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ORIGINAL ARTICLE

Diclofenac Transdermal Patch versus Oral Diclofenac on Post Endodontic Pain and Quality of Life: A Randomised Clinical Trial

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ABSTRACT

Objective: To compare the effect of pre-treatment transdermal and oral diclofenac on post-endodontic pain level and oral health-related quality of life (OHRQOL) in patients with symptomatic irreversible pulpitis with apical periodontitis in mandibular molars following single visit root canal treatment.

Methods: This parallel-arm, randomised, double-blinded clinical trial is reported according to the Consolidated Standards of Reporting Trials (CONSORT) 2020 guidelines. The protocol was approved by the Institutional Ethical Committee on 30th March 2021 (MADC/IEC-I/029/2021) and registered at the clinical trial registry of India (CTRI/2021/12/038696). Adult patients fulfilling the eligibility criteria were randomised into two groups. Group DTP received a diclofenac transdermal patch 100 mg, and Group DOT received a diclofenac oral tablet 100 mg one hour before root canal treatment. Pain scores were checked at baseline, 2, 4, 6, 8, 24, 48, and 72 hours after the treatment. OHRQOL was assessed at baseline and one week after the treatment.

Results: Both groups were associated with a significantly lower incidence of post-operative pain and improved OHRQOL. At 2 hours, the pain level was significantly lower with an oral diclofenac tablet, and at 24 hours, the pain level was significantly lower with a diclofenac transdermal patch. Regarding OHRQOL, there was no significant difference between the two groups.

Conclusion: Within the limitations of this study, the diclofenac transdermal patch had lesser post-operative pain at 24 hours, whereas the oral diclofenac tablet had lesser pain at 2 hours.

Keywords: Diclofenac, oral health-related quality of life, post-endodontic pain, transdermal patch

HIGHLIGHTS

- This study aimed at evaluating the effect of a diclofenac transdermal patch versus a diclofenac oral tablet on post-endodontic pain level and oral health-related quality of life following single visit root canal treatment in patients with symptomatic irreversible pulpitis in mandibular molars.
- This study found that at 2 hours post-operatively, the pain level was significantly lower with oral diclofenac tablet, whereas, at 24 hours post-operatively, the pain level was significantly lower with diclofenac transdermal patch.
- There was a significant improvement in oral health-related quality of life in both groups, with no statistically significant difference between them.
- Diclofenac transdermal patches can overcome the drawbacks of oral diclofenac, such as decreased bioavailability, systemic side effects and patient compliance. They can, therefore, be used as an effective alternative to oral diclofenac to reduce post-endodontic pain.

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INTRODUCTION

Post-endodontic pain (PEP) is a common, undesirable sequelae of root canal treatment that has a significant negative impact on a patient's oral health-related quality of life (OHRQOL) (1). Its incidence ranges from 25% to 69% at 24 hours (2, 3).

In a systematic review by Nagendrababu and Guttman in 2017, it was reported that PEP was significantly higher in patients presenting with pain before the commencement of treatment (4). There are various methods to reduce the incidence of PEP, such as the use of an analgesic pre-operatively as well as post-operatively, crown down method of instrumentation, adequate disinfection through irrigation, and relieving of occlusion (4). Among these, the use of oral premedication has been supported by various randomised clinical trials and systematic reviews (4, 5).

Oral non-steroidal anti-inflammatory drugs are most frequently prescribed for management of endodontic pain (6). Various comparative studies have reported Oral diclofenac to have a high efficacy in reducing PEP following root canal treatment (7, 8). However, the oral route leads to first-pass metabolism, decreasing its bioavailability and adversely affecting the gastrointestinal system (9). An alternative route of drug administration to circumvent these problems is the use of transdermal patches.

In dentistry, several randomised clinical trials have reported a reduction in post-operative pain with the use of transdermal patches in cases of extraction (10), periodontal flap surgery (11), orthognathic surgery (12), and root canal treatment (13, 14).

