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Office-based treatments for hemorrhoidal disease grades I-III – Comparing rubber band ligation and polidocanol foam sclerotherapy

Authors:
Andreia Guimarães, Marta Silva, Tiago Leal, Bruno Arroja, Tania Carvalho, Raquel Gonçalves, Ana Célia Caetano

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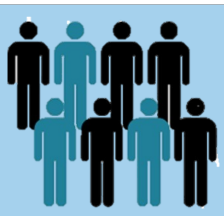
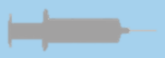
OFFICE-BASED TREATMENTS FOR HEMORRHOIDAL DISEASE GRADES I–III: COMPARING RUBBER BAND LIGATION AND POLIDOCANOL FOAM SCLEROTHERAPY

Study population



N= 441



Polidocanol foam sclerotherapy
N = 105

Rubber band ligation
N= 290

Methods

Mean 2.0 treatments per patient

25 months follow up

Outcomes

		
CLINICAL SUCESS	58%	79%
RELAPSE	14%	16%
FAILURE	9%	14%
ADVERSE EVENTS	16%	84%

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Office-based treatments for hemorrhoidal disease grades I-III – Comparing rubber band ligation and polidocanol foam sclerotherapy

Andreia Guimarães*[1]; Marta Silva*[2]; Tiago Leal[1]; Bruno Arroja[1]; Tânia Carvalho[1]; Raquel Gonçalves[1]; Ana Célia Caetano[1,2]

[1]Gastroenterology Department, Unidade Local de Saúde de Braga, Braga

[2]School of Medicine, Life and Health Sciences Research Institute (ICVS), University of Minho, Braga, Portugal.

*contributed equally to the work and share co-authorship

Short Title: Treatments for Hemorrhoidal Disease

Corresponding Author:

Andreia Guimarães

E-mail address: andreiaguimaraes32@gmail.com

Abbreviations: CI, Confidence Interval; CS, Clinical Success; DT, Double Standard Treatment; HD, Hemorrhoidal Disease; IQR, Interquartile Range; M, Mean; Mdn, Median; MT, Maintained Treatment; PFS, Polidocanol Foam Sclerotherapy; RBL, Rubber Band Ligation; RCT, Randomized Controlled Trial; RFS, Recurrence-Free Survival; SD, Standard Deviation; ST, Standard Treatment; TF, Treatment Failure.

Abstract

Background: Office-based treatments for hemorrhoidal disease (HD) are recommended when medical management fails. Rubber band ligation (RBL) and polidocanol foam sclerotherapy (PFS) can both be used; however, few studies compare these treatments. This study aimed to compare the efficacy and safety of PFS versus RBL.

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Methods: This retrospective cohort study analyzed patients with HD treated with RBL and/or PFS between January 2015 and April 2024. The patients were classified into 2 categories: standard treatment of up to four sessions (ST) or double standard treatment (DT) of up to eight sessions. The outcomes were clinical success (CS), relapse, relapse-free survival (RFS) and treatment failure (TF). Adverse events were registered.

Results: In total, 441 patients were included, 290/441 (65.8%) treated with RBL, 105/441 (23.8%) with PFS and 46/441 (10.4%) with both. After treatment, 289/395 patients (73.2%) achieved CS, with 260/289 (90.0%) needing ST and 29/289 (10.0%) DT. Patients treated with RBL were significantly more effective in achieving CS (78.6% vs 58.1%, $p<.001$, *phi* = .205). Of the patients with CS, 61/289 (21.1%) relapsed (75.4% of RBL and 24.6% of PFS, $p=.544$, *phi* = .033) with a median time to relapse of 15.5 [14.5] months (17.0 [15.0] of RBL vs 12.0 [7.0] of PFS, $p=.008$, $r = .339$). RFS did not differ between groups. A total of 49/395 (12.4%) required surgery (13.8% of RBL vs 8.6% of PFS, $p=.164$, *phi* = .070). Goligher I/II and RBL were independent predictors of CS. A total of 49/1223 (4%) adverse events were reported, 41/49 (83.7%) related to RBL and 8/49 (16.3%) related to PFS ($p=.003$, *phi* = .086).

Conclusions: Patients treated with RBL appeared more likely to achieve CS, while PFS showed a more favorable safety profile.

Keywords: Hemorrhoidal disease. Polidocanol foam sclerotherapy. Rubber band ligation.

Key Points

- Office-based treatments for hemorrhoidal disease, like rubber band ligation and polidocanol foam sclerotherapy, are recommended when medical management fails.

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- Few studies compare these treatments in terms of efficacy or safety.
- In our study, both rubber band ligation and polidocanol foam sclerotherapy demonstrated effectiveness in treating hemorrhoidal disease grades I to III, although patients treated with rubber band ligation was more likely to achieve clinical success.
- Polidocanol foam sclerotherapy exhibited a more favorable safety profile, with fewer complications reported.

Introduction

Hemorrhoidal disease (HD) is a very common condition that significantly impacts patients' quality of life. Despite its high occurrence, accurately assessing its prevalence is challenging, as anorectal discomfort is frequently attributed to symptomatic HD and many individuals with HD do not seek treatment [1–3]. Prevalence varies widely, ranging from 11% to 38.9% [3,4].

