

The effect of endoscopic polidocanol carbon dioxide foam for internal hemorrhoids: a retrospective study

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Aim : The purpose of this article is to investigate the efficacy of polidocanol carbon dioxide foam in the treatment of internal hemorrhoids.

Methods: A retrospective analysis was performed on 158 patients who underwent endoscopic polidocanol foam sclerotherapy for internal hemorrhoids from October 2022 to September 2023. Among them, endoscopic polidocanol sclerotherapy was administered 78 cases were treated with polidocanol air foam (control group), and 80 cases were treated with polidocanol carbon dioxide foam (study group). The primary outcome of this study is the clinical effect and the incidence of complications one month after surgery. Patients self-reported anal bleeding and anal prolapse were taken as the basis for with three classes of evaluation clinic efficacy criteria. We defined the clinical effect by the efficacy index. The final efficacy index was used to judge the efficacy. The incidence of various postoperative complications, including anal pain, anal swelling, urinary retention, perianal infection, ectopic embolization, and anal edema, were recorded. Secondary outcomes include: the cost of surgery, length of stay, and dosage of polidocanol.

Result: The treatment success at the end of the sclerotherapy session in the study and control group was 85.0% and 83.3%, respectively ($P = 0.829$). The effective rates of the study group and the control group were 98.8% and 98.0% respectively one month after endoscopic sclerotherapy ($P = 0.829$). Compared with the clinical effects one month after surgery of the two groups of patients, postoperative complications, surgical cost, hospitalization time and the dosage of polidocanol, we found 11 patients with anal pain and 12 patients with anal swelling in the control group. In the study group, 3 patients had anal pain, and 4 patients had anal swelling. The number of patients with anal pain and anal swelling in the study group were significantly lower than those in the control group ($P < 0.05$) and there were none of the severe complications. Both groups of the clinical effects, surgical costs, hospitalization time, and the dosage of polidocanol were similar, and there

were no significant difference (all $P > 0.05$).

Conclusion: The clinical efficacy of endoscopic polidocanol carbon dioxide foam and polidocanol air foam is comparable . Sclerotherapy of endoscopic polidocanol carbon dioxide foam for internal hemorrhoids can effectively reduce the occurrence of anal swelling and anal pain .

The effect of endoscopic polidocanol carbon dioxide foam for internal hemorrhoids: a retrospective study

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Abstract

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Methods: A retrospective analysis was performed on 158 patients who underwent endoscopic polidocanol foam sclerotherapy for internal hemorrhoids from October 2022 to September 2023. Among them, endoscopic polidocanol sclerotherapy was administered 78 cases were treated with polidocanol air foam (control group), and 80 cases were treated with polidocanol carbon dioxide foam (study group). The primary outcome of this study is the clinical effect and the incidence of complications one month after surgery. Patients self-reported anal bleeding and anal prolapse were taken as the basis for with three classes of evaluation clinic efficacy criteria. We defined the clinical effect by the efficacy index. The final efficacy index was used to judge the efficacy.

The incidence of various postoperative complications, including anal pain, anal swelling, urinary retention, perianal infection, ectopic embolization, and anal edema, were recorded. Secondary outcomes include the cost of surgery, length of stay, and dosage of polidocanol.

Result: The treatment success at the end of the sclerotherapy session in the study and control group was 85.0% and 83.3%, respectively ($P = 0.829$). The effective rates of the study and control groups were 98.8% and 98.0%, respectively, one month after endoscopic sclerotherapy ($P = 0.829$). Compared with the clinical effects one month after surgery of the two groups of patients, postoperative complications, surgical cost, hospitalization time and the dosage of polidocanol, we found 11 patients with anal pain and 12 patients with anal swelling in the control group. In the study group, three patients had anal pain, and four patients had anal swelling. The number of patients with anal pain and anal swelling in the study group was significantly lower than those in the control group ($P < 0.05$), and there were none of the severe complications. Both groups of the clinical effects, surgical costs, hospitalization time, and dosage of polidocanol were similar, and there were no significant differences (all $P > 0.05$).

