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Effect of Hyoscine Butyl Bromide on the Duration of First Stage of Labour at a Tertiary Health Facility in Southern Nigeria

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Abstract

Background: The quest for techniques that shorten and thus reduce the discomfort of labour processes without associated maternal or fetal adverse effects is still on-going. Hyoscine-N-butyl bromide (HBB) has been in use in contemporary obstetric practice but reports supporting its efficacy in reducing the duration of labour are still incongruous. **Aim:** To determine the effect of intravenous hyoscine-N-butyl bromide on the duration of first stage of labour in nulliparous women at the University of Port-Harcourt Teaching Hospital. **Material and Methods:** This was a randomized controlled double blind equivalence clinical trial, involving 128 parturients, who presented to the labour ward of the University of Port Harcourt Teaching Hospital at term and received an intravenous injection of either 20 mg of HBB or normal saline once active stage of labour (5 cm) was established. Data analysis was with SPSS version 28 using inferential statistics. **Results:** There was no significant difference in the mean duration of active stage of labour. The HBB group demonstrated a mean dilatation rate of 1.01 ± 0.1 cm/hour, whereas the placebo group showed a marginally higher rate of 1.03 ± 0.1 cm/hour (p = 0.4). The HBB group had a mean duration of 19.5 ± 5.1 minutes during the second stage of labour, compared to 19.5 ± 6.0 minutes in the placebo group (p = 1.0). However, the HBB group showed a significant (p = 0.04) increase in the fetal heart rate (143.4 ± 7.2 bpm), while the placebo group experienced a slight decrease (140.6 ± 7.9 bpm). **Conclusion:** The duration of the active phase of labour was not shortened by hyoscine butyl bromide. In addition, the feto-maternal outcomes remained unchanged. However, HBB slightly increased the fetal heart rate.

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Keywords

Hyoscine-N-Butyl Bromide, Duration of Labour, Feto-Maternal Outcome, Port Harcourt, Nigeria

1. Introduction

For many years, healthcare providers worked to manage labour actively and safely, with the main aim of shortening the duration of labour. There has been an extensive increase over the last two decades in using a multiplicity of labour techniques to improve outcomes for both mothers and babies [1]. Despite these, the concept of normality in labour in terms of progression and duration is not universal [2]. However, in clinical practice, it is crucial to differentiate normal from abnormal so that women and care givers can agree on what to anticipate and when labour interventions are appropriate [2].

Labour is a process that is subdivided into 3 stages. When labour starts, the first stage begins, and it ends when the cervical dilatation and effacement are complete. The second stage starts with full cervical dilatation and ends with the birth of the fetus. After the baby is born, the third stage commences, and it concludes with delivery of the placenta and membranes [3].

The duration of the first stage of labour takes about 12 - 16 hours for nulliparous women and 8 - 12 hours for multiparous women [4]. If the first stage of labour lasts more than 16 hours for a nulliparous woman and more than 12 hours for a multiparous woman, it is deemed prolonged [4]. Evidence shows that one-third of first-time mothers experience a delay during the initial phase of labour [5].

Prolonged labour often ends up in immense agony for the parturient and adverse outcomes for the fetus. Prolonged labour can result in maternal and perinatal complications. Maternal complications include fatigue, electrolyte imbalance, hypoglycaemia, and obstructed labour and its sequalae, including obstetric fistula, ruptured uterus, and primary postpartum haemorrhage. Fetal distress, birth asphyxia, increased risk of newborn resuscitation and intensive care unit hospitalization, hypoxic ischaemic encephalopathy, and cerebral palsy are some of the perinatal complications [6].

The strategies for shortening the duration of labour have been an area of continuous research. The active management of labour theory, which was initially presented in Dublin by O'Driscoll *et al.* in an effort to reduce the duration of labour, calls for the obstetric care provider to actively affect the course of labour as opposed to passive observation [7]. Many support active management of labour since it has been demonstrated to reduce the rate of caesarean sections, duration of labour, and prevent prolonged labour, without having a negative impact on the mother or the fetus [7].

The key factors guiding the course of labour are cervical dilation, uterine contractions, and the descent of the presenting part [8]-[10]. However, inhibitory compulsions in the form of spasms may prevent cervical dilatation even in the

case of adequate uterine contractions, resulting in prolonged labour. In such cases, the cervix may dilate with the aid of antispasmodics. Several randomized clinical trials have reported the use of antispasmodics to overcome cervical spasms [11].

