Tropical Journal of
Obstetrics & Gynaecology
ISSN-Print: 0189-5117
Online: 2543-148X
Official Publication of Society of
Obstetrics & Gynaecology of Nigeria

■ Original Article

The Efficacy of Hyoscine Butyl Bromide in Accelerating Cervical Dilatation in Labour: A Double Blind Randomized Controlled Trial

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ABSTRACT

Background: The use of hyoscine butyl bromide to reduce the duration of labor is an interesting area of research as part of the efforts to mitigate the complications of prolonged labor. ***Study Aim:*** The aim of this study was to evaluate the efficacy of hyoscine butyl bromide in acceleration of cervical dilatation in labor. **Methodology:** This was a double blind randomized controlled study done at National Hospital Abuja from 2017 to 2019, in which 130 parturients in spontaneous labor were randomized into one of two parallel treatment groups. The study group received a single dose of 20mg of hyoscine butyl bromide intramuscularly on diagnosis of active phase of labor while the control group received 1ml of distilled water. **Results:** The mean duration of the first stage of labor in the study group was 279.73±160min and 319.25±144min in the control group (t=-1.44, P=0.15, 95% CI -94.48-14.84). The differences in the duration of the second and third stages in both groups were not statistically significant. Subgroup analysis showed a statistically significant reduction in the first stage duration in the hyoscine group of the parous patients (183.23±116.58 min vs 288.28±151.19 min, t=-2.99, P= 0.004, 95% CI-175.31 to-34.78) There were no statistically significant differences in maternal drug side effects, estimated blood loss and immediate neonatal outcome (P>0.05). **Conclusion:** Intramuscular hyoscine butyl bromide did not show efficacy in accelerating cervical dilatation in the general study sample, however it was found to accelerate cervical dilatation in the parous parturients. It is recommended for acceleration of labor in women with previous parous experience.

Key Words: Hyoscine butyl bromide, Cervical dilatation, Acceleration, Labor

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Introduction

Labor is a memorable event in a woman's life. It marks the culmination of pregnancy and is uncomplicated in most cases. The major goal in obstetrics is to deliver a healthy baby to a healthy mother with no or minimal maternal trauma so the aim of labor

management is the prevention of prolonged labor as it has deleterious maternal and fetal consequences.[1]

The ability of the fetus to successfully negotiate the pelvis is dependent on the complex interaction of three variables: the powers (uterine contractions), the passenger (the fetus) and the passage (bony pelvis and soft tissues).[2] Thus the duration of labor is affected by rate of dilatation of the cervix, intensity of uterine contractions, pelvic floor dimension, fetal presentation, position and size, and the parity of the parturient.

The sensitive index of the quality of the health care delivery system of a country is reflected by its maternal and perinatal mortality rates.[3] Prolonged labor has far reaching maternal and fetal complications and impacts negatively on maternal and child survival. The prevention of prolonged labor therefore proportionately leads to a reduction in maternal and perinatal mortality and morbidity.[4] In recognition of this fact, efforts have been made to address and mitigate the factors that lead to prolonged labor.

The need for a departure from the usual passive management of labor to active management of labor was brought to prominence as a result of the work of Kieran O'Driscoll et al at National Maternity Hospital Dublin.[5] Active management of labor involves a prospective detection of deviation from normal progress of labor and augmentation of the powers to accelerate progress.

Active management of labor has been practiced over the years as a way of preventing prolonged labor. However it has been found to be too prescriptive and interventional and also difficult to domesticate in some centers because of logistic challenges.[6] Therefore the search for alternative labor accelerating mechanisms that will not undermine women's autonomy is still ongoing. The World Health Organization (WHO) considers the use of antispasmodic agents for treatment of delay in labor as a research priority.[7]

Antispasmodics that have been studied include hyoscine butyl bromide, valethamate bromide, drotaverine hydrochloride, rociverine and camylofin dihydrochloride.[8] They can be musculotropic or neurotropic. The musculotropic agents are phosphodiesterase type IV inhibitors that directly inhibit smooth muscle while the neurotropic agents competitively inhibit the action of acetylcholine at the neuromuscular junction.

