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Impact of intravenous Hyoscine N-Butyl bromide on the progress of labour during the active phase

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Abstract

Background and Aim: Higher rates of surgical delivery and maternal morbidity are linked to prolonged labour. A cervical spasmolytic drug called Hyoscine-N-butylbromide (Buscopan) may speed up labour by promoting cervical dilatation. This study assessed how intravenous Buscopan affected the length of labour and the outcomes for both the mother and the newborn in primigravida women.

Material and Methods: A randomised controlled trial with 120 primigravida women in active labour was carried out at SMGS Hospital, GMC Jammu. The trial group (n = 60) got 20 mg IV Buscopan at 4 cm cervical dilatation, while the control group (n = 60) did not receive any antispasmodic. Using the proper statistical tests, baseline features, maternal haemodynamics, adverse effects, newborn outcomes, cervical dilatation rate, stage-wise labour length, and mode of delivery were examined.

Results: Age, BMI, socioeconomic level, and gestational age were baseline characteristics that were similar among groups ($p>0.05$). The average duration of the active stage (189.87 vs. 298.89 min; $p<0.001$), second stage (24.59 vs. 29.84 min; $p<0.001$), and overall labour time (224.86 vs. 336.45 min; $p<0.001$) was all significantly decreased by Buscopan. In the study group, the cervical dilatation rate was almost twice (1.89 vs. 1.02 cm/hr). Both groups' third-stage duration and maternal haemodynamics were comparable. There was no significant difference in newborn outcomes, such as APGAR scores, birth weight, and NICU admissions, however dry mouth was more common with Buscopan (13.3% vs. 3.3%; $p=0.048$).

Conclusion: IV Buscopan given at a cervical dilation of 4 cm considerably reduces the length of labour without having a negative impact on the mother or the newborn. It serves as a secure and useful labour management adjunct.

Keywords: Buscopan, labour, cervical dilatation

Introduction

Childbirth is a complex physiological process characterized by a sequence of coordinated uterine contractions, cervical dilation, and eventual fetal expulsion. The successful progression of labor is dependent on various physiological factors, including maternal hormonal regulation, fetal positioning, and uterine contractility. The active stage of labor, defined as the period from 4 cm cervical dilation to full dilation at 10 cm, is of particular clinical significance as it determines the trajectory of labor progression and potential maternal and fetal outcomes. A prolonged or dysfunctional labor can lead to increased maternal exhaustion, heightened risks of cesarean delivery, and adverse neonatal outcomes, including fetal distress, low Apgar scores, and birth asphyxia^[1]. Prolonged labor is often associated with complications such as chorioamnionitis, postpartum hemorrhage, and neonatal hypoxia, which can have long-term implications for both maternal and neonatal health. Therefore, effective labor management strategies are crucial to ensure optimal birth outcomes and reduce the risk of obstetric complications.

Given the clinical importance of managing labor efficiently, numerous pharmacological interventions have been explored to optimize labor outcomes. Traditional methods such as oxytocin administration and artificial rupture of membranes (ARM) are frequently employed to accelerate labor; however, these interventions carry risks, including uterine hyperstimulation, fetal distress, and increased rates of operative deliveries. To address these concerns, newer pharmacological agents with a favorable safety profile have been investigated as alternatives for labor augmentation. One such intervention is the administration of Hyoscine-N-Butyl Bromide (HBB), an antispasmodic agent widely used in medical practice for its ability to relax smooth muscle by inhibiting muscarinic receptors.

Hyoscine-N-butylbromide, an antispasmodic, is often administered during the active phase of

Labour to reduce uterine hypertonicity and improve cervical dilation. By inhibiting the action of acetylcholine on smooth muscle, it facilitates a more relaxed uterine environment, potentially speeding up the labour process without compromising uterine function. The drug's effects on reducing painful uterine contractions and improving maternal comfort have made it a useful adjunct in certain labour management protocols. However, careful consideration is necessary when using this drug, as excessive uterine relaxation may contribute to labor dysfunction, such as prolonged deceleration or failure of descent^[2].

