Original Article

The effect of hyoscine butyl bromide in shortening the duration of first stage of labor: A single-blind randomized control study

Ibrahim R, Nwobodo EI[1], Tunau KA[1], Burodo AT [1], Sulaiman B, Garba JA, Saidu AD

Department of Obstetrics and Gynaecology, Usmanu Danfodiyo University Teaching Hospital, [1]Department of Obstetrics and Gynaecology, Usmanu Danfodiyo University, Sokoto, Nigeria

ABSTRACT

Background: Active management of labor reduces the number of prolonged labor and the duration of labor without having any adverse effects on the mother and the fetus. Intervention with drugs is among the options used for active management of labor. This includes use of analgesics, oxytocics, prostaglandins derivatives, and smooth muscle relaxants. The objectives of the study were to determine whether hyoscine N butyl bromide (HNBB) shortens the first stage of labor in term pregnancies, to compare the mean duration of labor between primigravidae and multigravidae in HBB group, to compare the maternal and fetal outcome between HBB and control group, and also to determine the side effects of HBB in parturients.

Materials and Methods: The study was a single-blind randomized control study carried out in Usmanu Danfodiyo University Teaching Hospital (UDUTH) over 4-month period. A total of 204 pregnant women at term in spontaneous labor who presented in active phase of labor at UDUTH and have met the inclusion criteria were recruited and randomized into 102 women as case group and 102 women as control. The women in the case group received 40 mg (2 mls) of HBB, while those in the control group received 2 mls of normal saline. Data entry and analysis was done with IBM SPSS version 20. The duration and outcome was monitored.

Results: The mean duration of labor in the first stage among the case group was 5:44 ± 2:11, while it was 6:52 ± 2:11 among the control group representing a decrease of 16.5%. This was statistically significant ($P < 0.05$). There was no difference in the duration of the second and third stages of labor among the two groups. There was no difference in the maternal and neonatal outcome among the two groups. Vomiting was the only maternal side effect that was statistically significant among the HBB group.

Conclusion: HBB reduced the duration of first stage of labor in both primigravid and multigravid women without adverse maternal and neonatal complications. It is recommended that HBB to be given to women in active phase of labor to reduce the incidence of prolonged labor.

Key words: Duration of first stage; hyoscine butyl bromide; labor.

Introduction

The duration of the first phase of labor takes about 12–16 hours for the first pregnancies and 8–12 hours for multiparous women.[1] Labor is said to be prolonged when the duration of the active phase last more than 16 hours in primigravida and 12 hours in multiparous women.[1] Prolonged labor contributes to increased perinatal and maternal morbidity. There is an increased incidence of maternal distress, postpartum hemorrhage, and sepsis.[1,2]

Access this article online	
Website: www.tjogonline.com	Quick Response Code
DOI: 10.4103/TJOG.TJOG_57_18	

Address for correspondence: Dr. Ibrahim R, Department of Obstetrics and Gynaecology, Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria. E-mail: rukayyaadua@gmail.com

How to cite this article: Ibrahim R, Nwobodo EI, Tunau KA, Burodo AT, Sulaiman B, Garba JA, *et al*. The effect of hyoscine butyl bromide in shortening the duration of first stage of labor: A single-blind randomized control study. Trop J Obstet Gynaecol 2019;36:28-32.

Active management of labor has been widely accepted and shown to be beneficial.[1] Active management of labor reduces the number of cesarean deliveries, the number of prolonged labour, and the duration of labor without having any adverse effects on the mother and the fetus.[2] Intervention with drugs is among the option used for active management of labor. This includes use of analgesics, oxytocics, prostaglandin derivatives, and smooth muscle relaxants.[3]

Apart from uterine contraction, cervical dilatation is an important factor which determines the duration of labor. 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.[3]

Hyoscine butyl bromide (HBB) is an anticholinergic and antispasmodic,[4] analgesic, and sedative drug.[3] It has direct effect on the smooth muscles of the gastrointestinal and genitourinary organs. In addition to anticholinergic activity, the drug also affects the central nervous system and has a sedative and long-lasting effect on the brain.[4] Hyoscine is also effective in improving cervical spasm and facilitating cervical dilatation during the course of labor.[5] Hyoscine has been used by obstetricians in many countries to accelerate the first stage of labor.[3] The mechanism by which it acts in the context of labor has not yet been evaluated and evidence of its efficacy has been largely anecdotal.

