https://doi.org/10.36377/ET-0086

Clinical assessment of polyhexanide as an endodontic irrigant in the management of chronic apical periodontitis

Yulia A. Generalova ✉, **Adam Yu. Umarov**, **Ahmad Wehbe**, **Marina Yu. Dashtieva**, **Inna V. Bagdasarova**
Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), Moscow, Russian Federation
✉ generalova-yua@rudn.ru

Abstract
INTRODUCTION. Chronic forms of apical periodontitis remain a relevant challenge in endodontic practice. The effectiveness of treatment largely depends on the quality of root canal irrigation. Polyhexamethylene guanidine (polyhexanide) is considered a promising alternative to sodium hypochlorite, offering antimicrobial activity with low cytotoxicity.
MATERIALS AND METHODS**.** The study included 49 patients with chronic apical periodontitis, divided into two groups. In the first group, a 0.2% polyhexanide solution was used as the primary irrigant, while the second group received a standard protocol with 3% sodium hypochlorite (NaOCl) and 17% EDTA. Treatment efficacy was evaluated based on clinical symptoms and radiographic changes at 6 and 12 months. The Mann–Whitney U test and Pearson's chi-squared (χ^2) test were used for statistical analysis.
RESULTS. The treatment success rate was 98% in the polyhexanide group and 93.6% in the control group. After 12 months, patients in the experimental group showed a lower incidence of persistent periapical lesions. Although the differences did not reach statistical significance ($p > 0.05$), there was a trend toward a more favorable healing process with polyhexanide use.
CONCLUSIONS. The use of a 0.2% polyhexanide solution as an irrigant demonstrated clinical efficacy comparable to the traditional protocol, with a potential reduction in the risk of adverse effects on hard tissues and surrounding structures. Further studies with larger sample sizes and longer follow-up periods are needed to definitively assess the advantages of this approach.

Keywords: endodontics, polyhexanide, root canal irrigation, apical periodontitis, antiseptics, clinical efficacy

Article info: received – 18.02.2025; revised – 23.04.2025; accepted – 29.04.2025

Conflict of interest: The authors report no conflict of interest.

Acknowledgements: There are no funding and individual acknowledgments to declare.

For citation: Generalova Yu.A., Umarov A.Yu., Wehbe A., Dashtieva M.Yu., Bagdasarova I.V. Clinical assessment of polyhexanide as an endodontic irrigant in the management of chronic apical periodontitis. *Endodontics Today.* 2025;23(2):216–224. https://doi.org/10.36377/ET-0086

Клиническая оценка эффективности полигексанида как ирриганта при лечении хронического апикального периодонтита

Ю.А. Генералова ✉, **А.Ю. Умаров**, **А. Вехби**, **М.Ю. Даштиева**, **И.В. Багдасарова**
Российский университет дружбы народов им. Патриса Лумумбы, г. Москва, Российская Федерация
✉ generalova-yua@rudn.ru

Резюме
ВВЕДЕНИЕ. Хронические формы верхушечного периодонтита остаются актуальной проблемой в эндодонтической практике. Эффективность лечения во многом определяется качеством ирригации корневых каналов. Полигексаметиленгуанидин (полигексанид) рассматривается как перспективная альтернатива гипохлориту натрия, обладая антимикробной активностью и низкой цитотоксичностью.
МАТЕРИАЛЫ И МЕТОДЫ**.** В исследование включены 49 пациентов с хроническим апикальным периодонтитом, разделённые на две группы. В первой группе в качестве основного ирриганта использовался 0,2% раствор полигексанида, во второй – стандартный протокол с 3% NaOCl и 17% ЭДТА. Оценка эффективности проводилась по клинической симптоматике и рентгенологической динамике через 6 и 12 месяцев. Для статистического анализа использовались U-критерий Манна–Уитни и χ^2-критерий Пирсона.
РЕЗУЛЬТАТЫ. Успешность лечения составила 98% в группе полигексанида и 93,6% в контрольной группе. Через 12 месяцев у пациентов экспериментальной группы наблюдалась меньшая частота сохранения периапикальных очагов. Полученные различия не достигли статистической значимости ($p > 0,05$), однако выявлена тенденция к более благоприятному течению заживления при использовании полигексанида.
ВЫВОДЫ. Применение 0,2% раствора полигексанида в качестве ирриганта продемонстрировало клиническую эффективность, сопоставимую с традиционным протоколом, при возможном снижении

риска неблагоприятного воздействия на твёрдые ткани и окружающие структуры. Необходимы дополнительные исследования с расширенной выборкой и длительным наблюдением для окончательной оценки преимущества данного подхода.

Ключевые слова: эндодонтия, полигексани, ирригация корневых каналов, апикальный периодонтит, антисептики, клиническая эффективность

Информация о статье: поступила – 18.02.2025; исправлена – 23.04.2025; принята – 29.04.2025

Конфликт интересов: авторы сообщают об отсутствии конфликта интересов.

Благодарности: финансирование и индивидуальные благодарности для декларирования отсутствуют.

