Section: Anaesthesiology

Original Research Article

# COMPARE THE EFFICACY OF TRANSDERMAL DICLOFENAC PATCH WITH INTRAMUSCULAR DICLOFENAC FOR POST OP ANALGESIA IN LAPAROSCOPIC CHOLECYSTECTOMY: RANDOMIZED CONTROLLED TRIAL

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*Received* : 17/12/2024
*Received in revised form* : 09/02/2025
*Accepted* : 25/02/2025

*Keywords:*
*Intradermal diclofenac patch, intramuscular diclofenac, laparoscopic cholecystectomy.*

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DOI: 10.47009/jamp.2025.7.1.191

Source of Support: Nil,
Conflict of Interest: None declared

*Int J Acad Med Pharm*
2025; 7 (1); 974-981

## Abstract

**Background:** Pain-induced discomfort is the most significant issue following surgery. Despite the fact that pain is an inevitable part of the healing process following the surgery, it is often not adequately managed, which can have adverse impacts. The objective is tto compare efficacy of intramuscular diclofenac injection and transdermal diclofenac patch in post laparoscopic cholecystectomy pain management. **Materials and Methods:** This Randomized controlled study was among patients admitted for laparoscopic cholecystectomy under general anaesthesia conducted in Department of Anaesthesiology, Rohilkhand Medical College and Hospital, Bareilly. **Result:** This study groups were comparable in demographic data including Age, Gender and ASA grading and all demographic variables were insignificant between both groups. VAS score was significantly higher in inj. Diclofenac group in comparison to transdermal diclofenac patch group at 2 hours and 4 hours. Also, the no. of patients requiring rescue analgesia was significantly higher in inj. Diclofenac group as compared to transdermal diclofenac patch group at 2 hours and 4 hours. The Quality of Recovery-15 score was significantly higher in transdermal diclofenac patch group in comparison to inj. Diclofenac group. Haemodynamic parameters such as heart rate, SBP, DBP, MAP and pulse oximetry were recorded at different intervals and we observed that there was no significant variation among both the groups in terms of these parameters. **Conclusion:** Visual analog score was higher in inj. Diclofenac group as compared to transdermal diclofenac patch and no. of patients requiring rescue analgesia was also higher in inj. Diclofenac group. The Quality of Recovery-15 score was significantly higher in transdermal diclofenac patch group as compared to inj. Diclofenac group. The transdermal diclofenac sodium diethylamine patch was more efficient drug and was well tolerated than inj. Diclofenac sodium.

## INTRODUCTION

The anxiety and psychological distress have huge impact on the health and well-being of the patients. Many factors play an important role in determining the range and duration of pain that follows a surgery, like the incision (site, size, type, and closure technique), the surgery (type, level of invasiveness, and the duration) and underlying co-morbidities.[1]

Pain is the most usual symptom for which a patient seeks medical help. The International Association for the study of pain has described pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage".[2]

Postoperative pain is a distinctive and common form of acute pain. Recent studies demonstrate that about 50-70% of patients encounter moderate to severe pain after surgery indicating that post operative pain remains badly treated.[3]

Commonly opioids and NSAIDs are used in peri-operative period to reduce the pain. Diclofenac sodium is a most common prescribed NSAID, which


ISSN (O): 2687-5365; ISSN (P): 2753-6556

shows anti-inflammatory, analgesic and anti-pyretic activity.[4]

Opioids were optional drugs initially for post-operative pain but it has higher degree of side effects like nausea, vomiting, respiratory depression and ileus. NSAIDS do not give rise to respiratory depression and ileus. NSAIDS are administered by many routes as IM,IV, oral, cutaneous patch and rectal route (suppositories).[5]

NSAIDs inhibit the synthesis of prostanoids (prostaglandin [PG]-E2, PGD2, PGF2, prostacyclin [PGI2], and thromboxane [TX] A2) by binding to the COX isozymes. PGE2 is the dominant prostanoid produced in inflammation, and inhibiting its synthesis by NSAIDs is believed to be the primary mechanism of these agents' potent analgesic and anti-inflammatory properties.[6]

Diclofenac is available in various forms like injectable agents, topical gel application, ophthalmic solution, rectal suppository and transdermal patch to cure pain.[7]

Parenteral composition of diclofenac is irritating and therefore it is extremely painful at site of administration. Occurence of skin, subcutaneous and even muscle tissue necrosis, abscess formation etc are infrequent but key complications of intramuscular injection of Diclofenac.[8]

Transdermal route is a new route of administration with many advantages as follows- it is simple, gentle procedure, increased bioavailability, maintainence of extended and sustained drug level, reduced incidence of dosing, reduction of variability between patients and between same patient, can be self administered and can be removed easily.[9]

