

CAN TERM GESTATION BE INDUCED BY MISOPROSTOL ON OPD BASIS?

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ABSTRACT: Stripping of membranes is wide used as OPD procedure for preripening and induction of labour. This study was planned to assess whether or not low single dose of vaginal misoprostol (25 mcg.) can be added to stripping in OPD and what is going to be the impact on the end result of labour induction. The study was applied in Datta Sugar mill Charitable Hospital, Shirol, Dist. Kolhapur. A total of eighty patients were taken for the study. They were divided in 2 equal teams – Group A with solely stripping of membranes and Group B Stripping along with 25 mcg Misoprostol. Primary observations were delivery at intervals forty eight hours from the beginning of induction and route of delivery. Secondary observations were interval from induction to onset of labour (latency period), interval from begin of induction to delivery (duration of labour), want for oxytocin augmentation, labour complications, Apgar scores at one and five minutes. Both teams were similar at begin with respect to age, parity and between forty weeks and forty one weeks gestation. There was a considerably shorter induction to onset of labour interval within the B group. The period of labour was considerably shorter in B group. Overall, baby outcomes were similar and comparable within the 2 teams.

The study gave following results and conclusion –

The patients who received Stripping with vaginal 25mcg.Misoprostol showed

1. A shorter latency period,
2. Less need for oxytocin augmentation,
3. Shorter duration of labour in patients.

The two induction strategies were similar with respect to baby outcomes. each were found safe as OPD strategies, though any assessment of the security profile with larger studies are required. More patients felt positive about the intervention in B group than in A group.

KEYWORDS: Cervical ripening; Induction; Misoprostol

INTRODUCTION: In obstetrics clinicians are always worried about pregnancy crossing expected date of delivery and it becomes commonest indication for induction of labour¹⁻³. It is well known fact that continuation of pregnancy beyond due date increases the risk to the fetus ^{4,5} and to the mother ^{6,7}. Induction of labour is necessary in such cases in the hope of vaginal delivery, but the success of induction depends upon many factors. The cervix should be ripe and favorable for induction. Many methods and scores like Bishop scoring are in use to judge the favorability of

ORIGINAL ARTICLE

cervix which depends on consistency, compliance and configuration of the cervix⁸. Various medical surgical and combined methods of cervical ripening and induction are in practice.

Stripping of membranes from the lower segment of the uterus is the commonly used method of induction which does not require admission in hospital^{9,10}. The results of effectiveness of stripping do not agree with each other^{2,7,10}. There may be difference in method used for it. A Cochrane review says that use of stripping between 38 and 40 weeks has not got important benefit clinically¹⁰. It may be beneficial in women with post term pregnancies^{11,12}.

The methods of cervical ripening and labour induction require admission to hospital. The patients are apprehensive and many times prefer to wait for spontaneous labour pain against medical advice. There is a fear in their mind that if they get admitted without pains the story will end with Caesarean section. Any safe and effective intervention that also cut costs is therefore desirable. This study was planned to see the comparative efficacy and safety of the two outpatient techniques of single-dose 25 mcg vaginal misoprostol after stripping and only stripping of membranes on the outcome of labour induction and their effects on reducing the need for hospital admission for cervical ripening/ labour induction in uncomplicated post-term singleton pregnancies

MATERIALS AND METHODS: This study was planned to compare usefulness of Stripping of membranes versus Stripping followed by 25 mcg vaginal Misoprostol on outpatient basis for full term pregnancies who have crossed due date. Expected due date was calculated by Naegle's rule and confirmed by early ultrasound studies. The study was conducted between April 2009 and March 2010 at SDSSSK Charitable Trust Hospital, Shirol, Kolhapur, India. Informed consent was taken from each patient. The patients residing very near to the hospital only were selected to avoid further complications. Half of the patients were grouped in Group A and rest half in Group B randomly.

Inclusion criteria:

Single live post term 40 weeks to 41 weeks
Bishop's score < or = 5
Vertex presentation.

Exclusion Criteria:

Post-term pregnancies of 41 weeks and above
Twin pregnancies,
Previous caesarean section or a uterine scar,
Fetal malpresentation,
Non reactive NST,
Cephalopelvic disproportion,
Antepartum haemorrhage,
Premature rupture of the membranes and medical disorders.

Eighty patients, randomised to 40 in each group, were studied.

A group:

ORIGINAL ARTICLE

In this Group membranes were stripped in OPD.

B group:

Membranes were stripped like Group A followed by 25mcg Misoprostol tablet kept in posterior fornix. All patients were counseled and told categorically to keep a watch on fetal kick count and any pervaginal show or pain in abdomen. They were asked to get admitted immediately if they get such symptoms or feel any abnormality. All patients in both groups who did not go into spontaneous labour after 24 hours were advised to get admitted for further supervision in hospital.