Для цитирования: Генералова Ю.А., Умаров А.Ю., Вехби А., Даштиева М.Ю., Багдасарова И.В. Клиническая оценка эффективности полигексанида как ирриганта при лечении хронического апикального периодонтита. *Эндодонтия Today.* 2025;23(2):216–224. https://doi.org/10.36377/ET-0086

INTRODUCTION

One of the key challenges in modern endodontics remains the achievement of stable clinical outcomes in the treatment of chronic apical periodontitis [1–3]. Despite advancements in instrumentation techniques and the development of obturation materials, treatment success largely depends on the effectiveness of antiseptic root canal irrigation. The presence of persistent microflora within the canal system creates favorable conditions for the development of resistant secondary infections, which significantly reduces the likelihood of complete healing of periapical tissues [4].

Current concepts of chemical irrigation are based on the use of combinations of solutions with pronounced antimicrobial and chelating properties. Traditionally, sodium hypochlorite has been the irrigant of choice in clinical practice due to its proven efficacy against a wide range of microorganisms and its ability to dissolve organic debris [1]. However, alongside its strong antimicrobial properties, sodium hypochlorite is associated with several adverse effects, including cytotoxicity, negative impact on dentin structure, and irritating action on periapical tissues [5].

In recent years, researchers have focused on a new-generation antiseptic – polyhexamethylene guanidine (polyhexanide) – which demonstrates stable biocidal activity, selective action, and low cytotoxicity [6]. In vitro studies have shown that polyhexanide causes less degradation of dentin microhardness and elastic modulus compared to sodium hypochlorite [2; 7]. This makes polyhexanide a promising alternative irrigant in endodontic practice, particularly in cases where minimal damage to hard dental tissues is of critical importance [1; 6].

However, to date, clinical and radiographic evidence on the effectiveness of polyhexanide irrigation for the treatment of chronic apical periodontitis remains limited. Most studies on this topic are laboratory-based and lack long-term clinical follow-up data [3]. In the absence of reliable randomized clinical trials, the use of polyhexanide as a primary irrigant requires further validation and evaluation under real-world clinical conditions [4; 8].

To address this, two null hypotheses were formulated within the framework of the present study: (1) the use of a 0.2% polyhexanide solution has no statistically significant effect on the clinical effectiveness of treatment for chronic apical periodontitis compared to the standard irrigation protocol; (2) there are no differences in the radiographic healing dynamics of periapical changes between patients treated with polyhexanide and those treated with sodium hypochlorite and EDTA.

AIM

The aim of this study was to evaluate the clinical and radiographic efficacy of using an antiseptic formulation based on a 0.2% polyhexanide solution in the treatment of chronic apical periodontitis. The study was based on a comparison of treatment outcomes between patients who underwent irrigation with polyhexanide and those treated with the traditional protocol involving sodium hypochlorite and EDTA. An objective assessment of the healing dynamics of periapical changes and the frequency of clinical symptoms after treatment will help to determine the potential of polyhexanide use in endodontic practice.

MATERIALS AND METHODS

To study the clinical effectiveness of root canal irrigation with an antiseptic formulation based on polyhexanide in the treatment of chronic apical periodontitis, dental examination and endodontic treatment were performed on 96 patients aged 18 to 65 years. All patients were diagnosed with various forms of chronic apical periodontitis (without acute exacerbation) – ICD-10 code K04.5: Chronic apical periodontitis. The diagnosis was established based on clinical and radiographic findings consistent with the Clinical Guidelines (Treatment Protocols) for diseases of periapical tissues dated September 30, 2014 (updated December 20, 2024).

All patients included in the study were fully informed about the purpose and nature of the procedures, and signed individual informed consent forms and information sheets were obtained. The patient interaction methods used in this study were approved by the Ethics Committee of the Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University) (Protocol No. 23 dated December 21, 2023).

In the laboratory phase of the study, certain advantages of the 0.2% polyhexanide solution over the 0.1% solution were identified. Based on the evident benefits of the 0.2% concentration, this formulation was selected for the clinical study as part of the experimental protocol.

Patients were randomly divided into two groups depending on the root canal irrigation protocol used:

– Group 1 (control group) – root canal irrigation was performed using the standard irrigation protocol (3% sodium hypochlorite solution without heating or sonic/ultrasonic activation; total exposure time in the root canal not less than 30 minutes; distilled water; 17% EDTA solution with an exposure time of at least 2 minutes) – 47 patients.

– Group 2 (experimental group) – root canal irrigation was performed using a 0.2% polyhexanide-based antiseptic solution without heating or sonic/ultrasonic activation; exposure time in the root canal not less than 2 minutes; 17% EDTA solution with an exposure time of at least 2 minutes – 49 patients.

The distribution of patients with chronic apical periodontitis by sex and age is presented in Table 1.

The data presented above indicate that the distribution of patients by age and sex in both groups was statistically comparable.

