Study Protocol

Project summary

Oral inflammatory diseases encompass a wide range of conditions, particularly apical Periodontitis [1]. This type of infection is caused by bacterial biofilm communities adhering to canal walls [2]. Effective management through root canal therapy focuses on eradicating existing infections and preventing bacterial re-infection of the pulp space and surrounding tissues [3]. Treatment success relies heavily on understanding the microbiological characteristics of apical periodontitis and implementing thorough cleaning, shaping, and irrigation techniques to reduce bacterial load within the root canal system [4].

The study aims to enhance our understanding of the importance of chemomechanical preparation in endodontic treatment specifically the final irrigation phase. Consequently, maximize the treatment outcomes quality, oral health and patient satisfaction.

This investigation included patients aged between 18 and 65 years who were referred to the Endodontic Department during the study period because of the presence of apical lesions. The patients also should have signs of asymptomatic periapical periodontitis such as minor percussion pain, or large untreated caries or fractures of the root/crown on one or more maxillary or mandibular anterior (central, lateral and premolar).

These patients were radiographed to ensure the existence of periapical lesions <5*5mm. The applied treatments included first Sodium hypochlorite (NaOCl) then the Iodine-Potassium Iodide (IKI) Solution. Two concentrations of IKI were used: 2% and 5%. In the control group, only Sodium hypochlorite (No IKI Solution) was applied.

All samples underwent immediate processing in a specialised laboratory within one hour of collection. The samples were plated onto nutrient agar plates and incubated for 48h at 37°C in aerobic conditions followed by counting colonies. Monitor the healing of apical periodontitis radiographically for 12 months. This study is conducted over a period spanning from May 2022 to August 2024. There is no funding for this study.

General information

Title: Evaluation of the Efficacy of lodine Potassium lodide IKI Irrigating Solution in Endodontic Treatment (In-vivo Bacteriologic and Radiographic Study).

The sponsor: Damascus University

There is no funding for this study

Investigator: Dr. Meerna Sarkees

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Rationale & background information

In general, endodontic treatment aims to eliminate bacteria and prevent re-infection within the root canal system [3,5]. Despite advancements in techniques and materials, unsuccessful endodontic treatments with persistent periapical lesions remain a challenge. While conventional irrigation protocols with sodium hypochlorite (NaOCl) and chlorhexidine (CHX) are effective, exploring alternative solutions with potentially superior disinfection is crucial [6,7]. Incomplete cleaning and disinfection of the root canal system during endodontic treatment is a primary cause of treatment failure. Residual bacteria within the complex root canal anatomy can persist and lead to the formation of periapical lesions [4,8]. Iodine potassium iodide (IKI) has emerged as a potential irrigant with promising antimicrobial properties. Studies suggest IKI may be superior to NaOCl and CHX in penetrating and disinfecting dentinal tubules, where bacteria can reside. This research investigates the effectiveness of using IKI as a final irrigation solution during single-visit endodontic treatment for maxillary or mandibular anterior teeth with periapical lesions. If IKI proves effective in reducing microbial count, it could offer a valuable addition to the endodontic armamentarium, potentially improving treatment success rates. Existing research on IKI presents conflicting results. While some laboratory and clinical studies demonstrate its efficacy as a final irrigant, others fail to show a significant antibacterial effect compared to conventional solutions [9–13]. The inconclusive nature of current research on IKI necessitates further investigation to definitively determine its potential role in improving endodontic treatment outcomes. This study aims to contribute valuable data on the effectiveness of IKI as a final irrigation solution in a specific clinical scenario.

References

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Study goals and objectives

The study aims to enhance our understanding of the importance of chemomechanical preparation in endodontic treatment specifically the final irrigation phase. Consequently, maximize the treatment outcomes quality, oral health and patient satisfaction. This object will be performed by investigating the impact of different final irrigation techniques on reducing microbial count in patients with a periapical lesion.

Study design

This is a single-centre interventional double-blinded randomized parallel clinical trial. The expected duration of the study is about 30 months.

This study included adult patients (18 and 65 years) from both sexes who were referred to the Endodontic Department with the presence of apical lesions. Meeting the inclusion criteria of asymptomatic periapical periodontitis such as minor percussion pain, large untreated caries or fractures of the root/crown on one or more maxillary or mandibular anterior (central, lateral and premolar). These patients were radiographed to ensure the existence of periapical lesions <5*5mm, and the teeth anatomy.

