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THE POSSIBILITY OF EFFECTIVE USING THE CONSERVATIVE AND THE MINIMALLY INVASIVE TREATMENT METHODS AT VARIOUS STAGES OF THE DUPUYTREN DISEASE

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ABSTRACT

A literature review is presented on the conservative and minimally invasive methods of treating the Dupuytren contracture. The investigators discuss both the methods implemented into clinical practice and those, which are currently at the stage of clinical and laboratory trials, including the minimally invasive methods, which can be used not only at the later stages, but also in cases of early manifestations of the disease. Among them there are the combined use of conservative methods, the radiation therapy, the injections of collagenase and steroids, the use of immunodepressive medicines and the needle aponeurotomy. These methods can be used at the earliest stages of the disease, however, the absence of proper evidence base often hinders their wide implementation. Up to the present moment, there is no commonly acknowledged approach to managing and treating the patients with early stage of the disease. The modern approach is focused on the invasive treatment of only later disease stages and of the severe contracture cases. This is why we would like to emphasize the potential of minimally invasive methods at the early stages of the Dupuytren disease, as well as the necessity of further research in this direction along with the importance of implementing such methods into everyday practice of the physicians.

Keywords: *Dupuytren contracture; palmar fibromatosis; needle aponeurotomy; percutaneous (needle) aponeurotomy.*

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INTRODUCTION

Dupuytren disease is a fibroproliferative disease, which affects the palmar fascia of the hand and results in the formation of the various degree fibrotic nodes and strands. Eventually, the disease may progress to developing a flexural contracture, which hampers and compromises the operation of the palm, decreasing the quality of life of the patients [1].

According to data from a comprehensive systematic review and meta-analysis with the total sample size of 6,628,506 individuals, conducted by a group of investigators from Iran, Great Britain and Malaysia, the occurrence rate of the Dupuytren disease worldwide is 8.2% (95% confidence level — 5.7–11.7), which confirms the worldwide topicality of the problem [2].

The most widespread methods currently used for the treatment of the Dupuytren disease include the needle aponeurotomy, the collagenase injections, the limited (segmental) fasciotomy (the gold standard) and the radiation therapy. The decision on using one of the methods should be based on the combination of factors, including the degree of contracture severity, the degree of joint involvement into the pathological process, the probability of recurrence and the complications, as well as the experience of the physician in performing the procedure [3]. The absence of pathogenetic therapy along with predominantly providing surgical aid to the patients that already have a disease degree of III–IV with the background of the currently available variety of treatment methods for this disease keeps the problem of recurrence very topical.

The provided review summarizes the updated data on the techniques of conservative and minimally invasive treatment of the Dupuytren disease at various stages of the disease, as well as on the options of the pathogenetic approach to solving this problem.

ВОЗМОЖНОСТЬ ЭФФЕКТИВНОГО ПРИМЕНЕНИЯ КОНСЕРВАТИВНЫХ И МАЛОИНВАЗИВНЫХ МЕТОДОВ ЛЕЧЕНИЯ НА РАЗЛИЧНЫХ СТАДИЯХ БОЛЕЗНИ ДЮПЮИТРЕНА

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АННОТАЦИЯ

Представлен обзор литературы по консервативным и малоинвазивным методам лечения контрактуры Дюпюитрена. Исследователи обсуждают как методы, внедрённые в клиническую практику, так и те, которые в настоящее время находятся на стадии клинических и лабораторных исследований, в том числе малоинвазивные методики, которые могут быть использованы не только на поздних стадиях, но и при ранних проявлениях патологии. Среди них комплексное применение консервативных методов, лучевая терапия, инъекции коллагеназы, стероидов, применение иммунодепрессивных препаратов, игольная апоневротомия. Эти методы могут применяться на самых ранних стадиях заболевания, однако отсутствие должной доказательной базы часто препятствует их широкому внедрению. До настоящего времени нет стандартов терапии пациентов с ранней стадией заболевания. Современный подход фокусируется на инвазивном лечении только поздних стадий заболевания с высокой степенью контрактуры. Поэтому мы хотим подчеркнуть потенциал минимально инвазивных методов на ранних стадиях болезни Дюпюитрена, а также необходимость дальнейших исследований в данном направлении и важность внедрения этих методов в повседневную практику врачей.

Ключевые слова: *контрактура Дюпюитрена; ладонный фиброматоз; игольчатая апоневротомия; чрескожная (игольная) апоневротомия.*

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CONSERVATIVE THERAPY OF THE DUPUYTREN DISEASE

Among the methods employed during the treatment of the early stages of the Dupuytren disease, there are manual methods, radiation therapy, injections of collagenase, steroids and immunodepressive medicines.

