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Treatment outcomes for grades I-II chronic hemorrhoids using the bipolar vaporization method

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Minimally invasive methods for the treatment of chronic hemorrhoids are a crucial component of modern proctology. However, they do not always provide optimal outcomes due to recurrences, complications, and the need for repeat procedures. Some methods have limited accessibility due to high requirements for physician expertise and expensive equipment, highlighting the need for improved approaches.

Objective — to evaluate the efficacy and safety of bipolar vaporization for treating grades I—II chronic hemorrhoids.

Materials and methods. The study included 32 patients (19 men and 13 women) aged from 19 to 70 years with chronic hemorrhoids of grades I—II that were resistant to conservative treatment. The duration of chronic hemorrhoids ranged from 1 to 20 years, with an average of 6.8 ± 4.5 years. The bipolar vaporization procedure was performed using the Ukrainian-made bio-welding generator EK-300M «Sarmed.» The primary endpoints included assessment of hemorrhoid symptoms, complications, patient satisfaction with treatment outcomes, and recurrence rates.

Results. Persistent bleeding and/or node thrombosis were the primary indications for surgery in 100 % of patients, affecting 14 patients (43.8 %). Intraoperative blood loss did not exceed 20 ml, with an average of 8.3 ± 3.7 ml. The mean duration of the procedure was 44.3 ± 7.1 minutes. The average number of ketorolac doses on the first postoperative day was 1.4 ± 0.9 doses (ranging from 1 to 4 doses), and on the second day, 1.8 ± 0.8 doses (ranging from 1 to 3 doses). The mean hospital stay was 2.3 ± 0.5 days (2 to 3 days), and the average period of incapacity for work was 5.8 ± 0.7 days (5 to 7 days). On the 7th postoperative day, 65.6 % of patients reported pain, but its intensity was low (1.62 ± 0.7 points, p = 0.003). At 6 weeks and 1 year postoperatively, none of the patients reported pain. After one year, 96.9 % of patients were free of prolapse, itching, or soiling, and bleeding was absent in all cases. Patient satisfaction after one year averaged 8.31 ± 0.74 points. Recurrence occurred in 3.1 % of patients.

Conclusions. Bipolar vaporization is an effective and safe method for treating chronic hemorrhoids of grades I—II, providing significant symptom relief, minimal blood loss, and a short recovery period. The method demonstrates a high level of patient satisfaction and a low recurrence rate. The study results confirm the high efficacy and safety of this method, making it a promising approach for the treatment of chronic hemorrhoids.

Keywords
chronic hemorrhoids, treatment, minimally invasive technologies, bipolar vaporization method, outcomes.

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Chronic hemorrhoids (CH) are among the most common anorectal disorders worldwide. According to a national medical survey in China, standardized detection rates for hemorrhoids were 17.7 % among men and 43.7 % among women [29]. In 1990, hemorrhoids affected 5 % of the U. S. population, while more recent studies report an incidence rate of 13—16 % [9, 12, 20]. In Austria, 38.93 % of the population is affected by hemorrhoids [30]. The peak age for hemorrhoid development is 45—65 years, with up to 50 % of individuals over 50 experiencing problems related to hemorrhoidal disease [15, 31]. Among patients undergoing colonoscopy as part of colorectal cancer screening programs, the prevalence of hemorrhoids was 38—39 %, with 55 % of cases being asymptomatic [27, 30].

According to Goligher's classification [6, 16], the majority of CH patients have grade I (72.89 %) and grade II disease (18.42 %), while grades III and IV account for 8.16 % and 0.53 %, respectively [30].

Guidelines and recommendations emphasize three main categories for CH treatment: conservative, instrumental, and surgical approaches [3, 9, 10, 13, 34, 35]. Conservative treatment is considered an integral part of managing all CH grades. However, definitive treatment often requires additional interventions.

