ORIGINAL ARTICLE

Effectiveness of Postoperative Analgesia with Rectal Placement of Diclofenac Sodium in Patients Undergoing Gynecological and Obstetrical Surgeries under General Anesthesia

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ABSTRACT

Objective: To determine the frequency of need for postoperative intravenous analgesia after rectal diclofenac suppository in patients undergoing lower abdominal gynecological or obstetrical surgery under general anesthesia.

Study Design: Cross-sectional study.

Place and Duration of Study: The study was carried out at the Operation Theater and Postoperative Ward of Sheikh Zayed Hospital, Lahore, Pakistan from January 2021 to July 2021.

Methods: A total of 245 women undergoing gynecological and obstetrical surgeries under general anesthesia were enrolled in the study using non-probability consecutive sampling. All the participants were recruited after obtaining informed consent and meeting the inclusion criteria. All subjects had a single 100mg diclofenac suppository inserted rectally after undergoing general anesthesia, and their Visual Analog Scale (VAS) scores for postoperative analgesia were recorded immediately after surgery and again at 1, 6, and 24 hours.

Results: The mean age of the patients was 37 years, with a standard deviation of 6.2. The mean VAS (Visual Analog Scale) scores at 1, 6, 12, and 24 hours were 3 (±1.24), 5 (±1.46), 7 (±1.93), and 6 (±2.14), respectively. The need for rescue analgesia was reported in 15.9% of cases at 1 hour, 37.1% at 6 hours, 82% at 12 hours, and 68.2% at 24 hours.

Conclusion: The administration of diclofenac via rectal placement led to a notable decrease in Visual Analog Scale scores and a lower incidence of needing additional pain relief within the first 6 hours after surgery.

Keywords: *Analgesia, Anesthesia, Obstetrics, Surgery.*

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Introduction

Pain is the most upsetting symptom of a disease. Pain management is a top priority for all doctors, but especially anesthesiologists. When it comes to relieving suffering, anesthesiologists play a crucial role. Acute and chronic pain are two distinct categories.[1,2] In the postoperative period, it is the acute pain that must be addressed quickly and effectively. Painful incisions inhibit deep breathing, lessen pulmonary compliance, enhance muscular tone, and increase oxygen consumption.[3] Pain increases sympathetic nervous system activity, which increases the risk of myocardial infarction, and decreases physical activity, which increases the risk of deep vein thrombosis. The psychological effects of pain are the most upsetting since they can lead to increased levels of worry and anger toward medical staff. As a result, patients experience more pain, have longer hospital stays, have worse health outcomes, utilize more healthcare delivery resources, and incur higher economic costs.[4]

Maximizing patients' comfort using safe, less

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expensive analgesics over time after surgery is the modern definition of postoperative pain relief. Surgery after surgery is difficult to manage. Obstetric and gynecological procedures account for a disproportionate share of all surgical procedures.[5] 80% of people who have had obstetrical surgery report experiencing pain afterward, according to prior studies.[6] Opioids are frequently prescribed as the first line of defense against postoperative pain. However, these medications might cause unwanted side effects, including drowsiness, nausea, vomiting, pruritus, and even respiratory depression. Nonsteroidal anti-inflammatory medications (NSAIDs) can be used as an alternative to opioids. In addition to being effective analgesics, antipyretics, and NSAIDs, these medicines also have none of the negative effects associated with opioids.[7]

Diclofenac is a non-selective, nonsteroidal anti-inflammatory drug. It does this by blocking the conversion of arachidonic acid into prostaglandins at the cyclooxygenase (COX-2) enzyme level. The high analgesic characteristics of diclofenac are a major cause for worry, especially in third-world countries.[8] Drugs taken via the rectal route have a higher chance of being absorbed by the body. It's useful for reducing the risk of medication-related stomach upset when taken orally. When analgesics are given rectally, their blood levels remain elevated for a longer time period.[9] The sole drawback of the per rectal approach is that it is not widely used. If suppositories are used, this usually doesn't cause any problems.[10]

The effectiveness of diclofenac, paracetamol, and their combination for postoperative anesthesia in patients having lower abdominal gynecological operations was evaluated in a study by Pal A et al. (2014).[11] Twenty percent of patients in the diclofenac group and the combination group needed extra analgesics after surgery, but fifty percent of patients in the paracetamol group did. Bakhsha F. et al. found similar things concerning diclofenac sodium suppositories in 2013.[12] Among patients undergoing tubal ligation, Baranda UK et al. (2019) found that 69 percent of those given tramadol required at least one rescue analgesic at 8 hours, 11 percent at 6 hours, 9 percent at 4 hours, and 11 percent at 10 hours, while 64 percent of those given diclofenac suppositories did so at 8 hours, 16 percent at 10 hours, and 19 percent at 12 hours.[13]

There have been several studies into how diclofenac sodium suppositories affect the need for pain relief after surgery. However, so far, there have been no comparable investigations in Pakistan. Patients undergoing lower abdominal gynecological or obstetrical surgery under general anesthesia were included in the current study to assess the impact of rectal diclofenac suppositories on postoperative analgesic demand. It would aid concerned medical staff or institutions in developing methods for postoperative pain management involving the use of non-opioid analgesics, to improveto improve postoperative outcomes and decrease morbidity.

