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Original Research Article

Intracervical foleys catheter: Can it serve as an alternative to standard pharmacological method of cervical ripening?

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ABSTRACT

Background: Ripening of cervix is a prerequisite for successful labour induction. Use of prostaglandins for this purpose incurs a high risk of uterine hyperstimulation and a relatively higher cost of treatment. intracervical Foleys catheter insertion is a mechanical method stated in literature. The present study was to compare the efficacy and safety and cost of intracervical Foleys catheter balloon insertion with intracervical dinoprostone application for preinduction cervical ripening in patients requiring labour induction at term.
Methods: This was a randomized, parallel group, active controlled study conducted in the obstetrics department of a tertiary care centre over a duration of one year. Group A received Dinoprostone cervical gel 0.5mg instilled in the cervical canal. Maximum of three doses (1.5mg dinoprostone) could be administered 6 hours apart. Patients randomized to group B were subjected to Foleys catheter insertion. Foleys catheter number 16 was used and balloon was inflated with 60ml of water. Primary efficacy parameter was change in Bishops score as compared to baseline and safety was monitored by comparing the total number of adverse events in the two groups.
Results: Total of 89 patients were enrolled into the study during one year period out of which 45 received dinoprostone gel and 44 received Foleys catheter insertion respectively. Change in Bishops score, mode of delivery and total number of maternal and foetal adverse events did not differ significantly between the two groups.
Conclusions: Efficacy and safety of Foleys catheter as a cervical ripening agent prior to induction of labour is comparable to dinoprostone gel. Since use of Foleys catheter is advantageous in terms of lack of specific storage conditions and cost of treatment, it could be considered a cost effective alternative for preinduction cervical ripening.

Keywords: Cervical ripening, Foleys catheter, Induction of labour, Prostaglandins

INTRODUCTION

In most pregnancies, process of labour starts spontaneously at term. However, in 15% of pregnant women, it needs to be artificially induced when continuation of pregnancy is perceived as a threat to either maternal or foetal well being.[1] In such cases, the aim is to achieve a safe vaginal delivery by artificially inducing onset of labour. However, success of induction of labour is largely dependent on the state of the cervix. A soft and pliable cervix (ripe cervix) is more likely to give rise to successful induction as compared to a hard non-pliable cervix. (Unripe cervix). Thus ripening of cervix is a prerequisite for successful labour induction.[2]

In pregnant women with an unripe cervix, cervical ripening can be achieved by mechanical, surgical or pharmacological means.[3,4] The commonest protocol for preinduction cervical ripening is intracervical instillation of a prostaglandin (PGE2- Dinoprostone gel).[5] Despite being a commonly adopted procedure, prostaglandin gel has to be refrigerated for storage, it is contraindicated in

patients of asthma and those allergic to prostaglandins, incur a high risk of uterine hyperstimulation and a relatively higher cost of treatment.[6] As a result, the search for an ideal cervical ripening agent which is stable at room temperature as well as cost effective and can be safely used for most patients eludes. This prompts the exploration of other alternatives like mechanical methods of cervical ripening. In contrast to pharmacological means of cervical ripening, intracervical Foleys catheter insertion is a mechanical method stated in literature. Use of this method overcomes the above shortcomings of dinoprostone but has not been routinely used for the fear of failure of induction and risk of infection. Recently, results from a few large scale studies have shown Foleys catheter insertion more promising if aseptic precautions are undertaken.[7,8] Thus, The purpose of the present study was to compare the efficacy and safety and cost of intracervical Foleys catheter balloon insertion with intracervical dinoprostone application for pre induction cervical ripening in patients requiring labour induction at term.

METHODS

This was a randomized, parallel group, active controlled study conducted in the obstetrics department of a tertiary care centre over a duration of one year. Study was approved by the institutional ethics committee and all the tenets of declaration of Helsinki were followed during the study. Study included patients at term with singleton gestation, cephalic presentation and an indication for induction of labour with an unripe cervix (defined as Bishop score less than or equal to 5). Study excluded patients with multiple pregnancies, scarred uterus, malpresentations, grand multiparas, premature rupture of membranes, ante partum haemorrhage and those with Bishop score more than 5.

Patients were enrolled into the study after obtaining a well informed written consent. Baseline data such as age, gravidity, parity, indication for induction and Bishop score at baseline were recorded and patients were randomized into one of the two groups. Randomization was done by computer generated random numbers. Patients randomized to Group A received Dinoprostone cervical gel. One prefilled syringe consisting of 0.5mg PGE2 was instilled in the cervical canal and patients were to remain in the supine position for 15 minutes after instillation. Maximum of three doses (1.5mg dinoprostone) could be administered 6 hours apart. Patients randomized to group B were subjected to Foleys catheter insertion. Foleys catheter number 16 was used and inserted into the cervical canal extra amniotically with aseptic precautions and balloon was inflated with 60ml of water. An adhesive tape was applied strapping the catheter to maternal thigh and patient was ambulated.

