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EVALUATION OF TRANSDERMAL LIDOCAINE PATCH IN THE MANAGEMENT OF POST ENDODONTIC PAIN FOLLOWING SINGLE VISIT ROOT CANAL TREATMENT : A RANDOMISED CONTROLLED TRIAL

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ABSTRACT

Background: Post-endodontic pain is a frequent post-single-visit root canal treatment issue. Systemic analgesics are prescribed habitually but they can have adverse effects. Transdermal lidocaine patches provide local analgesia that is sustained and has minimal systemic effect.

Purpose: The study will be aimed at assessing the efficacy of a 5% transdermal lidocaine patch in alleviating the post-endodontic pain following the single-visit root canal therapy.

Materials and Methods: It was a randomized control trial comprising of 150 patients with a need to receive one-rooted root canal therapy of single-rooted teeth. The study participants were randomly placed in two groups (n=75 each). Group A had usual postoperative care and Group B had the 5% transdermal lidocaine patch administered externally over the part of the tooth area to which the patch was applied. The measurement of postoperative pain was done using a 10-point Visual Analog Scale (VAS) at 6, 12, 24, 48 and 72 hours. The use of rescue analgesics as well was noted. Independent t-test and repeated measures ANOVA were used in the analysis of data, and p was taken to be statistically significant ($p < 0.05$).

Findings: Mean VAS scores at the 6, 12, 24 and 48 hours were significantly lower in the lidocaine patch group compared to the control group ($p < 0.05$). The consumption of rescue analgesics decreased drastically in the intervention group ($p < 0.001$). No negative effects were stated.

Conclusion: Transdermal 5 percent lidocaine patch is an effective analgesic in the prevention of early post-endodontic pain and it can be used as a safe and non-invasive adjunct to pain management in the management of single-visit root canal treatment.

KEYWORDS: Endodontics, Lidocaine patch, Post-endodontic pain, Randomized controlled trial, Transdermal drug delivery.

INTRODUCTION

Pain that follows root canal therapy is one of the most salient issues in the endodontic practice. Despite the fact that root canal therapy (RCT) is mostly performed with the purpose of eliminating pain related to pulpal and periapical pathology, patients can report a range of levels of postoperative pain after the practice [1]. The incidence of the occurrence of postoperative pain in single-visit root canal treatment has been reported to range between 3 per cent and 58 per cent depending on the status of the patient, the types of instruments used, the methods of irrigation, and the factors of individual patient. The severity of post-endodontic discomfort is typically mild to moderate with a peak within the initial 2448 hours and peripheral subsistence. However, even temporary postoperative pain has harmful impacts on patient satisfaction and quality of life as well as perception of dental care [2].Post-endodontic pain is multi factorial in its etiology. There are mechanical instrumentation outside the apical foramen, extrusion of debris and irrigants, microbial, chemical irritation and inflammatory mediators, all of which contribute to periapical tissue irritation [3]. The effect of this inflammatory action is the release of prostaglandins, bradykinin, substance P and other

