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Comparative Study of Mechanical Methods for Cervical Ripening

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ABSTRACT

Introduction

Cervical ripening may be achieved by using mechanical devices or by pharmacological agents. There are very few studies comparing the efficacy of mechanical methods of cervical ripening.

Objectives:

To compare the efficacy of EASI with Foleys catheter alone in cervical ripening.

Materials and methods:

This is comparative clinical study where all term pregnant women with unfavourable cervix were included. Eligible women were randomly assigned to ripening with either transcervical Foley catheter with EASI or Foley catheter alone. The outcome measures noted were the changes in Bishop Score (BS) and the proportion of deliveries achieved within 24 hrs. Data analysis was done using Student-t test.

Results

There was no significant difference between the groups in post induction BS and number of deliveries within 24 hours of cervical ripening.

Conclusion

EASI do not increase the efficacy of Foley catheter in cervical ripening.

KEYWORDS :Labour, Mechanical induction, Bishop Score, Extra amniotic saline infusion, Foley catheter

INTRODUCTION

Induction of labour means initiation of contraction prior to spontaneous onset of labour. Success of labour induction depends on the cervical status at the beginning. Those with unfavourable cervix are at an increased risk of prolonged labour and caesarean section.[1,2] Cervical ripening may be achieved bymechanical devices or by pharmacological agents. There are many studies comparing efficacy of mechanical methods with pharmacological methods.[3,4,5] But very few studies have compared two mechanical methods of cervical ripening.[6,7,8,] Hence, the purpose of this study is to know the advantages of extra amniotic saline infusion with Foley catheter over simple Foley catheter bulb insertion for cervical ripening and labour induction.

The mechanism of action of Foley catheter induction is by direct pressure and stretching of lower uterine segment and cervix. In addition to this, Extra-amniotic infusion separates the choriodecidual interphase and the release of endogenous prostaglandins and local cytokines.[9] The randomized studies which compared transcervical Foley catheter alone with Extra-amniotic saline infusion found conflicting results. The overall advantages of mechanical induction of labour are low cost, stability at room temperature, reversibility and lower incidence of contractile abnormality. Still many more studies are needed to conclude whether Foley catheter with EASI has advantages over only Foley catheter method.

OBJECTIVES:

To compare the efficacy of transcervical Foley bulb with and without extra amniotic saline infusion for preinduction cervical ripening in women with an unfavourable cervix in terms of improvement in Bishop Score after 12hrs of procedure and the proportion of deliveries achieved within 24 hrs.

MATERIALS AND METHODS:

This Comparative clinical study was conducted in the Department of Obstetrics and Gynecology of a private medical college, Kerala, from 1st July 2011 to 30th May 2012 with full institutional review board approval. All term pregnant women (37 to 42 week), who were undergoing induction of labour for various indications with unfavourable cervix (Bishop score ≤ 5) were included in the study. All eligible women were explained about the procedure and written informed consent was obtained. Eligible women were randomly assigned to ripening with either transcervical Foley catheter with EASI or transcervical Foley catheter alone. Randomization was done using a random number generating table with blocks of four.

Sample size was calculated based on our primary outcome for nulliparous and multiparous patients combined. Total number of patients in our study were 199 ie 100 women in EASI group and 99 in Foley catheter alone group. Inclusion criteria's were Singleton pregnancy, Cephalic presentation, term pregnancy and BS</=5.Exclusion criteria's were Preterm pregnancy, PROM, Intra uterine fetal demise, previous scar and bishop score <5.

Procedure:

Patients were put in dorsal position and preinduction Bishop Score was assessed by doing a per vaginal examination. Cervix was visualized by inserting a Sims speculum to retract the posterior vaginal wall and anterior lip of cervix held with a sponge holding forceps to stabilize it. Under direct observations 16F catheter was inserted through the cervical canal. Once the bulb had passed beyond the internal os, it was inflated with 40ml normal saline. The catheter was pulled back against the internal os and was strapped to medial aspect of the thigh with minimal traction. In EASI group, 200 ml of warm normal saline infused through catheter port into extra-amniotic space and a knot was placed at distal end, and then strapped to the medial aspect of thigh.. Fetal heart rate and vitals were monitored. All women underwent vaginal examination under aseptic precautions when indicated

clinically or after 12 hrs of labour induction and the change of Bishop Score was noted. Outcome measures were change in BS after 12 hrs of catheter insertion and the number of deliveries achieved within 24 hrs. Data analysis was done using student-t test and P value of <0.05 was taken as significant.

