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Original Research Article

Comparative study between transcervical extra-amniotic Foley's bulb and prostaglandin E2 gel for pre-induction cervical ripening

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ABSTRACT

Background: Induction of labor is an artificial initiation of uterine activity before the spontaneous onset of labor with the aim of achieving vaginal delivery. Various pharmacological and non-pharmacological methods have been studied for the purpose.
Methods: This randomized prospective study conducted in the Department of Obstetrics and Gynaecology at the Seth V. C. Gandhi & M. A. Vora Municipal General Hospital (Rajawadi Hospital), Mumbai from June 2019 to April 2020. It included pregnant patients admitted to the labor ward for induction of labor. A total 200 women were recruited and randomly allocated to the two study groups fulfilling the following selection criteria. Of these, 100 women were included in Foley's catheter group (group A) and 100 in (group B) prostaglandin E2 (PGE2) group.
Results: The subjects included mainly were of 24-28 years age group. The period of gestation was 37-42 weeks in majority of the women in both the groups. Maximum numbers of women in both groups were primigravidae, being 66% in group A and 70% in group B. Foley catheter proved to be a highly effective pre-induction ripening agent for unfavorable cervix, compared to PGE2 gel, as evident by the mean Bishop score at 12 hours ($p<0.05$) and by the difference in change of Bishop score over 12 hours ($p<0.05$) in both groups A and B. Women in both the groups had a high rate of normal vaginal delivery, rate being significantly more in Foley's group.
Conclusions: This study concludes that extra-amniotic Foley's catheter balloon is an effective, safe, simple, low cost, reversible, non-pharmacological mechanical method of pre-induction cervical ripening.

Keywords: Prostaglandin E2, Foley's catheter, Cervical ripening

INTRODUCTION

Induction of labor is an artificial initiation of uterine activity before the spontaneous onset of labor with the aim of achieving vaginal delivery.[1,2] In modern obstetrics, indications for induction of labor can be fetal, maternal or combination of both, in which prolongation of pregnancy would jeopardize both maternal and fetal wellbeing.[3]

From a practical standpoint, the success of induction of labor depends upon the degree of "ripening of cervix," which can be best assessed objectively by inducibility score as designed by Bishop EH 1964.[4-6] Higher the score, better is the prognosis of induction of labor.[7] Final goal of an obstetrician, is a pregnancy that results in a healthy infant and a minimally traumatized mother.8 Induction of labor when cervix is unripe, is associated

with frequent maternal and fetal complications, with high rate of induction failure and cesarean delivery rates.[9-11]

Methods used for induction of labor are mainly medical, surgical and combination of both. Oxytocin infusion is widely used, universally accepted and time honored method for induction of labor.[12,13] However it has some of its inherent problems like inconvenience because of intravenous administration, hypertonic uterine action, requirement of intensive and frequent monitoring of feto-maternal vitals and rarely rupture of uterus.[13,14] In addition to all these problems, the success of induction is not promising in women with unfavorable cervix so to improve the success of procedure concept of "pre-induction cervical ripening" has evolved.

Various pharmacological and non-pharmacological methods have been studied for the purpose.

Locally applied prostaglandins have been thought to be the most popular and physiological in initiating the process of labor.[15-21] These have remarkable success rate but may be associated with significant untoward effects on mother, fetus or newborn. To combat these side effects some alternative methods are always hoped for in obstetric practice.

The use of extra-amniotic catheter balloon applied above the internal cervical os has been advocated as a safe, low cost, mechanical method of cervical ripening.[22,23] Numerous reports have indicated the significant increase in Bishop Score and shortening of induction to delivery interval with extra-amniotic transcervical Foley's balloon catheter. The main argument against the use of Foley's catheter has been theoretical risk of introduction of infection, which can be reduced with aseptic precautions.

The purpose of this study is to explore the effectiveness of the extra-amniotic Foley's catheter balloon for ripening of cervix and inducing labor in patients with unfavorable cervix and compare its efficacy and safety with that of intracervical prostaglandin E2 (PGE2) gel.

