

Effect of rectal diclofenac (100mg) for postoperative analgesia in adult perineal surgeries

Rajajothi R^{1*}, Dhanasekaran C², Srinivasan K³, Subbulaksmi S⁴

¹Post Graduate, ²Professor, ³Professor And Head of The Department, ⁴Professor, Department of Anaesthesiology, Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamilnadu, INDIA.

Email: rajajothi86@gmail.com

Abstract

Background: Post operative pain results in patients' inability to perform activities, prolonged hospital stay, incapability of self-care, and causes financial burden. Pain is considered as the fifth vital sign and has to be managed appropriately failed which, postoperative complications can occur. Pain management remains a challenge in our environment and is one of the most important aspects of postoperative care. Many patients have moderate to severe postoperative pain. Diclofenac suppository is an effective adjunct analgesic for postoperative pain control. **Aim And Objective Of The Study:** To determine the effect of rectal diclofenac (100 mg) for postoperative analgesia in adult perineal surgeries. **Materials And Methods:** This prospective, randomized, comparative study was conducted on forty adult patients posted for elective perineal surgeries under spinal anesthesia between January 2020 and September 2021 in Rajah Muthiah Medical College and Hospital. After obtaining clearance from institutional research and ethical committee, informed consent was obtained and patients were divided into two groups of 20 patients each, to determine the efficacy of rectal diclofenac (100mg) for postoperative analgesia. GROUP:D (n=20) receiving rectal diclofenac (100mg) GROUP:C (n=20) Not receiving rectal diclofenac. All the patients underwent thorough preoperative evaluation, explained about visual analog scale for pain assessment during the preanesthetic checkup and were prepared for anesthesia and surgery. **Results:** Basal pulse rate, mean arterial pressure, respiratory rate, SpO₂ and duration of surgery were comparable in both groups and statistically not significant. The test shows that there is a significant difference in VAS between the groups at 2, 4, 6, 8 and 10 hours.. There is a significant difference in the duration of analgesia between the groups and it is statistically significant. **Conclusion:** Patients receiving rectal Diclofenac 100mg as postoperative analgesia in adult perineal surgeries provide long duration of analgesia compared to patients not receiving it.

Keywords: Diclofenac, Perineal Surgeries, Rectal Administration Surgerie, Vas Score.

*Address for Correspondence:

Dr Rajajothi R, Post Graduate, Department of Anaesthesiology, Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram, Tamilnadu, INDIA.

Email: rajajothi86@gmail.com

Received Date: 04/10/2021 Revised Date: 10/11/2021 Accepted Date: 14/12/2021

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Access this article online

Quick Response Code:	Website: www.medpulse.in
	DOI: https://doi.org/10.26611/10152125

INTRODUCTION

Pain is not just a sensory modality but is an experience. The international association for the study of pain defines

pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.¹ The effective management of postoperative pain remains a challenge because it influences the surgical outcome and its critical role in early mobilization and functionality. All nociception produces pain but not all pain results from nociception. Postoperative pain is now considered as the fifth vital sign in line with temperature, pulse, respiratory rate, and blood pressure. The pain which is inadequately relieved is deleterious and leads to many complications in the postoperative period. Untreated surgical pain results in a decrease in alveolar ventilation and vital capacity and even pneumonic consolidation.² It may be associated with deep vein thrombosis, pulmonary embolism, and delayed

How to site this article: Rajajothi R, Dhanasekaran C, Srinivasan K, Subbulaksmi S. Effect of rectal diclofenac (100mg) for postoperative analgesia in adult perineal surgeries. *MedPulse International Journal of Anesthesiology*. February 2022; 21(2):53-58.