There is limited published data on the effect of hyoscine in labor in the study area; hence the present study. The study aimed to determine whether HBB shortens the first stage of labor in term pregnancies, to compare the mean duration of labor between primigravidae and multigravidae in HBB group, to compare the maternal and fetal outcome between HBB and control group and also to determine the side effects of HBB in parturients.

Materials and Methods

Study area

The study was conducted at the labor ward of Usmanu Danfodiyo University Teaching hospital over a 4-month period.

Study design

It was a single-blind randomized control study.

Sample size determination

A sample size of 102 for each group was obtained using the formula for group comparison and considering 10% attrition rate.

Study population

Pregnant women at term in active phase of labor who presented to labor room during the study period and who agreed to participate in the study were recruited and randomly distributed into HBB group and control group.

Sampling method

All pregnant women who presented at term in active of phase of labor (4 cm cervical dilatation) during the study period were selected consecutively. The confirmation of labor and cervical dilatation was done by the researcher and trained research assistants (labor ward residents and certified midwives). Eligible women were then randomized into HBB and control group by selecting a number from a pool of serial numbers of 1–204. Those women who picked even numbers were assigned into HBB group and those that picked odd numbers were assigned into control group. Therefore, there were 102 women in each group. The HBB group received 40 mg of intravenous HBB and control group received a placebo (2 mls of intravenous normal saline).

Inclusion criteria

The inclusion criteria were: age 18–45 years, term pregnancy, spontaneous active phase of labor (4 cm cervical dilatation), singleton pregnancy, and vertex presentation in women who agree to participate in the study. There should be no contraindication to vaginal delivery.

Exclusion criteria

These included patients with preterm labor, antepartum hemorrhage, previous cesarian section, multiple pregnancy, induction of labor, cephalopelvic disproportion, malpresentations, prior rupture of membranes, preeclampsia/eclampsia and other hypertensive disorders of pregnancy, and any other medical diseases in pregnancy.

Drug administration and labor monitoring

HBB and normal saline were previously withdrawn into 2 ml syringes by the researcher. Both solutions were similar in color and quantity. The syringe containing HNBB was labeled Y, while that containing normal saline was labeled X. The women in the HBB group were given HBB 40 mg (2 ml) as solution Y intravenously, while the control group was given 2 ml of placebo (normal saline) as solution X intravenously by the research assistants. The content of each syringe was given as a single dose. The parturient was blinded to the drug. In either group, artificial rupture of membranes was done, while augmentation of labor with oxytocin was done only when indicated. Analgesia was also provided as indicated.

Labor was monitored using partograph and assessment of cervical dilatation was done 4 hourly. The time of

intervention to time of full cervical dilatation and also end of second and third stage of labor were recorded. Intrapartum and postpartum maternal observation were done. Assessment of neonatal Apgar score was done at 1st and 5th min. Comparison of the two groups regarding the effect of HBB on several variables of labor and outcome of labor was studied (duration of labor, outcome of labor, neonatal outcome, and incidence of maternal side effects).

Data analysis

Data analysis was done using Statistical Package for Social Science (SPSS) version 20 (SPSS Inc, Chicago, IL, USA). Descriptive characteristics of the respondents were obtained. Independent sample *t* test was used to compare the mean duration of stages of labor between HBB group and control. Chi-square test was used to compare outcome of delivery between the two groups. Level of significance was set at $P < 0.05$.

Ethical consideration

This study was conducted in line with Helsinki Declaration on human subject experiment. Ethical approval was obtained from committee on ethics and research of the Usmanu Danfodiyo University Teaching Hospital. Informed consent (both verbal and written) was also obtained from the patients before the questionnaire was administered.

