

(RESEARCH ARTICLE)



# Effectiveness of transdermal diclofenac patch versus intramuscular diclofenac injection in management of pain among patients with rib fracture in a tertiary care hospital

Arun Rao <sup>1,\*</sup>, Ramesh <sup>1</sup>, Meher Mehta <sup>2</sup> and Amulya Cherukumudi <sup>3</sup>

<sup>1</sup> Consultant General Surgeon, Salem Polyclinic, Salem.

<sup>2</sup> Senior Resident, Department of Orthopaedics, Shri Guru Ram Rai Institute of Medical Sciences and Research, Dehradun, India.

<sup>3</sup> Assistant Professor, Department of Cardiothoracic Surgery, Sds Trc and Rajiv Gandhi Institute of Chest Diseases, Bangalore, India

International Journal of Frontiers in Medicine and Surgery Research, 2024, 05(01), 019–025

Publication history: Received on 02 January 2024; revised on 24 February 2024; accepted on 27 February 2024

Article DOI: <https://doi.org/10.53294/ijfmsr.2024.5.1.0025>

## Abstract

Most common injuries in trauma are rib fractures which leads to increase risk of mortality and morbidity. In India alone, there is are about 10 million cases per year for incidence of rib fractures more commonly due to vehicle accidents whereas 6% are of global accidents in India, itself. The current modality of treatment is with NSAID's for relief of pain in rib fractures. A prospective study of 203 patients with rib fractures found a prevalence of chronic pain 22% and disability of 53%. Thereby, adequate pain management is crucial for improving the recovery and quality of life. The preferred route of administration of analgesics is either oral or intramuscular. This study entails in determining the effectiveness of transdermal Diclofenac patch versus intramuscular administration of Diclofenac.

**Keywords:** Anti-Inflammatory; Analgesic; Pain Clinic; Callous

## 1. Introduction

Most common injuries in trauma are rib fractures which leads to increase risk of mortality and morbidity. In India alone, there is are about 10 million cases per year for incidence of rib fractures more commonly due to vehicle accidents whereas 6% are of global accidents in India, itself. (1,2) The healing period is within 1 to 2 months for rib fractures.(3) Respiratory complications are significant cause of mortality and morbidity secondary to pain. (4) Surplus management in the pain management of rib fractures in the emergency department reduces secondary pulmonary complications including atelectasis, pneumonia, respiratory failure and need for respiratory support.

(4) The current modality of treatment is with NSAID's for relief of pain in rib fractures. (3) A prospective study of 203 patients with rib fractures found a prevalence of chronic pain 22% and disability of 53%. (5) Thereby, adequate pain management is crucial for improving the recovery and quality of life. The preferred route of administration of analgesics is either oral or intramuscular.

The aim of our study is to to assess the effectiveness of transdermal Diclofenac and intramuscular Diclofenac administration in management of pain among patients with rib fracture

\* Corresponding author: Arun Rao

## 2. Material and method

This is a Cohort, longitudinal study conducted in a tertiary care hospital done between January 2022 to December 2023 with a study population presenting to Department of general surgery and orthopaedics belonging to age group more than 18 years, after ethical committee clearance. The sampling technique used to consecutive sampling technique including 21 patients each fluffing the inclusion criteria falling in to the 1st and 2nd group and given treatment accordingly. The sample size 42 where each group will receive transdermal patch and the other intramuscular diclofenac injection.

The inclusion criteria is single or multiple rib fractures (less than 10 ribs) unilateral or bilateral in nature, admitted in the tertiary hospital. The exclusion criteria include i. Patients having already received for treatment for this injury in another centre following injury, ii. Patient associated with pneumothorax and hemothorax, iii. Patients requiring ICD insertion, iv. Mentally challenged patients, v. Glasgow coma scale <13, vi. Patients known to have a NSAID allergy and vii. Pregnant and lactating women.

Patients were classified in to 2 groups after fulfilling the criteria and sampled based on consecutive sampling technique and data was collected from the study participants using general questionnaire and visual analogue scale/ numerical pain scale at 0th hour (at the time of presentation), 24th hour and 96th hour after injury.

One group was administered a transdermal patch of diclofenac 100mg after measuring using VAS and corresponding numerical scale, following the administration the pain was reassessed at 24th and 96th hr. The consecutive patient in the study group was included in the 2nd group and was given intramuscular Diclofenac injection of 50mg twice daily and pain was measured at 0th hour, 24th hour and 96th hour. The pain relief was compared for both treatment modalities using paired t test and z test and X<sup>2</sup>.

