

# Clinical effect of the bergamot-derived gel (Benebeo gel®) associated with mesalazine for the treatment of anitis and proctitis

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## Abstract

Anitis and proctitis are frequent proctological disease whose cause is always unknown. The main treatment of these conditions is medical using local antiinflammatory and phlebotonic drugs. The aim of the present study was to evaluate the effect on symptoms relief using the association of local mesalazine and bergamot-derived gel (Benebeo gel®) in patients with anitis and/or proctitis. From January 2016 to January 2018, a total of 278 patients were treated with the association of local mesalazine and Benebeo gel® with good symptoms relief and improvement of local conditions at 1 months and maintained also at three months. The complementary effects of local antiinflammatory and bergamot-derived flavonoids lead to a good and prolonged clinical response with optimal satisfaction of the patients. Further studies are needed to confirm these preliminary results.

## Introduction

Anitis and proctitis are frequent proctological disease [1]. They may be caused by inflammatory bowel diseases with a specific histopathological features or, more frequently are aspecific or related to the hemorrhoidal disease. The principal causes are not often well known, however, bowel alteration such as chronic diarrhea, dismicrobiosis, parasitism, antibiotic therapy should be always investigated in case of inflammation of anus and/or rectum to identify potential conditions that needed to be treated [2]. The main treatment of these conditions is medical with local antiinflammatory (topical ointments or suppository) and phlebotonic drugs. It was recently introduced in the clinical practice a gel (Benebeo gel®) containing the main flavonoid species extracted from bergamot (esperidin, arginine, apigenine, erythrocytine). The aim of the present study was to evaluate the effect on symptoms relief using the association of local mesalazine and Benebeo gel® in patients with anitis and/or proctitis.

## Materials and methods

From January 2016 to January 2018, all the patients referred to our clinic with a diagnosis of idiopathic or hemorrhoids-related anitis and/or proctitis were treated using the association of local mesalazine and bergamot-derived gel. The mesalazine was administered once per day for 30 days (generally before going to sleep) using suppository excluding that cases in which the patient preferred the ointment. The bergamot-derived gel (Benebeo gel®) was used twice per day through the dedicated cannula for 30 days. After the first visit (T0), the follow-up was scheduled as follows: 30 days (T1) and 90 days (T2). All the visits were performed using the Digital Videoproctoscope. The symptoms investigated were pain (VAS scale 0-10), itching, bleeding (absent, mild, intense) and hyperemia (absent, mild, severe). The satisfaction of the patients after medical treatment was measured in a 0-10 scale.

## Results

From January 2016 to January 2018, a total of 278 patients (155 M -123 F) with a mean age of 53 year (range 24-76 y) were treated with the association of local mesalazine and bergamot-derived gel. 94% (261 pt) of the patients reported a symptoms relief at T1 with a maintained wellbeing at T2 in 89% (247 pt). The mean satisfaction rate after the treatment was 8.2 (range 6-10). The mean value of pain VAS scale before treatment was 6 and decrease to 2 after the treatment at T2 (Figure 1). The clinical evaluation performed with Digital Videoproctoscope showed a decreased of bleeding and the related hyperemia in 78.9% and 79.6% of patients respectively (Figure 2). The images of clinical improvement are shown in Figure 3.

## Conclusions

Idiopathic anitis and proctitis are frequent aspecific conditions that may influence the quality of life with both local symptoms [1,2]. The medical therapy still remains the principal way to treat this disease and it is based on two different kind of drugs: local antiinflammatory and phlebotonic medications. The effect of these drug may be enhanced and prolonged by their combined use as showed in the present study. In particular the effect of the flavonoid fraction of Bergamotto lead to a reduction of free-radical species and it decreases the expression of cyclooxygenase-2 (COX-2) [3,4]. On the other hand, the action

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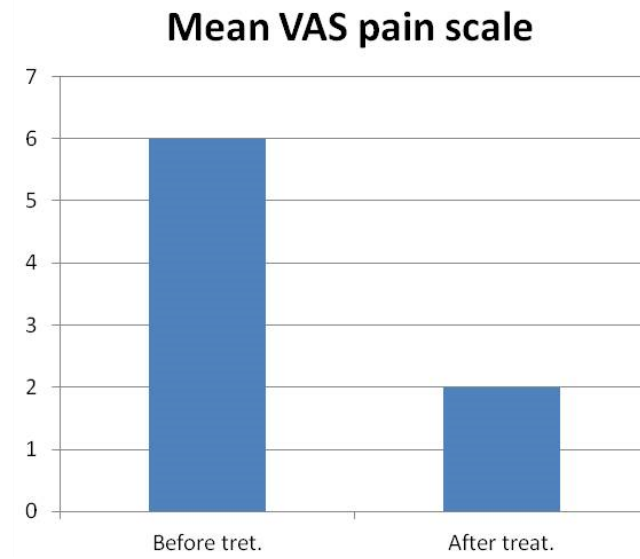


