

Treatment Protocol of the Most Common Anorectal Pathologies with Association between Micronized Purified Flavonoid Fraction and Sucralfate for Local Application

Nando Gallese*

UCP-Proctological Surgery Unit, St. Anthony Hospital, Cagliari, Italy

*Corresponding author:

Nando Gallese,
Casa di Cura Sant'Antonio, via Chironi 3,
09125 Cagliari – Italy,
E-mail info@nandogallese.com

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Proctitis; Anal fissure; Defecatory urgency; Rectal and anal prolapse with hemorrhoidal disease; Sucralfate; Micronized purified flavonoid fraction

1. Summary (Aim)

The author proposes to test the effectiveness of the combined action of

1- Micronized Purified Flavonoid Fraction - MPFF

associated with topical action "barrier effect" of

2 - Sucralfate (as SOS - Sucralfate Ointment with Soothing Herbs) for some of the most common anal

pathological situations with two main objectives:

1 - microcirculation optimization (reduction of edema, congestion and mucous permeability)

2 - barrier effect with control of irritative stimuli and reduction of severity of inflammation lesions, with

reduction of traumatism due to the transit of the stool and the chemical action of the stool itself

reduction of the microbial load in direct contact with the rectal and anal wall

reduction of wall permeability (always in synergy with MPFF)

2. Introduction

Anus-rectal diseases are numerous and varied in relation to causative factors and morphological and symptomatologic expression, even if usually trivialized by simplistic or frankly incorrect diagnoses including, too often, that of "hemorrhoids" or "hemorrhoidal disease", widely abused terms. The difference between a "real" proctologist and a "surgeon of ass hole" can be understood from how many times "hemorrhoids" are said during the visit and in subsequent diagnostic and therapeutic discussions, including the surgical option: " the

measure of proctological competence is inversely proportional to the number of times the term "hemorrhoids" (personal aphorism) is used [1-10].

To be tackled in the best way, each disease requires the identification of the pathogenetic causes, a precise diagnostic framework, a correct setting of the diagnostic-therapeutic process, with a targeted therapy, suitable for the previous concepts. of course, this methodology of behavior is the prerogative of only the most expert Specialists and, in the daily practice of the non-dedicated Doctor, it may be useful to make use of guidelines or protocol schemes, adaptable to different situations, able to mitigate the impact of injuries and related symptoms, even before of a proctological consultation, but with almost complete guarantee, not to add iatrogenic damage to the patient's clinical picture. The author, on the basis of over forty years of experience, in the last two decades completely dedicated to colorectal-anal and perineal pathologies, has developed a treatment protocol useful in the management of acute, subacute and chronic anal disease situations. A broad-spectrum treatment protocol of the most common anal pathological situations is proposed, by means of micronized diosmin or, more precisely, of the Purified and Micronized Flavonoid Fraction (MPFF in the continuation of the treatment) for the known reintegration characteristics of the microcirculation (with reduction of edema and congestion), in association with topical application of an ointment based on Sucralfate and soothing herbs (SOS below), capable of perform a "barrier effect" with protection of mucous, anal and skin tissues, adjuvanted by soothing substances such as Witch hazel, calendula, chamomile. Flavonoids are polyphenolic compounds that are found ubiquitously in fruit and vegetables: they

have antioxidant biological effects and inhibitory role in different stages of tumors development; in addition, the intake of flavonoids decreases the frequency of cardiovascular diseases and tumors. The micronized purified flavonoid fraction (MPFF) consists of 90% of micronized diosmin and 10% of other flavonoids: it improves venous tone and lymphatic drainage, reduces capillary hyperpermeability protecting the microcirculation from inflammatory processes; by inhibiting the leukocyte-endothelium interaction, MPFF is able to prevent the activation of the inflammatory cascade (Cytokines, Prostaglandins, Leukotrienes, Histamine and other inflammatory mediators). The absorption of diosmin is improved by micronization to particles less than 2 microns. Sucralfate is a complex formed by sucrose and aluminum hydroxide that has the ability to adhere to the cells of the rectal and anal mucosa (and other tracts of the digestive tract, such as esophagus and stomach, as better known), carrying out a cytoprotective effect and stimulating synthesis of the growth factor of the epidermis, thus promoting the recovery of any tissue damage. A study was conducted on 84 patients, with encouraging results.

3. Material and Methods

Research field: various aspects of "hemorrhoidal disease" (*) and / or ASS-SSA (**) with a prevalence of acute or chronic anal fissure, proctitis (specific, not-specific and secondary), urgency (primary and postsurgical). Exclusion of situations of "Acute anus" (***) except in selected cases (with lower intensity) of acute thrombotic anus (which generally requires additional pharmacological treatments and / or urgent surgery). (*) rectal-anal and muco-hemorrhoidal prolapse with vascular kinking, blood and lymphatic congestion and micro-circulatory alterations tending to inflammation (cascade of chemical inflammatory mediators of phlogosis: cytokines, prostaglandins, leukotrienes, histamine, etc.) (**) ASS-SSA: Anal Sphincter Syndrome or *Sindrome dello Sfintere Anale* (Italian) or *Gallese's Syndrome* (***) Acute Anus (*Gallese's disease*)

Table 1: Initial, intermediate (3rd month) and final checks by proctological examination (+ possible Colonoscopy) with objective clinical score (excellent, good, discrete, low, zero, negative) and subjective satisfaction score (excellent, good, discrete, mediocre, zero, negative) The patients enrolled.

