

## **A comparative study of the effect of drotaverine hydrochloride with hyoscine butylbromide in first stage of labor**

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### **ABSTRACT**

**Background:** Prolongation of labor is one such dilemma that every obstetrician tries to avoid. The ultimate aim of the obstetrician is to accomplish the delivery in the shortest possible time without compromising maternal and fetal safety. Prolonged labor often ends up in great suffering to the parturient because of dehydration, confusion, and infection. This study aims to compare the efficacy of drotaverine hydrochloride with hyoscine butyl bromide for increasing the rate of cervical dilatation and to compare their duration of labor.

**Methods:** This was a prospective interventional study conducted on 60 women who were randomly allocated to Group I, which was control group, women in Group II were injected hyoscine butylbromide one ampoule (20 mg) and the women in Group III were injected drotaverine hydrochloride one ampoule (40 mg) intramuscular at 3 cm dilatation of cervix. The data collected was statistically analyzed using SPSS version 15.

**Results:** When compared to Group I (control group), Group II and Group III took lower time for all the three stages of labor. However, intergroup difference was significant only for Stage I ( $p < 0.001$ ). However, no significant difference was observed between Groups II and III ( $p = 0.964$ ). A significant difference among group was observed in total duration of labor too ( $p < 0.001$ ). Between group comparisons for Stage II and Stage III did not show a statistically significant intergroup difference for any of the comparisons ( $p > 0.05$ ).

**Conclusions:** The finding in this study suggested a significant impact of both the drugs in first stage as well as total duration of labor as compared to control group. However, no significant difference between two study groups was observed. Thus, both drotaverine hydrochloride and hyoscine butylbromide could effectively reduce first stage as well as total duration of labor.

**Keywords:** Drotaverine hydrochloride, Hyoscine butyl bromide, Duration of labor, Stages of labor

### **INTRODUCTION**

Prolongation of labor is one such dilemma that every obstetrician tries to avoid. The ultimate aim of the obstetrician is to accomplish the delivery in the shortest possible time without compromising maternal and fetal safety. Prolonged labor often ends up in great suffering to the parturient because of dehydration, confusion and infection.<sup>1</sup> The fetus is exposed to high risk of infection and asphyxia. Inhibitory impulse in form of spasm often impairs the dilatation of cervix and prolongs the duration of labor.<sup>2</sup> Active management of labor is associated with low incidence of prolonged labor and low cesarean rate.<sup>3</sup> Spasmolytics and spasmolytic mixtures are administered to facilitate dilatation of cervix during delivery and to shorten first stage of labor.<sup>4</sup> An ideal

antispasmodic for acceleration of cervical dilatation should have prompt and long lasting action, no adverse effect on uterine contractility and it should have minimal side effects on mother and fetus.<sup>5</sup> Thus in order to accelerate the labor apart from early amniotomy and early administration of oxytocin, the use of antispasmodic agents to hasten the first stage of labor is a common practice.<sup>6</sup> Hyoscine butylbromide is a derivative of atropine (anticholinesterase) thus act by inhibiting cholinergic transmission, relieving smooth muscle spasm aiding cervical dilatation.<sup>7</sup> Drotaverine hydrochloride is highly potent antispasmodic agent which inhibits enzyme phosphodiesterase IV causing smooth muscle relaxation. This study aimed to compare the efficacy of drotaverine hydrochloride with hyoscine butylbromide for increasing rate of cervical dilatation and to compare the durations of labor.

**METHODS**

It is an interventional study conducted on all pregnant women undergoing labor those coming to gynecological outpatient department of Era’s Lucknow Medical College and Hospital selected by computer generated randomized numbers.

**Inclusion criteria**

All pregnant women with term pregnancy at 37-41 weeks in 3-4 cm cervical dilatation with vertex presentation with no contraindication for vaginal delivery.

**Exclusion criteria**

It includes women with preterm labor, previous caesarean section, twin pregnancy, antepartum hemorrhage, history of cervical encircilage, malpresentation.