Several drugs have been used to achieve effective dilatation of the internal cervical os, majority of which were observed to have adverse effects on mother and fetus [12]. Atropine is one such medication that was safe but had unpleasant side effects, such as heart problems, visual abnormalities, suppression of perspiration and salivary secretions [6]. This resulted in the production and use of many quaternary ammonium scopolamine derivatives [6].

Hyoscine-N-butyl bromide (scopolamine) is a derivative of quaternary ammonium that has been proposed to reduce the duration of labour [8] [13]. It is a semisynthetic derivative of scopolamine and is a member of the parasympatheticolytic medication class. Hyoscine-N-butyl bromide does not cross the blood brain barrier unlike atropine; consequently, at therapeutic doses, it does not cause the central effects of atropine [1].

Primarily, by reducing spasms in the smooth muscles of gastrointestinal tract, biliary system, urinary tract, and cervico-uterine plexus, hyoscine-N-butyl bromide aids in cervical dilatation. Intraneural parasympathetic ganglia in the abdominal organs and cholinergic transmission at synapses in pelvic and abdominal parasympathetic ganglia are both inhibited by this substance [14]-[16].

Hyoscine-N-butyl bromide has been used in obstetric practice in few countries to accelerate the first stage of labour. However, majority of the evidence demonstrating its efficacy has been anecdotal, and the mechanism that operates in the context of labour has not yet been evaluated [17].

2. Material and Methods

2.1. Study Area

The study was conducted at the labour ward of the University of Port Harcourt Teaching Hospital (UPTH) from January 3, 2023 to December 31, 2023. The University of Port Harcourt Teaching Hospital is located in Alakahia town, in Obio-Akpor Local Government Area of Rivers State, along the east-west road. It is a tertiary health facility established in 1985 with 988 beds. It offers specialized care to Rivers State and neighbouring states. The department of Obstetrics and Gynaecology has 175 bed spaces, of which the labour ward complex has 13 bed spaces. It also has an obstetric theatre with 2 theatre suites; annexed to it is the special care baby unit (SCBU). The average number of annual deliveries is about 1400.

2.2. Study Design

This was an interventional double-blind equivalence randomized clinical trial among 128 nulliparous women, who presented in labour at the UPTH. Simple randomization was used to allocate eligible patients to receive either HBB or placebo. Routine investigations, obstetric and general examinations, and a detailed history were obtained from patients when they presented in labour.

2.3. Study Population

The sample size was obtained using the formula $N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta_0} \right) \times s^2$ with 95% confidence interval and a power of study of 80%, which gave a sample size of 57. Giving allowance for 10% attrition, gave a sample size of 64. Hence, a total of 128 eligible women were recruited; 64 in the HBB group and 64 in the placebo group. This consisted of booked nulliparous women. They were recruited from the antenatal clinic during their routine antenatal visits and had given informed written consents before they presented in labour. Parturients who met the eligibility criteria were recruited for the study until the sample size of 128 was reached. Women who had not carried a pregnancy to fetal viability were considered nulliparous. Fetal viability was taken as 28 completed weeks.

2.4. Sampling Technique

Inclusion Criteria:

Booked nulliparous women, term pregnancies (gestational age between 37 - 42 weeks), singleton fetus in cephalic presentation with reassuring heart rate, average size baby (2.5 - 3.994 kg), confirmed by a late trimester ultrasound scan, and women with no contraindication to vaginal delivery.

Exclusion Criteria:

Known allergy to Hyoscine-N-butyl bromide, malpositions, prelabour rupture of membranes, antepartum haemorrhage, uterine scar or surgery, large fibroids in pregnancy, patients who received epidural analgesia, fetal distress in labour, medical disorders in pregnancy, and history of cervical surgery.

2.5. Patient Recruitment and Data Collection

Nulliparous patients who had consented during the antenatal period were recruited as participants. When they presented in labour and were confirmed to be in active phase labour (5 cm cervical dilation), they were recruited if they met the inclusion criteria. During antenatal health talks, the participants received adequate information on the methodology of the study. This was reiterated when they presented to the labour ward. Women who satisfied the eligibility criteria and gave consent were consecutively enrolled for the study. The patient gave written consent after being informed of the objectives of the study and administration of HBB to shorten first stage of labour, highlighting possible adverse effects. They were allowed to ask questions or express concerns. A pre-structured interviewer-administered questionnaire was used to obtain socio-demographic characteristics. Other data collected were gestational age, respiratory rate, pulse rate, blood pressure, vaginal examination findings, duration of labour, maternal and fetal outcomes for each study arm.

