Journal of Obstetrics, Gynecology and Cancer Research | ISSN: 2476-5848

Effect of Hyoscine-Bromide in Duration of the First Stage of Labor

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Article Info

10.24200/jogcr.10.7.537

Received: 2025/02/25
Accepted: 2025/04/09
Published Online: 30 Jun. 2025

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ABSTRACT

Background & Objective: To reduce the duration of labor with oxytocin infusion and achieve or maintain a low rate of cesarean birth, the active management of labor principle was created. Active labor management has a well-established track record of efficacy and has been demonstrated to lower the number of cesarean deliveries in facilities that follow procedures. To investigate if Hyoscine butylbromide (HBB) can help primigravid women shorten the initial stage of labor.

Materials & Methods: A total of 60 primigravid women who attended Ain Shams University Maternity Hospital for delivery participated in this double-blind placebo randomized controlled trial, which was carried out at a tertiary care hospital from October 2023 to August 2024 with approval from the ethical committee and written consent from the patients.

Results: There was no statistically significant difference between the studied groups regarding age, BMI and gestational age. There was no statistically significant difference between the studied groups regarding baseline cervical dilatation, effacement and membrane status. The need for oxytocin was significantly less frequent in HBB group. Needing analgesia was significantly less frequent in HBB group. The durations of active stage, second stage and third stage were significantly shorter in HBB group. The rate of completing active phase was significantly lower in HBB group. Both groups underwent vaginal delivery.

Conclusion: The study concludes that HBB is effective in significantly reducing the duration of the first stage of labor, as well as the overall need for labor augmentation with oxytocin and pain management with analgesia.

Keywords: First stage of labor, Hyoscine-bromide, Labor duration, Labor augmentation, Active phase of labor

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1. Introduction

In order to reduce the duration of labor with oxytocin infusion and achieve or maintain a low rate of cesarean birth, the active management of labor principle was created. The term "active management of labor" describes the obstetrician's active control of labor with oxytocin injection, as opposed to passive monitoring. Active labor management has been proven to be successful, and at institutions that use the protocols, it has been demonstrated to lower the number of cesarean births **(1,2)**.

The most frequent reason for both primary and emergency cesarean sections is still dystocia. As a result, it plays a significant role in instrumental and surgical intervention, particularly in nulliparous women **(3)**.

In contemporary obstetric practice and intrapartum care, this is a serious clinical issue that causes the mother and her child much pain **(4)**.

Researchers have considered factors that affect the outcomes of pregnancy for both the mother and the newborn. The number of fetuses, uterine activity, fetal lying or presentation, and demographic, clinical, and genetic variables all affect how long labor takes **(5)**.

Hyoscine Butylbromide (HBB) is a semisynthetic derivative of scopolamine and a member of the parasympatheticolytic medication class. It has strong antispasmodic properties without the negative side effects of atropine **(6,7)**.

Therefore, HBB's main function is to relax the smooth muscle fibers in the cervical region without having an equivalent effect on the muscles in the uterus. These results provide the mother and her fetus with the highest level of safety and effectiveness **(8)**.

Several hospitals throughout the world have employed HBB to reduce the length of labor. Its exact

mechanism of action in the context of labor is still unknown, and most of the data supporting its effectiveness was previously anecdotal **(9)**.

Therefore, the goal of the research is to determine if HBB may effectively shorten the initial stage of labor in primigravid women.

2. Materials and Methods

A total of 60 primigravid women who attended Ain Shams University Maternity Hospital for delivery participated in this double-blind placebo randomized controlled trial, which was carried out at a tertiary care hospital from October 2023 to August 2024 with approval from the ethical committee and written consent from the patients.

Among the requirements for inclusion were Primigravid women, presenting by the vertex, singleton pregnancy, and at least 20 years of age between 37 and 42 weeks of gestation. During the active phase of labor, the cervical dilation is between 4 and 5 cm, and the membranes are either intact or spontaneously ruptured within 12 hours.

Previous uterine scarring, twin pregnancy, antepartum hemorrhage, malpresentation, inducement of labor, contraindication to vaginal birth, epidural analgesia, contraindication to hyoscine, and patient refusal to participate were among the exclusion criteria.

