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RANDOMIZED CONTROLLED SINGLE-BLIND TRIAL TO COMPARE THE EFFICACY AND SAFETY OF DICLOFENAC SODIUM VERSUS TRAMADOL FOR POST-LSCS ANALGESIA IN PATIENTS WITH PREECLAMPSIA.

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ABSTRACT

BACKGROUND: Effective postoperative analgesia following lower segment caesarean section (LSCS) is crucial for maternal recovery, especially in preeclamptic (PE) patients who have unique pathophysiological challenges. In this background, this randomized controlled single-blind trial aimed is to compare the efficacy and safety of diclofenac sodium versus tramadol for post-LSCS analgesia in patients with preeclampsia.

METHODS: A total of 200 post-LSCS patients with preeclampsia were randomly assigned to two groups. Group A (n=100) received intramuscular diclofenac sodium (75 mg every 8 hours for 2 days), followed by oral diclofenac (100 mg TDS for 5 days). Group B (n=100) received intramuscular tramadol (100 mg every 8 hours for 2 days), followed by oral tramadol (100 mg TDS for 5 days). Pain relief was assessed using the Visual Analogue Scale (VAS) and Verbal Response Scale (VRS), while clinical parameters, including blood pressure, weight changes, and renal and hepatic functions, were monitored preoperatively and postoperatively at 48 hours, 5 days, and 7 days. Statistical analysis was performed using SPSS version 2.0.

RESULTS: The demographic characteristics of both groups were comparable. Tramadol was more effective in pain control, with a significantly higher proportion of patients reporting mild pain on the 7th postoperative day (96% vs. 85%, p=0.09). Diclofenac sodium showed higher incidences of mild to moderate pain on the 2nd postoperative day compared to tramadol (p<0.0001). Weight reduction and blood pressure control were significantly better in the tramadol group, with notable reductions in systolic (p=0.002) and diastolic blood pressure (p=0.0001). No major adverse effects or complications were reported in either groups.

CONCLUSION: Tramadol provided superior postoperative pain relief and better hemodynamic stability, hematologic & biochemical parameters in preeclamptic patients compared to diclofenac sodium, making it a preferable choice for post-LSCS analgesia in this high-risk group.

KEYWORDS: Preclampsia(PE)**,** lower segment cesarean section(LSCS); postoperative pain; Tramadol; diclofenac sodium; hemodynamic stability, efficacy and safety.

INTRODUCTION:

Effective postoperative pain management is critical in enhancing recovery and overall patient comfort following LSCS. [1] However, analgesic strategies in patients with preeclampsia requires special consideration due to their unique pathophysiologic challenges, including altered hemodynamics, increased risk of renal compromise, hematologic & biochemical parameters and potential for adverse neonatal outcomes.[2]

Diclofenac sodium, a nonsteroidal anti-inflammatory drug (NSAID), and tramadol, a synthetic opioid, are widely used for managing postoperative pain. [3] Diclofenac sodium acts by inhibiting cyclooxygenase (COX) enzymes, reducing prostaglandin synthesis and thereby reducing inflammation and pain. [4] On the other hand, tramadol is a centrally acting analgesic that has a strong affinity for μ receptors and weak affinity for κ and δ receptors. In addition to μ opioid agonist effects, tramadol enhances the function of the spinal descending inhibitory pathways by inhibition of neuronal reuptake of nor epinephrine and 5-hydroxytryptamine as well as presynaptic stimulation of 5-HT release. Though, both agents are effective, their differing mechanisms of action and safety profiles present distinct advantages and risks, particularly in preeclamptic patients.[5]

Preeclampsia complicates pain management due to the higher risk of thrombocytopenia, hepatic dysfunction, (renal function impartment) and sensitivity to fluid shifts. [6] Additionally, the choice of analgesic can significantly impact maternal recovery and neonatal outcomes. Although, NSAIDs like diclofenac sodium are effective, concerns about their impact on renal function and hemostasis in this high-risk group necessitates caution. [7] Tramadol, with its central mode of action, offers an alternative, but its potential for opioid-related side effects, including nausea, sedation, and dependency, remains a challenge. To address this gap this study aims to compare the efficacy and safety of diclofenac sodium and tramadol for post-LSCS analgesia in patients with preeclampsia.

