IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 16, Issue 3 Ver. VIII (March. 2017), PP 116-120
www.iosrjournals.org

Induction of Labour in women with Nonscarred Uterus Using Balloon Catheter: Randomised Controlled Trial

Dr M Othman[1],Dr R Alrouithy[2],Dr J Alhazmi[3]
[1]*Consultant and Assistant Professor, Department Of Obstetrics and Gynecology, Faculty of Medicine, Al-Baha University,*
[2]*Senior Resident, Department of Obstetrics and Gynecology, Madinah Maternity and Children Hospital)*
[3]*Consultant, Department of Obstetrics and Gynecology, Madinah Maternity and Children Hospital)*

Abstract: *Induction of labour is a common obstetric procedure. At present, different methods are used for induction of labour in women.One of these methods isFoley catheter, which is a low cost method that can induce labour with less risk to the fetus. This is one of the first studies in the Middle East aiming to study efficacy and safety of Foley catheter induction in nonscarred uterus of term pregnant women in comparison to prostaglandin vaginal tablet.*

This is a single centre, open-label, randomised controlled trial. It was performed in Madinah Maternity and Children Hospital (MMCH). Randomisation was conducted using simple alternative patient randomization.First patient received transcervical Foley catheter induction, while the next received 3mg prostaglandin vaginal tablets according to hospital protocol.There was no blinding of patients and caregivers, as this is not possible with these two treatment methods.

The induction to delivery time was shorter in the foley catheter group and that was statistically significant when compared to the prostin group. Foley catheter induction seems more effective, safer and less coasty for induction of labour than prostin induction.

Keywords: *Mechanical induction, Foley catheter induction, Induction of labour, Nonscarred uterus, Prostaglandin, Prostin*

I. Introduction

Induction of labour is a common procedure in now a day's contemporary obstetrics[1-3]. Labour induction may be indicated by medical or obstetrical complications of pregnancy or may be requested or chosen for non-medical or social reasons[3, 4]. When labour induction is decided, next step will be to choose amethod of induction. Many factors affects the choice of method used for induction of labour including cervical ripening and membrane status, parity, and patient and doctor preference[4, 5]. A closed, firm cervix (Bishop Score <6), that is difficult to distend increases the incidence of failed induction, longer duration of labour and caesareansection[4-7].Many methods (Pharmaceutical and Mechanical) are used to ripen the cervix before induction is attempted, but, there is little consensus on the best method[3, 8, 9]. Synthetic prostaglandins mimic the cervical ripening action of endogenous prostaglandins, while, synthetic oxytocin mimics the action of natural oxytocin. On the other hand, mechanical method in the form of balloon catheter and luminaria tent, both are from the oldest ways to induce labour[3, 4, 10]. Added to that, both promote cervical ripening and onset of labour by stretching the cervix[3, 5].

Foley catheter is a low cost method that can induce labour with less risk to the fetus[2, 3, 5, 8, 11].Usually Foley catheter is used for bladder drainage, but also, can be inserted into the cervix and balloon inflated by saline, then the catheter is gently traced by strapping it to the mother's thigh. It is then left for 12 hoursor until it falls out through the cervical os[3, 7].

Cervical Balloon dilator was first described by Gariel in 1854, but, first patient used water-distended rubber balloons to dilate the cervix reported by Braun in 1855. By the early 20th century warnings were raised about the balloon catheters, and it was concluded that they were not optimal for induction of labour[3, 6, 7].Rates of labour induction on the rise, in United States, in 1990 the rate was 9.5% of all deliveries but this rate increased to 23.2% in 2010. The rate of induction now a day is around 25-30% of all deliveries. Foley catheter balloon is the most commonly used mechanical device for labour induction[3]. It does not act only as a mechanical dilator of the cervix but also as a stimulator of endogenous prostaglandins release from the fetal membranes[3, 5]. Many previous studies concluded that, both balloon size and ripening time might affect the efficacy of induction. Induction with the Foley catheter appears to be as effective as current standard methods, but with lower rates of uterine hyperstimulation and better fetal outcomes[2, 3, 5]. Most of the previous studies on Foley catheter induction were conducted on patients with previous caesarean section while minimal studies conducted on nonscarred uterus. Added to that, most of the studies were conducted in western setting and only few on poor African countries[2, 3, 5, 8, 9, 11].

This is one of the first studies conducted in a developing country and in the Middle East to study efficacy and safety of Foley catheter induction in nonscarred uterus in comparison to prostaglandin vaginal tablet.

