Original Article

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The Efficacy of Transdermal Diclofenac Patch for Postoperative Analgesia in Comparison with Intramuscular Diclofenac in Patients Undergoing Lower Abdominal and Perineal Surgeries Under Sub-Arachnoid Block A Randomised Comparative Study

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Abstract

Background: Although, post-operative pain is a distinctive and most common form of acute pain, it remains poorly treated.

Aim: To evaluate the efficacy of Transdermal diclofenac patch versus IM diclofenac in patients undergoing lower abdominal and perineal surgeries under Subarachnoid block during postoperative period.

Methodology: This randomised comparative study included 90 ASA I and II patients of either sex aged 18 – 60 years. Patients were randomly divided by computer generated tables into two groups of 45 patients each. Group A was applied with a Transdermal Diclofenac patch (100mg) at the beginning of surgery after subarachnoid block.

In group B 75mg of Diclofenac sodium was given intramuscularly half an hour before the end of surgery. Data was analysed using Chi-square test and Mann Whitney U test

Results: The mean difference in the time of administration of rescue analgesia in group A is 8hr 37 mins ± 1 hr 4.2 mins and group B is 6 hrs 19 mins ±58.6 mins (P value is < 0.0001). Side effects in group A were very minimal.

Conclusion: Thus transdermal diclofenac patch is effective, non- invasive and safer way of treating postoperative pain.

Keywords: Transdermal Diclofenac Patch, IM Diclofenac, Post-operative Analgesia.

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Introduction

"All sane would agree that the relief of suffering of both human and animals is one of the noblest activity of man and in this field of human endeavour who can rank higher than the anaesthesiologist"Sir John C Eccles.

Post operative pain is a distinctive and common form of acute pain. Although ample evidence shows that an effective post operative pain treatment reduces patient morbidity and alleviates patient outcome, recent studies reveal that 50-70% of the patients experience moderate to severe pain after surgery indicating that post operative pain remains poorly treated.[1] Effective postoperative pain management leads to increased patient satisfaction; early mobilization and reduced hospital stay.

There are two types of modification in the responsiveness of the nervous system in postoperative pain. In peripheral sensitisation, there is a reduction in the threshold of nociceptive afferent peripheral terminals. In central sensitisation, an activity dependent increase in the excitability of spinal neurons occurs. This results in an overall hypersensitivity state in the post-operative period.[1] Prevention of this hypersensitivity state can reduce postoperative pain. This forms the basis of pre-emptive analgesia.[1]

Nonsteroidal anti-inflammatory drugs (NSAIDs) exert anti-inflammatory and analgesic effects through the inhibition of prostaglandin synthesis, by inhibiting Cyclooxygenase. Diclofenac is one such NSAID which is an analgesic antipyretic anti-inflammatory drug.

Parenteral route of administration is most commonly used for pain relief. But it has a lot of short coming such as pain at the injection site and gastrointestinal symptoms. Thus, alternative routes are being extensively studied. The transdermal diclofenac patch is a newly introduced delivery system for postoperative pain management. Transdermal route has advantage of being painless, non irritant and increased bioavailability.[2]

Though transdermal route has distinct advantage over parental route, there are very less studies which compared transdermal and parenteral route in patients undergoing surgeries.[2]

Material and Methods

This study was carried out in the Department of Anaesthesiology, B.L.D.E's (Deemed to be university) Shri B.M. Patil Medical College, Hospital and Research Centre, Vijayapura. This randomised comparative study was conducted from December 2018 to August 2020 after getting ethical committee clearance and obtaining consent from all patients. The sample size was calculated on the basis of Rao DG, Ravikumar GV, Akshay BR studies.[1] Sample size was 90 divided into two groups of 45 each.

Formula used was

$$N = 2\left[\frac{\left(Z_{1-\alpha/2} + Z_{\beta}\right) * S}{d}\right]^2$$

Z1-α/2 Level of significance=95%

Z1-β Power of study =90%

d=clinically significant difference between two parameters

SD= Common standard deviation

Statistical Analysis: Data was represented using Mean±SD, percentages and diagrams. Significant difference between quantitative data was found using Mann Whitney U test to compare two groups. Significant difference between Qualitative data was found using Chi square and Fisher's Exact test.

Study Group: Study was conducted on 90 ASA grade I or II adult patients of either sex, aged between 18-60 years scheduled for elective lower abdominal and perineal surgeries.

Inclusion criteria

ASA Class I and II, aged 18-60 years of either sex posted for elective lower abdominal and perineal surgeries consented for study.

Exclusion criteria

Body mass index >30, Pregnancy and lactation, History of bronchial asthma, urticaria or any other allergic reactions induced by aspirin or any other NSAIDs.