Results

A total of 204 women were recruited for this study. Of these, 102 women received HBB group and 102 women received placebo (control). And 76 women (37.3%) were between the age ranges of 20–24 years. The mean age of women that received HBB was 27 ± 5 years, while the mean age for those that received placebo was 25 ± 3 years. There was no statistically significant difference between the mean age of the two groups ($t = 2.638$, $P > 0.05$). And 47% of the HBB group and 58.8% of the controls were multiparous women and this difference was not statistically significant ($\chi^2 = 4.34$, $P > 0.05$) Table 1.

In the women studied, majority of the respondents were Muslims 162 (81.8%) and Hausa 150 (73.5%). A total of 96 (47%) of the respondents had tertiary level of education, while 122 (59.8%) were house wives. There was a statistically significant difference between HBB group and controls in terms of tribe ($\chi^2 = 14.24$, $P = 0.003$), educational status ($\chi^2 = 7.98$, $P = 0.046$), and occupation ($\chi^2 = 22.4$, $P = 0.0001$) Table 1.

The mean duration of labor among HBB group in the first stage of labor was 5:44 ± 2:11 hours, while it is 6:52 ± 2:55 hours among control group and this difference was statistically significant ($t = 5.86$, $P < 0.05$). The mean duration of 2nd and 3rd stage of labor among the HBB group and controls was not statistically significant, Table 2.

Among the HBB group, there was no statistically significant difference in the mean duration of the stages of labor between different primigravidae and multigravidae Table 3.

Two women in the HBB group (2%) and four women in the control group (3.9%) had cesarean section. This difference was not statistically significant ($\chi^2 = 0.687$, *P* value = 0.407) Table 4.

The median Apgar score in the 1st minute among HBB and control group were 8 and 7 respectively ($t = 4.2$, $P = 0.0001$), while it was 9 in both groups in the 5th minute ($t = 2.22$, $P = 0.027$). There was statistically significant difference in the 1st minute Apgar score between the two groups. There

Table 1: Sociodemographic characteristics of the respondents

Variable	Frequency		Statistics
	HBB group *n* (%)	Control *n* (%)	
Age			
15-19	8 (7.8%)	4 (3.9%)	t=2.638
20-24	30 (29.4%)	46 (45.1%)	df=202
25-29	29 (28.4%)	38 (37.3%)	P=0.09
30-34	25 (24.5%)	12 (11.8%)	
35-39	10 (9.8%)	2 (2%)	
Religion			
Islam	86 (84.3%)	76 (74.5%)	χ^2=2.99
Christianity	16 (15.7%)	26 (25.5%)	df=1, P=0.083
Tribe			
Hausa	78 (76.5%)	72 (70.6%)	χ^2=14.24
Igbo	8 (7.8%)	24 (23.5%)	df=3
Yoruba	12 (11.8%)	6 (5.9%)	P=0.003
Others	4 (3.9%)	0 (0%)	
Educational status			
None	4 (3.9%)	6 (5.9%)	χ^2=7.98
Primary	8 (7.8%)	10 (9.8%)	df=3
Secondary	32 (31.4%)	48 (47.1%)	P=0.046
Tertiary	58 (56.9%)	38 (37.3%)	
Occupation			
Business	6 (5.9%)	16 (15.7%)	χ^2=22.4
Civil servant	32 (31,4%)	8 (7.8%)	df=3
House wife	52 (51%)	70 (68.6%)	P=0.0001
Student	12 (11.8%)	8 (7.8%)	
Parity			
Primigravida	44 (43.1%)	38 (37.3%)	χ^2=4.34
Multipara	48 (47.1%)	60 (58.8%)	df=2
GrandMultipara	10 (9.8%)	4 (3.9%)	P=0.114

Table 2: Comparison of mean duration of labour among the two groups

Stage of labour	HBB group	Controls	*t* test	df	*P*
First stage (h)	5:44±2:11	6:52±2:55	5.86	202	0.0001
Second stage (min)	34±11.2	37.9±13	2.2	196	0.27
Third stage (min)	6.9±4	7.6±4	1.09	196	0.27

was no difference in neonatal admission between the two groups. ($t = 0.149$, $\chi^2 = 2.082$) Table 5.