Following medical treatment, the next therapeutic step for patients with symptomatic persistent grades I and II hemorrhoids resistant to conservative management typically involves minimally invasive procedures performed in either outpatient or inpatient settings. These procedures include rubber band ligation [29], sclerosing injections [14], transanal hemorrhoidal dearterialization [37], emborrhoid therapy [4], and thermal destruction methods such as infrared photocoagulation [33], laser coagulation [22, 23], radiofrequency ablation [21], and bipolar coagulation [32].

These methods reduce the vascularization of hemorrhoidal tissues, eliminate excess tissue, and minimize prolapse through ablation or fixation to the rectal wall.

Despite their effectiveness, these techniques have several specific drawbacks. They may require multiple sessions, cause pain or complications, and are often costly, technically demanding, and associated with high recurrence rates [3, 9, 10, 13, 34, 35].

As a result, there is currently no consensus on the prioritization of specific minimally invasive techniques for treating grades I—II CH, emphasizing the need for further research in this area.

Vaporization, also known as tissue evaporation, is a method of thermal tissue destruction used in medicine. This method has gained wide application in urology [8, 18] and gynecology [1], demonstrating excellent results. There is also evidence of its high efficacy in treating varicose veins in the lower extremities [5]. Given its technical characteristics and energy delivery mechanism, this method could potentially be applied for hemorrhoid treatment. However, the currently available research lacks data on the use of vaporization for this purpose.

Objective — to evaluate the efficacy and safety of the bipolar vaporization method for treating grades I—II hemorrhoids.

Materials and methods

The study included 32 patients: 19 men (59.4 %) and 13 women (40.6 %), aged from 19 to 70 years (mean age: 43.3 ± 14.7 years), with complicated CH grade I (10 patients, 31.3 %) and grade II (22 patients, 68.8 %) resistant to conservative treatment. The duration of CY history ranged from 1 to 20 years, with a mean duration of 6.8 ± 4.5 years.

Bipolar vaporization procedure

Ukraine has developed a unique energy source for bipolar coagulation, the bio-welding generator «Svarmed» EK-300M (Fig. 1, 2). Its technical characteristics facilitate the vaporization of hemorrhoidal nodes (HNs).

For the bipolar vaporization (BPV) of HNs, patients were placed on the operating table in the lithotomy position. Anesthesia was provided using spinal (22 patients) or epidural anesthesia (8 patients). In cases where these methods were contraindicated, general anesthesia was used (2 patients).

Antibiotic prophylaxis was performed in all patients by administering a single dose of broad-spectrum antibiotics 40 minutes before surgery and again in the evening on the day of surgery. The surgical field was prepared using a 10 % solution of

Figure 1. **Bipolar single-shaft electrode**

Figure 2. **Tissue welding device «Svarmed» EK-300M**

betadine or povidone-iodine, or a 0.05 % aqueous solution of chlorhexidine bigluconate.

The procedure began with the creation of a hydroanesthetic cushion at the typical locations of hemorrhoidal complexes, corresponding to the positions of 3, 7, and 11 o'clock on a standard clock face. This step improved the conductivity of the bipolar energy effect and enhanced the visualization of hemorrhoidal complex structures during the procedure.

The next stage involved sphincter dilatation using a rectal speculum, followed by antiseptic treatment of the rectal lumen with appropriate solutions. After identifying the HNs, a rectal speculum or a hemispherical anoscope was introduced into the anal canal.

The «vascular pedicle» of the HN was observed 1—2 cm from the dentate line or 3—4 cm from the transitional fold of the anal verge. It was ligated into the mucosal and submucosal layers of the rectal wall using absorbable monofilament sutures. Suturing was performed sequentially, twice from top to bottom, with 1.0—1.5 cm spacing between the stitches. After tying the suture, the «pedicle» of the node contracted, elevating the node by 1.0—1.5 cm upward, as schematically illustrated in Fig. 3.