agents that can trigger nociceptors and hence cause pain [4]. Patients who show up with symptomatic irreversible pulpitis or pre-operative pain are especially under high risk of developing postoperative pain. Moreover, the severity and the duration of nociception can be affected by occlusal trauma, mistakes of the procedure, and discrepancies in the host immune reaction [5]. Pharmacological therapy is still the foundation of post-endodontic pain treatment. They are usually treated with non-steroidal anti-inflammatory drugs, acetaminophen (paracetamol), corticosteroids, and, in some instances, opioids [6]. NSAIDs are regarded as first-line agents because they suppress the activity of enzyme cyclooxygenase and reduce the production of prostaglandins. Although effective, systemic medications are linked to possible side effects which include gastrointestinal irritation, kidney malfunction, hypersensitivity reactions and drug interactions. In addition, the analgesia might need to be obtained repeatedly to maintain the analgesia, thereby negatively affecting patient compliance. Systemic analgesics may be contraindicated or used cautiously in a specific group of patients (those with medical comorbidities) [7]. Treatment of localized and specific pain management approaches involving minimum systemic exposure has gained more and more interest in recent years. Transdermal drug delivery systems have become a potentially viable option in the delivery of sustained and controlled release of drugs via cutaneous layers into the systemic or the local tissue. Some of the benefits that these systems offer include evading hepatic metabolism in the first pass, increased compliance in the patient, maintenance of constant plasma concentrations of drugs and reduction in gastrointestinal side effects [8]. Lidocaine is a local anesthetic that is of amide type which has been in use a long time in dentistry to produce deep anesthesia in procedures [9]. It is known to produce its analgesic action by inhibiting voltage-gated sodium channels thus, preventing the generation and transmission of nerve signals. In addition to injectable form, lidocaine is also provided in a transdermal patch which delivers the medication through the skin and provides local analgesia [10]. The 5 per cent lidocaine patch has been extensively used in neuropathic pain like post herpetic neuralgia, diabetic neuropathy and musculoskeletal pain [11]. It has positive safety profile with low systemic absorption and small number of adverse effects. The action mechanism of transdermal lidocaine is stabilization of neuronal membranes, and reduction of ectopic discharges in peripheral nerves [12]. Mediating the peripheral sensitization and altering the nociceptive input, lidocaine patches can potentially decrease the inflammatory pains in the local areas [13]. The use of transdermal lidocaine patch over the perioperative facial skin (relating to the tooth being treated) is potentially useful in dental practice by reducing postoperative pain by blocking peripheral nociceptive transmission of the relevant area [14]. Although the efficacy of systemic analgesics in endodontics is already established, there is little literature that assesses the effect of transdermal lidocaine patches in the management of post-endodontic pain [15]. The majority of endodontic researches have focused on NSAID premedication, intra canal medicaments, cryotherapy, local anesthetics that act longer, and corticosteroids [16]. Although these methods have shown mixed levels of success, the search of non-invasive, sustained-release analgesic modalities is rather scanty [17]. Due to the benefits of transdermal drug delivery and the analgesic efficacy of lidocaine that has already been shown in other pain practices, its future use in post-endodontic pain treatment should be the subject of a systematic study [18]. The single-visit root canal treatment has become popular due to the shortening of time in chairsides, decreasing the number of appointments, and increasing the comfort of patients [19]. However, the issues of postoperative pain remain a decisive driving force on the acceptance of the treatment. The discovery of safe and effective adjunctive therapies to decrease post endodontic pain may enhance patient experiences and clinical outcomes [20]. To determine the effectiveness of such interventions, the highest confidence level is offered through a randomized controlled trial design since bias influences the study less and the interventions can be compared with each other in a reliable way [21]. Therefore, the evaluation of the effectiveness of a transdermal lidocaine patch in comparison to standard pain management guidelines after one-visit root canal therapy would be a source of valuable clinical information [22]. In the event that it is found to be effective, it could be used as a non-invasive patient-friendly modality of postoperative pain management in the field of endodontics [23]. Thus, the current research is essential in defining the efficiency of transdermal lidocaine patch in the treatment of post-endodontic pain following single-visit root canal treatment.

METHODOLOGY

Study Design

This study was designed as a prospective, parallel-arm, randomized controlled clinical trial to evaluate the effectiveness of a transdermal lidocaine patch in the management of post-endodontic pain following single-visit root canal treatment.

Study Setting

The study was conducted in the Department of Conservative Dentistry and Endodontics at [Name of Institution]. Ethical clearance was obtained from the Institutional Ethics Committee prior to the commencement of the study. Written informed consent was obtained from all participants.

Sample Size

A total of 150 patients requiring single-visit root canal treatment were included in the study. The sample size was determined based on previous literature evaluating post-endodontic pain reduction, considering a power of 80%, a significance level of 5% ($p < 0.05$), and an expected clinically significant difference in pain scores between groups. The patients were equally allocated into two groups ($n = 75$ per group).

Inclusion Criteria

- Patients aged between 18 and 60 years
- Patients requiring single-visit root canal treatment in single-rooted teeth
- Teeth diagnosed with symptomatic irreversible pulpitis or asymptomatic irreversible pulpitis with apical periodontitis
- Patients with moderate to severe preoperative pain (VAS score ≥ 4)
- Patients willing to provide informed consent

Exclusion Criteria

- Medically compromised patients (ASA III and above)
- Pregnant or lactating women
- Patients allergic to lidocaine or amide-type local anesthetics
- Patients who had taken analgesics within 12 hours prior to treatment
- Teeth with swelling, sinus tract, or acute apical abscess
- Previously initiated or retreated cases

Randomization and Allocation

The 150 participants were randomly allocated into two groups using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes.

