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Effect of Hyoscine Butyl Bromide in Shortening the Duration of First Stage of Labor in Primigravida Women in Al Gomhory Hospital, Taiz-Yemen

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Abstract

Background

Various agents have been used to accelerate the rate of cervical dilatation with subsequent reduction in the duration of labor, thus preventing prolonged labor.

Study Objectives

To evaluate the efficacy of intramuscular Hyoscine Butyl Bromide in shortening the active phase of the first stage of labor total duration of labor among primigravida women at Al-Gomhory Hospital, Taiz, Yemen (from January to December 2025).

Study Design

A prospective, interventional, comparative study.

Methods and Materials

A questionnaire was constructed for this study, including all information about the mother, such as age, gestational age, place of residence, antenatal check-up, cervical condition, mode of delivery, and maternal and neonatal outcomes. Cases were divided into two groups: the study group (n = 51) was given 20 mg of hyoscine intramuscularly when the laboring women in the active phase of the first stage (cervix dilated between 4 and 8 cm), while the control group (n= 51) was not given any drug. Data was collected for both groups, and the cases were followed up until delivery. The information was recorded and entered into SPSS Microsoft program for analysis.

Results

The mean age of women in the study group was 22.22±4.58 years, and in the control group, 22.29±4.1 years. There was no statistically significant differences between the two groups. There were also no statistically significant differences in place of residence, as the majority of both groups were urban residents. There were 74.5% of the study group did not visit the antenatal care clinic during pregnancy, compared to 72.5% of the control group.

One-third of the study group delivered prematurely (between 35 and 37 weeks), and the remaining two-thirds delivered at term. There was no statistically significant differences between the two groups in relation to gestational age at delivery, nor was any statistical differences between the two groups in cervical dilatation and cervical position at the time of giving hyoscine butyl bromide. Almost all of the two groups delivered spontaneously vaginally, with the exception of one case in the study group in which forceps was used. Maternal complications included postpartum hemorrhage (1.9%) and perineal laceration (5.9%). There were no statistically significant differences between the two groups in terms of the Apgar score, birth weight, or admission to postpartum intensive care.

The study showed that the use of hyoscine resulted in a significant reduction in the duration of the active phase of the first stage of labor compared to the control group. The study also showed that the drug did not shorten the duration of the second stage of labor, while it reduced the duration of the third stage of labor and also reduced the overall duration of labor compared to the control group. The study did not observe any increase in the amount of bleeding during labor between the two groups.

Conclusion

The study showed that the use of hyoscine butyl bromide resulted in a statistically significant acceleration in the duration of the active phase of the first stage of labor, but no acceleration in the second stage of labor. However, a statistically significant acceleration in the duration of the third stage was observed, and the overall duration of labor was reduced compared to the control group. The study did not observe any complications from the drug used for mothers or newborns, and postpartum bleeding was minimal, indicating that this drug is safe and effective.

Keywords: Hyoscine Butyl Bromide**,** primigravida women**,** acceleration in the duration of labor.

Introduction

Labor is one of the most important events in women's lives; therefore, negative labor experiences can be emotionally and psychologically challenging for mothers and their families [1-3]. The duration of the first phase of labor in primigravida women takes about 12–16 hours. Labor is said to be prolonged in these women when the duration of the active phase last more than 16 hours [4]. Prolonged labor can increase maternal and neonatal morbidity and mortality, including postpartum hemorrhage, rupture of the uterus, maternal death, neonatal injury, and perinatal asphyxia [5].

The two major factors that determine duration of labor are uterine contractility and rate of cervical dilation. In addition to mechanical factors such as sweeping of membranes, cervical stretching [6] and amniotomy [7]. Several studies showed that active management of labor could shorten the duration of labor, and the safety of this method has been demonstrated [8]. Mechanical, pharmacological and non-pharmacological factors can facilitate cervical dilatation. Prostaglandins, oxytocin, analgesics, and smooth muscle relaxants are examples of pharmacological agents. Several anti-spasmodic agents, including Hyoscine butyl bromide (HBB), drotaverine hydrochloride, phloroglucinol, and valethamate bromide, can shorten the duration of labor [9].

