Conservative Management of Hemorrhoids: A Comparison of Venotonic Flavonoid Micronized Purified Flavonoid Fraction (MPFF) and Sclerotherapy

BULENT C. YUKSEL, HALIL ARMAGAN, HUSEYIN BERKEM, YİĞİT YILDIZ, HAKAN OZEL, and SULEYMAN HENGIRMEN

First Department of Surgery, Ankara Numune Training and Research Hospital, Ankara, Turkey

Abstract

Purpose. To compare the results of the conservative management of hemorrhoids between venotonic flavonoid micronized purified flavonoid fraction (MPFF) and sclerotherapy, in terms of the subjective and objective outcome of patients after a follow-up period of 2 years.

Methods. One hundred and twenty-six patients who suffered from 1st- and 2nd-degree hemorrhoids were divided into 2 groups. The first \( (n = 64) \) and second \( (n = 62) \) groups underwent venotonic flavonoid MPFF (VF) and sclerotherapy (SCL). The Average Symptoms Score (ASS), Average Anascopy Score (AAS) and the subjective scale were used to assess the success of the treatments.

Results. A total of 113 patients agreed to participate in the follow-up study. ASS and AAS decreased in both of the groups in the first three visits \( (P < 0.05) \). At the end of the second visit, ASS and AAS significantly declined in the VF group. In addition, ASS and AAS decreased to the nadir level in the groups at the end of the 26th week. During the remaining time of the follow-up period, ASS showed a significant rise pattern in the VF group in comparison to the SCL group. The resolved and improved rate was significantly higher in the SCL group at the end of the study \( (P < 0.05) \).

Conclusions. Sclerotherapy was a more efficient treatment modality than VF in the long-term follow-up. SCL also had an acceptable success rate in the short-term follow-up.

Key words Hemorrhoid · Polidocanol · MPFF · Sclerotherapy

Introduction

Hemorrhoids are a common condition, but their true prevalence is unknown. According to some Western population statistics, the prevalence may be around 37% with an equal frequency in men and women.\(^1\) Despite the relatively good results reported in the literature, a surgical hemorrhoidectomy is associated with major complications including postoperative pain, incontinence, stenosis, and bleeding.\(^2,3\) These complications, together with surgical costs, hospitalization and the need for general anesthesia, make it an unattractive first-line treatment for internal hemorrhoids.\(^4,5\) The treatment of hemorrhoids has changed during the last decade. The development of many conservative treatment methods along with the patients' efforts to control their symptoms with the aid of appropriate dieting to change their bowel habits have led to a decline in surgical treatment.\(^6\) Micronized purified flavonoid fraction (MPFF) is a flavonoid vasoprotector venotonic agent whose active component is micronized flavonic that contains flavonoid extracts of rutaceae, equivalent to 150 mg diosmin expressed as hesperidine.\(^7\) Micronized purified flavonoid fraction is a common alternative treatment that is popular in continental Europe and the Far East. These drugs act to improve the venous tone while inhibiting the release of prostaglandins. As an adjunct, their use has been shown to reduce acute symptoms and secondary hemorrhaging after a hemorrhoidectomy.\(^8\) The administration of a venotonic flavonoid MPFF, which is easy to administer, is free of any significant complications and it reduces the likelihood of surgery, which would be attractive to patients and surgeons alike.

Sclerotherapy is a time-honored method and is widely practiced in the Western world. In other parts of the world this method is also administered for the treatment of 1st- and 2nd-degree hemorrhoids by creating this fibrous reaction in the submucosa of the hemorrhoidal
tissue. It was first used over a century ago, and throughout its development different sclerosants have been used. Therefore, less invasive methods of treatment such as nonfixation method with venotonic flavonoid MPFF and fixation method with injection sclerotherapy are widely performed in Western populations.

The purpose of the present study is to assess the short- and long-term subjective and objective outcome of patients enrolled in the trial after a follow-up at the end of 2 years, and to compare results between a venotonic flavonoid MPFF (VF) group and a sclerotherapy (SCL) group, in order to elucidate the long-term subjective and objective outcome in a prospective study on both medications.

