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ORIGINAL ARTICLE

Comparison of postoperative pain with and without apical patency technique in asymptomatic necrotic teeth: a randomized control trial

Iftikhar Akbar [1] ✉, Abdul Majeed [1], Junaid Islam [1], Rizwan Qureshi [1]

ABSTRACT

Objective: To evaluate the incidence and severity of post-operative pain in patients with asymptomatic necrotic pulp and apical periodontitis treated with or without the apical patency technique and to assess the corresponding use of analgesics.

Methods: This single-blinded, prospective randomized clinical trial was conducted from October 2022 to February 2023 at Peshawar Dental College, Peshawar-Pakistan. Sixty patients aged 18–60 years with maxillary or mandibular premolars and molars diagnosed with asymptomatic necrotic pulp and apical periodontitis were randomly assigned (1:1) to either the apical patency (AP) group or non-apical patency (NAP) group. Standardized root canal treatments were performed under local anesthesia with rubber dam isolation. In the AP group, a #10 K-file was extended 1 mm beyond the working length during instrumentation, while recapitulation in the NAP group was confined to the working length. Post-operative pain was self-assessed on a 0–10 numerical scale at 24 hours and daily for 7 days, with Ibuprofen 400 mg provided as rescue analgesia.

Results: Demographic characteristics were comparable between groups. Overall, 21 (35%) patients experienced post-operative pain, with similar incidence between AP (n=11, 36.6%) and NAP (n=10; 33.3%) groups (p =0.787). Overall, the AP group exhibited significantly higher mean pain scores during the first five days (P <0.05), with a greater proportion of patients requiring analgesics (16.7% vs. 10%) compared to the NAP group.

Conclusion: While the overall incidence of post-operative pain was similar, the apical patency technique was associated with increased early pain severity and higher analgesic consumption, warranting further studies to optimize its clinical application.

Clinical trial registration number: NCT05574088

Keywords: Apical Patency (MeSH); Tooth (MeSH); Asymptomatic necrotic teeth (Non-MeSH); Pain (MeSH); Post-operative Pain (MeSH); Root Canal Therapy (MeSH).

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1: Department of Operative Dentistry and Endodontics, Peshawar Dental College, Peshawar Affiliated with Riphah International University, Islamabad, Pakistan

Email ✉ : driftikhar156@hotmail.com
Contact #: +92-347-9368676

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INTRODUCTION

Biomechanical preparation is the fundamental aspect of root canal treatment, encompassing mechanical instrumentation and irrigation of the root canal system. Effective preparation and debridement of apical part of the root canal presents a challenge owing to its anatomical complexity.[1] During mechanical instrumentation, debris may be displaced to the apical portion, obstructing access and leading to procedural errors such as inability to reach the working length, ledge formation and transportation.[2]

To prevent accumulation of pulpal and dentinal debris in apical portion of the root canal, maintenance of apical patency is crucial, and the apical patency file technique proves effective for this purpose.[2,3] This technique ensures that apical foramen remains unobstructed.[4-6] The implementation of apical patency filing serves as a preventive measure, lowering the risk of procedural errors, aiding in maintaining the working lengths and facilitating irrigation of apical portion of the canal.[4,5] In cases involving necrotic pulp, apical patency filing also assists in eliminating microorganisms in the lesion around the apical foramen. The significance of this technique is supported by a study conducted by Arias et al.,[3] which noted reduced postoperative pain in non-vital pulp cases following patency filing.