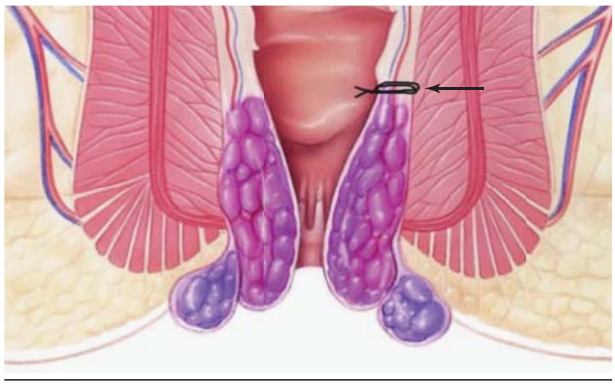

Figure 3. **Schematic representation of the dearterialization suture. Ligature on the pedicle of the hemorrhoidal complex is indicated by arrow**

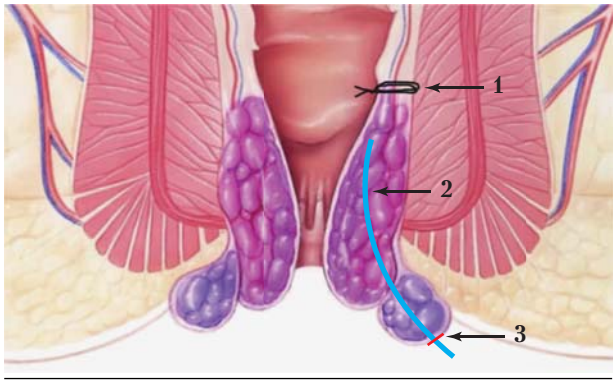

Figure 4. **Schematic representation of the placement of the bipolar electrode:** 1 — BPV of the hemorrhoidal node with a ligature on the vascular pedicle; 2 — a specialized bipolar electrode inserted into the hemorrhoidal complex; 3 — skin incision allowing electrode insertion into the hemorrhoidal complex

It should be noted that extending the suture beyond the dentate line is not recommended, as it can provoke postoperative pain syndrome.

Next, a linear incision of the skin, approximately 3—4 mm, was made at the external edge of the hemorrhoidal complex. Under manual guidance, a specialized bipolar electrode was inserted into the hemorrhoidal complex (Fig. 4).

The stage of direct BPV of the hemorrhoidal complex was performed using the «Svarmed EK-300M» device (see Fig. 2).

Vaporization was performed in the automatic welding mode pre-programmed in the device's system, with an exposure time of 20 seconds. The electrode was gradually withdrawn from the HN with careful movements to ensure complete vaporization of all vascular structures within the hemorrhoidal complex.

The completion of the vaporization cycle was pre-set by the manufacturer, and the device provided an automatic signal upon completion.

For pain management in the early postoperative period, ketorolac was prescribed. A single dose of ketorolac consisted of 30 mg of the medication.

Inclusion criteria

- Symptomatic CH of grades I—II according to Goligher's classification [6, 16], resistant to conservative treatment.
- Age 18 years or older.
- Absence of severe comorbid conditions (ASA class 4).
- Patient consent for surgical treatment and outpatient follow-up in the postoperative period.

Exclusion criteria

- History of infectious or undifferentiated colitis within the last six months prior to screening.
- Malignant neoplasms of the rectum and anal canal; inflammatory diseases of the rectum.
- Exacerbation of other chronic gastrointestinal diseases, such as pancreatitis, cholecystitis, hepatitis, gastritis, colitis, or acute surgical pathology.
- Positive HIV/AIDS status.
- Chronic diseases of the nervous system.
- Chronic diseases of the circulatory system.
- Systemic diseases.
- Endocrine pathology.
- Mental disorders.
- Autoimmune diseases.
- Cardiac and renal failure.
- Unstable psychological readiness of the patient to undergo the study.

- Presence of harmful habits (substance abuse).
- Logistical issues (failure of patients to attend timely examinations) or non-compliance with the recommended diagnostic and treatment plan.