Visual analogue scale (VAS) was used as a measuring tool to measure characteristic or an attitude that is believed to range across a continuum of values and its direct measurement is not easy. VAS is also used for pain measurement on a continuum. (6)

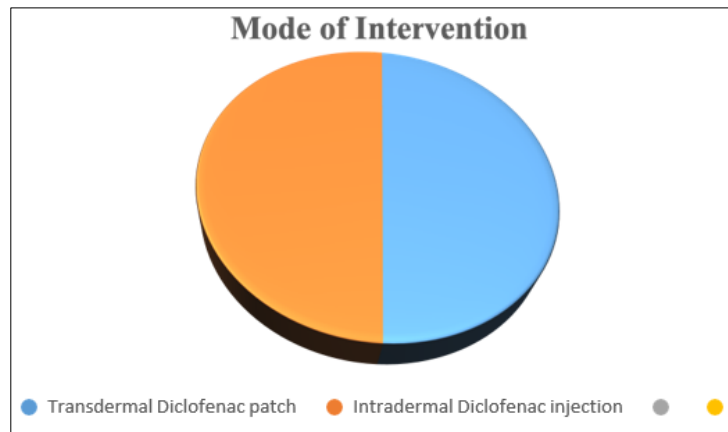
The Numerical Pain Rating Scale (NPRS) is a segmented numeric version of the visual analog scale (VAS) in which a respondent selects a whole number (0–10 integers) that best reflects the intensity of his/her pain. The common format is a horizontal bar or line. (6)

Each patient who meets the inclusion criteria is measured for pain with VAS and corresponding Number for Pain severity is noted at NPRS. Then transdermal patch of Diclofenac or intramuscular diclofenac injections were given according to expert's decision. 2 hours following administration the pain rating is done by VAS and NPRS. The data is compared for each group. The data was analysed with SPSS 23 version software. The hypothesis was tested at 0.01 level of significance.

Continuous data is presented with mean and standard deviation or median with IQR and categorical data in percentage. Comparison is done with paired T test and Wilcoxon sign rank test.

The frequency and distribution of patients with rib fractures based on age and gender were classified.

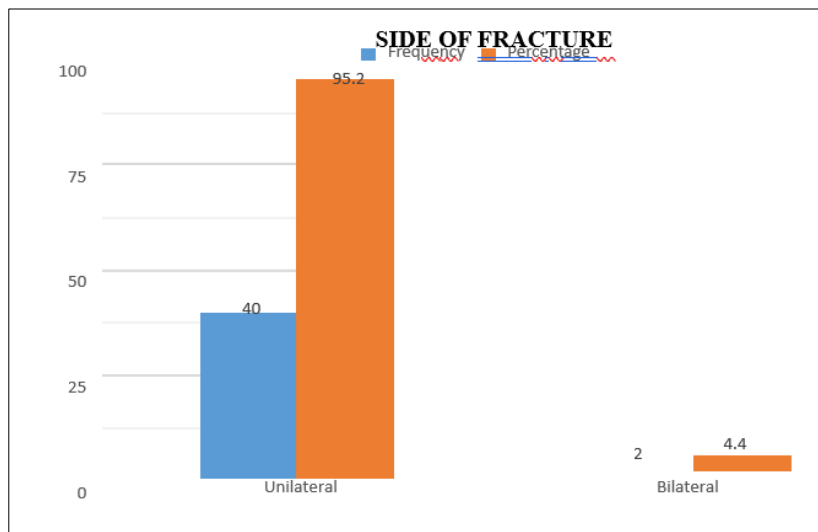
The table shows a majority of patient belonging to age >50 years (47.6%) and predominantly being males (78.6%).



**Figure 1** Frequency and distribution of patients with rib fractures based on mode of intervention

21 patients were treated within 1 hr of arrival and 1 hr after their arrival to the hospital and their percentage was 50% each.

76% of the patients had multiple rib fractures and 24% had single rib fractures.



Bar diagram indicates that 95.2% (40) patients had unilateral fracture.

**Figure 2** Frequency and distribution of patients with rib fracture based on the side of fracture N=42

**Table 2** Frequency and distribution of patients with rib fracture based on the mode of injury and presence of co-morbidities

Sociodemographic data	Frequency	Percentage
Mode of injury		
Fall	15	35.7
Road traffic accident	27	64.3
Others	0	0
Co-morbidities		
Yes	7	16.7
No	35	83.3

Pain scores of patients with rib fractures administered analgesics through intramuscular injection in group was calculated and noted.

