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CERVICAL RIPENING AND INDUCTION OF LABOUR WITH FOLEY'S CATHETER COMPARED TO OXYTOCIN

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Abstract:

Objective: The purpose of this study was to evaluate the effectiveness, efficiency, benefit, safety and maternal and fetal complications by using the Foley's urinary catheter size 20 versus oxytocin for preinduction ripening of the uterine cervix and induction of labour.

Design: Prospective randomized clinical trial.

Setting: Labour and delivery ward of Wad Medani Maternity Teaching Hospital.

Methods: In the period from Jul. 2004 to Feb. 2005 Seventy patients requiring induction of labour at term with a Bishop score of ≤ 5 were randomized to receive Foley's catheter or oxytocin. The two important indications for induction included in this study were prolonged pregnancy and pre-eclampsia.

Results: In the Foley's catheter group the balloon was expelled in 34/35 (97.14%). The Bishop score after expulsion of the balloon was 6 to 8. Nine cases (25.7%) had lower segment caesarean section compared to twenty cases (57.1%) in the oxytocin group. No maternal or neonatal morbidity or death in both groups**.**

Introduction:

Induction of labour is common in obstetric practice with a rate varies from 9.5 to 33.7% of all pregnancies annually [(1)]. It means artificial initiation of labour before its spontaneous onset for the purpose of delivery of the feto-placental unit.

Induction should be considered when the benefits of vaginal delivery outweigh the potential maternal and fetal risks of induction [(2)]. The most common indication for induction is post term pregnancy with a gestational age of at least 41 completed weeks [(3)], accounting for nearly 70% of reported induction [(4)]. Other common indications include hypertensive disorders, premature rupture of the membranes (PROM), oligohydramnios, intrauterine growth restriction, and maternal diabetes.[(5)]

Several factors play a role in the ability to successfully induce labour. These include the parity, gestational age and the method used for induction. However, the favorability of the cervix is the most significant predictor of induction success [(5)]. Labour induction in the presence of unfavourable cervix is associated with an increased likelihood of prolonged labour, and increased incidence of chorioamnionitis and cesarean section [(6)]. Bishop score proposed by Bishop in 1964 has been used to provide an assessment of the uterine cervix and induction success [(7)]. It assesses the cervical dilatation, effacement, consistency, position and station of the presenting part. It is found that nulliparous women with Bishop Scores of less than 3 have a 23-fold increased risk of induction failure and a two-to four fold increased risk of cesarean delivery compared with nulliparous women with Bishop Scores of over 3 [(8)]. Similarly, multiparous women with Bishop Scores of 3 or less have a six-fold increased risk of induction failure and a two-fold increased risk

of cesarean delivery compared with multiparous women with higher Bishop Scores [8].

The pharmacologic and mechanical methods are the most important methods used for cervical ripening. Mechanical cervical dilatation with a balloon catheter was first described by Barnes in 1863. [9] Subsequently, there have been a number of reports, including randomized trials describing the use of Foley catheters for cervical ripening and labor induction. [9, 10, 11, 12, 13.] These trials concluded that; regardless of the methodological differences, the use of the Foley catheter has consistently been associated with rapid improvement in Bishop scores and shorter labors compared with women receiving placebo, prostaglandins (PGE1 and PGE2), or oxytocin infusions. Foley catheter affects cervical ripening through mechanical dilatation of the cervix and through prostaglandin production. The release of prostaglandins seems to be increased by further separation of the amnion from the deciduas.[14] It has been suggested that the use of extra-amniotic catheter balloon has the advantages of simplicity, low cost, reversibility and lack of systemic or serious side effect over the use of medical methods (prostaglandins and oxytocin) for cervical ripening.[15, 16, 17] Oxytocin is the commonest pharmacologic induction agent used worldwide. It has been used alone, in combination with amniotomy or following cervical ripening with other pharmacological or non – pharmacological methods. [18]

Objectives of this study include the following:

1. To estimate the effectiveness of ripening of the unfavorable cervix using mechanical stimulation with Foley's catheter compared to oxytocin.
2. To identify the complications of using both methods for ripening of the cervix and induction of labour.
3. To study and analyze maternal and fetal outcome after using Foley's catheter for ripening of the cervix compared with oxytocin.

Methodology:

This was a prospective comparative study conducted in the period from July 2004 to February 2005 at Wad-Medani Maternity Teaching Hospital with ethical approval from the relevant ethics committees. It was designed to study the effectiveness, efficiency, benefit, acceptance, safety and maternal and fetal complications by using the Foley's urinary catheter size 20 versus oxytocin for preinduction ripening of the uterine cervix and induction of labour.

