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Efficiency and Safety of Vaginal Propess as an Approach for Cervical Ripening and Labour Induction in Full-Term Pregnant Patients in Indian Settings

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Abstract: Induction of labor is common in obstetric practice. Cervical ripening or preparedness for induction should be assessed before a regimen is selected. To investigate the efficiency and safety of vaginal Propess as a methodology for cervical ripening and labour induction in full-term pregnant patients. This retrospective observational study was carried out at Private Hospital in Pune city. Full term pregnant patients with Bishop score 5, singleton pregnancy, vertex presentation, unruptured membranes, and patients with only one prior cesarean delivery were included in the study. Vaginal Propess was used for cervical ripening and labour induction. Change in the Bishops score, induction to delivery interval, rate of vaginal delivery and caesarean section were calculated. Fetal and maternal outcomes were observed. Statistical analysis: Mean, Standard Deviation, Proportions, Percentages were used for descriptive statistics, and paired t test was used as test of significance. Total 50 patients were included in the study. Mean age of the patients was 29.5 years (S.D.=2.3 years). 35 (70%) patients were primi gravida. Mean Bishop Score on Admission was 2.74 (S.D.=1.08). Mean change in the Bishop's score after vaginal propess was used for cervical ripening was 6.3 (S.D.=1.65). Mean change in the Bishop's score was statistically significant (0.001). Mean induction to delivery interval was 13.6 hours (S.D.=4.45 hours). Rate of vaginal delivery was 51.61% and rate of caesarian section was 48.39%. Fetal outcome was good in all cases. No maternal complications were observed. Vaginal Propess was an effective and safe approach to promote cervical ripening and it was successfully used in induction of labour.
Keywords: Cervical ripening, Labour induction, Propess, Efficacy, Safety.

INTRODUCTION

Induction of labor is common in obstetric practice. According to the most current studies, the rate varies from 9.5 to 33.7 percent of all pregnancies annually. In the absence of a ripe or favorable cervix, a successful vaginal birth is less likely [1].

One of the most common indications for labour induction is prolonged pregnancy as it is associated with the increased risk to the fetus, including increased perinatal mortality rate, low 5-min Apgar scores, dysmaturity syndrome, and increased risk of death within the first year of life. A ripe or favorable cervix is a prerequisite for successful vaginal birth [2].

Therefore, cervical ripening or preparedness for induction should be assessed before a regimen is selected. Assessment is accomplished by calculating a Bishop Score. When the Bishop Score is less than 6, it is recommended that a cervical ripening agent be used before labor induction. Pharmacologic agents available for cervical ripening and labor induction include prostaglandins, misoprostol, mifepristone, and relaxin [3].

Propess vaginal delivery system is a pessary containing the active ingredient dinoprostone, which is a naturally occuring female hormone also known as prostaglandin E2. Studies found that Propess is an effective and safe approach to promote cervical ripening and be successfully used in induction of labour. However the Propess vaginal insert demonstrated a shorter application-delivery interval. The hospital stay was consequently shorter, contributing to cost effectiveness [4,5]

This study was carried out to investigate the efficiency and safety of vaginal Propess as a methodology for cervical ripening and labour induction in full-term pregnant patients in Indian settings.

MATERIALS AND METHODS

Type of study and study settings

This retrospective observational study was carried out at Private Hospital in Pune city. It was carried out for the period of Six months.

Inclusion criteria

Full term pregnant patients with Bishop score 5, singleton pregnancy, vertex presentation, unruptured membranes, and patients with only one prior cesarean delivery were included in the study.

Exclusion criteria

Estimated fetal weight >4,500 or <2,000 g, antepartum hemorrhages, previous cesarean section, chorioamnionitis, parity >4, any medical complications

Study protocol

Vaginal Propess was used for cervical ripening and labour induction. Change in the Bishops score, induction to delivery interval, rate of vaginal delivery and caesarean section were calculated. Fetal and maternal outcomes were observed.

STATISTICAL ANALYSIS

Mean, Standard Deviation, Proportions, Percentages were used for descriptive statistics and paired t test was used as test of significance and $p<0.05$ was considered as statistically significant.

Ethical considerations

The study was conducted according to the Declaration of Helsinki; the protocol was reviewed and approved by the institutional ethics committee. Written informed consent was obtained from the study subjects.

RESULTS

Total 50 patients were included in the study. Mean age of the patients was 29.5 years (S.D.=2.3 years). 35 (70%) patients were primi gravida.

Mean Bishop Score on Admission was 2.74 (S.D.=1.08). Mean change in the Bishop's score after vaginal propess was used for cervical ripening was 6.3 (S.D.=1.65). Mean change in the Bishop's score was highly statistically significant (0.001).

