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COMPARATIVE EFFECTS OF DIFFERENT ROUTES OF DICLOFENAC FOR POSTOPERATIVE SURGICAL PAIN MANAGEMENT IN LOWER LIMB ORTHOPEDIC SURGERIES

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ABSTRACT

Background and AIM -The pain is the worst symptom experienced by the patient after surgery. Most commonly prescribed analgesic nowadays are nonsteroidal anti-inflammatory drugs (NSAIDs). In this study we compare the analgesic efficacy, side effects and time of rescue analgesia of different routes of Diclofenac administration for postoperative pain relief in lower limb orthopedic surgeries.

Methods-The 141 participants of ASA grade 1&II with age group 20-60 yrs of either sex were randomly allocated in 3 groups of 47 each. Patients were induced in subarachnoid block. Transdermal diclofenac patch was applied in group A two hours before the beginnings of surgery; IV Diclofenac75mg injection given at the end of surgery in group B and IM Diclofenac 75 mg was given half an hours before the end of surgery in group C patients. Pain was assessed by using VAS at 2, 6, 12 and 24 hours postoperatively. Times of rescue analgesia were observed and statistical analysis done by SPSS 22 software.

Results-. VAS scores were comparable in all three groups at 6 hours with no significant difference (p =0.981).Duration of rescue analgesia was higher in group A as compared to group B and C.(p-0.017)

Conclusion–Transdermal diclofenac patch 100 mg has shown better efficacy in comparison to injection diclofenac75 mg given by IM and IV route in providing postoperative analgesia with minimal side effects in lower limb orthopedic surgery under subarachnoid block. Injection diclofenac given by IM route and IV route has shown equivalent efficacy when compared with each other.

Keywords- Transdermal diclofenac patch, post –operative analgesia, rescue analgesia

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INTRODUCTION

Now a days pain is considered as a vital sign. Pain impairs one's ability to carry out a productive life. Recent studies states that 50-70% of patients experience moderate to severe post operative pain indicating that it remains untreated. The management of post operative pain is an important part of peri-operative care during transition from the recovery unit to the patient's home[1].

Peripheral tissue injury in postoperative patients causes two types of changes in the responsiveness of the nervous system. In peripheral type of sensitization, there is a reduction in the threshold of nociceptive afferent peripheral receptors. In central sensitization, an activity-dependent increase in the excitability of spinal neurons occurs. This overall hypersensitivity state prevention in the postoperative period could lead to reduced postoperative pain[2].

A variety of agents used for this purpose including acetaminophen, NSAIDs, opiods, glucocorticoids etc. Lots of studies and RCT are conducted, specifying use of opioids to minimize post-operative pain. But since opioids are associated with side effects such as incomplete amnesia, histamine release, prolonged postoperative respiratory depression, increased blood volume requirement secondary to vasodilatation & hypotension these lead to use of better options for postoperative pain management[3].

Most commonly prescribed analgesic nowadays are nonsteroidal anti-inflammatory drugs (NSAIDs), which act by inhibition of prostaglandin synthesis, by blocking the activity of cyclo-oxygenase (COX). Analgesic drugs can be delivered in a variety of routes, including oral, parenteral (IM/IV), as well as transdermal. Oldest way of delivering drugs- i.e. oral route carries the risk of hepatic first-pass metabolism and loss of large quantities of drug (50%) before it reached in circulation[4,5].

In this study we compared the analgesic efficacy of different routes of Diclofenac administration such as intramuscular, intravenous and transdermal patch for postoperative pain relief in lower limb orthopedic surgeries.

MATERIAL & METHODS

This prospective, double-blind, randomized study was conducted after obtaining approval by the Institutional Ethics Committee. (No:4/IEC-GRMC/2019). The present study was undertaken on 141 patients scheduled for elective lower limb orthopedic surgery under subarachnoid block at G.R. Medical College and J.A. Group of Hospitals, Gwalior (M.P.). All the patients of ASA class I/II between 20- 60 years age with BMI between 18.5 to 24.9 kg/m^2 were included. Patients with evidence or history of cardiac, pulmonary, renal, or hepatic pathology; Pregnancy or lactation, active peptic ulcer within 6 months, bronchial asthma, urticaria or any other allergic reaction

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due to NSAIDs, patients with hemorrhagic diathesis were excluded from the study. Informed written consent was obtained from all patients.

Randomization of all patients was done by computer generated random number table and patients were divided into three groups with 47 patients in each group. After securing 18gauge cannula patients were shifted into the operation theatre and all parameters like blood pressure, ECG, pulse oximeter were attached. All patients were given subarachnoid block in sitting position by 0.3 mg/kg of 0.5% hyperbaric bupivacaine with 25 gauge quinkes spinal needle. No analgesics and sedative were given intra-operatively.

