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Original Research Article.

Assessment of Efficacy of Misoprostol as an Inducing Agent: An Observational Study

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ABSTRACT

Background: Labor induction is one of the most frequent procedures in obstetrics. Several Meta analyses, systematic reviews and randomised controlled trials have assessed the safety and efficacy of misoprostol as a cervical ripening and inducing agent and have come out with varied opinions. Hence; the present study was undertaken for assessing the efficacy of misoprostol as an inducing agent.

Materials & Methods: A total of 30 women were enrolled in the present study. Only those subjects were enrolled who required induction of labour. Clinical examination of all the patients was carried out and detailed clinical history was obtained. This was followed by a thorough obstetric examination. All the subjects received misoprostol tablet 25µg every 4 hourly intravaginally upto a maximum of 5 doses. Intravenous Oxytocin was administered as and when required. Cases in which the subject failed to enter the active phase of labour after 24 hours of starting of induction were regarded as failure of induction.

Results: The most common indication of labour induction was post-dated pregnancy with 11 subjects (36.66%) in the misoprostol group being of post-dated pregnancy. The next most common indication for labor induction was Pregnancy induced hypertension. Fourteen women in the Misoprostol group delivered in less than 12 hours. Thus, the vaginal delivery rates within 12 hours were 66.67% in the Misoprostol group. The mean induction to delivery interval in the misoprostol group was 10.40 hours.

Conclusion: Misoprostol is an effective method of induction of labour and is a well-tolerated drug.

Key words: Induction, Misoprostol.

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INTRODUCTION

Labor induction is one of the most frequent procedures in obstetrics. Recently the incidence of labor induction has increased drastically. Improved antenatal healthcare facilities with early recognition of indications for labor induction are responsible for this increase.[1, 2]

Out of the various methods of labor induction prostaglandins hold a very important place. Labor induction was associated with high incidence of prolonged labor, instrumental delivery and caesarean section rates in the pre prostaglandin era. For these reasons extensive research has been directed towards the development of agents for efficient cervical ripening.[3]

The ultimate aim of induction is to achieve a vaginal delivery with a safe maternal and perinatal outcome. Since ancient times, various methods have been used to induce labour, e.g. stimulation of nipples, massage of uterus, use of tents, digital stretching of cervix etc. At present, the various methods of labour induction include administration of oxytocin, prostaglandins and their analogues, mifepristone or mechanical procedures (amniotomy, intracervical Foley's catheter, hygroscopic cervical dilators, digital stretching of cervix and sweeping of membranes). Several Meta analyses, systematic reviews and randomised controlled trials have assessed the safety and efficacy of misoprostol as a cervical ripening and inducing agent and have come out with varied opinions. Prior to the use of prostaglandins labor induction was associated with a very high failure rate. With the advent of prostaglandins, the management of patients requiring labor induction has changed drastically.[4-7] Hence; the present study was undertaken for assessing the efficacy of misoprostol as an inducing agent.

MATERIALS & METHODS

The present study was conducted with the aim of assessing the efficacy of misoprostol as an inducing agent. A total of 30 women were enrolled in the present study. Only those subjects were

enrolled who required induction of labour. Written consent was obtained from all the patients after explaining in detail the entire research protocol. Complete demographic details of all the patients were obtained. Clinical examination of all the patients was carried out and detailed clinical history was obtained. This was followed by a thorough obstetric examination. All the subjects received misoprostol tablet 25µg every 4 hourly intravaginally upto a maximum of 5 doses. Intravenous Oxytocin was administered as and when required. Cases in which the subject failed to enter the active phase of labour after 24 hours of starting of induction were regarded as failure of induction. All the results were recorded in Microsoft excel sheet and were analysed by SPSS software.

Table 1: Age distribution in the two groups

Age (Years) (n=30)	Misoprostol
<20	0
20-25	21
>25	9
Mean age (in years)	24.8

Table 2: Parity distribution in the two groups

Parity	Misoprostol	
	N	(%)
Primi	20	66.67
Multi	10	33.33
Total	30	100

Table 3: Indications for induction in the two groups

Indication	Misoprostol	
	N	(%)
Post dated	11	36.66
PIH	11	36.66
IUGR with Oligohydramnios	5	16.67
GDM	1	3.33
Rh –ve	1	3.33
APH	1	3.33

PIH: Pregnancy induced hypertension, IUGR: Intrauterine growth retardation, GDM: Gestational diabetes mellitus, APH: Antepartum haemorrhage

Table 4: Table showing vaginal delivery rates at 12 hours

Induction to vaginal delivery interval	Misoprostol
< 12 hours	14
>12 hours	7
Total	21

RESULTS

In the present study the mean age in the misoprostol group was 24.8 years. Maximum number of subjects was in the age group of 20-25 years. 21 women in the misoprostol group aged in between 20-25 years. 9 women were above 25 years. In the misoprostol group 20(66.67%) women were primi and 10(33.33%) were multi. The most common indication of labour induction was post-dated pregnancy with 11 subjects (36.66%) in the misoprostol group being of post-dated pregnancy. The next most common indication for labor induction was Pregnancy induced hypertension. Fourteen women in the Misoprostol group delivered in less than 12 hours. Thus, the vaginal delivery rates within 12 hours were 66.67% in the Misoprostol group. The mean induction to delivery interval in the misoprostol group was 10.40 hours.

