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International Journal of Current Research
Vol. 9, Issue, 02, pp.46168-46173, February, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

ISSN: 0975-833X

RESEARCH ARTICLE

EVALUATION OF EFFICACY, SAFETY AND TOLERABILITY OF TRANSDERMAL DICLOFENAC SODIUM PATCH FOR IN THE MANAGEMENT OF POSTOPERATIVE PAIN FOLLOWING SURGICAL REMOVAL OF IMPACTED MANDIBULAR THIRD MOLARS

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ARTICLE INFO

Article History:
Received 12th November, 2016
Received in revised form
26th December, 2016
Accepted 24th January, 2017
Published online 28th February, 2017

Key words:

Diclofenac sodium patch,
Impacted third molar,
Transdermal patch.

ABSTRACT

The objectives of our study was to evaluate the efficacy, safety and tolerability of transdermal diclofenac sodium patch for in the management of postoperative pain following surgical removal of impacted mandibular third molars.

Material and method: 100 healthy subjects belonging to both the sexes in the age group of 18–40 years with impacted third molar teeth were included in the study. 60 minutes before extraction, Transdermal patch of Diclofenac sodium 100mg (Diclo-patch) was applied. Subsequently surgical removal of impacted tooth was done under local anesthesia after administering the nerve block and patient was asked to change patch every 24 hours for the next 3 days. The postoperative pain was recorded on The Visual Analog Scale (VAS), Verbal Rating Scale (VRS), Pain Intensity Scale (PIS), Pain Relief Scale (PRS). Any adverse effects were also noted. Readings were taken at 4hours, 6hours, 8hours, 12hours and 24 hours postoperatively, taking the time at which the surgery was completed as a reference. Participants were given Diclofenac Sodium Transdermal Patch 100mg once a day for 3 days after performing surgery followed by follow up of 2days.

Results: The statistical analysis was done using chi-square test and clinical observation revealed that on the first postoperative day significant relationship was somewhat less when diclofenac sodium administered transdermally. Though, on the second and third postoperative days there was no statistical or clinical difference in the pain control by this route of administration and found to be most effective in almost all patients whereas was even easy acceptable by them.

Conclusion: The study concludes that transdermal diclofenac sodium can be used as an alternative form of pain control following removal of impacted mandibular third molars, however considering that the analgesic potency might be lesser in the immediate postoperative period in sensitive and anxious patients.

Citation: Dr. Isha Kaur Bagga, Dr. Pratik Jain and Dr. Parikh Abhishek Vijaykumar, 2017. "Evaluation of efficacy, safety and tolerability of transdermal diclofenac sodium patch for in the management of postoperative pain following surgical removal of impacted mandibular third molars", *International Journal of Current Research*, 9, (02), 46168-46173.

INTRODUCTION

The disgrace over pain has been an extreme task since timeworn; pain bothers all living beings, although it is displeasing, it has a nature of self-defense. In the sixteenth century Rene Descartes, a French philosopher justified pain as a protective response and there has been rapid encroachment in its understanding since then, but still the practice of its management remains a challenge. The International association for the study of pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (Prithvi *et al.,* 2009). "This definition emphasizes that the experience of pain has two inseparable elements processed in parallel by the nervous system, i.e. sensory (nociception) and affective (emotional) and that pain can be experienced without discernable physical cause, i.e. injury or disease. Postoperative pain is commonphenomenon following surgery; because of surgical trauma and the release of pain mediators which is an overlooked entity that receives little care (Prithvi *et al.,* 2009; Hemantbhaskar *et al.,* 2010; SoumyaSamal *et al.,* 2013). In the early 1900's George Crile suggested, "Control of Post-operative pain could favourably influence the results of surgery" (Anil Agarwal *et al.,* 2007). Study has shown that post-operative pain is maximum during initial 48-72 hours & it declines thereafter[13]. Post-extraction pain has often been an