Internal hemorrhoids usually cause painless bright red rectal bleeding during defecation [2,5–7]. Prolapse is also frequent, often accompanied by soiling, mucous discharge, perianal fullness, skin irritation, or pruritus [2,5,6,8]. Pain can occur with prolapsed or strangulated hemorrhoids [2,5,6]. External hemorrhoids are more commonly associated with pain, typically triggered by thrombosis, and present a palpable perianal lump [2,5,7,8].

The first-line treatment for HD should prioritize dietary and lifestyle modifications [7,9–11]. Additionally, venotropic drugs and topical treatment can be considered as adjuvant therapy [9].

Most patients with symptomatic grade I or II hemorrhoids and select patients with grade III hemorrhoids, refractory to conservative treatment, can be effectively treated with office-based procedures, like rubber band ligation (RBL) or polidocanol foam sclerotherapy (PFS) [10]. Currently regarded as the first-line office-based treatment, RBL involves placing an elastic band just proximal to the dentate line. This technique strangulates the hemorrhoidal column while securing the mucosa to the submucosa, thereby reducing mucosal prolapse [6,8,10]. This procedure is associated with effective

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symptom control, particularly for hemorrhoid prolapse and bleeding, and has high patient satisfaction with a low incidence of symptom relapse compared to sclerotherapy [7,12]. While complications are rare, the most common include post-procedural pain or rectal discomfort [5,6,13–16]. Other possible complications are bleeding, vasovagal symptoms, priapism, anal fissure, and, more rarely, thrombosed external hemorrhoids, urinary retention, liver abscesses and perineal sepsis [5,6,13,14,17]. When compared to liquid injection sclerotherapy, RBL can offer a better treatment response and require fewer sessions; however, it was associated with significantly more post-procedure pain [10,12,13,18].

Sclerotherapy consists of local injection of sclerosing agents, causing inflammation and fibrosis of the hemorrhoidal tissue, leading to scarring and fixation of the mucosa to the anal canal [5,6,10,17,19].

Recently, interest in polidocanol has resurfaced due to its foam formulation, which involves adding air to liquid polidocanol just before injection [12,20]. This foam version is more effective than traditional liquid methods, allowing for lower concentrations while enhancing the sclerotic effect by increasing contact surface area and reducing the risk of intravascular hemorrhage [9,12,19–21]. Complications of PFS are generally minor and rare, but they can include mild discomfort or bleeding, local infections, urinary retention, erectile dysfunction, tenesmus, necrotizing fasciitis and abdominal compartment syndrome [5,9,12,14,17,22]. For patients on antiplatelet and/or anticoagulant medications, PFS may be a good option, as it poses a lower risk of bleeding compared to RBL [5,9,13,15,16,23].

There are few studies comparing treatment with RBL and PFS. A randomized controlled trial (RCT) found equivalent therapeutic success, with PFS showing a significantly lower relapse rate, fewer complications, and fewer required sessions, while RBL had a higher risk of bleeding [16]. A recent meta-analysis including 14 RCT revealed that sclerotherapy was not inferior to control interventions (namely RBL) in terms of success rate [24].

Considering our long-term experience with both techniques in an organized Proctology consultation, we decided to review a full decade of our data.

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Therefore, this study aims to evaluate and compare the efficacy and safety of two office-based procedures for the treatment of HD (PFS and RBL). The primary outcome is long-term clinical success (CS), defined as the complete absence of hemorrhoidal disease symptoms for at least six months after treatment. This outcome is particularly relevant, as it highlights the importance of symptom resolution rather than partial improvement, which has been commonly adopted in previous studies, and ensures a minimum follow-up of six months.

Secondary outcomes include the incidence of complications and relapse rates associated with both procedures.

Material and Methods

Study Design and Patients

This is a retrospective and observational study. All adult patients who underwent office-based procedures for symptomatic HD (RBL and/or PFS) between January 2015 and December 2024 were screened for eligibility. Patients with concomitant perianal diseases (anal fissure, perianal fistula or condyloma), inflammatory bowel disease or radiation proctitis were excluded from this study, as well as patients without a minimum follow-up period of 6 months after treatment. All procedures were carried out in an outpatient setting without sedation, and no prophylactic antibiotics were administered.

For RBL, patients were placed in the left lateral position. An anoscope was introduced to visualize the hemorrhoidal tissue above the dentate line. Using a multi-band suction ligator, the hemorrhoidal cushion was drawn into the applicator barrel, and one or two elastic bands were applied at its base.

For PFS, a 2% polidocanol solution was used. Foam was generated according to the Tessari method, by mixing the liquid sclerosant with air through a three-way stopcock until a homogeneous foam was obtained. Patients were placed in the left lateral position and an anoscope was introduced to visualize the hemorrhoidal tissue above the dentate line. The foam was then injected into the hemorrhoidal tissue above the

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dentate line, with a maximum volume of 10 mL administered per hemorrhoidal pile in each session.

The choice of treatment modality was determined by the attending gastroenterologist, a proctology specialist with extensive experience in HD and office-based interventions, considering resource availability, clinical expertise, and patient eligibility.

Clinical Data Collection

The data were retrospectively collected and included demographic information, such as age and sex, along with known comorbidities, use of antiplatelet and/or anticoagulant medications, and history of previous hemorrhoidal surgery. This study also gathered information on HD symptoms (rectal bleeding, anal pain, anal pruritus, mucus discharge, hemorrhoidal thrombosis, hemorrhoidal prolapse or soiling), presence of abnormal bowel habits (constipation or diarrhea), Goligher classification, type of treatment (RBL, PFS or both), number sessions, time between the first and last treatment and treatment complications (severe pain, bleeding, hemorrhoidal thrombosis, perianal abscess, fecal incontinence, fever, dysuria, vasovagal reaction, diarrhea, constipation, erectile dysfunction or vomiting).