By comparing the mean and standard deviation of pain scores of patients at different times, group 1 with intramuscular injection at 0th, 24th and 96th hr was  $6.43 \pm 0.978$ ,  $3.81 \pm 1.123$  and  $1.62 \pm 0.865$  respectively; while in another group 2 which had transdermal route of administration mean and standard deviation at 0th, 24th and 96th hr was  $4.71 \pm 1.189$ ,  $3.43 \pm 1.121$  and  $1.76 \pm 0.944$  respectively.

**Table 5** Comparing the pain score of patients at different times (paired t-test)

Sl.No	Pair	t-value	Degree of freedom	Sig(2-tailed)
1	Intradermal 0-transdermal 0	-5.832	0	0.000
2	Intradermal 24-transdermal 24	-1.504	20	0.148
3	Intradermal 96-transdermal 96	1.000	20	0.329

Because the computed t-value (-5.832) is higher than the table value at the 5% level of significance (2.56), the null hypothesis was rejected in the first pair. It suggests that the mean values of the chosen groups differ. The computed t-value in the final two pairs is smaller than the table value, which was -1.504 and 1.000, respectively. It demonstrates that the mean values of the conditions in each pair do not differ significantly. Thus, given these circumstances, the null hypothesis can be accepted.

The association of demographic variables and mean pain scores were selected with 3 variables of age, gender and number of ribs featured which revealed, the degree of freedom and chi-square value as 44, 0.397; 11, 0.220 and 11, 0.069 respectively. This showed a no significant association between the selected variables and mean pain score value of patient with rib fractures as the calculated p value  $>0.05$ .

### 3. Results

This longitudinal, cohort study in 42 patients in a tertiary care hospital who were studied with the above mentioned objectives and hypothesis, the findings were inferred under socio-demographic characteristics, comparison of pain scores, effectiveness of two modes of delivery of diclofenac, association between selected demographic variables and pain scores and comparison of side effects. Under socio-demographic characteristics out of 42 samples, 50% were given the transdermal route and the other intramuscular injection of Diclofenac. Majority of the patients belonged to age group  $>50$  years (47.6%) and the rest were divided in other age groups: 18-25 years, 26-33 years and 34-41 years (14.3%), the remaining 9.5% belonged to 42-49 years.

50% had arrived within 1 hr of injury and also, 23.82% had single rib fractures and 76.28% had multiple rib fractures. 95.24% had unilateral rib fractures and 4.76% had bilateral rib fractures. Majority of the patients 64.3% (27 patients) cause of the rib fracture entailed road traffic accident and the majority had no co-morbidities (83.3%).

Pain scores were calculated at 0th, 24th and 96th hr were administered in both groups with a mean score of 3 in majority of the cases showing a gradual decline, in group 2 intramuscular route. There was noted a decline in the group 1 patients, from 0th to 96th hr with a mean score of 5 who received the transdermal route.

By comparing means using Student's t-test, the difference in the mean value of the selected groups was found to be significantly different. This shows, there was a better response in the first hour of injury with intramuscular diclofenac when compared to transdermal route.

The results demonstrated that there is no significant correlation between the mean pain score of patients with rib fractures and the selected demographic variables (age, gender, and number of cracked ribs) (p value 0.922, 0.738 and 0.781 respectively). There was no significant correlation seen between the pain score and the eight patients who had

diabetes mellitus. When transdermal NSAIDs and intramuscular diclofenac treatment are compared for adverse effects, only pain is reported by 80% of patients receiving intramuscular diclofenac. All other side effects are absent.

---

#### 4. Discussion

This study was intended to determine the effectiveness between transdermal patch of diclofenac versus intramuscular injection for reducing pain in patients with rib fractures presenting to the emergency and outpatient department in a tertiary care hospital.

The present study shows a 64.3% of patients admitted with rib fracture due to road traffic accident and 47.6% were above the age of 50 years. Karmakar and M.H. Ho et al, were consistent with the same findings as our study. (7) Chest trauma was the most common in motor vehicle collision and accounted for 8% of the admissions. Morbidity and mortality significantly increased in elderly patients and patients with poor respiratory reserve.

It is more debilitating and harmful than the injury itself, showed that multiple fractured ribs(MFRs) causes sever pain as per the acute pain management of patients with multiple rib fractures and in our study, 76.27% had multiple rib fractures. (7)

Rib fractures were diagnosed using chest radiographs and computed tomography(CT) of the chest. The present study entails usage of Diclofenac as NSAID and found a mean pain score reduced by 96hrs from 3.3 and 3.9 respectively in intramuscular and transdermal route. There was significant p- value in patients who had received intramuscular injection within the initial hours of presentation. Kottareddygar VS et al, had similar findings where they had used the same type of administration routes in their study. (8) Their findings showed there is a slower onset of administration of NSAID transdermal administration with higher VAS reading on Day 1 when compared to analgesic effect of intravenous NSAID administration which had VAS reading on Day 3.

