INDUCTION OF LABOUR USING FOLEY CATHETER: TRACTION VERSUS NO TRACTION, A RANDOMISED CONTROLLED TRIAL AT HOSPITAL TENGKU AMPUAN AFZAN, KUANTAN

BY

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A dissertation submitted in fulfilment of the requirement for the degree of Master of Obstetrics and Gynaecology

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ABSTRACT

Induction of labour can be achieved by placement of a transcervical Foley catheter. The aim of this study was to assess the effectiveness of 750 ml traction on Foley catheter for labour induction. Randomised 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 foley without traction. The outcome measured were change in Bishop score, outcome of delivery, successful vaginal birth after cesarean section, pain score and risk of maternal and fetal infection. 160 women were randomised into traction group (n=80) and control 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 control group (49%). 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 different in neonatal outcomes and risk of maternal infections in both groups. In conclusion, application of traction resulted in more vaginal deliver and successful VBAC.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a dissertation for the degree of Master of Obstetrics and Gynaecology.

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DECLARATION

I hereby declare that this dissertation is the result of my own investigation, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

Siti Mariam Binti Ismail

Signature……. Date ….....

INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA

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LIST OF ABBREVIATIONS

ARM	Artificial Rupture of Membrane
AS	Apgar Score
BMI	Body Mass Index
BS	Bishop Score
BW	Birth Weight
CS	Caesarean Section
EFW	Estimated Fetal Weight
IOL	Induction of Labour
IUGR	Intrauterine Growth Restriction
MOD	Mode of Delivery
NICU	Neonatal Intensive Care Unit
PGE2	Prostaglandine E2
PROM	Prelabour Rupture of Membrane
VBAC	Vaginal Birth After Caesarean

CHAPTER ONE

INTRODUCTION

1.1 INTRODUCTION

Induction of labour is a common procedure in obstetrics, occuring in up to 30% of pregnancies. Both mechanical and pharmacological methods of induction of labour are available (Ryan & McCarthy, 2016). The ideal methods for cervical ripening are those that are safe to both fetus and mother, cost effective, low cost and do not require extensive monitoring. Transcervical Foley catheter for cervical ripening was first described by Embrey (Embrey & Mollison, 1967). Catheter works by mechanically stretching the cervical canal and causes release of prostaglandin which results in cervical changes (Sciscione, 2014) .

Methods of tension on Foley catheter used in prior studies included taping the transcervical catheter to the patient's inner thigh on tension (Sciscione, 2014; Edwards, Szychowski , Bodea –Braescu, Biggio,&Lin, 2015; Henry et al, 2013; Carbone,Tuuli, Fogertey, Roehl, & Macones, 2013; Lanka, Surapaneni , & Nirmalan, 2014; Ugwu et al., 2013; Maslovitz, Lessing, & Many ,2010; Levy et al., 2004; Lin et al, 2007; Forgie et al. , 2016).

Some studies applied no tension to Foley catheter (Cromi et al.,2011; Jozwiak et al., 2012 .; Pettker, Pocock, Smok, Lee, &Devine, 2008; Perry, Larmon, May, Robinette, &Martin , 1998 & Karjane, Brock, & Walsh, 2006). These studies did not address whether or not tension should be placed on the transcervical Foley catheter.

Later study was done to compare cervical catheter with and without traction by Gibson, Mercer, and Louis (2013). A randomised controlled trial done on 197 women , assessed the effectiveness of inner thigh taping compared to traction with 500 ml. Traction did shorten the time to spontaneous catheter expulsion ($p<0.001$) without affecting the time to delivery. Changes in Bishop score and pain score were similar between groups (Gibson et al . , 2013).

In previous study, traction was applied by hanging 500 ml weighted bag at the end of patient's bed resulted in restricted ambulation. We tried to overcome this issue by inventing a new technique.

