Original Article

THE EFFECT OF HYOSCINE-N-BUTYL BROMIDE ON THE DURATION OF LABOUR IN TERM PARTURIENTS IN YENAGOA: A RANDOMIZED DOUBLE-BLIND, CONTROL STUDY.

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Abstract

Background: Hyoscine –N- butyl bromide (HBB) is a quaternary ammonium derivative, which exerts a spasmolytic action on the smooth muscle of the gastrointestinal, biliary, and genitourinary tracts. Its spasmolytic action on the cervix can enhance cervical dilatation and prevent prolonged labour.

Objective: To determine the effect of Hyoscine-N-butyl bromide on the duration of labour in parturients in Yenagoa.

Materials and Methods: This was a randomized, double-blind, controlled study involving 144 parturients who received either intravenous hyoscine–N-butyl bromide (20 mg in 1 ml; n=72) or intravenous normal saline (1 ml, n = 72). The mean duration of the stages of labour were compared between the two groups. Cervical dilatation rate, duration of the first and second stages of labour was recorded. The neonatal outcome and drug adverse effects were also compared.

Results: The cervical dilation rate in the test group was faster than that of the placebo group and the difference was statistically significant ($p < 0.00$). The duration of the first stage of labour was shorter (319.22±45.59 mins) in the test group than that of the first stage of labour (345.03±42.67mins) in the placebo group and the difference was statistically significant. The duration of the injection delivery interval was shorter (353.54±49.37mins) in the test group than in the placebo group (380.14±51.79mins) and this difference was statistically significant ($p <0.00$). The duration of the second stage and third stages of labour did not show statistically significant difference between groups and this remained so even after the subjects were broken down by parity.
There was no statistically significant difference between groups in terms of maternal adverse effects and foetal response to the test drug.
Conclusion: Intravenous administration of 20 mg hyoscine–N-butyl bromide is safe for use in labour and has a role in reducing the duration of the first stage and overall duration of labour in nulliparous women.

Keywords: Hyoscine –N- butyl bromide, labour, neonatal outcome.

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INTRODUCTION

Childbirth is the period from the onset of regular uterine contraction until expulsion of the placenta.[1] The process by which this normally occurs is called labour. Labour lasting less than 3 hours is precipitate labour while that in which the active phase last more than 12 hours is prolonged[2].Labour does not always follow an ideal course. Sometimes it becomes prolonged which is likely to give rise to 3 types of distress, namely: maternal, foetal and

obstetrician's distress[3].

The principle of active management of labour was introduced in Dublin to shorten the length of labour, while achieving or maintaining low caesarean delivery rates.[4,5]
The hazards of prolonged labour have been well recognized. There is an increased incidence of maternal distress, postpartum haemorrhage, infection, dehydration and operative interference. The baby may suffer from asphyxia, sepsis and neurological insult[6].

Attempt to shorten the duration of labour, especially the first stage has been an endeavour for several years. Cervical dilatation and effacement are important factors apart from the driving force of uterine contractions, which determines the duration of labour. Among the various causes of prolonged labour, protracted dilatation and effacement of the cervix is a major contributor.[7]

Various pharmacologic agents with different modes and sites of action have emerged, aiming to prevent prolonged labour. Oxytocin is currently the pharmacologic agent used to prevent prolonged labour together with partograhic monitoring. Sometimes the use of oxytocin titration can lead to uterine hyperstimulation with its attendant risk of foetal distress and uterine rupture. Other side effects of oxytocin include predisposition to primary postpartum haemorrhage, cardiac arrhythmia, fatal afibrinogenemia, water intoxication. Foetal adverse effect such as bradycardia, permanent brain damage, neonatal jaundice, low APGAR score at 5 minutes can also occur.

Hyoscine (also known as scopolamine)-N-butyl bromide is a quaternary ammonium derivative, which exerts a spasmolytic action on the smooth muscles of the gastrointestinal, biliary, and genitourinary tracts.[8] Hyoscine-N-butyl bromide does not increase uterine contraction instead it has a spasmolytic effect on the smooth muscles of the cervix. It therefore will not cause uterine hyperstimulation with its attendant risk.

