cervical balloon catheter is widely used in developing countries for pre-induction cervical ripening. This is because it is much more affordable than intravaginal prostaglandins. Cervical foley catheter has been used for induction of labour to ripen the cervix by mechanical means without [13-15] causing hypertonic uterine contractions. It also stimulates the endogenous prostaglandins in the cervix [16]. Such mechanical methods are advantageous in terms of reversibility & reduced expenditure [17]. Misoprostol, a synthetic prostaglandin E_1 analogue, which was initially used in peptic ulcer treatment, is a promising agent in cervical ripening. Possible advantages of misoprostol may be the cost effectiveness, ease of administration, well tolerability and most notably its dual action in cervical ripening and labour induction [18]. Since misoprostol is relatively cheap, stable at room temperature & has good effect, it is frequently used in obstetrics & gynaecology for termination of pregnancy especially at third trimester [19]. Misoprostol may be the only affordable prostaglandin preparation for many poorly resourced countries. However, there is limitation to its widespread use which relates the issue of safety, particularly its association with uterine hyperstimulation [20, 21]. We therefore performed a randomized trial comparing the safety & efficacy between intravaginal misoprostol & intracervical placement of a Foley's ballon catheter for cervical ripening in patient with unfavorable cervix.

OBJECTIVES

a) General objective

- To compare the safety and efficacy of low dose intravaginal misoprostol tablet & intracervical foley's catheter for cervical ripening.

b) Specific Objectives

- To determine & compare the effects of misoprostol tablet & inflated foley's catheter for preinduction cervical ripening in case of unfavorable cervix.
- To find out the induction and delivery interval in both methods.
- To assess any maternal complications i.e. techysystole, postpartum haemorrhage and failed induction.
- To assess any fetal complications i.e. Asphyxia and perinatal death.

METHODOLOGY AND MATERIALS

It was a hospital based prospective study. The study period extends from July 2012 to December 2012. Department of obstetrics and gynaecology, Rajshahi medical college and hospital, Rajshahi. A total of 100 patients were selected as a study population. Primigravida patient with gestational age between 37 to 42 weeks with singleton pregnancy with cephalic presentation & patient not in labour with unfavorable cervix admitted for delivery. Patient was selected randomly from all the primigravida admitted in labour ward with gestational age between 37 weeks to 42 weeks after taking proper history and clinical examination including P/V examination having unfavorable cervix. Various indications for induction of labour volunteering to participate were included in the study. These women were randomly divided into two groups. Misoprostol group (including 50 patients) and Foley's catheter group (including 50 patients). For the first group 25 microgram vaginal misoprostol tablet was administered every 4 hours up to maximum of 6 doses. For the second group Foley's catheter 18F, inflated with

50cc distilled water was placed through the internal os of the cervix. After written informed consent each patient was questioned in details and examined thoroughly. The last menstrual period was ascertained clinically with other milestones and by ultrasonography. A Bishop's scoring was done before hand to assess the cervix.

INCLUSION CRITERIA

- Primigravida with gestational age between 37 weeks to 42 weeks on the basis of last menstrual period (LMP) or sonography at first trimester.
- Unfavorable cervix (Bishop's score <5).
- Singleton pregnancy with cephalic presentation.
- Patient not in labour.
- Gestational diabetes mellitus.
- Reassuring fetal heart rate tracing.

Exclusion Criteria

- Multiparity.
- History of hypersensitivity to misoprostol.
- Cephalopelvic disproportion.
- Multiple pregnancies.
- Fetal distress and fetal malpresentation.
- Previous caesarian delivery or other uterine surgery.

