Effect of hyoscine butylbromide first stage of labour in multiparus women

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Abstract

Background: Prolonged labor is one of the most important risk factors for perinatal compromise and, if caused by obstructed labor, it carries the risk of uterine rupture, postpartum hemorrhage (PPH), puerperal sepsis, and maternal death.
Objective: To determine whether or not hyoscine butylbromide shortens the stages of labor, without an increase in maternal or neonatal complications.
Method: In single-blinded randomized clinical trial study , 188 multiparas women in active phase of labor who were admitted to Shahid Sadoughi Hospital from October 2006 to April 2007 in Yazd - Iran , were evaluated . They were divided hyoscine group (n = 94) received 20mg (1ml) of hyoscine and control group (n = 94) received 1 ml of normal saline was given as placebo, intravenously. The effects of hyoscine in shortening labor time; and neonatal Apgar score was compared.
Results: Duration of the first (mean± SD: 186.8 ± 125.6 minutes vs. 260.4 ± 120.9 minutes, p= 0.00 1) and second stage of labor (mean± SD: 20.0 ± 8.1minutes vs. 25.8 ± 9.4 minutes, p= 0.03) was shorter in hyoscine group.
Frequency of cesarean section and mean of neonatal Apgar score at minutes of one and 5 were not different in both groups. No serious adverse events were seen in the two groups.
Conclusion: Injection of hyoscine in active phase of labor can be effective in shortening of labor without any adverse effect on mother and fetus.
Keywords: Hyoscine butylbromide, first stage of labor, cervical dilatation, Second stage of labor
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Introduction

Attempt to shorten labor time for both mother and fetus are useful. Active management of labor was introduced in1960s as a method to prevent prolonged labor.[1]. Prolonged labor is one of the most important risk factors for perinatal compromise and, if caused by obstructed labor, it carries the risk of uterine rupture, postpartum hemorrhage (PPH), puerperal sepsis, and maternal death.[2]
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 of membranes, cervical stretching[3] and amniotomy, [4] various pharmacological agents have been found to facilitate cervical dilation. The role of oxytocin and prostaglandins has been established worldwide in augmentation of labor[5] and the cervical application of hyaluronidase has also been used with some success.[6]

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.[7] 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. [8] After intravenous administration, the substance is rapidly distributed (t1/2= 29 minutes) into the tissues. Hyoscine butylbromide does not pass the blood–brain barrier, and plasma protein binding is low; approximately half of the clearance is renal, and the main metabolites found in urine bind have no significant clinical action. [9] It exerts a spasmolytic action on the smooth muscles of the gastrointestinal tract, biliary and genitourinary tracts. [10] 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.

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The specific objective of this study is to assess whether hyoscine butylbromideis effective in hastening cervical effacement and dilatation and thus in shortening the duration of the first stage of labor. We also intend to determine side effects of hyoscine butylbromide in first stage of labor such as rate of caesarean deliveries, or a decrease in neonatal Apgar score.

Methods

A single-blinded randomized clinical trial study was assessed on multiparous pregnant in active phase of labor who were admitted to Shahid Sadoughi Hospital -Yazd -Iran from October 2006 to April 2007 to determine efficacy of hyoscine butylbromide (Buscopan) in the first stage of labor. Sample size was calculated based on previous researches and formula: d =Ä/SD (d = standardized difference, Ä= smallest clinically significant difference and SD = standard deviation of the test group) and confidence interval of 95% with 80% power and type one error (alpha) of 0.05, with 85 women assessed per group. This is a university hospital that representative of the general population and 2000 – 2500 deliveries per year are occurred in it.

The women who have a normal singleton term (gestational age = 37-42 weeks) fetus with vertex presentation and normal labor (started spontaneously and presence of regular uterine contractions), be in active phase of labor (cervical dilatation of 3-4cm) and intact membrane were included; and the women with chronic or pregnancy-induced illnesses, any contraindication to vaginal delivery, ante- partum hemorrhage; multiple pregnancies, previous cesarean section and high parity (more than four) were excluded.

The trial used equal randomization and allocation ratio was 1:1 for the two groups.

Simple randomisation was done by a computer generated random number list prepared by an investigator with no clinical involvement in the trial and no restriction was exerted. All women were interviewed individually by the researcher and she had obtained their consent of the recruitment process for allocation consignment at the admission time.

Although the women and physicians specified to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation.

After the admission in labor ward, the women were divided into two groups and they received content of a syringe with 1 milliliter of colorless liquid under aseptic conditions. In hyoscine butylbromide group, 1 milliliter (20mg) of hyoscine butylbromide and in control group, 1 milliliter of normal saline as placebo was injected intravenously.

The progress of labor in 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 whom were found to have cervical dilatation of 4 cm or more, and who had not had spontaneous rupture of membranes. Oxytocin may be infused if the uterine contractions are not efficient. External fetal monitoring was done for all fetuses.