Observations were noted as follows:

Delivery within 48 hours after the start of induction and route of delivery.

Time interval from the start of induction to onset of labour,

Time interval from the start of induction to delivery,

Need for oxytocin augmentation, labour complications,

Apgar scores at 1 and 5 minutes.

Data were entered and analysed. Mean (\pm standard deviation (SD)), independent *t*-test, Pearson's chi-square were determined as necessary.

RESULTS: A total of 80 patients (40 in each group) were recruited for the study. At baseline the two groups were similar with regard to mean age, parity and days beyond 40 weeks' gestation (Table 1). Table 2 shows that the latency period was significantly shorter in B group than in A group, with a mean of 14.25 hours as opposed to 33.83 hours in A group ($p=0.005$). Seventy per cent of the patients in B group went into labour spontaneously within the latency period of 18 hours, as opposed to only 20% in A group ($p<0.005$). One patient in B group and 12 in A group went beyond the 48 hours time limit and were categorised as 'failed induction', but subsequently had a vaginal delivery after oxytocin augmentation of labour.

Thirty six patients in B group and 24 in A group had a vaginal delivery (90.0% v. 85.0%, $p>0.05$), with 11 and 18 patients, respectively, requiring oxytocin augmentation ($p=0.023$). Of the caesarean sections 4 in B group v. 6 in A group, were necessitated by presumed fetal distress. (Table 3). The duration of labour was significantly shorter in B group, in which 75.0% of those who had a vaginal delivery achieved it within 9 hours, compared with 55.88% in A group ($p<0.05$). (Table 4).

Overall, neonatal outcomes were similar and comparable in the two groups, with more babies in B group (5/40) than in A group (4/40) having moderate asphyxia at the first minute after birth. However, this was statistically insignificant. NICU admission rates were similar for the two groups. On a preference scale, 45% of the women in A group felt positive about the intervention, compared with 75% of the women in B group who said that they would agree to use of the drug in another post-term pregnancy.

ORIGINAL ARTICLE

Table 1. Age and Parity distribution of study patients

Biodata	Stripping Group(N=40) A Group	Strip+Miso Group(N=40) B Group	p-value
Age in Years Mean+/-SD	24.98(+/-3.04)	25.45(+/_3.08)	0.495
Parity			
Nulliparous , n(%)	28(70.00%)	17(42.50%)	
Multiparous,n(%)	12(30.00%)	23(57.50%)	
Days beyond 40 weeks	3.65(+/-1.19)	4.07(+/-0.93)	0.838

Table 2. Comparison of induction methods with relation to latency period

Latency period(hours)	Stripping Group(N=40) A Group	Strip+ Miso Group(N=40) B Group	p-value
<6	1(2.5%)	10(25%)	
>6-12	3(7.5%)	10(25%)	
>12-18	4(10.0%)	8(20%)	
>18-24	7(17.5%)	8(20%)	
>24-48	13(32.5%)	3(7.5%)	
>48	12(30%)	1(2.5%)	<0.005

Table 3. Comparison of eventual outcome of labour

Labour events	Stripping Group(N=40) A Group	Strip+ Miso Group(N=40) B Group
Oxytocin augmentation		
Yes	18(45.0%)	11(27.5%)
No	22(55.0%)	29(72.5%)
Mode of delivery		
Vaginal	34(85.0%)	36(90.0%)
Caeserean	6(15.0%)	4(10.0%)

Table 4. Comparison of labour duration

Duration(Hours)	Stripping Group(N=34) A Group	Strip+ Miso Group(N=36) B Group	p-value
<6	4(11.76%)	1(2.78%)	
>6-9	15(44.12%)	26(72.22%)	
>9-12	10(29.41%)	5(13.89%)	
>12-15	5(14.71%)	4(11.11%)	<0.005

Table 5. Neonatal outcomes

Outcome factors	Stripping Group(N=40)		p-value
	A Group	B Group	
Birth Weight Gms+/-SD	2850(+/-354)	2833(+/-458)	>0.05
Apgar 1 minute Mean+/-SD	7.7(+/-1.0)	7.4(+/-0.7)	>0.05
Apgar 1 minute <7	4(10.0%)	5(12.5%)	>0.05
Apgar 5 minute Mean+/-SD	9.4(+/-0.6)	9.48(+/-0.5)	>0.05
Apgar 5 minute <7	Nil	Nil	