RESULTS

Table I: shows that (mean± SD) age of the patient was 23.3±2.9yrs in misoprostol group and 24.0±3.2 yrs. in Foley's catheter group. Statistically, the difference in mean age between the groups is not significant. Mean height and weight of the study subjects in both the groups were similar. (Mean ±SD) gestational age of our study population was 37.7±0.909 weeks in misoprostol group and 38.1±0.707 weeks in foley's catheter group statistically the difference is not significant. (Mean ±SD) bishops score was 3.20±1.20 in misoprostol group and 3.60±1.27in Foley's catheter group. Table II: shows that in misoprostol group, 26 (52%) patients had less than taka 10,000 monthly incomes, where as in Foley's catheter group, it was 23 (46%). In misoprostol group 24 (48%) had monthly income between taka 10,000 and 30,000 and in Foley's catheter group 27 (54%). None of the patients, in either group, had income more than taka 30,000. The comparison of income status between the groups is statistically not significant. Table III: Shows the distribution of clinical diagnosis as indications for labour induction for in misoprostol and Foley's catheter group of patients. Postdated pregnancy was present in 20 (40%) and 18 (36%) cases, intrauterine fetal death in 14(28%) and 15(30%) cases, eclampsia in 6 (12%) and 5(10%) cases, preeclampsia in 5(10%) and 7(14%) cases, and gestational diabetes mellitus in 5(10%) and 5 (10%) cases in misoprostol and Foley's catheter groups, respectively. Statistical comparisons of the clinical parameters between groups were not significant. Table IV: shows the distribution of type of augmentations required in the two groups of patients. Oxytocin drip was required in 9 (18%) and 9 (18%) cases, artificial rupture membrane (ARM) required in 18 (36%) and 19 (38%) cases and both oxytocin drip and ARM required in 13 (26%) and 11 (22%) cases, in misoprostol and Foley's catheter groups, respectively, statistical analysis showed no significant difference between the groups. Table V: shows comparison of induction-labour pain interval, induction-full dilatation interval and induction-delivery interval between the two groups. Mean (± SD) duration of onset of labour was 10.58 ± 3.28 and 12.84 ± 3.01 hours, inductions to full dilatation was 18.48 ± 3.69 and 19.76 ± 3.91 hours and induction to delivery internal was 20.97 ± 3.99 and 21.47 ± 4.0 hours in the misoprostol & foley's catheter groups respectively. Comparison of mean difference of these parameters between the groups showed no significant difference. Table VI: shows number of doses (one dose equals to one fourth of a tablet) of misoprostol required for cervical ripening. 17 (34%) cases required 3 doses, followed by 14 (28%) cases 2 doses, 11 (22%) cases 4 doses and 8 (16%) cases 1 dose. Table VII: shows distribution of node of delivery. Overall 83 babies were delivered vaginally without any remarkable complication, but 17 mothers required caesarean section delivery. Group wise, 41 (82%) women in misoprostol group and 42 (84%) women in Foley's catheter group were delivered vaginally. The distribution is not statistically significant. However, caesarean delivery were 9 (18%) and 8 (16%) in misoprostol and Foley's catheter groups, respectively, which is also statistically not significant. Table VIII: shows that the caesarean section was higher in misoprostol group because of uterine hyperstimulation in 2 (22%). Eclampsia with recurrent convulsion was present in 2 (22%) cases in both the groups. Fetal distress was present in 5 (55.5%) cases of misoprostol and 6 (75%) cases of Foley's catheter group. Regarding indications of caesarean section, no statistically significant difference was observed between the groups. Table XI: shows the relationship between Bishop's score and induction full dilatation interval of cervix in the two study groups. Both the groups (misoprostol and Foley's catheter) shows a negative (r= -0.963, -0.879 respectively) and highly significant. (p <0.008, <0.050 in both groups) relationship, that is, increase in bishop's score, reduce the induction full dilatation interval. Table X: shows that nausea/vomiting was present in 6(12%) cases of misoprostol group and none in foley's catheter group within 24 hours after delivery which is statistically significant. Table XI: shows the agar score was >6 in 26 (37.2%) baby at 1st minutes and 40 (77.1%) at 5 minutes in misoprostol groups, whereas in Foley's catheter group Apgar score was > 6 in 32 (65.3%) at 1st minute and 40 (81.6%) at 5 minutes. The mean difference of Apgar score at 1 minute was statistically significant (p <0.05) between two groups but at 5 minutes was not statistically significant (p>0.05).Table XII: shows that 10 (20.0%) and 9 (18.0%) of the babies

required resuscitation in misoprostol group and Foley's catheter group respectively and the difference was not statistically significant ($p > 0.05$). Table XIII: shows comparison of cost involvement between the two study groups. The mean (± SD) cost was taka 118.62±68.89 and 160.20±52.52 respectively in misoprostol and Foley's catheter groups statistically the difference is significant ($p < 0.01$).

