



Evaluation of the effectiveness of a modified method for treating chronic pulpitis of evidence-based medicine

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Abstract

AIM. The aim of the study was to evaluate the effectiveness of the modified method of treating chronic pulpitis taking into account unfavorable outcomes from the standpoint of evidence-based medicine.

MATERIALS AND METHODS. Were examined 126 patients aged 20 to 60 years with a confirmed diagnosis of chronic fibrous pulpitis (K04.03) using evidence-based medicine criteria (ARR, RRR, NNT, OR) to evaluate the effectiveness of treating chronic pulpitis using a modified method developed by the authors in comparison with the standard treatment method. These were calculated based on outcome indicators: the primary endpoint was tooth extraction, the secondary endpoint was retreatment of endodontic therapy, and the surrogate endpoint was the presence of radiographic changes in the absence of clinical signs. Post-hoc comparisons were performed using the Pearson χ^2 test with Holm's correction. Differences were considered statistically significant at $p < 0.05$.

RESULTS. With the modified treatment method, no cases of tooth extraction were detected ($\chi^2 = 5.87$, $df = 1$, $p = 0.015$), the absolute risk reduction (ARR) was 4.9%, and the number of teeth that need to be treated to prevent 1 tooth extraction – NNT = 20. A shift from 1 OR value to the left determines a significant positive dynamic of the risk of tooth extraction in the modified treatment group. The results of the comparison for the secondary endpoint showed that the percentage of complications with the modified treatment method is three times lower than with the standard one: 2.5% versus 7.3%, respectively ($\chi^2 = 2.56$, $df = 1$, $p = 0.109$). The difference in the frequency of this complication (ARR) is 4.8%, and the number of teeth that need to be treated to prevent 1 repeated endodontic treatment is 21 cases (NNT = 20). A leftward shift of the OR value from 1 indicates a moderate decrease in the risk of endodontic retreatment in the study group. A surrogate assessment revealed that the percentage of radiographic changes observed with the new treatment method was in three times lower than with standard treatment: 1.7% versus 4.9%, respectively ($\chi^2 = 1.69$, $df = 1$, $p = 0.194$). The difference in these proportions (ARR) was 3.2%, and the number of teeth needed to treat to prevent one case of radiographic changes (NNT) was 31. A leftward shift of the OR value from 1 indicates that has been identified a tendency to decrease risk of occurrence the radiographic changes in the study group.

CONCLUSIONS. The obtained data indicate the clinical prospects of the modified treatment method and need for further research with an expanded sample.

Keywords: pulpitis, treatment, endodontics, evidence-based medicine

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Оценка эффективности модифицированного метода лечения хронического пульпита с позиции доказательной медицины

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Резюме

ЦЕЛЬ. Оценить эффективность предложенного авторами модифицированного метода лечения хронического пульпита с учетом неблагоприятных исходов с позиции доказательной медицины.

МАТЕРИАЛЫ И МЕТОДЫ. Для оценки эффективности лечения хронического пульпита разработанным авторами модифицированным способом в сравнении со стандартным методом лечения обследовано 126 пациентов в возрасте от 20 до 60 лет с подтвержденным диагнозом «хронический пульпит» (K04.03) с применением критериев доказательной медицины (CAP, COP, ЧЗНЛ, ОШ), которые рассчитывались по показателям исходов: первичная конечная точка – удаление зуба, вторичная конечная

точка – повторное эндодонтическое лечение, суррогатная – наличие рентгенологических изменений при отсутствии клинических признаков. Апостериорные сравнения выполнялись с помощью критерия χ^2 -Пирсона с поправкой Холма. Различия считались статистически значимыми при $p < 0,05$.

РЕЗУЛЬТАТЫ. При модифицированном способе лечения не выявлено ни одного случая удаления зуба ($\chi^2 = 5,87$, $df = 1$, $p = 0,015$), снижение абсолютного риска (САР) – 4,9%, а число зубов, которых необходимо пролечить, чтобы предотвратить 1 удаление зуба – ЧЗНЛ = 20. Смещение от 1 значения ОШ влево определяет существенную положительную динамику риска удаления зуба в группе модифицированного способа лечения. Результаты сравнения по вторичной конечной точке показали, что процент осложнений при модифицированном способе лечения в три раза меньше, чем при стандартном: 2,5% против 7,3%, соответственно ($\chi^2 = 2,56$, $df = 1$, $p = 0,109$). Разница частоты этого осложнения (САР) составляет 4,8%, а число зубов, которых необходимо пролечить, чтобы предотвратить 1 повторное эндодонтическое лечение составляет 21 случай (ЧЗНЛ = 20). Смещение значения ОШ от 1 влево означает среднюю динамику снижения риска повторного эндодонтического лечения в основной группе. При проведении оценки по суррогатной точке выявлено, что процент наличия рентгенологических изменений при применении нового способа лечения в три раза меньше, чем при стандартном лечении: 1,7% против 4,9%, соответственно ($\chi^2 = 1,69$, $df = 1$, $p = 0,194$). Разница этих долей (САР) составляет 3,2%, а число зубов, которых необходимо пролечить, чтобы предотвратить 1 случай рентгенологических изменений ЧЗНЛ = 31. Смещение от 1 значения ОШ влево означает, что выявлена тенденция к снижению риска возникновения рентгенологических изменений в основной группе.

