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RESEARCH ARTICLE
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EFFICACY OF TRANSDERMAL KETOPROFEN PATCH VS DICLOFENAC PATCH IN LAPAROSCOPIC CHOLECYSTECTOMY: A RANDOMIZED CONTROLLED TRIAL

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Abstract:
Background: Pain which occurs due to tissue damage modulates the somatosensory system, which increases the responsiveness of central and peripheral pain pathways. All methods of post operative pain analgesia must meet three basic criteria, it must be safe, effective and predictable.[2] **Objective:** to compare the effectiveness of a transdermal ketoprofen patch combined with a diclofenac patch in patients undergoing general anaesthesia during laparoscopic cholecystectomy **Methods:** Randomized controlled study was conducted at Department of Anaesthesiology, Rohilkhand Medical College and Hospital, Bareilly, UP. Total 76 patients were taken in the study which were divided into two groups, 38 patients in each group. In group 1, patients were given a transdermal patch containing ketoprofen and in group 2, patients were given a transdermal patch containing sodium diclofenac. 10-point Visual Analogue Scale (VAS) at immediate post operative, 2, 4, 6, 12 and 24 hours, Time to first rescue analgesia, Effectiveness of pain treatment in first 24 hours using APS-POQ-R, Haemodynamic changes adverse effects of patch were assessed. **Result:** The demographic profile was similar in both the groups Haemodynamic changes. There was no significant variation among both the groups in terms of these parameters. More VAS in diclofenac group as compared to ketoprofen group. VAS score was insignificant at 12 and 24 hour postoperatively. There was no difference significantly among the two groups in the time taken to first rescue analgesia. APS-POQ-R. assesses six aspects of quality: as pain intensity and relief, Impact of pain on activity and sleep, negative emotions, usefulness of information about pain treatment, the capacity to take part in decisions regarding pain management, usefulness of information about pain treatment and assessment of therapy side effects and patient satisfaction with pain management. Compared to the diclofenac group, the ketoprofen group experienced lower levels of pain severity, Both groups saw fewer side effects, which were not statistically significant
Conclusion: Transdermal ketoprofen patch is effective and safe in management of acute post operative pain with better pain relief, longer duration of action, better in reducing the severity of pain in post operative period and lesser adverse effects in laparoscopic cholecystectomy

Keywords: Transdermal ketoprofen patch, acute post operative pain, adverse effects, laparoscopic cholecystectomy

INTRODUCTION: The most dreaded aspect of any surgical procedure, as well as the post-operative phase, is pain. The International Association of Pain defines pain as "an unpleasant sensory and emotional experience associated with either actual or potential tissue damage." Pain is a complicated, multidimensional sensation. A fundamental and crucial component of the patient's care, post-operative pain management plays a significant role in the patient's transition from the recovery unit to the home environment.[1]

There are several ways to give analgesic medications, including transdermal, parenteral, inhalational, and oral. The oral route entails the danger of first-pass metabolism and significant drug loss prior to systemic circulation absorption. Administering drugs parenterally can be quite unpleasant, requires skilled staff, and may have unintended consequences if the drug concentration in the plasma suddenly rises.[2]

Minimally invasive laparoscopic procedures result in shorter hospital stays, lower rates of morbidity, and earlier discharge. For hundreds of years, people have been using opioids to treat anxiety and lessen surgical pain. Diclofenac is frequently used during the post-operative phase of NSAIDS. Diclofenac is an anti-inflammatory, antipyretic, and analgesic medication.[1] It is a non-specific inhibitor of the aryl acetic acid group's cyclooxygenase enzyme. It works by strongly inhibiting cycle-oxygenase, lowering the release of arachidonic acid, and increasing the absorption of arachidonic acid. As a result, it inhibits both the lipoxygenase and cyclooxygenase pathways.[3] Diclofenac reduces inflammation and by extension reduces nociceptive pain and combats fever.

Like other NSAIDs, Diclofenac is frequently used as a first-line treatment for a number of inflammatory and acute and chronic pain problems. Although diclofenac is fully absorbed from the digestive tract, only about 60% of the medication is anticipated to survive the first stage of metabolism unaltered. Many topical treatments are absorbed percutaneously and produce therapeutically significant plasma concentrations. PGs are involved in inflammation and pain signalling. Adding two chlorine groups locks the phenyl ring in maximal torsion, which seems to be linked to increased potency. PGE2 can penetrate the blood-brain barrier and then act on excitatory G q EP3 receptors on hypothalamic thermoregulatory neurons. A fever is caused by this activation, which also causes a decrease in heat loss and an increase in heat generation. NSAIDs lower the activity of these neurons by blocking the production of PGE2. Post-synaptically, it inhibits inhibitory glycinergic neurons and raises the activity of AMPA and NMDA receptors. When combined, these result in a lower activation threshold, which permits pain signals to be produced by stimuli of low intensity. It has been suggested that it is more significant in inflammatory, painful diseases like arthritis. NSAIDs significantly relieve inflammatory pain by blocking peripheral and central sensitization through these mechanisms. Dose-proportional absorption occurs between 25 and 150 mg. Food administration has no discernible effects. Diclofenac is converted to glucuronic acid, sulphate, and taurine in addition to undergoing oxidative degradation to hydroxy metabolites. The main metabolite produced by CYP2C9 is 4'-hydroxy diclofenac. Although parenteral administration is the most desired way of use, transdermal or suppository administration is also an option.[1]

Though transdermal patches of diclofenac and ketoprofen have been found to reduce postoperative pain, their impact on quality of analgesia is yet to be studied. Therefore, the present study is undertaken in patients undergoing elective laparoscopic cholecystectomy under general anaesthesia to evaluate and compare the efficacy of transdermal diclofenac patch with transdermal ketoprofen patch for post operative analgesia.