Table-I: Characteristics of the study subjects. (n=100)

Parameters (Mean ±SD)	Misoprostol Group (n= 50) No. (%)	Foley's catheter group (n=50) No. (%)	P value
Age	23.3+ 2.9	24.0+ 3.2	0.267 NS
Height (cm)	147.52 + 5.66	148.42 + 6.24	0.931 NS
Weight (kg)	52.21 + 3.1	53.30 + 4.1	0.840 NS
Gestational age (week)	37.7 + 0.909	38.1 + 0.707	0.058 NS
Bishop's score	3.20 + 1.20	3.60+ 1.27	0.108NS

Statistically the difference is not significant

Table-II: Socioeconomic status of the study subjects. (n=100)

Socioeconomic status	Misoprostol group (n=50) No. (%)	Foley's catheter group (n=50) No. (%)	P value [a]
Low (Monthly income taka < 10.000)	26 (52%)	23 (46%)	0.841 NS
Middle (Monthly income taka 10,000-30,000)	24 (48%)	27 (54%)	0.317 NS
High (Monthly income Taka 30,000+)	0	0	

[a]Chi-square test, NS = Not significant

Table-III: Indications for labour induction. (n=100)

Indications	Misoprostol group (n=50) No. (%)	Foley's catheter group (n=45) No.(%)	P value[a]
Postdated pg	20 (40)	18 (36)	1.000 NS
IUD	14 (28)	15 (30)	0.826 NS
Eclampsia	6 (12)	5 (10)	0.749 NS
Pre eclampsia	5 (10)	7 (14)	0.538 NS
Gestational diabetes mellitus	5 (10)	5 (10)	1.000 NS

[a]Z test, NS=Not significant

Table-IV: Comparison of augmentation required in misoprostol and Foley's catheter groups.(n=100)

Augmentations	Misoprostol group (n=50) No.(%)	Foley's catheter group (n=50) No.(%)	P value[a]
Oxytocin drip	9 (18)	9 (18)	0.790NS
ARM	18 (36)	19 (38)	0.836 NS
ARM + Oxytocin drip	13 (26)	11 (22)	0.817 NS
None	10 (20)	11 (22)	0.493NS

[a]Chi-square test ,NS=Not significant

Table-V: Comparison of intrapartum variables between two study groups.(n=100)

Parameters	Misoprostol Group (Mean ±SD)	Foley's catheter group (Mean ±SD)	P value[a]
Induction labour pain interval (hours)	10.58 ±3.28 (n = 50)	12.84 ±3.01	0.552NS
Induction-full dilatation interval (hours)	18.48±3.69 (n = 41)	19.76±3.91 (n = 42)	0.207NS
Induction-delivery interval (hours)	20.97±3.99 (n = 41)	21.47±4.00 (n = 42)	0.154NS

[a] Unparied students 't' test, NS=Not Significant.

Table-VI: Number of misoprostol doses required for cervical ripening (n=50)

Number of Doses	Number of Patients	Percentage
1	8	16
2	14	28
3	17	34
4	11	22

Table-VII: Comparison of mode of delivery between the two groups.(n=100)

Mode of delivery	Misoprostol Group (n=50) No. (%)	Foley's catheter group (n=50) No. (%)	P value[a]
Vaginal	41(82)	42(84)	0.183 NS
Caesarean Section	9(18)	8(16)	0.790 NS

aChi-square test ,NS=Not Significant.

Table-VIII: Indications for caesarean section (n=17)

Indications	Misoprostol group (n=9) No. (%)	Foley's catheter group (n=8) No. (%)	P value[a]
Fetal distress	5 (55.5)	6 (75)	0.627NS
Hyperstimulation	2 (22.2)	0	0.072NS
Eclampsia with recurrent convulsion	2 (22.2)	2 (25)	0.452 NS

[a]Chi-square test, NS=Not Significant

Table-XI: Relationship of Bishops score with induction full dilatation interval (hours) (n=100)

Bishops score	Misoprostol Group (Mean ± SD)	Foley's catheter group(Mean ± SD)
1	24.5 ± 1.05(n=6)	26.75 ±0.96(n=4)
2	20.57 ±1.90(n=7)	21.14 ± 2.16(n=7)
3	18.70 ± 3.33(n=17)	20.66 ± 1.50(n=12)
4	17.83 ± 3.16(n=12)	19.72 ± 1.42(n=11)
5	16.12 ± 1.64(n=8)	18.81 ±2.37(n=16)
r- value	**-0.963	*-0.879
p- value	<0.008	<0.050