In Endodontics, Mangal et al. in 2020 (13) and Dhanapal et al. in 2016 (14) reported a significant decrease in PEP with oral and transdermal administration of diclofenac with no significant difference between the groups following single visit root canal treatment (SVRCT). In the study by Mangal et al., medication was given post-operatively, and only premolars with single roots were included, whereas, in Dhanapal et al.'s (13, 14) study, the tooth type was not mentioned. In both trials, the sample size was small, which may have caused the validity of the findings of these studies to be considered low. Moreover, none of the studies measured the impact of premedication on PEP and OHRQOL.

Hence, this study aimed to evaluate the effect of pretreatment diclofenac transdermal patch (DTP) versus diclofenac oral tablet (DOT) on the PEP level and OHRQOL in patients having symptomatic irreversible pulpitis with apical periodontitis and in mandibular molars following SVRCT.

The null hypothesis is that there is no difference between DTP and DOT on the PEP level and OHRQOL.

MATERIALS AND METHODS

Study Design and Ethical Clearance

This study was a prospective, parallel-arm, randomised clinical trial wherein the principal investigator and outcome assessor were blinded.

The experimental design was done per the Consolidated Standards of Reporting Trials (CONSORT 2020) statement. The college Institutional Ethical Committee approved the study protocol on 30th March 2021 (MADC/IEC-I/029/2021) and registered with the clinical trial registry of India (CTRI/2021/12/038696). The study abided by the code of ethics of the World Medical Association, Declaration of Helsinki.

Inclusion Criteria

Systemically healthy patients of age between 18 and 60 years diagnosed with symptomatic irreversible pulpitis with apical periodontitis in mandibular molars caused by caries were included in this trial. Patients with pre-operative Visual Analogue Scale (VAS) pain score of equal to or less than 6 (mild to moderate pulpal or periapical pain) and radiographic periapical index score of equal to or less than 2 with periodontally sound tooth (mobility and periodontal pocket depth within normal limits and no bone loss) were only included in this study.

Exclusion Criteria

Patients with systemic diseases or allergic reactions and pregnant or lactating mothers were excluded from this trial. Patients who had taken analgesics or antibiotics within the last 3 days were also excluded. Teeth that were previously root canal treated or initiated, presence of swelling or sinus tract, teeth with curved canals >25° (measured using Schneider technique) or calcified canals, and patients with possible complications during the treatment such as broken files, over instrumentation, overfilling or incomplete filling were all excluded.

Sample Size Calculation

The sample size was calculated based on a pilot study. The sample size was 51 teeth per group using Stata (version 17, StataCorp LLC, Texas, USA) software with the power of the study as 80%, alpha error of 0.05, and considering 10% loss to follow up.

Randomisation, Blinding & Allocation Concealment

The recruited patients for this study were randomly allocated to one of the following two groups:

Group DTP- 100 mg diclofenac diethylamine transdermal patch Brand name: DicloPLAST [Zuventus Healthcare Limited, Mumbai, India])

Group DOT- 100 mg diclofenac sodium tablet (Brand name: Voveran SR 100 [Dr. Reddy's Laboratory Limited, Haryana, India])

Computer-generated simple block randomisation (Stata version 17, StataCorp LLC, Texas, USA) was used to randomise participants. Although patients were not blinded, the operator and outcome assessor were blinded. Allocation concealment was done using Sequentially Numbered Opaque Sealed Envelopes (SNOSE). Details of the allocated group were recorded by an assessor not involved in the clinical study.

Clinical Procedures

All patients who fulfilled the eligibility criteria were informed of the risks and benefits of the procedure, and consent was obtained before the treatment. The outcome assessor evaluated baseline pain scores and OHRQOL. Baseline and PEP assessment was done using a VAS score form consisting of a 10 cm line with "0" representing no pain and a "10" signifying the worst pain imaginable. OHRQOL was evaluated using Oral-Health Impact Profile 14 (OHIP-14), which consists of 14 questions, each with five options. Patients were asked to tick the most appropriate option according to them.

One hour before the commencement of the clinical procedure, the allocated drug from the sealed envelope was provided to the patients by a nursing staff member who was unrelated to the trial. The transdermal patch measuring 58 mm×87 mm was applied on the right or left arm of the patient. The patient was instructed to remove the transdermal patch after 24 hours.