Now the issue is that, what is the ideal pulling force on Foley catheter? (World Health Organization, 2011). Previous study used 500 ml traction. How much traction require during induction is not yet certain. This research was necessary to find the ideal traction value on foley catheter for better outcome on cervical ripening.

1.2 OBJECTIVES

The objectives were to determine the effectiveness, safety and patient's acceptance of labour induction by using Foley catheter with or without 750 g traction.

CHAPTER TWO

LITERATURE REVIEW

There are various methods for induction of labour which are PGE, single or double balloon Foley catheter.

A randomised controlled trial was done comparing double , single balloon catheters and PGE2 gel in 330 nulliparous women . Mechanical methods were deemed as effective as medical methods of cervical ripening in nulliparous women . No difference in caesarean delivery rates between the 3 groups. Single balloon catheter offers the best safety and patient comfort. Uterine hyperstimulation occurred in 14% of PGE group with none occuring in mechanical cervical ripening group (Pennell et al., 2009).

A randomised controlled trial study comparing single balloon catheter with double balloon catheter on 368 women revealed equal efficacy in inducing labour. Double balloon was associated with higher operative deliveries. Single balloon Foley catheters were more cost effective (Salim et al., 2011) .

Most studies used between 30ml and 80 ml of fluid to fill the balloon. By using 80 ml resulted in more advanced dilatation at the time of expulsion, faster labour time and augmentation with oxytocin in primigavida is less needed (Hoppe, Schiff, Peterson, & Gravett, 2016; Levy et al., 2004).

A previous study compared the volume either using 30 ml and 60ml on Foley catheter for cervical ripening on 88 women. By using 60 ml volume it showed higher proportion of cervical favourability ($p< 0.001$), higher proportion of vaginal delivery ($p= 0.01$), delivery within 30 hours ($p< 0.001$) was achieved and shorter duration

of labour (p= 0.001) (Wijepala & Najimudeen, 2013). The volume used for this study was 60 ml.

Foley catheter balloon is as effective as PGE for induction of labour. It also has the benefit of simplicity, reversibility, low cost and lack of systemic and serious side effects (Khamaiseh, Abdalla, & Al-Ma'ani, 2012).

A study done on 824 women, comparing between PGE and Foley catheter for IOL. Mechanical methods reduced the risk of hyperstimulation with fetal heart rate changes when compared to PGE. Serious adverse event occurred in PGE group, one had uterine perforation and one had uterine ruptured in PGE group (Jozwiak et.al, 2012).

The Foley catheter has only local effect to cervix and it is not like drugs which can cause systemic side effect. Labour induction using transcervical Foley catheter was not associated with an increase risk of uterine rupture (Bujold, Blackwell, & Gauthier, 2004).

A multicenter prospective randomized trial was addressing the risk of chorioamnionitis in women with premature rupture of membranes using Foley catheter (Fruhman et al., 2016). The use of Foley catheter for cervical ripening increase the risk of chorioamnionitis still remain controversial (Jozwiak et al., 2012). A study by Gibson et al., (2013) found chorioamnionitis rate of 6.8 %, without statistical difference between traction and taping groups.

Intravaginal misoprostol and intravaginal Foley catheter have similar effectiveness. Transcervical Foley catheter had a lower incidence of tachysystole (Fox et al., 2011).

Foley catheter is preferably used in previously scarred women to avoid uterine rupture. Clinical trial done for induction of labour in 70 women with one previous scar

using Transcervical Foley catheter versus PGE shows comparable effect on Bishop score after 12 hours and the delivery interval was slightly shorter with Foley catheter (18.15 hours) as compared to (21.06 hours) PGE2. Foley catheter has lower cost, reversibility, lower risk of uterine hyperstimulation and uterine rupture. There was similar effectiveness and safety of transcervical Foley catheter versus PGE2 for VBAC women (Ziyauddin, Hakim, & Beriwal, 2013).

