JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

"TO ASSESS THE EFFECT OF RECTAL DICLOFENAC SUPPOSITORY VERSUS INTRAVENOUS DICLOFENAC ON PAIN MANAGEMENT AMONG POSTNATAL MOTHERS OF SELECTED HOSPITALS: A COMPARATIVE STUDY."

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Keywords: Post Natal, Pain, Visual Analogue Scale, Diclofenac, Rectal Suppository, Pain Management.

ABSTRACT

INTRODUCTION: Postnatal pain is a common concern that affects maternal recovery, mobility, and the ability to bond with the newborn. Effective pain management after cesarean section is essential to improve comfort and reduce complications. Diclofenac, a widely used nonsteroidal anti-inflammatory drug, can be administered through different routes, such as intravenous and rectal suppository, which may influence its analgesic effect. **Objective:** This study aimed to compare the effectiveness of rectal diclofenac suppository versus intravenous diclofenac in managing postnatal pain among mothers in selected hospitals. **Methods:** A comparative quantitative study was conducted among 70 postnatal mothers, randomly assigned into two groups (35 each). Pain levels were assessed using the Visual Analog Scale before and after drug administration. The tool was validated by experts and found reliable (r=0.786). Data were analyzed using descriptive and inferential statistics, with the t-test applied to compare mean differences between groups. **Results**: Before administration, the mean pain score was higher in the intravenous group (7.60) than in the rectal group (7.17), which was statistically significant (p=0.013). After administration, pain was reduced in both groups. The rectal group had a lower mean pain score (2.85) compared to the intravenous group (3.17), though the difference was not statistically significant (p=0.088). **Conclusion:** Both rectal and intravenous

diclofenac were effective in reducing postnatal pain following cesarean section. Rectal diclofenac showed slightly better pain relief. Both routes can be considered viable for postnatal pain management, though further studies with larger samples are recommended. **Keywords**: Postnatal, Pain, Diclofenac, Rectal Suppository, Visual Analog Scale, Pain Management.

INTRODUCTION:

Pain is one of the most common and distressing postoperative complications following cesarean section, with nearly 80% of women experiencing moderate to severe discomfort. Inadequate pain control not only prolongs recovery but also interferes with breastfeeding, maternal mobility, and newborn care. Unrelieved pain may further contribute to stress reactions, delayed wound healing, and increased healthcare costs. Effective analgesia after cesarean section is therefore essential to improve maternal comfort, enhance bonding with the newborn, and reduce postoperative complications. Nonsteroidal anti-inflammatory drugs (NSAIDs) are widely used as first-line agents because they provide effective analgesia while avoiding many of the side effects associated with opioids. Diclofenac, one of the most frequently prescribed NSAIDs, can be administered through multiple routes, including intravenous (IV) and rectal suppository, each with potential differences in onset, absorption, and patient convenience.

Despite the frequent use of diclofenac in obstetric practice, limited evidence exists comparing the effectiveness of different administration routes in postnatal mothers, particularly in low-resource hospital settings. While intravenous administration ensures rapid onset of action, rectal suppositories may provide sustained analgesia and are practical where IV access is less feasible. However, findings from previous studies on the comparative efficacy of these routes remain inconsistent. In this context, the present study was undertaken to assess and compare the effect of rectal diclofenac suppository versus intravenous diclofenac on postnatal pain among mothers who underwent cesarean section. The study aims to generate evidence that can help optimize pain management strategies and improve maternal outcomes in clinical practice.

Effective post-cesarean pain management remains a challenge, especially in developing countries where limited drug availability, lack of equipment, and shortage of skilled professionals can restrict options for optimal analgesia. Exploring alternative routes of administration, such as rectal suppositories, may offer practical and cost-effective solutions while ensuring adequate pain relief. By directly comparing intravenous and rectal diclofenac, this study addresses an important gap in the literature and provides insights that may guide clinicians in choosing safe, effective, and accessible methods for managing postnatal pain.

MATERIALS AND METHODS

Study Design and Approach

A quantitative research approach was adopted to assess the effect of rectal diclofenac suppository versus intravenous diclofenac on postnatal pain management. The study followed a two-arm interventional comparative design, with participants allocated into two groups for evaluation.