Treatment was provided by a single operator who was trained to perform SVRCT. An inferior alveolar nerve block was administered using a 27 gauge needle and 1.8 ml of 2% lignocaine with 1:80000 epinephrine (Lignospan, Septodont, France). Under dental dam isolation, access opened using 014 round carbide bur and Endo Z bur (Dentsply Sirona International, York, PA, USA). The tooth was considered to have achieved profound pulpal anaesthesia if no response was elicited to the cold test. In case the patient experienced pain during access opening, intraligamentary or intrapulpal injection was administered with 2% lignocaine 1:80000 epinephrine for supplementary anaesthesia. Working length was determined using an electronic apex locator (J Morita, Europe GVBH, Frankfurt, Germany) and radiographically confirmed. A glide path was created using a #15 size K file (Mani Inc., Tochigi, Japan). The canals were prepared using a ProTaper Gold rotary file (Dentsply Sirona, Ballaigues, Switzerland) to file F2 for mesial canals and F3 for distal canals. The canals were irrigated with 2.5 mL of 3% sodium hypochlorite between two successive instrumentations using a 30-gauge closed-end side vented needle. Final irrigation was performed using 17% ethylenediaminetetraacetic acid and 3% sodium hypochlorite, followed by 0.9% physiological saline and dried with paper points. Obturation was done using a corresponding size single cone of gutta-percha (Dentsply Sirona Tulsa Dental, York, PA, USA) and resin sealer (AH Plus, Dentsply Sirona Tulsa Dental, York, PA, USA). The entrance filling was done with resin composite (FiltekTM Z350 XT universal restorative, 3M ESPE, St.Paul, MN, USA), and occlusal reduction of the treated tooth was done.

Outcome Assessment

The primary outcome assessed was PEP intensity, and the secondary outcome assessed was the change in OHRQOL post-operatively. Pain scores were evaluated at the following time intervals: baseline, 2, 4, 6, 8, 24, 48 and 72 hours. OHRQOL was evaluated at baseline and 1 week post-operatively. Both the VAS score form and OHRQOL were obtained via two methods. The first method was to provide the patients with a copy of the VAS score form and OHRQOL questionnaire. Patients were asked to maintain the scores and answers at the given time intervals for pain and after one week for OHRQOL. The second method was to assess using an electronic mode through a text message by the outcome assessor. Patients could either send a photo of the filled VAS score form and OHRQOL questionnaire electronically or report back to hand over the form.

In the case of patients experiencing unbearable pain, Ibuprofen 400 mg was prescribed as a rescue medication (dosage: 1 tablet every 6 hours), and these patients were eliminated from the study.

Statistical Analysis

The statistical analysis used Stata (version 17, StataCorp LLC, Texas, USA). Shapiro-Wilk test was done to check for the normality of the variables. Due to the non-normal distribution of the variables, intergroup comparison was done using the Mann-Whitney U test. Intragroup analysis for pain assessment was done using the Friedman test, followed by post-hoc analysis, which was done using the Dunn's test. For OHRQOL, an intragroup comparison was performed using the Wilcoxon signed-rank test. Binary logistic regression was performed, with the dependent variable being the incidence of pain and the independent variables being age, gender, and intervention. The binary logistic model was generated for each time interval. The p-value of <0.05 was considered statistically significant.

RESULTS

Single-visit root canal treatment (SVRCT) was done in 102 patients, with 51 in each group (Fig. 1). The trial began in November 2021, and the final sample size was achieved in July 2022. One patient from the DTP and two from the DOT group were unavailable over a phone call and did not report for follow-up and were therefore excluded. In addition, 5 patients of the DTP group and 6 patients of the DOT group took escape medicine and were excluded from the analysis. Hence, for the final analysis, a total of 88 patients were included: 45 in the DTP group and 43 in the DOT group. Table 1 represents the baseline demographic details of the patients included in the study. Demographic characteristics in both groups were similar. Supplementary injection was required in 7 patients (DTP: 5, DOT: 2).

Intra-Group Comparison (Fig. 2 and Fig. 3)

Both the groups showed a significant reduction in mean pain intensity at all the time intervals post-operatively compared to baseline (p<0.05).

