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Отдалённые результаты дезартеризации и мукопексии в лечении геморроя II–III стадии

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АННОТАЦИЯ

Обоснование. Малоинвазивное хирургическое лечение геморроидальной болезни в настоящий момент занимает лидирующие позиции. Однако необходимость использования ультразвуковой навигации HAL-RAR ставится под сомнение ввиду возможного пальцевого определения геморроидальных артерий, которые подвергаются лигированию.

Цель исследования — оценка отдалённых результатов лечения пациентов с геморроидальной болезнью при лигировании геморроидальных артерий в комбинации с мукопексией без ультразвуковой навигации в сравнении с традиционной методикой HAL-RAR.

Материалы и методы. Исследование носило рандомизированный контролируемый характер и включало 150 пациентов с II–III стадией геморроидальной болезни: в основной группе ($n=75$) выполняли дезартеризацию геморроидальных артерий путём пальцевого определения в комбинации с мукопексией; в контрольной группе ($n=75$) использовали традиционную методику HAL-RAR. Первичная конечная точка — частота рецидивов заболевания. Вторичными конечными точками были выраженность боли по 10-балльной шкале, удовлетворённость пациентов лечением, возобновление пролапса геморроидальных узлов и кровотечение.

Результаты. Статистически значимых различий по возрасту, полу, индексу массы тела, стадии и основным проявлениям геморроидальной болезни не отмечено. В сроки наблюдения до 12 мес группы не различались по возобновлению выпадения геморроидальных узлов ($p=0,49$), удовлетворённости результатом лечения ($p=0,95$), дискомфорту ($p=0,67$). Сохранение жалоб на периодическое выделение крови в основной группе составило 5,3%, в группе контроля — 17,3% ($p=0,037$). Болевой синдром через 2 мес после операции не отмечен ни в одном наблюдении. Рецидив заболевания на первом этапе оценки составил 8 (10,6%) и 22 случая (29,3%) соответственно. В средние сроки до 18 мес статистически значимых различий в удовлетворённости пациентов ($p=0,95$), дискомфорте ($p=0,89$) не получено, однако частота выпадения в основной группе составила 16,3%, в контрольной группе — 13,5% ($p=0,045$); кровотечения — 10,2 и 15,4% соответственно ($p=0,49$). Открытая геморроидэктомия выполнена 2 пациентам основной группы (2,6%) и 4 пациентам (5,3%) контрольной ($p=0,68$) из-за рецидива пролапса геморроидальных узлов.

Заключение. Дезартеризация геморроидальных артерий в комбинации с мукопексией без ультразвуковой навигации — безопасная, легко воспроизводимая методика, сравнимая по эффективности с методикой HAL-RAR в отношении отдалённых результатов, которая может быть рекомендована для лечения геморроидальной болезни II–III стадии.

Ключевые слова: геморроидальная болезнь; мукопексия; дезартеризация геморроидальных артерий; HAL-RAR.

Как цитировать

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Long-term results of dearterialization and mucopexy for stage II–III hemorrhoids

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ABSTRACT

BACKGROUND: Nowadays, minimally invasive procedures are mainly performed in the treatment of hemorrhoidal diseases. However, the feasibility of using ultrasound navigation for hemorrhoidal artery ligation-rectoanal repair (HAL-RAR) is still discussed because digital palpation of hemorrhoidal arteries for ligation is safe and easy to perform.

AIM: To evaluate the long-term results of HAL with mucopexy by digital examination in comparison with traditional HAL-RAR in the surgical treatment stage II–III hemorrhoidal disease.

MATERIALS AND METHODS: The controlled randomized trial included 150 patients with stage II–III hemorrhoidal disease. The study group ($n=75$) included patients who underwent surgery using digital palpation with mucopexy, and in the control group ($n=75$), the HAL-RAR was used. The primary endpoint was a recurrence of the main symptoms. Secondary endpoints included patient satisfaction and discomfort, pain intensity, prolapse of hemorrhoidal piles, and rectal bleeding.