Material and Methods: This Randomized controlled study was conducted among Patients admitted for laparoscopic cholecystectomy under general anaesthesia in Department of Anaesthesiology, Rohilkhand Medical College and Hospital, Bareilly after obtaining Institutional

Ethical Committee's approval. Duration of study was One year from August 2023 to July 2024

Inclusion criteria: Patients fulfilling the following:
- American Society of Anaesthesiologist grade I and II
- Either sex
- Age between 18 to 60yrs
- Weight between 40 to 80kgs[1]

Exclusion criteria: Patients having history of:
- Dermatitis
- Hypersensitivity reaction
- Bleeding disorder
- GI disorder like ulcer
- Patients on antipsychotics
- Hepatic disease
- Renal disease[1]

Sample size: In our study a total of 38 patients were taken in each group, which is statistically calculated by using software Power and sample size program.
Alpha-0.05 Power- 0.9
Delta- 0.6
Sigma- 0.8
Alpha – Type 1 error

METHODOLOGY

Institutional Ethics Committee approval was taken prior to conducting this study and the study was registered in CTRI(CTRI/2024/02/063154). Thorough pre-anaesthetic check- up was done a day before surgery and informed written consent for participation in the study was taken. CBC, urine routine and microscopy, blood urea nitrogen, serum creatinine, fasting blood and post-meal blood sugar, an x-ray of the chest, a PA view, and an ECG are all part of standard investigations that was done.

The patients were randomly divided among two groups: Group 1 and 2 using Computer Generated Random Number.

In group 1, Patients were given a transdermal patch containing ketoprofen (each patch of 70cm^2 contains 30mg).

In group 2, Patients were given a transdermal patch containing sodium diclofenac (each patch of 50cm^2 contains 100mg).

The patch application site was thoroughly washed with clear water before being dried. Before surgery, the patients were maintained NPO for eight hours. Two hours before the induction of anaesthesia, the patch was put on intact, dry, clean and hairless skin. When entering the preoperative room, the patient's systolic as well as diastolic blood pressure, and heart rate were recorded.

Multiple parameter monitoring including ECG, NIBP, and pulse oximetry were used in the operating room. Non-invasive brachial oscillometry was used to measure blood pressure (systolic, diastolic, and mean), and an electrocardiogram was used to measure heart rate.[1] Ongoing parameter were monitored.

The intravenous administration of butorphanol 0.02 mg/kg and midazolam 0.02 mg/kg. Pre-oxygenation was done for 3 minutes, after which I.V. propofol 2 mg/kg was used to induce anaesthesia. Vecuronium 0.1 mg/kg was then be given to help with tracheal intubation. A skilled anaesthesiologist performed laryngoscopy and tracheal intubation using the proper sized, cuffed

endotracheal tube, 3 minutes after administering vecuronium.

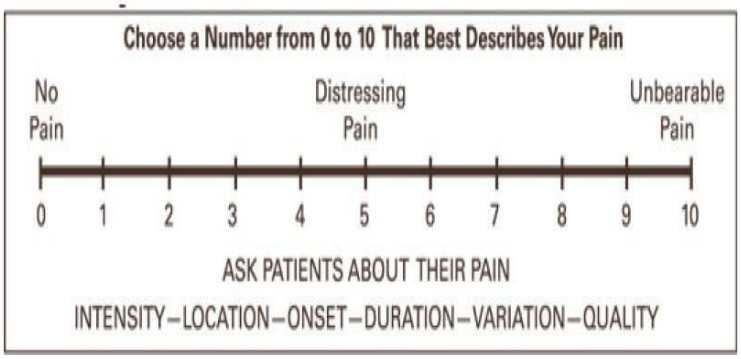
Throughout the procedure, the patient's heart rate and blood pressure readings (Systolic, Diastolic, and Mean Arterial Pressure) was monitored. Nitrous oxide 50 percent in oxygen and isoflurane was used to maintain anaesthesia. The mechanical ventilation of the patients lungs was minutely regulated to 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 following surgery and residual neuromuscular block was antagonized with appropriate doses of neostigmine (0.05 mg/kg) and glycopyrrolate (0.01 mg/kg). Following confirmation of recovery from anaesthesia and muscle relaxation, extubation was performed after thorough suctioning.

In the immediate post operative phase, severity of pain was recorded using 'the 10-point' Visual Analogue Scale (VAS)[1]. The patients were asked to rate their pain intensity after 2, 4, 6, and 12 hours. Until the requirement of first rescue analgesia, the postoperative analgesia duration was calculated. Every time the patient reported pain (VAS>4), tramadol hydrochloride 2 mg/kg was administered as an emergency analgesic.

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

Visual Analogue Scale



The effectiveness of pain alleviation during the first 24 hours after surgery was assessed, using the prescribed questionnaire, the Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R). The effect of pain on quality of life and assess the quality of pain relief was studied using Revised American Pain Society Patient Outcome Questionnaire (APS-POQ-R). It assesses six aspects of quality: as pain intensity and relief (Questions 1, 2 and 3 assessed pain in terms of severity in first 24hrs); Impact of pain on activity and sleep (Function interference due to pain was assessed in question 4); negative emotions (Emotion and mood assessment was done in question number 5); adverse effects of treatment (Nausea, itching, etc. in question 6); Participation in pain treatment decisions and the value of knowledge regarding pain management (question 7 and 8); patient satisfaction (question 9 and 10); and use of non-pharmacological strategies (question 11 and 12 assessed the use of non-pharmacological methods like meditation, music, massage, heat, etc.[4]

Adverse effects of the patch include:

- Local – Pruritis, Erythema, Dermatitis, Hyperhidrosis.
- Systemic – Nausea, Vomiting, Dizziness and Gastritis.[1]
- The incidence of adverse effects was noted and compared.