The mean and standard deviation pre-operative pain intensity was 4.71±0.84. Post operatively, the highest mean pain intensity was 1.63±0.91 at 2 hours, and the lowest mean pain intensity was 0.10±0.3 at 72 hours. Pre-operative mean OHIP for evaluating OHRQOL was 28.53±5.17, and post-operative mean OHIP was 14.87±85, resulting in a significant improvement in OHRQOL (p=0.041).

Group DTP (Diclofenac Transdermal Patch)

The mean and standard deviation pre-operative pain intensity was 4.71±0.84. Post operatively, the highest mean pain intensity was 1.63±0.91 at 2 hours, and the lowest mean pain intensity was 0.10±0.3 at 72 hours. Pre-operative mean OHIP for evaluating OHRQOL was 28.53±5.17, and post-operative mean OHIP was 14.87±85, resulting in a significant improvement in OHRQOL (p=0.041).

Group DOT (Diclofenac Oral Tablet)

The mean pre-operative pain intensity was 4.65±1.09. The highest mean pain intensity post operatively was 1.15±0.83 at 2 hours, and the lowest mean pain intensity was 0.08±0.26 at 72 hours. Moreover, group DOT also reported a significant improvement in OHRQOL (p=0.043), wherein the mean pre-operative OHIP was 29.±5.74, and the mean post-operative OHIP was 14.90±0.88.

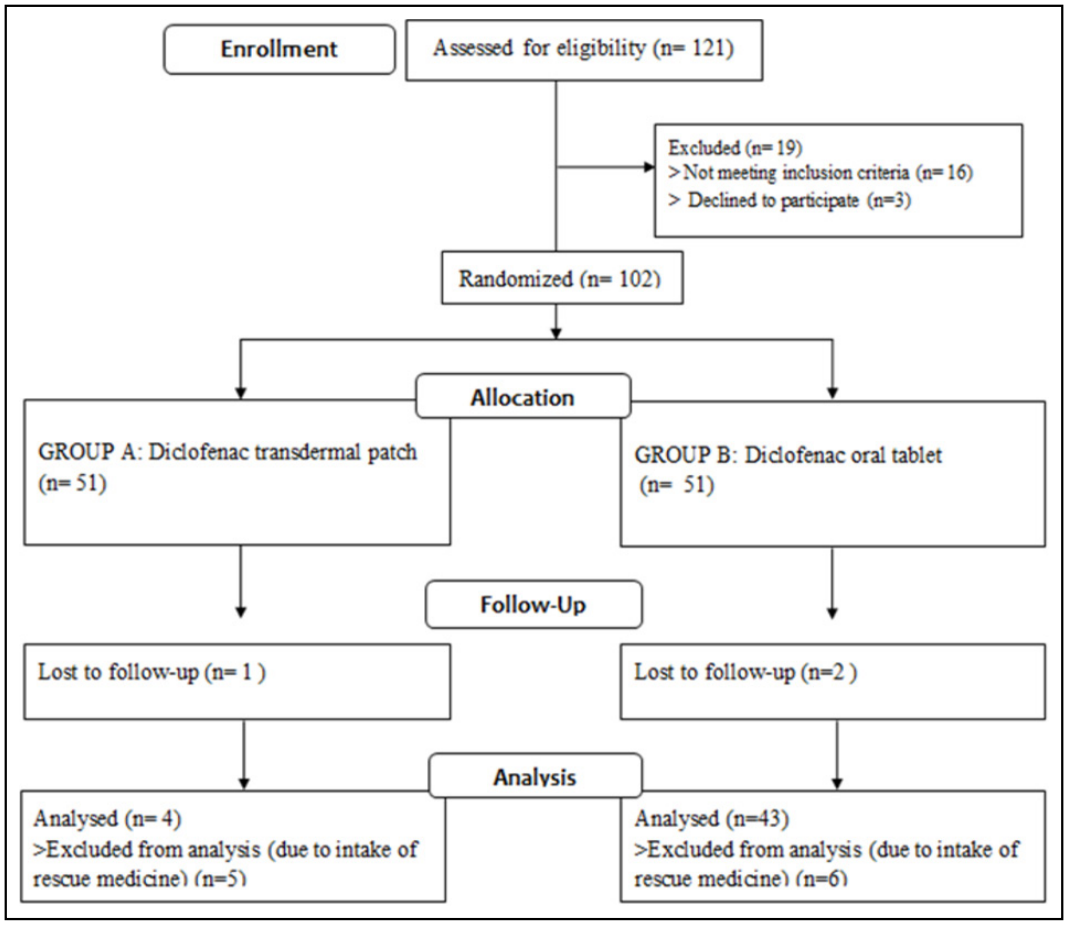

Figure 1. CONSORT 2010 flow diagram

Inter-Group Comparison (Fig. 4, Table 2 and Table 3)

