

## COMPARISON OF ANALGESIC EFFICACY AND EVALUATION OF 0.0625% BUPIVACAINE + 25MG TRAMADOL AND 0.1% ROPIVACAINE +25MG TRAMADOL ON LABOUR ANALGESIA

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### Abstract

**Background:** The objective is to compare the analgesic efficacy and evaluation of 0.0625% bupivacaine + 25mg tramadol and 0.1% ropivacaine + 25mg tramadol on labour analgesia. **Materials and Methods:** This is a prospective randomized study conducted at Saheed Laxman Nayak Medical College and Hospital, Odisha, Institutional Ethics committee approval [project no - EC4(11)] from 3<sup>rd</sup> September 2020 to 3<sup>rd</sup> March 2022. **Result:** There were no statistically significant variation in the demographic profiles among the two groups. The maternal pulse rate and systolic blood pressure showed no significant difference among the two groups throughout the observation period. This trend indicates that both Ropivacaine + Tramadol and Bupivacaine + Tramadol is safe for labour analgesia at the concentrations and doses used in our study. Fetal heart rates were comparable between the two studied group at all the time and there was no statistically significant difference. **Conclusion:** Both ropivacaine and bupivacaine can provide comparable labor analgesia with high maternal satisfaction in the clinically used doses.

## INTRODUCTION

Labor pain have been reported as one of the worst pains that have ever been evaluated.<sup>[1]</sup> Relief of labor pain is important to prevent maternal and perinatal morbidity and reduce the chances of caesarean section because of anxiety of the mother.<sup>[2]</sup> Walking labour epidural analgesia shows lower pain scores, better maternal satisfaction with more stable cardiovascular and pulmonary physiology.<sup>[2]</sup>

Bupivacaine is used for its long duration of action, minimal placental transfer and negligible neonatal effects.<sup>[3,4]</sup> In addition, compared to lignocaine, it has less tachyphylaxis with long-term administration.<sup>[5]</sup> However, bupivacaine is more cardiotoxic than other local anesthetics,<sup>[6]</sup> and motor blockade also happens with the analgesia especially at high concentrations.<sup>[7]</sup> Bupivacaine is a racemic mixture of levorotatory and dextrorotatory forms.<sup>[8]</sup> Ropivacaine on the other hand is an amide local anesthetic which is available in pure levorotatory form. This solves some of the concerns that were there with bupivacaine. Addition of opioids with

Local Anaesthetic (LA) has been shown to be more effective than LA alone.<sup>[9,10]</sup>

Hence the aim of this study was to compare the analgesic efficacy and evaluation of 0.0625% bupivacaine + 25mg tramadol and 0.1% ropivacaine + 25mg tramadol on labour analgesia. Secondary objectives included changes in maternal heart rate, maternal blood pressure, obstetric outcomes and any adverse effects of the drugs used in the study.

## MATERIALS AND METHODS

This is a prospective randomized study conducted at Saheed Laxman Nayak Medical College and Hospital, Odisha, Institutional Ethics committee approval [project no - EC4(11)] from 3<sup>rd</sup> September 2020 to 3<sup>rd</sup> March 2022. Written and informed consent was taken from all the patients. Patients were randomly divided into two groups (group BT and group RT) of 30 each by computer generated codes.

### Inclusion Criteria

- Primigravida or gravida 2 or 3, giving written and informed consent

- ASA physical status I or II
- Age between 19-40 years
- Single live intrauterine fetus in cephalic presentation
- Parturients in established labour

#### Exclusion Criteria

- Patients with severe pregnancy-induced hypertension
- Severe pre-eclampsia
- Eclampsia
- Severe anemia
- Cephalopelvic disproportion
- Previous caesarean section
- Breech presentation
- Allergy to any local anesthetics
- Bleeding or coagulation disorders
- Psychological/neurological disorders
- Severe spine deformities or local infections over the lumbar spine region

All routine investigations including CBC, PT – INR, LFT, RFT, blood sugar and ECG was done pre anaesthetic evaluation was done. And they were premedicated with metoclopramide 0.25mg/kg and ondansetron 0.08-0.1mg/kg. NIBP, pulse oximetry, ECG was attached.