METHODS

This randomized prospective study conducted in the Department of Obstetrics and Gynaecology at the Seth V. C. Gandhi & M. A. Vora Municipal General Hospital (Rajawadi Hospital), Mumbai from June 2019 to April 2020. It included pregnant patients admitted to the labor ward for induction of labor. A total 200 women were recruited and randomly allocated to the two study groups fulfilling the following selection criteria. Of these, 100 women were included in Foley's catheter group (group A) and 100 in (group B) prostaglandin E2 (PGE2) group. Patients with singleton live fetus with cephalic presentation with period of gestation>33 weeks to<42 weeks with intact membranes and Bishop score<4 are included in study. Patients with placenta previa with history of cardiac disease, glaucoma, convulsion disorder, asthma or jaundice, hypersensitivity to drugs previous caesarian section, myomectomy, hysterotomy, uterine unification and presence of cervicovaginal infection are excluded in this study.

After taking informed consent, as in the above prescribed proforma, particulars of the patients such as name, age, parity, detailed history of present pregnancy, menstrual history and obstetric history was recorded, and period of gestation and indication for induction of labor was reascertained. Significant family history and past history was also noted to rule out any exclusion criteria.

To exclude any maternal disease, thorough general examination and systemic examination was done. Abdominal examination was done to see the fundal height and to confirm the presence of single live fetus. Ultrasonography was done whenever it was indicated to rule out placenta previa and to confirm presentation. Speculum examination was carried to rule out vaginal and cervical infection. Vaginal examination was performed to assess modified Bishop Score and pelvic assessment for adequacy.

Investigations which are done as a routine in all pregnant women i.e. hemoglobin estimation, urine examination for protein and sugar, blood group and Rh type if not already performed were done. Other investigations pertaining to case were done, if required.

With empty bladder vaginal examination was performed to assess the Bishop's score and the pelvis. If Bishop's score was<4 and pelvis was adequate, then with the aid of Sim's speculum, the portio-vaginalis part of cervix was cleaned with betadine solution.

Procedure

Foley's catheter group (group A)

Anterior lip of cervix was held with a sponge holding forceps, prepacked sterile Foley's catheter of 22-gauge size was introduced through the external os, with the help of sterile artery forceps beyond the internal os. After that the catheter balloon was inflated with 50 ml of sterile normal saline and the catheter was pulled back, so that the bulb got hitched back against the internal os. The outside portion of the catheter was folded and strapped loosely by leucoplast to the medial aspect of upper thigh of the patient. Patients were observed for 10-15 minutes for leakage of amniotic fluid, deflation of balloon and were monitored for fetal distress and uterine activity over the next twelve hours.

After twelve hours the catheter was deflated and removed if not already expelled. Rescoring of the cervix was done. A note was made on spontaneous expulsion or removal of catheter and whether the subject was in active labor.

In the absence of active labor, patients were prepared for further induction of labor with I.V. oxytocin infusion.

Initially oxytocin was started at the dose of 1 mU/minute and escalating doses of I.V. oxytocin, every half an hour, by arithmetic regimen. (e.g. 1,2,4,6,8,10,12 mU/ minute) The IV oxytocin dose was titrated against the response and was increased till the patient got good contractions lasting for 40 seconds with a frequency of three contractions every ten minutes. I.V. oxytocin infusion was not increased above a maximum of 64 mU/minute.

Prostaglandin E2 gel group (group B)

The prostaglandin E2. (brand name- cerviprime 0.5 mg, Astra Zeneca) prepacked in sterile prefilled ready to use syringe was instilled into the endocervix. Cold chain maintenance was confirmed.

Patient was asked to lie supine for at least 30 minutes and was monitored for fetal heart rate and uterine activity. After six hours if on pelvic examination Bishop score did not change and repeat instillation was done. After twelve hours, vaginal examination was done and rescoring was performed. Active labor pains were noted. In the absence of active labor, oxytocin induction was done as described above.

The outcome of the study was compared between the two groups in terms of the following parameters: Bishop scoring before and after 12 hours of insertion of Foley's catheter or instillation of prostaglandin E2 gel, percentage of subjects entering spontaneous labor, insertion-expulsion interval of Foley's catheter, procedure-delivery interval, amount of oxytocin used (total number of units), outcome of labor (number of normal deliveries, number of forceps, number of cesarean sections) and side effects and complications, if any.