**Correlation is significant at 0.01 level,* Correlation is significant at 0.05 level

Table- X: Postdelivery nausea/vomiting. (n=100)

Nausea/vomiting	Misoprostol group (n=50) No. (%)	Foley's catheter group (n=50) No. (%)	P value[a]
Present	6(12)	0	0.012S
Absent	44(88)	50(100.0)	0.092NS

[a]Chi-square test, Significant at p < 0.05 NS=Not significant

Table-XI: Distribution and comparison of agar score (1 minute and 5 minute) of the babies of the two study groups.(n=100)

Apgar score	Misoprostol group (n=50) No. (%)	Foley's catheter group(n=50)No.(%)	P value
At 1 minute			
< 3	5 (17.2)	2 (4.1)	
4 – 6	19 (45.7)	15 (30.6)	
> 6	26 (37.2)	33 (65.3)	
Mean + SD	6.7 + 3.0	7.9 + 2.7	0.042S
At 5 minutes			
< 3	1 (8.6)	2 (4.1)	
4 - 6	9 (14.3)	7 (14.3)	
> 6	40 (77.1)	41 (81.6)	
Mean + SD	8.4 + 2.3	8.4 + 2.5	0.986 NS

[S] = Significant NS = Not significant, P-value considered significant P<0.0

Table-XII: Resuscitation Required.(n=100)

Resuscitation	Misoprostol Group (n= 50) No. (%)	Foley's catheter group (n=50) No. (%)	P value
Required	10 (20)	9 (18)	0.799 NS
Not required	40 (80)	41 (82)	0.603 NS

Table-XIII: Cost involvement in the two groups of study subjects.(n=100)

Groups	Cost (Taka) (Mean ± SD)	P value[a]
Misoprostol (n=50)	118.62 ± 68.89	
Foley's catheter (n=50)	160.20 ±52.52	0.002**

[a]Unpaired student's 't' test. [**]Significant at P < 0.01

DISCUSSION

The need to ripe the cervix prior to induction of labour has become a reality in our lives as obstetricians. Analysis of the United States birth statistics (National Center for Health Statistics) shows that approximately 10 percent of all inductions require cervical ripening. With improving maternal and perinatal care in Bangladesh, more pregnant women will be identified with one or other indications for induction and be referred to the hospitals. The purpose of this study was to highlight a simple method for ripening of cervix that may be suitable for an obstetrical unit, where a number of patients are referred for induction of labour. Induction of labour before the cervix is favorable often results in prolonged labour or a failed induction with subsequent delivery by Caesarean section, which is associated with increased maternal and fetal morbidity as well as mortality. Therefore, iatrogenic ripening of the unfavorable cervix should shorten labour and lead to a higher incidence of successful induction. In this study, 100 patients were selected by simple randomization, 50 in each group (misoprostol and Foley's catheter). Demographic, socioeconomic and obstetric characteristics were compared between the two study groups. None of these characteristics showed any significant difference between these two groups. Prostaglandins are currently the most commonly used agents for the ripening of unfavorable cervix and for induction of labour. These pharmacologic agents are, however, unstable and may have less potency if they are not stored properly and their effects are not readily reversible. However, misoprostol tablets do not require any special temperature to store, and they are available in strips like other normal tablets. Prostaglandins have some disadvantages, such as variable absorption, unpredictable patient response, vomiting, diarrhoea, tachycardia, bronchospasm, etc. No pharmacologic methods of cervical ripening and induction of labour possess the advantages of lack of systemic side-effects and easy reversibility. Foley's catheter has been used to ripen the cervix prior to surgical induction of labour [22]. When women with low Bishop's score and unripe cervix are subjected to induction by Foley's catheter, it helped in ripening of the cervix. Inflated Foley's catheter when placed extra amniotically has been found to improve the inducibility of cervix [23, 24]. The main argument against the use of this method could be the risk of introduction of infection because many potential pathogens inhabit vagina and endocervix. But the risk was not quantitatively assessed.