Outcomes

The primary outcome was CS defined as the absence of HD symptoms following standard treatment (ST) (up to four sessions) or double standard treatment (DT) (up to four additional sessions beyond standard), without the need for further interventional procedures for at least six months after the last treatment.

Secondary outcomes included relapse, relapse-free survival (RFS), treatment failure (TF) and safety. Relapse was defined as the reappearance of HD-related symptoms, unresponsive to medical therapy, requiring new office-based procedures or surgery after prior CS. We define RFS as the time from the date of diagnosis to the first documented relapse. Patients without the event of interest were censored at the date

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of last follow-up. TF was defined as the need for surgical intervention following office-based procedures. For safety analysis, all complications related to office-based procedures were recorded, and multiple complications per procedure or per patient could be reported during the treatment course.

Primary and secondary outcomes were evaluated and compared across the 2 types of office-based procedures (RBL vs PFS).

A subset of patients was classified as receiving maintained treatment (MT) due to personal preference or not suit for surgery for several reasons and this subset of patients was excluded from the statistical analysis. This group comprised individuals who required ongoing office-based sessions throughout the follow-up period to sustain HD control.

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics Software, version 29. Statistical significance was defined for $p < .05$ with 95% confidence interval.

The sample size was determined based on complete therapeutic success, using the results from a comparable study [15]. An 80% statistical power (with a type II error, β, of 20%) and a 5% significance level (type I error, α) were applied in the calculations. As a result, the total sample size was estimated to be 117 patients.

In descriptive statistics, qualitative variables were described as absolute frequency (*n*) and percentage (%). Quantitative variables were described by the mean (*M*) and standard deviation (*SD*), or by the median (*Mdn*) and interquartile range (*IQR*), as appropriate.

Means were compared using the Student's *t* test, with effect sizes assessed using Cohen's *d*, interpreted according to Cohen's (1988) guidelines [23]. Medians were compared using the Mann-Whitney test, and effect sizes were calculated using *r* [23]. Categorical variables were compared using the Chi-square (χ^2) test or Fisher's exact test, as appropriate. Effect sizes were measured using phi or Cramér's V, when applicable [23].

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Kaplan–Meier analysis was performed to estimate patients' RFS. Differences between survival curves were compared using the log-rank test. Multivariate Cox proportional hazards regression was performed calculating adjusted hazard ratios. Binary logistic regressions were performed to identify potential predictive factors for CS and relapse. Predictor variables included type of treatment, Goligher grade (I/II vs. III), age, sex, diarrhea, constipation, and higher bleeding risk. Multicollinearity was assessed using Pearson's *r*, and model fit was evaluated with the Hosmer-Lemeshow test, where $p > .05$ indicated a good fit. Odds ratios (*OR*) were reported, and the explained variance was determined using Nagelkerke's R^2.

Ethics

This study was conducted in accordance with the principles of the Declaration of Helsinki and its subsequent amendments. The protocol was reviewed and approved by the Ethics Committee of Local Health Unit of Braga (Nr 150_2024). Given the retrospective design and the use of anonymized data, the requirement for individual informed consent was waived.

Results

Study Population

A total of 558 patients were analyzed, of which 441 were included in this study. The flowchart for patient selection and inclusion is presented in Figure 1. Concerning the type of treatment, 65.8% (*n* = 290) were treated with RBL, 23.8% (*n* = 105) with PFS, and 10.4% (*n* = 46) with both treatments. The median number of treatment sessions received was 2.0 (1.0 – 3.0) and the mean follow-up time was 24.6 ± 18.7 months.

The most common symptom was rectal bleeding (*n* = 401; 90.9%) followed by hemorrhoidal prolapse (59.2%, *n* = 261). Most patients had HD Goligher grade I (*n* = 164; 37.2%). All patient characteristics are summarized in Table 1.

Outcomes

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Treatment Efficacy

As comparison between both instrumental treatment options was performed in the evaluation of primary and secondary outcomes, the 46 patients who had received both treatments were excluded, yielding a final sample of 395 patients. Overall, 73.2% (289/395) achieved CS: 90.0% (260/395) with standard treatment and 10.0% (29/395) with double standard treatment.

Among the 290 patients treated with RBL, 78.6% (228/290) achieved CS, whereas 58.1% (61/105) of the 105 patients treated with PFS achieved CS ($p < .001$). Of those with CS after RBL, 90.8% (207/228) required only ST and 9.21% (21/228) required DT, compared with 86.9% (53/61) and 13.1% (8/61), respectively, after PFS ($p = .367$). The mean number of sessions required to achieve CS did not differ significantly between RBL and PFS ($p = .377$).

In patients who achieved CS, 21.1% (61/289) experienced relapse of symptoms, with a mean time to relapse of 19.5 ± 13.9 months. Time to relapse was significantly shorter in the PFS group than in the RBL group (12.0 ± 7.0 vs. 17.0 ± 15.0; $p = .008$). Of these, 75.4% (46/61) relapsed after RBL, while 24.6% (15/61) relapsed after PFS ($p = .544$). When considering the total number of patients, relapse occurred in 15.9% of those treated with RBL (46/290) and 14.3% of those treated with PFS (15/105).

