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СРАВНИТЕЛЬНАЯ КЛИНИКО-ЛАБОРАТОРНАЯ ОЦЕНКА ЭФФЕКТИВНОСТИ ВОССТАНОВИТЕЛЬНОЙ ТЕРАПИИ У БОЛЬНЫХ ОСТЕОАРТРИТОМ КОЛЕННЫХ СУСТАВОВ

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Comparative Clinical and Laboratory Assessment of the Effectiveness of Rehabilitation Therapy in Patients with Osteoarthritis of the Knee Joints

Резюме

Цель. Оценить эффективность курсового введения озоно-кислородной смеси в периартикулярные ткани коленного сустава у пациентов с остеоартритом, перенесших тотальное эндопротезирование одного из суставов и изучить влияние этой методики на состояние перекисного окисления липидов и антиоксидантной системы защиты организма относительно традиционных методов восстановительного лечения. **Материалы и методы.** В исследование включено 120 больных, с двусторонним гонартрозом, после эндопротезирования одного из коленных суставов. Средний возраст пациентов составил 60 [46; 76] лет. В зависимости от способа реабилитационного лечения пациенты были разделены на 3 равные группы (n=40): 1-й группе была назначена периартикулярная подкожная озонотерапия в сочетании с лечебной физкультурой, 2-й группе — магнитотерапия и электрофорез на область коленного сустава в комбинации с лечебной физкультурой, и 3-й группе — только комплекс лечебной физкультуры. У всех больных перед реабилитационным лечением и после него (через 14 дней и через 3 месяца) была произведена оценка клинико-функционального состояния с помощью шкалы Western Ontario and McMaster Universities Osteoarthritis Index и исследованы показатели интенсивности течения процессов свободнорадикального окисления и активности антиоксидантной защиты. **Результаты.** При детальном анализе клинико-функционального состояния среди больных 1-й группы относительно 2-й и 3-й был выявлен наилучший «отдаленный» результат: выраженное снижение уровня боли ($p < 0,05$, $p < 0,0001$), скованности ($p < 0,05$, $p < 0,0001$), ограничения физической активности ($p < 0,01$, $p < 0,0001$) — за счет улучшения на фоне проводимой терапии основных показателей антиоксидантной системы защиты: каталазы ($p < 0,01$) и супероксиддисмутазы ($p < 0,01$). **Заключение.** Применение периартикулярной озонотерапии позволяет добиться более стойкого положительного эффекта у больных после тотального эндопротезирования коленного сустава относительно традиционных методов восстановительного лечения, за счет выраженного антиоксидантного действия, направленного на стабилизацию процессов перекисного окисления липидов.

Ключевые слова: *остеоартрит; реабилитационное лечение; периартикулярная озонотерапия*

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Авторы заявляют, что данная работа, её тема, предмет и содержание не затрагивают конкурирующих интересов

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Abstract

Purpose. To evaluate the effectiveness of the course administration of an ozone-oxygen mixture into the periarticular tissues of the knee joint in patients with osteoarthritis who underwent total arthroplasty of one of the joints and to study the effect of this technique on the state of lipid peroxidation and the antioxidant defense system of the body relative to traditional methods of restorative treatment. **Materials and methods.** The study included 120 patients with bilateral gonarthrosis after endoprosthetics of one of the knee joints. The average age of the patients was 60 [46; 76] years. Depending on the method of rehabilitation treatment, the patients were divided into 3 equal groups (n=40): the 1st group was prescribed periarticular subcutaneous ozone therapy in combination with therapeutic exercise, the 2nd group — magnetotherapy and electrophoresis on the knee joint area in combination with therapeutic exercise, and 3rd group — only the complex of therapeutic exercise. In all patients, before and after rehabilitation treatment (after 14 days and 3 months), the clinico-functional status was assessed using the Western Ontario and McMaster Universities Osteoarthritis Index scale and the indicators of the intensity of the free radical oxidation processes and the activity of antioxidant protection were studied. **Results.** A detailed analysis of the clinico-functional state among patients of group 1 relative to group 2 and 3 revealed the best "long-term" result: a marked decrease in pain ($p < 0.05$, $p < 0.0001$), stiffness ($p < 0.05$, $p < 0.0001$), limitations physical activity ($p < 0.01$, $p < 0.0001$) due to the improvement of the main indicators of the antioxidant protection system against the background of ongoing therapy: catalase ($p < 0.01$) and superoxide dismutase ($p < 0.01$). **Conclusion.** The use of periarticular ozone therapy makes it possible to achieve a more stable positive effect in patients after total knee arthroplasty relative to traditional methods of restorative treatment due to its pronounced antioxidant effect aimed at stabilizing the processes of lipid peroxidation.