In order to compare and assess the effects of oral diclofenac sodium tablets and the transdermal patch for postoperative analgesia, adverse events, patient tolerance, and compliance after numerous premolar extractions in patients receiving orthodontic treatment, a study was conducted. A good environment for comparing the two formulations was created when young orthodontic patients had their mandibular and maxillary first premolars extracted bilaterally. In this cross-over trial, the patients acted as the control group, and the same operative procedures could be carried out on the same people twice. For post-dental extraction pain, a transdermal diclofenac patch of 100 mg used once day was shown to be just as effective as an oral dose of 150 mg per day.(9) However, the current study contrasted intramuscular diclofenac injection with transdermal diclofenac patch. The results of this investigation do not support intramuscular injections over transdermal patches.

Patients in the current trial who used the transdermal patch reported a mean VAS score of 5 for 96 hours, a statistically and clinically significant reduction in pain scores. However, there was no statistical significance in these results.

Regarding safety, the patch exhibited good tolerance and did not result in any side effects, either local or systemic. In contrast, five patients undergoing diclofenac injection expressed discomfort and anxiety related to injections.

A localised erythematous rash or pruritis occurred at the site of application of the transdermal diclofenac patch, according to Agarwal et al., who used it to reduce pain during venous cannulation. This result deviates from the current study's findings, possibly because the diclofenac patch was applied at a different location for each subsequent treatment. Thankfully, no adverse effects were recorded after using the diclofenac patch. (10)

Numerous trials proved diclofenac's efficacy as a strong nonsteroidal anti-inflammatory drug (NSAID) in various dosage forms. On the other hand, numerous cases of gastric irritation have been reported with oral diclofenac treatment. Due to its intrusive nature, injectable diclofenac caused pain at the injection site.

Due to the high likelihood of significant inter-individual difference in VAS evaluation, the duration of analgesic medication was assessed in the current investigation as a potential indicator of analgesic effects. For both groups, the treatment period was almost the same. The results demonstrate the strong analgesic effects of both intramuscular and transdermal diclofenac injections.

## 5. Conclusion

We found that there was a better response in the first hour of injury with intramuscular diclofenac when compared to transdermal route. However, there was no significant correlation seen between the pain score and other demographic variables. When transdermal NSAIDs and intramuscular diclofenac treatment are compared for adverse effects, only pain is reported by 80% of patients receiving intramuscular diclofenac.

---

## Compliance with ethical standard

### *Disclosure of conflict of interest*

No conflict of interest to be disclosed.

### *Statement of ethical approval*

Ethical committee clearance sought.

### *Statement of informed consent*

Informed consent was obtained from all individual participants included in the study.

