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Comparative Effects of Ballooning Intracervical Catheter and Prostaglandin Pessary on Cervical Ripening

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Abstract

Labor is induced to stimulate the uterine contraction in effort to have vaginal birth. Induction may be advocated to reduce fetal or neonatal morbidity and mortality. Indication of labor needs to be considered when risk and benefits analysis indicates that delivering the baby is safe option for mother or both rather than continuing the pregnancy and when there are no clear indications for caesarean section and no contraindication for vaginal delivery.

Keywords

Induction, Foley's Cather, Prostaglandin

1. Introduction

Induction of labor is one of the most common procedures in obstetrics [1]. Labor induction is the artificial initiation of labor prior to its spontaneous onset and purpose to accomplishing delivery of feto-placenta [2]. Labor induction is defined as the stimulation of regular uterine contractions before spontaneous onset of labor, using mechanical or pharmacologic methods in order to generate progressive cervical dilation and subsequent delivery [3].

Worldwide, 20% - 30% of deliveries are induced [4]. Unpublished data from WHO Global survey on maternal and perinatal health, which included 373 health-care facilities in 24 countries and nearly 300,000 deliveries, showed that 9.6% of the deliveries involved labor induction. Over all, the survey found that facilities in African countries tended to have lower rate of induction of labor (lowest: 1.4% in Niger) compared with Asian and Latin

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American countries (Highest: 35.5% in Srilanka) [5] [6].

Cervix is considered unfavorable if the derived score is less than 6 and cervical ripening is indicated prior to artificial rupture of membranes and oxytocin infusion to reduce the incidence of failed induction and caesarean delivery [7]. Induction should be considered when it is felt that the benefits of vaginal delivery out weight the potential maternal and fetal risks of induction. These issues should be discussed with the woman prior to initiation of induction.

One of the most common indications for induction is post term pregnancy with the gestational age of at least 41 completed weeks. Induction for this indication has been shown to reduce the likelihood of perinatal death [8] [9]. Other indications for induction include premature rupture of membranes [10] [11], potential fetal compromise (significant fetal growth restriction, non-reassuring fetal surveillance), maternal medical conditions, (Type-I diabetes, renal disease, significant pulmonary disease, hypertension—gestational or chronic), antiphospholipid syndrome, suspected or proven chronioamnionitis, abruption and fetal death. This list is not meant to be all inclusive.

Induction is sometimes performed for "social" or "geographic" reasons, without a medical or obstetric indication [12] [13]. There have been few well designed studies evaluating induction for this indication, with no randomized clinical trial since 1983 [14] [15], but the sample size did not provide adequate power to make these conclusions. A retrospective study [16] concluded that elective induction should be discouraged in then nulliparous women since the rate of cesarean delivery is increased with elective induction. A meta-analysis of early trials concluded that there is no benefit to elective induction and there is no place for it in term pregnancy [14]. The American College of Obstetricians and Gynecologists suggests that labor may be induced for logistic reasons, including risk of rapid labor, distance from hospital and psychosocial reasons [17].

Potential risks of induction include increased rate of operative vaginal delivery [14], caesarean birth [18], excessive uterine activity [19], abnormal fetal heart rate patterns, uterine rupture [20], and maternal water intoxication [21], delivery of preterm infant due to incorrect estimation of dates and possibly cord prolapse with artificial rupture of membranes [22].

The contraindications to induction of labor include contraindications to labor or vaginal delivery. Examples of this include previous myomectomy entering the uterine cavity, previous uterine rupture, fetal transverse lie, placenta previa, vasa previa, invasive cervical cancer, active genital herpes, and previous classical or inverted T uterine incision (except in unusual circumstances such as extreme prematurity) [23] [24].

Numerous techniques have been used to ripen the unfavorable cervix to achieve the changes necessary for labor [25]. Presently pharmacological and mechanical agents are used to modify the cervical status 2. Prostaglandins are the most commonly used pharmacological agents for ripening of cervix and prostaglandin E2 (PGE2) is the agent of choice for this purpose [26], but are expensive [27].

