

Original Research Article

Comparative Evaluation of Pre-Induction Use of Misoprostol in Post-Term Pregnancies for Cervical Ripening on Outpatient Basis

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ABSTRACT

Objective: To compare the efficacy of sweeping and stretching of membranes versus sweeping and stretching combined with single dose 50 mcg misoprostol sublingually on ripening of cervix in singleton uncomplicated post term pregnancies on an outpatient basis.

Design: Randomized prospective comparative study.

Setting: Tertiary care teaching hospital, Government Doon Medical College, Dehradun.

Method: A total of 100 women with uncomplicated post term pregnancy, single live cephalic presentation with bishop score less than 5 were included in this study and were equally randomized to the two groups. Membrane sweeping and stretching was done in group A while women in group B received tab misoprostol 50mcg sublingually along with membrane sweeping.

Results: Pre-induction cervical ripening with sublingual misoprostol along with membrane sweeping stretching in post-term pregnancy showed significant shorter latency period as compared to group A (pre-induction cervical ripening with only membrane sweeping) with p value <0.05. Duration of labor was also lesser in group B as compared to group A (p value=<0.05). The need for further augmentation was also very significantly reduced in group B as compared to group A (p value=0.001). There were no significant difference in mode of delivery in both groups. Neonatal outcomes were comparable in both the groups.

Conclusion: Single dose sublingual tab misoprostol along with membrane sweeping stretching is safe and effective measure for pre-induction cervical ripening in post-term pregnancy on outpatient basis.

Key words: Pre-induction cervical ripening, Misoprostol, Membrane sweeping and stretching, Outpatient basis, Post-term pregnancy.

INTRODUCTION

It is well known that pregnancies crossing the due date are associated with fetal, neonatal and maternal complications.

^[1] Risks increases after 40 weeks and significantly so after 41 weeks of pregnancy and hence, it becomes commonest indication for induction of labor in the hope of vaginal delivery. ^[2]

Ideally, the methods of cervical ripening and labor induction require admission to hospital. But many times the patients are apprehensive and prefer to wait

for spontaneous labor pains against advice. On the other hands, in a developing country like India, government hospitals more than often are overburdened with patients. Hence, any safe and effective intervention that would reduce the duration of hospital stay, financial burden without compromising the feto-maternal outcome is desirable.

Sweeping and stripping of membrane (MS) is commonly used method for induction of labor on outdoor patient basis but some studies showed that it is

beneficial in post term pregnancies. A Cochrane review suggested that routine use of MS between 38 and 40 weeks does not seem to produce clinically important benefits; however, it may be beneficial in women with post-term pregnancies. [3-5] Misoprostol, a PGE1 analogue, has been reported to be an effective and affordable cervical ripening and medical induction agent. It can be used intra-vaginally or orally with these factors this has immensely advantage in low-resource tropical countries. [6,7]

This study was planned to see the efficacy of single dose of 50 micrograms misoprostol sublingual combined with sweeping and stretching of membranes versus sweeping and stretching of membranes alone in pregnancies crossing 40 weeks but not more than 41 weeks on reducing the need for hospital admission for cervical ripening or labor induction in uncomplicated post term singleton pregnancies.

MATERIALS AND METHODS

Objective: To assess and compare the efficacy of the two outpatient processes of membrane sweeping (MS) versus single-dose 50 µg sublingual misoprostol along with membrane sweeping (MP) for pre-induction cervical ripening in uncomplicated post-term singleton pregnancies. The outcomes were measured in terms of:

1. Time interval from the start of pre-induction cervical ripening measure to onset of labor (latency period).
2. Time interval from the start of pre-induction cervical ripening measure to delivery.
3. Need for oxytocin augmentation, labor complications
4. Apgar scores at 1 and 5 minutes

Study groups

A total of 100 women with uncomplicated post term pregnancies, single live cephalic presentation with bishop's score <5 were included in the study and were

equally randomized into two groups. Group A had membrane sweeping and stretching (MS). And group B had membrane sweeping and received single dose of 50 mcg misoprostol sublingually (MP).

All the women were outpatients and residing in the near vicinity of the hospital so that they would be able to report and get admitted immediately after going in labor. Each participant's details along with their hospital registration number was recorded and entered into the proforma design for the study. Each participant was informed about the nature of the study and written consent was taken. All patients recruited had early ultrasound dating of their pregnancy, which was correlated with the expected delivery date to exclude wrong dates.

Study Design

A randomized prospective comparative clinical study in a tertiary care teaching hospital.

Place of study

Department of Obstetrics and Gynecology, Government Doon Medical College, Dehradun

Duration of study: 1 July-31 December 2016

Drugs used in study: Misoprostol Tablet

Inclusion criteria

1. Women with 40-41 weeks of pregnancy
2. Singleton uncomplicated pregnancy with vertex presentation
3. Reactive NST and normal AFI (Normal modified BPP)
4. Bishop score ≤ 5

Exclusion criteria

1. Any high risk pregnancy. e.g. – twin pregnancy, previous cesarean or a uterine scar, fetal malpresentation, APH, PROM, medical disorders etc.
2. Non Reactive NST
3. CPD

RESULT

Total 100 post term women were recruited randomly and divided into two

groups. Bogroups were similar in mean age, parity and gestational age (Table-1).The latency period (duration between pre-induction cervical ripening measure to the start of labor) is significantly shorter in group B than group A with p-value 0.0336 (Table-2). Within 24 hours of latency period 82% of group B went into spontaneous labor whereas only 46% women in group A went into spontaneous labor which is statistically very significant(p value <0.05).Only 8% of women in group B had no effect of pre-induction ripening whereas 28% of women in group A didn't have any effect. Duration of labor was also significantly lesser in group B, 47.82% patients delivered within 12 hours of initiation of labor as compared to only 22.2% patients delivered in same period in the MS group (p value=0.036). Further, only 13 patients required augmentation in group B as compared to 28 patients in the MS group. There were no significant differences in mode of delivery in both groups. Neonatal outcomes were comparable in both the groups.

