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Safety and Efficacy of Intramuscular Diclofenac for the Postoperative Pain Management in Elective Inguinal Hernia Surgery: A Prospective Observational Study

Sudharsan S[1]; Kalaikumar K[2]; Dr. N Junior Sundresh[3]

[1,2]Department of Pharmacy, Annamalai University, Chidambaram.
[3]Medical Superintendent, Department of Surgery, Government Cuddalore Medical College and Hospital, Chidambaram.

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Abstract: This study looked at how well intramuscular diclofenac works for reducing pain after surgery for an inguinal hernia. The research was done at a large hospital that provides advanced medical care. It involved 50 adult patients who had their hernia repaired. Each person got 75 mg of diclofenac injected into the muscle every 8 hours for 24 hours after the operation. Pain was measured using a scale called the Visual Analog Scale (VAS) before the first dose and again at 1, 4, and 24 hours after. The study also checked for any side effects by tracking vital signs and noting any unwanted reactions. The findings showed that pain levels decreased a lot. On average, pain scores went from 7.4 before the treatment to 2.1 after 24 hours ($p < 0.001$). Most patients felt their pain was well-controlled. Some patients had mild side effects like soreness at the injection site in 8% of cases and mild stomach discomfort in 4%. There were no serious side effects or cases where patients had to stop the treatment. In summary, the study found that using diclofenac injections is a good and safe way to manage pain after hernia surgery. It works quickly and lasts for a long time, making it a good choice when oral pain medicine isn't possible.

Keywords: *Postoperative Pain, NSAIDs, Analgesics, Pain Measurement, Visual Analog Scale.*

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I. INTRODUCTION

Inguinal hernia repair is one of the most common surgeries done around the world. Managing pain after the surgery is very important because it helps patients recover faster and feel better. If pain is not controlled, it can slow down walking, make hospital stays longer, and lead to problems like difficulty urinating and long-term pain. ERAS guidelines focus on using pain medicines that don't rely much on opioids, which help patients recover quicker and have fewer side effects.

NSAIDs, like diclofenac sodium, are often used before and after surgery because they help reduce both pain and inflammation. Giving diclofenac by injection into the muscle has benefits like quick action, long-lasting effect, and avoiding the need for taking pills or getting a needle in the vein, which is helpful when patients can't take medicine by mouth right away.

Studies comparing different ways to give diclofenac to hernia patients show that injecting it into the muscle gives better pain control in the first 24 hours than using suppositories or patches.

While some research suggests that taking it by mouth or through a vein might cause fewer side effects, many places with fewer resources still prefer the injection method. However, there isn't enough high-quality real-world information about how safe and effective intramuscular diclofenac is specifically for hernia repair. Because of this, a study was done to check how safe and good diclofenac injections are for controlling pain after hernia surgery. The study also looked at when the pain relief starts, how long it lasts, and how often side effects happen.

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II. MATERIALS AND METHODS

➢ *Study Design and Setting*

A study was done over six months in the General Surgery Department at Government Cuddalore Medical College and Hospital, which is a large teaching hospital with 1200 beds located in Tamil Nadu, India.

➢ *Study Population*

In this study, 50 adult patients who were going to have elective inguinal hernia surgery were included. The number of patients was chosen to be larger than the minimum needed to show meaningful results, considering the expected differences in pain scores measured by VAS, and to allow for analysing different groups within the study and to account for any patients who might drop out.

➢ *Inclusion Criteria*

- Age between 18 and 65 years
- Diagnosis of inguinal hernia requiring elective surgical repair
- Ability to provide written informed consent

➢ *Exclusion Criteria*

- Known allergy to NSAIDs
- Severe renal or hepatic dysfunction
- History of peptic ulcer disease or gastrointestinal bleeding
- Paediatric patients, psychiatric illness, or refusal to participate

➢ *Ethical Considerations*

The study plan was approved by the Ethics Committee at Government Cuddalore Medical College and Hospital. Every person who took part signed a written consent form before joining the study.