Hyoscine–N-butyl bromide is cheap, easily available, temperature stable and with low side effect profile. Most of the published studies on the effect of hyoscine-N-butyl bromide on the duration of labour were done in Asia, Caribbean and Europe with different outcomes. The reasons for the discrepancies in outcomes are mostly from methodological issues especially in reports from studies between women of different parities.[9]

The objective of this study is to assess whether hyoscine-N-butyl bromide has any effect on the duration of labour among parturient. The study also aims to determine whether there is any maternal or foetal side effect associated with use of hyoscine-N-butyl bromide in labour.

MATERIALS AND METHODS

This was a randomised double-blind, control study to assess the effect of hyoscine-N-butyl bromide on the duration of labour in parturients in Yenagoa. It compared two groups of parturients: one group received 20 mg of intravenous hyoscine-N-butyl bromide while the other (control group) received 1 ml of sterile water.
This study was carried out at Federal Medical Centre, Yenagoa, the capital city of Bayelsa State, South-South Nigeria.

The participants comprised women between 18 – 35 years of age at 37 weeks to 41 weeks and 6 days' gestational age with viable cephalic presenting singleton pregnancies and no contraindication to vaginal delivery and in spontaneously established labour with cervical dilatation of 4 cm – 6 cm.

Obese women (≥90 kg) were excluded from the study. Parturients with chronic or pregnancy-induced illnesses, any contraindication to vaginal delivery, previous Caesarean section, any other surgery on the uterus, multiple pregnancies and antepartum haemorrhage were also excluded. Parturients with premature rupture of membranes, induced labour and also those on epidural analgesia were excluded. Parturients with known

hypersensitivity hyoscine butyl-bromide or its excipients, parturients with history suggestive of or diagnosed previously to have glaucoma, myasthenia gravis, obstructive uropathy, Down's syndrome, asthma, cardiac, liver or renal disease, persistent gastro-oesophageal reflux disease, megacolon, ulcerative colitis, seizure disorders or psychiatric illness were excluded from the study. Patient on drugs with known interaction with hyoscine butyl-bromide such as tricyclic antidepressants, antipsychotic, atropine-like compounds, antihistamine, quinidine, disopyramide, amantadine, anticholinergic, monoamine oxidase inhibitor, beta adrenergic agents, antacids, dopamine antagonist were excluded from the study.

Sample size was determined based on primary outcome variable which was the mean duration of active phase of labour.
Sample size for the test and control group was calculated using previous works as a guide. The formula;

$d = \Delta/SD$ where d = standardized difference Δ = target difference and SD = standard deviation was be used.[10]

A target difference of 60 minutes in the duration of labour between the test and control group was taken as the smallest clinically significant difference. The SD of 84 minutes was from the work of Trevino-Salinas et al involving parturients irrespective of parity and 20 mg of hyoscine-N-butyl bromide (IDA brand) twice 1 hour apart.[10]

$d = \Delta/SD$
$d = 60/84$
$d = 0.7$

With a standardised difference of 0.7, a nomogram was used to obtain the required sample size for each arm of the group at a P value of 0.05 and 80% power.[10] Thus, it was determined that 65 women will be needed for each arm, a total number of 130 parturients.

To correct for attrition of patients due to withdrawal of consent and/or intrapartum medical and obstetric complications in the exclusion criteria, a 10% attrition rate was anticipated.

N = n/1-q where n = initial total sample size, N = final total sample size, q = expected attrition.[10]
N = 130/1-(10%)
N = 130/ 1-0.1
N = 130/ 0.9
N = 144

Patient recruitment started after written informed consent was obtained from the parturients after appropriate and adequate counselling on the purpose of the study, brief methodology of the study and possible side effects of the drug.
It was clearly stated to the parturients that refusal to partake in the study or withdrawal of consent at any time in the study will not in any way affect the care they will receive.