Statistical analysis:

Data was entered on Microsoft Excel spreadsheet and statistical analysis was done using a licensed

version of SPSS 23.0. Descriptive analysis was done by calculating proportions, means and standard deviation. Appropriate statistical test was applied depending on the distribution and type of data. $p<0.05$ was considered statistically significant.

Results: In our study, out of total 38 patients in each group, mean age of group 1 patients was 41.61±12.69 years and that of group 2 was 42.37±13.42 years. There was no major difference in age of both the groups patients.

In our study, out of total 38 patients in group 1, there were 8 males and 30 females and that in group 2 there were 11 males and 27 females. There was no remarkable difference in gender of patients in both the groups. In our study, out of total 38 patients in each group, the mean weight of patients in group 1 was 55.21±10.40 kg and that in group 2 the mean weight was 54.42±12.08 kg. There was no significant difference in weight of patients in between both the groups.

Table – 1 Comparision Of Mean Vas Score At Various Time Intervals In Between Group 1 And Group 2

Variables	GROUP	N	Mean	Std. Deviation	P-Value
VAS Score 2hr	1	38	3.92	0.98	0.028*
	2	38	4.46	1.12	
VAS Score 4hr	1	38	2.48	0.73	0.019*
	2	38	2.97	1.03	
VAS Score 6hr	1	38	1.53	0.65	0.049*
	2	38	1.96	1.16	
VAS Score 12hr	1	38	0.84	0.92	0.338#
	2	38	1.05	0.98	
VAS Score 24hr	1	38	0.55	0.86	0.354#
	2	38	0.74	0.86	

statistically significant *, statistically not significant #

Mean VAS score at 2 hours after surgery for group 1 was 3.92±0.98 and for group 2 was 4.46±1.12. At 4 hours it was 2.48±0.73 for group 1 and 2.97±1.03 for group 2. At 6 hours it was 1.53±0.65 for group 1 and 1.96±1.16 for group 2. Thus, statistically significant difference was found between both the groups at 2, 4 and 6 hours after surgery. VAS score was statistically not significant at 12 and 24 hours post-operatively which was recorded at 12 hours as 0.84±0.92 for group 1 and 1.05±0.98 for group 2 and at 24 hour, 0.55±0.86 for group 1 and 0.74±0.86 for group 2.

In our study, which included 38 patients in each group, we found that the average time to first rescue analgesia was 1.34±1.91 hours for group 1 and 1.24±1.60 hours for group

2. The time it took for the two groups to get their first dose of rescue analgesia did not differ significantly.

Table -2 Comparison Of (Aps-Poq-R) Q-1 To Q-10 In Between Group 1 And Group 2

Variables	GROUP	N	Mean	Std. Deviation	P-Value
(APS-POQ-R) Q-1 (out of 10)	1	38	0.53	0.80	0.272#
	2	38	0.74	0.86	
(APS-POR-R) Q-2 (out of 10)	1	38	3.29	1.41	0.002*
	2	38	4.32	1.38	
(APS-POQ-R) Q-3(out of 100%)	1	38	32.89	13.13	0.177#
	2	38	28.68	13.79	
(APS-POQ-R) Q-4 (out of 40)	1	38	8.79	4.21	0.013*
	2	38	11.68	5.59	
(APS-POQ-R) Q-5 (out of 40)	1	38	8.92	4.18	0.030*
	2	38	11.29	5.09	
(APS-POQ-R) Q-6 (out of 40)	1	38	8.24	3.61	0.001*
	2	38	11.50	4.62	
(APS-POQ-R) Q-7(out of 100%)	1	38	85.60	11.10	0.0413*
	2	38	80.84	8.74	
(APS-POQ-R)	1	38	10.00	.000[a]	------

Q-8 (out of 10)	**2**	**38**	**10.00**	**.000[a]**	
(APS-POQ-R)	**1**	**38**	**8.83**	**1.11**	**0.0299***
Q-9 (out of 10)	**2**	**38**	**8.18**	**1.43**	
(APS-POQ-R)	**1**	**38**	**9.03**	**0.75**	
Q-10 (out of 10)	**2**	**38**	**8.72**	**1.29**	**0.2043#**

statistically significant *, statistically not significant #

In our study, which included 38 patients in both groups, the mean score for question 1 on the APS-POQ-R qualitative analysis of pain was 0.53±0.80 for group 1 and 0.74±0.86 for group 2. Regarding this subject, no significant difference was found among the two groups. The average score on question 2 was 3.29±1.41 for group 1 and 4.32±1.38 for group 2. In this question, there was a statistically significant difference between the two groups. In question 3, no significant difference was found in both groups with the mean score of 32.89±13.13 in group 1 and 28.68±13.79 in group 2. Statistically significant
difference was seen in question 4, 5, 6 and 7 with mean score in question 4 as 8.79±4.21 in group 1 and 11.68±5.59 in group 2. The mean score in question 5 was 8.92±4.18 in group 1 and 11.29±5.09 in group 2. The mean score in question 6 was 8.24±3.61 in group 1 and 11.50±4.62 in group 2. In question 7, the mean score in group 1 was 85.60±11.10 and in group 1 the score was 80.84±8.74 in group 2. There was no statistically significant difference in between both the groups in question 8. Question 9 shows the score of
8.83±1.11 in group 1 and 8.18±1.43 in group 2 and significant difference was found in between both the groups. The mean score in question 10 was 9.03±0.75 in group 1 and in group 2 the score was 8.72±1.29. The score was statistically insignificant.

