Comparison of Intracervical Catheter Vs Misoprostol for Induction of Labour

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ABSTRACT

Objective: Comparison between intra cervical catheter vs Misoprostol for successful induction of labor. Study Design: Randomised-controlled trial Settings: Department of Gynecology and obstetrics, Allama Iqbal Memorial Teaching Hospital, Sialkot. Duration: July to December 2018. Methodology: The cases were chosen between the age of 20 to 40 years with gestation age of more than 37 weeks at presentation. The cases with Bishop score, equal or less than 4 were divided into two equal groups where the cases in group A were managed by intra vaginal Misoprostol (25 micro-gram tablet, every 4 hours for a maximum of 6 doses) and those in group B with intra cervical Foleys catheter and were assessed for outcomes like time for induction of delivery and uterine status. Results: In this study there were total 100 cases, 50 in each group. The mean age of the participants in group A and B was 28.17±5.37and 29.13±7.03 years (p=0.88). Mean gestation age at presentation was 38.78±1.3 vs 38.14±1.1 weeks with p= 0.95. There were 38% cases in group A and 44% in B that were primi gravida. Most common cause for labor induction was pre-eclampsia seen in 20% case each with p= 1.0 as shown in table I. Latent phase in group A and B was 8.4±4.9 vs 10.1±6.7 (p= 0.21) and mean time to delivery was 10.67±5.1 vs 13.9±9.67 hours with p= 0.01. Conclusion: Misoprostol is better than intra cervical catheter regarding mean time of delivery. Keywords: Misoprostol, Intra cervical catheter, Delivery, Induction

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INTRODUCTION

Labor is a complex combination of sequence of events and have been augmented in a number of chemical, physiological and structural changes in the body to deliver the baby safely. Induction of labor (IOL) is needed in certain condition and in the recent times, the rate of induction is increasing and according to a survey this prevalence is seen in 20% of the cases.¹

Induction of labor is needed when there is a risk to either fetus or the mother in case of continuing with spontaneous method. It is observed by the ripening of the cervix which has a linear association with spontaneous induction or augmentation required. There are number of scoring methods to assess this and BISHOP score is most commonly used and describes that labor induction is needed where the score is equal or less than 4.2-3

Unsuccessful labor induction leads to increased rate of cesarean sections that has its won morbidity outcomes. To avoid this the methods that potentiate the cervical ripening are needed and there are many with different degree of success or side effect profiles. The most commonly used in the past include misoprostol i.e. Prosta-glandin-E1 and trans-vaginal Foleys catheter. Misoprostol is a cheap agent, easily available and has shown relatively good results. It can be used even transrectally.⁴ On the other hand, Foleys catheter is a sterile tube that avoids exposure to non-sterile medication and also has the benefit to avoid drug exposures and different volumes of the fluid administration in the balloon tried and most common one is 50 ml.⁵⁻⁶

The data is variable regarding their efficacies in the past, for that this study was planned to carry out such study in our population.⁷⁻⁹

OBJECTIVE

Comparison between intra cervical catheter vs Misoprostol for successful induction of labor.

METHODOLOGY

Study Design: Randomized-Controlled Trial.

Settings: Department of Gynecology and obstetrics, Allama

Igbal Memorial Teaching Hospital, Sialkot,

Duration: Six months from July to December 2018.

Sample Technique: Non-Probability consecutive sampling. **Inclusion Criteria:** The cases were chosen between the age of 20 to 40 years with gestation age of more than 37 weeks at presentation (assessed on the basis of history and medical record of last menstrual period).

Exclusion Criteria: The cases with premature rupture of membrane (PROM), gestational diabetes mellitus (GDM), cervical dilatation of more than 2.5 cm, fever, poly hydromnios and history of previous C section were excluded from this study. **Methods:** The cases were further assessed if Bishop score was equal or less than 4. Then these cases were divided into two equal groups by simple lottery method. The cases in group A were managed by intra vaginal Misoprostol (25 micro-gram tablet, every 4 hours for a maximum of 6 doses) and those in group B with intra cervical Foleys catheter of appropriate size

and the attached balloon was filled with 50 ml of saline and was fixed at the inner part of thigh and cervical examination is done every 6 hours to check for spontaneous expulsion of balloon or after artificial rupture of membrane or augmentation of pregnancy with oxytocin injection in a dose of 2.5 to 5 IU in 500 ml fluid. These cases were assessed for outcomes like time for induction of delivery and uterine functionality i.e. hypertonic or atony.

Statistical Analysis: SPSS-version 23.0 was used for data analysis. Both the groups were compared by using chi square test for categorical data and independent sample t test for numerical data taking p value less than 0.05 as significant.