Recent studies have explored the effects of hyoscine-N-butylbromide on both the maternal and fetal outcomes in the context of labour. Some studies suggest that the use of hyoscine-N-butylbromide may be associated with shorter active labour durations and improved maternal satisfaction, but concerns remain regarding its safety profile, particularly in terms of potential fetal side effects^[3]. The impact on neonatal outcomes, including Apgar scores and incidence of neonatal resuscitation, is an area of ongoing research.

The rationale for this study lies in the ongoing need for effective and safe interventions to manage the active phase of labor. Despite the use of agents like oxytocin, which often require careful monitoring due to the risk of uterine hyperstimulation, there is limited research on the use of Hyoscine-N-butylbromide as a pharmacological intervention for reducing labor duration in clinical settings. This study aims to evaluate the impact of intravenous HBB (20 mg) on the duration of the active phase of labor and assess its maternal and fetal outcomes.

- **Material and Methods:** This prospective, randomized controlled interventional trial was conducted over a period of one year from 1st May 2024 to 30th April 2025, in the department of obstetrics and gynecology, SMGS Hospital, GMC, Jammu. The study was approved by the Institutional Review Board (IRB) and received permission from the Department of Obstetrics and Gynecology at SMGS Hospital GMC Jammu.
- **Sample size:** A minimum sample size of 120 subjects was calculated using the effect size ($d = 0.6$), Type 1 error ($\alpha = 0.05$), and Type 2 error ($\beta = 0.1$). The sample size calculation was performed using G*Power software version 3.1.9.7. These subjects were randomly assigned to two groups, each consisting of 60 women.
- **Study group:** The study group comprised of 60 women who received 20mg hyoscine-N-butylbromide intravenously at 4cm cervical dilatation, post-amniotomy. This intervention aimed to assess its impact on the progression of labor.
- **Control group:** The control group consisted of 60 women who did not receive any intervention (i.e., no 20mg hyoscine-N-butylbromide was administered). This group served as a comparative baseline to evaluate the effectiveness of the intervention.

Inclusion criteria

- Primigravida.
- Spontaneous labour at term, 37 to 42 weeks (259 to 294 days).
- Single-ton pregnancy.
- Vertex presentation, station $[-2]$ or below at onset of active stage of labour.
- Cervical effacement $\geq 50\%$ at onset of active stage of labour.

- Normal admission CTG.
- Post-amniotomy-clear liquor and normal CTG.

Exclusion Criteria

- Age of mother less than 20 years or more than 30 years.
- Previous abortion, spontaneous or induced.
- Previous preterm delivery.
- Birth weight of first child less than 2.5kg.
- Presentations other than vertex.
- Non-engaged head.
- CPD.
- Women with high risk factors, in previous or present pregnancy- like Preeclampsia, Ante-partum hemorrhage, Gestational diabetes, Anemia, Heart disease, any medical or surgical disorder.
- History of procedure involving dilatation of cervix other than previous normal delivery
- History of cervical/perineal tear in previous delivery.
- Previous uterine scar.
- Contraindications to vaginal delivery.
- Meconium.
- Any contraindication for Buscopan usage.

Methodology

- All eligible participants were informed about the procedure, its benefits, and risks.
- Written informed consent was obtained from each participant prior to the procedure.
- Eligible participants were randomized into two equal groups
 - **Study Group:** 60 women received 20mg IV hyoscine-N-butylbromide at 4cm cervical dilatation, post-amniotomy and
 - **Control Group:** 60 women did not receive 20mg hyoscine-N-butylbromide.
- Detailed patient history was taken, including demographics, presenting complaints, past, family, and personal medical history, drug history, obstetric history, immunization status, and menstrual history.
- Per abdomen examination was performed to assess fundal height, lie, presentation and fetal heart sound.
- Per vaginal examination was performed to evaluate cervical dilatation, effacement, fetal station, presentation, position, pelvic adequacy, membrane status, and liquor.
- Admission cardiotocography (CTG) was conducted for all participants to assess fetal well-being.
- Venous Access:** was secured prophylactically in all participants.
- Amniotomy**
At 4cm cervical dilatation, amniotomy was performed on all women.
Only women with clear amniotic fluid and normal CTG were selected for the study.
- Labor Progress Monitoring**
 - Labor progression was monitored using the WHO partograph.
 - In accordance with institutional protocol, internal examinations were performed every two hours to monitor the progress of labor.

