Comparative Efficacy and Safety of Intramuscular CamylofinDihydrochloride versus Intravenous Valethamate Bromide on Cervical Dilatation in the Active Phase of Labour: A Hospital-Based Cross-Sectional Study.

Abstract

Background: Labour dystocia due to inadequate cervical dilatation is a major contributor to prolonged labour and operative delivery. CamylofinDihydrochloride and Valethamate Bromide are widely used cervical antispasmodics, but comparative evidence on their efficacy and safety remains limited from central India.

Methods: A hospital-based cross-sectional study was conducted in the Department of Obstetrics and Gynaecology, Pt. J.N.M. Medical College and Dr. B.R.A.M. Hospital, Raipur, between March 2024 and February 2026. Four hundred parturients with singleton term pregnancy in the active phase of labour (cervical dilatation > 4 cm) were allocated by closed-envelope randomisation to receive a single intramuscular dose of CamylofinDihydrochloride 25 mg (Group A, n = 200) or intravenous Valethamate Bromide 8 mg, up to three half-hourly doses (Group B, n = 200). The primary outcome was the rate of cervical dilatation (cm/hr); secondary outcomes included duration of labour, mode of delivery, blood loss, APGAR score, NICU admission, maternal side effects, labour complications and pain perception (VAS).

Results: The two groups were well matched at baseline for age, gravida, parity, gestational age, BMI, and cervical status at admission and drug administration (all $p > 0.05$). The mean rate of cervical dilatation was significantly higher with Valethamate Bromide than with CamylofinDihydrochloride (0.93 ± 0.37 vs 0.81 ± 0.31 cm/hr; $p = 0.001$), and the active phase was correspondingly shorter (309.4 ± 111.5 vs 342.8 ± 142.9 min; $p = 0.017$). However, Valethamate was associated with significantly greater blood loss (573.4 ± 291.6 vs 476.5 ± 195.5 mL; $p < 0.001$), lower APGAR scores at 1 and 5 minutes ($p < 0.001$ and $p = 0.001$), higher rates of meconium-stained liquor (20.0% vs 11.5%; $p = 0.020$) and NICU admission (16.0% vs 8.0%; $p < 0.001$), more frequent maternal side effects (22.0% vs 10.5%; $p < 0.001$) and labour complications including fetal tachycardia, cervical tears and atonic postpartum haemorrhage (all $p < 0.001$), and higher VAS pain scores (7.70 ± 1.55 vs 6.95 ± 1.59; $p < 0.001$).

Conclusion: Intravenous Valethamate Bromide produces faster cervical dilatation and a shorter active phase than intramuscular CamylofinDihydrochloride, but at the cost of greater maternal blood loss, more frequent complications and side effects, poorer neonatal outcomes, and greater maternal pain. CamylofinDihydrochloride offers a substantially safer overall profile and may be preferred for labour augmentation where maternal and fetal safety are prioritised.

Keywords: *Camylofindihydrochloride; Valethamate bromide; Cervical dilatation; Active phase of labour; Labour augmentation; Antispasmodic*

Introduction

Labour is a complex physiological process culminating in delivery through coordinated uterine contractions and progressive cervical effacement and dilatation, the final outcome of biochemical, hormonal and mechanical events that intensify toward term [1,2]. Cervical ripening and remodeling, involving enzymatic collagen degradation and infiltration of inflammatory mediators, is a crucial determinant of labour progress, and failure of adequate dilatation despite effective contractions remains a major cause of dystocia, affecting more than half of women in some obstetric populations [3-6].

Pharmacological cervical antispasmodics are widely used to facilitate dilatation and shorten labour. CamylofinDihydrochloride is a selective smooth-muscle antispasmodic acting via calcium-channel antagonism and phosphodiesterase inhibition, while Valethamate Bromide is a mixed anticholinergic and smooth-muscle relaxant

acting on both smooth muscle fibres and autonomic ganglia [7-9]. Despite their common use, robust comparative data on the relative efficacy and maternal-neonatal safety of these two agents in the active phase of labour remain limited, particularly from central Indian obstetric populations.

This study was therefore designed to evaluate and compare the effect of intramuscular CamylofinDihydrochloride versus intravenous Valethamate Bromide on the rate of cervical dilatation in the active phase of labour, and to assess their relative impact on maternal and neonatal secondary outcomes.

Aim and Objectives

To evaluate if there is any difference in the effect of intramuscular CamylofinDihydrochloride versus intravenous Valethamate Bromide on cervical dilatation in the active phase of labour.

