



EndoTHEF: Endoluminal Treatment of Hemorrhoids with Foam

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Received 2018 November 11; Accepted 2018 December 11.

Abstract

Background: Hemorrhoids are normal anatomical structures, present in individuals from birth and recognisable even in intrauterine life. When we talk about haemorrhoids in actual fact we refer to the symptoms caused by haemorrhoids. Currently surgery is considered the gold standard in the treatment of hemorrhoids.

Objectives: In our work we propose the application of an alternative, outpatient and painless treatment of hemorrhoids using intraluminal injection of sclerosing foam (EndoTHEF), demonstrating the safety and feasibility of this procedure.

Methods: We enrolled 615 patients from May 2008 to September 2018 with proctorrhagy from second and third degree hemorrhoids. Regular 3-week control examinations for all patients were scheduled. A total of 1427 procedures were carried out, with an average of 2.32 sessions per patient.

Results: Four hundred seventy six patients were available for follow-up, which lasted on average 12 months. In 83% of the cases proctorrhagy disappeared as early as after the first session. The analysis of a validity score concerning bleeding, pain level and sense of discomfort reported by patients showed a statistically significant difference ($P < 0.0015$) between before and after procedure.

Conclusions: Hemorrhoidal endosclerosis with foam seems to be an effective and safe method to cure hemorrhoidal pathologies and seems to offer good results in the short-middle term with acceptable results in terms of patient comfort and overall cost to society.

Keywords: Hemorrhoids, Foam, Endovascular, Sclerosis, Endoscopy, Minimally Invasive, Outpatient

1. Background

Suffering from hemorrhoids is a common pathology in countries with a high standard of living (1).

It has been calculated that in western countries 5% of the population is affected by hemorrhoids and that at least 50% of adults have experienced symptoms related to this condition in his life (2).

When talking about hemorrhoids there is a general initial misunderstanding. We often forget that hemorrhoids are natural elements of the human anatomy. In common language we use the word "hemorrhoids" to refer to symptoms and complications related to the latter, such as local pain or proctorrhagy.

This initial misunderstanding has led to the wrong conviction that, in order to cure symptoms connected with hemorrhoids, it is essential to remove the anatomical elements which have created them.

The choice of the treatment disease depends on the severity of the symptoms reported, on the extent of the hemorrhoidal prolapse and, lastly, on how familiar the

doctor is with the various surgical and outpatient techniques available nowadays.

2. Objectives

In this report we have analyzed the results of the outpatient treatment of hemorrhoids using intraluminal injection of sclerosing foam.

3. Methods

We examined 695 patients suffering from proctorrhagy from June 2008 to May 2018. They all underwent colonoscopy and a complete study of the colon.

Of the above number of patients 80 showed various causes of bleeding such as polyps, diverticula, angiodysplasia, tumors and therefore they were excluded from this study.

Six hundred fifteen patients were included, 237 males (38.54%) and 378 females (61.46%) with an average age of

48.5 (range 23 - 74), where the only ascertained cause for bleeding was the presence of hemorrhoids (Table 1).

In 28 cases we found secondary, fourth degree hemorrhoids. These patients were affected by liver cirrhosis and suffered from a serious portal hypertension with active bleeding at the time of the examination. The remaining 587 patients had primitive hemorrhoids, respectively first degree hemorrhoids in 17 (2.8%) patients, second degree hemorrhoids in 317 patients (51.4%), third degree hemorrhoids in 253 patients (41.1%) according to Goligher's classification (Table 2) (3).

97 patients had already undergone surgery for their hemorrhoids: Twenty nine were submitted to an hemorrhoidopexy according to Longo's procedure and 39 had an hemorrhoidectomy according to the Milligan-Morgan technique. One patient had already undergone three surgical operations in sequence: Two Milligan-Morgan treatments and 1 hemorrhoidopexy treatment according to Longo's technique.

Seventy three patients (11.8%) under examination showed generic symptoms of chronic fatigue syndrome and deep asthenia, connected to serious microcytic hypochromic anaemia, with hemoglobin values under 8 g/dL and an MCV lower than 70.

During the first discussion with the patients it was necessary to explain the meaning of hemorrhoidal pathology, the various possible treatments and the various surgical and non-surgical treatments available, the endosclerosis technique using a mousse, and to obtain their informed consent to the treatment.

At the first visit all patients were also requested to fill in a questionnaire concerning the quality of the information they had received, the symptoms reported, the number of bleeding episodes which occurred, the level of pain experienced (VAS scale), and the duration of discomfort (difficulty to carry out daily activity) (Table 3). The answers to

those three questions are used to obtain a final score concerning the suitability of the method. This was defined as "validity score", with a range between 3 and 12.