<http://medpulse.in/Anesthesiology/index.php>

wound healing. Attenuation of postoperative pain with certain analgesics may decrease perioperative morbidity and mortality. The analgesics commonly used in the postoperative period are parenteral opioids and NSAIDs. As opioids have side effects such as nausea, vomiting, itching, addiction, constipation, respiratory depression, and mental changes.³ NSAIDs are recommended as the first-line therapy and opioids as alternatives. NSAIDs develop their mode of action by blocking the cyclooxygenase (COX) enzyme and thus the biosynthesis of prostaglandins.⁴ Two isoforms of the COX enzyme have been characterized: cyclooxygenase-1(COX-1) and cyclooxygenase-2(COX-2).⁵ Diclofenac is the most commonly prescribed NSAID. It can be given via oral, intramuscular, or rectal routes. Oral consumption of analgesics is not usually suggested due to side effects and less efficacy. Therefore, intravenous or intramuscular methods are most acceptable. If it is not contraindicated and tolerated by the patient, suppository seems better. The provision of safe and effective pain relief for perineal trauma using rectal analgesia is one of the several therapies used in clinical practice. The rectal route of analgesic administration has been favored when oral preparation causes gastric irritation, nausea, and vomiting.

MATERIALS AND METHODS

This prospective, randomized, comparative study was conducted on forty adult patients posted for elective perineal surgeries under spinal anesthesia between January 2020 and September 2021 in Rajah Muthiah Medical College and Hospital. After obtaining clearance from institutional research and ethical committee, informed consent was obtained and patients were divided into two groups of 20 patients each, to determine the efficacy of rectal diclofenac(100mg) for postoperative analgesia. GROUP:D (n=20) Receiving rectal diclofenac (100mg) GROUP: C (n=20) Not receiving rectal diclofenac.

Inclusion criteria

Patients aged between 20 and 70 years of both sexes. Patients belonging to physical status ASA I-III. Patients posted for elective perineal surgeries.

Exclusion criteria

Patients refusal, Patients who have contraindications for regional anesthesia, Patients allergic to the drug, Patients with prolonged BT and CT, Patients with a history of asthma, bleeding disorders, liver and kidney diseases, Patients on analgesics, anti convulsants, and anticoagulants.

All the patients underwent thorough preoperative evaluation, explained about visual analog scale for pain assessment during the preanesthetic checkup and were prepared for anesthesia and surgery. All the patients were adequately fasted as per guidelines, 8 hours for solid food and 4 hours for clear fluid. They were premedicated with T.Alprazolam 0.5 mg orally on the night before surgery. On the day of surgery patients were shifted to the holding room where an intravenous line was established under aseptic precautions and Ringers lactate was started. After checking the anesthesia machine patients were shifted to the operating room. Standard patient monitors like ECG, pulse oximeter, and NIBP were connected followed which baselines values of heart rate, systolic and diastolic BP and SpO2 were recorded. Under aseptic precautions, a subarachnoid block was conducted at L2-L3/ L3-4 space with Bupivacaine (H) 0.5% 1.5 ml was administered. Vitals were monitored intraoperatively and the duration of surgery was noted. After completion of the surgery, Diclofenac suppository 100 mg was inserted rectally for postoperative analgesia in a sterile manner for group-D patients. Patients were assessed for pain scores at 2 hourly intervals. If the VAS score is 4 and above, rescue analgesia (Tramadol 1mg/kg IV) was given and time was noted. The visual analog score was assessed every 2nd hour for 12 hours and vitals were recorded simultaneously.

STASTICAL ANALYSIS

All the observations were recorded in the patient proforma and relevant details were made into a master chart. Statistical analysis was performed using the statistical package SPSS version 12. All the data were analyzed with students ‘t to test and reported as mean ± SD. P values <0.05 were taken to be statistically significant.

OBSERVATIONS AND RESULTS

Table 1: DEMOGRAPHIC PROFILE OF PATIENTS

VARIABLES	GROUP D(N=20)	GROUP C (N=20)	P-VALUE
AGE (YEARS)	40.7±10.8	35.5±9.49	0.11(NS)
SEX	MALE=14 FEMALE=6	MALE=15 FEMALE=5	
WEIGHT(Kg)	64.55±4.94	68.05±8.413	0.108(NS)
PHYSICAL STATUS			
ASA I	6(30%)	8(40%)	
ASA II	13(65%)	11(55%)	
ASA III	1(5%)	1(5%)	

TABLE :1 SHOWS Patients were selected randomly. The mean age, sex, weight, and physical status were comparable and statistically not significant.