Transdermal Drug Delivery Systems, also known as "patches," are separate, self-contained dosage forms that, when applied to healthy skin, allow medications to enter the bloodstream through the skin at a regulated pace. To lessen patient noncompliance caused by traditional dose forms, such as first-pass metabolism and pharmaceutical breakdown due to enzymes or pH changes in the gastrointestinal system, transdermal patches are crucial. To increase the medicine's bioavailability and facilitate a controlled release of the treatment into the bloodstream through the skin, transdermal drug delivery system was developed. The medicine to be administered is incorporated into polymeric membranes in the transdermal delivery of drug method, which causes the drug to diffuse to the skin at predetermined and regulated rate. Compared to oral dosing forms, it takes fewer doses, which reduces the possibility of an overdose entering the bloodstream and, consequently, the adverse consequences.[10]

Laparoscopic cholecystectomy has recently become highly regarded because it provides quick recovery and early post operative mobilization, although surgical pain has been a very important issue limiting patient comfort.[9]

In laparoscopic cholecystectomy, overall pain is a combination of three different and clinically unrelated components: incisional pain (somatic pain), visceral pain (deep intra-abdominal pain), and shoulder pain (presumably referred diaphragmatic pain). Pain is most fiercing on day 0 and on the following day and subsequently reduces to low levels within 3–4 days.[11]

QoR-15 (Quality of recovery-15) score is a global score for assessing the status of recovery after anaesthesia and surgery. It includes 15 questions covering 5 domains:-patient's psychological support, emotional support, physical comfort, physical independence in doing his routine work and severity of pain.[1]2

There are less number of studies regarding control of acute post-operative pain of laparoscopic cholecystectomy using diclofenac transdermal patch and intramuscular diclofenac in this region.[5] Hence to gain further information, the present study is being conducted to compare efficacy of intramuscular diclofenac injection and transdermal diclofenac patch in post laparoscopic cholecystectomy pain management.

## MATERIALS AND METHODS

This Randomized controlled study was among patients admitted for laparoscopic cholecystectomy under general anaesthesia conducted in Department of Anaesthesiology, Rohilkhand Medical College and Hospital, Bareilly after getting Institutional Ethical Committee's approval. Duration of study was one year from August 2023-July 2024

**Sample Size:** In our study a total of 60 no. of patients were taken in each group, which is statistically calculated by using software Power and sample size program.8

The sample size calculated in each group was 30.

**Inclusion Criteria:**

**Patients Fulfilling the Following**

- ASA grade I and II13
- Either sex
- Age between 18 to 60 yrs

**Exclusion Criteria: Patients having history of:**

- Dermatitis, Hypersensitivity reaction, Bleeding disorder, GI disorder like ulcer, Patients on antipsychotics, Hepatic disease, Renal disease.

**Methodology**

After obtaining informed written consent, Patients were randomly divided in 1:1 allocation ratio, each comprising 30 patients. This study was registered in CTRI with no. CTRI/2023/10/058555.

Methodology of this study is according to ethical principles for medicine research involving human subjects outlined in the Helsinki declaration and general anaesthesia was given according to institutional's standard protocol.

**Procedure:** Thorough pre-Anaesthetic check-up was done one day before the surgery and informed written consent for participation in study was taken. The individuals were assigned randomly into two groups: Group '1' and Group '2'. In group 1, Patients were given transdermal diclofenac sodium diethylamine


ISSN (O): 2687-5365; ISSN (P): 2753-6556

patch (each patch of 75cm2 contains 200 mg) two hours before induction while in group 2, Patients were given an intramuscular injection comprising diclofenac sodium (each injection of 1ml contains 75 mg) thirty minutes prior to extubation.

Prior to surgery, the technique and protocols were explained and the patient was informed about follow-up until 24 hours after surgery.

**Pre-anaesthetic preparation and premedication:** All patients in this study group were kept fasting up to 8 hours before induction. Tablet Alprazolam 0.25 mg orally and tablet Ranitidine 150 mg orally one day prior to surgery and on coming morning of the surgery was given. The patch application site was thoroughly washed with clear water before being dried and transdermal diclofenac sodium diethylamine patch was applied 2 hours before induction. NPO status was verified in the morning, at which point the patient was shifted to the preoperative room. The SBP, DBP, MAP, Heart rate and Pulse oximetry reading of the patient were noted in pre operative room.