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antagonist for dental surgeons who are constantly attempting for an analgesia that would be best accepted and tolerated by the patients, hence ensuring patient compliance. Post-operative analgesia should be effective, safe and predictable. In the field of dental therapeutics, for pain control; transdermal patches have developed as an innovative topical drug delivery system for diclofenac and other NSAIDS which appear to have been in consistently used in various medical fraternities for a significant period of time now and recommending the advantage for sustained drug delivery with reduced incidence of systemic detriments of causing adverse effects because of lower plasma concentration. The objective of this clinical analysis was to evaluate the analgesic efficacy of post operative period, adverse events, patient's safety and tolerability and compliance with the use of transdermal diclofenac sodium patch following surgical removal of impacted mandibular third molars.

MATERIALS AND METHODS

Materials and armamentarium: (as shown in figure 1)

- Mouth mirror, probe.
- Drape.
- Gloves.
- 2% Lignocaine (1:200,000 adrenaline).
- Diclofenac transdermal Patch (figure 2)
- 2mL syringe.
- BP blade no.15 and BP handle.
- Elevators
- 3rd molar forceps.
- Austin's retractor.
- Micromotor and straight hand piece, burs-702 and 703.
- 3-0 silk suture

Methodology

The study was conducted after taking approval of Institutional Ethics Committee. In total 100 healthy participants belonging to both the sexes and within the age groups of 18–40 years with impacted third molar teeth requiring surgical extraction were included in the study. Subjects undergoing treatment with other NSAIDs or any other analgesics or corticosteroids and those with history or clinical evidence of allergy to NSAIDs or history of urticaria and hypersensitivity to any components of patch were excluded from the study. This prospective study was carried out following ethical clearance which was provided by an approved institutional ethical committee. All the participants were well-informed about the nature of study and a written informed consent was obtained from all the participants. A transdermal patch of Diclofenac sodium 100mg or 200mg (Diclo-patch) was applied 60 minutes before extraction. Subsequently surgical removal of impacted tooth was done under local anesthesia after administering the nerve block using standardized armamentarium. The teeth were either sectioned or removed in Toto. Of the 100 cases, the teeth were sectioned and removed in 60 cases while in the remaining cases the teeth were extracted in Toto. Participants were asked to change patch every 24 hours for the next 3 days. Analgesics and Antibiotics were administered postoperatively. Analgesic (Ketorolac DT) in the form of a dispersible medium was prescribedand permitted to be used as a rescue dose for anintenseand spontaneous pain. Participants were asked to report for pain intensity and relief on four subjective scales; The Visual Analog Scale (VAS), and three other 5 point scales (from 0 to 4); Verbal Rating Scale (VRS), Pain Intensity Scale (PIS), Pain Relief Score (PRS). Contrary effects were also noted, if any. Patients had to assign the scores for each parameter at interval of 4hours, 6hours, 8hours, 12hours and 24 hours postoperatively, taking the time at which the surgery was completed as a reference.

