# A STUDY OF THE EFFECTS OF DROTAVERINE HYDROCHLORIDE AND HYOSCINE BUTYLBROMIDE IN THE ACCELERATION OF THE FIRST STAGE OF LABOUR IN PRIMIGRAVIDAE AT SMIMS

*Shwetha B. R[1], Saraswathi Subramanian[2], Prashant V. Solanke[3]*

*[1]Assistant Professor, Department of Obstetrics & Gynaecology, Sree Mookambika Institute of Medical Sciences.*
*[2]Professor, Department of Obstetrics & Gynaecology, Sree Mookambika Institute of Medical Sciences.*
*[3]Professor, Department of Community Medicine, Sree Mookambika Institute of Medical Sciences.*

**ABSTRACT**

**BACKGROUND**

With regard to normal labour, many eminent obstetricians have aptly remarked that of all the journeys the most dangerous is the very first one we make through the last ten centimetres of the birth canal. Hence, it is imperative that this short but crucial process is made safest for the baby. The role of a good obstetrician is to convert an abnormal situation where the events are not happening to one in which order is regained. Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the 1st stage of labour are always accepted by the obstetricians and patients.

**OBJECTIVES**

To compare the effect of Inj. Buscopan IV and Inj. Drotaverine & to find out which of the above drugs is more effective in shortening the labour.

**METHODOLOGY**

This study was undertaken at Sree Mookambika Institute of Medical Sciences from June 2015 to December 2015. The sample size was calculated using the formula sample size $n=2Z_1^2S^2/d^{2.}$, sample size required is 29. We have taken 50 sample sizes per group. This is a cross-sectional study. Inclusion criteria was primigravidae with full term gestation with vertex presentation in active labour.

**RESULTS**

The mean duration of 1st stage (active phase) of labour in group D was 118.04 mins., that of group H 129.74 mins. and of group C 185.38 mins. The mean duration of 2nd stage of labour in group D was 23.20 mins., that of group H 25.38 mins. and of group C 23.97 mins. The mean duration of 3rd stage of labour in group D was 11.44 mins., that of group H 14.02 mins. and of group C 15.16 mins. Rate of cervical dilatation is significantly more in Group D when compared to Group C (3.147 mins. vs. 1.97 mins.) ($p<0.001$). The rate of cervical dilatation is significantly more in Group H when compared to Group C (2.78 mins. vs. 1.97 mins.) ($p<0.001$). Rate of cervical dilatation was also significantly more in Group D when compared to Group H (3.147 mins. vs. 2.78 mins.) ($p<0.001$). Frequency of usage of higher number of doses is significantly more in Group D compared to Group H with $p<0.001$. There was no significant difference in the Apgar score at 1 min. and 5 mins., birth weight and NICU admissions among the three groups.

**CONCLUSION**

There is a distinct advantage in using drotaverine hydrochloride as an antispasmodic of choice for effectively shortening the first stage of labour. It re-establishes the pivotal role of drotaverine hydrochloride in the acceleration of the first stage of labour. It is also reassuring that neither of the drugs used were associated with any untoward maternal or foetal effects while accelerating the first stage of labour.

**KEYWORDS**

Drotaverine hydrochloride, Labour, Buscopan, Cervical dilatation.

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*Corresponding Author:*
*Dr. Prashant V. Solanke,*
*Professor, Department of Community Medicine,*
*Sree Mookambika Institute of Medical Sciences,*
*Kulasekharam, Kanyakumari, Tamilnadu.*
*E-mail: drprashantsolanke@rediffmail.com*
*DOI: 10.18410/jebmh/2016/267*

**INTRODUCTION:** With regard to normal labour, many eminent obstetricians have aptly remarked that of all the journeys the most dangerous is the very first one we make through the last ten centimetres of the birth canal. Hence, it is imperative that this short but crucial process is made safest for the baby.

The course of events in normal labour is that the uterus contracts, the cervix dilates and the foetus assumes a proper

position to pass through the birth canal with relative ease. The role of a good obstetrician is to convert an abnormal situation where the events are not happening to one in which order is regained.

Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the 1st stage of labour are always accepted by the obstetricians and patients.[1]

The present study was conducted to find whether hyoscine butylbromide shortens the first stage of labour more efficiently than drotaverine.

**AIMS AND OBJECTIVES:** The present study has been undertaken with the following objectives:

1. To compare the effect of Inj. Buscopan IV and Inj. drotaverine IV on.
   a) Duration of active phase of first stage of labour.
   b) Rate of cervical dilatation.
   c) Mode of delivery.
   d) Total duration of labour.
2. To find out which of the above drugs is more effective in shortening the labour?