---

## References

- [1] Ramani VK, Pattankar J, Puttahonnappa SK. Acute respiratory infections among under-five age group children at urban slums of gulbarga city: A longitudinal study. *Journal of clinical and diagnostic research: JCDR*. 2016 May;10(5):LC08.
- [2] Prapphal N. Respiratory infection and allergy in children. *Chula Med J* 2002; 46:459-60.
- [3] Simoes EAF, Cherian T, Chow J, ShahidSalles S, Laxminarayan R, John TJ. Acute respiratory infections in children. In: Jamison DT, Breman JG, Measham AR, Alleyne G, Claeson M, Evans DB, et al, editors. *Source Disease Control Priorities in Developing Countries*. 2nd edition. Washington (DC): World Bank; 2006. Chapter 25.
- [4] Rudan I, O'Brien KL, Nair H, Liu L, Theodoratou E, Qazi S, et al. Epidemiology and etiology of childhood pneumonia in 2010: estimates of incidence, severe morbidity, mortality, underlying risk factors and causative pathogens for 192 countries. *J Glob Health [Internet]*. 2013;3(1):010401.
- [5] Krishnan A, Amarchand R, Gupta V, Lafond KE, Suliankatchi RA, Saha S, et al. Epidemiology of acute respiratory infections in children - preliminary results of a cohort in a rural north Indian community. *BMC Infect Dis [Internet]*. 2015;15(1):462.
- [6] Feldman AS, Hartert TV, Gebretsadik T, Carroll KN, Minton PA, Woodward KB, et al. Respiratory severity score separates upper versus lower respiratory tract infections and predicts measures of disease severity. *Pediatr Allergy Immunol Pulmonol* 2015; 28:117- 20.
- [7] Ducharme FM, Chalut D, Plotnick L, Savdie C, Kudirka D, Zhang X, et al. The pediatric respiratory assessment measure : a valid clinical score for assessing acute asthma severity from toddlers to teenagers. *J Pediatr* 2008;152:476-80.
- [8] Gold DL, Mihalov LK, Cohen DM. Evaluating the Pediatric Early Warning Score (PEWS) system for admitted patients in the pediatric emergency department. *Acad Emerg Med* 2014; 21:1249- 56.
- [9] Beyeng RTD, Purniti PS, Naning R. Validity of bacterial pneumonia score for predicting bacteremia in children with pneumonia. *Paediatr Indones* 2011;2: 322-6.
- [10] Miyaji Y, Sugai K, Nozawa A, Kobayashi M, Niwa S, Tsukagoshi H, Pediatric Respiratory Severity Score (PRESS) for Respiratory Tract Infections in Children. *Austin Virol and Retrovirology* 2015; 2:1009.
- [11] Destino L, Weisgerber MC, Soung P, Bakalarski D, Yan K, Rehborg R, et al. Validity of respiratory scores in bronchiolitis. *Hosp Pediatr* 2012;2: 202- 9
- [12] Thokngaen J, Karoonboonyanan W. Pediatric respiratory severity score evaluates disease severity of respiratory tract infection in children. *Chulalongkorn Medical Journal*. 2019 Jan 25;63(1):41-6.

- [13] Nayani K, Naeem R, Munir O, Naseer N, Feroze A, Brown N, Mian AI. The respiratory severity score predicts paediatric critical care disposition in children with respiratory distress presenting to the emergency department. *BMC pediatrics*. 2018 Dec;18(1):1-8.
- [14] Alexandrino AM, Santos RI, Melo MC, Bastos JA, Postiaux G. Subjective and objective parameters in paediatric respiratory conditions: cultural adaptation to Portuguese population. *Fisioterapia em Movimento*. 2017 Jan; 30:49-58.
- [15] Ashraf, H.; Alam, N. H.; Chisti, M. J.; Salam, M. A.; Ahmed, T.; Gyr, N. (2012). Observational follow-up study following two cohorts of children with severe pneumonia after discharge from day care clinic/hospital in Dhaka, Bangladesh. *BMJ Open*, 2(4), e000961–e000961. doi:10.1136/bmjopen-2012-000961
- [16] Kamble MB, Singh RK. Respiratory severity score and pediatric respiratory severity score criteria in grading and management of pediatric acute respiratory illness. ( 2017)
- [17] Rodriguez H, Hartert TV, Gebretsadik T, Carroll KN, Larkin EK. A simple respiratory severity score that may be used in evaluation of acute respiratory infection. *BMC research notes*. 2016 Dec;9(1):1-4.
- [18] Carey MA, Card JW, Voltz JW, Arbes SJ, Jr, Germolec DR, Korach KS, et al. It's all about sex: gender, lung development and lung disease. *Trends Endocrinol Metab* (2007) 18(8):308– 13.
- [19] Thurlbeck WM. Postnatal human lung growth. *Thorax* (1982) 37(8):564–71.
- [20] Fleisher B, Kulovich MV, Hallman M, Gluck L. Lung profile: sex differences in normal pregnancy. *Obstet Gynecol* (1985) 66(3):327–30.
- [21] Kimura Y, Suzuki T, Kaneko C, Darnel AD, Akahira J, Ebina M, et al. Expression of androgen receptor and 5alpha-reductase types 1 and 2 in early gestation fetal lung: a possible correlation with branching morphogenesis. *Clin Sci (Lond)* (2003) 105(6):709–13.
- [22] Dammann CEL, Ramadurai SM, Mccants DD, Pham LD, Nielsen HC. Androgen regulation of signaling pathways in late fetal mouse lung development. *Endocrinology* (2000) 141(8):2923–9.
- [23] Massaro D, Massaro GD. Estrogen receptor regulation of pulmonary alveolar dimensions: alveolar sexual dimorphism in mice. *Am J Physiol Lung Cell Mol Physiol* (2006) 290(5):L866–70.
- [24] Patrone C, Cassel TN, Pettersson K, Piao YS, Cheng G, Ciana P, et al. Regulation of postnatal lung development and homeostasis by estrogen receptor. *Mol Cell Biol* (2003) 23(23):8542–52.