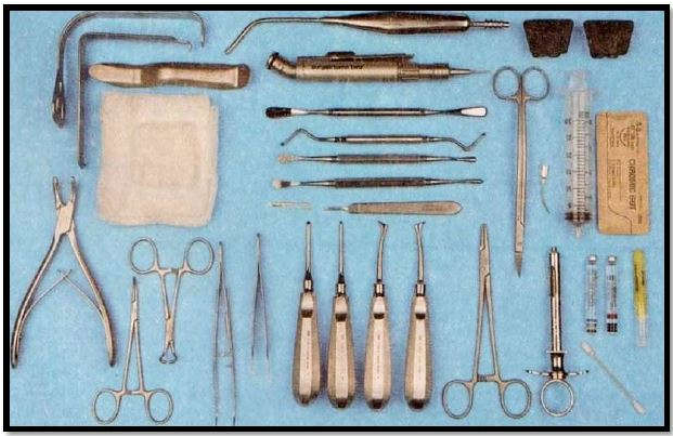


Figure 1. Armamentarium for the procedure

Figure 2. Diclofenac Transdermal Patch

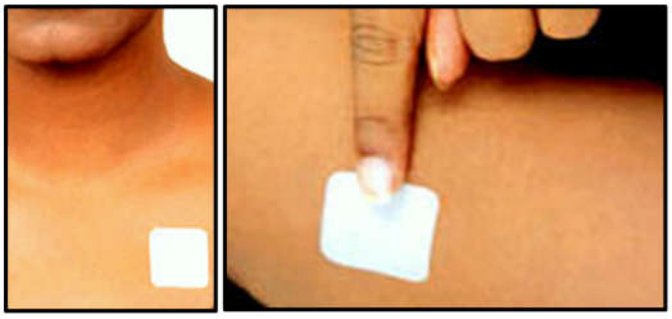


Figure 3. Application of Diclofenac Patch

RESULTS AND OBSERVATION

This study was devised to evaluate the efficacy, safety and tolerability of transdermal diclofenac sodium patch for the management of postoperative pain following surgical removal of impacted mandibular third molars

Patients were evaluated at regular intervals for following parameters:

Patient's name:
Age:
Sex:
OPD No.:

Visual Analog Scale
0 - NO PAIN
1-3 - MILD PAIN
4-6 - MODERATE PAIN
7-9 - SEVERE PAIN
10 - WORST PAIN POSSIBLE

Verbal Rating Scale
0 - COMFORTABLE
1 - MILD
2 - MODERATE
3 - SEVERE
4 – VERY SEVERE

Pain Intensity Scale
0 - NONE
1 - VERY MILD PAIN
2 - MILD PAIN
3 - MODERATE PAIN
4 – SEVERE PAIN

Pain Relief Scale
0 - NONE
1 - A LITTLE
2 - SOME
3 - A LOT
4 – COMPLETE

Complications
PURITUS
ERYTHEMATOUS RASH
PUSTULAR RASH

Visual Analog Scale (VAS) Table 1, 5, Graph 1

The VAS provides a simple, efficient, and non invasive measure of pain intensity that has been used commonly in clinical and research settings where a quick index of pain is required and to which a numerical value can be assigned. The VAS consists of a 10 cm horizontal or vertical line with the two endpoints labeled 'no pain' and 'worst pain ever.' 0-no pain ,1-3 mild pain, 4-6-moderate pain, 7-9 severe pain, 10-worst pain possible. Based on the statistical data, for the visual analog scale, the P value suggested significantly better pain relief and the results obtained indicated that 75% participants at 4hrs, 90% at 6hrs, and 72.5% at 8hrs had moderate pain respectively while, 62.5% at 12hrs, and 87.5% at 24hrs of Day 1 had mild pain. On Day 2; 45% participants at 4hrs had moderate pain, 37% at 6hrs, 90% at 8hrs, 100% at 12hrs respectively encountered mild pain whereas on Day 3; 70% participants at 4hrs, 50% at 6hrs, 72.5% at 8hrs and 70% at 12hrs had mild pain; while, 50% at 6hrs, 30% at 12hrs and 72.5% at 24hrs of Day 3 had no pain. So according to chi-square test statistically significant P value ($p<0.001$) was obtained.

