In Search of Efficacy of Valethamate Bromide, a Cervical Dilator

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ABSTRACT
Background: Labour is a normal physiological process, progress of which depends upon the strength and frequency of uterine contractions and simultaneous active cervical dilatation. But sometimes active cervical dilatation lags behind even though there is presence of uterine contraction and causes pain abdomen, prolongation of labour which can hamper both maternal and foetal health. Hence comes the need to use the cervical dilators to encourage the cervical dilatation to compete with the frequent uterine contractions and facilitates the labour process. Valethamate Bromide (VB) belongs to those groups of drugs which can be used as a cervical dilator in need. Now a day, the use of VB has become very less in comparison with other cervical dilators and reason is not clearly established yet.

Aim & Objectives:
1. To compare the safety of VB in comparison to Drotaverine Hydrochloride
2. To compare the efficacy of VB with Hyoscine Butylebromide and
3. To study the actions of Valethamate Bromide upon duration of labour.

Methods/Study Design: It was an interventional, hospital based study done in MMC&H, India. After taking necessary permissions for the study, total 450 primi gravida patients without any obstetrical abnormality and contraindications to the drugs were selected randomly for six months. Three equal (150 each) groups were formed to satisfy each objective separately. First two groups were divided into three (50 each) and rest into two (75 each) equal sub-groups. All of the drugs were given intramuscularly only in first stage of labour following the prescribed doses. Necessary clinical evaluations were done at a regular interval and collected data were analyzed with SPSS software.

Results/Findings: In first group, Drotaverine HCl has proved to be quicker cervical dilator than Valethamate Bromide; but produced cervical lacerations in considerable number of patients (12.5% unilateral, 19% bilateral). In second group, sub-groups were given Valethamate Bromide, Hyoscine Butylbromide, and distilled water (placebo) respectively. Average rate of cervical dilatations were (2.05±0.58)cm/hr, (1.79±0.64)cm/hr and (1.12±0.14)cm/hr & Average duration of labour was 5 hours, 6.7 hours and 9.5 hours respectively. In remaining study group Valethamate Bromide significantly reduced both the first stage (p<0.01) and second stage (p<0.01) of labour in respect to the group got placebo.

Study Limitations: It was single handed study done on small population and many clinical correlations were overlooked to focus the aims only.

Conclusion: Leaving the contraindications in normal pregnancy with no abnormal obstetric problems the Valethamate Bromide can be used to achieve safe, accelerated delivery with least complications

Keywords: Labour, Cervical dilators, Valethamate Bromide, Hyoscine Butylbromide, Drotaverine Hydrochloride
IN SEARCH OF EFFICACY OF VALETHAMATE BROMIDE, A CERVICAL DILATOR

Background

Labour is a normal physiological process of expulsion of foetus and placenta from mothers’ womb. Progress of labour depends upon the strength and frequency of uterine contractions to force the foetus towards outside where simultaneous active cervical dilatation makes the way for it. This is controlled by nature and sequential hormonal interplay effective both on uterus and cervix. But sometimes active cervical dilatation lags behind even though there is presence of uterine contraction and causes pain abdomen, prolongation of labour which can hamper both maternal and foetal health even lead to mortality. Here comes the need to use the cervical dilators from external sources to encourage the cervical dilatation to compete with the frequent uterine contractions and facilitates the labour process.

There are many procedures to dilate cervix with external resources which included medications which intern includes various kind of drugs. As days progress, the choice of drugs in cervical dilation is being changed. Daily practices say that the choice also varies from physician to physicians.

Valethamate Bromide (VB) is chemically Diethyl(methyl)(2-(3-methyl-2-phenylvaleryloxy)ethyl)ammonium bromide with C_{19}H_{32}NO_{2}Br as molecular formula, 386.37 molecular weight and belongs to those groups of drugs which can be used as a cervical dilator in need. Now a day, the use of VB has become very less in comparison with other cervical dilators and reason is not clearly established yet.

Aim & Objectives

The study was aimed mainly to answer a definite question:

Why Valethamate Bromide is being off market now a day? And to find the answer this study was carried out with following objectives:

4. To compare the safety of VB in comparison to Drotaverine Hydrochloride
5. To compare the efficacy of VB with Hyoscine Butylebromide and
6. To study the actions of Valethamate Bromide upon duration of labour.
Methods/Study Design

Three equal (150 each) groups were formed to satisfy each objective separately. First two groups were divided into three (50 each) and rest into two (75 each) equal sub-groups. All of the drugs were given intramuscularly only in first stage of labour following the prescribed doses. Necessary clinical evaluations were done at a regular interval and collected data were analyzed with SPSS software.

- **Study design:** It was a interventional, hospital based, descriptive study
- **Study area:** Dept. of Gynaecology and Obstetrics, Midnapore Medical College and Hospital, Midnapore, India.
- **Study period:** 6 months
- **Study population:** 450 primi gravida patients were randomly selected for the study throughout the six months period of study.
- **Exclusion criteria:** Patients with serious illness, obstetrical abnormality, contraindication to the drug VB or associated diseases were not allowed to be a part of the study.

**Tools:**

1. Informed consent form
2. Injection Valethamate Bromide, Drotaverine HCl, Hyoscine Butylebromide samples, placebo injections, disposable syringes with needles.
4. Computer with statistical software

**Methodology**

Ethical Safeguard: Necessary permission from Institutional Ethical Committee was taken as ethical committee clearance. All the participants were taken from Antenatal Ward of Midnapore Medical College and Hospital. They were requested to volunteer for the study only after filling up and signing the detailed informed consent form which was written in their own local language i.e. Bengali. Illiterate participants were requested to come along with a literate family member or friend to do the job on behalf of them.

Sample distribution: Total of 450 patients was blindly divided into three equal parts with 150 patients in each and each part was used to satisfy single aim. First two groups were again divided into three equal parts composed of 50 in each and last group was divided into two equal parts with 75 patients in each. In very first group, patients received intramuscular inj. VB, Drotavarine HCl and placebo accordingly in three sub-groups. Second group patients received intramuscular VB, Hyoscine Butylebromide and placebo accordingly in three groups. And the rest group
received intramuscular VB and placebo accordingly in two sub groups. All drugs were given in perfect doses according to pharmacology. The details are given in a graphical format in figure 1.

Data compilation/collection: All necessary data were collected at proper time after an injection were applied and stored in softcopy format in computer with a back up.

Statistical analysis: Variable data were put into statistical software and analysed with sincerity.

Report Writing: With all data and statistical values in hand report was written in scientific way with wide range of information for reader in a short space and was submitted to authority concern.

Results/Findings

Figure 1: Showing the distribution of study population and results in single graph
In first group, Drotaverine HCl has proved to be quicker cervical dilator than Valethamate Bromide; but produced cervical lacerations in considerable number of patients (12.5% unilateral, 19% bilateral). In second group, sub-groups were given Valethamate Bromide, Hyoscine Butylbromide, and distilled water (placebo) respectively. Average rate of cervical dilatations were (2.05±0.58)cm/hr, (1.79±0.64)cm/hr and (1.12±0.14)cm/hr & Average duration of labour was 5 hours, 6.7 hours and 9.5 hours respectively. In remaining study group Valethamate Bromide significantly reduced both the first stage (p<0.01) and second stage (p<0.01) of labour in respect to the group got placebo.

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Leaving the contraindications in normal pregnancy with no abnormal obstetric problems the Valethamate Bromide can be used to achieve safe, accelerated delivery with least complications.

References