Hyoscine is a neurotropic antispasmodic agent that is stable at room temperature.[9] It is a cheap, readily available smooth muscle relaxant in most labor wards which has not been found to have hazardous materno-fetal effects. It is often prescribed randomly in some obstetric units usually with the aim of accelerating cervical dilatation in labor.

Studies have been carried out mostly outside Nigeria to evaluate the effects of hyoscine on cervical dilatation; while majority of these studies demonstrated the efficacy in augmenting cervical dilatation, one study however showed no effect on accelerating cervical dilatation.[10-16] However, a meta-analysis on the use of antispasmodics in labor provided low quality evidence that antispasmodics reduce the duration of labor.[8]

Nigeria, is located in West Africa which is a region plagued by poverty, dearth of skilled birth attendants, poor health infrastructure and high level of illiteracy. A low cost, easy to use agent that can accelerate labor without the need for intensive patient monitoring will be of immense benefit in this region. The aim of this study was to evaluate the efficacy of hyoscine butyl bromide in enhancing cervical dilatation in labor.

Methods

a) **Study Design/Centre**

This was a double blind randomized controlled study on the efficacy of hyoscine butyl bromide in the acceleration of cervical dilatation in labor done at National Hospital, Abuja from April 2017 to July 2019. This is a tertiary hospital located in the Federal Capital Territory of Nigeria with average annual delivery of 1500 and vaginal delivery rate of about 52%. The study group received a single dose of 20mg of hyoscine butyl bromide intramuscularly on diagnosis of active phase of

labor while the control group received 1ml of distilled water.

b) **Study Participants**

The trial was approved by the Health Research Ethics Committee of National Hospital Abuja (NHA/EC/082/2016). Included in the study were consenting nulliparous and parous parturients in spontaneous active phase of labor with singleton fetus at term. Excluded were patients with known allergy to hyoscine, patients with previous uterine surgeries, fetal malpresentation, multiple gestation and chronic illnesses. All consecutive patients who met the inclusion criteria were counselled on the purpose of the study and written informed consent obtained. Structured questionnaires were interviewer administered to the patients. Patients were recruited consecutively until the desired sample size was achieved. Information obtained include patient's age, marital status, educational level, ethnicity, booking status, parity, gestational age and height.

c) **Sample Size Determination**

Sample size was determined using the formula for comparison of means in randomized controlled trials. With a significance level of 5%, statistical power of 80%, anticipated dropout rate of 5%, considering an effect size of 100 minutes and with the mean duration of first stage of labor and standard deviation derived from the study by Nagi et al,[12] the calculated minimum sample size was 130. Sixty-five (65) participants were allocated to each study arm.

d) **Randomization/ Blinding**

Based on the sample size of 130, a random sequence of numbers was computer generated. Sequentially numbered, sterile 2ml syringes were then prepared using the random numbers to determine their content: 65 syringes contained 20mg (1ml) hyoscine butyl bromide while 65 contained 1ml of distilled water (placebo). The drug and placebo were prepared in batches by a Pharmacist who was not involved in the study and were stored in the refrigerator in labor ward. All were designated with the random numbers. Both liquids are colorless, so the syringes containing the drug were indistinguishable from those containing placebo. The designation of the syringes were known only to the Pharmacist and this was made known to the Research team at the time of final analysis. The participants and labor ward staff were also blinded to the syringe designation. As patients were recruited, they were given an injection from the pool of already prepared injections. The hyoscine butyl-bromide injection used was from Laborate Pharmaceuticals India (Marketed by Embassy Pharmaceuticals Lagos, Nigeria).

e) **Intervention**

Once the parturients were admitted into labor ward, history and physical examination were conducted to ascertain eligibility. Written informed consent were obtained and the study questionnaire interviewer administered by a member of the study team. The drugs were administered by the midwife intramuscularly at 4cm cervical dilatation. The labor ward staff and research team together with the patients were all blinded to the designation of the syringes.