At 2 hours and 24 hours, there was a significant difference between the groups ($p<0.05$). At 2 hours, the mean pain intensity in patients who received DOT (1.15±0.83) was significantly lesser ($p=0.015$) than in DTP (1.63±0.91), whereas, at 24 hours, DTP (0.2±0.4) group had significantly lesser ($p=0.036$) mean pain intensity than DOT (0.48±0.6). There was no significant difference in the mean pain intensity between the two groups at 4, 6, 8, 48 and 72 hours.

With regards to mean post-operative OHIP, despite the DTP group having a slightly higher improvement in OHRQOL (14.87±0.85) than the DOT group (14.87±0.85), the difference was minimal with no statistical significance ($p>0.05$).

A total of 5 patients (10%) who applied DTP and 6 patients (12%) who took DOT consumed escape medication due to severe pain. None of the patients from the DTP group reported any adverse effects, whereas one patient from the DOT group reported gastric discomfort at 6 hours.

TABLE 1. Baseline demographic details of included patients

Variable	DTP		DOT		p
	n	%	n	%	
Age, mean±SD	32.63±10.68		33.77±11.52		0.619
Gender					0.811
Male	21	47	18	42	
Female	24	53	25	58	
Pre-operative VAS					0.769
Mean±SD	4.71±0.84		4.65±1.099		
Median (IQR)	5 (2)		5 (2)		
Pre-operative OHRQOL					0.298
Mean±SD	28.53±5.17		29.72±5.74		
Median (IQR)	30.5 (21)		30 (16)		

DTP: Diclofenac transdermal patch, DOT: Diclofenac oral tablet, SD: Standard deviation, VAS: Visual analogue scale, IQR: Interquartile range, OHRQOL: Oral health-related quality of life

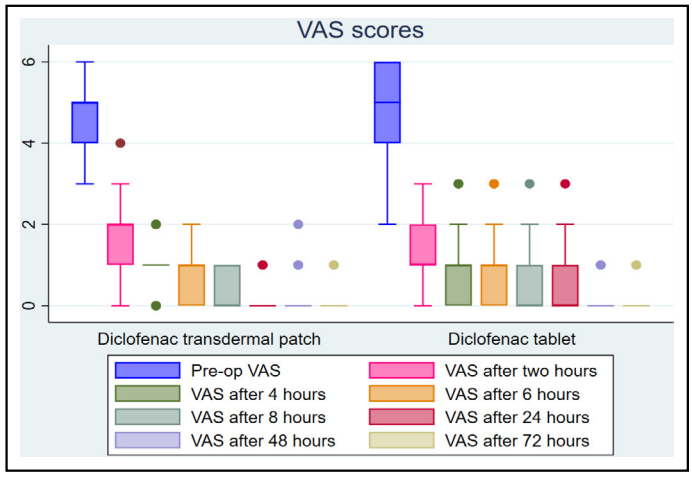

Figure 2. Box and whisker plot for pain score (VAS) at different time intervals for diclofenac transdermal patch and oral diclofenac tablet