**Anaesthesia:** Once patient entered operating room, standard anaesthesia monitoring was attached and vitals were noted after induction. General anaesthesia was induced identically in both groups using this technique:

We administered inj. Midazolam 0.02 mg/kg and inj. Butorphanol 0.02 mg/kg intravenously while preoxygenating with 100% oxygen. After this induction was done with inj. Propofol 2mg/kg followed by Inj. Vecuronium 0.1 mg/kg iv and patient was ventilated with bag and mask for 3 minutes using 100% oxygen. 3 minutes after administering vecuronium, laryngoscopy & tracheal intubation was done using the proper sized, cuffed endotracheal tube. For maintenance of anaesthesia, nitrous oxide and oxygen in the ratio 0f 40-60 and isoflurane were administered. The mechanical ventilation of the patient's lungs was minutely regulated to maintain normocapnia (EtCO2 between 35 and 40mm Hg). Vecuronium 0.02 mg/kg was taken for use as an additional neuromuscular blocker to maintain relaxation.

Isoflurane was discontinued half hour before completion of surgery and group 2 patients were given an intramuscular injection comprising diclofenac sodium (each injection of 1ml contains 75 mg) thirty minutes prior to extubation. Residual neuromuscular block was reversed with appropriate doses of neostigmine (0.05 mg/kg) & glycopyrrolate (0.01 mg/kg). Following confirmation of recovery from anaesthesia and muscle relaxation, extubation was performed after thorough suctioning.

Immediately following surgery, patients were evaluated for adverse effects and intensity of pain was recorded using 'the 10-point' Visual Analogue Scale (VAS)14. The patients were asked to rate their pain intensity after 2, 4, 6, 12 hours & 24 hours. Every time the patient reported pain (VAS>4), inj. Tramadol hydrochloride 2 milligram/kg was given as rescue analgesia and no. of patients requiring rescue analgesia were recorded.

- Pain score '0' to '3' - Mild pain,
- Pain score '3' to '7' – Moderate pain,
- Pain score > 7 - Severe pain

The effectiveness of pain alleviation in the first 24 hours after surgery was evaluated, using the prescribed questionnaire, the Quality Of Recovery-15 score(QOR-15) and responses were recorded. The QoR-15 assesses 5 dimensions of health: physical comfort (questions 1-4 & 13),physical independence (questions 5 & 8), pain (questions 11 & 12), emotional state (questions 9,10,14 and 15), and psychological support (questions 6 and 7).

**QoR-15 score12**

- Score-0-40-Poor recovery group
  41-80-Good recovery group
  81-120-Moderate recovery group
  121-150-Excellent recovery group

**Statistical Analysis:** Data from present analysis was systematically collected, compiled, and statistically analysed. Descriptive & inferential statistical analysis were derived from results on continuous measurements, conferred as mean ± SD while results on categorical measurements were presented in numbers (%age). The data were entered on a Microsoft Excel spreadsheet and imported into Statistical Package for Social Sciences (SPSS) version 23 for statistical analysis. Qualitative data was present in frequency and percentage and quantitative data was presented in mean & standard deviation. The p-value was taken significant when less than 0.05 ($p<0.05$) and Confidence interval of 95% was taken.

## RESULTS

In our study, mean age of cases in 1st Group was 41.43 ± 11.85 years and mean age of cases in 2nd Group was 43.33 ± 13.3 years. No significant difference was noted in the mean age of cases in between the 1st Group and 2nd Group (P=0.268).

In our study out of 30 cases in Group 1, 83.3% were female and 16.7% were male and out of 30 cases in Group 2, 80.0% were female and 20.0% were male. There was no significant difference in gender of cases between 1st Group and 2nd Group (P=0.739).

In our study, mean weight of the cases in 1st group were 61.6 ± 12.7 kg and mean weight of the cases in 2nd group were 58.27 ± 12.0 kg. No significant difference was noted in mean weight of cases between Group 1 and Group 2 (P=0.077).

**Table 1: Mean vas score of patients at distinct time intervals.**

| | GROUP1 | GROUP2 | |
|---|---|---|---|
| **VAS Score** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| at 2hr | 3.13 ± 0.51 | 4.33 ± 1.03 | 0.000* |


ISSN (O): 2687-5365; ISSN (P): 2753-6556

| | | | |
|---|---|---|---|
| at 4hr | 2.23 ± 0.77 | 3.13 ± 0.9 | 0.000* |
| at 6hr | 1.67 ± 0.88 | 1.9 ± 1.09 | 0.367# |
| at 12hr | 0.73 ± 0.87 | 1.03 ± 0.96 | 0.210# |
| at 24hr | 0.57 ± 0.86 | 0.43 ± 0.68 | 0.507# |

*Statistically significant, Statistically not significant.