➢ *Drug Details and Administration*

Each patient got an injection of diclofenac sodium 75 mg into the muscle every 8 hours for 24 hours after their surgery. The medicine used was Diclofenac Sodium Injection I. P. The injection was given in the upper part of the backside muscle by nurses who were trained, and they made sure everything was clean and safe.

➢ *Pain Assessment*

Postoperative pain was measured using the Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain). VAS scores were recorded at four time points:

- Baseline (pre-dose)
- 1-hour post-dose
- 4 hours post-dose
- 24 hours post-dose

➢ *Safety and Adverse Effects Monitoring*

During the study, healthcare providers regularly checked important health measurements like heart rate, blood pressure, body temperature, and breathing rate. Any bad side effects from the medicine, such as pain at the injection site, stomach inflammation, allergic reactions, or whole-body reactions, were noted and handled according to standard medical procedures.

➢ *Data Collection*

Patient information was written down using a special form called a case report form. This form had details like the patient's age, gender, other health problems, the kind of hernia and which side it was on, what was found during surgery, how long it took for the patient to start walking again, how long they stayed in the hospital, pain levels measured using a VAS scale, and any problems or unwanted side effects that happened.

➢ *Statistical Analysis*

The data that was collected was processed and analysed using Microsoft Excel 2021 and JASP version 0. 18. For quantitative data like VAS scores, we calculated the average along with the standard deviation. To compare changes in VAS scores over time, we used paired t-tests. Categorical data such as hernia location, hernia type, existing health issues, and walking ability were analysed using the Chi-square test. A p-value was used to determine statistical significance.

III. RESULTS

Fifty adult patients who were planned to have elective inguinal hernia surgery took part in this study. The demographic, clinical and outcome data are presented below.

➢ *Demographic and Clinical Profile*

Most of the people in the study were men, which made up 92% of the group. The biggest group was people who were between 51 and 60 years old. The average age of everyone in the study was 49.6 years, with a standard deviation of 10. 8 years.

Table 1 Distribution of Study Participants by Age and Gender

Variable	Category	No. of patients (n=50)	Percentage (%)
Age	18-30	6	12.0
	31-40	8	16.0
	41-50	12	24.0
	51-60	14	28.0
	61-65	10	20.0
Gender	Male	46	92.0
	Female	4	8.0

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➢ *Comorbidities*

Twenty-five patients, which is 50%, had no other health conditions. For the rest, the most common issues were high blood pressure, which affected 28%, and long-term alcohol use, which was present in 20%.

➢ *Hernia Type and Laterality:*

Most hernias were indirect (64%) and located on the right side (56%).

Table 2 Distribution of Comorbidities Among Study Participants

Comorbidity	No. of patients (n=50)	Percentage (%)
No Comorbidities	25	50.0
Hypertension (SHTN)	14	28.0
Chronic Alcohol Use	10	20.0
Type 2 Diabetes Mellitus	8	16.0
History of Previous Hernia Surgery (Recurrent Hernia)	6	12.0
Chronic Obstructive Pulmonary Disease (COPD)/Bronchial Asthma	2	4.0
Chronic Kidney Disease (CKD)	1	2.0

Table 3 Types and Laterality of Inguinal Hernia

Variable	Category	No. of patients (n=50)	Percentage (%)
Hernia type	Indirect	32	64.0
	Direct	12	24.0
	Recurrent	6	12.0
Laterality	Right-sided	28	56.0
	Left-sided	12	24.0
	Bilateral	10	20.0

➢ *Postoperative Pain Assessment (VAS Scores):*

Pain levels were measured using the Visual Analog Scale (VAS) at different times after giving diclofenac by injection. The average score before treatment was 7. 4 ± 1. 2. This went down to 5. 6 ± 1. 0 after one hour, 4. 1 ± 1. 1 after four hours, 2. 3 ± 1. 0 after 24 hours, and 1. 2 ± 0. 7 after 48 hours. This shows a steady and significant decrease in pain over time ($p < 0.001$). These results are shown in figure 1

➢ *Paired Analysis of VAS Scores:*

The paired t-tests found that all the decreases in VAS scores at later time points were statistically significant ($p < 0.001$).