Seventy pregnant women at term with unripe cervices and scheduled for induction of labour were included in the study after giving written consent. 35 of them were induced with Foley's catheter and 35 with oxytocin. The indications for labour induction included gestational age ≥ 41weeks and pre-eclampsia (blood pressure > 140/90 and proteinuria > 300 mg/24 hours). Other inclusion criteria include term (≥ 37 weeks gestation) singleton live fetus in cephalic presentation, intact membranes and a Bishop Score of 5 or less. Patients were excluded if they had any of the following: fetal distress, multiple pregnancy, previous cesarean section, placenta previa and ruptured membranes.

After enrollment, baseline data, including maternal age, gestational age, gravidity, parity, weight, height, cervical Bishop score and indication for induction were recorded. All women were managed by a registrar under direct supervision of a consultant.

Women in the Foley's catheter group had a number 20 Foley's with a 50-ml balloon inserted into the cervix under direct visualization. After explanation of the procedure, the patient was placed in the lithotomy position using leg supports. The vulva and the vagina were cleaned with antiseptic solution and a sterile Cusco's bivalve speculum was gently inserted into the vagina. Then the cervix was visualised and if

excessive mucous was obliterating the view then this was cleared with the use of a cotton wool ball. The balloon-tipped Foley catheter was then gripped with the sponge forceps and advanced up the endocervical canal; about 5cms of the catheter tip was passed through the cervix to ensure that the balloon was beyond the internal os. The balloon was then slowly inflated with the 50mls of normal saline and the catheter was connected with urinary bag. For the balloon to rest on the internal os, the catheter was then pulled down gently and tapped under gentle traction to the inner aspect of the patient's thigh. The catheter was checked for Foley bulb extrusion every 4 hours by cervical examination and the traction was adjusted so that gentle traction was continued. The patient was allowed to ambulate and take by mouth with fetal heart assessment every hour. Also the patient's pulse, blood pressure and temperature were checked regularly. Once the catheter fell out or was pulled out– usually 6 hours after insertion- one of the following options was taken: Immediate start of syntocinon with or without artificial rupture of the membranes, ARM without syntocinon or wait and re-evaluate later depending on the station of the presenting part. The Foley catheter was not left in situ for greater than 18 hours. We commenced syntocinon after 18 hours if patient was not in established labour after removal of catheter.

The group assigned to receive oxytocin, were managed according to standardized department protocol for induction of labour with oxytocin. Intravenous oxytocin was started at 1mU/min and increased by 2mU/min at 30-minutes intervals until adequate uterine activity was maintained (3 contraction in 10 minutes). The maximum dose of oxytocin allowed was 36mU/min.

Results:

Seventy cases were included in this study for preinduction ripening of the cervix and induction of labour. Thirty-five women were induced with Foley's catheter, and Thirty-five women were induced with oxytocin according to the criteria put as a protocol for this study.

(**Table 1**) shows the maternal demographic characteristics for the two groups. 32 patients (91.4%) of Foley's group and 22 patients (62.9%) of oxytocin group were in the middle age of the reproductive life; 20-29 years. The gestational age, parity and the indications for induction were similar in both groups. 21 patients (60%) in Foley's group were from rural areas, while 27 patients (77%) in oxytocin group were from urban areas.

(Table 2) presents Bishop Score values at insertion of Foley's catheter and after expulsion. At the time of the balloon insertion, Bishop score value ranges between 2 to 5 with the median of 3.5 (unfavorable cervix). At the time of balloon expulsion Bishop Score value ranges between 6 and 8 with median of 7. The change in Bishop Score value ranges between 3 and 4 with the median of 3.5.

About 2/3 of the Foley's group had artificial rupture of the membranes (ARM) after expulsion of the catheter during 6-11 hours; while in oxytocin group the majority of patients (76%) had ARM during 2-5 hours **(Table 3)**. The difference between the two groups is statistically significant. This means; an early ARM may affect the progress of labour and mode of delivery.