**METHODOLOGY:** This study was undertaken at Sree Mookambika Institute of Medical Sciences from June 2015 to December 2015. The sample size was calculated using the formula

**Sample Size:** $n=2Z_1^2S^2/d^2$

$S=S_1+S_2/2$

$S_1=1.14^{(2)}$

$S_2=1.16^{(2)}$

Sample size required is 29. We have taken 50 sample sizes per group.

Total number of cases in this study was 150 primigravidae. This is a cross-sectional study. Women with term gestation, in active labour were chosen by simple randomization for the administration of drugs and written informed consent for the same was taken.

**The cases were divided into 3 groups:**

**Group A:** Consisted of 50 women who were given none of the cervical dilatation drugs i.e. control group.

**Group B:** Consisted of 50 women who were given Inj. drotaverine IV during labour at an interval of 30 mins. up to a maximum of 3 injections.

**Group C:** Consisted of 50 women who were given Inj. hyoscine (Buscopan) IV at an interval of 1 hour up to a maximum of 3 doses.

**Inclusion Criteria:** Primigravidae with full term gestation with vertex presentation in active labour.

**Exclusion Criteria:**

- Preterm labour.
- Absence of membranes.
- Abnormal presentation.
- Antepartum haemorrhage.
- Cephalopelvic disproportion.
- Multifoetal gestation.
- Intrauterine death of the foetus.
- H/o cervical encerclage.

Sampling technique used was convenient sampling.

**Procedure of Study: On entry into the study:**

- History was taken.
- General physical examination.
- Systemic examination.
- Per abdomen examination and,
- Per vaginal examination were done and drugs were given according to the group to which the patient belonged.
- Labour was monitored clinically and plotted on partogram.
- Per vaginal examination was done before giving each dose of the drug or earlier if:
  - Rupture of membranes occurred.
  - Patient started bearing down.
  - Significant changes in foetal heart sounds were found.
  - Meconium stained liquor was observed.

Following parameters were recorded in every patient.

1. Duration of active phase (1st stage) of labour.
2. Rate of cervical dilatation.
3. Duration of 2nd stage.
4. Mode of delivery.
5. Injection to delivery interval.
6. Duration of 3rd stage.
7. 3rd stage complications.
8. Neonatal condition at birth.

- Data was entered in Microsoft excel 2013.
- Data was analysed by SPSS trail version 20.
- Statistical test used are mean, Standard deviation, student t test & ANOVA to find the significance of study parameters.
- Institutional ethical committee clearance obtained prior to study.

**RESULTS:** The mean duration of 1st stage (active phase) of labour in group D was 118.04 mins., that of group H 129.74 mins. and of group C 185.38 mins.

The mean duration of 2nd stage of labour in group D was 23.20 mins., that of group H 25.38 mins. and of group C 23.97 mins.

The mean duration of 3rd stage of labour in group D was 11.44 mins., that of group H 14.02 mins. and of group C 15.16 mins.

Rate of cervical dilatation is significantly more in group D when compared to group C (3.147 mins. vs. 1.97 mins.) ($p<0.001$).

The rate of cervical dilatation is significantly more in group H when compared to group C (2.78 mins. vs. 1.97 mins.) ($p<0.001$).

Rate of cervical dilatation was also significantly more in group D when compared to group H (3.147 mins. vs. 2.78 mins.) ($p<0.001$).

Frequency of usage of higher number of doses is significantly more in group D compared to group H with $p<0.001$.

There was no significant difference in the Apgar score at 1 min. and 5 mins., birth weight and NICU admissions among the three groups.

| | Group C vs. Group D | Group C vs. Group H | Group D vs. Group H |
|---|---|---|---|
| **Difference** | | | |
| Duration of 1st stage (active phase) of labour (min.) | 67.34 | 65.34 | -11.74 |
| Duration of 2nd stage of labour (min.) | 0.78 | -1.41 | -2.18 |
| Duration of 3rd stage of labour (min.) | 3.71 | 1.14 | -2.57 |
| **p value** | | | |
| Duration of 1st stage (active phase) of labour (min.) | <0.001 | <0.001 | 0.013 |
| Duration of 2nd stage of labour (min.) | 0.707 | 0.322 | 0.068 |
| Duration of 3rd stage of labour (min.) | <0.001 | 0.443 | 0.019 |

***Table 1: Comparison of 1st stage (active phase) of labour, Duration of 2nd stage and 3rd stage of labour between groups***

| | Rate of Cervical Dilatation | |
|---|---|---|
| | **Mean** | **SD** |
| Group C | 1.97 | 0.28 |
| Group D | 3.14 | 0.51 |
| Group H | 2.78 | 0.54 |
| **Comparison** | **Difference** | **p value** |
| Group C vs. Group D | 1.17 | <0.001** |
| Group C vs. Group H | 0.81 | <0.001** |
| Group D vs. Group H | 0.36 | <0.001** |