Key words: *osteoarthritis; rehabilitation treatment; periarticular ozone therapy*

Conflict of interests

The authors declare no conflict of interests

Sources of funding

The authors declare no funding for this study

Conformity with the principles of ethics

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APS — antioxidative protection system, ROI — reactive oxygen intermediate, VAS– visual analogue scale, DC — diene conjugates, BMI — body mass index, CAT — catalase, KJ — knee joint, ET — exercise therapy, MDA — malonyldialdehyde, OA — osteoarthritis, LPO — lipid peroxidation, RF — rheumatoid factor, SOD — superoxide dismutase, CRP — C-reactive protein, SRO — free-radical oxidation, TEP — total endoprosthetics, NO — nitrogen oxide, WOMAC — Western Ontario and McMaster Universities Osteoarthritis Index

Introduction

Patients, whose osteoarthritis (OA) is resistant to the standard therapy, need total endoprosthetics (TEP) of the joint. This method can resolve the pain syndrome and improve physical functioning. However, the positive result of surgery in a majority of patients can be completely negated without sufficient rehabilitation measures in the post-surgery period [1].

As of today, periarticular ozone therapy is gaining popularity; this method is based on the use of the curative properties of ozone/oxygen mix (OOM) in the projection of operated joints. Biological effects of ozone are associated with a jump in the levels of reactive oxygen intermediate (ROI) in the injection site, which triggers a cascade of consecutive reactions to induce expressing genes, encoding antioxidative protection system (APS) enzymes [2-3].

A drawback of this method is the lack of a clearly approved algorithm to use the calculated OOM doses in para-articular administration in order to achieve therapeutic effects, which is why this study is so relevant.

The objective of the study is to assess the efficiency of a course of OOM administration to periarticular tissue of the knee joint (KJ) in patients with OA, who underwent TEP of one of the joints, and to study the effects of this method for lipid peroxidation (LPO) status and body APS in comparison to the standard rehabilitation treatments.

Patients and methods

The medical rehabilitation ward No. 1 of the Regional Centre for Medical Rehabilitation was used as the site for the study of 120 patients (74 females and 46 males) aged 45 to 80 years with bilateral KJ OA (based on the OA ACR classification criteria (Altman et al., 1991) [4], after endoprosthesis replacement of one KJ, who were referred to the third stage of rehabilitation. The mean age of patients was 60 [46; 76] years; body mass index (BMI) [5] — 30.60 [27.00; 32.40] kg/m^2. The average clinical duration of KJ OA was 16 [2; 30] years; first complaints were recorded approx. at the age of 29 [25; 32] years of age. The median post-surgery period was 4 [3; 5] months.

Inclusion criteria for rehabilitation therapy were: 45 to 80 years old; post-surgery period of 3 to 6 months.

Exclusion criteria were: other rheumatoid conditions with articular syndrome; acute conditions or exacerbation of chronic diseases during the study; malignancies; recurrent thromboembolic complications.

The study was approved by the Local Ethics Committee at the Orenburg State Medical University of the Ministry of Health of Russia (Minutes No. 235 dated September 27, 2019).