Data was collected and subjected to statistical analysis.

Statistical analysis: Data so collected was tabulated in an excel sheet, under the guidance of statistician. The means and standard

deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). For each assessment point, data were statistically analyzed using t test and chi square test. The level of significance was set at $p < 0.05$.

Results: The mean age of participants in the study group was

24.75 years (SD = 2.91), while in the control group, it was 24.88 years (SD = 2.62). Socioeconomic classification revealed that the majority of participants in both groups belonged to the upper lower and lower middle categories. Most of the subjects in control (71.67%) as well as study group (68.33%) had normal BMI (table 1).

Table 1: Maternal Baseline Characteristics

Maternal Characteristic	Study Group	Control Group
Age (years), Mean \pm SD	24.75 \pm 2.91	24.88 \pm 2.62
Lower SES (%)	8.3%	1.7%
Lower Middle SES (%)	35.0%	25.0%
Upper Lower SES (%)	40.0%	56.7%
Upper Middle SES (%)	13.3%	11.7%
Upper SES (%)	3.3%	5.0%
Underweight (%)	13.3%	15.0%
Normal BMI (%)	68.3%	71.7%
Overweight (%)	10.0%	6.7%
Obese (%)	8.3%	6.7%
Gestational Age (weeks)	38.55 \pm 0.72	38.64 \pm 0.69

The mean duration in the study group was 189.87 minutes (SD=8.89), whereas the control group had a substantially longer mean duration of 298.89 minutes (SD=9.90). A statistically significant difference ($p < 0.001$) was observed in the duration of the active stage of labor between the study and control groups when compared using t test. This finding strongly supports the hypothesis that hyoscine-N-butylbromide (Buscopan) significantly shortens the active phase of labor in primipara

women as shown in table 2. Administration of hyoscine-N-butylbromide also facilitated a more efficient second stage of labor, which is crucial for safe maternal and fetal outcomes. In contrast, the third stage of labor was comparable between the groups. Women who received Buscopan experienced a mean total labor duration of 224.86 minutes (SD = 10.06), compared to 336.45 minutes (SD = 9.74) in the control group. The difference was statistically significant as $p < .001$.

Table 2: Labor Progress & Duration Outcomes

Outcome	Study Group	Control Group	p-value
Active Stage (min)	189.87 \pm 8.89	298.89 \pm 9.90	<0.001
Second Stage (min)	24.59 \pm 3.41	29.84 \pm 2.71	<0.001
Third Stage (min)	7.19 \pm 1.02	7.49 \pm 0.90	0.091
Total Labor Duration (min)	224.86 \pm 10.06	336.45 \pm 9.74	<0.001
Cervical Dilatation Rate (cm/hr)	~1.89	~1.02	0.014
SVD (%)	95.0%	85.0%	0.089
Assisted (%)	0%	6.7%	
LSCS (%)	5.0%	8.3%	

Dry mouth was reported by 8 participants (13.3%) in the study group and 2 participants (3.3%) in the control group. The difference was statistically significant as $p = .048$. Tachycardia was noted in 3 participants (5%) of the study group, while none were observed in the control group. Nausea was reported by

only 1 participant (1.7%) in the study group and none in the control. These outcomes affirm that while Buscopan may lead to mild side effects such as dry mouth, serious adverse events were rare and manageable (table 3).