The estimated RFS time was 64.0 months (95% CI: 55.5–72.4) in the RBL group and 61.7 months (95% CI: 53.4–70.5) in the PFS group ($p = .512$). In a multivariate Cox regression analysis, treatment with RBL was not a significant predictor (HR = 1.23; 95% CI: 0.68–2.23; $p = 0.487$) (Fig. 2). Other factos, including HD grade I /II (HR = 1.01; 95% CI: 0.58–1.76; $p = 0.967$), sex (HR = 1.15; 95% CI: 0.69–1.91; $p = 0.597$), and age (HR = 1.00; 95% CI: 0.98–1.02; $p = 0.966$), were also not significantly associated with the hazard of relapse.

Overall, 12.4% (49/395) experienced TF requiring surgery, including 13.8% (40/290) of RBL patients and 8.6% (9/105) of PFS patients ($p = .164$).

In addition, 14.4% (57/395) either elected or were limited to MT due to clinical conditions, comprising 7.59% (22/290) of RBL patients and 33.3% (35/105) of PFS patients ($p < .001$).

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Comparison of Treatment-Related Complications

Considering the 1223 procedures performed, 4.0% (49/1223) resulted in an adverse event, 83.7% (41/49) related to RBL and 16.3% (8/49) with PFS (p = .003). The per-procedure complication rate was 5.3% for RBL (41/774) compared with 1.8% for PFS (8/449). The complications are outlined in Table 2. Additionally, no significant statistical difference was noted between the occurrence of adverse events and the patients' risk of bleeding (p = .505).

Analysis of Predictive Factors of Treatment Efficacy

Univariate analysis showed that Goligher grades I/II, RBL treatment, age, and diarrhea were significantly associated with CS (Table 3). None of these variables were associated with relapse in the univariate analysis. In multivariate analysis, patients with Goligher grades I/II (OR = 1.96; p = .009) and those treated with RBL (OR = 3.31; p < .001) had higher odds of achieving CS, whereas diarrhea was associated with lower odds of CS (OR = 0.23; p = .015). Each additional year of age was associated with a 4% increase in the likelihood of achieving CS (OR = 1.04; p < .001).

Discussion

This study is a large retrospective analysis, drawing on nine years of data from over 1.000 procedures performed on more than 400 patients, comparing RBL and PFS for the treatment of HD grades I to III.

In this study, PFS treatment was less likely to achieve CS when compared to RBL. However, PFS had a more favorable safety profile than RBL.

RBL success rates in other studies range from 77.6% to 96% [12,15], with our study showing a comparable success rate of 78.6%. In contrast, the success rate for PFS was lower, at 58.1%, likely due to our stricter criteria for success that required patients to be symptom-free and without the need for additional treatment for at least 6 months.

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Other studies employed shorter follow-up periods, reporting higher PFS success rates: one study found 78.8% success after one session with a 1-week follow-up and 86% after a second session with a 4-week follow-up [19]. Another large study on PFS followed patients for 4 weeks and reported a 98% success rate [23]. In a RCT comparing RBL with PFS, PFS showed an 88.3% success rate 12 weeks post-treatment [16]. A recent systematic literature review supports the superiority of polidocanol foam over RBL, demonstrating higher success rates and lower relapse [25].

However, the higher success rates reported in other studies may be explained by their definition of success as improvement of HD symptoms, rather than complete symptom resolution, as in our study [23].

The lower efficacy observed with PFS could also be explained by differences in the technique, namely polidocanol formulation and volume. Most studies have used 3% polidocanol [16,19,21,26] as opposed to our 2% formulation. In addition, the total volume of polidocanol foam was 10 ml per patient, in comparison with around 20 ml in previous studies [16,27].

In multivariate analysis, Goligher grades I/II and RBL emerged as independent predictors for CS. The association of lower-grade HD (Goligher I/II) with positive outcomes suggests that less advanced disease may respond more effectively to RBL interventions, which is consistent with treatment guidelines [9,10]. Similarly, the correlation between RBL and higher success rates reinforces its efficacy as a preferred office-based treatment for achieving symptom resolution.

Consistent with other reports, complications were generally minor and RBL demonstrated a worse safety profile, with complications occurring in 5.3% of procedures compared to 1.8% for PFS. Post-procedure pain and bleeding were the most common complications, with 3.9% of RBL procedures resulting in pain and 0.93% in bleeding. These rates are lower than those reported in previous studies, where pain ranged from 8% to 80% and bleeding from 3.5% to 50% [15]. The RCT by Salgueiro *et al*, report 30% of complications associated with RBL [16]. The retrospective design of this study may have contributed to some degree of underreporting of complications; however, this limitation applies equally to both RBL and PFS. With regard to PFS, one

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study reported a 0.7% rate of serious complications, which aligns closely with our findings [23].

No significant difference was found between the symptom relapse rates for RBL (15.9%) and PFS (14.3%). In contrast, significantly lower relapse rates for PFS (16.1%) compared to RBL (41.2%) was previously reported [16]. However, that study had a total follow-up duration of one year and our study, spanning from 2015 to 2024, included some patients with follow-up periods exceeding a year. This longer follow-up in our study can capture late relapses that may not be detected in studies with shorter intervals between sessions or shorter total follow-up periods. In fact, relapses observed in that study after 3 weeks might, in our study, be classified as not yet having achieved CS, potentially explaining the differences in reported relapse rates. Other studies have found lower relapse rates with RBL of 10-18 %, which is closer to our findings [19]. Although previous comparative studies between PFS and RBL have reported overall success and recurrence rates, to the best of our knowledge, none has specifically evaluated time to relapse between these two office-based procedures. Despite similar relapse-free survival between groups, suggesting comparable long-term efficacy, among those who relapsed, the time to relapse was shorter in patients treated with PFS.