CHAPTER THREE

METHODOLOGY

3. 0 DESIGN/SETTING OF THE STUDY

A randomised controlled trial study was conducted at Hospital Tengku Ampuan Afzan, Kuantan. The study involved 160 pregnant ladies who were admitted for induction of labour between Jan 2015 till April 2016.

3.1 Study population

The study population included all pregnant women at 37-41 week gestation who were admitted for induction of labour. The inclusion criteria were women with singleton viable pregnancy with intact membrane and had unfavourable cervix (Bishop Score of 5/13 or less).

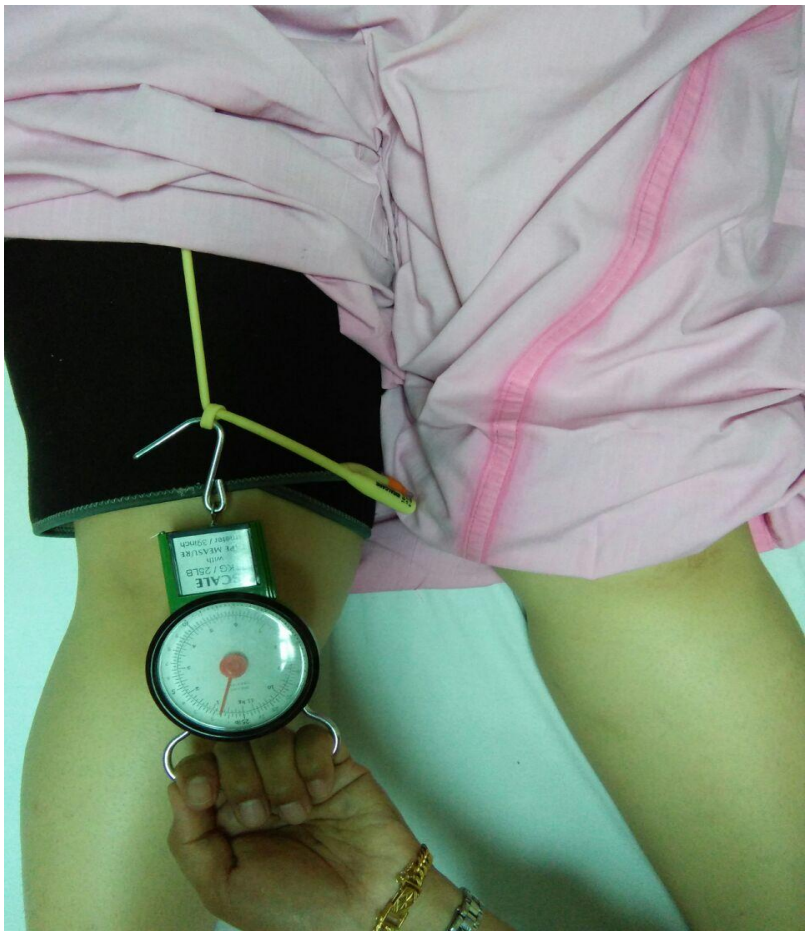
The exclusion criteria were those with closed cervical os, multiple pregnancy, 2 previous scars or more, fetal malpresentation, maternal infections, polyhydramnion, signs or symptoms of maternal and fetal compromise.

3.2 Methods

All women who were admitted for IOL were screened for eligibility. After getting the informed consent, they were randomly allocated into group A (with traction) and group B (control/without traction). Type of randomization is simple randomization.

Cervical assessment was performed by principle investigator with modified Bishop Score. In this study, Foley catheter with size 16 was used and inflated with 60 ml