According to the rehabilitation treatment strategy, patients were randomised to three equal groups (n = 40) using the stratified randomisation for preliminary definition of the parameters, which could affect the varied efficacy of rehabilitation (age, gender, BMI, disease duration and onset, X-rate stage and clinical functional presentation (pain, extra-articular and infra-articular oedema, limitation of active and passive movements in the operated KJ), caused by surgery). Thus, we have taken into account those parameters, which could affect the rehabilitation therapy efficiency. All patients were recommended a set of rehabilitation exercises for post-TEP patients (10 days). Patients in group 1 had periarticular subcutaneous ozone therapy combined with rehabilitation exercises; group 2 — physical therapy (magnet therapy and electrophoresis with 3 % potassium iodide and 2 % Novocaine on their KJ) combined with rehabilitation exercises; and group 3 — only a set of rehabilitation exercises.

Magnet therapy was administered using Polyus-2m (Russia) for 20 minutes prior to electrophoresis. Electrophoresis with 3 % potassium iodide and 2 % Novocaine (Potok-1, Russia) lasted for 20 minutes. A cycle of physical therapy comprised 10 daily sessions before rehabilitation exercises.

The ozone/oxygen mix produced by Medozon VM-03 (Russia), where ozone concentration was 5,000 μg/L, administered every other day after rehabilitation exercises in a volume of 20 mL. The total cycle included seven sessions.

Clinical functional status of patients with gonarthrosis after KJ TEP was determined with the help of WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) (N. Bellamy et al., 1998) [6].

Laboratory tests were performed to measure serum C-reactive protein (CRP) and rheumatoid factor (RF).

The interdepartmental biochemistry laboratory of the Orenburg State Medical University of the Ministry of Health of Russia was engaged in assessing APS enzymes in all patients before and after rehabilitation therapy (14 days and three months later): superoxide dismutase (SOD) and catalase (CAT) in RBC hemolysate (spectrophotometer GENESYS 5); and LPO product levels: diene conjugates (DC) and malonyldialdehyde (MDA) in dark blood (spectrophotometer BeckmanCoulter DU 800 (Germany)).

For pain management, patients used non-steroidal anti-inflammatory drugs (NSAIDs) symptomatically.

Statistica 10.0 software was used for statistical data processing. Results were presented as a median value (Me) or interquartile range (25th; 75th centile). Qualitative variables were presented as absolute and relative values. In order to compare three independent groups in terms of quantitative attributes, the level of significance of p was determined using Kruskal-Wallis test; if there were significant differences ($p \le 0.05$) or trends, a further pairwise analysis was performed for the study groups using non-parametric Mann–Whitney U test. A correlation analysis was conducted, where Spearman's rank correlation was calculated. Differences were statistically significant at $p < 0.05$.

Results

The WOMAC scale (Table 1) was used to assess changes in the clinical functional status before and after rehabilitation therapy (14 days and three months later) in patients with gonarthrosis after KJ TEP.

As shown in Table 1, when clinical functional parameters were compared, patients after KJ TEP were comparable in all subscales of the WOMAC questionnaire to values before rehabilitation therapy. In the pairwise comparison of WOMAC values, the closest rehabilitation therapy result (14 days later) was recorded in patients on complex therapy, comprising physical therapy and rehabilitation exercises ($p < 0.001$). However, the best long-term outcome (three months later) vs. baseline data was observed in group 1: marked abatement ($p < 0.001$),

Table 1. Distribution of the WOMAC index values before and after rehabilitation treatment in both groups

