Original Article

Comparitive Study Of Transdermal Diclofenac Patch Versus Im Injection Diclofenac In Patients With Inguinal Hernia Surgery: Post Operative Pain Relief

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Abstract

Background: Peri-operative pain management is a very crucial entity as it decides the morbidity and outcome of the patient's post-surgery. Optimal pain relief helps early mobilization and discharge. Oral medications are not permitted in early post-operative period and therefore, injectable analgesia is the most commonly employed to treat pain. With the understanding of pain pathophysiology and newer routes of drug administration, efforts are being put to benefit the patients with adequate pain relief with maximum action of drug and minimal systemic effects so that when administered via a suitable route, it is also complaint with the patient.

Methods: In a similar effort we conducted a study on 100 patients belonging to ASA I and II grades, age between 18- 60 years, either gender, posted for elective inguinal hernia surgeries under spinal anesthesia for comparing the analgesic effects of diclofenac transdermal patch 100 mg and diclofenac intramuscular injection 75 mg. The participants were randomly divided into 2 groups of 50 each: group DP who received diclofenac patch and group DI who received intramuscular injection diclofenac, using computer generated random number table. Hemodynamic parameters such as heart rate, systolic blood pressure, diastolic blood pressure was noted in perioperative period. Comparison of the duration of post operative analgesia in both the study groups by assessing VAS score and hemodynamic response to pain was done. The time and requirement of total number of recue analgesia in both study groups was noted. Injection tramadol 2 mg/kg was given when VAS score was more than 3 in the first 24 hours. Adverse effects like: Nausea, Gastritis, Vomiting, Erythema, Pruritis were looked for after administration of the study drugs.

Results: The change in mean VAS was found to be similar over the timeline in both the groups with p value > 0.05. The pattern of change between the groups was also found to be similar with P value of more than 0.05. 16% in group DP and 96% in group IM required rescue analgesia within 24 hours.

Among the participants in group DP, 16% had duration of 4 hours and 84% had duration of 24 hours or more. Among those in group DI, 84% had duration of 6 hours and 16% had analgesia for 24 hours or more. The duration was significantly more in patch group than in the IM injection group with p value of less than 0.05. Administration as transdermal patch produced a smaller number of systemic side effects than IM injection and showed fewer local side effects.

Conclusions: It was concluded that, transdermal diclofenac patch 100 mg, as a pre-emptive analgesic is beneficial and can be a useful alternative to IM diclofenac 75 mg in patients undergoing inguinal hernia correction surgeries under subarachnoid block. Although the onset of action of diclofenac patch takes time to achieve its peak plasma concentration as compared to diclofenac injection, the patch has an

advantage because of its ease of application, self-administration and self-termination, fewer local side effects, no systemic side effects, bypasses the first pass metabolism in the liver, can be used in patients who are nil per oral post operatively thus having a better patient compliance.

Keywords: Diclofenac, Intramuscular injection, Pre-emptive analgesia, Transdermal patch.

INTRODUCTION

"**For all the happiness mankind can gain is not in pleasure, but rest from pain**."
- John Dryden

The organization for the international research of pain has described pain as a sensory experience which is unpleasant and emotionally taxing which is caused because of the tissue damage[1].Prostaglandins and other chemical mediators released from injured or inflamed cells cause nociceptors, which are sensory nerve endings, to be stimulated, resulting in the unpleasant localized sensation of pain[2.]

Post operative pain can be described as a distinct yet frequent type of acute pain, which is a crucial and fundamental component since the care provided to the patient during their transit from the recovery unit to their home setting decides their morbidity[1,3]. Untreated post-operative pain results in psychological side effects as depression, anxiety, stress reaction, hypertension, tachycardia, increased risk of myocardial infarction.

With a prevalence of 1.7% across all age groups and 4% in people over 45 years, abdominal wall hernias are quite common[4], with lifetime risk of 27% for males and 3% for women. Inguinal hernia repair is the treatment of choice for which subarachnoid block (SAB) is the most common mode of regional anesthesia used. The most commonly used intrathecal local anesthetic drug for SAB is hyperbaric bupivacaine, however, it has a limited duration of action. To expedite the onset of the block and increase the duration of the block, various adjuvants like morphine[5], fentanyl[6] and sufentanil[7], and other drugs such as dexmedetomidine[8,9], clonidine[10,11], magnesium sulfate (MgSO4)[12], neostigmine[12], ketamine[13] and midazolam[14] are added to bupivacaine. However, standard local anesthetic drugs and adjuvants are unable to provide analgesia for long-duration surgeries. Since each drug has its own set of limitations a need for alternative methods or drugs always persisted for addressing postoperative analgesia requirements.

