Original Research Article
MVP Journal of Medical Sciences, *Vol 5(1), 104–109, January-June 2018*

ISSN (Print) : 2348–263X
ISSN (Online) : 2348-2648
DOI: 10.18311/mvpjms/2018/v5i1/10839

The Comparative Effects of Transdermal and Intramuscular Diclofenac for Postoperative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy

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Abstract

Aims and Objectives: To compare the analgesic effectiveness of transdermal diclofenac patch and intramuscular diclofenac in patients undergoing laparoscopic cholecystectomy. To compare the adverse effects of transdermal Diclofenac patch and intramuscular diclofenac. **Methods:** Sixty ASA I and II patients of either sex aged eighteen to sixty years ready for laparoscopic cholecystectomy were enclosed during this study. Patients were divided into 2 groups, A (n = 30) received transdermal diclofenac patch (100 mg) three hours before surgery B (n = 30) intramuscular diclofenac (75 mg) was given forty five minutes before surgery. Postoperative pain was assessed using Visual Analogue Scale (VAS). Adverse effects were noted over a period of twelve hours. Patients with VAS score greater than 3 received intravenous tramadol 2mg/kg to relieve pain. **Results:** In each group the VAS scores were higher for ten hours post surgery. There was no significant difference in the surgical pain in both the groups. There was no significant difference in both the groups statistically for the need of rescue analgesia. Erythema was observed in group A patients whereas pain at injection site and rubor was observed in group B who received the injection diclofenac. **Conclusion:** Diclofenac skin patch and IM injection are unit comparable in terms of effectiveness for pain relief in surgical laparoscopic cholecystectomy patients. Transdermal patch is thought of as an efficient, non-invasive and value effective means of managing surgical pain.

Keywords: Diclofenac, Shot, Skin Patch, VAS scores

1. Introduction

Laparoscopic surgery has recently become highly regarded because it provides quick recovery and early post operative mobilization, although surgical pain has been a very important issue limiting patient comfort[1]. Opioids area equally effective analgesics for pain related to outpatient laparoscopic surgery, however use of high doses have adverse effects like nausea, vomiting, constipation and metabolic process depression.[2] Nonsteroidal anti-inflammatory drugs(NSAIDs), Panadol and intraperitoneal drugs which are used nowadays are equally effective and they show less severe adverse effects as seen with opioids. In most clinical trials, NSAIDs are shown to cut back the opioid analgesic demand and reports of adverse effects as compared to opioids are also very minimal.[2-5]

Therapeutic choices for maintaining the vital parameters both intraoperatively and postoperatively have changed significantly after advances in transdermal nonsteroidal anti-inflammatory drug delivery system has come in. This will offer sustained plasma levels of medica-

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tion and no peaks and troughs related to drug dosing are seen, this also avoids the primary first pass metabolism seen with oral dosing.[6] Studies have shown that diclofenac in laparoscopic surgery have additionally improved pain scores and reduced opioid consumption.[7,8]

Intra muscular injection is painful for patients; transdermal diclofenac patch is painless and straightforward to use. The skin patch could be a recently introduced delivery system for Diclofenac and is on the market in India since 2005. Thus, the aim of this study is going to be to check the analgesic effectiveness of contractor and transdermal diclofenac in surgical pain treatment in patients undergoing cholecystectomy.

2. Aims and Objectives

- To compare the analgesic effectiveness of transdermal diclofenac patch and intramuscular diclofenac for surgical patients undergoing cholecystectomy.
- To compare the adverse effects of the transdermal diclofenac patch and intramuscular diclofenac in patients undergoing laparoscopic cholecystectomy.

3. Materials and Methods

Type of study: This was a comparative interventional style of study disbursed at the Department of Anaesthesiology at Dr. Vasant Rao Pawar Medical College

Sample size 60(sixty)

Participants were the patients within the age bracket of eighteen to sixty years (18 to 60) of either sex who are posted for elective laparoscopic cholecystectomy after the full written informed consent. ASA (American Society of Anaesthesiologists) I and II class patients were enclosed within the study.

The study was started after the permission and clearance from institutional ethical committee Participants were instead divided in,

Group A (n = 30): Patients received a hundred mg of transdermal diclofenac patch three hours before the surgery.

Group B (n = 30): Patients received intramuscular diclofenac 75mg diclofenac injection 45 minutes before induction.

All the information was entered within the predesigned proforma.