METHODOLOGY

This randomized controlled trial was conducted among post-LSCS patients with preeclampsia (PE) from the postnatal care (PNC) ward of the Gynecology and Obstetrics Department at Dr. P.D.M.M.C., Amravati, a tertiary hospital in central India, over a period of 12 months. Ethical approval was obtained from the Institutional Ethical Committee. This was registered with CTRI (CTRI Registration No. CTRI/2013/02/003395) prior to the initiation of the trial, and written informed consent was obtained from all selected participants.

Post-LSCS patients with PE admitted to the PNC ward were included in this study. Patients with eclampsia, those with PE complicated by renal failure or cardiac decompensation, and normotensive patients who underwent LSCS for obstetric indications other than PE were excluded.

The selected participants provided written informed consent before enrolment. Equal numbers of patients were randomly assigned to two analgesic protocols. The drug protocols followed in each group were as follows:

- **Group A (100 patients):** Injection Diclofenac Sodium 75 mg intramuscularly every 8 hours for 2 days, followed by tablet Diclofenac Sodium 100 mg TDS for 5 days.
- **Group B (100 patients):** Injection Tramadol 100 mg intramuscularly every 8 hours for 2 days, followed by capsule Tramadol 100 mg TDS for 5 days.

In this study, comprehensive evaluations were conducted to monitor the participant's physical (clinical, haematological) and biochemical parameters at baseline and during the postoperative period. Physical and clinical parameters included blood pressure measurements to assess hypertension, evaluation of edema, and weight monitoring. Biochemical parameters comprised hematological investigations, renal function tests (RFT), liver function tests (LFT), and urine

analysis. These parameters were recorded preoperatively, at 48 hours, and on the 5th and 7th postoperative days.

Efficacy for analgesia was assessed using the Visual Analogue Scale (VAS) and Verbal Response Scale (VRS) to evaluate pain relief in the two study groups. Throughout the study, changes in and biochemical parameters were monitored to ensure patient health status. Then, analgesic effectiveness was compared between two analgesic regimens after this thorough examination.

Statistical analysis:

Data were analyzed using SPSS. Mean ± SD was used for expression. Pain scores were evaluated via the Kruskal-Wallis test, followed by the Mann-Whitney test for intergroup comparison. Onset, duration, and dose data were analyzed using ANOVA with post-hoc Least Significant Difference test. Side effects were compared using the Chi-square test. Statistical significance was set at $p < 0.05$.

RESULTS:

A total of two hundred subjects were included in the current trial and divided into two groups; Group A consisted of Diclofenac sodium and Group B consisted of Tramadol, each with 100 subjects.

Table-1: Demographic characteristics

Parameters	**Group-A (Diclofenac Sodium)**		**Group-B (Tramadol)**	
Age (Years)	27.27 ± 4.99		26.11 ± 3.34	
Gestational age (Weeks)	39.77 ± 36.08		37.08 ± 2.40	
Gravida				
Primi	36 (36.00%)		39 (39.00%)	
Multi	64 (64.00%)		61 (61.00%)	
Duration of stay (days)	9.97 ± 3.35		10.06 ± 6.58	
Pregnancy	**Intra-operative course**	**Post-operative Course**	**Intra-operative course**	**Post-operative Course**
Concealed abruption (300 cc clot)	3 (3.00%)	0 (0.00%)	8 (8.00%)	0 (0.00%)
Uneventful	97 (97.00%)	100 (100.00%)	92 (92.00%)	100 (100.00%)

Group-A had a mean age of 27.27 ± 4.99 years, while Group-B had 26.11 ± 3.34 years. Gestational age was 39.77 ± 36.08 weeks for Group-A and 37.08 ± 2.40 weeks for Group-B. Most participants were multi-gravida, with 36% in Group-A and 39% in Group-B being primi. The duration of stay was similar for both groups. While 3% of Group-A had concealed abruption, 8% of Group-B did, but most had uneventful intra-operative courses (Table 1).

Table-2: Indications of LSCS between Group-A and Group-B

Indications of LSCS	**Group-A (Diclofenac Sodium)**	**Group-B (Tramadol)**
PE	45 (45.00%)	30 (30.00%)
Labor related Conditions	20 (20.00%)	22 (22.00%)
Fetal distress-related Conditions	7 (7.00%)	16 (16.00%)
Previous LSCS	22 (22.00%)	23 (23.00%)
Other Obstetric Conditions	6 (6.00%)	9 (9.00%)
P-value	0.12	

In Group-A, 45% of patients hadPE, 20% had labor-related conditions, 7% had fetal distress, 22% had previous LSCS, and 6% had other obstetric conditions. In Group-B, 30% had PE, 22% had labor-related conditions, 16% had fetal distress, 23% had previous LSCS, and 9% had other obstetric conditions (Table 2). The p-value was 0.12, indicating no statistically significant difference between the groups.

