■ ***Original Article***

Randomized clinical trial comparing the efficacy of vaginal misoprostol and Foley catheter for cervical ripening and induction of labour

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Abstract

Introduction: Induction of labour is commonly practiced intervention in modern obstetrics. There are various methods of induction of labour. The primary objective of the study is to compare the efficacy of vaginal misoprostol over Foley catheter for preinduction cervical ripening. **Methods:** Patients with term, vertex, singleton pregnancy and Bishop score <6, without previous caesarean section, no hypersensitivity to prostaglandins and with intact membranes admitted for induction of labour were enrolled. Random allocation to either vaginal misoprostol (n=100, 25 mcg) or Foley catheter (n=100, intracervically) was done. Maximum dose of misoprostol was 3, reassessed and inserted every 4 hourly. Foley catheter was inserted once and reassessed after 12 hours or when there was spontaneous expulsion of catheter. Main outcome majors were improvement in Bishop Score of e"7 (success rate), rate of spontaneous vaginal delivery and caesarean delivery. **Results:** The success rate was significantly higher in misoprostol (86%) group than in Foley catheter (35%) group (p <0.001). Rate of vaginal delivery was 62% in misoprostol and 58% in Foley catheter group (p=0.66). Caesarean section was 38% in misoprostol and 42% in Foley catheter group (p=0.66). **Conclusion:** Cervical ripening is significantly better in misoprostol group though there is no difference in vaginal delivery rate or rate of caesarean section.

Keywords: Prostaglandin, Foley catheter, cervical ripening, induction of labour

Introduction

Induction of labour can be defined as an intervention intended to artificially initiate uterine contractions resulting in the progressive effacement and dilatation of the cervix.[1] The aim of induction of labour is to initiate labour when maternal and fetal conditions necessitate delivery before the onset of spontaneous contractions with purpose to achieve safe vaginal delivery. The success of this obstetric practice is highly dependent upon the condition of the cervix and it is well known that unfavourable cervix is associated with failure of induction and caesarean section.[2]Failed induction is defined as the failure to enter the active phase of labour after 12 hours of regular uterine contractions.[3]

Cervical ripening is the process by which the cervix becomes soft, compliant, and partially dialated.[4] Assessment of cervical ripening is done with Bishop Score. Any score <6 recommends that a cervical ripening agent be used before labour induction.[5, 6] There are various methods of cervical ripening. It can be broadly divided into two categories: Pharmacological and Mechanical.

Prostaglandins have a central role in the physiological events of cervical ripening and parturition. Prostaglandins have been widely used for induction of labour.[7] These can be administered orally, vaginally, intracervically and by extra-amniotic or intra-amniotic routes. The present study was undertaken to compare misoprostol and Foley catheter regarding the efficacy for cervical ripening prior to induction of labour.

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Methods

This study is a randomized clinical trial conducted in the department of obstetrics and gynaecology, BP Koirala Institute of Health Sciences, Dharan, Nepal (BPKIHS) from March 2006 –March 2007. Total number of patients was 200. The study was approved

by the BPKIHS Institutional ethical review board.

Inclusion criteria include all term pregnancies of > 37 weeks having indication for induction of labour, Bishop Score <6, singleton pregnancy with cephalic presentation and intact membranes.

Exclusion criteria were hypersensitivity to prostaglandins, antepartum hemorrhage, non-reassuring fetal heart rate tracing, previous caesarean section, chorioamnionitis and premature rupture of membrane, known case of bronchial asthma, heart disease and diabetes. Women satisfying the selection criteria were given verbal information about both the method of cervical ripening. Subjects gave informed consent and were allocated to either misoprostol or Foley catheter group using computer generated randomization. Bishop score, fetal heart rate and uterine contractility were assessed prior to drug administration. A non-stress test was performed in all patients prior to drug administration. Fetal heart rate auscultation was performed every half hourly and maternal pulse, blood pressure, and temperature recorded every two hourly.

Misoprostol was administered in the posterior fornix every four hourly by the attending doctor with maximum dose of up to three. Vaginal examination was performed after four hours of drug administration or earlier if rupture of the membrane occurs. Next dose after 4 hours was withheld if the patient demonstrated frequent contractions (e"3 contractions in 10 minutes or Bishop Score e"7). Once in active labour, amniotomy was performed.