It was essential to define the inclusion, non-inclusion, and exclusion criteria for patient enrollment in the study. The inclusion criteria were as follows:

– age older than 18 years and younger than 65 years;

– signed informed consent and voluntary agreement of the patient to participate in the study;

– diagnosed chronic apical periodontitis (without acute exacerbation);

– first-time endodontic treatment of the studied tooth;

– no history of antibiotic therapy within the last 3 months.

The non-inclusion criteria were:

– age younger than 18 years or older than 65 years;

– diagnosed exacerbation of chronic apical periodontitis;

– previously performed endodontic treatment of the studied tooth;

– vertical furcation fractures;

– tooth root cracks;

– tooth mobility grade III;

– bone resorption exceeding ½ of the root length;

– root perforations and resorptions;

– pregnant women at any gestational stage;

– history of severe allergic reactions;

– malignant neoplasms of various organs and systems;

– acute cardiac dysfunction;

– tuberculosis and its complications, HIV infection, viral hepatitis, syphilis;

– bronchial asthma, bronchiectasis;

– other severe systemic diseases in a decompensated state;

– hypersensitivity to the test irrigant;

– use of antibiotics for any reason within the past 3 months.

Exclusion criteria for withdrawal from the study included:

– voluntary withdrawal of the patient from the study at any stage;

– detection of antimicrobial drug use for any reason at the time of microbiological sampling or within the previous 3 months;

– confirmation of pregnancy;

– patient non-compliance with the study protocol;

– detection of decompensated systemic diseases in the patient.

All patients included in the study were fully informed about the study procedures, provided with a patient information sheet, and signed the approved informed consent form. It should also be noted that all patients received first-time endodontic treatment of the studied teeth.

To diagnose chronic apical periodontitis and determine indications for endodontic treatment, primary and auxiliary dental examination methods were performed. The primary methods included patient interview, clinical examination, palpation, percussion, probing of the hard tooth tissues, and others. The auxiliary methods included radiographic examination (intraoral periapical radiography, orthopantomography, cone-beam computed tomography), electric pulp testing, and thermal testing.

During the interview, patient complaints and medical history were recorded, including the onset, severity, and duration of symptoms, disease progression, presence or absence of self-administered measures to relieve symptoms, history of exacerbations or remissions, and general medical history (systemic diseases, allergy history, living conditions, dietary habits, oral hygiene practices, and oral hygiene products used).

Table 1. Distribution of patients with chronic apical periodontitis in the Group 1 and Group 2 by sex and age

Таблица 1. Распределение больных с хроническим периодонтитом в группах 1 и 2 по полу и возрасту

Number group	Diagnostic classification									
	Absolute number	Age 18–44			Age 45–59			Age 60–65		
1	47	23	M	F	14	M	F	10	M	F
		Number, 48.94%	58%	42%	Number, 29.79%	58%	42%	Number, 21.28%	58%	42%
	48,96%	23	13.3	9.7	14	8.1	5.9	10	5.8	4.2
2	49	25	M	F	15	M	F	9	M	F
		Number, 51,02%	58%	42%	Number, 30.61%	58%	42%	Number, 18.37%	58%	42%
	51,04%	25	14.5	10.5	15	8.7	6.3	9	5.22	3.78

The clinical examination involved extraoral and intraoral assessments. Extraoral evaluation focused on the symmetry and contour of the face, skin and mucosal coloration, sclera of the eyes, and the presence of any primary or secondary lesions of the skin and lips.

Palpation assessed the condition of the soft tissues of the maxillofacial region (if asymmetry was present), regional lymph nodes (submandibular and submental on both sides), and the temporomandibular joint.

Intraoral examination evaluated the condition of the free and attached gingiva, the depth of the vestibule, the presence or absence of vasoparesis symptoms around the affected tooth, frenulum attachments of the upper and lower lips, mucosal bands, and the condition of the oral mucosa including color, moisture, and the presence of any lesions. The orifices of the major salivary glands were examined, as well as the tongue and its frenulum. The number, color, size, and alignment of teeth were assessed, along with the presence or absence of carious and non-carious lesions, unmineralized and mineralized dental plaque and calculus.

Probing of the hard dental tissues was performed to detect carious lesions and evaluate the integrity of direct and indirect restorations. Vertical percussion, palpation of the vestibule, and assessment of tooth mobility were also conducted.

Auxiliary diagnostic methods used in this study included radiographic examination and electric pulp testing.

Radiographic examination included obtaining intraoral periapical radiographs (Schick CDR computer dental radiography system, Schick Technologies Inc., USA), orthopantomograms (ORTHOPHOS XG panoramic X-ray system, Sirona Dental Systems GmbH, Germany), and, in some cases, cone-beam computed tomography (CBCT) scans (NewTom 3G dental diagnostic X-ray system, NIM S.r.l., Italy).

Radiographic evaluation was used to identify the presence of periapical bone lesions, which was necessary to confirm the diagnosis of **K04.5 Chronic apical periodontitis**, assess the anatomical features of the root canal systems of the treated teeth, evaluate the quality of root canal obturation, and monitor the healing of bone lesions at 6- and 12-months post-treatment.