A variety of more economical mechanical methods are also used for cervical ripening like intracervical Foley catheter with or without extra amniotic saline infusion, bogies and hygroscopic laminaria tents. The use of Foley's catheter to effect cervical ripening was first described by Embrey and Mollison in 1967 [28]. There is clinical evidence which shows that the appropriate utilization of mechanical methods for pre-induction cervical ripening is safe, not expensive and with a similar success rate to that of intravaginal PGE2. The most commonly used mechanical method is the intracervical Foley's catheter [29].

Our study aimed to compare the safety and efficacy of prostaglandin E2 vaginal pessary and the cheaper intracervical Foley's catheter in women with unfavorable cervices (modified Bishop Score ≤ 4).

2. Data Collection Procedure

During the study period, 100 patient were selected for cervical ripening and out of 100 fifty (50) patients had Intracervical Foley's catheter insertion, No-16-F catheter with 50CC saline in the blub (Group-I) and 50 had 3 mg of dinoprostone OR Prostaglandin E2 (PGE2) pessary (Group-II). Pre-induction cervical scoring was noted. After 6 hours change in bishop's score was noted in both groups. The cervical dilatation and improvement in bishop's cervical score and outcome of induction of labor were compared in both the group.

The protocol followed was as follows:

1) Time for score greater than 6 was noted and if the score still was less than 6, then in cases of PGE2 pessary, reinstallation done after a period of 4 hours.

2) If score was more than 6 then all patients (of both groups) were subjected to artificial surgical anatomy of

the membranes, followed by titrated oxytocin drip at rate of 1 mu/min and then increased by algebraic progression.

3) The course of labor was charted on a partograph in every case.

Indications for cervical ripening and induction of labor were:

Post term pregnancy.

Pregnancy induced hypertension/Toxaemia of pregnancy.

- Oligohydramnios.
- Intrauterine growth retardation.
- Suspected fetal jeopardy.
- Suspected placental insufficiency.
- Bad obstetrical history.
- Diabetes mellitus.

In cases of systemic illnesses like bronchial asthma, Foley's catheter was used as PGE2 was contraindicated. Prophylactic antibiotic was given to every patient.

Out of the total 100 patients studied, 50 had Foley's insertion, No-16-F catheter with 50 cc saline in the bulb (Group-I) and 50 had PGE2 pessary insertion (Group-II). These patients were admitted for induction of labor due to various indications described above. Under aseptic conditions patients kept in the lithotomy position, cervix was assessed on the Bishop's scoring scale. In Group I, cervical os was exposed with a bivalve speculum and Foley's catheter No-16 was inserted into the extra amniotic space and bulb was inflated with 50ml of normal saline, the distended bulb was hitched on the internal os and catheter was strapped to the abdomen for 6 hours. Prophylactic antibiotic was given.

After 6 hours, catheters were either removed by deflation of bulb, or were expelled out spontaneously. Bishop's cervical scoring was again repeated and if score was more than 6, artificial rupturing of membranes was done for color of liquor, followed by induction of labor and augmentation with oxytocin at 1 mu/min with titration if Liquor was clear. In Group-II 3 mg dinoprostonePGE2 pessary was inserted intracervical by the withdrawal technique aseptically, patient lied recumbent for 30 minutes, repeat per vaginal examination was done later after 6 hours, improvement in Bishop's score more than 6 was noted. Fetal heart rate and uterine activity was monitor strictly and half hourly intrapartum monitoring of fetal heart rate on CTG machine and progress of labour on partograph recorded in all cases.

3. Results

During the study duration from 14 Feb 2011 to 13 Feb 2012 of the 100 women recruited in the study, study carried out at Gynecological ward of Liaquat University of Medical and Health Sciences Hospital Hyderabad.