Table 3: Maternal Safety & Adverse Events

Parameter	Study Group	Control Group	p-value
Pulse (bpm)	79.64 \pm 2.95	79.91 \pm 3.11	0.63
Systolic BP (mmHg)	118.31 \pm 3.59	118.12 \pm 3.63	0.77
Diastolic BP (mmHg)	84.06 \pm 2.78	84.18 \pm 3.42	0.82
PPH (%)	0%	0%	1
Dry Mouth (%)	13.3%	3.3%	0.048
Tachycardia (%)	5.0%	0%	0.079
Nausea (%)	1.7%	0%	0.315

Hyoscine-N-butylbromide administration had no detrimental effect on fetal growth outcomes. No case of NICU admission

was found in two groups (table 4).

Table 4: Neonatal Outcomes

Neonatal Parameter	Study Group	Control Group	p-value
Birth Weight (kg)	3.08±0.39	3.04±0.44	0.544
APGAR 1 min Score 8 (%)	33.3%	38.3%	0.620
APGAR 1 min Score 9 (%)	30.0%	33.3%	
APGAR 1 min Score 10 (%)	36.7%	28.3%	
APGAR 5 min Score 8 (%)	30.0%	28.3%	0.583
APGAR 5 min Score 9 (%)	18.3%	21.7%	
APGAR 5 min Score 10 (%)	51.7%	50.0%	
NICU Admission (%)	0%	0%	1

Discussion: Many studies have evaluated the effects of HBB on cervical dilatation, and the majority demonstrated its efficacy in augmenting labor. However, Gupta *et al.* [4] reported no effect of HBB on accelerating labor. Due to conflicting literature; the present study was conducted to assess the impact of hyoscine-N-butylbromide (Buscopan) on the duration of the active stage of labor and associated maternal and neonatal outcomes.

The mean age of participants in the study group was 24.75 years (SD = 2.91), while in the control group, it was 24.88 years (SD = 2.62). Serpil Kirim *et al* [5] in their study found that the mean age was 25.9 years (SD=6.1) and 26.1 (SD=5.3) in the HBB and placebo groups, respectively. There were no statistically significant difference in term of age between two groups. Their findings are similar to the present study.

All the BMI categories viz. underweight, normal, overweight and obese were found to be comparable between control and study groups when compared using chi square test as $p > 0.05$. Similarly in a study conducted by Serpil Kirim *et al* [5]. The body mass index (BMI) was 27.2 ± 2.9 and 27.4 ± 2.17 in the HBB and placebo groups, respectively. There was no statistically significant differences in two groups regarding BMI.

The mean duration in the study group was 189.87 minutes (SD=8.89), whereas the control group had a substantially longer mean duration of 298.89 minutes (SD=9.90). A significant difference ($p < 0.001$) was observed in the duration of the active stage of labor between the study and control groups when compared using t test. Approximately similar results were reported by Imaralu *et al.* [6] (2017), who demonstrated a significant reduction in active phase duration with Buscopan administration (365.1 vs. 388.5 minutes, $p = .001$). Similarly, Elegbua *et al* [7]. (2024) documented an average active phase duration of 234.6 minutes in the Buscopan group versus 328.3 minutes in the control group ($p < .001$), further supporting the cervical smooth muscle-relaxing properties of this drug. Study conducted by El-Mallah E. M. *et al* [8]. Showed that the mean duration of the first stage of labor in the study group was significantly shorter, with a reduction of 50 minutes compared to the control group (208.16 ± 17.24 minutes vs. 258.16 ± 15.27 minutes, $p = 0.00$). Makvandi *et al* [9] found similar result in their study. The mean duration of the active phase of labor was 141.0 ± 81.7 -minute in the experimental and 230.1 ± 169.6 -minute in the control group ($P = 0.001$).