**Sample size**

$$n = (Z_{\alpha} + Z_{\beta})^2 (\sigma_1^2 + \sigma_2^2) / d^2 \tag{3}$$

$\alpha$ =level of significance=5%

$\beta$ =(type II error)=10%

Power of test=90%

$\sigma_1$ =13.2

$\sigma_2$ =63.6

d=63.6

Thus sample size comes out to be=20 per group

The study was conducted on 60 women in labor who were randomly allocated to three groups (Groups I-III). Each group had 20 patients. Group I: control group (no intervention) Group II: injected one ampoule (20 mg) of hyoscine butylbromide intramuscular (IM) at 3 cm cervical dilatation. Group III: injected one ampoule (40 mg) of drotaverine IM at 3 cm cervical dilatation.

The following parameters were recorded:

- Time from admission to 3 cm cervical dilatation
- Time at which antispasmodics were injected
- Time at which full dilatation of cervix was achieved
- Total duration of first stage of labor
- Duration of second and third stage of labor
- Amount of bleeding in third of labor.

Data collected was subjected to analysis using SPSS version 15 by using various formulas (Chi-square test, ANOVA, Student’s “t” test).

- p value: level of significance
- p>0.05: not significant
- p<0.05: significant
- p<0.01: highly significant
- p<0.001: very highly significant

**RESULTS**

The patients were randomly allocated to three groups - Group I comprised the control group and included 20 patients (33.3%) in whom no intervention was done. In Group II, there were 20 patients (33.3%) in whom 1 ampoule injection hyoscine butyl bromide was injected intramuscularly whereas in Group III, there were 20 patients (33.3%) in whom 1 ampoule injection drotaverine hydrochloride was administered intramuscularly (Table 1).

Majority of subjects in all the three groups had initial cervical dilatation of 3 cm. There were 5 (25%) cases in Group I who had cervical dilatation of 4 cm whereas in Group II 1 (5%) subject had 3.5 cm dilatation and 3 (15%) had 4 cm dilatation. In Group III, 3 (15%) had 4 cm cervical dilatation. Statistically, there was no significant difference among group (p=0.583) (Table 2).

As compared to Group I both Groups II and III took lower time for all the three stages of labor. However, intergroup difference was significant for Stage I (F=18.741; p<0.001). A significant difference among groups was observed in total duration of labor too (p<0.001) (Table 3).

Majority of subjects in Groups I and II had spontaneous labor and in Group III had induced labor. Statistically this difference was found significant (p=0.054) (Table 4).

**Table 1: Group wise distribution of subjects.**

Group	Description	Number of subjects	Percentage
I	Control group-no intervention	20	33.3
II	Injection hyoscine one amp IM was given	20	33.3
III	Injection drotaverine one amp IM was given	20	33.3

IM: Intramuscular

**Table 2: Distribution of subjects in two groups (study and control) according to initial cervical dilatation.**

Initial cervical dilatation	N (%)		
	Group I	Group II	Group III
3 cm	15 (75)	16 (80)	17 (85)
3.5 cm	0 (0)	1 (5)	0 (0)
4 cm	5 (25)	3 (15)	3 (15)

$\chi^2=2.852$  (df=4), p=0.583

**Table 3: Duration of different stages of labor in three groups.**

Stage	Mean±SD (n=20)			Significance of difference (ANOVA)	
	Group I	Group II	Group III	F	P
I (hrs: mins)	5:45±1:16	3:40±1:14	3:34±1:09	18.741	<0.001
II (mins)	36.11±23.55	24.00±10.08	27.25±11.97	2.872	0.065
III (mins)	7.78±3.42	6.60±2.33	6.25±2.61	1.525	0.227
Total	6:26±1:25	4:11±1:13	4:11±1:16	18.697	<0.001

SD: Standard deviation

**Table 4: Duration of subjects in two groups according to type of labor.**

Type of labor	N (%)		
	Group I	Group II	Group III
Induced	7 (35)	6 (30)	13 (65)
Spontaneous	13 (65)	14 (70)	7 (35)

$\chi^2=5.847$  (df=2), p=0.054

Side-effects like nausea, fetal tachycardia, and maternal tachycardia were observed in 3 (15%) in Group II and 5 (25%) in Group III subjects. On comparing the data statistically, no significant intergroup difference was observed (p=0.065) (Table 5).