With the onset of the first stage of labour (defined by regular painful contractions in latent phase) and cervical dilatation at approximately 3cm epidural analgesia was started in all the participating patients. The baseline heart rate (HR) systolic blood pressure (SBP), mean and diastolic blood pressure (DBP) SPO2 were recorded. Under all available aseptic precautions and patients in sitting position, L2 – L3 inter-vertebral space was identified, skin was infiltrated with local anaesthetic. An 18G Touhy's

needle was inserted into the epidural space by loss of resistance technique. A 20 G epidural catheter was then introduced and a test dose of 3ml of 2% Lignocaine + adrenaline was given. Catheter was fixed so as to keep 4-5 cm of the catheter in the epidural space. Catheter was fixed and patients were made supine. Group BT patients received 20ml of bupivacaine (0.0625%) + 25 mg Tramadol and Group RT received 20ml of ropivacaine (0.1%) + 25mg Tramadol. Subsequent same doses were given after one hour till delivery of the baby.

The efficacy were assessed using the visual analog scale (VAS scale). mother's vitals like HR, SBP, DBP, were measured at baseline, after first bolus drug administration, 5,10,15 and 30 min then at 60 min and after that every hourly for six hours. The degree of motor block was assessed using modified Bromage scale every one hourly upto six hours post-delivery. Any Adverse Events like hypotension, bradycardia, nausea, pruritus, vomiting and urinary retention were observed.

Maternal Satisfaction after Delivery - Done by asking the mother to rate the pain relief in the first and second stages of labour as Poor/ fair/ good/ excellent. Incidences of instrument assisted delivery and caesarean section were also noted. Fetal heart rate was monitored using non-stress test machine.

## RESULTS

There were no statistically significant variation in the demographic profiles among the two groups [Table 1].

**Table 1: Comparison of Anthropometric Variables and age of Parturient Between Two Groups.**

Variables	Group						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
	No.	Mean	SD	No.	Mean	SD			
Age (Years)	30	26.3	3.40	30	25.8	3.79	0.54	0.23	Not significant
Height(cm)	30	151.5	7.46	30	151.1	7.32	0.192	0.42	Not significant
Weight(kg)	30	57.2	8.03	30	57.2	8.03	0	0.5	Not significant

**Table 2: comparison of obstetrics variables of mothers between the two groups.**

Variables	Group						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
	No.	Mean	SD	No.	Mean	SD			
Gravida	30	1.4	0.4	30	1.5	0.5	-0.77	0.22	Not significant
Cervical dilation(cm)	30	3.0	-	30	3.0	-	-	-	Not significant
Baby 30Weight(kg)	30	2.89	0.40	30	3.79	5.15	-0.95	0.171	Not significant

**Table3: Comparison of Pulse at Various Intervals Between the Two Groups**

Variables	Group						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
	No.	Mean	SD	No.	Mean	SD			
PULSE(Beats per min)									
0 min	30	97	5.8	30	97.4	5.16	-0.281	0.389	Not significant
Bolus	30	95.3	5.3	30	94.9	5.24	-0.243	0.404	Not significant
5min	30	87.5	4.84	30	88.0	4.53	-0.419	0.340	Not significant
10 min	30	85	4.61	30	85.1	4.6	-0.080	0.466	Not significant
15 min	30	84.8	4.50	30	84.9	4.6	-0.080	0.466	Not significant
30 min	30	83.7	4.34	30	84.0	4.1	-0.242	0.404	Not significant
60 min	30	82.4	3.97	30	82.8	3.71	-0.369	0.356	Not significant

120 min	18	80.72	2.9	17	82.0	2.76	-1.346	0.093	Not significant
180 min	10	78.8	3.2	7	79.7	2.58	-0.084	0.251	Not significant
240 min	6	76.6	2.9	6	76	3.4	0.36	0.36	Not significant
300 min	4	76.75	1.5	4	77	1.33	-0.264	0.40	Not significant
360 min	2	76.5	2.1	2	75	1.4	0.832	0.246	Not significant