2.6. Randomization and Blinding

Randomization of participants was done with ballot papers by simple random

sampling and assigned into 2 groups: A and B. They were made to pick from a bag containing 128 folded papers with letters A or B written on them. Each patient was asked to pick one paper only from the bag, which they picked without returning it to the bag. In accordance with the time of presentation, each participant was given a number in a sequential manner. The first patient to present was assigned number 1, and the second patient to present was allocated number 2, in that sequence. The hospital pharmacy, with the assistance of a pharmacist provided and prepared the HBB and saline in a sterile manner. Of the 128 syringes prepared, 64 had 2 ml of 20 mg of HBB, while the remaining 64 contained 2 ml of saline. The HBB-containing syringes and the placebo-containing syringes were therefore identical. Double blinding was done in this study as only the pharmacist knew the content of the syringes, and labelled them as A or B. The patients were unaware of the medications (HBB or placebo) that were given to them, as they were blinded to the medication. Also, the researcher, research assistants and other obstetric care providers in the labour ward were unaware of the medication assigned to patients. The syringes, which contained either HBB or saline were packaged in batches of four, each in sealed Ziploc bags labelled A or B, and stored at room temperature. Only when they were exhausted, were new batches made available. The pharmacist took note of the batch number, production date, and expiration date. The hospital pharmacy also handled the packing, sealing, and numbering without disclosing the contents to the researcher. All members of the study team had access to the syringes containing HBB or placebo, which were stored in the labour ward complex. At the conclusion of the study, the researcher decrypted the letters A and B.

2.7. Data Analysis

Data was analyzed using SPSS version 28. Tables were used for data display. Categorical data were presented as frequencies and proportions, while descriptive statistics were used for numerical data that were normally distributed (mean ± standard deviation). To compare the means of two groups, inferential analyses were performed using independent t-test. Non-parametric independent t-test was employed for non-normally distributed data. Statistically significant was set at p-value ≤ 0.05. For continuous data and categorical variables respectively, the χ^2 test was applied.

2.8. Ethical Consideration

Ethical clearance was obtained from the Health and Research Committee of the Teaching Hospital. Throughout the research, the ethical precepts of autonomy, beneficence, non-maleficence, fairness, and honesty were meticulously upheld.

3. Results

The socio-demographic characteristics are shown in Table 1. Most were aged 19 - 30 years, accounting for 67.2% of the HBB group and 71.9% of placebo group,

with a mean age of 27.5 ± 4.4 years in the HBB group and 27.7 ± 4.1 years in placebo group (p = 0.8). The mean gestational age was 39.4 ± 1.3 weeks for the HBB group and 39.2 ± 1.4 weeks for the placebo group (p = 0.3). The HBB group had a mean cervical dilatation rate of 1.01 ± 0.1 cm/hour, whereas the placebo group showed a marginally higher rate of 1.03 ± 0.1 cm/hour (p = 0.4). This is shown in Table 2.

The fetal heart rate was similar between the groups, with means of 142.6 ± 7.7 bpm for the HBB group and 142.5 ± 7.3 bpm for the placebo group (p = 0.9). There was a significant difference in the fetal heart rate 30 minutes post-administration. The HBB group showed a slight increase to 143.4 ± 7.2 bpm, while the placebo group experienced a small decrease to 140.6 ± 7.9 bpm (p = 0.04), suggesting a potential effect of HBB on fetal heart rate. This is shown in Table 3.

Table 4 shows the mean duration of labour. Regarding the first stage, the HBB group had a mean duration of 295.1 ± 29.0 minutes, while the mean duration for the placebo group was 293.6 ± 29.5 minutes (p = 0.8). Thus, suggesting that HBB had little effect on the duration of the first stage. For the second stage of labour, the HBB group had a mean duration of 19.5 ± 5.1 minutes, compared to 19.5 ± 6.0 minutes in the placebo group (p = 1.0). When considering the duration of the first and second stages, the HBB group showed a slightly longer mean time (314.6 ± 29.3 minutes) compared to the placebo group (313.2 ± 30.0 minutes). However, this difference was not statistically significant (p = 0.8). The third stage of labour showed a trend towards a longer duration in the HBB group (4.5 ± 1.4 minutes) compared to the placebo group (4.0 ± 1.4 minutes). The total duration of labour was longer in the HBB group (319.0 ± 29.2 minutes) compared to the placebo group (317.1 ± 29.9 minutes), with no statistical significance (p = 0.7), suggesting that HBB did not significantly alter the overall duration of labour. The time from drug administration to delivery was similar in both groups. The HBB group had a mean interval of 5.1 ± 0.6 hours, while the placebo group was 5.1 ± 0.7 hours (p = 0.8).