RESULTS: The groups did not differ in sex, age, body mass index, and stage, and symptoms of hemorrhoidal disease. During the 12-month follow-up, no difference in the prolapse of hemorrhoidal piles ($p=0.49$), patient satisfaction ($p=0.95$), and discomfort ($p=0.67$) was found. Periodic bleeding occurred in 5.3% and 17.3% of the patients in the study and control groups, respectively ($p=0.037$). After 2 months of follow-up, pain recurred in 8 (10.6%) patients in the study group and 22 (29.3%) in the control group ($p=0.037$). At 18 months follow-up, no difference in patient satisfaction ($p=0.95$) and discomfort ($p=0.89$) was noted; however, the rate of hemorrhoidal prolapse was significantly higher in the study group (16.3%) than in the control group (13.5%) ($p=0.045$), and bleeding was reported in 10.2% and 15.4% of the patients in these groups, respectively ($p=0.86$). Open hemorrhoidectomy for relapse of hemorrhoidal prolapse was performed in 2 (2.6%) patients in the study group and 4 (5.3%) patients in the control group ($p=0.68$).

CONCLUSION: Ligation of hemorrhoidal arteries in combination with mucopexy without ultrasound guidance is a safe, easy, and reproducible technique, with comparable effectiveness, and long-term results to HAL-RAR. This procedure can be recommended for the surgical treatment of stage II–III hemorrhoids.

Keywords: haemorrhoidal disease; mucopexy; dearterialization of haemorrhoidal arteries; HAL-RAR.

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BACKGROUND

The working population aged 45–65 years most often seeks medical help for clinical manifestations of hemorrhoidal disease. This is the fourth most common pathology among all diseases of the gastrointestinal tract, with a prevalence in the Russian Federation of 130–145 cases per 1000 people. In most cases, patients are diagnosed with stage II of the disease (>40% of cases); stages I and III are less common (approximately 26% and 24%, respectively) [1].

Regardless of the stage of hemorrhoidal disease, its treatment starts with lifestyle modification, which includes a set of measures aimed at normalizing stool and nutrition, including avoiding alcohol and spicy foods and taking adequate fluids. Compliance with the above recommendations leads to a clinically significant improvement in the condition and refusal of surgical intervention in more than 60% of patients with manifestations of hemorrhoidal disease [2, 3]. However, in the absence of long-term effects from conservative measures, 10%–30% of patients undergo surgical treatment. Although open hemorrhoidectomy is the “gold standard” treatment for hemorrhoidal disease with a recurrence rate of up to 5%, minimally invasive techniques are currently of increasing interest [4].

One of the widespread and popular minimally invasive techniques that has already proven its effectiveness for treating stage II–IV hemorrhoidal disease is hemorrhoidal artery ligation (HAL) [5–7]. For better navigation, a transanal Doppler ultrasound probe is used to detect the terminal branches of the superior rectal artery (SRA). The advantages of this technique include low pain syndrome, elimination of bleeding, and short rehabilitation periods for patients [8–10]. The combination of this method with mucopexy (rectoanal repair, RAR), which involves suture fixation of prolapsed internal hemorrhoidal plexuses, was used to resolve hemorrhoidal prolapse [11, 12]. However, some researchers question the need to use ultrasound sensors owing to the high cost of the equipment, anatomical homogeneity in the location of the SRA terminal branches, and a sufficient simple transanal digital detection of the necessary structures for ligation and, accordingly, obtaining similar long-term treatment results [13, 14].

This study aimed to evaluate the long-term results of treatment of patients with hemorrhoidal disease with ligation of hemorrhoidal arteries in combination with mucopexy without ultrasound navigation compared with the traditional HAL-RAR technique.

METHODS

Study design

An interventional, single-center, prospective, controlled, single-blind, randomized study was conducted.

Compliance criteria

The exclusion criteria were intake of anticoagulants, presence of an anal fissure and rectal fistula, colorectal

cancer, pregnancy, and history of previous surgical interventions for hemorrhoidal disease.

Conditions

The study was conducted at the University Clinical Hospital No. 2 of the I.M. First Moscow State Medical University (Sechenov University) in the Diagnostic and Treatment Department of the Clinic of Coloproctology and Minimally Invasive Surgery from November 2018 to January 2020.

Study duration

The study was performed from November 2017 to January 2020. Long-term results were assessed at 12 and 18 months after surgery.

Description of medical intervention

Surgical interventions were performed with patients under subarachnoid (spinal) anesthesia. No preoperative preparation of the colon was conducted.

