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Long-Term Results of Medical and Surgical Methods for Elimination of the Internal Anal Sphincter Spasm in Chronic Anal Fissure (NCT03855046)

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Aim: evaluation of long-term results of injection of botulinum toxin type A into the internal anal sphincter and performing lateral internal sphincterotomy in combination with excision of chronic anal fissure.

Materials and methods. The study included 176 patients (73 (41.5 %) men and 103 (58.5 %) women) older than 18 years; randomization into the compared groups was carried out by random number generation in a computer program. Patients, researchers and surgeons were not blinded. Patients of the main group underwent fissure excision in combination with relaxation of the internal anal sphincter by botulinum toxin type A (BTA) at a dosage of 40 units, patients of the control group underwent lateral internal sphincterotomy (LIS) with excision of chronic anal fissure. Long-term results of complex treatment were studied in 126 patients (54 (43 %) men and 72 (57 %) women), the median follow-up was 12.3 (12.2; 15.7) months. Statistical analysis was carried out in the program Statistica 13.3 (TIBCO Software Inc., USA).

Results. In the long-term postoperative period, the indicators of mean resting anal pressure were lower in the LIS group ($p = 0.04$). The compared groups were comparable in terms of the level mean squeeze anal pressure ($p = 0.69$); however, in patients of the BTA group, the level of this indicator increased over time ($p = 0.001$). None of the patients of the compared groups had anal incontinence and relapse of the disease.

Discussion. In the framework of the performed study, in some patients from the compared groups, spasm of the internal anal sphincter persisted throughout the observation period, and in some patients it occurred again, while no signs of relapse fissure were detected. The functional and clinical results of treatment obtained by us cast doubt on the exclusivity of the increased tone of the internal anal sphincter as the main link in the pathogenesis of chronic anal fissure in some patients and indicates the presence of other factors in combination with which the course of the disease is determined. The above facts do not exclude the possibility of recurrence of anal fissure in a more distant period of observation.

Conclusion. Medical relaxation with botulinum toxin type A at a dosage of 40 units can serve as an alternative to lateral internal sphincterotomy as a method of eliminating spasm of the internal anal sphincter.

Keywords: anal fissure, internal anal sphincter spasm, botulinum toxin type A, lateral internal sphincterotomy, BTA, LIS

Conflict of interest: the authors declare that there is no conflict of interest.

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Отдаленные результаты медикаментозного и хирургического методов ликвидации спазма внутреннего анального сфинктера при хронической анальной трещине (NCT03855046)

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Цель исследования: оценка отдаленных результатов инъекции ботулинического токсина типа А во внутренний анальный сфинктер и выполнения боковой подкожной сфинктеротомии в сочетании с иссечением хронической анальной трещины.

Материалы и методы. В исследование были включены 176 пациентов (73 (41,5 %) мужчины и 103 (58,5 %) женщины) старше 18 лет; рандомизацию в сравниваемые группы проводили методом генерации случайных чисел в компьютерной программе. Ослепление пациентов, исследователей и хирургов не проводили. Больным основной группы выполняли иссечение трещины в сочетании с медикаментозной релаксацией внутреннего анального сфинктера ботулиническим токсином типа А (БТА) в дозировке 40 ЕД, пациентам контрольной группы — боковую подкожную сфинктеротомию (БПС) с иссечением дефекта анодермы. Отдаленные результаты комплексного лечения были изучены у 126 пациентов (54 (43 %) мужчины и 72 (57 %) женщины), медиана наблюдения составила 12,3 (12,2; 15,7) месяца. Статистический анализ проводили в программе Statistica 13.3 (TIBCO Software Inc., США).

Результаты. В отдаленном послеоперационном периоде показатели среднего давления в анальном канале в покое были ниже в группе БПС ($p = 0,04$). Сравнимые группы были сопоставимы по уровню среднего давления в анальном канале при волевом сокращении ($p = 0,69$), однако у пациентов группы БТА уровень указанного показателя повышался с течением времени ($p = 0,001$). Ни у одного из пациентов сравниваемых групп не было выявлено явлений недостаточности анального сфинктера и рецидива заболевания.