Both groups showed a high rate of vaginal deliveries, with the HBB group having a slightly higher proportion (92.2%) compared to the placebo group (84.4%). Conversely, the rate of caesarean deliveries was lower in the HBB group (7.8%) than in the placebo group (15.6%). These differences were not statistically significant (p = 0.2). This is shown in Table 5.

The mean birth weight in the HBB group was 3.4 ± 0.4 kg, while in the placebo group it was 3.3 ± 0.4 kg (p = 0.6). Regarding APGAR scores, at 1 minute, the mean APGAR score for the HBB group was 7.3 ± 0.9, compared to 7.3 ± 1.0 for the placebo group (p = 0.6). Similarly, at 5 minutes, the HBB group showed a slightly higher mean score (8.6 ± 0.5) compared to the placebo group (8.5 ± 0.6), again, this difference was not statistically significant (p = 0.2). In the HBB group, 6.3% of newborns required NICU admission, compared to 10.9% in the placebo group (p = 0.3). In the HBB group, 50% of NICU admissions were due to Infants of diabetic mothers (IDM), while in the placebo group, 57.1% of admissions were due to birth asphyxia (p = 0.2). This is displayed in Table 6.

Table 7 compared the incidence of various side effects and complications between the HBB and placebo groups. The most notable finding was occurrence of dry mouth, which was reported by 9.4% of participants in the HBB group compared to 3.1% in the placebo group (p = 0.3). Nausea and vomiting were reported in both groups, with a slightly lower incidence in the HBB group (9.4%) compared to the placebo group (10.9%). However, this difference was not statistically significant (p = 1.0), indicating that HBB did not significantly increase the risk of these common symptoms during labour.

Table 1. Socio-demographic characteristics.

Variables	Group		χ^2/t-test (P-value)
	HBB (64) n (%)	Placebo (64) n (%)	
Age group (years)			
19 - 30	43 (67.2)	46 (71.9)	0.3 (0.6)
31 - 40	21 (32.8)	18 (28.1)	
Age[α]	27.5 ± 4.4	27.7 ± 4.1	0.3 (0.8)
Weight (kg)[α]	78.4 ± 10.8	81.8 ± 10.7	1.8 (0.07)
Gestational age (weeks)[α]	39.4 ± 1.3	39.2 ± 1.5	1.1 (0.30)
Level of Education			
Primary	1 (1.6)	2 (3.1)	
Secondary	17 (26.6)	16 (25.0)	0.8[μ]
Tertiary	46 (71.9)	46 (71.9)	

α = Mean ± SD; χ^2 = Chi-Square; t-test = Student t-test; μ = Fisher's exact p.

Table 2. Mean rate of cervical dilatation between HBB and Placebo groups.

Variables	Group		t-test (P-value)
	HBB Mean ± SD	Placebo Mean ± SD	
Cervical dilatation rate (cm/hour)	1.01 ± 0.1	1.03 ± 0.1	0.9 (0.4)

t-test = Student t-test.

Table 3. Comparison of vital signs between HBB and Placebo groups before and after drug administration.

Variables	Group		t-test (P-value)
	HBB Mean ± SD	Placebo Mean ± SD	
Before Drug Administration			
Pulse rate	83.8 ± 8.2	84.9 ± 8.9	0.7 (0.5)
Systolic BP	126.2 ± 11.	125.4 ± 10.8	0.4 (0.7)

Continued

Diastolic BP	73.81 ± 9.3	74.0 ± 9.5	0.09 (0.9)
Fetal Heart Rate	142.6 ± 7.7	142.5 ± 7.3	0.07 (0.9)
30 minutes after Drug Administration			
Pulse rate	83.5 ± 8.7	84.7 ± 8.5	0.8 (0.4)
Systolic BP	125.7 ± 10.8	125.0 ± 10.1	0.4 (0.7)
Diastolic BP	72.4 ± 9.2	72.8 ± 10.2	0.2 (0.8)
Fetal Heart Rate	143.4 ± 7.2	140.6 ± 7.9	2.1 **(0.04)***

*Statistically significant ($p \leq 0.05$); t-test = Student t-test.