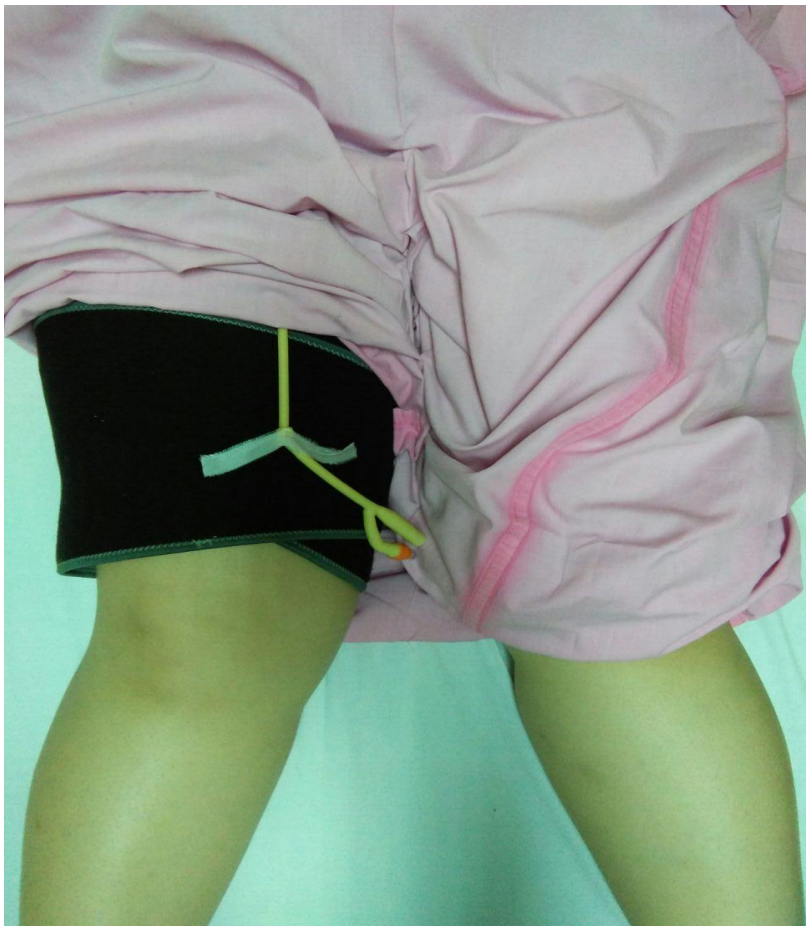
normal saline. The Foley catheter was inserted by principal investigator under aseptic technique.



Group A

Figure 3.1 Foley catheter with traction

A scale was attached to Foley catheter and pull down until 750 g was obtained.



Group A

Figure 3.2 Foley catheter with traction and thigh strap

The distal part of Foley was anchored to right thigh using strap to allow easy ambulation.

The Foley catheters either dislodged spontaneously or removed within 24 hours. Reassessment of cervical score was then performed by the same researcher without knowing which group they belong to. Bishop score of more than 6 was considered favourable. Those with favourable cervix were then sent to delivery suite for artificial rupture of membrane following the local protocol. PGE2 was inserted in those women with unfavourable cervix after failed Foley's catheter if deemed necessary. Antibiotic,

analgesia and artificial rupture of membrane and oxytocin were given accordingly. The women were monitored for any side effects of mechanical induction. Neonatal outcomes which included Apgar score at 1 and 5 min of life and admission to NICU or fetal infection were recorded.

Pain score were assessed before and after the induction on both groups using Wong Baker Faces rating scale. The score is based on scale of 1 to 10. Post delivery, the women were monitored for sign of infection.

This study was approved by Medical Research and Ethics Committee (NMMR-15-561-24021).

3.3 Sample size

PS Software was used to calculate the sample size with a level of significance at ≥ 0.05, power of study 80 % and the estimated sample size (N) is 138. Taking into consideration an expected 20 % drop out, the sample was size was 166.

Sample size = (N + expected drop out)

= [(1.96/0.05)2 x 0.90 x (1-0.90)] + 20% N

=138 + 28

=166

3.4 Statistical analysis

The data was analysed using SPSS Software version 20. Descriptive data were expressed as mean, median, standard deviation (SD) or percentage. Comparisons between groups were performed with Chi- square test, independent t test, Mann-Whitney and Fisher‘s Exact test. P value of < 0.05 considered as statistically significant.