(Table 4) demonstrates the outcomes of labour and delivery. Most of the patients in Foley's group delivered vaginally, {24 (68.6%) cases vs.14 (40.1%) in oxytocin group}.however, they have prolonged induction-vaginal delivery time. 16 (45.7%) cases in Foley group delivered in 12-24 hours compared to 9 patients (25.8%) in oxytocin group. Cesarean section rate in Foley group was less than that in oxytocin group {9 (25.7%) cases vs. 20 (57.1%) cases in oxytocin group}. The indications for C/S were significantly different between the two groups, as 4 cases (11.4%) in Foley group had C/S due to failure of progress compared to 12 cases (34.3%) in oxytocin group, 2 cases (5.7%) indicated by failed induction in oxytocin group

compared to 1 (2.9%) in Foley group and 5 cases (14.3%) from oxytocin group indicated by fetal distress with no patients from Foley's group. The high rate of Cesarean section in oxytocin group explained the prolonged duration of stay in hospital in this group, {20 (57.1%) cases vs. 10 (28.6%) in Foley group} stayed for more than 48 hours.

Neonatal outcomes were comparable in both groups **(table 5)**. Newborn resuscitations were common in oxytocin group but the difference did not reach statistical significance.

Table 1. Demographic data:

Characteristics	Foley (n = 35)	Oxytocin (n = 35)	*Total (n, %)*
Maternal age(y):			
< 20	Zero	2(5.7%)	2 (2.9%)
20 – 29	32(91.4%)	22(62.9%)	54 (77.1%)
30 – 35	3(8.6%)	11(31.4%)	14 (20%)
Gestational age (wk):			
38-40	12(34.3%)	13(37.1%)	25(35.7%)
≥ 41	23(65.7%)	22(62.9)	45(64.3%)
P value		0.80	
Parity (n, %):			
Primigravida	32(91.4%)	31(88.6%)	63(90%)
Para 1	3(8.6%)	4(11.4%)	7(10%)
P value		0.69	
Residence:			
Urban	14 (40%)	27 (77.1%)	41 (58.6%)
Rural	21 (60%)	8 (22.9%)	29 (41.4%)
P value		.002	
Indications for induction:			
Prolonged pregnancy(n)	23 (65.7%)	24 (68.6%)	47 (67.1%)
Preeclampsia (PE) (n)	12 (34.3%)	11 (31.4%)	23 (32.9%)
P value		0.799	
Pre-induction Bishop score (mean & range)	2 -5 (3.5)	2 -5 (3.5)	

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Table 2. Bishop score value before & after catheter expulsion in Foley's group

Bishop score value at time of balloon insertion (range & median)	2 – 5 (3.5)
Bishop score value at time of balloon expulsion (range & median)	6 – 8 (7.0)
Change in Bishop score value range & median	3 – 4 (3.5)

Table 3. Time to artificial rupture of membranes

	Foley (n 35)	Oxytocin (n 35)	*Total (n, %)*
2 hrs	5 (14.3%)	10 (28.6%)	15 (21.4%)
3-5 hrs	9 (25.7%)	17 (48.6%)	26 (37.1%)
6-8hrs	8 (22.9%)	8 (22.9%)	16 (22.9%)
9-11 hrs	13 (37.1%)	0	13 (18.6%)
P value	.001		

Table 4. Labour and delivery outcomes

	Foley n,(%)	Oxytocin n, (%)	Total n, (%)
Induction-vaginal delivery time (24)			.
< 12 hrs	8 (22.9)	5 (14.3)	13(18.6)
12 - 17 hrs	12 (34.3)	8 (22.9)	20 (28.6)
18 - 24 hrs	4 (11.4)	1 (2.9)	5(7.1)

P value		0.01	
Mode of delivery:			
Vaginal delivery	24 (68.6)	14 (40.1)	38 (54.3)
Instrumental vaginal delivery	2 (5.7)	1 (2.9)	3 (4.3)
Cesarean section	9 (25.7)	2 0(57.1)	29 (41.4)
P value		0.028	
Indications of C/S:			
Failed induction	1 (2.9)	2 (5.7)	3 (4.3)
Fetal distress	0	5 (14.3)	5 (7.1)
Failure to progress	4 (11.4)	12 (34.3)	16 (22.9)
Other	4 (11.4)	1 (2.9)	5 (7.1)
P value		0.014	
Stay in hospital:			
24 - 48 hrs	25 (71.4)	15 (42.9)	40 (57.4)
> 48 hr	10 (28.6)	20 (57.1)	30 (42.9)
P value		0.004	

Table 5. Neonatal outcomes

	Foley group n=35, %	**Oxytocin group n=35, %**	***P***
Newborns weight, Lbs:			
6-6.9	9 (25.8)	6 (17.1)	
7-7.9	20 (57.1)	22 (62.9)	
8-8.9	6 (17.1)	7 (20)	
Newborn resuscitation	2 (5.7)	7 (20)	0.074
Need for NICU	0	1 (2.9)	0.03
Immediate breast feeding	35 (100)	34 (79.1)	0.314

Discussion:

In this study we compared a mechanical method for preinduction cervical ripening, a Foley catheter (35 cases), with a pharmacological method, oxytocin (35 cases).

