Section: Anaesthesia

Original Research Article

A COMPARATIVE STUDY BETWEEN TRANSDERMAL DICLOFENAC PATCH AND INTRAMUSCULAR INJECTION OF DICLOFENAC FOR POST-OPERATIVE PAIN MANAGEMENT

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ABSTRACT

Background: Postoperative pain management in arthroplasty Surgeries can reduce the discharge and recovery time. Thus conventional Intramuscular nonsteroidal anti-inflammatory. Drugs have been used for this purpose. The aim of this trial was to compare the analgesic efficacy of diclofenac sodium. Intramuscular (IM) with diclofenac transdermal patch in the Management of post-operative pain.

Material and Methods: Patients were randomized to receive IM diclofenac 75 mg (n=30) 30 minutes before completion of surgery or transdermal diclofenac (n=30) 30 mins before THR and TKR Orthopaedic surgery. Postoperative visual analogue pain scores (VAS, 0 to10) and adverse reactions were recorded over a 24-hour period. If VAS values were >4, a rescue analgesic was given.

Results: In both groups, mean time of rescue analgesia was significantly higher in TD group than IM group there were statistical significant differences in mean time of rescue analgesia between the 2 groups. In this study 2 rescue analgesia were required in all patients of TD group and 3 rescue analgesia required in all patients of IM group with statistical significant differences. Injection site pain was observed in the IM diclofenac group, but for both groups no skin reactions were observed at the application sites of the drugs.

Conclusion: we conclude that transdermal diclofenac patch (100 mg) is a better analgesic route than intramuscular diclofenac sodium (75 mg) for postoperative analgesia in patients undergoing TKR and THR Surgeries.

Key Words: Trans Dermal Patch, Intramuscularinjction, Diclofenac, Total Hip Replacement, Total Knee Replacement.

INTRODUCTION

The proper management of pain remains one of the most important pressing issues of society in general and the medical community in particular. The postoperative period is an integral part of the surgical experience of a patient. If surgery is an injury, then allowing the patient to suffer postoperative pain is like adding insult to injury. Pathophysiology of acute pain includes alteration in respiratory, renal, neuroendocrine, GIT, autonomic nervous system and circulatory system. Efficient management of postoperative pain is as important as management of intra-operative pain. However, postoperative pain is not simple due to tissue injury alone but is the final result of various neurophysiological interactions. This makes efficient postoperative pain management much more difficult and an ideal pain management program is still elusive.[1]

In postoperative period, due to tissue injury, the responsiveness of the patient's nervous system develops two kind of modification i.e. Peripheral sensitization and central sensitization. In peripheral sensitization, there is a reduction in the threshold of nociceptive afferent peripheral terminals. In central sensitization, there occurs an, activity dependent increase in the excitability of spinal neurons. This results in overall hypersensitivity state in the

postoperative period. Prevention and establishment of this hypersensitivity could lead to reduced postoperative pain. This formed the basis of preemptive analgesia.[2]

Non-steroidal anti-inflammatory drugs (NSAIDs) have long been used for preemptive, intraoperative and postoperative analgesia. NSAIDs exert anti-inflammatory and analgesic effects through the inhibition of prostaglandin synthesis, by blocking the activity of cyclooxygenase (COX).[3]

Diclofenac sodium is a commonly used non selective NSAID and is available in various forms for the treatment of pain this includes parental preparations, oral tablets, ointments, rectal suppositories and transdermal patch. In daily practice oral administration is a route of choice but it is impractical to use this route before and after surgery because of the inability of the patient to take it in some cases and due to high first pass metabolism. The parenteral route is very painful and irritating at the site of administration and may cause complications like skin, muscle necrosis, abscess formation. The Diclofenac transdermal patch is a newly introduced delivery system for Diclofenac and is free of the drawback of oral and parenteral diclofenac preparation. Its administration is also simple, noninvasive and only once in 24 hrs.[4]

There is sustained delivery of drug with lesser systemic side effects due to lower plasma concentrations. Hence this clinical study was undertaken to evaluate the analgesic efficacy of Diclofenac transdermal patch in comparison to intramuscular diclofenac in patients undergoing TKR and THR under neuroaxial blockade.

MATERIALS AND METHODS

After obtaining institutional ethical clearance we conducted hospital based Randomized control trial in tertiary hospital 2020-2022.