In our study, mean VAS score of the cases at 2 hr in 1st group was 3.13 ± 0.51, at 4 hr in 1st Group was 2.23 ± 0.77, at 6 hr in 1st Group was 1.67 ± 0.88, at 12 hr in 1st Group was 0.73 ± 0.87 and at 24 hr in 1st Group was 0.57 ± 0.86 and the mean VAS score of the cases at 2 hr in 2nd Group was 4.33 ± 1.03, at 4 hr in 2nd Group was 3.13 ± 0.9, at 6 hr in 2nd Group was 1.9 ± 1.09, at 12 hr in 2nd Group was 1.03 ± 0.96 and at 24 hr in 2nd Group was 0.43 ± 0.68. No significant difference in mean VAS score of cases was noted at distinct time intervals between 1st Group and 2nd Group except at 2-hour and 4-hour of time intervals.

**Table 2: Comparison Of No. Of Patients Receiving Rescue Analgesia in 1st Group and 2nd Group**

| | Group 1(n=30) | | Group 2(n=30) | | |
|---|---|---|---|---|---|
| | Yes | No | Yes | No | |
| **Rescue Analgesia** | **Number (%)** | **Number (%)** | **Number (%)** | **Number (%)** | **P-Value** |
| at 2hr | 4(13.3) | 26(86.7) | 16(53.3) | 14(46.7) | <0.001* |
| at 4hr | 0(0) | 30(100) | 9(30.0) | 21(70.0) | <0.001* |

In our study,out of 30 patients 4 patients(13.3%) in group 1 required rescue analgesia at 2 hrs, and nil of the patients required rescue analgesic at 4 hours in 1st group and 16 patients (53.3%) in group 2 required rescue analgesia at 2 hrs, and 9 patients(30.0%) required rescue analgesia at 4 hours.In our study, the no. of patients requiring rescue analgesic were more in group 2 in comparison to group 1 at 2 hours and 4 hours and there was significant difference between 1st group and 2nd (p<0.001).

**Table 3: total mean qor-15 score of patients**

| | Group 1 | Group 2 | |
|---|---|---|---|
| | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| Total QOR Score | 128.67 ± 11.73 | 83.4 ± 9.53 | 0.000 |

In our study, the mean Total QOR-15 Score of the cases in 1st Group was 128.67 ± 11.73 and the mean Total QOR-15 Score of the cases in 2nd Group was 83.4 ± 9.53. There was a difference which was significant in mean Total QOR-15 Score of cases between 1st Group and 2nd Group (P=0.000).

**Table 4: Mean heart rate (BPM) of patients at different time intervals.**

| | Group1 | Group2 | |
|---|---|---|---|
| **Heart Rate(BPM)** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| Pre-Operative | 78.07 ± 9.03 | 80.07 ± 8.92 | 0.392# |
| After Induction | 84.27 ± 9.57 | 85.4 ± 10.49 | 0.664# |
| 2hr | 79.67 ± 10.36 | 83.6 ± 10.58 | 0.151# |
| 4hr | 82.53 ± 12.28 | 88.33 ± 12.21 | 0.072# |
| 6hr | 78.87 ± 10.03 | 81.53 ± 9.81 | 0.302# |
| 12hr | 78.73 ± 9.66 | 81.67 ± 10.23 | 0.258# |
| 24hr | 77.53 ± 8.06 | 80.47 ± 10.14 | 0.220# |

#Statistically not significant.

In this study, the mean Heart rate of the cases at Pre-Operative in 1st Group was 78.07 ± 9.03, After Induction was 84.27 ± 9.57, at 2hr was 79.67 ± 10.36, at 4 hr was 82.53 ± 12.28, at 6 hr was 78.87 ± 10.03, at 12 hr was 78.73 ± 9.66and at 24 hr in 1st Group was 77.53 ± 8.06 and the mean Heart rate of the cases at Pre-Operative in 2nd Group was 80.07 ± 8.92, After Induction was 85.4 ± 10.49, at 2hr was 83.6 ± 10.58, at 4 hr was 88.33 ± 12.21, at 6 hr was 81.53 ± 9.81, at 12 hr was 81.67 ± 10.23 and at 24 hr in Group 1 was 80.47 ± 10.14. No significant difference was noted in the mean Heart rate of cases at distinct time intervals between 1st Group and 2nd Group.