Figure 1. Mean value of VAS pain scale before the treatment after the treatment at 90 days (T2)

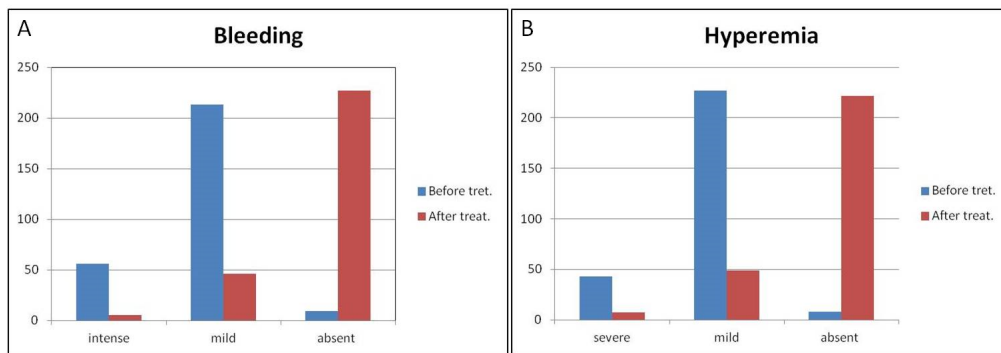


Figure 2. A. Improvement of bleeding before the treatment after the treatment at 90 days (T2). B. Improvement of local hyperemia before the treatment after the treatment at 90 days (T2)

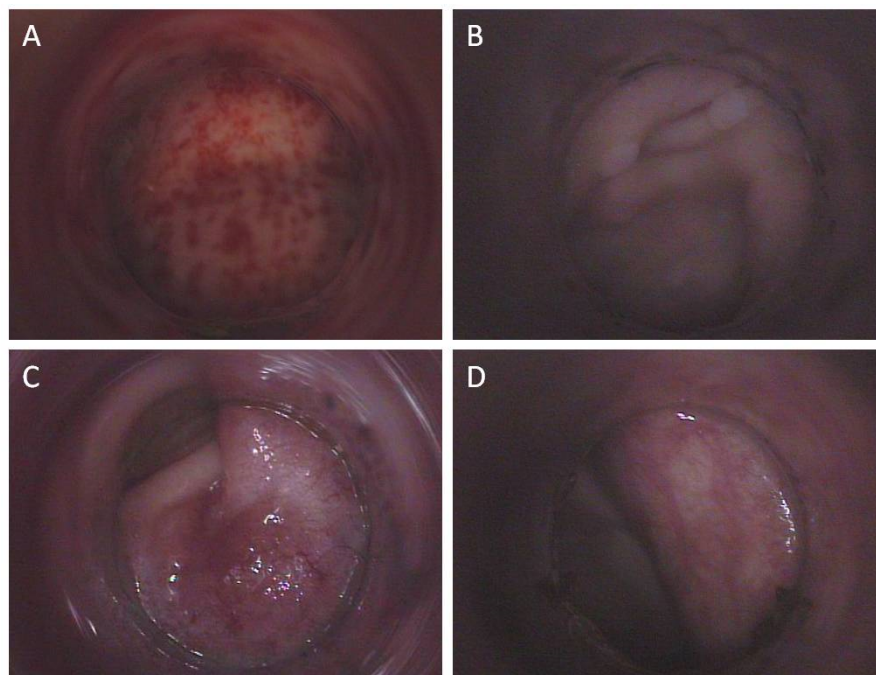


Figure 3. A-C. Ano-proctoscopy before treatment with hyperemia, B-D. Ano-proctoscopy after treatment with the resolution of local inflammation

mechanism of mesalazina is different, in fact it interferes into the modulation of mediator of the inflammatory response, such as the prostaglandins and leukotrienes [5]. This complementary effect lead to a good and prolonged clinical response with optimal satisfaction of the patients. Further studies are needed to evaluate how much this good response may be due only to bergamot-derived gel (Benebeo gel®).

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