At the initial stages of the disease, many patients consider the primary conservative therapy as a treatment option. The latter includes using various types of ortheses, therapeutic exercises, laser and shock-wave therapy. According to the Dutch interdisciplinary guideline on Dupuytren disease, the primary conservative therapy can not be recommended as the primary treatment of the disease [4]. A systematic review of non-surgical treatment methods, conducted by our colleagues [5], shows that the combined use of conservative methods (ultrasound, nighttime splinting using wrist splints, stretching exercises and massage) at the early stage of the disease leads to the positive functional result (increased angle of active extension and the grip strength). Due to the qualitative and quantitative non-representativity of the sample in the provided trials, these methods cannot be considered evidence-based. The use of shock-wave therapy for decreasing the intensity of the disease symptoms was researched by the physicians of the Isfahan University and shows a tendency to decreasing the pain intensity within 14 weeks from the therapy date [6].

Radiation therapy

As of today, there are limited evidences of the efficiency of radiation therapy. The issue of the

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mechanism of action remains open for discussion, however, it is considered that the histological changes during the Dupuytren disease can be compared to the formation of keloid, while the mitotic cycle of the fibroblasts can be interrupted using radiotherapy, decreasing the development and the growth rate in the latter, as well as in the myofibroblasts [7]. A systematic review of the articles devoted to the use of this method [3] indicate that the most widespread daily radiation dosage was 30 Gr. According to data from J. Nanchahal et al. [5], doubtful results were obtained when using this method in more than 50% of the analyzed trials. The progression of the disease after radiation therapy is observed in 3–10% of the patients; also, the decrease of treatment efficiency was reported as the degree of the flexural contracture increases [8].

Among the main complications, skin dryness and redness were reported along with the erythema, edema and skin atrophy with telangiectasias. There were no reports on the radiation-induced malignant neoplasms, but the use of ionizing radiation does not rule out the probability of developing mutations. The risk calculations have demonstrated that, for medium age humans, radiation therapy increases the risk of deadly oncological process within the course of the statistical life expectancy by 0.02–0.05%. For younger individuals (aged up to 25 years), the risk percentage should be multiplied by 2, for elderly people (older than 60 years) — divided by 2.

Due to the low evidentiality, according to the Dutch interdisciplinary guideline, it is recommended to limit the application of radiation therapy to only clinical research.

MINIMALLY INVASIVE METHODS OF TREATING THE DUPUYTREN DISEASE

Collagenase injections

The *Clostridium histolyticum* collagenase is an injectable mixture of two purified collagenases (AUXI and AUXII), which predominantly cleaves type I and III collagen to form aminopeptide fragments, not interacting with the type IV collagen — the main component of the basal membranes of the blood vessels and of the epineurium.

The use of collagenase for the treatment of early stage diseases, due to its doubtful safety and efficiency, is not approved by the US Food and Drug Administration (FDA), just like in none of the European countries [9].

According to data from the double-blinded placebo-controlled trial [10], the registered findings included a decrease of the area and the density of the nodes. Two years of follow-up conducted by the American colleagues, demonstrate an improvement in the extension of the metacarpophalangeal joints by Δ=33.7°, of the proximal interphalangeal joints — by Δ=18° [11]. After three years of follow-up, the authors have reported the 16% rate of recurrences (defined as ≥20) for the metacarpophalangeal joints and 38% — for the proximal phalangeal joints, which has increased to 39% and 66%, respectively, to the end of 5 years.

The complications of using this method happen in approximately 80% of the patients. Among the most frequent ones are the swelling and the hematoma, the lymphadenopathy and the skin rupture. The rate of serious complications, such as tendon ruptures or neurovascular injuries, was reduced to the level of 1% [12]. When comparing to the open fasciotomy, lower complication rate was reported with the complications including neurovascular injuries and combined regional pain syndrome with the equal efficiency in terms of resolving the contracture and preventing recurrences [9]. The absence of certified collagenase medicines in some countries of Europe and Asia also acts as one of the main limitations for using this method.