Navigation to detect pulsation of the hemorrhoidal arteries was performed using digital examination above the dentate line in the main group and using the ANGIODIN-Procto complex (BIOSS, Russia) and a disposable LDL-2 proctoscope from the same manufacturer in the control group.

After identifying the hemorrhoidal arteries, the first Z-suture was placed above the pulsation site, at least 2.0–2.5 cm from the dentate line, capturing the muscle layer and tightening the knot. Then, the mucopexy stage was conducted by forming 2–3 “steps” in the distal direction of continuous encircling stitches, capturing the rectal mucosa up to 0.7–1.0 cm wide and ending at least 8–12 mm proximal to the dentate line. The knot was tightened by plication starting from the last stitch and fixing it to the first seam. The suture material used in both groups was a 2/0 polyglycolide braided thread (70 cm) with a 5/8, 28-mm needle.

Primary research outcome

The main indicator that characterizes the safety and efficiency of the technique used is the incidence of disease relapses manifested by the return of clinical presentation of the disease.

Additional research outcomes

Among the long-term results, the intensity of pain syndrome, subjective satisfaction with the results of treatment on a 5-point Likert scale [15], resumption of clinical symptoms, and presence of discomfort were assessed.

Analysis of subgroups

All 150 patients included in the study were randomized into two groups. In the main group ($n=75$), suture ligation (desarterization) of hemorrhoidal arteries was performed with mucopexy without the use of ultrasound navigation of the terminal branches of the SRA with the Doppler effect, but using digital examination. In the control group ($n=75$), the traditional HAL-RAR technique (ultrasound) was used.

Methods of result registration

The main and additional indicators of the study were recorded by examining patients at follow-up appointments after surgery and using a questionnaire. Satisfaction with the results of treatment was evaluated on a 5-point Likert scale [15] and pain intensity on a visual analog scale.

Ethical considerations

All stages of the study comply with the legislation of the Russian Federation, international ethical standards, and regulatory documents of the research organization. The work was approved by the local ethics committee (meeting no. 10-19, October 17, 2017) and registered in the international clinical research platform ClinicalTrials.gov (no. NCT04119401).

Statistical analysis

Sample size calculation principle. All 150 patients included in the study were randomized using Research Randomizer v. 4.0 (Urbanik G.C., Plous S., 2013) into two groups of 75 people each.

Methods of statistical data analysis. Analysis was performed using IBM SPSS v. 23.0 (SPSS: An IBM Company, USA). The normality of the distribution was determined using the Kolmogorov–Smirnov test. Means and standard deviations were used to demonstrate the normal distribution

of indicators; non-corresponding values are presented as median and interquartile range. Comparison of quantitative data in groups was performed using the unpaired Student’s test and Mann–Whitney test, and that of categorical data comparison was performed using Fisher’s exact and Pearson’s chi-square tests. Differences were considered statistically significant at $p < 0.05$.

RESULTS

Subjects (participants) of the study

Patients aged >18 years diagnosed with stage II–III chronic hemorrhoids were consecutively included in the study after signing informed voluntary consent to participate in the study and ruling out another source of anorectal bleeding (total colonoscopy was performed).

The operated patients in both groups were comparable to age, sex, body mass index, and stages of hemorrhoidal disease (Table 1).

The main clinical symptoms of stage II–III hemorrhoidal disease include blood discharge, hemorrhoid prolapse during defecation, pain in the anus, or a combination of symptoms. No significant differences were found between the compared groups regarding complaints. Table 2 summarizes the main complaints of patients during their initial visit to a coloproctologist.

Table 1. Clinical characteristics of the patients

Indicators	Main group, digital control (n=75)	Control group, ultrasound (n=75)	p
Patient age, years	40.06±9.80	43.10±12.40	0.108
Body mass index, kg/m ²	24.33±4.10	25.26±4.80	0.254
M:F	40:35	43:32	0.495
Stage of hemorrhoidal disease, n/%:			
II	28/18.67	30/20.0	0.737
III	47/31.33	45/30.0	

Table 2. Main clinical symptoms of the study and control group

Primary complaints	Main group, n/%	Control group, n/%	p
Blood discharge	6/8.0	10/13.3	0.43
Prolapse of hemorrhoids	15/20.0	12/16.0	0.67
Blood and prolapsed hemorrhoids	20/26.6	24/32.0	0.6
Blood, prolapsed hemorrhoids and pain	8/10.6	9/12.0	1.0
Blood and pain	5/6.6	8/10.6	0.56
Pain	4/5.3	1/1.3	0.36
Pain and prolapse of hemorrhoids	9/12.0	5/6.6	0.4
Prolapse of hemorrhoids as a cosmetic defect	1/1.3	1/1.3	1.0

Main research results

The average follow-up period in the compared groups did not differ significantly ($p=0.62$) and was 13.95 ± 6.03 months in the main group and 14.48 ± 6.85 months in the control group. The minimum follow-up period in both groups was 6 months, and the maximum was 20 months.