Conclusion: The clinical efficacy of endoscopic polidocanol carbon dioxide foam and polidocanol air foam is comparable. Sclerotherapy of endoscopic polidocanol carbon dioxide foam for internal hemorrhoids can effectively reduce the occurrence of anal swelling and anal pain.

key words: hemorrhoids, endoscopic sclerotherapy, polidocanol, carbon dioxide, air.

Introduction

Hemorrhoids are a common disease worldwide, with a peak prevalence between 45 and 65 years of age in both men and women[1]. Epidemiological survey results in China show that the prevalence of anorectal diseases is as high as 50.1%, among which 98.08% of patients have hemorrhoid symptoms[2]. Patients often show repeated hematochezia, anal swelling and pain etc., which have severe effects on their health and life[3].

Nowadays, endoscopic sclerotherapy is widely practised as a minimally invasive procedure to treat internal hemorrhoids and provides an alternative to conventional hemorrhoidectomy[4], it

has simple operation, less trauma, good efficacy, low cost and fewer postoperative complications[5]. Common sclerosants have Aluminum potassium sulfate tannic acid (ALTA), phenol in almond oil (PAO) and polidocanol. Polidocanol has the advantages of being safer and more effective, and it can effectively reduce complications and improve patient satisfaction[6].

But at present, most hospitals use air foam hardening agent to treat internal hemorrhoids, which has the characteristics of slow postoperative absorption, long duration of anal swelling and so on. A search of relevant articles found that with the development of sclerotherapy, the treatment of varicose veins was significantly reduced if CO₂ rather than air was employed to make the sclerosing foam for chemical ablation of superficial veins of the lower extremity [7]. Also, in a literature report, patients with CO₂ / O₂ foam were well tolerated with fewer similar therapeutic side effects than air foam[8]. In a study that specifically investigated the neurological side effects associated with migraine for the use of sclerotherapy and physiological foam, the use of CO₂ or CO₂ / O₂ foam should be considered for those patients at increased risk of neurological side effects, such as patients with migraine with aura and those with known Patent foramen ovale [9]. The half-life of air and carbon dioxide binding with polidocanol was different. This leads to the different stability of the foam[10]. The combination of air and polidocanol has the longest half-life, which results in a prolonged contact time between the sclerosant and the tissue. Additionally, air is not easily absorbed by the human body, leading to prolonged stimulation, which may trigger a series of complications. Carbon dioxide, a common physiological gas, is frequently used as the foundational gas for establishing pneumoperitoneum in laparoscopic surgery and is easily absorbed by the human body, potentially addressing these issues. Although similar findings have been reported in studies on the application of carbon dioxide foam in varicose veins and other sclerotherapy treatments, there has been no specific report on the effects of polidocanol foam sclerosing agents made with air or carbon dioxide respectively in the treatment of internal hemorrhoids. Therefore, this paper makes a retrospective and comparative analysis of the efficacy of endoscopic polidocanol carbon dioxide foam sclerotherapy and polidocanol air foam sclerotherapy of internal hemorrhoids.

MATERIALS & METHODS

Study design and setting

The protocol was approved by the Medical Ethics Committee of the Affiliated Traditional Chinese Medicine Hospital to Southwest Medical University (approval number:BY2023033). The flowchart of this trial is shown in Figure 1.

A retrospective analysis was performed on 158 patients who underwent endoscopic polidocanol foam sclerotherapy for internal hemorrhoids in the Anorectal Department of the Affiliated Traditional Chinese Medicine Hospital to Southwest Medical University from October 2022 to September 2023. Among them, polidocanol sclerotherapy was administered 78 cases were treated with polidocanol air foam (control group), and 80 cases were treated with polidocanol carbon dioxide foam (study group).

Participants

All the patients were from the Affiliated Traditional Chinese Medicine Hospital to Southwest Medical University.

Inclusion criteria

Participants will need to meet the following criteria:(1) Patients who met the diagnostic criteria for degree I–III internal hemorrhoids by using the most commonly used Goligher classification of internal hemorrhoids[11];(2) Patients willing to receive endoscopic sclerotherapy;(3) Complete clinical data.