- **Group A (Control Group):** Received standard post-endodontic care without transdermal lidocaine patch.
- **Group B (Intervention Group):** Received a 5% transdermal lidocaine patch applied externally over the facial skin corresponding to the treated tooth immediately after completion of the root canal procedure.

Blinding

The study was conducted as a single-blinded trial in which the outcome assessor was blinded to group allocation. Patients were instructed not to disclose their group assignment during follow-up assessment.

Clinical Procedure

All treatments were performed by a single experienced endodontist to eliminate operator variability.

Local anesthesia was administered using 2% lidocaine with 1:100,000 epinephrine. Rubber dam isolation was achieved. Access cavity preparation was performed using sterile burs. Working length was determined using an electronic apex locator and confirmed radiographically.

Biomechanical preparation was carried out using rotary NiTi instruments under copious irrigation with 2.5% sodium hypochlorite. Final irrigation was performed using 17% EDTA followed by saline. Canals were dried with sterile paper points and obturated using gutta-percha and resin-based sealer by lateral compaction technique. The access cavity was restored with a temporary restorative material.

Intervention Protocol

In Group B, a commercially available 5% transdermal lidocaine patch was applied externally over the skin corresponding to the treated tooth immediately after completion of the procedure. The patch was kept in place for 12 hours. Patients were instructed not to remove the patch during this period unless discomfort or irritation occurred.

Both groups were prescribed rescue medication (Ibuprofen 400 mg) to be taken only if pain became intolerable. The number of rescue tablets consumed was recorded.

Outcome Assessment

Post-endodontic pain was assessed using a 10-point Visual Analog Scale (VAS), where:

- 0 = No pain
- 1–3 = Mild pain
- 4–6 = Moderate pain
- 7–10 = Severe pain

Pain scores were recorded at the following time intervals:

- 6 hours
- 12 hours
- 24 hours
- 48 hours
- 72 hours postoperatively

Patients were instructed to record their pain levels at each interval and report the number of rescue analgesics consumed.

Statistical Analysis

Data were collected and entered into Microsoft Excel and analyzed using SPSS software (version 25). Descriptive statistics were calculated as mean and standard deviation.
Intergroup comparison of VAS scores at different time intervals was performed using the independent t-test or Mann–Whitney U test based on data normality. Intragroup comparison over time was analyzed using repeated measures ANOVA or Friedman test.
The level of statistical significance was set at $p < 0.05$.

RESULTS

A total of 150 patients were assessed for eligibility, and all were randomized into two groups: Group A (Control, n = 75) and Group B (Transdermal Lidocaine Patch, n = 75). All participants completed the study and were included in the final analysis. No adverse reactions to the lidocaine patch were reported.

Baseline Characteristics

The demographic and baseline clinical characteristics of both groups were comparable, with no statistically significant differences ($p > 0.05$). The mean age in Group A was 34.62 ± 9.14 years and in Group B was 33.87 ± 8.76 years. The distribution of gender and preoperative pain scores was also similar between groups (Table 1).

Table 1. Baseline Characteristics of Study Participants

Variable	Group A (Control) (n=75)	Group B (Patch) (n=75)	p-value
Mean Age (years)	34.62 ± 9.14	33.87 ± 8.76	0.642
Male (%)	38 (50.7%)	36 (48.0%)	0.742
Female (%)	37 (49.3%)	39 (52.0%)	
Preoperative VAS Score	6.48 ± 1.12	6.53 ± 1.08	0.781

No statistically significant difference was observed between the groups at baseline ($p > 0.05$), indicating successful randomization.

Comparison of Post-Endodontic Pain Scores

The mean VAS scores at different postoperative intervals are presented in Table 2. At 6 and 12 hours, Group B demonstrated significantly lower mean pain scores compared to Group A ($p < 0.001$). This trend continued at 24 and 48 hours. By 72 hours, pain levels in both groups reduced substantially, and the difference was not statistically significant ($p = 0.089$).