ВЫВОДЫ. Полученные данные свидетельствуют о клинической перспективности модифицированного метода лечения и необходимости дальнейших исследований с расширением выборки.

Ключевые слова: пульпит, лечение, эндодонтия, доказательная медицина

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INTRODUCTION

According to current scientific evidence, the search for rational approaches to the treatment of complicated forms of dental caries remains a priority in modern dentistry; however, the rate of unfavorable outcomes continues to be considerable [1; 2]. Inadequate management of this pathology, particularly chronic pulpitis, frequently results in the need for retreatment, which is technically more complex and financially demanding, or in premature tooth extraction [3; 4].

According to the clinical guidelines for the diagnosis “Diseases of the dental pulp” published by the Russian Dental Association on August 2, 2018, delayed treatment of pulpitis leads to the progression of pathological processes in the periodontium and, consequently, to tooth loss. This, in turn, contributes to the development of secondary dental arch deformities and temporomandibular joint disorders. Pulp diseases have a direct impact on patients’ overall health status and quality of life [5].

It has previously been reported that the challenges in treating chronic pulpitis are associated both with the variability of root canal anatomy and with limitations at different stages of treatment, including a restricted ability to achieve adequate endodontic access, insufficient mechanical cleaning and disinfection of root canals, and inadequate obturation with filling materials [6]. According to Poleshchuk et al., the complex anatomy and topographical variability of the root canal system significantly restrict treatment predictability, even in the hands of experienced clinicians [7]. Moiseev et al. emphasize that insufficient access cavity preparation and limited visibility of the pulp chamber complicate endodontic instrumentation and increase the risk of instrument fracture [8].

Arora et al. concluded that violations of instrumentation protocols and inadequate irrigation lead to apical extrusion of infected debris, particularly when using rotary instruments, thereby initiating or exacerbating inflammatory processes [9]. In a retrospective study by Adamchik et al. evaluating endodontic treatment quality, it was demonstrated that complications are most frequently associated with incomplete root canal obturation [10].

Thus, it is essential for practicing clinicians to ensure strict adherence to endodontic treatment protocols in order to reduce the risk of complications and preserve patient oral health, given that pulp diseases have a direct impact on both general health status and quality of life [11]. However, data from the specialized literature indicate a relatively low effectiveness of conventional endodontic approaches in the treatment of pulpitis, with reported post-treatment complication rates ranging from 32% to 50% [12]. The above findings highlight the relevance of developing a modified treatment approach for complicated forms of dental caries.

AIM

The aim of the study was to evaluate the effectiveness of the authors’ proposed modified method for the treatment of chronic pulpitis, taking into account unfavorable outcomes from the perspective of evidence-based medicine.

MATERIALS AND METHODS

The effectiveness of the treatment of chronic pulpitis using the authors’ modified technique, in comparison with the standard treatment method, was assessed according to evidence-based medicine pa-

rameters, specifically negative outcomes (primary and surrogate endpoints). A total of 126 patients aged 20 to 60 years with a confirmed diagnosis of chronic pulpitis (K04.03) were examined and randomly allocated using the sealed envelope method into two groups: Group I – 42 patients ($n = 82$ teeth), treated using the standard method; Group II – 84 patients ($n = 118$ teeth), treated using the modified approach.

No statistically significant differences were found between the groups in terms of age, sex, or number of root canals ($p > 0.05$); therefore, the groups were considered representative and comparable.

Inclusion criteria comprised: age between 20 and 60 years, absence of concomitant systemic pathology, confirmed diagnosis of chronic pulpitis (K04.03), and signed informed consent for participation. Exclusion criteria included: other forms of endodontic pathology, tooth extraction for prosthodontic indications, internal or external root resorption, teeth with incomplete root formation, presence of severe systemic disease, and patient refusal to participate in the study.

The standard treatment protocol applied in Group I ($n = 82$ teeth) included local anesthesia, isolation of the operative field using a rubber dam, carious lesion removal and endodontic access cavity preparation, initial canal negotiation and glide path creation, working length determination using a digital apex locator, mechanical preparation of root canals using a rotary Pro-Taper Universal system (Dentsply Sirona), and irrigation with 3% sodium hypochlorite solution. Final irrigation for smear layer removal was performed using 17% EDTA solution. Root canals were dried with paper points and obturated using the vertical condensation technique with thermoplastic gutta-percha and an epoxy resin-based sealer, followed by radiographic control and post-endodontic restoration of the tooth.