RESULTS

A total of 200 women admitted for induction of labor were included in this prospective randomized study to compare the safety and efficacy of transecervical extra-amniotic Foley's catheter balloon (group A) with PGE2 gel (group B) for pre-induction cervical ripening (Table 1).

Table 1: No. of patients studied in two groups.

Group	No. of patients
A	100
B	100
Total	200

The age of the women in both Group A and Group B was in the range of 19-35 years. The age distribution is shown in Table 2.

Maximum number of women belonged to the age group of 24-28 years. Gravidity ranged from 1 to 6 in group A and 1 to 3 in group B.

Table 2: Distribution of women according to age.

Age in years	Group A (n=100)	Group B (n=100)
19-23	36	38
24-28	44	54
29-33	16	8
>34	4	0
Mean±SD	25.04±3.9	24.4±3.4

Maximum numbers of women in both groups were primigravidae, being 66% in group A and 70% in group B (Table 3).

Table 3: Distribution of women according to gravidity.

Gravidity	Group A (n=100)	Group B (n=100)
G1	66	70
G2	14	25
G3	8	5
>G3	12	0

Majority of the women were between 37-42 weeks of gestation (82% in group A and 81% in group B). Incidence of preterm delivery was 16% in group A and 15% in group B (Table 4).

Table 4: Distribution of women according to period of gestation.

Period of gestation(week)	Group A (n=100)	Group B (n=100)
<37	16	15
37-40	40	38
40.1-42	42	43
≥42	2	4
Mean gestation±SD	38.81±2.2	39±2.3

The commonest indication found for induction of labor was postdated pregnancy in both group A (43%) and group B (46%) (Table 5).

Table 5: Indications for induction of labor.

Indication	Group A	Group B
	No. of women	**No. of women**
Postdated pregnancy	43	46
PIH	32	26
IUGR	13	10
Poor BPP	9	15
GDM	2	3
Rh isoimmunisation	1	0

The Bishop score in group A was compared with group B at '0 hrs' i.e. at the start of procedure and at '12 hrs' i.e. at the completion of procedure (Table 6).

Table 6: Bishop scores at 0 hour.

	No. of women	Bishop score at 0 hr. (Mean±SD)
Group A	100	2.72±0.90
Group B	100	2.38±0.94
p Value		>0.05

The number of women included in each group A and group B for assessing cervical ripening were 90 at 12hrs, because in both groups 10 women delivered before 12 hrs i.e. before the completion of procedure. 20% cases needed reinstillation of PGE2 gel, having no change in the score at 6 hrs. So, average patient required 1.2 applications (Table 7).

Table 7: Bishop scores at 12 hours and the change in Bishop score.

	No. of women	Bishop Score at 12 hrs. (Mean±SD)	Change in Bishop score (Mean±SD)
Group A	90	6.4± 1.12	3.7± 1.5
Group B	90	5.2 ± 1.2	2.7± 1.4
p Value		< 0.05	<0.05

Table 8: No. of women having spontaneous expulsion (SE) of Foley's catheter.

No. of women having SE	Mean time of SE (hrs)
32	**7.94**

Table 9: Procedure -delivery interval (in hours).

PDI (hours)	Group A (n=100)	Group B (n=100)	P value
	No.	No.	
<12 hours	10	10	>0.1
12-24 hours	42	66	
>24 hours	48	24	
Mean (PDI)±SD	23.621±0.58	22.10±8.6	

Table 10: Mode of delivery.

Type of delivery	Group A (n=100)	Group B (n =100)
NVD	76	54
Instrumental delivery (OFD)	8	20
Caesarean delivery	16	26

Chi square p value is<0.05, NVD=Normal vaginal delivery, OFD=Outlet forcep delivery

Table 9 shows the interval (in hours) between the pre-induction procedure of ripening of cervix and the delivery of the baby in both the groups A and B.