Primary objective: To assess and compare the effect of the two drugs on the rate of cervical dilatation in terms of Bishop score.

Secondary objectives: To assess maternal outcomes (duration of labour, mode of delivery), neonatal outcomes (APGAR score), and to compare side effects of the two drugs.

Materials and Methods

This was a hospital-based, cross-sectional comparative study conducted in the Department of Obstetrics and Gynaecology, Pt. J.N.M. Medical College and Dr. B.R.A.M. Hospital, Raipur, Chhattisgarh, between March 2024 and February 2026, after approval from the Institutional Scientific and Ethics Committees. Written informed consent was obtained from all participants in accordance with the Declaration of Helsinki and ICMR ethical guidelines.

Women with singleton term pregnancy (≥ 37 weeks), cephalic presentation, no cephalopelvic disproportion, in spontaneous active labour with cervical dilatation > 4 cm, aged 18-35 years, were included. Women with malpresentation, antepartum haemorrhage, medical complications, fetal distress, multiple gestation, preterm pregnancy, previous caesarean section or inadequate uterine contractions were excluded.

Sample size was calculated using the formula for two independent means ($Z_1-\alpha/2 = 1.96$, $Z_1-\beta = 0.84$, $\delta_1 = 0.32$, $\delta_2 = 0.28$, mean rates 1.70 and 1.58 cm/hr), yielding a minimum of 100 cases per group; a total of 400 patients (200 per group) were enrolled. Eligible women were allocated by closed-envelope randomisation into Group A (CamylofinDihydrochloride) or Group B (Valethamate Bromide), 200 in each.

Group A received a single intramuscular dose of CamylofinDihydrochloride (1 ampoule, 25 mg) at a cervical dilatation of 4 cm. Group B received intravenous Valethamate Bromide (1 ampoule, 8 mg) as a bolus at half-hourly intervals, up to a maximum of three doses. Vitals, fetal heart rate and Bishop score were monitored at regular intervals, and pelvic examination was performed hourly with findings plotted on a partograph until safe delivery. Both groups were compared for duration of labour, rate of cervical dilatation, mode of delivery, side effects and neonatal outcomes.

Data were analysed using SPSS version 20.0. Continuous variables were expressed as mean ± standard deviation and compared using the unpaired t-test or Mann-Whitney U test as appropriate; categorical variables were expressed as frequencies and percentages and compared using the chi-square or Fisher exact test. A two-sided p-value < 0.05 was considered statistically significant.

Results

A total of 400 parturients were enrolled, 200 in each group. The two groups were well matched for all baseline demographic and obstetric characteristics, including age (mean 25.23 ± 4.28 vs 25.12 ± 4.32 years; $p = 0.798$), gravida (2.03 ± 1.05 vs 2.31 ± 1.13; $p = 0.111$), parity (0.70 ± 0.76 vs 0.77 ± 0.83; $p = 0.346$), gestational age (38.45 ± 1.17 vs 38.74 ± 1.39 weeks; $p = 0.095$) and BMI (22.17 ± 3.12 vs 22.23 ± 3.17 kg/m²; $p = 0.840$), as summarised in Table 1.

Table 1. Baseline demographic and clinical characteristics (n = 400).

Characteristic	Group A – Camylofin (n=200)	Group B – Valethamate (n=200)	Total (n=400)	p-value
Mean age (years)	25.23 ± 4.28	25.12 ± 4.32	25.18 ± 4.29	0.798 (NS)
Mean gravida	2.03 ± 1.05	2.31 ± 1.13	2.17 ± 1.10	0.111 (NS)
Mean parity	0.695 ± 0.758	0.770 ± 0.831	0.733 ± 0.795	0.346 (NS)
Mean gestational age (weeks)	38.45 ± 1.17	38.74 ± 1.39	38.60 ± 1.29	0.125 (NS)
Mean BMI (kg/m²)	22.168 ± 3.116	22.232 ± 3.171	22.200 ± 3.140	0.840 (NS)

Values are mean ± standard deviation. Comparisons by independent t-test. NS = not significant.

Cervical dilatation and Bishop score at admission were also comparable between groups (1.695 ± 1.018 vs 1.665 ± 0.898 cm, p = 0.470; and 6.79 ± 2.06 vs 7.08 ± 2.08, p = 0.851), as were values at the time of drug administration, confirming that both groups entered the study at an equivalent stage of cervical favourability (Table 2).