Steroids

The justification of intranodular and intralesional injections of steroids was based on the early clinical and experimental research works exploring their inhibiting effects on the development of the connective tissue [13–15] and the degradation of mature collagen in the hypertrophic scars [16]. At the present moment, the largest trial is the retrospective review by L.D. Ketchum et al. [16], which included 63 patients (75 palms) with the early stage of Dupuytren disease. The patients were receiving injections at a dosage of 80–120 mg of Triamcinolon acetonide into each node with 6 weeks intervals. In 6 months, if necessary, the course could be repeated. The follow-up period lasted from 30 months to 27 years. The regression of the nodes by 60–80% was defined in 73 palms. In this group, there were no changes in the finger contractures. One patient with bilateral contracture (palms 74 and 75) has required surgical treatment. The repeated activation of the disease, leading to additional injections, has occurred in 50% of the patients in 1–3 years after the last injection. The adverse effects, including the transient depigmentation or subcutaneous atrophy in the injection area, which have resolved spontaneously

within 6 months after the last injection, were registered in 50% of the patients.

The use of hydrocortisone acetate in the treatment of the disease was studied by L. Zachariae et al. [14] within the research including 9 patients (9 palms) with the early stage of the disease, defined as palmar fibrosis without contractures or the contracture in all the joints of the finger by ≤30°. Six patients were receiving a total of 3 injections (25 mg), 1 patient — 2 injections of 50 mg, 1 patient — 2 injections of 10 mg, followed by 1 injection of 25 mg, and another patient had 2 injections of 25 mg. All the injections were given with an interval of 2–3 weeks within a period of 2–5 weeks. The follow-up period lasted from 2 to 24 months. The result was assessed clinically along with the subjective information on the decrease of pain with a background of decreasing dimensions of the nodes or their softening in all the cases. The recurrence was registered in 14 months in 1 patient who had two injections of 10 mg and a single 25 mg injections.

The research works evaluating the efficiency of intralesional injections of steroid medications are limited due to their insufficient number, due to the absence of blinded method or randomization, as well as due to using the subjective assessment of the results.

The research on the local application of steroids in cases of Dupuytren disease was described by the American colleagues in 1993 [17]. The research included 6 patients with the disease of interest and employed the local application of the Clobetasol cream twice daily and application of 0.1% Tretinoin before going to sleep. The average course duration and the details of the methods were not described by the authors. They have reported a positive treatment effect in all the patients expressed as the relief of pain and as the decrease of the contracture. No remote results of the research were provided.

The use of immunosuppressive medicines (Adalimumab, Pirfenidone)

The ideal therapy for Dupuytren disease should be aimed at the patients with the early stages of the diseases for preventing the progression and developing strands and further flexural contractures in the fingers. Currently, there is no approved therapy or the evidence-proven treatment in terms of the early stages of the disease.

Based on the results of examining the dissected fibrous tissue of the palmar aponeurosis from the patients, it was found that myofibroblasts in cases of Dupuytren disease get aggregated into nodules located near the affected joints, while the patients with later stages of the disease do not have such nodules [18]. The nodule contains the disseminated immune cells, including macrophages, T-cells and mast cells, with the nodular cells producing various cytokines — the interleukins (IL) 6 and 1β, the transforming growth factor beta (TGF-β) and the tumor necrosis factor (TNF). The comparison of the effects of each of these cytokines has shown that only TNF has turned the palmar fibroblasts of the Dupuytren disease patients into myofibroblasts with the observed low ex vivo concentrations, but not the non-palmar fibroblasts. On the contrary, TGF-β was unselectively turning all the fibroblasts into myofibroblasts. Unlike the TNF, other pro-inflammatory cytokines (IL-6 and IL-1β) did not affect the contractility of the cells. The Dupuytren myofibroblasts have demonstrated a dose-dependant decrease of their contractility during the treatment with anti-TNF with the concomitant decrease in the expression of the alpha-smooth muscle actin (α-SMA). All the approved anti-TNF agents that were clinically studied, were efficient in decreasing the contractility of the Dupuytren myofibroblasts *in vitro*, while the two completely human immunoglobulin G (IgG) molecules, the Adalimumab and the Golimumab, were shown as the most effective at the tested dosages [19].

The clinical and double-blind placebo-controlled research conducted by J. Nanchahal et al. [20], provides the evidence that the intranodular injections of 40 mg (0.4 ml) Adalimumab result in a significant decrease in the expression of α-SMA and I type procollagen, hence, the anti-TNF suppresses the phenotype of the myofibroblasts found in the Dupuytren nodules. Data from the next phase clinical research has allowed for supposing that the intranodular injections of Adalimumab can be efficient in delaying and preventing the progression of the early stage Dupuytren disease.

