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# OSTEOPATHY IS A NEW MEDICAL SPECIALTY. ASSESSMENT OF CLINICAL EFFECTIVENESS OF OSTEOPATHIC MANIPULATIVE THERAPY IN VARIOUS DISEASES

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# ОСТЕОПАТИЯ – НОВАЯ МЕДИЦИНСКАЯ СПЕЦИАЛЬНОСТЬ. ОЦЕНКА КЛИНИЧЕСКОЙ ЭФФЕКТИВНОСТИ ОСТЕОПАТИЧЕСКОГО ЛЕЧЕНИЯ ПРИ РАЗЛИЧНЫХ ЗАБОЛЕВАНИЯХ

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The review shows the effectiveness of osteopathic manipulative therapy (OMT) of various diseases basing on randomized controlled trials. OMT reduces pain and increases the mobility of joints and spine in musculoskeletal diseases. OMT has an analgesic effect. It influences on the peripheral and central links of the nociceptive system, and activates the antinociceptive system. OMT gives good results in functional disorders such as urinary incontinence in women, irritable bowel syndrome, and postoperative ileus. OMT improves the lymph flow and the lymphatic drainage, which is extremely difficult to obtain by other methods. Osteopathic treatment is safe. It provides an individual approach to patients, allows reducing the drug load. It can be successfully combined with other treatment methods. OMT complements the toolkit of clinical medicine and can take its rightful place in the system of provision of medical care to the population.

*Keywords: osteopathy, osteopathic manipulative therapy, functional disorders, musculoskeletal disorders, pain*

Показана эффективность остеопатического лечения различных заболеваний на основе контролируемых рандомизированных исследований. Остеопатическое лечение уменьшает боль, увеличивает подвижность суставов и позвоночника при костно-мышечных заболеваниях, оказывает противоболевое действие, влияя на периферические и центральные звенья ноцицептивной системы и активируя антиноцицептивную систему. Остеопатическое лечение дает хорошие результаты при функциональных расстройствах, таких как недержание мочи у женщин, синдром раздраженного кишечника, послеоперационная кишечная непроходимость. Остеопатическое лечение улучшает лимфодренаж тканей и лимфоток, что крайне затруднительно получить другими методами воздействия на организм. Остеопатическое лечение безопасно, обеспечивает индивидуальный подход к пациентам, позволяет снизить лекарственную нагрузку, хорошо сочетается с другими методами лечения. Остеопатическое лечение дополняет арсенал клинической медицины и может занять достойное место в системе оказания медицинской помощи населению.

*Ключевые слова: остеопатия, остеопатическое лечение, функциональные расстройства, костно-мышечные заболевания, боль*

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CTM – Connective Tissue Massage
IBS – Irritable Bowel Syndrome
FIQ – Fibromyalgia Impact Questionnaire
LBP – Low Back Pain
MLDT – Manual Lymph Drainage Therapy
OMT – Osteopathic Manipulative Therapy
PT – Pain Threshold
RA – Rheumatoid Arthritis
SUT – Sham Ultrasound Therapy
TMD – Temporomandibular Disorders
UOBC – Usual Obstetric Care
VAS – Visual Analogue Scale

**Osteopathy is a branch of clinical medicine, which includes provision of medical care to patients with somatic dysfunctions on the stages of prevention, diagnosis, treatment, and rehabilitation, which bases on the anatomical and functional entity of the body and which uses manual methods for restoration of the body's ability to self-correction. This is one of the few manual medical disciplines, regulated by World Health Organization. It has proven its effectiveness in many developed countries.**

Osteopathy originated almost a century and a half ago, in the second half of the XIX century in the United States of America. It was founded by Dr. Andrew Taylor Still, who step by step created medicine based on the laws of nature. Despite the fact that osteopathy has developed relatively apart from official medicine, the world has accumulated a large amount of evidence of its effectiveness and safety in treatment of a wide range of diseases.

The history of osteopathy in Russia began in 1991 when an outstanding American osteopath Viola M. Frymann came to St. Petersburg. Since 2012, a work on the creation of the system of state regulation of osteopathy has been conducted. To date, a number of legal normative acts determining the further development of osteopathy within the framework of the official Russian public health system have been adopted. The orders of the Ministry of Public Health of the Russian Federation approved the job title «osteopathic physician» and Qualification requirements for osteopathic physicians. The specialty «osteopathy» was included in the list of specialties of higher medical education. Thus, nowadays osteopathy is a new medical physician's specialty. Recognition of osteopathy at the state level allowed it to take its place in the existing health care system of Russia, on an equal basis with other medical specialties, and to contribute to the preservation and maintenance of public health.