	The period of therapy	1st group (n=40)	2nd group (n=40)	3rd group (n=40)	p
Tenderness	Before treatment	13,00 [8,50; 14,00]	12,50 [9,50; 14,00]	12,70 [8,50; 13,50]	н.д./ n.r.
	After 14 days	6,50 [3,50; 9,50]*	5,50 [4,50; 7,00]**	7,50 [5,50; 10,00]**	<0,05# <0,001## <0,0001###
	After 3 months	3,80 [2,50; 4,00]***	4,50 [3,00; 4,70]**	8,00 [5,50; 8,50]	<0,05# <0,01## <0,0001###
Swelling	Before treatment	6,00 [4,00; 6,00]	6,00 [4,50; 8,00]	6,00 [4,00; 6,00]	н.д./ n.r.
	After 14 days	4,50 [4,00; 5,00]	4,00 [2,00; 5,00]**	5,00 [3,00; 5,00]	н.д./ n.r.
	After 3 months	2,50 [2,00; 3,50]**	3,50 [2,00; 4,00]**	5,00 [3,05; 5,50]	<0,05## <0,01###
Physical function	Before treatment	47,20 [45,00; 48,00]	48,00 [42,00; 50,00]	48,00 [42,00; 50,00]	н.д./ n.r.
	After 14 days	34,00 [30,00; 37,00]	30,00 [19,00; 33,50]**	38,00 [33,50; 43,50]	<0,05##
	After 3 months	23,50 [18,50; 28,00]***	27,00 [18,50; 34,00]**	38,50 [33,00; 42,00]	<0,05# <0,001## <0,0001###
Final score	Before treatment	64,50 [57,50; 71,50]	63,00 [53,00; 69,50]	64,50 [57,50; 71,00]	н.д./ n.r.
	After 14 days	45,00 [34,00; 53,50]	37,50 [24,50; 46,50]**	52,50 [45,00; 59,50]	<0,001##
	After 3 months	29,00 [26,50; 35,00]***	34,00 [24,50; 37,50]**	53,00 [46,50; 59,50]	<0,01# <0,001## <0,0001###

Note. n.r. — not reliable; reliability in relation to the initial data (before treatment): ** — p <0,01, *** — p <0,001; # — comparison of patients of 1st and 2nd groups, ## — comparison of patients of 2nd and 3rd groups, ### — comparison of patients of 1st and 3rd groups

Table 2. Dynamics of the main parameters of the APS and POL products before and after rehabilitation therapy

Group	The period of therapy	CD, nmol/ml	MDA, mcmol/l	CAT, mcmol $H_2O_2 r^{-1}c^{-1}$	SOD, U/ml
1st group (n=40)	Before treatment	1,30 [0,80; 1,40]	5,60 [4,50; 8,80]	48,80 [34,20; 60,80]	98,10 [57,50; 126,90]
	After 14 days	1,20 [0,90; 1,50]	5,40 [4,10; 8,30]	52,30 [33,90; 59,10]	104,00 [78,90; 144,90]
	After 3 months	0,70 [0,30; 0,90]**	3,60 [2,80; 8,20]**	66,50 [60,80; 71,70]**/II	149,60 [126,10; 237,02]**/II
2nd group (n=40)	Before treatment	1,20 [0,75;1,40]	5,60 [4,10; 6,10]	49,50 [31,70; 56,90]	98,90 [77,60;139,70]
	After 14 days	0,90 [0,80; 1,40]*	4,70 [3,50; 9,70] *	58,30 [33,90; 59,10] **	123,60 [83,40; 112,20]**
	After 3 months	0,80 [0,70; 1,20]*	4,40 [3,30; 9,10] *	61,20 [44,50; 63,40] **	126,00 [78,90; 144,90]**
3rd group (n=40)	Before treatment	1,20 [0,70; 1,50]	5,50 [3,80; 7,00]	47,80 [39,30; 57,80]	97,70 [49,20; 84,90]
	After 14 days	1,00 [0,60; 1,10]	4,70 [3,01;7,60] *	53,70 [36,40; 82,80]	110,60 [126,10; 237,02]*
	After 3 months	1,10 [0,80; 1,40]	5,00 [3,30; 9,10]	52,20 [33,90; 59,10]	105,30 [83,40; 112,20]

