



THE EFFICACY OF HYOSCINE BUTYLBROMIDE IN THE AUGMENTATION OF LABOUR

Gynaecology

**Dr. Sameena
Ashraf**

MD Department of Obstetrics and Gynaecology, Lal Ded Hospital, Government Medical College, Srinagar

ABSTRACT

Objective: The aim of this study was to determine whether Hyoscine butylbromide shortens the first stage of labor, without an increase in maternal or neonatal complications. **Method:** Three hundred pregnant women with full term pregnancies in active labor were selected by simple randomization and were divided into two groups having 150 cases each. Group A where Hyoscine butylbromide 10 mg rectal suppository was instilled and group B where no drug was given.

Results: The mean duration of first stage of labor was 159.3 min and 299.0 min in groups A and B, respectively. Rate of cervical dilatation in groups A and B was 2.9 cm/hr and 2.0 cm/hr respectively. There was no significant change in the duration of the second and third stages of labor, and no difference was noted in the mean APGAR scores. Most of them delivered vaginally. There were no statistically significant differences in the rates of caesarean section and instrumental delivery between the two groups.

Conclusion: We concluded that Hyoscine butylbromide significantly reduces the duration of the first stage of labor, without an increase in maternal or neonatal complications.

KEYWORDS

Hyoscine butylbromide, first stage of labor, cervical dilatation.

Introduction

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. There is an increased incidence of maternal distress, postpartum hemorrhage and sepsis.^{1,2} The fetus is exposed to a higher risk of infection and asphyxia.^{1,2} There is also an increased incidence of medical intervention. Thus it is logical to reduce the duration of labor with minimal complications to both the mother and the baby.

Active management of labor, as conceptualized by Prof. O' Driscoll,¹ has been widely accepted in clinical practice by obstetrician all over the world and has been shown to be beneficial.^{1,4} Its aim is to reduce the duration of labor. Amniotomy, with the judicious use of oxytocin, has been shown to be beneficial in augmenting labor. Various other methods have also been used to augment labor and have been evaluated in studies. Various medications have been used to shorten the duration of labor in many hospitals all over the world. One such drug is Hyoscine butylbromide.

Hyoscine butylbromide is a quaternary ammonium derivative which exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary and genitourinary tracts.⁵ It acts primarily by blocking the transmission of neural impulses in the parasympathetic ganglia of abdominal organs.⁶ After intravenous administration the substance is rapidly distributed ($t_{1/2} = 29$ minutes) into the tissues.⁵ It does not pass the blood brain barrier, and plasma protein binding is low; approximately half the clearance is renal and the main metabolites found in urine have no significant clinical action.⁵ Hyoscine butylbromide has been used to shorten the duration of labor. The mechanism by which it acts in the context of labor has not yet been elucidated and the evidence for its efficacy was previously largely anecdotal. The specific objective of this study is to assess whether Hyoscine butylbromide is effective in hastening cervical effacement and dilatation, thus shortening the duration of the first stage of labor without an increase in the fetomaternal complications.

Methods

It was a randomized, prospective study carried out at Lal Ded Hospital, an associated hospital of Government Medical College, Srinagar from Jan 2009 to Jan 2010. Total of 300 pregnant women with term gestation, in active labor were chosen by simple randomization from the admissions to the labor ward for the administration of drugs and written informed consent for the same was taken. The patients were divided into 2 groups, each having 150 cases. Group A (received Hyoscine butylbromide rectal suppository) and group B (received no drug). Following inclusion and exclusion criteria were considered for selection of the uncomplicated patients.

Inclusion criteria: Primigravida and multigravida, age between 18-

30 year, intact fetal membranes with vertex presentation, 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, no evidence of maternal or fetal distress.

Exclusion criteria: 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 antihypertensive therapy, if any other spasmolytic agent had been used within 48 hours.

