

## A comparative study of intravenous drotaverine and rectal hyoscine for augmentation of labour

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### ABSTRACT

**Background:** Contractility of the myometrium is usually diminished during pregnancy to accommodate and protect the growing products of conception; drugs like Hyoscine butylbromide and Drotaverine are used to shorten the duration of labor.

**Aim:** To compare the effect of intravenous Drotaverine and rectal Hyoscine Butylbromide suppository in duration of labour and rate of cervical dilatation.

**Methods:** 90 pregnant women with term pregnancy in active labour were selected by simple randomization and were divided into three groups: Group A, where injection Drotaverine intravenous was given; Group B, where Hyoscine Butylbromide rectal suppository was kept; and in Group C, where no drug was given.

**Result:** Mean duration of first stage of labour was 178.6 min, 144.3 min, 288.7 min in groups A, B and C, respectively. Rate of cervical dilatation in groups A, B and C was 2.6, 2.8 and 2.1 cm/hr, respectively. Most of the subjects delivered vaginally. No serious side effects were noted in both the groups.

**Conclusion:** Hyoscine Butylbromide is more effective than Drotaverine in reducing the duration of active phase of labour. There is a significant improvement in the rate of cervical dilatation with Hyoscine Butylbromide as compared to Drotaverine.

**Key words:** hyoscine butylbromide, drotaverine, cervical dilatation, labour

### INTRODUCTION

Caesarean section rates have been noted to vary considerably across countries<sup>1</sup> and between regions within the same country.<sup>1</sup> Active management of labour has been proposed as an alternative to the high rate of caesarean section; a clinical protocol that includes selective admission to the labour ward, early augmentation of mild delays in labour, continuous professional social support and selective use of electronic fetal monitoring.<sup>2</sup>

There are many indications for term labor inductions. More than 15% of all gravid women require aid in cervical ripening and labor induction as their labor course is longer than that of spontaneous labor and this is the most common met problem. The prolonged course of spontaneous labor among nulliparous women is another common problem.

Drotaverine, an isoquinoline derivative, is a phosphodiesterase (PDE) inhibitor and is selective for type IV isoenzyme. It acts

specifically on spastic sites and corrects the cAMP and calcium balance relieving smooth muscle spasm.<sup>3</sup> This action is thought to facilitate cervical dilatation. Leroy et al., found that in the third trimester and near term, a high concentration of PDE type IV is seen in the human myometrium.<sup>4</sup> This predominance may suggest its role in labour and its spasmolytic action is presumed to be the mechanism for facilitating cervical dilatation.

Hyoscine butylbromide is a quaternary ammonium derivative, which exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary, and genitourinary tracts. Hyoscine butylbromide belongs to a parasympatholytic group of drugs and it is a semisynthetic derivative of scopolamine, it has effective antispasmodic activity but devoid of side effects of atropine, it does not cross the blood brain barrier, it acts primarily by blocking the transmission of neural impulses in the parasympathetic ganglia of abdominal organs.<sup>5</sup>

This study aims at comparing the effect of per rectal hyocine and intravenous drotaverine for augmentation of labour.

## MATERIAL AND METHODS

This study is a prospective single blind randomized control trial. After institutional ethical committee approval and written informed consent; total 90 patients at term were recruited for the study. Patients included were primi and multigravida both in the age group of 18-30 year. Other parameters fixed as inclusion criteria are: intact fetal membranes, vertex presentation, and regular established uterine contraction at the rate of at least 2/10 minute, each contraction lasting for at least 20 seconds, cervical dilatation of 3-4 cms and no evidence of maternal or fetal distress. Patients with malpresentation, twin pregnancy, cervical surgery in the past or history of cervical injury, induced labor, maternal systolic pressure below 100mm Hg or above 150 mm Hg, patients on an antihypertensive therapy, known hypersensitivity to Drotaverine or Hyoscine butylbromide and if any other spasmolytic agent had been used within 48 hours were excluded from the study.