The developed methodology of osteopathic diagnostics made it possible to conduct scientific research meeting the requirements of evidence-based medicine, and to develop clinical recommendations for the use of osteopathic manipulative therapy (OMT) in treatment of different diseases.

Clinical studies of the effectiveness of OMT are complicated by the fact that the impact is manual. A double blind, placebo controlled study is difficult or not possible. For some other methods of treatment (surgical interventions, physiotherapy, methods of restorative medicine) this is also impossible for objective reasons. However, it is possible to organize randomized studies with a sufficient number of patients, to form main and control groups of patients with similar characteristics (age, main disease etc.), and to use instrumental research methods in order to objectify the results of treatment.

Objective of our study was to demonstrate the effectiveness of osteopathic treatment of various diseases basing on the review of randomized controlled trials.

**OMT in Treatment of Musculoskeletal Disorders**

Most publications present the results of osteopathic treatment of musculoskeletal diseases.

Low back pain (LBP) is a worldwide problem and the leading cause of disability. The high effectiveness of OMT in treatment of lumbar pain has been proven. In 2014, a systematic review and meta-analysis of 15 randomized controlled trials found moderate-quality evidence that OMT reduces pain and improves functional status in acute and chronic nonspecific low back pain [1].

Stratified analysis showed a significant reduction in pain in trials of osteopathic treatment versus active treatment or placebo/no treatment. There was a significant reduction in LBP associated with OMT during the short-term (1 month, $p=0.01$), intermediate term (3 months, $p<0.001$), and long-term (1 year, $p=0.03$) follow -up periods. Studies have been conducted in the United Kingdom and the United States [2]. A randomized placebo controlled (treatment simulation) study was conducted in order to determine the effectiveness of 6 OMT sessions held during 8 weeks. Recovery of 455 patients was assessed at week 12 in accordance with the pain visual analogue scale (VAS) and the Roland-Morris Disability Questionnaire used for the evaluation of back functions. High effectiveness of osteopathic treatment (pain reduction of more than 50 % ($p=0.001$) and improvement of the back functions ($p=0.02$)) was noted [3]. A randomized controlled trial conducted in 2016 confirms good results of OMT in treatment of chronic back pain. The OMT regimen was associated with significant and clinically relevant measures for recovery from chronic LBP. A trial of OMT may be useful before progressing to other more costly or invasive interventions in the medical management of patients with chronic LBP [4].

About 50 % of pregnant women will have LBP at some point during or after their pregnancies, and the impact of LBP on quality of life can be considerable.The management of back pain and related problems during pregnancy is complicated by potential or unknown risks of drug therapies and other interventions.

In a randomized controlled study (Germany), the back pain intensity was assessed according to VAS in 80 women with back pain associated with pregnancy and lasting for at least 3 months after delivery. The main

group consisted of 40 patients who received OMT, the control group consisted of 40 patients who did not receive any treatment. After the OMT course, the pain intensity reduced on the average from 6 to 2 points ($p<0.001$) [5]. Another study evaluated the use of OMT during labor for lumbar pain. Women receiving OMT during labor used less pain medication than those who did not receive OMT during labor ($p<0.01$) [6]. The new randomized sham-controlled trial includes 3 parallel treatment arms: usual obstetric care and OMT (UOBC+OMT), usual obstetric care and sham ultrasound therapy (UOBC+SUT), and usual obstetric care (UOBC). A total of 144 patients were randomly assigned and included in intention-to-treat analyses. Osteopathic manual treatment gave medium to large treatment effects in preventing progressive back-specific dysfunction during the third trimester of pregnancy ($p<0.0001$ UOBC+OMT vs UOBC). The findings are potentially important with respect to direct health care expenditures and indirect costs of work disability during pregnancy [7]. Osteopathic treatment is personalized, safe and can be successfully used in order to help pregnant and lactating women.

OMT is effective not only for chronic, but also for acute pain in the spine. 70 % of people can remember at least one episode of acute pain in the neck. McReynolds T.M., Sheridan B.J. compared the effectiveness of an intramuscular injection of one dose of ketorolac with the effectiveness of OMT in the treatment of acute pain in the neck [8]. A randomized clinical trial was performed. The subjective index of pain intensity was assessed on an 11-point numerical scale immediately before the treatment and one hour after the treatment. 29 patients received an intramuscular injection of ketorolac, and other 29 patients received OMT. Both groups showed a significant decrease in the intensity of the pain syndrome. Patients who received OMT reported a significantly greater reduction in pain intensity ($p=0.02$). Thus, OMT reduces the intensity of pain in the neck significantly better than intramuscular injection of ketorolac. At the same time, OMT is safe for patients and does not have such side effects as non-steroidal anti-inflammatory drugs [8].