Exclusion criteria

Participants will be excluded if they meet any of the following criteria:(1) Patients with other diseases such as incarcerated hemorrhoids, ring mixed hemorrhoids, perianal abscess, anal fissure, anal fistula, rectal prolapse, intestinal tumours and other diseases;(2) Treatment with hemorrhoid ligation. (3) Important organs include the heart, brain, liver and kidney, lungs, and others with primary severe diseases.(4) Abnormal coagulation function or the use of antiplatelet anticoagulants.

Withdrawal/termination criteria

If participants meet the following criteria, they will be withdrawn or terminated from the trial: (1) Data are incomplete or missing during the follow-up process, so the curative effect cannot be determined. (2) Those who also receive traditional surgery and other treatments during observation; (3) Do not cooperate with the follow-up observers.

Interventions

Patients in the control group provided informed consent prior to surgery, underwent fasting, and performed an enema on the day of the procedure. The left lateral decubitus position was adopted during the surgery, and a transparent cap was affixed to the tip of the colonoscope. After completing the ileocolon examination, internal hemorrhoids were observed, and their specific location and degree were evaluated. The foam hardening agent was prepared by the Tessari technique[12](Figure 2). A U-shaped inverted mirror or a transparent cap was utilized to ensure clear visibility during the procedure. The injection needle is inserted at an angle of 30° to 40° , targeting the injection sites located within the submucosal vessels of the hemorrhoids, which are positioned over 0.5 cm above the dentate line. A volume of 1 to 2 ml of polidocanol sclerosing agent is injected at each site, with a total of 4 to 5 injection points selected for treatment. The total injection volume typically does not exceed 20 ml. Specifically, the injection should be administered such that the mucosa at the injection site appears grey and white, with clearly defined blood vessel textures. The needle should be withdrawn slowly while the injection is being administered. After the injection, pressure is recommended to be applied to the injection site for 5 to 8 seconds to prevent bleeding (Figure 3). Post-surgery, patients should adhere to a liquid diet, ensure smooth bowel movements, and utilize laxatives if necessary to prevent constipation. Patients are followed up for one month. Those in the treatment group received a 3% polidocanol carbon dioxide foam injection (Figure 4). The preoperative preparation, injection site, injection method, injection depth, and volume are consistent with those of the control group. The preparation of the foam hardening agent also employs the Tessari technique. The control group extracted 8 ml of indoor air, while the treatment group extracted 8 ml of carbon dioxide. The subsequent treatment procedures were identical for both groups. Both groups received the

same postoperative care. All surgeries were performed by attending physicians or higher-level medical professionals.

Outcomes

The primary outcome of this study is the clinical effect and incidence of complications one month post-surgery. Patients self-reported instances of anal bleeding and anal prolapse were used as the basis for evaluating clinical efficacy, categorized into three classes: (1) Cure—very satisfied with no or mild symptoms; (2) Improvement—occasional symptoms; and (3) Invalid—no improvement or worsening of symptoms[13]. In order to evaluate the clinical effect more accurately, we defined the clinical effect by the efficacy index (efficacy index (%) = [(pre-treatment score - post-treatment score)/pre-treatment score] × 100%). We defined anal bleeding and anal prolapse scores by the following method (anal bleeding score: 0 was < 1 episodes per month, 1 was <1 episode per week, 2 was 1–3 episodes per week and 3 was 4 more episodes per week; anal prolapse score: no anal prolapse = 0, mild anal prolapse = 1, moderate anal prolapse = 2, severe anal prolapse = 3)[14-15]. We defined the efficacy index as follows: a value of ≥90% indicates a cure, 30% to 89% signifies improvement, and <30% is classified as invalid. By calculating the efficacy index for anal bleeding and anal prolapse, we determined that both cure and improvement qualify as effective outcomes. The incidence of various postoperative complications, including anal pain, anal swelling, urinary retention, perianal infection, ectopic embolization, and anal edema, was meticulously recorded. Secondary outcomes included the dosage of polidocanol, the cost of surgery, and the length of hospital stay.

Statistical analysis

Data are analyzed by using the SPSS 25.0 statistical software. Count data are represented by the number of cases and percentage [n (%)]. Comparisons between groups are performed using the χ^2 test. Rank data are compared by using the rank-sum test. Measurement data are expressed as mean ± standard deviation ($\bar{x} \pm s$). Comparisons between the groups are performed by using the t-test. $P < 0.05$ is considered as a statistically significant difference.