II. Methods

The aim of this study is to assess the safety and effectiveness of induction of labour with a transcervical Foley catheter as compared to induction with vaginal prostaglandin tablet in term pregnant women with nonscared uterus.Eligiblewomen are 18 years old or more with a gestational age 37 weeks or more with a viable singleton in cephalic presentation, intact membranesand an unfavourable cervix. They are induced because they are postdate,Oligohydramnios, or 38 weeks with gestational diabetes mellitus or preeclampsia. Exclusion criteria are hypersensitivity for any of the productsused, a history of caesarean section, placenta previa or vasa previa, malpresentation, rupture of membranes, abnormal fetal surveillance (e.g. CTG) requiring immediate delivery, any other contraindication to labour or vaginal birth or patient unwilling to participate.

This trial was a single centre, open-label, randomised controlled trial. The study was performed in Madinah Maternity and Children Hospital (MMCH). MMCH is a secondary hospital where medical care is given free of charge. MCH cover the whole region of Madinah which is 151,990 km2 (58,680 mi^2), with a total multi ethnic population of 1,977,933. MCH average number of deliveries is 15,000 per year, and caesarean section rate is 21%. The trial will be conducted for 12 months from beginning of October 2015 until the end of September 2016.

After the decision of induction is agreed on by patient, she will be informed about the aims, methods, reasonably anticipated benefits and potential hazards of the study. She will be informed that her participation is voluntary and she may withdraw consent for participation at any time during the study. Choosing not to participate will not affect her care. After counselling, written informed consent will be obtained.Randomisation was conducted using simple alternative patient randomization. First patient received transcervical Foley catheter induction, while the nextreceived 3mg prostaglandin vaginal tablets according to hospital protocol. When a women is admitted to the hospital she was randomised to the method according to her turn. Since there is no prespecific randomisation list and no one knows who the next patient is, it was hardly possible for anyone to know specific patient allocation.

There was no blinding of patients and caregivers, as this is not possible with these two treatment methods. Baseline demographic, obstetric and medical histories, and details of delivery and health care received till the time of discharge was recorded for all women.Women were randomised to either transcervical Foley catheterinduction (F Group) or 3mg prostaglandin vaginal tablets (P Group).In the F group, a 16 or 18 F Foley catheter was introduced into the cervix and the balloon is filled with 30 cc of 0.9% saline. The Foley catheter was placed using a speculum by the treating physician. No recommendations regarding disinfection was given as there is no evidence for the best method. The external end of the Foley catheter was tapped to the thigh without giving traction. Foley catheter location after placement can be evaluated digitally and/or by ultrasound. Fetal condition and uterine activity was monitored using Cardiotocogram (CTG) every 12 hours. Women were examined every 12 hours if the transcervical Foley catheter does not detach spontaneously. If the catheter did not fall after 24 hours and cervix still the same this was considered failure of the inductionand further management was decided individually by the treating physician.

In the P group, women received the hospital's normal PGE2 protocol of 3 mg tablet per vagina for nulliparous and 1.5 mg tablet per vagina for parous women, inserted into the posterior vaginal fornix. A post-insertion CTG was performed for at least 30 minutes. The cervix examined after eight hours and, if required, the procedure repeated for a maximum of 3 doses per 24 hours. If cervix still the same this was considered failure of the inductionand further management was decided individually by the treating physician.

Outcomes included induction to delivery interval, mode of birth, maternal morbidity, Apgar score less than 7 at 5minutes, and fetal admission to NICU. We will examine nulliparous and parous women separately in a pre-specified subgroup analysis. Hyperstimulation will be considered if 5 or more uterine contractions in 10 minutes associated with non-reassuring fetal heart rate pattern.

Analysis was intention-to-treat.Categorical data was presented as frequencies and percentages and analysed using the Chi square test. Continuous variables were presented as means with standard deviation or medians with ranges and analysed using Student's t-test and Mann–Whitney U test as appropriate for normally distributed and skewed data respectively. All tests are two-tailed with statistical significance defined as a probability value of <0.05. Initial sample size of 180 based on an ability to detect with 95% power a 5% difference between groups for outcomes. With taking in mind women who withdraw or refuse to participate, a final sample size of 200 participants was accepted.

III. Results

During the period of the study, 241 induction patients recruited to join the study. 17 participants refused to join the study and 224 agreed to join. Participants randomised between both groups. As a result, 112 joined the transcerival Foley catheter induction (F Group)and 112 joined 3mg prostaglandin vaginal tablets (P Group).Participants of both groups were comparable demographically (Table 1). Most of the participants never had IOL before and were Para 4. Most of the participants were Saudis between the age of 28 and 38 years old and university educated.

