

## COMPARATIVE STUDY OF EFFICACY OF HYOSCINE BUTYLBROMIDE AND DROTAVERINE FOR AUGMENTATION OF LABOR

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### Abstract

**Introduction:** Prolonged labour contributes to increased perinatal and maternal morbidity. Various drugs have been tried to hasten the cervical dilatation. The ultimate aim of the obstetrician is to accomplish the delivery in the shortest possible time without compromising maternal and fetal safety. This study aims to compare the efficacy of Hyoscine Butyl Bromide with Drotaverine Hydrochloride for augmentation of labor.

**Material and Methods:** This was a prospective study conducted on 120 women with term gestation; in active labor. The patients were chosen by simple randomization and were divided into 3 groups- A, B and C respectively of 40 patients each. Group A received intramuscular injection drotaverine hydrochloride one ampule (40 mg), group B received intramuscular injection hyoscine butylbromide (20 mg) and group C which was control group, received no drug.

**Results:** The mean rate of cervical dilatation with buscopan was 2.23cm/hr while it was 2.03cm/hr and 2.08cm/hr in drotaverine group and control group respectively. Thus the drug delivery interval was less in buscopan group. Mean duration of active phase of first stage of labor was 156.13 minutes in buscopan group against 181.25 minutes in drotaverine group though buscopan was found to have less effect on duration of second stage of labor.

**Conclusion:** Buscopan was found to be an effective and safe drug in shortening the duration of first stage of labor without any significant detrimental effects on the mother and newborn thereby minimizing maternal and fetal morbidity.

**Keywords:** Drotaverine hydrochloride, Duration of labor, Hyoscine butylbromide.

### INTRODUCTION

Labor is a multifactorial process, which involves myometrial contraction, cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly manner.<sup>1</sup> Normal labor is a retrospective diagnosis.

The obstetrician and the laboring woman would like to accomplish the delivery in the shortest possible time without compromising the maternal and fetal safety. The management of normal labor is both an art and a science.<sup>2</sup> A shorter duration of labor from admission to delivery has also been consistently reported in numerous studies of women treated with the active management protocol.

The two major factors that determine duration of labor are uterine contractility and rate of cervical dilatation.<sup>3</sup> Various drugs have been tried in the past to reduce the tone of the cervical tissue. Intervention with drugs is among the options used through active management of labor; this

includes use of analgesics, oxytocin, prostaglandin derivatives, and smooth muscle relaxants. Spasmolytic drugs are frequently employed in delivery rooms to overcome cervical spasms and thus reduce the duration of labor.<sup>4</sup>

The present study was undertaken to compare the efficacy of Hyoscine Butylbromide (Buscopan) and Drotaverine for augmentation of labor.

Thus the objective of this study was to compare the rate of cervical dilatation and duration of labor of Hyoscine Butyl Bromide and Drotaverine with Control group in first stage of labor and to assess the perinatal outcome and maternal side effects of drug.

### MATERIAL AND METHODS

The present study was conducted in the Department of Obstetrics & Gynaecology, Shri Ram Murti Smarak

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Institute of Medical Sciences, Bhojipura, Bareilly. Total of 120 women with term gestation; in active labor were chosen by simple randomization.

#### Inclusion Criteria

1. Primigravida and multigravida with age between 18-30 years.
2. Intact fetal membranes
3. Vertex presentation
4. Regular established uterine contractions at the rate of at least 2/10 minutes.
5. Each contraction lasting for at least 20 seconds
6. Cervical dilatation of 3-4cms and no evidence of maternal or fetal distress.

#### Exclusion Criteria

1. Malpresentation
2. Twin pregnancy
3. Cervical surgery in the past or history of cervical injury
4. Induced labor
5. Maternal systolic pressure below 100 mmHg or above 150mmHg
6. Patients on anti hypertensive therapy
7. Known hypersensitivity to drotaverine or Hyoscine butylbromide.

An informed consent was taken prior to administration of drugs. A detailed history was taken for each patient followed by a meticulous general and systemic examination. Obstetric examination was carried out to determine lie, presentation, uterine contractions and fetal heart sounds. This was followed by a per vaginal examination to see for bishop's score, status of membranes and adequacy of pelvis. A partogram was maintained throughout labor and vaginal examination was done before giving each dose of the drug or if rupture of membranes occurred or patient started bearing down.

After detailed history and examination, patients were randomly divided into 3 groups- A, B and C respectively of 40 patients each.

**Group A-** These patients received intravenous injection Drotaverine 40 mg to be repeated after 2 hrs as per cervical dilatation to a maximum of 3 injections.

**Group B-** These patients received intramuscular injection 10mg Hyoscine Butylbromide to be repeated every hour to a maximum of three doses depending upon the cervical dilatation.