Note. Reliability in relation to the initial data (before treatment): * — p <0.05, ** — p <0.01; reliability in relation to data obtained 14 days after treatment: II — p <0.01

Table 4. Correlation coefficients between the clinical and functional indicators of the WOMAC scale and laboratory parameters after 3 months of treatment

WOMAC	CD, nmol/ml	MDA, mcmol/l	CAT, mcmol $H_2O_2 r^{-1} c^{-1}$	SOD, U/ml
Tenderness	0,38*	0,53*	0,38	0,54**
Swelling	0,22	0,27	0,34	0,41*
Physical function	0,41*	0,57**	0,44*	0,62**
Final score	0,42*	0,59**	0,42*	0,58**

Note. * — p <0,05; ** — p <0,01; **** — p <0,0001

improvement in stiffness ($p < 0.01$) and limited physical activity ($p < 0.001$). Moreover, only group 1 demonstrated significant reduction in the mentioned WOMAC values, obtained three months later, vs. results for the first 14 days ($p < 0.01$), evidencing the more significant efficiency of periarticular ozone therapy in combination with rehabilitation exercises, if compared to rehabilitation exercises alone or combined with physical therapy.

Assessment of laboratory results showed lower CRP and RF values after the rehabilitation therapy; however, there were no statistically significant difference between groups ($p = 0.08$).

On day 14 of rehabilitation therapy, patients with gonarthrosis after KJ TEP demonstrated lower concentrations of LPO products (DC and MDA) in all three groups vs. baseline; however, 25 % reduction in DC levels was recorded only in group 2 after rehabilitation exercises in combination with physical therapy ($p < 0.05$). MDA levels reduced by 4 % ($p > 0.05$) after periarticular ozone therapy, whereas a set of rehabilitation exercises, either alone or with physical therapy, resulted in significant reduction in its concentration by 14 % ($p < 0.05$) and 16 % ($p < 0.05$), respectively. After three months of therapy, significant reduction in DC and MDA levels in group 1 by 41 % ($p < 0.01$) and by 43 % ($p < 0.01$) was observed vs. baseline, respectively; and in group 2 — by 34 % ($p < 0.05$) and 20 % ($p < 0.05$). Group 3 patients did not demonstrate significant reduction in these values at the mentioned time points.

It has been shown that the use of a set of rehabilitation exercises combined with magnet therapy results in significantly higher activity of APS enzymes within the shortest period of time (14 days): plasma CAT activity increased by 15 % ($p < 0.01$), SOD levels rose by 25 % ($p < 0.01$) vs. baseline. Patients in this group had persistently higher APS activity three months later; however, there was no significant difference vs. data for the first 14 days of rehabilitation therapy. At three months, marked increase in CAT and SOD activity was observed in group 1 vs. baseline ($p < 0.01$) and first two weeks of rehabilitation ($p < 0.01$). After three months of rehabilitation exercises, patients in group 3 demonstrated minor reduction in enzyme activity of the antioxidant system ($p > 0.05$) vs. first 14 days.

The comparison of clinical functional and laboratory data was followed by a correlation analysis in order to assess the correlations between qualitative parameters of the status of gonarthrosis patients before and after rehabilitation therapy. It has been shown that with ageing, patients have lower blood SOD ($r = –0.45$, $p < 0.05$), whereas there were no age-related effects for CAT activity ($r = –0.16$, $p > 0.05$). There was positive correlation between MDA and increased BMI ($r = 0.32$; $p < 0.05$), irrespective of the rehabilitation method. Then we analysed the correlation between clinical functional parameters of WOMAC and post-therapy LPO and APS status.

Fourteen days after rehabilitation therapy initiation, patients in group 2 demonstrated that lower WOMAC pain levels and limited physical activity were associated with plasma MDA concentrations ($r = 0.32$, $p < 0.05$ and $r = 0.32$, $p < 0.05$, respectively) and elevated SOD activity ($r = –0.32$, $p < 0.05$ and $r = –0.32$, $p < 0.05$, respectively).