TABLE 2: BASELINE VITAL SIGNS

Variables	GROUP C(N=20)	GROUP D(N=20)	T-value	P-value
Pulse Rate/min	81.7	83.1	1.69236	0.323839(NS)
Mean arterial pressure(mmHg)	108	103.5	1.687094	0.079562(NS)
Resp.Rate/min	15	15.4	1.685954	0.103221(NS)
Spo ₂	98.55	98.45	1.688298	0.323875(NS)

TABLE:2 SHOWS Basal pulse rate, mean arterial pressure, respiratory rate, SpO₂ were comparable in both groups and statistically not significant.

TABLE 3 COMPARISON OF VAS SCORE BETWEEN THE GROUPS

TIME	GROUP (N=20)	MEAN	T VALUE	P VALUE
0 HRS	D	0	0	0
	C	0		
2 HRS	D	0	2.09	0.03(S)
	C	6.5		
4 HRS	D	0.15	2.06	0.00112(S)
	C	2.45		
6 HRS	D	1.7	2.04	0.001(S)
	C	0.45		
8 HRS	D	4.2	2.09	0.02(S)
	C	0		
10 HRS	D	1.5	2.09	0.0001(S)
	C	0		
12 HRS	D	0.15	1.83	0.08(NS)
	C	0		

TABLE:3 The test shows that there is a significant difference in VAS between the groups at 2, 4, 6, 8 and 10 hours. The patients of group C had VAS score of 6.5 at 2 hours after which rescue analgesia was given, hence VAS score decreased and the patients had no pain at 8, 10 and 12 hours following the administration of rescue analgesia. But the patients of group D has VAS score of 4.2 only at 8 hours, followed which rescue analgesia was given and VAS score decreased.

TABLE 4: DURATION OF ANALGESIA

Variable	Group	Mean	Std. Deviation	Std. Error Mean	t	P-value
Duration of surgery (min)	D	35.50	5.35	1.20	0.70	0.480
	C	34.25	5.91	1.32		
Duration of analgesia (hrs)	D	07.95	0.76	0.17	23.90	0.001
	C	02.30	0.73	0.16		

TABLE 4: There is a significant difference in the duration of analgesia between the groups. Both of the variables are significantly higher in Group D. The duration of analgesia between the groups is statistically significant.

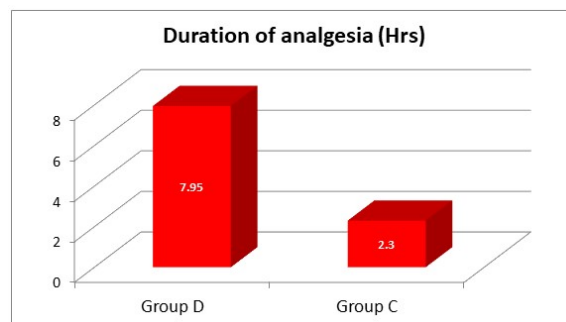


Figure 1: Duration of analgesia (Hrs)

