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Comparative Analysis of Intramuscular Diclofenac Injection Vs Transdermal Diclofenac (Nu Patch) In Post-Operative Pain Management

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ABSTRACT

Background: The problem of inadequate post- operative pain relief have been a debate for many years so there has been the considerable research on the subject of post- operative pain management. The present study was conducted to compare intramuscular diclofenac injection vs transdermal diclofenac nupatch in post- operative pain management. **Methods:** 100 adult patients were divided into 2 groups. 50 Patients GROUP A (TP) was treated by Diclofenac transdermal patch. 50 Patients GROUP B (DI) was treated by intramuscular diclofenac injection. Parameters such as pain relief, pain intensity, vital monitoring, adverse effects noted at various time intervals (0,3rd,6th,9th,12th hour,1st,2nd, 3rd, 4th day). **Results:** Age of patients in this study varied from 18-90 years. Most of the patients (34%) were in age group of 30-39 years. Next most common age group was of 40 to 49years which included 26% of patients. 22% of patients were in age group 20-29 years and 14% were in age group of 50-59 years. The operative time between two groups has a mean of 0.79±0.32 and it is not significant. 8 patients required rescue analgesia at 6th hour post-operatively in transdermal diclofenac patch group shows significant results. Statistical analgesic requirement at various time intervals is non-significant in between two groups. **Conclusion:** Transdermal diclofenac patch is as effective as intramuscular diclofenac injection and with fewer complications in post-operative pain management.

Keywords: Transdermal, diclofenac patch, post- operative pain.

INTRODUCTION

The pain of surgery is nociceptive (i.e. it is caused by tissue damage and it is transmitted by normal physiological pathways), acute and for short duration which subsides when the damaged tissue heals.[1] Adverse effects of untreated postoperative pain include psychological effects (suffering, anxiety, depression, anger), stress response (sympathetic activation, hypertension, tachycardia, increased risk of myocardial infarction, stroke, renal failure), metabolic abnormalities, immobility (chest infection, venous thrombosis, pressure sore, delayed recovery) and development of chronic pain.[2]

The problem of inadequate post- operative pain relief have been a debate for many years so there has been the considerable research on the subject of post- operative pain management.8 Despite advances in the knowledge of analgesics patho-physiology of pain and pharmacology and development of more effective techniques of post- operative pain control, many patients continue to suffer from pain in post-operative peroid.[3]

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Diclofenac is an analgesic-antipyretic-anti-inflammatory drug. It inhibits prostaglandin synthesis by inhibiting cyclooxygenase enzyme. Diclofenac is available in various forms to treat pain like injectable, topical gel, ophthalmic solution, suppository and transdermal patch to treat pain.20 Parenteral or oral administration of diclofenac has its own adverse effects related to gastrointestinal and cardiovascular side effects.[4]

The effect of transdermal patches is more than skin deep. All transdermal systems attempt to create a balance between a number of key factors including size of patch, or coverage area, concentration of the drug, duration of therapeutic drug level and use of an enhancer/reserve drug.[5] So, the present study was conducted to compare intramuscular diclofenac injection vs transdermal diclofenac nupatch in post-operative pain management.

MATERIALS AND METHODS

The study was carried out on 100 adult patients admitted in surgery department of Rajindra Hospital, attached to Govt. Medical College, Patiala. The patients were explained about the study in detail and consent for participation in the study was taken.

Patients were divided into 2 groups. 50 Patients GROUP A (TP) was treated by Diclofenac transdermal patch. 50 Patients GROUP B (DI) was treated by intramuscular diclofenac injection. Parameters such as pain relief, pain intensity, vital monitoring, adverse effects noted at various time

intervals (0, 3rd, 6th, 9th, 12th hour, 1st, 2nd, 3rd, 4th day). Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

RESULTS

[Table 1] shows that age of patients in this study varied from 18-90 years. Most of the patients (34%) were in age group of 30-39 years. Next most common age group was of 40 to 49years which included 26% of patients. 22% of patients were in age group 20-29 years and 14% were in age group of 50-59 years. The mean age of the patients in this study was 38.66±11.37 and 38.60±11.58 years.

[Table 2] shows the operative time between two groups has a mean of 0.79±0.32 and it is not significant.

[Table 3] shows that maximum cases were of lap cholecystectomy seen in 12 cases in both groups.

[Table 4] shows that difference between two groups of pain intensity at various time intervals postoperatively is non- significant between two groups.

[Table 5] shows that difference between two groups of pain relief at various time intervals postoperatively is non-significant between two groups.