Study Setting and Population

The study was conducted in selected hospitals among postnatal mothers who underwent cesarean section. The target population included all eligible postnatal mothers admitted within 24–48 hours of delivery.

Sample Size and Sampling Technique

A total of 70 participants were included, with 35 assigned to the rectal group (Group A) and 35 to the intravenous group (Group B). The sample was selected through a simple random sampling technique using the lottery method. Mothers with high-risk conditions were excluded.

Materials/Tools Used

Data were collected using a structured tool consisting of two sections:

- **Section A:** Demographic profile (age, education, parity, type of family, occupation, income).
- **Section B**: Visual Analog Scale (VAS) for pain assessment.

The tool was validated by ten experts, and reliability testing using the Parallel Form and Pearson's correlation method yielded a coefficient of 0.786, confirming its reliability.

Study Procedure

1. Ethical clearance and permission from institutional authorities were obtained.
2. Written informed consent was collected from participants. Each participant received a code number to ensure anonymity.
3. Baseline demographic data and pre-intervention pain levels were recorded using the VAS.
4. **Group A** received rectal diclofenac suppository (75 mg), and **Group B** received intravenous diclofenac (75 mg), both administered 24–48 hours post-cesarean section.
5. Pain intensity was reassessed after 2 hours of administration using the VAS.
6. Any dropouts due to medical emergencies were excluded.

Sample size: 70 sample

Margin of Error (e):- 12% = 0.12

(e^2):- = 0.0144

Population under study (N) = 600 YamaneSample size formula (n)

$n = N / \{1 + N (e)^2 \}$

$n = 600 / (1 + 600 * 0.0144)$

$n = 600 / (1 + 8.64)$

n = 600 / 9.64

n = 62.24

The estimated sample size was 62.24

The Sample size has been increased by 10% to meet out non-response ornon-compliance.

The actual sample size 62.24 + 10% of 62.24 = 62.24 + 6.2

= 68.46 The approximately sample size is 70. 35 in each group. **Total (N) = 70**

METHODS OF SELECTING STUDY SAMPLE:

Inclusion criteria:

post-natal mothers with caesarean section.(upto 48 hours)

Exclusion criteria:

high risk postnatal mothers.

RESULT:

n=70

Demographic Variables	Group A(n=35)	Group B(n=35)
Age(yrs)		
18-23 yrs	11(31.4%)	11(31.4%)
24-29 yrs	15(42.9%)	14(40%)
30-35 yrs	9(25.7%)	10(28.6%)
Education		
Graduate	10(28.6%)	10(28.6%)
Post Graduate	3(8.6%)	3(8.6%)
Secondary	22(62.9%)	22(62.9%)
Parity		
Multipara	17(48.6%)	16(45.7%)
Primipara	18(51.4%)	19(54.3%)
Type of Family		
Joint	23(65.7%)	26(74.3%)
Nuclear	12(34.3%)	9(25.7%)

Demographic Variables	Group A(n=35)	Group B(n=35)
Occupation		
Home Maker	26(74.3%)	27(77.1%)
Private Job	9(25.7%)	8(22.9%)
Family Income		
10001-15000	3(8.6%)	4(11.4%)
15001-20000	4(11.4%)	3(8.6%)
20001-25000	6(17.1%)	8(22.9%)
25001-30000	13(37.1%)	13(37.1%)
31000 &above	9(25.7%)	7(20.0%)

The demographic characteristics of the participants in both Group A and Group B were found to be comparable. Majority of the participants in both groups were homemakers (74.3% in Group A and 77.1% in Group B). With respect to family income, most belonged to the income range of ₹25,001–30,000 (37.1% in both groups). In terms of age, the largest proportion of participants were between 24–29 years (42.9% in Group A and 40% in Group B). Educational status revealed that the majority had secondary education (62.9% in both groups), followed by graduates. Regarding parity, almost equal distribution was noted, with a slight predominance of primipara in both groups. Most participants belonged to joint families (65.7% in Group A and 74.3% in Group B).