**Table 5: mean SBP of patients at different time intervals.**

| | Group1 | Group2 | |
|---|---|---|---|
| **SBP** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| 2 hrs before induction(mmHg) | 122.73 ± 6.8 | 121.13 ± 9.27 | 0.449# |
| Preoperative | 125.13 ± 6.0 | 123.8 ± 7.83 | 0.462# |
| After Induction | 122.47 ± 6.27 | 121.33 ± 8.29 | 0.553# |
| 2hr | 121.8 ± 5.69 | 118.2 ± 8.18 | 0.053# |
| 4hr | 121.4 ± 6.91 | 118.6 ± 6.37 | 0.108# |
| 6hr | 122.47 ± 6.3 | 119.67 ± 7.99 | 0.061# |
| 12hr | 122.4 ± 7.07 | 119.13 ± 8.77 | 0.118# |
| 24hr | 122.6 ± 5.9 | 120.4 ± 8.04 | 0.066# |

#Statistically not significant


ISSN (O): 2687-5365; ISSN (P): 2753-6556

In the study, mean SBP of the cases in Group 1 two hrs before induction was 122.73 ± 6.8 at Pre-Operative was 125.13 ± 6.0, After Induction was 122.47 ± 6.27 , at 2hr was 121.8 ± 5.69 , at 4 hr was 121.4 ± 6.91 , at 6 hr was 122.47 ± 6.3 , at 12 hr was 122.4 ± 7.07 and at 24 hr in 1st Group was 122.6 ± 5.9 and the mean SBP of the cases in Group 2 two hrs before induction was 121.13 ± 9.27 at Pre-Operative was 123.8 ± 7.83, After Induction was 121.33 ± 8.29 , at 2hr was 118.2 ± 8.18 , at 4 hr was 118.6 ± 6.37 , at 6 hr was 119.67 ± 7.99 , at 12 hr was 119.13 ± 8.77 and at 24 hr in Group 2 was 120.4 ± 8.04 . No significant difference was noted in the mean SBP of cases at different time intervals between 1st Group and 2nd Group.

**Table 6: mean DBP of patients at distinct time intervals.**

| | GROUP1 | GROUP2 | |
|---|---|---|---|
| **DBP** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| 2 hrs before induction(mmHg) | 79.13 ± 6.47 | 79.67 ± 6.06 | 0.743# |
| preoperative | 81.4 ± 5.83 | 81.53 ± 5.19 | 0.926# |
| After Induction | 78.27 ± 4.75 | 78.47 ± 5.19 | 0.877# |
| 2hr | 77.4 ± 4.46 | 75.2 ± 4.38 | 0.059# |
| 4hr | 77.13 ± 4.29 | 75.27 ± 4.02 | 0.087# |
| 6hr | 77.8 ± 3.91 | 76.87 ± 5.48 | 0.079# |
| 12hr | 77.33 ± 5.07 | 75.6 ± 4.8 | 0.179# |
| 24hr | 78.07 ± 3.88 | 76.07 ± 6.86 | 0.052# |

#Statistically not significant.

In the study, mean DBP of the cases in Group 1 two hrs before induction was 79.13 ± 6.47 at Pre-Operative was 81.4 ± 5.83 , After Induction was 78.27 ± 4.75, at 2hr was 77.4 ± 4.46, at 4 hr was 77.13 ± 4.29 , at 6 hr was 77.8 ± 3.91, at 12 hr was 77.33 ± 5.07 and at 24 hr in 1st Group was 78.07 ± 3.88 and the mean DBP of the cases in Group 2 two hrs before induction was 79.67 ± 6.06,at Pre-Operative was 81.53 ± 5.19, After Induction was 78.47 ± 5.19 , at 2hr was 75.2 ± 4.38, at 4 hr was 75.27 ± 4.02 , at 6 hr was 76.87 ± 5.48, at 12 hr was 75.6 ± 4.8 and at 24 hr in Group 2 was 76.07 ± 6.86. No significant difference was noted in the mean DBP of cases at distinct time intervals between 1st Group and 2nd Group.

**Table 7: mean map of patients at distinct time intervals.**

| | GROUP1 | GROUP2 | |
|---|---|---|---|
| **MAP** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| 2 hrs before induction(mmHg) | 93.43 ± 5.94 | 93.03 ± 6.33 | 0.802# |
| Preoperative | 95.7 ± 5.43 | 95.37 ± 5.08 | 0.807# |
| After Induction | 92.77 ± 4.72 | 92.83 ± 5.2 | 0.959# |
| 2hr | 92.03 ± 4.15 | 89.13 ± 6.84 | 0.066# |
| 4hr | 91.43 ± 4.22 | 89.47 ± 3.95 | 0.068# |
| 6hr | 92.33 ± 3.71 | 90.13 ± 5.43 | 0.074# |
| 12hr | 92.17 ± 4.81 | 89.7 ± 5.4 | 0.067# |
| 24hr | 92.47 ± 4.11 | 89.97 ± 6.72 | 0.072# |

#Statistically not significant.