VAS: Visual analogue scale

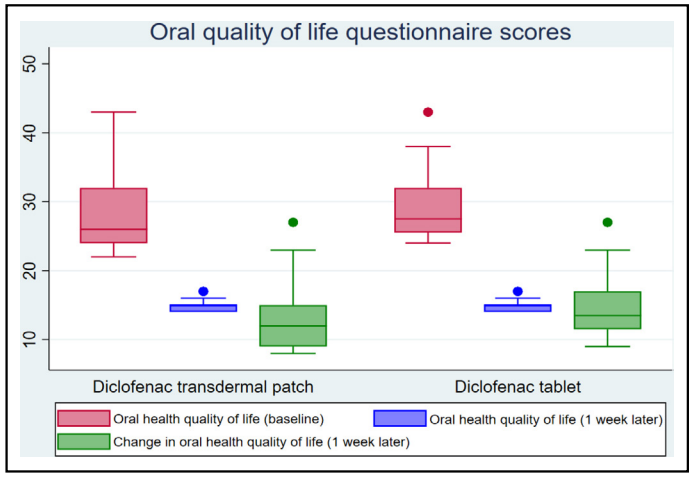

Figure 3. Box and whisker plot for oral health-related quality of life for diclofenac transdermal patch and oral diclofenac tablet

Logistic Regression Analysis (Table 4)

Age, gender and intervention were taken as the independent variables to establish the association of these variables with the incidence of pain perceived by the patients. The logistic regression results showed that age and gender had no significant association with the incidence of pain at any of the time intervals. However, between the intervention and comparison groups, the odds of incidence of postoperative pain were significantly higher in the DOT group at 24 hours (OR: 2.75; p>0.05).

DISCUSSION

Numerous shortcomings of the oral route of diclofenac necessitate an alternate mode of drug delivery, like transdermal patches. For PEP following SVRCT, there is limited and low-quality evidence in the literature comparing DTP and DOT.

Mandibular molars are reported to have a significantly greater amount of PEP when compared to other teeth (4). As the tooth type influences PEP, mandibular molars with symptomatic irreversible pulpitis were included in this study. To eliminate PEP due to other factors, a crown-down technique was used, and occlusal reduction was also performed (4).

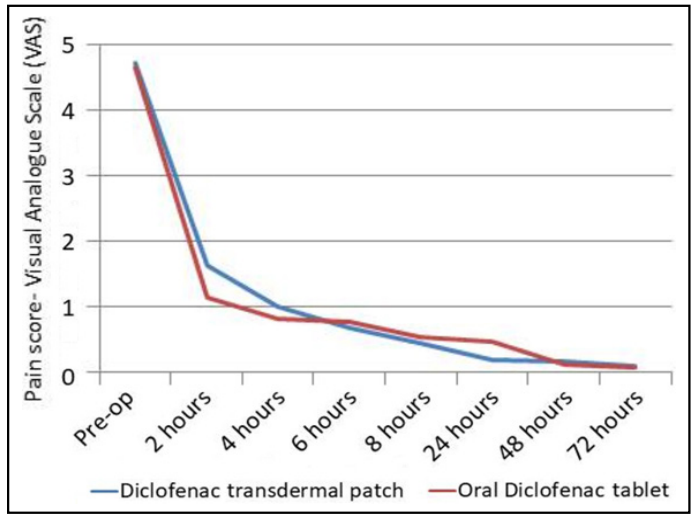

Figure 4. Line graph representing pain scores (VAS) at different time intervals for diclofenac transdermal patch and oral diclofenac tablet

VAS: Visual analogue scale

As a drug's administration mode plays a major role in its pharmacokinetics, the onset of action of Diclofenac differs in oral and transdermal routes. Oral administration of the diclofenac tablet has a rapid onset of action of 20 to 30 minutes (15). On the other hand, the transdermal patch has a delayed onset of action of about 3 to 4 hours (16). This difference in the onset of action between the two routes could be why there was a significantly lesser mean pain intensity in the DOT group at 2 hours compared to the DTP group in the present study (p<0.05). The reduced pain intensity at 2 hours for DOT and 12 hours for DTP (p<0.05) can also be attributed to the time taken for Diclofenac to reach the peak plasma concentration, which is observed at 2 to 3 hours for DOT and 10 to 12 hours for DTP (15, 16).

Considering both the onset of action and peak plasma concentration of Diclofenac in oral and transdermal routes, it can be inferred that during the time DTP begins to produce its analgesic effect, the DOT reaches its maximum drug concentration, producing profound analgesia at 2 and 4 hours.

The oral route of Diclofenac has a short duration of action of the drug of about 6–8 hours (15). On the other hand, DTP maintains a relatively sustained plasma concentration and has a longer duration of action of 24 hours (16). Hence, Diclofenac's more prolonged therapeutic effect through the transdermal route could be why there was a significant reduction in the mean pain intensity at 24 hours in the DTP group compared to the DOT group (p<0.05).