On the day of surgery, participants within the group A were applied with a transdermal diclofenac patch containing 100mg of diclofenac dimethylamine three hours before the laparoscopic surgery.

The group B received intramuscular diclofenac 75mg injection at gluteal region 45 minutes before the induction. Patients of both the groups received the premedication's in form of Inj. Ranitidine (2 mg/kg intravenous), Inj. Ondansetron (0.15mg/kg intravenous), Inj. Glycopyrrolate (4 microgram/kg, intravenous), Inj. Fentanyl (2 microgram/kg intravenous).

Pain was assessed postoperatively at 2,4,6,8,10, hours employing a visual analogue scale (VAS). If the VAS SCORE any time throughout study amount was greater than or equal to 3, then injection Tramadol 2mg/ kg intravenously was administered as a rescue analgesic. Time of giving the rescue analgesia was noted. Adverse effects with the utilization of transdermal diclofenac patch and intramuscular diclofenac were additionally noted.

Table 1. ASA grading was comparable between the 2 teams

Variables	Group	N	Mean	SD	SEM	p- value
Age (years)	A	30	45.73	8.25	1.51	0.977
	B	30	45.67	9.21	1.68	
Weight (Kg)	A	30	64.83	6.15	1.12	0.804
	B	30	64.43	6.26	1.14	
Duration of Surgery (min.)	A	30	123.73	34.64	6.33	0.869
	B	30	125.00	23.30	4.25	
Rescue Analgesia Dose	A	30	129.67	12.31	2.25	0.804
	B	30	128.87	12.53	2.29	
Rescue Analgesia time (hrs.)	A	30	7.20	1.86	0.34	0.111
	B	30	6.47	1.63	0.30	

4. Results

The mean period of surgery in A was 123.7 min ± 34.6 min and in B it had been 125 min ± 23.3 min. The period of surgery was comparable between two groups with p value = 0.869 the difference was not statistically significant.

Pain was assessed postoperatively at two, 4,6,8 and 10 hours by Visual Analogue Scale (VAS), if the patient had a score of 3 or more a rescue analgesic was given (Inj. Tramadol 2mg/ kg⁻¹ intravenously).

Within the group A, at 2 hours postoperatively 5 of the 30 patients had no pain, twenty patients had a VAS of 2 and five patients of 3. At four hours postoperatively five patients had VAS of 1,21 patients had VAS of 2 and four patients had VAS of 3 and requested for rescue analgesia. At six hours postoperatively 17 had a VAS of 2,9 patients had VAS of 3 and received rescue analgesic dose, whereas at 8 hours postoperatively 5 had a VAS of 2 and 12 received the rescue analgesic as their VAS was 3. At 10 hours postoperatively there have been 5 patients requested for the rescue physiological state with the VAS of 3. The mean solar time of rescue analgesia in group A was 7 hours 20 minutes with a standard deviation of 1 hour 8 minutes (Table 2).

In group B, at 2 postoperatively 5 patients had no pain, that is, a VAS of zero, 20 patients had VAS of 1, 5 patients of had VAS of 2 and 5 patients had VAS of 3 who

Table 2. Pain score in A

Pain Score	Pain Score (Group A)				
Pain Score	2 hr	4 hr	6 hr	8 hr	10 hr
0	5	0	0	0	0
0	16.7%	0.0%	0.0%	0.0%	0.0%
1	20	5	0	0	0
1	66.7%	16.7%	0.0%	0.0%	0.0%
2	5	21	17	5	0
2	16.7%	70.0%	65.4%	29.4%	0.0%
3	0	4	9	12	5
3	0.0%	13.3%	34.6%	70.6%	100.0%
Total	30	30	26	17	5

Table 3. Pain score in B

Pain Score	Pain Score (Group B)				
Pain Score	2 hr	4 hr	6 hr	8 hr	10 hr
0	5	0	0	0	0
0	16.7%	0.0%	0.0%	0.0%	0.0%
1	20	5	0	0	0
1	66.7%	16.7%	0.0%	0.0%	0.0%
2	5	19	12	1	0
2	16.7%	63.3%	50.0%	8.3%	0.0%
3	5	6	12	11	1
3	16.7%	20.0%	50.0%	91.7%	100.0%
Total	30	30	24	12	1