Sample Justification:

Using the STATA program, with the alpha error set at 5% and power at 90%, and based on data from a previous study (10), the mean duration of active phase (first stage) among HBB group was 191.13±43.06 compared to 248.21±66.4 in control group. Based on this considering 20% dropout rate, the sample needed is 30 cases per group (60 total).

Allocation and Concealment:

A third party (a nurse) who assigned the ladies to research arms will get the sealed opaque envelopes. We'll ask each woman to take out an envelope. A computer-generated random list will be used to assign women to either group 1 or group 2, based on the number inside their envelope.

After that, they were split up into two groups: Group 1 (the study group) consisted of 30 expectant mothers who were given an intravenous injection of one dosage of prefilled 2 ml HBB (40 mg). Group 2 (the control group) consisted of 30 expectant mothers who were given an intravenous injection of prefilled 2 milliliters of normal saline.

The dose of Hyoscine N_Butylbromide administration:

The resident prepared the syringes with hyoscine and regular saline. Each syringe had either 2 ml of medicine (40 mg) or 2 ml of placebo; as neither liquid is colored, it was difficult to tell the difference between the two **(11)**. The drugs were taken before the active phase.

Using a trial sequence created with a random number table, recruited women were randomized to one of the therapies mentioned upon admission. The assigned sequence was then concealed in opaque, sealed envelopes with sequential numbers.

All decisions were taken by experts and supervisors (lecturers and professors). Both the participants and the caregivers were blinded to the kind of intervention during the double-blind experiment.

Follow-up of the patients:

Throughout labor, a partogram was kept tracking the development of the labor. Fetal heart rate was recorded using cardiotocography (CTG), which also helped to monitor the fetus' health. If necessary, oxytocin augmentation was performed.

The dose of Oxytocin administration:

Additionally, the Polish Society of Gynecologists and Obstetricians (PSOGO https://www.ptgin.pl/) published national recommendations on the use of synthetic oxytocin for augmentation and induction of labor. According to these recommendations, two distinct oxytocin delivery schedules are suggested: (i) low dosage (beginning at 0.5–2 mU/min and increasing at intervals of 1-2 mU/min at 15–40 minutes) and (ii) high dose (beginning at 6 mU/min and increasing at intervals of 3-6 mU/min at 15–40 minutes) **(1)**.

Monitor Plan:

The principal investigator rolled regular meetings with the research team to assess data and adverse events.

Outcomes:

Primary outcome: assessment of duration of the active phase of labor between HBB and placebo group, and as a primary outcome measure the mean duration (min) of the first stage of labor was measured.

Secondary outcomes: Evaluation of the need for oxytocin and analgesia. APGAR scores were measured to assess the neonatal outcome. Maternal evaluation of side effects of the drug, postpartum hemorrhage, caesarean section rate, duration of second stage and third stage of labor.

Statistical analysis: IBM Statistical Package for Social Sciences software version 28.0, IBM Corp., Chicago, USA, 2021, was used to code, tabulate, and statistically analyze the gathered data. The quantitative data was represented as mean±SD (standard deviation) along with the range's lowest and maximum. The appropriate statistical analyses were then performed. When the p-value was less than 0.050, it was considered significant; otherwise, it was considered non-significant.

3. Results

Sixty participants (30 in each group) were enrolled in the research after 79 people had their eligibility evaluated. Six patients declined to participate in the trial, while 13 of the eligible patients were disqualified from it due to inclusion rules. The data of 60 primigravid women who went to the hospital for birth served as the final basis for the analysis (Figure 1).

(Table 1) showed that: No statistically significant difference between the studied groups regarding age, BMI and gestational age.

(Table 2) showed that: No statistically significant difference between the studied groups regarding baseline cervical dilatation, effacement and membrane status.

(Table 3) showed that the need to oxytocin was significantly less frequent in HBB group.

(Table 4) showed that: Need for analgesia was significantly less frequent in HBB group.

(Table 5) showed that: Durations of active stage, second stage and third stage were significantly shorter in HBB group.

(Table 6) showed that: All cases of both groups underwent vaginal delivery. Instrumental delivery was not significantly less frequent in HBB group.

(Table 7) showed that: No statistically significant difference between the studied groups regarding postpartum hemorrhage.