Treatment of patients in Group II ($n = 118$) was performed using the authors' modified protocol (Russian Patent No. 2771916, dated 13.05.2022), which included the combined use of ultrasound and a diode laser applied at each irrigation stage to activate antiseptic solutions.

Low-frequency ultrasound (VDW Ultra, VDW, Germany) was used with the following parameters: oscillation frequency of 28 kHz and exposure time of 30–60 seconds. The final stage of canal disinfection involved laser activation using a Doctor Smile Wiser diode laser (Italy) with a wavelength of 980 nm in a nanosecond pulsed mode, average output power of 1.2 W, and pulse duration of 200 ns, delivered via a 200 μ m optical fiber.

The application protocol was as follows: root canal irrigation with 3% sodium hypochlorite solution,

followed by insertion of the fiber tip 1 mm short of the working length. The insertion depth was standardized using a silicone stop. Laser activation was performed with reciprocating and rotational movements of the fiber tip in three cycles of 5 seconds, with a 100 ns interval between pulses. The canal was then dried using paper points and obturated using a custom-developed instrument (Russian utility model patent "Endodontic instrument for sealer delivery into the root canal", No. 208382 dated 16.12.2021), individually fabricated to match the canal size and taper for each patient. Root canal obturation was completed using vertical condensation of thermoplasticized gutta-percha with an epoxy resin-based sealer, followed by post-endodontic restoration.

When comparing the two treatment approaches using evidence-based medicine principles, the following outcomes were assessed: primary endpoint – tooth extraction; secondary endpoint – retreatment; surrogate endpoint – presence of radiographic changes in the absence of clinical symptoms. For each complication, a clinical question was formulated according to the PICO framework, and contingency tables were constructed.

Statistical analysis was performed using IBM SPSS Statistics v.24. Comparison of proportional data in multi-field contingency tables was conducted using Pearson's chi-square test (χ^2). Post hoc comparisons were performed using Pearson's chi-square test with Holm correction. Differences were considered statistically significant at $p < 0.05$. Evaluation of the effectiveness of the modified treatment compared with the standard protocol was performed by calculating evidence-based medicine indicators (absolute risk reduction, relative risk reduction, number needed to treat, and odds ratio) based on outcome measures, including primary, secondary, and surrogate endpoints.

RESULTS

The effectiveness of endodontic treatment of chronic pulpitis in patient groups managed using the standard method and the modified technique was evaluated based on the occurrence of adverse outcomes observed in the long-term follow-up period, 12 months after treatment. The frequency of complications (primary and secondary endpoints, as well as surrogate endpoints) in the study groups is presented in Table 1.

When comparing the modified and standard treatment methods for chronic fibrous pulpitis, a contingency table was constructed for both patient groups with respect to the primary endpoint – tooth extraction. The corresponding data are presented in Table 2.

Table 1. Complication rates in study groups (end and surrogate points)

Таблица 1. Частота осложнений в группах исследования (конечные и суррогатные точки)

Endpoints of evidence-based medicine	Primary and secondary endpoints		Surrogate endpoints
	Primary endpoint – tooth extraction	Secondary endpoint – endodontic retreatment	Presence of radiographic changes in the absence of clinical signs
Group I – Standard treatment method (42 patients, 82 teeth)	4 (4.9%)	6 (7.3%)	4 (4.9%)
Group II – Modified treatment method (84 patients, 118 teeth)	0 (0.0%)	3 (2.5%)	2 (1.7%)

Table 2. Efficacy of treatment of chronic pulpitis for the primary endpoint – tooth extraction

Таблица 2. Эффективность лечения хронического фиброзного пульпита по первичной конечной точке – удаление зуба

Treatment effectiveness indicators: primary endpoint – tooth extraction	Value
Incidence of the outcome in the modified treatment group (in units)	0 of 118
Incidence of the outcome in the standard treatment group (in units)	4 of 82
Complication rate in Group II (as a proportion)	0.00
Complication rate in Group I (as a proportion)	0.049
Absolute risk reduction (ARR) (as a proportion)	0.049
Relative risk reduction (RRR) (as a proportion)	1.000
Number needed to treat (NNT)	20
Odds ratio (OR)	0.000
Chi-square (χ^2)	5.87
Probability (p -value)	0.015

Table 3. Efficacy of treatment of chronic pulpitis according to the secondary endpoint – endodontic retreatment

Таблица 3. Эффективность лечения хронического фиброзного пульпита по вторичной конечной точке – проведение повторного эндодонтического лечения