Considering the duration of action of both the modes of diclofenac administration, it can be inferred that by the time DTP achieves and sustains its analgesic effect, the analgesic efficacy of DOT starts to wear off.

In the present study, at 48 and 72 hours, there was no significant difference in pain reduction between the two groups. This is in accordance with the study done by Mangal et al. (13) and Dhanapal et al. (14), wherein both groups had comparable efficacy after two days.

TABLE 2. Intergroup comparison for pain scores (VAS) at different time intervals performed using Mann-Whitney U test

Variables	DTP		DOT		p
	Mean±SD	Median (IQR)	Mean±SD	Median (IQR)	
Pre-op VAS	4.71±0.840	5 (2)	4.65±1.099	5 (2)	0.913
VAS after 2 hours	1.63±0.915	2 (2)	1.15±0.834	1 (1)	0.015*
VAS after 4 hours	1.00±0.548	1 (0)	0.83±0.747	1 (1)	0.092
VAS after 6 hours	0.68±0.567	1 (1)	0.78±0.862	1 (1)	0.970
VAS after 8 hours	0.46±0.505	0.5 (1)	0.55±0.714	0 (1)	0.850
VAS after 24 hours	0.20±0.401	0 (1)	0.48±0.679	0 (1)	0.036*
VAS after 48 hours	0.17±0.442	0 (0)	0.13±0.335	0 (0)	0.750
VAS after 72 hours	0.10±0.300	0 (0)	0.08±0.267	0 (0)	0.720

*: p<0.05: Statistically significant. VAS: Visual Analogue Scale, DTP: Diclofenac transdermal patch, DOT: Diclofenac oral tablet, SD: Standard deviation, IQR: Interquartile range

TABLE 3. Intergroup comparison for oral health-related quality of life performed using the Mann-Whitney U test

Variables	DTP Mean±SD	DOT Mean±SD	p
OHRQOL (baseline)	28.53±5.17	29.72±5.74	0.3
OHRQOL (1 week later)	14.87±0.85	14.90±0.88	0.94
Change in OHRQOL	13.66±4.86	14.82±0.84	0.28

DTP: Diclofenac transdermal patch, DOT: Diclofenac oral tablet, SD: Standard deviation, OHRQOL: Oral health-related quality of life

TABLE 4. Logistic regression analysis at different time intervals

	OR	p	95% CI lower	95% CI upper
At 2 hours				
DOT	0.29	0.10	0.70	1.26
Age	1.02	0.42	0.96	1.09
Gender	0.38	0.19	0.91	1.62
At 4 hours				
DOT	0.35	0.06	0.11	1.05
Age	0.98	0.66	0.94	1.03
Gender	1.04	0.93	0.36	3.01
At 6 hours				
DOT	0.74	0.53	0.29	1.86
Age	1.01	0.50	0.97	1.05
Gender	2.45	0.058	0.97	6.21
At 8 hours				
DOT	0.91	0.83	0.37	2.22
Age	1.02	0.29	0.98	1.06
Gender	2.14	0.10	0.85	5.34
At 24 hours				
DOT	2.75	0.04*	1.01	7.47
Age	0.99	0.90	0.95	1.04
Gender	1.01	0.97	0.37	2.73
At 48 hours				
DOT	0.82	0.76	0.22	2.97
Age	1.02	0.40	0.96	1.08
Gender	1.18	0.79	0.31	4.40
At 72 hours				
DOT	0.74	0.71	0.15	3.56
Age	1.00	0.96	0.93	1.07
Gender	1.21	0.80	0.24	5.96

OR: Odds ratio, CI: Confidence interval, DOT: Diclofenac oral tablet

The present study found that immediate PEP (2–4 hours) was relieved for patients who took DOT, whereas DTP exhibited a longer duration of pain relief (6 to 24 hours). However, at the end of 72 hours, both groups were equally efficacious in relieving the pain experienced by the patients. Hence, the null hypothesis was partially rejected.