Patients aged 18 -60 years with ASA: I & II undergoing THR and TKR orthopedic surgery under spinal anesthesia are included in our study

A patients with bronchial asthma, urticaria, history of allergy to study drug, clinical evidence of active peptic ulceration within 6 months, Pregnant and lactating females, patients with any contraindication to spinal anesthesia like abnormal coagulation profile, sepsis. Are excluded from the study. Informed consent was obtained from all patients.

The patient underwent thorough pre anesthetic evaluation assessment and patients detailed history, general physical examination and systemic examination were carried out to rule out exclusion criteria. Basic demographic data like age, sex, height, weight were recorded. Routine investigations such as complete blood count, blood sugar, renal function test, liver function test, bleeding time, clotting time, chest x-ray, ECG carried out. Patients were explained in detail about the anesthesia procedure. All the patients planned for elective procedure will be instructed for fasting as per ASA guidelines before surgery. Visual analogue scale for pain was explained to the patient.

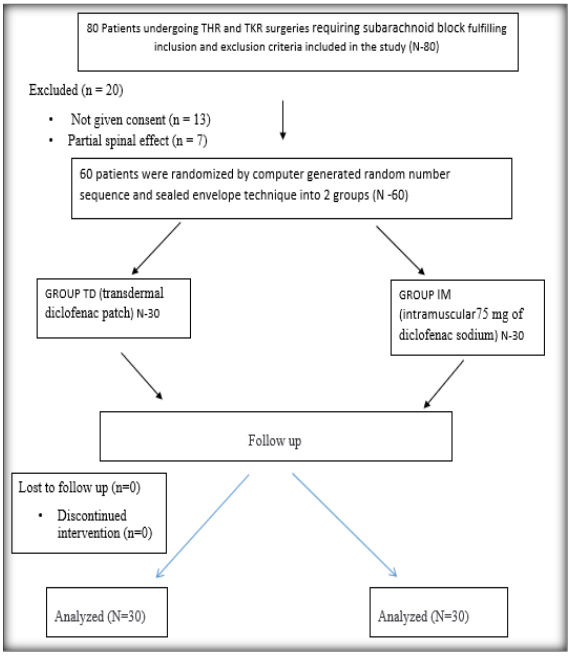
Randomization

In this proposed study 60 patients, who were posted for THR and TKR surgeries were randomized by computer generated random number sequence and sealed envelope technique into 2 groups: Group A and Group B (3O in each group).

Group TD: Received transdermal diclofenac patch containing 100mg of diclofenac diethyl amine.

Group IM: Received intramuscular 75 mg of diclofenac sodium.

All patients were administered subarachnoid block in sitting position in L3-L4 intervertebral space using 0.5% hyperbaric bupivacaine inj. using 25G quincke's needle under all aseptic precautions, to obtain a sensory block up to T10 level. Both groups did not receive any intravenous analgesics or sedatives during the surgery. A transdermal diclofenac patch containing 100mg of diclofenac diethyl amine was applied to the participants in the study group A just before the induction of anesthesia. In the group B, 75 mg of diclofenac sodium Inj. Was given intramuscularly half-an-hour before the end of surgery.



Pain was assessed postoperatively at 0, 1/2, 2, 4, 8, 12, 16 and 24 hrs. By using visual analogue scale (VAS) score. At any time during the study, if the VAS was more than 5 then intravenous Tramadol 2mg/kg was administered as rescue analgesia and the time noted

RESULTS

Total 80 patients were selected for this study out of which 13 patients not given consent to participate in

the study and 7 patients had partial spinal effect and converted to general anesthesia
So 20 patients were excluded from the study
60 Patients were participated in the study, 30 patients in each group

Demographic variable like age, sex are comparable with 2 groups with no statistical significance

In this study initially VAS score was zero in both the groups then increased with time till the patient received the rescue analgesia. In, intramuscular group mean VAS decreased at 8 hr. because rescue analgesia was given to all the patients before that time. p value is significant only at 8 hour which is 0.00 as at this time VAS score was higher in TD group. [Table 1]

In this study mean time of rescue analgesia was significantly higher in TD group than IM group as p-value is significant i.e.0.0001. [Table 2]

In this study 2 rescue analgesia were required in all patients of TD group and 3 rescue analgesia required in all patients of IM group which is significant as p value is 0.001. [Table 3]

Complications

In this study all patients of IM group complained of pain at local site, while in Transdermal patch group none of the patients had any complications.