Methods

Study Design and Participants

From 2004 to 2005, 126 patients were included in a randomized controlled trial to undergo VF and SCL treatment (VF group, n = 64; SCL group, n = 62). Randomization was determined by hospital registration number (even = VF group; odd = SCL group). The patient selection and the study design included 126 consecutive patients who suffered from symptomatic 1st- and 2nd-degree hemorrhoids, according to Goligher’s classification. They were divided into two groups. The patients of the first group (n = 64) underwent venotonic flavonoid with MPFF, and the second group (n = 62) underwent sclerotherapy with polidocanol. Six patients decided to withdraw from the study during the first and second visits. After 2 years, 5 patients were lost to the follow-up. As a result, a total of 113 patients were available for the long-term follow-up. All of them resumed normal activity immediately after each treatment session. All patients were asked about their medical history and they underwent proctosigmoidoscopic examination. When any suspicion arose, either colonoscopy or barium enema was performed to exclude any other possible causes of bleeding.

In the VF group, the patients received 1000 mg/day MPFF (Les Laboratoires Servier, Orleans, France) p.o. for 3 months, as described by Lyseng-Williamson et al. In the SCL group, a submucosal injection of 3% polidocanol (Aethoxysclerol, Kreussler Pharma, Wiesbaden, Germany) solution was used as described by Gabriel. The amount of sclerosing solution used was 2 ml per pile and 2–6 ml in total per session, which was injected into the subepithelial plane just above the center of the veins, proximal to the dentate line. The treatment was administered in the office, without anesthesia. A surgeon who was very experienced in the field of coloproctology performed all the procedures. We routinely performed the procedure in the three classic positions, namely, the right anterior, right posterior, and left lateral, modified in a small proportion of patients as clinically indicated. According to the protocol, additional second sclerotherapy was administered to the patients who did not benefit from the first sclerotherapy. The second sclerotherapy was performed 4 weeks after the first administration. All patients were informed about possible immediate or later complications, and they were given written instructions for stool softening. The SCL group protocol was performed using 2–6 ml of polidocanol 3% into the submucosal space above each of the three principal hemorrhoids. The injection was facilitated by a split anoscope (Welch Allyn, Skaneateles Falls, NY, USA) with an attached cold light source, which permitted a full view of the length of anal canal and hemorrhoidal tissue. A special handout was given to each patient. The symptoms and anoscopic examination were noted during follow-up visits before treatment, and at the 2nd, 4th, 6th, 52nd, and 104th weeks after treatment. All procedures were approved by the local ethics committee and all subjects gave their informed consent to participate in the study.

Evaluation of Average Symptoms Score (ASS)

The symptomatic criteria included bleeding, pain (including discomfort and tenesmus during or other than at the time of defecation), heaviness, pruritus, and discharge. These symptoms were scored using a pain score ranging from 0 (no pain) to 10 (the worst pain). A symptom score between 8 and 10 was regarded as 2 points, between 5 and 7 was scored as 1 point, and between 1 and 5 was, together with no symptoms, scored as 0 points. The severity of bleeding was assessed by the number of bleeding episodes per day over a given week, before and after the treatment. Bleeding was considered as 2 points if it occurred more than five times a week, as 1 point if three to five times per week, and as 0 points if less than three times per week. After each patient’s symptoms were scored, the mean of the individual points was also scored and a general statistical evaluation was done. The ASS indicates patients’ average value of total symptoms score.

Evaluation of Average Anoscopic Score (AAS)

An anoscopic examination was conducted at each consultation, and the findings of the size (normal, minimal inflammation, or hemorrhoidal disease) and position of the hemorrhoids were carefully recorded. Average Anoscopic Score was evaluated between 0 and 2 points. A score of zero was evaluated as normal mucosa. One point was evaluated as minimal inflammation on mucosa.