Among the women who received HBB, 72.2% had vomiting compared to 27.3% among the control group. This difference was statistically significant (P value = 0.02) Table 6.

Discussion

HBB has been used to shorten the duration of labor in different studies.[2,6] Whereas its analgesic properties are probably negligible in the context of labor, its value lies in the reduced time spent in the first stage of labor and consequently the reduced overall time spent in pain by the woman in labor. The mean age of the respondents in this study was 27 ± 5 years in the case group, while it was 25 ± 3 years for the controls. This is similar to finding by Al-Khishali *et al*. and Samuels *et al*.[6,7] Majority of the women were multiparous, 47.7% in the HBB group and 58.8% for the control group. Most of the women in this study were Muslims and comprise of 84.3% of the HBB group and 74.5% of the control group. Also majority were Hausa/Fulani by tribe. This is due to the fact that Hausa/Fulani and Islam are the dominant tribe and religion respectively in this part of the country. Among the respondents, 56.9% of cases and 37.3% of controls had a tertiary level of education.

Table 3: Comparison of mean duration of labour between primigravidae and multigravidae in HBB group

Stage of labour	Primigravida	Multigravida	*t* test	df	*P*
First stage (h)	5:52±3:11	5:45±2:46	0.27	202	0.7
Second stage (min)	37±12	37±12	1.1	196	0.2
Third stage (min)	7±4	7±4	1.25	196	0.2

Table 4: Outcome of labour among HBB group and controls

Outcome	HBB group	Control	χ^2	*P*
Caesarian section	2 (2%)	4 (3.9%)	0.687	0.407
SVD	100 (98%)	98 (96.1%)		

Table 5: Neonatal outcome

Outcome	HBB group	controls	Test	*P*
Apgar scores				
1st min	8	7	t=4.2	0.0001
5th min	9	9	t=2.22	0.027
NICU				
No admission	100 (98%)	96 (94.1%)	df=1	0.1
Admission	2 (2%)	6 (5.9%)	χ^2=2.082	

Table 6: Frequency of side effects

Side effects	HBBgroup (%)	Control group (%)	χ^2	*P*
Dry mouth				
Yes	36 (48.6%)	38 (51.4%)	0.85	0.7
No	66 (50.8%)	64 (49.2%)		
Urinary retention				
Yes	12 (46.2%)	14 (53.8%)	1.7	0.6
No	90 (50.6%)	88 (49.4%)		
Headache				
Yes	8 (80%)	2 (20%)	3.7	0.05
No	94 (48.5%)	100 (51.5%)		
Vomiting				
Yes	16 (72.7%)	6 (27.3%)	5.09	0.02
No	86 (47.3%)	96 (52.7%)		
Blurring of vision				
Yes	10 (62.5%)	6 (37.5%)	1.08	0.2
No	92 (48.9%)	96 (51.1%)		

The mean duration of labor in the first stage of labor among the HBB group was 5:44 ± 2:11 hours, while it was 6:52 ± 2:55 hours in the control group. This difference was statistically significant ($P = 0.0001$). HBB reduced the mean duration of labor by 16.5% in this study. The results of this study are similar to the findings by Samuels *et al*. in Jamaica, where there was a shortening of the first stage of labor by 32%.[6] Similarly, Movahed *et al*. in Iran found a significant reduction in the duration of first stage of labor among women who received HBB.[4] In this study, HBB shortened the duration of labor in both primigravid and multigravid women with no significant difference in the duration among them. This was similar to the findings by Aggarwal *et al*. and Sreelatha *et al*.[3,8] The study is in contrast with the findings by Al-Khishali *et al*. where the effect of HBB was more pronounced in the multigravid women.[7] This may be due to the experience of the multigravid women to normal labor as compared to primigravida.

