Scientific Research Publishing

Open Journal of Obstetrics and Gynecology, 2018, 8, 1102-1108
http://www.scirp.org/journal/ojog
ISSN Online: 2160-8806
ISSN Print: 2160-8792

Effect of Hyoscine Butyl Bromide on the Course of Labour

Dauda Deba Barau, Eyaofun Teddy Agida, Olatunde Onafowokan, Francis Olayemi Adebayo*

Department of Obstetrics and Gynaecology, University of Abuja Teaching Hospital, Abuja-FCT, Nigeria
Email: *preciousdavis67@yahoo.com

How to cite this paper: Barau, D.D., Agida, E.T., Onafowokan, O. and Adebayo, F.O. (2018) Effect of Hyoscine Butyl Bromide on the Course of Labour. *Open Journal of Obstetrics and Gynecology*, **8**, 1102-1108.
https://doi.org/10.4236/ojog.2018.812111

Received: August 28, 2018
Accepted: September 27, 2018
Published: September 30, 2018

Abstract

Background: Hyoscine butyl bromide (Buscopan) is being used as an agent for reducing the duration of labour. There are however conflicting results on the effect of this agent on cervical dilation. **Materials and Methods:** This was an open label clinical trial of one hundred and thirty two (132) pregnant women in labour. Women were grouped to receive either 20 mg of hyoscine butyl bromide intramuscularly at the onset of active phase labour or placebo "Normal saline". The main outcome measure was to compare the duration of first stage labour in the study and control groups as well as feto-maternal outcomes. Relevant data were collected using a proforma. The data were analysed using Statistical Package for Social Sciences (SPSS) version 20. **Results:** A total of 132 were randomised and 123 yielded for analysis. Of these 59 received hyoscine butyl bromide and 64 received placebo. There was no significant difference in the mean duration of active labour to second stage between the drug and placebo arms (312.5 versus 305.3 minutes, respectively, P = 0.788). The feto-maternal outcomes were similar between both arms. **Conclusion:** Hyoscine butyl bromide does not shorten the duration of labour in spontaneous labour. It also does not change feto-maternal outcomes.

Keywords

Hyoscine Butyl Bromide, Labour, Prolonged Labour

1. Introduction

Prolonged labour and its attendant complications contribute immensely to the high maternal morbidity and mortality recorded in the developing countries [1] [2]. Although there is a wide variation in the duration of labour, it has been found that there is an acceptable period that is considered normal. The range for the duration of normal labour is from 3 to 12 hours. Labour lasting less than 3

hours is classified as precipitate labour while that exceeding 12 hours is said to be prolonged [3] [4] [5]. Various studies conducted on the duration of labour suggested a decline in recent decades [3] [6].

The modern obstetric practice involves active management of labour with the use of partograph and cardiotocograph as the monitoring tool [6]. The aim of active management of labour is to prevent prolonged labour which is associated with increased maternal and perinatal morbidity and mortality.

Identified maternal morbidities include maternal exhaustion, electrolyte derangement, hypoglycaemia, obstructed labour and its sequelae such as rupture uterus, primary post partum haemorrhage and obstetric fistula. Some of the perinatal complications include fetal distress, birth asphyxia, increased risk for neonatal resuscitation and admission into neonatal intensive care unit, hypoxic ischemic encephalopathy and cerebral palsy [7] [8].

Active management of labour refers to active control rather than passive observation over the course of labour by the obstetric care provider. There is clearly documented evidence of the success of active management of labour and it has been shown to reduce the number of caesarean deliveries in institutions employing the protocol [8].

The safety of active management of labour has been demonstrated by several prospective randomised clinical trials. The shorter duration of labour from admission to delivery has also been constantly reported in numerous studies of women treated with the active management protocol [9].

One of the causes of prolonged labour is cervical dystocia [5]. The use of antispasmodic drugs to overcome cervical spasms has been documented in several randomised clinical trials [10]. Drugs such as atropine have been used and found reliable but had unpleasant side effects, for example inhibition of salivary and sweat secretions, disturbances of vision, and cardiac symptoms. This led to the synthesis of a series of quaternary ammonium derivatives of scopolamine. In clinical use, one of the most effective of these derivatives was found to be hyoscine butyl bromide [11].