Any modality for postoperative analgesia must meet three basic criteria: it must be effective, safe, and predictable. Opioids have been administered for hundreds of years to allay anxiety and reduce the pain associated with surgery. However, though effective, they have undesirable effects like sedation, respiratory depression, nausea, vomiting, hypotension, bradycardia, pruritis, inhibiting bowel functions, etc.[4] Hence, non-opioid analgesics play an important role in postoperative pain control to provide adequate analgesia for patients while avoiding any potential hazards due to excessive administration of opioids.

Non-steroidal anti-inflammatory drugs (NSAIDs) are non-opioid analgesic agents used for the control of less severe to severe pain associated with significant anti-inflammatory components[2]. They are the most commonly used drugs in our institution for postoperative pain management. NSAIDs are known to inhibit pain by blocking the enzyme cyclo-oxygenase which converts arachidonic acid to prostaglandins[2,15]. Diclofenac is a well-established NSAID available in various forms: Parenteral, oral, suppositories, and local application. Though intramuscular administration of diclofenac has its own set of limitations including pain and discomfort to patients, anxiety, and less patient compliance due to needle prick, systemic administration leading to fluctuations in pain control and gastrointestinal complications. For these reasons, transdermal drug delivery systems (TDDS) have been introduced. There are numerous advantages to transdermal drug delivery systems (TDDSs) including ease of use, simplicity, safety, reliability, compliance, and sustained delivery of drugs.

Hence, a newer route of diclofenac administration via transdermal diclofenac patch is amongst the innovative drug delivery mechanisms which provide sustained drug delivery, requiring only once-a-day application, and is convenient to use for postoperative pain management. Transdermal patch offers added advantages like painless technique, by-passes the first-pass metabolism in the liver, increased bioavailability, maintenance of constant and prolonged drug level, reduced frequency of dosing, and easy termination of medication, leading to better patient compliances, and overcoming concerns regarding drugs that are poorly absorbed in the gastrointestinal tract.[2]

Thus, this study was undertaken in patients undergoing elective inguinal hernia surgeries under regional anesthesia to evaluate the efficacy of transdermal diclofenac patch in comparison to Intramuscular (IM) Injection diclofenac for postoperative analgesia.

MATERIALS AND METHODS

The present comparative study was conducted on 100 patients belonging to ASA I and II grades, age between 18- 60 years, either gender, posted for elective inguinal hernia surgeries under spinal anesthesia for comparing the analgesic effects of diclofenac transdermal patch 100 mg and diclofenac intramuscular injection 75 mg.

Inclusion criteria:

1) ASA grade I or II fit patients.
2) Ages between 18-60 years of either gender.
3) Patients undergoing inguinal hernia correction surgeries under spinal anesthesia.
4) Hemodynamically stable patients with all routine investigations within normal limits without any other co-morbidities.

Exclusion criteria:

1) Patients with ASA physical status III or more.
2) Patients contraindicated for spinal anesthesia.
3) Patients with co- morbidities like diabetes, hypertension, neurological, psychiatric or neurovascular disorders.
4) Patients with drug allergies.
5) Patient refusal.

Methodology

Institutional ethics committee approval was taken prior to the commencement of the study.100 patients undergoing surgeries for inguinal hernia under spinal anesthesia were selected randomly after applying already mentioned stringent inclusion and exclusion criteria and were divided into 2 groups of 50 each using computer generated random number table.

• Group (DP) – Diclofenac patch of 100 mg.

• Group (DI) –IM injection of Diclofenac 75mg.

Preoperative evaluation was done on the previous day of surgery and detailed history and complaints was noted. General and systemic examination of cardiovascular, respiratory and central nervous system will be done. Routine laboratory investigations such as hemogram, liver function tests (LFTs), renal function tests (RFTs), serum electrolytes, urine routine, bleeding time and clotting time (BT-CT), were done. Patients were nil by mouth from midnight prior to surgery. Written informed consent was taken.

Preoperative heart rate (HR), systolic blood pressure (SBP) and diastolic blood pressure (DBP), mean arterial pressure (MAP), ECG and oxygen saturation (SPO2) was noted. Peripheral venous access was established with 20G IV cannula for preloading the patient with 10ml/kg of Ringer's lactate.