		VAS				Total
		No Pain	Mild Pain	Moderate Pain	Severe Pain	
Time	Day1 2hrs	0	8	30	2	40
		.0%	20.0%	75.0%	5.0%	100.0%
	Day1 4hrs	0	1	36	3	40
		.0%	2.5%	90.0%	7.5%	100.0%
	Day1 8hrs	0	11	29	0	40
		.0%	27.5%	72.5%	.0%	100.0%
	Day1 12hrs	0	25	15	0	40
		.0%	62.5%	37.5%	.0%	100.0%
	Day1 24hrs	0	35	5	0	40
		.0%	87.5%	12.5%	.0%	100.0%
	Day2 2hrs	0	22	18	0	40
		.0%	55.0%	45.0%	.0%	100.0%
	Day2 4hrs	0	37	3	0	40
		.0%	92.5%	7.5%	.0%	100.0%
	Day2 8hrs	0	36	4	0	40
		.0%	90.0%	10.0%	.0%	100.0%
	Day2 12hrs	0	40	0	0	40
		.0%	100.0%	.0%	.0%	100.0%
	Day2 24hrs	14	26	0	0	40
		35.0%	65.0%	.0%	.0%	100.0%
	Day3 2hrs	12	28	0	0	40
		30.0%	70.0%	.0%	.0%	100.0%
	Day3 4hrs	20	20	0	0	40
		50.0%	50.0%	.0%	.0%	100.0%
	Day3 8hrs	11	29	0	0	40
		27.5%	72.5%	.0%	.0%	100.0%
	Day4 12hrs	12	28	0	0	40
		30.0%	70.0%	.0%	.0%	100.0%
	Day3 24hrs	29	11	0	0	40
		72.5%	27.5%	.0%	.0%	100.0%
Total		98	357	140	5	600
		16.3%	59.5%	23.3%	.8%	100.0%

Table 1. Visual Analog Scale (VAS)

Chi-Square Tests			
	Value	Df	P-value
Pearson Chi-Square	547.7	42	<0.001

Verbal Rating Scale (VRS) Table 2, 5, Graph 1

VRS is a four-point scale with values assigned ranging from 0–3. Comfortable, Mild, Moderate and Severe. Based on the statistical figures, for the verbal rating scale, the P value suggested significantly better pain relief using transdermal patch and showed significant P value ($p<0.001$) according to chi-square test analysis. On Day 1 at 4hrs and 6hrs 67.5% had mild pain and 72.5% had moderate pain respectively. While at 8hrs, 12hrs and 24hrs; 70%, 75% and 70%participants respectively showed moderate pain. On Day 2; at 4hrs and 6hrs 75% and 70% participants respectively had mild pain; whereas at 8hrs, 12hrs and 24hrs 77.5%, 87.5% and 100% participants felt comfortable. On Day 3; at 4hrs and 6hrs 90% participants while at 8hrs, 12hrs and 24hrs 100% participants felt comfortable.

Pain Intensity Scale (PIS) Table 3, 5, Graph 1

The Pain Intensity Scale is a scale which is similar to the Verbal Rating Scale. In this scale, the interpretation for the values was 'none, mild, moderate and severe' for corresponding scores between 0–3. An evaluation of pain intensity suggested gradual decline in pain intensity. However, results achieved were; mild pain in 50% participants at 4hrs, 100% discomforting pain at 6hrs, 52.5% at 8hrs had distressing pain while at 12hrs 97.5% had discomforting pain but at 24hrs 50% had mild and 50% had discomforting pain on Day 1, which according to chi square test analysis indicated statistically significant P value ($p<0.001$).

		VRS				Total
		Comfortable	Mild	Moderate	Severe	
Time	Day1 2hrs	0	27	13	0	40
		.0%	67.5%	32.5%	.0%	100.0%
	Day1 4hrs	0	11	29	0	40
		.0%	27.5%	72.5%	.0%	100.0%
	Day1 8hrs	0	1	28	11	40
		.0%	2.5%	70.0%	27.5%	100.0%
	Day1 12hrs	0	0	30	10	40
		.0%	.0%	75.0%	25.0%	100.0%
	Day1 24hrs	0	12	28	0	40
		.0%	30.0%	70.0%	.0%	100.0%
	Day2 2hrs	0	30	10	0	40
		.0%	75.0%	25.0%	.0%	100.0%
	Day2 4hrs	5	28	7	0	40
		12.5%	70.0%	17.5%	.0%	100.0%
	Day2 8hrs	31	9	0	0	40
		77.5%	22.5%	.0%	.0%	100.0%
	Day2 12hrs	35	5	0	0	40
		87.5%	12.5%	.0%	.0%	100.0%
	Day2 24hrs	40	0	0	0	40
		100.0%	.0%	.0%	.0%	100.0%
	Day3 2hrs	36	4	0	0	40
		90.0%	10.0%	.0%	.0%	100.0%
	Day3 4hrs	36	4	0	0	40
		90.0%	10.0%	.0%	.0%	100.0%
	Day3 8hrs	40	0	0	0	40
		100.0%	.0%	.0%	.0%	100.0%
	Day4 12hrs	39	1	0	0	40
		97.5%	2.5%	.0%	.0%	100.0%
	Day3 24hrs	40	0	0	0	40
		100.0%	.0%	.0%	.0%	100.0%
Total		302	132	145	21	600
		50.3%	22.0%	24.2%	3.5%	100.0%

