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Induction of labour using Foley catheter: Traction versus non traction Technique, a Randomized Prospective study

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Abstract

Background: Cervical ripening of an unfavourable cervix can be achieved by placement of a transcervical Foley catheter. **Objective:** To assess the effectiveness of 750 ml traction on Foley catheter compared to no traction for labour induction. **Study design:** A randomized controlled trial performed on pregnant women at 37-41 week who were admitted for induction of labour with unfavourable cervix. They were randomly assigned into two groups, Foley's with 750 ml traction and and without traction. The primary outcomes were improvement in Bishop Score, number of favourable cervix following induction and the mode of delivery. The secondary outcomes were maternal pain score, neonatal outcome, and maternal infection. **Results: A** total of 160 women were randomized into traction group (n=80) and non-traction group (n=80). The mean change in Bishop Score was similar in both groups. Traction group had significantly (p=0.006) higher number of vaginal delivery (70%) compared to non-traction group. The rate of successful VBAC was also significantly (p= 0.001) higher in the traction group. Participants were comfortable using both methods with low pain score. There was no difference in neonatal outcomes and risk of maternal infections in both groups. **Conclusion:** application of traction did result in more vaginal delivery and successful VBAC without risk of maternal and neonatal infection.

Keywords: Induction of labour, Foley catheter, traction, mode of delivery, VBAC.

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INTRODUCTION

Induction of labour (IOL) is a common procedure in obstetrics, occuring in up to 30% of pregnancies. Methods of induction of labour include either mechanical or pharmacological [1]. The ideal method for cervical ripening should be safe for both fetus and mother, cost effective, and does not require extensive monitoring. Transcervical Foley catheter for cervical ripening was first described by Embrey [2]. The catheter works by mechanically stretching the cervical canal and causes release of prostaglandin which results in cervical changes [3].

Some studies applied no tension on Foley catheter [4-9] while others had described the method of applying tension by taping the transcervical catheter on the patient's inner thigh [3, 10-18].

A later randomized control trial (RCT) was done by Gibson *et al* [19] to compare transcervical catheter with and without traction on 197 women. The aim was to assess the effectiveness of inner thigh taping compared with traction using a 500ml weighted bag. Traction did shorten the time to spontaneous catheter expulsion ($p < 0.001$) without affecting the time to delivery, while change in Bishop score and pain score were similar between groups.

In the previous study, traction was applied by hanging a 500 ml weighted bag of fluid at the end of patient's bed which resulted in restricted ambulation. We tried to overcome this issue by inventing a new technique. The other problem with regards to the tension is that we need to look for the ideal pulling force on the Foley catheter [20]. It is not yet ascertained how much traction is necessary during induction for better outcome on cervical ripening.

The aim of this study was to determine the effectiveness, safety and patient's acceptance of labour induction by using Foley catheter with 750 g traction compared to without traction.

METHODOLOGY

Trial design and participants

Our study is a randomised controlled trial study which involved 160 pregnant women between 37 to 41 weeks with unfavourable cervix (Bishop Score ≤ 5/13) who were admitted for induction of labour between January 2015 till April 2016 in a tertiary hospital. The study was approved by the local medical ethics review board (NMMR-15-561-24021).

Exclusion criteria were women with closed cervical os, ruptured membrane, multiple pregnancy, two previous caesarean scars or more, fetal malpresentation, maternal infections, polyhydramnion and presence of signs or symptoms of maternal and fetal compromise. All patients were provided with written informed consent.

Interventions

All women who were admitted for IOL were screened for eligibility. After getting the informed consent, they were randomized online to either group A (with traction) or group B (without traction). Cervical assessment was performed by principle investigator with modified Bishop Score. In this study, Foley catheter with size 16G was used and inflated with 60 ml normal saline. It was inserted by the principal investigator under aseptic technique. A scale was attached to Foley catheter and pulled down until 750 g traction was obtained. The distal part of catheter was anchored to the right thigh using a strap to allow easy ambulation (Figure 1.0 and 2.0).

Assessments

The Foley catheters were either dislodged spontaneously or removed within 24 hours. Reassessment of cervical scoring was then performed by the principal investigator. Bishop score of more than 6 was considered favourable. Women with favourable cervix were then sent to delivery suite for artificial rupture of membrane following the local protocol. Prostaglandin E2 (PGE2) was inserted in women whose cervices remain unfavourable following Foley catheter. Antibiotic, analgesia and oxytocin were given according to local protocol. Women were monitored for any side effects of mechanical induction. Neonatal outcomes which include Apgar score at 1 and 5 minutes of life and admission to Neonatal Intensive Care Unit (NICU) or neonatal infection were recorded. Pain score were assessed before and after the induction on both groups using Wong Baker faces rating scale. Post-delivery, all women were monitored for signs of infection.