		P Group N=112 (100%)	F Group N=112 (100%)
Age	18-28 Y's	33 (29.5%)	36 (32.1%)
	28<-38 Y's	59 (52.7%)	54 (48.2%)
	38<-45 Y's	20 (17.8%)	22 (19.7%)
Nationality	Saudi	97 (86.6%)	99 (88.4%)
	Non-Saudi	15 (13.4%)	13 (11.6%)
Education	High school	8 (7.1%)	7 (6.3%)
	University	87 (77.7%)	91(81.3%)
	Higher education	17 (15.2%)	14 (12.4%)
Parity	PG	20 (17.9%)	20 (17.9%)
	P1	13 (11.6%)	16 (14.3%)
	P2	4 (3.6%)	3 (2.7%)
	P3	22 (19.5%)	20 (17.9%)
	P4	33 (29.5%)	31 (27.7%)
	P5≤	20 (17.9%)	22 (19.5%)
Previous IOL	Yes	13 (11.6%)	15 (13.4%)
	No	99 (88.4%)	97 (86.6%)

Table 1; Demographic properties of participants

All participants in both groups were singleton term pregnancy induced because of postdate, gestational diabetes mellitus and pregnancy induced hypertension (Table 2).Mode of delivery can be seen in (Table 2).Most of the participants delivered virginally, while one patient in the F group delivered Ventouse and baby kept under observation for 4 hours then discharged with mother next day. There were no maternal morbidity in any participants of both groups.

Parameters		P Group N=112 (100%)	F Group N=112 (100%)	P
Indication of IOL	Postdate	89 (79.5%)	88 (78.6%)	0.57
	Gestational diabetes mellitus	12 (10.7%)	14 (12.5%)	0.34
	Pregnancy induced hypertension	11 (9.8%)	10 (8.9%)	0.59
Mode of delivery	SVD	93(83%)	100 (89.3%)	0.09
	LSCS	19 (17%)	11 (9.8%)	0.94
	Ventouse	0	1 (0.9%)	0.5

Table 2; indications of IOL and mode of delivery

Indication for LSCS was fetal distress, or Failure to progress (Table 3). Number of caesarean sections was more in the P group but this is not statistically significant. Even analysis of the indications of LSCS was not statistically significant. Most of the caesarean sections were indicated due to fetal distress. Only one patient in the F group had caesarean section due to fetal distress post minor abruptio placenta and patient was in good condition post-operative and did not need any blood transfusion.

Parameters		P Group N=19 (100%)	F Group N=11 (100%)	P
LSCS indications	FD	15 (78.9%)	9 (81.8%)	0.42
	FTP	4 (21.1%)	2 (18.2%)	0.58

Table 3; Indications for LSCS

Regarding induction to delivery interval, this can be seen in (Table 4). Intervals were divided into 6 hours intervals and most of the Foley catheter induction group delivered in the first 18 hours post induction and this was statistically significant in all these 3 six hours intervals. The mean time for induction with prostin was 644 minutes (10 hours 44 minutes) while that of the foley catheter induction group was 520 minutes (8 hours and 40 minutes), which is almosttwo hours less.

Interval	P Group N=112 (100%)	F Group N=112 (100%)	P
360 minutes ≥	27 (24.1%)	39 (34.9%)	0.04 (0.11-0.01)
361-720	46 (41.1%)	64 (54.1%)	0.008 (0.16-0.001)
721-1080	23 (20.5%)	8 (7.1%)	0.004 (0.9-0.001)
1081-1440	15 (13.4%)	1 (0.9%)	0.86
1441≤	1 (0.9%)	0	0.5

Table 4;induction to delivery interval

Looking at admissions to NICU (Table 5). Less than 4% of all neonates in both groups were admitted to NICU but this did not reach statistical significance. All neonates admitted to NICU were discharged in good condition, no neonatal death were recorded.

In the P group, one neonate delivered SVD admitted to NICU as birth asphyxia and discharged 13 days later and three neonates delivered LSCSadmitted to NICU as birth asphyxia and discharged day 17, 18 and 21later in good condition. In the F group, one neonate delivered SVD admitted to NICU as birth asphyxia and discharged 17 days later and two neonates delivered LSCS admitted to NICU as birth asphyxia and discharged day 18 and 22 later in good condition.