These medications are commonly used during labor in both developing and developed countries [10]. HBB (also known as scopolamine is an anticholinergic and anti-muscarinic medication that has shown spasmolytic function on the smooth muscle of the female genital tract, especially the cervico-uterine plexus [11,12]. This medication can progress cervical dilatation without any effect on contractions of the uterus [12]. The Hyoscine does not pass the brain barrier and does not have a central anti-cholinergic effect. It is rapidly distributed into the tissues after intravenous injections and acts as a cervical spasmolytic agent in labor. The mechanism by which HBB acts in labor is unknown [13]. Several clinical trial studies that describe the effects of HBB on labor progress. Some trials reported that the mean duration of the first stage of labor was significantly shorter in HBB group than that in the placebo group [11, 13].

The effect of HBB on the duration of active phase of labor is unsure and studies yielded conflicting results [11–16]. Without reaching definitive

conclusions as these studies had different parties and used different doses of the drug. There is a great need to study the effect of HBB on primipara with prolonged 1st stage of labor and that was the aim of our study. Also, this study for the first time we work in al Gomhory hospital, Taiz, Yemen.

Problem Statement

Labor dystocia, or prolonged labor, is a major cause of maternal and perinatal morbidity and mortality, particularly among primigravida (first-time mothers). In low-resource settings like Yemen, where healthcare infrastructure has been severely compromised by conflict, the risks associated with prolonged labor are exacerbated. These risks include postpartum hemorrhage, maternal exhaustion, obstetric fistulas, fetal distress, and increased rates of operative interventions (caesarean sections and instrumental deliveries).

At Al Gomhory Hospital in Taiz, a significant number of primigravida women admitted for labor experience prolonged first and second stages. This leads to overcrowding in the labor ward, overstretching of limited staff resources, and poor patient outcomes. Current management often relies on oxytocin augmentation, which requires intensive monitoring and is not without risks like uterine hyperstimulation.

There is a need for a safe, effective, and easily administrable pharmacological agent that can reduce the duration of labor without significant side effects. Hyoscine Butyl Bromide (HBB), an antispasmodic agent, has been proposed to shorten labor by relieving cervical spasm and facilitating cervical dilation. However, its efficacy has shown variable results in different populations, and no formal study has been conducted to evaluate its use in the specific socio-demographic and clinical context of primigravida women in Yemen. This study aims to fill that evidence gap by systematically evaluating the role of HBB in the active management of labor in this vulnerable population.

Justification of the Study

- **High Burden of Prolonged Labor in Primigravida**: Primigravida are inherently at higher risk for dysfunctional labor due to an unyielding cervix and inefficient uterine contractions. Addressing this issue directly targets a high-risk group.

- **Contextual Relevance to Yemen**: The ongoing humanitarian crisis in Yemen has crippled the healthcare system. Any intervention that can safely reduce labor duration can help alleviate the burden on overwhelmed facilities like Al Gomhory Hospital, reduce resource utilization, and potentially lower costs.
- **Potential for Improved Maternal & Neonatal Outcomes**: Shortening labor can reduce the physical and psychological stress on the mother, decrease the risk of infections and hemorrhage, and improve fetal outcomes by reducing the period of potential hypoxia.
- **Reduction in Operative Interventions:** By potentially facilitating a more efficient labor process, HBB could contribute to a lower rate of caesarean sections and instrumental deliveries, which carry higher risks, especially in low-resource settings.
- **Evidence Gap:** While HBB has been studied globally, its efficacy is not universally accepted, and data from the Middle East, particularly from conflict-affected areas like Yemen, is scarce. This study will provide locally relevant evidence to inform clinical practice guidelines at Al-Gomhory Hospital and similar settings.
- **Safety and Practicality**: HBB is a low-cost, readily available drug with a known safety profile and is easy to administer (intramuscular injection). If proven effective, it can be easily integrated into standard labor protocols.