There was no difference in the duration of second and third stages of labor among the HBB and control groups in this study. This is similar to the findings by Al-Khishali *et al*. in Iraq and Movahed *et al*. in Iran.[4,7] This showed that HBB acts mainly on the smooth muscles of the cervix and does not interfere with the contractile function of the uterus.[4] This is important as it obviates the concern regarding an excessively rapid second stage which can predispose to both maternal complications like perineal lacerations and neonatal complications, such as intracranial hemorrhage due to rapid, uncontrolled decompression of the fetal head at delivery.[6] It is however different from the study by Alani in Iraq where there was reduction in the duration of second and third stages of labor.[9]

In this study, two (2.0%) of the women in the HBB group, while four (3.9%) of women in the control group had cesarean section and the difference was not statistically significant. The indication for the cesarean section in three women was persistent occipitoposterior position, two cases were due to fetal distress and one case was due to cervical dystocia. This

is similar to findings by other authors.[4,6] This is in contrast to the study by Aldahhan where the rate of cesarean section is higher among the HBB group.[10]

The median Apgar score among the HBB group in the first minute was higher than that among the control group and this is statistically significant ($P < 0.0001$). This suggests that HBB does not cross the placenta and therefore does not cause respiratory depression in the neonates.

The median Apgar score at the fifth minute was the same in both groups. Different studies have shown no difference in the median Apgar scores in HBB and control group.[4,6,7]

There was no difference in the neonatal admission in the intensive care unit in both groups. Six of the neonates were admitted for observation on account of the cesarean delivery, while two neonates were admitted due to mild birth asphyxia. All neonates were discharged to the mothers within 36 hours in good condition.

In this study, 72.7% of women in the HBB group and 27.3% of the control had vomiting. This was statistically significant ($P < 0.05$). This is in contrast to other studies where there was no difference in the incidence of side effects in HBB group and control group.[3-4,6,8] There was no significant symptom associated with HBB.

Conclusion

HBB reduced the mean duration of labor in this study. This reduction in duration of labor occurred in the first stage of labor in both primigravid and multigravid women, but there was no difference between them. There were no adverse maternal or fetal outcomes.

Recommendation

The administration of HBB in active phase of labor for all pregnant women is worthwhile to reduce the incidence of prolonged labor and its attendant complications.

A larger multicenter study is recommended to fully evaluate this finding.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Bohra U, Donnelly J, O'Connell MP, Geary MP, MacQuillan K, Keane OP. Active management of labour revisited: The first 1000 primiparouslabours in 2000. J Obstet Gynecol 2003;23:118-20.
2. Sadler LC, Davison T, MacCowan LM. A randomized control trial and meta analysis of active management of labour. BJOG 2000;107:909-15.
3. Aggarwal P, Zutshi V, Batra S. Role of Hyoscine N butyl bromide as labour analgesic. Indian J Med Sci 2008;62:179-84.
4. Movahed F, Galeh TD, Lalooha F, Aziziyan S, Mashrabi O. Effects of Hyoscine on first stage of labour in full term pregnancy. Res J Bio Sci 2011;6:648-51.
5. Kaur D, Kaur R. Comparison of drotaverine and epidosin in first stage of labour. J Obstet Gynecol 2003;53:449-52.
6. Samuels LA, Christie L, Roberts-Gittens B, Fletcher H, Frederick J. The effect of hyoscine butyl bromide on the first stage of labour in term pregnancies. BJOG 2007;114:1542-6.
7. Al Khishali WA, Rasheed FA, Husaini SA. The effect of 20 mg hyoscine butylbromide on normal labor in Iraqi primi and multi gravid women. J Adv Sci Res 2012;3:70-3.
8. Sreelatha S, Nayak V, Gayathri C, Ramaiah R. A study of the effect of Hyoscine butyl bromide on the duration of labour. WJPR 2015;4:2485-91.
9. Alani H, Salim RT. The effect of Hyoscine -N butyl bromide on the duration of active phase of labour. Zanco J Med Sci 2013;17:549-5.
10. Aldahhan FH, Alweely FA, Raheem F. The evaluation of the effect of Buscopan (hyoscine N- butyl bromide) on the duration of labour. Bas J Surg 2011;17:25-9.