Hyoscine butyl bromide has a selective action on cervico-uterine plexus, and when administered in the face of cervical dilatation resulted in facilitated dilatation of the cervix and shortened the duration of labour. In several studies it has not demonstrated unfavourable side effect on uterine contractions or on the foetus [12]. Unlike atropine, hyoscine butyl bromide does not cross the blood brain barrier; therefore it does not produce the central effects of atropine at therapeutic doses [13].

Recently, a Cochrane systematic review considered the effect of hyoscine butyl bromide on the course of labour and concluded that there is low evidence that hyoscine butyl bromide reduce the duration of first stage labour. There is also insufficient evidence to make any conclusions regarding the safety of this drug for both mother and baby [14]. The burden of prolonged labour in Nigeria is the rationale behind this research. There is paucity of prospective study on the sub-

ject in Nigeria. Therefore, there is a need for a prospective study that may provide concrete data and firm conclusion on this subject the purpose of this study is to determine the effect of hyoscine butyl bromide on labour.

2. Materials and Methods

This was a clinical trial of one hundred and thirty two women in labor at University of Abuja Teaching Hospital, Abuja between January 1st 2017 and December 31st, 2017. The study commenced after obtaining written permission from Ethical Committee of the Hospital. Women were grouped to receive either 20mg of either Hyoscine Bromide or Normal saline. The study population comprised of all women in spontaneous labour at term that have cervical dilatation of 4 to 5 cm during the study period.

Included were all multigravida who had given consent and with; spontaneous onset of labour, singleton cephalic presenting pregnancy at term with no contraindication for vaginal delivery.

Patients who refused consent to participate were excluded alongside those with any chronic medical or pregnancy induced illness, parturient who were administered antispasmodic medication before presentation in labour ward, rupture of membranes (more than 12 hours) and history of drug allergy.

Enrolled patients were randomly allocated to one of the two therapeutic regimens of 20 mg Hyoscine Bromide or Normal saline. Randomisation was performed using computer-generated list by means of sequentially numbered, opaque, sealed envelopes indicating their medication. One group of patients received 20 mg Hyoscine Bromide and the other group 20 mg Normal saline. Hyoscine butyl bromide 20 mg (2 ml) or placebo (normal saline 2 ml) was given intramuscularly only when the parturient was in active phase labour with a cervical dilation of 4 - 5 cm.

The duration of labour was counted from the time hyoscine butyl bromide or placebo was administered. The attending Nurse or Doctor completed a form detailing the duration of 1st stage of labour from administration of the drug to full cervical dilatation. The 2nd stage starts from full cervical dilatation to delivery of the foetus; and the 3rd stage of labour from delivery of the foetus to the delivery of the placenta. Maternal complications, APGAR, score at 1 min and 5min were documented. Both the patient and attending Nurse or Doctor were blinded to whether its HBB or Normal saline that was served as they both appear colourless in the syringe.

The sample size was calculated using the formula [15] $n = \frac{2Z^2Pq}{d^2}$.

n = Minimum sample size; Z = Standard normal deviation set at 1.96; P = Prevalence of prolonged labour = 4.39% [6]; q = 1.0 − P; d = Degree of precision set at 0.05; $n = \frac{2\times 1.96^2 \times 0.0439 \times 0.9561}{0.05 \times 0.05}$; n = 120.

Given attrition rate of 10% the calculated sample size was 132.

Clinical data for each participant were collected and recorded on a data sheet for analysis. Patients that had augmentation of labour were analysed while those that had emergency caesarean section and instrumental delivery were not analysed. Data were analysed using Statistical Package for Social Sciences (SPSS) version 20. P-value of less or equal to 0.05 was accepted as indicating statistical significance.

3. Results

A total of one hundred and thirty two women (66 in each group) consented to the study and were grouped and evaluated. Of these, two patients from placebo and seven from hyoscine group were excluded because it became necessary for them to have abdominal birth or instrumental vaginal deliveries. Upon comparison of patients characteristics and initial labour assessment as shown in Table 1, the distribution with respect to age, height, weight, gestational age, cervical dilatation at presentation and spontaneous rupture of membrane were comparable in both groups with no significant statistically difference. This indicates that the two groups were homogenous.

Table 2 shows comparison of cases and controls regarding cervical dilatation in the first and second stage of labour. The duration of first stage labour was shorter in placebo group compared with drug group whereas second stage labour duration was found to be shorter in drug group compared with placebo. Hence, the mean time duration of both first and second stage labour in the control group was 305 minutes, compared with 312 minutes in the drug group, representing a slight (but statistically insignificant, P = 0.788) increase of 2.3%.

