Induction of labour : Foley catheter revisited

Jozwiak, M.

10

GENERAL DISCUSSION

GENERAL DISCUSSION

With the introduction of prostaglandins for cervical ripening in the 70s and 80s the challenges of the unfavourable cervix were thought to be banned. Unfortunately, prostaglandin analogues for cervical ripening and induction of labour were introduced without robust trials to prove their efficacy and safety, and consequently their advantages over older methods, such as a Foley catheter.

In this thesis we aimed to examine the effectiveness and safety of Foley catheter compared to prostaglandins, particularly prostaglandin E2. Based on the findings of the studies described in this thesis effectiveness, safety, costs, patient preference, and applicability for women with prior caesarean birth will be conferred. We will then discuss newer methods under study, and the implementation of Foley catheter use for induction of labour. This chapter will end with a general conclusion on induction using a Foley catheter.

Effectiveness

The main effectiveness outcome of the studies in this thesis was caesarean section rate. In **Chapter 2 and 4, 5 and 6** we found that a strategy using Foley catheter for cervical ripening compared to prostaglandin analogues for cervical ripening is effective, yielding comparable caesarean section rates.

A second measure of effectiveness, time from the start of induction to birth, has been examined in **Chapter 2, and 4 through 6**. In the review of mechanical methods versus prostaglandin analogues, no significant difference was found in the number of births within 24 hours after the start of induction. Many studies, however, did not report on this outcome. In **Chapter 4, and 6** we showed that the time to birth is longer in the Foley catheter group, when compared to prostaglandin E2 gel (median 29 versus 18 hour) and misoprostol (median 36 versus 25 hours). No difference was found in **Chapter 5**, when comparing Foley catheter to slow-release prostaglandin E2 inserts (median 28 versus 27 hours).

First we need to ask ourselves if this difference is a real difference. Despite our protocol, advising to examine women with the same interval in both study groups, in clinical practice this advise was not always followed. Women in the Foley catheter group mostly did not experience contractions, slept during the night, and as a result were examined the following day. In most cases the catheter was found lying in the vagina, and the cervix was found to be favourable for further induction. Women in the prostaglandin E2 gel and misoprostol group were examined more often, due to contractions. As a result, amniotomy was performed earlier than in the Foley catheter group, when the cervix was deemed favourable for further induction. This is illustrated by the Kaplan Meier curves in **Chapter 4**, where we see that the active phase of labour was reached at night in very few women in the Foley catheter group, whereas many more women in the PGE2 group reached the active phase of labour at night. This phenomenon has also been shown in early studies of the Foley catheter, by Embrey and Mollison.[1] It was recently confirmed by Cromi and

collegues,[2] that if women induced with a Foley catheter are offered amniotomy earlier, the time to birth will be comparable with prostaglandin E2. Women in the prostaglandin inserts group, were generally examined after 24 hours, as were women in the Foley catheter group, and no difference in time to birth was found in this comparison. This further supports our hypothesis. In conclusion, we cannot be sure if the time to birth difference is an actual difference.

Secondly, how relevant is a potential difference in time to birth?

The Cochrane collaboration, WHO and NICE established that birth within 24 hours of the start of induction is the 'clinically most relevant measure of effectiveness for trials of methods of labour induction'. This is arguable, as the goal of labour induction is a safe vaginal delivery for mother and child. To optimise the probability of vaginal delivery, adequate time to enter into, and progress in labour should be allowed after induction. Adequate time should be defined as the medically and psycho-socially acceptable time in the light of safe vaginal delivery. Even in women with spontaneous labour, it is well known that the duration of the latent phase can vary greatly, and it is difficult to define a normal range,[3] let alone in women where the natural process of labour is induced. Zhang and colleagues[4] showed in their retrospective multicenter observational study of 62415 women in spontaneous labour, that the active phase often does not start before six centimetres dilation. They showed that, even in women with spontaneous labour, no change in dilation for 4 hours may be normal in early labour, and that it may take more than 6 hours for women to progress from 4 to 5 cm, and more than three hours to progress from 5 to 6 cm. Zhang and colleagues[4] conclude that allowing labour to take longer before 6 cm of dilation may reduce the rate of intrapartum caesarean section due to failure to progress in the first stage of labour. Several researchers have shown that standards that we commonly use to evaluate adequate progress of labour, do not apply to women in whom labour is induced.[5,6] Therefore, these women are especially at risk of undergoing an unnecessary caesarean section due to failure to progress or failed induction, whereas they have not been given adequate trial of labour yet.[5,6] Simons and Grobman[7] undertook a retrospective study of 397 nulliparous women who had labour induced at term to study vaginal delivery rates in relation to the time spent in the latent phase of labour. They defined latent phase as the beginning of oxytocin infusion after amniotomy was performed and the end of the latent phase as dilation of 4 cm and 80% effacement, or 5 cm dilation. They found that women with a latent phase of 15-18 hours had a vaginal delivery rate of 64%, and even women with a latent phase of 18-24 hours had vaginal births in 32%.[7] This supports the idea of not defining induction of labour as failed, until no regular contractions or cervical change occur after at least 24 hours of oxytocin infusion with ruptured membranes, providing maternal and fetal condition allows it.[8]