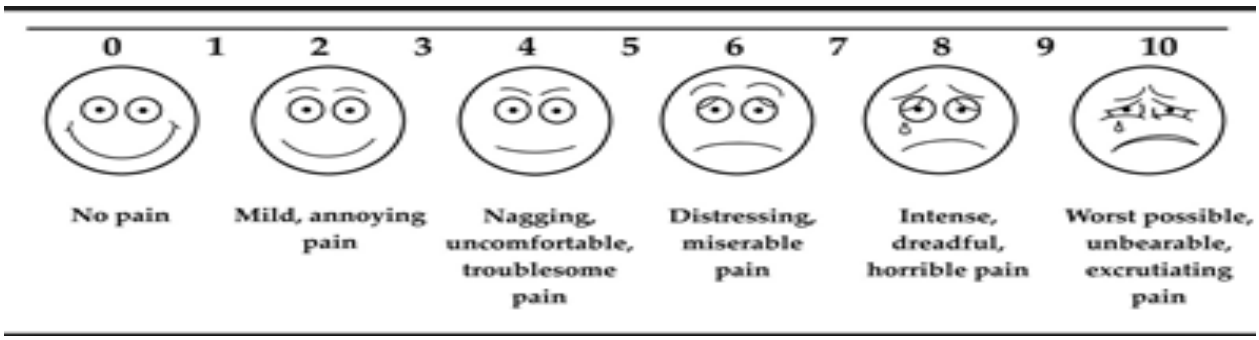
Transdermal patch (58mm× 87mm,100mg) was applied over subscapular region two hours before the beginnings of surgery to all patients in group A, intravenous Diclofenac (75mg) injection given at the end of surgery in group B and intramuscular Diclofenac(75mg)) was given half an hour before the end of surgery of group C patients. haemodynamic parameters Systolic BP, Diastolic BP, Mean BP, heart rate, ECG and SPO2 were monitored during the surgery and peri-operative period. Pain was assessed by using Visual analogue scale (VAS)at 2, 6, 12 and 24 hours postoperatively. Injection tramadol 2mg/kg was administered intramuscular as a rescue analgesic when any patients have VAS equal or more than 5. Times of rescue analgesia were observed and side effects with the study drug (nausea/vomiting, erythema, itching, shivering, abdominal pain, hypertension, hypotension, bradycardia, tachyarrhythmia, urinary retention, itching, local site reaction and injection pain) were also noted.

VAS score is a psychometric response scale which is subjective. When responding to VAS system respondent specify their level of agreement to a statement by indicating a position along a continuous line between two end positions.

0 --- No pain 1 to 4 --- Mild pain

4 to 7 --- Moderate pain 8 to 10 ---Severe pain

VASSCALE



Data were initially entered in Microsoft excel sheet from customized proforma. For data analysis SPSS (Statistical Package for Social Sciences) 22.0 version, IBM, Chicago was used for calculating the p-value. Comparison of means between the two groups was done by using chi-square test. Descriptive statistics was presented

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in the form of numbers and percentage. One –way ANOVA test was used for analysis of numbers and student t-test was used for inter-group comparison. A p-value of <0.05 was taken as statistically significant.

RESULT

As per the table 1,demographic data of the patient in all 3 groups were nearly same without any significant differences. All 3 groups were statistically comparable on the basis of duration of surgery (P > 0.05). Haemodynamic parameters were comparable in all 3 groups at all time interval.

Table 1 : Demographic data and other parameters

	Group A (n=47)	Group B(n=47)	Group C(n=47)	P value
Age In Years (Mean± SD	42.19±12.92	39.66±14.30	37.40±12.89	0.226
Sex M/F	36/11	35/12	38/9	0.685
Weight in Kg (mean±SD)	61.06±4.10	62.12±3.45	61.97±3.55	0.326
Height in cm (mean±SD)	166.76±1.16	166.59±1.72	166.74±1.43	0.828
Duration of surgery(min)	110.21±30.50	109.04±25.44	111.59±25.49	0.902

Table 2. VAS after 6 hour (mean±SD)

Group A (n=47)	Group B(n=47)	Group C(n=47)	P value
1.19±1.27	1.19±1.22	1.23±1.08	0.981

Though Group C has higher VAS at 6 hours (1.23±1.08) while group A and B have nearly similar VAS at 6 hours (1.19±1.27), but there was no statistically significant difference in all three groups on the basis of VAS at 6 hours [Table 2].