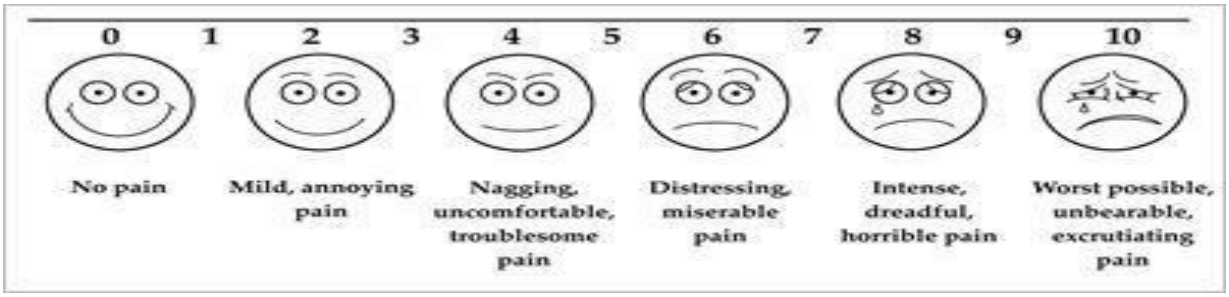
On arrival to Operation theater all monitors like NIBP, pulse-oxymeter, ECG were attached. Under aseptic precautions, with patient in sitting position, lumbar puncture was performed by the consultant anesthesiologist at level L3-L4 using 26G Quincke's spinal needle, 3.5ml of Bupivicaine 0.5% heavy was injected after confirmation of needle tip in the subarachnoid space by free and clear flow of CSF. Patients was made to lie down in supine position immediately after spinal anesthesia. After confirming adequate level of sensory blockade (T10, at level of umbilicus), diclofenac patch (100 mg) was applied on lateral aspect of contralateral thigh in group (DP) and intramuscular Injection of diclofenac (75mg) was given in contra lateral gluteal region in group (DI) patients at the beginning of the surgery.

Following parameters were noted:

1. Time of administering spinal anesthesia,
2. Time of beginning of surgery,
3. Time of administering of study drug and route.

The two groups were given their respective drug. All vitals were recorded intra-operatively and peri-operatively. Side effects like nausea, vomiting, Pruritis were noted. At any time during the study, if visual analogue scale is equal to or more than 3, then an intravenous injection of Tramadol 2mg/kg was administered, and the study was ended. The time at which rescue analgesic is given was noted.

Visual Analog Scale:



Statistical analysis: The data collected was entered into Microsoft excel 360 in order to create a master chart. The master chart was then loaded into statistical package for social sciences (SPSS) version 26 for further statistical analysis. Both quantitative and qualitative variables were present in the master chart. Both descriptive and inferential statistics were used for analysis. For describing the qualitative variables, frequency and percentages were used. For describing the quantitative data, mean and standard deviation were used. In order to find out difference in distribution of qualitative variable between the experimental arms, chi-square test was applied. To find out the difference in mean between two groups, independent samples to test was applied. To find out the difference in change of mean between the groups for a repeatedly measured variables, Repeated measures analysis of variance (RM-ANOVA) was used. A p value of less than 0.05 was considered to be statistically significant.

OBSERVATIONS AND RESULTS

The demographic profile was comparable in all three groups. The distribution of ASA was found to be similar between both groups with p value > 0.05 which was statistically insignificant. The mean weight was found to be similar between both groups with p value of 0.113 which was > 0.05 and was statistically insignificant.

There was no statistically significant difference between the study groups with respect to their values for the parameters of HR, SBP, DBP and RR.

Table 1: Comparison of Visual Analogue Score (VAS) among the two groups.

Variable	GROUP DP (n=50)		GROUP DI (n=50)		P value	
	Mean	SD	Mean	SD	With in	Between
Baseline	0	0	0	0	0.776	0.136
1 hour	0.02	0.14	0.02	0.14		
2 hours	0.26	0.06	0.42	0.08		
4 hours	0.84	0.05	0.96	0.09		
6 hours	1.96	1.48	2.20	1.51		
12 hours	1.62	0.49	1.66	0.47		
24 hours	1.24	0.55	1.32	0.58		

Graph 1: Figure Comparing Visual Analogue Score (VAS) among the two groups.

