Original Article

A Comparison of Effectiveness of Hydrostatic Membrane Sweeping with Intracervical Foley's Catheter Ballooning Alone in Pre Induction Cervical Ripening

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Abstract

Induction of labor is a keystone in modern obstetric practice and a safe procedure. The success of induction, however depends upon whether the cervix is ripe or unripe. Hydrostatic membrane sweeping is a better option as this is more effective and can be used in situations where pharmacological methods are contraindicated. **Study design:** Randomised clinical trial. **Place and duration:** Department of obstetrics and gynaecology unit II, Punjab Medical College and affiliated hospitals, Faisalabad from 15-12-2008 to 15-6-2009. **Subjects and methodology:** 260 Patients each in group A and B were randomly assigned for cervical ripening by Foley's catheter ballooning alone (foley) and hydrostatic membrane sweeping (HMS) method respectively. The patients were reassessed at the time of spontaneous expulsion of the catheter or at the onset of effective uterine contractions or after 18 hours of insertion. Amniotomy was done and syntocinon infusion was started at this point. The improvement in Bishop score and mode of delivery were studied. **Results:** 260 patients were allocated each in Group A and B. Improved Bishop score (>8) was achieved in 67.3% (175/260) of patients in Group A and 76% (197/260) of patients in Group B. Out of 260 patients in Group A 70% (182) had vaginal delivery and 30% (78) were delivered by caesarean section. In Group B, out of 260 patients, 78% (203) delivered vaginally and 22% (57) by caesarean section. P value was 0.036. **Conclusion:** Both Foley's catheter ballooning and hydrostatic membrane sweeping are effective methods of cervical ripening however the later was more effective for improvement in Bishop Score and in achieving vaginal delivery. **Key words:** Labour induction, cervical ripening, caesarean section, intracervical foley's catheter, hydrostatic membrane sweeping.

INTRODUCTION

Cervical ripening is a physiological process whereby the cervix becomes softer, shorter and more pliable.[1] Induction of labour (IOL) is the artificial initiation of uterine contractions leading to progressive dilatation and effacement for the purpose of establishing vaginal delivery.[2] About half of women undergoing induction have an unripe cervix.[3] An unripe cervix may require a total quantity of uterine work that is three to four times greater than that needed for a favorable (ripe) cervix[4]. The prostaglandins (PGs) had superseded the mechanical methods of cervical ripening in the recent past. However the growing body of evidence that PGs have maternal and fetal side effects led the researchers to explore and reconsider mechanical methods of induction. There is now a clear shift from pharmacological methods towards intracervical ballooning with or without extra amniotic saline infusion (EASI) especially with an unripe cervix.[5] Foley catheter effects changes on the various components of the Bishop score (BS). It acts by physically dilating the cervix, disrupting collagen and causing localized inflammation, thus increasing prostaglandin and oxytocin secretion[6]. The addition of extra amniotic saline infusion, promotes endogenous prostaglandin release by membrane stripping and supplies additional mechanical force. It reduces the induction to delivery interval that leads to potential saving when considering such issues as nursing and hospitalization costs. There is an 8 fold reduction in tachysystole and fewer heart rate abnormalities with no

increase in the risk of infection. Compared to foley alone, it results in better improvement in BS and more patients achieving vaginal delivery and shorter induction to delivery interval. The studies do not document any serious maternal complications with mechanical methods[7,8]. The IOL with the aforementioned methods is effective and has the advantages of simplicity, low cost, reversibility, lack of systemic or other serious side effects and uterine hyperstimulation over the use of medical methods.[9, 10] Therefore, it can be used for inducing labour in women who are planning a vaginal birth after a previous caesarean birth (VBAC), bronchial asthma and in cases of raised intraocular pressure[11]**.** It reduces the duration of labour and increase the number of deliveries within 24 hours.[12] Some women wish to avoid the side effects of medications and regard foley catheter as a 'safer' way of inducing labour.