A computer program was used to generate a random sequence of numbers. Sequentially numbered syringes using the list of unique computer-generated random numbers were prepared by the pharmacy aseptically with 72 containing 20 mg (1 ml) of hyoscine-N-butyl bromide (IDA brand) with the same batch number, date of manufacturing and expiry date and another 72 containing 1ml of sterile water. Both liquids are colourless so the syringes containing the drug are indistinguishable from those containing the sterile water. The syringes were produced in a rolling basis in batches of 10, each labelled with its own unique number (fresh batches are made as more people are enrolled). These were stored in the refrigerator until a qualified patient was admitted. Only the pharmacist knew the content of each syringe. Following an informed consent, a parturient that met the criteria for randomisation was admitted into the labour ward. Information on her biodata was obtained and recorded on the proforma. At cervical dilatation of 4 cm – 6 cm a pre-filled labelled syringe was selected and the number noted on the form. The injection was given intravenously over 1 minute through an already sited intravenous access. 30 minutes following injection, the patient's pulse rate, blood pressure and foetal heart rate were checked. Possible side effects were asked for every 30 minutes till delivery.

The monitoring of the progress of labour was done in accordance with our labour ward protocol which

is based on the principles of active management of labour. Opioid analgesia was given to those that required it; amniotomy was done for intact membranes and oxytocin was instituted for those with unsatisfactory progress as shown by the partograph. However, parturients that had augmentation of labour were not included in the final analysis. Operative interventions were carried out when indicated.

After delivery, the proforma was completed noting the duration of the first, second and third stages of labour, drug side effects, neonatal condition at birth, postpartum complications and patients' acceptability. All data sheets were properly stored in electronic and hard copies. At the end of the study, the pharmacy handed over the record of unique numbers with details on which contained hyoscine-N-butyl bromide. The data was disaggregated, using the record of unique random numbers to allocate the participants into test and control groups.

The data obtained from this study was analysed with the Statistical Package for Social Sciences (SPSS®) version 22.0 (2013, IBM, Armonk, New York, USA). Absolute and relative frequencies of categorical variables and mean and standard deviations of continuous variables were calculated. Continuous variables were analysed using t-test while categorical variables were analysed using Chi-square. Categorical variables like first minute APGAR score where Chi-square cannot be used was analysed using Fisher exact test. P-value when less than or equal to 0.05 was taken as significant.
Ethical approval for this study was obtained from the Health Research Ethics Committee of the Federal Medical Centre, Yenagoa, Bayelsa State.

RESULTS

After the codes for identifying the syringe samples were received from the pharmacist, it was discovered that for the test group, 3 women required augmentation of labour after the partograph revealed that an intervention was required in their labour. Of these three, two went on to have vaginal delivery while one had a Caesarean section. Two other women in the test group had an urgent Caesarean section for cephalo-pelvic disproportion due to malposition. Of the 72 women who received intravenous hyoscine-N-butyl bromide, only the parameters of 67 subjects were subjected to intervention-dependent analysis.

In the placebo group, 7 of the 72 women had augmentation of labour after the partograph revealed that an intervention was required. Of these seven, six had a vaginal delivery while one had a Caesarean delivery. Two other women who did not have augmentation of labour had an urgent Caesarean delivery for suspected foetal distress. It was noted intrapartum that one of them had a baby with a nuchal cord, while in the other, the finding of retroplacental blood clots led to a retrospective diagnosis of placental abruption. In the placebo group, parameters obtained from 63 women were subjected to intervention-dependent analysis.

A comparison of the two groups revealed that they were not statistically different in terms of age ($p = 0.63$), weight ($p = 0.36$), gestational age ($p = 0.57$), cervical dilation at the time of admission ($p = 0.86$), artificial rupture of membranes ($p = 0.13$) and parity ($p = 0.51$). This non statistical difference between the groups in terms of the parameters stated implies that these groups may be considered to be similar. The characteristics of both groups are highlighted in Table 1.

Augmentation of labour with oxytocin was 4.17% for the test group and 9.72% for the placebo group. A Fisher's exact test (see table 2) demonstrated that this difference was not statistically significant ($p = 0.58$).

The groups were separated based on the mode of delivery into spontaneous vaginal delivery, assisted vaginal delivery and abdominal delivery. There was no statistically significant difference between the groups ($p = 0.90$). See table 3.

There was a non-statistically significant difference ($p = 0.07$) in the rate of cervical dilation between

the two groups with the cervical dilation rate being faster in the test group than in the placebo group. The duration of the first stage was shorter in the test group by an average of twenty-four minutes when compared to the placebo group. This difference was statistically significant (p = 0.003). The difference between the groups for the duration of the second stage of labour (p = 0.71) and the third stage of labour (p = 0.13) did not show any statistical significance. The injection delivery interval for the test group was shorter than that of the placebo group by an average of twenty-four minutes and this difference was statistically significant (p = 0.01). These findings are demonstrated in Table 4.

