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Original Research Paper

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COMPARATIVE STUDY OF ORAL MISOPROSTOL AND VAGINAL MISOPROSTOL IN THE INDUCTION OF LABOUR

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ABSTRACT

Introduction: Misoprostol has been in use for cervical priming since 1979 [1]. Even though there are many methods of induction of labour, misoprostol is the commonest medical agent used for induction of labour [2]. A comparative study of oral misoprostol and vaginal misoprostol was conducted at Kannur Medical College during a period of two years from 2016 to 2018, in the effectiveness of induction of labor

Objectives:

1. To compare the efficacy of misoprostol and oxytocin in the induction of labor
2. To compare the complications of oral misoprostol and vaginal misoprostol
3. To compare the induction-to-active phase of labor time
4. To compare the induction-to-delivery time
5. To compare the need for oxytocin augmentation
6. To compare the failure rate

Methods: A total number of cases selected for study purpose were 150 for a period of about 2 years from 22 November 2016 to 28 July 2018. Induction was done for various indications. Oral misoprostol group received 50 µg every four hours and vaginal insertion group received a 25 µg for every four hours. The duration between onset of induction and delivery was recorded in both groups. The onset of active phase of labour was also noted. Maternal and fetal complications also were noted separately. Labour was monitored by partogram and cesarean delivery were conducted in case of dysfunctional labour. Such cases were counted as failure of induction

Result : Failure of induction by misoprostol was less with oral misoprostol, 17.9% comparing to vaginal insertion which was 24.6%, with statistical significance ($P < 0.001$). Induction-to-delivery time was shorter for oral misoprostol group ($P < 0.001$). Induction-to-active labor was also shorter for oral misoprostol group ($P < 0.001$). Use of oxytocin augmentation in oral group was less in oral misoprostol group ($p < 0.001$). Complications, maternal, and fetal were similar in both groups (p 0.1) except uterine hyperstimulation which was more in vaginal group ($p < 0.01$). Failure rate was also less in oral misoprostol group. ($p < 0.001$)

Conclusion: Oral misoprostol is a safe and effective method of induction of labor which is far superior to vaginal insertion of misoprostol.

KEYWORDS : Induction of labour, misoprostol, oxytocin, arrest of descent, cesarean, dysfunctional labor, protracted descent, protracted cervical dilatation, arrest of cervical dilatation, arrest of descent

INTRODUCTION

Induction of labour is a common procedure adopted in the obstetric practice. It is defined as artificial method of initiation of uterine contraction and cervical changes, shortening and dilatation [3].

Induction is indicated when the benefits of delivery outweigh the risk of continuation of pregnancy in utero [3]. There are so many indications for inductions of labour. Common indications are post-dated pregnancy, preeclampsia, pre-labor rupture of membranes, uncontrolled gestational diabetes, oligohydramnios, non-reassuring non-stress test [2].

Various methods have been used for induction of labour. Common methods are stripping of membranes, artificial rupture of membranes, extra-amnionic saline infusion, transcervical balloons, and hygroscopic cervical dilators. Other effective methods include PGE1 (misoprostol) and PGE2 (dinoprostone). Misoprostol has been in use since the later part of 20th century [1]. The American College of Obstetricians and Gynecologists (2013b) [2] approved its use in induction of labour because of proven safety and efficacy. ACOG insists to have protocol pertaining to each institution as a part of excellent perinatal care [4]

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MATERIALS AND METHODS

The study period was 2 years from 22 November 2016 to 28 July 2018. The study was approved by the Ethical committee of Kannur Medical College. The total number of cases taken for study purpose were 150.

Inclusion Criteria

1. Term pregnancy
2. Vertex presentation
3. Fetus with average weight assessed clinically and ultrasound

Exclusion Criteria

1. Short women, height <147 cm
2. Cephalopelvic disproportion
3. Antepartum hemorrhage
4. Previous cesarean deliveries.
5. Gross fetal congenital anomalies

Pregnant ladies were admitted in the first stage of labour. Thorough evaluation was done. They were explained the method of induction. All the side effects and complications were explained to these ladies. Failure of induction and chance of cesarean also were informed to them. An informed consent for induction was obtained from theses pregnant ladies

Drugs Used

Misoprostol used was Misoprost-25 (each tablet has 25 µg

misoprostol) manufactured by Cipla India Ltd. The strength was 25 µg for vaginal insertion and 50 µg (2 tablets) for oral use