Обсуждение. В рамках выполненного исследования у некоторых больных из сравниваемых групп спазм внутреннего анального сфинктера сохранялся в течение всего периода наблюдения, а у части пациентов он возникал вновь, при этом признаков развития рецидива заболевания у них выявлено не было. Полученные нами функциональные и клинические результаты лечения ставят под сомнение исключительность повышенного тонуса внутреннего анального сфинктера как основного звена патогенеза хронической анальной трещины у части пациентов и указывают на наличие других факторов, в сочетании с которыми определяется течение заболевания. Вышеизложенные факты не исключают вероятность развития рецидива анальной трещины в более отдаленные сроки наблюдения.

Выводы. Медикаментозная релаксация ботулиническим токсином типа А в дозировке 40 ЕД может служить альтернативой боковой подкожной сфинктеротомии в качестве метода ликвидации спазма внутреннего анального сфинктера.

Ключевые слова: анальная трещина, спазм внутреннего сфинктера, ботулинический токсин типа А, боковая подкожная сфинктеротомия, БТА, БПС

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Introduction

Chronic anal fissure is one of the most common diseases of the coloproctological profile, which, due to the pronounced pain syndrome, leads to a significant decrease in the quality of life [1, 2]. The main link in the pathogenesis of chronic anal fissure is considered to be an internal anal sphincter spasm, which occurs during traumatization of the anoderm and prevents the healing of the defect [1, 3–5]. Thus, the treatment of the disease is primarily aimed at eliminating the increased tone of the internal anal sphincter [1].

Currently, lateral internal sphincterotomy is the traditional and most effective method of treating chronic anal fissure worldwide [6, 7]. In turn, dissection of the fibers of the internal sphincter entails irreversible changes in the obturator apparatus of the rectum and can lead to the development of postoperative anal incontinence reaching 35 % [4, 8].

In order to reduce the frequency of postoperative anal incontinence, alternative (medical)

methods for the elimination of internal anal sphincter spasm have been proposed, the most effective and safe of which is the injection of botulinum toxin type A into the internal anal sphincter [9, 10].

A randomized clinical trial was conducted on the basis of the Ryzhikh National Medical Research Center for Coloproctology, dedicated to comparing the excision of a fissure with injection of botulinum toxin type A at a dosage of 40 units into the internal anal sphincter and the excision of a fissure in combination with lateral internal sphincterotomy. The immediate results of treatment of patients from the compared groups were published earlier [9]. To assess the safety and effectiveness of the compared methods of influencing the increased tone of the internal anal sphincter in more distant follow-up periods, we studied the clinical and functional results of treatment of patients included in the study one year or more after surgical treatment (follow-up period — more than one year).

Materials and methods

From November 2019 to March 2022, a single-center, prospect *Figure 1*. Long-term (12.3 (12.2; 15.7) months) results of treatment of patients in the compared group *ive*, comparative, randomized clinical trial was conducted at the Ryzhikh National Medical Research Center for Coloproctology, registered on the website www.ClinicalTrials.gov (ID: NCT03855046). Patients, researchers and surgeons were not blinded.

The study included patients with chronic anal fissure older than 18 years with confirmed spasm of the internal anal sphincter according to anorectal profilometry. All patients signed an informed voluntary consent to participate in the study. Patients previously operated on the anal canal and rectum with anal sphincter insufficiency, stage 4 chronic hemorrhoids, inflammatory bowel diseases, pectinosis, and myasthenia gravis were not included in the study. If patients refused to participate in the study at any of its stages, as well as if the protocol was not followed, they were excluded from the study.

Patients with a diagnosis “chronic anal fissure with sphincter spasm” included in the study were randomized by random number generation in a computer program into the compared groups. The patients of the main group underwent fissure excision in combination with medical relaxation of the internal anal sphincter with botulinum toxin type A (BTA) at a dosage of 40 units. Patients of the control group underwent lateral internal sphincterotomy (LIS) with excision of the chronic anal fissure [9].