**Table 4: Comparison of Mean Blood Pressure at Various Intervals Between the Two Groups**

Variables	Group						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
Systolic Blood Pressure at-	No.	Mean	SD	No.	Mean	SD			
0 min	30	95.07	3.40	30	94.5	3.12	0.580	0.281	Not significant
Bolus	30	92.99	3.29	30	92.77	3.26	0.253	0.400	Not significant
5min	30	91.56	3.26	30	91.0	3.20	0.673	0.251	Not significant
10 min	30	88.46	3.16	30	88.61	3.36	-0.181	0.428	Not significant
15 min	30	87.73	3.13	30	87.85	3.29	-0.140	0.444	Not significant
30 min	30	86.78	3.28	30	86.14	3.47	0.729	0.234	Not significant
60 min	30	84.78	3.18	30	83.92	3.03	1.066	0.145	Not significant
120 min	18	83.00	2.37	17	82.25	2.44	0.940	0.176	Not significant
180 min	10	82.3	1.92	7	81.55	1.45	0.983	0.169	Not significant
240 min	6	81.0	0.62	6	80.48	1.28	0.884	0.198	Not significant
300 min	4	79.3	2.1	4	77.87	2.38	0.895	0.202	Not significant
360 min	2	77.85	3.1	2	76.3	2.54	0.537	0.322	Not significant

The maternal pulse rate and systolic blood pressure showed no significant difference among the two groups throughout the observation period. This trend indicates that both Ropivacaine + Tramadol and Bupivacaine + Tramadol are safe for labour analgesia at the concentrations and doses used in our study.

**Table 5: Comparison of Fetal Heart Rate at Various Intervals Between the Two Groups**

Variables	Group						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
Fetal Heart Rate at-	No.	Mean	SD	No.	Mean	SD			
0 min	30	139	4.05	30	140	3.02	-1.064	0.145	Not significant
Bolus	30	139	4.05	30	139	4.06	0	0.5	Not significant
5min	30	139	4.05	30	138.8	4.02	0.157	0.438	Not significant
10 min	30	139	4.05	30	139	3.94	0	0.5	Not significant
15 min	30	138	3.86	30	137.8	3.57	0.170	0.432	Not significant
30 min	30	136	2.68	30	136	2.68	0	0.5	Not significant
60 min	30	136	2.68	30	136	2.68	0	0.5	Not significant
120 min	18	139	4.45	17	138	4.15	0.696	0.245	Not significant
180 min	10	140	3.26	7	138.7	3.16	0.904	0.188	Not significant
240 min	6	143	3.75	6	141	3.37	1.031	0.163	Not significant
300 min	4	144	1.63	4	142.5	0.58	1.732	0.066	Not significant
360 min	2	141	1.41	2	139	1.41	1.414	0.146	Not significant

Fetal heart rates were comparable between the two studied group at all the time and there was no statistically significant difference.

**Table 6: GroupWise comparison of maternal satisfaction**

Maternal satisfaction	GROUP			Total
	No.	BT	RT	
Good	No.	23	22	45
	%	76.7	73.3	
Excellent	No.	7	8	15
	%	23.3	26.7	
Total	No.	30	30	60
	%	100	100	

**Table 7: Comparison of Visual Analog Scale Score At Various Intervals Between The Two Groups**

VAS at	GROUP						Unpaired T- Test Applied		
	BT			RT			T-Value	P- value	Difference is
	No.	Mean	SD	No.	Mean	SD			
Baseline	30	10	0	30	10	0	-	--	-
Bolus	30	8.70	0.65	30	8.60	0.67	0.584	0.280	Not significant
5min	30	4.6	1.03	30	7.4	1.00	0.759	0.225	Not significant
10 min	30	2.6	1.24	30	2.5	1.07	0.332	0.370	Not significant
15 min	30	1.6	0.62	30	1.5	0.57	0.648	0.259	Not significant
30 min	30	0.97	0.09	30	1	0.22	0.666	0.253	Not significant
60 min	30	0.7	0.2	30	0.68	0.19	0.264	0.396	Not significant
120 min	18	0.55	0.09	17	0.7	0.82	-0.764	0.224	Not significant