These risks can be eliminated by aseptic precautions, and use of aseptic techniques during the insertion of catheters, and the use of sterile water for inflating the balloon. Sandhu et al. in their study reported that the rate of infection with Foley's catheter method is not significant and is comparable to the incidence of hospital acquired infection as stated by different authors with different procedures [24]. The results from this small study show that an inflated Foley's catheter placed in the extra amniotic space was as efficient as intravaginal misoprostol tablet, in ripening the unfavorable cervix prior to induction of labour. The success of induction of labour was apparently similar in both the groups. The number of Caesarean sections was 9 (18%) in misoprostol group, whereas it was 8 (16%) in Foley's catheter group. Though there was higher Caesarean section in misoprostol group, but statistically there was no significant difference. The Caesarean section was apparently higher in misoprostol group because of uterine hyperstimulation (presence of hypertonous uterine contraction associated with abnormal FHR). These patients were treated immediately with oxygen therapy, left lateral positioning followed by emergency Caesarean section. Two newborns had severe asphyxia and had poor Apgar score at 1 -minute, but they improved substantially and 5-minute Apgar score became 10 after neonatal resuscitation. The use of Foley's catheter was as acceptable to the patients as the misoprostol intravaginal tablet. None of the babies or the mothers had any adverse reaction. None of the patients developed any complication during the period of observation. None of our patients had accidental rupture of membrane, antepartum or postpartum pyrexia attributable to the use of Foley's catheter. Whereas, six patients developed vomiting in misoprostol group. Vomiting was not so severe and simply managed by reassurance to the patient. The mean (± SD) cervical score in misoprostol group and Foley's catheter group was 3.20$\pm$1.20 and3.60$\pm$1.27, respectively; and the difference is not statistically significant. Foley's catheter is as effective as vaginal misoprostol in enhancement of inducibility, with similar induction-to-onset of labour pain interval, induction-to-full dilatation interval and induction-to-delivery interval. Outcomes of labour in these two groups are also similar. There was no stillbirth or neonatal death in either group. Embrey and Moleison describe the use of Foley's catheter to effect cervical effacement and dilatation [40]. They concluded that this method was effective in bringing about the initial effacement and dilatation of the cervix required for successful induction. This study shows that there is a negative correlation between Bishop's score and time of full dilatation of cervix, which is similar in both the groups. The findings of this study indicate that pre-induction Bishop's scoring should not be an indicator for selection of method for induction. Misoprostol conferred no advantage over Foley's catheter in terms of induction-labour pain interval, induction-full dilatation interval and induction delivery interval, operative delivery rate and condition of the baby at 5-minute after birth. The need for ARM and the amount of syntocinon required were not significantly different between the groups. We did not find any complain of discomfort on the use of Foley's catheter and it was equally acceptable as misoprostol by our study patients. Moreover, in misoprostol group, two patients developed hyperstimulation and emergency Caesarean section

were done in these patients. There was no such side-effect in Foley's catheter group. In a randomized comparison of oral misoprostol versus Foley's catheter and oxytocin for induction of labour at term, it was found by Abramovici et al. that in multiparous patients the percentage of delivery of neonates within 24 hours and the median induction-lo-delivery lime were similar in the two groups [25]. In nulliparous patients, however, delivery within 24 hours was significantly less likely in the misoprostol group and the median induction-to-delivery time was longer. A randomized trial of misoprostol and extra amniotic saline infusion for cervical ripening and labour induction by Shyla *et al*. Showed that both methods of labour induction appeared to be equally effective[26]. Several studies have shown superiority of the Foley balloon catheter over other techniques, resulting in improved cervical Bishop score, increased rate of labour induction and a higher number of vaginal deliveries [27,28] Barkai *et al.* found no side-effects from the Foley catheter method for either the mother or the baby[29]. A comparative study of induction of labour by Foley's catheter with that by sweeping of the membrane in prolonged pregnancy by Dewan *et al*.[30] showed that induction of labour by Foley's catheter is an effective method of induction of labour, especially in postdated pregnancies with very unripe cervix. It has been found to result in a safe vaginal delivery with short induction delivery interval when compared with induction by sweeping of the membranes. A clinical study of induction of labour by Foley's catheter was done by Begum *et al*.[31] in Sir Salimullah Medical College and Mitford Hospital and found the time interval between insertion of catheter and delivery was in most cases between 24 and 48 hours in the prolonged pregnancy and hypertensive disorder group and more than 48 hours in the IUD group. In our study patients mean gestational age was 37.7 and 38.1 weeks in misoprostol and Foley's catheter groups, respectively, and the difference is not statistically significant. We also found low Apgar scores in both the groups because most of the patients had antepartum eclampsia as well as low gestational age. But all of these distributions are similar in both the groups and so did not affect our results. The total cost of the procedure is less in misoprostol group (mean Taka 118.62) in comparison to Foley's catheter group (mean Taka 160.20). Statistically the difference is significant ($P<0.01$). Although cost involvement is less in misoprostol group, the cost to the Foley's catheter group is not as high, which is beyond the capacity of the general population. In addition, results of both the groups, in terms of cervical ripening, induction-delivery interval, mode of delivery and fetal outcome is similar. Considering requirement of proper monitoring of mother and fetus, irreversible effect on uterine contraction which may lead to rupture uterus by misoprostol, lack of adequate facilities and experts at periphery hospitals in Bangladesh, it is beneficial to use Foley's catheter than misoprostol.