The primary control points of the study were: the frequency of transient anal incontinence on day 60 after the surgery according to the Wexner scale and the frequency of epithelialization the postoperative wound on day 60 after surgical treatment. Secondary points: intensity of pain syndrome in the postoperative period; frequency and structure of postoperative complications; duration of transient postoperative anal incontinence; indicators of the functional state of the obturator apparatus of the rectum (anorectal profilometry) for days 30 and 60 after surgical treatment and in the long-term postoperative period; duration of hospital stay; frequency of disease recurrence; frequency of transient anal incontinence in the long-term postoperative period in accordance with the Wexner scale [9].

In total, 176 patients completed the full scope of the study and met the requirements of its protocol. Long-term treatment results were studied in 126/176 (76 %) patients (54 men and 72 women) included in the study: group BTA — 67/88

(76 %) patients (27 men and 40 women; median age — 37.5 (32; 45) years); group LIS — 59/88 (67 %) (27 men and 32 women; median age — 39 (33; 52) years) (Fig. 1). The median follow-up of patients was 12.3 (12.2; 15.7) months.

In the long-term follow-up period, a telephone survey of patients was conducted in order to identify the presence of symptoms associated with the area of surgical exposure and incontinence of gases, liquid and solid intestinal contents in accordance with the Wexner scale [11].

According to the results of a telephone survey, none of the 126 patients of the BTA and LIS groups interviewed by phone (67/88 and 59/88, respectively) complained of symptoms associated with the area of surgery and with the anal incontinence in accordance with the Wexner scale (Fig. 1). All respondents were asked to come for a checkup and examination.

Among the patients of the compared groups, 41 patients (41/67 — the BTA group, 41/59 — the LIS group) showed up for a control examination. Patients underwent anorectal profilometry (functional assessment of the condition of the obturator apparatus of the rectum) on a Solar GI HRAM device (Netherlands). The presence of spasm of the internal anal sphincter was established with an increase in at least one of the following profilometry indicators: mean resting anal pressure (norm — 44.0–60.4 mmHg), maximum resting anal pressure (norm — 89.4–112.2 mmHg) [12]. To assess the functional state of the external anal sphincter, the indicators of mean and maximum squeeze pressure in the anal canal were used.

The above-mentioned patients who showed up for a follow-up examination underwent a physical examination, including an external examination of the perianal region and the anus, a finger examination of the rectum and anoscopy to diagnose a recurrence of chronic anal fissure and postoperative complications.

Statistical analysis was performed using the Statistica 13.3 program (TIBCO Software Inc., USA).

Results

Functional results

Mean resting anal pressure (MRAP)

In the long-term follow-up period (365 days), MRAP was lower in the LIS group ($p = 0.04$), and in patients of the BTA group the studied indicator increased statistically significantly compared to day 60 of the postoperative period ($p = 0.007$) (Fig. 2).