Long-term data (three months after rehabilitation initiation) for group 1 patients, who had a cycle of periarticular ozone therapy, showed that low WOMAC values were associated with lower LPO process intensity (MDA and DC levels) and antioxidant system activation (SOD and CAT activity) (see Table 3).

Discussion

KJ TEP is a method to get rid of pain and improve physical functioning; it is most efficient at the later stages of OA. However, the positive result of surgery in a majority of patients can be completely negated without active rehabilitation measures in the post-surgery period [1], which correlates with the findings in this study. All patients referred to rehabilitation therapy were complaining of pain, morning stiffness for approx. 30 minutes and limited mobility in the operated KJ.

Given the above, adequate rehabilitation remains an important aspect of the management of post-endoprosthetic patients. Currently, there are numerous approaches to physical therapy of patients undergoing KJ TEP [7], aiming to strengthen muscles, reduce swelling, increase mobility of the affected limb, and normalise walking. Patients in this study (n = 40) were indicated a set of physical therapy (magnet therapy and electrophoresis of KJ region) for 10 days combined with a set of rehabilitation exercises. A combination of magnet therapy and electrophoresis is known to affect free-radical mechanisms, thus considerably reducing the intensity of LPO processes due to APS activation [7]. The findings in this study confirmed it: the short-term therapy (14 days) resulted in significant reduction in DC levels by 25 % ($p < 0.05$) and MDA levels by 16 % ($p < 0.05$); as well as marked increase in plasma CAT activity by 15 % ($p < 0.01$) and CAD activity by 25 % ($p < 0.01$) vs. baseline. An assessment of the clinical functional status of group 2 patients showed a significant reduction in WOMAC parameters (pain, stiffness, limited physical activity) in 14 days ($p < 0.001$); the positive result lasted for three months after therapy initiation ($p < 0.001$).

Over the past decade, ozone/oxygen mix injections to the joint projection to treat OA have been gaining popularity. Positive effects of periarticular ozone therapy in OA patients have already been demonstrated in numerous clinical trials and is associated with a sharp, short-term rise in free radicals in the injection site, triggering a cascade of consecutive reactions to induce expression of genes, which encode APS enzymes [2-3]. As compared to groups 2 and 3, patients in group 1 showed the best long-term result measured using the WOMAC scale (significant reduction of pain and stiffness, improved physical activity), and changes in the main parameters of APS, evidencing more pronounced efficiency of periarticular ozone therapy combined with rehabilitation exercises, vs. rehabilitation exercises alone or in combination with physical therapy.

Therefore, ozone-oxygen injections in periarticular tissue are based on marked anti-inflammatory and analgetic effect due to pronounced antioxidant action. Although ozone-oxygen injections do not provide fast positive effects vs. traditional physical therapy, the use of ozone therapy provides for long-lasting, long-term positive effects in patients with gonarthrosis after KJ TEP.

However, this study was limited to a period of three months, which can have affected the study results. Besides, there is no information on OA phenotyping (age-related, metabolic, post-traumatic, biomechanical, mixed) [8] and comorbidities, which might have an impact on clinical functional parameters of efficiency of the rehabilitation therapy and intensity of free radical oxidation processes, antioxidant protection activity, and might limit our conclusions.

Conclusion

Periarticular ozone therapy provides for a more long-lasting positive result vs. traditional rehabilitation methods: pain relief, improvement in stiffness and physical activity, as seen on the WOMAC scale, by significantly reducing the LPO processes due to APS activation. Thus, correction of oxidative stress typical for degenerative dystrophic joint conditions is an element of the pathogenetic justification of the use of this therapy in the comprehensive rehabilitation of patients with gonarthrosis after KJ TEP.

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Author Contribution:

All the authors contributed significantly to the study and the article, read and approved the final version of the article before publication

Rechkunova O.A.: research concept and design, obtaining data, analyzing and interpreting data, writing articles, approving the final version of the publication.

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