Parameters		P Group N=112 (100%)	F Group N=112 (100%)	P
Admission to NICU	Yes	4 (3.6%)	3 (2.7%)	0.65
	No	108 (96.4%)	109 (97.3%)	0.35

Table 5; Admission to NICU

IV. Discussion

From first of October 2015 until the end of September 2016 there was 14492 deliveries, 10003 vaginal deliveries and 4489 LSCS deliveries. During this time, this study was conducted including 224 participants randomly assigned to both arms of the study, 112 in each arm. Both groups were comparable inn their demographic characteristics, were most participants Saudi university educated multipara not previously induced women. Most women delivered vaginally, while women who underwent LSCS were because of fetal distress mainly and failure to progress. The induction to delivery time was shorter in the foley catheter group and that was statistically significant when compared to the prostin group and this was going with all previous studies and reviews [3-6, 11]. No participants suffer from hyperstimulation due to strict method of induction followed in the study. Previous studies showed that foley induction has less hyperstimulation morbidity for patients than prostin [5, 11].

Number of operative delivery was less in the foley catheter group compared to prostin induction, but this did not reach statistical significance. There was no morbidity for both mothers and neonates in both groups. When compared to previous studies foley induction seems more safe than prostin induction [5, 8, 10, 11].We did not study the cost effectiveness of foley catheter compared to prostin but this was studied in previous studies and foley induction was found to be cheaper than prostin [1, 3]. Women opinion was not studied but previous studies showed that more women were satisfied with foley induction especially that the pain was less than that of prostin induction [1, 5, 11].

V. Conclusion

The result of this study supports the use of mechanical foley catheter induction of labour in non-scarred uterus. Foley catheter induction seems more effective, safer and less coasty for induction of labour than prostin induction, but larger studies are needed to study the effect on scarred uterus and to study women opinion and cost effectiveness.

References

1. Baaren, G.v., M. Jozwiak, B. Opmeer, K. Rengerink, M. Benthem, d. MGK Dijksterhuis, M.v. Huizen, P.v.d. Salm, N. Schuitemaker, D. Papatsonis, D. Perquin, M. Porath, J.v.d. Post, R. Rijnders, H. Scheepers, M. Spaanderman, M.v. Pampus, J.d. Leeuw, B. Mol, and K. Bloemenkamp, *Cost-effectiveness of induction of labour at term with a Foley catheter compared to vaginal prostaglandin E2 gel (PROBAAT trial).* BJOG, 2013. **120**: p. 987–95.
2. Demosthenes, L. and K. Eichelberger, *Outpatient cervical ripening: Has its time come?* Contemporary OB/GYN, 2015: p. 1-4.
3. Mozurkewich, E., J. Chilimigras, D. Berman, U. Perni, V. Romero, V. King, and K. Keeton, *Methods of induction of labour: a systematic review.* Biomed Central Pregnancy and Childbirth, 2011. **11**(84): p. 1-19.
4. Maso, G., S. Alberico, U. Wiesenfeld, L. Ronfani, A. Erenbourg, E. Hadar, Y. Yogev, and M. Hod, *GINEXMAL RCT: Induction of labour versus expectant management in gestational diabetes pregnancies.* Biomed Central Pregnancy and Childbirth, 2011. **11**(31): p. 1-7.

5. Noor, N., M. Ansari, S. Ali, and S. Parveen, *Foley Catheter versus Vaginal Misoprostol for Labour Induction.* International Journal of Reproductive Medicine, 2015: p. 1-4.
6. Pennell, C., J. Henderson, M. O'Neill, S. McCleery, D. Doherty, and J. Dickinson, *Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel.* BJOG, 2009. **116**: p. 1443–52.
7. Smith, J., *Balloon Dilators for Labor Induction: a Historical Review.* Journal of Medical Ethics and History of Medicine, 2013. **6**(10): p. 1-4.
8. Gu, N., T. Ru, Z. Wang, Y. Dai, M. Zheng, B. Xu, and Y. Hu, *Foley Catheter for Induction of Labor at Term: An Open-Label, Randomized Controlled Trial.* PLOS ONE, 2015: p. 1-12.
9. Kehl, S., C. Weiss, U. Dammer, E. Raabe, S. Burghaus, J. Heimrich, J. Jackl, M. Winkler, M. Beckmann, and F. Faschingbauer, *Induction of labor; change of methods and its effects.* Geburtshilfe Frauenheilkd, 2015. **75**(3): p. 238-243.
10. Bracken, H., S. Mundle, B. Faragher, T. Easterling, A. Haycox, M. Turner, Z. Alfirevic, B. Winikoff, and A. Weeks, *Induction of labour in pre-eclamptic women: a randomised trial comparing the Foley balloon catheter with oral misoprostol.* Biomed Central Pregnancy and Childbirth, 2014. **14**(408): p. 1-5.
11. Henry, A., A. Madan, R. Reid, S. Tracy, K. Austin, A. Welsh, and D. Challis, *Outpatient Foley catheter versus inpatient prostaglandin E2 gel for induction of labour: a randomised trial.* Biomed Central Pregnancy and Childbirth, 2013. **13**(25): p. 1-11.