The primary outcomes were improvement in Bishop Score, number of favourable cervix following induction and the mode of delivery. The secondary outcomes were maternal pain score, neonatal outcome, and maternal infection.

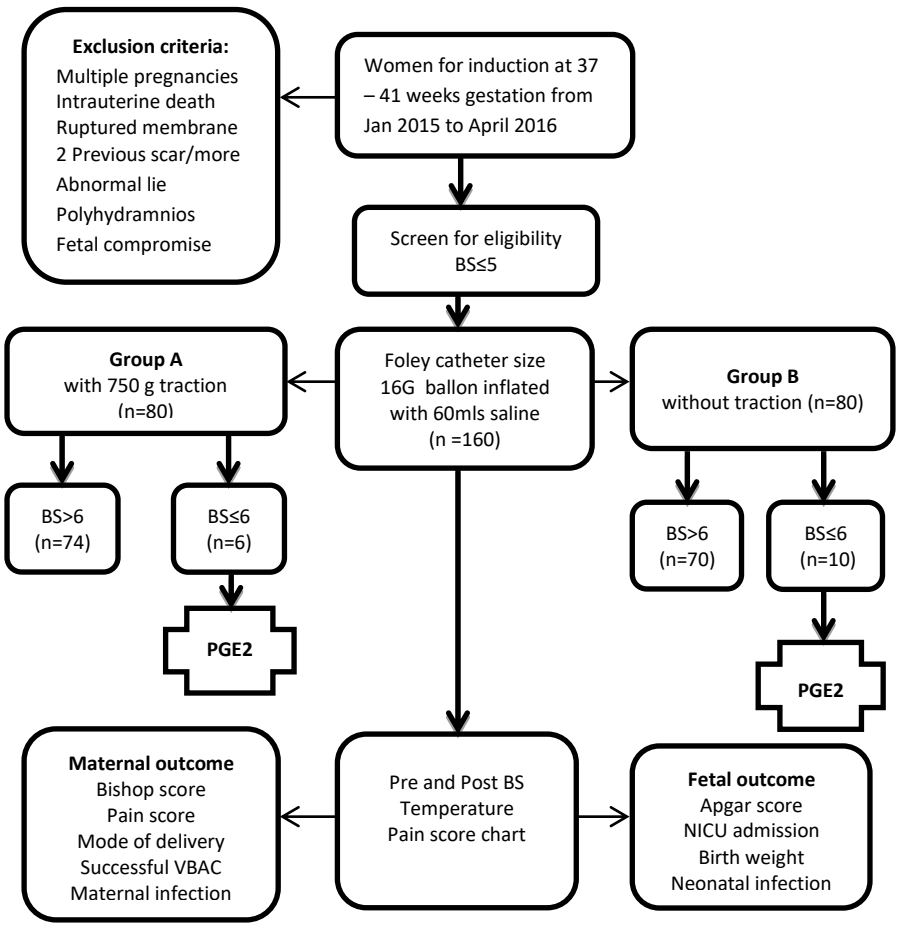
Sample size calculation

A sample size calculation was done using a two-tailed test with an α level of 0.05 and a 90% power to detect a difference of -2.0 (3.35SD). This resulted in a sample size of 138 patients. Counting on a drop out of 20%, 166 patients were included.

Statistical analysis

All data was analysed using Statistical Package for Social Sciences (SPSS) version 20.0. Descriptive data were expressed as mean, median, standard deviation (SD) or percentage. Comparisons between groups were performed with Chi-square, independent t-test, Mann-Whitney and Fisher's Exact test. *p* value of less than 0.05 is considered as statistically significant.

Study flow chart



RESULTS

A total of 160 women were recruited during the study period which included 80 women in both groups. The study population was comparable in terms of age, parity, gestation and indication of labour. However Group A had more cases of previous caesarean section. Indication of labour was mainly diabetes mellitus and post-dated pregnancy. Reduced fetal movement and oligohydramnion were categorized under others. Both groups had comparable Bishop Score pre induction (Table 1).