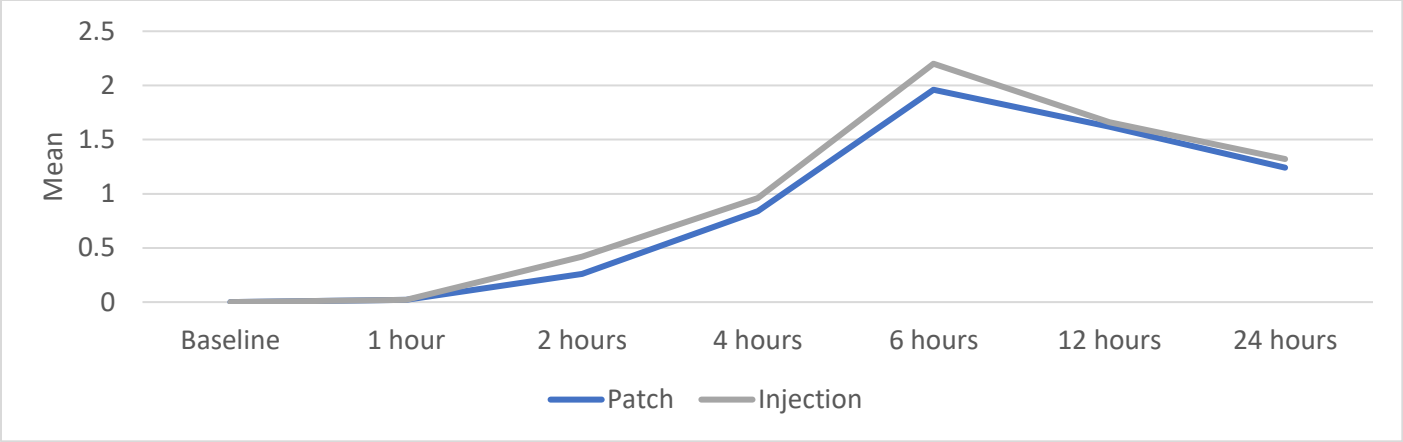


Table:1 and Graph:1, shows comparision VAS score among participants.

In group DP the mean VAS score was 0, 0.02 ± 0.14, 0.26 ± 0.06, 0.84 ± 0.05, 1.96 ± 1.48, 1.62 ± 0.49, 1.24 ± 0.55 at 0, 1, 2, 4, 6, 12 and 24 hours respectively.

In group DI the mean VAS score was 0, 0.02 ± 0.14, 0.42 ± 0.08, 0.96 ± 0.09, 2.20 ± 1.51, 1.66 ± 0.47, 1.32 ± 0.58 at 0, 1, 2, 4, 6, 12 and 24 hours respectively.

The mean change in VAS was similar over the timeline in both the groups with p value of 0.776 which was > 0.05 and was statistically insignificant.

However, the intergroup comparison in both groups, the change in mean VAS was found to be similar over the timeline in both the groups with p value of 0.136 which was > 0.05 and was statistically insignificant.

Table 2: Comparison of rescue analgesia in two groups.

Variable	GROUP DP (n=50)		Group DI (n=50)	
	N	%	N	%
Baseline	0	0	0	0
1 hour	0	0	0	0
2 hours	0	0	0	0
4 hours	8	16	0	0
6 hours	0	0	42	84
12 hours	0	0	0	0
24 hours	0	0	6	12

Graph 2: Figure showing comparison of rescue analgesia in two groups.

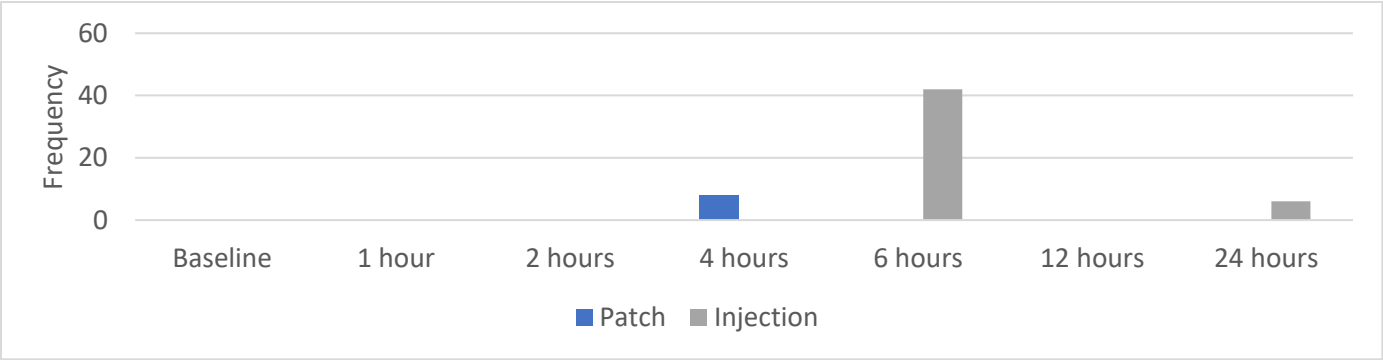


Table:2 and Graph:2, shows comparison of rescue analgesia required in both groups.