Future studies specifically designed to assess time to symptom recurrence are warranted to validate these observations.

Our study has certain limitations. First, it was conducted at a single center, which may restrict the generalizability of the findings to broader populations. Second, its retrospective design, based on clinical records, meant that some data were missing, either due to incomplete patient reporting or inaccuracies in documentation. For this reason, standardized scales could not be applied to quantify symptoms and complications. Nonetheless, to the best of our knowledge, this study represents one of the largest cohorts of patients with HD in which RBL and PFS have been directly compared. Moreover, the substantial sample size and the extended follow-up period strengthen the reliability and external validity of our results.

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In conclusion, both RBL and PFS demonstrated effectiveness in treating HD grades I to III. However, RBL was more likely to achieve success. Conversely, PFS exhibited a more favorable safety profile compared to RBL, with fewer complications reported. These findings suggest that while both treatments are effective, RBL may offer superior long-term outcomes, whereas PFS presents as a safer alternative with fewer adverse events.

References

1. Sandler, R. S., & Peery, A. F. (2019). Rethinking What We Know About Hemorrhoids. *Clinical Gastroenterology and Hepatology: The Official Clinical Practice Journal of the American Gastroenterological Association*, *17*(1), 8–15. https://doi.org/10.1016/j.cgh.2018.03.020

2. Bleday, R., & Breen, E. (2023, July 11). *Hemorrhoids: Clinical manifestations and diagnosis*. Hemorrhoids: Clinical Manifestations and Diagnosis. https://www.uptodate.com/contents/hemorrhoids-clinical-manifestations-and-diagnosis

3. Sheikh Parvez, Régnier Catherine, Goron Fabienne, & Salmat Ghislaine. (2020). The prevalence, characteristics and treatment of hemorrhoidal disease: Results of an international web-based survey. *Journal of Comparative Effectiveness Research*, *9*(17), 1219–1232. https://doi.org/10.2217/cer-2020-0159

4. Riss, S., Weiser, F. A., Schwameis, K., Riss, T., Mittlböck, M., Steiner, G., & Stift, A. (2012). The prevalence of hemorrhoids in adults. *International Journal of Colorectal Disease*, *27*(2), 215–220. https://doi.org/10.1007/s00384-011-1316-3

5. Sun, Z., & Migaly, J. (2016). Review of Hemorrhoid Disease: Presentation and Management. *Clinics in Colon and Rectal Surgery*, *29*(1), 22–29. https://doi.org/10.1055/s-0035-1568144

6. Lohsiriwat, V. (2012). Hemorrhoids: From basic pathophysiology to clinical management. *World Journal of Gastroenterology*, *18*(17), 2009–2017. https://doi.org/10.3748/wjg.v18.i17.2009

7. Lohsiriwat, V. (2015). Treatment of hemorrhoids: A coloproctologist's view. *World Journal of Gastroenterology*, *21*(31), 9245–9252. https://doi.org/10.3748/wjg.v21.i31.9245

8. Mott, T., Latimer, K., & Edwards, C. (2018). Hemorrhoids: Diagnosis and Treatment Options. *American Family Physician*, *97*(3), 172–179.

9. Salgueiro, P., Caetano, A. C., Oliveira, A. M., Rosa, B., Mascarenhas-Saraiva, M., Ministro, P., Amaro, P., Godinho, R., Coelho, R., Gaio, R., Fernandes, S., Fernandes, V., & Castro-Poças, F. (2020). Portuguese Society of Gastroenterology Consensus on the Diagnosis and Management

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of Hemorrhoidal Disease. *GE - Portuguese Journal of Gastroenterology*, *27*(2), 90–102. https://doi.org/10.1159/000502260

10. Hawkins, A. T., Davis, B. R., Bhama, A. R., Fang, S. H., Dawes, A. J., Feingold, D. L., Lightner, A. L., Paquette, I. M., & On behalf of the Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. (2024). The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Hemorrhoids. *Diseases of the Colon & Rectum*, *67*(5), 614–623. https://doi.org/10.1097/DCR.0000000000003276

11. Van Tol, R. R., Kleijnen, J., Watson, A. J. M., Jongen, J., Altomare, D. F., Qvist, N., Higuero, T., Muris, J. W. M., & Breukink, S. O. (2020). European Society of ColoProctology: Guideline for haemorrhoidal disease. *Colorectal Disease*, *22*(6), 650–662. https://doi.org/10.1111/codi.14975

12. Salgueiro, P., Ramos, M. I., Castro-Poças, F., & Libânio, D. (2022). Office-Based Procedures in the Management of Hemorrhoidal Disease: Rubber Band Ligation versus Sclerotherapy − Systematic Review and Meta-Analysis. *GE - Portuguese Journal of Gastroenterology*, *29*(6), 409–419. https://doi.org/10.1159/000522171

13. Albuquerque, A. (2016). Rubber band ligation of hemorrhoids: A guide for complications. *World Journal of Gastrointestinal Surgery*, *8*(9), 614–620. https://doi.org/10.4240/wjgs.v8.i9.614