Table-1: Bishop's score on admission and after induction

	N	Mean (Bishop's score)	Standard Deviation
On admission	50	2.74	1.08
After induction	50	6.30	1.65

t=13.75 with 49 d.f. , p =0.0001; HS

Mean induction to delivery time was 13.6 hours (SD= 4.49 hours). Minimum time was 5 hours and maximum time was 22 hours.

Rate of vaginal delivery was 52% and rate of caesarian section was 48%. In majority of the cases indication for LSCS was non-progess of the labour and most of these cases had Bishop's score less than 6 even after induction. Fetal outcome in all cases were good and no maternal complications were observed.

DISCUSSION

Labor is a process through which the fetus moves from the intrauterine to the extra uterine environment. It is a clinical diagnosis defined as the initiation and perpetuation of uterine contractions with the goal of producing progressive cervical effacement and dilation. The exact mechanisms responsible for this process are currently not well understood [6] Induction of labor refers to the process whereby uterine contractions are initiated by medical or surgical means before the onset of spontaneous labor [1].

Before 1970s the phrase "once a cesarean, always a cesarean" dictated obstetric practice. Later because of escalating rates of cesarean section (CS) suggestions were made that vaginal birth after CS (VBAC) might help in reducing the rates of CS. So trial of labor in cases of previous CS (PCS) has been accepted as a way to reduce the overall CS rates [3].

Induction of labor is common in obstetric practice. Nonpharmacological approaches to cervical ripening and labor induction have included herbal compounds, castor oil, hot baths, enemas, sexual intercourse, breast stimulation, acupuncture, acupressure, transcutaneous nerve stimulation, and mechanical and surgical modalities. Of these nonpharmacological methods, only the mechanical and surgical methods have proven efficacy for cervical ripening or induction of labor. Pharmacologic agents available for cervical ripening and labor induction include prostaglandins, misoprostol, mifepristone, and relaxin. When the Bishop score is favorable, the preferred pharmacologic agent is oxytocin [1].

Propess vaginal delivery system is a pessary containing the active ingredient dinoprostone, which is a naturally occuring female hormone also known as prostaglandin E2. The Propess pessary is inserted high up into the vagina to induce labour. It releases dinoprostone continuously next to the cervix until it is removed (for up to 24 hours). The pessary has a special retrieval tape that allows it to be removed quickly and easily once labour has started, or if there are any problems during the induction.

In the present study we observed that there was statistically significant improvement in the Bishop's score after induction with Propess pessary. Mean induction to delivery interval was 13.6 hours

(S.D.=4.45 hours). Rate of vaginal delivery was 51.61% and rate of caesarian section was 48.39%. Fetal outcome was good in all cases. No maternal complications were observed. Chen W *et al*. investigated the efficiency and safety of vaginal Propess as a methodology for cervical ripening and labour induction in full-term pregnant patients. Women at term with a Bishop's score of < 6 and without any contraindications, to vaginal delivery, or the use of prostaglandin or oxytocin in induction of labour, were divided into three groups: oxytocin group (n = 59), intact membranes (Propess I group; n = 58) and natural rupture (Propess R group; n = 52) groups. The main outcome measures, including change in Bishop's score, induction to delivery interval, total delivery time, rate of vaginal delivery, fetal outcome and maternal complications during induction, were recorded. In the Propess groups, the Bishop's score and rate of vaginal delivery were significantly higher while the induction to delivery interval and total delivery time were much shorter, as compared with oxytocin patients ($p < 0.01$). There were no significant differences in fetal and maternal outcome during induction between the Propess groups and oxytocin group ($p > 0.05$). In addition, there were no significant differences of Bishop's score, rate of vaginal delivery, induction to delivery interval and total delivery time between the Propess I group and Propess R group ($p > 0.05$). This study concluded that Propess is an effective and safe approach to promote cervical ripening and be successfully used in induction of labour [4].

Vollebregt A *et al.* compared the efficacy and safety of intracervical PGE (2) gel (Prepidil) with intravaginal PGE (2) insert (Propess) in cervical ripening and induction of labour. This study concluded that Both prostaglandin E (2) agents are safe and effective in achieving cervical ripening; however the vaginal insert demonstrated a shorter application-delivery interval. The hospital stay was consequently shorter, contributing to cost effectiveness [5].

Grignaffini A *et al.* also compared the effectiveness and safety of a slow release vaginal PGE2 insert (Propess) with intracervical PGE2 gel (Prepidil gel) in the induction of cervical ripening and labour. They concluded that both the systems proved equally effective, nevertheless Propess seems to be safer thanks to the lower incidence of cardiotocographic changes such as to indicate urgent cesarean section. Propess would seem to be more acceptable on the part of patients thanks to the smaller number of applications necessary [7].

CONCLUSION

This study concluded that vaginal Propess was an effective and safe approach to promote cervical ripening and it was successfully used in induction of labour.

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