Table 4. Mean durations of the first, second and third stages of labour in the first stage of labour between the test and placebo group.

Variables	Group		t-test (P-value)
	HBB Mean ± SD	Placebo Mean ± SD	
Duration of the 1st stage of labour (min)	295.1 ± 29.0	293.6 ± 29.5	0.3 (0.8)
Duration of the 2nd stage (min)	19.5 ± 5.1	19.5 ± 6.0	0.01 (1.0)
Duration of the 1st and 2nd stage (min)	314.6 ± 29.2	313.2 ± 30.0	0.3 (0.8)
Duration of the 3rd stage (min)	4.5 ± 1.4	4.0 ± 1.4	1.9 (0.06)
Total labour duration (1st, 2nd, 3rd stages) (min)	319.0 ± 29.2	317.1 ± 29.9	0.3 (0.7)
Injection-delivery interval (hr)	5.1 ± 0.6	5.1 ± 0.7	0.3 (0.8)

*Statistically significant ($p \leq 0.05$); t-test = Student t-test.

Table 5. Mode of delivery.

Variables	Group		χ^2 (P-value)
	HBB n (%)	Placebo n (%)	
Mode of delivery			
Vaginal delivery	59 (92.2)	54 (84.4)	1.9 (0.2)
Caesarean delivery	5 (7.8)	10 (15.6)	
Indications for CS ($n_1 = 5$; $n_2 = 10$)			
Antepartum haemorrhage	1 (20.0)	2 (20.0)	0.8$^{\mu}$
Cephalopelvic disproportion	3 (60.0)	4 (40.0)	
Fetal distress	1 (20.0)	3 (30.0)	
Cord prolapse	0 (0.0)	1 (10.0)	

*Statistically significant ($p \leq 0.05$); χ^2 = Chi-Square; μ = Fisher's exact p.

Table 6. Neonatal outcome.

Parameters	Group		t-test (P-value)
	HBB Mean ± SD	Placebo Mean ± SD	
Birth Weight (kg)	3.4 ± 0.4	3.3 ± 0.4	0.5 (0.6)
APGAR scores at 1 min	7.3 ± 0.9	7.3 ± 1.0	0.5 (0.7)
APGAR scores at 5 min	8.6 ± 0.5	8.5 ± 0.6	1.2 (0.2)
Need for NICU	**n (%)**	**n (%)**	**Fisher's exact p**
No	60 (93.8)	57 (89.1)	
Yes	4 (6.3)	7 (10.9)	0.3$^{\mu}$
Indications for NICU admission			
Birth Asphyxia	2 (33.3)	4 (57.1)	
Infant of Diabetic mother	3 (50.0)	1 (14.3)	0.2$^{\mu}$
Observation	0 (0.0)	2 (28.6)	
Others	1 (16.7)	0 (0.0)	

*Statistically significant ($p \leq 0.05$); t-test = Student t-test; μ = Fisher's exact p.

Table 7. Maternal outcome.

Variables	Group		Fishers exact p
	HBB n (%)	Placebo n (%)	
Dry mouth			
Yes	6 (9.4)	2 (3.1)	0.3$^{\mu}$
No	58 (90.6)	62 (96.9)	
Headache			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	
Nausea & Vomiting			
Yes	6 (9.4)	7 (10.9)	1.0$^{\mu}$
No	58 (90.6)	57 (89.1)	
Tachycardia			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	
Urinary urgency			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	

Continued

Hypotension			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	
Blurred vision			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	
Skin rashes			
Yes	0 (0.0)	0 (0.0)	-
No	64 (100.0)	64 (100.0)	

4. Discussion

Shortening the duration of labour is a key goal of intrapartum care, as it reduces pain, anxiety, and stress for mothers [16]. This, in turn, can greatly enhance their overall satisfaction with the childbirth experience. Furthermore, reducing the duration of labour can also decrease the need for medical interventions, leading to better outcomes for both mothers and babies [16].

In this study, the duration of the first stage of labour was comparable. This was consistent with the study by Barau [6], who also reported no statistical difference, but Aldahhan observed a significantly longer duration in the intervention arm [17].