Table 2. Cervical dilatation and Bishop score at admission and at drug administration.

Parameter	Group A – Camylofin	Group B – Valethamate	Total	p-value
Cervical dilatation at admission (cm)	1.695 ± 1.018	1.665 ± 0.898	1.680 ± 0.959	0.470 (NS)
Bishop score at admission	6.790 ± 2.063	7.075 ± 2.079	6.933 ± 2.073	0.851 (NS)
Cervical dilatation at drug administration (cm)	5.935 ± 0.809	5.695 ± 0.791	5.815 ± 0.808	0.063 (NS)
Bishop score at drug administration	10.195 ± 1.106	10.235 ± 1.186	10.215 ± 1.145	0.727 (NS)

Values are mean ± standard deviation. NS = not significant.

The primary outcome, rate of cervical dilatation in the active phase, was significantly higher in Group B than Group A (0.9286 ± 0.3652 vs 0.8114 ± 0.3095 cm/hr; p = 0.001), and the active phase of labour was correspondingly significantly shorter in Group B (309.37 ± 111.52 vs 342.82 ± 142.92 min; p = 0.017), while the duration of the second stage (p = 0.298) and total duration of labour (p = 0.401) were comparable between groups (Table 3).

Table 3. Primary outcome – rate of cervical dilatation and duration of labour.

Parameter	Group A – Camylofin	Group B – Valethamate	Total	p-value
Rate of cervical dilatation (cm/hr)	**0.8114 ± 0.3095**	**0.9286 ± 0.3652**	**0.8681 ± 0.3422**	**0.001 (S)**
Duration of active phase (min)	**342.82 ± 142.92**	**309.37 ± 111.52**	**326.69 ± 129.63**	**0.017 (S)**
Duration of 2nd stage (min)	36.53 ± 14.01	38.10 ± 13.68	37.28 ± 13.86	0.298 (NS)
Duration of 3rd stage (min)	8.477 ± 3.843	8.429 ± 4.095	8.454 ± 3.960	0.912 (NS)
Total duration of labour (min)	720.46 ± 197.37	702.81 ± 188.90	711.94 ± 193.25	0.401 (NS)

Values are mean ± standard deviation. Comparisons by independent t-test. S = statistically significant; NS = not significant.

Vaginal delivery was the predominant mode in both groups (overall 80.0%), with caesarean and instrumental delivery rates comparable between groups (p = 0.241). However, mean blood loss was significantly higher in Group B (573.40

± 291.62 vs 476.45 ± 195.54 mL; p < 0.001), and labour complications – fetal tachycardia, cervical tears and atonic postpartum haemorrhage – were all significantly more frequent in Group B (all p < 0.001), as shown in Table 4.

Table 4. Mode of delivery, blood loss and labour complications (n = 400).

Parameter	Group A – Camylofin n (%)	Group B – Valethamate n (%)	p-value
Vaginal delivery	166 (83.0)	154 (77.0)	0.241 (NS)
Instrumental delivery	10 (5.0)	10 (5.0)	0.241 (NS)
Caesarean section (LSCS)	24 (12.0)	36 (18.0)	0.241 (NS)
Mean blood loss (mL)	**476.45 ± 195.54**	**573.40 ± 291.62**	**< 0.001 (S)**
Fetal tachycardia	0 (0.0)	17 (8.5)	< 0.001 (S)
Cervical tear	6 (3.0)	12 (6.0)	< 0.001 (S)
Atonic postpartum haemorrhage	13 (6.5)	21 (10.5)	< 0.001 (S)

Values are n (%) unless otherwise specified. S = statistically significant; NS = not significant.

Neonatal outcomes were significantly better in Group A across all measured parameters. Mean APGAR scores at 1 and 5 minutes were significantly higher in Group A (7.65 ± 1.27 vs 7.15 ± 1.52, p < 0.001; and 8.925 ± 1.116 vs 8.510 ± 1.315, p = 0.001), and meconium-stained liquor (11.5% vs 20.0%, p = 0.020) and NICU admission (8.0% vs 16.0%, p < 0.001) were both significantly less frequent in Group A (Table 5).

Table 5. Neonatal outcomes (n = 400).