➢ *Time to Ambulation:*

Most patients (56%) were able to walk around within 12 hours after their surgery. A small number (8%) needed more than 24 hours before they could walk. (Table.5).

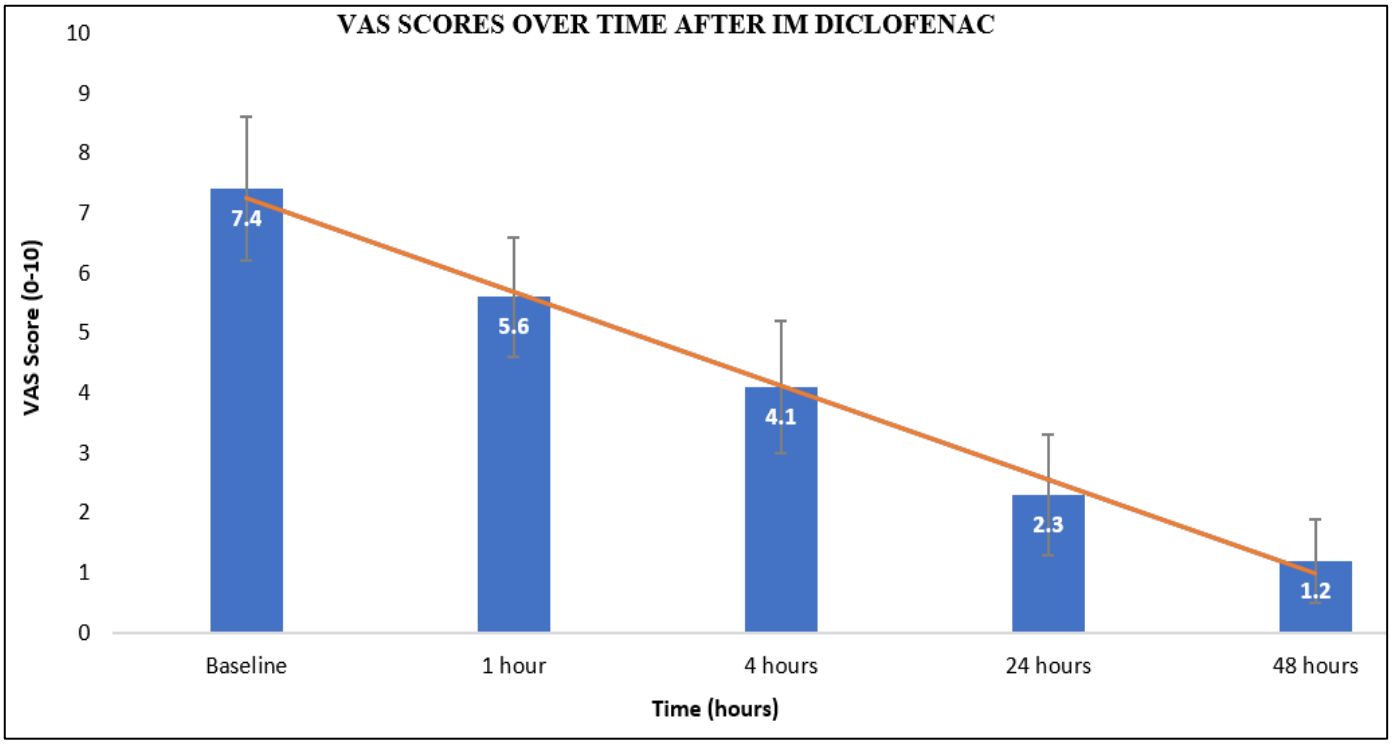

Fig 1 Mean VAS Scores at Different Time Points following IM Diclofenac Administration

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Table 4 Paired t-Test Comparison of VAS Scores at Different Time Intervals (n=50)

Time points compared	Mean difference	*p-value
Baseline vs 1 hour	1.8	<0.001
1 hour vs 4 hours	1.5	<0.001
4 hours vs 24 hours	1.8	<0.001
24 hours vs 48 hours	1.1	<0.001
p< 0.001 indicates statistically highly significant differences		