Table-3: Distribution according to Clinical characteristics between Group-A and Group-B

Weight	Group-A (Diclofenac)	Group-B (Tramadol)	P-value
Weight			
Pre-Op	66.54 ± 7.19	63.02 ± 7.81	0.008
2nd PO	62.17 ± 7.91	58.24 ± 5.37	0.17
7th PO	60.65 ± 7.54	57.47 ± 5.32	0.0007
P-value	<0.0001	<0.0001	
SBP			
Pre-Op	146.92 ± 15.00	143.18 ± 11.47	0.049
2nd PO	134.64 ± 14.44	132.06 ± 11.68	0.16
7th PO	136.40 ± 16.85	129.72 ± 12.58	0.002
P-value	<0.0001	<0.0001	
DBP			
Pre-Op	98.10 ± 10.61	93.38 ± 4.57	0.0001
2nd PO	89.5 ± 9.25	89.16 ± 8.26	0.78
7th PO	89.98 ± 9.92	84.84 ± 8.82	0.0001
P-value	<0.0001	<0.0001	

The findings indicated that Tramadol (Group-B) showed better findings than Diclofenac (Group-A), with more significant weight reduction and better control of both systolic and diastolic blood pressure by the 7th post-operative day. Tramadol's weight reduction and blood pressure improvements were statistically significant, (Table 3) with P-values of 0.0007 for weight, 0.002 for SBP, and 0.0001 for DBP.

Table-4: Comparison of Pain scale using VAS score between Group-A and Group-B

Pain scale (VAS Score)	Group-A (Diclofenac)		Group-B (Tramadol)		P-value
	2nd post-operative	7 th post-operative	2nd post-operative	7 th post-operative	
No (0)	0 (0.00%)	8 (8.00%)	0 (0.00%)	3 (3.00%)	-
Mild (1-3)	39 (39.00%)	85 (85.00%)	27 (27.00%)	96 (96.00%)	0.09
Moderate (4-6)	38 (38.00%)	5 (5.00%)	73 (73.00%)	1 (1.00%)	0.02
Severe (7-10)	23 (23.00%)	2 (2.00%)	0 (0.00%)	0 (0.00%)	-
P-value	<0.0001		<0.0001		

Tramadol was more effective than Diclofenac in pain control, as a higher percentage of patients reported mild pain, while fewer experienced moderate or severe pain, (Table 4) with statistically significant differences (P-values <0.0001 and 0.02).

Table-4 (A): Comparison of Pain scale using VAS score on 2nd post-operative (day) between Group-A and Group-B

Pain scale (VAS Score)	2nd Post-operative	
	Group-A (Diclofenac)	Group-B (Tramadol)
No (0)	0 (0.00%)	0 (0.00%)
Mild (1-3)	39 (39.00%)	27 (27.00%)
Moderate (4-6)	38 (38.00%)	73 (73.00%)
Severe (7-10)	23 (23.00%)	0 (0.00%)
P-value	<0.0001	

On the 2nd post-operative day, Group-B (Tramadol) was more effective than Group-A (Diclofenac), with no patients in Group-B experiencing severe pain, while 23% of Group-A patients did. The P-value of <0.0001 indicated a statistically significant difference, Table 4 (A).

Table-4(B)-: Comparison of Pain scale using VAS score on 7th post-operative (day) between Group-A and Group-B

Pain scale (VAS Score)	7 th post-operative	
	Group-A (Diclofenac)	Group-B (Tramadol)
No (0)	8 (8.00%)	3 (3.00%)
Mild (1-3)	85 (85.00%)	96 (96.00%)
Moderate (4-6)	5 (5.00%)	1 (1.00%)
Severe (7-10)	2 (0.00%)	0 (0.00%)
P-value	0.005	

On the 7th post-operative day, Group-B (Tramadol) showed better results, with more patients reporting mild pain (96% vs. 85%) and fewer experiencing moderate or severe pain. The p-value of 0.005 indicated a significant difference, favouring Tramadol for pain relief, as shown in Table 4 (B).

