

The Effect of Hyoscine Butylbromide on the First Stage of Labor in Multiparous Women

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Abstract

Objective: To determine whether hyoscine butylbromide shortens the first stage of labor, without an increase in maternal or neonatal complications.

Method: A prospective randomized study conducted on 188 multiparas who were in active phase of labor. 94 women were administered hyoscine butylbromide 1ml

(20mg) IV once (study group) and 94 women were administered 1ml normal saline in the same way (control group). The duration of the first and second stage of labor, and APGAR scores in the neonate's compared between the two groups.

Results: The mean duration of first stage of labor was 131.5 ± 88.9 minutes in the study group and 418.4 ± 94.1 minutes in the control group ($P = 0.00$). These differences were statistically significant. There was no significant change in the duration of the second stage of labor or cesarean section rate. APGAR scores in the neonate's were the same in two groups.

Conclusion: Injection of Hyoscine butylbromide in active phase of labor can be effective in shortening the duration of the first stage of labor without any adverse effect on mother and fetus.

Keywords: Hyoscine butylbromide, cervix dilatation, first stage of labor, second stage of labor.

Introduction

Attempts to augment labor and shorten its duration are beneficial for both mother and fetus. Active management of labor is described as a policy to reduce the rate of prolonged labor.¹ The two major factors that determine duration of labor are uterine contractility and rate of cervical dilation

In addition to mechanical factors such as sweeping membranes, cervical stretching,² and amniotomy,³ various pharmacological agents have been found to facilitate cervical dilation. The role of oxytocin and prostaglandins has been established worldwide in the augmentation of labor,⁴ and the cervical application of hyaluronidase has also been used with some success.⁵

Spasmolytic drugs are frequently employed to overcome cervical spasm and thus reduce the duration of labor. One of these spasmolytics is hyoscine butylbromide which has been used to shorten the duration of labor.⁶ Hyoscine butylbromide acts primarily by blocking the transmission of neural impulses in the intraneural parasympathetic ganglia of abdominal organs, apparently inhibiting the cholinergic transmission in the synapses.⁷ After intravenous administration, the substance is rapidly distributed ($t_{1/2} = 29$ minutes) into the tissues. Hyoscine butylbromide 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 bind have no significant clinical action.⁸ It exerts a spasmolytic action on the smooth muscles of the

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gastrointestinal tract, biliary and genitourinary tracts.⁹ 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. We also intend to determine whether the use of hyoscine butylbromide in the first stage of labor has any associated increase in complications, such as rate of caesarean deliveries, or a decrease in neonatal APGAR scores.

Methods

This prospective study, carried out on 188 full term multiparous pregnant women between 38 and 41 weeks of gestation admitted in active phase of labor (cervical dilatation 3-4cm), was designed to evaluate the efficacy of hyoscine butylbromide (Buscopan) in the first stage of labor. Sample sizes for the control and study groups were calculated using previous studies as a guide, with the formula: $d = \frac{t}{SD}$, where d = standardized difference, t = smallest clinically significant difference and SD = standard deviation of the test group. We determined that we would need 85 women in each arm for a power of 95%, using an alpha value of 0.05.

All the patients were referred to Shahid Sadoughi hospital in Yazd; from October 2006 to April 2007. The adopted protocol was approved by the hospital research and ethics committee. All women were interviewed individually by the researcher. Written informed consent was obtained from all the patients. The questionnaires were filled out for each patient at the beginning of the study. Questionnaire included several items such as maternal age, education, gestation age, prenatal care situation, number of gravida and para, dilatation and effacement of cervix, length of labor, mode of delivery, maternal complication and neonatal condition at birth and its APGAR.

Women with normal singleton pregnancies at 38-41 weeks' of gestation with vertex presentation, intact membranes and spontaneous onset of labor were included in the study. Those with chronic or pregnancy-induced illnesses, any contraindication to vaginal delivery, ante-partum hemorrhage; twin pregnancy and grand multiparty were excluded from the study. An informed consent will be taken from the patients then all women will be submitted to history taking, general and vaginal examination to detect inclusion and exclusion criteria, then women with cervical dilatation 3-4 cm will be included in the study. Established labor was defined as the presence of regular uterine contractions associated with progressive cervical effacement and dilatation. Then 94 women will be

injected by 1ml (20mg) hyoscine butylbromide and 94 women will be injected by 1ml normal saline (placebo) on admission to labor delivery ward.

Each syringe contained either 1 ml of hyoscine butylbromide (20 mg) or 1 ml of normal saline was prepared under aseptic conditions and as additional participant was enrolled (Both liquids are colorless, so the syringes containing the drug were indistinguishable from those containing placebo). A computer program was used to generate a random sequence of numbers. Sequentially numbered, sterile syringes were then prepared using the random numbers to determine their content. Only the principal investigator knew the correlation between the labels of the syringes and their contents, and this was only showed after the study was completed. Participants received the contents of a syringe as a single dose, given intravenously. The woman and the caregivers were blinded as to whether the active hyoscine butylbromide or saline normal was being administered. The progress of the participants was closely documented, with the conduct of labor for both the hyoscine and normal saline groups in accordance with our normal labor ward protocol, which is based on the principle of active management. Thus, artificial amniotomy was performed for all women who were found to have cervical dilatation of 4 cm or more, and who had not had spontaneous rupture of membranes. Oxytocin infusion may be used if the uterine contractions are not efficient. External fetal monitoring was done for all fetuses. Total duration of labor, mode of delivery, maternal complication and neonatal condition at birth and APGAR were recorded.

The data were then analyzed using the SPSS version 11.5 by student's t-test. P value < 0.05 was statistically significant.