Analysis of booking status listed in **Table 1** revealed that 76.0% (n = 76) were un-booked having no antenatal care and 24.0% (n = 24) were booked had statistically significant difference P = 0.001.

50 women had intracervical Foley catheter (Group I) and 50 had PGE2 pessary (Group II). There were no protocol violation, relation to the parity listed in **Table 2** showed maximum number of patients (n = 52) 52.0% Primigravida and (n = 48) 48.0% multigravidas were included, had no significant difference P = 0.143.

Age distribution is listed in **Table 3** maximum patients (n = 51) 51.0% at age between 26 - 35 years, 29 (29.0%) were between 20 - 25 years, 16 (16.0%) were >35 years and 04 (4.0%) patients were belong to less than 20 years. Two groups had significant difference in maternal age P = 0.002.

Regarding the gestational age 69 (69.0%) patients in our study presented between 37 - 39 weeks of gestation. However, 31 (31.0%) patients were at 40 - >40 weeks of gestation had a significant difference value 0.0014 (**Table 4**).

Table 1. Booking status.

Distribution of cases	Number	Percentage	P-value
Un-booked	76	76.0%	
Booked	24	24.0%	0.003
Total	100	100	

Table 2. Parity of patients.

Parity	Total No.	Foley's Catheter	PGE2	P-value
Primigravida	52	26	26	
Multigravidas	48	24	24	0.143
Total	100	50	50	

Table 3. Age distribution.

Age (years)	No. of cases (100)	Percentage	P-value
<20	04	4.0%	
20 - 25	29	29.0%	0.143
26 - 35	51	51.0%	
>35	16	16.0%	

Table 4. Duration of gestation.

Gestational age (W)	Number	Percentage	P-value
37 - 39 weeks	69	69.01%	
40 - >40 weeks	31	31.0%	0.0014
Total	100		

Indication for cervical ripening and induction of labor is listed on **Table 5** commonest indication was pregnancy induced hypertension followed by prolonged pregnancy in both groups, however Foley's catheter use in other indication (IUGR) etc.

Table 6 shows the Bishop score between Foley's catheter and Prostaglandin group. 9 (18%) had Bishop Score 2 - 3 in Foleys catheter and 10 (20%) patients had Bishop Score 2 - 3 in Prostaglandin group. Similarly, 41 (82%) patients had Bishop Score 4 - 5 in Foleys catheter and 40 (80%) had Bishop Score 4 - 5 in Prostaglandin group.

Table 7 shows induction-delivery interval was significantly shorter in Prostaglandin group than that in catheter group (11.58 hours vs. 19.45 hours; $P \leq 0.002$). Also greater number of women (44/50) delivered within 24 hours of start of induction in Prostaglandin group than those in Catheter group (36/50) $P = 0.045$.

The mode of delivery did not reveal any significant difference in two groups listed in **Table 8**.

Table 9 shows two babies had an APGAR score 4/10 at end of 1 min and 7/10 at end of 5 min in Prostaglandin group whereas all babies in Foley's catheter group had an APGAR score of 9/10 had no significant difference $P = 0.148$.

The indications for caesarean section are shown in **Table 10**. There were 04 (8%) cases of failed induction in Foley's catheter group vs. 2 (4%) in Prostaglandin group. However 4 (8%) cases of fetal distress, 4 (8%) cases of meconium stained liquor in the Prostaglandin group. There was no increased incidence of neonatal sepsis or chorioamniotis or puerperal sepsis in any of our patients. There was no accidental rupture of membranes while introducing Foley's catheter. No perinatal morbidity or mortality or any severe maternal complications were noted while mild side effects in either group were noted (**Table 11**).

4. Discussion

The need to ripe the cervix prior to induction of labor 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 [30].

A randomized trial of use of prostaglandins and extra-amniotic saline infusion for cervical ripening and labor induction by Shyla *et al.* showed that both methods of labor induction to be equally effective [31].