DISCUSSION: This study randomised 80 patients, with established gestations beyond 40 weeks but less than 41 weeks, into two groups receiving only Stripping of membranes or stripping with 25mcg.Misoprostol in posterior fornix of vagina on an outpatient basis. The intention of this study was to compare the efficacy of these two methods for induction of labour, evaluate their possible impact on the number of post-term women requiring hospital admission for induction of labour and compare fetomaternal safety profiles of the two methods. Various studies have shown benefits of Misoprostol as opposed to no stripping, ^{13,14} and of oral Misoprostol as opposed to intravaginal misoprostol ^{15,16}. Outpatient management of post-term pregnancies will reduce the financial and social burden on families. It will also allow women to go in labour at home and only come into hospital for delivery, which is more like the natural process of labour and liked by patients. At baseline the two groups were similar with regard to age distribution and number of days beyond 40 weeks' gestation. It has been argued that membrane stripping may be more effective in multiparous than nulliparous patients. This assumption has been disputed by de Miranda *et al.*¹³. Previous studies ^{3,16} have demonstrated that intravaginal misoprostol was more effective at improving cervical effacement and consistency than cervical os dilatation, and also that misoprostol was a better agent for initiating labour than the transcervical Foley catheter.

Our findings suggest that both 25 mcg Vaginal Misoprostol and Membrane stripping, administered on an outpatient basis, are safe and effective methods for inducing labour in uncomplicated post-term single pregnancies, provided patient resides in the near vicinity of hospital and able to report and get admitted immediately after going in labour. In this study Misoprostol had the advantages of a shorter latency period, less need for oxytocin augmentation in labour and shorter duration of labour. Within 18 hours of initiation of the induction at the clinic, 70.0% of the patients in Misoprostol group (28/40) reported back in labour, compared with 20.0% in Stripping only group (8/40). Misoprostol is a PGE1 analogue and undergoes rapid de-esterification to its active, free acid metabolites, its onset of action will be speedier than the local PG production via a cascade of synthetic processes that would be expected in Stripping.^{18,19} Studies on misoprostol have demonstrated less need for oxytocin augmentation than there was with Stripping, similar to our findings.¹⁹ This further enhances acceptability of Misoprostol, as women perceive their labour as more 'natural' with less intervention.

The proportions of vaginal deliveries were similar in the two groups, (85% v. 90%). When duration of labour was compared, 72.22% of Misoprostol group, but only 44.12% of the Stripping group achieved vaginal delivery within 9 hours of onset of labour. Neonatal outcomes in the two

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groups were similar. All admissions to the NICU in both groups were for observation only and the infants were discharged within 24 hours.

A major limitation of randomised trials like ours is that they are seldom large enough to study rare adverse effects. No harmful adverse effects of Membrane Stripping have been reported in previous studies.¹⁰ Reported adverse effects of misoprostol, such as vomiting, diarrhoea, tachysystole or hyperstimulation, were not recorded in this study, possibly because of the single low dose administered. However, 20% of all the patients (in Stripping group and stripping along with Misoprostol group) reported that the procedure was uncomfortable and/or painful, similar to earlier reports,^{15,20} and 6% had minimal spotting after the procedure, which subsequently subsided. No case of rupture of the membranes or antepartum haemorrhage was recorded.

CONCLUSION: This study showed a shorter latency period, less need for oxytocin augmentation and a shorter duration of labour in patients given single-dose vaginal Misoprostol 25 mcg, compared with Stripping of membranes on an outpatient basis. The two induction methods were similar with regard to neonatal outcomes and need for NICU admission, but differences in outcomes cannot be excluded owing to the small numbers studied. A larger sample study is planned with multicenter approach.

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Chart 1. Bar chart showing number of patients with relation to latency period

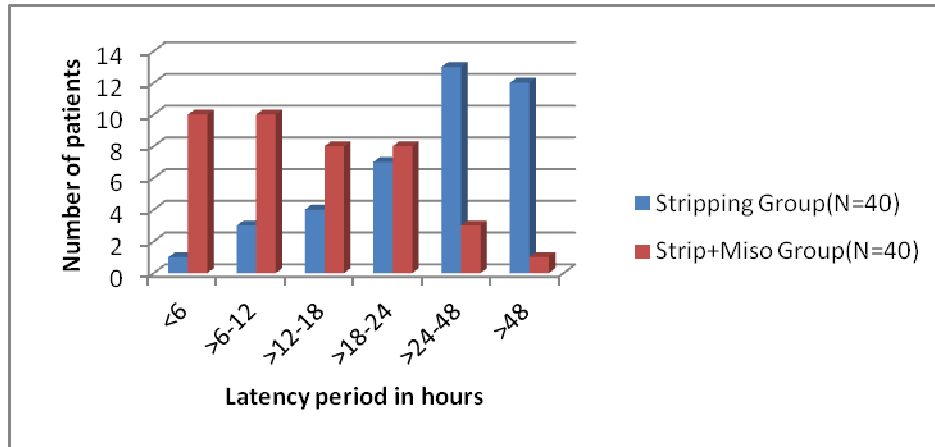


Chart 2. Bar Chart showing labour duration