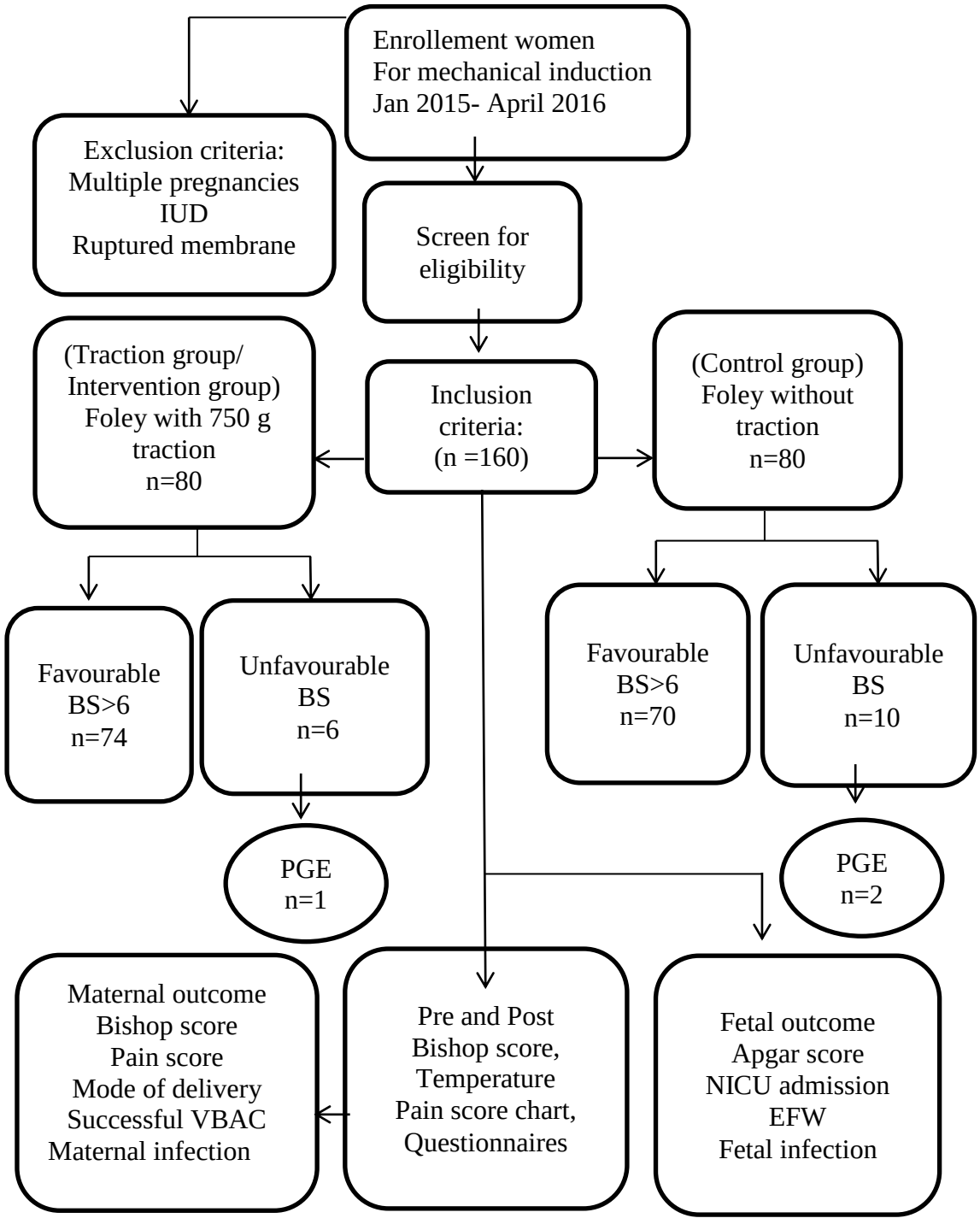


Figure 3.3 Study Flow Chart

CHAPTER FOUR

RESULTS AND FINDINGS

A total of 160 women were recruited during the study period which included 80 women in intervention group using Foley catheter with traction and another 80 women in control group using Foley catheter without traction.