Result:

A total of 168 patients consented to participate in the study. General data for both groups are presented in Table 1. The mean ages of the patients in the study and control groups were 48.76 ± 12.05 years and 50.71 ± 10.46 years, respectively. The study group consisted of 56 males and 24 females, whereas the control group included 60 males and 18 females. No significant differences were observed in general demographics, including age and sex, between the two groups (all $P > 0.05$).

Table 2 presents a comparison of the clinical effects between the study and control groups. The treatment success rates at the conclusion of the sclerotherapy session were 85.0% for the study group and 83.3% for the control group ($P = 0.829$), indicating that the difference is not statistically significant.

The comparison of the clinical effects between the study group and the control group is presented in Table 2. One month after endoscopic sclerotherapy, the effective rates were 98.8% for the study group and 98.0% for the control group, with no significant difference observed ($P = 0.829$). Table 3 illustrates the comparison of postoperative complications. In the control group, 11 patients reported postoperative anal pain, while only 3 patients in the study group experienced this complication, indicating a significant difference ($P = 0.022$). Additionally, anal swelling was reported in 4 patients from the study group and 12 patients from the control group, which was also statistically significant ($P = 0.031$). Neither group experienced urinary retention, perianal infection, ectopic embolism, or anal edema, and no significant differences were found for these complications ($P > 0.05$).

The comparison of the two treatments is shown in Table 4. The cost of surgery and length of stay in study group were significantly less than those in control group (all $P < 0.05$). The dosage of polidocanol were similar, and there was no significant difference ($P > 0.05$).

Discussion:

Hemorrhoids are one of the most common anorectal diseases that can occur at any age and of any sex and have been reported to occur in half of the population over 50 years[16]. Despite the relatively good results reported in the literature, the significant haemorrhoidectomy

complications include postoperative pain, urinary incontinence, stricture, and bleeding. Thus, dramatic changes have occurred in treating hemorrhoids in the past few decades, including non-surgical modalities such as sclerotherapy. Sclerotherapy is widely used in Western countries to cause fibrous reactions in the submucosal and haemorrhoid tissues. Sclerotherapy has gradually been recognized as a minimally invasive treatment for internal hemorrhoids in adults.

In 1928, Blanjold first used sclerotherapy for hemorrhoids, but it was gradually replaced due to severe complications. Subsequently, sclerotherapy has gradually become a well-established clinical treatment. Usually, sclerosing agents are critical to efficacy. Different sclerosants have their own advantages and disadvantages and are not identical in treatment. Aluminum potassium sulfate and tannic acid is obviously more useful than phenol in almond oil for injection sclerotherapy; ALTA was more effective than PAO in hemostatic [17]. In a study comparing 3% polidocanol and 5% phenol, polidocanol needs less treatment frequency and higher patient satisfaction [5]. Three percent polidocanol foam vs 3% polidocanol liquid, foam polidocanol is more effective and equally safe compared to liquid polidocanol [18]. PAO is effective for internal hemorrhoids up to grade III, while ALTA has shown efficacy in treating prolapsing internal hemorrhoids at grades II, III, and IV [19]. Polidocanol has the advantages of being safer and more effective, and it can effectively reduce complications and improve patient satisfaction[20].

Polidocanol foam hardener belongs to the surface activator, which has the advantages over other hardening agents[21]: First, the foam inside it naturally replaces the blood in the blood vessels, and the degree of dilution to the minimum so that the drug concentration in the vein to get a better grasp. As the volume of the bubble becomes smaller, the surface area of the hardening agent increases the area in contact with the inner membrane, which improves the therapeutic effect and can significantly reduce the total dose injected. Second, the foam sclerosing agent can be evenly distributed on the surface of the vascular endothelium, which extends the contact time between the sclerosing agent and the endothelium. Finally, the strong cohesion of foam means that it can be aspirated and reinjected after the first injection. 3% polidocanol foam sclerotherapy has already become an effective conservative treatment for

symptomatic second- and third-degree hemorrhoids.[22] In a comparative study on the treatment of grade I/II/III hemorrhoidal disease, the efficacy of polidocanol foam sclerotherapy was found to be superior to rubber band ligation.[23]

