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Clinical and economic analysis of non-medical technologies in Russia

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ABSTRACT

Health technology assessment includes several aspects: (1) technology position in health care system (characteristic of disease burden and expected socio-economic impact of technology), (2) the main characteristics of studied technologies, (3) clinical efficacy (experimental and in typical clinical practice), (4) safety, (5) clinical and economic evaluation, (6) the ethical aspects of technology applications, (7) psychological aspects, (8) legal aspects, (9) organizational and logistic issues, (10) social issues, including equitable distribution of resources and fair access to technology. Any assessment of medical technology expects answers to be provided to all the above questions.

Non-drug medical technologies can be divided on the basis of different classification approaches. From the position of the functional approach – there are diagnostic, therapeutic (invasive, non invasive), rehabilitation, prevention, and technologies for care and maintenance functions.

Regarding the use of different components, there are technologies which include drugs or blood components, also foodstuffs for special nutritional uses or medical devices. An example of medical devices may be laboratory gear used for in vitro studies. The paper presents evaluation results of technologies, which employ medical devices.

Finally, there are institutional medical technologies.

In this article, the authors present studies about therapeutic, prophylactic and organizational technologies. Prevention of contact dermatitis and ulcers in immobilized patients with urinary incontinence. Clinical and economic research unit for physiotherapy and an assessment of the organization of medical technologies that was conducted, due to reforms in the Russian health care system.

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(2) the main characteristics of studied technologies,
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During any assessment of medical technology answers are expected to be provided to all the above-mentioned questions.

THE FEATURE OF NON-DRUG TECHNOLOGIES IN TERMS OF CLINICAL AND ECONOMIC ANALYSIS IS LESS SCRUTINY OF BOTH EFFICIENCY AND SECURITY AND THE COSTS ARE MUCH LESS STUDIED.

Non-drug medical technologies can be divided on the basis of different classification approaches. From the position of the functional approach – there are diagnostic, therapeutic (invasive, non invasive), rehabilitation and prevention technologies, as well as technologies for the care and maintenance functions. From the position of using different components, there are those which include medicinal products and blood components, foodstuffs for special nutritional uses and medical devices, which include, for example, laboratory gear for in vitro studies. Laboratory blood tests or magnetic resonance tomography, diagnostic surgery or biopsy are examples of diagnostic technologies. Medical technologies – such as surgery – involve the use of various devices with therapeutic effects (for example - physical therapy), the use of different non medical devices, such as catheters or cardiac pacemakers.

Preventive vaccination in a clinical and economic analysis can be considered similar to assessing drug technologies. At the same time, clinical examination or application of anti-smoking activity (for example, a legislative ban on smoking in public places) requires a different approach to assess the cost-effectiveness of technologies.

Similar problems arise in the clinical and economic evaluation of rehabilitation approaches. This may be a simple procedure, such as a logopedic manual for patients who have had a stroke, or more complex, for example, activities to adapt a disabled person to his / her familiar environment. Here, complex, psychological techniques are used and the development of technical equipment, ranging from simple light switches or TV to robotic devices (device for moving a patient lying on the toilet or use the exoskeleton to walk).

Finally, organizational technologies are usually massive. For example, the treatment of rare diseases, which is at the expense of the state budget, which is conventionally called the “7 Diseases program.” There is also a drug component and the logistics of drug delivery to regions and patients and the results of the monitoring system and the maintenance patient registers. Such a program should be evaluated holistically, not isolating it from the various components.

It is clear that an evaluation of the effectiveness of non-pharmacological medical technologies requires appropriate criteria. These criteria may be similar to the indicators for assessing medical technologies, especially when it comes to the treatment and prevention technologies, or may differ materially. Thus, in order to study the effectiveness of prevention of bedsores by the use of diapers, an adequate indicator can be not only the incidence of pressure sores but the evaluation of quality of life or QALY index.