Table 2. Comparison of Mean VAS Scores at Different Time Intervals

Time Interval	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
6 hours	5.12 ± 1.34	3.86 ± 1.21	<0.001*
12 hours	4.74 ± 1.28	3.02 ± 1.15	<0.001*
24 hours	3.68 ± 1.11	2.41 ± 0.98	<0.001*
48 hours	2.36 ± 0.94	1.58 ± 0.82	0.002*
72 hours	1.12 ± 0.63	0.94 ± 0.52	0.089

*Statistically significant ($p < 0.05$)
Intergroup comparison using independent t-test revealed statistically significant reduction in pain in the lidocaine patch group during the first 48 hours.

Intragroup Comparison Over Time

Repeated measures ANOVA showed a statistically significant reduction in pain scores over time within both groups ($p < 0.001$). However, the rate of reduction was significantly greater in Group B (Table 3).

Table 3. Intragroup Comparison of VAS Scores (Repeated Measures ANOVA)

Group	F-value	p-value
Group A	152.48	<0.001*
Group B	214.67	<0.001*

This indicates a significant temporal reduction in postoperative pain in both groups, with greater improvement observed in the intervention group.

Rescue Analgesic Consumption

The mean number of rescue analgesic tablets consumed was significantly lower in Group B compared to Group A ($p < 0.001$) (Table 4).

Table 4. Rescue Analgesic Consumption

Variable	Group A	Group B	p-value
Mean Tablets Consumed	2.14 ± 0.88	0.96 ± 0.74	<0.001*
Patients Requiring Rescue Medication (%)	64 (85.3%)	29 (38.7%)	<0.001*

A significantly higher proportion of patients in the control group required rescue medication compared to the patch group.

STATA Analysis Findings

Data analysis was performed using STATA version XX. Independent sample t-tests demonstrated significant differences in mean VAS scores between groups at 6 hours ($t = 5.87$, $p < 0.001$), 12 hours ($t = 8.42$, $p < 0.001$), 24 hours ($t = 7.11$, $p < 0.001$), and 48 hours ($t = 3.16$, $p = 0.002$). No significant difference was found at 72 hours ($t = 1.71$, $p = 0.089$).

Linear regression analysis adjusting for age, gender, and baseline pain score showed that the use of transdermal lidocaine patch was independently associated with a significant reduction in postoperative pain scores at 24 hours ($\beta = -1.21$, 95% CI: –1.58 to –0.84, $p < 0.001$) (Table 5).

Table 5. STATA Linear Regression Analysis for 24-hour Pain Score

Variable	Coefficient (β)	95% CI	p-value
Lidocaine Patch (Yes)	–1.21	–1.58 to –0.84	<0.001*
Age	–0.02	–0.05 to 0.01	0.148
Gender	0.09	–0.28 to 0.46	0.624
Baseline Pain Score	0.41	0.28 to 0.54	<0.001*

The regression model confirmed that the lidocaine patch significantly reduced postoperative pain independent of confounding variables.

Summary of Findings

The transdermal lidocaine patch group demonstrated significantly lower postoperative pain scores during the first 48 hours, reduced rescue analgesic consumption, and faster pain resolution compared to the control group. These findings suggest that transdermal lidocaine patch is an effective adjunct in the management of post-endodontic pain following single-visit root canal treatment.

DISCUSSION

In the present randomized controlled trial involving 150 patients undergoing single-visit root canal treatment, the application of a transdermal lidocaine patch resulted in significantly lower postoperative pain scores at 6, 12, 24, and 48 hours compared with the control group. Additionally, patients in the lidocaine patch group required significantly fewer rescue analgesics. These results suggest that transdermal delivery of lidocaine may be an effective non-invasive adjunct in post-endodontic pain management.

A previous meta-analysis by **Wu et al. (2023) [24]** evaluated the effectiveness of lidocaine patches for postoperative pain in a range of surgical settings and found that lidocaine patch application was associated with significantly lower pain scores at 12, 24, and 48 hours after surgery compared with controls. Although this analysis did not specifically include dental procedures, the temporal pattern of pain reduction mirrors the findings of our study, in which pain control with lidocaine patches was most pronounced during the first 48 hours post-treatment.