The primary outcomes were total duration of first, second and third stages of labor and cervical dilatation rate. Secondary outcomes were delivery route, clinical side effects and neonatal Apgar score at minutes one and 5 at birth.

The data were analyzed using SPSS: 13 statistical software. Chi-square, Fisher and T student tests used for data analysis. Differences were considered significant at P values of less than 0.05.

This study has been approved by the ethic committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran. The researchers did not get any support from the drugs company.

The design and conduct of this trial was straightforward, and we did not have any losses to follow-up or exclusions

Result

One hundred eighty eight women (94 in each group) with mean age of 27.3 ± 3.4 years were evaluated. The drug has not any adverse effect. Comparison of some characteristics of the women is shown in table 1 which indicates that mean of age, gestational age and cervical dilatation at admission time and parity number were the same inboth groups. Cesarean section due to arrest of labor was performed in 13 women in hyoscine group and in 18 of them in normal saline group ($p = 0.06$).

Comparison of labor characteristics is shown in table 2 which indicates that duration of the first and second stages of labor was shorter in hyoscine group and cervical dilatation rate (in centimeter per hour) was higher in hyoscine group. However, the duration of third stages of labor and rout of delivery were the same in two groups.

Table 1: Comparison of some characteristics of women in both groups

Data	Hyoscine (n = 94)	Normal saline (n = 94)	P value
Age in years (mean ± SD)	26.1 ± 5.4	26.9 ± 4.8	0.5
Mean of parity number	3	3	1
Gestational age in weeks (mean ± SD)	38.4 ± 1.9	38.8 ± 1.5	0.4
Cervical dilation in admission time in centimeter (mean ± SD)	3.9 ± 0.9	4.1 ± 0.8	0.1
Manual rupture of membranes (%)	72 (76.6)	77 (81.9)	0.09
Labor augmentation with oxytocin (%)	40 (42.6)	51 (54.3)	0.04

Table 2: Comparison of labor characteristics in both groups

Data		Hyoscine (n = 94)	Normal saline (n = 94)	P value
Cervical dilation rate in centimeter per hour (mean ± SD)		2.8 ± 0.7	1.9 ± 0.8	0.001
Duration of first stage of labor in minute (mean ± SD)		186.8 ± 125.6	260.4 ± 120.9	0.001
Duration of second stage of labor in minute (mean ± SD)		20.0 ± 8.1	25.8 ± 9.4	0.03
Duration of third stage of labor in minute (mean ± SD)		5.4 ± 1.2	6.1 ± 2.0	0.1
Delivery rout	Vaginal	81	76	0.06
	Cesarean section	13	18	

Comparison of neonatal outcome of these mothers in both groups is shown in table3 which indicates that no statistically significant differences were seen in Apgar score at minutes of one and 5 , need to resuscitation and Neonatal intensive care unit (NICU) admission in both groups.

Two babies in the hyoscine group and one in the normal saline group needed to resuscitate, and one baby of each group was admitted in NICU. These babies were kept in a nursery under observation for 36 hours and were discharged in good condition.

Table 3: Comparison of neonatal outcome in hyoscine and normal saline groups

Data	Hyoscine (n = 94)	Normal saline (n = 94)	P. value
Apgar score at five minutes (mean ± SD)	7.8 ± 1.2	8.1 ± 0.9	0.1
Apgar score at one minute (mean ± SD)	8.4 ± 1.6	8.1 ± 1.8	0.2
Need to resuscitation	2	1	0.8
NICU admission	1	1	1

Discussion

In present study, multiparus women were assessed because they had at least an experience of labor.

In this study, administration of hyoscine butylbromide in active phase of labor led to a significant shortening of the first and second stages of labor and higher cervical dilation rate. The process of labor puts great strain on the mother and her fetus. Shortening of labor duration would therefore minimize maternal and fetal morbidity and mortality[11].

This result implies 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 (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, mean of cervical dilatation rate was 2.8 ± 0.7 centimeter per hour in hyoscine group which is similar to another study by Samuels[7].

Other studies, reported an almost 40–50% reduction in duration of labor with hyoscine butylbromide. [7, 10, 12] 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]. But, Al Dohami stated in a study that hyoscine butylbromide is a muscarinic antagonist that acts as a cervical spasmolytic agent and had not any effect on duration of active phase of labor or cervical dilatation rate[13].

In present study, hyoscine butylbromide had not any effect on duration of the third stage of labor which is in agreement to another study by Al Dohami[13].

In this study, hyoscine butylbromide had not any adverse effect on mother or neonatal Apgar score. It is suggested that further studies be conducted with larger sample sizes and longer follow up periods.

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 stages of labor and that it is not associated with any obvious adverse outcomes in mother or neonate.

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