RESULTS

In this study there were total 100 cases, 50 in each group. The mean age of the participants in group A and B was 28.17 ± 5.37 and 29.13 ± 7.03 years (p=0.88). Mean gestation age at presentation was 38.78 ± 1.3 vs 38.14 ± 1.1 weeks with p=0.95. There were 38% cases in group A and 44% in B that were primi gravida. Most common cause for labor induction was preeclampsia seen in 20% case each with p= 1.0 as shown in table 1

Table 1: Comparison of both groups with study variables (n= 50 each)

| Variables | Group A | Group B | p value | |
|---------------------------------|------------|-------------|---------|--|
| Age (years) | 28.17±5.37 | 29.13± 7.03 | 0.88 | |
| Gestational age (weeks) | 38.78±1.3 | 38.14±1.1 | 0.95 | |
| Gravida | | | | |
| Primi-gravida | 19 (38%) | 22 (44%) | 0.74 | |
| Multi-gravida | 31 (62%) | 28 (56%) | 0.71 | |
| Indications for labor induction | | | | |
| Pre-eclampsia | 10 (20%) | 10 (20%) | 1.0 | |
| Oligo-hydramnios | 9 (18%) | 8 (16%) | 0.85 | |
| IUGR | 6 (12%) | 7 (14%) | 0.91 | |
| GDM | 2 (4%) | 1 (2%) | 0.33 | |

Latent phase in group A and B was 8.4±4.9 vs 10.1±6.7 (p= 0.21) and mean time to delivery was 10.67±5.1 vs 13.9±9.67 hours with p= 0.01 in group A and B respectively as in table 2.

Table 2: Comparison of both groups vs parturition (n= 50 each)

| Variable | Treatment group | | |
|--------------------|-----------------|-----------|------|
| variable | Group A | Group B | р |
| Latent phase | 8.4±4.9 | 10.1±6.7 | 0.21 |
| Time till delivery | 10.67±5.1 | 13.9±9.67 | 0.01 |

Table 3 reveals various uterine outcomes in both groups with p= 0.43.

Table 3: Comparison of both groups vs Outcome (n= 50 each)

| Outcome | Group A | Group B | p value |
|----------------|-----------|-----------|---------|
| Residue | 1 (2%) | 0 (0%) | |
| Atony | 2 (4%) | 3 (6%) | 0.43 |
| Hyper-tonicity | 1 (2%) | 0 (00%) | 0.45 |
| None | 46 (92%) | 47 (94%) | |
| Total | 50 (100%) | 50 (100%) | |

DISCUSSION

Labor is a complex process of certain changes that can put the mother as well as the fetus in distress, if its prolonged to a certain period of time and hence, induction is needed if risk vs benefit increases. There are number of causes that can lead to its need and include, eclampsia, premature rupture of membranes, oligo-hydromnios, fetal distress or IUGR and need early delivery of the fetus. 10-11

In the present study the latent phase in group A (Misoprostol) and B (Intra cervical Foleys catheter) was 8.4 ± 4.9 vs 10.1 ± 6.7 (p= 0.21) and mean time to delivery was 10.67 ± 5.1 vs 13.9 ± 9.67 hours with p= 0.01.

These results were comparable to the findings of the studies done in the past. According to a study done by Roudsari FV et al mean latent time was 8.5 ± 5.1 vs 10 ± 6.8 (p= > 0.01) and mean time of delivery was 11.08 ± 5.6 vs 13.6 ± 16.9 hours (p= < 0.05) in cases with Misoprostol vs Foleys catheter. Turthermore, uterine atony was seen in 6% vs 5% and hyper tonicity in 2% vs 0% in same groups respectively with p values > 0.01 each. These results were comparable to the present study where atony was seen in 4% vs 6% and hypertonisity in 2% vs none in misoprostol vs foleys catheter group with p value of 0.43.

In another similar randomized controlled trial from India by Noor N et al, hypertonisity of uterus was seen in 11.7% case with misoprostol and none with foleys catheter and none of the cases was seen with uterine rupture. Mean duration of delivery in misoprostol group was 14.03 ± 7.61 vs 18.40 ± 8.02 hours with foleys catheter with p values < 0.01.

In another study done by Shikher et al and Filho et al misoprostol was significantly better in terms of mean duration of delivery as compared to intra uterine catheter and the most common side effect noted was uterine hyper tonisity. 14-15 On the other hand, in a study done by Tuuli et al they found non-significant difference in both groups neither in terms of success of induction nor in side effect profiles. 16

CONCLUSION

Misoprostol is better than intra cervical catheter regarding mean time of delivery.

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