To maintain apical patency, a deliberate approach involves the intentional adjustment of a K-file, usually a size #10, to extend 1 mm beyond the working length. This file is then carefully maneuvered through the apical constriction without binding. After each instrumentation, widening is purposefully avoided before proceeding with irrigation. This meticulous technique helps ensure that the apical foramen remains unobstructed and contributes to the overall success of root canal procedure.[7,8]

However, maintaining apical patency is not without challenges. One potential issue is risk of displacing infected debris through the apical foramen, which could lead to an acute apical inflammatory response and subsequent postoperative pain. Conversely, in a study by Oliveira at all, no such complications were observed.[9]

Numerous studies have investigated the consequences of patency filing. In teeth with nonvital pulp, Arias et al.,[3] observed a significant reduction in postoperative pain following patency filing, although that study did not specify the periapical diagnosis of the teeth

involved. Conversely, another randomized controlled trial did not detect any substantial difference in postoperative pain among teeth with necrotic pulp and apical periodontitis. [10]

In light of these conflicting findings and limitations in previous research, this investigation hypothesized that there is no significant difference in postoperative pain between the use and non-use of patency filing. Accordingly, this randomized controlled trial was designed to explore the correlation between postoperative pain and the maintenance of apical patency in teeth with preoperatively asymptomatic necrotic pulp and apical periodontitis. The primary objective of this study was to determine both the incidence and severity of post-operative pain in two distinct groups: one utilizing apical patency technique and the other not using it in cases with asymptomatic necrotic pulp and apical periodontitis. The secondary objective focused on assessing the post-operative use of analgesics in both groups.

METHODS

This study was approved by the Institutional Ethical Review Board of Prime Foundation (Prime IRB/2022/170) and registered as a randomized clinical trial on clinicaltrials.gov (NCT05574088). It was conducted at the Department of Operative Dentistry and Endodontics, Peshawar Dental College, Peshawar, Pakistan. This single-center, single-blinded prospective randomized clinical trial was carried out between October 2022 and February 2023. The study followed the guidelines outlined in the CONSORT statement for reporting clinical trials.

The inclusion criteria comprised maxillary and mandibular premolars and molars diagnosed with asymptomatic necrotic pulp and apical periodontitis, involving male and female patients aged between 18 and 60 years. Exclusion criteria involved pregnant patients, those experiencing complications during the procedure, individuals with previously accessed teeth, and those who had taken analgesics within the past 3 days. The diagnosis of asymptomatic necrotic pulp was confirmed following a clinical examination that included the absence of a response to sensitivity tests, was further validated by the complete lack of bleeding on endodontic access opening.

Upon conducting sample size calculation, it was determined that a minimum of 30 patients in each group would be sufficient to detect clinically significant differences in pain levels, maintaining an alpha of 0.05, power at 90%, and an effect size of 0.8.

Written informed consent was obtained, and the patients were randomly assigned to two groups, namely apical patency (AP) and non-apical patency (NAP), in an equal distribution allocation ratio (1:1). This randomization was achieved using envelopes containing sequentially assigned concealed assignment codes for eligible patients. Importantly, the patients were kept blind to the assigned procedure throughout the study (Figure 1).