Primary efficacy parameter of the study was to assess the change in Bishops score which determined the extent of ripening of the cervix. Cervix was assessed for initial Bishop score in both groups and change after 6 hours of last dose of dinoprostone or onset of contractions whichever was earlier in dinoprostone group and either after 6 hours or after expulsion of catheter, whichever was earlier in Foleys catheter group. Secondary efficacy parameters included mode of delivery, induction to delivery interval, failure of induction and need for oxytocin augmentation. Patients who failed to achieve bishop score of more than 5 after three doses of dinoprostone 6 hours apart or 12 hours of Foleys catheter insertion were labelled as treatment failure and were posted for caesarean section. Patients were objectively examined for any adverse events on temperature, blood pressure, foetal heart rate and uterine activity. Any subjective adverse effects reported by patient like pain, nausea, vomiting was also recorded. After delivery, foetal safety was assessed by 5 minute APGAR score and rate of admission to neonatal intensive care unit. Safety was assessed by comparing the total number of adverse events observed in the two groups. Mean cost of therapy incurred for cervical ripening in the two groups was calculated and depicted graphically.

Quantitative data like mean age, mean change in Bishop score, mean induction to delivery interval were analysed by t test. Qualitative data like maternal and foetal adverse events were analyzed by Fishers exact test. Chi square test was used to compare the mode of delivery.

RESULTS

Total of 89 patients were enrolled into the study during one year period out of which 45 received dinoprostone gel and 44 received Foleys catheter insertion respectively. Groups were comparable with respect to demographic and baseline characteristics like age, parity and indication for induction of labour (Table 1).

Both groups achieved cervical ripening with mean change in Bishops score being significantly higher than baseline. Mean change in Bishops score, albeit a little higher in the dinoprostone group as compared to Foleys catheter group, (7.2 vs 6.81) the difference between them was not statistically significant (Table 2).

Induction delivery interval was almost similar in the two groups (11.6 vs 11.1 in dinoprostone and Foleys catheter group respectively). Proportion of patients requiring additional oxytocin augmentation and caesarean section rate were apparently higher in the Foleys catheter group while failure of induction was apparently higher in dinoprostone group. These differences however were not statistically significant. (Table 3).

The total number of adverse events in both study groups for maternal and fetal safety parameters was not statistically different (Table 4 and 5).

Table 1: Demographic and baseline parameters of the two study groups.

Sr. no	Parameter	Dinoprostone group (n=45)	Foleys catheter group (n=44)	P value
1.	Mean age	23.44 years	23.06 years	0.2820
2. Parity	Nullipara	34 (75.66%)	32 (72.72%)	0.8489
	Multipara	11 (24.44%)	12 (27.27%)	
3. Indication for induction	Postdate pregnancy	29 (64.44 %)	26 (59.90%)	0.0760
	PIH	9 (20%)	6 (13.63%)	
	Oligohydramnios	2 (4.44 %)	11(25%)	
	IUGR	1 (2.22%)	0 (0%)	
	Uteroplacental insufficiency	1(2.22%)	0 (0%)	
	Decreased foetal movements	3 (6.66%)	1 (2.27%)	

Table 2: Comparison of Bishops scores in the two study groups.

Bishops score	Dinoprostone group (n=45)	Foleys catheter group (n=44)	P value
Mean pre-induction Bishops score	3.288	3.25	0.5238
Mean post-induction Bishops score	10.488	10.0681	0.1853
Mean change in Bishops score from baseline	7.2	6.8181	0.2322

Table 3: Comparison of secondary efficacy parameters in the study groups.

Secondary efficacy parameter	Dinoprostone group (n=45)	Foleys catheter group (n=44)	P value
Mean induction to delivery interval	11.6252 hours	11.1395 hours	0.4593
Proportion of patients requiring oxytocin augmentation	44%	63%	0.2026
Mode of delivery: Vaginal delivery Caesarean section	20(44.44%) 25(55.55%)	13(41%) 26(59%)	0.6355
Patients with failed induction	2(4.44%)	0(0%)	0.4944

All patients in Foleys catheter group required a single catheter and thus the mean cost of therapy in this group was rupees 55 amounting to the cost of one piece. On the contrary, out of 45 patients in the dinoprostone group, 3 patients required a second dose of dinoprostone gel for cervical ripening. The mean cost of cervical ripening in this group was rupees 277.86 per patient. The difference between mean cost of therapy in the two groups was considerable.

Table 4: Comparison of maternal safety parameters amongst the two groups.