Table 1: Maternal Demographic Profile

Parameters	**Group A Mean (SD)**	**Group B Mean (SD)**	***p***
Maternal age (18-49 year old)	30.83 (5.59)	30.81 (6.26)	0.989
Gestational age (37-42 weeks)	39.2 (1.4)	39.5 (1.4)	0.239
Parity (0-10)	1.89 (2.2)	1.93 (2.11)	0.900
Baby birth weight (kg)	3.0 (0.39)	3.0 (0.396)	0.537
BMI(kg/m2)	28.2 (3.48)	28.0 (3.8)	0.715
Bishop score pre induction	3.25 (0.98)	3.19 (1.025)	0.813
	n (%)	**n (%)**	
Parity			
Primigravida	17 (21.3)	15 (8.8)	0.894
Multipara	58 (72.5)	59 (73.8)	
Grandmultipara	5 (6.3)	6 (5.0)	
Indications for induction			
Post date	21 (44.7)	26 (55.3)	
Hypertension	8 (42.1)	11 (57.9)	
Diabetes	32 (60.4)	21 (39.6)	0.320
Others	19 (46.3)	22 (53.7)	
Previous caesarean section	20 (36.4)	35 (63.6)	**0.013**

There was an improvement in Bishop Score following induction in both groups with more improvement seen in Group A (Table 2). Group A had significantly more vaginal delivery.

Table 2: Difference in Bishop Score and mode of delivery based on cervical favourability in the two groups

Parameter	**Group A n (%)**	**Group B n (%)**	***p***
Mean Difference in BS (SD)	4.17 (1.19)	3.91 (1.57)	0.236
Favourable cervix	74 (92.5)	70 (87.5)	0.292
Vaginal delivery	55 (74.3)	36 (51.4)	
Caesarean section	19 (25.7)	34 (48.6)	0.008
Unfavourable cervix	6 (7.5)	10 (12.5)	
Vaginal delivery	1 (16.7)	3 (30.0)	
Caesarean section	5 (83.3)	7 (70.0)	0.313

Caesarean section was significantly higher in Group B (51.3%) (Table 3). The indication for caesarean section was mainly fetal distress in both groups especially Group A. Group B had higher rate of failed induction which ended up with caesarean section. There were a total of 55 women who had previous caesarean section in this study. Twenty three of them had successful vaginal birth after caesarean (VBAC) with more from Group A (70%, *p*=<0.001).

Table 3: Mode of delivery in both groups

Mode of delivery	**Group A n (%)**	**Group B n (%)**	***p***
Total vaginal delivery	56 (70)	39 (49)	**0.006**
Successful VBAC	14 (70)	9 (25)	**<0.001**
Caesarean section	24 (30)	41 (51.3)	0.016
Indication of caesarean section			
Fetal distress	13 (54.20)	19 (46.3)	
Poor progress	2 (8.30)	8 (19.5)	
Failed IOL	1 (4.20)	5 (12.2)	
Others	8 (33.3)	9 (22.0)	

*VBAC: Vaginal Birth After Caesarean

The pain score was slightly higher in Group A which is not statistically significant (*p* = 0.07) (Table 4).

Table 4: Maternal Pain Score During Procedure

Parameters	**Group A Mean (SD)**	**Group B Mean(SD)**	***p***
Insertion	1.00 (1.025)	1.00 (1.166)	0.25
Removal	0.69 (1.038)	0.44 (0.691)	0.075

Both groups had comparable birth weight (Table 5). Neonatal Apgar Score was good and similar in both groups. Majority of babies who were admitted to NICU belong to Group B (n = 4). The reason for NICU admission was transient tachypnia of newborn. All neonates who were admitted were discharged well. None of the mothers and neonates developed infection in both groups.

Table 5: Neonatal clinical characteristics in two groups

Parameters	**Group A n (%)**	**Group B n (%)**	***p***
Baby birth weight (kg)			
<2.5	7 (8.8)	10 (12.5)	
2.6-3.0	66 (82.5)	65 (81.3)	0.870
3.1-3.5	7 (8.8)	5 (6.3)	
Apgar score at 1 and 5 minutes (mean)	8/9	8/9	0.709
NICU admission	2 (1.25)	4 (2.5)	