To determine if the parity of the clients had an effect on the intervention outcomes, the cervical dilatation rate, duration of the different stages of labour and the injection delivery interval were analysed by parity. Subjects were classified as nulliparous, primiparous, multiparous and grand multiparous.

The cervical dilation rate amongst nulliparous women was faster in the test group as compared to the placebo group and this difference was statistically significant (p = 0.02).

The difference in cervical dilatation rate between the groups for the primiparous women (p = 0.07), multiparous women (p = 0.42) and grand multiparous women (p = 0.19) was not statistically significant.

The duration of the first stage of labour when analysed by parity showed that for nulliparous women, the first stage of labour was shorter in those who received the intervention as compared to those who received the placebo. This difference was statistically significant (p = 0.00). The difference between groups in the duration of the first stage of labour for the primiparous women (p = 0.09), multiparous women (p = 0.88) and grand multiparous (p = 0.10) was not statistically significant.

The difference between groups in the duration of the second stage of labour for the nulliparous women (p = 0.35), primiparous women (p = 0.22), multiparous women (p = 0.81) and grand multiparous (p = 0.76) was not statistically significant. These findings are highlighted in table 5.

The injection-delivery interval when analysed by parity showed that the difference was shorter in nulliparous women who received hyoscine-N-butyl bromide as compared to those who got the placebo and that this difference was statistically significant (p = 0.00). The difference between groups in the injection delivery interval for the primiparous women (p = 0.17), multiparous women (p = 0.95) and grand multiparous women (p = 0.10) was not statistically significant. These findings are shown in table 6.

To determine the safety of the intervention drug, the maternal and foetal cardiovascular statuses were assessed before the administration of the drug and then 30 minutes after administration of the contents of the syringe. There was no statistically significant difference between groups for maternal pulse (p = 0.85), maternal systolic blood pressure (p = 0.35), maternal diastolic blood pressure (p = 0.14) as well as the foetal heart rate (p = 0.27). These findings are highlighted in Tables 7 and 8.

Six women (6/72, 8.33%) who received the test drug had side effects with dry mouth (3/6) being the most common side effect. No woman in the placebo group had any side effect. The APGAR scores at the first minute (p = 0.28) and the fifth minute (0.29) showed no statistically significant difference between groups. No baby born in this study required anything other than routine resuscitative measures at birth and two babies born to women in the placebo group were admitted into the special care baby unit due to macrosomia (Table 10).

TABLE 1: PARTURIENTS CHARACTERISTICS IN BOTH GROUPS

Parameter	Test group n = 72	Placebo group n = 72	P-value
Age in years (mean ± S.D)	29.08±3.92	28.78±3.66	0.63
Weight in kg (mean ± S.D)	71.34±8.09	75.80±5.32	0.36
Gestational age in weeks (mean ± S.D)	39.07±0.86	38.98±0.92	0.57
Cervical dilation on admission in cm (mean ± S.D)	4.85±0.72	4.87±0.71	0.86
Artificial rupture of membranes in %	48.6% (35/72)	67.7 (48/72)	0.13
Parity			0.51
Para 0	16	17	
Para 1	7	9	
Para 2- 4	41	33	
Para ≥ 5	8	13	

TABLE 2: ANALYSIS OF AUGMENTATION OF LABOUR IN THE TEST GROUP AND CONTROL GROUP.

Parameter	Test group	placebo group	p- value
Augmentation of labour	3/72	7/72	0.58 (Fisher s test)

TABLE 3: MODE OF DELIVERY.

Parameter		Test group n = 72		Placebo group n = 72	P-value
Spontaneous vaginal delivery in percentage (%)		67/72 (93.05%)		66/72 (91.67)	
Ventouse delivery in percentage (%)		2/72 (2.78)		3/72 (4.17)	0.90
Forcep delivery (%)		0/72		0/72	
Caesarean section (%)	3/72(4.17)			3/72(4.17)	

TABLE 4: MEAN DURATIONS OF THE FIRST, SECOND AND THIRD STAGES OF LABOUR WITH RATE OF CERVICAL DILATATION IN THE FIRST STAGE BETWEEN THE TEST AND PLACEBO GROUP.