Study Objective

General Objective

To evaluate the efficacy of intramuscular Hyoscine Butyl Bromide in shortening the total duration of active labor among primigravida women at Al-Gomhory Hospital, Taiz, Yemen.

Specific Objectives

1- To compare the mean duration of the first stage of labor between primigravida receiving Hyoscine Butyl Bromide and those control group
2- To compare the mean duration of the second stage of labor between the two groups.
3- To compare the overall total duration of labor (from time of hyoscine administration cm to delivery of the baby) between the two groups.
4- To assess the maternal side effects (e.g., tachycardia, dry mouth, blurred vision) and neonatal outcomes (Apgar scores at 1 and 5 minutes) associated with the use of HBB.

Hypothesis

Null Hypothesis (H_0):

There is no significant difference in the mean duration of the active labor of the first stage between primigravida women receiving Hyoscine Butyl Bromide and those receiving a placebo at Al Gomhory Hospital.

Alternative Hypothesis (H_1):

There is a significant difference in the mean duration of the active labor of the first stage between primigravida women receiving Hyoscine Butyl Bromide and those receiving a placebo at Al-Gomhory Hospital.

Study Questions

1- What is the difference in the mean duration of the first stage of labor between primigravida women administered HBB and the control group?
2- What is the difference in the mean duration of the second stage of labor between the two groups?
3- Does the use of HBB lead to a significant reduction in the total duration of active labor compared to the placebo?
4- What is the incidence of transient maternal side effects (tachycardia, dry mouth) in the HBB group compared to the control group?
5- Is there a significant difference in the immediate neonatal outcomes, as measured by Apgar scores at 1 and 5 minutes, between the two groups?

Materials and Methods

Study area

The study was conducted in obstetric emergency department of Al-Gomhory Hospital in Taiz governorate. The hospital affiliated to ministry of health.

Study design

Prospective interventional, comparative study carried out during one year (From Jan1st to Dec 30th 2024)

Study population

Primigravida women at term or near term (≥ 35 weeks of gestation) in active phase of labor who presented to labor room during the study period and who agreed to participate in the study recruited and randomly distributed into HBB group and control group.

Inclusion criteria

- Primigravida at age 18–45 years
- Term or near term pregnancy (≥ 35 weeks of gestation)

- Spontaneous active phase of labor (4- 8cm cervical dilatation, good cervical effacement, and effective uterine contraction)
- Singleton pregnancy
- Vertex presentation
- In women who agree to participate in the study
- No contraindication to vaginal delivery.

Exclusion criteria

- Pregnant < 35 weeks of gestation
- Multiple pregnancies
- Antepartum hemorrhage
- Previous uterine scar
- Induction of labor
- Cephalopelvic disproportion
- Malpresentations
- Prior rupture of membranes
- Preeclampsia /Eclampsia and other hypertensive disorders of pregnancy
- Contra indication to use of HBB
- Any other medical diseases in pregnancy.

Sample size

Using the smallest clinically significant difference and confidence interval of 95% with 80% power and type one error (alpha) of 0.05, with 51 women assessed per group. Therefore 102 primigravida women was the sample size of this study.

Sampling method

Primigravida women who presented at term or near term (> or = 35 weeks of gestation) in active of phase of labor (4-8cm cervical dilatation) during the study period were selected consecutively. The confirmation of labor, uterine contraction and cervical dilatation was done by the researcher and trained research assistants (labor ward residents and certified midwives). Eligible women were then randomized into HBB and control group by selecting a number from a pool of serial numbers of 1–102. Those women who picked even numbers were assigned into HBB group and those that picked odd numbers were assigned into control group. Therefore, there will 51 women in each group. Study was open label. The HBB group being

received 1 or 2 ampoules (20 - 40 mg) of intramuscular route of HBB and control group did not receive any drug.

