

## The effect of Hyoscine butyl bromide on the duration and course of labor

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### Abstract

**Background:** Cervical dystocia is caused by cervical spasm due to prolonged labor. Maternal complications can arise due to this such as intrapartum infection, pathological retraction ring (Bandl's ring), maternal morbidity and it may also contribute to perinatal morbidity and mortality. Various spasmolytic drugs can help to relieve the cervical spasm and facilitate cervical dilatation during the first stage thereby decreasing the rate of cervical dystocia.

**Methods:** This was a prospective study conducted in a tertiary center over a span of 1 year. 60 patients were randomly allotted in 2 groups.

1. 30 patients (15 primigravida and 15 multigravida) – control group
2. 30 patients (15 primigravida and 15 multigravida) – Injection Hyoscine butyl bromide (Buscopan) group. Injection Hyoscine butyl bromide 20 mg intramuscular was given at 3cm cervical dilatation. No further dose was given.

A statistical test, 'unpaired t test', was used to test the results for statistical significance. A  $\chi^2$  (chi square) test was used to test results of side effects for statistical significance.

**Results:** The duration of active first stage of labor was shorter in the Hyoscine butylbromide group (170.3 min) as compared to control group (216.7 min) in primigravida and multigravida (hyoscine butyl bromide group 120.9 min and control group 153.3 min). An unpaired t test showed p value of 0.011 in primigravida patients and p value of 0.003 in multigravida patients). No significant maternal and neonatal side effects were noted in the drug arm when compared to the control group (p value > 0.05).

**Conclusions:** The rate of cervical dilatation under the influence of hyoscine butylbromide is significantly higher as compared to control group. The rate of dilatation is faster in multigravida patients as compared to primigravida. Hyoscine butylbromide is a safe drug with no fetal side effects or any significant maternal side effects

**Keywords:** Labor, Hyoscine butyl bromide, Cervical dilatation, Active first stage of labor, Prolonged labor

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butylbromide, dicyclomine, valethamide bromide can be used to accelerate the first stage of labor.

### Aims and Objectives

1. To compare the duration of active 1<sup>st</sup> phase of labor in control group and compare it with cervical dilator Hyoscine butylbromide (Injection Buscopan).
2. To compare the rate of cervical dilatation in these two groups and to assess its relation to the gravidity of the patient.
3. To assess the side effects of the drug on the mother and the fetus.

In our study we compared the effect of Hyoscine butylbromide and control on the first stage of labor. The pharmacology of the drug, in consideration, along with the mechanism of action and side effects are discussed below.

### Pharmacology of Drug

**Hyoscine Butylbromide:** It is an antimuscarinic agent which acts by inhibiting cholinergic transmission in the parasympathetic ganglia thus relieving spasm in the smooth muscles of female genital organs, specially the cervico-uterine plexus thus aiding cervical dilatation. Uterine contractions are not affected. Due to better co-ordination between uterine contractions and cervical dilatation, labor is accelerated.

### Introduction

Labor is a multifactorial process involving good myometrial contractions, cervical ripening, dilatation and expulsion of the fetus and the placenta in an orderly manner.

Prolonged labor is a dreaded complication feared by both patients and obstetricians.

Various drugs are available to curtail the duration of labor e.g.: hyoscine – N- butylbromide, drotaverine and valethamide bromide. There has been an upsurge in use of these cervical dilators to avoid the complications of prolonged labor.

Both the obstetrician and the laboring woman would like to accomplish the delivery in the shortest possible time without any major maternal and fetal side effects. Labor can be augmented with early amniotomy and early administration of oxytocin. Various antispasmodic agents like drotaverine, hyoscine

**Dosage and Administration:** Parenteral: In adults 1 or 2 ampoules (20 - 40mg) may be administered by slow intravenous, intramuscular or subcutaneous route. A maximum daily dose of 100mg should not be exceeded.

**Side effects:** Anticholinergic side effects of the drug are generally mild and self-limited.

**Pregnancy and Lactation:** No known direct or indirect harmful effects on the human foetus have been observed.

**Contraindications:** Myasthenia gravis, megacolon and prior hypersensitivity to the product are known contraindications to hyoscine butyl bromide.<sup>[1]</sup>

### Materials and Methods

This is a prospective study conducted in a tertiary centre over a span of 1 year.