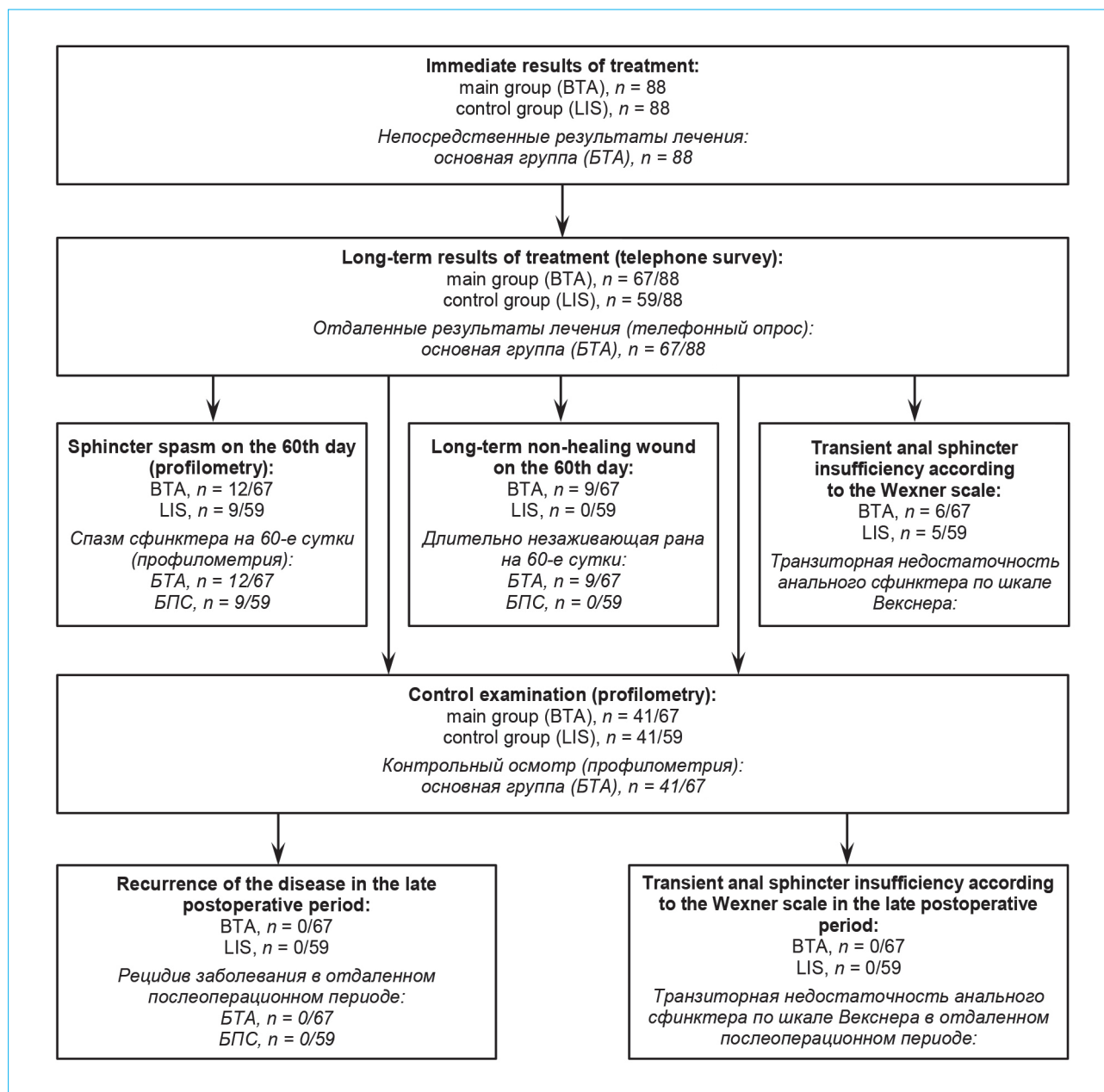


Figure 1. Long-term (12.3 (12.2; 15.7) months) results of treatment of patients in the compared group

Рисунок 1. Отдаленные (12,3 (12,2; 15,7) мес.) результаты лечения пациентов в сравниваемых группах

MRAP values were below the reference figures in 23/41 (56 %) patients of the BTA group on day 60 after the surgery. When assessing the dynamics of changes in the studied indicator on day 365 of follow-up, MRAP returned to reference values in 14/23 (61 %) patients, and in the remaining 9/23 (39 %) it remained reduced.

Among 18/41 (44 %) patients of the LIS group with reduced mean pressure in the anal canal at rest for 60 days, in the long-term follow-up period, only 3/18 (17 %) patients returned to the

standard values, in 1/18 (6 %) it turned out to be slightly higher than normal, and in 14/18 (78 %) it remained reduced.