Patients (enrolled 84)	N°	%
Complete cycle	65	77.4
Cycle interrupted	11	13.1
Lost	8	9.5
Pathologies considered		
a- Aspects of hemorrhoidal disease (prolapse, bleeding)	22	26.2
b- Aspects ASS - Anal Sphincter Syndrome (Anal fissure, Thrombosis)	45	53.6
c- Chronic phlogistic aspects (Proctitis 11, Urgency 5)	16	19.0
d- Other (post-Milligan-Morgan chronic inflammatory outcomes)	1	1.2

3.1. Pharmacological Devices

MPFF (Micronized Purified Flavonoid Fraction) cps of 500 mg of active ingredient + excipients SOS (Sucralfate Ointment with Soothing Herbs) in the form of Sucralfate-based rectal ointment in combination with other natural soothing supplements (chamomile, witch hazel, calendula)

3.2. Basic Therapeutic Protocol

MPFF (cps 500 mg) 1 cps x 2 / day for 1, 2 or more months (up to check) SOS (ointment) endorectal applications, several times a day, h24 / 24 (up to check) Acute patients with therapeutic combination of mesalazine and / or corticosteroids or other drugs (oral, parenteral and topical) were excluded. other general treatments, which cannot be stopped, for important associated diseases, have been admitted. Period under examination from 1 October 2019 to 30 April 2020 (6 months) Initial, intermediate (3rd month) and final checks by proctological examination (+ possible Colonoscopy) with objective clinical score (excellent, good, discrete, low, zero, negative) and subjective satisfaction score (excellent, good, discrete, mediocre, zero, negative) The patients enrolled (Table 1). were initially 84: of these 8 (9.5%) abandoned the therapeutic protocol and were excluded from the study. 76 patients (90.5%) continued: of these 65 (85.5%) completed the treatment and 11 (14.5%), on their own initiative, reduced or discontinued therapy after the 3rd month checkup, because they have achieved well-being, by performing, however, final check and test (Table 2).

The controls, in the 6-month study period, were from 3 (min > initial, 3rd month, final 6th month) to 6 (max). At the intermediate check of the 3rd month, in cases of significant resolution of the symptomatic picture and evident improvement of the local state, the MPFF dosage was halved (1 cps/ day) in 31 patients (40.8%) and in 2 cases (2.6%) completely suspended, but with continuation of SOS. The basic protocol was conducted up to the 3rd month for all enrolled patients.

Table 2: were initially 84: of these 8 (9.5%) abandoned the therapeutic protocol and were excluded from the study.

Results (out of 76 patients)					
Subjective satisfaction			Objective result		
	N°	%		N°	%
complete	7	9.2	excellent	9	11.8
almost complete	15	19.7	good	19	25.0
discreet	28	36.8	acceptable	25	32.9
poor	12	15.8	low	13	17.2
nothing	12	15.8	zero	9	11.8
worsened	2	2.7	worsened	1	1.3

4. Conclusions

The number of completed therapeutic cycles is discreet, but relatively small. The simultaneous presence of 2 or more concomitant pathologies, among those considered, is frequent (> 50%). In 8 cases (10.5%) there were collateral pathologies of different nature (cardiovascular, diabetes, thyroid diseases) with relative contemporary non-interruptible therapies. All these reasons may involve a certain imprecision in the interpretation of the symptomatic variations found in the clinical course of the patients. However, it can be said that there is a positive trend in the majority of cases, both from a subjective (50 patients = 65.7%) and objective (53 patients = 69.7%) points of view, compared to 26 dissatisfied patients (34.2%) and 23 controls (30.3%) without observation of improvement. In total, the improvements were more than double the less good results.

4.1. The Benefits of the Treatment Protocol Concerned

Pain reduction

Reduction of urgency and frequency of evacuations

Reduction of bleeding, mucorrhea, wet anus

Reduction of evacuation difficulties dependent on edema of the anal terminal canal

Reduction (indirect) of the anxious state, especially linked to the fear of evacuating

Reduction of healing times for anorectal lesions (fissures, ulcers, thrombi, micro abscesses)

In addition, a reduction in the incidence of iatrogenic anal-perianal dermatitis caused by the use of incongruous topicals.

The most significant improvements occurred in group a- (hemorrhoidal disease) for symptoms such as pain, edema, bleeding; fair results in group b- (ASS-SSA) especially on the congestive component, but, consequently, to a certain extent also on the hypertonic one; lower results, as expected, due to the characteristics of chronicity, in the c- (inflammatory diseases) group, however, with 3 out of 16 completely satisfied patients, 4 out of 16 with significant improvement, 3 out of 16 with moderate improvement, including 2 with actinic proctitis (RT for prostatic cancer) and 6/16 without subjective improvement (of which 1 with actinic proctitis), but, of these, 2 with

objective reduction of the state of inflammation (also confirmed by endoscopic biopsies); excellent result in the only case of the d- group (post-surgical urgency: Milligan-Morgan) with complete subjective well-being and objective disappearance of the signs of proctitis. The current study does not claim to present statistically significant conclusions but constitutes a useful direction towards a subsequent multicenter study, involving the major proctological center on the national territory.

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