However, the endoscopic polidocanol sclerotherapy of internal hemorrhoids also has postoperative complications. Related articles show that postoperative complications of sclerotherapy of internal hemorrhoids are anal swelling and anal pain, et al., and they are almost curable[24]. Although the complications are curable, they reduce the patient's quality of life. Medical technology has made significant progress, but patients' demand for minimally invasive technology and an excellent medical experience remains unchanged. Currently, most hospitals use air foam hardening agent to treat internal hemorrhoids. However, our study found that polidocanol carbon dioxide foam sclerosant can be effective in reducing the occurrence of postoperative complications. This may be due to the different half-lives of air and carbon dioxide when combined with polidocanol, which results in varying degrees of foam stability. The combination of air and polidocanol has the longest half-life, leading to a prolonged contact time of the sclerosing agent with the tissue, thereby causing longer-lasting irritation post-surgery. Additionally, air is not easily absorbed by the human body, further contributing to increased inflammation. Carbon dioxide, as a common physiological gas, is frequently used as the foundational gas for establishing pneumoperitoneum in laparoscopic surgery and is readily absorbed by the body, thereby reducing the occurrence of complications. This innovative method of medication deserves further promotion.

As this study is retrospective and involves a relatively small sample size, it may impact the accuracy, reliability, and generalizability of the research findings. To minimize potential errors, we accurately recorded cases through the hospital's electronic medical record system. Therefore, although retrospective cohort studies have inherent limitations, such as recall bias, the use of objective medical records helps mitigate the distortion of results caused by such biases. Moreover, we enhanced the validity of the study by strictly assessing and recording complication scores through patient follow-up visits at the hospital.

The limitations of this study are that it is a single-centre study and the sample size needed to be larger. The study still needs a multicenter, large sample, prospective randomized controlled clinical trial for further confirmation. We lack in-depth research on the mechanisms by which carbon dioxide foam can reduce complications, and in the future, we will further explore its underlying mechanisms.

In conclusion, the clinical efficacy of endoscopic polidocanol carbon dioxide foam and polidocanol air foam is comparable. Sclerotherapy of endoscopic polidocanol carbon dioxide foam for internal hemorrhoids can effectively reduce the occurrence of anal swelling and anal pain.

Data Availability The following information was supplied regarding data availability: The raw measurements are available in the Supplemental File.

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Table 1(on next page)

General data of patients in both groups

1

Table 1 General data of patients in both groups

Baseline date	Study group (n=80)	Control group (n=78)	χ^2/t	<i>P value</i>
Sex			0.970	0.325
Male	56(70.0%)	60(76.9%)		
Female	24(30.0%)	18(23.1%)		
Age (year)	48.76±12.05	50.71±10.46	-1.081	0.294
Height (cm)	167.69±8.69	168.11±6.59	-0.348	0.728

2

Table 2 (on next page)

Comparison of the clinical effects one month after surgery between the two patient groups

Table 2 Comparison of the clinical effects one month after surgery between the two patient

groups [n (%)]

Clinical effects	Study group (n=80)	Control group (n=78)	χ^2	<i>P value</i>
Cured	68 (85.0%)	65 (83.3%)	0.376	0.829
Improved	11 (13.8%)	11 (14.1%)		
Invalid	1 (1.2%)	2 (2.6%)		

Table 3(on next page)

Complication rates one month after surgery in both groups

1 Table 3 Complication rates one month after surgery in both groups [n (%)]

Complication	Study group (n=80)	Control group (n=78)	χ^2	<i>P value</i>
Anal pain	3 (3.8%)	11 (14.1%)	5.208	0.022
Anal swelling	4 (5.0%)	12 (17.9%)	4.680	0.031
Urinary retention	0	0	-	-
Perianal Infection	0	0	-	-
Ectopic Embolization	0	0	-	-
Anal edema	0	0	-	-

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Table 4(on next page)

Table 4

1

Table 4 Comparison of relevant indicators for treatment between the two patient groups						
Indicators	Study group (n=80)	Control group (n=78)	t	P value	MD (95% CI)	
The cost of surgery (RMB)	3846.58±1890.82	3969.08±2331.66	-0.363	0.717	-788.82-543.82	
Length of stay (d)	4.73±1.65	4.67±1.66	0.173	0.863	-0.47-0.57	
The dosage of polidocanol (ml)	1.90±0.13	1.88±0.15	0.883	0.379	-0.02-0.06	

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Figure 1

The flowchart of this trial.