Table 2. Verbal Rating Scale (VRS)

Chi-Square Tests			
	Value	Df	P-value
Pearson Chi-Square	805.8	42	<0.001

		PIS				Total
		None	Mild	Discomforting	Distressing	
Time	Day1 2hrs	0	20	20	0	40
		.0%	50.0%	50.0%	.0%	100.0%
	Day1 4hrs	0	0	40	0	40
		.0%	.0%	100.0%	.0%	100.0%
	Day1 8hrs	0	0	19	21	40
		.0%	.0%	47.5%	52.5%	100.0%
	Day1 12hrs	0	0	39	1	40
		.0%	.0%	97.5%	2.5%	100.0%
	Day1 24hrs	0	20	20	0	40
		.0%	50.0%	50.0%	.0%	100.0%
	Day2 2hrs	0	13	27	0	40
		.0%	32.5%	67.5%	.0%	100.0%
	Day2 4hrs	0	29	11	0	40
		.0%	72.5%	27.5%	.0%	100.0%
	Day2 8hrs	0	36	4	0	40
		.0%	90.0%	10.0%	.0%	100.0%
	Day2 12hrs	0	40	0	0	40
		.0%	100.0%	.0%	.0%	100.0%
	Day2 24hrs	7	33	0	0	40
		17.5%	82.5%	.0%	.0%	100.0%
	Day3 2hrs	22	18	0	0	40
		55.0%	45.0%	.0%	.0%	100.0%
	Day3 4hrs	25	15	0	0	40
		62.5%	37.5%	.0%	.0%	100.0%
	Day3 8hrs	39	1	0	0	40
		97.5%	2.5%	.0%	.0%	100.0%
	Day4 12hrs	40	0	0	0	40
		100.0%	.0%	.0%	.0%	100.0%
	Day3 24hrs	40	0	0	0	40
		100.0%	.0%	.0%	.0%	100.0%
Total		173	225	180	22	600
		28.8%	37.5%	30.0%	3.7%	100.0%

Table 3. Pain Intensity Scale (PIS)

Chi-Square Tests			
	Value	Df	P-value
Pearson Chi-Square	1063	42	<0.001

Pain Relief Scale (PRS) Table 4,5, Graph 1

The Pain Relief Scale is also a four-point scale, again with values from 0–3. In this scale, the interpretation for the values was complete relief for a score of 0 and no relief for a score of 3. On assessing deviation in pain relief all participants presented almost complete or complete pain relief with the end of third day. The evaluation of pain relief showed gradual rise in pain relief. Results acquired by evaluating Pain Relief Scale (PRS) showed 62% participants at 4hrs had little pain relief, 100% participants at 6hrs and 8hrs had moderate pain relief. 77.5% at 12hrs and 82.5% at 24hrs had moderate pain relief on Day 1. On Day 2; 65% participants at 4hrs had moderate pain relief, 70% had as lot pain relief at 6hrs, while 90% had a lot pain relief at 8hrs. On Day 3; 100% participants at 4hrs, 90% at 6hrs, 57.5% at 8hrs had moderate pain relief while at 12hrs 90% had a lot pain relief whereas at 24hrs 64% had complete pain relief. So according to chi square test analysis it indicated statistically significant P value ($p<0.001$). On comparing the difference of pain levels experienced by the participants from Day 1 to Day 2 and 3 for transdermal form of treatment using following parameters showed Both the statistical analysis and clinical observation showed that on the first postoperative day diclofenac sodium administered orally has slightly more significant efficacy when compared to the drug administered transdermally. However, on the second and third postoperative days there was no statistical or clinical difference in the pain control by either route of administration.