Effectiveness indicators: secondary endpoint – endodontic retreatment	Value
Incidence of the outcome in the modified root canal treatment group (in units)	3 of 118
Incidence of the outcome in the standard treatment group (in units)	6 of 82
Complication rate in Group II (as a proportion)	0.025
Complication rate in Group I (as a proportion)	0.073
Absolute risk reduction (ARR) (as a proportion)	0.048
Relative risk reduction (RRR) (as a proportion)	0.653
Number needed to treat (NNT)	20
Odds ratio (OR)	0.330
Chi-square (χ^2)	2.56
Probability (p -value)	0.109

From Table 2 it follows that in the modified treatment group no cases of tooth extraction were observed (0%), whereas in the standard treatment group this outcome occurred in 4 out of 82 cases (4.9%) ($\chi^2 = 5.87$, $df = 1$, $p = 0.015$). The absolute risk reduction (ARR) was 4.9%, and the number needed to treat (NNT) to prevent one tooth extraction was 20. The odds ratio (OR) for the new treatment approach was 0.000. The deviation of the OR from unity towards zero indicates a significant reduction in the risk of tooth extraction in the modified treatment group.

The results of comparing the modified and standard treatment methods for chronic pulpitis with respect to the secondary endpoint – retreatment of endodontic therapy – are presented in Table 3.

Table 4. The effectiveness of treatment of chronic pulpitis based on the presence of radiographic changes

Таблица 4. Эффективность лечения хронического пульпита по показателю наличие рентгенологических изменений

Treatment effectiveness indicators: primary endpoint – tooth extraction	Value
Incidence of the outcome in the modified root canal treatment group (in units)	0 of 118
Incidence of the outcome in the standard treatment group (in units)	2 of 82
Complication rate in Group II (as a proportion)	0.017
Complication rate in Group I (as a proportion)	0.049
Absolute risk reduction (ARR) (as a proportion)	0.032
Relative risk reduction (RRR) (as a proportion)	0.653
Number needed to treat (NNT)	31
Odds ratio (OR)	0.336
Chi-square (χ^2)	1.69
Probability (p -value)	0.194

Table 3 shows that the complication rate in Group II was three times lower than in the standard treatment group: 2.5% versus 7.3%, respectively ($\chi^2 = 2.56$, $df = 1$, $p = 0.109$). The absolute risk reduction (ARR) for this outcome was 4.8%, and the number needed to treat (NNT) to prevent one case of endodontic retreatment was 21 (NNT = 20). The odds ratio (OR) for the use of the modified treatment was 0.330. The shift of the OR value away from unity towards the left indicates a moderate reduction in the risk of endodontic retreatment in the main group.

The surrogate endpoint – presence of radiographic changes in periapical tissues in the absence of clinical symptoms – was also evaluated. The treatment outcomes using the modified root canal therapy method compared with the standard approach are presented in Table 4.

From Table 4 it can be concluded that the incidence of radiographic changes in Group II was three times lower than in Group I under standard treatment: 1.7% versus 4.9%, respectively ($\chi^2 = 1.69$, $df = 1$, $p = 0.194$). The absence of statistically significant differences for the surrogate endpoint indicates that the proposed modified method may be considered a competitive treatment option relative to the standard approach.

The absolute risk reduction (ARR) for this outcome was 3.2%, and the number needed to treat (NNT) to prevent one case of radiographic changes was 31. The odds ratio (OR) for the modified treatment was 0.336. The shift of the OR away from unity towards the left indicates a trend toward a reduced risk of radiographic changes in the main group.

DISCUSSION

The results of the comparative analysis of adverse outcomes in the treatment of chronic fibrous pulpitis from the perspective of evidence-based medicine, based on the primary endpoint – endodontic retreatment – did not reveal statistically significant differences between the groups, thereby confirming the competitiveness of the proposed treatment method.

It should also be noted that comparison between patients treated with the modified technique and those treated using the standard protocol demonstrated statistically significant differences for the secondary endpoint ($\chi^2 = 20.5$, $p = 0.015$). In the modified treatment group (Group II), no cases of tooth extraction were recorded, whereas in the standard treatment group (Group I), tooth loss occurred in 4 out of 82 cases (4.9%).

The treatment effectiveness indicator – number needed to treat (NNT), representing the number of teeth that must be treated to prevent one extraction – was 20, and may serve as a reference parameter for future research.

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CONCLUSION

In the comparative effectiveness analysis of the novel modified root canal treatment method versus the standard treatment protocol, performed in accordance with evidence-based medicine principles, a statistically significant difference was identified ($\chi^2 = 5.87$, $df = 1$, $p = 0.015$).

In the modified treatment group, no cases of tooth extraction were recorded, whereas in the standard treatment group this outcome occurred in 4 out of 82 cases (4.9%). These findings indicate the clinical potential of the modified technique and underscore the need for further studies with an expanded sample size to confirm and validate the observed effects.

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