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Research Article

The Effect of 20 mg Hyoscine Butylbromide on Normal Labor in Iraqi Primi- and Multi-gravida Women

Weqar Akram Hussein Al-Khishali[1], Faris Anwer Rasheed[2], Saad Abdulrahman Hussain[3]*

[1]*Department of Gynecology and Obstetrics, College of Medicine, Al-Nahrain University,Baghdad, Iraq*
[2]*Department of Gynecology and Obstetrics, Al-Kindi College of Medicine, University of Baghdad, Baghdad, Iraq*
[3]*Department of Pharmacology and Toxicology, College of Pharmacy, Unversity of Baghdad, Baghdad, Iraq*
**Corresponding author: saad_alzaidi@yahoo.com*

ABSTRACT

The objective of the current study was to determine whether hyoscinebutylbromide (HBB) shortens first stage of labor in both primi- and multigravida women. A prospective, double blinded, controlled clinical trial carried out in Al-Elwiya Maternity Teaching Hospital, from January to December 2009; 200 primi- and multigravidae were allocated into two groups, the HBB, received 20mg HBB and control group, received 1.0ml of normal saline intravenously once they enter the active phase of labor. Duration of the active phase of the first stage was monitored in addition to comparison with second and third stages, rate of caesarean section, Apgar score and neonatal admission to neonatal intensive care unit**.** HBB shortens the first stage of labor only in primigravidae, with no differences in duration of second and third stages, rate of caesarean section. There was a significant difference in Apgar score at 1.0 min between HBB and control groups in primigravidae, with no increase in the rate of neonatal admission to the neonatal intensive care unit and adverse effects. HBB significantly decreases duration of the first stage of labor only in multigravida women, and not associated with any obvious adverse outcomes on mothers and neonates.

Keywords: Hyoscine butyl bromide, In term pregnancy, Labor management.

1. INTRODUCTION

Active management of labor reduces the number of cesarean deliveries, the number of prolonged labors, and labor duration, without having any adverse effects on the mother or the fetus [1].The safety of active management of labor has been demonstrated by many randomized clinical trials involving thousands of women [2]. A shorter duration of labor from admission to delivery has also been consistently reported in numerous studies that include women treated with the active management protocol [3, 1]. For active management of labor, prospective detection of departure from normal progress is very important, and should be automatically managed by augmenting the powers to accelerate progress, because this was the only variable open to manipulation by the clinician [4]. Intervention with drugs is among the options used through active management of labor; this includes use of analgesics [5], oxytocin [6], prostaglandin derivatives [7] and smooth muscle relaxants [8]. Smooth muscle relaxants are well accepted in progression of labor. Apart from uterine contraction, cervical dilatation is an important factor; which determines the duration of labor. It is the resistant off all driving forces of uterine contraction against passive tissue resistance. Smooth muscle relaxants inhibit impulses in the form of spasm that impairs the effective cervical dilatation. Various agents have been used to combat cervical muscle spasm [9]. Antispasmodics, including Hyoscine butyl bromide (HBB), inhibit cholinergic transmission in the abdominal and pelvic parasympathetic ganglia, with consequent relief of spasm in the smooth muscles of gastrointestinal, biliary, urinary tract and female genital organs, especially the cervico-uterine plexus, and thus aiding cervical dilatation [10,11]; thus they can be used for enhancing cervical ripening and shortening stages of labor [12]. Many studies have been carried out to evaluate the effects of injectable or suppository forms of HBB on cervical dilatation [13, 14]; the results are conflicting, some of these studies demonstrated the efficacy of HBB in augmenting labor, while others showed no effect of HBB on accelerating labor [15,16]. Moreover, the differences between primi- and multigravidae in this respect are not clearly defined. The present study was designed to determine whether HBB shortens the first stage of labor in both primi- and multigravida women with in term pregnancies and the incidence of maternal and neonatal complications.

2. MATERIAL AND METHODS

The study was designed as a double blind, randomized, controlled clinical trial comparing two groups of women:one group received HBB, while the other (control) group received a placebo; the two groups are further subgrouped according to parity state into primi and multigravida. The study was conducted at Al-Elweiya Maternity Teaching Hospital in