Methods

For study purpose two groups of 75 each were created. First group ladies were selected for oral misoprostol and second one for vaginal misoprostol. Bishop score was calculated for all cases. Scores below 6 were chosen for study purpose. Four indications were considered for induction; postdated pregnancy, premature rupture of membranes, pre-eclampsia, and gestational diabetes. Ladies in the first group, that is oral misoprostol group, were given 2 tablets of 25 µg and the given time was noted. A repeat Bishop score was assessed after 6 hours. When the Bishop Score attains or crossed 7, further dose had been withheld. Cervix assessment was done by examination per vaginam 4th hourly. Active labour is said to occur when cervix dilates to 4 cm [2]. Misoprostol 25 µg was inserted in the posterior fornix to the second group ladies. Insertion criterion is same as those for the first group, that is, Bishop Score less than 7. Here also cervix was assessed by vaginal examination 4th hourly. Labour of all the pregnant ladies including the first and second group were monitored by portogram. For effective labour induction regular rhythmic uterine contractions resulting into effacement and cervical dilatation is essential. 3 contractions in 10 min are considered adequate [2]. Fetuses were monitored continuously by electronic monitoring system, CTG Machine. Those who had inadequate uterine contractions, augmentation with oxytocin was done. Appearance of complications were closely watched. Complications observed were, tachysystole and fetal cardiac abnormalities. Tachysystole is defined as frequency of uterine contractions ± 6 in 10 minutes [4]. Abnormal fetal cardiac activities noted are, tachycardia, late deceleration and bradycardia. Fetal tachycardia is defined as heart rate >160 beats per minute [4]. Late deceleration is a pathological phenomenon where deceleration starts after the peak of uterine contraction. Tachysystole was controlled by terbutaline injection 250 µg intramuscular injection. The following factors decided failure of progression. First factor is protraction of cervical dilatation. Protraction of cervical dilatation is defined as failure to achieve cervical dilatation a rate of 1cm/ hour. Second factor is arrest of cervical dilatation which is defined as no cervical dilatation within 4 hours of examination. These two combined is popularly known as dysfunctional labour [4]. Third factor is protraction of descent. Here also definition is failure of presenting part to descend a rate of 1cm/hour. Fourth factor is arrest of descent which is defined as no descent of presenting part in 4 hours examination. The third and fourth combined is a sign of obstructed labour [4]. Cesarean delivery was conducted in cases of failed induction. Other indications for cesarean were hyperstimulation syndrome, thick meconium stained liquor and fetal bradycardia. Hyperstimulation syndrome is defined as tachysystole plus non-reassuring fetal heart rate (FHR) pattern. Frequency of uterine contractions ≥6 is known as tachysystole [2]. The non-reassuring pattern is a sign of fetal hypoxia and hypoxemia. It is diagnosed by the following abnormal features; tachycardia (FHR more than 180 a minute), bradycardia (FHR <110/ minute) reduced variability, late deceleration, and variable deceleration with shouldering. Failure of induction was diagnosed by the following factors.

Protracted cervical dilatation which required oxytocin induction and augmentation
Arrest of cervical dilatation
Protracted descent
Arrest of descent
Fetal bradycardia
Late deceleration
Thick meconium stained liquor.
Number of successful vaginal deliveries achieved in both groups were recorded for statistical analysis
Adequate postpartum care was rendered to both group ladies and they were discharged on the 3rd day of delivery

Statistical Analysis

Results were given as mean plus or minus SD. Statistical analysis was performed using the SPSS 16.0 statistical software package (SPSS Inc, Chicago, IL, USA). Time intervals were analyzed with Mann–Whitney U test, and other data were analyzed with the χ^2 test for qualitative and Student's t-test for quantitative variables. P value < 0.05 was considered significant.

RESULT

Pregnant ladies from each group were studied for the demographic variables. No statistically significant difference was found (Table 1).

TABLE 1. General variables

VARIABLES	ORAL MISOPROSTOL n=75	VAGINAL MISOPROSTOL n=75	P VALUE
Age	24.7 ± 4.5	23.4 ±4.1	0.1
Height	150 ± 6.3	151 ± 5.9	0.2
Parity	0.9± 1.2	0.72 ±1.12	0.1
GA	41.1 ±	40.1± 3.2	0.5
Initial Bishop Score	4.5 ±2.1	4.7 ±2.1	0.5
Labour Duration	20.6 ±18.1	13.5± 8.2	0.001

4 Indications of induction of labour were considered (Table 2).

TABLE 2. Indications of induction

INDICATIONS OF INDUCTION	ORAL MISOPROSTOL n=75	VAGINAL MISOPROSTOL n=75	P VALUE
Postdated pregnancy	55 (41.3%)	58 (43.5%)	0.1
Premature rupture of membranes	15 (11.3%)	12 (9%)	0.2
Preeclampsia	3 (2.3%)	4 (3%)	0.2
Gestational diabetes	2 (1.5)	1 (0.8%)	0.2

There was statistically significant difference in route of delivery, duration from induction-to-active phase and total duration of labor (Table 3) and (4).