Table 5 Time to Ambulation After Surgery

Time (in hours)	No. of patients (n=50)
<12 hours	28
12-24 hours	18
>24 hours	4

➢ *Association Analysis:*

Chi-square tests were used to check if there was a link between different categories of variables. It was found that there was no significant connection between the side of the hernia (right-sided versus left-sided or bilateral) and how long it took for patients to walk on their own within 24 hours (p = 0. 28). Also, having other health conditions like high blood pressure, diabetes, or long-term alcohol use did not make a significant difference in how long it took to walk (p = 0. 34). Additionally, the type of hernia was not linked to how long a patient stayed in the hospital (p = 0. 41).

➢ *Hospital Stays:*

Most of the patients, which is 84%, were released from the hospital four days after their surgery. (Table.6)

➢ *Adverse Events*

No serious problems were seen. Some people experienced pain at the injection site, which was reported by 8%. Four percent had a mild stomach inflammation. One person got an infection at the surgery site. (Table.7)

Table 6 Distribution of Patients based on Duration of Hospital Stay

Hospital Stay (days)	No. of patients (n=50)	Percentage (%)
≤ 4 days	42	84.0%
> 4 days	8	16.0%

Table 7 Postoperative Adverse Drug Events

Adverse event	No. of patients (n=50)	Percentage (%)
Injection site pain	4	8.0%
Mild gastritis	2	4.0%
Surgical Site Infection	1	2.0%

IV. DISCUSSION

This study shows that giving diclofenac directly into the muscle (intramuscular) consistently and significantly lowers pain levels as measured by the Visual Analog Scale (VAS) in the first 48 hours after surgery for inguinal hernia. This confirms that diclofenac is effective for managing pain during the early recovery period. These results are in line with previous studies that found that using diclofenac this way provides faster and longer-lasting pain relief compared to other forms like suppositories or patches. Giving diclofenac intramuscularly avoids the digestive system and the liver's first step of breaking down the medicine, which makes it work quickly and last longer—important benefits in the early days after surgery. In our group of patients, few needed extra painkillers like opioids, which supports the use of NSAID-based pain management as suggested in ERAS guidelines. Similar results have been seen in other abdominal surgeries were using diclofenac intramuscularly reduced the need for opioids without causing major side effects. Our study found that diclofenac was safe, with only minor issues like soreness at the injection site or mild stomach irritation occurring in less than 10% of patients, and no serious problems. These findings match large studies and trials that show low chances of complications when using diclofenac this way for short periods. Importantly, our data didn't find an increased risk of stomach bleeding or kidney problems when it was given for less than 48 hours to carefully selected patients. The strengths of this study include using real-world surgical situations, regularly checking pain levels with VAS, and using the same dose of diclofenac each time. However, there are also some limitations. There was no group for comparison, which makes it harder to draw direct conclusions. The follow-up period was only 48 hours, so we might have missed any delayed side effects. Also, the sample size was not very large, which limits the ability to look at different patient groups or types of hernias. Even with these limits, the study met its goals and provides important evidence that intramuscular diclofenac is a safe and effective pain treatment in hernia surgery—especially in situations were taking pills or getting it intravenously isn't possible. Future research should include controlled studies comparing intramuscular diclofenac with other pain medicines, methods, or combinations to better support its use in standard recovery pathways.

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V. CONCLUSION

Intramuscular diclofenac sodium was found to be effective in controlling pain after surgery for elective inguinal hernia repair. Patients experienced a noticeable decrease in pain levels, as shown by lower VAS scores, over the course of 24 hours. It also had a good safety record. The medicine starts working quickly and keeps providing pain relief for a long time, which makes it useful as part of a pain management plan that uses multiple methods. This is especially helpful when oral or intravenous options aren't available. These results show that using intramuscular diclofenac can be a practical and dependable choice in regular surgical pain management. More studies, like randomized controlled trials, are needed to better understand how well it works compared to other treatments in faster recovery programs.

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