Pulp vitality was assessed using electric pulp testing with the "Estus Pulp" device (Geosoft, Russia).

The standardized initial endodontic treatment protocol for all patient groups is described below.

Topical anesthesia (20% benzocaine gel-paste "DiSi-Lan", Estaide-Servicegroup, Russia) and infiltration or nerve block anesthesia ("Ultracain D-S forte": 40 mg articaine hydrochloride + 10 mcg epinephrine/1 ml, 1.7 ml cartridges) were administered depending on tooth location. Dental plaque was removed using fluoride-free prophylactic paste ("CLEANIC", Kerr, USA) and a circular brush. The working field was isolated with a rubber dam (Blossom latex sheets, 0.18 mm, Blossom, USA). Carious cavities were disinfected with a 0.05% aqueous solution of chlorhexidine bigluconate. Cavity and defective restoration preparation was performed with turbine and/or mechanical handpieces and diamond or carbide burs of various shapes, followed by straight-line endodontic access preparation.

A glide path was established using stainless steel K-files (MANI, Japan) ISO sizes 06–20, taper 0.02 (21, 25, 28, 31 mm depending on canal length). Working length was determined using an apex locator (Ipex-Locator, Nakanishi Inc., Japan). Canal shaping was performed with RaCe rotary nickel-titanium instruments (FKG Dentaire Swiss Dental Products, Switzerland) using the following sequence: 25.06 for the coronal/middle third, 25.04 to full working length, 25.06 to full working length, and 30.04 to full working length.

Root canal irrigation protocols differed between the two groups. All irrigants were delivered under low pressure using endodontic syringes (Omega-Dent, Russia); the needle tip was positioned 2–5 mm short of the working length and controlled by a rubber stop. Irrigation was performed after each instrumentation step.

In Group 1 (control), irrigation was performed with "Belodez" (3% sodium hypochlorite, VladMiVa, Russia) without heating or sonic/ultrasonic activation for at least 30 minutes, followed by rinsing with distilled water and 17% EDTA solution ("MD Cleanser", Meta, South Korea) with an exposure time of at least 2 minutes.

In Group 2 (experimental), irrigation was performed with 0.2% polyhexanide-based antiseptic solution ("Lavasept", B. Braun Melsungen AG, Switzerland) without heating or sonic/ultrasonic activation for at least 2 minutes, followed by 17% EDTA solution ("MD Cleanser", Meta, South Korea) for at least 2 minutes.

After mechanical and chemical preparation, the root canals were dried with paper points (Dispodent, USA) and obturated using the lateral condensation technique with spreaders of various sizes (MANI, Japan), positioned 2 mm short of the working length, gutta-percha points (Dispodent, USA), and epoxy resin-based sealer (AH Plus, DENTSPLY SIRONA Inc., Charlotte, USA). Restoration of the tooth crown was performed as indicated using either direct or indirect methods.

The success of endodontic treatment in both groups was evaluated at 6 and 12 months based on clinical symptoms and radiographic findings.

Data analysis was performed using IBM SPSS Statistics software, applying both parametric and non-parametric tests depending on data distribution. Intergroup comparisons of quantitative variables were performed using the Mann–Whitney U test, and differences in frequency distributions were assessed using Pearson's χ^2 test. A p-value < 0.05 was considered statistically significant. For multiple comparisons, Bonferroni correction was applied. Median values, interquartile ranges (IQR), and 95% confidence intervals were reported where appropriate.

Clinical Case

A 43-year-old male patient presented to the dental clinic with complaints of a carious lesion and a significant fracture of the coronal part of tooth 2.4 (Figure 1).

Examination findings

A deep carious cavity with fractured tooth walls was observed, caused by thinning from carious progression. The cavity communicated with the pulp chamber.

Both superficial probing (of the cavity floor and walls) and deep probing (in the area of root canal orifices) were painless. Percussion was negative. Palpation of the mucosa in the vestibular fold in projection of the apices of tooth 2.4 was painless. The mucosa over the apices of tooth 2.4 was pink and moderately moist. The vasoparesis test was negative. Thermal sensitivity test was negative.

An intraoral periapical radiograph showed a deep carious lesion communicating with the pulp chamber, and an area of bone rarefaction with ill-defined irregular borders in the periapical area of tooth 2.4. Electric pulp testing (EPT) value was 126 μA.

Diagnosis

Tooth 2.4 – **K04.5 Chronic apical periodontitis**. Chronic granulomatous periodontitis (*Periodontitis chronica granulans*).

Treatment method

Endodontic treatment of tooth 2.4 was performed. In this case, the experimental protocol for root canal disinfection was selected, using a 0.2% polyhexanide-based antiseptic solution without heating or sonic/ultrasonic activation.

According to the data presented above, the use of a 0.2% polyhexanide solution as an antibacterial irrigant may positively influence the prognosis of endodontic treatment and the degree of healing of periapical bone destruction lesions, while reducing the risk of secondary endodontic infection. Improved tooth survival following root canal treatment, as well as the potential to use these teeth as abutments for prosthetic restorations, undoubtedly enhances the patients' quality of life.