Functional state of the internal anal sphincter

On day 60 after the surgery, internal anal sphincter spasm persisted in 10/41 (24 %) patients of the BTA group and in 6/41 (15 %) patients of the LIS group ($p = 0.4$) (Table 1). In the long-term postoperative period (365 days), the number of patients with spasm in the botulinum

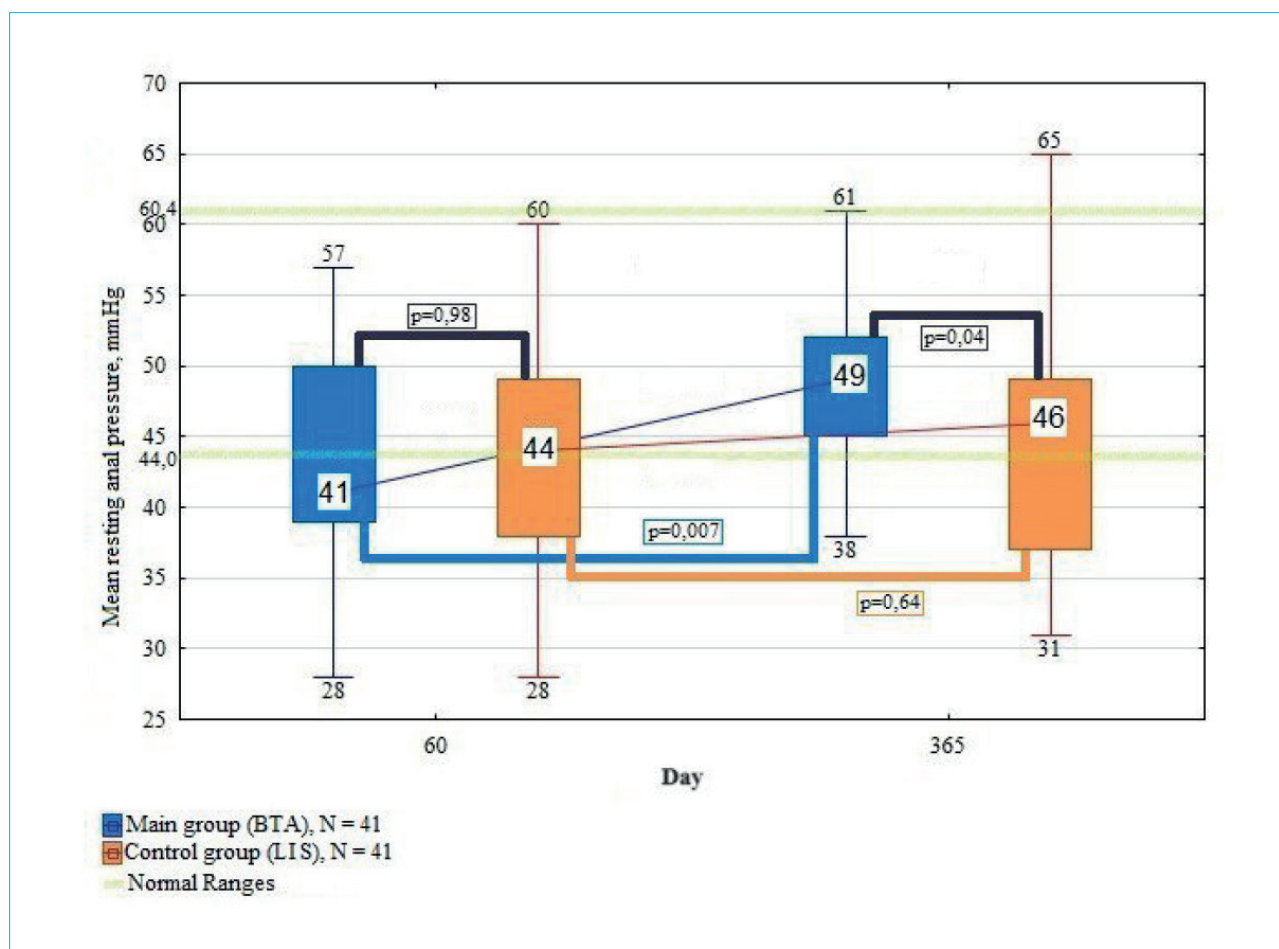


Figure 2. Average pressure in the anal canal at rest on day 60 of observation and in the long-term postoperative period (day 365)

Рисунок 2. Среднее давление в анальном канале в покое на 60-й день наблюдения и в отдаленном послеоперационном периоде (365-е сутки)

toxin group decreased to 9/41 (22 %), and in the sphincterotomy group remained unchanged.