Table 5. Indication for cervical ripening and induction of labor.

Indication	Foley's Catheter	Prostaglandin
PIH/HT in pregnancy	24 (48%)	30 (60%)
Postdates	12 (24%)	20 (40%)
Other (IUGR) etc.	14 (28%)	00

Table 6. Bishops scoring scale and change in bishop score.

Bishop's score	Foley catheter (n = 50) n%	Prostaglandin (n = 50) n%
2 - 3	9 (18%)	10 (20%)
4 - 5	41 (82%)	40 (80%)

Table 7. Outcome of labor induction.

	Foleys catheter	Prostaglandin	P-value
Induction-delivery interval (hours)	19.45 (5.48 - 40.25)[a]	11.58 (6 - 55.13)[a]	<0.002
Number of delivered within 24 hour	36/50 (72)[b]	44/50 (88)[a]	0.045

Table 8. Mode of delivery.

Mode of delivery	Foley's Catheter	PGE2 P-value
Normal vaginal delivery	40 (80%)	37(74%) 1.06
Forceps delivery	Nil	02 (4%) 0.06
Vacuum delivery	6 (12%)	01 (2%) 1.0
LSCS	4 (8%)	10 (20%) 1.03

Table 9. Apgar score.

	Score	Foley's Catheter	PGE2	P-value
APGAR at 1 min	4 - 6	Nil	02	
	7 - 8	Nil	Nil	0.12
	9 - 10	50	48	
APGAR at 5 min	4 - 6	Nil	Nil	
	7 - 8	Nil	02	0.148
	9 - 10	50	48	

Table 10. Indication of LSCS.

Meconium stained liquor	Foley's Catheter	PGE2	P-value
Fetal distress (non-reactive CTG)	Nil	04 (8%)	0.07
Failed induction	04 (8%)	02 (4%)	
Uterine hyper stimulation	Nil	Nil	

Table 11. Side effects.

Side effects	Foley's Catheter	PGE_2
Nausea	Nil	24
Vomiting	Nil	10
Diarrhea	Nil	02
Fever	Nil	05
Accidental rupture of membrane	Nil	Nil
Chorioamniotis	Nil	Nil
Infection	03	Nil
Uterine hyper stimulation	Nil	Nil

Several studies have been shown superiority of the Foley's balloon catheter over the other techniques, resulting in improved cervical Bishops score increase rate of labor induction and higher number of vaginal deliveries [32] [33].

In our study most of patients (n = 76, 76.0%) were unbooked having no antenatal care that indicates the lack of antenatal care is a major contributing factor for maternal and fetal morbidity and mortality.

A study done in Karachi revealed that women receiving antenatal care were more knowledgeable about the importance of nutrition and health awareness [34].

In our study (n = 26, 52%) women were primary gravidas and (n = 24, 48%) were multigravidas in Foley Catheter group, while it was not matched with the study done in Dhaka. Similarly (n = 26, 52%) women were primary gravidas and (n = 24, 48%) were multigravidas in prostaglandin group, while it was contradict with the study done in Dhaka. In both groups there was no significant difference regarding gravidity (P = 1.00).

Maximum patients were seen in age group of 26 - 35 years (51%) while 16% patients were above 35 years of age and 04% patients were below 20 years of age.

Minimum and maximum gestational age were 37 & 42 weeks respectively while minimum gestational age was 28 weeks in the study of F. Dewan [35], while maximum gestational age was 42 weeks in the study of F. Dewan that was similar with our study [35].

The common indications for induction of labour was Hypertensive disorders of pregnancy it was given 24 (48%) in Foleys catheter group, while 22 (44%) in Prostaglandin group, while it was lower in the study done in Dhaka while it was matched with the study done in Punjab [36].