RESULTS

Based on the results of clinical examination using primary and additional dental diagnostic methods, it was found that in the majority of cases, patients diagnosed with chronic forms of apical periodontitis were asymptomatic, with the condition identified incidentally on radiographs (79.2%) during visits to the clinic for oral cavity sanitation, professional oral hygiene, or for other reasons unrelated to chronic apical periodontitis (Fig. 2).

However, it should be noted that some patients reported discomfort or a sense of unease in the tooth when biting hard food or clenching their teeth (20.8%), as well as discoloration of the tooth crown. The latter was particularly common in female patients with periodontal pathology in the anterior tooth region (12.5%).

According to probing data, in the majority of patients without a history of any previous dental intervention on the affected tooth (81.25% of patients), a deep carious lesion filled with softened dentin and communicating with the pulp chamber was detected. Both superficial probing (of the cavity floor and walls) and deep probing (in the area of the root canal orifice/orifices) were painless in all cases (100%).

In cases where the tooth had previously been restored due to caries (18.75% of patients), intraoral examination typically revealed a restoration with marginal discoloration and/or defective adaptation, which had led to further progression of the pathological process and the development of carious complications.

Percussion was painless in most cases (79.2%). However, in 20.8% of cases, patients reported discomfort on comparative percussion, which correlated with complaints of discomfort when biting hard food.

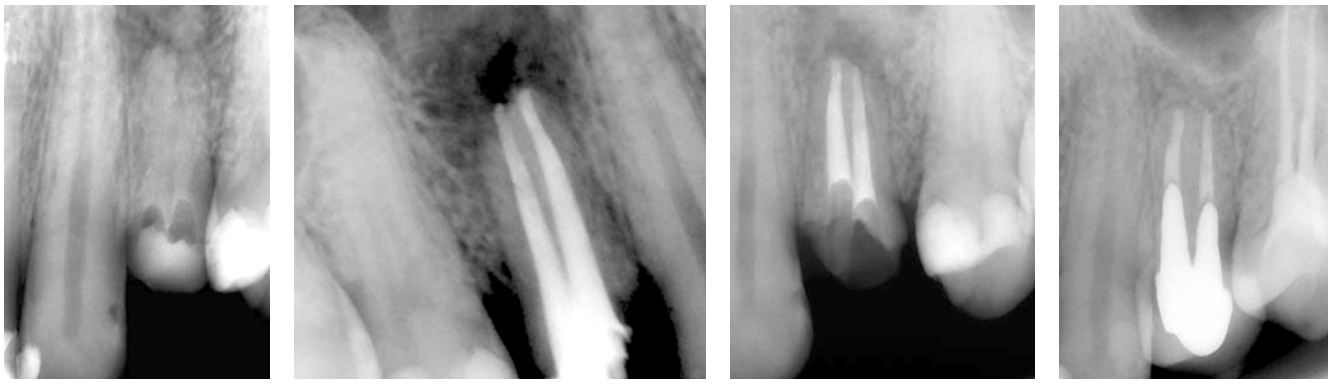

Fig. 1. Periapical radiograph of tooth 2.4: *A* – an area of bone rarefaction with ill-defined, irregular borders is noted in the periapical region of tooth; *B* – the root filling is homogeneous, with no extrusion of filling material beyond the apices of tooth; *C* – six months after endodontic treatment (interim follow-up), the radiograph clearly shows a reduction in the periapical bone destruction lesion, the tooth is being prepared for prosthetic restoration; *D* – twelve months after endodontic treatment (follow-up examination), the radiograph shows complete healing of the periapical bone destruction lesion, full prosthetic rehabilitation of tooth has been completed

Рис. 1. Прицельная рентгенограмма зуба 2.4: *A* – отмечается очаг разрежения костной ткани с нечеткими неровными контурами в периапикальной области зуба; *B* – после обтурации корневых каналов, корневая пломба гомогенна, без выведения пломбировочного материала за верхушки корней зуба; *C* – спустя 6 месяцев после эндодонтического лечения (промежуточный контроль), визуализируется уменьшение периапикального очага деструкции костной ткани, подготовка зуба к протезированию; *D* – спустя 12 месяцев после эндодонтического лечения (контрольный осмотр), отмечается полное заживление периапикального очага деструкции костной ткани, произведена полная ортопедическая реабилитация зуб

Examination of the mucosa over the apices of the affected root showed no significant changes (the mucosa was pink and moderately moist) in all cases (100%). Palpation of the mucosa in the same area was also painless in all patients (100%).

Thermal testing was negative in all patients (100%), with no response to cold or heat stimuli. Additionally, electric pulp testing values exceeded 100 μA in all cases (100%), confirming pulp necrosis and the absence of sensory activity in the tooth's neurovascular bundle (Fig. 3).

In Group 1, standard endodontic irrigants were used: "Belodez" (3% sodium hypochlorite solution, VladMiVa, Russia) without any activation, and "MD Cleanser" (17% EDTA solution, Meta, South Korea).