Baghdad. The study protocol was approved by the Obstetrics and Gynecology Committee of the Iraqi Board for Medical Specialization and the Local Hospital Ethics Committee; full informed consent was obtained from all participants. Two hundred pregnant women (100 primigravida and 100 multigravida) who completed 37-42 weeks of gestation were randomly selected and included in the study; the progress of labor was assessed, supervised by the specialist on call, for any decision for C/S or if complications occur. The women were allocated into two groups: first group treated with 20mg HBB given as I.V injection, while the second group received 1.0 ml of normal saline and saved as control. The inclusion criteria include: 18 years age and older, singleton pregnancy, from completed 37 wks to completed 42 wks, vertex presentation, established spontaneous labor, and reassured fetal heart rate. The Exclusion criteria include: women with previous uterine scar, fetal malpresentation, cephalopelvic disproportion, ante partum hemorrhage, and chronic or pregnancy induced illnesses. Gestational age was established according to the last normal menstrual period (LMP), or with early pregnancy ultrasound examination when available. Once the patient was admitted in active labor, a history and physical examination was conducted by the attending physician. A partogram was maintained throughout labor and vaginal examinations were conducted and recorded every 2 hours. The drug was given only when the cervix was fully effaced and was dilated to 3-4 cm. The attending physician completed a form detailing the duration of labor during the first, second, and third stages, the mode of delivery, maternal complications, and neonatal conditions at birth (Apgar score).The progress of labor in the participants was closely documented with the conduct of labor for both the drug and the control groups in accordance with our normal labor ward protocol which is based on the principle of active management. Thus amniotomy was performed for women in established labor who were found to have cervical dilatation of 4 cm or more, and those who had no spontaneous rupture of membranes. Oxytocin augmentation was also initiated if the progress of labor (as assessed through a partograph) was unsatisfactory for both groups. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 11 (SPSS Inc., Chicago IL, USA).Descriptive statistics, Student's t-test, Mann-Whitney test, Chi-square and Fisher's exact test (when Chi-square was not applicable) were used to find the significant of associations. Pvalues less than 0.05 were considered statistically significant.

3. RESULTS

Table 1 showed the demographic characteristics of both the main and subgroups, they were comparable with no significant differences among them regarding age, parity, use of oxytocin, artificial rupture of membrane (ARM), and gestational age at delivery (GA). In table 2, only the duration of labor of the first stage in multigravida group was significantly decreased ($P<0.05$) compared with respective control, while no other significant differences were reported among groups ($P>0.05$). Regarding the need for cesarean section, table 3 showed that the need for cesarean section was comparable in all groups and no significant differences were reported in this respect ($P>0.05$).Fetal outcome, represented by Apgar score at 1.0 and 5.0 min, was presented in table 4. Apgar score at 1.0 min of more and less than 7 was reported in 74% and 26% of neonates respectively in HBB treated primigravidae versus 92% and 8% respectively in the control group which was a statistically different ($P<0.05$).No other significant differences were reported in this respect. The data presented in table 5 clearly showed that the need for admission to the NICU was comparable in all groups and no significant differences were reported in this respect. Moreover, regarding the reported adverse effects due to intravenous injection of 20mg HBB, the incidence of adverse effects was comparable in all groups and no significant differences were reported.

Table 1. The distribution of the Prim- and Multi-gravida women in HBB and control groups regarding their demographical characteristics

Parameter	Primgravida		Multigravida	
	Hyoscine n=50	Control n=50	Hyoscine n=50	Control n=50
Age (years) (mean±S.D)	25.9±5.2	25.7±5.5	27.5±5.6	27.02±5.4
Parity	0	0	2.8±1.4	2.6±1.2
With Oxytocin	45	43	22	26
Without Oxytocin	5	7	28	24
With ARM	48	47	41	39
Without ARM	2	3	9	11
GA (weeks) (mean±S.D)	38.1±1.4	38.2±1.3	38.4±1.2	38.2±1.4

ARM= Artificial Rupture of Membrane; GA= Gestational Age at delivery.
No significant differences among groups (P>0.05)

Table 2.Effect of 20mg HBB on the duration of first, second and third stages of labor in Prim and Multi-gravida

Stage of Labor	Duration (min)			
	Primgravida		Multigravida	
	Hyoscin (n=50)	Control (n=50)	Hyoscin (n=50)	Control (n=50)
First stage	167.7±76.2	193.8±58.0	90.1±37.9*	195.6±72.0
Second stage	23.4±10.6	22.6±10.3	10.3±6.7	9.7±4.8
Third stage	11.7±6.7	9.7±5.2	9.98±6.5	9.85±6.8

*Values are expressed as mean±S.D; * significantly different compared to the respective control (P<0.05).*

Table 3.Effect of HBB on theneed forcesarean section in Iraqi primigravidae and multigravidae women during in term labor

Parity type	Need for Cesarean Section			
	Hyoscine Number (%)	Control Number (%)	P value Fisher Exact test	Likelihood Ratio
Primigravida	3 (6)	2 (4)	0.318	0.212
Multigravida	2 (4)	2 (4)	0.382	0
Total	5 (10)	4 (8)	-	-

