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Osteoarthritis: possibilities of complex use of the medication Zeel T within the framework of bioregulatory approach

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Abstract

Background: In the article it is considered the essence and possibilities of the bioregulatory approach in the therapy of osteoarthritis/osteoarthritis (OA) that is realized with the help of the use of complex bioregulatory medications (CBM) of the German company Biologische Heilmittel Heel GmbH. It is described in detail the composition and characteristics of the CBM Zeel T – the chondroprotective compound with a bioregulatory action. Zeel T is registered in the Republic of Moldova as a solution for injections, sublingual tablets and cream. Zeel T contributes to the restoration of the disturbed metabolic and reparative processes in the articular cartilage. There are considered important distinguishable moments of the mechanism of Zeel T action from the traditional chondroprotective compounds and its advantages. It should be noted that Zeel T has more than 40 years research history and it is widely used in more than 30 countries. Every year almost one million patients worldwide are treated with Zeel T. In the article it is presented the overview of clinical studies on the use of Zeel T at OA that demonstrate that Zeel T has comparable clinical efficacy with various traditional medicinal products (MP). **Conclusions:** It has also a good tolerability, does not cause characteristic for NSAIDs and corticosteroids (CS) side effects, and therefore can be used for a long time. The medicine is well combined with other medicinal products that increases the effectiveness and reduces the duration of the treatment course of OA.

Key words: Zeel T, bioregulatory approach.

Relevance of the bioregulatory approach

At the present moment, medicine considers the osteoarthritis/osteoarthritis (OA) as a degenerative-dystrophic process in the articular cartilage, at which there are noted pathologically altered areas of the cartilage and adjacent bone, in which it is disturbed the equilibrium between the degradation and synthesis processes that leads to destruction of the cartilage and a characteristic rearrangement of the subchondral bone plate [3, 15].

At the therapy of the OA are most widely used in the world chondroprotective compounds, NSAIDs, CS, less often – antioxidants, vitamins, minerals, osteotropic medical preparations (MP) and improving intraosseous and regional blood circulation, etc. [2,15]. However, at a long-term use, a number of MP cause various side effects – gastropathies, colitis, cardiomyopathy, influence on arterial tension indices, decrease of the filtration function of kidneys, toxic hepatitis, secondary osteoporosis, etc. [2,3,15]. The same happened also with the COX-2 inhibitors (selective NSAIDs). It turned out that in case of the decrease of analgesic effect, patients increase independently the single and, correspondingly, the daily therapeutic dose that leads to a sharp increase of side effects, including with a lethal outcome. Foreign experts note that this process has an uncontrollable character. The treatment of the OA is complicated also by age restrictions and inability of the use of traditional MP in this or that concomitant pathology. Development of the majority of undesirable side effects, the presence of limitations and contraindications is related to pharmacological paradigm of the accumulation of a certain concentration of the active substance in order to provide an impact on a certain “target” (for example, block-

ing of COX or certain receptors, occurrence of the excess of the administered substrate at the use of average therapeutic dose, without establishment of individual dose). The development of habituation and decrease of the effectiveness of MP is associated also with the paradigm of the use of large doses of active substance, the task of which is by the “force” of high concentration to keep control over the symptoms in the needed parameters.

In connection with this, there remains an urgent need to optimize the treatment regimens of the OA with the help of MP that have other mechanisms of action and allow ensuring simultaneously high efficacy and safety of treatment. Also, taking into consideration a high risk of the appearance of side effects and poor tolerability of MP at a long-term admission, it is also important the object of the reduction of the duration of their use [15].

As the world clinical experience shows, the above-mentioned tasks are solved successfully by the inclusion in the OA therapy regimens of complex bioregulatory medications (CBM) that were previously called in the literature as antihomotoxic medications (AHTM). The bioregulatory effect is exerted by ultra-small doses (USD) of the active substances of the CBM that are obtained with the help of homeopathic technology. This “pharmacology of ultra-small doses”, thanks to a different mechanism of action, introduces fundamentally new possibilities in the treatment regimens of the “pharmacology of large doses” (traditional MP), that at a correct and timely administration, makes it possible to improve significantly the effectiveness of standard therapy regimens. At the same time, the acceleration and quality of recovery is caused by the activation of the processes of self-healing/reparation, due to the launch of USD recovery of

Table 1

Use of the dosage forms of CBM Zeel T depending on the period of OA

Dosage form	Acute period, exacerbation	Continuation of treatment course
Solution for injections* (ampoules of 2,0 ml each)	1 amp. every other day №5	1 amp. 2 times/week - №5-10
Tablets (50 tabl. in container)	1 tab. sublingually every 30 minutes – 1 hour (15 minutes before meals or 1 hour after), up to 12 times per day, the first 2-3 days	1 tabl. 3 times/day
Cream (50 g in tube)	4-5 cm of cream to apply to the skin in the area of the affected joint and to rub in easily: up to 4 times/day in the first 2-3 days	To rub in 2-3 times/day (administration can be combined with phonophoresis, amplipulse)

*solution for injections is injected: intramuscularly, intraarticularly, subcutaneously and intradermally paraarticularly (circumarticularly) and at spondyloarthritis – paravertebrally.

self-regulation processes in the body [4-6,9,15]. Also, USD are not metabolized in the body and are not energy-consuming for it, and therefore do not have an additional pharmacological load on the body.