14. Brown, S. R. (2017). Haemorrhoids: An update on management. *Therapeutic Advances in Chronic Disease*, *8*(10), 141–147. https://doi.org/10.1177/2040622317713957

15. Cocorullo, G., Tutino, R., Falco, N., Licari, L., Orlando, G., Fontana, T., Raspanti, C., Salamone, G., Scerrino, G., Gallo, G., Trompetto, M., & Gulotta, G. (2017). The non-surgical management for hemorrhoidal disease. A systematic review. *Il Giornale Di Chirurgia*, *38*(1), 5–14. https://doi.org/10.11138/gchir/2017.38.1.005

16. Salgueiro, P., Garrido, M., Santos, R. G., Pedroto, I., & Poças, F. C. (2022). Polidocanol Foam Sclerotherapy Versus Rubber Band Ligation in Hemorrhoidal Disease Grades I/II/III: Randomized Trial. *Diseases of the Colon & Rectum*, *65*(7), e718–e727. https://doi.org/10.1097/DCR.0000000000002117

17. Trompetto, M., Clerico, G., Cocorullo, G. F., Giordano, P., Marino, F., Martellucci, J., Milito, G., Mistrangelo, M., & Ratto, C. (2015). Evaluation and management of hemorrhoids: Italian society of colorectal surgery (SICCR) consensus statement. *Techniques in Coloproctology*, *19*(10), 567–575. https://doi.org/10.1007/s10151-015-1371-9

18. MacRae, H. M., & McLeod, R. S. (1995). Comparison of hemorrhoidal treatment modalities: A meta-analysis. *Diseases of the Colon & Rectum*, *38*(7), 687–694.

Accepted Article

https://doi.org/10.1007/BF02048023

19. Lobascio, P., Laforgia, R., Novelli, E., Perrone, F., Di Salvo, M., Pezzolla, A., Trompetto, M., & Gallo, G. (2021). Short-Term Results of Sclerotherapy with 3% Polidocanol Foam for Symptomatic Second- and Third-Degree Hemorrhoidal Disease. *Journal of Investigative Surgery*, *34*(10), 1059–1065. https://doi.org/10.1080/08941939.2020.1745964

20. Nastasa, V., Samaras, K., Ampatzidis, Ch., Karapantsios, T. D., Trelles, M. A., Moreno-Moraga, J., Smarandache, A., & Pascu, M. L. (2015). Properties of polidocanol foam in view of its use in sclerotherapy. *International Journal of Pharmaceutics*, *478*(2), 588–596. https://doi.org/10.1016/j.ijpharm.2014.11.056

21. Moser, K.-H., Mosch, C., Walgenbach, M., Bussen, D. G., Kirsch, J., Joos, A. K., Gliem, P., & Sauerland, S. (2013). Efficacy and safety of sclerotherapy with polidocanol foam in comparison with fluid sclerosant in the treatment of first-grade haemorrhoidal disease: A randomised, controlled, single-blind, multicentre trial. *International Journal of Colorectal Disease*, *28*(10), 1439–1447. https://doi.org/10.1007/s00384-013-1729-2

22. Acheson, A. G., & Scholefield, J. H. (2008). Management of haemorrhoids. *British Medical Journal*, *336*(7640), 380–383. https://doi.org/10.1136/bmj.39465.674745.80

23. Fernandes, V., & Fonseca, J. (2019). Polidocanol Foam Injected at High Doses with Intravenous Needle: The (Almost) Perfect Treatment of Symptomatic Internal Hemorrhoids. *GE - Portuguese Journal of Gastroenterology*, *26*(3), 169–175. https://doi.org/10.1159/000492202

24. Gallo, G., Picciariello, A., Armellin, C., Lori, E., Tomasicchio, G., Di Tanna, G. L., Santoro, G. A., Alharbi, M., Sorrenti, S., & Grossi, U. (2024). Sclerotherapy for hemorrhoidal disease: Systematic review and meta-analysis. *Techniques in Coloproctology*, *28*(1), 28. https://doi.org/10.1007/s10151-023-02908-w

25. Gallo, G., Grossi, U., De Simone, V., Picciariello, A., Diaco, E., Fan, P., He, H., Li, J., Lin, H., La Torre, M., Laforgia, R., Lobascio, P., Ma, H., Pata, F., Perinotti, R., De Parades, V., Pozzo, M., Realis Luc, A., Salgueiro, P., … Gravante, G. (2025). Real-world use of polidocanol foam sclerotherapy for hemorrhoidal disease: Insights from an international survey and systematic review with clinical practice recommendations. *Updates in Surgery*, *77*(5), 1439–1450. https://doi.org/10.1007/s13304-025-02258-2

26. Gallo, G., Pietroletti, R., Novelli, E., Sturiale, A., Tutino, R., Lobascio, P., Laforgia, R., Moggia, E., Pozzo, M., Roveroni, M., Bianco, V., Luc, A. R., Giuliani, A., Diaco, E., Naldini, G., Trompetto, M., Perinotti, R., & Sammarco, G. (2022). A multicentre, open-label, single-arm phase II trial of the efficacy and safety of sclerotherapy using 3% polidocanol foam to treat second-degree haemorrhoids (SCLEROFOAM). *Techniques in Coloproctology*, *26*(8), 627.