DISCUSSION

The real art of anesthesia lies not only in the anesthetic management of surgical patients but also in treating pain in postoperative period. Inadequately treated postoperative pain will lead to a higher morbidity and mortality. Mostly opioids are used for postoperative pain relief but due to side effects like nausea, vomiting, and respiratory depression, efforts had been made to search for newer alternative drugs. Diclofenac is a nonsteroidal anti-inflammatory drug with potent analgesic action, by inhibiting the synthesis of prostaglandins and is somewhat COX-2 selective. Renal effects of NSAIDs are not marked in normal individuals but become significant in those with CHF, hypovolemia, hepatic cirrhosis, renal disease, and in patients receiving diuretics or antihypertensives. Drugs can be administered by a variety of routes. The rectal route is one of the systemic routes, where the drug is absorbed into the blood circulation and distributed all over the body including the site of action. Certain irritants, or unpleasant drugs can be given rectally as suppositories for systemic effect. Rectal route can be preferred when the patient has recurrent vomiting or in unconscious state. Drugs absorbed into external haemorrhoidal veins (about 50%) bypasses the liver, but not that absorbed into internal haemorrhoidal veins. Diclofenac is the most commonly prescribed NSAID. It can be given via oral, intramuscular, intravenous, or rectal routes. The rectal suppository is absorbed in 30- 60min and achieves T_{max} after 50 min of insertion and bypasses the enteric system, where the danger of NSAID lurks. Suppository preparations are known to have a stimulatory effect on the gastrointestinal tract hence reducing the incidence of postoperative ileus who have had abdominal/ pelvic surgery. Diclofenac suppository acts locally and has a protective soothing effect on the mucous membrane of the rectum. The present study was designed to estimate the effect of rectal diclofenac(100mg) for postoperative analgesia in adult perineal surgeries. A total of forty patients were randomized into two groups (D and C) of twenty each. Group D receives rectal diclofenac(100mg) while Group C does not receive diclofenac. Both the groups were monitored for postoperative VAS score, heart rate, blood pressure, and postoperative nausea and vomiting. There were no differences between groups in patient characteristics (sex, age, and weight), type of surgery. Both the groups were comparable concerning demographic profiles like heart rate, mean arterial pressure, respiratory rate, SpO₂ which are not significant. In this study, the proportion of patients with moderate to severe pain assessed at 2,4,6,8,10,12 hrs were significantly lower in the diclofenac group compared with those in the control group. Only 15% of Group D patients complained of moderate pain in 10 hours and 85% of Group D patients have moderate pain in 8 hours but 10%

of Group C (control Group) patients have severe pain in 4 hours. Ninety percent of patients in the control group has severe pain in 2 hours. None of the patients in the diclofenac group has severe pain in 12 hours postoperatively and no patients have side effects like nausea or vomiting. The Duration of analgesic effect for Group D was 7.95 ± 0.759 hours and for the control group was 2.30 ± 0.73 hours., the difference being highly significant ($P < 0.001$).

Acharyapota *et al.* (2008)⁶ assessed the effectiveness of diclofenac rectal suppository for relief of perineal pain after perineoraphy in 72 term patients by a randomized double-blinded placebo controlled trial. Each group received two tablets of 50 mg diclofenac suppository or two tablets of look a like placebo rectal suppositories. The median pain scores was reduced in diclofenac group at 12 and 24 hours after administration when compared to the control group. ES Adarsh *et al.*(2012)⁷ conducted a randomized clinical trial on 60 children posted for cleft palate repair with group D (30 patients) Diclofenac group (1mg/kg diclofenac suppository) and group C, Conventional group(30 patients).pain was evaluated 6th hourly postoperatively using modification of the objective pain scale, if pain score >3 rescue analgesia i.v fentanyl 0.5mg/kg was administered. It has been observed that preoperative rectal diclofenac provided effective analgesia in the immediate postoperative period and reduced opioid requirement. There is no evidence of any increased postoperative bleeding in the diclofenac group. Jabbari ali(2014)⁸ *et al.* conducted a study on Early post-operative relief of pain and shivering using diclofenac suppository versus intravenous pethidine in spinal anesthesia in 180 patients and he concluded a single dose of sodium diclofenac can provide safe satisfactory analgesia without complications Khobgrade *et al.* (2018)⁹ compared the analgesic efficacy and safety of i.m diclofenac , diclofenac suppository and intravenous tramadol in patients undergoing gynecological surgeries in 90 patients with the conclusion of diclofenac suppository provides effective postoperative analgesia than other groups H.Ejnell *et al.*(1992)¹⁰ compared diclofenac sodium suppositories (150-200mg) with placebo in a double blind study during the first three days after uvulopalatopharyngoplasty in 40 patients with habitual snoring or OSA syndrome. Consumption of rescue analgesia (paracetamol suppository) and pain assessed by vas score were significantly less in the diclofenac group. Jodie Michele dodd *et al.*(2004)¹¹ evaluated rectal diclofenac in the relief of perineal pain after trauma during childbirth in 133 women, 67 randomized to diclofenac suppositories and 66 to placebo and concluded use of rectal diclofenac suppository is a simple, effective, and safe method of reducing pain following perineal traumain the first 24