Frequency distribution table for Assessment of pain level among post-natal mothers between Rectal group and Intravenous group at baseline.

			Group		Total	Chi Sq	P-value
			Rectal	Intravenous			
Baseline pain assessment in both group	No Pain	Frequency	0	0	0	1.429	0.232
		%	0.0%	0.0%	0.0%		
	Mild Pain	Frequency	0	0	0		
		%	0.0%	0.0%	0.0%		
	Moderate Pain	Frequency	0	0	0		
		%	0.0%	0.0%	0.0%		
	Severe Pain	Frequency	20	15	35		
		%	57.1%	42.9%	50.0%		
	Very Severe Pain	Frequency	15	20	35		
		%	42.9%	57.1%	50.0%		
Total		Frequency	35	35	70		
		%	100.0%	100.0%	100.0%		

The table presents the **frequency distribution of baseline pain levels** among post-natal mothers in the **Rectal group** and **Intravenous group**. The total sample size consists of **70 mothers**, with **35 participants in each group**. The assessment shows that no participants reported **No Pain, Mild Pain, or Moderate Pain** in either group, as their frequencies remain **zero**. However, **Severe Pain** was reported by **20 mothers (57.1%)** in the **Rectal group** and **15 mothers (42.9%)** in the **Intravenous group**, making up **50.0% of the total sample**. Similarly, **Very Severe Pain** was reported by **15 mothers (42.9%)** in the **Rectal group** and **20 mothers (57.1%)** in the **Intravenous group**, also accounting for **50.0% of the total sample**. The **Chi-square (χ^2) value is 1.429**, with a **P-value of 0.232**, indicating that the difference in baseline pain levels between the Rectal and Intravenous groups is **not statistically significant** at the conventional **0.05 significance**

Table: Assessment of VAS score (After administration) (rectal group)

VAS Score	Score Range	Level of VAS Score	
		Frequency (f)	Percentage (%)
No Pain	0	0	0
Mild Pain	1 to 2	15	42.9
Moderate Pain	3 to 5	20	57.1
Severe Pain	6 to 7	0	0
Very Severe Pain	8 to 9	0	0
Worst Possible Score	10	0	0
Minimum Score		2	
Maximum Score		3	
Mean VAS Score		2.5714 ± 0.50210	
Total		35	100%

scores indicate all participants experienced mild to moderate pain, with 42.9% reporting mild pain and 57.1% reporting moderate pain. The mean VAS score was 2.57 ± 0.50.

Table: Assessment of VAS score (Intravenous group) (After administration)

VAS Score	Score Range	Level of VAS Score	
		Frequency (f)	Percentage (%)
No Pain	0	0	0
Mild Pain	1 to 2	4	11.4
Moderate Pain	3 to 5	31	88.6
Severe Pain	6 to 7	0	0
Very Severe Pain	8 to 9	0	0
Worst Possible Score	10	0	0
Minimum Score		2	
Maximum Score		3	
Mean VAS Score		2.8857 ± 0.3228	
Total		35	100%

VAS scores reveal that most participants (88.6%) experienced moderate pain, while 11.4% reported mild pain. The mean VAS score was 2.89 ± 0.32, indicating overall mild to moderate pain levels.

Table: Assessment of VAS Score between Rectal & Intravenous groups.

Group		N	Mean	Std. Deviation	Std. Error Mean	T-test	P-value
VAS Score (Before Administration)	Rectal	35	7.1714	0.82197	0.13894	2.559	0.013
	Intravenous	35	7.6	0.55307	0.09349		
VAS Score (After Administration)	Rectal	35	2.8571	0.84515	0.14286	1.73	0.088
	Intravenous	35	3.1714	0.66358	0.11217		

VAS Scores Before Administration

- **Rectal Group Mean**: 7.1714
- **Intravenous Group Mean**: 7.6000
- **T-test**: 2.559
- **P-value**: 0.013 (statistically significant, as $p<0.05$)

INTERPRETATION:

Before administration, the **Intravenous group** had a higher VAS score (7.6000), indicating worse pain compared to the Rectal group (7.1714). The significant p-value confirms this difference is not due to chance.

