



Randomized Controlled Trial of Preinduction Cervical Ripening- Dinoprostone Versus Foley’s Catheter

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ABSTRACT

Induction of labour is an intervention intended to artificially initiate labour ideally resulting in vaginal delivery. Ripeness of cervix is of critical importance to the success of induction of labour. Cervical ripening refers to softness of cervix which is needed for cervical dilatation; therefore delivery of fetus. Cervical ripening methods are:

- 1) Mechanical-Foley's catheter, membrane stripping
- 2) Pharmacological-Dinoprostone(PGE2), Misoprostol(PGE1)

Randomized controlled trial was conducted in GOVT RSRM LYING IN HOSPITAL, STANLEY MEDICAL COLLEGE, on 200 pregnant women admitted for induction of labour. 100 received Foley's catheter and 100 dinoprostone gel. Two groups were comparable with respect to maternal age, parity, gestational age, indication for induction, initial Bishop's score. Both were found to be effective induction agents. Foley's caused less fetal distress, cheap and safety profile even for outpatient basis making it comparable or even superior to dinoprostone gel for cervical ripening specially for developing countries.

KEYWORDS

INTRODUCTION:

Induction of labour is a common obstetric intervention occurring in approximately 25% of term pregnancies in developing countries. The success of labour induction varies based on the state of cervix before ripening, which is measured by Modified Bishop's score. Patients with a low Bishop's score have high probability of Caesarean delivery. To decrease failure of induction, cervical ripening is done. The first method developed were the mechanical methods such as catheter and laminaria tents which were introduced into cervix. It not only dilates cervix but also increase prostaglandin and oxytocin release by causing localized inflammation. Second method were introduced in 70s and 80s; the pharmacological agents such as Prostaglandins. For example :Dinoprostone, Misoprostol. They act to promote both cervical ripening and uterine activity. Mechanical methods were never completely abandoned, but were replaced by pharmacological agents during recent years. The potential advantage of mechanical methods include simplicity of preservation, lower cost and reduction of side effects compared to Prostaglandins group.

AIMS AND OBJECTIVES:

The purpose of this study is to compare the efficacy of extra amniotic Foley's catheter with intracervical Dinoprostone gel for preinduction cervical ripening in women with an unfavourable cervix.

1) PRIMARY OUTCOME MEASURES-

Vaginal delivery within 24 hours

2) SECONDARY OUTCOME MEASURES:

To compare in both groups:

- a) Improvement in Bishops score
- b) Induction to onset of active labour and induction to delivery interval.
- c) Mode of delivery.
- d) Occurrence of maternal complications and fetal outcome.
- e) Cost effectiveness.

MATERIALS AND METHODS:

STUDY PLACE :RSRM HOSPITAL

STUDY PERIOD: JUNE 2015 – JULY 2016

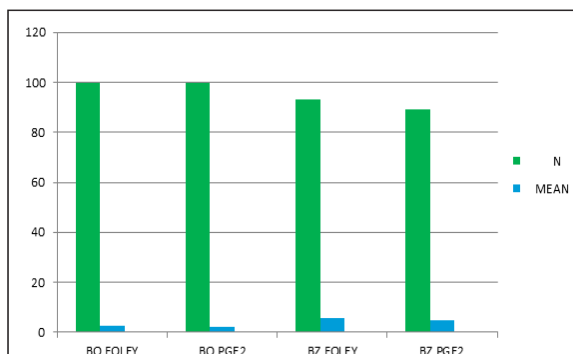
STUDY SAMPLE: 200 PREGNANT WOMEN

METHOD OF STUDY:

- 1) Informed consent
- 2) Patients randomly allocated to either Foley's catheter and Dinoprostone gel group.
- 3) 0.5mg in preloaded syringe placed in endocervical canal under strict aseptic precautions. Improvement in Bishop's score seen after 6 hours, if needed repeated gel kept. Fetal heart monitoring done
- 4) Foley's catheter inserted into cervical canal and filled with 30ml of saline, strapped in inner aspect of one thigh on slight tension for 12 hours. Fetal heart monitoring done.
- 5) All parameters were tabulated and statistical analysis done. P value <0.05 is taken as significant.

RESULTS:

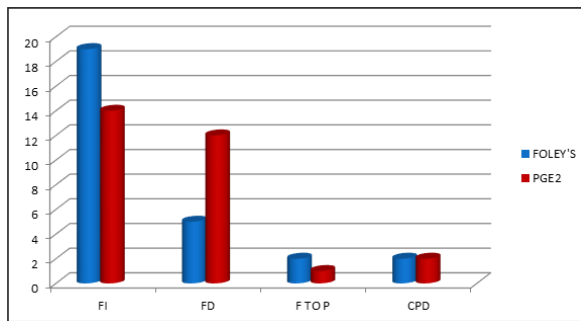
BISHOPS SCORE AT INDUCTION AND CHANGE IN BISHOPS SCORE



BO=Bishop score at 0 hour

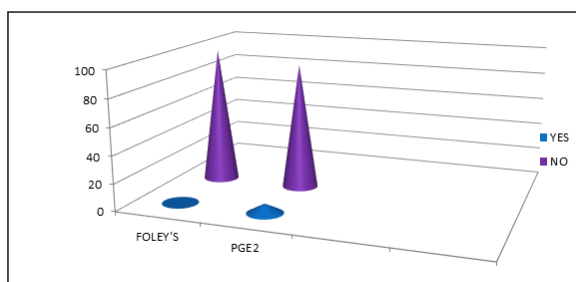
BZ=Change in Bishop score

LSCS INDICATION GROUP DISTRIBUTION:



FI=Failed induction, P=Failure, FD=Fetal distress, FTOP=Failed to Progress, CPD=Cephalopelvic disproportion

MATERNAL COMPLICATION GROUP DISTRIBUTION



DISCUSSION:

In the present study, mean age group was 21-25yrs for Foley's and 18-20 yrs for PGE2 group which were similar with other studies. The parity distribution were 74 nulliparous and 26 para-1 patients in Foley's, whereas 78 nulliparous and 22 para-1 patients in PGE2 group which were found to be comparable. In some studies exclusively nulliparous were studied. The mean gestational age in Foley's group is 270.60 days, PGE2 group is 269.64 days. Women with Bishop's score ≤ 5 were included whereas in other studies a wider range included. The commonest indication for induction in this study is post-dated pregnancy in both groups. The mean change in Bishop's score in Foley's was 5.80 and PGE2 was 4.92 which was statistically very significant. Induction to onset of active labour and to delivery for Foley's mean duration being 16.48 hours, for PGE2 being 14.66 hours whereas in some studies no significant noticed. In present study, the mean mode of delivery between both groups was not statistically significant $P=0.856$. Commonest indication for LSCS was failed induction where 39% of PGE2 group needed regel which was statistically significant $P<0.001$. Second was Fetal distress 3 patients for Foley's and 6 patients for PGE2 which was significant. 7 patients in PGE2 group developed hyperstimulation to induction but no adverse effect in Foley's which was statistically very significant. In other studies no such were seen while in another studies, PGE2 group has high risk of hyperactivity and meconium liquor. The average birth weight of newborn in Foley's group was 2.8442kg, in PGE2 group 2.8886kg. Mean APGAR in Foley's was 8.07 and PGE2 was 8.27. Cost in Foley's was Rupees 40 and 100 for PGE2.

SUMMARY:

Majority of patient included in the study were in age group 21-25yrs for Foley's and 18-20yrs in PGE2. Parity distribution were found to be comparable. Maximum numbers of patients were in 260-280 gestational days in both groups. Commonest indication for induction in both groups was post dated, second was for oligohydramnios in Foley's, pre-eclampsia in gel. Foley's was found to cause significant improvement in Bishop's

score compared to gel. PGE2 causes significant reduction in mean induction to onset of active labour and induction to delivery interval between the two groups. No statistically significant result observed for spontaneous delivery for both groups. Incidence of Caeserean was 33.8% of nulliparous and 11.5% of para1 in Foley's whereas 25.6% of nulliparous and 40.9% of para1 in PGE2 group. Thus in Foley's more women delivered by labour naturale in para1 whereas no significant difference with respect to nuliparous.

In both groups, failed induction was commonest indication for Caeserean section. Second indication was fetal distress which was higher for PGE2. The number of patients developing non-reassuring fetal heart rate during induction and ending in Caeserean was 9 in gel whereas none in Foley's. The number of patients delivering vaginally within 24hrs was similar for both. However within 12hrs, more delivery for PGE2. 7 patients in gel developed hyperstimulation to induction but no maternal adverse affects in Foley's. The average birth weight and Apgar for both groups were found to be of no statistical significance. The cost of Foley's was significantly less compared to PGE2 gel thus making it more cost effective.

CONCLUSION :

In conclusion, although both Foley's catheter and Dinoprostone(PGE2) gel found to be an effective preinductional cervical ripening agents, Foley's can be useful in low resource countries due to low cost, safety, easy storage and decreased need for fetal surveillance during ripening phase of induction. Further Foley's can be used in conditions such as patients with glaucoma, bronchial asthma where prostaglandins are not preferred for cervical ripening. Currently, prostaglandins are believed to be a better method for induction of labour in women with unfavourable cervix over the use of Foley's, but findings from my study show reduced side effects, cost effective, less chance of fetal distress, safety profile which makes Foley's superior method with the potential for even outpatient cervical ripening.

REFERENCES:-

- 1) Sandhu SK, Tung R. Use of Foley's catheter to improve the cervical cervical score prior to induction of labour. J Obstet Gynaecol India. 1984
- 2) O'Brien JM, Mercer BM, Cleary NT, Sibal BM, 1995. Efficacy of outpatient induction with low dose intravaginal prostaglandin E2 ; A randomized double blind, placebo controlled trial. Am J Obstet Gynaecol. Dec; 173(6):1855-9
- 3) Tenore JL. Methods for cervical ripening and induction of labour. Am Fam Physician 2003; 67:2123-8
- 4) Ian Donalds practical obstetrical problems-6th edition
- 5) William's Obstetrics 23rd edition