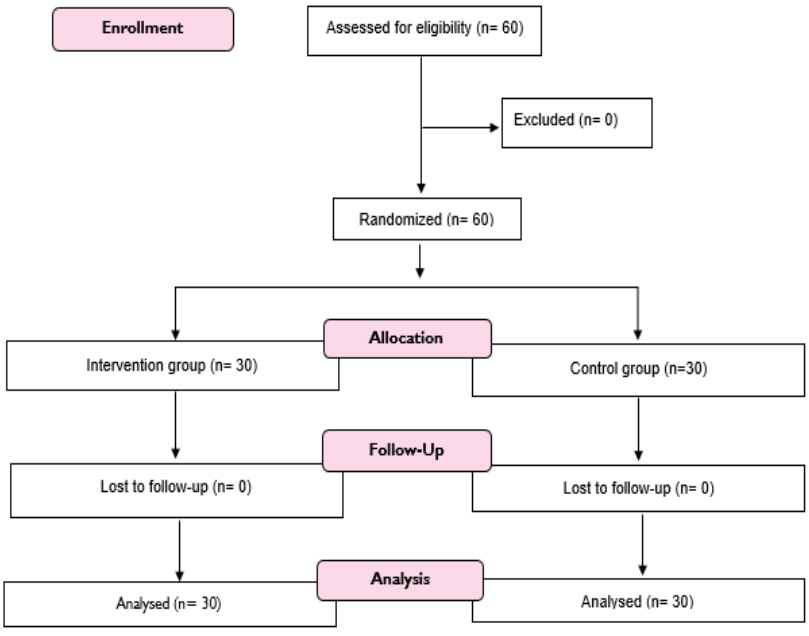

Figure 1: Flow chart of methodology

Local anesthesia (2% lidocaine with 1:100,000 epinephrine, Mdicaine) was administered to the patients. After rubber dam isolation, an access cavity was prepared. The working length (WL) was measured using an electronic apex locator (Root ZXII; J.Morita USA, Inc) along with #15 K-files (Mani, Japan). The accuracy of the working length was verified through both parallel and angled digital radiographs, ensuring that the file tip was within 0.5–1 mm of the radiographic apex. Canal shaping was performed using the ProTaper Universal File system (Dentsply, USA), following the manufacturer's guidelines.

A #10 K-file was maneuvered 1 mm beyond the working length during each successive use of rotary files in the patency group, whereas in the non-patency group, it was directed up to the working length for recapitulation. The irrigation process involved the use of sodium hypochlorite (3%) (Vista Dental USA), followed by EDTA (17%) (Vista Dental USA) for one minute, succeeded by a final rinse with sodium hypochlorite. The canals were filled with calcium hydroxide, and temporary restoration was performed using Cavit (3 M ESPE, Germany).

Post-operative pain assessment after the root canal treatment involved the use of a pain scoring chart. Patients were instructed to mark their pain intensity on a scale ranging from 0 to 10. Subsequently, their reported pain levels were categorized as follows: no pain (score of 0), mild pain (scores 1-3), moderate pain (scores 4-6), and severe pain (scores 7-10). This categorization allowed for a comprehensive evaluation

of post-operative pain intensity over a period of 7 days following the root canal procedure.

Following the procedure, the patients were informed of possibility of pain and were given instructions to document the pain intensity they experience at any time during 24 h, day 2, day 3, day 4, day 5, day 6 and day 7 in the proforma following the procedure, and were asked to submit at the subsequent scheduled appointment. They were advised to take recommended medicament (ibuprofen 400mg at each 6–8h), in-case of pain.

SPSS 22 (SPSS Inc, Chicago, IL) was used to analyze all statistics data. Analyzing the baseline data revealed all characteristics normally distributed ($P>0.05$, Kolmogorov Smirnov test), independent samples were evaluated using the Student t-test. The categoric variables differences were evaluated utilizing the chi-square test. A P value of ≤ 0.05 was considered significant.

RESULTS

Data analysis of the demographic characteristics (Table I) of the two groups revealed no significant differences in age and gender ($P > 0.05$, χ^2 test). In total, 32 (53.33%) females and 28 (46.67%) males participated in the study. No significant difference in pain occurrence was observed between the maxillary and mandibular premolars and molars ($P > 0.05$, χ^2 test). Overall, pain was reported by 21 (35%) patients, while 39 (65%) patients experienced no pain in both groups, with no significant difference between them ($P = 0.787$) (Table II).

Primary outcome: The post-operative Pain was experienced by 21 (35%) patients. The non-apical patency group reported a slightly lower incidence of pain in 10 (33.3%) patients compared to the patency group, with 11 (36.6%) patients, yet the disparity was not deemed clinically significant ($P= 0.787$). During the first 5 days while maintaining patency there was significantly higher reported pain ($P<0.05$, independent sample t test) in comparison with NAP group; later on, it was insignificant. Overall, in this study higher mean pain levels persisted in the AP group ($P<0.05$) compared to that of NAP group (Table III). Analysis revealed no significant difference for pain levels at later days in both the groups. The study also examined severity of different postoperative pain levels and their distribution among both groups, which were formed based on pain scores on the Numerical Rating Scale (0-10) during the follow-up period. It was noted that with each passing day there was gradual reduction in pain levels. After 2 days, no patient reported moderate level of pain in the NAP group while one of the patients from AP group still experienced moderate level pain. Only one patient (1.7%) reported with severe level of pain (flare-up) in the AP group at 24h time interval necessitating unscheduled appointment in the follow-up period.