In the study, mean MAP of the cases in Group 1 two hrs before induction was 93.43 ± 5.94, at Pre-Operative was 95.7 ± 5.43, After Induction was 92.77 ± 4.72, at 2hr was 92.03 ± 4.15, at 4 hr was 91.43 ± 4.22, at 6 hr was 92.33 ± 3.71, at 12 hr was 92.17 ± 4.81 and at 24 hr in 1st Group was 92.47 ± 4.11 and the mean MAP of the cases in Group 2 two hrs before induction was 93.03 ± 6.33 ,at Pre-Operative was 95.37 ± 5.08, After Induction was 92.83 ± 5.2 , at 2hr was 89.13 ± 6.84, at 4 hr was 89.47 ± 3.95 , at 6 hr was 90.13 ± 5.43,at 12 hr was 89.7 ± 5.4 and at 24 hr in Group 2 was 89.97 ± 6.72.No significant difference was noted in mean MAP of cases at different time intervals between 1st Group and 2nd Group .

**Table 8: mean SPO2 of patients at distinct time intervals.**

| | GROUP1 | GROUP2 | |
|---|---|---|---|
| **SPO2** | **Mean ± SD** | **Mean ± SD** | **P-Value** |
| 2 hrs before induction(mmHg) | 97.83 ± 1.26 | 97.73 ± 1.14 | 0.749# |
| Preoperative | 97.43 ± 1.52 | 98.03 ± 1.03 | 0.080# |
| After Induction | 98.8 ± 1.13 | 99.1 ± 0.96 | 0.271# |
| 2hr | 97.7 ± 1.37 | 97.67 ± 1.09 | 0.917# |
| 4hr | 97.23 ± 1.25 | 97.57 ± 1.28 | 0.312# |
| 6hr | 97.43 ± 2.28 | 97.4 ± 1.06 | 0.321# |
| 12hr | 97.63 ± 1.43 | 97.67 ± 1.18 | 0.317# |
| 24hr | 97.73 ± 1.28 | 97.57 ± 1.3 | 0.620# |

#Statistically not significant.


ISSN (O): 2687-5365; ISSN (P): 2753-6556

In the study, mean SPO2 of the cases in Group 1 two hrs before induction was 97.83 ± 1.26 at Pre-Operative was 97.43 ± 1.52 , After Induction was 98.8 ± 1.13 , at 2hr was 97.7 ± 1.37, at 4 hr was 97.23 ± 1.25 , at 6 hr was 97.43 ± 2.28, at 12 hr was 97.63 ± 1.43 and at 24 hr in 1st Group was 97.73 ± 1.28 and the mean SPO2 of the cases in Group 2 two hrs before induction was 97.73 ± 1.14 ,at Pre-Operative was 98.03 ± 1.03, After Induction was 99.1 ± 0.96, at 2hr was 97.67 ± 1.09, at 4 hr was 97.57 ± 1.28 , at 6 hr was 97.4 ± 1.06 , at 12 hr was 97.67 ± 1.18 and at 24 hr in Group 2 was 97.57 ± 1.3 . No significant difference in mean SPO2 of cases at distinct time intervals between 1st Group and 2nd Group.

In Our study out of 30 patients in Group1 Pruritis was in 20.0% of cases, Erythema in 10.0% of cases, Dermatitis in 6.7% of cases, Nausea in 36.7% of Cases, Vomiting in 16.7% of cases, Gastritis in 20.0% of cases and Dizziness in 13.3% of cases and out of 30 patients in Group2 16.7% of cases having Pruritis, Erythema in 20.0% of cases, Dermatitis in 23.3% of cases, Nausea in 73.3 of Cases, Vomiting in 30.0% of cases, Gastritis in 43.3% of cases and Dizziness in 30.0% of cases. Adverse effects were more in Group2 as compared to Group1 but no significant difference was noted in Adverse effects in patients in between Group1 and Group2 except in the Nausea effect.

## DISCUSSION

In our randomised controlled study, 60 adult patients of either sex, between the ages of 18 and 60, and categorized as ASA grade I or II who were scheduled for laparoscopic cholecystectomy were randomly allocated into 2 groups using a computer-generated randomization procedure.In group 1, transdermal patch of diclofenac sodium was applied while in group 2,intramuscular injection having diclofenac sodium was given.

The demographic profile including age, gender and weight were compared between the 2 groups.

Mean age of patients in 1st group was (41.43 ± 11.85) and in 2nd group was (43.33 ± 13.3) years with p value of 0.268 which was statistically insignificant.