SUBJECTS AND METHODS

The trial was conducted on 260 patients each in group A and B making a total sample size of 520. The patients were sampled by using non-probability purposive sampling**.** All the women requiring induction of labour with singleton live pregnancy at gestational age of 41 weeks or more with vertex presentation aged between 20-35 years having BS of <6 were included in the study. Women with placenta previa, placental abruption, ruptured membranes, vaginal infection, congenital anomalies and medical problems were excluded. The patients were taken from the outdoor and those who met the inclusion criteria were randomly allocated, using random number tables, to Group A and B, Foley and HSM respectively. The technique of foley catheter ballooning was explained to the patient and informed consent was taken. In lithotomy position, cleansing of vulva and vagina was carried out with sterile water. The cervix was visualized with the help of Cuscos speculum. While holding the Foley's catheter no.16 with a long artery forceps near its tip, it was passed into the cervical canal extra-amniotically under vision and the tip was advanced up to 5 cm to ensure that the balloon was within the uterine cavity. The balloon was inflated with about 30 cc of sterile water. The catheter was pulled down to bring the balloon into the cervical canal and was tapped around the thigh under minimal strain.
The same technique was applied with HMS and 40 cc of sterile water was injected slowly, extra-amniotically through the main channel of the catheter and the channel was clamped. A 20 minute fetal heart trace was obtained before starting the procedure and repeated if indicated. The feto-maternal monitoring was carried out hourly. Bishop score was reassessed at the time of spontaneous expulsion of the catheter or at the onset of effective uterine contractions or after a period of 18 hours of insertion. Amniotomy was done in both the groups at this time and syntocinon infusion containing 5 iu in one litre of Ringer's lactate was started with 30 minutes increment. The fetomaternal monitoring was performed every 20 minutes thereafter. The procedure was discontinued in case of antepartum haemorrhage, infection, fetal distress, tonically contracted uterus or serious maternal complication. The data was collected through proforma The main outcome variables were improved Bishop score >8 and vaginal delivery. The data was analysed using SPSS version. Improvement in Bishop score (>8) and vaginal delivery (VD) were qualitative variables and were interpreted as frequencies and percentages. Comparison with the findings of other studies was done through Chi Square and $P \leq 0.05$ was taken as significant.

RESULTS

Two hundred and sixty patients were recruited each in group A &B. No patient fulfilling the criteria refused to be part of the study and none opted out once enrolled. The protocol was strictly followed. Maternal demographics like age and parity (shown in table1) in both the groups were same. In group A, mean maternal age in years was 27.80 $\pm$ 4.03. In group B, the mean maternal age was 28.15 $\pm$ 3.79 (P= 0.308). The age range was 20-35 years in both the groups. Most women in both groups were nullipara, 40% (104/260) in group A and 43% (112/260) in group B. In both the groups A & B 35% (91/260) of patients were primipara. Whereas 25% (65/260) in group A and 22% (57/260) in group B were multipara (P=0.663). The mean BS after 18 hours or earlier at the time of catheter expulsion or onset of effective uterine contractions was 9.04 $\pm$ 2.46 in group A and 9.94 $\pm$ 2.40 in group B ($p<0.033$). The mean increase in BS after treatment for cervical ripening was 6.46 $\pm$ 1.74 in group A and 6.76 $\pm$ 1.54 in group B (P=0.038) The successful cervical ripening with a BS of >8 was seen in 67.3% (175/260) of the patients in group A and 75.8% (197/260) of patients in group B (P=0.033).

Mode of delivery was vaginal in 70% (182/260) of the patients in group A and 78% (203/260) of the patients in group B (P<0.036). Spontaneous expulsion of catheter occurred in 58% (151/260) in group A and 60% (156/260) of patients in group B. In group A 11% (29/260) and in group B 16% (42/260) of the patients went into spontaneous labour while undergoing cervical ripening with out oxytocin induction and all had uneventful deliveries. The frequency of caesarean section was 30% (78/260) in group A and 22% (57/260) in group B. No serious maternal complications like antepartum haemarrhage, ruptured uterus, pyrexia, postpartum haemarrhage (atonic uterus), puerperal sepsis or bleeding was noted. Although some of the patients complained of discomfort with the foley catheter but it was not severe enough to demand catheter removal.