LIMITATIONS OF THE STUDY

The safety of misoprostol is a matter of concern. In this study, the incidence of tachysystole is higher in the misoprostol group. We do not have the facilities to test this hypothesis or to properly measure the effect of vaginal misoprostol on uterine contractility.

CONCLUSION AND RECOMMENDATIONS

From this study, it was found that the safety and efficacy of Foley's catheter is comparable to misoprostol. In addition, Foley's catheter is free from side effects of misoprostol, like vomiting and hyperstimulation. Therefore, we feel that Foley's catheter can be used instead of misoprostol safely and effectively for cervical ripening, especially in the developing countries. The present study was done in a small group of patients and that is why we find it difficult to arrive at a definite conclusion. Therefore, a well-defined study needs to be performed to compare the effectiveness of Foley's catheter with misoprostol or other prostaglandins for cervical ripening. To arrive a definite conclusion, it is suggested that a long-term study with a larger number of subjects need to be carried out to make a plan of action in the selection of method of induction of labour for Bangladeshi women. Though the cost of foley's catheter group is slightly higher than misoprostol group, the outcome of labour in both these groups is similar. Drug related side effect such as hyperstimulation of uterus & post-delivery nausea and vomiting is higher in misoprostol group. So further study is recommended to see the side effects of misoprostol.

REFERENCES

1. JOSIEL TENORE, MD. SM. Methods for cervical ripening &induction of labour. Am FAM physician. 2003. May. 15;67(10): 2123-2128.
2. Arias F. Pharmacology of oxytocin andprostaglandins. Clin obstet Gynecol. 2000;43:455-68.
3. Tenore J (2003). "Methods for cervical ripening &induction of labor". Am FAM physician 67(10):2123-8. PMID 12776961.
4. ^ Cat. inist (http: // cat inist. fr/ ? a modele = affiche N &cpsidt = 2381313.
5. ^ Dutta DC. Text Book of obstetrics. 6ed. New central Book Agency. 2001. ISBN. 978-81-7381-142-5.
6. Pery KG, Larman JE, May WL Robinette LG, Martin RW, cervical ripening: A randomized comparison between intravaginal misoprostol and an intracervical balloon catheter combined with dinoprostane, Am J obstet, Gynaecol. 1998; 178: 1333-40.
7. Wing DA, Ham D &Paul RH. A comparison of orally administered misoprostol with vaginally