DISCUSSION

The need for artificially stimulating the process of delivery has been known since long and the indications have only grown in the last century. Initially it was done to expel a dead fetus, then came the realization that in certain conditions like hypertensive disorders of pregnancy, fetal growth restriction, prolonged pregnancy etc. the induction of labor could be beneficial to both the mother as well as the baby. Though necessary in certain situations induction of labor is associated with increased incidence of operative vaginal delivery, caesarean birth, excessive uterine activity, abnormal fetal heart rate patterns, uterine rupture and maternal water intoxication.[7, 8]

The early methods of inducing labor involved mechanical manipulations, including douches, tents, bougies and catheters. Discovery of pharmacological myometrial stimulants and their use along with the mechanical methods characterised the latter half of the twentieth century. The use of prostaglandins for cervical ripening and labor induction has revolutionized the procedure of induction of labor.[8,9] Vaginal application of misoprostol has been reported in over 9000 women worldwide and seems to have safety profile similar to that of dinoprostone.[10] Hence; the present study was undertaken for assessing the efficacy of misoprostol as an inducing agent.

In the present study the mean age in the misoprostol group was 24.8 years. Maximum number of subjects was in the age group of 20-25 years. 21 women in the misoprostol group aged in between 20-25 years. 9 women were above 25 years. In the misoprostol group 20(66.67%) women were primi and 10(33.33%) were multi. A S Dongol et al to assess safety and effectiveness of Misoprostol for induction of labour. A total of 70 patients were included in this study. All patients received 50 µg of Misoprostol in the posterior fornix with maximum dose up to 3 doses at interval of 6 hours. Out of 70 patients, 21 (30%) required augmentation. Among 70 patients, 46 (65%) underwent normal delivery, 6 (8.6%) underwent instrumental delivery and 18 (25%) patients underwent caesarean section for various indications (p=0.00). Total 31 (44%) patients delivered within 10 hours of induction, 16 (22%) within 15 hours and 4 (4.7%) took more than 18 hours. Misoprostol is an effective cervical ripening agent with favorable outcome and comparable with other inducing agents.[11]

In the present study, the most common indication of labour induction was post-dated pregnancy with 11 subjects (36.66%) in the misoprostol group being of post-dated pregnancy. The next most common indication for labor induction was Pregnancy induced hypertension. Ambusaidi Q et al evaluated the effectiveness of misoprostol in the termination of first-trimester miscarriages. 200 patients received misoprostol and the rates of successful termination were measured. Patient satisfaction was assessed using a short questionnaire. Termination with misoprostol was successful in 61.38% of the subjects. Of the

remaining subjects requiring additional surgical evacuation (n = 112), 58.93% required evacuation due to failed termination with misoprostol and 65.18% underwent early evacuation (≤24 hours since their last misoprostol dose). The majority of patients experienced no side-effects due to misoprostol (89.66%). Pain was controlled with simple analgesics in 70.00% of the subjects. Misoprostol was a well-tolerated drug which reduced the rate of surgical evacuation among the study subjects.[12]

In the present study, fourteen women in the Misoprostol group delivered in less than 12 hours. Thus, the vaginal delivery rates within 12 hours were 66.67% in the Misoprostol group. The mean induction to delivery interval in the misoprostol group was 10.40 hours. Bolla D et al compared misoprostol vaginal insert (MVI) with misoprostol vaginal tablets (MVT) for induction of labor in term pregnancies. 200 consecutive women induced with 200-μg misoprostol 24-h vaginal insert (Misodel®) were compared with a historical control of 200 women induced with Misoprostol 25-μg vaginal tablets (Cytotec®) every 4-6 h. Main outcomes variables included induction-to-delivery interval, vaginal delivery within 24-h, incidence of tachysystole, mode of delivery, and neonatal outcome. A subanalysis in the MVI group was performed in order to identify predictive factors for tachysystole and vaginal delivery within 24 h. The time from induction to vaginal delivery was 1048 ± 814 min in the MVI group and 1510 ± 1043 min in the MVT group ($p < 0.001$). Bishop score was the only predictor for vaginal delivery within 24 h ($p < 0.001$) in MVI group. Caesarean delivery rate (27% vs. 20%) and vaginal-operative deliveries (15.5% vs. 15.5%) did not differ significantly between the two groups. Neonatal outcomes were similar in both groups. MVI achieves a more vaginal delivery rate within 24 h and Tachysystole events compared to MVT.[13]

CONCLUSION

From the above results, the authors concluded that Misoprostol is an effective method of induction of labour and is a well-tolerated drug. However; further studies are recommended.

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