Accepted Article

https://doi.org/10.1007/s10151-022-02609-w

27. Salgueiro, P., Rei, A., Garrido, M., Rosa, B., Oliveira, A. M., Pereira-Guedes, T., Morais, S., & Castro-Poças, F. (2022). Polidocanol foam sclerotherapy in the treatment of hemorrhoidal disease in patients with bleeding disorders: A multicenter, prospective, cohort study. *Techniques in Coloproctology*, *26*(8), 615–625. https://doi.org/10.1007/s10151-022-02600-5

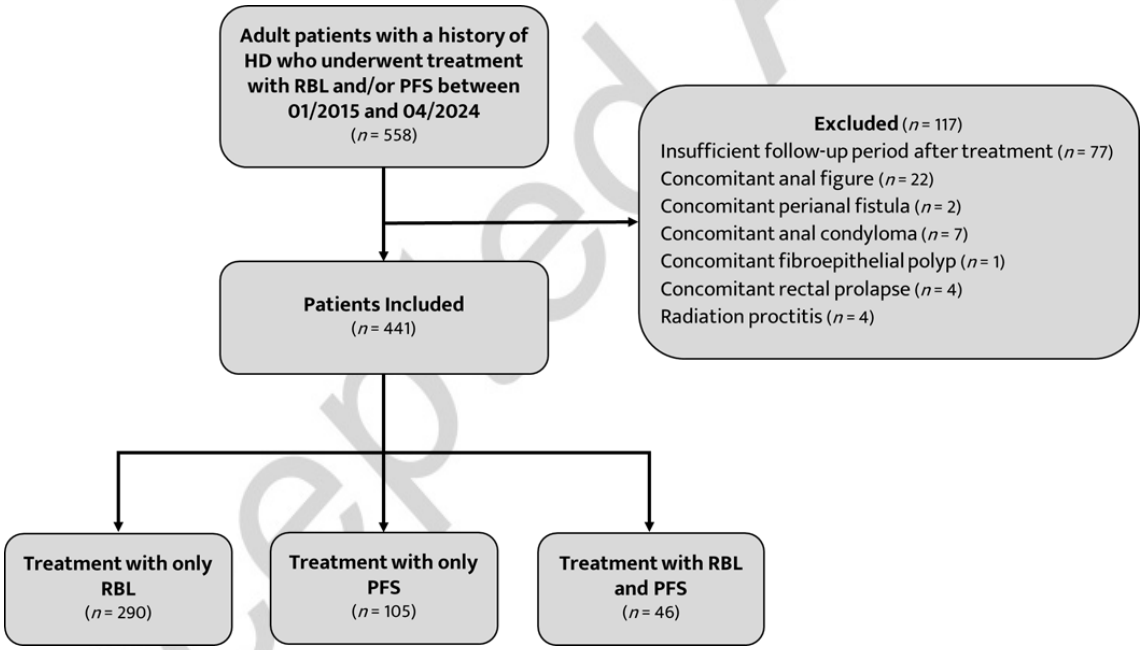

Figure 1. *Flowchart for patient selection and inclusion in the study.*

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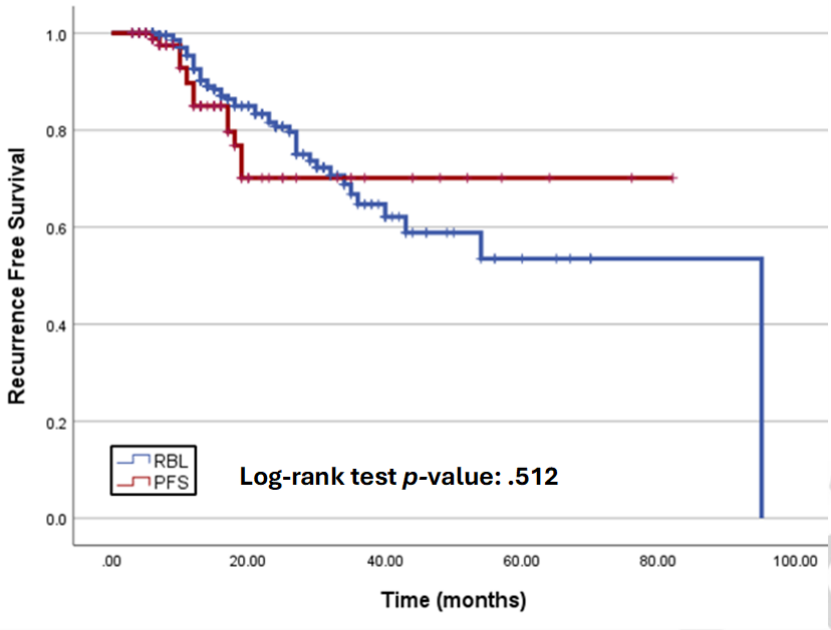

Figure 2. *Kaplan–Meier curves showing relapse-free survival in patients treated with polidocanol foam sclerotherapy (PFS) and rubber band ligation (RBL).*

Table 1 *- Patients' Characteristics and Symptoms.*

Patients' Characteristics	Total (*n* = 441)	RBL (*n* = 290)	PFS (*n* = 105)	*p*
Age (years), mean ± SD	59.1 ± 15.5	58.4 ± 15.0	62.9 ± 16.7	**.007**
Male, n (%)	202 (45.8%)	138 (47.6%)	44 (41.9%)	.317
Goligher Classification, *n* (%)				
Grade I	164 (37.2%)	116 (40%)	34 (32.4%)	.168
Grade II	142 (32.1%)	88 (30.3%)	39 (37.1%)	.201
Grade III	135 (30.5%)	86 (29.7%)	32 (30.5%)	.875
Anticoagulant or Antiplatelets Therapy, *n* (%)	74 (16.8%)	23 (7.9%)	44 (41.9%)	**< .001**
Patients with Chronic Liver Disease, *n* (%)	3 (0.7%)	0	3 (2.9%)	**.004**
Previous Surgical Treatment for HD, *n* (%)	37 (8.4%)	22 (7.6%)	11 (10.5%)	.350
HD symptoms, *n* (%)				
Rectal bleeding	401 (90.9%)	266 (91.7%)	93 (88.6%)	.336
Hemorrhoidal prolapse	261 (59.2%)	162 (55.9%)	68 (64.8%)	.113
Anal pain	88 (20.0%)	50 (17.2%)	23 (21.9%)	.291