As additional step, patients were asked about the exhaustiveness of the information received, the time lapse before going back to work and which information obtained led them to prefer this technique to others.

The rectum was prepared using microclisms the evening before treatment and in the morning when the session was performed.

Patients arrived in the consulting room and were asked to lie on their left side. In all cases vital functions were monitored using a pocket oxygen meter.

Endoscopic examination was carried out using a dedicated flexible video-endoscopic device with a diameter of 10mm which had been washed and sterilized at everytime with peracetic acid.

We never used systemic sedation or local anesthesia.

Before rectoscopy manual exploration of the rectal ampulla was carried out. After introducing the endoscope into the rectum, this was rotated 180° on its longitudinal axis with a movement called "inversion". This movement makes it possible to visualize the pectinate line and the hemorrhoidal plexus completely. At this point a needle with a diameter of 23G is introduced through the operating channel of the endoscope. Each hemorrhoidal mass is punctured at its origin, cranially to the pectinate line (Figure 1) where no sensitive innervation exists. Therefore the procedure does not require anesthesia.

The decision concerning which masses had to be treated depended on local objective evaluation at the time when rectoscopy was carried out.

Table 1. Patients in Whom the Only Known Cause of Bleeding Was Hemorrhoids

	No.	%
Males	237	38.54
Females	378	61.46

Table 2. Patients with Primitive Hemorrhoids Classified by the Goligher's Classification

	No.	%
1st degree	17	2.8
2nd degree	317	51.4
3rd degree	253	41.1
4th degree	28	4.7

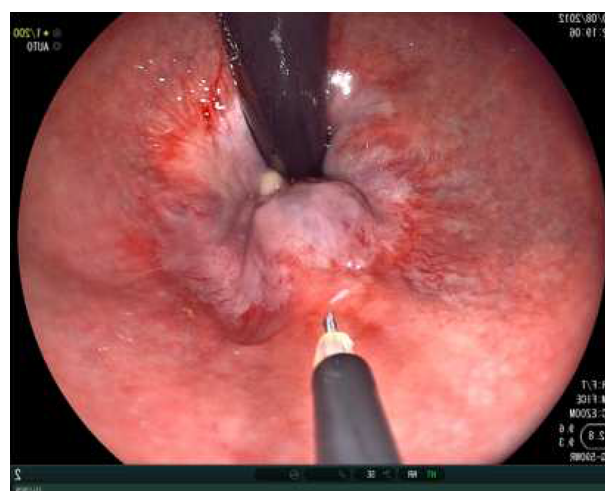


Figure 1. Endoscopic vision of hemorrhoids with the "inversion manoeuvre"

Table 3. Endoscopic Vision of Hemorrhoids with the "Inversion Manoeuvre"

	Validity Score			
	1	2	3	4
Proctorrage	Never	< 1 episode/mo	< 1 episode/wk	> 1 episode/mo
VAS	0-1	2-4	5-7	8-10
Discomfort	< 3 d/mo	< 7 d/mo	> 7 d/mo	Always

Abbreviation: VAS, visual analogue scale.

The sclerosing foam (mousse) was injected into each mass to be treated. The foam had already been prepared according to the Tessari's method (1). Two 10 cc and 5 cc syringes were connected by a 3-way stopcock luer-lock (Figure 2). The syringes contained air and a sclerosing agent (3% polydocanole), with a gas/liquid ratio of 4:1 respectively. Twenty passages from one syringe to the other were made in order to create a good quality foam with small tough bubbles.

The quantity of injected medication per individual hemorrhoidal mass was never higher than 2 cc. The average quantity of foam injected during each session was from 6 cc up to a maximum of 8 cc.

At the end of the session we always removed the air which had been conveyed into the rectum. The average duration of each session was 8 minutes (range 5 - 12).

During the first treatments we used the angiographic hall method and checked the foam injection using iodate contrast means mixed with foam (Figure 3) to assess whether the foam had been distributed correctly inside the hemorrhoidal mass.

After getting dressed, patients were instructed on the therapy they had to follow at home. Medical therapy included the use of bio-flavonoids with a dosage of 3000

**Figure 2.** Preparing sclerosing foam**Figure 3.** Angiographic scan

mg/day for the first six days and then 1000 mg/day for the remaining weeks of treatment. We always recommended a diet rich in fibre (5 g per day) and the application of a local perirectal cream based on calcium antagonists. The use of a mesalamine based endo-rectal gel until the disappearance of symptoms was recommended to patients suffering from local pain which had been the result of former hemorrhoidal flebitis.

At the end of this procedure patients resumed their usual daily activity.

We scheduled regular 3-week control examinations for all patients and they underwent an average of three sessions each. At the end of the last session, further treatment was planned in the case of persistence of symptoms or of incomplete sclerosis resulting from endoscopic examination.

