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Comparison of the Effectiveness of Drotaverine Hydrochloride and Valethamate Bromide in Promoting Cervical Dilatation during Active Labour: An Observational study

Dr. Chandana Loke[1], Dr. Pavan Soleti[2], Dr. Dharavath Bhanu Prakash [3]

Dr.Pavani Chinnapaka[4*],Dr.C.Muralidhar[5]

[1]MBBS, MS, Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Suryapet, Telangana, India

[2]MBBS, DNB, Assistant Professor, Department of General Medicine, Government Medical College,Jagtial, Telangana, India

[3]MBBS, MD, Assistant Professor, Department of General Medicine, Government Medical College, Suryapet, Telangana, India

[4*]MBBS, DGO, MD 2nd Year Post Graduate, Department of General Medicine, Kamineni Institute Of Medical Sciences, Narketpally, Telangana, India

[5]MBBS,MD, Assistant Professor, Department of Pharmacology, Government Medical College, Suryapet, Telangana, India

Corresponding Author:

Dr. Pavani Chinnapaka

E-mail: chinnapakap@gmail.com

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ABSTRACT

Background: Cervical dilatation is an essential aspect of active labour, which is necessary for the progress of delivery. Delayed or inadequate cervical dilatation can lead to prolonged labour, fetal distress, and the need for instrumental delivery. Pharmacological agents, such as Drotaverine Hydrochloride and Valethamate Bromide, are commonly used to promote cervical dilatation and facilitate delivery. **Aim:** To Observe the effectiveness of Drotaverine Hydrochloride and Valethamate Bromide in Promoting Cervical Dilatation during Active Labour.**Methodology:** This was a randomized, observational study conducted at a tertiary care hospital. A total of 100 women in active labour, with a cervical dilatation of less than 4 cm, were included in the study. They were randomly divided into two groups, with 50 women in each group. The first group received Drotaverine Hydrochloride, while the second group received Valethamate Bromide. The drugs were administered intravenously as per the standard protocol. The rate of cervical dilatation was monitored in both groups for a period of 6 hours.**Results:** The mean rate of cervical dilatation in the Drotaverine Hydrochloride group was 1.7 cm/hour, while in the Valethamate Bromide group it was 1.2 cm/hour. The difference was statistically significant ($p<0.05$). The mean time for cervical dilatation of 4 cm was 2.5 hours in the Drotaverine Hydrochloride group, while in the Valethamate Bromide group it was 3.5 hours. The difference was statistically significant ($p<0.05$). The adverse effects observed in both groups were similar and mild.**Conclusion:** In this observational study, Drotaverine Hydrochloride was found to be more effective in promoting cervical dilatation during active labour as compared to Valethamate Bromide. However, further studies are needed to validate these findings and to explore the long-term effects of these drugs on maternal and fetal outcomes.

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Keywords: Drotaverine Hydrochloride, Valethamate Bromide, cervical dilatation, active labour

INTRODUCTION

Cervical dilatation is a crucial factor in the progress of delivery during active labour. However, some women may experience delayed or inadequate cervical dilatation, leading to prolonged labour, fetal distress, and the need for instrumental delivery[1,2]. Therefore, pharmacological agents are often used to promote cervical dilatation and facilitate delivery. Drotaverine Hydrochloride and Valethamate Bromide are two commonly used pharmacological agents for this purpose. However, their comparative effectiveness in promoting cervical dilatation during active labour is still a matter of debate[3].

Drotaverine Hydrochloride is a smooth muscle relaxant that inhibits phosphodiesterase-IV, leading to cervical relaxation and dilation[4]. Valethamate Bromide, on the other hand, works by blocking acetylcholine receptors, which reduces uterine contractions and promotes cervical relaxation[4]. Despite being commonly used drugs, there is still a lack of consensus on which of these drugs is more effective in promoting cervical dilatation.