Table-5: Edema

Edema	Group-A (Diclofenac)			Group-B (Tramadol)		
	Pre-Op.	(2nd PO)	(7th PO)	Pre-Op.	(2nd PO)	(7th PO)
No	0 (0.00%)	0 (0.00%)	8 (8.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Mild	92 (92.00%)	84 (84.00%)	92 (92.00%)	70 (70.00%)	76 (76.00%)	100 (100.00%)
Moderate	0 (0.00%)	16 (16.00%)	0 (0.00%)	9 (9.00%)	15 (15.00%)	0 (0.00%)
Severe	8 (8.00%)	0 (0.00%)	0 (0.00%)	21 (21.00%)	9 (9.00%)	0 (0.00%)
P-value	<0.0001			0.0003		

Edema severity differed significantly between the groups. By the 7th postoperative day, Tramadol resolved all moderate and severe cases, with 100% mild edema, while Diclofenac had 8% complete resolution and 92% mild cases, (Table 5). Tramadol was superior than diclofenac ($p < 0.0001$).

Table-6: Surgical scar tenderness

Surgical scar tenderness	Group-A (Diclofenac)		Group-B (Tramadol)	
	48 th hour	7th day	48 th hour	7th day
No	0 (0.00%)	8 (8.00%)	69 (69.00%)	22 (22.00%)
Mild	23 (23.00%)	84 (84.00%)	31 (31.00%)	78 ()78.00%
Severe	77 (77.00%)	8 (8.00%)	0 (0.00%)	0 (0.00%)
Breast Feeding (2nd PO Day)				
EBF	82 (82.00%)	88 (88.00%)	100 (100.00%)	100 (100.00%)
Mild	8 (8.00%)	12 (12.00%)	0 (0.00%)	0 (0.00%)

Tramadol was superior to Diclofenac. At 48 hours, 69% of the Tramadol group had no tenderness, while 77% of the Diclofenac group reported severe tenderness.

By the 7th day, Tramadol achieved 22% with no tenderness and 78% mild, compared to Diclofenac's 8% and 84%, respectively. Exclusive breastfeeding was 100% in the Tramadol group, compared to 82–88% in the Diclofenac group (Table 6).

Table-7 Kidney function between Group-A and Group-B

Parameters	Group-A (Diclofenac)	Group-B (Tramadol)	P-value
	Mean ± SD	Mean ± SD	
Urea			
Pre OP	34.18 ± 23.12	23.82 ± 12.34	0.0001
2nd PO	40.21 ± 52.99	23.16 ± 7.42	0.002
7th PO	32.00 ± 21.41	22.8 ± 7.27	0.0001
Creatinine			

Pre OP	0.92 ± 0.31	0.78 ± 0.33	0.002
2nd PO	0.99 ± 0.98	0.86 ± 0.21	0.19
7th PO	0.75 ± 0.26	0.77 ± 0.21	0.37
Uric Acid			
Pre OP	5.94 ± 1.68	5.77 ± 1.03	0.39
2nd PO	5.72 ± 1.56	5.74 ± 0.67	0.90
7th PO	5.24 ± 1.45	5.30 ± 0.74	0.71

In the comparison of kidney function between Group-A (Diclofenac) and Group-B (Tramadol), it was found that Tramadol had no significant effect on kidney function over time. The P-values for urea, creatinine, and uric acid at the 7th post-operative day were 0.71, 0.37, and 0.90, respectively, indicating stable kidney parameters. On the other hand, Diclofenac (Group-A) showed significant changes in kidney function, particularly in urea levels, with P-values of 0.0001 at all-time points (pre-operative, 2nd post-operative, and 7th post-operative). Creatinine levels also showed a significant change at pre-operative (P-value 0.002). This indicated that while Tramadol had no significant impact, Diclofenac affected kidney function, particularly in terms of urea and creatinine (Table 7).

Table-8 Kidney function between Group-A and Group-B

Parameters	**Group-A (Diclofenac)**	**Group-B (Tramadol)**
	Mean ± SD	**Mean ± SD**
Urea		
Pre OP day	34.18 ± 23.12	23.82 ± 12.34
2nd PO	40.21 ± 52.99	23.16 ± 7.42
7th PO	32.00 ± 21.41	22.8 ± 7.27
P-value	0.24	0.73
Creatinine		
Pre OP	0.92 ± 0.31	0.78 ± 0.33
2nd PO	0.99 ± 0.98	0.86 ± 0.21
7th PO	0.77 ± 0.26	0.75 ± 0.21
P-value	0.036	0.008
Uric Acid		
Pre OP	5.94 ± 1.68	5.77 ± 1.03
2nd PO	5.74 ± 1.56	5.72 ± 0.67
7th PO	5.30 ± 1.45	5.24 ± 0.74
P-value	0.013	0.0001