During follow-up periods of up to 12 months, no significant differences were noted in the resumption of hemorrhoid prolapse, the degree of satisfaction with the result of treatment ($p=0.95$), or the severity of discomfort during defecation ($p=0.67$), which were designated by different patients as different symptoms experienced during defecation. Some patients used the term "discomfort" to refer to a burning sensation in the anal canal after defecation, whereas others referred to a pulling sensation in the anal canal. Pain syndrome was not noted in any patient during the 6–12-month follow-up period.

In the main group, significantly fewer complaints about periodic bleeding were observed compared with the control group (5.3% and 17.3%, respectively; $p=0.037$). The resumption of clinical symptoms such as a combination of symptoms (bleeding and hemorrhoid prolapse) did not differ significantly ($p=0.62$) in both groups; however, disease relapse such as manifestation of individual symptoms in the main group was recorded significantly less frequently. Table 3 shows the long-term results of treatment at follow-up stage 1.

At stage 2, long-term results were monitored in 101 patients; 49 patients (32.7%) were not contactable. The average follow-up period in the compared groups did not differ significantly ($p=0.62$) and was 18.95 ± 5.41 months in the main group and 19.48 ± 4.85 months in the control group.

In reevaluating the main parameters, no statistically significant differences in patient satisfaction, discomfort, and main clinical manifestations were observed. Table 4 presents the long-term results of treatment at stage 2 of follow-up.

In both groups, there was a tendency toward an increase in the frequency of anal discomfort after defecation and an increase in the incidence of recurrence of the main symptoms of the disease; however, in the main group, this dynamics was more pronounced and statistically significant. In contrast, indicators of quality of life with increase in the follow-up periods remain at a rather high level and do not differ statistically significantly between the main and control groups.

Table 5 reveals a comparative assessment of long-term results at stages 1 and 2 of treatment.

Adverse events

In the long-term follow-up period, surgical interventions were performed for relapse of the disease, namely, open hemorrhoidectomy in two cases in the main group (2.6%) and in four cases (5.3%) in the control group ($p=0.68$) due to complaints of prolapse of hemorrhoids. Additionally, one patient of the main group underwent thrombectomy from the external hemorrhoid because of the thrombus size, the intensity of the pain syndrome, and the short period of time that had elapsed since the development of thrombosis.

DISCUSSION

Summary of primary research result

The data obtained may indicate the efficiency of using digital "navigation" without the routine use of ultrasound

Table 3. Evaluation of the effectiveness of treatment, follow-up at 12 month

Evaluated parameters	Main group ($n=75$)	Control group ($n=75$)	p
Periodic hemorrhage, $n/\%$	4/5.3	13/17.3	0.037
Resumption of prolapse of hemorrhoids, $n/\%$	3/4.0	6/8.0	0.49
Discomfort during defecation, $n/\%$	14/18.7	12/16.0	0.67
Patient satisfaction (Likert scale), points	4.39 ± 0.76	4.39 ± 0.89	0.95
Disease relapse, $n/\%$	8/10.6	22/29.3	0.007

Table 4. Evaluation of the effectiveness of treatment, follow-up at 18 month

Evaluated parameters	Main group ($n=49$)	Control group ($n=52$)	p
Periodic hemorrhage, $n/\%$	5/10.2	8/15.4	0.437
Prolapse of hemorrhoids, $n/\%$	8/16.3	7/13.5	0.69
Discomfort during defecation, $n/\%$	10/20.4	10/19.2	0.89
Patient satisfaction (Likert scale), points	4.39 ± 0.74	4.42 ± 0.87	0.95

Table 5. Comparison of the long-term results at the 12- and 18-month follow-up of the study