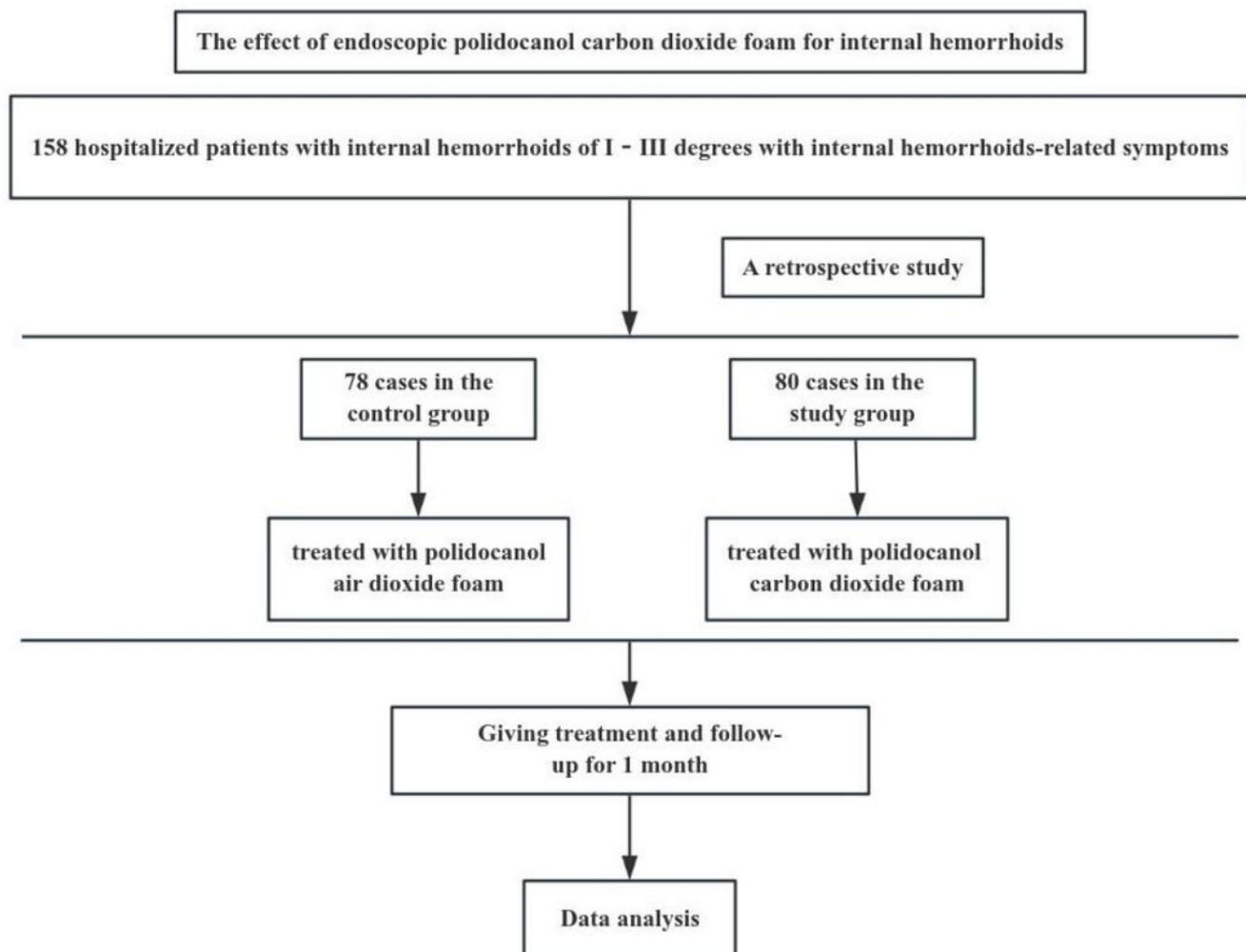


Figure 2

Preparation of polidocanol air foam hardener: A. Instrument preparation, B-D. 2ml of 3% polidocanol injection and 8ml of indoor air are mixed rapidly for 15-20 times.