Second most common indication was postdates done in 2 (24%), 12 (24%) respectively it was closer with the other studies [35] [36]. In our study 14 patients (28%) had given induction due to IUGR in Foley catheter group patients and 08 patients (16%) had given Prostaglandin pessary while it was lower in the study done in Punjab [36].

In our study 9 patients (18%) had Bishop Score 2 - 3 in Foley catheter group and 10 patients (20%) had Bishop Score 2 - 3 in prostaglandin group. Similarly 41 (82%) patients had Bishop Score 4 - 5 in Foley catheter and 40 (80%) in a prostaglandin group. These results correlate with the study done in Dhaka [35].

Induction delivery interval was significantly shorter in prostaglandin group than that of Foley catheter group. (11.58 hours versus 19.45 hours, $P \leq 0.002$). The results were similar with the study done in Punjab [36] while contradict with the studies done by F. Dewan [35] and E. L. Torkey *et al.* [37].

Greater number of new women 44/50 (88%) delivered within 24 hours of start of induction in prostaglandin group then those in a catheter group 36/50 (P = 0.045). The results were similar in different studies [35] [36].

The time from start of induction to the birth was substiantionally longer with the Foley catheter group; it was similar with the study of Martafozwik [38].

Number of caesarean sections was 10 (8%) in prostaglandin group, where as it was 4% in Foley catheter group. Though there was higher caesarean section in prostaglandin group but statistically there was significant difference between these two groups, while the caesarean section was 9 (20%) in prostaglandin group and 8% (17.8%) in Foley catheter group in the study done in Bangladesh [39].

The caesarean section was apparently higher in prostaglandin group because of Meconium stained liquor, fet-

al distress and failed induction. It was 4%, 4%, 2% respectively. These patients were immediately treated with oxygen therapy, Left lateral positioning, followed by emergency caesarean section. Our findings along with results of other randomized controlled trials [40]-[42]. Shows that, Foley's catheter and prostaglandin pessary give similar vaginal delivery rate although we hypothesized that Foley's catheter reduce caesarean delivery.

Caesarean section deliveries done because of failed induction were seen more often whereas caesarean section deliveries for fetal distress were not seen with the use of prostaglandin same was reported by the study done in Netherland [38].

Two of ten newborns had poor Apgar score at one minute but they improved subs intentionally and five minute APGAR score becomes 10 after neonatal resuscitation.

The main argument against the use of this method could be the risk of introduction of infection because many potential pathogens inhabit vagina and end cervix. But the improvement was not quantitatively assessed. These risks can be eliminated by aseptic precaution, use of aseptic techniques during the insertion of the catheters and the use of sterile water for inflating the balloon. In the present series, it was not possible to ensure that there was no obvious vaginal infection in all of these patients as there were limited facilities for culture and sensitivity tests of high vaginal and endocervical swabs. We have taken high vaginal swabs (HVS) in 10 patients of the Foley catheter group to detect infection. Among them in three (20%) cases there was mild growth of organism, which responded promptly to antibiotics. Garry *et al.* [43] states that the presence of catheter can be a constant risk of infection. But Sandhu *et al.* [44] 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 using different procedures.

5. Conclusion

Though prostaglandins are currently most commonly accepted and widely used agents for the ripening of unfavorable cervix and for induction of labour in the developed countries, but they are associated with some problems, such as absorption, unpredictable patient response, vomiting, diarrhea, tachycardia, fever, bronchospasm, and sometimes unavoidable irreversible hypertonic uterine contraction. An alternative approach for cervical ripening has been sought. This alternative approach should be safe, easy available, preserved at normal temperature, as effective as prostaglandins, cost-effective, less side effects and acceptable to the patients as well as to the physicians. Foley's catheter for cervical ripening has been found as an alternative method to prostaglandins, as it has almost all the expected criteria; its inducibility rate is high and the success rate is 80% in our study. The potential advantages of Foley's catheter over prostaglandin E_2 are low cost and reversibility.

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