Table -3 Comparison Of (Aps-Poq-R) Q-11 And Q-12 In Between Group 1 And Group 2

Variables	**GROUP**	**YES**	**NO**	**P-Value**
	1	0	38	
(APS-POQ-R) Q-11	2	0	38	**1.000#**
	GROUP	**YES**	**NEVER**	**P-Value**
	1	0	38	
(APS-POQ-R) Q-12	2	0	38	**1.000#**

Statistically not significant.

There was no significant difference in between both the groups in question 11 and 12.

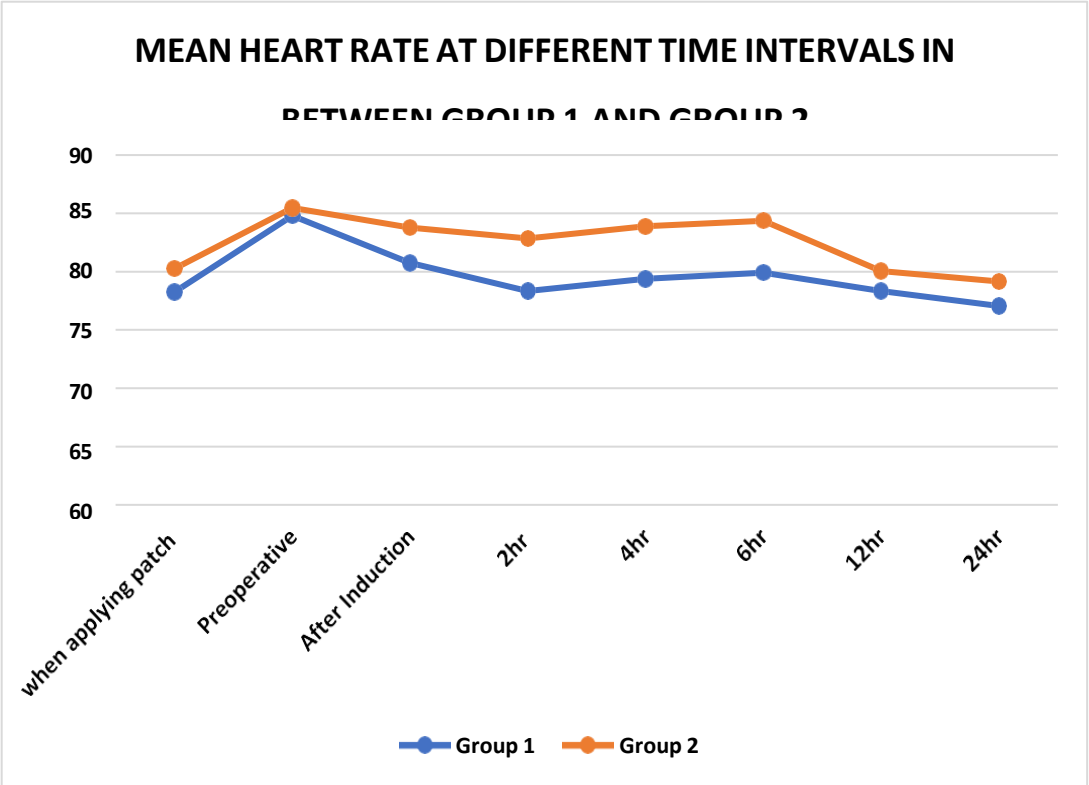
TABLE -4 SIDE EFFECTS IN BETWEEN GROUP 1 AND GROUP 2

SIDE EFFECTS	**GROUP 1**	**GROUP 2**	**P-Value**
Pruritis	7	9	0.527#
Erythema	3	9	0.059#
Dermatitis	3	10	0.067#
Nausea	13	21	0.064#
Vomiting	6	13	0.064#
Gastritis	6	13	0.063#
Dizziness	4	11	0.083#

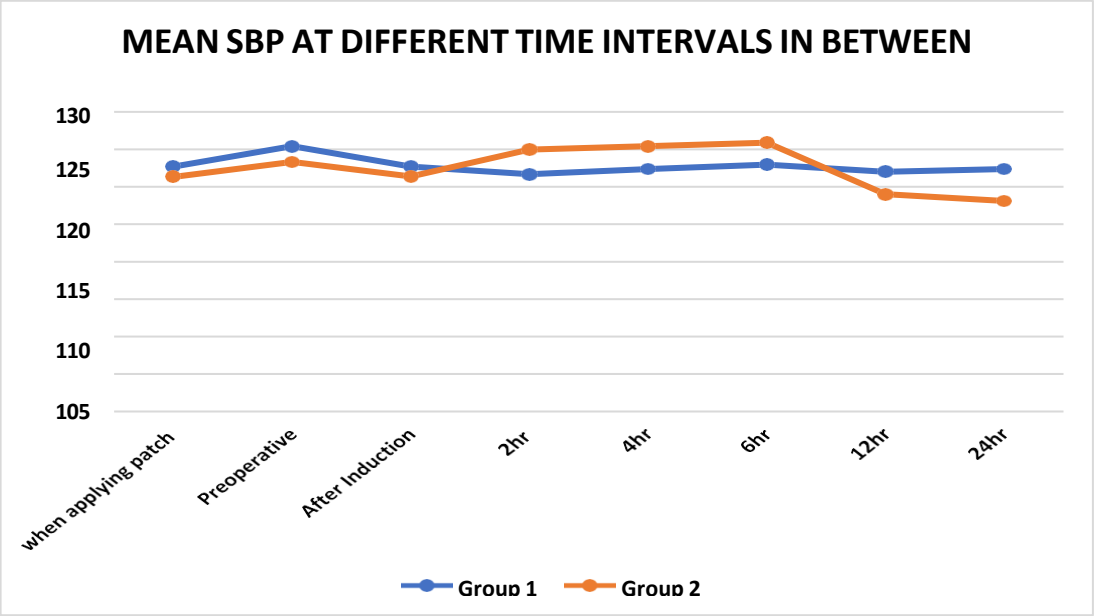
Statistically not significant

In our study of 38 patients in each group, it was observed that only few patients showed side effects as 7 patients in group 1 and 9 patients in group 2 complained of pruritis. Patients complaining of erythema was 3 in group 1 and 9 in group 2. The number of patients having dermatitis in group 1 was 3 and 10 in group 2. Nausea was observed in 13 patients in group 1 and 21 patients in group 2. 6 patients in group 1 and 13 patients in group 2 complained of vomiting. Gastritis was complained of,