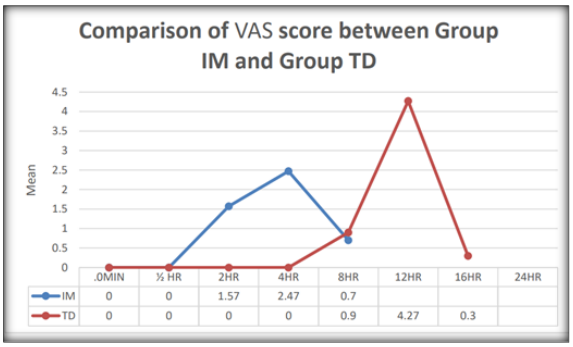


Figure 1: Comparison of VAS score between Group IM and Group TD

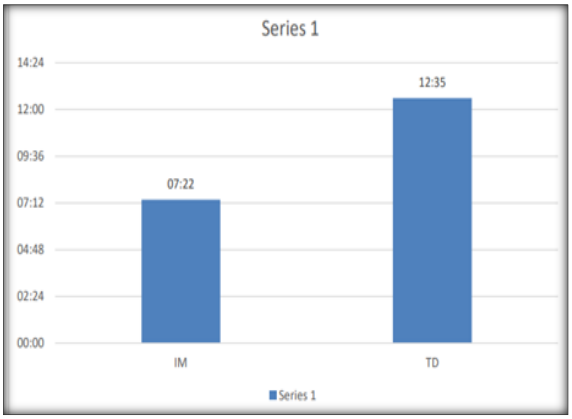


Figure 2: Comparison between time of rescue analgesia needed in both groups

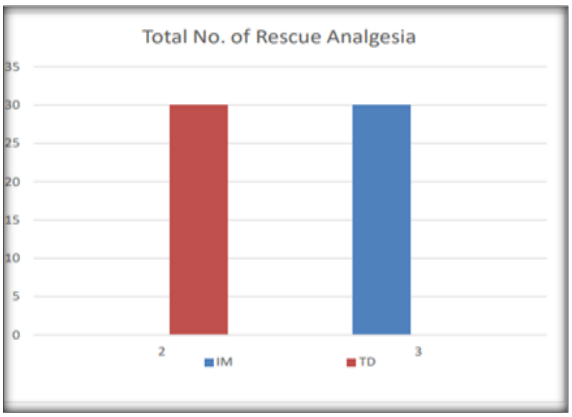


Figure 3: Total no. of Rescue Analgesia

Table 1: Comparison of VAS score between both group

	Group					Rescue Analgesia	
	IM		TD			IM	TD
VAS	MEAN	SD	MEAN	SD	P VALUE		
0 HR	0	0	0	0	NA		
30mins	0	0	0	0	NA		
2 HR	1.57	0.9	0	0	0.165		
4 HR	2.47	1.22	0	0	0.549	28	
8 HR	0.7	1.26	0.9	1.01	0.00	2	
12 HR			4.27	0.45			8
16 HR			0.3	0.47			22
24 HR							

Table 2: Comparison between time of rescue analgesia needed in both groups

TIME OF RESCUE ANALGESIA	MEAN	SD	P VALUE
IM	7.22	0.014236	0.0001(significant)
TD	12.35	0.02099	

Table 3: Total No of Rescue Analgesia in First 24 hours

GROUP	NO OF PATIENTS	NO OF RESCUE ANALGESIA IN 24HR	P VALUE
IM	30	3	0.0001(significant)
TD	30	2	

DISCUSSION

NSAIDs are excellent analgesics with no clinically important difference in efficacy among specific drugs. Important side effects include gastrointestinal bleeding, renal dysfunction and platelet dysfunction. Selective COX-2 inhibitors are associated with significant number of thrombotic cardiovascular events, which offsets the increased number of gastrointestinal adverse effects observed with NSAIDs, hence the benefits of the COX-2 inhibitors in treating acute nonspecific pain is doubtful.[5] We conducted study to compare the analgesic efficacy of transdermal diclofenac patch with intramuscular diclofenac injection for postoperative analgesia in patients scheduled for TKR and THR Surgeries.

In our study, increase in VAS score was noted in transdermal patch group till 12 hrs (mean 4.2). However after that VAS score decreased at 16 hrs (mean0.3). This was because rescue analgesia was given to the patients at (mean 12 hrs 35 min). VAS score at 24hrs was not calculated because the study ended before that i.e. at the time when patient required rescue analgesia. Similarly increase in VAS score was noted in diclofenac injection group till 4 hrs (mean 2.47). However after that VAS score decreased at 8hrs (mean 0.7) because rescue analgesia was required by the patients at (mean 7 hrs 22 min). VAS score was not calculated at 12hrs, 16hrs and 24hrs because the study ended before that i.e. at the time when patient required rescue analgesia.