Procedure

After obtaining consent, all patients were examined and investigated according to institution protocol. They were educated about nil per oral and Visual analogue score on the previous day of surgery. On the day of surgery, patient was taken to operation theatre and connected to standard monitoring devices including ECG, Sphygmomanometer cuff, and pulse oximeter and baseline values were recorded. All participants were administered subarachnoid block using 3ml of 0.5% hyperbaric Bupivacaine. Group A were applied with Transdermal Diclofenac patch containing 100mg of

Diclofenac diethylamine directly on the chest or the back at the beginning of surgery immediately after subarachnoid block.In Group B 75mg of Diclofenac sodium was given intramuscularly half an hour before the end of surgery.

Pain was assessed postoperatively at 2, 4, 6, 8 hrs using a visual analogue scale (VAS). If the VAS during any time during study is more or equal to five then injection Tramadol 2mg/kg was administered intramuscularly as rescue analgesia. Time duration between the administration of transdermal patch or intramuscular diclofenac and the demand for rescue analgesia, side effects were noted.

Results

Demographic data as shown in Table 1 and Figure 1 denotes that the VAS scores of group B were significantly higher than group A at 2, 4, 6, 8 hours. Age, sex, gender,duration of surgery were all comparable variables in this study.

Table 1: Comparison of Visual Analogue Score between Group A and Group B.

Visual Analogue Score	Group A		Group B		Mann Whitney U test	P value
	Mean	±SD	Mean	±SD		
2 Hours	0.02	0.149	0.76	0.609	U=358.000	P=0.001*
4 Hours	1.02	.723	2.58	0.753	U=171.000	P=0.001*
6 Hours	2.58	.723	4.21	0.630	U=74.000	P=0.001*

*: Highly Significant

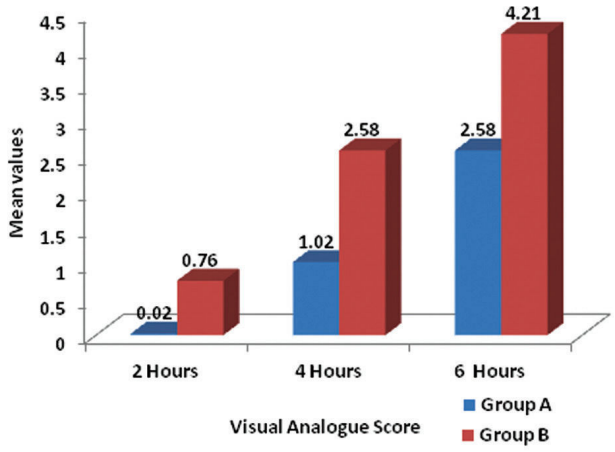

Fig. 1: Comparison of VAS scores at 2, 4, 6 hours.

The time at which rescue analgesia was given in Group A is 8 hr 37 minutes ± 1 hr 4.2 minutes and Group B was 6 hrs 19 minutes ± 58.6 minutes. The need for rescue analgesia between two groups is highly significant ($p < 0.001$) as denoted by Table 2 and figure 2.

Table 2: Comparison of Time of Rescue analgesia (hrs) between Group A & Group B.

Comparison between	Group A		Group B		Mann Whitney U test	P value
	Mean	± SD	Mean	±SD		
Time of Rescue analgesia (hrs)	8.37	0.642	5.79	0.586	U=00.0	P=0.001*

*: Highly Significant

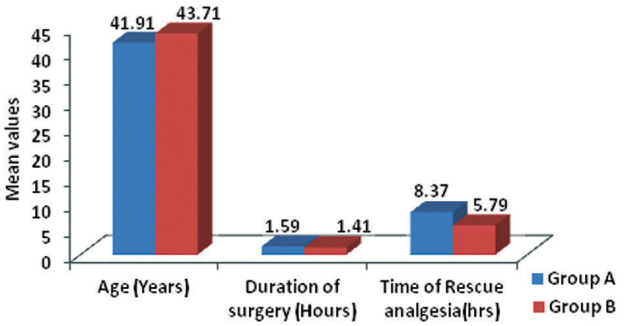

Fig. 2: Comparison of age, duration of surgery, time of rescue analgesia (hrs) between two groups.

Table 3: Distribution of patients according to side effects.

Side Effects	Group A		Group B		Chi square test	P value
	No. of patient	Percentage	No. of patient	Percentage		
RASH	3	6.6	0	0		
Gastritis	0	0	1	2.22		
Nausea	0	0	9	20		
Vomiting	0	0	1	2.22	X2= 17.351	P= 0.0039*
Pain at injection site	0	0	2	4.45		
NIL	42	93.4	32	71.11		
Total	45	100.0	45	100.0		

*: Highly significant

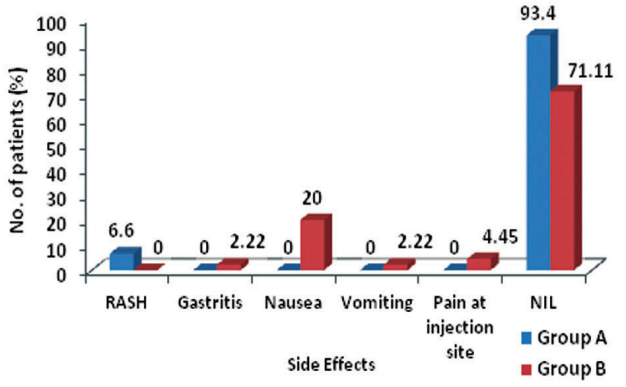

Fig. 3: shows the side effects.