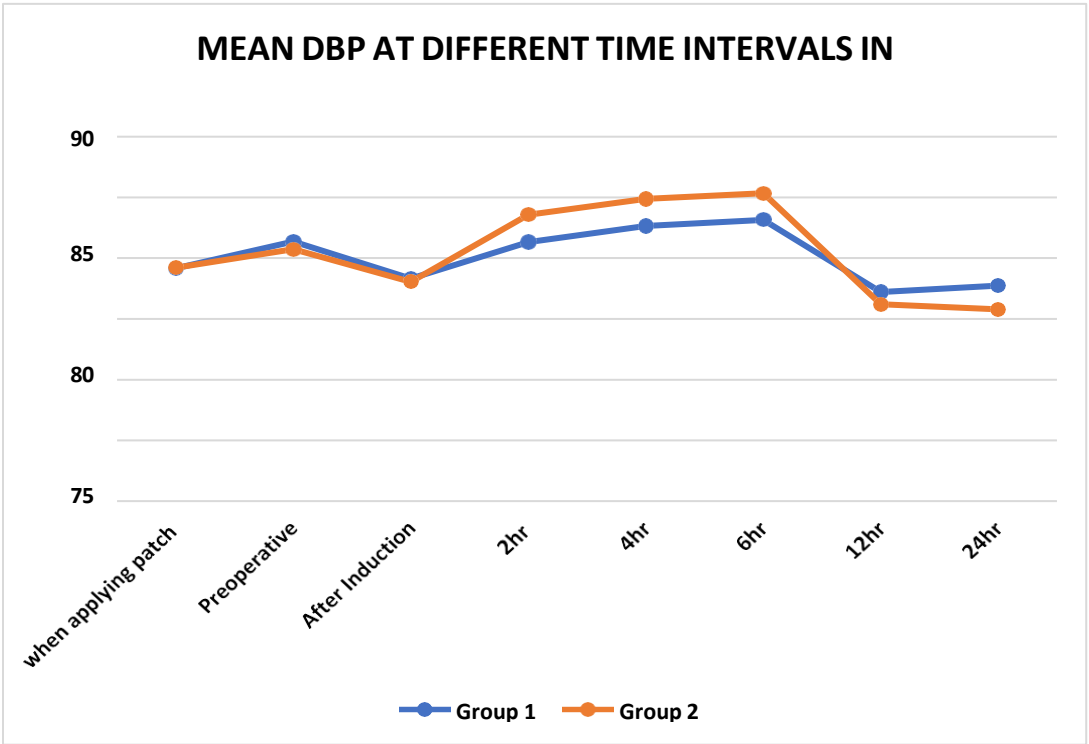
in 6 group 1 patients and 13 group 2 patients. 4 group 1 patients and 11 patients in group 2 complained of dizziness. There was no significant difference in between both the groups in all these parameters.
In our study, with total 38 patients in each group, mean heart rate when applying the patch was 78.26±9.41 bpm in group 1 and 80.26±8.98 bpm in group 2. Heart rate in preoperative room was 84.79±10.89 bpm in group 1 and in group 2 heart rate was 85.47±10.14 bpm. After induction of anaesthesia heart rate was 80.74±11.79 bpm in group 1 and in group 2 it was 83.79±10.97 bpm. After 2 hours of surgery heart rate in group 1 was 78.32±8.84 bpm and in group 2 heart rate was 82.84±11.77 bpm. Heart rate was 79.37±8.45 bpm in group 1 and 83.89±11.79 bpm in group 2 after 4 hours of surgery. After 6 hours of surgery heart rate was 79.92±8.03 bpm in group 1 and 84.37±11.23 bpm in group 2. Heart rate was 78.32±9.18 bpm in group 1 and in group 2 heart rate was 80.05±9.65 bpm after 12 hours. After 24 hours of surgery heart rate was 77.05±6.85 bpm in group 1 and in group 2 heart rate was 79.16±8.78 bpm.