Table-1
Frequency (percentage) distribution of maternal age (n = 260 each in group A&B)

Age (Years)	Group A	Group B
20-25	70 (26.9)	61 (23.5)
26-30	126 (48.5)	137 (52.7)
31 – 35	64 (24.6)	126 (24.2)

Group A:
Mean±SD= 27.80 ± 4.03
Range= 20-35 years
Group B:
Mean±SD= 28.15 ± 3.79
Range 20-35 years
t=1.021
df =518
P value: 0.308

Table 2
Bishop score frequency (percentage) Distribution
(n=260 each in group A&B)

Bishop Score	Group A		Group B	
	BS -1	BS-2	BS-1	BS-2
0-1	55 (21.2)		18 (6.9)	
2-3	135 (51.9)		144(55.4)	
4-5	70 (26.9)	31 (11.9)	98(37.7)	20 (7.7)
6-8		54 (20.8)		43 (16.5)
9-10		109 (41.9)		56 (21.5)
11-13		66 (25.4)		141 (54.2)
Successful ripening (BS>8)	175/260 (67.3%)		197/260 (75.8%)	

Bishop Score= BS
BS-1= Pre ripening Bishop Score
BS-2=Post ripening Bishop Score

Table-3
Bishop Score Analysis

Bishop Score	Mean ± SD	p value	Range	No. of cases
BS-1				
Group A	2.25± 1.17		1-5	260
Group B	3.17± 1.19		1-5	260
BS-2				
Group A	9.04± 2.46	000	4-13	260
Group B	9.94± 2.40	000		260

BS-1= Pre ripening Bishop Score
BS-2=Post ripening Bishop Score

Table-4
Mode of delivery
(n=260 each in Group A&B)

Groups	Vaginal delivery		Caesarean Section	
	Frequency	Percentage	Frequency	Percentage
Group A	182	70	78	30
Group B	203	78	57	22

Chi Square= 4.412
df =1
P value= 0.036

DISCUSSION

The IOL in the presence of an unfavorable cervix remains a challenge for the obstetricians. About half of women undergoing induction have an unripe cervix. IOL after cervical priming leads to successful vaginal delivery in 80-98% of cases[9]. The several observations and studies conducted in USA, Israel, Nigeria and Pakistan has quoted successful ripening in 52 to 82% of patients with the use of intracervical foley catheter.[3,10,13,] The current study was done on 260 patients, each in group A and B taken from out door for pre induction cervical ripening. The results from a similar study conducted at Nishtar medical college and hospital, Multan in 2003 and 2004 in patients with poor BS between 37 and 42 weeks of gestation showed an improvement in BS in 60% of subjects in Foley group and 72% of subjects in HSM group. The results were comparable to our study.[3] Cromi A et al conducted a study at department of obstetrics and gynaecology university of Insubria, Italy on 602 patients. The induction was started at a mean Bishop Score of 2 (range 0-4) and the BS after removal of the catheter was 5 (range 0-13). The mean increase in BS was 3 contrary to our study.[14] There are two possible reasons for this difference. Firstly the BS 1 was lower in the former study. Secondly this study included patients from 31 to 42 weeks. About 12% of the

patients were <36 weeks. These factors might have contributed to the lesser increase in mean BS. The gestational age or uterine size appears to be an important factor when the Foley catheter is used to ripen the cervix for induction of labour.[15] The VD rate was comparable to our study.

A similar study by Kashanian M and colleagues. The results of the study show a mean increase in BS of 1.46±0.79 and post repining Bishop score was 7.12±1.4. The successful VD was achieved in 83.3% of patients compared to 70% in our study.[7] Two factors might have contributed to this difference. Firstly, gestational age in this study was 37-42 wks. Our study included post dated patients only and as described earlier, post dated pregnancies in itself mean some dysfunction in the labour initiating pathway. Secondly, the oxytocin was started earlier, 6 hours after foley catheter insertion compared to 18 hrs in our study unless the balloon was expelled or spontaneous labour started. In the above mentioned study an additional characteristic was constant traction by 500 cc weight that was suspended to the patients bed. Patrick M and fellows conducted a study in Loss Angles, Calif. A continuous EASI was given through the central lumen of the foley catheter. Successful VD was achieved in 79% of patients that is comparable to 76% in our study.[8] In another study by zafarghandi *et al* using extra amniotic saline infusion vaginal delivery rate of 90.9% in contrast to 78% in our study was achieved. However, the number of patient in this study was too small (22 compared with 520 in our study).[16] A subgroup analysis of a study done on 3532 patients suggested that Foley balloon in combination with oxytocin and EASI may indeed have a higher VD rate and lower rate of tachysystole[17]. The main argument against the use of foley catheter has been a risk of introduction of infection with accidental rupture of fetal membranes. In our study, no such accidental rupture occurred and we encountered no case of infection. We postulate that this is because the procedure was performed under aseptic conditions. Also in our study, repeat digital pelvic examination was done only after balloon expulsion, unless the uterine contractions started or after 18 hours. Some people may argue that the insertion of foley catheter is cumbersome, archaic and aesthetically sub-optimal. However this can be overcome by appropriate training and it was well tolerated by our patients.