Parameter	Test group n = 67	Placebo group n = 63	P-value
Cervical dilatation rate in c m per hour (mean ± S.D)	0.92±0.25	0.85±0.19	0.07
Duration of first stage of labour in minutes (mean ± S.D)	325.94±45.32	349.79±45.05	0.003
Duration of second stage of labour in minutes (mean ± S.D)	34.16±13.39	35.10±14.56	0.71
Duration of third stage of labour in minutes (mean ± S.D)	16.30±4.45	17.49±4.49	0.13
Injection –Delivery Interval in minutes	360.67±51.05	384.59±55.03	0.01

TABLE 5: DURATION OF LABOUR STAGES IN THE TEST AND PLACEBO GROUP BROKEN DOWN IN TERMS OF PARITY.

Parameter	parity	Test		Placebo		P-value
Cervical dilatation rate at cm/hr (mean ± S.D)	0	N 14	0.87±0.22	N 15	0.69±0.13	0.02
	1	7	0.92±0.08	8	0.84±0.08	0.07
	2 – 4	38	0.98±0.14	28	0.95±0.17	0.42
	≥ 5	8	0.93±0.09	12	0.87±0.09	0.19
Duration of first stage of labour in minutes (mean ± S.D)	0	14	340.57±35.52	15	407.00±28.52	0.00
	1	7	327.14±60.75	8	373.75±38.52	0.09
	2-4	38	322.11±49.69	28	320.43±40.22	0.88
	≥5	8	313.75±27.22	12	348.75±18.11	0.10
Duration of second stage of labour in minutes (mean ± SD)	0	14	52.79±8.06	15	56.07±10.36	0.35
	1	7	37.29±4.96	8	34.25±5.47	0.22
	2-4	38	27.42±10.44	28	27.25±9.77	0.81
	≥5	8	30.88±3.56	12	30.42±2.64	0.76

TABLE 6: INJECTION - DELIVERY INTERVAL IN MINUTES (MEAN ± S.D) BROKEN DOWN IN TERMS OF PARITY

Parity	Test group		Placebo group		P-value
0	14	393.21±34.85	15	462.93±32.23	0.00
1	7	364.43±60.67	8	404.13±39.42	0.17
2 – 4	38	349.75±55.47	28	346.96±44.46	0.95
≥ 5	8	344.63±28.14	12	379.17±18.45	0.10

TABLE 7: MATERNAL RESPONSE 30 MINUTES FOLLOWING ADMINISTRATION OF 1 ML SOLUTION.

Parameter (mean ± S.D)	Test group	Placebo group	P – value
Maternal pulse rate per minute	80.40±11.87	81.56±8.17	0.85
Maternal systolic blood pressure (mmHg)	124.40±5.18	121.33±5.83	0.35
Maternal diastolic blood pressure (mmHg)	80.00±2.45	77.54±3.13	0.14
Estimated blood loss (ml)	291.34±49.33	284.92±55.54	0.49

TABLE 8: FOETAL RESPONSE 30MINUTES FOLLOWING ADMINISTRATION OF 1ML SOLUTION.

Parameter (mean ± S.D)	Test group	placebo group	P-value
Foetal heart rate	141.60±12.99	133.33±11.83	0.27

TABLE 9: MATERNAL ADVERSE EFFECTS FOLLOWING ADMINISTRATION OF THE 1 ML SOLUTION.

Adverse effect	Test group	Placebo group	Total
Urinary urgency	0	0	0
Blurred vision	0	0	0
Hypotension	0	0	0
Nausea and vomiting	1	0	1
Headache	0	0	0
Dry mouth	3	0	3
Skin rash	0	0	0
Dizziness	2	0	2
Total	6	0	6

TABLE 10: NEONATAL OUTCOME.