(Table 8) that: No statistically significant difference between the studied groups regarding birth weight. APGAR-1 was significantly higher in HBB group.

Table 1. Demographic characteristics between the studied groups

Variables		HBB group (Total=30)	Control group (Total=30)	P-value
Age (years)	Mean±SD	21.7±2.9	22.8±3.6	^0.217
	Range	18.0–29.0	18.0-32.0	
BMI (kg/m^2)	Mean±SD	25.6±2.8	26.4±2.1	^0.203
	Range	21.5–32.4	20.1-30.2	
Gestational age (week)	Mean±SD	38.4±1.1	38.4±1.1	^0.909
	Range	37.0-42.0	37.0-41.0	

BMI: Body Mass Index. ^Independent t-test

Table 2. Baseline labor progress between the studied groups

Variables		HBB group (Total=30)	Control group (Total=30)	P-value
Cervical dilatation (cm)	Mean±SD	4.6±0.5	4.4±0.5	^0.203
	Range	4.0-5.0	4.0-5.0	
Effacement (%)	Mean±SD	67.0±16.4	64.3±15.0	^0.514
	Range	40.0-80.0	50.0-80.0	
Ruptured membrane (n, %)		12(40.0%)	17(56.7%)	#0.196

^Independent t-test. #Chi square test

Table 3. Need to oxytocin between the studied groups

Status	HBB group (Total=30)	Control group (Total=30)	P-value	Relative effect Relative risk 95% CI
Needed	2(6.7%)	25 (83.3%)	#<0.001*	0.08
Not needed	28(93.3%)	5 (16.7%)		0.02-0.31

#Chi square test. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group

Table 4. Need to analgesia between the studied groups

Status	HBB group (Total=30)	Control group (Total=30)	P-value	Relative effect Relative risk 95% CI
Needed	2(6.7%)	8(26.7%)	#0.038*	0.25
Not needed	28(93.3%)	22(73.3%)		0.06-1.08

#Chi square test. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group.

Table 5. Durations of labor stages between the studied groups

Stages		HBB group (Total=30)	Control group (Total=30)	^P-value	Relative effect Mean±SE 95% CI
Active phase (hours)	Mean±SD	2.4±0.7	6.0±1.5	<0.001*	-3.5±0.3
	Range	1.5-3.8	2.5-9.0		-4.2-2.9
Second stage (minutes)	Mean±SD	33.8±19.9	53.7±29.1	0.003*	-19.8±6.4
	Range	10.0-80.0	15.0-120.0		-32.7-7.0
Third stage (minutes)	Mean±SD	7.4±2.5	9.2±3.2	0.024*	-1.7±0.7
	Range	5.0-10.0	5.0-20.0		-3.2-0.2

^Independent t-test. SE: Standard error. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group.

Table 6. Mode of delivery between the studied groups

Variables	HBB group (Total=30)	Control group (Total=30)	P-value	Relative effect Relative risk 95% CI
Vaginal delivery	30(100.0%)	30(100.0%)	NA	NA
Instrumental delivery	0(0.0%)	3(10.0%)	§0.237	NA

NA: Not applicable. §Fisher's Exact test. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group.

Table 7. Postpartum hemorrhage between the studied groups

Status	HBB group (Total=30)	Control group (Total=30)	P-value	Relative effect Relative risk 95% CI
Occurred	0(0.0%)	1(3.3%)	§0.999	NA
Not occurred	30(100.0%)	29(96.7%)		

NA: Not applicable. §Fisher's Exact test. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group.

Table 8. Neonatal status between the studied groups

Variables		HBB group (Total=30)	Control group (Total=30)	^P-value	Relative effect Mean±SE 95% CI
Birth weight (kg)	Mean±SD	2.9±0.3	2.8±0.3	0.408	0.1±0.1
	Range	2.1-3.5	2.3-3.5		-0.1-0.2
APGAR-1	Mean±SD	8.2±0.6	7.5±0.8	<0.001*	0.7±0.2
	Range	7.0-9.0	5.0-9.0		0.3-1.0
APGAR-5	Mean±SD	8.9±0.3	8.7±0.5	0.121	0.2±0.1
	Range	8.0-9.0	8.0-9.0		0.0-0.4

^Independent t-test. SE: Standard error. CI: Confidence interval. Relative effect: Effect in HBB group relative to that in control group.