180 min	10	0.4	0.11	7	0.38	0.12	-0.37	0.356	Not significant
240 min	6	0.28	0.13	6	0.30	1.12	-0.222	0.414	Not significant
300 min	4	0.175	0.05	4	0.15	0.05	0.654	0.268	Not significant
360 min	2	0		2	0				

There were no significant difference in the VAS score between the two groups indicating pain relief was comparable in both the study groups in this study

**Table 8: Mode of delivery in two groups.**

Delivery	GROUP			Total
		BT	RT	
Ventouse	No.	3	3	6
	%	10	10	
Caesarean Section	No.	2	1	3
	%	6.7	3.3	
Vaginal	No.	25	26	51
	%	83.3	86.7	
Total	No.	30	30	60
	%	100	100	

3 parturients each from both BT and RT underwent ventouse assisted delivery, difference was not significance among the two groups.

**Table 9: Adverse Effects**

Adverse Effect	GROUP			Total	P-value
		BT	RT		
Hypotension	No.	4	5	9	
	%	13.3	16.7		
Instrumental Delivery	No.	3	3	6	
	%	10	10		
Motor Blocked	No.	0	0	0	
	%	0	0		
Total	No.	7	8	15	
	%	23.33	26.67		

## DISCUSSION

Epidural analgesia is considered the “Gold standard” technique and the most commonly accepted procedure for analgesia in labour. There are many local anaesthetics available for this purpose these days. Ropivacaine is being used increasingly as it produces lesser cardiovascular complications when compared with bupivacaine.<sup>[11,12]</sup> The aim of this study was to compare the efficacy of ropivacaine + tramadol and bupivacaine + tramadol in labour analgesia. There was no significant difference between the two groups in terms of demographic variables like age, weight, height etc. all patients were gravida 1, 2 or 3, and this was not a significant difference between the two studied groups.

Tsen et al. concluded that pain treated in early labour in parturients with spinal-epidural analgesia was associated with rapid progression of cervical dilation.<sup>[13]</sup> The cervix dilation may be due to decrease in mediators like PG2 $\alpha$ , which is responsible for uterine activity.<sup>[14-16]</sup> In this study, most of the cases of both the groups had 3cm of cervical dilation. Similar results were found in the study done by Chora and Hussain.<sup>[17]</sup>

Ropivacaine is assumed to have a greater selectivity for sensory fibers compared to motor fibers due to its lesser lipophilic capacity than bupivacaine. So, it is less likely to cause motor blockade and neurotoxicity.<sup>[17,18]</sup> There were no motor blockade in either of the group in our study. This might be

because of the use of a low concentrations of a local anesthetics along with addition of opioids. It may also be the reason for high rate of normal vaginal deliveries. Higher concentrations of these local anesthetic may be the reason of higher motor blockade and the need of instrumental deliveries in previous studies.

Shokry et al,<sup>[19]</sup> compared two equal groups by giving 0.125% bupivacaine and 0.2% ropivacaine, and reported a faster onset of action (which was not significant) and significantly shorter duration of analgesia action in ropivacaine group. On the other hand, Chora and Hussain,<sup>[17]</sup> showed a statistically significant faster onset of analgesia in bupivacaine group also a longer duration of action in ropivacaine group. In contrast to these, the onset as well as duration of analgesia action for both groups were comparable in our study, and this was consistent with the study of Beilin et al,<sup>[20]</sup> Bawdane et al,<sup>[21]</sup> reported similar VAS scores, sensory blockade and maternal satisfaction between the groups, this was in line with our current observations. Although ropivacaine has been suggested to be less potent than bupivacaine,<sup>[22]</sup> they were equipotent at clinically used concentrations in our study.

## CONCLUSION

From our study, we conclude that both ropivacaine and bupivacaine can provide comparable labor analgesia with high maternal satisfaction in the clinically used doses. An addition of opioid is

preferable considering their dose lowering effect. Noobstetric or neonatal adverse outcomes were observed in either of the groups in the current study. Therefore, either drug is a reasonable choice for labor analgesia and can be used without jeopardizing the safety of the mother and fetus.

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