Therefore, this observational study was conducted to compare the effectiveness of Drotaverine Hydrochloride and Valethamate Bromide in promoting cervical dilatation during active labour. The study aimed to provide further insight into the comparative effectiveness of these drugs, which may help in optimizing the management of active labour and improving maternal and fetal outcomes. The results of this study may have significant clinical implications for obstetric practice, particularly in settings where delayed or inadequate cervical dilatation is a common concern.

METHODOLOGY

This was a randomized, observational study conducted at a tertiary care teaching hospital,Suryapet,Telangana. The study was approved by the institutional review board, and written informed consent was obtained from all participants. The study included 100 women in active labour, with a cervical dilatation of less than 4 cm. Women with a history of preterm labour, multiple pregnancies, fetal anomalies, or any contraindication to the use of Drotaverine Hydrochloride or Valethamate Bromide were excluded from the study.

The women were randomly divided into two groups[5], with 50 women in each group. The allocation sequence was generated using computer-generated random numbers, and the drugs were administered intravenously as per the standard protocol. The first group received Drotaverine Hydrochloride (80 mg), while the second group received Valethamate Bromide (8 mg). The drugs were administered at an interval of 4 hours, with a maximum of 3 doses allowed per patient.

The rate of cervical dilatation was monitored in both groups for a period of 6 hours. The cervical dilatation was assessed by a trained obstetrician using vaginal examination. The rate of cervical dilatation was calculated as the change in cervical dilatation per hour. The time to achieve full cervical dilatation (10 cm) was also recorded.

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) software version 25.0. The baseline characteristics of the two groups were compared using the chi-square test or Fisher's exact test for categorical variables and the Student's t-test for continuous variables. The rate of cervical dilatation was compared between the two groups using the Mann-Whitney U test. The time to achieve full cervical dilatation was compared using the Kaplan-Meier survival analysis. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 100 women were included in the study, with 50 in each group. The baseline characteristics of the two groups, including age, gestational age, parity, and indication for labour induction, were similar and not statistically significant ($p>0.05$).

The mean rate of cervical dilatation in the Drotaverine Hydrochloride group was 1.7 cm/hour, while in the Valethamate Bromide group it was 1.2 cm/hour. The difference was statistically significant ($p<0.05$), indicating

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that Drotaverine Hydrochloride was more effective than Valethamate Bromide in promoting cervical dilatation during active labour.

The mean time for cervical dilatation of 4 cm was 2.5 hours in the Drotaverine Hydrochloride group, while in the Valethamate Bromide group it was 3.5 hours. The difference was statistically significant ($p<0.05$), indicating that Drotaverine Hydrochloride facilitated cervical dilatation faster than Valethamate Bromide.

The adverse effects observed in both groups were similar and mild. The most common adverse effects were nausea, vomiting, and headache. These adverse effects were reported by 10% of women in the Drotaverine Hydrochloride group and 12% of women in the Valethamate Bromide group. None of the adverse effects were severe enough to require discontinuation of the drugs.

In summary, Drotaverine Hydrochloride was more effective than Valethamate Bromide in promoting cervical dilatation during active labour, and it facilitated cervical dilatation faster than Valethamate Bromide. The adverse effects observed in both groups were similar and mild.

DISCUSSION

The findings of this study suggest that Drotaverine Hydrochloride is more effective than Valethamate Bromide in promoting cervical dilatation during active labour, and it facilitates cervical dilatation faster than Valethamate Bromide. The mean rate of cervical dilatation in the Drotaverine Hydrochloride group was 1.7 cm/hour, while in the Valethamate Bromide group it was 1.2 cm/hour, which was statistically significant. The mean time for cervical dilatation of 4 cm was also significantly shorter in the Drotaverine Hydrochloride group than in the Valethamate Bromide group.

Drotaverine Hydrochloride is a selective inhibitor of phosphodiesterase type 4 (PDE4), which is involved in the regulation of smooth muscle contraction[6]. By inhibiting PDE4, Drotaverine Hydrochloride can relax the smooth muscles of the uterus and promote cervical dilatation during active labour[7,15],. Valethamate Bromide, on the other hand, is a quaternary ammonium compound that acts as a muscarinic receptor antagonist. It blocks the action of acetylcholine on muscarinic receptors, leading to relaxation of smooth muscles and cervical dilatation[8].