The effectiveness of BPV of HNs was evaluated using parameters established for hemorrhoidal disease treatment in the international Delphi study [36].

The primary endpoint of the study was the «Hemorrhoid symptoms» domain, which included pain, prolapse, itching, soiling (leakage or discharge of small amounts of mucus, liquid stool, or contamination of the perianal skin), and bleeding (presence of blood in stool during defecation).

Secondary endpoints included the following domains: «Complications» (incontinence, abscess, urinary retention, anal stenosis, and fistula), «Recurrence»: the reappearance of initial symptoms reported by the patient and «Satisfaction»: patient satisfaction with surgical outcomes.

The «Hemorrhoid symptoms» domain was scored on a scale from 0 (no symptoms) to 9 (maximum discomfort).

The «Complications» domain included: incontinence: assessed using the Wexner incontinence Scale [19]; abscess and anal stenosis: determined via physical examination; urinary retention: diagnosed using ultrasound; fistula: identified with MRI in cases of inconclusive physical examination results.

The «Satisfaction» domain was scored from 0 (no satisfaction with the procedure) to 9 (maximum satisfaction with surgical outcomes).

«Recurrence» was defined as the reappearance of initial symptoms reported by the patient.

Evaluation time points for «Symptoms» and «Satisfaction» domains were evaluated at the following time points: pre-procedure (baseline), 7 days, 6 weeks, and 1 year after the procedure. Abscess and urinary retention were assessed 7 days after the procedure. Anal stenosis, incontinence, and fistula were evaluated 1 year after the procedure. «Recurrence» was determined at 1 year after the procedure.

Statistical analysis

Data analysis was performed using IBM SPSS Statistics 22.0.

For comparing two independent samples, the Student's t-test was applied for normally distributed variables, and the Mann–Whitney U test was used for non-normally distributed variables. For comparing two dependent samples, the paired t-test or Wilcoxon signed-rank test was employed, as appropriate. For categorical variables, the chi-square test or Fisher's exact test was used. Categorical variables are presented as the number of cases and percentage, while quantitative values are presented as mean and standart deviation (M ± SD).

The null hypothesis of equality between variables was rejected at $p < 0.05$.

Results

The primary reasons prompting patients to undergo surgery were persistent hemorrhoidal bleeding (100.0 %) and/or a history of HN thrombosis (Table 1).

During the BPV procedure, shrinkage and a one-third reduction in the volume of HNs were observed, accompanied by the characteristic crackling sound typical of vaporization. The color and structure of the mucous membrane of the anal canal and HN remained unchanged. Completion of the vaporization process resulted not only in the reduction of the HNs but also in their retraction into the anal canal.

The duration of BPV ranged from 32 to 55 min, with an average of 44.3 ± 7.1 min. Perioperative

Table 1. **Baseline characteristics of patients with grades I—II chronic hemorrhoids**

Index	Value
Men	19 (59.4 %)
Women	13 (40.6 %)
Age, years	43.3 ± 14.7 (19—70)
BMI, kg/m^2	27.4 ± 3.8 (19.5—36.7)
Duration of disease, years	6.8 ± 4.5 (1—20)
History of hemorrhoidal thrombosis	14 (43.8 %)
Cluster «Hemorrhoid Symptoms»	
Pain	18 (56.3 %)
Pain score	2.72 ± 1.4 (1—6)
Prolapse	22 (68.8 %)
Prolapse score	4.6 ± 1.3 (3—7)
Itching	9 (28.1 %)
Itching score	2.8 ± 0.7 (2—4)
Soiling	8 (25.5 %)
Soiling score	3.1 ± 0.8 (2—4)
Bleeding	32 (100.0 %)
Bleeding score	4.7 ± 1.1 (3—7)

Note. Categorical variables are presented as the number of cases and percentage, while quantitative indicators are presented as M ± SD (Min–Max). Mean scores are calculated based on the number of patients who exhibited the corresponding symptoms.

blood loss did not exceed 20 ml, averaging 8.3 ± 3.7 ml. Submucosal hematomas (up to 1 cm in diameter) were observed in 7 patients (21.9 %).