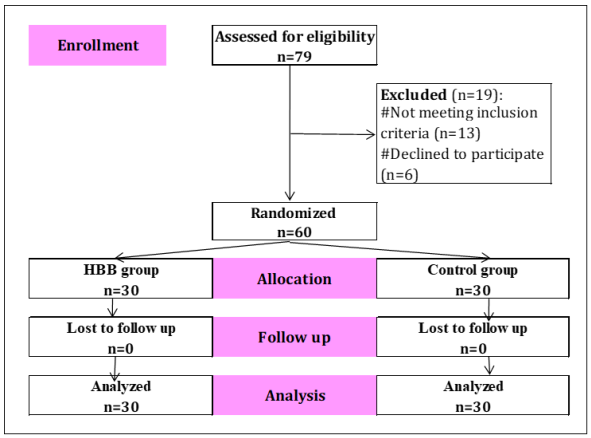


Figure 1. Flow chart showing the enrollment of the patients

4. Discussion

Buscopan, a type of HBB, is frequently used in operating rooms. Numerous research on the usage of HBB during childbirth has shown contradictory findings **(12)**.

Thus, the purpose of this study was to determine if HBB might effectively shorten the initial stage of labor in primigravid women.

Sixty primigravid women who gave birth at Ain Shams University Maternity Hospital participated in this double-blind, placebo-randomized controlled experiment, which was carried out in a tertiary care hospital between October 2023 and August 2024.

In this study, 60 patients (30 in each group) were enrolled after 79 individuals had their eligibility evaluated. Based on the inclusion criteria, 13 of the eligible patients were disqualified from the trial, while 6 patients declined to take part. Ultimately, the data from 60 primigravid women who went to the hospital to give birth served as the basis for the research.

The study's analysis of the efficacy of HBB in shortening labor revealed promising outcomes. The primary focus was on evaluating how HBB affected the duration of the first stage of labor among primigravid women compared to a placebo group. The randomized control trial design ensured reliable comparisons between the HBB group and the control group, with key outcomes addressing labor duration, the need for labor augmentation, analgesia use, and maternal and neonatal outcomes.

As regards labor Duration and Stages, one of the most significant findings was the reduction in the duration of the active phase of labor in the HBB group. Women who received HBB experienced a much shorter active phase, with an average of 2.4 hours, compared to 6.0 hours in the control group. This acceleration extended into the second and third stages of labor as well, which were also notably shorter in the HBB group. This shortening of labor stages suggests that HBB can efficiently aid in cervical dilatation and labor progress, potentially reducing overall labor time and associated stress.

The primary outcome evaluated in nearly all studies is the reduction in the duration of the first stage of labor. Across most trials, HBB consistently demonstrated a significant reduction in labor time as in our study.

This was consistent with the findings from Kamkong et al. where the active phase of labor was shortened by an average of 100 minutes in the HBB group compared to the control **(12)**. Similarly, Qahtani et al., found a 23.3% reduction in the duration of the first stage of labor, translating to a difference of 50 minutes between the HBB and placebo groups **(13)**.

Other studies like Bashir & Mushtaq **(14)** and Kirim et al., **(10)** echoed these findings, Bashir & Mushtaq (14) reporting a mean reduction in labor time, though without statistical significance (P=0.135), while Kirim et al**., (10)** observed statistically significant reductions of 57 minutes in primigravida and 54 minutes in multigravida women receiving HBB. In contrast, the study by Gaudernack et al., **(15)** did not find a significant reduction in labor duration with HBB, suggesting that it might not be effective in cases of slow labor progression, particularly in nulliparous women.

The second and third stages of labor showed more variability across the studies. Our study found that both the second and third stages were significantly shorter in the HBB group (33.8±19.9 minutes) compared to the placebo group (53.7±29.1 minutes), and the third stage was also reduced (7.4±2.5 minutes in the HBB group versus 9.2±3.2 minutes in the control group), with a 19-minute reduction in the second stage and 1.7-minute reduction in the third stage. In contrast, Gaudernack et al., **(15)** found no effect of HBB on the second or third stages of labor and Kamkong et al., **(12)** also reported a shorter second stage in multiparous women only, though no significant difference was found in nulliparous women.