**Group C-** received no drug represents control group.

Statistical testing was conducted with the statistical

package for the social science system version SPSS 18.0. The values were represented in Number (%) and Mean  $\pm$  SD. Continuous variables were presented as mean  $\pm$  SD, and categorical variables were presented as absolute numbers and percentage. Nominal categorical data between the groups were compared using Chi-squared test. For all statistical tests, a p value less than 0.05 was taken to indicate a significant difference. Data were checked for normality before statistical analysis using Shaipro Wilk test. Normally distributed continuous variables were compared using ANOVA.

## RESULTS

Of the total of 120 patients recruited in our study 60% were in age group of 20-24 years. Maximum number of patients either primigravidae or multigravidae in all the three groups belonged to lower middle class. In group A and B maximum number of patients were multigravida i.e. 21% and 29 % while 19% and 11% were primigravidae in group A and group B respectively. Group C had equal number of primigravida and multigravida. Mean gestational age in Group A was 38.4 weeks while it was 38.5 weeks and 38.5 weeks in group B and C respectively. Most of patients in our study belonged to those with normal BMI ( $19-24.9 \text{ kg/m}^2$ ) in each group.

Table-1 shows that the maximum rate of cervical dilatation among primigravidae was in group B i.e.  $2.15 \pm 0.23 \text{ cm/hr}$ , while that in Group A is  $2.09 \pm 0.31 \text{ cm/hr}$  which was significantly more as compared to Group C. Amongst multigravidae also the rate of cervical dilatation was observed maximum in group B i.e.  $3.12 \pm 0.44 \text{ cm/hr}$  as compared to group A and C which is statistically significant with a p value of  $<0.001$ .

**Table-1:** Rate of cervical dilatation (cm/hr)

		Rate of Cervical Dilatation cm/hr			p value	Group A V/S Group B	Group A V/S Group C	Group B V/S Group C
		Group A	Group B	Group C				
Primi	Mean $\pm$ SD	$2.09 \pm 0.31$	$2.15 \pm 0.23$	$1.97 \pm 0.27$	0.197	0.866	0.368	0.223
Multi	Mean $\pm$ SD	$2.76 \pm 0.51$	$3.12 \pm 0.44$	$2.32 \pm 0.61$	$<0.001^*$	$0.041^*$	$0.020^*$	$<0.001^*$

As depicted in Table-2, the duration of active phase of first stage of labor was  $200.3 \pm 43.85 \text{ min}$  in the control group while it was  $156.13 \pm 37.08 \text{ mins}$  and  $181.25 \pm 40.55 \text{ mins}$  in group B and A respectively which was statistically significant with a p value of  $<0.001$ . The mean duration of second stage of labor in group B was  $8.38 \pm 8.7 \text{ min}$  which is similar to control Group while group A has a shorter duration of second stage of labor though it is not statistically significant. The mean duration of third stage of labor is lower in both group A and B i.e.  $5.23 \pm 0.77 \text{ mins}$  and

5.28±0.96 mins respectively as compared to Control group where the mean duration of third stage is 6.38±1.25mins which was statistically significant.

**Table-2:** Duration of active phase of first stage, second stage and third stage of labor (mins)

	Group A (n=40)	Group B (n=40)	Group C (n=40)	P Value	Group A V/S Group B	Group A V/S Group C	Group B V/S Group C
	Mean ± SD	Mean ± SD	Mean ± SD				
Active Duration of First Stage of labor	181.25 ± 40.55	156.13 ± 37.08	200.30 ± 43.85	<0.001	0.018	0.094	<0.001
Duration of Second Stage Of Labor	7.65 ± 5.46	8.38 ± 8.70	8.98 ± 8.18	0.737	0.904	0.715	0.933
Duration of Third Stage Of Labor	5.23 ± 0.77	5.28 ± 0.96	6.38 ± 1.25	<0.001	0.974	<0.001	<0.001

When compared between Group A and Group B, maternal side effects were more in Group A i.e. 22.5% against 17.5% in Group B. The most common side effect in either group was nausea and vomiting. Maternal tachycardia was observed more in group A. (Table-3)

**Table-3:** Maternal side effects of drugs

Maternal Side Effects	Group A N (%)	Group B N (%)	P Value
None	31 (77.5%)	33 (82.5%)	0.793
Dryness of Mouth	1 (2.5%)	1 (2.5%)	1.000
Flushing	1 (2.5%)	1 (2.5%)	
Nausea	3 (7.5%)	2 (5.0%)	
Tachycardia	2 (5.0%)	1 (2.5%)	
Vomitting	2 (5.0%)	2 (5.0%)	
Total	40 (100%)	40 (100%)	

Table-4 shows that in all the groups maximum no. of cases had Apgar score of 9. Though apgar score i.e. ≤ 8 was observed in four neonates each in group A and B and seven neonates in group C, however it was statistically insignificant.