All patients required pain relief after the procedure. The average number of ketorolac doses on the first postoperative day was 1.4 ± 0.9 (ranging from 1 to 4 doses), and on the second day, 1.8 ± 0.8 (ranging from 1 to 3 doses). The average hospital stay was 2.3 ± 0.5 days (ranging from 2 to 3 days), and the mean time to return to work was 5.8 ± 0.7 days (ranging from 5 to 7 days).

Seven days after the procedure, the number of patients experiencing pain increased compared to the preoperative level, reaching 21 (65.6 %), p = 0.422. However, the mean pain score significantly decreased to 1.62 ± 0.7; p = 0.003. At 6 weeks and 1 year postoperatively, no patients reported pain (Table 2).

Prolapse was observed in one patient (3.1 %) one year after surgery, which was significantly lower than the preoperative level (p < 0.001). The patient rated the condition at 3 points.

One patient (3.1 %) reported itching, scoring it at 2 points. The frequency of itching was significantly reduced compared to the preoperative level (p = 0.006).

Soiling was noted by 10 patients (31.3 %) on the 7th day after surgery, which did not differ statistically from the preoperative level (p = 0.022). However, the mean soiling score was lower at 2.2 ± 0.2 compared to 3.1 ± 0.8 preoperatively (p = 0.022). At 6 months and one year after surgery, only one patient reported soiling, scoring it at 2 points.

No bleeding was reported in any patient throughout the follow-up period.

One week postoperatively, the satisfaction score averaged 6.8 ± 0.4 points. A quarter of the patients rated the results as moderately successful, while 24 patients (75 %) rated the outcome as successful. However, at this time point, no patients rated the surgical results at 8 or 9 points (Fig. 5).

Table 2. **Frequency of symptoms in the «Hemorrhoid symptoms» cluster at follow-up time points**

Symptom	Preoperative	Day 7	Day 42	Day 360
Pain	18 (56.3 %)	21 (65.6 %)	0*	0*
Prolapse	22 (68.8 %)	0*	0*	1 (3.1 %)*
Itching	9 (28.1 %)	0*	0*	1 (3.1 %)*
Soiling	8 (25.5 %)	10 (31.3 %)	1 (3.1 %)*	1 (3.1 %)*
Bleeding	32 (100.0 %)	0*	0*	0*

Note. * The difference compared to preoperative values is statistically significant (p < 0.05).

By 6 weeks (Day 42), a significant improvement in the satisfaction domain was observed, both in the distribution of scores and in the mean score (p < 0.001). At this stage, all patients considered the results successful, with 29 (90.6 %) rating their satisfaction at 8 or 9 points. The mean satisfaction score at 6 weeks was 8.34 ± 0.65 points.

One year postoperatively, the satisfaction scores did not differ statistically from those recorded at 6 weeks. Specifically, 29 (90.6 %) patients rated their satisfaction at 8 or 9 points. However, one patient with a recurrence rated their satisfaction at 6 points. The mean satisfaction score one year after the procedure was 8.31 ± 0.74 points.

From the «Complications» domain, assessed on day 7, an abscess was observed in 1 patient (3.1 %), and partial urinary retention occurred in 2 patients (6.2 %). At one year postoperatively, 2 patients (6.2 %) reported incontinence, specifically gas incontinence. Both cases were classified as mild incontinence, with a Wexner score of 3. No cases of anal stenosis or fistula were observed.

A recurrence of hemorrhoidal disease occurred in 1 patient (3.1 %) one year after surgery. The recurrence manifested as prolapse, itching, and soiling. The patient opted not to undergo repeat minimally invasive intervention.

Discussion

Chronic hemorrhoids remain a significant medical and social issue due to their high prevalence in the population and substantial impact on patients' quality of life [12, 17, 30].