TABLE 3. Mode of delivery

VARIABLES	ORAL MISOPROSTOL n=75 %	VAGINAL MISOPROSTOL n=75%	P VALUE
Vaginal delivery	62 (82.1)	57 (76.4)	0.001
Cesarean	38 (17.9)	43 (24.6)	0.001

TABLE 4. Vaginal Delivery Time

VARIABLES	ORAL MISOPROSTOL n=75	VAGINAL MISOPROSTOL n=7	P VALUE
Total delivery time	12.3 ± 7.2	17.4 ± 6.8	0.01
Induction to active phase time	5.9 ±1.2	8.6 ± 2.7	0.01

Complications were more or similar and statistically not significant except uterine hyperstimulation which was more with vaginal group which is statistically significant (p <0.01) Table (5). Need for oxytocin augmentation was also more in vaginal group

TABLE 5. Complications of induction

VARIABLES	ORAL MISOPROSTOL n=75 MEAN VALUE	VAGINAL MISOPROSTOL n=75 MEAN VALUE	P VALUE
No of oxytocin augmentation	26 (34%)	36 (48%)	0.001
Uterine tachysystole	1 %	1%	NS
Uterine hyperstimulation	1%	4%	0.01

Meconium stained liquor	3 (4%)	2 (3%)	0.12
Apgar score	8.2	7.9	0.12

There was a significant increase in the rate of cesarean in the second group (Table 3) ($P < 0.001$). The interval from induction-to-active phase (cervical dilatation ≥ 4 cm) was shorter in the first group (oral misoprostol group) ($P < 0.01$) which is significant. The total duration of delivery also decreased in oral misoprostol group ($P < 0.01$) which also is significant. (Table 4) There was no statistically significant difference in the fetal complications also. Which is assessed by APGAR (Table 5) In our study, the induction to active phase was 5.9 ±1.2 hours in oral misoprostol group and 8.6 ± 2.7 hours in vaginal misoprostol group ($p < 0.01$). Similarly, induction to delivery time was 12.3 ± 7.2 hours in oral misoprostol group and 17.4 ± 6.8 hours in the vaginal misoprostol group. ($p < 0.01$). (Table 4) Demographic variables were not statistically significant (Table 1)

DISCUSSION

Misoprostol is the mainstay of induction of labour though dinoprostone is used in some institutions [3]. Misoprostol was used as pessary, means insertion into the posterior fornix. Recently the trend is towards oral use of misoprostol. Present study is to highlight the advantage of oral misoprostol on vaginal insertion. Reviewing the literature there are studies for and against the advantage of misoprostol in inducing labour. Among so many three important studies are listed below. Masomeh et al [5] in their study points out the advantage of oral misoprostol. In their double-blind study, 180 postdated pregnancy were selected. They concluded that oral misoprostol is superior to vaginal misoprostol in terms of induction time, maternal and neonatal outcome in their analysis

Aqueela Ayaz et al [6] in their study, 80 cases were selected, out of which 44 cases were for oral group and 36 cases for vaginal group. They concluded that oral misoprostol has the advantage of effective induction of labour and delivery and they suggested a 50-µg dose. Shi-Yann Cheng, et al [7] in their study selected 207 cases. In the oral misoprostol group, vaginal delivery occurred within 12 hours (74.3%). On the other hand, in vaginal misoprostol group, only 27 ladies (25.5%) effected vaginal delivery within 12 hours ($p < 0.01$). Prameela et al [8] in their studies concluded that both oral and vaginal use of misoprostol were equally effective. Their sample size was only 104. There are studies which conclude that vaginal misoprostol is superior to oral misoprostol in inducing labour. A sample size of 310 was used for the study by Rozina Rasheed et al [9]. Mean induction to delivery time was shorter in the vaginal misoprostol group ($p < 0.010$). Zoqeen Akhtar et al [10] selected 100 cases for study purpose and equally divided into two groups. Mean labour delivery time was less in vaginal group ($p < 0.04$).

CONCLUSION

The following conclusions have been arrived by the present study

1. Misoprostol is an effective drug for induction of labour
2. Misoprostol is administered orally and vaginally
3. Present study supports the supremacy of oral route over vaginal route
4. Demographic variables are insignificant in two groups
5. Complications are more or less same in both groups
6. Further randomized control trials are necessary to conclude the supremacy of oral route over vaginal route

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CONFLICT OF INTEREST—Nil

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