Table 4. VAS Score at 2, 4, 6, 8 and 10 hours

VAS Score	Group	N	Mean	SD	SEM	p- value
2 hours	A	30	1.000	0.587	0.107	1.00
	B	30	1.000	0.587	0.107	
4 hours	A	30	1.967	0.556	0.102	0.661
	B	30	2.033	0.615	0.112	
6 hours	A	26	2.350	0.485	0.095	0.28
	B	24	2.500	0.511	0.104	
8 hours	A	17	2.710	0.470	0.114	0.18
	B	12	2.920	0.289	0.083	
10 hours	A	5	3.000	0.000	0.000	NA
	B	1	3.000			

requested for rescue analgesia. At 4 hours postoperatively, 5 patients still had a VAS of 1, nineteen patients of 2 and 6 patients had VAS of 3 receiving rescue analgesia. At 6 hours postoperatively 12 patients had a VAS of 2 and 12 had VAS of 3. At 8 hours postoperatively, 1 patient had a VAS of 2 whereas eleven had 3 and got the rescue analgesic dose. At 10 hours only 1 patient demanded rescue analgesia at VAS of 3. The mean solar time postoperatively of rescue analgesia was 6 hours 47 minutes with a standard deviation of 1 hour 12 minutes (Table 3).

The observation showed that the time, rescue analgesics were needed in group B was not considerably prolonged (p worth of 0.111).

At two hours: The VAS was comparable between the teams and wasn't statistically important (Table 4).

($p = 1.00$).

At four hours: Th VAS was comparable between the teams and wasn't statistically important

($p = 0.661$).

At six hours: The VAS was comparable between the teams and wasn't statistically important

($p = 0.28$).

At eight hours: The VAS was comparable between the teams and wasn't statistically important ($p = 0.18$).

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 ($p = 0.067$).

5. Discussion

We conducted a study to compare the analgesic effectiveness of transdermal diclofenac patch with intramuscular diclofenac in patients posted for elective laparoscopic cholecystectomy.

In our study the demographic information were comparable for age and sex in each the groups.

Statistical analysis has been done by applying paired t test to both the study groups. The two groups are assessed for period of surgery and rescue analgesia which is required according to Visual Analogue Scale for pain and results are calculated statistically.

The mean period of surgery (Table 1) in A was 123.73 ± 34.64 min. compared to B where the period of surgery was 125 ± 23.30 min. 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. In our study the mean period of surgery was comparable between the two groups (p worth 0.804).

The exact period of surgical pain differs wide among people and is influenced by a mess of interconnected factors. Isolation of individual factors that will influence the period of surgical pain is so not possible. The visual analogue scale utilized in this study to work out the intensity of pain is one-dimensional and thus has its limitations. It was chosen as it is compliant as patients understood it simply and even illiterate subjects might participate. In this study pain was assessed postoperatively at 2,4,6,8 and 10 hours. A VAS of 3 was thought of to represent the requirement for added analgesics or rescue analgesia.

During this study we tend to use Inj. Tramadol (2 mg/kg) as rescue analgesia.

Within the group A, at 2 hours postoperatively 5 of the 30 patients had no pain, twenty patients had a VAS of 2 and five patients of 3. At four hours postoperatively five patients had VAS of 1, 21 patients had VAS of 2 and four patients had VAS of 3 and requested for rescue analgesia. At six hours postoperatively 17 had a VAS of 2, 9 patients had VAS of 3 and received rescue analgesic dose, whereas at 8 hours postoperatively 5 had a VAS of 2 and 12 received the rescue analgesic as their VAS was 3. At 10 hours postoperatively there have been 5 patients requested for the rescue physiological state with the VAS of 3. The mean solar time of rescue analgesia in group A was 7 hours 20 minutes with a standard deviation of 1 hour 8 minutes

In group B, at 2 hours postoperatively 5 patients had no pain, that is, a VAS of zero, 20 patients had VAS of 1, 5 patients of had VAS of 2 and 5 patients had VAS of 3 who requested for rescue analgesia. At 4 hours postoperatively, 5 patients still had a VAS of 1, nineteen patients of 2 and 6 patients had VAS of 3 receiving rescue analgesia. At 6 hours postoperatively 12 patients had a VAS of 2 and 12 had VAS of 3. At 8 hours postoperatively, 1 patient had a VAS of 2 whereas eleven had 3 and got the rescue analgesic dose. At 10 hours only 1 patient demanded rescue analgesia at VAS of 3. The mean solar time postoperatively of rescue analgesia was 6 hours 47 minutes with a standard deviation of 1 hour 12 minutes.