The progress of labor was monitored with the aid of the modified WHO Partograph with the maternal vital signs, fetal heart rate, nature of uterine contractions, state of the cervix and other key events in labor recorded in the Partograph. Amniotomy was done for parturients with intact membranes at 4cm cervical dilatation and the state of the cervix assessed two hourly till 8cm cervical dilatation, then hourly thereafter. The parturients were counselled on the possible side effects of hyoscine and encouraged to notify the labor ward staff if they had mouth dryness, nausea and vomiting or headache.

Active phase of labor was defined as the

period spanning from 4cm cervical dilatation to full dilatation. The time interval in minutes between 4cm cervical dilatation and full cervical dilatation (active phase of first stage), full cervical dilatation to delivery of the baby (second stage) and from delivery of the baby to delivery of the placenta (third stage) in minutes was recorded. Maternal drug adverse effects like headache, nausea and vomiting, dry mouth, tachycardia and hypotension, estimated blood loss(assessed by visual estimation), 1st and 5th minute Apgar scores of the baby, need for neonatal admission, and need for augmentation of labor or caesarean section were documented in the study proforma for each patient.

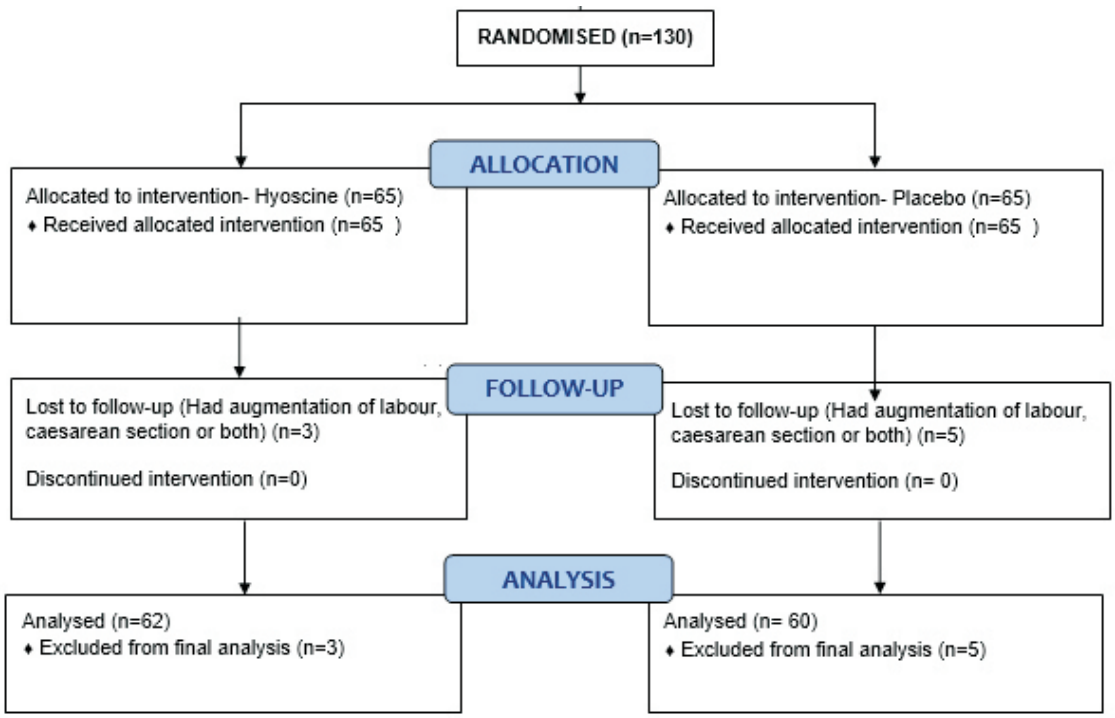
f) **Outcome Measures**

The primary outcome measure was duration of first stage of labor, while the secondary outcome measures were duration of second and third stages of labor, maternal drug side effects, estimated blood loss, Apgar scores of the neonate and need for neonatal admission.

g) **Data Analysis**

The data was collated and analyzed with the aid of Statistical Package for Social Sciences (SPSS) version 23. P value less than 0.05 at 95% confidence interval was regarded as statistically significant.