The feature of non-drug technologies in terms of clinical and economic analysis is less scrutiny of both efficiency and security and the costs are much less studied. Convincing studies are now concentrated on technology, behind which there are instruments, and these technologies are recorded in health technology assessment bodies of different countries (NICE, IQWIG, etc.) for inclusion in the program of cost refund. At the same time, the old, traditionally used technologies (e.g., clinical blood tests or ECG monitoring) are not assessed from the position of clinical and cost-effectiveness. It is that due to the lack of need for such an analysis in regulators and payers – it is simpler to pay for traditionally used non-drug technologies than to enter into a conflict with the manufacturers of this equipment, accustomed to its use by doctors and patients, who are in need of these technologies. For example, a convincing evidence of the effectiveness of the procedures, associated with magnetization of tissues, the impact of various weak currents on tissues - what is called physiotherapy in Russia

- talking about it causes a negative reaction from doctors, patients, and administrators.

For Russia, this problem is particularly acute, due to the fact that, for the last 7-8 years, the Russian health care projects have involved a procurement of medical equipment worth billions of euro. Only the health care IT project - the Unified National Health Information System – consumed nearly a billion of dollars in 2012 from the state budget.. That money has funded a project of doctor appointments via the internet. Accordingly, even if a sick person turns up personally at the clinic, he / she has to make an appointment with the doctor in the terminal. It is clear that such "service" is not conducive to an increased access to health care and no one tried to evaluate the cost-effectiveness of the project, even to assess the effectiveness of investments, using objective indicators.

Another example. April 2013. The conversation of the Minister of Health, Ms. Veronika Skvortsovaya, with Mr Vladimir Putin, the Russian President, regarding perinatal centers. It has been planned to spend some 50-60 billion rubles (1 460 million euros) on the program, including building of new 100-bed medical centers at 5 regions, 130-bed medical centers at other five regions, 150-bed medical centers at 9 regions and 200-bed medical centers at 6 regions. According to the Minister of Health's concept, women with uncomplicated pregnancy will give birth at standard maternity hospitals; those with minor complications and chronic diseases - at large hospitals, while the new centers will be designed only for very difficult deliveries. The smallest center will cost 2 billion rubles (49 million euro), and the largest one - 3 billion rubles (73 million euro).

However, nothing has been said about how the pregnant women are going to be selected and distributed (the logistic aspect),. The criteria for assessment of risks and their validity seem to be beyond the understanding of the official organs..

Our assessment of this situation is following: all over the country, small maternity units in towns and villages are closed. The result: women cannot drive hundred miles off-road or fly (aviation is not available everywhere) to luxury apartments so they give birth in unsuitable conditions. The medical centers, equipped with high tech diagnostic and therapeutic apparatus but located off the general hospitals, will not be able to provide highly qualified assistance that requires participation of different specialists: bringing required staffs of experts and medical gear will be very difficult in isolated centers. Therefore, the path-

way to develop perinatal centers leads to a dead end, while its costs, being extremely high, make the project little cost-effective..

Another challenge was the design and construction of expensive high-tech medical centers. Planned at the beginning of 2006 as a priority project, 15 federal centers should have been completed by 2009 but none of them was and, only in 2013, the construction of 13 centers was completed, the other two will be demolished (the Federal Center of Traumatology, Orthopedics and Arthroplasty in Vladivostok and the Federal Center of Traumatology, Orthopedics and Prosthetics in Krasnodar). The construction costs of the Krasnodar center - at the moment the construction was stopped – amounted to 3.923 billion rubles. Its demolition and construction of a new building on the site will need other

2 billion rubles, and the cost of equipment to be transferred to regional hospitals, has been estimated at 200 million rubles.

In Russia, there is no public system of health technology assessment. Since the late 1990s, by orders of the Ministry of Health, attempts have been made to draft clinical cost estimates with lists of available therapies, reaching an appropriate standard of evaluation. However, those approaches have not been implemented into the practice of decision-making officials and administrators, and, moreover, they do not apply to non-drug medical technologies. In 2010, a standard for evaluation of medical technology was created, approved and developed by our team, but it has not been used by administrative organs.

However, the course taken by the Russian government on the commercialization of medicine, is leading to the mainstreaming of surrogate economic evaluations of medical technologies from the standpoint of searching for additional incomes. The surrogate assessments concentrate on how to obtain more money from patients, how to increase capital turnover, leaving aside the aspect of economic benefit, the incurred costs and their economic effectiveness.