DISCUSSION

Over the last two decades, the incidence of induction of labor has increased dramatically. It is now well accepted that ripening of cervix by a variety of methods serves to decrease the induction failure.[24] The final goal of an obstetrician is a pregnancy that results in a healthy infant and minimally traumatized mother.[8]

Endogenous prostaglandins play a key role in the initiation of labor at molecular levels, this makes prostaglandins most physiological. But they are not always safe.[25] From times, many alternative methods are being tried to prove superiority. Mechanical agents like balloon catheter above the internal os may be a more reasonable alternative to initiate cervical ripening.

The use of an extra-amniotic Foley's catheter balloon, inflated over the internal cervical os, first described by Embrey and Mollison in 1967 and later evaluated by numerous investigators has been advocated as a safe, low cost and non-pharmacological method of cervical ripening before induction of labor.[26]

The present prospective randomized study is aimed at comparing the efficacy and safety of extra-amniotic Foley's catheter balloon with intracervical prostaglandin E2 gel for pre-induction cervical ripening.

In the Present study the subjects included mainly were of 24-28 years age group (Table 2). Mean age (in years) for Group A and Group B was 25.04±3.9 and 24.4±3.4 respectively. which was statistically not significant.

In the study conducted by Perry et al in 1998 mean age in years of patient was 23±6.3 and 24±5.9 in vaginal misoprostol plus intracervical balloon catheter and intravaginal dinoprostone gel group, respectively.[27]

Gravidity ranged from 1 to 6 in group A and 1 to 3 in group B. Maximum numbers of women in both groups were primigravidae, being 66% in group A and 70% in group B. Likewise maximum number of patients were nulliparus, 66% in Group A and 70% in group B (Table 3).

A randomized comparative study conducted by Perry et al in 1998 included 52% and 44% primigravida in vaginal misoprostol plus intracervical balloon catheter and intravaginal dinoprostone gel group respectively.27 In the present study, majority of the women were between 37-42 weeks of gestation (82% in group A and 81% in group B). Mean gestational age in weeks was 38.81±2.2 and 39±2.3 for group A and B respectively which was statistically not significant (p>0.05) (Table 4). In the study by Ezimokhai M, Nwabinelli JH mean gestational

age in wks was observed to be 40.6±1.1 and 40±1.9 in Foleys catheter and misoprostol group respectively.[28]

In the present study main indication for induction of labor was postdated pregnancy 43% and 46% in Group A and B respectively. Pregnancy Induced Hypertension was next common indication 32% and 26% in Group A and B respectively. Patient belonging to gestational age 40.1-42 wk were 42% and 43% in group A and B respectively and out of total patients only 2% in group A and 4% in group B satisfied the definition of prolonged pregnancy(>42wks). This is because of our hospital policy of induction of every patient beyond 40 weeks of gestation (Table 5). In study done by St. Onge RD majority of the indications for induction were pregnancy induced hypertension (47%) in catheter group and oligohydramnios (42%) in PGE2 group.[29]

The bishop score in group A was compared with group B at '0 hrs' i.e. at the start of procedure and at '12 hrs' i.e. at the completion of procedure. One of the inclusion criteria of patient in this study was Bishop score of<4. Mean Bishop score at the start of procedure was 2.72±0.90 and 2.38±0.94 for group A and B respectively which was statistically not significant (P>0.05) (Table 6 and 7). Ezimokhai M, et al included patients with bishop score ≤3.28. Rouben D, et al included 112 patients with Bishop score of 5 or less.[30] In 2001 Sherman et al included 116 patients with bishop score of 3 or less.[31]

The number of women included in each group for assessing cervical ripening were 90 at 12hrs, because in both groups 10 women delivered before 12 hrs i.e. before the completion of procedure. Mean Bishop score at 12 hr of procedure was 6.4±1.12 and 5.2+1.2 in group A and B respectively which was statistically significant (P<0.05). After 12 hrs of cervical ripening procedure change in Bishop score was 3.7±1.5 for group A and 2.7±1.4 for group B. This change in Bishop score was statistically significant (P<0.05).