DISCUSSION

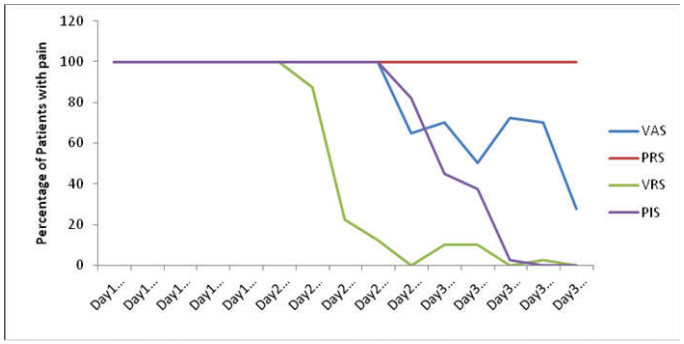
Skin represents the largest and most easily accessible organ of the body. A transdermal patch, which may also be considered a Transdermal Drug Delivery System (TDDS), is outlined as a flexible, multi-layered, pharmaceutical single dose preparation of varying size containing one or more active substances to be applied to the intact skin for systemic absorption. Topical therapy has been practiced for a long time to treat local ailments. Since the approval of the first scopolamine patch in 1979, transdermal drug delivery began to foster as a systemic mode of drug administration. One of the most common symptoms for which a patient seeks medical advice is pain. The International Association for the study of pain has defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage".[1] Postoperative pain is a unique and common form of acute pain. Although ample evidence indicates that an efficacious postoperative pain treatment reduces patient morbidity and patient outcome, recent studies demonstrate that about 50–70% of patients' experience moderate to severe pain after surgery.

The participants included in the study were free from any systemic conditions and were between the age group of 18 and 40 years; it was ensured that these participants were not on any analgesics for a period of 7 days before the day of extraction. A chi-square test was applied over various Parameters which included:

		PRS				Total
		Little	Moderate	Lot	Complete	
Time	Day1 2hrs	25 62.5%	15 37.5%	0 .0%	0 .0%	40 100.0%
	Day1 4hrs	0 .0%	40 100.0%	0 .0%	0 .0%	40 100.0%
	Day1 8hrs	0 .0%	40 100.0%	0 .0%	0 .0%	40 100.0%
	Day1 12hrs	9 22.5%	31 77.5%	0 .0%	0 .0%	40 100.0%
	Day1 24hrs	7 17.5%	33 82.5%	0 .0%	0 .0%	40 100.0%
	Day2 2hrs	0 .0%	26 65.0%	14 35.0%	0 .0%	40 100.0%
	Day2 4hrs	0 .0%	12 30.0%	28 70.0%	0 .0%	40 100.0%
	Day2 8hrs	0 .0%	4 10.0%	36 90.0%	0 .0%	40 100.0%
	Day2 12hrs	0 .0%	24 60.0%	16 40.0%	0 .0%	40 100.0%
	Day2 24hrs	0 .0%	32 80.0%	8 20.0%	0 .0%	40 100.0%
	Day3 2hrs	0 .0%	40 100.0%	0 .0%	0 .0%	40 100.0%
	Day3 4hrs	0 .0%	38 95.0%	2 5.0%	0 .0%	40 100.0%
	Day3 8hrs	0 .0%	23 57.5%	17 42.5%	0 .0%	40 100.0%
	Day4 12hrs	0 .0%	4 10.0%	36 90.0%	0 .0%	40 100.0%
	Day3 24hrs	0 .0%	0 .0%	14 35.0%	26 65.0%	40 100.0%
Total		41 6.8%	362 60.3%	171 28.5%	26 4.3%	600 100.0%