Results

Table 1. shows Demographic characteristics of the women in hyoscine and normal saline groups. Two groups were similar in age, parity, gestational age and cervical dilatation at admission.

The first stage of labor in hyoscine group (study group) was 186.8 ± 125.6 min and 260.4 ± 120.9 min in normal saline group (control group). This difference was statistically significant (P value = 0.00). There was significantly difference between cervical dilatation rate in hyoscine and normal saline groups (1.9 ± 0.8 cm/h and 2.8 ± 0.7 cm/h respectively P value = 0.000). Second stage of labor in hyoscine group was slightly shorter than normal saline group (20.0 ± 8.1 min and 25.8 ± 9.4 min respectively P value = 0.03). There was no statistical significant difference in the third stages of labor in the two groups (Table 2). The mode of delivery was

Table 1. Demographic characteristics of the women in hyoscine and normal saline groups

Variables	Hyoscine (n = 94)	Normal saline (n = 94)	P value
Age (years)(mean ± SD)	26.1 ± 5.4	26.9 ± 4.8	0.5
Parity (median)	3	3	1
Gestational age (weeks)(mean ± SD)	38.4 ± 1.9	38.8 ± 1.5	0.4
Dilation at admission (cm)(mean ± SD)	3.9 ± 0.9	4.1 ± 0.8	0.1
Artificial rupture of membranes N (%)	72 (76.6)	77 (81.9)	0.09
Oxytocin augmentationN (%)	40 (42.6)	51 (54.3)	0.04

Table 2. Labor characteristics of the women in hyoscine and normal saline groups

Variables	Hyoscine (n = 94)	Normal saline (n = 94)	P value
Rate of cervical dilation (cm/h)(mean ± SD)	2.8 ± 0.7	1.9 ± 0.8	0.00
First stage time (minutes)(mean ± SD)	186.8 ± 125.6	260.4 ± 120.9	0.00
Second stage time (minutes)(mean ± SD)	20.0 ± 8.1	25.8 ± 9.4	0.03
Third stage time (minutes)(mean ± SD)	5.4 ± 1.2	6.1 ± 2.0	0.1
Mode of deliveryN (%)VaginalCesarean section	81 (86.2)13 (13.8)	76 (80.9)18 (19.1)	0.06

Table 3. Neonatal outcome in hyoscine and normal saline groups

Variables	Hyoscine(n = 94)	Normal saline(n = 94)	P value
Apgar score at 5 min(mean ± SD)	7.8 ± 1.2	8.1 ± 0.9	0.1
Apgar score at 1 min(mean ± SD)	8.4 ± 1.6	8.1 ± 1.8	0.2
Need to resuscitation(N (%))	2 (2.1)	1 (1.1)	0.8
NICU admission(N (%))	1 (1.1)	1 (1.1)	1

cesarean section in 13 women of hyoscine group and 18 women of normal saline group due to arrest of labor (P value = 0.06). There was also no difference in the APGAR scores noted at 1 and 5 minutes in the two groups. Out of 188 neonates, 2 babies in the hyoscine group and one baby in the normal saline group needed to resuscitation; and one babies of each group admitted in NICU. These babies were kept in a nursery under observation for 36 h and were discharged in good condition. The drug was well tolerated by all patients and no adverse effect was noted.

Discussion

The process of labor puts great strain on the mother and her fetus. Acceleration of labor to shorten its duration without adverse events for mother and fetus condition would therefore minimize the maternal and fetal morbidity and mortality.¹⁰ Hyoscine butylbromide has been used to shorten the duration of labor. Whereas its analgesic properties are probably negligible in the context of labor, its value lies in the reduced time spent in the first stage, and consequently the reduced overall time spent in pain by the laboring mother.⁸

In this study we used Hyoscine butylbromide at the active phase of labor to intend whether hyoscine

butylbromide is effective in hastening cervical effacement and dilatation, thus shortening the duration of the first stage of labor. We studied on multiparus women because they have at least an experience of normal vaginal labor and excluded women with repeated cesarean section. Our study has shown that hyoscine butylbromide causes a significant reduction in the first and second stage of labor. This result implying that the action of hyoscine butylbromide is primary 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) and neonatal complications (such as intracranial hemorrhage, due to rapid, uncontrolled decompression of the fetal head at delivery). In the present study the mean rate of cervical dilatation was 2.8 ± 0.7m/h in hyoscine group in compare to 1.9 ± 0.8 in normal saline group. This result was reported in other study.⁶

Many authors reported an almost 40–50% reduction in duration of labor with hyoscine butylbromide.^{6, 9, 11} These results are in contrast to those reported by Al Dohami, who stated that hyoscine butylbromide is a muscarinic antagonist that acts as a cervical

spasmolytic agent. The present study did not show any effect on either the duration of the active phase of labor or the rate of cervical dilatation.¹² There was no effect on the duration of the third stage of labor by hyoscine butylbromide in this study.

There is no adverse effect on mother and fetus (i.g. the contractile ability of the uterus in the postpartum period).; qqqqAnd this might be theoretically deduced based on anti-parasympathetic pharmacological actions of hyoscine butylbromide. 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. Although the study was not sufficiently powered for the absolute exclusion of fetal/neonatal adverse effects, the initial examination of each infant, on which the APGAR scores were based, showed no discernible difference in the infants of the hyoscine butylbromide group compared with the normal saline group.

Conclusion

Based on the results of our study, we conclude that hyoscine butylbromide is effective in significantly reducing the duration of the first and second stage of labor and that it is not associated with any obvious adverse outcomes in mother or neonate.

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