administered misoprostol for cervical ripening & labourinduction. Am J. obstet, Gyncol. (1999)180: 1155-60.
8. Zieman M, Fong Sk. Benowitz NL, benskter D& Darney PD. Absorption kinetics of misoprostol with oral of vaginal administration. Obstet, Gynaecol (1997) 90:88-92.
9. Boulvain M, Kelly A, Lonse C, Stan C &lirion O, Mechanical methods for induction of labour. Cochrane Database syst, Rev. (2001) 4: CD001233.
10. Keirse MJ Nc. Prostoglandins in preinduction cervical ripening: meta -analysis of worldwide clinical, experience, Journal of reproductive medicine. 1993,38:89-100.
11. Heinberg EM, Wood RA, chambers RB. Elective induction of labour in multiparous women. Does it increase the risk of cesarean section? Journal of reproductive medicine. 2002, 47(5): 399-403.
12. Adeniji Ao, olayemi O &odukogbe AA. Intravaginal misoprostol versus transcervical Foley catheter in preinduction cervical ripening. Int. J. Gynaecol. Obstet. 2006; 92: 130-2.
13. St, onge R.D &Connors, G.T. preinduction cervical ripening: a comparison of intracervical prostaglandin E_2 gel versus Foley catheter. AmJ. obstet. GynecoL. 1995; 172: 687-690.
14. Ezimokhai, M. &Nwabinineli, J.M. The use of Foley's catheter in ripening the unfavorable cervix prior to induction of labor. Brit. Obstet Gynecol. 1980; 87:1-6.
15. Thomas, I.L Chenoweth, J.N. Trino, G.N &Johnson, I.R. preparation for induction of labour of the unfavorable cervix with Foley catheter compared with vaginal prostaglandin. Aust. N.Z.J. obstet. Gynaecol. 1986; 26: 30-35.
16. A Tad J. Hallak M, Auslendev R poratpacker, T zafarati, D. Abranchovci H. A randomized comparison of prostaglandin E_2, Oxytocin &the double balloon device in induction of labour, Obstet. Gynaecol. 1996; 87: 223-7.
17. Syeda BM. Saba S, Ghazala M. Induction of labuor, A Randomized Trial comparing prostaglandin E_2 pessary, intracervical Foley catheter &Extra Amniotic saline infusion J Sung Dec. 2000; 19-20: 12-8.
18. Ozan H, Gurkan U, Volkan Y. Melike O, Hana FK, Mephara T, Misoprostol in labour induction. J Obstet Gynaecol. Res. 2001; 27: 17-20.
19. Hill JB, Thigpen BD, Bofill JA , Magann E, Moore LE &Martin JN Jr. A randomized clinical trial comparing vaginal misoprostol versus cervical Foley plus oral misoprostol for cervical ripening &labour induction. Am. J. perinatol. (2009) 26: 33-8.
20. Hofmeyr GJ, Gulmezoglu AM, Z Alfirivic, Z. Misoprostol for induction of Labor: a systemic review. Brit J. obstet. Gynaecol. 1999; 106: 798-803.
21. Bishop. E.H. pelvic scoring for elective induction. Obstet. Gynaecol. 1964; 24:266-268.
22. Embery MP, Mollison BG. The unfavorable cervix and induction of labour using a cervical balloon. J Obstet Gynaeol Br Commwlth. 1967; 74:44-8.
23. Anthony CS, Helen M, James SM, Philip AS, Marjorie P, Garrette HC a prospective, randomized comparison of Foley catheter versus intracervical prostaglandin E_2 gel for preinduction cervical ripening. Am J Obstet Gynecol. 1988; 180:55-9.
24. Ezimokhai M, Nwabinelli JN. The use of Foley's catheter in ripening the unfavorable cervix prior to induction of labour. Br J Obstet Gynaecol. 1980; 87:281-6.
25. Ashrafunnessa KS, Khatun S, Chowdhury AR, Begum SR, Rashid M, Khatun S. Induction of labour by intracervical prostaglandin gel and oxytocin infusion in primigravid women with unfavourable cervix. Bangladesh Med Res Counc Bull. 1997; 23:66-71.
26. Vengalil SR, Guinn DA, Olabi NF, Burd LI, Owen J. A randomized trial of misoprostol and extraamniotic saline infusion for cervical ripening and labor induction. Obstet Gynecol. 1998; 91:774-9.
27. Atad J, .Hallak M, Austender R, Porat-Packer T, Zarfali D, Abramovici H. A randomized comparison of prostaglandin E_2, oxytocin and the double-balloon device in inducing labor. Obstet Gynecol. 1996; 87:223-7.
28. Rouben D, Arias F. A randomized trial of extra-amniotic saline infusion plus intracervical Foley catheter balloon versus prostaglandin E_2 vaginal gel for ripening the cervix and inducing labor in patients with unfavorable cervix. Obstet Gynecol. 1993; 92:290-4.
29. Barkai G, Cohen SB, Kees L. Induction of labor with use of a Foley catheter and extraamniotic corticosteroids. Am J Obstet Gynecol. 1997; 177:1145-8.
30. Dewan F, Begum R, Chowdhury SB. Comparative study of induction of labour by Foley catheter with that of sweeping of the membrane in prolonged pregnancy. Sir Salmullah Med Coll J. 1995; 3:22-7.
31. Begum A, Dewan F, Chowdhury SB. Clinical study of induction of labour by Foley's catheter. Bangladesh J Obstet Gynaecol. 1996; 11:83-9.