In Group 2, a novel irrigant was used in the form of a 0.2% polyhexanide-based antiseptic solution ("Lavasept", B. Braun Melsungen AG, Switzerland) without any activation, followed by "MD Cleanser" (17% EDTA solution, Meta, South Korea).

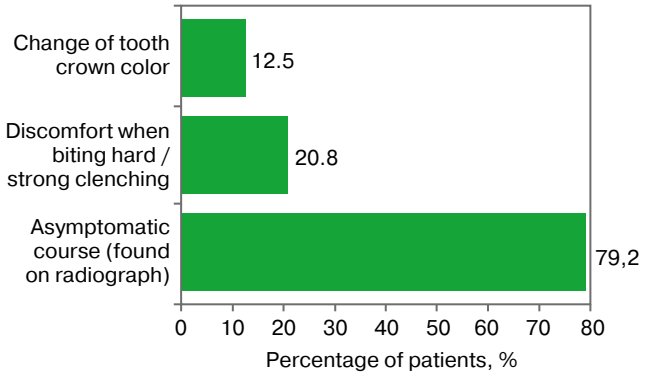

Fig. 2. Frequency of reasons for patient visits to the clinic with chronic apical periodontitis

Рис. 2. Частота причин обращения пациентов с хроническим верхушечным периодонтитом в клинику

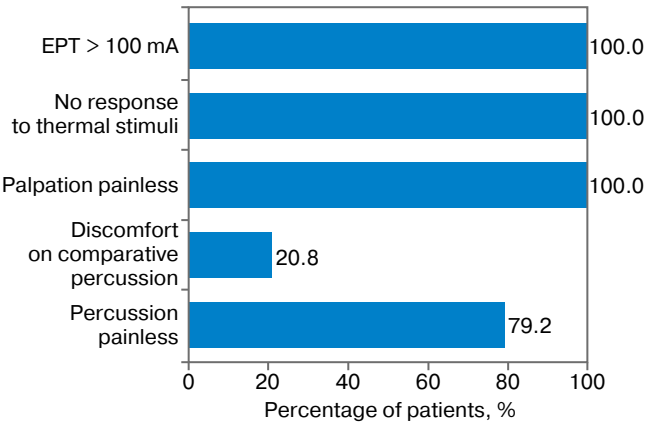

Fig. 3. Local status of teeth affected by chronic apical periodontitis

Рис. 3. Status localis причинных зубов с хроническим верхушечным периодонтитом

Post-obturation periapical radiographs, taken after permanent root canal obturation using the lateral condensation technique with gutta-percha, confirmed the presence of a homogeneous root filling with no extrusion of filling material beyond the apical foramen.

All patients who underwent endodontic treatment within the framework of this study attended both the interim follow-up (at 6 months) and the final control examination (at 12 months).

Treatment was considered successful if, at the time of the control examination, there were no clinical symptoms and radiographic evidence showed a reduction of pathological changes in the periapical bone. Treatment was considered unsuccessful if clinical symptoms or exacerbation of periodontal disease were present at the control examination or during the 12-month observation period, or if there was no evidence of healing or an increase in the size of the periapical bone destruction lesion.

The clinical and radiographic evaluation yielded the following data:

At the 6-month follow-up, in Group 1, 3 patients (6.4%) reported discomfort or a sense of unease in the tooth when biting. Six patients (12.8%) reported moderate or mild post-obturation pain lasting up to 2 weeks after endodontic treatment, which resolved with the use of non-steroidal anti-inflammatory drugs. Radiographically, the same 3 patients (6.4%) with persistent symptoms showed no evidence of periapical bone healing.

In Group 2 at the 6-month follow-up, no patients exhibited adverse clinical symptoms. Five patients (10.2%) reported moderate or mild post-obturation pain lasting up to 2 weeks after endodontic treatment, which resolved with non-steroidal anti-inflammatory drugs. One patient (2%) showed no evidence of periapical bone healing on radiographs.

Based on the data from clinical and additional examinations, a comparison of Groups 1 and 2 at the 6-month interval after endodontic treatment revealed no statistically significant differences in the incidence of biting discomfort ($p \approx 0.7$; $p > 0.05$), post-obturation pain ($p \approx 0.4$; $p > 0.05$), or lack of radiographic evidence of periapical healing ($p \approx 0.2$; $p > 0.05$), regardless of the irrigation protocol used.

At the 12-month control examination of Group 1 patients, no clinical symptoms were detected. However, 3 patients (6.4%) showed no radiographic evidence of periapical bone healing.

At the 12-month control examination of Group 2 patients, no clinical symptoms were detected, and only 1 patient (2%) showed no radiographic evidence of periapical bone healing.

Based on the data obtained from primary and additional examination methods, the comparison of Groups 1 and 2 at the 12-month interval after endodontic treatment showed no statistically significant differences in the lack of periapical healing as determined by radiographic findings ($p \approx 0.2$; $p > 0.05$), regardless of the irrigation protocol used.