Majority of subjects had full term normal delivery. There were 6 (30%) subjects in Group I, 1 (5%) Group II and 2 (10%) in Group III who delivered through cesarean section. Statistically this data was not found to be significant (p=0.065) (Table 6).

## DISCUSSION

Labor pain is among the most severe pain experienced by women. Acceleration of labor to shorten its duration without adverse events on mother and fetus would therefore minimize the maternal and fetal morbidity and mortality.<sup>8</sup> During active management of labor along with good uterine contraction, simultaneous softening and cervical dilatation is required. However sometimes, in spite of good uterine contractions cervical dilatation is hampered due to spasm caused by inhibitory impulse. For such reasons antispasmodics are being used to hasten the cervical dilatation and hence it reduces the duration of first stage of labor as well as total duration of labor too. Sedatives and belladonna alkaloids have also been tried for cervical dilatation, but have many adverse effects on mother and fetus.<sup>9</sup> Although methods to increase uterine contractility such as amniotomy and oxytocics are also used to accelerate cervical dilatation, but these methods are also associated with complications.<sup>10</sup> In the present study we observed an initial cervical dilatation to be lying in the range of 3-4 cm (Table 2).

In this study, both hyoscine butylbromide and drotaverine hydrochloride showed significant reduction in first stage of labor as compared to placebo group. Although the mean difference between placebo and hyoscine butyl bromide

**Table 5: Incidence of side effects in different groups.**

Side effects	N (%)		
	Group I	Group II	Group III
No	20 (100)	17 (85)	15 (75)
Yes	0 (0)	3 (15)	5 (25)

$\chi^2=5.481$  (df=2), p=0.065

**Table 6: Distribution of subjects in three groups according to mode of delivery.**

Mode of delivery	N (%)		
	Group I	Group II	Group III
FTND	14 (70)	19 (95)	17 (85)
LSCS	6 (30)	1 (5)	2 (10)
Forceps	0 (0)	0 (0)	1 (5)

$\chi^2=5.490$  (df=4), p=0.064. FTND: Full term normal delivery, LSCS: Lower segment caesarean section

group for first stage of labor was 2:04±0:23 hr:mins and between drotaverine hydrochloride and placebo was 2:10±0:24 hr:min yet this mean difference of around 6 mins did not differentiate between the two study groups. Thus as regards the duration of first stage as well as total duration of labor, both the study groups showed a significantly shorter time as compared to the placebo group (Table 3). However, the difference between two study groups did not show a significant difference. Tehalia et al.<sup>6</sup> observed the mean time from injection to full dilatation to be significantly lower in hyoscine butylbromide group as compared to drotaverine hydrochloride group. While Nicholson JM et al (2004)<sup>8</sup> did not find a significant effect of either of two drugs on first stage of labor as well as on total duration of labor.

In different studies hyoscine butylbromide and drotaverine hydrochloride have independently shown controversial results Chan et al.<sup>11</sup> did not find an impact of hyoscine butylbromide on the duration of first stage of labor whereas Sirohiwal et al.<sup>12</sup> have found that hyoscine N-butylbromide suppositories have a significant reducing effect on first stage of labor. Samuels et al.<sup>13</sup> too showed a similar reducing effect of hyoscine butylbromide on the mean duration of first stage of labor against a labor. While, Raghavan et al. in a comparative assessment of hyoscine butylbromide with valethamate bromide against a placebo showed a significantly better efficacy in both the test groups in acceleration of first stage of labor. Similarly for drotaverine hydrochloride too

Sharma et al.,<sup>14</sup> Khosla et al.,<sup>15</sup> Singh et al.<sup>10</sup> Have shown a proven efficacy of drotaverine hydrochloride over placebo and other drugs. These results are in agreement with our study. Roy et al.<sup>16</sup> reported it to be highly efficacious in reducing duration of the first stage of labor. Similar results have been reported in other studies too.<sup>17,18</sup>

## CONCLUSION

The findings in the present study showed a significant impact of both the drugs in first stage of labor as well as on total duration of labor too, which was significantly reduced as compared to control group.

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