Continuous data was described using means and standard deviation while categorical variables were described using percentages. Chi square test or Fisher's exact test where appropriate was used to test the significant difference between categorical variables while test of significance for continuous variables was done with the student's t-test. Multivariate analysis using multiple linear regression analysis was used to assess the effect of confounding factors.



Results

Study Flow Diagram

This study participants were recruited from April 2017 to July 2019. In the period under which this study was done, there were 2,488 deliveries at the study center of which 1,287(51.7%) were vaginal deliveries.

TABLE 1: The mean age in the hyoscine group was 29.5±4.9years while in the placebo group it was 29.7±4.9years.

TABLE 2: The mean height and gestational age was comparable in both groups. Most of the patients were booked patients and there were almost equal proportion of nulliparous and parous women in both groups.

TABLE 3: Three women (4.6%) in the hyoscine group and four (6.2%) in the placebo group had augmentation of labor while one patient (1.5%) in the hyoscine group and 3 women (4.6%) in the placebo group had caesarean section. The differences were not statistically significant.

TABLE 4: The mean duration of labor in the hyoscine group was 279.7±160mins while it was 319.6±144mins in the placebo group. This represents a 12.5% reduction in the mean duration of the first stage of labor in the study group but it did not reach statistical significance (P=0.15). The second and third stages of labor, admission delivery interval and cervical dilatation rate were also comparable in both groups (P>0.05). The hypothesis testing did not provide enough evidence to reject the null hypothesis.

TABLE 5: There was a 36.5% reduction in the duration of the first stage of labor in the parous women of the hyoscine Group (P=0.004). The differences in the third stages of labor, admission delivery interval and cervical dilatation rate were also statistically significant. There were no statistically significant differences in the nulliparous.

TABLE 6: The mean blood loss in the hyoscine group was 216.1±103mls while it was 229.2±132mls in the placebo group (P>0.05). The Apgar scores and need for neonatal admission were also comparable.

TABLE 7: Dry mouth was the most common reported side effect but the differences were not statistically significant. The differences in nausea/vomiting and headache were also not significant.

TABLE 8: Parity was the only predictor variable that was significantly associated with the dependent variable (duration the first stage of

Table 1: Comparison of Socio-Demographic Characteristics

Variables	Hyoscine (n=65)	Placebo (n=65)	Test Statistic	P-Value
Mean Age ± SD(years)	29.46±4.92	29.69±4.89	-0.27†	0.79
Marital status				
- Single				
- Married	65(100%)	65(100%)		
- Divorced/separated				
- Widowed				
Social Class				
- Class 1	21(32.3%)	12(18.5%)	5.75‡	0.22
- Class 2	33(50.8%)	45(69.2%)		
- Class 3	3(4.6%)	2(3.1%)		
- Class 4	2(3.1%)	3(4.6%)		
- Class 5	6(9.2%)	3(4.6%)		

Variables	Hyoscine (n=65)	Placebo (n=65)	Test Statistic	P-Value
Ethnicity				
- Igbo	11(16.9%)	25(38.5%)	7.68§	0.05
- Yoruba	14(21.5%)	9(13.8%)		
- Hausa	16(24.6%)	12(18.5%)		
- Others	24(36.9%)	19(29.2%)		

SD- Standard deviation; †-t test; ‡-Fisher's Exact Test; §-Pearson's Chi square

Table 2: Comparison of Clinical Characteristics of the Study Population

Variables	Hyoscine (n=65)	Placebo (n=65)	Test Statistic	P-Value
Mean Height ± SD(cm)	162.66±5.33	162.19±5.48	0.49†	0.62
Mean Gestational Age ± SD	39.69±1.15	39.45±1.23	1.17†	0.25
Parity				
- Nulliparous	33(50.8%)	35(53.8%)	0.12§	0.73
- Parous	32(49.2%)	30(46.2%)		
Booking Status				
- Booked	64(98.5%)	63(96.9%)	0.34‡	0.56
- Unbooked	1(1.5%)	2(3.1%)		
Spontaneous membrane Rupture				
- Yes	14(21.5%)	10(15.4%)	0.82§	0.36
- No	51(78.5%)	55(84.6%)		