Table 1: Distribution of patients

Age (Years)	Group A(TP)		Group B(DI)	
	Patients	Percentage	Patients	Percentage
20-29	11	22%	12	24%
30-39	17	34%	17	34%
40-49	13	26%	12	24%
50-59	7	14%	7	14%
60-69	2	4%	2	4%
Total	50	100%	50	100%
Mean± SD	38.66±11.37		38.60±11.58	
p value	0.979 (NS)			

Table 2: According to operative time

OP Time (Hours)	Group A (TP)		Group B(DI)	
	Patients	Percentage	Patients	Percentage
30 Min	15	30%	15	30%
1 Hours	35	70%	35	70%
Total	50	100%	50	100%
Mean± SD	0.79±0.32		0.79±0.32	
p value	1.000 (NS)			

Table 3: Diagnosis of cases

Diagnosis	Group TP		Group DI	
	Patients	Percentage	Patients	Percentage
Appendicectomy	5	10%	5	10%
Lap Cholecystectomy	12	24%	12	24%
Fibro adenoma	5	10%	5	10%
Fistulotomy/ fistulectomy	2	4%	2	4%
Hemorrhoidectomy	4	8%	4	8%
Hydrocoele	4	8%	4	8%
Ileostomy Closure	4	8%	4	8%
Breast ca	1	2%	1	2%
Inguinal Hernia	6	12%	6	12%
Incisional Hernia	2	4%	2	4%
Para umbilical hernia	3	6%	3	6%
Thyroidectomy	1	2%	1	2%
Total	50	100%	50	100%
X2	0.00			
p value	1.000 (NS)			

Table 4: Pain intensity at Different Time Interval

Time Interval	Pain Intensity	Group A(TP)		Group B(DI)		p value
		Patients	Percentage	Patients	Percentage	
0 Hours	0	0	0%	0	0%	1.000 (NS)
	1	50	100%	50	100%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
3rd Hours	0	0	0%	0	0%	0.526 (NS)
	1	0	0%	0	0%	
	2	37	74%	27	54%	
	3	13	26%	23	46%	

6th Hours	0	0	0%	0	0%	0.440 (NS)
	1	0	0%	0	0%	
	2	40	80%	35	70%	
	3	10	20%	15	30%	
9th Hours	0	0	0%	0	0%	0.110 (NS)
	1	38	76%	37	74%	
	2	12	24%	13	26%	
	3	0	0%	0	0%	
12th Hours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	50	100%	50	100%	
	3	0	0%	0	0%	
24th Hours	0	0	0%	0	0%	1.000 (NS)
	1	50	100%	50	100%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
2nd Day	0	29	58%	29	58%	0.917 (NS)
	1	21	42%	21	42%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
3rd Day	0	50	100%	50	100%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
4th Day	0	50	100%	50	100%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	

Table 5: Pain relief at Different Time Interval

Time Interval	Pain Relief	Group A(TP)		Group B(DI)		p value
		Patients	Percentage	Patients	Percentage	
0 Hours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	50	100%	1	2%	
	3	0	0%	49	98%	
	4	0	0%	0	0%	
3rd Hours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	50	100%	1	2%	
	3	0	0%	49	98%	
	4	0	0%	0	0%	
6th Hours	0	0	0%	0	0%	0.123 (NS)
	1	0	0%	0	0%	
	2	15	30%	1	2%	
	3	35	70%	49	98%	
	4	0	0%	0	0%	
9th Hours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	50	100%	50	100%	
	4	0	0%	0	0%	
12thHours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	50	100%	50	100%	
	4	0	0%	0	0%	
24th Hours	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
	4	50	100%	50	100%	
2nd Day	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
	4	50	100%	50	100%	
3rd Day	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
	4	50	100%	50	100%	

4th Day	0	0	0%	0	0%	1.000 (NS)
	1	0	0%	0	0%	
	2	0	0%	0	0%	
	3	0	0%	0	0%	
	4	50	100%	50	100%	

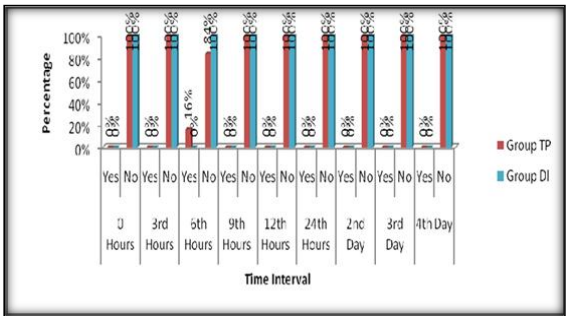

Figure 1: Rescue analgesia at Different Time Interval

[Figure 1] shows that 8 patients required rescue analgesia at 6th hour post-operatively in transdermal diclofenac patch group shows significant results. Statistical analgesic requirement at various time intervals is non- significant in between two groups.