After OMT, the volume of movements in the back and neck increases. A series of manual effects on the neck and shoulders reduces the excitability of α-motoneurons of m. flexor carpi radialis (Hoffmann reflex). The amplitude of the electromyogram decreases, the range of neck motions increases in all directions [9].

OMT increases the range of motions in the joints of the limbs. Szlezak A. M. et al. suggests that unilateral lumbar spine zygapophyseal joint mobilization can immediately restore posterior chain neurodynamic. The effectiveness of the osteopathic treatment was assessed according to the amplitude of passive raising of the straight leg. In the group of patients who received OMT, the angle of passive raising of the straight leg increased significantly more than in the comparison group ($p<0.001$) [10]. The osteopathic technique of dynamic stretching of the plantar flexors effectively increased the flexibility of the ankle joint due to the lengthening of the tendon tissue. Ankle dorsiflexion increased significantly after the dynamic stretching ($p<0.0001$) [11].

Temporomandibular disorders (TMD) is a term reflecting chronic, painful, craniofacial conditions usually of unclear etiology with impaired jaw function. Patients were randomly divided into two groups: an OMT group (25 patients, age 40.6±11.03) and a conventional conservative therapy group (25 patients, age 38.4±15.33). The state of patients of both groups was improving during 6 months. Patients who received OMT needed significantly less medication (non-steroidal anti-inflammatory drugs and muscle relaxants ($p<0.001$) [12]. The meta-analysis showed a significant difference ($p<0.0001$) and large effect on active mouth opening and on pain during active mouth opening in favor of musculoskeletal manual techniques when compared to other conservative treatments for TMD [13].

Osteopathic treatment showed significantly better results (in comparison with the standard treatment) in children who had traumas of the temporomandibular joint and limited mouth opening. The study was conducted on 28 children with non-specific TMD symptoms, limited mouth opening, history of trauma (delivery trauma, accident trauma). Patients were randomly divided into two groups: an OMT group (study group) and a no-intervention group (control group). The kinesiographic data of the study group showed a moderate statistically significant difference ($p<0.07$) of maximal mouth opening parameter and a high statistically significant difference ($p<0.03$) of maximal mouth opening velocity parameter. No statistically significant difference (null hypothesis confirmed) of kinesiographic parameters in the control group was observed [14].

About half of the people suffering from cervicogenic headaches have temporomandibular disorders. A series of manual techniques for the joint reduces headache and restores neck function [15]. In case of pain in the temporomandibular joint, a series of manual techniques for the cervical vertebrae reduces pain, increases the pain threshold and the amplitude of the painless mouth opening [16].

**Analgesic Effect of OMT**

As mentioned above, one of the main effects of OMT is a significant reduction in pain. Many researchers write about the analgesic effect of OMT, including in the postoperative period. Goldstein et al. demonstrated that patients receiving an OMT protocol after elective total abdominal hysterectomy used less morphine than those in the group receiving a postoperative sham protocol treatment during the first 24 hours ($p=0.02$) and 25 to 48 hours after the operation ($p=0.01$) [17]. In a more recent randomized study, Le Blanc-Louvry et al. found that individuals receiving postoperative abdominal wall massage after a colectomy had less pain ($p<0.001$), had less analgesic use ($p<0.05$), and passed gas sooner ($p<0.01$) than those individuals who did not receive abdominal massage [18].

High velocity low amplitude techniques on the C5-C6 zygapophysial joints cause a slow increase of the pain threshold during the pressure on the lateral epicondyles of the elbows [19].

Manipulations performed on the paravertebral muscles cause postsynaptic relief of α-motoneurons and / or cortical neurons which innervate these muscles. With the help of bipolar surface electrodes fixed on the back and on the extremities of a person, it is shown that the manual impact systematically excites the reflex pathways: the response appears within 20–200 ms and lasts for 100–400 ms. Probably, this is how the therapeutic effects develop. The muscle pain and hypertension reduce [20].