SD- Standard deviation; †-t test; ‡-Fisher's Exact Test; §-Pearson's Chi square

Table 3: Comparison of Need for Caesarean Section and Augmentation of Labour

Variables	Hyoscine (n=65)	Placebo (n=65)	Fisher's Exact Test	P-Value
Augmentation				
- Yes	3(4.6%)	4(6.2%)	0.15	0.69
- No	62(95.4%)	61(93.8%)		
Caesarean Section				
- Yes	1(1.5%)	3(4.6%)	1.032	0.31
- No	64(98.5%)	62(95.4%)		
Augmentation or Caesarean Section or both*				
- Yes	3(4.6%)	5(7.7%)	0.53	0.47
- No	62(95.4%)	60(92.3%)		

**-4 patients had augmentation only, 3 patients had both augmentation and caesarean section while 1 patient had caesarean section only*

Table 4: Comparison of the Duration of Labour in the Study and Control Groups

Variables	Hyoscine (n=62)	Placebo (n=60)	t-test	P-Value	95% CI
First Stage Duration(min)¶	279.73±160††	319.55±144	-1.44	0.15	-94.48 - 14.84
Second Stage Duration(min)	23.65±21.03	27.55±25.70	-0.92	0.36	-12.31 - 4.50
Third Stage Duration(min)	4.08±2.04	4.48±1.86	-1.14	0.26	-1.10 - 0.29
Admission Delivery Interval(min)	289.82±157	342.73±157	-1.85	0.07	-109.42 - 3.60
Cervical Dilatation(cm/hour)	1.89±1.56	1.62±1.22	1.09	0.28	-0.23 - 0.78

¶ -Active phase of first stage of labor, ††-Values expressed as mean±standard deviation; CI- Confidence Interval

Table 5: Subgroup Analyses of the Duration of Labour in Nulliparous and Parous Women

Variables	Hyoscine (n=62)	Placebo (n=60)	t-test	P-Value	95% CI
Nulliparous	**n=31**	**n=31**			
First Stage Duration(min)¶	376.22±139.19††	348.81±132.66	0.79	0.43	-41.66-96.50
Second Stage Duration(min)	35.45±22.62	40.39±28.38	0.76	0.45	-17.97-8.10
Third Stage Duration(min)	4.65±1.99	4.19±1.97	0.89	0.37	-0.56-1.46
Admission Delivery Interval(min)	384.58±133.66	379.94±140.81	0.13	0.89	-65.10-74.39
Cervical Dilatation(cm/hour)	1.31±1.28	1.53±1.32	-0.65	0.52	-0.88- 0.44
Parous	**n=31**	**n=29**			
First Stage Duration(min)	183.23±116.58	288.28±151.19	-2.99	0.004*	-175.31 to -34.78
Second Stage Duration(min)	11.84±9.95	13.83±12.31	-0.69	0.49	-7.76-3.77
Third Stage Duration(min)	3.52±1.96	4.79±1.72	-2.67	0.01*	-2.23 to -0.33
Admission delivery interval(min)	195.06±118.67	302.97±167.18	-2.87	0.006*	-182.44 to -33.36
Cervical Dilatation(cm/hour)	2.49±1.62	1.72±1.12	2.12	0.04*	0.04-1.49

¶ -Active phase of first stage of labor, ††-Values expressed as mean±standard deviation; CI- Confidence Interval

Table 6: Comparison of Blood Loss at Delivery and Immediate Neonatal Outcome

Variables	Hyoscine (n=62)	Placebo (n=60)	Test Statistic	P-Value
1 Minute Apgar	7.98±1.26	8.05±1.08	-0.31†	0.75
5 Minute Apgar	8.79±0.44	8.92±0.33	-1.76†	0.08
Estimated blood loss(mls)	216.13±103	229.17±132	-0.61†	0.55
Neonatal Admission				
- Yes	3(4.8%)	2(3.3%)	0.18‡	0.68
- No	59(95.2%)	58(96.7%)		