In group DP, out of 50 patients, 8 patients (16%) required rescue analgesia at 4 hours post operatively.

In group DI, out of 50 patients, 42 patients (84%) required rescue analgesia at 6 hours and 6 patients (12 %) at 24 hours post operatively.

Hence, in total 16% patients in group DP and 96% patients in group DI required rescue analgesia within 24 hours.

On comparing the duration of rescue analgesia amonst participants,

In group DP, 16% had duration of analgesia of 4 hours and 84% had duration of 24 hours or more.

In group DI, 84% had duration of analgesia 6 hours and remaining 16% had analgesia for 24 hours or more.

Table 3: Comparison of Adverse effects in two groups:

Side effects	GROUP (DP) (n=50)		GROUP (DI) (n=50)	
	N	%	N	%
Nausea	0	0	4	8
Gastritis	0	0	5	10
Vomiting	0	0	2	4
Erythema	1	2	0	0
Pruritis	2	4	0	0

Graph 3: Figure Comparing adverse effects among the two groups.

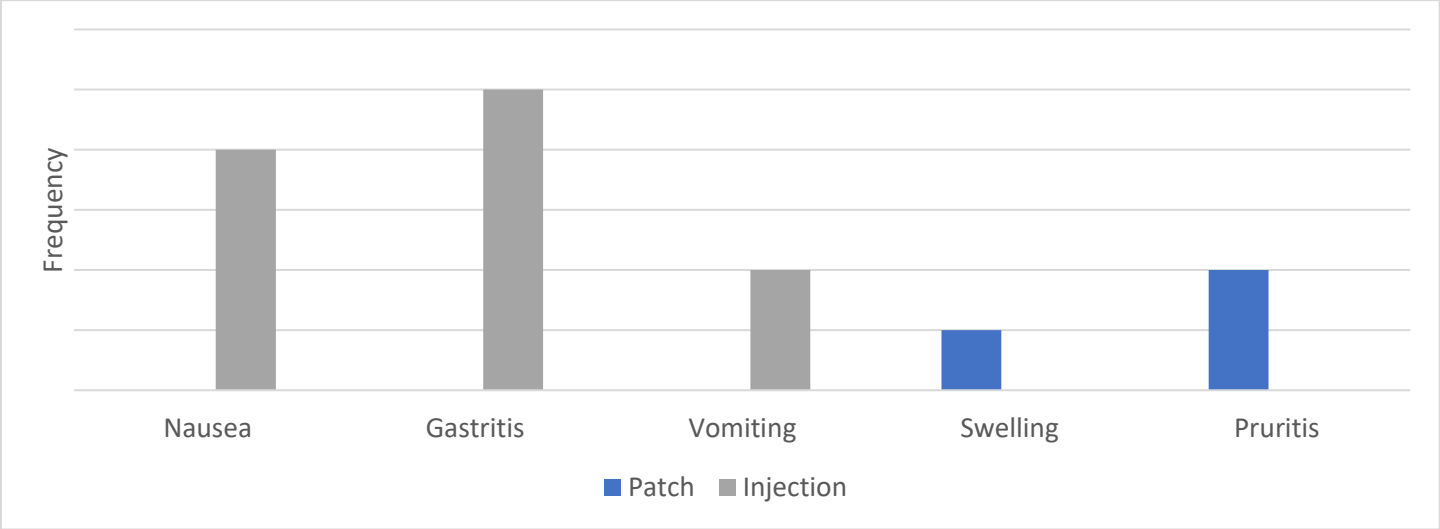


Table:3 and Graph:3 shows the comparison of the side effects between the two groups.

In group (DP), out of 50 patients, 1 patient (2%) had complaints of erythema and 2 patients (4%) had complaints of pruritis.

In group (DI), out of 50 patients, 4 patients (8%) had nausea, 5 patients (10%) had gastritis and 2 patients (4%) had vomiting.

Table.4: Distribution according to number of rescue analgesia provided between the groups.

Number of rescue analgesia	GROUP (DP) (n=50)		Group (DI) (N=50)		X^2	P value
	N	%	N	%		
1st dose	8	16	42	84	58.31	**0.001***
2nd dose	0	0	6	12		
NIL	42	84	2	4		

Graph.4: Figure showing distribution of number of rescue analgesia between the groups.