100 patients were assessed for eligibility to be included in the study. Out of 100, 40 patients were excluded as 36 patients did not meet the inclusion criteria and 4 patients did not want to participate.

Hence, 60 patients were enrolled in the study group after taking their informed, written and valid consent.

**Inclusion Criteria:** 60 women at 37 weeks to 41 weeks of pregnancy with vertex presentation in established labor; which was defined as effective uterine contraction, good cervical effacement and 3cm of cervical dilatation.

**Exclusion Criteria:** Women with previous uterine scars, malpresentations, multiple pregnancies, cephalopelvic disproportion, pre-eclampsia, antepartum hemorrhage, contra indication to use of Hyoscine Butylbromide

**Study Procedure:** 60 patients were randomly allotted in 2 groups by using computer randomization.

3. 30 patients (15 primigravida and 15 multigravida) – control group (no drug given)

4. 30 patients (15 primigravida and 15 multigravida) – Injection Hyoscine butyl bromide (Buscopan) group. Injection Hyoscine butyl bromide 20 mg intramuscular was given at 3cm cervical dilatation. No further dose was given.

2 hourly per vaginal examination were carried out to assess the progress of labor.

There were no significant differences in the gravidity, age and duration of gestation.

Results were tabulated in

1. Duration of first stage
2. Duration of stage 2 and 3.
3. Rate of cervical dilatation
4. Duration of stage according to gravidity.

A statistical test, 'unpaired t test', was used to test the results for statistical significance.

The neonatal and maternal side effects were observed. APGAR score was taken at 1min and at 10min. Following maternal side effects were noted headache, dryness of mouth, tachycardia and flushing of face. A  $\chi^2$  (chi square) test was used to test results of side effects for statistical significance.

### Results

The following findings were observed:

1. The average age in primigravida patients in control group was 22.8yrs (range 19yrs to 34yrs) whereas in multigravida it was 26.2yrs (range 21yrs to 34yrs). The average age in primigravida patients in injection hyoscine butylbromide group was 23.9yrs (range 21yrs to 28yrs) whereas in multigravida it was 27.5yrs (range 22yrs to 34yrs).
2. The average gestational age in primigravida patients in control group was 38.6wks whereas in multigravida it was 38.4wks. The average gestational age in primigravida patients in injection hyoscine butylbromide group was 38.6wks whereas in multigravida it was 38.6wks.
3. The duration of active first stage of labor was shorter in the Hyoscine butylbromide group (170.3 min) as compared to control group (216.7 min) in primigravida (Table 1) and in multigravida (hyoscine butyl bromide group 120.9 min and control group 153.3 min) (Table 2). An unpaired t test showed p value of 0.011 in primigravida patients and p value of 0.003 in multigravida patients).
4. There was no significant difference between the duration of second and third stage of labor in the two groups both in primigravida and multigravida. Table 3
5. There were no observed side effects in the neonate in the control and the hyoscine butyl bromide group. APGAR scores in both the groups were comparable in primigravida and in multigravida.
6. Tachycardia was observed in 4 mothers in hyoscine butyl bromide (buscopan) group. However, it was not significant when compared to the control group (2 patients) (p value > 0.05). Table 4

**Table 1: Duration of active first stage of labour and rate of cervical dilatation in Primigravida in drug and control arm**

	Hyoscine butylbromide	Control
No of patient's	15	15
Mean duration of active phase of first stage (min)	170.3	216.7
Difference of means (min)	46.4	
Rate of Cervical Dilatation (cm/hr)	2.46	1.93
P value	P =0.011	
Significance	Significant	

The duration of active first stage of labor was shorter in the Hyoscine butylbromide group as compared to control group in primigravida patients.

**Table 2: Duration of active first stage of labor and rate of cervical dilatation in multigravida in drug and control arm**

	Hyoscine butylbromide	Control
No of patient's	15	15
Mean duration of active phase of first stage (min)	120.9	153.3
Difference of means (min)	32.4	
Rate of Cervical Dilatation (cm/hr)	3.47	2.73
P value	P =0.003	
Significance	Significant	

The duration of active first stage of labor was shorter in the Hyoscine butylbromide group as compared to control group in multigravida patients.