The comparison of kidney function between Group-A (Diclofenac) and Group-B (Tramadol) showed that Tramadol had no significant impact on kidney function over time, with P-values of 0.73 for urea, 0.008 for creatinine, and 0.0001 for uric acid, indicating stable kidney parameters. In contrast, Diclofenac (Group-A) showed a significant effect on kidney function, particularly in creatinine and uric acid levels, with P-values of 0.036 and 0.013, respectively, suggesting it affected kidney function. Overall, while Tramadol did not significantly affect kidney function, Diclofenac appeared to influence kidney parameters, especially in terms of creatinine and uric acid levels (Table 8).

DISCUSSION:

Pain is a fundamental sensory and emotional experience with critical physiological implications for the parturient. The present study is the first to observe that, on the 2nd postoperative day, moderate-to-severe pain was significantly more common in Group A, with 23% experiencing severe pain, whereas none in Group B reported severe pain. By the 7th postoperative day, a higher proportion of Group B patients experienced only mild pain (96% vs. 85%), with fewer cases of moderate or severe

pain. The statistically significant p-values (<0.0001 and 0.005) further establish the superior efficacy of Tramadol in postoperative pain management. Previous studies have suggested similar findings **DemiraranY, et al., (2013)**[8] reported that, Tramadol, when used as a local anesthetic, reduces postoperative analgesia demand in major surgeries, including C-sections. **Kumari K, et al., (2015)**[9] demonstrated effective pain relief in 27 patients, moderate relief in 16, and mild relief in 7. Additionally, **Verstraete S, et al., (2012) [10]** highlighted Tramadol as an effective and well-tolerated agent for post-cesarean section analgesia. These shades light on the confirmation of the present study findings.

An interesting finding of the current investigation revealed that, during the 7th post-operative day, all moderate and severe edema cases had resolved in Group B, while 92% of Group A patients still had mild edema. Tramadol's superior efficacy was confirmed by a significant p-value (<0.0001). Similarly, surgical scar tenderness was markedly reduced in Group B, with 69% of patients reporting no tenderness at 48 hours compared to none in Group A. By the 7th day, 22% of Group B had no tenderness, while Group A still had 8% with severe tenderness. Exclusive breastfeeding rates were higher in Group B (100%) compared to Group A (82-88%), suggesting improved maternal comfort and post-operative recovery with Tramadol.

Mitra S, et al., (2012)[11] reported that, the diclofenac-tramadol combination provided superior analgesic efficacy but was associated with a higher incidence of postoperative nausea. **Shareef SM, et al., (2014)**[12] identified a gap in the literature regarding the analgesic benefits of tramadol-diclofenac combination therapy specifically in post-cesarean pain management. According to their study, patients those administered with either tramadol or diclofenace alone revealed with poor outcomes. The present study addresses this gap by demonstrating that tramadol monotherapy enhances maternal comfort and facilitates postoperative recovery following post- LSCS.

The present study additionally identified significant differences in renal function, with Group B showed that, better preservation of renal parameters. Preoperative and postoperative urea levels were significantly lower in Group B compared to Group A ($p = 0.0001$), suggesting a potential nephroprotective effect of tramadol over diclofenac. However, to the best of our knowledge, there is no conclusive evidence to definitively prove that, tramadol has nephroprotective benefits over diclofenac. Henceforth, to address this gap, we recommended future well-designed clinical trials are required which supports our findings.

CONCLUSION:

The findings suggest that, Tramadol provides superior pain relief, better hemodynamic stability, less surgical scar tenderness, improved edema resolution, and better renal function preservation compared to Diclofenac Sodium. Additionally, the improved comfort levels in Group B facilitated higher exclusive breastfeeding rates. Therefore, Tramadol may be preferred for post-cesarean pain management, particularly in patients at risk of hypertensive disorders or renal impairment. To the best of our knowledge, this is the first study to report these findings. Therefore, further studies with larger sample sizes are recommended to supports and confirm our results.

Conflict of interest: None

Ethical approval: In the present study ethical approval was obtained fromInstitutional Ethical Committee (CTRI Registration No. CTRI/2013/02/003395)

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