Drug administration and labor monitoring

HBB drug was prepared in 20 mg (2 ml) syringes by the hospital staff. The syringe containing HBB was given intramuscularly as a single dose, while the control group was not given any drug. Labor was monitored using partograph and assessment of cervical dilatation was done 4 hourly. The time of intervention to time of full cervical dilatation and also end of second and third stage of labor were recorded. Intrapartum and postpartum maternal observation was noted. Assessment of neonatal Apgar score was done at 1st, 5th min. Comparison of the two groups regarding the effect of HBB on several variables of labor and outcome of labor was studied (duration of labor, outcome of labor, neonatal outcome, and incidence of maternal side effects).

Data analysis

- Data analysis was processed using Statistical Package for Social Science (SPSS) 24 statistical program.
- Quantitative variables were presented as means ± SD while qualitative variables were presented as frequencies and percentages.
- Independent sample t test was used to compare the mean duration of stages of labor between HBB group and control group.
- Chi-square test (x2) was used to compare outcome of delivery between the two groups. Level of significance was set at P 0.05.

Ethical consideration

The study ethical approval was obtained from committee on ethics and research of the AL-Gomhory Teaching Hospital and TAIZ University. Informed consent (verbal) was also obtained from the patients before the questionnaire was administered. For each recruited subject the following issues were considered: Securing the subject's informed consent, keeping the subject's privacy, assuring the subjects of their data confidentiality, and the right to withdraw at any time.

Results

This study analyzed 102 women as a study group who had used HBB (n = 51) and control group (n = 51).

Table (1):

Distribution of age among the two groups.

Age (year)	Study		Control		P value
	N	%	N	%	
< 20	12	23.5	19	37.2	X^2 =12.539 P 0.706
20 – 25	31	60.8	24	47.0	
26 – 30	6	11.7	5	9.8	
31 – 35	2	3.9	3	5.9	
Mean ± SD	22.22 ± 4.58		22.29 ± 4.1		0.5
Total	51	100	51	100	
All calculations were done from the total of each group					

This table shows the maximum age of the study group was between 20-25 year with the percentage of 60.8% compared to 47% of the control group. The least age recorded was in the age of 31 – 35 years (3.9 % in the study group and 5.9 % in the control group. There was no significant difference between the two groups in relation to the age (P 0.70).

Gestational age

Table (2):

Distribution of gestational age among the two groups.

Gestational age	Study		Control		P value
	N	%	N	%	
35 – 37	17	33.3	18	35.2	0.86
38 – 40	34	66.7	33	64.7	
Mean ± SD	37.95 ± 1.50		37.96 ± 1.58		
Total	51	100	51	100	

There were two thirds of women in the study group had gestational age at delivery between 38-40 weeks compared to 64.7% of the control groups. At least one third of the study group delivered preterm (<37 weeks) and also 35.2% of the control group were preterm with no significant difference between the two groups (P 0.86).

Per vaginal examination

Table (3):

Distribution of per vaginal examination findings of women who received HBB.

Item	Study		Control		P value
	N	%	N	%	
Cervical dilation (cm)					0.27
4	0	0	1	1.9	
5	9	17.6	8	15.6	
6	21	41.1	12	23.5	
7	14	27.4	21	41.1	
8	7	13.7	9	17.6	
Effacement (%)					
< 50	17	33.3	3	5.9	0.38
≥ 50	34	66.7	48	94.1	
Consistency					
Thick	18	35.2	17	33.3	0.09
Moderate	17	33.3	17	33.3	
Soft	16	31.3	17	33.3	

There was no significant difference between the two groups in relation to cervical dilatation, effacement and consistency at time of per vaginal examination.

Maternal complications

Table (4):

Maternal complications.