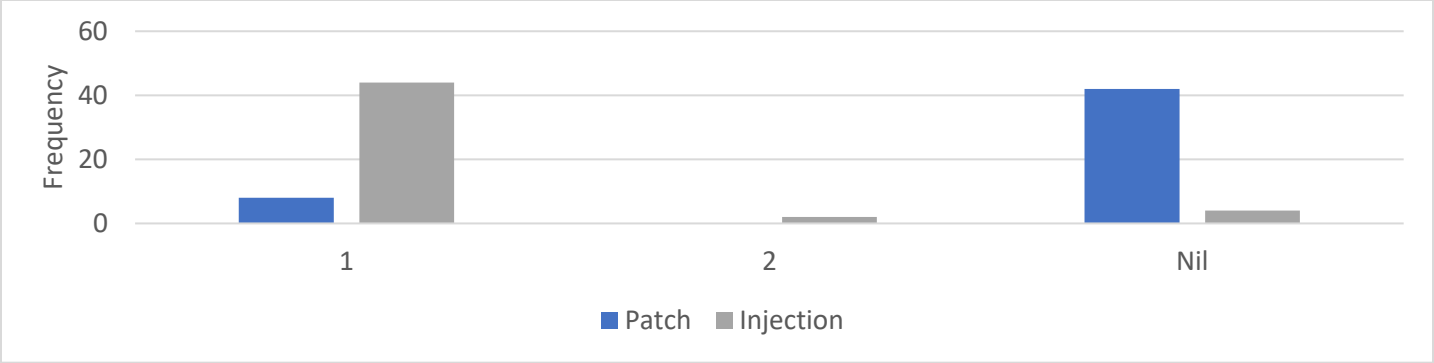


Table:4 and Graph:4, shows comparison between two groups for requirement of total rescue analgesia.

In group DP, out of 50 patients, 8 patients (16%) required 1st dose of rescue analgesia.

In group DI, out 50 patients, 42 patients (84%) required 1st dose of rescue analgesia and 6 patients (12%) required 2nd dose of rescue analgesia.

Therefore, out of 50 patients, 42 patients (84%) patients in group DP and 2 patients (4%) patients in group DI did not receive any rescue drug, with p value of **0.001*** which was statistically significant.

DISCUSSION

Nociception is a nervous system activity brought about by the stimulation of nociceptors which leads to pain that can affect a person's quality of life and overall functioning and is a key symptom of numerous medical conditions.

Pre-emptive analgesia is described as a medication that is started prior to surgery in order to avoid the development of central sensitization which is triggered by incision leading to inflammatory damage that happen during surgery and in the initial post-operative period. Because of this "protective" effect on the nociceptive system, pre-emptive analgesia is more effective than a similar analgesic treatment started after surgery. Also, by changing the central sensory processing brought on by incisional injury and inflammatory injuries, it reduces the development of chronic pain [16].

The precise timing of analgesic drug delivery is equally important as the selection of analgesic drug for effective pre-emptive analgesia because, the pharmacodynamics and pharmacokinetics of the analgesic medication used, the timings of its the peak analgesic effect and its duration ultimately decides the effectiveness and decides whether the purpose of effective pre-emptive analgesia is served. [17]

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) which includes diclofenac sodium, prevents the production of Cyclo-oxygenase enzymes and Prostaglandins, which mediates inflammation, pain, stiffness, soreness, swelling, and elevated body temperature, and therefore it aids in the reduction of both pain and inflammation.[16] At high tissue concentrations diclofenac appears to have the capacity to act as a sodium channel blocker to mediate local-anesthetic like effects on nociceptive afferent fibers. Animal studies have suggested recently that peripheral NMDA receptor antagonism may contribute to analgesic effects of locally administered diclofenac. There has been some evidence that diclofenac may inhibit L-type calcium channels which participate in pain perception.

A relatively recent development is the systemic drug delivery of medications for post-operative analgesia by adhesive skin patches (Transdermal Drug Delivery Systems, or TDDS). They have been demonstrated to offer a consistent plasma concentration of the drug as they offer sustained drug delivery, enhanced patient acceptance due to no discomfort during administration, and once daily to once every three days application. All of these elements improve patient adherence to therapy [19].

Taking into consideration the importance perioperative pain management, Institutional Ethics Committee Clearance was obtained, and Prospective, comparative, randomized study was conducted by us, wherein 100 patients belonging to ASA I and II grades, age between 18- 60 years, either gender, undergoing elective inguinal hernia surgeries under sub arachnoid block, to evaluate the efficacy of trans dermally applied diclofenac patch 100 mg versus Intramuscular Injection diclofenac 75 mg for postoperative analgesia.

100 participants were divided in to 2 groups:

- Group DP – Diclofenac patch of 100 mg.
- Group DI–IM injection of Diclofenac 75mg.

Demographic Profile:

In each group, 50 patients were selected after considering the inclusion and exclusion criteria.