The mean duration of the second stage of labor was significantly shorter in the study group ($M = 24.59$ minutes, $SD = 3.41$) than in the control group ($M = 29.84$ minutes, $SD = 2.71$). This difference was statistically significant ($p < .001$). Eleje *et al* [10]. (2020) reported a significantly shorter second stage among primigravidas receiving Buscopan (28.1 vs. 30.5 minutes, $p = .013$), which is comparable to our data. Makvandi *et al* [9] in their study also found that the second stage of labor was significantly shorter in the HBB group compared to the placebo controls. The mean duration of the second stage of labor was 38.8 ± 24.3 -minute in the experimental and 51.7 ± 23.8 -minute in the control

group ($P < 0.001$). However, Qahtani *et al* [11] in their study found no significant differences in the durations of the second stage of labor between the two groups.

The third stage of labor was comparable between the groups. This observation suggests that while Buscopan may enhance uterine and cervical compliance during the dilatation and expulsion phases, it does not significantly influence placental separation or uterine contractility in the third stage. Similar patterns were reported by Imaralu *et al* [6]. (2017) where HBB group has (8.96 minutes, SD 4.34) and placebo group has (9.23 minutes, SD 5.92) and Asogwa *et al* [12]. (2025), both of whom found no meaningful difference in third stage duration between groups. Serpil Kirim *et al* [5] found in their study that the duration of 3rd stage in HBB group was 16.88 minutes (SD 3.81) and in placebo group was 18.76 minutes (SD 4.63) their results are similar to our study.

A notable strength of our study is the calculation and estimation of the cervical dilatation rate, which was indirectly assessed through active labor duration. The average rate was estimated at approximately 1.89 cm/hr in the study group versus 1.02 cm/hr in the control group, suggesting a nearly two-fold increase in efficiency of cervical progression. This is similar to the findings by Asogwa *et al* [12] (2025) the rate of cervical dilatation was also significantly faster in the Hyoscine group (2.3 ± 2.8 cm/h) than in the placebo group (1.7 ± 2.7 cm/h; $p = 0.01$). Akiseku AK *et al* [13]. (2021) found that the rate of cervical dilation was also significantly higher in the HBB group, with a mean of 1.4 ± 0.8 cm/hour, compared to 1.0 ± 0.5 cm/hour in the placebo group ($p = 0.004$). Sekhavat L. *et al* [14]. (2012) found in their study that the cervical dilation rate was higher in the hyoscine group, indicating a faster progression of labor (2.8 ± 0.7 cm/hour in study group vs. 1.9 ± 0.8 cm/hour in the control group, $p = 0.001$).

All the hemodynamic parameters viz. pulse rate, systolic BP and diastolic BP was found to be comparable among the two groups. These findings confirm that the administration of Buscopan had no significant adverse impact on maternal cardiovascular parameters post-delivery. No case of postpartum haemorrhage was found among the two groups. These findings corroborate those of Elegbua *et al* [7]. (2024) and Mohaghegh *et al* [15]. (2020), who also reported no hemodynamic instability associated with Buscopan use. Lack of postpartum hemorrhage (PPH) in both groups further supports the maternal safety profile of the drug.

Dry mouth was reported by 8 participants (13.3%) in the study group and 2 participants (3.3%) in the control group. This is consistent with the anticholinergic mechanism of Buscopan and is frequently cited in the literature as a mild and self-limiting side effect. The difference was statistically significant as $p = .048$. Tachycardia was noted in 3 participants (5%) of the study group, while none were observed in the control group. Nausea was reported by only 1 participant (1.7%) in the study group and none in the control. Serpil Kirim *et al* [5] in their study too found that no adverse maternal effects were observed in either the HBB or placebo group.

Limitations: Nevertheless, the study's findings should be interpreted in light of its limitations, including its single-center design and modest sample size. Future large-scale, multicentric studies with diverse obstetric populations and longer-term maternal and neonatal follow-up are warranted to further validate these findings and explore subgroup-specific responses.

Conclusion: So, the present study reported significantly faster cervical dilatation rates in the Buscopan groups. Such quickening is clinically beneficial, as it may decrease the need for labor augmentation, reduce maternal exhaustion, and potentially minimize the incidence of operative delivery.

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