DISCUSSION

As the understanding of pain pathophysiology and treatment increases, new routes of drug delivery are being discovered with the objective of attempting to block pain at peripheral sites, with maximum active drug and minimal systemic effects. Topical preparations are the result of such exploration.[6] The goal of topical NSAIDs is to minimize systemic adverse effects and encourage compliance. Most topical preparations are available as transdermal patches, ointments, or creams. Based on contents, there are two primary types of analgesic patches: 1) Patches containing counterirritants- contain ingredients such as capsaicin, methyl salicylate, camphor, or menthol, which are thought to mask pain signals by causing other sensations (itching, warmth, or cooling) in the areas they are applied to. 2) Patches containing narcotics or NSAIDS- e.g. fentanyl, Buprenorphine and diclofenac patch.[7]

In this study total of 100 patients were selected in the age group of 18- 90 years, for the study of comparative analysis between intramuscular diclofenac injections vs transdermal diclofenac patch (Nupatch) for post- operative pain management. Pain intensity and pain relief were recorded on 4-point and 5-point scale respectively.

The patients both male and female were in age group of 18-90 years. The mean age of the patients in this study was 38.66±11.37 in diclofenac patch group and the mean age of diclofenac injection is 38.60±11.58 years respectively. In a similar study conducted by Dinesh et al.[8] The mean age in group Diclofenac injection was 46.06±13.14 years while that in group Diclofenac Patch was 45.36±13.07.

Pain intensity and pain relief on 4 and 5-point scale showed the efficacy of transdermal diclofenac patch and intramuscular diclofenac injection. It was further observed that no rescue medicine was used in patients of diclofenac injection group where as in transdermal patch group 8patient needed rescue analgesia at 6th hr and no rescue analgesia needed for this group at other various time interval. Twelve patient who undergone laproscopic cholecystectomy had no need for rescue analgesia in the post operative period. The period of surgery encompasses the need of rescue analgesia along with the surgical analgesic demand as prolonged period of tissue handling will increase the native production of inflammatory substances and dropsy, thus increasing the need for analgesics. The exact period of surgical pain differs wide among people and is influenced by a mess of interconnected factors.[9] Isolation of individual factors that will influence the period of surgical pain is so not possible. Comparing both groups of pain intensity and relief there was no significant difference between two groups at various time interval. Difference of Pain relief at 3hrs (p=1.000), 6hrs (p=0.123) and 1st, 2nd day (p=1.000) is non- significant between two groups. In our study transdermal patch was more effective for minimally invasive surgery patients.

In a similar study conducted by Debashish Borkotoky et al,[10] study results showed at 6th hour between group A and group B. There was no significant difference between the groups at other various time intervals. There were no side effects seen in any of the patients in both the groups.

In a similar study conducted by Aditi Maruti et al.[11] The Comparative Effects of Transdermal and Intramuscular Diclofenac for Postoperative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy comparable between the Two groups at 2 hrs was (p=1.00) and wasn't statistically important and at four hours: comparable between two groups was (p=0.661) and wasn't statistically important (p=0.661) and at six hours comparable between two groups was (p=0.28) and wasn't statistically important (p = 0.28) and at eight hours comparable between two groups (p = 0.18) and wasn't statistically important.

It is seen that patch is as effective as intramuscular injection in providing post operative analgesia. Krishna and Nataraj,[12] reported that intaoperative 100 mg diclofenac patch was as effective as intramuscular injection (75mg) for acute postoperative pain when diclofenac was used as pre-emptive analgesic.

The operative time between two groups Diclofenac injection vs transdermal patch has a mean of 0.79±0.32. The statistical analysis between two group was not significant. In a similar study

conducted by Aditi et al.[11] The mean period of surgery in group A was 123.7 min ± 34.6 min and in group B it had been 125 min ± 23 min. The period of surgery was comparable between two groups with p value= 0.869 the difference was not statistically significant.

In this study conducted between intramuscular diclofenac injection and transdermal diclofenac patch. In intramuscular diclofenac injection group two patients had gastritis symptoms after application of intramuscular diclofenac injection at 6th hour one patient who undergone laproscopic cholecystectomy and an patient undergone appendicetomy. Patient had intramuscular pain at injection site at various time interval in intramuscular diclofenac injection group. But no adverse effects was seen in transdermal diclofenac patch group and no significant difference had seen between both groups.

In a similar study conducted by Abinav et al,[13] adverse effects that were observed in patients receiving intramuscular diclofenac were abdominal pain (gastritis) in 2 patients and pain at injection site in 3 patients. 2 patients developed erythroderma at the positioning of application of patch within the group A. Transdermal Diclofenac patch is effective in reducing the GI adverse effects associated with IM and oral Diclofenac. If the adverse effects were compared between the teams statistically it had been not significant (p = 0.067).

CONCLUSION

Our study concludes that transdermal diclofenac patch is as effective as intramuscular diclofenac injection and with fewer complications in post-operative pain management. However, further studies are needed to establish the importance of transdermal diclofenac patch in minimal invasive surgery to further support the benefits like painless delivery of analgesic, maintenance of constant and prolonged drug level, reduced frequency of dosing, reduced incidence of gastritis, self-administration and easy termination of medication, leading to better patient compliance.

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