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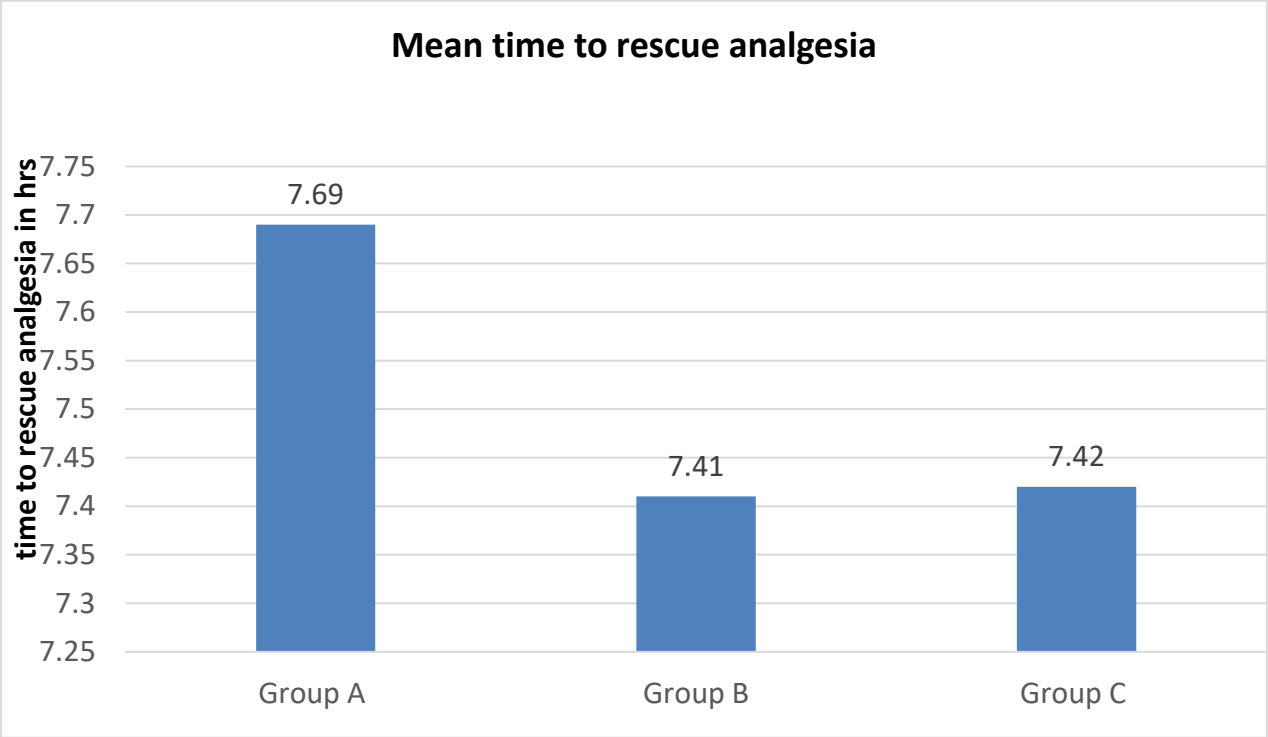

figure 1: Mean time of rescue analgesia

The time of rescue analgesia in Group A was7.69±0.68; in Group B 7.41±0.46 and in Group C were 7.42±0.42 hours. In group A time of rescue analgesia was significantly higher than group B and C ($p < 0.05$) [Table 3].

In Group C, 9 patients reported various side effects; in Group B, 8 patients reported side effects while in Group A only 3 patients have side effect that was itching at patch site [Table 5].