Parameter	Test group n = 72	Placebo group n = 72	P-value
APGAR score at 1st minute (mean ± S.D)	7.94±0.24	7.98±0.22	0.28
APGAR score at 5th minute (mean ± S.D)	8.99±0.12	8.95±0.22	0.29
Need for resuscitation	0	0	
Special Care Baby Unit Admission	0	2	

DISCUSSION

Both groups were compared to ensure that there was no statistically significant difference in the groups prior to data analysis. This was necessary since subjects that were recruited into the study were not matched for the parameters. The finding was a non-Statistically signicant difference between the groups in terms of age, weight, gestational age, cervical dilation, artificial rupture of membranes and parity. No statistically significant difference was noted when comparison was made as the effect of rates of augmentation of labour between the groups and the mode of delivery amongst subjects in the groups. The absence of a statistically significant difference between the groups suggests that there is a reduced risk of bias in interpreting the results from both groups.

The cervical dilation rate in the test group of 0.92±0.25cm/hr was faster than the rate in the placebo group which was 0.85±0.19 cm/hr and this difference was not found to be statistically significant (p = 0.07).

There was a statistically significant shortening of the first stage of labour in the test group by 24 minutes (p = 0.003) and the injection delivery interval by 24 minutes (p = 0.01) in the test group as compared to the placebo group. The shortening of the first stage of labour by 24 minutes found in this study is similar to shortening of the first stage of labour by 23.35 minutes in patients who received 20 mg of hyoscine-N-butyl bromide intravenously in the study carried out by Imaralu et al.[11] This is however longer than the 13 minutes in the study conducted by Faride et al[12] but shorter than the statistically significant average shortening of the first stage of labour by 74.34 minutes in the test group reported in a meta-analysis.[9] These studies [9,11,12] which reported a statistically significant shortening of the first stage of labour with the use of intravenous hyoscine-N-butyl bromide did not report the average cervical dilation at the time the drug was administered and the time taken to achieve full cervical dilation or delivery. In this study, the average cervical dilation for the test group at the time of admission was 4.85±0.72 cm and full cervical dilation and delivery were achieved at 325 minutes (5.4 hours) and 360 minutes (6 hours) respectively.

To determine if parity had an effect on the rate of cervical dilation and the time to full cervical dilation as well as delivery, the parturients were disaggregated by their parity. Amongst the nulliparous women, the rate of cervical dilation was faster in the test group (0.87±0.22 cm/hr) as compared to the placebo group (0.69±0.13) and this difference was statistically significant (p = 0.02). The duration of the first stage of labour in the test group (340.57±35.52) was shorter than that of subjects in the placebo group (407.00 ± 28.52) and this difference was

statistically significant (p = 0.00). The injection delivery interval in the test group was shorter in the test group (393.21±34.85) than in the placebo group (462.93±32.23) and this difference was statistically significant (p = 0.00).

The cervical dilation rate though faster in the test group for the entire population was not statistically significantly different from the cervical dilation rate for the placebo group. This was however different when the groups where disaggregated by parity as the cervical dilation rate was statistically significantly faster in the test group as compared to the placebo group for the nulliparous women. The smaller number of nulliparous women (14) as against parous women (53) may have been responsible for this finding.

Amongst the primiparous, multiparous and grand multiparous women, the durations noted for the test groups were better than those of the placebo groups but differences noted between the groups for cervical dilation rate (p = 0.07, 0.42, 0.19 respectively), duration of the first stage of labour (p = 0.09, 0.88, 0.10 respectively) and the injection delivery interval (p = 0.17, 0.95, 0.10 respectively) were found not to be statistically significant.

In a similar study by Kirim et al[13], there was a statistically significant shortening of the duration of the first stage of labour for both primigravid subjects and multigravid subjects as compared to the placebo group when the data was disaggregated by gravidity. In the study by Imaralu et al[11], while there was shortening in the duration in the first stage of labour for subjects in the test groups as compared to those in the placebo group when disaggregated by parity, this shortening was statistically significant only amongst multiparous women who received oxytocin infusion for the augmentation of labour.
Non synchronous uterine contractions are considered to be the characteristic pattern of labour in the nulliparous woman and oxytocin infusion is used to correct this and allow for the synchronous uterine contractions which lead to cervical dilation and delivery. There is evidence to show that spasmolytic action of hyoscine-N-butyl bromide[8] may explain why nulliparous subjects in the test group had a statistically significant shortening of the first stage of labour as compared to women of higher parity.