Rouse and colleagues[6] pose that it is reasonable to avoid deeming labour induction a failure in the latent phase until oxytocin has been administered for

at least 12 hours after membrane rupture, because an additional 40% of women with a latent phase longer than 12 hours after membrane rupture deliver vaginally if allowed longer oxytocin infusion. Furthermore, the diagnosis of labour arrest should be reserved for women who have actually entered the active phase of labour, as only after a dilation of 6 cm is reached during induction, labour progress is similar to women in spontaneous labour.[9]

The goal of induction of labour is to warrant a safe delivery for mother and child, but also to prevent caesarean sections in view of the increased maternal and neonatal morbidity and mortality in subsequent pregnancies. If we leave the idea that women should deliver within 24 hours from the start of induction, allow more time in the latent phase of labour, and define arrest disorders as such after the active phase of labour has been reached, we could prevent unnecessary caesarean deliveries. For the Cochrane collaboration, WHO and NICE, the time has come to redefine the 'clinically most relevant measure of effectiveness' for trials of methods of labour induction.

Safety

The main goal of labour induction is a safe and uncomplicated delivery for mother and child. As described in the introduction of this thesis, potential complications of induction include hyperstimulation and subsequent neonatal and maternal complications, infectious morbidity, and serious adverse events such as uterine rupture. The latter especially feared in women with prior caesarean birth.

Foley catheter versus vaginal PGE 2 gel

In the PROBAAT study (Chapter 4), we did not find a difference in hyperstimulation rate in the trial, but a significant decrease in hyperstimulation was found in meta-analysis of studies investigating Foley catheter versus vaginal PGE2 gel. We found a significantly lower rate of instrumental deliveries due to fetal distress in the Foley catheter group. Furthermore, we showed that fewer women were in need of intra-partum antibiotic use, and fewer neonates were admitted to a neonatal ward post partum after Foley catheter induction. No difference was seen between the groups in neonatal infections. We also found a significant decrease in post partum haemorrhage when using a Foley catheter in meta-analysis with comparable studies (Chapter 4). No serious adverse events were found in the Foley catheter group, while one uterine rupture in an unscarred uterus, and one uterine perforation due to the introduction of an intrauterine pressure catheter occurred in the prostaglandin E2 gel group.

Foley catheter versus other prostaglandin preparations

In our comparison of Foley catheter to 25 microgram vaginal misoprostol, we found fewer cases of hyperstimulation and, in meta-analysis, fewer vaginal instrumental deliveries after induction with a Foley catheter. Also fewer contraction abnormalities in the ripening phase of induction were seen when a Foley catheter is used, compared to 10 mg vaginal prostaglandin E2 inserts. Serious adverse

events, such as uterine rupture did not occur in either the Foley catheter group, or the prostaglandin groups.

Based on our randomised controlled trials and meta-analyses we conclude that Foley catheter for cervical ripening is safe in term women with an unfavourable cervix. We also conclude that it causes fewer cases of hyperstimulation, in comparison with all prostaglandin preparations studied. The Foley catheter showed clinical benefits, in means of fewer neonatal admissions, a reduction in post partum haemorrhage and instrumental deliveries due to suspected fetal distress when compared to PGE2 gel.

Very large numbers would be needed to prove statistical differences in rarely occurring complications, such as pH <7.10. A cohort study would probably be a better design to assess side effects.[10] Retrospective cohort studies are generally less costly than randomised controlled trials, and therefore more likely to include much larger groups of subjects and evaluate rarely occurring side-effects. On the other hand, the costs of such a study must be weighed against the impact of these very rarely occurring complications, which do not have a great clinical impact. In the case of the comparison of Foley catheter with prostaglandins in women without a prior caesarean delivery, a large cohort study would probably not have additional value.