On the other hand, this study excluded patients with systemic diseases compromising general immune status, pregnancy, preoperative anxiety, antibiotic therapy within the past 3 months, open-apex teeth, teeth with multiple canals, internal or external resorption, advanced periodontitis (more than 5mm periodontal attachment loss and bone loss), teeth unsuitable for single-visit treatment, or containing moist canals with exudation or pus.

Additionally, every patient can freely withdraw from this research whenever he wants, even after written consent, without affecting my medical care.

Methodology

The applied treatments included first Sodium hypochlorite (NaOCl) then the Iodine-Potassium Iodide (IKI) Solution. Two concentrations of IKI were used: 2% and 5%. In the control group, only Sodium hypochlorite (No IKI Solution) was applied.
Teeth were allocated, using the simple randomization method, into three groups at a ratio of 1:1:1 depending on the IKI utilized concentration. Patients were asked to randomly select an envelope from a batch of opaque, sealed envelopes per study group, each containing cards with varying final irrigation solutions. This study was blinding the patients which helped to mitigate bias and ensure the objective assessment of treatment effectiveness. By maintaining patient blinding, we aimed to prevent any potential influence on their reporting of symptoms or perceptions of the treatment received.
The utilization of trained PhD student researchers who were calibrated to the assessment criteria further strengthened the objectivity of the evaluation process. Their blinding to the final irrigation used during the therapy ensured that treatment results were assessed without any preconceived thoughts.

The bacterial count was determined by culturing the samples on nutrient agar plates for 48h at 37°C in aerobic conditions, followed by counting colonies.
Monitor the healing of apical periodontitis radiographically for 12 months. This is a single-centre study performed at Damascus University.

Safety considerations

Any reported adverse events will be recorded and follow-up.

Follow-up

All patients will be followed up until verification the full healing by a Monitor of the healing of apical periodontitis radiographically for 12 months.

Data management and statistical analysis

The sample size for this study was determined using G* Power 3.1.9.4 to account for the reduction in bacterial counts measured in Colony Forming Units (CFUs).

Depending on the result, we expect to use a t-test, ANOVA test, Mann-Whitney U and Kruskal-Wallis test. Statistically significant results will be achieved at a level of 0.05 and a power of 95%. These calculations were based on data from a prior study [14]. This approach to determining sample size ensures that the study will have sufficient statistical power to detect meaningful differences between the treatment groups.

Expected outcomes of the study

The outcomes of this study will enhance our understanding of the importance of chemomechanical preparation in endodontic treatment specifically the final irrigation phase. Consequently, maximize the treatment outcomes quality, oral health and patient satisfaction.
Additionally, it will contribute to the existing body of knowledge on the treatment of teeth with apical periodontitis and may aid in the development of treatment protocols for such cases.

Duration of the project

30 months

Project management

The authors put the design of this study and directed its implementation, including data analysis, writing paper, and quality assurance and control.

Meerna Sarkees and Hisham Alafif conceptualized the idea, provided the treatment, and contributed to the writing and documenting. Hisham Alafif and Samar Alsalameh conceptualized the idea and supervised the PhD thesis for Meerna Sarkees.

Informed consent forms

Syrian Arab Republic
Ministry of Higher Education and Scientific Research
Damascus University
Faculty of Dentistry
Department of Endodontics

الجمهورية العربية السورية
وزارة التعليم العالي والبحث العلمي
جامعة دمشق
كلية طب الأسنان
قسم مداواة الأسنان

Research Participant Consent Declaration

تصريح موافقة المشارك بالبحث

I am the undersigned.....

أنا الموقع أدناه .....

After going through the consultation to clarify the stages of the research work and realizing its content and answering all the questions in my mind, and accordingly, I freely agree to participate in the research, and I understand that the researcher will be ready to answer my future questions.

I also know that I am free to withdraw from this research whenever I want, even after written consent, without affecting my medical care.

بعد اطلاعي على الاستشارة الخاصة بتوضيح مراحل العمل بالبحث وإدراكي لمضمونها وإتمام الإجابة على جميع الأسئلة التي تجول في ذهني وبناءً عليه فإني حراً ومختاراً أوافق على المشاركة بالبحث، وفهمت أن الباحثة ستكون مستعدة للإجابة عن أسئلتي المستقبلية.

كما أعلم أني حر في الانسحاب من هذا البحث متى شئت ولو بعد الموافقة التحريرية دون أن يؤثر ذلك على العناية الطبية المقدمة لي.

Participant Name.....

اسم المشارك: .....

Signature .....

التوقيع: .....

Date .....

التاريخ: .....