We carried out a total of 1427 procedures on 615 pa-

tients, with an average of 2.32 sessions per patient.

Four hundred seventy six patients were available for follow-up, which lasted on average 12 months. A second questionnaire, similar to the questionnaire given before starting the treatment, was filled in at the end of the observation period.

The data of the questionnaires given to the same patients before and after treatment was then compared.

A statistical analysis of the results of the “validity score” was carried out using the student’s “t” test.

4. Results

The X-ray control of the applied method has made possible the control of the foam distribution. It was possible to demonstrate the presence of foam only in the treated hemorrhoids, without loss of contrast in the perirectal tissues.

In 12 cases we carried out more than five sessions due to persistent bleeding.

After beginning the treatment, after three and five sessions respectively, 2 patients suffering from 3rd degree hemorrhoids opted for a surgical hemorrhoidectomy due to recurring proctorrage.

Out of the 73 patients suffering from serious anemia 41 underwent transfusion with two units of concentrated red blood cells. The other 32 showed normalization of the hematocrite on average 30 days after the treatment with the sclerosing mousse and after suitable iron-tablet therapy.

In 83% of the cases proctorrage disappeared as early as after the first session.

Twenty three patients (3.7%) reported local itchiness which decreased naturally after a few days. Seventy patients (2.7%) reported local pain which was kept well under control using local anti-inflammatory medication. No further complications were observed.

The assessment of the questionnaires returned showed that the treatment had been generally well appreciated. Patients especially appreciated the total absence of pain during and after the treatment and the immediate resumption of normal daily activities. When asked why they had opted for this method, 98.3% of patients answered that they wished to solve their problems using a method potentially without pain, even though the possibility of having to repeat the treatment existed. Another frequent answer was that patients had heard about the positive experiences of relatives or acquaintances who had undergone this treatment.

The analysis of the validity score showed a statistically significant difference ($P < 0.0015$) as far as bleeding, the pain level and the sense of discomfort reported by patients before and after the procedure were concerned (Figure 4).

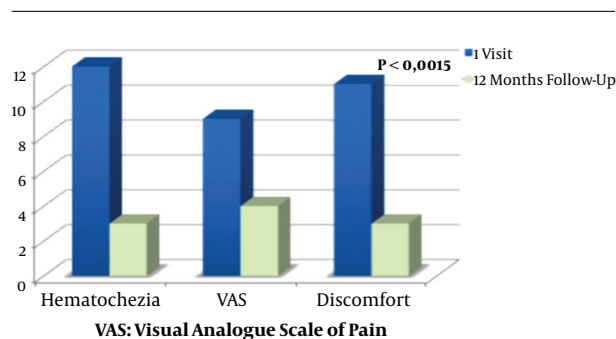


Figure 4. Questionnaire result

5. Discussion

Hemorrhoids are normal anatomical elements present in each individual since birth, recognizable even during intrauterine life (1, 2).

When we talk about hemorrhoids we refer to the symptoms caused by the latter. Local pain in the perianal area and proctorrage are two of the most frequent causes which lead patients to turn to their GP, generally after suffering for a long time.

Until today, surgery remains the most frequently proposed treatment for curing hemorrhoids. Each surgical operation is based on precise indication, has consolidated results and has a documented number of complications and recurrences (4-7). Also in our experience 97 patients had recurrence after several hemorrhoidectomy treatments.

Sclerosis is probably the oldest technique among non-invasive methods. Already in the eighties Badon published a systematic work on hemorrhoid sclerosis (8). Sclerosing foam injected directly into the hemorrhoid by an anoscope is able to create a fibrosis in the hemorrhoid. However sclerosing treatment has always been indicated for first or, maximum, second degree hemorrhoids and after the initial enthusiasm which lasted a few years, this technique was basically abandoned due to the high number of recurrences.

The renaissance of phlebology occurred around the early years of the new century thanks to the introduction of the foaming foam (9-22) has allowed to reconsider the sclerosis of hemorrhoids, no longer injecting liquid medicine but sclerosing foam (23).

The advantages of injecting sclerosing medication in the form of foam rather than liquid are multiple. First of all the amount of active medication able to damage the endothelium is higher. This happens due to the fact that the foam is able to dislocate blood, to create a marked vessel spasm and to the fact that bubbles, if very small, make it possible to distribute the medication homogeneously on

all the walls of the blood vessel (9, 10). In an “*in vivo*” study Orsini and Brotto demonstrated that severe damage of the endothelium and of the tunica media of the vein sclerosed (11) take place only two minutes after injecting the foam. After a few minutes the endothelium actually detaches itself from the wall. About 30 minutes after the injection microthrombi form and a fibrotic reaction leading to the sclerosis of the blood vessel takes place.