Table 4.Effect of 20mg HBB on the APGAR scores in the newborns of Iraqi Primgravidae and multigravidae women after in term labor

APGAR score	Incidence in neonates			
	Primgravida		Multigravida	
	Hyoscine Number (%)	Control Number (%)	Hyoscine Number (%)	Control Number (%)
Apgar score (1 min)				
≥7	37 (74)*	46 (92)	37 (74)	45 (90)
<7	13 (26)*	4.0 (8)	3.0 (6)	5.0 (10)
Apgar score (5 min)				
≥7	49 (98)	49 (98)	49 (98)	49 (98)
<7	1.0 (2)	1.0 (2)	1.0 (2)	1.0 (2)

** Significantly different compared with respective control (P<0.05) according to Fisher Exact test outcome; Number of subjects=50 in each group*

Table 5. Comparisons for the Need of NICU admission in primigravidae and multigravidae

Parity state	Neonates need admission to NICU			
	Hyoscine Number (%)	Control Number (%)	P Value Fisher Exact test	Likelihood Ratio
Primigravida	1.0 (2)	1.0 (2)	0.50	0
Multigravida	0 (0)	2.0 (4)	0.24	2.813
Total	1.0 (2)	3.0 (3)	-	-

Table 6.Incidence of side effects due to administration of 20mg HBB to Iraqi prim and multi-gravidae women during in term labor

Type of adverse effect	Incidence of adverse effects (Number)							
	Primgravida				Multigravida			
	Hyoscine	Control	Total	P value	Hyoscine	Control	Total	P value
Dry mouth	7	3	10	0.11	5	4	9	0.25
Headache	2	4	6	0.23	2	1	3	0.37
Nausea & vomiting	2	1	3	0.37	2	3	5	0.31
Tachycardia	2	1	3	0.37	2	1	3	0.37
Urinary urgency	2	2	4	0.38	2	1	3	0.37
Hypotension	2	1	3	0.37	1	1	2	0.50
Blurred vision	2	1	3	0.37	2	0	2	0.24
Total	19	13	32	0.07	16	11	27	0.09

4. DISCUSSION

The use of HBB as cervical spasmolytic has been evaluated by many researchers, with conflicting results regarding its clinical significance in this respect [17, 18]. The results of the present study confirm that reported by Samuels *et al* (2007), who showed shortening of the first stage of labor by 32%, without any adverse effects on the mother or neonate, with 20 mg intravenous dose [12]; however, in the present study such effect of HBB was pronounced in multigravida women only compared with control, and relatively greater than its effect in primigravidae. Such type of response seems reasonable and experience of multigravida women with normal labor may be of significant importance in this respect. However, the 35 min decrease in duration of the first stage in primigraviae cannot be neglected. Several studies, which included both primigravid and multigravid women, have shown that intravenous administration of HBB (20-40 mg) during the active phase of labor increases cervical dilatation [19, 20] and decreases duration of the first stage of labor [17], but when given in the latent phase, during which the contractions are still not strong, HBB actually delays the labor progress by decreasing the intrauterine tension [21]. Meanwhile Tewari *et al* (2003) indicated that HBB shortens the duration of the first stage in both primi- and multigravida women [14]. In tune with many reported data, our results confirmed that HBB do not interfere with the contractile function of uterus during labor and its effect was limited to cervical dilatation; this point is important, since it obviates the concern regarding an excessively rapid second stage, which can predispose to both maternal complications (as an increased risk for laceration, particularly in the primigravida) and neonatal complications (intracranial hemorrhage due to rapid, uncontrolled decompression of the fetal head at delivery) [22]. In the present study, no toxic effects were noted in either mother or fetus and results are comparable with the study conducted by Samuels *et al* [23], while use of other spasmolytics are associated with side effects as reported by Sharma [9]. In the present study, administration of HBB affect significantly the Apgar score at 1.0 min compared with respective control, this may be attributed to the ability of HBB to cross the placental circulation to the fetus and lead to respiratory muscles relaxation at the first min of life, which then abolished after 5 min. This result suggests that there were no clinically significant effects on the neonates in many of the organ systems. Although the study was not sufficiently powered for the absolute exclusion of neonatal adverse effects, on which the Apgar scores were based, it showed no discernible difference in infants of both primi- and multigravida women compared with their respective control groups.

5. CONCLUSION

Based on the results of our study, we conclude that intravenously administered dose of 20mg HBB was effective in significantly decreasing the duration of the first stage of labor only in multigravida women, and not associated with any obvious adverse outcomes on mothers and neonates. However, more research with a prospective study design and a larger sample size is needed to establish the exact dose and definite outcome for using HBB during management of normal labor.

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