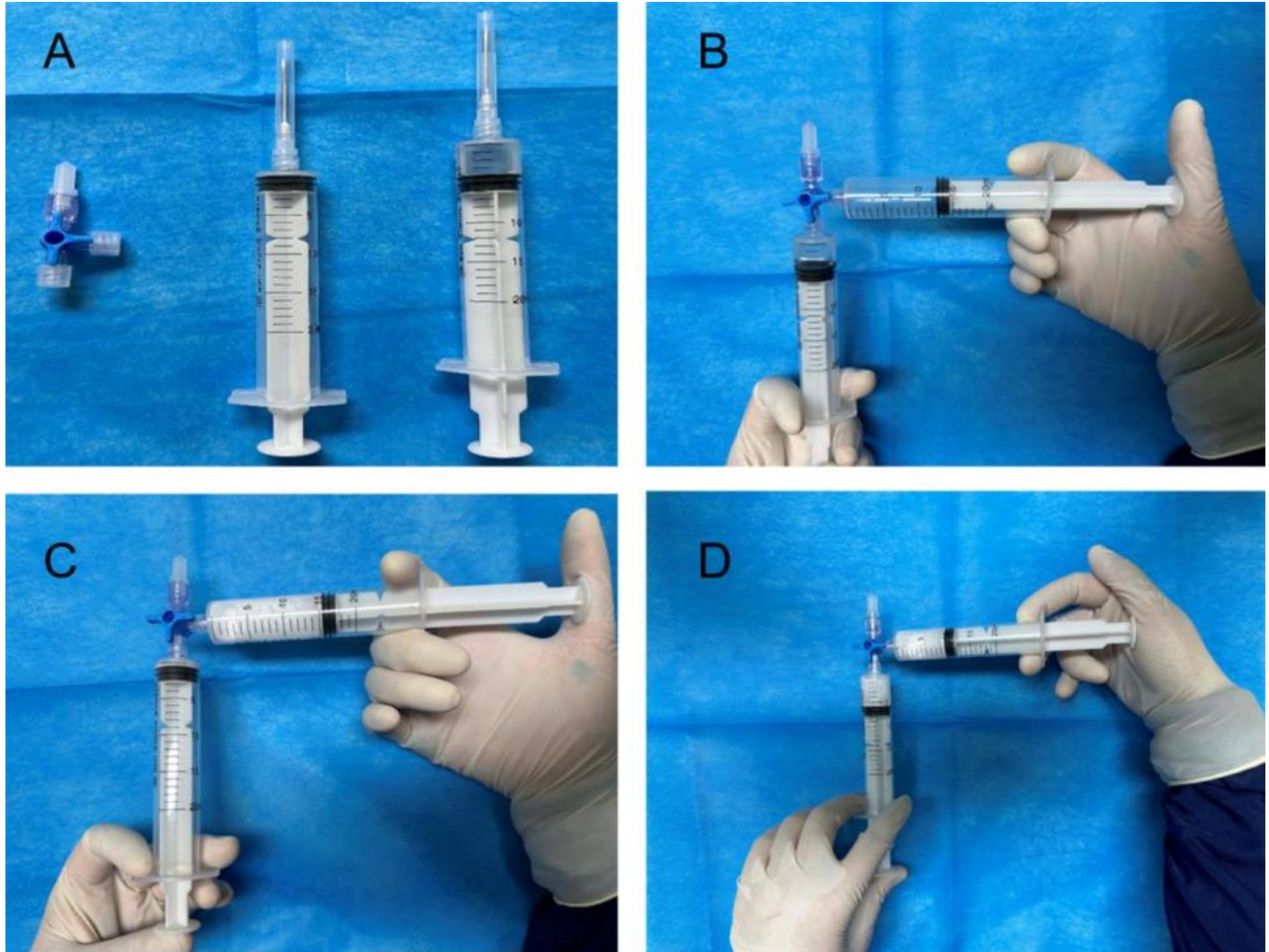


Figure 3

The injection site for 5 to 8 seconds to prevent bleeding