hours after childbirth. Aziza Mohammad Hussain(2008)¹² *et al.*, conducted a study on two groups for postoperative pain after cesarean section. Group T(30 patients) receiving tramadol suppository(100mg) and Group D (30 patients) receiving diclofenac suppository (100mg). Side effects like nausea, vomiting, GI bleeding were recorded during same period. It was concluded that Diclofenac is better alternative than tramadol as it is devoid of nausea and vomiting and have longer duration of action. Naresh Dhawan *et al.*(2009),¹³ assessed the analgesic efficacy, side effects and need for rescue analgesia after CABG surgery comparing Diclofenac and Placebo rectal suppository in 37 patients and concluded rectal Diclofenac suppository with Tramadol provides adequate pain relief after cardiac surgery and also reduces Tramadol consumption and side effects commonly associated with it. Faiza shafi *et al.*(2011)¹⁴ compared the efficacy of rectally administered diclofenac sodium(group A) with orally administered mefenamic acid (group B) for relief of perineal pain associated with childbirth. Pain scores were significantly lower in diclofenac. Vali Imantalab *et al.*(2014)¹⁵ compared the effects of morphine and diclofenac suppositories on postoperative pain management of CABG patients using double blinded clinical trial in 120 patients with 60 patients in each group. Analgesics were administered after the operation at ICU and VAS was evaluated in both groups at 4 hours interval after extubation for 24 hours. It was concluded both morphine and diclofenac suppository reduced pain significantly after CABG surgery. S.N Shaikh *et al.* (2016)¹⁶ studied the efficacy of single dose of diclofenac rectal suppository for perineal pain after childbirth vaginally in 169 patients by cross-sectional study. Overall analgesia was superior in the diclofenac group. Frequency of perineal pain was predominantly mild in diclofenac group.

Shivamurthy H M *et al.*(2016),¹⁷ compared the efficacy of rectal diclofenac suppository with orally administered tramadol for relief of Perineal pain following vaginal delivery in 300 patients with 150 patients in each group. Pain scores were significantly lower in diclofenac sodium suppository group. Thus the use of rectal diclofenac sodium suppositories is simple, faster acting, effective and safe method of reducing the perineal pain experienced by women following normal vaginal delivery within 24 hours of normal vaginal delivery. Sagar Sahil *et al.* (2017)¹⁸ compared the effects of Diclofenac(100mg) and Tramadol suppository(100mg) as pre-emptive analgesia in abdominal hysterectomy patients and also to compare the side effects of the same using block randomization method. Pain was assessed using VAS score. Duration of analgesia is statistically highly significant in Group D and required less of rescue analgesia and side effects. Juthikaa Abhijit Deherkar (2019)¹⁹ *et al.* conducted a study in pain

management over 2000 cases in a span of 6 yrs in a tertiary centre for acute fissure in ano in outpatient department care. A control group(A) of 1000 patients received oral diclofenac plus local analgesics and another group(B) of 1000 patients was treated with 100mg diclofenac suppository twice a day with glycerin as lubricant. Pain scores of group B was much lower than group A which proved excellent pain management method for acute fissure in ano cases in OPD. Our patients can be considered low-risk patients for renal complications as they were free from preoperative renal problems. There were no clinical signs of hemostatic disturbances such as increased postoperative bleeding or development of hematomas in our patients. Patient satisfaction is an essential consideration concerning many interventions in clinical practice, especially in this era of evidence-based medicine and when the choices of patients are increasingly becoming important. This study shows that a significantly higher proportion of patients in the Diclofenac group were satisfied with analgesia compared to the control group.

CONCLUSION

Rectal Diclofenac (100mg) provides a longer duration of postoperative analgesia in adult perineal surgeries when compared to the control group without side effects. Diclofenac suppository is safe, well-tolerated, patient satisfactory, cost-effective, and easy to administer and helps to reduce consumption of opioids in the postoperative period.

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Source of Support: None Declared
Conflict of Interest: None Declared