Due to the absence of the possibility to rule out the effects of the abovementioned TGF-β1 in the active recurrence of contractures in patients with Dupuytren disease, a group of American investigators [21] has studied the use of the TGF-β1 inhibitor (Pirfenidone) *in vitro*. It was found that Pirfenidone can inhibit the proliferation of cells and the contractions of the Dupuytren fibroblasts, also being able to suppress the expression of collagen and fibronectin — the two key components of the extracellular matrix in cases of the Dupuytren disease. The proven efficiency of Pirfenidone *in vitro* against the pathological fibroblasts

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in contracture patients can show similar *in vivo* efficiency, potentially softening the progression of the disease and its recurrence. The issue of the administration route for this medication for the purpose providing better effects in the target cells is still open for investigators.

Needle Aponeurotomy

Despite the short-term success of the open-access surgical methods, there are still cases of disease recurrences reported, as well as the presence of postoperative complications, such as delayed healing of the wounds and the vascular-neural damage. This has led to searching the minimally invasive treatment variants, including the transcutaneous needle aponeurotomy [22], which was done by means of mechanical disruption of the strands of cicatrically modified palmar aponeurosis at several levels using the percutaneous introduction of needles. The absence of radical excision of the palmar aponeurosis along with the absence of affecting the pathogenetical mechanisms of fibrosis results in high risk of recurrence (68%) [23].

With the development of plastic surgery in the treatment of Dupuytren contracture, the wide spreading was provided to the methods of combined surgical treatment with the transplantation of autologous adipose tissue — the lipofilling. The method includes the introduction (after previous needle aponeurotomy) of non-centrifugable sedimented lipo-aspirate at the volume of 8 to 10 ml to the supra-aponeurotic space [24]. The contents of the adipose tissue (which originates from the embryonic mesenchyma) in the adult human, besides fat cells, includes the so called stromal-vascular fraction cells: pre-adipocytes, endothelial and smooth muscle cells of the blood vessels, perivascular fibroblasts, the supporting fibrous collagen stroma and a number of immune cells, such as the adipose tissue macrophages. In the stromal-vascular fraction, a population of stem cells was found, showing the multi-linear differentiation potential, which are similar to the mesenchymal stem cells, originating from the bone marrow, which allows for using the stromal-vascular fraction of the adipose tissue for transplantation and tissue engineering. The easily available material (unlike the bone marrow) can be obtained in a sufficient quantity by means of lipo-aspiration of the subcutaneous fat under topical anesthesia [25]. The research conducted by A.A. Bogov et al. [26] on the application of the needle aponeurotomy combined with lipofilling, has demonstrated that, in patients with grade II–III contracture, the restoration of the palm functions in full range has occurred within the first 24 hours after surgery, and this was explained by the fact that the stromal cells of the adipose tissue (the adipose tissue-derived stromal cell, ADSC) inhibit the proliferation of contractible myofibroblasts, which are the key cells promoting the development of fibrosis. However, in patients with grade IV–V contracture, dermal ruptures were observed (due to the decreased elasticity of the skin), as well as the disease recurrences in 3 years after treatment (in 17% of the patients of the total number of examined individuals).

According to the Dutch interdisciplinary guideline on the Dupuytren disease, conducting the needle aponeurotomy is indicated to young patients willing to undergo minimally invasive interventions, as well as to elderly patients in case of the presence of the palpable strand with pointing out the high percentage of recurrences [4].

CONCLUSION

Currently, the surgical intervention for the treatment of the Dupuytren contracture is conducted only in case of later stages of the disease, in cases of significantly damaged functions of the palm. At early stages of the disease, taking into consideration the needs of patients for decreasing the post-operative pain, the faster restoration of the palm functions, and, respectively, its working capacity, as well as in cases of decreased quality of life after developing a severe contracture, there is a necessity of using the safe and effective treatment methods. Many of the described treatment methods show good results, helping in avoiding surgical interventions, simplifying the treatment and by this attracting the attention of the patients. For example, with the development of collagenase injections, the treatment of the Dupuytren disease has notably changed and started being more prone to the out-patient practice. Some patients in the hands of the experienced surgeons stay satisfied with the good result from the needle aponeurotomy, resulting in rapid recovery and helping with returning to everyday life. The detailed understanding of the molecular basis of the disease, the identification of TNF and TGF-β1 as a therapeutic target helps implementing a new pathogenetic approach with using the medicinal and cellular methods, capable of preventing both the progression and the recurrences of the disease.

Despite the presence of multiple publications describing the use of various minimally invasive methods, they often lack the clear pathogenetic and

biological justification, and the research works are starting to look empirical. The clinical results are reported without using the control groups, without blinding, bringing into question the benefits of the methods described. It is necessary to continue the conduct of more precise research works for better objectivization of the results from the conservative and minimally invasive approaches for the purpose of developing the standards of early treatment and prevention of contracture recurrences, as well as for preventing surgical interventions.

ADDITIONAL INFORMATION

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