Interestingly, the main 'drawback' of Foley catheter use, the longer time from the start of induction to birth, also is its main advantage. The Foley catheter causes less hyperstimulation with and without fetal heart rate changes, as compared to prostaglandins (**Chapter 2**), and does not seem to cause contractions during the ripening phase (**Chapter 3, 4, and 5**), in contrast to prostaglandins.

Based on the outcomes of the PROBAAT studies, and the Cochrane review presented in **Chapter 2, and 4-6**, we can conclude that the Foley catheter effectuates ripening, without inducing labour contractions, and could therefore especially be suitable in situations in which decreased placental blood flow, or contractility are unwanted side-effects.

Systematic reviews, including the systematic review in **Chapter 2**, have been including different dosing regimens of prostaglandins, and adding them up in meta-analysis.[11,12] As described in the introduction, different dosing regimens of pharmacological agents have different side-effects. It is therefore important to conduct adequate comparisons of Foley catheter with one single dosing regimen an route of administration of the various prostaglandins. Many researchers have investigated Foley catheter in comparison with vaginal misoprostol, however studies have been underpowered to prove superiority or non-inferiority of one of both methods. A Cochrane review showed that oral misoprostol as opposed to vaginal misoprostol has similar effectiveness, but appears to be safer when administered orally, with lower rates of hyperstimulation, and fewer Apgar scores <7 after 5 minutes.[13] This is why in 2012 we have started an adequately powered randomised controlled trial comparing Foley catheter to oral misoprostol, the PROBAAT 2 trial.

Costs

In this time of paucity of economic means and cuts in budgets for medical care, it is essential to consider costs of medical interventions, especially when an intervention is applied as often as induction of labour. Yearly, labour is induced in over 30% of pregnant women in the Netherlands.[14] The costs of a method are not only determined by the costs of the ripening agent, but the whole period of the treatment of a woman before, during and after delivery. As we showed in **Chapter 7**, induction of labour using a Foley catheter, as we did in the PROBAAT study, generated comparable costs as induction of labour using prostaglandin E2 gel, but Foley catheter induction brought along health benefits. The incremental cost to avoid one admission to the neonatal ward or PPH/asphyxia by using a Foley catheter instead of prostaglandin E2 for induction were acceptably low. Outpatient management of women induced with a Foley catheter will reduce the time spent on the delivery ward, causing major effect on costs and shifting the balance in favour of the Foley catheter.

Women's preference

Effectiveness, side effects, and costs should be weighed with pain and discomfort experienced by women. Especially in a time when women are more involved in medical choices, women's preference is essential in the ultimate choice for a method. Not studying women's preferences is one of the major drawbacks of most induction of labour trials, including the PROBAAT studies. As we did not study women's preferences, unfortunately we can only presume that women would prefer a longer course of ripening with a Foley catheter with possibly less discomfort in the ripening phase over ripening with prostaglandins.

Pennell and colleagues,[15] to our knowledge, are the only authors who investigated patient satisfaction comparing Foley catheter to vaginal prostaglandin E2 gel. They found no difference in overall patient satisfaction but lower pain scores in women induced with a Foley catheter, suggesting Foley catheters as a women's preference.[15] Future clinical trials should include investigation of patient preference, to ensure all aspects of a method are involved when in decision making. To evaluate women's preference in method of induction, validated questionnaires will have to be developed first, as they are not available at present.

From studies examining women's preference for inpatient or outpatient settings using prostaglandins, we know that women generally indicate a preference for outpatient ripening.[16-18] Because of the lack of contractions during the ripening phase, outpatient cervical ripening could be considered. Several researchers have studied the possibilities of cervical ripening in an outpatient setting, comparing it to an inpatient setting. They found no significant differences in mode of delivery, maternal and neonatal morbidity, but a significant decrease in hospitalization time and costs.[19,20] Unfortunately, also in these trials, women's preferences were not studied. More research is needed to confirm the safety of outpatient Foley catheter use for cervical ripening and to study patient satisfaction and costs.