The majority of CH patients present with grade I (72.89 %) and grade II disease (18.42 %), while

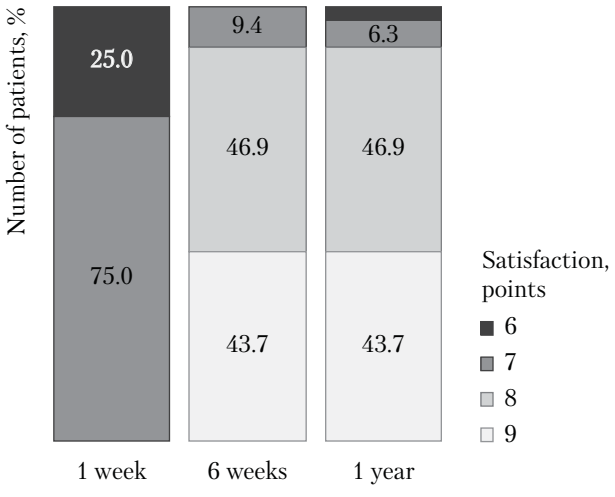

Figure 5. **Distribution of patients by satisfaction score at follow-up time points**

stages III and IV account for 8.16 % and 0.53 %, respectively [30].

Patients with symptomatic persistent hemorrhoids of grades I and II, resistant to conservative therapy, typically require minimally invasive interventions performed in outpatient or inpatient settings [3, 34, 35].

Existing minimally invasive methods, such as rubber band ligation (RBL), sclerotherapy (SI), transanal hemorrhoidal dearterialization (THD), and endovascular embolization of the superior rectal artery (Emborrhoid therapy), demonstrate high efficacy in patients with grades I—II CH. However, these methods are associated with certain drawbacks, including pain, risk of recurrence, and the need for repeat procedures [7, 11, 24, 28, 38].

Moreover, the technical complexity of procedures like THD and Emborrhoid therapy limits their availability in facilities with insufficient technical resources.

Thermal destruction methods, including laser coagulation, radiofrequency ablation, and bipolar coagulation, have demonstrated high success rates in reducing prolapse and vascularization of HNs. However, these techniques often require expensive equipment, and specialized staff training, and carry the risk of complications such as scarring and stenosis [10, 23, 25].

The method of infrared photocoagulation, while more accessible, shows relatively low treatment success rates, ranging from 75 % to 80 % one year after the procedure [2, 26].

Tissue vaporization, previously shown to be effective in urology [8, 18], gynecology [1], and the treatment of varicose veins [5], holds potential for application in the treatment of CH.

In our study, we employed the BPV method for grades I—II hemorrhoids using the Ukrainian-manufactured EK-300M «Svarmed» bio-welding generator in 32 patients with grades I—II CH. To our knowledge, no prior studies have investigated the use of BPV for hemorrhoid treatment. The method demonstrated high effectiveness and safety. Intraoperatively, a reduction and shrinkage of hemorrhoidal nodes by one-third of their volume were observed. The procedure had an average duration of 44.3 ± 7.1 minutes with minimal blood loss (8.3 ± 3.7 ml).

The average postoperative hospital stay was 2.3 ± 0.5 days, and the average time to return to work was 5.8 ± 0.7 days.

The outcomes assessed following the recommendations established for hemorrhoidal disease treatment in the international Delphi study [36] indicate a consistent resolution of symptoms, such as pain, prolapse, itching, and bleeding, in 96.9 %–100.0 % of patients during one year of follow-up, with minimal postoperative complications.

Patient satisfaction with treatment outcomes was high, with 90.6 % rating their results at 8—9 points six weeks and one year after the procedure, while the remainder rated their satisfaction at 7 points. A recurrence occurred in only one patient (3.1 %).