The main intent of induction of labour is a rapid, uneventful and successful vaginal delivery. Improved cervical Bishop score leads to faster and improved vaginal delivery [19]. Among the important factors that determine the improved Bishop score is cervical dilatation [19,20].Using an extra-amniotic catheter balloon

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for induction of labor, particularly a larger balloon volume produces larger dilatation and a more advanced cervical ripening. Embery and Mollison [21] advanced a theory on the possible mechanism by which a Foley's catheter effects changes on the various components of the Bishop score (dilatation, effacement and consistency). The mechanical action of the Foley's strips the fetal membranes from the lower uterine segment and causes rupture of lysosomes in the decidual cells, part of which is phospholipase A. These lytic enzymes act on phospholipids to form arachidonic acid which in turn is converted to prostaglandin A which improves the consistency and effacement of the cervix. Our finding strongly supports this statement because we found that ripening of the unfavourable cervix with a balloon inflated with 50 ml of normal saline was associated with high Bishop score after cervical ripening, short induction-delivery interval, lower caesarean section rate and short hospital stay.

As in other studies [21, 22, 23], we waited until the balloon got expelled spontaneously; during 6 to 11 hours. The mean cervical dilatation at the time of expulsion of the balloon was 4.1 cm with standard deviation SD ± 1.3 cm. Amniotomy and augmentation with oxytocin were immediately offered after expulsion of the balloon. Oxytocin group had the amniotomy during 2-5 hours in 76% of cases.

At the time of balloon expulsion Bishop score value ranges between 6 and 8 with median of 7. The change in Bishop score value ranges between 3 and 4 with the median of 3.5.

Most of our patients in Foley's group delivered vaginally, {24/35 (68.6%) vs.14/35 (40.1%) }. However, 16/35 (45.7%) in Foley's group delivered in 12-24 hours compared to 9 patients (25.8%) in oxytocin group. Regarding this, Sciscione, et al. [23] stated that, induction to delivery time is probably related to Bishop score after ripening and to the method of induction used. For accurate comparison of time from induction to delivery, the method of induction must be consistent in both groups. Also, a randomized study [25], comparing early versus late amniotomy following cervical ripening with a Foley catheter, found that early amniotomy was associated with prolonged interval to delivery compared with late amniotomy.

Our study revealed that about 1/4th of the Foley's group delivered by cesarean section compared to more than 50% in oxytocin group. The difference is statistically significant. One patient in Foley group had failed balloon expulsion, also had failed induction with misoprostol. On caesarean sections, a tough fibrous ring at the level of internal os was found. These results are similar to a Cochrane study [26], reviewing mechanical methods for induction of labour: When compared with oxytocin, use of mechanical methods reduced the risk of caesarean section (4 trials; 198 women; 17% versus 32%; RR 0.55; 95% CI: 0.33 – 0.91). Compared with prostaglandins, several studies. [24, 26, 27] have found that the Foley catheter results in no deference in operative delivery rates or maternal or neonatal morbidity.

Several side effects have been cited as resulting from use of Foley catheter for preinduction cervical ripening: premature rupture of the membranes, displacement of the presenting part, bleeding and fever. [13.] These appear to be isolated instances and occur infrequently at most. None of these side effects has occurred in our study except one case in the Foley's group complicated by postpartum hemorrhage due to vaginal tear.

All the newborns in Foley's group and oxytocin group had Apgar score value of 10 at 5 minutes including those with fetal distress. Seven (20%) newborns from oxytocin group needed resuscitation compared to two (5.7%) newborns from Foley group.

Conclusion:

Induction of labour is a powerful tool in obstetric management. It should be used only when the benefits to fetus or mother outweigh those of pregnancy continuing. When induction is used, there should be sound

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indications and reasonable chance that it will succeed. Using Foley's urinary catheter is probably the most useful method for ripening of uterine cervix before starting formal induction of labour. It is an acceptable method for induction of labour by the clients because it is available all the time, easy to be used, cheaper, not harming the mother or the baby, not needing continuous electronic fetal monitoring and has less side effects than other methods of ripening of the cervix like oxytocin.

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