We based ourselves on the abundant Literature concerning sclerosing mousse (9-22) and on the work already published on the subject (23) and started treating our patients suffering from bleeding hemorrhoids with sclerosing foam. We injected the mousse directly into the hemorrhoidal varicose masses by using a flexible endoscope and a disposable endoscopic needle. We decided to approach hemorrhoids endoscopically and not by puncturing them directly from the outside for anatomical reasons: It is well known that the toothed (or pectinate) line from which hemorrhoidal plexus originate marks the passage between a proximal area covered by the colon epithelium which does not have pain sensitive receptors, and a more distal area covered by squamous epithelium rich in sensitive nerves. Endoscopic vision makes it possible to recognize this line very clearly due to the magnification of the image using digital technique and puncture the hemorrhoidal plexus in a non-sensitive area. This is why this technique can be applied without anesthesia or sedation.

In contrast to various surgical operations and other outpatient treatment, at the end of the treatment patients are invited to stand up and leave the surgery. Patients generally go back to their daily activities on the same day as the treatment.

At the end of the three sessions, considered the best therapeutical plan, the technique has shown that both pain and bleeding can be kept under control and that after one month following the first treatment hematocrite values go back to a normal level in patients who were suffering from serious anemia.

Rare complications reported in the literature (24) concerning direct injection into the hemorrhoid using liquid medication are perirectal abscess, pain in the area of injection or in the prostatic area and erection malfunction. We did not observe any complications when we injected sclerosing foam into the hemorrhoidal masses. Only two patients had to be treated with local medication due to perianal itching, which disappeared quickly after this local therapy.

Our patients’ follow-up period is still too short to evaluate the long-term results of this method. In two cases we carried out five applications due to renewed signs of bleeding even twelve months their the last session.

In all cases we treated recurrence with one or two ad-

ditional sessions and patients did not report any discomfort. In 2 cases patients interpreted the recurrence of bleeding as a failure of this method and wished to undergo traditional surgery. On the contrary, in our experience we treated 73 patients suffering from proctorrage years after surgery. Twelve months after the last endosclerosis session, one patient whose work had been significantly limited by local pain and constant bleeding after two Milligan-Morgan treatments and one Long treatment, reported absolute well being and normal daily activity after three endosclerosis sessions.

At this point the following questions arise spontaneously:

- First question: Do we really have to strip hemorrhoids or is it enough to keep symptoms under control? If, as it appears from our first experience, this technique seems to stop proctorrage and reduce local pain to a point that it disappears, maybe we should discuss whether it makes sense to subject our patients to the stress of surgery.

- Second question: Can hemorrhoids be effectively and definitively cured using the various surgical techniques available today? Having seen the recurrence data reported in the literature (23), the answer can only be questionable. In literature we have already seen that a variable degree of proctorrage is reported even after surgery is considered radical (23). In contrast, we do not have any response concerning treatment of hemorrhoids using foam. The technique is too recent and not yet widely used and follow-up has been too short to make assessments. But, Yet again, is this a really important matter? If a successful, painless treatment with foam makes it possible to resume normal activity immediately, is it so inconvenient for patients in terms of pain, discomfort and loss of time to undergo a new sclerotherapy session when symptoms should reappear?

- At the end, the real questions are: Is it really so important to cure hemorrhoids in an extreme way? Is it not more important to concentrate our resources on solving our patients’ symptoms connected to hemorrhoids?

There are still no answers based on solid and proven scientific evidence to these questions. New prospective, multi-centre, randomized studies are necessary to compare the methods available to cure hemorrhoids. In any case, sclerosing foam should be considered modernly as an effective and safe method for the treatment of hemorrhoids.

5.1. Conclusions

The use of foam within the phlebological ambit has changed the approach to varicose pathologies in many countries. Consolidated surgical methods such as the

stripping of the great saphenous vein or surgical correction of various recurrence are being redefined as foam has shown to be effective in the treatment of these pathologies, to improve patient quality of life and overall cost to society.

The work we have presented refers to this context.

Even in its initial experimental phase, hemorrhoidal endosclerosis using foam seems to be an effective and safe method to cure hemorrhoidal pathologies and seems to offer good results in the short term with acceptable results in terms of patient comfort and overall cost to society.

Further work involving a larger number of cases and a longer follow-up period are necessary to validate this method.

Footnotes

Authors' Contribution: All the authors have made substantial contributions to the conception and design of the study, acquisition of data, analysis and interpretation of data.

Conflict of Interests: All the authors declare that there is no potential personal conflict of interest.

Ethical Considerations: No ethical consideration needs. The work is an outpatient, extra-hospital work.

Financial Disclosure: All the authors declare that there is no potential personal conflict of interest or financial disclosures.

Funding/Support: This study was not supported by grant in any of his parts.

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