Table 4. Pain Relief Scale (PRS)

Chi-Square Tests			
	Value	df	P-value
Pearson Chi-Square	927.0	42	<0.001



Graph 1. Mean Value of VAS, VRS, PIS, PRS

The Visual Analog Scale (VAS) : 0-no pain, 1-3 mild pain, 4-6-moderate pain, 7-9 severe pain, 10- worst pain possible. Verbal Rating Scale (VRS)- is a four point scale with values assigned ranging from 0–3. 0-Comfortable, 2- Mild, 4-Moderate, 6-Severe, 8-very severe 10- worst pain possible. Pain Intensity Scale (PIS): 0-none, 1-2 mild, 3-5 discomforting, 6-7 distressing, 8- intense, 9-10 worst pain possible. Pain Relief Scale (PRS): 0- none, 1-a little, 2-moderate, 3- a lot, 4- complete and any adverse effects or complications; for obtaining the data. All the scores were obtained at intervals of 6 ,8, 12, 24hrs and the results obtained for Visual Analog Scale (VAS) showed that 75% participants at 4hrs, 90% at 6hrs, and 72.5% at 8hrs had moderate pain respectively while, 62.5% at 12hrs, and 87.5% at 24hrs of Day 1 had mild pain. On Day 2; 45% participants at 4hrs had moderate pain, 37% at 6hrs, 90% at 8hrs, 100% at 12hrs respectively encountered mild pain whereas on Day 3; 70% participants at 4hrs, 50% at 6hrs, 72.5% at 8hrs and 70% at 12hrs had mild pain; while, 50% at 6hrs, 30% at 12hrs and 72.5% at 24hrs of Day 3 had no pain. Therefore, according to chi-square test; it provided statistically significant value ($p<0.001$). Results obtained by Verbal Rating Scale (VRS) indicated that on Day 1 at 4hrs and 6hrs 67.5% had mild pain and 72.5% had moderate pain respectively. While at 8hrs, 12hrs and 24hrs; 70%, 75% and 70%participants respectively showed moderate pain. On Day 2; at 4hrs and 6hrs 75% and 70% participants respectively had mild pain; whereas at 8hrs, 12hrs and 24hrs 77.5%, 87.5% and 100% participants felt comfortable. On Day 3; at 4hrs and 6hrs 90% participants while at 8hrs, 12hrs and 24hrs 100% participants felt comfortable. Hence according to chi square test analysis it indicated statistically significant value ($p<0.001$)

Outcomes accomplished by Pain Intensity Scale (PIS) were; mild pain in 50% participants at 4hrs, 100% discomforting pain at 6hrs, 52.5% at 8hrs had distressing pain while at 12hrs 97.5% had discomforting pain but at 24hrs 50% had mild and 50% had discomforting pain on Day 1. So according to chi square test analysis it indicated statistically significant value ($p<0.001$). Outcomes accomplished by evaluating Pain Relief Scale (PRS) showed 62% participants at 4hrs had little pain relief, 100% participants at 6hrs and 8hrs had moderate pain relief. 77.5% at 12hrs and 82.5% at 24hrs had moderate pain relief on Day 1. On Day 2; 65% participants at 4hrs had moderate pain relief, 70% had a lot pain relief at 6hrs, while 90% had a lot pain relief at 8hrs. On Day 3; 100% participants at 4hrs, 90% at 6hrs, 57.5% at 8hrs had moderate pain relief while at 12hrs 90% had a lot pain relief whereas at 24hrs 64% had complete pain relief. So according to chi square test analysis indicated statistically significant value ($p<0.001$). Many comparative studies have been undertaken to pattern the efficacy of transdermal patch. The results of VAS and PIS obtained in our study indicates similar results as with the study undertaken by Sriram Krishnan et al in 2012 which was a pilot study which also said its safe for the use dental situations. Study done by Predel *et al*., 2004 who compared topical diclofenac with transdermal patch for the treatment of sports injuries and concluded that transdermal patch is very safe and effective for the treatment of blunt and impact injuries. The most frequently observed adverse events were local tissue reactions, such as pruritus and a rash of minor severity. No complications and adverse effects were encountered during their study which was similar to our study. They also concluded that the patch has anti- inflammatory and anti-odematous effect whereas it is also easy to handle. They used transdermal patch twice a day per day for a week. Funk and Colleagues 2007 concluded that diclofenac patches provides significantly better pain relief compared to tablets in the early postoperative period following arthroscopic shoulder surgery. Similar results were obtained in relation to VRS and PRS analysis as with the study of Funk *et al.* 2008.