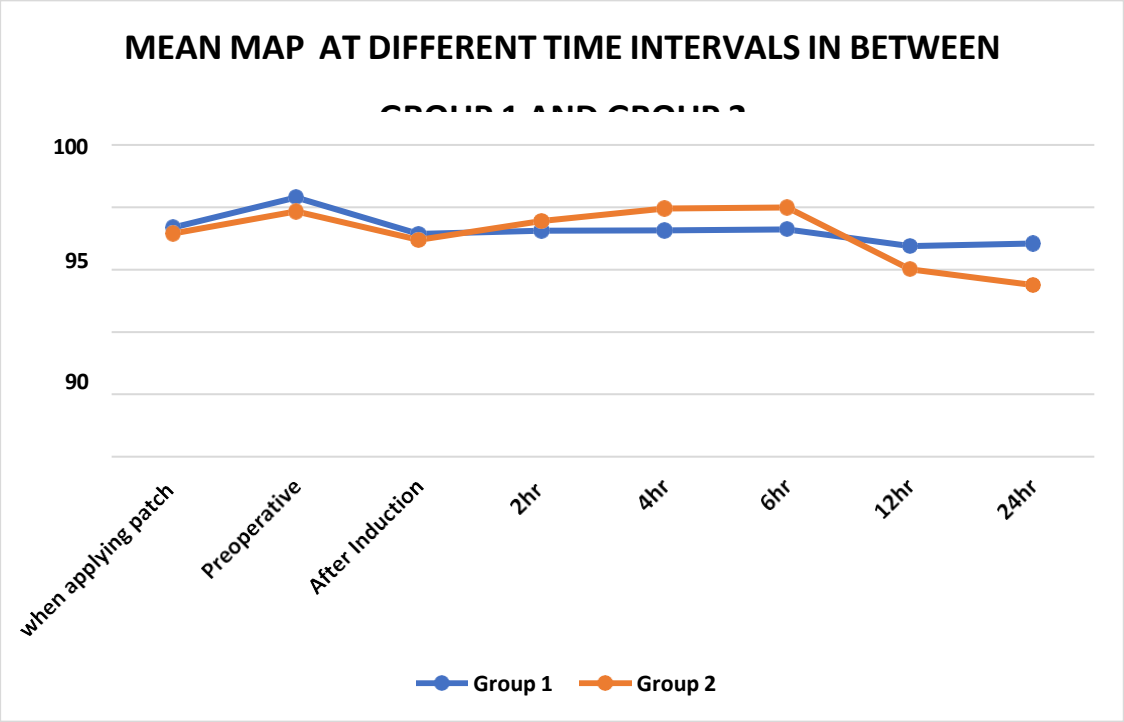
In our study of 38 patients in both the groups mean SBP in group 1 122.68±7.01 mmHg and in group 2 SBP was 121.32±8.72 mmHg. SBP in group 1 in preoperative period was 125.42±6.34 mmHg and in group 2 was 123.32±7.40 mmHg. SBP after induction of anaesthesia was 122.68±6.14 mmHg in group 1 and 121.37±7.74 mmHg in group 2. SBP was 121.68±5.14 mmHg in group 1 and 124.97±7.84 mmHg in group 2 after 2 hours of surgery. After 4 hours of surgery SBP was 122.38±5.48 mmHg in group 1 and SBP was 125.42±7.96 mmHg in group 2. SBP after 6 hours was 122.96±5.68 mmHg in group 1 and SBP was 125.88±7.48 mmHg in group 2. After 12 hours of surgery SBP was 122.00±6.83 mmHg in group 1 and SBP was 119.00±8.34 mmHg in group 2. After 24 hours of surgery SBP was 122.37±5.90 mmHg in group 1 and in group 2 SBP was 118.11±11.92 mmHg. There was no statistically significant difference in Systolic Blood Pressure in between both the groups at various time intervals.



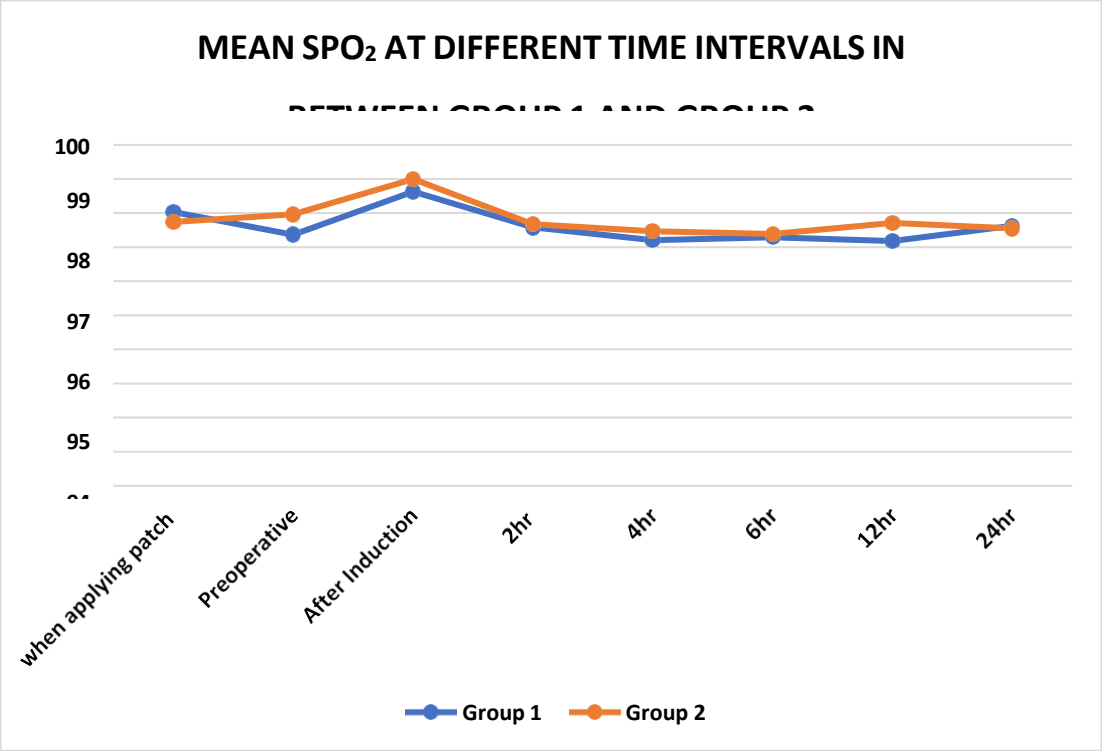
In our study of 38 patients in each group mean DBP in group 1 79.16±6.52 mmHg and in group 2 DBP was 79.21±6.58 mmHg. DBP in group 1 in preoperative period was 81.37±5.75 mmHg and in group 2 was 80.74±5.74 mmHg. DBP after induction of anaesthesia was 78.32±4.50 mmHg in group 1 and 78.05±5.93 mmHg in group 2. DBP was 81.32±3.50 mmHg in group 1 and 83.56±6.93 mmHg in group 2 after 2 hours of surgery. After 4 hours of surgery DBP was 82.65±4.36 mmHg in group 1 and DBP was 84.88±6.12 mmHg in group 2. DBP after 6 hours was 83.15±4.14 mmHg in group 1 and DBP was 85.34±6.18 mmHg in group 2. After 12 hours of surgery DBP was 77.21±5.00 mmHg in group 1 and DBP was 76.21±5.77 mmHg in group 2. After 24 hours of surgery DBP was 77.74±4.11 mmHg in group 1 and in group 2 DBP was 75.79±7.22 mmHg. There was no difference significantly in Diastolic Blood Pressure in between both the groups at various time intervals.