Among the observed maternal outcomes considered in drugs and control group were blood loss, episiotomy, perineal tear as illustrated in Table 3. Although in both study groups indicates that no statistically difference, the blood loss were more in placebo group than drug group while the perineal tear were more in drug group compared with placebo group. Comparison of the fetal outcomes of these mothers in both groups indicates that no statistically significant

Table 1. Patient's characteristics and initial labour assessment.

Characteristics	placebo group n = 64	HBB group n = 59	P-value
Age (years)	30.2 ± 4.8	29.9 ± 4.9	0.686
Height (m)	1.6 ± 0.1	1.6 ± 0.1	0.808
Weight (kg)	79.3 ± 17.3	79.9 ± 12.0	0.814
Parity Nulliparous multiparous	 24 (47.8) 40 (52.2)	 20 (45.7) 39 (54.3)	 0.710
Gestational age (weeks)	39.3 ± 1.0	39.4 ± 1.1	0.479
Cervical dilatation at presentation (cm)	4.5 ± 0.5	4.5 ± 0.6	0.373
Spontaneous rupture of membrane	26 (40.6)	22 (37.3)	0.705

Table 2. Mean Duration of 1st and 2nd stages of Labour.

Stages of Labour	placebo group n = 64	HBB group n = 59	P-value
First stage (minutes)	269.3 ± 135.9	279.1 ± 134.0	0.691
Second stage (minutes)	34.1 ± 18.2	33.6 ± 18.1	0.886
First + Second stage (minutes)	305.3 ± 148.9	312.5 ± 146.9	0.788

Table 3. Maternal and foetal outcome.

Outcome	placebo group n = 64	HBB group n = 59	P-value
Blood loss	35.1 ± 3.3	34.6 ± 2.8	0.414
Episiotomy	12 (18.8)	12 (20.3)	0.824
Perineal tear	15 (23.4)	17 (28.8)	0.497
Birth weight (g) Mean ± SD	3150 ± 230	3300 ± 210	0.612
Apgar score			
1 min	8.1 ± 1.3	8.2 ± 1.2	0.839
5 min	9.4 ± 1.0	9.4 ± 1.0	0.855

differences were seen in the APGAR Scores at minutes of one and five in both groups.

4. Discussion

The goal of obstetrics has always been a pregnancy which results in a healthy infant and minimally traumatized mother. The problems of prolonged labour are many. A painless and short duration is a cherished dream of every mother [16]. There has been growing attempt to shorten labour time since the process of labour puts great strain on the mother and her fetus. These includes; active management of labour, sweeping of membranes, cervical stretching and amniotomy [17].

Also, various pharmacological agents have been found to facilitate cervical dilatation. The role of oxytocin and prostaglandins has been established worldwide. Spasmolytic drugs most especially Hyoscine butyl bromide are frequently employed to overcome cervical spasm and thus reduce duration of labour.

The characteristics and initial labour assessment of women in the study were homogenous in terms of age, height, weight, gestational age, cervical dilatation and spontaneous rupture of membrane in both groups indicating that subjects were well randomised.

Also in this study, the main result, the duration of first stage labour was more in the drug group compared with placebo whereas duration of second stage labour in the hyoscine group was lesser than placebo group. Though, none of these were statistically significant. Samuels *et al.* so found no significant changes in the duration of second stage. The reason for this disparity might be due to challenges in determining the beginning of second stage labour.

The mean duration of labour (first and second stagelabour) was 305.3 and 312.5 minutes for placebo and hyoscine group respectively. Thus, administration of hyoscine butyl bromide in active phase labour do not led to a significant shortening of the first and second stage of labour. This finding is similar to findings of Rohwer and colleagues, Al Dohami *et al.* [13] [18]. These were however, different from most studies such Samuels *et al.*, where hyoscine butyl bromide was found to significantly shorten the duration of labour.

There was also no statistically difference in the mater no-fetal outcomes such as associated blood loss or APGAR Scores noted at first and five minutes, respectively. Studies by Samuels *et al.* and Mukaindo *et al.* [19] [20], also recorded similar findings in the mater no-fetal outcomes.

5. Conclusion

In conclusion, therefore, just as documented in previous studies, there appears to be no statistically significant difference in the duration of labour between the hyoscine butyl bromide group and placebo group. Also, there were no associated adverse feto-maternal outcomes.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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