In Russia, medical devices for self-treatment and home care are massively distributed. The devices are in 100% purchased by patients from their personal budgets. It would seem that the manufacturers of such devices should be the target group of researchers of economic efficiency but the reality is not like that: there are no barriers to unscrupulous marketers who impose on customers, not familiar with the system of the evidence of effectiveness, devices and related technologies that have never passed performance tests but have been registered with fake documents or have not been registered at all. The lack of transparent directories of registered technologies and devices, lack of instructions of use and no guidelines or standards for the use of proposed technologies, create conditions for fraud, in which there is no room for clinical or economic evaluations.

IN RUSSIA, MEDICAL DEVICES FOR SELF-TREATMENT AND HOME CARE ARE MASSIVELY DISTRIBUTED. THE DEVICES ARE IN 100% PURCHASED BY PATIENTS FROM THEIR PERSONAL BUDGETS.

Thus, the economic assessment of non-drug medical technologies is a top issue for Russia. The Russian branch of ISPOR – Russian Society for Pharmacoeconomics Research (RSPOR) – has conducted several studies of non-pharmaceutical diagnostic and therapeutic technologies. For example - two studies involved modeling and two - clinical trials, where one was a randomized, double-blind study. Below, these two studies have been summarized.

PREVENTION OF CONTACT DERMATITIS AND ULCERS IN IMMOBILIZED PATIENTS WITH URINARY INCONTINENCE [2]

Among available preventive measures, we need to identify methods to prevent the use of non-pharmaceutical products, such as diapers or nursing facilities to prevent pressure sores in immobile patients.

There is no data on the incidence of contact dermatitis and pressure ulcers in Russia [3]. On the contrary, the world medical literature offers many reports of studies on the epidemiology of contact dermatitis and ulcers in patients with urinary incontinence. The incidence of contact dermatitis and ulcers varies widely [4].

The studies have mainly been focused on the development of new therapies of already formed ulcers; too little attention is paid to their prevention. Adequate prevention of pressure sores can avert their development in more than 80% of patients at risk [5]. The Industry standard: “Treatment Protocol. Bedsores”, developed by our group and approved by Regulation of the Ministry of Health of Russia from 17.04.2002 № 123 [3], recommends absorbing agents and skin care products for prevention of pressure ulcers but the low level of use of these devices is probably due to their high cost.

The purpose of the undertaken clinical and economic analysis was to analyze the cost-effectiveness of the use of diapers of particular manufacturers for prevention of contact dermatitis and pressure sores in patients with fixed incontinence. The work was to estimate typical practice of the management of these patients who developed contact dermatitis or pressure sores on the

basis of a survey of 7 experts with experience in treating these patients at different institutions in Russia. We have calculated the direct medical costs of prevention and treatment of contact dermatitis and pressure sores. Then we have developed an economic Markov model and conducted clinical and economic analysis of the use of diapers in prevention of dermatitis and ulcers.

Evaluation of the cost of medical services was performed, as described by RSPOR, in accordance with the Moscow regional health care fund's tariffs (2010) [1]. Calculations of nursing service costs were based on the nomenclature, works and services in health care, approved by the Ministry of Health in Russia on 12.07.2004. Calculations of the cost of absorbent materials and skin care products were based on their retail prices, acquired from the Internet (www.aptekamos.ru) in November 2011, for the sensitivity analysis, wholesale prices from 2 sources (www.tovary-plus.ru, www .air.ru / optom.html) were applied. The cost of medicines was calculated from their average prices, obtained from the www.pharm-index.ru database for the same period.

The calculated costs took into account hotel services (hospital stay), care, medicines, absorbents and care laboratory and instrumental methods of examination, as well as expert counseling;

Markov model (Figure), was based on the following assumptions:

- **one step in the cycle was assumed to be 4 weeks;**
- during the first 4 weeks, prevention of dermatitis and ulcers was conducted in 100% of the patients;
- adsorbing state is death, the incidence of which was extrapolated from the study by Fleurence RL [6], and accounted for 8% of patients in each cycle;
- for patients, who died at the end of the cycle, prevention of dermatitis and ulcers was conducted through all that time (4 weeks) because it was assumed that they had died on the last day of the cycle;
- the percentage of patients who developed stage 1 / stage 2 pressure sores, when standard preventive schemes were followed - extrapolated from studies by Palese A. [7], Gray M. [8], amounted to 22%;
- the percentage of patients who developed stage 3 / stage 4 pressure ulcers, when standard preventive schemes were followed - from studies of Palese A. [7], Gray M. [8], amounted to 7%;
    - the percentage of patients with stage 1 / stage 2 pressure sores, in whom no appropriate prophylactic standards were applied, was determined for 28%; that percent was extrapolated from a study by Fleurence RL (6).
    - the percent of patients, who developed stage 3 / stage 4 pressure sores, with initially absent stage 1 / stage 2 pressure sores, when standard prevention schemes were applied at the onset of stage 3 / stage 4 pressure sores, amounted to 8% - extrapolated from the study by Fleurence RL [6].
- the percentage of patients who developed bedsores of the same stage, when standard preventive schemes were applied, amounted to 12% and was extrapolated from the study by Fleurence RL [6];
- the percentage of patients who developed bedsores without the use of standard prevention procedures is twice higher, according Brandeis GH [9]

DISTRIBUTION OF PATIENTS BY MARKOV STATES: ABSORBENT CONDITION - DEATH

Model 1. Prevention and treatment of contact dermatitis and ulcers in patients with fixed incontinence, using absorbents and care products for over 20 weeks, each Markov cycle of 4 weeks, and a total of 5 cycles (see Table 1).

Model 2. Prevention and treatment of contact dermatitis and ulcers in patients with fixed incontinence without absorbers and care products for over 20 weeks, the duration of each Markov cycle: 4 weeks for a total of 5 cycles (see Table 2).

There is an assumption that the treatment of contact dermatitis or bedsores without absorbents and skin care products increases the

Table 1. Coefficients, used to calculate costs in model 1, 5 cycles (20 weeks)

PATIENT'S CONDITION	AT THE BEGINNING OF CYCLE	AT THE END OF THE 1ST CYCLE	AT THE END OF THE 2ND CYCLE	AT THE END OF THE 3RD CYCLE	AT THE END OF THE 4TH CYCLE
NO OF COMPLICATIONS	100	63	46.41	38.36	33.67
STAGE 1 / STAGE 2 PRESSURE SORES	0	22	30.34	31.67	30.55
STAGE 3 / STAGE 4 PRESSURE SORES	0	7	7.89	7.84	7.42
DEATH	0	8	15.36	22.13	28.36
ALL	100	100	100	100	100

Table 2. Coefficients, used to calculate costs in model 2, 5 cycles (20 weeks)

PATIENT'S CONDITION	AT THE BEGINNING OF CYCLE	AT THE END OF THE 1ST CYCLE	AT THE END OF THE 2ND CYCLE	AT THE END OF THE 3RD CYCLE	AT THE END OF THE 4TH CYCLE
NO OF COMPLICATIONS	100	34	25	21.74	19.75
STAGE 1 / STAGE 2 PRESSURE SORES	0	44	41.96	38.99	36.00
STAGE 3 / STAGE 4 PRESSURE SORES	0	14	18.68	18.05	16.73
DEATH	0	8	15.36	22.21	27.52
ALL	100	100	100	100	100

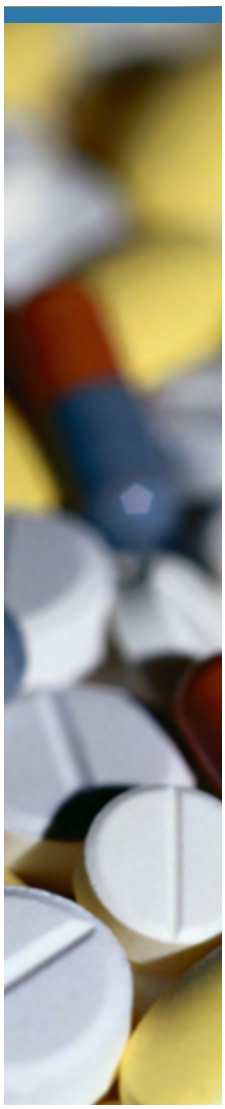
number of nursing procedures: preparation and change of bed clothes and the care of the perineum are held every 2 hours, while moving the patient in bed. Total costs for care without the use of absorbents and care products accounted for 10,165 rubles. As it can be seen in Table 3, the use of absorbents and care products for prevention is cheaper than their lack. The treatment of contact dermatitis and ulcers in stationary incontinent patient, using absorbents and care products, is cheaper than without their application (see Table 4 and 5).