Parameter	Group A – Camylofin	Group B – Valethamate	p-value
Mean APGAR at 1 min	**7.650 ± 1.271**	**7.150 ± 1.523**	**< 0.001 (S)**
Mean APGAR at 5 min	**8.925 ± 1.116**	**8.510 ± 1.315**	**0.001 (S)**
Meconium-stained liquor, n (%)	23 (11.5)	40 (20.0)	0.020 (S)
NICU admission, n (%)	16 (8.0)	32 (16.0)	< 0.001 (S)

Values are mean ± standard deviation or n (%). S = statistically significant.

Maternal side effects were significantly more frequent in Group B (22.0%) than Group A (10.5%; p < 0.001), predominantly palpitations and dry mouth, consistent with the anticholinergic profile of Valethamate. Pain perception on the Visual Analogue Scale was also significantly higher in Group B (7.70 ± 1.55 vs 6.95 ± 1.59; p < 0.001), as summarised in Table 6.

Table 6. Maternal side effects and pain perception (VAS) (n = 400).

Parameter	Group A – Camylofin	Group B – Valethamate	p-value
Any maternal side effect, n (%)	21 (10.5)	44 (22.0)	< 0.001 (S)
Palpitations, n (%)	0 (0.0)	11 (5.5)	< 0.001 (S)
Dry mouth, n (%)	0 (0.0)	8 (4.0)	< 0.001 (S)
Mean VAS pain score	**6.945 ± 1.592**	**7.700 ± 1.547**	**< 0.001 (S)**

Values are n (%) or mean ± standard deviation. S = statistically significant.

Discussion

In this cross-sectional comparative study of 400 parturients in the active phase of labour, intravenous Valethamate Bromide produced a significantly faster rate of cervical dilatation and a shorter active phase of labour than

intramuscular CamylofinDihydrochloride, consistent with its dual anticholinergic and smooth-muscle relaxant action and rapid intravenous onset, compared with the selective calcium-channel-mediated and comparatively slower-onset action of intramuscularly administered Camylofin [49,52,53].

This efficacy advantage of Valethamate, however, was accompanied by a consistently poorer safety profile. Blood loss was significantly higher in the Valethamate group, plausibly reflecting impaired uterine contractility in the third stage from non-selective anticholinergic action, consistent with prior reports of higher postpartum blood loss with Valethamate relative to selective smooth-muscle relaxants [50]. Neonatal outcomes – APGAR scores, meconium staining and NICU admission – were all significantly worse in the Valethamate group, attributable to transplacental anticholinergic effects producing fetal tachycardia and uteroplacental haemodynamic alteration, mirroring findings reported by Tripathi et al. and Nanda et al. [49,53].

Maternal side effects, principally palpitations and dry mouth, and labour complications including fetal tachycardia, cervical tears and atonic postpartum haemorrhage were all significantly more frequent with Valethamate, in keeping with its well-characterised anticholinergic adverse-effect profile [50]. Counter-intuitively, despite faster dilatation, women receiving Valethamate also reported significantly higher VAS pain scores, possibly reflecting intensified uterine contraction strength and stretch-receptor stimulation accompanying accelerated cervical change, together with physiological arousal from anticholinergic side effects.

These findings indicate that the choice between CamylofinDihydrochloride and Valethamate Bromide for augmentation of the active phase of labour should not rest on cervical dilatation efficacy alone, but must integrate the totality of maternal and neonatal safety data. Camylofin may be preferable where maternal and neonatal safety are paramount, such as resource-limited settings with constrained NICU capacity, while Valethamate may retain a selective role where rapid labour progression is the overriding clinical priority and close fetal monitoring is available.

Strengths of this study include its large sample size (n = 400) and well-matched baseline characteristics, which minimised confounding and enabled robust comparison of both efficacy and safety outcomes. Limitations include the cross-sectional, non-randomised design, single-centre setting, short-term follow-up, and potential observer bias in the subjective assessment of pain (VAS). Larger multicentric randomised controlled trials with longer-term neonatal follow-up are warranted to further define the optimal role of each agent in contemporary obstetric practice.

Conclusion

Intravenous Valethamate Bromide is more effective than intramuscular CamylofinDihydrochloride in accelerating cervical dilatation and shortening the active phase of labour, but this efficacy is accompanied by significantly greater maternal blood loss, more frequent labour complications and side effects, poorer neonatal outcomes, and greater maternal pain. CamylofinDihydrochloride, although marginally less effective in accelerating labour, demonstrates a substantially safer maternal and neonatal profile and may therefore be considered the preferable agent for augmentation of labour, particularly where maternal and fetal safety are of paramount clinical importance.

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Conflict of Interest

The authors declare that they have no conflicts of interest relevant to this work.

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