Secondary outcome: Overall 16.7% (5 out of 30) subjects in the AP group and 10% (3 out of 30) in the NAP group required medication for pain relief. Data analysis revealed significant difference in the proportion of analgesics needed ($P<0.05$, χ^2 test) between the two groups.

DISCUSSION

The intent of current study was to assess the association between postoperative pain and apical patency while the patency is maintained in teeth with asymptomatic necrotic pulp and apical periodontitis. The present study showed that the maintenance of patency resulted in higher post-operative pain levels, compared to confining the recapitulation filing to the canal system as in the NAP group that resulted in significantly lower post-operative pain levels during the first 5 days. This study supports the hypothesis that patency filing leads to in higher post-operative pain level, and it demonstrated that there was a difference in medication needed for pain relief between the two groups during the follow-up period.

While patency filing, the appropriate file size to use has not been clearly established.[11, 12] File size #10 K, #15 K, and #20 K for patency filing has been taught in about 50% of U.S. dental schools.[13,14] In current study, a #10 K-file size was used for patency filing as greater file sizes have been shown to

Table I: Mean age, gender and type of teeth distribution in patency and non-patency group

Variables		AP (n=30)	NAP (n=30)	p-value
Age (mean±SD) in years		35.4±10.9	38.4±10.9	0.560
Gender [n (%)]	Male	12(40)	16(53.3)	0.129
	Female	18(60)	14(46.7)	
Teeth [n (%)]	Maxillary molar	6(20)	3(10)	0.206
	Mandibular molar	10(33.3)	5(16.7)	
	Maxillary premolar	5(16.7)	10(33.3)	
	Mandibular premolar	9(30)	12(40)	

AP: Apical Patency; NAP: Non-apical Patency; SD: Standard Deviation

Table II: Incidence of post-operative pain

Apical patency group	Postoperative Pain		Pain Incidence (%)	p-value
	Yes	No		
Apical Patency	11	19	36.6	0.787
Non-apical Patency	10	20	33.3	
Total	21	39	35	

Table III: Mean pain values (mean±SD) of apical patency and non-apical patency group at time intervals with corresponding p-values

Apical patency group	Pain severity at 24h	pain severity at day-2	pain severity at day-3	pain severity at day-4	pain severity at day-5	pain severity at day-6	pain severity at day-7
Apical	1.33±1.	0.80±1.15	0.23±0.4	0.17±0.37	0.07±0.25	0.03±0.18	0.03±0.18
Patency	936	7	30	9	4	3	3
Non-Apical	0.93±1.	0.47±0.73	0.20±0.4	0.13±0.34	0.03±0.18	0.00±0.00	0.00±0.00
Patency	172	0	07	6	3	0	0
P value	0.000	0.000	0.000	0.000	0.015	0.175	0.175

cause damage to periapical tissues and resultant elevated post-operative pain levels. File size #25 K has been observed to be particularly damaging when used for patency filing.[15]

Several studies have shown that maintenance of apical patency (AP) doesn't significantly affect the post-operative pain levels. In a study by Arora et al.[10] maintaining patency in first mandibular molars with apical periodontitis and necrotic pulp showed no significant post-operative pain. However, the author conduced a small study to examine the effects of maintaining an AP on pain levels in 68 participants using continuous rotational system for canals preparation. Arias et al. [16] noted that maintaining an apical patency in nonvital pulps significantly reduced the pain levels following a preparation with hand files. Nonetheless, the study didn't reveal the periapical diagnosis of the teeth. In a study by Yaylali at al.[1] a significant pain reduction was shown only 12 hours following the cleaning and shaping procedure using reciprocating system in the AP group and following 24 hours in the NAP group.