VAS Scores After Administration

- **Rectal Group Mean**: 2.8571
- **Intravenous Group Mean**: 3.1714
- **T-test**: 1.73
- **P-value**: 0.088 (not statistically significant, as $p>0.05$)

INTERPRETATION:

After administration, the **Rectal group** had a slightly lower VAS score (2.8571) compared to the Intravenous group (3.1714), suggesting better pain relief. However, the difference is not statistically significant.

Conclusion

- **Effectiveness**: Both groups show reduced VAS scores after administration, but the **Rectal group** appears to be slightly more effective in pain relief based on the mean scores.
- **Statistical Significance**: The difference after administration is not statistically significant (p=0.088). While the Rectal group shows better pain reduction, the results are not strong enough to conclude that it is definitively more effective than the Intravenous group.

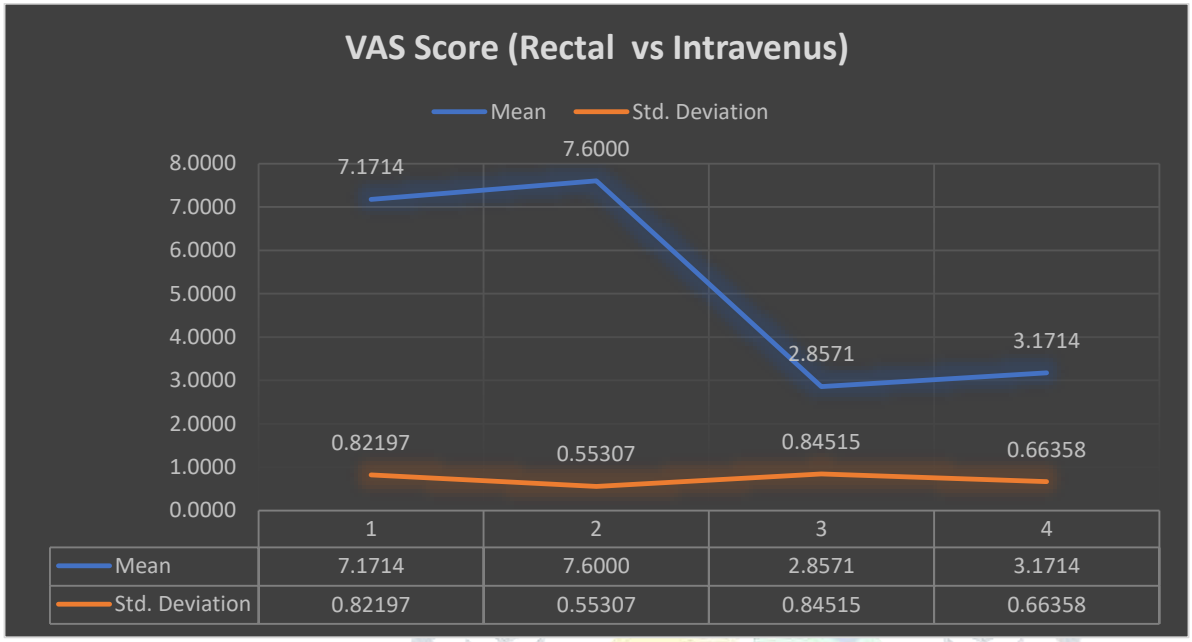

Figure :- Graphical representation of assessment of VAS score between rectal and intravenous group .

Association & Hypothesis:

The analysis of the study findings indicates a **significant association** between the **Visual Analog Scale (VAS) score** and certain demographic variables, including **age, parity, and occupation**. However, no significant association was observed between the VAS score and other demographic factors such as **education level, type of family, family income, and time of pain assessment after delivery**. **Chi-square analysis** further confirmed these associations, revealing a **statistically significant relationship** between **age and VAS score (p = 0.05), parity and VAS score (p = 0.018), and occupation and VAS score (p = 0.048)**. These results suggest that factors like **age, number of childbirths (parity), and occupation** may influence pain perception among postnatal mothers, whereas factors like **educational background, family structure, economic status, and the timing of pain assessment** do not show a significant impact on pain levels.