In the study of Ezimokhai M, Nwabineli JN they had observed the mean Bishop score of 6.2 and 5.8 after a priming period of 12 hours in Foley's balloon and intracervical PGE2 gel respectively.[28] There was no statistical difference between the two groups. In the study of Shreyer et al mean Bishop score increased from 1.7 to 7.8 in a mean time of 2.8 hrs in Foley's catheter group, while in the control group (PGE2) it increased from 1.9 to 5.6 during a mean time of 8.5 hrs.[32] Therefore, extra amniotic saline infusion with Foley's catheter was associated with greater change in Bishop Score in less time. Rouben D, Arias F observed extra-amniotic saline infusion plus intracervical Foley catheter balloon was more effective than PGE2 vaginal gel in causing cervical ripening.30 Mean Bishop score of 6.2 and 5.8 after a priming period of 12 hours with Foley's balloon and intracervical PGE2 gel respectively was observed which was statistically significant.

Spontaneous expulsion (SE) of Foley's catheter was noted in 32 women of group A, taking a mean of 7.94 hours (Table 8). However, the insertion-expulsion time in the study done by Sherman et al was relatively short, averaging 6.5± 0.6 in saline group and 4.7±0.4 in PGE2 group, because of the extra-amniotic saline infusion through the catheter's port.[31] On the other hand, St. Onge had observed the mean time of 10 hours of Balloon expulsion after cervical ripening.[29]

In the present study, 10 out of 100 in group A and 10 out of 100 women in group B went into spontaneous labor and did not require IV oxytocin. Ezimokhai and Nwabineli reported spontaneous labor in 9.5% cases in Foley's group & 14.3% cases in PGE2 group.[28] In a study by Cromi, Ghezzi et al out of 602 women undergoing cervical ripening with a Foley's catheter, 160 (26.6%) went into active labor without additional interventions.[33] These small rates were probably due to inclusion of lesser number of multigravidae in these studies.

The mean dose of oxytocin required in group A (8.62±4.59 U) was more than in group B (7.59±4.15U). The difference was not statistically significant (P>0.05). Thus, despite the significantly more change in bishop score in group A, the requirement of oxytocin was statistically similar in both groups. Parallel impression can be made from the study of Sciscione et al in which they proved significantly greater Bishop score change in Foley's catheter group, yet the oxytocin use was not significantly different in the groups.[34] (Foley group & PGE2 group). The above observation does not go with Anderson MM et al report that women with unripe cervix require more oxytocin.[7] But this hints some factors, other than cervical ripening influence oxytocin requirements.

To discuss more, we can go to basic mechanism that both Foley's catheter & PGE2 improved the various components of cervical assessment (dilatation, effacement & consistency), but PGE2 gel improved the consistency to a greater extent and it has effect on uterine myometrial contractility. Cervical consistency could have greater bearings regarding induction of labor.

In the present study, mean procedure-delivery interval (group A=23.621±0.58 hrs and group B=22.10±8.6 hrs) in both groups was statistically similar (p>0.1) (Table 9).

Ezimokhai, Nwabineli et al showed mean time of 8.96 hrs in Foley's catheter group and 10.59 hrs in PGE2 group, which was statistically comparable.28 St Onge and conors reported significantly shorter induction to delivery interval in Foley catheter group (16.0±1.7hrs) compared with the PGE2 gel (21.5±3.2 hrs) group (p=0.014).[29] Although this is an interesting observation, no direct conclusion could be drawn from it, as their method of induction was not uniform and was according to discretion of attending physician.

In the comparison of intracervical prostaglandin E2 gel with insertion of a Foley bulb for pre-induction cervical ripening by Sciscione et al the pre-induction time (9.9 vs. 17.2 hours, P<0.001) and the total induction time (22.4 vs. 30.4 hours, P<0.001) were significantly shorter in the Foley's group.34 This can be explained well based on their study design, in which they began induction immediately after the expulsion of Foley's catheter & took the advantage of shorter mean ripening time in Foley's group. Dalui R, Suri V et al showed preparation delivery interval was significantly shorter (P<0.05) in women who underwent cervical ripening with Foley's catheter balloon than with the PGE2 gel.[35] Ferdous et al designed a study to compare the effectiveness of misoprostol and Foley's catheter on cervical ripening.[36] They found induction-delivery interval was 20.04±2.82 and 21.18±2.32 hours in the misoprostol and Foley's catheter groups respectively. The differences were not significant.