Out of 60 patients, in Group 1 there were 25 female and 5 male while in Group 2 24 female and 6 male patients with p value of 0.739 which was found to be statistically insignificant.

Mean weight of patients in 1st group was (61.6 ± 12.7) and in 2nd group was (58.27 ± 12.0) with p value of 0.077 which was statistically insignificant. The difference was not statistically significant in weight, ASA grade, sex, or mean age between the 2 groups.

**VAS (Visual Analog Score) Score**

In our study, we measured mean VAS score of each patient after completion of surgery at 2h, 4h, 6h, 12h and 24 hours for the pain assessment in the range of 0-10 (where 0= no pain and 10= worst possible pain imaginable). We observed that mean VAS score of the patients at 2 hr in 1st Group was (3.13 ± 0.51), and in 2nd Group was (4.33 ± 1.03).VAS score was significantly higher in Group 2 as compared to Group 1 with a p value of 0.000.

In our study, mean VAS score of the patients at 4 hr in 1st Group was (2.23 ± 0.77), and in 2nd Group was (3.13 ± 0.9). VAS score was significantly higher in Group 2 as compared to Group 1 with a p value of 0.000. No significant difference was noted in mean VAS score of patients between 1st Group and 2nd Group at 6, 12 and 24 hour intervals.

This depicts that mean Visual Analog Score was much greater in Group 2 as compared to Group 1.

In accordance with our study, Ural SG et al,[15] did a comparison on analgesic effects of diclofenac sodium, its oral form, transdermal and IM, in early postoperative period in laparoscopic cholecystectomy operations and found that Post operative VAS pain scores were much lesser in the 30th & 60th minutes in transdermal group and in 60th minute in intramuscular group when compared with the 15th minute scores ($p<0.05$).

In accordance with our study, Banjare M, Kabir KK, Agarwal A, Arora KK,[16] did a study to assess the safety & efficacy of using an intramuscular diclofenac injection in conjunction with a transdermal patch and found that the VAS score at 8 hours was more in diclofenac injection group (5.92 ± 0.41) than transdermal patch group(4.41 ± 0.83), with p value of 0.00 and hence considered statistically significant.

**Rescue Analgesia:** In this study, we evaluated post-operative pain in patients at 2,4,6,12 and 24 hours using VAS score. Iif the Visual Analog Score was more than or equal to 4, rescue analgesia was given as injection tramadol 50 mg iv stat.

We observed that out of 30 patients, 4 patients (13.3%) in group 1 required rescue analgesia at 2 hrs, and zero patients required rescue analgesia at 4 hours in group 1 with p value of 0.001 and 16 patients (53.3%) in group 2 required rescue analgesia at 2 hours, and 9 patients (30.0%) required rescue analgesia at 4 hours with p value of 0.001 which was statistically significant. None of the individuals required rescue analgesia at 6,12 and 24 hours in either group.

This depicts that the significantly more no. of patients needed rescue analgesic in group 2 in comparison to group 1 at 2 hours and 4 hours.

Similar results were seen in a study done by Samal S et al,[4] did a comparative study between transdermal diclofenac with IM diclofenac for pain in post-operative period evaluation and found that the no. of times the rescue analgesic required during post-operative period in both the groups was significantly greater in IM diclofenac group i.e. Group I. The difference in mean no. of times rescue analgesic was required was found to be significant statistically in laparoscopic & gynaecologic surgeries and much significant in orthopaedic surgeries (P = 0.003).

In consensus to our study Borkotoky D,Sequeira J2 did a Comparative Study to Determine the


ISSN (O): 2687-5365; ISSN (P): 2753-6556

Effectiveness of one Dose of Transdermal patch containing Diclofenac with IM Diclofenac Injection Postoperatively and found that One patient in Group B (Intramuscular diclofenac injection) was administered with Injection Tramadol during the 6th hour and the results showed a significant difference at 6th hour between group A & group B (pvalue = 0.049). Requirement of Rescue analgesic is less with transdermal patch containing diclofenac than IM diclofenac during postoperative analgesia.

**QOR-15 (Quality Of Recovery-15 Score)**

In our study, we used Quality of Recovery-15 (QOR-15) score to evaluate the quality of postoperative functional recovery. The questionnaire consisted of 15 items. The total sum of scores ranged from 0-150 and was further divided into 4 categories: 0-40 (poor recovery group), 41-80 (good recovery group), 81-120 (moderate recovery group) and 121-150 (excellent recovery group).