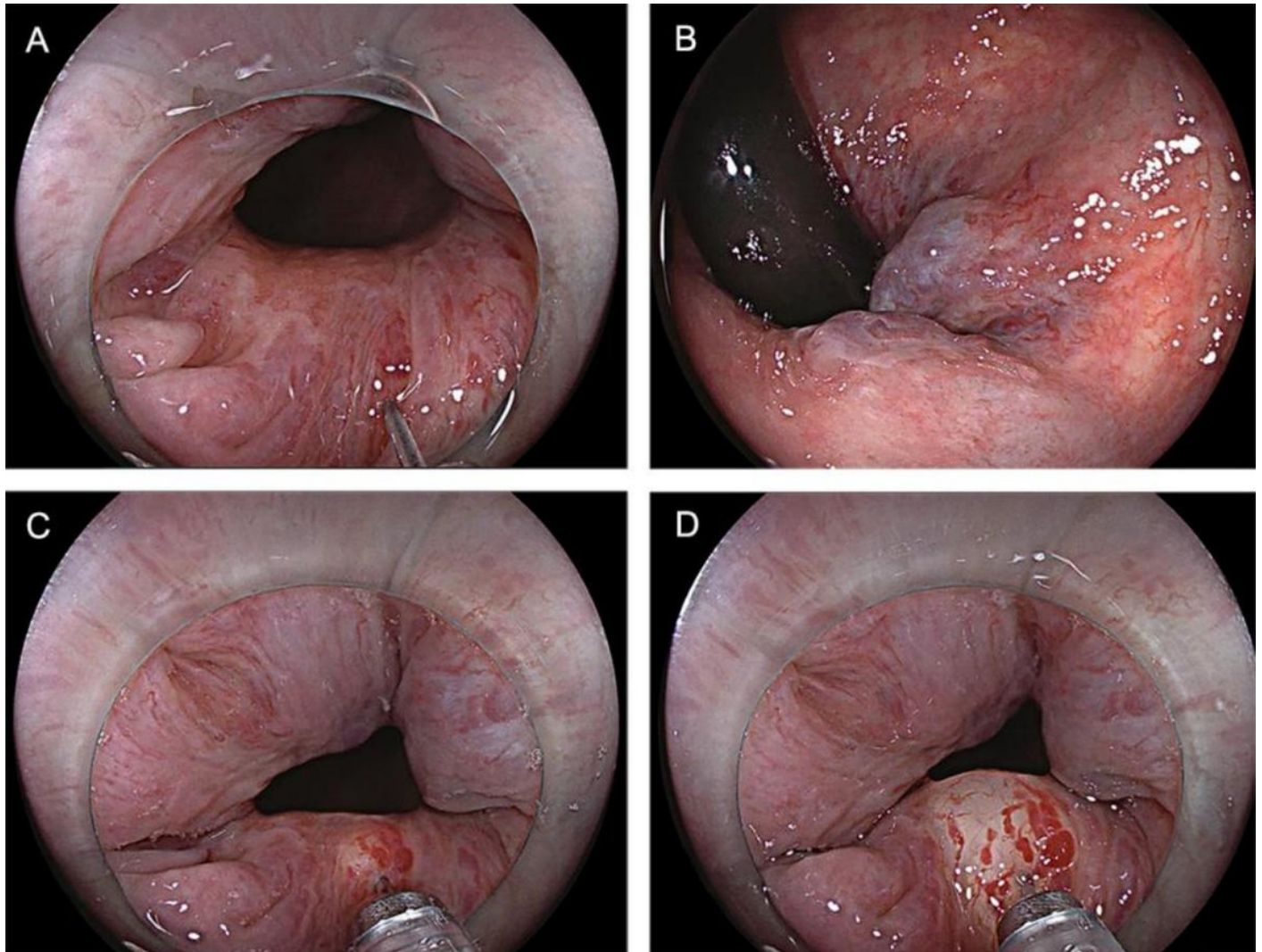


Figure 4

3% polidocanol carbon dioxide foam injection