A thorough general and systemic examination of the recruited subjects was conducted. Changes of clinical significance; uterine height, presentation, frequency- intensity of contractions, cervical dilatation, effacement, consistency and station of the presenting part were noted. Pelvic assessment was done to rule out any pelvic contraction or cephalopelvic disproportion. Per vaginal examination was done prior to each dose of the drug to look for status of membranes and ensuing of bearing down.

The drug was administered in patients with established labor i.e., at 3 or 4 cm cervical dilatation with regular uterine contractions of >2 per 10 min each lasting 20 seconds. The Group A (N=30) cases received intravenous Drotaverine (40mg). Injection was repeated after 2 hours as per cervical dilations upto a maximum of 3 injections. The Group B (N=30) received 10mg rectal suppository. The drug was repeated every hour up to a maximum of three doses depending upon the cervical dilatation. In Group C (N=30) no drug was given and represented the control group. All women were monitored for pulse, temperature, respiratory rate, blood pressure, foetal heart rate and adverse reactions every 30 min in the first stage and every 5 min in the second stage. Medical staff delivered all the babies. Caesarean section or assisted vaginal delivery was conducted as per obstetric indications. Salient parameters like, duration of first, second and third stages of labour, rate of cervical dilatation, mode of delivery, neonatal condition at birth, side effects of drugs and maternal complications were noted down in each case.

Parametric data was expressed as mean  $\pm$  SD, and percentage, thereby the inter group comparisons were made by student's t-test. The statistical analysis was done by using Graphpad Prism V.6.0.

## RESULT

Amongst 90 recruited subjects, divided into three groups; no significant differences were observed in relation to demographic variability (Table 1).

**Table 1:** Demographic profile

Demographic variable	Group A	Group B	Group C	P value
Age (years)	23.4 ± 1.6	23.2 ± 1.9	23.6 ± 1.5	> 0.05
Gestational Weeks	38.2 ± 1.1	38.3 ± 1.1	38.2 ± 1.1	> 0.05
Primi Gravida (n)	13 (43.33%)	14 (46.67%)	13 (43.33%)	
Multi Gravida (n)	17 (56.67%)	16 (53.33%)	17 (56.67%)	
Initial cervical dilatation (cm)	3.5 ± 0.4	3.5 ± 0.5	3.5 ± 0.4	

**Table 2.** Characteristics of Labour women

	Group A	Group B	Group C	P value
Total duration of labour (min)	216.2 ± 52.3	184.8 ± 49.6	318.9 ± 56.4	P < 0.05
Duration of 1 <sup>st</sup> stage (min)	178.6 ± 24.2	144.3 ± 19.7	288.7 ± 36.3	P < 0.05
Duration of 2 <sup>nd</sup> stage (min)	28.4 ± 10.4	27.9 ± 10.2	26.4 ± 10.9	P > 0.05
Duration of 3 <sup>rd</sup> stage (min)	8.6 ± 2.3	8.1 ± 2.1	7.9 ± 1.9	P > 0.05
Rate of cervical dilatation (cm/hr)	2.6 ± 1.1	2.8 ± 1.0	2.1 ± 0.9	P < 0.05
<b>Mode of Delivery</b>				
Normal	27 (90%)	26 (86.67%)	27 (90%)	
Instrumentation	1 (3.33%)	2 (6.67%)	2 (6.67%)	
LSCS	2 (6.67%)	2 (6.67%)	1 (3.33%)	

Total duration of labour was significantly low in Group B and then group A as compared to control group. Duration of 1<sup>st</sup> stage was also less with Hyocine group as compared to drotaverine and control group. While duration of 2<sup>nd</sup> stage and 3<sup>rd</sup> stage remains insignificant in all three groups.

