



Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial

Peer review status:

Yes

Corresponding Author:

Dr. Mohammad Othman,
Assistant Professor, Al-Baha University, Saudi Arabia, Al-Hada - Saudi Arabia

Submitting Author:

Dr. Mohammad Othman,
Assistant Professor, Al-Baha University, Saudi Arabia, Al-Hada - Saudi Arabia

Other Authors:

Dr. Rehab Ruwathi,
Senior Resident, Madinah Maternity and Children Hospital, Obstetrics and Gynecology Department, Madinah - Saudi Arabia

Dr. Jehan Al Hazmi,
Consultant Obstetrician and Gynecologist, Madinah Maternity and Children Hospital, Obstetrics and Gynecology Department, Madinah - Saudi Arabia

Article ID: WMC005075

Article Type: Research Protocol

Submitted on: 29-Feb-2016, 04:13:08 PM GMT **Published on:** 01-Mar-2016, 05:32:17 AM GMT

Article URL: http://www.webmedcentral.com/article_view/5075

Subject Categories: OBSTETRICS AND GYNAECOLOGY

Keywords: Balloon catheter, prostaglandin, induction of labour, nonscarred uterus, open label, randomized

How to cite the article: Othman M, Ruwathi R, Al Hazmi J. Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial. WebmedCentral OBSTETRICS AND GYNAECOLOGY 2016;7(3):WMC005075

Copyright: This is an open-access article distributed under the terms of the [Creative Commons Attribution License \(CC-BY\)](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

Source(s) of Funding:

None

Competing Interests:

None known

WebmedCentral Peer Reviewed: Yes

Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial

Author(s): Othman M, Ruwathi R, Al Hazmi J

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

Outcomes included induction to delivery interval, mode of birth, maternal morbidity, APGAR score less than 7 at 5minutes, and fetal admission to NICU. Sample size of 500 participants planned over the study period of 12 months. Intention to treat analysis will be used.

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 a method 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 that is difficult to distend increases the incidence of failed induction, longer duration of labour and caesarean section [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 hours or 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 the first study or one of the first studies to be 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.

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 nonscarred uterus.

Eligible women are 18 years old or more with a gestational age 37 weeks or more with a viable singleton in cephalic presentation, intact membranes and 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 products used, 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 will be a single centre, open-label, randomised controlled trial. The study will be 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 mi²), 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 will be conducted using simple alternative patient randomization. First patient will

receive transcervical Foley catheter induction, while the next will receive 3mg prostaglandin vaginal tablets according to hospital protocol. When a women is admitted to the hospital she will be 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 will be hardly possible for anyone to know specific patient allocation.

There will be 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 will be recorded for all women.

Women will be randomised to either transcervical Foley catheter induction (F Group) or 3mg prostaglandin vaginal tablets (P Group).

In the F group, a 16 or 18 F Foley catheter will be introduced into the cervix and the balloon is filled with 30 cc of 0.9% saline. The Foley catheter will be placed using a speculum by the treating physician. No recommendations regarding disinfection will be given as there is no evidence for the best method. The external end of the Foley catheter will be taped to the thigh without giving traction. Foley catheter location after placement can be evaluated digitally and/or by ultrasound. Fetal condition and uterine activity will be monitored using Cardiotocogram (CTG) every 12 hours. Women will be 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 will be considered failure of the induction and further management will be decided individually by the treating physician.

In the P group, women will receive 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 will be performed for at least 30 minutes. The cervix will be 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 will be considered failure of the induction and further management will be 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 will be by intention-to-treat. Categorical data will be presented as frequencies and percentages and analysed using the Chi square test. Continuous variables will be presented as means with standard deviation or medians with ranges and will be 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 386 was based on an ability to detect with 95% power a 5% difference between groups for outcomes. With taking in mind women who will withdraw or refuse to participate, a final sample size of 500 participants was accepted.

11. Henry, A., et al., 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.

References

1. Baaren, G.v., et al., 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., et al., Methods of induction of labour: a systematic review. *Biomed Central Pregnancy and Childbirth*, 2011. 11(84): p. 1-19.
4. Maso, G., et al., 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., et al., Foley Catheter versus Vaginal Misoprostol for Labour Induction. *International Journal of Reproductive Medicine*, 2015: p. 1-4.
6. Pennell, C., et al., 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., et al., Foley Catheter for Induction of Labor at Term: An Open-Label, Randomized Controlled Trial. *PLOS ONE*, 2015: p. 1-12.
9. Kehl, S., et al., Induction of labor; change of methods and its effects. *Geburtshilfe Frauenheilkd*, 2015. 75(3): p. 238-243.
10. Bracken, H., et al., 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.

Reviews

Review 1

Review Title: Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial

Posted by Mr. Mohamed M Najimudeen on 24 May 2016 10:44:17 AM GMT

1	Is the subject of the article within the scope of the subject category?	
2	Are the interpretations / conclusions sound and justified by the data?	
3	Is this a new and original contribution?	
4	Does this paper exemplify an awareness of other research on the topic?	
5	Are structure and length satisfactory?	
6	Can you suggest brief additions or amendments or an introductory statement that will increase the value of this paper for an international audience?	
7	Can you suggest any reductions in the paper, or deletions of parts?	
8	Is the quality of the diction satisfactory?	
9	Are the illustrations and tables necessary and acceptable?	
10	Are the references adequate and are they all necessary?	
11	Are the keywords and abstract or summary informative?	

Rating: 6

Comment:

The paper deserves publication

Competing interests: .

Invited by the author to make a review on this article? : Yes

Experience and credentials in the specific area of science:

I am a British qualified obstetrician. I had worked as consultant for 20 years and presently I am working as a professor in Obstetrics and gynaecology in Malaysia

Publications in the same or a related area of science: No

How to cite: Najimudeen M. Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial [Review of the article 'Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial ' by Othman M]. WebmedCentral Obstetrics And Gynaecology 1970;7(5):WMCRW003288

Review 2

Review Title: Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial

Posted by Prof. Muhammad Aslam on 18 Mar 2016 05:02:09 PM GMT

1	Is the subject of the article within the scope of the subject category?	
2	Are the interpretations / conclusions sound and justified by the data?	
3	Is this a new and original contribution?	
4	Does this paper exemplify an awareness of other research on the topic?	
5	Are structure and length satisfactory?	
6	Can you suggest brief additions or amendments or an introductory statement that will increase the value of this paper for an international audience?	
7	Can you suggest any reductions in the paper, or deletions of parts?	
8	Is the quality of the diction satisfactory?	
9	Are the illustrations and tables necessary and acceptable?	
10	Are the references adequate and are they all necessary?	
11	Are the keywords and abstract or summary informative?	

Rating: 7

Comment:

None

Competing interests: .

Invited by the author to make a review on this article? : Yes

Experience and credentials in the specific area of science:

I am a Professor of Obs & Gyn, teaching and practicing obstetrics for 28 years.

Publications in the same or a related area of science: No

How to cite: Aslam M. Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial [Review of the article 'Induction of labour in women with nonscarred uterus using balloon catheter: Randomised controlled trial' by Othman M]. WebmedCentral Obstetrics And Gynaecology 1970;7(3):WMCRW003277