CONCLUSION

Foley catheter is an effective method of cervical ripening with additional benefit of low cost, reversibility, easy availability and lack of need for special storage. Both methods confer significant improvement in Bishop Score and vaginal delivery was achieved in majority of patients. However hydrostatic membrane sweeping is more effective than foley catheter ballooning alone in improving Bishop score and achieving vaginal delivery.

REFERENCES

1. Hertelendy F, Zakar T. Prostaglandins and the myometrium and cervix. Prostaglandins, Leukot and Essent Fatty Acids 2004; 70:207-22.
2. Hayman R. Induction of labour. In: Luesley DM, Baker PN. editors. Obstetrics and Gynaecology-An evidence based text for MRCOG. 1st ed. London: Arnold, 2004; 327-38.
3. Ifnan F, Jameel MB. Ripening of cervix for induction of labour by hydrostatic sweeping of membrane versus Foley's catheter ballooning alone. J Coll Physicians Surg Pak 2006; 16:347-50.
4. Summers L, Methods of cervical ripening and labour induction. J Nurse-Midwifery 1997; 42:71-85.
5. Moini A, Riazi K, Honar H, Hasanzadeh Z. Preinduction cervical ripening with the foley catheter and saline infusion Vs. cervical dinoprostone. Int J Obstet Gynaecol 2003; 83:211-3.
6. Quality and Patient Safety Committee. Foley catheter for cervical ripening.guideline [reviewed February 2011]. Royal Hospital for women. The committee; 2011. available from: http://www.sesiahs.health.nsw.gov.au/rhw/Manuals/documents/Induction/Foley%20Catheter%20for%20Cervical%20Ripening.pdf.
7. Kashanian M, Nazemi M, Malakzadegan A. Comparision of 30 ml and 80 ml foley catheter balloons and oxytocin for pre induction cervical ripening. Int J gynaecol Obstet 2009; 105:174-5.
8. Mullin PM, House M, Paul RH, Wing DA. A comparison of vaginally administered misoprostol with extra amniotic saline solution infusion for cervical ripening and labour induction. Am J Obstet Gynacol 2002; 187:847-57.

9. Nooh A, Baghdadi S, Raouf S. Induction of labour: How close to the evidence based guidelines are we? J Obstet Gynaecol 2005; 25:451-4.
10. Levy R, Ferber A, Ben-Arie A, Paz B, Hazan Y, Blickstein I, et al. BJOG 2002; 109:168-72.
11. ssue Year : 2010, Issue Number : 1, Issue Month : March Written By : Arif N, Mushtaq M. A randomized comparison of foley catheter insertion versus prostaglandin E2 vaginal pessary for induction of labour in post date pregnancy. Pakistan armed forces medical journal 2010; 1:
12. Gelber S, Sciscione A. Mechanical Methods of Cervical Ripening and Labor Induction. Clin Obtet Gynaecol 2006; 49: 642-57.
13. Idrisa A, Kyari O, Kawuwa MB, Usman HA. Preparation for induction of labour with an unfavourable cervix using a Foley's catheter. J Obstet Gynaecol 2007; 27:157-8.
14. Cromi A, Ghezzi F, Tomera S, Uccela S, Lischetti B, Bolis PF. Cervical ripening with foley catheter. Int J of Gynaecol Obstet 2007; 97:105-9.
15. Ekele BA, Isah AY. Cervical Ripening: How long can the foley catheter safely remain in the cervical canal? Afr J Reprod Health 2002; 6:98-102.
16. Zafarghandi AS, Zafarghandi N, Baghaii N. Foley catheter cervical ripening with extra amniotic infusion of saline or corticosteroids: A double-blinded randomized controlled study. Acta Medica Iranica 2004; 42:338-42.
17. Aaron E G. Cervical Ripening [online]updated May 27 2011. available from: http://emedicine.medscape.com/article/263311-overview.

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