Previous studies have reported that root canal treatment significantly improves patient's OHRQOL (17, 18). In accordance with the previous studies, there was a significant improvement in OHRQOL in the present study before and after performing SVRCT in both groups (p<0.05).

In the present study, escape medication was taken by 5 patients (10%) who applied DTP and 6 patients (12%) who took DOT. In the DTP group, three patients took escape medicine at 4 hours, and two patients took escape medicine at 48 hours. All six patients took escape medication in the DOT group at 24 hours. This could be attributed to the varying pharmacokinetic properties of DTP and DOT. All the patients who consumed rescue medication were excluded from the final statistical analysis. All the patients who consumed rescue medicine reported no pain following the intake of the rescue medicine. Hence, no clinical intervention was required for these patients.

As loss to follow-up can affect the study outcome, post-operative data was collected via two modes: reporting back with the filled questionnaire and through electronic means. Despite that, in the present study, follow-up data was lost for three patients (2 in the DTP group and 1 in the DOT group).

DOT carries a high risk of systemic side effects like gastrointestinal toxicity and nephrotoxicity on long-term or high-dosage consumption (19). On the other hand, systemic adverse effects associated with DTP are rare (20). Local side effects of DTP have been reported, including skin reactions at the site of drug administration, such as erythematous rash, burning, itching, and dry skin/crusting (20). In the present study, none of the patients who had received DTP reported any adverse effects, and only one patient in the DOT group reported gastric discomfort at 6 hours.

Most of the studies that have compared oral and transdermal routes of Diclofenac in various fields of dentistry have reported similar efficacy of both the routes of drug administration in reducing post-operative pain (10–14). However, DTP has several added advantages. It is considered safe, patient-friendly, and requires only a single patch application for 24 hours (16, 20, 21). It has good patient compliance (16), especially by those who have difficulty swallowing tablets, such as geriatric patients and patients with physical or mental disability. However, apart from the risk of local side effects, other drawbacks of the transdermal route include higher cost than Diclofenac tablets and improper adherence if the skin is oily, too hairy, or exposed to water or sweat (21).

The strengths of this study are that block randomisation and allocation concealment were done along with the blinding of the principal investigator and outcome assessor to prevent bias. Standardised procedures were followed for both groups to eliminate any possible confounders. Moreover, an adequate sample size was included. This study has a high clinical significance as it shows that DTP can be an alternative to the oral route with comparable efficacy in reducing PEP following SVRCT.

One of the limitations of this study is that only patients experiencing mild to moderate pain were included. Patients with severe pain, periapical radiolucency on radiographs, or necrotic pulp were excluded from the study. Thus, the effect of the tested intervention is not known in such a clinical scenario. The patients were not blinded, which could lead to a potential bias.

In future studies, the diclofenac transdermal patch can be compared with other commercially available analgesic transdermal patches, such as a ketoprofen patch, to test their efficacy in reducing PEP. Analgesic efficacy of DTP can also be assessed in patients following root canal treatment in teeth with necrotic pulp and periapical lesion or following endodontic periapical surgery. A comparison between oral, transdermal, and parental routes can also be done in future studies.

CONCLUSION

Within the limitations of this study, the diclofenac transdermal patch had lesser PEP at 24 hours, whereas the oral diclofenac tablet had lesser PEP at 2 hours. However, there was no significant difference in this pain between the two groups at all the other time intervals. Both groups significantly improved patients' OHRQOL following SVRCT, with no significant difference.

Disclosures

Ethics Committee Approval: The study was approved by the Meenakshi Ammal Dental College (Chennai, Tamil Nadu, India) Ethics Committee (no: MADC/IEC-I/029/2021, date: 30/03/2021).

Authorship Contributions: Concept – V.N., S.S.; Design – K.M., V.N., S.S., D.K.; Supervision – V.N., S.S., D.K.; Funding – K.M., V.N., S.S., D.K.; Materials – K.M., V.N., S.S., D.K.; Data collection and/or processing – K.M., V.N., S.S., D.K.; Data analysis and/or interpretation – K.M., V.N., S.S., D.K.; Literature search – K.M., V.N., S.S., D.K.; Writing – K.M., V.N., S.S., D.K.; Critical review – V.N., S.S., D.K.

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