However, according to the assessment of the presence of internal anal sphincter spasm in dynamics, the increased tone was not preserved in the same patients from the compared groups. After injection of neurotoxin in 10/41 (24 %) patients of the BTA group with spasm of the internal anal sphincter on day 60, it was not diagnosed by day 365 in 4/10 (40 %) patients. At the same time, among 31/41 (76 %) patients with the absence of spasm on day 60 after surgical treatment, in 3/31 (10 %) it reappeared in the long-term follow-up period.

A comparable picture of the dynamics of the presence of increased tone of the internal anal sphincter in the long-term postoperative period was also in the sphincterotomy group. After LIS in 6/41 (15 %) patients with internal anal sphincter spasm on day 60 of follow-up, in the long-term postoperative period it was not diagnosed in 4/6

of the observed. Of the 35/41 (85 %) patients who did not have increased sphincter tone on day 60, 4/35 (11 %) patients had it reappear on day 365 of follow-up.

Mean squeeze anal pressure (MSAP)

The compared groups were comparable in terms of the level MSAP in the long-term postoperative period ($p = 0.69$), however, in patients of the BTA group, the level of mean squeeze anal pressure increased in comparison with 60 postoperative days ($p = 0.001$) (Fig. 3).

Among 8/41 (20 %) patients of the BTA group with reduced MSAP on the 60th postoperative day, in 7/8 (88 %) of the observed patients, this indicator returned to reference values on day 365, and only in 1/8 (13 %) it remained below normal.

When assessing mean squeeze anal pressure in the LIS group in 6/41 (15 %) patients who had reduced values of the studied indicator on day 60

Table. Spasm of the internal anal sphincter in patients of the compared groups on day 60 of observation and in the long-term postoperative period (day 365)

Таблица. Спазм внутреннего анального сфинктера у пациентов сравниваемых групп на 60-й день наблюдения и в отдаленном послеоперационном периоде (365-е сутки)

Spasm of the internal anal sphincter Спазм внутреннего анального сфинктера	Day 60 / 60-й день			Day 365 / 365-й день		
	The BTA group Группа БТА n = 41	The LIS group Группа БПС n = 41	p	The BTA group Группа БТА n = 41	The LIS group Группа БПС n = 41	P
Yes / Да	10 (24 %)	6 (15 %)	0.4	9 (22 %)	6 (15 %)	0.57
No / Нет	31 (76 %)	35 (85 %)		32 (78 %)	35 (85 %)	

Note: BTA — botulinum toxin type A; LIS — lateral internal sphincterotomy.

Примечание: БТА — ботулинический токсин типа А; БПС — боковая подкожная сфинктеротомия.