In our study of 38 patients in both groups, mean MAP in group 1 93.37±6.10 mmHg and in group 2 MAP was 92.89±6.52 mmHg. MAP in group 1 in preoperative period was 95.79±5.42 mmHg and in group 2 was 94.66±5.41 mmHg. MAP after induction of anaesthesia was 92.87±4.49 mmHg in group 1 and 92.39±5.44 mmHg group 2. MAP was 93.12±4.19 mmHg in group 1 and 93.89±3.15 mmHg in group 2 after 2 hours of surgery. After 4 hours of surgery MAP was 93.16±4.18 mmHg in group 1 and MAP was 94.89±3.62 mmHg in group 2. MAP after 6 hours was 93.22±4.12 mmHg in group 1 and MAP was 94.98±3.62 mmHg in group 2. After 12 hours of surgery MAP was 91.89±4.78 mmHg in group 1 and MAP was 90.03±5.44 mmHg in group 2. After 24 hours of surgery MAP was 92.11±4.05 mmHg in group 1 and in group 2 MAP was 88.76±9.62 mmHg. There was no statistically significant difference in Mean Arterial Blood Pressure in between both the groups at various time intervals.



In our study, out of total 38 patients in each group, the mean SPO_2 of patients in group 1 when applying patch was 98.03±1.22 % and in group 2 was 97.74±1.13 %. SPO_2 in Preoperative room was 97.37±1.46 % in group 1 and 97.97±1.05 % in group 2. SPO_2 just after induction of anaesthesia was 98.63±1.22 % in group 1 and 99.00±0.93 % in group 2. After 2 hours of surgery SPO_2 was 97.58±1.45 % in group 1 and 97.68±1.09 % in group 2. SPO_2 after 4 hours post operatively was 97.21±1.26 % in group 1 and 97.47±1.27 % in group 2. After 6 hours SPO_2 was 97.29±1.44 % in group 1 and in group 2 it was 97.39±1.45 %. SPO_2 after 12 hours of surgery was 95.18±1.49 % in group 1 and in group 2 it was 97.71±1.18 %. After 24 hours of surgery SPO_2 was 97.63±1.26 % in group 1 and 97.55±1.29 % in group 2. There was no difference significantly in SPO_2 in between patients in both the groups at various time intervals.



Discussion:

Using a computer-generated randomised technique, 76 adult patients of either sex, aged 18–60 years, weighing 40–80 kg, and classified as ASA grade I or II, who were scheduled for laparoscopic cholecystectomy, were randomly assigned to two groups. In our investigation, there was no statistically significant difference in mean age between the two groups, sex, ASA grade, or weight. Verma R et al (2016)[5] carried out a study that was comparable to ours in which patients with ASA physical status I and II, of either sex, between the ages of 18 and 50, who were seeking lower limb surgery were included. For these criteria, there was no statistically significant difference between the two groups.

Similarly, Jadhav P et al (2018)[6] included patients in the age group 18-26years, ASA grade I and II, undergoing bi-jaw surgery. Both the groups had comparable demographic characters like age, sex, ASA physical status and duration of surgery. They reported insignificant association between both the groups studied in all these parameters.

VAS SCORE POST-OPERATIVELY

We found that VAS score at 2 hours post operatively was 3.92±0.98 for Ketoprofen group and 4.46 ±1.12 for diclofenac group, at 4 hours post-surgery was 2.48±0.73 for ketoprofen group and 2.97±1.03 for diclofenac group and at 6 hours post-operatively was

1.53±0.65 for ketoprofen group and 1.96±1.16 for diclofenac group. VAS score was significantly higher in diclofenac group. Thus, showing statistically significant

difference in VAS score among the two groups at 2 hour, 4 hour and 6 hour. At 12 hour and 24 hour VAS score was statistically insignificant among the two groups.

The evidence based on literature search comparing the analgesic efficiency of ketoprofen to that of diclofenac suggests that the ketoprofen is a superior alternative to achieve analgesia in post operative pain management.[3]

In a study by Jadhav P et al (2018)[6], they compared post-operative analgesia in patients receiving transdermal diclofenac and ketoprofen patch used for orthognathic surgery. All patients received patch just before induction of anaesthesia. VAS score was recorded at 2 hour, 6 hour, 12 hour and 24 hour but was not compared in between the two groups.

TIME TO FIRST RESCUE ANALGESIA

In our study, the time taken for the first rescue analgesia in Ketoprofen group was1.34±1.91 hours and 1.24±1.60 hours for diclofenac group that was statistically not significant between both the groups. Similarly, in a study done by Kabir et al (2020)[7], on comparing diclofenac and ketoprofen patch as pre-emptive analgesia in inguinal hernia surgeries, it was observed that timing to first rescue analgesia was statistically not significant between both the groups.

Pandey et al (2023)[3], compared the efficiency of patch of transdermal diclofenac and ketoprofen in post-orthodontic exodontia pain and found that consumption of first rescue analgesia was between 2 and 6 hours post-operatively for both the groups and was statistically not significant.