-Values expressed as mean±Standard Deviation; †-t test; ‡-Fisher's Exact Test

Table 7: Comparison of Maternal Drug Side Effects

Variables	Hyoscine (n=62)	Placebo (n=60)	Test Statistic	P-Value
Dry Mouth(Xerostamia)				
- Yes	22(35.5%)	20(33.3%)	0.06§	0.80
- No	40(64.5%)	40(66.7%)		
Nausea/Vomiting				
- Yes	3(4.8%)	3(5.0%)	0.002†	0.97
- No	59(95.2%)	57(95%)		
Headache				
- Yes	3(4.8%)	1(1.7%)	0.97†	0.33
- No	59(95.2%)	59(98.3%)		
Tachycardia				
- Yes	0(0%)	0(0%)		
- No	62(100%)	60(100%)		
Hypotension				
- Yes	0(0)%	0(0)%		
- No	62(100%)	60(100%)		

b-*Fisher's Exact Test;* **c**-*Pearson's Chi-Square*

Table 8: Multiple Linear Regression Analysis of Potential Confounders for Duration of First Stage Labour

Variables	Unstandardized Coefficients		Unstandardized Coefficients	*t*	P-Value	95% CI For B	
	B	Std. Error	Beta			Lower	Upper
Parity	-125.16	28.13	-0.410	-4.45	0.000*	-180.87	-69.46*
Gestational Age	8.22	11.46	0.06	0.72	0.48	-14.48	30.91
Height	0.88	2.68	0.03	0.33	0.74	-4.42	6.18
Age	-1.08	2.99	-0.03	0.36	0.72	-7.01	4.85
Ethnicity	0.38	11.32	0.003	0.03	0.97	-22.03	22.79

B/**Beta**-*Coefficient of regression;* **Std. error**-*Standard error for B,* **t**-*test statistic;*
*-*Statistically Significant*; **CI**-*Confidence interval*

labor) in the linear regression model.

Discussion

Reducing the duration of labor has been the long term goal of labor management, thus the aim of this study was to investigate whether hyoscine butyl bromide has any effect on cervical dilatation in labor thereby leading to reduction in the duration of first stage of labor.

The study and control groups were comparable with respect to demographic and clinical characteristics like age, social class, ethnicity, gestational age, parity and height. This indicates that randomization was proper and that any difference in the outcomes of interest would likely be attributed to the drugs used.

The duration of the first stage of labor in the study and control groups were 279.73±160 min and 319.55±144 min respectively with P value of 0.15. The differences in cervical dilatation rate and admission delivery interval were also not statistically significant. This concurs with the study by Gupta et al in India in which non significant differences was found in the duration of first stage of labor and cervical dilatation in both groups.[16]

In contrast however, Ibrahim et al in a study in Sokoto reported mean duration of the first stage of labor in cases and controls of 5.44 hours/6.52 hours with P value of 0.0001.[14] Likewise Nagi et al in their study in Egypt also found statistically significant differences in both groups(186min vs. 268min, P= 0.026).[12] Similarly, Mohaved et al, Makvandi et al, Al-Quatani et al and Samuels et al in their separate studies in Iran, Iraq, Saudi Arabia and West Indies respectively reported significant differences in the duration of the first stage in both the study and control groups (P<0.05).[10,11] The disparity may be attributed to some methodological differences with the current study. The methodological differences include cervical dilatation at recruitment, the dose and route of administration of hyoscine and the exclusion criteria. Some studies that evaluated the effect of other antispasmodic agents on progress of labor also showed superiority over placebo. [,]

The admission delivery interval was also calculated to correct for possible errors in determining the exact time of cervical dilatation and the result showed non statistically significant differences in the duration in both study and control groups(289.82±157min vs. 342.23± 157.64min, P=0.07).