***Table 2: Comparison of rate of cervical dilatation***

| No. of doses | Group D (n=50) | Group H (n=50) |
|---|---|---|
| 1 | 0 | 18(36.0%) |
| 2 | 2(4.0%) | 28(56.0%) |
| 3 | 48(96.0%) | 4(8.0%) |

***Table 3: Comparison of number of doses***

| Foetal outcome | Group C (n=50) | Group D (n=50) | Group H (n=50) | p value |
|---|---|---|---|---|
| **Apgar score at 1 min.** | | | | |
| Score <7.0 | 3(6.0%) | 4(8.0%) | 3(6.0%) | 1.000 |
| Score >7.0 | 47(94.0%) | 46(92.0%) | 47(94.0%) | |
| **Apgar score at 5 min.** | | | | |
| Score <7.0 | 1(2.0%) | 2(4.0%) | 1(2.0%) | 1.000 |
| Score >7.0 | 49(98.0%) | 48(96.0%) | 49(98.0%) | |
| **Birth weight** | | | | |
| <2.5 kg | 0 | 2(4.0%) | 1(2.0%) | 0.773 |
| >2.5 kg | 50(100.0%) | 48(96.0%) | 49(98.0%) | |
| **NICU admission** | | | | |
| Yes | 1(2.0%) | 2(4.0%) | 2(4.0%) | 1.000 |
| No | 49(98.0%) | 48(96.0%) | 48(96.0%) | |

***Table 4: Comparison of foetal outcome between three groups***

**DISCUSSION:** Cervical ripening, expressed as a remodelling of the cervical connective tissue has been proved to be necessary for an uncomplicated vaginal delivery.[3]

Rigidity of the cervix, as a cause for poor progress was often cited by obstetricians previously. Cervical dystocia is still acknowledged as a cause for non-progress of labour and non-achievement of vaginal delivery. Available biochemical evidence also suggest that the cervix could obstruct labour by a sustained spasm due to insufficient connective tissue remodelling. While various immunohistochemical studies concentrate upon collagen type remodelling and stabilization, it is a known fact that up to 10-15% of the non-pregnant cervix is constituted by smooth muscle fibres.[4] Hughesdon reveals the probability of the existence of an outer muscular layer in the cervix corresponding to the smooth muscle of the vagina. Studies have also shown that besides a decrease in fibrous connective tissue in the cervix at term, there is an increase in the proportion of smooth muscle fibres, which also become dissociated and hypertrophic, and are aligned in a particular direction.[5]

These studies, relating to the presence of smooth muscle fibres in the cervix logically support the role of antispasmodics and smooth muscle relaxants in helping the cervix to dilate. Drotaverine hydrochloride and hyoscine butylbromide are two such smooth muscle relaxants with different mechanisms of action.

Buscopan is a quaternary alkaloid that is a competitive antagonist of acetylcholine at muscarinic receptors. The drug has a selective blocking action on the intramural parasympathetic ganglia. It is a competitive antagonist of acetylcholine at postganglionic parasympathetic nerve endings. It has no effect on nicotinic receptors. It does not cross the blood brain barrier and hence has no central effects. Hence, its effects are only on the abdominal hollow organs which have an autonomic intramural nervous plexus like gastrointestinal tract, urogenital organs, etc. Its influence on eye, salivary glands and heart is extremely weak.[6,7]

Drotaverine hydrochloride or isoquinolone 1, 2, 3, 4-tetrahydro 6, 7 diethoxy-1-(C-3, 4–diethoxyphenyl methylene) hydrochloride is a highly potent spasmolytic agent, acting on the smooth muscle but is devoid of anticholinergic effects as it acts through inhibitory effect on phosphodiesterase enzyme, mainly PDE IV. Near term, human myometrium contains a higher proportion of rolipram-sensitive type IV PDE isoforms. Drotaverine inhibits them and in turn increases the intracellular concentration of cAMP and cGMP and causes smooth muscle relaxation. It does not cross the placenta and hence has no side effects on the foetus.[8]

In our study, it was consistently noted that the time taken to full dilatation was less and the rate of cervical dilatation was more with both the drugs when given in the active phase of labour. The action of drotaverine hydrochloride was consistently found to be much better than that of hyoscine butylbromide without an increase in any untoward maternal or foetal side effects.

**CONCLUSION:** There is a distinct advantage in using drotaverine hydrochloride as an antispasmodic of choice for effectively shortening the first stage of labour. It re-establishes the pivotal role of drotaverine hydrochloride in the acceleration of the first stage of labour. It is also reassuring that neither of the drugs used were associated with any untoward maternal or foetal effects while accelerating the first stage of labour.

**LIMITATIONS:**

1. This is a hospital based study. So we cannot apply results to general population. As each unit in the study have not got equal chance of selection to be included in this study.
2. Random sampling technique is not used in this study. That's why statistical significant results cannot be generalized to the population.

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