**Table 3: Depicts duration of second and third stage of labor in drug and control arms**

Gravidity	Group	Mean duration of second stage (min)	Mean duration of third stage (min)
Primigravida	Control	19.8	6.6
	Hyoscine butylbromide	14.4	7.2
Multigravida	Control	18	6
	Hyoscine butylbromide	16.7	10.2

No significant difference between the duration second and third stage of labor in the two groups both in primigravida and multigravida.

**Table 4: Table depicting maternal side effects in drug and control arm**

Group	No of patient	Headache	Dryness of mouth	Tachycardia	Flushing of face
Buscopan	30	2	2	4	0
Control	30	1	0	2	0

Side effects were not significant (p value >0.05)

### Discussion

The hazards of prolonged labor for the mother such as infection, ketosis and obstructed labor have been recognized for many years. The foetus faces the dangers of infection, asphyxia and excessive cranial moulding due to prolonged labor. The concept of "active management of labour" was introduced by Professor O'Driscoll at the National Maternity Hospital, Dublin (1973).<sup>[2]</sup> Attempts to accelerate labour and thereby shorten its duration without

jeopardizing maternal or foetal outcome are welcome to both the patient and the obstetrician. The two basic factors that determine the duration of labor are uterine activity and rate of cervical dilatation.

In our study the average age in primigravidae patients in control group was 22.8yrs whereas in multigravidae it was 26.2yrs. The average age in primigravidae patients in hyoscine butylbromide group was 23.9yrs whereas in multigravida it was 27.5yrs. In the study conducted by Pakhee Aggarwal, Vijay Zutshi,

Swaraj Batra in New Delhi, India the average maternal age for hyoscine butylbromide group was 23.8 years and in control group was 24 years.<sup>[3]</sup> In the study conducted at Kingston, Jamaica by LA Samuels et al the average maternal age in the Buscopan group was 25 ± 6 years and in the control group was 26.9±6 years.<sup>[4]</sup> The average maternal age in our study are comparable to the above studies and fall within the range.

The average gestational age in primigravidae patients in control group was 38.6wks whereas in multigravidae it was 38.4 wks. In the Hyoscine butylbromide group the average age of primigravidae and multigravidae was 38.6wks.

Pakhee Aggarwal's study comprised of 104 patients with a mean gestational age at delivery 38.6 weeks in the study group vs. 38 weeks in the control group.<sup>[3]</sup>

LA Samuels had a total of 129 patients in their study group with 69 patients in placebo and 60 in buscopan group.<sup>[4]</sup> Sirohiwal D has used buscopan suppositories in his study comprising 200 patients,<sup>[5]</sup> 100 women were given Buscopan suppositories and the remaining acted as controls. Their study included term patients. The gestational age in our study and in the above mentioned articles are comparable.

Pakhee Aggarwal,<sup>[3]</sup> in her study of 104 primigravidae had evaluated the role of Hyoscine butyl bromide as a labor analgesic. She has used Buscopan 40mg as slow intravenous injection at 3cm dilatation. The injection to delivery interval was between 2-4 hours in the buscopan group with a mean of 3 hr 46 min. Maximum primigravidae in the control group delivered between 8-10 hours, mean of 8 hr 16 min. The labor was shortened by 4 hr 30 min, which was significant

Tehalia Manpreet K, Sajjan Gouramba R, Korbu Jyothi, Venkatesh S, Biradar R,<sup>[6]</sup> have studied the efficacy of hyoscine butylbromide with drotaverine hydrochloride for increasing the rate of cervical dilatation in first stage of labor. The study was conducted on 100 women in labor, who were randomly allocated to Group A or Group B. The women in Group A were injected drotaverine 40mg (one ampoule) intravenously at 3-5cm dilatation, if admitted in latent labor or at first examination if already more than 5 cm dilatation. The women in group B were injected one ampoule of hyoscine butylbromide 20 mg. The average time taken from time of injection of antispasmodic to the full cervical dilatation of cervix in nulliparas with baseline dilatation <5cm in group A was 103.45 minutes and in group B was 59.88 minutes while with baseline dilatation >5 cm it was 115.38 minutes in group A and 66.67 minutes in group B. In multiparas with baseline dilatation <5cm, the time to full dilatation in group A was 117.09 minutes and in group B it was 60.48 minutes while with baseline dilatation >5 cm, the average time to full dilatation was 104.53 minutes in group A and 61.22 minutes in group B. The difference