In the subgroup analyses, the duration of the first stage of labor was significantly lower in the hyoscine group of the parous women but was not the case in the nulliparous (P=0.004). This is in consonance with the study done by Al-Kishali et al in Iraq in which they reported significant differences in the multigravida but not in the primigavida.[15] This can be explained by the fact that the process of labor becomes more efficient with increasing parity. Kirim et al in their work in Turkey however reported significant differences in the duration of the first stage of labor in both primigravidas and multigravidas.[13]

The duration of the second stage of labor in this study was 23.65±21.02 min vs. 27.55±25.70 min, P=0.36. This shows a non-statistically significant difference and is also comparable with findings by Ibrahim et al, Nagi et al and Samuels et al.[10,12,14] This is because hyoscine predominantly acts on the cervix, does not have any uterotonic effect and has no effect on the expulsive powers and pelvic floor architecture which predominantly determines the duration of the second stage of labor. However Sekhavat et al reported significant decrease in the 2nd stage in the hyoscine group.[] Their study was done exclusively on multiparous women and the influence of parity may have been contributory. Likewise Makvandi et al also reported significant decrease in the 2nd stage of labor, however rectal hyoscine was used in that study.[18]

The duration of the third stage of labor had no statistically significant difference in both cases and controls. This is comparable to studies by Samuels et al and Mohaved et al.[10,17] the similarity in the findings from these studies suggests that hyoscine does not have any significant effect on uterine tone. This is also buttressed by the fact that the estimated blood loss was also comparable in both groups as is the case in other studies.[10,12] Furthermore, Imaralu et al even reported less blood loss in the hyoscine group.[] This

observation is particularly important as there has been concerns of the theoretical risk of uterine atony secondary to hyoscine use which may lead to prolonged second or third stage of labor and postpartum hemorrhage.

There were no statistically significant differences in the Apgar scores of the neonates at the 1st and 5th minute in both study and control groups. There was also no difference in the incidence of neonatal admission. This is comparable to studies by Samuels et al, Al Quatani et al, Nagi et al, and Imaralu et al.[10,11,12,22] This confirms that hyoscine butyl-bromide has no adverse effect on immediate neonatal outcome. In contrast, Al-Kishali et al however reported a difference in Apgar scores at the 1st minute which they attributed to the effect on neonatal respiratory muscles although this effect disappeared within 5 minutes as the difference in the Apgar scores at the 5th minute was not statistically significant.[15]

In this study, there were no significant differences in the rate of emergency caesarean section and augmentation of labor in both groups. This is similar to findings by Samuels et al, Al-Quatani et al, Makvandi et al and Ibrahim et al.[10,14,11,18]

The differences in the incidence of side effects in the both groups were not statistically significant. However this is not consistent with reports by Ibrahim et al of significant differences in the incidence of vomiting (P=0.02).[14] When compared with this study, the dose of hyoscine used in that study was higher and the drug was administered by the intravenous route. The greater bioavailability of the intravenous route may have resulted to more systemic effects. However, some other studies, in consonance with this study reported no significant differences.[11,15,18]

Linear regression analysis of potential confounders showed significant effect of parity as a confounder for the duration of the first stage of labor. This fact was also reflected in the subgroup analyses of the duration of labor in parous and nulliparous women which showed significant difference in the parous women.

The strength of this study lies in the methodology. It was a randomized double blind controlled trial thus obviating selection, performance and detection bias.

The major limitation of this study was that cervical dilatation assessment was done at intervals so the exact time of full cervical dilatation may not have been captured. In addition, there may have been some errors arising from lack of reproducibility of vaginal examination findings. This was mitigated by proper training of research assistants and reduction in the interval of vaginal examination.

Conclusion

There was no significant effect on acceleration of cervical dilatation in the entire study sample with the use of a single dose of 20mg intramuscular hyoscine butyl bromide, however it was found to accelerate labor significantly in parous women. The use was not associated with any obvious adverse maternal or immediate neonatal outcomes.

It is recommended for acceleration of labor in women with previous parous experience. Multicenter, well designed randomized controlled study on the efficacy of hyoscine butyl bromide on cervical dilatation acceleration is also recommended to add weight to the body of evidence.

Source of Support: None

Acknowledgement

We appreciate the support of Pharmacist Cyril Ijeh who prepared the drugs used for the study and also the invaluable support of the labor ward staff.

Conflict of interest

The authors declare no conflict of interest

Author contribution

- **ACE**: Conceptualization, Design, Data extraction/analysis, Literature review, Manuscript writing.
- **COA, ERE, KWD**: Design, Literature review,

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