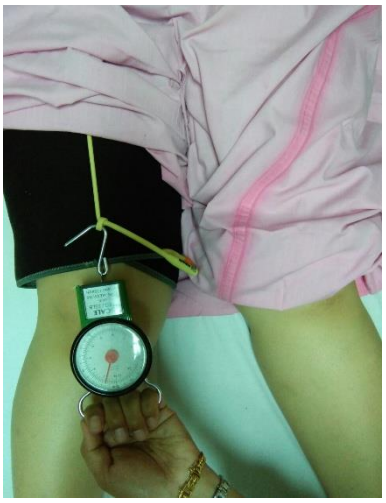


Figure 1: Foley catheter with traction at the thigh

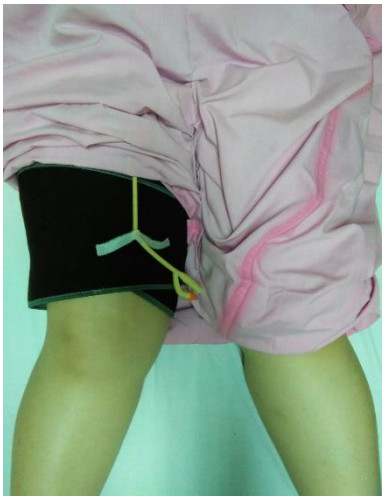


Figure 2: Foley catheter without traction and thigh strap

DISCUSSION

A prospective RCT in 140 women by Fruhmam *et al* [21] comparing induction of labour using transcervical catheter with or without traction followed by low dose oxytocin administration showed that there were no significant difference in terms of vaginal delivery between both groups (79% vs 71%, *p*= 0.365*).* The data from this study showed that placement of 750g traction on Foley catheter during induction had more successful vaginal delivery compared to without traction (70% vs 49%, *p*=0.006). The mean change in Bishop Score was similar in both methods. Women were comfortable using both methods with low pain score.

A randomized study on 45 women by Lutgendorf *et al* [22] comparing taping Foley catheter to women's thigh versus Foley catheter with tension using 1L bag of fluid placed to gravity showed the mean time to expulsion was shorter in the tension group (p = 0.001). Another randomized controlled trial by Gibson *et al* [19] on 197 women compared the effectiveness of inner thigh taping with traction using a 500 ml weighted bag. Traction did shorten the time to spontaneous catheter expulsion (p < 0.001) without affecting the time to delivery. Change in Bishop score and pain score were similar between group [19]. In this study, the use of 750g traction resulted in more favourable cervix. Even though it was not statistically significant, it significantly increased the rate of vaginal delivery.

Mechanical IOL in women with previous caesarean section due to non-recurrent cause was safe and most often successful, therefore help to reduce repeat caesarean section [23] (Iqbal *et al*., 2015). In this study, the application of traction resulted in more successful VBAC (p < 0.001).

The use of Foley catheter for cervical ripening increase the risk of chorioamnionitis remained controversial [5] (Jozwiak *et al*., 2012). However, a meta-analysis on 26 randomized trials by McMaster *et al* [24] revealed that there is a similar rate of chorioamnionitis between cervical ripening with Foley catheter versus PGE2 (relative risk [RR] 0.96; 95% confidence interval [CI] 0.66-1.38). This study showed that there was no difference in neonatal outcomes and risk of maternal infection.

Limitations

Women were managed by different obstetrician and there was no standard definition of failed induction of labour. This study did not look into the time of induction to delivery. The longer duration of induction will increase the hospital stay, risk of infection and cost. This study was also unable to maintain the same amount of traction throughout the induction period. Foley catheter which is made of rubber will lost it's elasticity on prolonged traction causing less tension compared to the initial pressure.

Recommendation

It is recommended to invent an accurate tool – a cervical catheter with applied traction for induction of labour. The catheter material should be non elastic and non allergen. Further research need to look for the ideal material that will be able to maintain the same traction throughout induction. A strap with traction manometer attached and adjustable hook to adjust the traction force should be incorporated.

IOL with Foley catheter is found to be safe with no risk of infection, thus this procedure can be managed in outpatient setting.

CONCLUSION

Foley catheter is effective in induction of labour and does not increase the risk of maternal and neonatal infection. The use of 750 g traction on Foley catheter further increase the rate of successful vaginal delivery especialy for women with previous caesarean section (VBAC).

Conflict of Interest

There is no conflict of interest in this study.

Author's Contribution

Siti Mariam Ismail – Preparing protocol and conducting research

Zalina Nusee – Design of the study, analysis and writing of manuscript

Nurul Hikmah M Noh – Analysis and writing of manuscript

Hamizah Ismail – Analysis of study

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