Group A (transdermal diclofenac patch) – 3

Patients had erythematous rash at the local site whereas the other 42 patients showed no symptoms.

Group B (IM Diclofenac) 9 patients developed nausea, 2 patients had pain and swelling at the injection site, 1 had one episode of vomiting, 1 patient had gastritis and rest of 32 patients had no symptoms. Trandermal patch is highly effective is reducing the gastric symptoms of IM Diclofenac (P value of 0.0039 is highly significant).

Discussion

Postoperative pain can lead to psychological, physiological, neuroendocrine, respiratory and cardiovascular complications, leading to increase in postoperative morbidity and mortality. Effective control of postoperative pain remains one of the most important issue in the field of anaesthesia.[3] Intra operative pain management has to be extended to the post operative period immediately to provide pre-emptive analgesia.

Narcotics and NSAIDS are the drugs easily available in the post operative period. Narcotic analgesia is associated with drowsiness, constipation, urinary retention, circulatory and respiratory disturbances and hence NSAIDS are preferred. In NSAIDS, routine oral administration is impractical in post operative period. First pass metabolism, decreased patient compliance, painful parenteral administration are few issues that make them inadvisable; there comes the importance of transdermal patch[4].

Rao DG et al also applied transdermal diclofenac patch at the beginning of surgery in their studies, similar to our study. In their study post operative analgesia was assessed by using VAS (Visual Analogue Scale) at 2, 6 and 12 hours post operatively. The mean duration of post-operative analgesia in their study was 8.9±2.16 hours for IM diclofenac and 10.28±2.54 hours for transdermal diclofenac patch 1 which were very consistent with Krishna et al studies.[5]

In Banjare M et al studies, mean time for the requirement of rescue analgesia in the transdermal diclofenac patch group is 8.28 ± 0.86 hours while in IM diclofenac injection group mean time of the first analgesia is 6.63 ± 0.81 hours and was statistically significant (p=0.000).[6]

These findings correlate with Pragati et al[7] and Krishna et al[5] where transdermal patch group had duration of analgesia for 8 hours 6 minutes ± 1 hour 4 minutes.

The difference in mean of the number of times rescue analgesia required was found to be statistically significant in laparoscopic & gynaecologic surgeries & highly significant in orthopaedic surgeries (P = 0.003) in Soumya Samal et al studies.[3]

Other studies in this aspect reported similar findings. F. Alessandri[8] & Colleagues found that 35% of patients required rescue analgesia in transdermal diclofenac group where as 71.7% of patients required rescue analgesia in placebo group (p<0.001) in patients undergoing laparoscopic surgery for gynecologic conditions.

Topical and transdermal preparations are associated with a lower incidence of systemic side-effects because of the lower plasma concentration achieved by these modes. The most often side effects in our study were minor local tissue reactions, such as pruritus and minor rash in transdermal patch compared to gastritis and pain at local site in IM diclofenac.

Similarly, in Banjare M et al[6] study, In IM diclofenac injection group 12 patients (40%) had pain at local site while in the transdermal diclofenac patch group, none of the patients had any side effects. These findings show that the transdermal diclofenac patch is safer and better. Side effects were also documented in MASON et al[14] in which topical NSAIDs were used to treat chronic musculoskeletal pain and only 6% had local adverse reactions and 3% systemic adverse reactions. Safety profile was also documented in PREDEL et al[13] in which the diclofenac patch used in blunt impact injuries was well tolerated.

Conclusion

90 patients of ASA grade I and II posted for elective lower abdominal and perineal surgeries were randomly allocated into two groups A and B. All patients were given spinal anaesthesia with 3 ml of Bupivacaine heavy with no adjuvant. Patients in Group A were applied transdermal diclofenac patch (NU patch) immediately after spinal anaesthesia on the either side of the chest wall or on the back. Patients in group B were given IM diclofenac half an hour before the end of surgery.

All patients were assessed post operatively by using VAS score at 2, 4, 6 and 8 hrs. At VAS score 5 or above Inj Tramadol 2mg/kg was given as rescue analgesia and the assessment was stopped. Side effects were also noted. Based on the results obtained we conclude that the application of transdermal diclofenac patch (100 mg) significantly prolong the time at which patient requires rescue

analgesia i.e. 8 hr 37 mins ± 1 hr 4.2 mins compared to 75 mg of intra muscular diclofenac i.e. 6 hrs 19 mins ± 58.6 mins with minimal side effects. Thus transdermal diclofenac patch is effective, non-invasive and safer way of treating postoperative pain.

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