Parameters	Follow-up period		<i>p</i>
	Twelve mon (n=150)	Eighteen mon (n=101)	
Anal discomfort, n/%:			
main group	75/9.46	49/20.4	0.07
control group	75/8.11	52/19.2	0.06
Prolapse of hemorrhoids, n/%:			
main group	75/5.3	49/16.3	0.045
control group	75/12.0	52/13.5	0.51
Bleeding from hemorrhoids, n/%:			
main group	75/6.6	49/10.2	0.35
control group	75/21.3	52/15.4	0.86
Quality of life, score:			
main group	4.38±0.76 (n=75)	4.39±0.74 (n=49)	0.88
control group	4.41±0.89 (n=75)	4.42±0.87 (n=52)	0.70

with the Doppler effect, with the possibility of suture ligation together with mucopexy of the main complexes of hemorrhoidal tissue.

Discussion of the primary research result

Minimally invasive techniques for treating hemorrhoidal disease, or “no-incision” surgeries, have become more attractive for patients owing to the absence of wounds in the anal canal, less pronounced and prolonged pain in the postoperative period, short rehabilitation period, and quick return to work activities.

Farag [16] proposed mucopexy (suture ligation of the hemorrhoid with its fixation in the anal canal in the “anatomical position,” above the dentate line) as an alternative to traditional methods of open and closed hemorrhoidectomy. The development of fibrous tissue at the site of the sutured hemorrhoidal pile subsequently ensured its natural fixation, thereby eliminating prolapse. The results of using this method with an average follow-up period of 10 years or more confirmed its efficiency and safety. Despite the low rate of disease relapse (no more than 8%), recurrence of prolapse (7%), and high patient satisfaction (up to 90%), thrombosis of hemorrhoids in the early postoperative period was a specific complication of this procedure [17–19]. Thus, this procedure has only one drawback: it is performed only under the control of the surgeon’s eyes, who is oriented toward anatomically enlarged hemorrhoids.

Morinaga et al. [6] proposed the disarterization of hemorrhoidal arteries using a transanally inserted ultrasound sensor under Doppler ultrasound control. The effectiveness of this procedure is based on the pathogenetically substantiated detection and ligation of the SRA terminal branches, which number, according to various authors, can vary from 6 to 16, which reduces blood flow in the arteries [20, 21]. However, the rate of disease relapse in this case can reach 35% within 5 years after surgery [22].

Giordano et al. [23] published the first systematic review, which included 17 articles from 1995 to 2008. The incidence of prolapse ranged from 0% to 37%, bleeding up to 21%, and the severity of pain did not exceed 3–4 points and was observed only in 18% of patients.

In 2007, by modifying and combining two surgical techniques to form the combined HAL-RAR method, the results of treatment of the first 112 patients were demonstrated: satisfactory results in 78% of patients with prolapse, disappearance of bleeding in 95%, and elimination of pain in 96% of cases [24]. In a multicenter study, Infantino et al. [20] demonstrated a relapse rate for treating stage II–III hemorrhoidal disease of up to 14.3%, whereas in other studies, the rate of prolapse ranged from 5% to 17% [25–27]. The combination of methods possibly ensured the elimination of the two main symptoms of hemorrhoidal disease (bleeding and hemorrhoid prolapse) against low pain syndrome.

Furthermore, some studies [28] indicate that the incidence of disease relapses in the form of prolapse and hemorrhoidal bleeding increases with follow-up time and at a higher stage of hemorrhoidal disease, which is confirmed by the long-term results of our study. However, given the fact that increasing the number of ligated arteries to 16 and even ligating 6 arteries (under ultrasound guidance according to the HAL-RAR protocol) does not cause a decrease in the frequency of disease relapses, the surgeon’s finger can act as an “ultrasound sensor,” allowing detection of up to three arteries, on average, which corresponds to the location of hemorrhoids at typical points with the disease recurrence incidence not exceeding 3% [13, 21, 22, 29–31].

Study limitations

Limitations of this study include the follow-up time and loss of contact with 23% of respondents.

CONCLUSION

Ligation of hemorrhoidal arteries along with mucopexy without ultrasound navigation using the Doppler effect is a safe and easily reproducible technique. It is a minimally invasive intervention comparable in efficiency to the HAL-RAR technique in terms of long-term results and can be recommended for the treatment of stage II–III hemorrhoidal disease.

ADDITIONAL INFORMATION

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