On entry into the study a detailed history of the subjects was taken. A thorough general and systemic examination was done. Per abdomen examination was done to note height of the uterus, presentation, frequency and intensity of contractions. Fetal well-being was monitored by noting the rate, rhythm and regularity of fetal heart sounds. By per vaginum examination cervical dilatation, effacement and consistency and station of the presenting part were noted. Pelvic assessment was done to exclude any pelvic contraction or cephalopelvic disproportion etc. Per vaginal examination was to be done before giving each dose of the drug or earlier if rupture of membranes occurred or when patients started bearing down. Routine investigations were advised including Hb, BT, CT, blood grouping, blood sugar, HIV, HBSAg and VDRL, urine for routine and microscopic examination.

The drug administration was done 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. In group A 10 mg rectal suppository was put per rectum. The drug was repeated every hour up to a maximum three doses. In group B no drug was given and represented the control group.

All women were monitored for pulse, temperature, respiratory rate, blood pressure, fetal 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 for obstetric indications. Following parameters were recorded in every patient –

1. Duration of first, second and third stages of labor.
2. Rate of cervical dilatation
3. Mode of delivery
4. Neonatal condition at birth.
5. Maternal complications
6. Side effects

Statistical Analysis:

Parametric data was expressed as mean $\pm$ SD, thereby the inter group comparisons were made by student's t-test and ANOVA. The non-

parametric data was represented in percentage, thereby the inter group comparisons were made by Mann-Whitney U test and Kruskal Wallis test. Significance was checked at 95% CI. SPSS 19.0 software was used for data analysis.

RESULTS

Table I shows demographic characteristics of the women in Hyoscine butylbromide and Control groups. There was no statistical difference in the two groups in age, gestational age, parity and cervical dilatation at admission.

Table I. Demographic characteristics of the women in various groups

Variables	Hyoscine butylbromide N=150	Control N=150	P value
Age (years)	24.8 ± 3.0 (20, 30)	25.0 ± 3.3 (20, 30)	0.608
Gestational age (weeks)	38.5 ± 1.1 (37, 40)	38.5 ± 1.1 (37, 40)	0.876
Primigravida N (%)	59 (39.3%)	57 (38%)	0.813
Multigravida N (%)	91 (60.7%)	93 (62%)	
Initial cervical dilatation (cm)	3.6 ± 0.5 (3, 4)	3.5 ± 0.5 (3, 4)	0.165

Values are expressed as mean ± standard deviation (maximum, minimum)

As shown in Table II, the duration of first stage of labor (159.3 ± 40.9 min) in the Hyoscine butylbromide group was statistically lower than the control group (299.0 ± 86.0 min). The difference in the duration of second and third stages of labor in the two groups was not statistically significant. The cervical dilatation rate, as shown in Table II, was statistically higher in the Hyoscine butylbromide group (2.9 ± 1.2 cm/h), compared to the control group (2.0 ± 0.8 cm/h). As far as the mode of delivery is concerned, most of the patients delivered vaginally, seven women had instrumental vaginal delivery in each group for fetal distress. Caesarean section was done on five in Hyoscine butylbromide group and eight women in control group, the indications being arrest of labor and fetal distress.

Table II Labor characteristics of the women in various groups

Variables	Hyoscine butylbromide(N=150)	Control (N=150)	P Value
Mean total duration of labor (min)	191.2 ± 42.5 (118, 274)	332.5 ± 88.1 (163, 503)	0.001
Mean duration of first stage of labor (min)	159.3 ± 40.9 (90, 228)	299.0 ± 86.0 (146, 445)	0.001
Mean duration of second stage of labor (min)	24.9 ± 11.3 (6, 44)	26.8 ± 13.1 (5, 50)	0.210
Mean duration of third stage of labor (min)	7.0 ± 1.9 (4, 10)	6.7 ± 1.9 (4, 10)	0.148
Rate of cervical dilatation (cm/hr)	2.9 ± 1.2 (2, 8)	2.0 ± 0.8 (2, 6)	0.001
Mode of delivery N (%)			
Vaginal delivery	138 (92%)	135 (90%)	
Instrumental delivery	7 (4.7%)	7 (4.7%)	0.528
Caesarean Section	5 (3.3%)	8 (5.3%)	

Values are expressed as mean ± standard deviation (maximum, minimum)

As shown in Table III no significant adverse effects were noted in the group of women receiving Hyoscine butylbromide, compared with the control group and the maternal and fetal complications seen in the two groups were also not significantly different in these groups.