Verma R et al (2016)[5] evaluated the effectiveness of diclofenac patches and ketoprofen in patients having lower limb orthopaedic surgery. They observed that only 3 patients in ketoprofen group required rescue analgesia in the first 24 hours but in diclofenac 11 patients required rescue analgesia. The time to rescue analgesia was comparable and statistically insignificant.

PAIN EVALUATION IN FIRST 24 HOURS USING APS-POQ-R

The APS-POQ-R detects the differences in outcomes among patient populations on specific aspects like pain intensity levels and subscales like, interference with function. It also determines if nonpharmacological techniques play a role in increasing patients' participation in their care. Because of the importance for Quality Improvement of the duration of time in pain and to decrease the overall patient burden, querying the percentage of time severe pain was experienced over 24 hours was done to measure the amount of time being spent with a level of pain and to know the negative impact on persons.

The complicated structures of pain intensity and relief measurements can be described as a reflection of several external and internal elements. The APS-POQ-R employed a horizontal scale of a percentage (0% to 100%) to measure the level of pain relief obtained from all of the patient's pharmacological and nonpharmacological therapies. This scale was modified from the Brief Pain Inventory (BPI). Side effects of therapy can compromise safety, quality of life, patient adherence, and ability to re-medicate. Multimodal therapy is encouraged in pain treatment to reduce pain and minimize the side effects.

To evaluate how pain interferes with functioning like walking, working, performing general activity and sleeping; and well-being which includes mood and emotions; in the outpatient setting were focused in APS-POQ-R. Here, pain experience included, how pain caused the patient to feel-anxious, angry, depressed, frightened, frustrated, helpless and overwhelmed along with two well-being positive emotions like relaxed and satisfied. Measurement of satisfaction with pain management and how much patients were allowed to participate in decision making was taken into consideration. Nonpharmacological related therapies have shown an impact on patient outcomes and satisfaction and are now widely recognised as appropriate for patient treatment. Subsequently, three new items were added: (1) to evaluate the usefulness of the patient care information provided, (2) to evaluate the kind of nonpharmacological strategies patients use to control pain and (3) if health care providers encouraged the use of nonpharmacological strategies.

- Questions 1 and 2 assessed the intensity of pain and was observed that ketoprofen showed less pain than diclofenac.
- Question 3 assessed the severity of pain and was observed that diclofenac group showed more severe pain as compared to ketoprofen.
- Question 4 the effect of pain on daily activities like walking, sitting, repositioning, standing and interference with sleep and showed that patients in diclofenac group had more difficulty in performing daily activities as compared to ketoprofen.
- Question 5 assessed the emotional impact of pain like depressed, frightened and helpless. It was assessed that ketoprofen group patients felt less depressed and helpless.
- In Question 6 adverse effects like nausea, drowsiness, itching, dizziness was assessed and found that less side effects like were seen in ketoprofen group.

- Question 7 assessed pain relief experienced by patients in terms of both medicine and non-medicine treatment. It was observed that ketoprofen group experienced better pain relief.
- Question 8 recorded patient participation in decisions regarding pain treatment and was observed that both the group were allowed to take part in decision making.
- Question 9 showed feedbacking in terms of patient satisfaction. Comparing with diclofenac group, the ketoprofen group was found to be more satisfied.
- Question 10 assessed the information given to patients regarding treatment and showed that both of the groups were given proper information about pain treatment.
- Question 11 considered other non-medicine methods like cold pack, meditation, music, deep breathing, massage, prayer, relaxation, walking, heat, watching TV, reading, etc and showed that there was not much difference among both the groups regarding other non-medicine methods used to relieve pain.
- Question 12 showed that either nurse or the doctor encouraged both the groups to use non-medication methods.

As APS-POQ-R is in local language, through this score we were able to successfully validate, assess and manage acute postoperative pain.[4]

The qualitative assessment of pain through APS-POQ-R showed that ketoprofen not only relieved pain quantitatively in terms of VAS but also performed superior to diclofenac regarding intensity, severity, limitation of daily activities like walking, sitting, etc., sleep, emotion, well-being, patient participation and patient satisfaction.

SIDE EFFECTS:

In current study, we observed that only few patients reported incidences of post-operative erythema, pruritus, gastroenteritis, nausea, vomiting, and dizziness. There was no significant difference in regard to these side effects among the two groups. Shankar et al (2021)[8] in his study compared diclofenac and ketoprofen patch for orthodontic purpose and reported no significant adverse effects in both the groups. The only symptom reported was mild fever noted in both the groups. No allergic reactions or vomiting was observed in the study population. Bhargava et al (2019)[9] also carried out a comparative analysis between patches of ketoprofen and diclofenac in orthodontic treatment and observed no complications among the patients post-operatively in both the groups. Kabir KK et al (2020)[7] conducted a study in patients undergoing inguinal hernia surgery and concluded that patch related local side effects were nil in both the groups.

Vasava NG et al (2020)[1] in his study conducted in laparoscopic abdominal surgery found that in group D no one complained of local complications like dermatitis, erythema, pruritis and hyperhidrosis. The incidence of side effects on other systems was nausea (20%), vomiting (10%), gastritis (6.66%), dizziness (3.33%). In group K, incidence of nausea was 20% and no one complained of gastritis, vomiting, dizziness and other local complications. Jadhav P et al (2018)[8] conducted a study in patients undergoing orthognathic procedure and concluded that none of the patients in either group developed post-operative nausea, vomiting, headache, allergy or skin rash.

Conclusion: Transdermal ketoprofen patch is effective and safe in management of acute post operative pain with better pain relief, longer duration of action, better in reducing the severity of pain in post operative period and lesser adverse effects in laparoscopic cholecystectomy

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