Patients in both groups did not show any significant statistical differences with respect to age, body weight and ASA- grade distribution.

However, all the patients in the study were co-incidentally males.

This finding of our study also corresponds with the following study:

Dr. Manisha Saini, et al [16], in 2018, did a comparative study for the quality of analgesia of diclofenac transdermal patch (100mg) versus diclofenac intramuscular injection (75 mg). 160 eligible cases were selected and management of pain post-operatively with regard side effects, effectiveness, duration, quality of pain relief on visual analogue scale of both.

Hemodynamic Parameters:

For our study, the Heart Rate (HR), Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), and Respiratory Rate (RR) were comparable in both groups. The mean change in all the hemodynamic parameters, was found to be similar over the timeline in both the groups with p value of more than 0.05. The pattern of change on comparison intergroup was also found to be similar with p value of more than 0.05 which was statistically insignificant ($p > 0.05$).

These findings of our study also correspond with the following study:

Neha G Vasava, Richa V Patel [20], in 2020, did a study for Evaluation of effectiveness of transdermal diclofenac sodium patch versus transdermal ketoprofen patch for relief of acute post-operative pain in laparoscopic abdominal surgery wherein they compared the mean pulse rate, mean systolic blood pressure and mean diastolic blood pressure in both groups and the difference was statistically insignificant ($p>0.05$).

However, in their study the comparison was in between two different drugs.

Visual Analogue Score (VAS score) and Rescue analgesia:

VAS is an established and subjective method for scoring acute and ongoing pain. On a 10-cm line which is indicative of a continuum between "no pain" and "worst pain". But, the experience of pain is very subjective. Sometimes, two people may have same clinical diagnosis, but, the intensity of their perception of pain might show variations.[21]

In our study it was observed that, 16 % of patients in group DP but none of the patients in group DI had received rescue analgesia at 4 hours post operatively. Hence, there was earlier onset of pain in group DP as compared to group DI. Also, in group DI, 84 % patients received rescue analgesia at 6 hours and 12% patients received rescue analgesia at 24 hours post operatively. However, none of the patients in group DP received any rescue drug at 6, 12 and 24 hours. Even though the mean change in VAS score was similar in both groups over the time, the number of patients requiring rescue analgesia in group DI was significantly higher as compared to group DP. Even though the onset of pain was earlier in group DP, the total requirement of rescue drugs over 24 hours was significantly low.

Similar studies were conducted previously where in the comparison of VAS score and time and number of rescue analgesic requirement in patients show variations from our study:

Dinesh Govinda Rao, et.al [15] compared the transdermal diclofenac patch (100 mg) as pre-emptive analgesic in providing post-operative analgesia in Hernia correction surgeries with intramuscular diclofenac injection (75 mg). The study drugs were administered to the study groups just after spinal anesthesia which was same as our study. The post operative analgesia was assessed by using VAS (Visual Analogue Scale) at 2, 6 and 12 hours post operatively. However, they did not assess pain at 4 hours. The mean duration of post-operative analgesia in this study in group DI was 8.9±2.16 hours and in group DP was 10.28 ± 2.54 hours. Which differed from our study because the mean post operative analgesia in our study in group DP was 4 hours and in group DI it was 6 hours. Also, the time of administration of rescue drug in their study was on VAS score of 8 whereas in our study, it was VAS score of 3.

Gopal Swaroop Bhargava, et al [22] compared the analgesic effects of diclofenac transdermal patch (100mg) and diclofenac intramuscular injection (75 mg) for post-operative pain relief to see its efficacy, duration, quality of analgesia on visual analogue scale and side effects of each. On assessment of pain on VAS it was found that pain scores in both the groups were maximum at 8 hours. Mean time of first rescue dose needed in patch group was 7.21 hours whereas in injection group was 7.43 hours. The p value calculated came out to be 0.128 which was insignificant. The observations, also showed variations in

comparison to our study. However, it was observed that the study drugs were administered in their study 1 hour prior to the end of the surgery in contrast to our study where study drugs were given just after induction of spinal anesthesia. Also, the administration of rescue drug was at a VAS score of 5 in contrast to our study. Hence the onset of drug action and its peak effect can be varying.