The BPV method demonstrates promise as an effective and safe instrumental technique for treating grades I—II CH. Further research should focus on exploring long-term outcomes, optimizing equipment specifications, and integrating the method into broader clinical practice. The inclusion of vaporization in comprehensive therapy for CH could significantly improve treatment outcomes and patient quality of life. The study has certain limitations, including a small sample size, single-center design, and a relatively short follow-up period. While the results of BPV in treating grades I—II hemorrhoids are promising, further studies are needed with larger cohorts and comparisons with other minimally invasive methods. Additionally, its efficacy and safety should be evaluated for treating grade III hemorrhoids.

Conclusions

Bipolar vaporization is an effective and safe method for treating grades I—II CH, providing significant symptom relief, minimal blood loss, and a short recovery period. The method achieves high levels of patient satisfaction and low recurrence rates. The findings support its high efficacy and safety, positioning it as a promising approach for treating CH.

Declaration of interests

The authors declare no conflict of interest.

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Authors contributions

L. S. Bilianskyi: conception and design, critical revision of the article; I. V. Voloshyn: acquisition, analysis and interpretation of data, statistical analysis, drafting, critical revision of the article, L. Y. Markulan: statistical analysis, drafting the article.

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Результати лікування хронічного геморою I—II ступеня з використанням методу біполярної вапоризації

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Малоінвазивні методи лікування хронічного геморою є важливим компонентом сучасної проктології, однак вони не завжди забезпечують оптимальні результати через рецидиви, ускладнення та необхідність повторних процедур. Деякі з них обмежено доступні через високі вимоги до кваліфікації лікаря та дороге обладнання, що свідчить про потребу в удосконаленні підходів.

Мета — оцінити ефективність і безпечність методу біполярної вапоризації для лікування хронічного геморою I—II ступеня.

Матеріали та методи. У дослідження було залучено 32 пацієнти (19 чоловіків та 13 жінок) віком від 19 до 70 років із хронічним гемороєм I—II ступеня, резистентним до консервативного лікування. Тривалість хронічного геморою становила від 1 року до 20 років, у середньому — (6,8 ± 4,5) року. Для проведення біполярної вапоризації використовували вітчизняний біозварювальний генератор «ЕК-300М Свармед». Основними кінцевими точками були оцінка симптомів геморою та ускладнень, задоволення пацієнтів результатами лікування і частота рецидивів.

Результати. У всіх пацієнтів основними причинами операції були кровотечі, що персистують, та/або тромбоз вузлів (14 (43,8 %)). Об'єм інтраопераційної крововтрати не перевищував 20 мл (у середньому — (8,3 ± 3,7) мл). Середня тривалість процедури становила (44,3 ± 7,1) хв. Середня кількість доз кеторолаку в першу добу — 1,4 ± 0,9 (1—4), на другу — 1,8 ± 0,8 (1—3). Середній ліжко-день становив (2,3 ± 0,5) доби (2—3), середній термін втрати працездатності — (5,8 ± 0,7) доби (5—7). На 7-й день після операції біль відчували 65,6 % пацієнтів, але його інтенсивність була невисокою ((1,62 ± 0,7) бала за візуально-аналоговою шкалою болю, p = 0,003). Під час контрольних оглядів через 6 тиж та 1 рік жоден хворий на біль не скаржився. Через рік 96,9 % пацієнтів не мали пролапсу, свербіжу чи забруднень, а кровотечі були відсутні в усіх. Задоволення пацієнтів процедурою через рік становило в середньому (8,31 ± 0,74) бала за 10-ти бальною шкалою, де 0 — немає задоволення, 9 — максимальне задоволення. Рецидив виник у 3,1 % пацієнтів.

Висновки. Біполярна вапоризація є ефективним і безпечним методом лікування хронічного геморою I—II ступеня, що суттєво зменшує симптоми, об'єм крововтрати й період відновлення. Метод асоціюється з високим рівнем задоволеності пацієнтів і низьким показником рецидивів. Результати дослідження свідчать про високу ефективність і безпечність цього методу, що робить його перспективним методом у лікуванні хронічного геморою.

Ключові слова: хронічний геморой, лікування, малоінвазивні технології, метод біполярної вапоризації, результати.

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