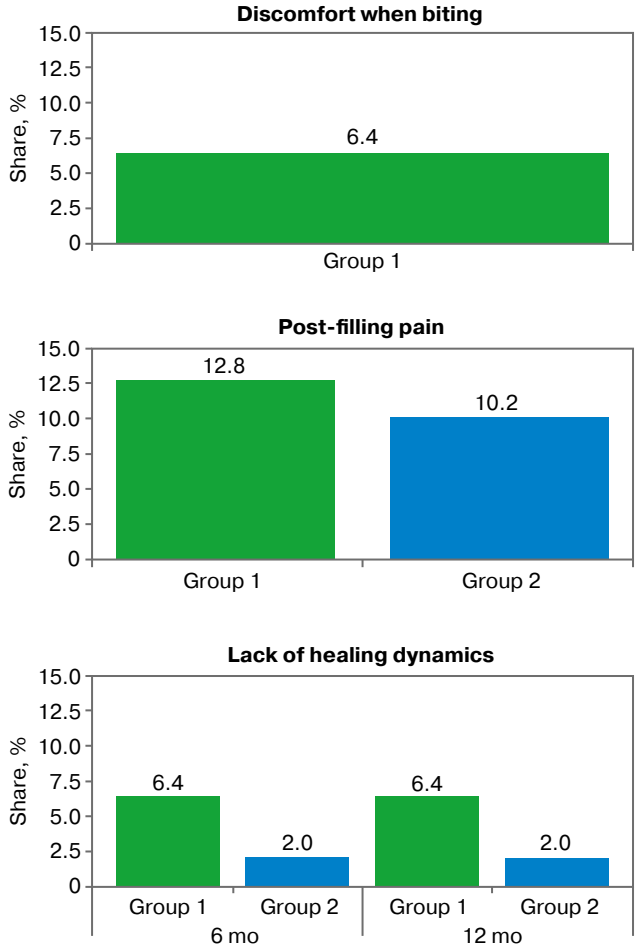

Fig. 4. Aggregated data of clinical and radiographic findings in the affected tooth after endodontic treatment

Рис. 4. Агрегированные данные клинических и рентгенологических проявлений в причинном зубе после эндодонтического лечения

The data presented above indicate that the success or complications of chronic apical periodontitis treatment can be assessed as early as 6 and 12 months after endodontic therapy (Fig. 4).

The frequency of post-obturation pain (tooth discomfort or pain on mastication shortly after root canal obturation), according to patient reports in both groups, does not appear to be a specific variable dependent on the irrigation method used. The number of patients reporting such complaints was relatively comparable in both groups. The presence of transient post-obturation pain is not considered a failure of endodontic treatment.

In 6.4% of patients in the control group, there was no reduction in the size of the periapical lesion, indicating persistent infection within the filled root canal system and leakage of toxins and antigens into the periapical area. The radiographic findings remained unchanged after one year. The treatment success rate in this group was 93.6%.

In the experimental group, 1 patient (2%) showed no evidence of periapical bone healing; however, no clinical symptoms were present, and the radiographic findings remained stable after one year. The treatment success rate in this group was 98%.

The overall success rates of endodontic treatment were comparable between the groups. In the experimental group, clinically and radiographically confirmed success was 98%, compared to 93.6% in the control group. Despite a higher proportion of favorable outcomes in the experimental group, statistical analysis using Fisher's exact test revealed no significant difference between the groups ($p = 0.617$).

DISCUSSION

In this study, the effectiveness of a 0.2% polyhexanide solution as an irrigant in the treatment of chronic apical periodontitis was evaluated and compared with the traditional protocol based on sodium hypochlorite and EDTA. The results suggest that the use of polyhexanide promotes a high success rate of endodontic treatment, providing clinical and radiographic outcomes comparable to the traditional approach. A trend toward a higher success rate (98%) was observed with polyhexanide use, although the difference was not statistically significant ($p = 0.617$).

Similar results regarding the effectiveness of polyhexanide were reported by Kulikova et al. [9], who also found that polyhexanide exhibits lower cytotoxicity and less detrimental effects on dentin microhardness compared to traditionally used irrigants.

The null hypotheses–that the use of 0.2% polyhexanide solution does not influence clinical effectiveness or the dynamics of radiographic healing–were partially rejected. Despite the lack of statistically significant differences, the observed trends indicate potential advantages of polyhexanide over sodium hypochlorite, particularly in the long-term healing of periapical tissues.

These findings are supported by the recent review by Hashim et al. [10], in which the authors highlighted the high biocidal activity and low toxicity of polyhexanide, making it a promising antiseptic agent for endodontic use.

It is noteworthy that in the control group treated with a 3% sodium hypochlorite solution, 6.4% of patients exhibited persistent radiographic evidence of periapical lesions, in line with the findings of Teughels et al. [11], which emphasize the limited efficacy of sodium hypochlorite against resistant biofilms.