Significant number of cases deliver only after the ripening is complete (>12hrs). This observation supports the fact that the success of labor depends to a large degree upon the consistency, compliance, and anatomic configuration of the uterine cervix. If the cervix is not ripened, then prolonged labor results.[37,38]

It is reasonable that the unripe cervix is associated with lower concentrations of myometrial oxytocin receptors and gap junctions with relatively high rates of operative vaginal deliveries and caesarean deliveries.[39]

In the present study women in both groups had a high rate of normal vaginal delivery which was statistically more (P<0.05) in group A (76%) than in group B (54%) (Table 10).

High rates for vaginal delivery in our study can be attributed to better scrutiny of cases at the time of recruitment, excluding factors like cephalopelvic disproportion and active management of labor.

Perry et al obtained vaginal delivery of 75% in foley's group and 77% in Misoprostol group.[27] Ferdous et al in their study had vaginal delivery of 82.2% in foley's catheter group and 80% in misoprostol group which was statistically not significant.[36]

Eight women of group A and 20 of group B were delivered by instrumentation. Commonest indication found was foetal bradycardia in 2nd stage followed by poor maternal expulsive effort in both groups. Labor was interrupted with caesarean section in 16 cases in group A and 26 in group B. Commonest indication for caesarean delivery in both groups were fetal distress followed by non-progress of labor. Instrumentation (20%) and caesarean section (26%) rates both were higher in group B than in group A. There was statistically significant difference for each mode of delivery in both the groups (p<0.05). Ezimokhai & Nwabinelli's study had LSCS of 14.3% in foley's group and 42.9% in PGE2 group.[28] St. Onge & Connors's study had LSCS of 17.6% in foley's group and 25% in gel group.[29] Perry et al had LSCS of 25% in foley's group and 23% in Misoprostol group.[27] Ferdous J et al in their study had LSCS of 20% in foley's catheter group and 17.8% in misoprostol group which was statistically not significant.[36]

These rates probably reflect the high-risk nature of the population undergoing cervical ripening, different obstetric practices and the lack of appropriate control groups. Regarding the incidence of complications and side effects, Embrey and Mollison reported very few side effects of cervical ripening by a Foley's catheter balloon, the most common are intrapartum or post-partum fever and vaginal bleeding after insertion.[26]

In the present study 5% patients in group A had puerperal pyrexia. The incidence was statistically like group B (4%). In the present study 4 women in group A had bleeding per vaginum (3-5 ml) just after insertion of Foley's catheter. These patients had no ultrasonography (USG) evidence of placenta previa. Bleeding stopped immediately, not requiring any active intervention, delivered uneventfully without any further episode of bleeding. The bleeding seems to be due to stretching of cervix and stripping of membranes after inflation of the balloon. The potential complications of balloon method are accidental rupture membranes and prolapse of umbilical cord. None of these were registered in the present study. Lieberman et al in his study described slight vaginal bleeding in 1 case, during an attempt to introduce the Foley's balloon.[40] Placenta previa was presumed and the procedure was abandoned. Though, PGE2 is generally accepted as the best ripening agent, it is associated with hyper stimulation, leading to fetal distress and gastrointestinal symptoms such as nausea and vomiting.[38]

In the present study 8 cases of hyper contractility noted after PGE2 gel administration were all transient, these women had no fetal bradycardia and had responded to the usual measures, i.e. left lateral position. They delivered vaginally with normal outcomes. No incidence of nausea and vomiting was registered. Uterine hypertonicity was reported in 8 cases ripened with PGE2. Uterine hypertonicity was reported in 2-3% of cases by Burnstein et al.[41]

The main argument against the use of Foley's catheter balloon as a ripening agent had been the risk of introduction of infection. These risks were reduced by strict aseptic precautions. Ezimokhai and Nwabinelli, Leiberman et al who had used the Foley's catheter extra-amniotically had not reported an increase in the infection rate clinically. No neonatal complication reported in this study.[28,40] The current study was underpowered by its small sample size and further large sample size randomized clinical trials are needed for evidence-based recommendations.

CONCLUSION

This study concludes that extra-amniotic Foley's catheter balloon is an effective, safe, simple, low cost, reversible, non-pharmacological mechanical method of pre-induction cervical ripening.

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