Characteristics of Zeel T

For treatment of the OA, in the capacity of basic CBM it is used the Zeel T. In the Republic of Moldova, the medication is presented in three dosage forms: injection solution, sublingual tablets and cream (during the last re-registration by the manufacturer there was specified the basis of the dosage form “ointment” and changed to “cream”). What is the difference between Zeel T and traditional chondroprotective compounds? It does not introduce various components of the connective tissue into the body but has a chondroprotective effect due to bioregulatory effect on the metabolism of chondrocytes and fibroblasts. It restores the efficiency of energetic and metabolic processes in them that improves the synthesis of the missing components of the articular cartilage.

At the same time Zeel T has an anti-inflammatory and analgesic effect. The inclusion of the given CBM in the standard therapy regimens improves the efficiency of the assimilation of connective tissue components that come with classical chondroprotective compounds [7,8,9,15].

Clinical efficiency of Zeel T was confirmed by numerous clinical studies: observational, cohort, prospective, multicentre, randomized, placebo-controlled, double-blind, in vitro [15].

The dosage and mode of administration of Zeel T are presented in the table 1.

Clinical researches

Italian scholars conducted a clinical study “Research of therapeutic efficiency and tolerability of antihomotoxic medication “Zeel T”, in which with the help of the method of diffractometric and polarising-microscopic investigation, before and after the course of intra-articular injections Zeel T, there were studied the samples of patients’ cartilages. After therapy, the structure of the cartilaginous tissue was significantly improved and no cases of poor tolerance were recorded. This confirms the pronounced chondroprotective effect of Zeel T [10].

The use of Zeel T in the form of ointment at degenera-

tive joint diseases was described by the German specialists in the study “Therapy of Degenerative Joint Diseases by the medication Zeel T – the results of a multicentre investigation of 498 patients”. At the evaluation of the tolerability of the ointment Zeel T in 95% of the cases there were registered the results “very good” and “good”. At the same time in 75.1% of cases, the effectiveness of therapy with the help of the given CBM was assessed as “good” and “very good”, in 17.5% – “satisfactory”, i.e. therapeutic effect was observed in 92,6% of cases. Whereby the highest score received the therapy of monoarthritis with the help of the ointment Zeel T – 76.1% of good and excellent assessments [7,15].

The efficiency of the medication Zeel T (tablets) in comparison with diclofenac was studied in 121 patients with gonarthrosis within the framework of a double-blind randomized study conducted by the German doctors. At the end of the 10-week course of therapy, there was noted a veracious clinical improvement of the mobility and functionality of the affected knee joint in both groups of patients. While the effect of the investigated CBM appeared to be equivalent to the efficiency of diclofenac, in case of the use of the latter there were noted repeatedly side effects (primarily – on the part of gastrointestinal tract). The fact that was not observed at the use of the medication Zeel T. It was concluded that the therapy of light and medium forms of gonarthrosis with the help of the medication Zeel T leads to a significant improvement of the mobility, reduction of pain sensations that improves the quality of life of patients [12].

The data of comparative study showed that to its effectiveness the periarticular injections Zeel T are comparable with intraarticular injections. The results of the therapy by periarticular injections were evaluated as good, the tolerance of the medication was assessed as excellent. It should be noted that at the execution of periarticular injections there is no risk of the contamination of joint. Thus, the injections Zeel T should be administered subcutaneously or intradermally, as close as possible to the affected joint [13].

By Lviv specialists in the work “Osteoarthritis of knee joints in patients with somatic pathology: experience of complex conservative treatment with the inclusion of AHTM” there was studied the possibility of the use of CBM (Zeel T and other CBM) in the therapy of the patients with the OA of knee joints with severe progressive chronic somatic diseases that limited the use of pharmacological allopathic

MP. The results indicate high efficiency, good tolerability and sufficient level of safety of the therapy by Zeel T and other CBM in patients with gonarthrosis of radiologic stages II-III. Also, the authors noted that the treatment with the help of CBM contributes to positive dynamics of clinical signs of acute inflammatory articular syndrome, reducing the pain and movement limitation, improving the functional capacity of joints and improving the quality of life of patients [14].

In the research thesis "Influence of glucocorticoids and antihomotoxic medications on articular cartilage at its mechanical damage in athletes" it was shown that intra-articular injection of the medication Zeel T in the early stages of the damage of articular cartilage of the knee joint causes the suppression of the development of degenerative-dystrophic process and positively influences the formation of chondroid tissue in the defect of articular cartilage [17].