Arora et al.,[10] reported no significant difference of mean post-operative pain levels at any time during the study between the two groups. These observations contradict the findings of this study, in which there was a significant difference in mean post-operative pain scores in the first 5 days between the two groups, which is in agreement with that of Yaylali at al.,[2] This discrepancy in the current study may be attributed to differences in preoperative pulp status and pain scores as only asymptomatic necrotic pulp teeth were investigated.

In this study, it has been observed that the maintenance of patency results in higher incidence of post-operative pain levels. Statistically analyzing the data also revealed that higher levels of pain persisted throughout most of the follow-up period. in the AP group compared to the NAP group, similar to Shubham et al.,[17] who reported greater pain levels in AP group during the 1st, 2nd and 7th day period. However, this finding contrasts with those of Yaylali et al., [2]and Arora et al.,[10] who reported that incidence was significantly lower when AP was maintained. This variation could be attributed to the loss of apical constriction during patency filing resulting in extrusion of debris into the periapical tissue. [18,19] In addition, the variations might result from in file system and filing technique or NRS scale used in this study or difference in pain perception among different populations. Overall, 35% of subjects had post-operative pain that is analogous to earlier studies on pain prevalence (Arora et al.,[13], Arias et al., [5] Unlike Yaylali et al.,[2] who reported some level of pain from mild to moderate following the preparation in 100% of the participants in both groups, which might be attributed to either the small size of the sample used in current study or use of different file system for preparation or NRS scale used. This study used a continuous rotary system, whereas Yaylali et al.,[2] used a reciprocating system. Gambarini et al.,[19] reported significantly higher VAS pain scores with a reciprocating file system. Lower pain level was illustrated in the NAP group (33.3%) in comparison to the AP group (36.6%), which contrasts with the findings of Arias et al., [5] and Arora et al.[13] This difference could be attributed to smaller sample size and strict selection criteria in the current study.

In this study, only one patient (1.7%) experienced pain of severe intensity (flare-up) in the apical patency group. Current study demonstrated that there was a clinical difference in medication needed for pain relief in both groups as patency group consumed more analgesics than the non-patency group during the follow-up interval. This finding contradicts the findings of previous RCTs. [20,21] This difference could be attributed to the smaller sample size and strict selection criteria as only asymptomatic necrotic cases with apical periodontitis were included.

This study has several limitations; its single-center nature, conducted exclusively at a specific dental college, a relatively small sample size, and the potential challenge of generalizing the findings to broader populations or different settings. Additionally, a longer-term follow-up could have provided valuable insights into the durability of the interventions.

CONCLUSION

This study concluded that the incidence of post-operative pain following root canal treatment in patients with asymptomatic necrotic pulp and apical periodontitis was similar between the apical patency and non-apical patency groups. However, the apical patency group experienced significantly higher mean pain scores during the first five days post-treatment and required more analgesics compared to the non-apical patency group. These findings suggest that while the apical patency technique did not result in a higher incidence of pain, it was associated with greater pain severity and increased analgesic consumption. Further research with larger sample sizes and longer follow-up periods is needed to validate these

results and investigate the long-term effects of the apical patency technique.

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AUTHORS' CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

IA: Conception and study design, acquisition, analysis and interpretation of data, drafting the manuscript, critical review, approval of the final version to be published

AM: Study design, analysis and interpretation of data, drafting the manuscript, critical review, approval of the final version to be published

JI: Conception and study design, drafting the manuscript, approval of the final version to be published

RQ: Acquisition of data, critical review, approval of the final version to be published

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

Authors declared no conflict of interest, whether financial or otherwise, that could influence the integrity, objectivity, or validity of their research work.

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DATA SHARING STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request

KMUJ web address: www.kmuj.kmu.edu.pk
Email address: kmuj@kmu.edu.pk