Manish Banjare, et al [23], compared the effectiveness and safety of diclofenac transdermal patch with intramuscular diclofenac injection as preemptive analgesia for post operative patients undergoing inguinal hernia surgeries. In their study, the duration of analgesia was assessed by mean VAS score in both the groups and was statistically significant. In transdermal diclofenac patch group, the mean VAS score at 2 hours were low which increased gradually at 4 hours, 6 hours and at 8 hours. Also, similar patterns were seen in IM diclofenac injection group. There was increase in VAS score at 8 hours in injection group than patch group, with p value of 0.00 which was statistically significant. Also, the time required for rescue analgesia in patch group was about 8 hours and in injection group the time of rescue analgesia was 6 hours which was significant statistically. This study differs from our study in a way that, the study drugs were administered to study groups prior to induction of spinal anesthesia also, their patients received rescue drugs at VAS score of 5 where in our study rescue drugs were given at VAS score of 3.

Krishna, et al [24] did a study in 60 patients, to compare the effectiveness of diclofenac patch with diclofenac injection as a pre-emptive analgesic. Diclofenac patch 100mg was applied at the beginning of surgery in study group and diclofenac injection 75mg was given intramuscularly half an hour prior to the end of surgery in control group. The pain assessment was done after surgery at 2, 6 and 12 hours on VAS. The study stopped on patients demand for rescue analgesia or VAS >5. The mean duration of analgesia in control group (injection group) was 7 hours 28min and was 8 hours 6min in patch group.

The time taken for induction of anesthesia and total duration of surgery in various cases could vary and hence the time of drug administration, its onset, its peak plasma concentration needs to be taken into consideration so as to come to conclusion regarding the optimal time for the administration of pre-emptive analgesic. The fact that this data was not compiled in our study sets limitations in understanding and comparing the mean time of analgesia for the study drugs with significant differences in the observation. Also, VAS score being a subjective way of pain assessment, cannot be completely relied upon.

Adverse effects:

In our study, Table.10 and Graph.10, shows the comparison of the side effects between the two groups.

In group DP, out of 50 patients, 1 patient (2%) had complaints of erythema and 2 patients (4%) had complaints of pruritis. These side effects were self-limiting and did not need any intervention.

In group DI, out of 50, 4 patients (8%) patients had nausea, 5 patients (10%) had gastritis and 2 out of 50 (4%) had vomiting as adverse effects. These adverse effects were treated with injection Ondansetron 4 mg intravenous and injection Pantoprazole 40 mg intravenous.

These observations were similar to following studies:

Manish Banjare, et al[23] compared the effectiveness and safety of diclofenac transdermal patch and intramuscular diclofenac injection as preemptive analgesia in patients posted for inguinal hernioplasty. Which showed, in IM diclofenac injection group 40% had pain at local site but in the patch group, no patients had any side effects. These findings show that the transdermal diclofenac patch is better because it is safe and compliant.

Gopal Swaroop, et al [22] compared the analgesic effects of diclofenac transdermal patch (100mg) and diclofenac intramuscular injection (75 mg) in the management of post-operative pain in terms of effectiveness, duration, quality of analgesia and side effects of both and concluded that if applied at optimal time, diclofenac patch was as effective as diclofenac injection but application of patch does not cause pain, local side effects, drug degradation by gastric and digestive juices and by passes the first pass metabolism in liver.

Maisha Saini, et al [16] concluded that transdermal patch of diclofenac was better than intramuscular diclofenac because it was almost free of local side effects like skin erythema, pruritus, oedema, abscess, necrosis which was significant. But at the same time diclofenac patch proved effective as diclofenac injection in providing post-operative analgesia.

Conclusion: Even though the onset of action of diclofenac patch takes time to achieve its peak plasma concentration as compared to diclofenac injection, the patch has an advantage over intramuscular injection because of its ease of application, self-administration and self-termination, fewer local side effects, no systemic side effects, bypasses the first pass metabolism in the liver, can be used in patients who are nil per oral post operatively and in those who have complains of nausea or vomiting. Hence better patient compliance. Also, prolong duration of action because of steady and sustained release of drug with fewer requirement of rescue drugs post operatively makes it a better choice.

Hence it was concluded that, transdermal diclofenac patch (100 mg), as a pre emptive analgesic is beneficial and can be a useful alternative to IM diclofenac (75 mg) in patients undergoing inguinal hernia correction surgeries under subarachnoid block.

Limitations of the study:

1) The study sample was small to draw further conclusive evidence.
2) Cost effectiveness of the study was not performed.
3) Only ASA Grade I and II patients were included with no significant comorbidities.
4) Only patients in age group 18 to 60 years were included in study.
5) All the patients in the study were co incidentally males.
6) The VAS score is a subjective pain perception score; hence the assessment is subject to inter-patient variations.
7) Patients posted for emergency procedures were not included in the study.

Hence, we can suggest further studies to overcome the above stated limitations to recommend its use in female patients, pediatrics and geriatrics age group (below 18 years and above 60 years of age) and high-risk patients with a larger sample size.

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