Applicability for women with prior caesarean delivery

Methods for induction of labour in women with prior caesarean birth have been studied in retrospective manner, however prospective evaluations of these methods are scarce and inadequate (**Chapter 8**). As caesarean section rates have risen substantially in recent decades,[14,21,22] causing a rise in women with prior caesarean birth requiring induction of labour in a subsequent pregnancy, we have been confronted with a new challenge: a safe en effective method for cervical ripening in these women. After the worrying publication on the rate of uterine rupture in induction of labour in general, and the use of prostaglandins specifically, in women with a prior caesarean birth by Lydon-Rochelle,[23] this method has almost completely been abandoned in many countries. It has been considered unethical to study prostaglandins in women with a prior caesarean delivery. This has stimulated the use of non-pharmacological methods, e.g. Foley catheter, or elective repeat caesarean section (**Chapter 3**). Due to reduced contractility during ripening, the use of a Foley catheter is a valuable method for cervical ripening in women with a caesarean scar. One of the goals of the NHS,[22,24] as well as ACOG,[25] is reducing repeat caesareans and its associated morbidity,[26] and promoting vaginal birth after caesarean section. In this light, Foley catheter induction is a means to promote planned vaginal deliveries in women with prior caesarean birth. As showed in **Chapter 8** of this thesis, prospective evaluations of Foley catheter for labour induction in these women are scarce and inadequate, but retrospective studies show promising results. The applicability of Foley catheters for labour induction in women with prior caesarean birth is currently studied in a prospective cohort study of methods for induction in women with prior caesarean birth, the PROBAAT S study.[27]

Newer methods

In recent years, Nitric oxide donors have been studied as methods for cervical ripening, without inducing uterine contractions. Although nitric oxide donors induce cervical ripening without inducing uterine contractions, they do not hasten the onset of delivery or reduce the need for additional agents when used for induction of labour.[28-30] Even more importantly, substantial maternal side effects, such as severe headaches, palpitations, nausea and vomiting have been noted using nitric oxide donors.[31,32] Therefore, at present they have no place in cervical ripening.[33]

Double balloon devices, with one balloon filled with 50-80 cc above the internal os, and one balloon filled with 50-80 cc below the external os, have been proposed for cervical ripening. Two reasonably sized studies comparing single to double balloon devices have been published, both showed no difference in efficacy.[15,34] Salim et al[34] found that there might be more operative deliveries when a double balloon is used. Pennell et al[15] studied patient preference, and found that single balloon caused significantly less pain than a double balloon. Furthermore, the Foley catheter is significantly less expensive than an double balloon device. Therefore, Foley catheter should be preferred over double balloon devices until more adequate comparisons are completed.

Little evidence exists on the optimal balloon volume of Foley catheter for induction. In most trials, a balloon volume of 30 cc is used.[12], as was used in the trials described in current thesis. One small study, comparing 30 to 80 cc in the balloon, concluded that in the subgroup of nulliparous women, higher balloon volume led to more dilation after ripening, decreased rates of oxytocin stimulation and increased rates of vaginal delivery within 24 hours. Caesarean delivery rates were comparable between the groups.[35] Later, Delaney and colleagues[36] found that the proportion of women who delivered within 12 hours was higher when a 60 cc balloon was used compared to a 30 cc balloon, this was not statistically significant in the subgroup of nulliparous women. Other outcomes, such as deliveries within 24 hours, caesarean deliveries and median time to delivery were not different.[36] As existing evidence is scarce and inconsistent, adequately powered randomised controlled trials are needed before we can advise a higher balloon volume than 30 cc.

IMPLEMENTATION

Foley catheter should be considered the primary method for cervical ripening, due to comparable efficacy with prostaglandin analogues, low cost, easy storage, and fewer cases of hyperstimulation during the ripening phase of induction.

After the publication of the PROBAAT study, some hospitals in the Netherlands already switched to Foley catheter as preferred method. Dutch and international guidelines, however, have remained unchanged, still recommending prostaglandins as method of first choice in women without prior cesarean delivery and an unfavourble cervix.[37-39] These guidelines urgently need to be reviewed and adapted.

Foley catheter is increasingly part of protocols used in hospitals that induce labor in women with a scarred uterus, as has been shown in **Chapter 3**. As, at present, there are no safe alternatives for induction of labour in women with prior cesaeran delivery, Foley catheter should be incorporated in international guidelines for this purpose.

Foley catheter could probably be useful as a ripening agent in low-resource countries, due to low cost, easy storage, and decreased need of fetal surveillance during the ripening phase of induction. Although Foley catheters compared with prostaglandin E2 have been studied and found to be effective in low-resource settings, these studies were all too small to address safety issues, and further research is needed in low-resource settings before implementation of this method.[40-43]

CONCLUSIONS

Labour can be induced effectively and safely using a Foley catheter. Currently, prostaglandins are believed to be a better method for induction of labour in women with unfavourable cervix at the start of induction over the use of a Foley catheter. The studies in this thesis demonstrate that Foley catheter yields similar caesarean section rates compared to vaginally administered prostaglandins, making both

methods equally effective. Findings from RCTs and meta-analysis in this thesis show reduced side effects with Foley catheter, with comparable costs that could be further reduced in favour of Foley catheter when used in outpatient setting.