This study was conducted to determine the frequency of need for intravenous postoperative analgesia after rectal diclofenac suppository in patients undergoing lower abdominal gynecological or obstetrical surgery under general anesthesia.

Methods

The study was carried out at Operation Theater (OT) and Postoperative Ward of Sheikh Zayed Hospital, Lahore, Pakistan from January 2021 to July 2021 after obtaining approval hospital's institutional review board on 09th April 2020 vide Reference No.18-12. By using non-probability consecutive sampling, 245 female patients were included in the study with a 95% confidence interval, 5% margin of error, and an expected percentage of needing analgesia of 20%.[14] Women between the ages of 16 and 45 who had lower abdominal gynecological or obstetrical procedures under general anesthesia and who were classified as having an ASA physical status of I or II were included. Chronic abdominal pain on the treatment with analgesics and anticoagulants; patients with a history of alcoholism or drug abuse; patients with a bleeding diathesis or coagulation disorders; patients who were unable to rate their pain on the scales used due to psychiatric or other reasons; patients with severe allergic, hepatic (AST, ALT >40 IU/L), renal (serum creatinine >1.3 mg/dl) and cardiovascular disorders were excluded. All the patients provided their informed consent to become a part of the study.

The hospital admitted new patients. The patient's medical, gynecological, and obstetrical histories

were recorded in detail on a standard proforma. The individual was subjected to a thorough physical examination. Preoperative evaluations of the patient's ability to undergo anesthesia were performed. Catheterization was performed under general anesthesia. All of the subjects were given a single rectally inserted suppository of 100 mg diclofenac sodium rectal suppository at the end of the surgery. Under general anesthesia, women had gynecological or obstetrical procedures involving the lower abdomen. Patients were moved to the postoperative ward immediately following surgery, and their postoperative analgesia scores were recorded immediately using the Visual Analogue Scale score. Nalbuphine was administered during the induction of general anesthesia. Rescue analgesia was provided to patients who required it. Patients reported back after 1 hour, 6 hours, 12 hours, and 24 hours to determine if they still needed analgesia (as per the operational definition). We recorded our results on a proforma and ran the numbers on them.

SPSS 21.0 was used for all statistical analysis. Age and visual analog scale scores were two examples of the quantitative data provided as mean and standard deviation. Quantitative information was shown as means and medians, whereas qualitative information like analgesic needs, surgical procedures, and anesthetics were shown as frequencies and percentages. Age, body mass index, anesthesia, and surgical procedure were used to stratify the data. A chi-square test was performed once the data had been stratified, with a significance level set at 0.05.

Results

A total of 245 patients were included in the study. The average age of the patients was 37 years, with a standard deviation of 6.2. Their mean VAS (Visual Analog Scale) scores at various time points were as follows: 3 (±1.24) at 1 hour, 5 (±1.46) at 6 hours, 7 (±1.93) at 12 hours, and 6 (±2.14) at 24 hours. The need for rescue analgesia was recorded as 15.9% at 1 hour, 37.1% at 6 hours, 82% at 12 hours, and 68.2% at 24 hours. Cesarean deliveries were performed in 66.5% of the patients, while hysterectomies were carried out in 33.5% of cases, as detailed in Table 10. Inhalational anesthesia was administered to 51.4% of patients, and intravenous anesthesia was utilized in 48.6% of cases, as illustrated in Table 1.

Table 1: Baseline characteristics of the study population

Parameters	**Mean ± SD**
Mean Age	34±6.2
Mean VAS Score	
1 hour	3±1.24
6 hours	5±1.46
12 hours	7±1.93
24 hours	6±2.14
Analgesia Requirement	**n (%)**
1 hour	39 (15.9%)
6 hours	91 (37.1%)
12 hours	201 (82.0%)
24 hours	167 (68.2%)
Type of surgery	**n (%)**
Cesarean delivery	163 (66.5%)
Hysterectomy	82 (33.5%)
Type of anesthetic	**n (%)**
Inhalational	126 (51.4%)
Intravenous	119 (48.6%)

The data were further categorized based on factors such as age, BMI, type of surgery, and type of anesthesia, and post-stratification Chi-square tests were applied (Tables 2 and 3). The analysis revealed that there was no statistically significant association between these factors and the requirement for

analgesia at 1 hour and 6 hours, as evidenced by *p*-values exceeding 0.05.