Table 3. Total costs of prevention of dermatitis and ulcers in 1 patient (7 days)

GROUPS OF SERVICES	TOTAL COSTS WITH THE USE OF ABSORBENTS AND CARE PRODUCTS, EURO	TOTAL COSTS WITHOUT THE USE OF ABSORBENTS AND CARE PRODUCTS, EURO
HOTEL SERVICES IN HOSPITAL	106.65	106.65
NURSING SERVICES	104.45	248.35
ABSORBENTS	38.06	–
MEANS OF CARE	2.13	–
TOTAL	269.85	355

Table 4. Total costs for one patient with urinary incontinence, using absorbents and care products, with dermatitis or pressure ulcers (7 days)

GROUPS OF SERVICES	TOTAL COSTS FOR THE TREATMENT OF DERMATITIS OR PRESSURE ULCERS OF 1-2ND DEGREE, EURO	TOTAL COSTS FOR THE TREATMENT OF PRESSURE ULCERS OF 3-4TH DEGREE, EURO
HOSPITAL STAY	106.65	106.65
LABORATORY TESTS	6.30	12.31
THE USE OF INSTRUMENTS	2.57	4.40
CONSULTATION WITH SPECIALISTS	6.08	8.43
SERVICES FOR PREVENTION AND TREATMENT	18.47	60.40
DRUGS	1.83	41.51
NURSING SERVICES	104.45	109.06
ABSORBENTS	38.06	38.06
MEANS OF CARE	2.13	2.13
TOTAL	305.1	401.54



EVALUATION OF THE COST OF MEDICAL SERVICES WAS PERFORMED, AS DESCRIBED BY RSPOR, IN ACCORDANCE WITH THE MOSCOW REGIONAL HEALTH CARE FUND'S TARIFFS (2010)

Table 5. Total costs for one patient with urinary incontinence without the use of absorbents and care products who developed dermatitis or pressure sores (7 days)

GROUPS OF SERVICES	TOTAL COSTS FOR THE TREATMENT OF DERMATITIS OR PRESSURE ULCERS OF 1-2ND DEGREE, EURO	TOTAL COSTS FOR THE TREATMENT OF PRESSURE ULCERS OF 3-4TH DEGREE, EURO
HOSPITAL STAY	106.65	106.65
LABORATORY TESTS	6.30	12.31
THE USE OF INSTRUMENTS	2.57	4.40
CONSULTATION WITH SPECIALISTS	6.08	8.43
SERVICES FOR PREVENTION AND TREATMENT	18.47	60.40
DRUGS	1.83	41.51
NURSING SERVICES	248.35	248.35
TOTAL	390.25	482.04

Table 6. Costs of prevention and treatment of contact dermatitis and pressure ulcers in 1 patient with urinary incontinence for 20 weeks, rub

CYCLES OF RESEARCH	MODEL № 1		MODEL № 2
	RETAIL PRICES	RETAIL PRICES	
CYCLE 1 (4 WEEKS)	1079.40	1030.83	1419.96
CYCLE 2 (4 WEEKS)	1147.30	1098.73	1553.16
CYCLE 3 (4 WEEKS)	1077.40	1032.71	1474.69
CYCLE 4 (4 WEEKS)	999.56	958.47	1362.67
CYCLE 4 (4 WEEKS)	922.70	884.88	1254.43
TOTAL	5226.36	5005.62	7064.94

The treatment of contact dermatitis and ulcers in stationary incontinent patient, using absorbents and care products, is cheaper than without their application (see Table 4 and 5).

Overall costs of prevention and treatment of contact dermatitis and pressure sores in bed-ridden patient with urinary incontinence were obtained for 20 weeks by model 1 and model 2 simulations.

Sensitivity analysis was performed on model 1 and retail prices of absorbents and care were changed to wholesale prices. The results are shown in Table 6.

The sensitivity analysis showed that cost reduction in absorbent and care materials by 12.14 euro leads to total cost reduction by 220.74 euro.

Therefore, the prevention and treatment of contact dermatitis and pressure sores in patients with fixed incontinence is cheaper, when using absorbents and care products than without their use: the total cost, calculated on the Markov model for prevention and treatment of contact dermatitis and ulcers of 1-4 - degree in a still patient with urinary incontinence for 20 weeks with the use of absorbents and care products in retail prices amounted for 5,226.36 euros, while without their application - 7,064.94 euro. Consequently, the use of absorbents and care products for the prevention and treatment of contact dermatitis and ulcers in patients with fixed incontinence should be a dominant approach.