This makes Foley catheter a superior method, with potential for outpatient cervical ripening, cervical ripening in low-resource settings, and cervical ripening in women with prior caesarean birth.

REFERENCES

1. Embrey MP, Mollison BG. The unfavourable cervix and induction of labour using a cervical balloon. J Obstet Gynaecol Br Commonw 1967;74:44-48
2. Cromi A, Ghezzi F, Agosti M et al. Is transcervical Foley catheter actually slower than prostaglandins in ripening the cervix? A randomized study. Am J Obstet Gynecol 2011;204:338-7
3. McNiven PS, Williams JI, Hodnett E, Kaufman K, Hannah ME. An early labor assessment program: a randomized, controlled trial. Birth 1998;25:5-10
4. Zhang J, Landy HJ, Branch DW et al. Contemporary patterns of spontaneous labor with normal neonatal outcomes. Obstet Gynecol 2010;116:1281-1287
5. Rinehart BK, Terrone DA, Hudson C, Isler CM, Larmon JE, Perry KG, Jr. Lack of utility of standard labor curves in the prediction of progression during labor induction. Am J Obstet Gynecol 2000;182:1520-1526
6. Rouse DJ, Weiner SJ, Bloom SL et al. Failed labor induction: toward an objective diagnosis. Obstet Gynecol 2011;117:267-272
7. Simon CE, Grobman WA. When has an induction failed? Obstet Gynecol 2005;105:705-709
8. Spong CY, Berghella V, Wenstrom KD, Mercer BM, Saade GR. Preventing the first cesarean delivery: summary of a joint Eunice Kennedy Shriver National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, and American College of Obstetricians and Gynecologists Workshop. Obstet Gynecol 2012;120:1181-1193
9. Hannah ME, Hannah WJ, Hellmann J, Hewson S, Milner R, Willan A. Induction of labor as compared with serial antenatal monitoring in post-term pregnancy. A randomized controlled trial. The Canadian Multicenter Post-term Pregnancy Trial Group. N Engl J Med 1992;326:1587-1592
10. Vandenbroucke JP. Observational research, randomised trials, and two views of medical science. PLoS Med 2008;5:e67
11. Fox NS, Saltzman DH, Roman AS, Klauser CK, Moshier E, Rebarber A. Intravaginal misoprostol versus Foley catheter for labour induction: a meta-analysis. BJOG 2011;118:647-654
12. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012;3:CD001233
13. Alfirevic Z, Weeks A. Oral misoprostol for induction of labour. Cochrane Database Syst Rev 2006;CD001338
14. Stichting Perinatale Registratie Nederland. Obstetrics in the Netherlands : trends 1995-1999. Bilthoven: Stichting Perinatale Registratie Nederland; 2005
15. Pennell CE, Henderson JJ, O'Neill MJ, McChlery S, Doherty DA, Dickinson JE. 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;116:1443-1452
16. Oster C, Adelson PL, Wilkinson C, Turnbull D. Inpatient versus outpatient cervical priming for induction of labour: therapeutic landscapes and women's preferences. Health Place 2011;17:379-385
17. Reid M, Lorimer K, Norman JE, Bollapragada SS, Norrie J. The home as an appropriate setting for women

undertaking cervical ripening before the induction of labour. Midwifery 2011;27:30-35