Dhondt W. et al. used pressure algometer pain threshold (PT). The rheumatoid arthritis (RA) patients showed a significantly ($p<0.05$) lower PT than the healthy adults at all investigated points, which suggests that in RA certain changes arise in the peripheral and central nociceptive processing system, as mentioned in the literature. In the second measurement session for the RA patients the PT was significantly higher ($p<0.05$) after manual oscillations than after rest, at

the paraspinal area of T6, L1 and L3. Further research into the long-term effect of repeated manual oscillation sessions is warranted. It is assumed that the mechanical action of the hands of an osteopath initiates a cascade of neurophysiological responses of the peripheral and central nervous system in the patient's body, which leads to therapeutic effects [21].

Musculoskeletal injuries induce an inflammatory response in the periphery which initiates the healing process and influences pain processing. Inflammatory mediators and peripheral nociceptors interact in response to injury and OMT may directly affect this process. For example, Teodorczyk-Injeyan et al. observed a significant reduction of blood and serum level cytokines in individuals receiving joint biased OMT which was not observed in those receiving sham OMT or in a control group. A significant ($p<0.001$) reduction of proinflammatory cytokine secretion was observed from spinal manipulation therapy receiving subjects [22]. Additionally, changes of blood levels of β-endorphin, anandamide, N-palmitoylethanolamide, serotonin [23] and endogenous cannabinoids [24] have been observed following OMT. Concentrations of several circulatory pain biomarkers were altered after OMT. The degree and duration of these changes were greater in subjects with chronic LBP than in control subjects without the disorder. Increases from baseline in β-endorphin and N-palmitoylethanolamide levels and a decrease in anandamide levels occurred immediately posttreatment. McPartland J.M. et al. received an increase of the level of serum anandamide after OMT by 168 % compared with the initial level. The authors propose that healing modalities popularly associated with changes in the endorphin system, such as OMT, may actually be mediated by the endocannabinoid system. Endogenous cannabinoids activate cannabinoid receptors in the brain and elicit mood-altering effects. Parallel effects (eg, anxiolysis, analgesia, sedation) may be elicited by OMT [24].

Thus, OMT influences on the peripheral and central links of the nociceptive system, and activates the antinociceptive system.

**OMT in Functional Disorders**

Osteopathic treatment gives good results in treatment of functional disorders.

Urinary incontinence occurs in 8 % to 42 % of young and middle-aged women, and in 17–55 % of elderly women. The review by Franke N., Hoesele K. included only randomized studies (in total 312 women). Quantitative analysis showed a statistically and clinically significant improvement in the group of patients who received OMT in comparison with the group of patients who did not receive any treatment ($p=0.001$). Two studies comparing the effectiveness of OMT with the effectiveness of pelvic floor muscle training showed almost the same therapeutic effect ($p=0.94$) [25].

Irritable bowel syndrome (IBS) is a chronic, recurring gastrointestinal illness that varies in symptoms and characteristics. Approximately 10 % of the population has IBS at any given time – about 200 people per 100,000 receive an initial diagnosis of IBS each year [26]. The review by M ller A. et al. included 5 randomized trials of the effectiveness of OMT (in total 204 patients with irritable bowel syndrome). Three studies used visual analogue scales to assess abdominal pain, and two studies used the Index of severity of functional bowel disorders (severity of diarrhea, constipation, flatus and abdominal pain). The studies assessed in the present systematic review suggest that OMT can benefit patients with IBS. These studies reported that OMT reduced the symptoms of IBS, such as abdominal pain, constipation, diarrhea, and improved general well-being. No study reported any serious or statistically significant adverse events from OMT. Other researchers reported a more pronounced short-term improvement in patients with irritable bowel syndrome who received OMT compared to the simulation or standard treatment ($p<0.05$) [27].

Numerous data confirming the faster recovery of the functions of various organs under the influence of OMT after surgical interventions have been obtained.

Sleszynski et al. found no difference in the incidence of postoperative atelectasis status after cholecystectomy, but patients who were treated with the thoracic lymphatic pump technique had an earlier recovery and quicker return to preoperative respiratory values for forced vital capacity and forced expiratory volume than patients who were treated with incentive spirometry [28].

Two retrospective studies have evaluated the effect of OMT on postoperative ileus after a variety of surgical procedures. Herman found that patients routinely receiving OMT postoperatively had an extremely low incidence (0.3 %) of postoperative adynamic ileus, whereas patients not receiving OMT had a higher incidence (7.6 %) [29]. Crow and Gorodinsky found that patients who received OMT after developing a postoperative ileus had an average postoperative hospital length of stay that was 2.7 days shorter than those who did not receive OMT [30]. Osteopathic manipulative treatment applied after a major gastrointestinal operation is associated with decreased time to flatus and decreased postoperative hospital length of stay [31].