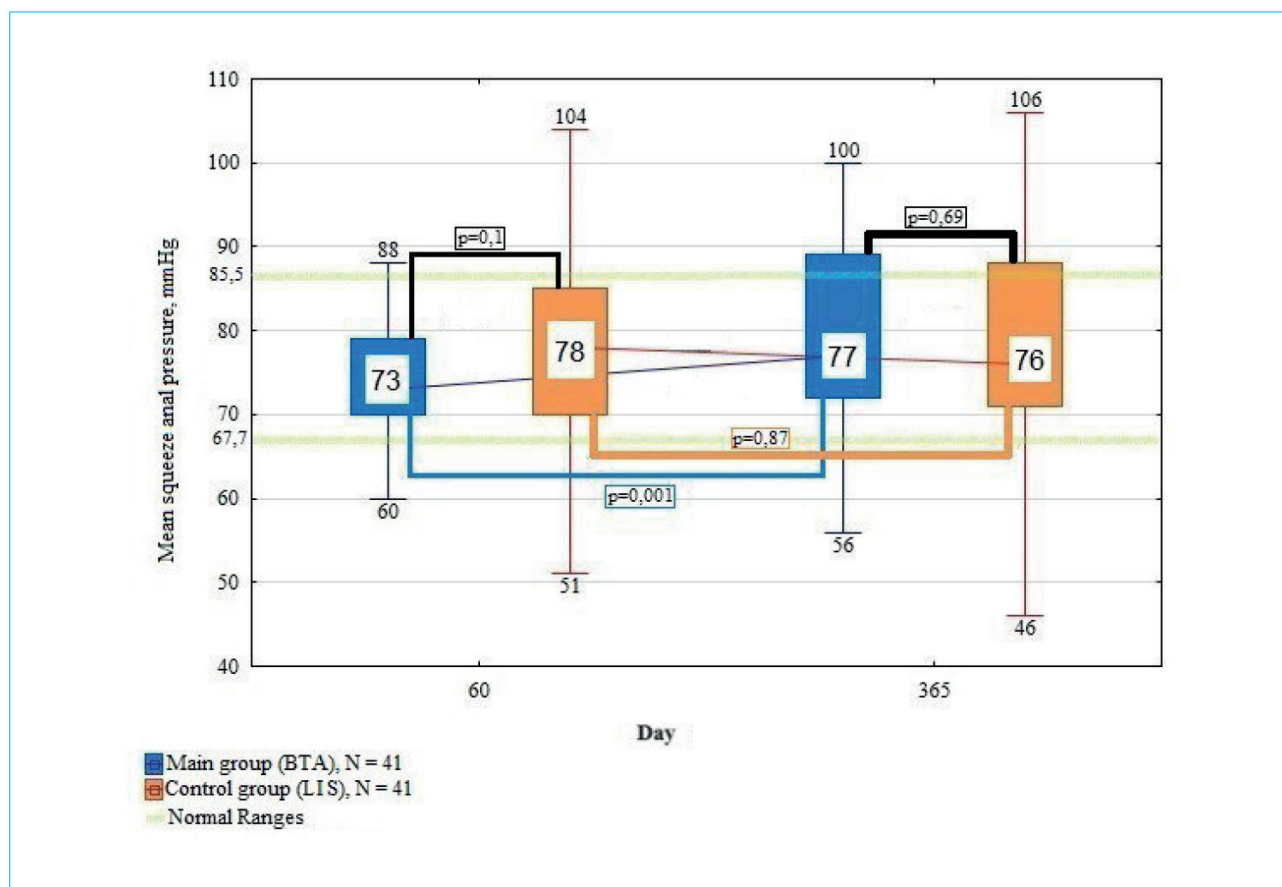


Figure 3. Average pressure in the anal canal during voluntary contraction on day 60 of observation and in the long-term postoperative period from day 60 to day 365 after surgery

Рисунок 3. Среднее давление в анальном канале при волевом сокращении на 60-й день наблюдения и в отдаленном послеоперационном периоде с 60-х по 365-е сутки после операции

of observation, in the long-term period, only in 1/6 (17 %) patient it returned to reference values, and in 5/6 (83 %) it remained lower norms.

Clinical results

According to an independent subjective assessment of the degree of anal incontinence by the subjects (41/67 patients of the BTA group,

41/59 patients of the LIS group) according to the Cleveland scale, none of the patients had anal incontinence (0 points according to the Wexner scale). Also, these patients showed no signs of relapse of the disease and internal anal sphincter spasm according to the results of physical examination (external examination of the perianal region, finger rectal examination and anoscopy).