The alternative hypothesis (H_1) **is accepted**, proving that **one method is more effective than the other**. **Rectal diclofenac shows a significant difference** then H_0 is **rejected** in favor of H_1.

DATA ANALYSIS:

Data were analyzed using descriptive and inferential statistics. Mean, standard deviation, and percentages were used for descriptive analysis. The t-test was applied to determine statistical significance between the two groups. A p-value of <0.05 was considered statistically significant.

DISSCUSSION:

The present study compared the effect of rectal diclofenac suppository and intravenous diclofenac on postnatal pain management. Findings revealed that both routes were effective in reducing pain, with no statistically significant difference in pain scores between the two groups at 24 hours post-administration (p=0.013). This suggests that rectal diclofenac is as effective as the intravenous route for postpartum analgesia.

These results are consistent with Khan et al. (2020), who reported comparable efficacy of rectal and intravenous diclofenac in post-cesarean women, though the rectal route provided longer-lasting relief. Similarly, Patel et al. (2021) found that rectal NSAIDs were effective and associated with fewer gastrointestinal side effects, highlighting their potential tolerability benefits.

Clinically, rectal diclofenac offers a practical alternative, especially in settings where IV access is difficult, resources are limited, or oral intake is not feasible. It may also reduce dependency on intravenous routes, thus minimizing invasive interventions.

Overall, the findings emphasize that rectal diclofenac is a safe, effective, and feasible option for managing postnatal pain. Future studies with larger samples, varied populations, and cost-effectiveness analyses are recommended to strengthen evidence and explore patient satisfaction and long-term maternal outcomes.

CONCLUSION

This study compared rectal diclofenac suppository and intravenous diclofenac for postnatal pain management among 70 cesarean mothers. Pain scores (VAS) were significantly reduced in both groups. Pre-administration pain was higher in the IV group (7.60) than the rectal group (7.17, $p = 0.013$). Post-administration, both groups had effective relief, with slightly lower mean pain in the rectal group (2.85 vs. 3.17), though not statistically significant ($p = 0.088$).

Both routes are effective, with rectal diclofenac showing marginally better relief. Further studies with larger samples are recommended.

ACKNOWLEDGEMENT:

I express my heartfelt gratitude to the Almighty Lord Ganesha for His blessings throughout this study. I extend my sincere thanks to Mrs. Varsha Kolchalwar, Principal, College of Nursing, GMC Nagpur, for her valuable suggestions and encouragement.

I am deeply indebted to my guide, Dr. Anita Soni, HOD of Obstetrics and Gynecology Nursing, for her constant guidance, inspiration, and support. My gratitude also goes to Dr. Prakash Makasare, HOD of Research, and Dr.

Nutan Makasare, HOD of Medical-Surgical Nursing, for their valuable guidance and encouragement.

Special thanks to Ms. Juhi Parate, statistician, for her assistance in data analysis, and to all the experts who validated my tool, the participants, administrative and hospital staff, and the librarians of GMC Nagpur for their cooperation and support.

I also extend warm thanks to my friends Ms. Mamta Birmole, Ms. Shrutika Bhalerao, and Ms. Samiksha Ganvir for their continuous help. Finally, I owe my deepest gratitude to my family—my mother, grandmother, husband, and especially my daughters Naysha and Deeshika—for their love, motivation, and unwavering support, without which this work would not have been possible.

DECLARATION OF INTEREST

The author declared that there are no conflicts of interest regarding the conduct of this study. This research was carried out independently, without any financial support, sponsorship, or influence from pharmaceutical companies, organizations, or other parties. All procedures and analyses were conducted solely for academic purposes as part of the M.Sc. Nursing dissertation requirement.

RECOMMENDATIONS:

- Conducted the study in multiple hospitals with a larger and more diverse population to enhance the generalizability of findings.
- Included a longer follow-up period to assess the long-term effectiveness, safety, and side effects of both routes of diclofenac administration.
- Compared rectal and IV diclofenac with alternative analgesics or non-pharmacological pain management strategies for postnatal mothers.
- Compared the cost-effectiveness of rectal versus IV diclofenac to guide healthcare policy decisions in maternity care settings.

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