Anil Agrawal and Colleagues 2004 compared the efficacy of transdermal diclofenac patch with eutectic mixture of local anaesthetics (EMLA) for venous cannulation pain. They concluded that transdermal diclofenac patch and EMLA are equally effective in reducing venous cannulation pain, but signs of erythema, induration and edema are less frequently observed with the transdermal diclofenac patch. Bruhlmann and Colleagues 2007 in a randomized, double blinded,

controlled clinical trial found that topical diclofenac patch is more effective in patients with knee osteoarthritis. Galer and Colleagues (Funk *et al.* 2008). in a multicentric controlled clinical trial found that topical diclofenac patch relieves minor sport injuries effectively. The safety outline of diclofenac patches has also been highlighted by Mason *et al.,* 2004 in their systematic review of the use of topical NSAIDs in the UK, and by studies reporting the use of a diclofenac transdermal patch in osteoarthritis and in sports-related injuries. Study done by Krishna in 2014, compared IM Diclofenac with transdermal patch of diclofenac where the problem that they faced during the study was the poor adhesiveness of the transdermal patch. The patch would loosen and peel off when applied to mobile parts of body, such as the arms or the gluteal region. Rather, the transdermal patch needs to be applied to the anterior chest wall or the abdomen which was not encountered in our study.

The transdermal diclofenac has usually the tendency to be subjected to absorption interferences due to the presence of anatomical barriers such as the epidermis, dermis, and the underlying muscle tissue. The drug is usually retained or may undergo metabolism during its journey to the nearest vascular supply, hence, the amount of drug that reaches the circulation establishes a minimum plasma concentration. This low concentration hence leads to a lesser incidence of systemic adverse effects; however, a larger dosage may have been incorporated onto the patch but still the mean plasma diclofenac concentration remains lower than that of the other modes of administration (Devi and Paranjothy, 1999). Various studies have been reported where certain additional agents can be applied onto the patch or site of placement of patch that may enhance the absorption of the drugsystemically, hence increasing the plasma concentration and also hastening the time of action of the drug. Certain additional combination can also be added onto the patch that can have a synergistic effect on the analgesic action and help in further reduction in post-procedure pain as compared to the current option of individual drug (Biswajit Mukherjee *et al.,* 2005). The management of postoperative pain is an essential and integral part of the care given to the patient that assumes an important role in transition from the recovery unit to the home environment. The results of the study, both statistically and clinically showed that diclofenac sodium when administered orally showed slightly better pain control in the first 24 hours when compared to the transdermal form. Transdermal administration has its role in pain control following minor surgical procedures, especially in patients who are susceptible to gastritis and in whom compliance is a problem.

Conclusion

The management of postoperative pain is an essential and integral part of the care given to the patient that assumes an important role in transition from the recovery unit to the home environment. The results of the study, both statistically and clinically showed that diclofenac sodium when administered orally showed slightly better pain control in the first 24 hours when compared to the transdermal form. Transdermal administration has its role in pain control following minor surgical procedures, especially in patients who are susceptible to gastritis and in whom compliance is a problem.

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