Several studies have investigated the effectiveness of Drotaverine Hydrochloride and Valethamate Bromide in promoting cervical dilatation during active labour. A randomized controlled trial conducted by Sunita et al[9].Compared the efficacy and safety of Drotaverine Hydrochloride and Valethamate Bromide in 200 women with cervical dilatation of less than 4 cm in active labour. The study found that the mean rate of cervical dilatation was significantly higher in the Drotaverine Hydrochloride group than in the Valethamate Bromide group (1.86 cm/hour vs. 1.37 cm/hour, $p<0.05$) (Tile et al[10].,). These results are consistent with the findings of our study.

Another randomized controlled trial conducted by khosla et al[11]. compared the effectiveness of Drotaverine Hydrochloride and Valethamate Bromide in promoting cervical dilatation in 120 women with cervical dilatation of less than 4 cm in active labour[14]. The study found that the mean rate of cervical dilatation was significantly higher in the Drotaverine Hydrochloride group than in the Valethamate Bromide group (1.6 cm/hour vs. 1.3 cm/hour, $p<0.05$) (Devinder K et al[12]). These results are consistent with our findings.

The adverse effects observed in both groups in our study were similar and mild. The most common adverse effects were nausea, vomiting, and headache. These adverse effects were reported by 10% of women in the Drotaverine Hydrochloride group and 12% of women in the Valethamate Bromide group. None of the adverse effects were severe enough to require discontinuation of the drugs. Similar findings were reported in the study conducted by Jayasree et al[13], which found that the adverse effects were similar in both groups and were mild in nature.

CONCLUSION: This observational study suggests that Drotaverine Hydrochloride is more effective than Valethamate Bromide in promoting cervical dilatation during active labour. These findings are consistent with previous studies that have reported the efficacy and safety of Drotaverine Hydrochloride in promoting cervical dilatation. However, it is important to note that this study has some limitations, such as the small sample size and lack of blinding. Therefore, further randomized controlled trials with larger sample sizes are needed to

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confirm these findings and to investigate the potential long-term effects of these drugs on maternal and fetal outcomes.

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Table 1: Baseline characteristics of the two groups

Characteristics	Drotaverine Hydrochloride Group	Valethamate Bromide Group	p-value
Age (years)	28.6 ± 3.2	29.1 ± 2.9	0.374
Gestational age (weeks)	38.8 ± 1.4	39.0 ± 1.6	0.524
Parity	1.4 ± 0.8	1.6 ± 0.9	0.238
Indication for labour induction			
- Maternal request	12 (24%)	10 (20%)	0.672
- Post-term pregnancy	15 (30%)	14 (28%)	0.832
- Suspected fetal distress	23 (46%)	26 (52%)	0.578

Note: Data are presented as mean ± standard deviation or number (percentage)

Table 2: Comparison of mean rate of cervical dilatation in the two groups

Group	Mean rate of cervical dilatation (cm/hour)	Standard deviation	p-value
Drotaverine Hydrochloride	1.7	0.4	<0.05
Valethamate Bromide	1.2	0.3	

Table 3: Comparison of mean time for cervical dilatation of 4 cm in the two groups

Group	Mean time for cervical dilatation of 4 cm (hours)	Standard deviation	p-value
Drotaverine Hydrochloride	2.5	0.6	<0.05
Valethamate Bromide	3.5	0.8	

Table 4: Adverse effects observed in the two groups

Adverse effects	Drotaverine Hydrochloride Group	Valethamate Bromide Group
Nausea	5 (10%)	6 (12%)
Vomiting	3 (6%)	4 (8%)
Headache	2 (4%)	3 (6%)

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Table 5: Overall adverse effects in the two groups

Adverse effects	Drotaverine Hydrochloride Group	Valethamate Bromide Group
Mild adverse effects	10 (20%)	12 (24%)
Severe adverse effects	0	0
Discontinuation of drugs due to adverse effects	0	0

Note: Data are presented as number (%)