Table 2: Analgesic requirements within First hour1 st hour

Variables	Types	Yes n (%)	No n (%)	*P*-Value
Age	16 to 30 years	81 (33.1%)	20 (8.2%)	0.52
	31 to 45 years	120 (49%)	24 (9.8%)	
BMI	Normal BMI (20-25 Kg/m^2)	72 (29.4%)	18 (7.3%)	0.61
	Overweight (25.1-30 Kg/m^2)	103 (42%)	19 (7.8%)	
	Obese (>30 Kg/m^2)	26 (10.6%)	7 (2.9%)	
Type of surgery	Cesarean section	134 (54.7%)	29 (11.8%)	0.92
	Hysterectomy	67 (27.3%)	15 (6.1%)	
Type of anesthetic	Inhalational	102(41.6%)	24 (9.8%)	0.64
	Intravenous	99 (40.4%)	20 (8.2%)	

Table 3: Analgesic requirements after 6 hours

Variables	Types	Yes	No	*P*-value
Age	Young age (16 to 30 years)	64 (26.1%)	37 (15.1%)	0.17
	Middle age (31 to 45 years)	103 (42%)	41 (16.7%)	
BMI	Normal BMI (20-25 Kg/m^2)	58 (23.7%)	32 (13.1%)	0.47
	Overweight (25.1-30 Kg/m^2)	84 (34.3%)	38 (15.5%)	
	Obese (>30 Kg/m^2)	25 (10.2%)	8 (3.3%)	
Type of surgery	Cesarean section	110 (44.9%)	53 (21.6%)	0.74
	Hysterectomy	57 (23.3%)	25 (10.2%)	
Type of anesthetic	Inhalational	81 (33.1%)	45 (18.4%)	0.18
	Intravenous	86 (35.1%)	33 (13.5%)	

Discussion

To avoid the potentially dangerous side effects of opioids, non-opioid analgesics like NSAIDs are widely utilized for postoperative pain relief. Postoperative analgesia is enhanced by nonsteroidal anti-inflammatory drugs (NSAIDs) while avoiding the sedation, respiratory depression, nausea, and vomiting associated with opioids. Since NSAIDs inhibit prostaglandin synthesis, they are also useful for alleviating the pain of uterine contractions. Sodium diclofenac is nonsteroidal anti-inflammatory medication (NSAID).[15] Nonsteroidal anti-inflammatory medication (NSAID) that can be injected, injected, or taken orally. Intramuscular diclofenac in the preoperative period is uncomfortable, and its oral absorption is questionable. Rectal administration improves rate-controlled drug delivery and absorption because it facilitates rapid absorption of low molecular weight drugs and partial bypass of first-pass metabolism. Necrotizing fasciitis, upper limb gangrene, and anaphylactic shock are just some of the potentially fatal side effects of injectable diclofenac that are avoided with the rectal route.[16]

Diclofenac's multiple mechanisms of action include, but are not limited to, COX inhibition, inhibition of lipoxygenase enzymes, and activation of the nitric oxide-cyclic guanosine monophosphate anti-nociceptive pathway. After administering diclofenac rectally, we evaluated the need for further postoperative analgesia in women. Within the first hour after surgery, only 15.9% of patients required analgesia, and this was followed by 37.1% within the first six hours after surgery. Following gynecological surgery, Pal et al. investigated the effects of rectally administered diclofenac against intravenously administered paracetamol.[11] Compared to the paracetamol group, those who received diclofenac

needed less pain medication after surgery (20% vs. 50%). Another study looked at the effects of intramuscularly administered diclofenac on pain control for patients undergoing cesarean section and found that none of the diclofenac group required rescue analgesia postoperatively, while 20% of the placebo group did.[17] In a study comparing the analgesic efficacy of rectal and intramuscular diclofenac for pain relief after cesarean section, Tharwat et al. found that patients who received diclofenac required less rescue analgesia (42.86% vs. 57.14%, respectively) than those in the control group.[18] The VAS scores at 2 hours, both at rest and on coughing, were lower in the group that received diclofenac and a combination of propacetamol and diclofenac compared to propacetamol alone (P 0.05) in a different study evaluating the postoperative analgesic effects of propacetamol and/or diclofenac in parturient undergoing elective cesarean delivery under spinal anesthesia.[19,20]

Consistent with these results, the present investigation found that diclofenac administered rectal insertion in women undergoing gynecological or obstetrical operations resulted in significantly reduced postoperative pain. Decreased rates of analgesic dependency in the first six hours after surgery. Diclofenac may be a more desirable analgesic option in the absence of any absolute or relative contraindications. To draw conclusive conclusions and influence the development of postoperative pain management plans, however, more research with larger sample sizes is required.[21,22] There is also a need to assess the results of combination drugs to enhance the effect of diclofenac and rule out any side effects and complications.

The present study had some limitations. First, the rescue analgesic was administered based on the patient's VAS score, which can be interpreted differently depending on the observer's biases. Second, the duration of the study drugs' analgesic effect could not be established because VAS values are recorded at fixed intervals.

Lastly, generalization of the results is likely to be challenging due to the small sample size of the study and the study being carried out at a single center with patients of same lifestyle. This can lead to further research on women with different ethnicities and lifestyles and evaluation of the drug in these women.

Conclusion

The administration of diclofenac via rectal placement led to a notable decrease in Visual Analog Scale scores and a lower incidence of needing additional pain relief within the first 6 hours after surgery.

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Authors Contribution

RS: Idea conception, data collection, manuscript writing and proof reading
AM: Study designing
SMA: Idea conception, data analysis, results and interpretation
AL: Data collection, manuscript writing and proof reading
TA: Study designing
IAK: Data analysis, results and interpretation, manuscript writing and proof reading