Complication	Study		Control		P value
	N	%	N	%	
Uterine atony (PPH)	1	1.9	2	2.9	0.36
Perineal tear	3	5.9	2	3.9	
No complication	47	92.1	47	92.1	
Total	51	100	51	100	

Uterine atony was the cause of PPH in one case of the study group and two cases of the control group had also PPH Perineal tear complicated 3 cases of the study group and two cases of the control group. There was no significant difference between the two groups in relation to maternal complication.

Course of labor

Table (5):

Comparison of the labor course between the two groups.

Item	Study	Control	P value
Duration of active phase (First stage) (min).			**0.001**
Mean ± SD	**107.04 ± 7.05**	**154.61 ± 7.411**	
Minimum	**25**	**30**	
Maximum	**420**	**355**	
Duration of 2nd stage (min)			**0.97**
Mean ± SD	**14.12 ± 8.1**	**14.22 ± 8.7**	
Minimum	**5**	**5**	**0.15**
Maximum	**50**	**50**	
Duration of 3rd stage (min)			
Mean ± SD	**16.57 ± 12.22**	**21.95 ± 6.1**	
Minimum	**5**	**5**	**0.007**
Maximum	**75**	**80**	
Total duration (min)			
Mean ± SD	**132.73 ± 69.83**	**188.8 ± 107**	**0.001**
Minimum	**30**	**40**	
Maximum	**450**	**760**	

This table shows a significant shortening of the active phase of the first stage of labor in the study group compared to control group. There was no significant difference in the duration of the second stage of labor. However, the duration of the third stage and the total duration of labor were significantly reduced in the study group compared to control group (P 0.001).

Discussion

present study aimed at evaluating the role of Hyoscine Butyl Bromide (HBB) in shortening the overall duration of the active phase of the first stage of labor in primigravida of women whose vaginal delivery is anticipated. HBB is used and confirmed to have benefits in many studies [17].

The present study found that the mean age of the study group was 22.22 ± 4.58 years compared to 22.29 ± 4.1 years of the control group with no significant difference between the study and control group in relation to maternal age. These findings are in line with another study [108] which reported that the mean age of the study group was 22.14 ± 3.72 years and

for control group 22.38 ± 4.00 years. The maximum age of the study and control groups was between 20 – 25 years (60.8%) and 47% respectively. This result is similar to another study [17] which reported similar trends. However, early age of women is expected because this study was carried out among primigravida women.

The present study found that the majority the study population were from urban settings with no significant difference between the study and control group. This finding is in agreement with another study (17). It suggests that women in urban setting may seek medical care early when labor pain started.

It is showed in this study that the majority of women among the study and control groups were unbooked during the index pregnancy and only almost a fourth had been attended antenatal care clinics. This is in contrast to another study by Asqua et al [19] which reported that booking status was positive for 96.5% and 92% of the study and placebo group. Clearly the low rate of antenatal care attendance in our study population is multifactorial including poverty, low education and inadequate covering of the service for all areas particularly remote regions. However, improvement of antenatal care service is mandatory, and the service should be feasible and accessible for all pregnant women.

The present study found that at least a third of cases had been delivered in late preterm (between 35-37 weeks of gestation). There was no significant difference between the study and control group. This finding is in agreement with another study [19] which reported that the gestational age of the study group was 37.5 ± 1.2 weeks and that for placebo group 38.51 ± 1.1 week. This finding suggests that the HBB can be safely used for women when early termination is recommended for maternal or fetal causes. However, most of the other studies reported that HBB is often used in term pregnancy [17,18].

The present study found that there was no significant difference between the study and control group as regards cervical dilation, effacement and consistency at the beginning of HBB use. This result is in line with another study by Nawara et al [20] from Egypt which reported insignificant difference between the two groups (P 0.203). Such results support the validity of the comparison in our study.

Almost all women in both groups delivered vaginally with one woman of the study group delivered instrumentally. This finding is in agreement with another study [20].