However, Gaudernack et al., found no significant difference in the duration of the second or third stages of labor, even though the first stage was marginally shorter in the HBB group. This discrepancy indicates that the impact of HBB may be less consistent on these later stages of labor, and further research could explore this variability **(15)**.

As regards oxytocin and Analgesia Use, A notable outcome was the dramatic reduction in the need for oxytocin, which is commonly used to stimulate or accelerate labor. In the HBB group, only 6.7% of women required oxytocin, compared to 83.3% in the control group. This difference underscores HBB's role in facilitating natural labor progress, reducing the need for medical intervention. Furthermore, the need for analgesia was also significantly lower in the HBB group (6.7%) than in the control group (26.7%). This

indicates that HBB may contribute to a less painful labor experience, potentially reducing the demand for pain management interventions.

The need for oxytocin to augment labor was a critical outcome evaluated in several studies investigating the effects of HBB. A consistent finding across these studies is that the use of HBB significantly reduces the need for oxytocin, highlighting its effectiveness in promoting natural labor progression without additional medical intervention.

Similarly, Kamkong et al. reported a significant reduction in the need for oxytocin in women administered 20 mg of HBB. Although specific statistics on oxytocin usage were not highlighted in the report, the overall shortened duration of the active phase of labor suggests a lesser requirement for oxytocin **(12)**.

In earlier studies, such as those by Qahtani et al., **(13)** and Kirim et al., **(10)** the need for oxytocin was generally lower in the HBB groups. For instance, in Kirim et al., fewer women who received 20 mg of HBB required oxytocin induction compared to the placebo group. This finding reinforces the conclusion that HBB can reduce reliance on labor-augmenting drugs, contributing to smoother and more natural labor progress **(10)**.

Contrasting with other studies, Gaudernack et al., **(15)** found no significant difference in the need for oxytocin between the HBB and placebo groups. The study, which focused on nulliparous women with early signs of prolonged labor, did not show a clear benefit of HBB in reducing oxytocin use. This might be due to the study's population, which involved women already experiencing labor complications, or differences in the dosing protocol compared to other studies. The neutral result in this trial suggests that HBB may not be as effective in more complex or slow-progressing labor scenarios.

The need for additional analgesia in labor has been a key focus across multiple studies investigating the effects of HBB. A notable outcome in several trials is that HBB reduces the requirement for analgesic interventions during labor, likely due to its ability to shorten the duration of the active phase of labor, thus minimizing the time women spend in discomfort.

Similarly, Qahtani et al., demonstrated a substantial reduction in the need for opioid analgesia with the use of HBB. In their study, only 40% of women in the HBB group required additional analgesia compared to 100% in the control group, highlighting the drug's significant impact on labor pain management. This finding underscores HBB's dual role, not only in expediting labor, but also in reducing the discomfort associated with prolonged labor **(13)**.

Other studies, such as Bashir & Mushtaq, although focused primarily on the duration of labor, indirectly indicated that fewer interventions, including analgesia, were needed in the HBB group **(14)**. By shortening the first stage of labor, HBB potentially reduces the necessity for pain management, further demonstrating its effectiveness in labor augmentation without additional medication.

As regards Maternal and Neonatal Health Outcomes, our study showed that HBB did not lead to adverse outcomes for mothers or babies. The rate of postpartum hemorrhage was similar between the groups, and there were no significant differences in the mode of delivery, with all women in both groups experienced 100% vaginal delivery rates, with no significant difference in instrumental delivery. This suggests that HBB did not increase the likelihood of requiring surgical assistance during delivery.

Importantly, the Apgar scores at one minute were significantly higher in the HBB group, indicating better immediate neonatal outcomes. Although the Apgar scores at 5 minutes were comparable between the groups, the initial improved scores suggest that HBB may positively influence the baby's condition immediately after birth. Additionally, there were no significant differences in birth weight between the groups, indicating that HBB did not pose risks to either maternal or neonatal health.

Across all studies, neonatal outcomes such as Apgar scores were consistently unaffected by HBB administration. Similarly, Kamkong et al., found no significant differences in neonatal outcomes between the HBB and control groups **(12)**. Apgar scores at both 1 and 5 minutes were normal across both groups, and there were no NICU admissions, further supporting the safety of HBB in relation to neonatal health.