However, the main distinction between the current study and that of Barau was that the former included women with cervical dilation of 5 cm, whereas the latter included women in spontaneous labour at term with a cervical dilatation of 4 to 5 cm. Furthermore, whereas our study only looked at nulliparous women, Barau included both nulliparous and multiparous women. Conflicting results from other studies suggested that HBB actually shortened the initial stage of labour, underscoring the need for more study to elucidate these differences [18]-[20]. One possible explanation for the discrepancy in the study by Ejikeme *et al.* was that a higher dose of 40 mg of HBB was used. This may be because it may be difficult to ascertain when the second stage of labour begins [21].

The placebo group showed a faster cervical dilation rate than the HBB group early on in labour. This is not consistent with those of previous studies that showed that HBB increased the rate of cervical dilatation [22] [23]. The study by Kinyna *et al.* included both nulliparous and multiparous women, which might have accounted for this disparity. In the study by Akiseku *et al.* despite recruiting nulliparous women like the current study, it demonstrated a significant difference in the mean rate of cervical dilatation between the hyoscine group and the placebo group [23].

The total duration of labour, encompassing all three stages, was longer in the HBB group (319.0 ± 29.2 minutes) compared to the placebo group (317.1 ± 29.9

minutes). Although the HBB group had a slightly longer duration of labour, this variance was not statistically significant, suggesting that HBB did not significantly alter the overall duration of labour.

In terms of maternal side effects, this study showed that dry mouth was the most common side effect in the HBB group compared to the placebo group. It is particularly noteworthy that no participants in either group experienced cardiovascular symptoms. This is reassuring, as it suggests that HBB does not have significant cardiovascular effects, which is an important consideration for any medication used during labour. Hence, a single dose of 20 mg HBB given intravenously is relatively safe with minimal side effects to women in labour. This finding is similar to previous studies [8] [20] [23]-[25]. Aldahan *et al.* differed from our study, their study showed that the HBB group had significantly higher rates of maternal tachycardia [17].

Given that the increase in fetal heart rate was statistically significant, the use of HBB during labour may be associated with increased fetal risk. Despite this increase, the Apgar score did not change substantially from that of the control group. This is comparable to the findings by Aldahhan *et al.*, who reported that fetal heart rate was considerably higher in cases than in controls [17].

High proportion of vaginal births was observed in both groups; indicating that HBB may encourage vaginal deliveries. Furthermore, Qahtani *et al.* [26] revealed that although the control group had a somewhat higher rate of instrumental delivery, the rate of caesarean births among women who had HBB was not notably greater. This is contrary to what was reported by Aldahhan *et al.* [17] who reported that the HBB group had a higher caesarean delivery rate, which contradicts our findings. This difference might be because HBB significantly reduced cervical dilatation rate in the test group.

Based on APGAR scores at one minute and five minutes, the groups did not significantly vary for neonatal outcomes. This implies that HBB does not have a deleterious effect on newborn well-being. The results of previous studies are comparable to this, where Apgar scores of newborns delivered to mothers in the two groups were similar, irrespective of the dosage of HBB used and their routes of administration [8] [13] [18]. These findings provide confidence in the safety profile of HBB as demonstrated in our study.

5. Conclusions

The duration of the active phase of labour in nulliparous women was unaffected by a single 20 mg dose of intravenous hyoscine butyl bromide. HBB did not cause significant maternal side effects, nor did it alter the feto-maternal outcomes. However, after administration, there was a significant increase in the fetal heart rate. Based on the findings of this study, the routine use of 20 mg IV HBB to shorten labour in nulliparous women is not supported, as there was no significant change in the duration of the active phase of labour.

The trial, which was the first in the study center, was used as a pilot for more

extensive research. In addition, meticulous attention was paid to the recruitment of participants by adhering strictly to the inclusion criteria. Furthermore, since randomization was used, the possibility of selection bias was minimized. This study only included nulliparous women in labour with term pregnancies, the effect of increasing parity on reducing labour duration was excluded. The external validity was further enhanced by the use of an impartial assessor throughout the entire process.

6. Limitations of the Study

It was a single center study with a small sample size, and a significant number of women were excluded, thus findings may not accurately reflect the general population. Another limitation was the unavoidable inter- and intra-observer error that could have occurred in assessing for cervical dilatation.

7. Recommendations

It is recommended that a larger multi-center study may be conducted to further evaluate the usefulness of HBB in shortening the duration of labour. This may be done by randomized controlled trials to evaluate the impact of higher or repeated doses of HBB. A dose of 40 mg or even two intravenous doses of 20 mg HBB spaced a few hours apart could be used instead. However, from the findings of this study, HBB did not shorten the active phase of the first stage of labour, and as such should not be recommended.

Conflicts of Interest

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

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