Regarding to the efficacy of HBB in shortening the overall duration of labor, the present study found that there was a significant difference between the study and control group in terms of reduction of the active phase of the first stage of labor with approximately 47.57 minute reduction of the active phase of the first stage of labor among women who received HBB. A study from Egypt found that use of HBB was associated with shorter active phase of the first stage of labor by 2.4 hours compared to 6.0 hour in the placebo group [20]. This effect extended in the second and third stage of labor indicating that HBB accelerates labor process significantly compared with the group who did not receive HBB. Another study from Iran [21] reported that the duration of the first stage, second stage and the third stage of labor was consistently shorter among women who received HBB compared with those who received placebo. Another study by Trevi˜no-Salinas et al [22] found significant reduction of the first, second and third stage of labor when compared with control group. It is also reported in another study that using intravenous HBB in a dose of 20 mg is able to diminish the efforts of labor by 32% [22]. Some authors compared the use of HBB with oxytocin without finding a statistically significant difference to the effort of labor which is the reason for this drug to be used instead of oxytocin among primigravida women who cannot receive oxytocin [23]. Rectal use of HBB was reported to have faster absorption and avoids gastric irritation and more effective in the reduction of the duration of labor [18,21]. Another study from Pakistan conducted to assess the effects of HBB on the duration of the first stage of labor in term pregnancy [24] found that the mean duration of the first stage of labor was 178.98 ± 92.44 minutes compared to 214.74 ± 147.44 minutes in the control group which suggested that the reduction of the first stage was observed between the two groups but did not reach significant difference (P 0.13). Another study from Nigeria [19] found that the HBB effects was significantly shortening of the first stage duration while there was no effect on the second and third stage of labor. This was explained by the fact that HBB acts on the cervix mainly with a little effects on the promotion of uterine contractility [25]. However, in our study there was no effect of HBB on the second stage

but the third stage was significantly reduced. This result supports the above evidence that HBB is not acting through increasing uterine contractions. There is evidence that HBB has antispasmodic effects on the cervix, acting on the cervico-uterine plexus relieving spasm resulting from the contraction of the smooth muscles of the cervix and acceleration of the cervical dilatation as cervix contains approximately 10% of the smooth muscle[19] so this leads to facilitated the exit of the placenta mechanically after its separations. Meta-analysis study was conducted to assess the effects of HBB on the duration of labor [26] found that the first stage of labor was accelerated while there was no effects on the second and third stage of labor. Regarding parity, our study was conducted on primigravida however it seems that HBB was effective in the first stage of labor among primiparous women compared with multiparous women [26].

There was no need for augmentation of labor process among women received HBB which indicating that the reducing of the first stage of labor is independent factor accelerating the cervical dilatation.

The present study found that there was no significant difference between the study and control group regarding fetal outcome (P 0.5) and such outcome was favorable for both groups. Likewise, there was no significant difference between the study and control group regarding maternal outcome and using of HBB, and there was no adverse side effects observed among the study group. These results are in agreement with other studies [19,26].

Limitations of the Study

The study has several limitations. First, the sample size was relatively small (51 women in each group), which may limit the generalizability of the findings. Larger studies would be needed to confirm these results across diverse populations and settings. Another limitation is that the study only included primigravida women, so the findings may not be applicable to multigravida women or those with high-risk pregnancies. Additionally, the study did not explore long-term neonatal outcomes beyond the initial Apgar scores, leaving questions about the longer-term safety of HBB for newborns

Conclusion

- Uses of hyoscine butyl bromide are associated significantly with shortening the duration of the active phase of the first stage of labor compared with control group.

- There was no acceleration of the second stage of labor among the study group as the duration approached that of the control group.
- The effects of hyoscine butyl bromide extended to the third stage of labor which appears promising to use for acceleration the placental delivery.
- There was no significant difference between the study and control groups regarding the fetal and maternal adverse outcomes indicating that hyoscine butyl bromide is safe as well as effective.

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