Table 4.1 Maternal Demographic Profile (N =160)

Baseline characteristic	Traction Group	Control Group	P value
Age (range 18- 49 years)	30.83 (5.59)[a]	30.81 (6.26)[a]	0.989
Mean Parity (0-10)	1.89 (2.2)[a]	1.93 (2.11)[a]	0.900
Baby BW(kg)	3.0 (0.39)[a]	3.0 (0.396)[a]	0.537
BMI(kg/m2)	28.2 (3.48)[a]	28.0 (3.8)[a]	0.715
Bishop score pre induction	3.25(0.98)	3.19(1.025)	0.813
Prev scar	20 (36.4) [b]	35 (63.6) [b]	**0.013***

[a] Mean (SD), [b] N(%)

The study population was comparable in term of age, parity, gestation and indication of labour. Both groups had comparable Bishop Score pre induction. However the control group had more cases of previous scar.

Main indication for induction of labour was gestational diabetes mellitus involved 53 pregnant women. Indication for induction of labour also post date included 47 women.

Table 4.2 Change in Bishop score after Foley catheter induction

Cervical scoring	Traction Group (N= 80)	Control Group (N=80)	P value
Mean Difference in BS(mean/SD)	4.17(1.19)[a]	3.91(1.57)[a]	0.236
Favourable cervix (BS>6) n (%)	74 (92.5) [b]	70 (87.5) [b]	0.292
UnFavourable cervix (BS<7)n(%)	6 (7.5) [b]	10 (12.5) [b]	0.313

[a] Mean (SD), [b] N (%)

There was improvement in Bishop Score following induction of labour in both groups but it was not statistically different (p=0.236). Traction group had more favourable Bishop Score (92.5%) compared to control group (87.5%) but it was not statistically significant (P= 0.292).

Table 4.3 Outcome of delivery

Outcome of delivery	Traction Group (N=80) (N %)	Control Group (N=80) (N %)	P value
Vaginal delivery	56 (70)	39 (49)	**0.006***
LSCS	24 (30)	41 (51)	**0.016**

Traction group had significantly (p= 0.006) more successful vaginal deliveries (70%) compared to control group (49%). Caesarean section was significantly higher in control group (51%). The main indication for caesarean section was fetal distress included 32 women. Control group had higher rate of failed induction which ended up with caesarean section included 5 women.

Table 4.4 Outcome of delivery in previous scar (N = 55)

Outcome of delivery in previous scar	Traction Group N=20 (N %)	Control Group N=35 (N %)	P value
Vaginal birth after caesarean	14(70)	9(25)	**<0.001***

Out of 160 women, 55 women had previous scar. Majority of them randomly fall into control group. Twenty three of them had successful VBAC. There was statistically significant with $p < 0.001$,which 14 from 20 women in traction group had successful VBAC , compared to traction group which only 9 women in controlled group had successful VBAC.

Table 4.5 Maternal Pain Score pre and post induction

Pain Score	Traction Group (N=80)		Control Group (N=80)		P value
	Mean	SD	Mean	SD	
during insertion	1.01	1.025	1.26	1.166	0.250
during removal	0.69	1.038	0.44	0.691	0.075

Women were comfortable using both methods with low pain score.

Table 4.6 Neonatal outcome

Neonatal outcome	Traction Group (N=80)	Control Group (N=80)	P value
Median Apgar score at 1 min/5 min	8/9	8/9	0.709
NICU admission	2(1.25%)	4(2.5%)	0.870

Neonatal Apgar score was good and similar in both groups. Majority of babies who were admitted to NICU were belong to control group (n=4). The reason for NICU admission was Transient Tachypnia of Newborn. Those babies admitted were discharged well to the mothers. None of mothers and fetus developed infection in both groups.