**Table 3.** Side effects profile

	Group A	Group B	Group C
Maternal tachycardia	1 (3.33%)	0	0
Fetal tachycardia	1 (3.33%)	1 (3.33%)	0
Nausea/Vomiting	2 (6.67%)	1 (3.33%)	0
Flushing	3 (10%)	0	0
Fetal distress	3 (10%)	2 (6.67%)	2 (6.67%)
Prolonged 2nd stage of labour	1 (3.33%)	1 (3.33%)	1 (3.33%)
Vaginal Tear	1 (3.33%)	1 (3.33%)	1 (3.33%)

## DISCUSSION

Cervical dilatation and augmentation of labour has been an issue of controversies among obstetrician. Acceleration of labor is considered to be an important factor in reducing maternal morbidity as well as the neonatal complications. Several drugs like antispasmodics, tranquillizers, prostaglandins and psychotherapeutic methods have been tried in the past to facilitate cervical dilatation and hence augment labour, but majority of these were found to have ill effect on the mother and the fetus.

Antispasmodic drugs; Hyoscine butylbromide and Drotaverine are safe and effective in shortening duration of labor. This study has compared the effect of I.V Drotaverine and Hyoscine butylbromide rectal suppository on duration of labour and rate of cervical dilatation. Though both drugs have shown to shorten the duration of first stage of labour, Hyoscine butylbromide group showed significant shortening than the Drotaverine group. No serious maternal or fetal side effects were observed with both the drugs.

The present study showed a significant decrease in labor duration when a 20 mg rectal suppository of Hyocine was used in the active phase of labor. Sirohiwal et al., also found a significant difference in the duration of active phase of labor between the control and study group. However, the duration of second and third stage of labor has remain unaffected.<sup>6</sup> In our study, we have also observed similar results. On the other hand, Gupta et al., found that the active phase duration and rate of cervical dilatation in the group that received Hyocine were not significantly different from the control group.<sup>7</sup> Similar observations were made by Mortazavi and Rakhshani also who reported a longer first stage of labor with intramuscular Hyocine.<sup>8</sup> although the exact mechanism of action is not established, possibly the results were influenced by the local effect of the rectal suppository on the cervical region. It is possible that induced relaxation enables more effective myometrical contractions. Hector Mario Barachio *et al.* conducted a study using buscopan for labour augmentation and reported shortening of first stage of labour by 1 hour 32 minutes in primigavidae and 1 hour 27

minutes in multigravidae and total duration of labour by 2 hours and 1 min in primigravidae without any untoward side effects either on the mother or the foetus.<sup>9</sup> Bhattacharya *et al.*, conducted a study using Buscopan for acceleration of first stage of labour and noted that the duration of first stage of labour was shortened by 3 hours and 40 mins.<sup>10</sup>

A study conducted using 20 mg intravenous Hyocine for active management of labor in 100 primigravidae women with 100 primigravidae women as control. It reported that 24% of fetuses in the experimental group and 10% of fetuses in the control group had heart rate variation (8% bradycardia and 16% tachycardia vs 2% bradycardia and 8% tachycardia).<sup>11</sup> Our study showed no such difference, possibly these differences could be an effect of intravenous application of Hyocine which, in comparison with rectal suppository, can rapidly alter the fetal heart beat. We have observed very less effect on fetal heart rate with hyocine and drotaverine group as well.

A similar study reported shortening of labour by 2 hours 42 minutes with 88% women delivering within 8 hours following Buscopan administration. No serious side effects were noticed on mother and foetus.<sup>12</sup> Another study demonstrated labour being shortened by 5 hours 12 minutes as compared with controls following the administration of Buscopan.<sup>13</sup> Yet another study using Drotaverine for acceleration of first stage of labour and found that total duration of labour was shortened by 62 mins, Duration of active phase of 1st stage shortened by 60 mins, duration of 2nd and 3rd stage differed only by 4 mins and there was no

serious side effects noticed on mother and foetus.<sup>14</sup>

A study had reported that on administering 40 mg of Drotaverine intramuscularly to 141 labouring patients; mean duration of active phase was reduced by 17.3% in primi patients. It concluded that Drotaverine is more effective when the membranes have ruptured either spontaneously or by amniotomy.<sup>15</sup> The finding is comparable with our study.

## CONCLUSION

Drotaverine and Hyocine are effective in shortening duration of labour without any significant adverse effect on mother or fetus. However; Hyoscine butylbromide has an edge over Drotaverine. In situations where trained medical personnel is not available, because of its convenience of administration it is definitely serves as a better option.

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## AUTHOR NOTE

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