In this study, the duration of the second stage of labour amongst parturients in the test group (34.16±13.39) was in the same range as that of those who received the placebo (35.10±14.56) and a test of statistical significance showed that there was no difference between the groups (p = 0.71). This finding is similar to the findings from other studies[11,12,13] where no statistically significant difference was found in the duration of the second stage between groups. Two other studies[14,15], reported a statistically significant difference in the duration of the second stage of labour between the test group and the placebo group with the duration being shorter in the test group. In the study by Alani and Salim[15], it is thought that the higher dose of hyoscine-N-butyl bromide (40 mg) used for the study may be responsible for the shorter duration of the second stage of labour in the test group than in the placebo group while it may be difficult to find an explanation for the statistically significant shortening of the second stage of labour in the test group in the study by Sekhavat et al in which 20 mg of hyoscine-N-butyl bromide was administered.[14]

None of these studies which reported a statistically significant shortening of the second stage of labour took into account the effect of assisted vaginal delivery on the duration of the second stage of labour or on the comparability of the groups in terms of mode of delivery. In this study, two parturients in the test group had an assisted vaginal delivery with a mean second stage duration of 47.50±10.61 and three women in the placebo group had an assisted vaginal delivery with a mean second stage duration of 57.67±2.88. This difference was not statistically significant (p = 0.54).

When the groups were disaggregated by parity, it

was found that any difference noted in the duration of the second stage between groups for the nulliparous (p = 0.35), primiparous women (p = 0.22), multiparous women (p = 0.81) and grand multiparous (p = 0.76) was not statistically significant.

Taking into cognizance that there is a component of maternal effort with the use of the abdominal wall muscles in effecting the second stage of labour, hyoscine-N-butyl bromide which exerts its effect more on the smooth muscles[8] may not really play a role in the duration of the second stage of labour.

The use of AMTSL may explain the similarity in the duration of the third stage of labour in the test group (16.30±4.45) and the placebo group (17.49±4.49) with the test of significance showing no difference between groups (p = 0.13). This is similar to findings from other studies[11,12,13,14] where no difference was noted between groups as regarding the duration of the third stage of labour. In the study by Alani and Salim[15] where a statistically significant shortening of the third stage of labour was noted in the test group as compared to the placebo group, there was no mention if AMTSL was used for the third stage or physiologic management of the third stage of labour.

There was no statistically significant difference in the maternal cardiovascular response in those who received the test drug as compared to those who received the placebo. The commonest side effect noted was dryness of the mouth which occurred in three subjects, one complained of nausea while two complained of dizziness. These effects were transient and resolved spontaneously within a short time. These adverse effects are associated with hyoscine-N-butyl bromide and have been reported by Imaralu et al[11], who stated that dry mouth and tachycardia were the common side effects amongst subjects who received HBB in their study.

There is nothing to suggest that hyoscine-N-butyl bromide is associated with primary post-partum haemorrhage as there was no statistically significant difference in the average estimated amounts of blood lost (p = 0.49).

There was no statistically significant difference between groups in the APGAR scores at the first minute (p = 0.28) and at the fifth minute (p = 0.29). This is similar to the findings from other studies[11,12,14] where no difference was found in the APGAR scores of neonates born to parturients in either group.

No baby in this study had a need for additional resuscitative efforts and two babies in the placebo group were admitted into the special care baby unit for observation after they were noted to be macrosomic and at risk of hypoglycaemia. In the study by Sekhavat et al[14] the need for neonatal resuscitation was not significant and neither was the need for admission into the neonatal intensive care unit.

CONCLUSION

Findings from this study show that hyoscine-N-butyl bromide is effective in reducing the duration of the first stage of labour and in turn the overall duration of labour in the absence of oxytocin augmentation of labour and this effect is more pronounced in nulliparous women who have the drug administered intravenously at a dose of 20 mg stat. The findings also show that the drug has no effect on the second and the third stage of labour in any group of parturients. With the minimal side effects noted during the course of the study, it can be concluded that the drug is safe for both the mother and the baby at the dose administered during this study after parturients have been warned about the possibility of a side effect and that the side effects usually resolve spontaneously.

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CONFLICT OF INTEREST

The authors declared not conflict of interest.

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