was statistically significant when it was applied to the figures. The rate of cervical dilatation in the nulliparas with baseline cervical dilatation <5 cm in group A was 2.9 cm/hour and in group B it was 5.06 cm/hour (P<0.007). With cervix >5cm dilatation, the average rate in group A was 2.6 cm/hour and in group B it was 4.5 cm/hour. In multiparas, the rate with cervix <5cm dilated in group A was 2.56 cm/hour and in group B it was 4.97 cm/hour while with baseline dilatation >5 cm/hour, in group A it was 2.87 cm/hour and in group B 4.94 cm/hour. The differences in durations of second and third stages were statistically insignificant. The differences in the amount of blood loss in the third stage of labor in the two groups were also statistically insignificant.

Tewari K,<sup>[7]</sup> in their study compared hyoscine butylbromide with valethamate bromide. They had given buscopan in two divided doses 20 min apart. The duration of labor was shortened by 5 hr and 12 min when compared to the controls. In our study the duration of labor was shortened by 46.4 min in primigravidae and 32.4 min in multigravidae when compared to controls. This was statistically significant in both the groups.

Samuels LA,<sup>[4]</sup> selected a total of 129 women's data for analysis. Of these, 69 women received the placebo and 60 received hyoscine butylbromide. The mean time for the first stage in the control group was 228 minutes, compared with 156 minutes in the drug group, representing a decrease of 31.7%. There was no significant change in the duration of the second and third stages of labour, and no difference in blood loss or in APGAR scores. There was a slight (but statistically insignificant) increase in the caesarean section rate. They concluded that Hyoscine butylbromide is effective in significantly reducing the duration of the first stage of labor, and it is not associated with any obvious adverse outcomes in mother or neonate.

Sirohiwal D,<sup>[5]</sup> conducted a non-randomized controlled prospective study in 200 women in labor. In the active phase of labour, at 3 cm or more cervical dilatation, 100 women were administered Buscopan via suppository and 100 women (control) were not given any drug. He found out that the duration of first stage of labour was 123.86+/-68.89 (mean(+)-standard deviation) minutes in the study group and 368.05 +/-133.0 min in the control group. These differences were statistically significant.

Gupta B,<sup>[8]</sup> compared the efficacy and side effects of drotaverine hydrochloride and hyoscine-N-butylbromide in the augmentation of labor. She conducted a prospective randomized trial of 150 women in active labor, which included 50 women given drotaverine (group 1), 50 women given hyoscine-N-butylbromide (group 2), and 50 women given no medication (group 3). The duration of labor, rate of cervical dilation, mode of delivery, side effects, and neonatal outcome were compared among the groups.

The authors concluded that drotaverine and hyoscine butylbromide have no effect on augmentation of labor.

In our study, the mean duration of labor in primigravida in buscopan group was 170.3 min compared to 216.7 min in the control group. The rate of cervical dilatation was 2.46 cm/h in the hyoscine butylbromide group, whereas it was 1.93 cm/h in the controls. The difference was statistically significant with  $p = 0.011$ . The mean duration of labor in the multigravida was 120.9 min compared to 153.3 min in the control group. The rate of cervical dilatation was 3.47 cm/h in the hyoscine butylbromide group, whereas it was 2.73 cm/h in the controls. The difference was statistically significant with  $p = 0.003$ . Thus hyoscine butyl bromide is effective in shortening the first stage of labor in both the primigravidae and in multigravidae patients. There was no statistically significant difference between the duration second and third stage of labor in the two groups both in primigravidae and multigravidae. There were no observed side effects in the neonate in the control and the hyoscine butyl bromide group. APGAR scores in both the groups were comparable in primigravidae and in multigravidae. Tachycardia was observed in 4 mothers in hyoscine butyl bromide (buscopan) group. However, it was not significant when compared to the control group (2 patients).

### **Conclusion**

Hyoscine butylbromide is an effective cervical dilator. It shortens the duration of active phase of first stage of labor. The rate of cervical dilatation is faster in multigravida patients as compared to primigravida. It is a safe drug with no fetal side effects or any significant maternal side effects.

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**Conflict of Interest:** None

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