Table III: Side Effects of drugs and Complications found in women in two groups

Variables	Hyoscine Butylbromide N=150(%)	Control N=150 (%)	P value
Maternal Tachycardia	1 (0.7)	–	0.317
Foetal Tachycardia	3 (2.0)	1 (0.7)	0.315
Dryness of Mouth	3 (2.0)	2 (1.3)	0.653
Nausea/Vomiting	2 (1.3)	–	0.157
Flushing	2 (1.3)	1 (0.7)	0.001
Foetal Distress	8 (5.3)	11 (7.3)	0.644
Birth Asphyxia	2 (1.3)	1 (0.7)	0.562
Meconium	2 (1.3)	2 (1.3)	1.000
Prolonged Second Stage of labour	6 (4.0)	4 (2.7)	0.521
Vaginal Tear	1 (0.7)	2 (1.3)	0.562

Values are expressed as mean ± standard deviation (maximum, minimum)

As shown in Table IV, the birth weight of neonates was not statistically different in two groups and there was also no difference in the APGAR scores noted at 1 and 5 minutes in the two groups.

Table IV: Neonatal outcome of women in various groups

Variables	Hyoscine butylbromide N=150	Control N=150	P value
Birth weight (kg)	2.9 ± 0.4 (2.2, 3.6)	2.9 ± 0.4 (2.2, 3.7)	0.550
Apgar score at 1min	7.0 ± 0.8 (6, 8)	7.0 ± 0.8 (6, 8)	0.624
Apgar score at 5min	9.1 ± 0.9 (8, 10)	9.2 ± 0.9 (8, 10)	0.696

Values are expressed as mean ± standard deviation (maximum, minimum)

DISCUSSION

In active management of labor along with good uterine contraction, simultaneous cervical dilatation and softening are required. But in spite of good uterine contractions, the cervical dilatation may be hampered due to inhibitory impulse in the form of spasm. In such cases antispasmodics help in the dilatation of cervix. Various drugs have been used so far to obtain effective dilatation of the internal os, majority of them were found to have its effect on the fetus and mother. Modern Obstetricians are now in search of new drugs, which have got the sole beneficiary effect on the dilatation of the internal os with minimal maternofetal side effects.

Hyoscine butylbromide, a smooth muscle relaxant, can be used as rectal suppository for cervical dilatation. It has been used to shorten the duration of labor. In this study we used Hyoscine butylbromide in the active phase of labor to see whether it is effective in hastening cervical dilatation, thus shortening the duration of the first stage of labor. Our study has demonstrated that Hyoscine butylbromide causes a significant reduction in the first stage of labor. However, we also demonstrated that there was no statistical difference in the times for the second and third stages of labor, implying that the action of Hyoscine butylbromide is primarily on the cervix, and not so much on promotion of uterine activity. This is important, as it obviates the concern regarding an excessively rapid second stage, which can predispose to both maternal complications (such as an increased risk for lacerations, particularly in the primigravida) and neonatal complications (such as that of intracranial hemorrhage, due to rapid, uncontrolled decompression of the fetal head at delivery). This suggests that there is no adverse effect on the contractile power of the uterus in the postpartum period. The advantage of rectal route is rapid onset of action and by pass of hepatic metabolism. Many authors reported almost similar reduction in duration of labor with hyoscine butylbromide.