The use of polyhexanide was also associated with a lower incidence of transient post-obturation pain (10.2% in the experimental group vs. 12.8% in the control group), suggesting a less irritating effect of this antiseptic. Similar observations were previously reported by Kalhan et al. [12], who stressed the importance of minimizing tissue inflammatory response when selecting an irrigant.

However, our study has limitations, including a limited sample size and a relatively short follow-up period (12 months). Large-scale randomized studies with extended follow-up periods are needed to confirm these findings and further assess the long-term efficacy of polyhexanide.

The introduction of polyhexanide into clinical practice may contribute to improving the overall success of chronic apical periodontitis treatment, reducing the frequency of secondary infections, and enhancing patient quality of life, as supported by the study of Nannan et al. [13].

The results of this study regarding the potential of polyhexanide are fully consistent with current trends in endodontic therapy focused on selecting antiseptics that are both effective and minimally aggressive. Nevertheless, the individual clinical characteristics of each patient should be taken into account when selecting an irrigation solution.

In conclusion, the findings of this study provide sufficient evidence to recommend the use of a 0.2% polyhexanide solution as an alternative irrigant in endodontic practice. The potential benefits of its use are supported by both the data from this investigation and current literature [14].

CONCLUSION

The use of a 0.2% polyhexanide solution in the treatment of chronic apical periodontitis provides clinical and radiographic effectiveness comparable to the traditional protocol involving 3% sodium hypochlorite and EDTA. Polyhexanide use is associated with a slight reduction in clinical symptoms compared to the traditional protocol. Although the radiographic healing dynamics of periapical lesions did not differ significantly between the polyhexanide and control groups, a trend toward more favorable outcomes was observed with polyhexanide. Therefore, a 0.2% polyhexanide solution can be recommended as an alternative irrigant in clinical practice, particularly when minimizing adverse periapical tissue reactions is a priority.

This study highlights the need for further investigation of polyhexanide, including additional clinical trials with larger sample sizes and longer follow-up periods.

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INFORMATION ABOUT THE AUTHORS

Yulia A. Generalova – Assistant, Department of Therapeutic Dentistry, Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), 6 Miklukho-Maklaya Str., Moscow 117198, Russian Federation; https://orcid.org/0000-0003-1926-7162

Adam Yu. Umarov – Resident, Dentist, Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), 6 Miklukho-Maklaya Str., Moscow 117198, Russian Federation; https://orcid.org/0009-0005-6327-4492

Ahmad Wehbe – Assistant, Department of Dentistry, Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), 6 Miklukho-Maklaya Str., Moscow 117198, Russian Federation; https://orcid.org/0009-0009-5325-3793

Marina Yu. Dashtieva – Assistant Department of Dentistry, Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), 6 Miklukho-Maklaya Str., Moscow 117198, Russian Federation; https://orcid.org/0000-0001-8903-2487

Inna V. Bagdasarova – Associate Professor, Peoples' Friendship University of Russia named after Patrice Lumumba (RUDN University), 6 Miklukho-Maklaya Str., Moscow 117198, Russian Federation; https://orcid.org/0000-0002-2348-4939

ИНФОРМАЦИЯ ОБ АВТОРАХ

Генералова Юлия Алексеевна – ассистент кафедры терапевтической стоматологии, ФГАОУ ВО «Российский университет дружбы народов им. Патриса Лумумбы», 117198, Российская Федерация, г. Москва, ул. Миклухо-Маклая, д. 6; https://orcid.org/0000-0003-1926-7162

Умаров Адам Юнусович – ординатор, стоматолог, ФГАОУ ВО «Российский университет дружбы народов им. Патриса Лумумбы», 117198, Российская Федерация, г. Москва, ул. Миклухо-Маклая, д. 6; https://orcid.org/0009-0005-6327-4492

Вехби Ахмад – ассистент, ФГАОУ ВО «Российский университет дружбы народов им. Патриса Лумумбы», 117198, Российская Федерация, г. Москва, ул. Миклухо-Маклая, д. 6; https://orcid.org/0009-0009-5325-3793

Даштиева Марина Юзбеговна – ассистент кафедры стоматологии, ФГАОУ ВО «Российский университет дружбы народов им. Патриса Лумумбы», 117198, Российская Федерация, г. Москва, ул. Миклухо-Маклая, д. 6; https://orcid.org/0000-0001-8903-2487

Багдасарова Инна Владимировна – доцент, ФГАОУ ВО «Российский университет дружбы народов им. Патриса Лумумбы», 117198, Российская Федерация, г. Москва, ул. Миклухо-Маклая, д. 6; https://orcid.org/0000-0002-2348-4939

AUTHOR'S CONTRIBUTION

All the authors made equal contributions to the publication preparation in terms of the idea and design of the article; data collection; critical revision of the article in terms of significant intellectual content and final approval of the version of the article for publication.

ВКЛАД АВТОРОВ

Все авторы внесли равноценный вклад в подготовку публикации в части замысла и дизайна исследования; сбора данных; критического пересмотра статьи в части значимого интеллектуального содержания и окончательного одобрения варианта статьи для опубликования.