CLINICAL AND ECONOMIC RESEARCH FOR PHYSIOTHERAPY

ALMAG-01 – a magnetotherapy device for local effects on human body of pulsed magnetic field. The theoretical basis for the use of the instrument is the concept of change and the impact of changing the pulsating magnetic field, inducing electric currents in human body. The impact on the living system is activating the sub-molecular, molecular and supramolecular structures, with changes at the cellular, organ and systemic levels.

In several observational studies with a low degree of evidence, the efficacy and safe use of the ALMAG-01 device were demonstrated in patients with osteoarthritis. The patients reported good tolerability and, when assessing the overall clinical effectiveness of the technology to reduce the clinical symptoms and get better the general condition of patients, an improvement was seen in 79% of patients and a slight improvement - in 21% of patients. Deterioration of patient condition was not observed in any case. The device is widely advertised in the media and sold to the population for the treatment of joint diseases.

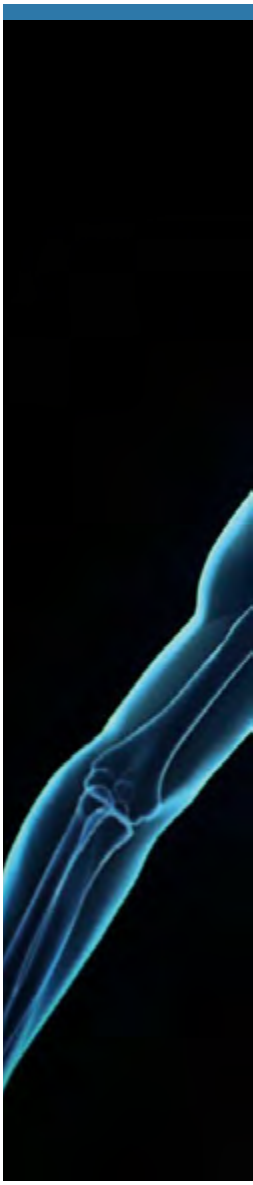
The purpose was to conduct clinical and economic analysis of the ALMAG-01 device in patients with osteoarthritis. To do that, criteria were defined to evaluate the effectiveness of magnetic therapy, a clinical study of the efficacy and safety of the ALMAG-01 device in patients with osteoarthritis was conducted, the direct medical costs of physiotherapy with the ALMAG-01 device were calculated comparisons were made, and clinical and economic analysis of the ALMAG-01 device was carried out.

Study Design: prospective, controlled, randomized, double-blind study. All the enrolled patients were divided into 2 groups: the main group used the ALMAG-01 device - in the control group, a placebo unit, similar in appearance and design was applied. The only difference was the absence of contact between the generator and effector of electromagnetic radiation.

The object of study - patients with gonarthrosis undergoing treatment in hospital. The period of observation of the patient - 21 days. Each patient filled physician clinical maps, which included data on costs of resources, tolerability and efficacy of treatments.

Two types of randomization were assumed: cluster (between centers) and randomization of patients directly at the clinical center. Cluster randomization was performed by employees of RSPOR, who prepared 6 sets of devices (4 sets, including ALMAG-01 and placebo, 1 set including 2 ALMAG-01 and 1 set including two placebo-devices). All devices in the sets were labeled with numbers “1” and “2” (random numbering by machines). The numbering was known only for the RSPOR employees. At the research center after, following patient recruitment, the doctor opened and envelope with the number of the machine on which the patient had been treated.

The study included men and women, aged 18 years and older, with gonarthrosis or coxarthrosis, except for severe (stage IV in X-ray), with informed consent of patient to participate in the study.



The following criteria were applied to assess the effectiveness of treatment: reducing the intensity of pain (visual analog scale), the intensity of functional disorders (6 scales from the International Classification of functional disorders (WHO, 2001) - mobility of several joints, total joint mobility, stability of several joints, the overall stability of the joints, walking short distances, walking long distances), the quality of life for EQ-5D. The angle of flexion and extension of affected joint and its circle were evaluated.