O-Yurvati et al. demonstrated that OMT had a beneficial effect on the recovery of patients after coronary artery bypass graft surgery as indicated by changes in cardiac function and perfusion with significant differences for mixed venous oxygen saturation ($p<0.005$) and cardiac index ($p<0.02$). The authors conclude that OMT has immediate, beneficial hemodynamic effects after coronary artery bypass graft surgery when administered while the patient is sedated and pharmacologically paralyzed [32].

A prospective study investigating the use of OMT in the postoperative care of patients undergoing elective knee or hip arthroplasty found that compared with patients not receiving OMT, those patients receiving OMT negotiated stairs 20 % earlier ($p=0.006$) and ambulated farther during the first 4 postoperative days ($p=0.008$). The OMT group also required less analgesia and had shorter hospital stays, but the differences were not statistically significant [33].

Pomykala et al. surveyed 160 medical, postoperative, and obstetric patients who had OMT and found that more than 75 % of patients reported that OMT decreased stress and anxiety, improved recovery, and improved overall comfort during their hospital stay. In addition, 94 % of patients felt OMT was helpful for their recovery, and 98 % would recommend OMT for other hospitalized patients. Osteopathic manipulative treatment may be of tremendous benefit to hospitalized patients, regardless of their diagnoses [34].

**Influence of OMT on the Lymphatic System**

In osteopathic medicine, the lymphatic system plays a key role in health maintenance, with lymphatics identified as 1 of 7 care modalities of osteopathic manipulative medicine [35].

The study analyzed and compared the effects of manual lymph drainage therapy (MLDT) and connective tissue massage (CTM) in women with primary fibromyalgia. The study design was a randomized controlled trial. Fifty

women with PFM completed the study. The patients were divided randomly into 2 groups. Whereas 25 of them received MLDT, the other 25 underwent CTM. The treatment program was carried out 5 times a week for 3 weeks in each group. Pain was evaluated by a visual analogue scale and algometry. The Fibromyalgia Impact Questionnaire (FIQ) and Nottingham Health Profile were used to describe health status and health-related quality of life. In both groups, significant improvements were found regarding pain intensity, pain pressure threshold, and health-related quality of life ($p<0.05$). However, the scores of FIQ-7 ($p=0.006$), FIQ-9 ($p=0.006$), and FIQ-total ($p=0.010$) were significantly lower in the MLDT group than they were in the CTM group at the end of treatment. The results indicate that these manual therapy techniques might be used in the treatment of PFM. However, MLDT was found to be more effective than CTM according to some subitems of FIQ (morning tiredness and anxiety) and FIQ total score [36].

OMT improves the lymph flow in cases when the difference in pressures created by the diaphragm adversely affects it. Also, osteopathic treatment restores regulation of lymphatic contractility and improves lymph circulation by influencing the autonomic nervous system [37].

An osteopathic technique intended to stimulate the lymph flow was imitated on the anesthetized rats. As a result the mechanical pressure to body regions physically distant from the location of lymph formation enhances lymph uptake. [38].

Thus, OMT improves the lymphatic flow and the lymphatic drainage of tissues. Such effects are extremely difficult to obtain by other methods of influence on the body.

**Conclusions.** The clinical effectiveness of osteopathic treatment caused widespread use of this type of medical care. This facts and legal regulation allowed osteopathy to take its rightful place in the existing health care system of Russia, along with other medical specialties, to contribute to the preservation and maintenance of public health. The results of studies conducted according to the criteria of evidence-based medicine permit to recommend OMT as the main treatment or an integral part of complex treatment for a wide range of diseases, especially at the rehabilitation stages in order to prevent aggravations and complications. Doctors of various specialties need to know that as a result of osteopathic treatment pain decreases, functioning of the musculoskeletal system, lymphatic drainage, blood supply and neural trophism of various organs improve, which increases the adaptability of the organism in a wide range of pathological processes.

Contraindications to osteopathic treatment are cancerous and infectious diseases, as well as acute conditions requiring urgent intervention of competent specialists.

Osteopathic treatment is safe. It provides an individual approach to patients, permits to reduce the drug load and the risk of the development of polypragmasy. It works well with other methods of treatment. Osteopathic manual techniques can complement the toolkit of clinical medicine and take their rightful place in the system of medical care.

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The authors declare no conflict of interest.

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