In the research thesis "Treatment of gonarthrosis by homeopathic medication Zeel T in the conditions of polyclinic" there are presented comparative data of two schemes of the 4-week therapy of gonarthrosis in 80 patients. The 1st scheme: 40 people received NSAIDs, vascular medications, physiotherapy. The 2nd scheme: to 40 patients was additionally prescribed the medication Zeel T (tablets). The control of the results of the investigation was carried out according to clinical and ultrasound study of knee joints for 1 year. It is objectively proved that combination of allopathic therapy with the medication Zeel T gives a more pronounced and persistent therapeutic effect, manifested by the reduction of pain and improvement of the function of knee joints. The combination of traditional treatment with Zeel T is recommended in case of periarthrititis, tendinitis, mildly/moderately pronounced forms of synovitis and at their combination. The given thesis was awarded the International Prize of G.G. Reckeweg for 2001 [18, 19].

German scientists conducted a comparative study on the use of the medication Zeel T and hyaluronic acid for the therapy of gonarthrosis [21]. Both medications demonstrated similar therapeutic efficiency with a good analgesia, while side effects at the treatment with the help of Zeel T were 2 times less frequent (5,5%) than at the use of hyaluronic acid (11%). Also, the total cost of treatment course with the help of Zeel T was 2 times lower. In another study in Germany in the course of multicentre randomized blind controlled investigation there was carried out the comparison of the efficiency and tolerability of the medications Zeel T and hyaluronic acid in the treatment of the OA of knee joint. Within 5 weeks, patients received 10 injections of Zeel T or 5-of hyaluronic acid (2 groups of 57 patients in each). The therapeutic efficiency of Zeel T was recognized as equivalent to hyaluronic acid, not only in patients suffering of medium intensity pain, but also in patients with severe pain. At the same time, the use of Zeel T twice as less led to undesirable effects. The results of the given investigation confirm the favourable experience of the use of Zeel T, collected for many years [20].

At the department of traumatology and orthopaedics of the Lviv National Medical University there were elaborated methodical recommendations of the Ministry of Health of Ukraine on the application of CBM in the pathology of the joints and vertebral column: "Pathogenetically directed medicinal therapy of destructive-dystrophic diseases of the vertebral column and joints". It is noted that Zeel T contributes to the transfer of arthrogenic disease during the period of persistent remission, and the inclusion of CBM in the therapy schemes contributes to significant improvement of the results of treatment, makes it possible to reduce the dosage of allopathic MP, and in some cases, to cancel them [11].

Table 2

Combination of Zeel T dosage forms and dosage at different stages of OA

Stage of OA	Dosage form	Acute period, exacerbation	Continuation of treatment course	Repeated treatment courses (prevention of exacerbations)
Stage I	Tablets	To start with the initiation mode: 1 tab. every 30 minutes – 1 hour, up to 12 times a day, the first 2-3 days	Further to take 1 tab. 3 times/day, 5-7 weeks	- During 5-7 weeks - 2 times/year
	Cream	Up to 4 times/day in the first 2-3 days	Further 2-3 times/day	
Stage I-II	Solution for injections *	To start with the initiation mode: 1 amp. every other day, №5	-	- During 7-9 weeks - 2-3 times/year
	Tablets	-	1 tab. 3 times/day During 5-7 weeks	
	Cream	Up to 4 times/day in the first 2-3 days	Further 2-3 times/day	
Stage II	Solution for injections *	To start with the initiation mode: 1 amp. every other day, №5	2 times/week №5-10. Total for course: №10-15	- During 10-12 weeks - 2-3 times/year
	Tablets	-	After the course of injections: 1 tab. 3 times/day, 5-7 weeks	
	Cream	-	2-3 times/day	
Stage III	Solution for injections *	To start with the initiation mode: 1 amp. every other day, №5	2 times/week №10-15 Total for course: №15-20	- During ≈ 3 months - 3 times/year
	Tablets	-	After the course of injections: 1 tab. 3 times/day, 5 weeks	
	Cream	Up to 4 times/day in the first 2-3 days	2-3 times/day	

*solution for injections is injected: intramuscularly, intraarticularly, subcutaneously and intradermally – paraarticularly (circumarticularly) and in case of spondyloarthrosis – paravertebrally.

Practical recommendations

A faster and more pronounced clinical effect in the treatment of the OA is achieved by the combination of systemic and local dosage forms of the medication Zeel T: injections with cream and tablets with cream (recommendations in the table 2) [2,8,11].

Conclusions

On the basis of the properties of Zeel T and clinical studies [1-3, 7-15, 19-21], the following conclusions can be made:

1. Zeel T is a complex chondroprotective compound, which, unlike traditional chondroprotective compounds, has a different bioregulatory mechanism of action.
2. Zeel T has similar therapeutic efficiency with traditional MP.
3. Zeel T has a good tolerability, without causing herewith the side effects characteristic for NSAIDs and other MP.
4. The presence of three dosage forms of the medication Zeel T allows to choose for each patient the most optimal or to use the combination of them.
5. Zeel T can be used as a monotherapy or in combination with other MP that contributes to the reduction of the duration of treatment course and increase of its effectiveness.

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