The distinction between rescue analgesia wants of patients wasn't statistically important. Erythroderma was ascertained in one c group whereas pain at injection site and rubor was ascertained within the injection group. There was no distinction within the need of rescue analgesia doses of the 2 groups. The distinction between the incidence of adverse effects wasn't statistically important ($p = 0.067$).

In a similar study conducted by Bhargava et al., to compare the analgesic effects of diclofenac skin patch (100 mg) - Nupatch and diclofenac shot (75 mg) within the management of post operative pain, to watch the effectiveness, duration, quality of analgesic result on visual analogue scale and to watch any adverse effects of diclofenac patch and diclofenac injection .It is seen that patch is as effective as intramuscular injection in providing post operative analgesia[9]. The problem that was faced throughout the study was the stickiness of the skin patch because the patch would lose its stickiness and would peel off once applied to mobile elements of body like arms or skeletal muscle region. Thus, we tend to advocate that the skin patch is also applied to comparatively non-mobile elements of body like anterior chest wall or abdomen. Transdermal preparations offer a gradual plasma concentration and avoid 1st pass metabolism.[10] Diclofenac could be a potent nonsteroidal anti-inflammatory drug and its anti-inflammatory and antioedema action is useful in reducing surgical pain, however the adverse effects associated with diclofenac like internal organ tissue layer harm and pain at the positioning of injection area are commonly encountered with parenteral preparations.[3,5,6] This can be overcome with the use of transdermal diclofenac patch.

6. Conclusion

Based on the results obtained from our study we tend to conclude that, transdermal diclofenac diethylamino and intramuscular diclofenac are equally effective in terms of effectiveness for pain relief in postoperative laparoscopic cholecystectomy surgery patients.

Transdermal patch is thought of as an efficient, non-invasive and value effective means of managing surgical pain.

7. References

1. Hepner, David L. Preventive analgesia: What will it very mean? Medicine. 2000; 93(5):1368.
2. Ong CKS, Lirk P, Saymour R. The effectiveness of preventive physiological state for acute surgical pain management- A metanalysis. Anaesthesia and Physiological State. 2005; 100:575–73.
3. Pointers for the utilization of Nonsteroidal. Medicament medicine within the perioperative amount. The Royal School of Anaesthetists; 1998 Mar.
4. Shang AB, Gan TJ. Optimising surgical pain management within the ambulant Patient. Medicine. 2003; 63(9):855–67.
5. Sachs CJ. Oral analgesics for acute nonspecific pain. Am Fam Doctor. 2005; 71:913–8.
6. Bannwarth B. Do selective cyclo-oxygenase-2 inhibitors have a future? Drug Safety. 2005; 28(3):183–9 https://doi.org/10.2165/00002018-200528030-00001 PMid:15733024
7. Naedal J, Brown K. NSAID-associated adverse effects and acid management aids to forestall them. A review of current treatment choices. Drug Safety. 2006; 29(2):119–32. https://doi.org/10.2165/00002018-200629020-00002

8. Vaile JH, Davis P. Topical NSAIDs for contractor Conditions. A review of the literature. Medicine. 1998; 56(5):783–99.
9. Bhargava GS, Sidhu AS, Bansal D, Bhatia AS. Comparative study within the management of surgical pain with diclofenac patch versus diclofenac injection. CIB Tech J Surg. 2015; 4(1):10–5.
10. Hadgraft J, Lane ME. Passive transdermic drug delivery systems. Recent issues and advances. Am J Drug Deliv. 2006; 4(3):153–60. https://doi.org/10.2165/00137696-200604030-00003

Cite this article as: Abnave AM, Sankalecha SS. The Comparative Effects of Transdermal and Intramuscular Diclofenac for Postoperative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy. MVP Journal of Medical Sciences 2018; 5(1):104-109.

Appendix 1

ASA grading

American Society of Anesthesiologists (ASA) Score

American Society of Anesthesiologists (ASA) Score is a global score that assesses the physical status of patients before surgery.

It is sometimed refereed to as ASA-PS, because it is a measure of 'physical status'.

ASA 1 A normal healthy patient.

ASA 2 A patient with mild systemic disease.

ASA 3 A patient with severe systemic disease.

ASA 4 A patient with severe systemic disease that is a constant threat to life.

ASA 5 A moribund patient who is not expected to survive

There are modifications - the addition of "E" for an emergency, the addition of "P" for pregnancy, and ASA 6 for organ retrieval in brain-dead patients.

The ASA Score is a useful global measure of health.

Appendix 2

Visual Analogue Scale for pain