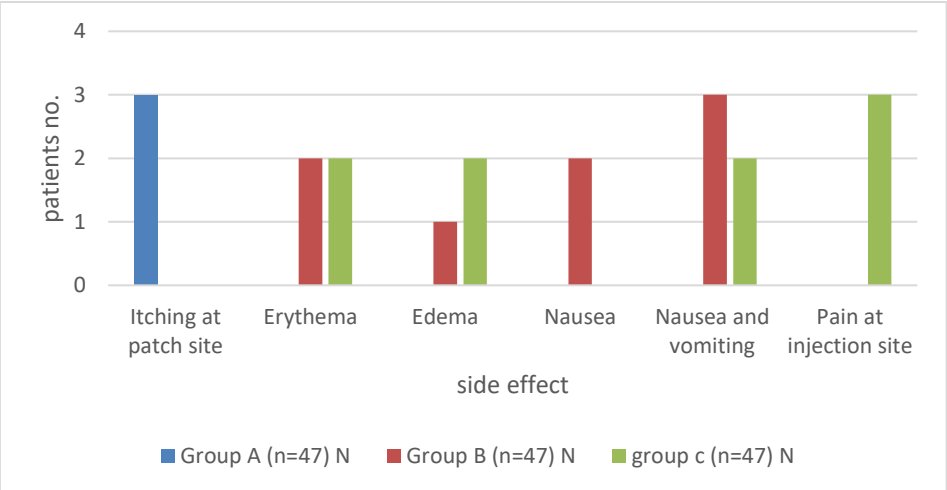

FIGURE 2- DIFFERENT SIDE EFFECTS IN THREE GROUPS

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DISCUSSION

Nowadays non-steroidal anti-inflammatory drugs have been studied by many authors and has been found effective for post-operative pain relief. Diclofenac Sodium is a well established drug used for post- operative pain management since many years. Narcotic analgesic have been used for post-operative pain by different routes but because of many side effects other group of drugs are used. Recently better drugs with minimal side effects and more profound analgesic effect have been evaluated. Inadequately treated pain in lower limb surgeries can result in various complications like deep vein thrombosis, delayed recovery , myocardial ischemia , urinary retention and residual psychological trauma .Because of that pain relief in perioperative period is very important. Transdermal drug delivery system is a very good method of pain management in postoperative period as it avoids the first pass metabolism and gastrointestinal complications associated with oral route. Furthermore There are very few studies to show the efficacy and tolerability of diclofenac patch in comparison to other routes of diclofenac for postoperative analgesia in surgeries. So In this study we evaluated the effect of transdermal , intravenous and intramuscular route of diclofenac in postoperative pain management in lower limb surgeries

In our study patients all three groups were comparable (P value >0.05) with respect to Mean ± SD of age, weight, height, BMI and sex. All three groups were comparable on the basis of duration of surgery (P value=0.902). These demographic data were also comparable in study done by Narzaree P et al [6]; Karabayirli S et al[7] and Khan DJ et al[8]. In our study mean ± SD of VAS score at 6 hours in group A was 1.19±1.27; in group B was 1.19±1.22 and in group C was 1.23±1.08. The VAS score at 6 hours was comparable in all 3 study groups(P = 0.981). these findings was similar as study done by Krishna R et al[2]&Bhargava GS et al[11].

The time at which rescue analgesia were required in the Group A was significantly prolong (p value <0.05) than Group B and C. on inter group comparison group B and C have no significant difference in time of rescue analgesia (p=0.110). Long duration of action seen with transdermal diclofenac is due to its slow absorption into the circulation and high tissue penetration.

Similar results were also found in studies conducted by Banjare P et al[9].In there study, mean time for the requirement of rescue analgesia in the transdermal diclofenac patch group was 8.28 ± 0.86 hours while in IM diclofenac injection group mean time of the first analgesia is 6.63 ± 0.81 hours (p=0.000). Rao DG et al[1] and Perepa A et al[10] also found similar result· where time of rescue analgesia in transdermal patch group is significantly higher than intramuscular groups (p <0.05). Time of rescue analgesia in studies conducted by Krishna R et al[2] & **Bhargava G S et al[11]were** in contrast to our study. Findings of these studies showed that the transdermal patch and intramuscular groups had statistically comparable mean time of rescue analgesia (p>0.05).

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In a study by Gupta US et al[3] only one patient has complaint of erythema out of 30 patients of transdermal group whereas in IM group 3 (10%) patients reported gastric upset (abdominal pain and heart burn) another 3 (10%) patients reported pain and indurations at injection site. In our study 3(6.38%) participants from group A reported 'itching at patch site' while Nausea - vomiting and Pain at injection site was reported by 2(4.25%) and 3 (6.38%) patients respectively in IM group. In IV group of our study Erythema was reported by 2 patients (4.25%), Edema by 1 (2.13%), Nausea by 2 (4.25%) and Nausea and vomiting by 3 (6.38%) patients.

Perepa, A et al[10] found nausea and gastritis in 5(18%) and pain at injection site in 7 (24%) patients in control group (Diclofenac IM group) whereas no noticeable side effects were found in study group (transdermal group). Safety profile was documented in Mason L et al[12] in which topical NSAIDs were used for chronic musculoskeletal pain and he found 6% local adverse events and only 3% systemic adverse event. Safety profile was also documented in Predel HG et al[13] in which the diclofenac patch was used in blunt impact injury and he found that diclofenac transdermal patch was well tolerated[9].

Conclusion

we concluded that transdermal diclofenac patch has shown better efficacy in comparison to injection diclofenac given by intramuscular and intravenous route in providing post operative analgesia with minimal side effects in lower limb orthopedic surgery under subarachnoid block. Injection diclofenac given by intramuscular route and intravenous route has shown equivalent efficacy when compared with each other.

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