Data from 170 patient profiles were analyzed (75, used ALMAG-01, 44.1%, 95 used the placebo 55.9%). The groups were comparable at baseline in terms of knee joint and foot status and movement, except there were significantly more patients with no knee mobility disturbances in the main group, in comparison with the control group (8% vs. 1%, respectively, p <0.05). In the study group, the flexion angle was greater than in the placebo-treated group (about 71.88 and about 64.9, respectively), and the circumference of the affected joint was less (47.15 cm and 50.05 cm, respectively) than in the control group.

In the study group, there were significantly less patients with moderate or severe deterioration of the quality of life in terms of self-service (18.7% and 55.8%, respectively), and activities of daily living (61.3% and 80%, respectively). Despite the significant differences between groups in the proportion of patients who did not experience pain or discomfort, as well as having severe anxiety and depression, those differences did not affect the composite indicator - the proportion of patients with moderate or severe handicaps, which is the basis for the analysis. Quality of life scores on the visual analog scale were 0.51 (+ / -0.11, median - 0.50, 1st quartile - 0.45, third quartile - 0.60) in the intervention group and 0 , 59 (+ / -0.13, median - 0.58, 1st quartile - 0.50, third quartile - 0.70) in the control group.

The average duration of treatment in the study group was 13.2 + / - 5.2 days, median - 13 (1 quartile - 10, quartile 3 - 17) in the control group - 10.4 + / - 6.9 days, the median - 10 (quartile 1 - 3, quartile 3 - 17).

The test group showed a greater, but not statistically significant decrease in the volume of affected joint, as compared with the control group (3.9 cm and 2.9 cm, respectively), the affected joint flexion angle decreased in the intervention group by about 0.31, while in the control group, it increased by about 2.4. The angle of extension of affected joint increased in both groups, but the increase in the study group was larger, compared with the control group (-7.41 and -3.15, respectively).

Neither group differed in terms of the quality of life dynamics but the study group had less patients with moderate or severe disorders in

terms of pain or discomfort (38.7% and 62.1%, respectively). However, at the onset of the study, the parameters differed. The quality of life score on the visual analog scale was 0.62 (+ / -0.12, median - 0.63, 1st quartile - 0.5, third quartile - 0.7) in the intervention group and 0 , 69 (+ / -0.14, median - 0.70, 1st quartile - 0.60, third quartile - 0.75) in the control group. Change in the quality of life, measured on the visual analog scale in the study group was 0.11 points and 0,1 in the control group. Thus, significant differences were noted in the quality of life dynamics, as assessed by the EQ-5D visual-analog scale questionnaire..

No statistically significant differences were noted in the dynamic and functional parameters within the studied groups but the positive dynamics of joint mobility was indicated in pulmonary diseases and their absence was significantly more pronounced in the study group, compared with the control group (21.3% and 9.5%, respectively).

In the control group, a significant reduction in the proportion of patients with severe or moderate disturbances in terms of walking distance to 1 km (from 69.4% to 46.3%) and an increase in the proportion of patients with mild impairment of that ability (with 10.5% to 31.6%) were statistically observed. A comparison of both groups revealed that, in the „short distance walking" context, there were significant differences, depending either on the presence or the absence of pulmonary medical conditions (14.6 vs. 4.2%).

Thus, the ALMAG-01 DEVICE has a more significant influence on the quality of life component, associated with the presence of pain and discomfort, compared with the placebo device, what was not confirmed by the indicators of the EQ-5D questionnaire, where a greater effect was demonstrated when using the placebo. ALMAG-01 did not demonstrate any significant effect on the functional parameters (angle of flexion and extension, the amount of joint performance impairment). Opposite changes at different scales do not allow to speak of clinical benefits from the use of electromagnetic interference with the use of the ALMAG-01 device vs. placebo.

The total cost of keeping a patient in the study group was 186,86 euro, in the control group - 234.65 euro. Taking into account the hypothesis on electromagnetic field efficacy in the context of ALMAG-01 applications, one may perceive is as a cost-effective strategy, improving the quality of life by reducing severe and moderate pain sensations and aiding the comfort of patients.

In the study group, 327.80 euro were spent for reduction of moderate to severe quality of life violations, associated with pain and discomfort in 1 patient, which was almost twice lower than in the control group - 634.16 euro to achieve the same effect in 1 patient. ■

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