RESULTS:

The demographic characteristics like nulliparity, gestational age and pre induction Bishop Score were comparable between the two groups (Table:1)

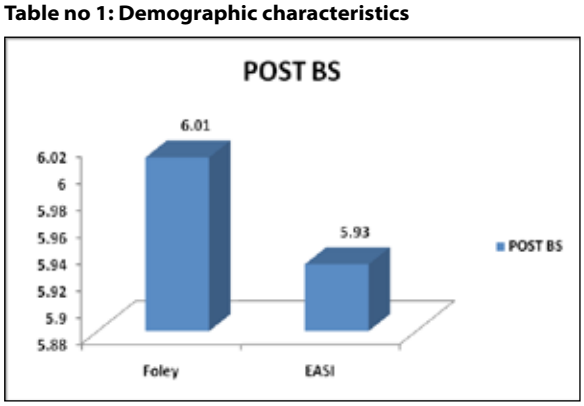
The indications for induction were Gestational Diabetes Mellitus, Postdated pregnancy, Oligohydramnions, Preeclampsia, chronic hypertension, IUGR, abnormal Doppler, decreased fetal movements and others. All indications were comparable except oligohydromnios which was 44 cases in Foley catheter group and 22 in EASI group, with P value of 0.001. This difference was statistically significant.

The post induction Bishop Scores showed significant improvements in both groups. It was 6.01 and 5.93 but with no statistically significant difference between the groups (p=0.686). Another important outcome measured was the number of deliveries within 24 hours of induction. 68 women in Foley catheter alone and 80 women in EASI group delivered within 24 hours and the difference was not statistically significant (p=0.068).

The outcome measures showed significant effectiveness of both methods for induction of labour. But addition of EASI to Foley catheter bulb did not show any advantage in the improvement of BS compared to Foley catheter alone group.

Sl.No	Characters	Foley catheter alone	EASI	P value
1	Nulliparous	73.7%	68%	0.373
2	Gestational age	38.36 weeks	38.13 weeks	0.071
3	Preinduction BS	3.21	3.27	0.724

Table no 1: Demographic characteristics



Graph-1: Mean post induction BS. (P = 0.686)

Graph-2: Deliveries within 24 hours. (P = 0.068)

DISCUSSION:

The incidence of induction of labour is increasing day by day. As the proportion of elective induction is also significantly increasing we need to know a method which is safe for mother and the fetus. In the recent years, systemic or local administration of cervical ripening agents have wide spread use but mechanical methods for cervical ripening are less popular. Among the mechanical methods, Foley catheter and saline infusion via catheter lumen are quite popular.[10,11] Cervical ripening means shortening and dilatation of cervix which occurs naturally before spontaneous labour[12]. Ripening of cervix is done in patients who have low Bishop Score.[13]

In this study, transcervical Foley catheter alone was compared with EASI with Foley catheter for cervical ripening in women with unfavourable cervix. The mean pre-induction Bishop Score in our study was 3.27 in EASI and 3.21 in Foley catheter group. It was 3 in both groups in Karjane et al study, 3.3 and 3.7 in Guinn study and in Lin MG study as 3 and 2 in EASI and Foley catheter group respectively. Statistically these parameters were similar, thus the groups were comparable in all studies including our study.

Thus the results of our study, showed no statistically significant difference between the mode of catheter removal/ expulsion, which was 95% manual removal and 5% spontaneous expulsion in EASI group and 97% manual removal and 2% spontaneous expulsion in Foley catheter group (P<0.05). This parameter was not compared in previous studies.

The addition of EASI to Foley catheter for cervical ripening will not reduce the induction to delivery interval. This finding is in agreement with the findings of Guinn et al study and Lin MG et al study but not with study of karjane and co-worker. Although the efficacy of Foley catheter and Foley catheter with EASI is thought to be due to its mechanical effect on cervix to promote cervical ripening, cytokines release which occurs while balloon is inflated also had a role to play. Theoretically, EASI may lead to cytokines release on a large scale than Foley catheter alone but this might get diluted by saline .Thus decreasing its effect and hence the results are similar in both groups. Main limitation of this study is that it's not blinded to observers and participants.

CONCLUSION

The two mechanical methods of cervical ripening-Foley catheter alone and extra amniotic saline infusion with Foley catheter are equally effective in cervical ripening. EASI to Foley catheter does not increase the efficacy of Foley catheter alone.

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