Discussion

According to the literature, after injection of botulinum toxin type A into the internal anal sphincter the frequency of transient anal incontinence reaches 19 %, and after lateral internal sphincterotomy — 44 % [8, 13]. According to meta-analyses conducted by R. Nelson et al. and dedicated to evaluating the results of medical and surgical methods of the treatment chronic anal fissure, lateral internal sphincterotomy and other methods of eliminating internal anal sphincter spasm were comparable in frequency of development anal incontinence with a follow-up period of up to three years [14, 15]. Within the framework of the study, by day 365 of follow-up, the above phenomenon did not occur in any of the patients of the compared groups. The data obtained should be interpreted with caution, since they reflect to a greater extent the subjective assessment by patients of the degree of anal incontinence in accordance with the Wexner scale and may be associated with the lack of adequate understanding by patients of the concept of “norm” associated with the presence of severe pain syndrome for a long time before surgical treatment. Also, the absence of anal incontinence after irreversible mechanical action on the muscle fibers of the structures of obturator apparatus of the rectum may also be due to the compensatory capabilities of a particular patient, which does not exclude the risk of their development in more distant follow-up periods. On the other hand, such disparate results in terms of the frequency of development of anal incontinence may indicate the absence of a generally accepted technique for injecting botulinum toxin type A into the internal anal sphincter and performing lateral internal sphincterotomy, as well as the absence of objective control over the performance of surgical manipulations [4, 9, 12].

In the framework of previous studies, the relationship between the effectiveness of the treatment and the achievement of reference values anorectal profilometry was not evaluated, and the functional assessment of the presence of internal anal sphincter spasm was carried out using devices from various manufacturers, which causes a high heterogeneity of normative indicators [1, 5].

The heterogeneous functional results of treatment obtained by us, characterizing the function of the external and internal sphincters, were not accompanied by clinical manifestations of anal incontinence and the development of relapse of the disease in patients in compared groups. At the same time, in patients of the botulinum toxin group in the long-term postoperative period, a statistically significant increase in the level of mean

squeeze anal pressure was revealed with volitional contraction and to a lesser extent changes in indicators at rest than in patients of the sphincterotomy group, which confirms the temporary and reversible effect of neurotoxin in comparison with mechanical violation of the integrity of internal anal sphincter after lateral internal sphincterotomy.

The compared methods of treatment of chronic anal fissure are primarily aimed at eliminating spasm of the internal anal sphincter as the leading link in the pathogenesis of chronic anal fissure [1, 3, 16–18]. In the long-term postoperative period, there was a decrease in the number of patients with an internal anal sphincter spasm in the botulinum toxin group from 24 to 22 % and no changes in the frequency of its occurrence in the sphincterotomy group. At the same time, in the category of patients of the compared groups with increased tone internal anal sphincter persisting and reappearing in the long-term follow-up period, no signs of recurrence of chronic anal fissure were diagnosed during the follow-up period of 12.3 (12.2; 15.7) months. However, according to the results of our earlier metaanalysis, the recurrence of chronic anal fissure after BTA is 6 times higher than after LIS in the period of follow-up from 4.5 to 60 months [8]. Thus, in patients of the compared groups with an internal anal sphincter spasm, the occurrence of a relapse of the disease during traumatization of the anoderm in a more delayed follow-up period is not excluded due to ischemic phenomena occurring against the background of a persistent increased tone of smooth muscles.

The functional and clinical results of the treatment obtained by us cast doubt on exclusivity of the increased tone of the internal anal sphincter as a main link in the pathogenesis of chronic anal fissure in some patients, and indicates the presence of other factors in combination with which the course of the disease is determined. In the pathogenesis of anal fissure at various stages of its development, violations of reflex relaxation of external anal sphincter during defecation, infectious agents leading to the formation microabscesses and later ulcers in the anoderm area, fibrous changes in the internal anal sphincter leading to loss of its elasticity and permanent ruptures during the act of defecation can play a role [2, 7, 19, 20].

Conclusion

Medical relaxation of the internal anal sphincter with botulinum toxin type A at a dosage of 40 units in combination with fissure excision is an effective, minimally invasive and easily reproducible method in patients with chronic anal fissure,

and the reversible effect of botulinum toxin type A on the muscular structures of the obturator apparatus of the rectum significantly reduces the risk of postoperative anal incontinence. Injection of neurotoxin at a dosage of 40 units can serve as

an alternative to lateral internal sphincterotomy as a method of eliminating the increased tone of the internal anal sphincter and be used in a day hospital or a one-day hospital.

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