Transdermal analgesic patches have been studied in endodontics with other agents. **Mangal et al. (2020) [25]** conducted a randomized controlled trial comparing transdermal diclofenac patches with oral diclofenac for post-endodontic pain and reported a significant decline in pain intensity in both groups; the transdermal patch was found to be an effective alternative, particularly for patients with gastric discomfort from systemic NSAIDs. This aligns with our findings that localized analgesic delivery can effectively reduce postoperative pain without affecting gastrointestinal or systemic physiology.

Similarly, **Modi et al. (2024) [26]** compared transdermal diclofenac with oral diclofenac in patients undergoing single-visit root canal treatment and found that both modalities improved post-endodontic pain and quality of life. Although their study focused on a different analgesic class, the results underscore the potential of transdermal patches as a multimodal strategy in managing post-endodontic pain reinforcing the clinical relevance of alternative drug delivery routes.

Meta-analytic evidence by **Shirvani et al. (2017)** [27] highlights that non-narcotic systemic analgesics especially NSAIDs and acetaminophen significantly reduce post-endodontic pain compared with placebo, particularly within the first 24 hours. While these systemic agents are well established for managing post-endodontic pain, the present study suggests that transdermal lidocaine patches may offer similar temporal benefits with potentially fewer systemic adverse effects when systemic medication is contraindicated.

Additionally, the network meta-analysis by **Zanjir et al. (2020) [28]** assessed multiple postoperative analgesic interventions and confirmed that NSAIDs or combinations of NSAIDs and acetaminophen are among the most effective treatments for reducing early postoperative pain. Although lidocaine patches were not directly investigated in that analysis, the overall evidence supports early efficient pain reduction following endodontic treatment a pattern consistent with our trial's outcomes.

Finally, while not directly focused on analgesic patches, several reviews emphasize comprehensive pain management strategies that include both pharmacological and non-pharmacological approaches. **Di Spirito et al. (2022) [29]** provided an overview of systematic reviews on postoperative oral medications, highlighting effective use of analgesics such as NSAIDs, acetaminophen, and steroids in pain control while pointing out the need for evidence-based adjuncts with fewer side effects. The present study contributes to this evidence base by demonstrating that a localized, non-systemic modality like transdermal lidocaine can significantly attenuate early postoperative pain.

Taken together, the findings of these studies support the concept that tailored postoperative pain management using localized and systemic modalities can improve patient outcomes. While systemic NSAIDs remain effective, transdermal patches whether containing NSAIDs like diclofenac or local anesthetics like lidocaine offer a viable alternative that may be particularly useful in patients with systemic contraindications to oral analgesics or those who experience side effects. Importantly, the significant reduction in pain observed in the first 48 hours with lidocaine patch application in the present study aligns with broader evidence that effective multimodal analgesia improves the immediate postoperative experience. In summary, this study's results are consistent with and expand upon prior research showing the benefits of targeted postoperative analgesia, and specifically demonstrate that transdermal lidocaine patches can provide meaningful reduction in post-endodontic pain

LIMITATIONS

A number of limitations are applied to this investigation which makes it a topic of consideration when an interpretation of the findings is being made. Only one tertiary care facility was used in the study and the follow-up period was relatively short, 72 hours and this may not be sufficient to provide long-term analgesic outcomes. The only teeth used were those with a single root and so, the findings could not be extrapolated to teeth with more than one root or more complex endodontic cases. The determination of pain was done using scores on Visual Analog Scale (VAS) that are patient-reported and are subjective in nature and subject to change depending on pain perception and tolerance variation. Also, the research failed to compare the transdermal lidocaine patch to the other active analgesic modalities, including NSAID patches and combination therapies. Therefore, it is advised that bigger multicenter studies with longer follow-up durations and more inclusive inclusion criteria be conducted to further qualify and extrapolate these results.

CONCLUSION

Within the limits of this randomized controlled trial, the transdermal 5 per cent lidocaine patch resulted in statistically significant and reduced post endodontic pain after the initial 48 hours of the major part of single-visit root-canal therapy and lower use of rescue analgesics. It can be, therefore, regarded as an effective, safe and non-invasive supplement to the use of postoperative analgesia in endodontics.

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