Samal *et al* reported in a study shortening of labor by two hours 42 minutes with 88% women delivering within eight hours on administration of Hyoscine butylbromide at active labor. Neonatal

outcomes were similar in two groups.⁷ K. Tewari *et al* were the first to use a dose of 40 mg intravenously of Hyoscine butylbromide, but in two divided dose 20 minutes apart and found labor to be shortened by 5 hours 12 minutes as compared with controls.⁸ Sirohiwal D *et al* observed that Hyoscine butylbromide suppositories were highly effective in shortening the duration of the first stage of labour without increasing any fetomaternal adverse effect.⁶ LA Samuels *et al* reported in a study shortening of first stage of labor by 32%, without any adverse effect on mother or neonate, with 20 mg intravenous dose.⁹ Pakhee Aggarwal *et al* found in a similar study found that Hyoscine butylbromide shortened the duration of active phase of labor by 4 hours 30 minutes as compared with the controls.¹⁰ Leila Sekhavat *et al* also found Hyoscine butylbromide to be highly effective in reducing duration of first stage of labour without causing any obvious adverse effect on mother or fetus.¹¹

There was no adverse effect on mother and fetus. The average APGAR scores for the infants were identical in both groups. This suggests that there were no clinically significant effects on the neonate in any of the major organ systems. Hyoscine butylbromide did not statistically increase the incidence of cesarean delivery. Since the sample size is small and period of study short, many outcomes like fetal heart rate abnormalities, long term neurodevelopmental outcomes, maternal side effects may not have surfaced which may be better evaluated in larger well designed double blind control studies.

Conclusion

Based on the results of our study, and noting the supportive data from similar clinical trials, we conclude that hyoscine butylbromide is effective in significantly reducing the duration of the first stage of labor and that it is not associated with any obvious adverse outcomes in mother or neonate. Further long-term evaluation will be necessary to fully evaluate the scope of benefits that this reduction in labor may confer.

REFERENCES

1. O'Driscoll K *et al*. Active management of labour. *Br Med J*. 1973; 3:135–137
2. Socol M, Peaceman AM. Active management of labour. *Obstet Gynaecol Clin North Am* 1999; 26(2):287–294.
3. Sadler LC, Davison T, McCowan LM. A randomized controlled trial and meta-analysis of active management of labour. *BJOG*. 2000; 107(7):909–915.
4. Drug Information: Buscopan®. Ingelheim, Germany: Boehringer Ingelheim Limited. Revised December 2005.
5. Hotwani J, Ainapure SS. Hyoscine Butylbromide suppositories. *Indian Medical Gaz*. 2000; 217–9.
6. Sirohiwal D, Dahiya K. Efficacy of hyoscine-N-butyl bromide (Buscopan) suppositories as a cervical spasmolytic agent in labour. *Aust N Z J Obstet Gynaecol* 2005; 45:128–9.
7. Samal S, Gupta U, Wable M. Buscopan (Hyoscine Butyl Bromide) in acceleration of labour. *Indian Med Gaz* 1998; 132: 8–10.
8. Kamlesh Tiwari, Roshan Jabeen, NA Sabzposh, Jam Kin Rabbani: Comparison of Hyoscine N – butyl bromide and Valethamate bromide in shortening the duration of labour. *Indian Med Gaz* 2003 Jan; 137:15–19.
9. Samuels LA, Christie L, Roberts-Gitten B, Fletcher H, Frederick J. The effect of hyoscine butylbromide on the first stage of labor in term pregnancy. *Br J Obstet Gynecol* 2007; 114:1542–6.
10. Pakhee Aggarwal, Vijay Zutshi, Swaraj Batra. Role of Hyoscine N-Butyl Bromide (HBB, Buscopan) as labor analgesic. *Ind J of Med Sci* 2008; 62:179–84.
11. Leila Sekhavat, Sedighah Akhavan Karbasi. The effect of hyoscine butylbromide on the first stage of labor in multiparous women. *NJOG* 2009; 4 (2): 40–43.