18. Biem SR, Turnell RW, Olatunbosun O, Tauh M, Biem HJ. A randomized controlled trial of outpatient versus inpatient labour induction with vaginal controlled-release prostaglandin-E2: effectiveness and satisfaction. J Obstet Gynaecol Can 2003;25:23-31
19. McKenna DS, Duke JM. Effectiveness and infectious morbidity of outpatient cervical ripening with a Foley catheter. J Reprod Med 2004;49:28-32
20. Sciscione AC, Muench M, Pollock M, Jenkins TM, Tildon-Burton J, Colmorgen GH. Transcervical Foley catheter for preinduction cervical ripening in an outpatient versus inpatient setting. Obstet Gynecol 2001;98:751-756
21. Menacker F, Hamilton BE. Recent trends in cesarean delivery in the United States. NCHS data brief 2010;35
22. National Health and Social Care Information Centre. Focus on: cesarean section, 2013. Available at: http://www.institute.nhs.uk/quality_and_value/high_volume_care/focus_on:_caesarean_section.html.
23. Lydon-Rochelle M, Holt VL, Easterling TR, Martin DP. Risk of uterine rupture during labor among women with a prior cesarean delivery. N Engl J Med 2001;345:3-8
24. Kuehn BM. Expert panel calls for greater access to trial of labor after cesarean delivery. JAMA 2010;303:1683-1685
25. ACOG Practice bulletin no. 115: Vaginal birth after previous cesarean delivery. Obstet Gynecol 2010;116:450-463
26. Solheim KN, Esakoff TF, Little SE, Cheng YW, Sparks TN, Caughey AB. The effect of cesarean delivery rates on the future incidence of placenta previa, placenta accreta, and maternal mortality. J Matern Fetal Neonatal Med 2011;24:1341-1346
27. Huisman, C. M. A., Jozwiak, M., de Leeuw, J. W., van Pampus, M. G., Kwee, A., van Roosmalen, J., Mol, B. W. J., and Bloemenkamp, K. W. M. Prostaglandin or Balloon for induction of labour in women with at least one previous caesarean section, 2011. Available at: http://www.studies-obsgyn.nl/probaats/page.asp?page_id=1043.
28. Bollapragada SS, MacKenzie F, Norrie JD et al. Randomised placebo-controlled trial of outpatient (at home) cervical ripening with isosorbide mononitrate (IMN) prior to induction of labour--clinical trial with analyses of efficacy and acceptability. The IMOP study. BJOG 2009;116:1185-1195
29. Norman JE, Thomson AJ, Greer IA. Cervical ripening after nitric oxide. Hum Reprod 1998;13:251-252
30. Romero R. Clinical application of nitric oxide donors and blockers. Hum Reprod 1998;13:248-250
31. Ekerhovd E, Bullarbo M, Andersch B, Norstrom A. Vaginal administration of the nitric oxide donor isosorbide mononitrate for cervical ripening at term: a randomized controlled study. Am J Obstet Gynecol 2003;189:1692-1697
32. Hatanaka AR, Moron AF, Auxiliadora de Aquino MM et al. Interruption of a study of cervical ripening with isosorbide mononitrate due to adverse effects. Clin Exp Obstet Gynecol 2012;39:175-180
33. Kelly AJ, Munson C, Minden L. Nitric oxide donors for cervical ripening and induction of labour. Cochrane Database Syst Rev 2011;CD006901
34. Salim R, Zafran N, Nachum Z, Garmi G, Kraiem N, Shalev E. Single-balloon compared with double-balloon catheters for induction of labor: a randomized controlled trial. Obstet Gynecol 2011;118:79-86
35. Levy R, Kanengiser B, Furman B, Ben AA, Brown D, Hagay ZJ. A randomized trial comparing a 30-mL and an 80-mL Foley catheter balloon for preinduction cervical ripening. Am J Obstet Gynecol 2004;191:1632-1636
36. Delaney S, Shaffer BL, Cheng YW et al. Labor induction with a Foley balloon inflated to 30 mL compared with 60 mL: a randomized controlled trial. Obstet Gynecol 2010;115:1239-1245
37. Utrecht: Nederlandse vereniging voor Obstetrie en Gynaecologie. "Inductie van de baring" Guidline. 2006.
38. ACOG Practice Bulletin No. 107: Induction of labor. Obstet Gynecol 2009;114:386-397

39. Guidline Development Group RCOG. NICE guidline Induction of labour. 2001. London: Royal College of Obstetricians and Gynaecologists.
40. Dalui R, Suri V, Ray P, Gupta I. Comparison of extraamniotic Foley catheter and intracervical prostaglandin E gel for preinduction cervical ripening. Acta Obstet Gynecol Scand 2005;84:362-367
41. Niromanesh S, Mosavi-Jarrahi A, Samkhaniani F. Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. Int J Gynaecol Obstet 2003;81:23-27
42. Saleem S. Efficacy of dinoprostone, intracervical foleys and misoprostol in labor induction. J Coll Physicians Surg Pak 2006;16:276-279
43. Rudra T. Is foley's catheter a safe and cost effective way of iol in low resource countries? International Journal of Gynecology and Obstetrics 2012;Conference:S468