**Table-4:** Analysis in relation to Apgar Score of baby

Apgar Score	Group A	Group B	Group C	P value
≤7	N	1	1	0.772
	%	2.50%	2.50%	
8	N	3	3	0.67
	%	7.50%	7.50%	
9	N	36	36	0.504
	%	90.00%	90.00%	
Total	40(100%)	40(100%)	40(100%)	

Four neonates in group A had meconium stained liquor while group B had two neonates with meconium stained liquor against three neonates in group C though this observation was statistically not significant

Seven neonates in group C had NICU admission while four neonates each in group A and group B were admitted to NICU. This observation was also not significant statistically.

## DISCUSSION

The subject of cervical dilatation and progress of labor has puzzled obstetricians for a long time, with prolonged labor having implications for both the mother and the fetus. Acceleration of labor is considered to be an important factor in reducing maternal morbidity as well as neonatal complications. Several drugs like antispasmodics have been tried in the past to facilitate cervical dilatation and hence decrease the duration of labor.<sup>5</sup>

The mean rate of cervical dilatation in our study who received Buscopan was 2.15±0.23cm/hr in primigravida and 3.12±0.44cm/hr in multigravida while that in Drotaverine group was 2.09±0.31cm/hr in primigravidae and 2.76±0.51cm/hr in multigravidae. The mean rate of cervical dilatation in control group where no drug was administered was 1.97±0.27cm/hr and 2.32±0.61cm/hr in primigravida and multigravida respectively. Other study by Maria Aziz et al.<sup>6</sup> with the use of Buscopan showed a mean rate of cervical dilatation of 2.04cm/hr and 3.9cm/hr in primigravida and multigravida respectively which is comparable to our study.

In the present study, mean duration of active phase of first stage of labor in Buscopan group was 156.13±37.08mins while in Drotaverine group was 181.25±40.55mins as compared to control group where the mean duration of first stage was 200.3±43.85mins. Our result was comparable to study conducted by Kumkum et al.<sup>7</sup> where the mean duration of labor with use of Buscopan and Drotaverine was 220±74mins and 214±69 mins in first stage and 24±10.08 mins and 27.25±11.97 mins respectively in second stage.

Of total 80 cases in our study, side effects observed with either of the drugs were minor in form of flushing, dryness of mouth, nausea and vomiting and tachycardia. Nine patients in Drotaverine group and seven patients in Buscopan group had these minor side effects.

In Buscopan group, side effects of our study are comparable to another study conducted by Shridhar S et al<sup>8</sup> who observed tachycardia in 2%, dryness of mouth in 4%, nausea and vomiting and flushing in 2% each.

In the present study, in all the groups maximum no. of cases had Apgar score of nine among both primigravida and multigravida. Group C had two i.e. 5% cases with low apgar score i.e. ≤ 7 while it was 2.5% each with Drotaverine and Buscopan group. A similar study conducted by Maria Aziz et al<sup>6</sup>, a low apgar score of <7 was observed in less than 5% of cases receiving Buscopan.

Meconium staining was seen in four cases (10%) in Drotaverine and two cases (5%) in Buscopan group in our study as compared to three cases (7.5%) where no drugs were administered. Our findings were consistent with study conducted by Sameena et al.<sup>5</sup> where meconium staining was seen in 2% and 1.3% with Drotaverine and Buscopan administration respectively.

NICU admission was advised in four cases each in both Drotaverine and Buscopan group compared to seven cases in patients where no drugs were administered, this was due to low apgar score of  $\leq 8$  either for observation or respiratory support. Two neonates each in group A and C who had MSL were admitted to NICU.

This study places Hyoscine Butyl Bromide superior compared to Drotaverine in decreasing the duration of active phase of first stage of labor and improving the rate of cervical dilatation thus decreasing the duration of onset of labor to delivery interval hence decreasing the overall duration of labor. There was no significant difference in neonatal outcome and NICU admission between the two drugs.

## CONCLUSION

Following concluding points can be derived from the study-

Mean rate of cervical dilatation is found to be more in buscopan group and mean duration of active phase of first stage of labor is found to be least in buscopan group. Minor side effects in form of flushing, dryness of mouth, nausea and vomiting and tachycardia were slightly higher in drotaverine as compared to buscopan. Perinatal outcome in the form of apgar score, meconium stained liquor and NICU admission was observed better in buscopan group as compared to drotaverine group.

From the study it was concluded that Buscopan was found to be an effective and safe drug in shortening the duration of first stage of labor without any significant detrimental effects on the mother and newborn thereby minimizing maternal and fetal morbidity.

Our study being very small larger randomized trials are required for establishing its effectiveness and equivalence between standard spasmolytic agent in augmentation of labor.

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