In Gaudernack et al., neonatal health outcomes were also positive, with no abnormal findings in Apgar scores or other neonatal parameters. No adverse neonatal events were reported, confirming that the use of HBB did not compromise neonatal safety **(15)**.

Other studies, such as Maged et al., **(2)** and Qahtani et al., **(13)** also reported no significant differences in birth weight or Apgar scores between neonates in the HBB and control groups. The absence of significant neonatal complications suggests that HBB can be used safely during labor without increasing risks to the newborn.

In terms of maternal safety, the studies generally indicated that HBB was well tolerated. Similarly, Kamkong et al., did not find significant differences in maternal outcomes such as uterine atony, postpartum hemorrhage, or estimated blood loss between the HBB and control groups **(12)**. This study reinforces the idea that HBB does not contribute to major maternal risks. The safety of the drug was further confirmed as no abnormal neurological, ocular, or urological side effects were reported.

Other studies, such as Qahtani et al., **(13)** and Kirim et al., **(10)** found that HBB did not result in significant

adverse maternal outcomes. Both studies reported no increase in cesarean section rates or instrumental deliveries, and no significant changes in blood loss at delivery. In these trials, the overall maternal safety profile of HBB was deemed satisfactory.

On the contrary, Gaudernack et al., **(15)** reported an increased occurrence of minor adverse events in the HBB group, including a higher rate of maternal tachycardia (39.5%) and visual disturbances compared to the placebo group. Despite these side effects, no serious maternal complications were noted, and the adverse events were generally considered mild.

Strengths of the Study:

One of the main strengths of this study is its randomized, double-blind, placebo-controlled design, which minimizes bias and ensures a reliable comparison between the treatment and control groups. The inclusion of well-defined criteria for participant selection ensures homogeneity in the study population, thereby enhancing the validity of the results. Additionally, the study's use of multiple outcome measures, including labor duration, need for oxytocin and analgesia, and neonatal health metrics (such as Apgar scores) provides a comprehensive view of HBB's effects on both maternal and neonatal outcomes.

Limitations of the Study:

Despite its strengths, the study has several limitations. First, the sample size was relatively small (30 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 primigravid 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.

5. Conclusion

The study concludes that HBB is effective in significantly reducing the duration of the first stage of labor, as well as the overall need for labor augmentation with oxytocin and pain management with analgesia. The findings suggest that HBB can facilitate a smoother, faster labor process without increasing the risk of maternal or neonatal complications. The improved Apgar scores at 1 minute further support its potential benefits for newborn health, although more research is needed to confirm these findings.

6. Declarations

Acknowledgments

The authors would like to thank the Ain Shams University Maternity Hospital, and all medical staff involved in the study for their invaluable support and assistance throughout the research. Special thanks are extended to the patients who participated in the study, whose cooperation made this research possible.

Ethical Considerations

The patient information was anonymous. Patient confidentiality was maintained, and data were presented by diagnosis rather than by name. Every participant gave their informed permission, which was verified by date and time and was in Arabic. By giving the patient's initials a number that only the researcher knew, confidentiality was maintained.

Authors' Contributions

Whether it was in the idea, study design, data collection, every author made major contributions to the work reported; they all engaged in the article's drafting, editing, or critical review; they all agreed on the journal to which the paper was submitted; and they all agreed to accept responsibility for all aspects of the work.

Conflict of Interest

There are no disclosed conflicts of interest for the authors.

Confidentiality of Data

Regarding the publishing of patient data, the authors affirm that they have complied with their work center's procedures.

Protection of Human and Animal Subjects: The authors affirm that the methods used were compliant with the World Medical Association's Code of Ethics (Declaration of Helsinki) and the rules of the applicable clinical research ethics committee.

Fund or Financial Support

None.

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How to Cite This Article:

Nawara, M.M., Abd El Megeed, I., Salah Hammuda El Shikhi, I., Mahmoud Riad, A.A. Effect of Hyoscine-Bromide in Duration of the First Stage of Labor. J Obstet Gynecol Cancer Res. 2025;10(7):537-44.

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