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Anal pruritus	38 (8.6%)	28 (9.7%)	5 (4.8%)	.121
Hemorrhoidal thrombosis	24 (5.4%)	17 (5.9%)	5 (4.8%)	.674
Mucus discharge	13 (2.9%)	7 (2.4%)	4 (3.8%)	.456
Soiling	12 (2.7%)	4 (1.4%)	7 (6.7%)	.005

n = absolute frequency; RBL = rubber band ligation; PFS = polidocanol foam sclerotherapy. The values in bold stand for statistically significant differences, $p < .050$.

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Table 2 – Comparison of outcomes between RBL and PFS treatments.

	Total (n=441)	RBL (n=290)	PFS (n=105)	*p*
Total number of officed based procedures, *n*	1223	774	449	--
Number of procedures sessions (per patient), median (IQR)	2.0 (3.0)	2.0 (1.75)	2.0 (2.0)	.076
Total number of rubber bands applied (per patient), median (IQR)	-	4.0 (3.0)	-	-
Volume of polidocanol foam applied (per patient), median (IQR)	-	-	8.0 (12.5)	-
Standard Treatment, *n* (%)	371 (84.1%)	262 (90.3%)	87 (82.9%)	.040
Double Standard Treatment, *n* (%)	70 (15.9%)	28 (9.7%)	18 (17.1%)	
Clinical success, *n* (%)	315 (71.4%)	228 (78.6%)	61 (58.1%)	**< .001**
Recurrence, *n* (%)	81 (18.4%)	46 (15.9%)	15 (14.3%)	.544
Recurrence-free survival (months), median (IQR)	-	64.0	61.7	.512
Treatment failure, *n* (%)	60 (13.6%)	40 (13.8%)	9 (8.6%)	.164
Complications (per procedure), *n* (%)	49 (4.0%)	41 (5.3%)	8 (1.8%)	**.003**
Severe Pain, *n* (%)	37 (3.0%)	30 (3.9%)	7 (1.6%)	**.023**
Bleeding, *n* (%)	8 (0.65%)	7 (0.93%)	1 (0.22%)	--
Hemorrhoidal Thrombosis, *n* (%)	4 (0.33%)	4 (0.52%)	-	--
Fever, *n* (%)	4 (0.33%)	4 (0.52%)	-	--
Vasovagal Reaction, *n* (%)	3 (0.25%)	2 (0.26%)	1 (0.22%)	--
Diarrhea, *n* (%)	3 (0.25%)	3 (0.39%)	-	--
Dysuria, *n* (%)	2 (0.16%)	2 (0.26%)	-	--
Fecal Incontinence, *n* (%)	2 (0.16%)	2 (0.26%)	-	--
Perianal Abscess, *n* (%)	1 (0.08%)	-	1 (0.22%)	--
Hypogastric Pain, *n* (%)	1 (0.08%)	1 (0.13%)	-	--
Constipation, *n* (%)	1 (0.08%)	1 (0.13%)	-	--
Erectile Dysfunction, *n* (%)	1 (0.08%)	1 (0.13%)	-	--
Vomiting, *n* (%)	1 (0.08%)	1 (0.13%)	-	--
Time of follow-up after last session (months), median (IQR)	8.0 (9.0)	14.0 (20.0)	6.0 (1.5)	**< .001**

n = absolute frequency; RBL = rubber band ligation; PFS = polidocanol foam sclerotherapy.
The value in bold stands for statistically significant difference, $p < .050$.

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Table 3 *- Univariate Binary Logistic Regression Analysis of Factors Associated with Success and Multivariate Binary Logistic Regression Analysis for Success*

Variables	*OR*	95% CI		*p*	Nagelkerke R^2
		LB	UB		
Univariate Binary Logistic Regression Analysis of Factors Associated with Success					
Goligher I/II	1.94	1.22	3.11	**.005**	.028
RBL	2.65	1.64	4.28	**< .001**	.057
Age	1.03	1.01	1.05	**< .001**	.057
Diarrhea	0.19	0.06	0.58	**.004**	.032
Constipation	0.58	0.33	1.02	.057	.013
Male	1.29	0.82	2.02	.271	.004
Higher Bleeding Risk	1.26	.687	2.32	.452	.002
Multivariate Binary Logistic Regression Analysis for Success					
Goligher I/II	1.96	1.19	3.24	**.009**	.176
RBL	3.31	1.97	5.57	**< .001**	
Age	1.04	1.02	1.05	**< .001**	
Diarrhea	0.23	0.07	0.75	**.015**	

OR = odds ratio; CI = confidence interval; LB = lower bound; UB = upper bound; R^2 = determination's coefficient; RBL = rubber band ligation.

The values in bold stand for statistically significant differences, $p < .050$.

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