Under all aseptic precautions a no. 22 Foley catheter was placed intracervically and the balloon was inflated with 30ml of sterile water. The catheter was strapped to the medial aspect of thigh fixing with bandage creating traction. The catheter was placed in situ till 12 hours or till it expelled spontaneously. Reassessment was done after 12 hours or if there was spontaneous rupture of membranes or with spontaneous expulsion of catheter. On reassessment, if the cervix was favourable, amniotomy was done.

Oxytocin drip was started according to labour room protocol in both groups. Once in labour women were cared for according to current obstetric practice. If there was no progress in cervical dilatation, effacement or effective contractions even after maximum dose of cervical ripening agent, patient were taken for caesarean

section. After 12 hours of regular uterine contractions if the patients did not reach active phase, caesarean section for failed induction was done.

The outcomes were change in Bishop score, mode of delivery, induction to delivery time, need for oxytocin augmentation, indication for caesarean section, FHR changes and short term neonatal outcome(e.g. Apgar score, need for neonatal admission) and maternal complications.

Results

Total number patients were 200, 100 in each group. Most of the patients were in the age group between 20-24 years. 70% of total patients in both groups were primigravida. Most common indication for induction of labour was prolonged pregnancy.

The difference in improvement in Bishop Score was statistically significant in between two groups (86% in misoprostol and 35% in Foley catheter group, p=0.001). Augmentation with oxytocin was more in Foley catheter group (85% in Foley catheter and 61% in misoprostol, p=0.00017). There was no significant difference in the mode of delivery (p= 0.665). The difference in mean induction to delivery time was not statistically significant in two groups (11hours 53minutes in Foley catheter and 11hours 38minutes in misoprotol, p=0.71).

Most common indication for caesarean section was meconium stained liquor in both the groups. There was no significant difference in fetal heart rate abnormality in both the groups (p=0.47). There was no significant difference in 1, 5, and 10 minutes Apgar score in neonates. Maternal complications were not significant in both the groups.

Discussions

Induction is the commonest obstetrics intervention at BPKIHS. The average number of induction at BPKIHS ranges from 4-5 per day. Prolonged pregnancy is the commonest indication for induction of labour.

So we are in search of safe, cheap and efficacious inducing agent. Our study shows that Bishop Score was improved more in misoprostol group compared to Foley catheter group.

Success rate was more with misoprostol than with Foley catheter in our study and was statistically significant[8]. Jindal et al also found that the success

rate was more with misoprostol (98%) as compared to Foley catheter (78%) group (p=0.002).[9]

The present study indicates that misoprostol was associated with less need of oxytocin augmentation. Afolobi et al showed that oxytocin requirement was more with Foley catheter group (p<0.05).[10] However, Chung et al found no difference in use of oxytocin in both groups. In this study, rate of vaginal delivery was 62% in misoprostol and 58% in Foley catheter group, but it was not significant (p=0.66).[11] Several other studies also did not show any significant differences in vaginal delivery rates between the two groups. Chung et al found that the vaginal delivery rates between two groups were not significant (p=0.81).[11]

Similar to vaginal delivery, caesarean section rate was also not significantly different between the two groups in the present study. Various other studies also had the similar results regarding rate of caesarean section.[8, 12]

The mean induction to delivery interval did not differ significantly between the two groups (p=0.21) in our study. Sciscione et al did not find any difference in induction to delivery interval.[12] However, Afolobi et al found shorter induction delivery interval in misoprostol group as compared to Foley catheter group (p<0.05). In our study, there was no significant difference in 1, 5, and 10 minutes Apgar score. Abramovici et al found that Apgar score of <7 at 5 minutes was not significant (p=0.68).[13] Adeniji et al also found that 1 minute Apgar score of <7 in two groups was not significant. Overall, this study has compared two different inducing agents regarding various aspects. Blinding if possible, could have added strength to the study.

However, based on randomisation, the study confirmed misoprostol to be more effective than Foley catheter for pre-induction cervical ripening.

Conclusion

Misoprostol is more effective than Foley catheter for pre-induction cervical ripening as it has high success rate achieving cervical ripening. However, there was no difference in vaginal delivery rate or rate of caesarean section. Maternal and fetal outcomes were also not different in two groups.

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