Question no.1-4 and 13 assessed physical comfort by enquiring about breathing, food, rest, sleep, nausea and vomiting. Question 5 and 8 assessed physical independence by enquiring about personal hygeiene and physical activities and return to work. Question 11 and 12 assessed about pain by enquiring about pain's severity. Question 9,10,14 and 15 assessed emotional state by enquiring about comfort, general well being, anxiety and depression.

The mean Total QOR-15 Score of the cases in 1st Group was (128.67 ± 11.73) and the mean Total QOR-15 Score of the cases in 2nd Group was (83.4 ± 9.53). QOR-15 score was much greater in Group 1 in comparison to Group 2 with a p value of 0.000. This depicts that mean Quality Of Recovery-15 score was significantly greater in Group 1 in comparison to Group 2. This depicts that patient's satisfaction was higher in group 1 as compared to group 2.

In a study done by Chazapis M, Walker EMK., Rooms M.A., Kamming, D. and Moonesinghe SR,[17] for measuring quality of recovery-15 after day care surgery and found that following day case surgery, the QoR-15 is a therapeutically practical and acceptable patient-centered outcome measure. The score showed strong responsiveness, validity, and reliability.

**Hemodynamic Parameters**

In our study we found out that there was not any significant change in the heart rate when applying patch (76.12 ± 9.23) and (78.07 ± 8.68) beats/minute with p-value of 0.402 between group 1 & 2 respectively. Also at pre-operative, there was no significant change in mean heart rate (78.07 ± 9.03) and (80.07 ± 8.92) beats/minute with p-value of 0.392 between group 1 & 2 respectively.

Similarly, there was not any significant change in mean heart rate after induction and at 2,4,6,12 and 24 hrs after surgery in both groups.

There was no significant change in mean SBP (125.13 ± 6.0) and (123.8 ± 7.83) mm Hg with p-value of 0.462 between group 1 and 2 respectively.

Similarly, there was not any significant change in the mean SBP after induction and at 2,4,6,12 and 24 hrs after surgery in both the groups.

at pre-operative, there was not any significant change in mean DBP (81.4 ± 5.83) and (81.53 ± 5.19) mm Hg with p-value of 0.926 between 1st group and 2nd group respectively.

Similarly, there was not any significant change in the mean DBP after induction and at 2,4,6,12 and 24 hrs after surgery in both groups.

Also at pre-operative, there was not any significant change in mean MAP (95.7 ± 5.43) and (95.37 ± 5.08) mm Hg with p-value of 0.807 between 1st group and 2nd group respectively.

Similarly, there was not any significant change in the mean MAP after induction and at 2,4,6,12 and 24 hrs after surgery in both groups.

at pre-operative time, there was not any significant change in mean SPO2 (97.43 ± 1.52) and (98.03 ± 1.03) with p-value of 0.807 between 1st group and 2nd group respectively.

Similarly, there was not any significant change in the mean SPO2 after induction and at 2,4,6,12 and 24 hrs after surgery in both groups.

In consensus to our study, Samal S,Jena SK, Behera BK,[4] did a comparative study for analgesia in post-operative period between transdermal patch of diclofenac and IM diclofenac and found that the difference in the mean pulse rate was insignificant in between the two groups among gynaecological (P = 0.819), laparoscopic (P = 0.287) & orthopedic surgeries (P = 0.957) Likewise, the difference in the mean MAP, O2 saturation & respiratory rate was statistically insignificant in between the 2 groups among different categories of the surgeries (P > 0.05).

Group1 has lower incidences of post operative nausea as compared to group 2 (p =0.004). This also concludes that overall number of adverse events were less in group 1 when compared to group 2 though not statistically significant.

In consensus to our study Shah B,Boat AS,[13] did a study for comparison of Transdermal Patch containing diclofenac with IM Diclofenac Injection In Patients With Inguinal Hernia Surgery for evaluating Pain Relief in post-operative period and found that administration as transdermal patch produced a smaller number of the systemic adverse effects than IM injection and showed fewer local side effects.

## CONCLUSION

Visual analog score was higher in inj. Diclofenac group as compared to transdermal diclofenac patch and no. of patients requiring rescue analgesia was also higher in inj. Diclofenac group. We also observed that the Quality of Recovery-15 score was significantly higher in transdermal diclofenac patch group as compared to inj. Diclofenac group. We also concluded that the inj. Diclofenac group experienced


ISSN (O): 2687-5365; ISSN (P): 2753-6556

a slightly higher incidence of drug-related adverse events than the transdermal patch of diclofenac group, with statistically significant higher incidence of nausea. The transdermal diclofenac sodium diethylamine patch was more efficient drug and was well tolerated than inj. Diclofenac sodium.

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ISSN (O): 2687-5365; ISSN (P): 2753-6556