Similar trend of VAS score was documented in SHIMIKORE et al,[6] in which VAS score assessed at 3 hours, 6 hours, 12 hours and 24 hours and he observed that mean VAS score of both the group at 3hours were low (0.23±0.63 vs 0.37±0.76), which increased (2.47±1.59 vs 2.53±1.53) at 6 hours and there was further increase at 12 hours that is 4.00±1.93 vs 4.07±1.84 and at 24 hours light reduction was noted i.e.3.77±1.55 vs 3.17±1.62. But the time at which transdermal patch (3 hours before incision) and intramuscular diclofenac injection (20 min before incision) was administered was different.

In our study, mean time for the requirement of rescue analgesia in the transdermal diclofenac patch group is 12.35 ± 0.02 hours while in IM diclofenac injection group mean time of the first analgesia is 7.22 ±0.01hours. The mean time of requirement of post-operative rescue analgesia in the transdermal diclofenac patch group was prolonged compared to the IM diclofenac injection group and the difference was statistically significant (p =0.0001). These findings show that the pain relief provided by single transdermal diclofenac patch (100mg) is longer in comparison to intramuscular diclofenac sodium (75 mg) and the difference was statistically significant. These findings are similar to those of PRAGATI et al,[7] in which the duration of analgesia in the IM diclofenac injection group was 6.38±1 hour, and intramuscular diclofenac 75 mg received 30 min before the end of surgery (same as in our study).

In IM diclofenac injection group 30 patients (100%) had pain at local site while in the transdermal diclofenac patch group, none of the patients had any of the side effects. These findings show that safety and compliance of the transdermal diclofenac patch is better. Safety profile was documented in MASON et al,[8] in which topical NSAIDs were used for chronic musculoskeletal pain and they found 6 % local adverse event (erythema and rash at site of diclofenac patch application) and only 3 % systemic adverse event. Safety profile was also documented in PREDEL et al,[9] in which the diclofenac patch was used in blunt impact injuries and he found that the diclofenac transdermal patch was well tolerated.

CONCLUSION

Based on the results obtained from our study, we conclude that transdermal diclofenac patch (100 mg) is a better analgesic route than intramuscular diclofenac sodium (75 mg) for postoperative analgesia in patients undergoing TKR and THR Surgeries under SAB based on the following parameters

1. The duration and efficacy of analgesia are significantly higher in the transdermal diclofenac patch group than in the intramuscular diclofenac injection group. And The time at which the patient requires rescue analgesia following surgery is significantly higher in the transdermal diclofenac patch group than the Intramuscular diclofenac injection group.
2. In our study, transdermal diclofenac patch group did not have any local and systemic complications as compare to the intramuscular diclofenac injection group.
3. Transdermal diclofenac patch group has better patient compliance and ease of administration.

REFERENCES

1. Hepner, David L. Preemptive analgesia: What does it really mean? Anesthesiology 2000; 93(5): 1368.
2. Ong CKS, Lirk P, Saymour R. The efficacy of preemptive analgesia for acute postoperative pain management – A metanalysis. Anesthesia and Analgesia 2005; 100: 575-73.
3. The Royal College of Anesthetists. Guidelines for the Use of Nonsteroidal. Anti-inflammatory Drugs in the Perioperative Period. March 1998.
4. Shang AB. and Gan TJ. Optimizing Postoperative Pain Management in the Ambulatory Patient. Drugs 2003; 63 (9): 855-67.

5. Burian M, Tegeder I, Seegel M, and Geisslinger G. Peripheral and central antihyperalgesic effects of Diclofenac in a model of human inflammatory pain. Clin Pharmacol Ther 2003; 74: 113-20.
6. Bachalli PS, Nandakumar H, Srinath N. A comparative study of diclofenac transdermal patch against oral diclofenac for pain control following removal of mandibular impacted third molars. J Maxillofac Oral Surg 2009;8: 167-72.
7. Pragati Arora Trivedi, Malini Mehta. Int J Res Med 2015,4(4),96-101/e ISSN,2320-2742/p ISSN:2320-2734
8. Mason L, Moore RA, Edwards JE, Derry S, Mc Quay HJ. Topical NSAIDs for acute pain: a meta-analysis. BMC Family Practice 2004, 5:10.
9. Predel HG, Koll R, Pabst H, Dieter R, Gallacchi G, Giannetti B et al. Diclofenac patch for topical treatment of acute impact injuries: a randomised, double blind, placebo controlled, multicentre study. Br J Sports Med 2004; 38; 318-23.