TABLE 1: Demographic characteristics of patients

| Characteristics | Group A (MS group) N=50 | Group B (MP group) N=50 | p-value |
|---------------------|-------------------------|-------------------------|---------|
| Mean age (in years) | 23.14 | 23.45 | 0.085 |
| Parity | | | |
| Nulliparous | 27 | 32 | |
| Multiparous | 23 | 18 | |
| Mean gestation age | 40.36 | 40.56 | |

TABLE 2: Comparison of latency period of the two pre-induction methods

| Latency period | Group A (MS group) N=50 | Group B (MP group) N=50 | p-value |
|------------------|-------------------------|-------------------------|---------|
| <6 | 1 (2%) | 6 (12%) | 0.0336 |
| 6-12 | 7 (14%) | 15 (30%) | |
| 12-18 | 8 (16%) | 10 (20%) | |
| 18-24 | 7(14%) | 10 (20%) | |
| 24-48 | 13 (26%) | 5 (10%) | |
| >48 or no effect | 14 (28%) | 4 (8%) | |

TABLE 3: Comparison of duration of labor in the study groups

| Duration of labor (hours) | Group A (MS group) N=36 | Group B (MP group) N=46 | p-value |
|---------------------------|-------------------------|-------------------------|---------|
| <6 | 4 (11.11%) | 6 (13.04%) | 0.036 |
| 6-12 | 8 (22.22%) | 22 (47.82%) | |
| >12 | 24 (66.66%) | 18 (39.13%) | |

TABLE 4: Comparison of events and outcomes of labour in the study groups

| Labour events | Group A (n=36) | Group B (n=46) | p-value |
|----------------------|----------------|----------------|-----------------------|
| Further augmentation | | | |
| Yes | 28 (77.8%) | 13 (28.3%) | P<.001 Highly sig. |
| No | 8 (22.2%) | 33 (71.7%) | |
| Mode of delivery | | | |
| Vaginal | 30 (83.3%) | 39 (84.8%) | P >0.05 |
| Caesarean | 6 (16.7%) | 7 (15.2%) | |

TABLE 5: Neonatal outcomes in the two study groups

| Outcome Factor | Group A | Group B |
|--------------------|---------|---------|
| Birth Weight | 2850 | 2830 |
| Apgar at 1 minute | 7.3 | 7.32 |
| Apgar at 5 minutes | 9.4 | 9.5 |

DISCUSSION

The intention of this study was to compare the efficacy of the two methods for induction of labor, evaluate their possible impact on the number of post term women requiring hospital admission for induction of labor and compare fetomaternal outcomes of the two methods. At baseline the two groups were similar with respect to age distribution, parity and number of days beyond 40 weeks gestation. Various studies on pre-induction cervical ripening have shown the benefits of membrane sweeping as opposed to no sweeping, of oral misoprostol as opposed to intravaginal misoprostol and of oral misoprostol as opposed to membrane sweeping. [8-12] However there were few studies on pre-induction cervical ripening in post-term pregnancies on outpatient door basis but we did not find any study that compared the membrane sweeping with sublingual misoprostol.

In our study we found the pre-induction cervical ripening with membrane sweeping and sublingual misoprostol in uncomplicated post-term pregnancies is a beneficial procedure before getting admitted the patient in terms of safety, shorter latency period and duration of labor, less need of augmentation of labor. Almost similar finding were found in two studies which were done on outdoor patient basis. A.O Adeniji and Akenda S.E did study oral misoprostol verses membrane sweeping for labour induction in post-term pregnancies. [12] Another randomised double blind placebo controlled study done by Ponmalar

J with pre-induction use of 25 mcg vaginal misoprostol after stretch and sweep in the outpatient setting decreased the intervention to delivery interval when compared with placebo. [13]

In our study we found that, within 18 hours of pre-induction cervical ripening procedure 62% patients in Group B reported in labor room with labor pain pains compared to 32% in Group A (membrane sweeping) with p-value <0.05 which is statistically very significant. The duration of labor is also significantly shorter in Group B. The need for further augmentation was also reduced with the misoprostol group as only 28.3% women required oxytocin augmentation as compared to 77.8% in the MS group. These findings were similar and comparable to the studies done by A.O.Adeniji and Javedkar. [12]

Neonatal outcomes were comparable in both the groups. No adverse effects of misoprostol like vomiting, diarrhoea or hyperstimulation were reported, possibly due to the single dose given.

CONCLUSION

This study showed that pre-induction cervical ripening with sublingual misoprostol along with sweeping and stretching in post-term pregnancy is more safer, effective method on an outpatient basis. It shortens the latency period, duration of labor, reduces need of augmentation of labor without compromising fetomaternal outcome. Although further assessment of the safety profile with larger studies will be needed

Declarations

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