Adverse events	Dinoprostone group (n=45)	Foleys catheter group (n=44)
Vomiting	3	0
Chills	2	0
Fever	3	2
Hyperstimulation	1	0
Hypertonous	1	0
Premature rupture of membranes	0	3
Bleeding	0	2
Total *	10	7

*Difference between total numbers of maternal adverse events in the two groups was not statistically significant. (p value by Fishers test =0.5912)

Table 5: Comparison of neonatal safety parameters amongst the two groups.

Adverse events	Dinoprostone group (n=45)	Foleys catheter group (n=44)
NICU admission	2	4
Transient tachypnea	0	1
Low APGAR score	1	1
Total*	3	6

Difference between total numbers of neonatal adverse events in the two groups was not statistically significant. (p value by Fishers test =0.3148)

DISCUSSION

Uterine cervix is composed of smooth muscle and fibroblast cells interspersed between thick bundles of

collagen, elastin and glycosaminoglycans.[9,10] Cervical remodelling that occurs throughout pregnancy and especially towards term corresponds to apoptosis of smooth muscle cells, dispersion of collagen bundles due to increased hydration making the cervix softer and ripe. Many methods are available to assess extent of cervical ripening and the most widely used and accurate is Bishops score. This score takes into consideration parameters like cervical dilatation, effacement, consistency, position and head station. Cervix is considered favourable for inducing contractions if Bishops score is more than 5 and unfavourable if score is 5 or less. Thus change in Bishops score was considered as the primary efficacy parameter in this study. In both dinoprostone and Foleys catheter groups the cervical ripening was achieved to a similar extent with mean change in score being 7.2 in dinoprostone group and 6.8 in Foleys catheter group. The difference between these scores was not statistically significant. Other studies have reported average increase in cervical ripening in the Foleys catheter group by 5.1 scores which is lesser than our study.[11,12] The observed discrepancy may be related to the amount of water used for dilation of catheter, which was only 30 ml in contrast to 60 ml in our study. A randomized controlled trial designed to compare the rates of success with respect to volume of inflation also states that a higher volume of water used to inflate catheter increases the chances of obtaining a favourable cervix.[13-15] Being a mechanical method, Foleys catheter induces cervical ripening by separation of membranes and cervical dilation that leads to secretion of endogenous prostaglandins. Thus the amount of water used to dilate balloon of Foleys catheter plays a very important role in the extent of cervical ripening achieved. Since cervical ripening is forerunner of induction of labour and the success of induction depends on the extent of ripening, secondary efficacy parameters of the study were related to success of labour induction like need for oxytocin augmentation, induction delivery interval, mode of delivery and failure of induction. None these parameters differed significantly in the study groups. Many other studies comparing dinoprostone gel with Foleys catheter have come up with similar results. Although the caesarean section rate was higher in our study compared to the other studies, the indications for caesarean section were similar to other studies.[5,15,16] Study of maternal outcome parameters to compare safety profile of the drugs showed that a total of 10 adverse events were reported in the dinoprostone group while only 7 adverse events were reported in the Foleys catheter group. Although there was no statistically significant difference in the adverse events reported quantitatively, events like uterine hyper stimulation and hypertonus were reported only in the dinoprostone group while premature rupture of membranes was reported only in Foleys catheter group.[17] Another study conducted at Rothak also shows that only patients in the dinoprostone group experienced hyperstimulation. [17] Difference in pharmacodynamics of Foleys catheter and PGE2 gel may partly explain the qualitative difference observed in type of adverse events. Foleys catheter acts by increasing endogenous prostaglandin synthesis and has limited capacity to hyperstimulate the uterus while dinoprostone gel increases the local availability of prostaglandings to a greater extent ultimately culminating in hyperstimulation in a few cases. On the contrary, since Foleys leads to mechanical cervical dilation and partial separation of membranes, premature rupture of membrane was more common in this group. Foetal outcome parameters were also comparable in both groups and no neonatal deaths occurred in this study. Similar results with respect to foetal safety were obtained in other studies comparing dinoprostone with Foleys catheter for cervical ripening.[11,18] Comparison of cost of incurred in the two groups showed that cost of one prefilled syringe of dinoprostone is 260.50 and Foleys catheter varies from Rs 9 per piece to rupees 260 per piece. The Foleys balloon catheter used for this study costs rupees 55 per piece. Comparison of the cost of cervical ripening showed considerable difference in the mean cost of therapy.

CONCLUSION

To conclude, efficacy and safety of Foleys catheter as a cervical ripening agent prior to induction of labour is comparable to dinoprostone gel used for the same purpose. Since use of Foleys catheter is advantageous in terms of lack of specific storage conditions and cost of treatment, it could be considered a cost effective alternative for pre induction cervical ripening.

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