Dott. Antonio Canero

Specialista in Chirurgia Generale e d'Urgenza
Dottore in Ricerca delle malattie delle vene e dei linfatici – Università di Perugia Azienda Ospedaliera Universitaria San Giovanni di Dio e Ruggi d'Aragona
P.O. **Cava de' Tirreni (SA) U.O.C. – Chirurgia Generale e d'Urgenza**
Colonproctologia – Flebologia – Senologia
Coordinatore regionale per la Campania della (S.I.C.C.R.) Società Italiana di chirurgia colonrettale

THE ROLE OF PROCTEN® CREAM IN THE TREATMENT OF TENESMUS

Introduction

The anorectal tenesmus is represented by the constant or intermittent perception, often painful, of having to urgently defecate, even in the absence of a real filling of the rectal ampoule. It is often sustained by local-regional irritative / inflammatory conditions that act on the sphincter muscles of the anus, which responds through (painful) spasms of its fibres. The causes that come into play in the determinism of anorectal tenesmus are many and multifactorial: chronic inflammatory intestinal diseases, specific loco-regional inflammatory processes, proctitis; functional causes such as constipation and chronic diarrhoea; infectious causes; causes of steric hindrance of the middle-distal rectum and anal canal such as rectocele, rectal prolapse, anal stenosis, haemorrhoids, faecalomas, colorectal and anal canal cancers, anal fissures. Personally, I believe it is fundamental to include a condition that is often present in clinical practice but often little treated in the literature among the causes: post-operative anorectal tenesmus.

The "standard" therapy of tenesmus is based primarily on the prompt identification of the cause. The therapeutic paraphernalia consists of steroidal and non-steroidal anti-inflammatory drugs, antibiotics, surgery, symptomatic therapy.

Although there is no great evidence in the literature, it is believed that a pivot in the treatment of many cases of anorectal tenesmus may be represented by use of topical preparations, able of acting on the anal pressure at rest.

The main components of PROCTEN® CREAM are Ozoile®, cera alba, arginine, ribes nigrum, hyaluronic acid, glycyrrhetinic acid, melaleuca alternifolia etc. In particular, the formulation claims the association of Ozoile® with Cera alba to form a protective natural barrier.

Ozoile® (stable Ozonides) is an exclusive pool of molecules obtained by a patented process, in which the ozone binds to olefinic bonds of organic olive oil forming the stable Ozonides.

In Literature there are molecular biology studies which put in evidence the anti-inflammatory, regenerating and repairing tissues action of Ozoile® even in comparison with Corticosteroids. In particular, the following is evident:

Ozoile® presents an anti-inflammatory action through the COX-2 inhibition and the pro-inflammatory (TNF-α, IL 1β, IFN-γ) and anti-inflammatory (IL-13) cytokines expression modulation, contrasting pain, redness, itching, burning, swelling, degenerative process, radiation damages.

Ozoile® promotes the tissue regeneration because it regulates the transcription of proteins and enzymes related to structural and morphological tissue alterations such as TG2 and NOS; in case of hypoxia, it increases the HIF-1α factor transcription responsible for the cellular resistance towards the oxygen deficiency, promotes the neovascularization increasing the VEGF transcription and contributes to a right and appropriate re-epithelialization positively regulating E-Cadherin transcription, responsible for the right adhesion between the forming neocells.

Ozoile® presents microbicidal action as broad spectrum for the high affinity towards the lipoproteic components of the bacterial and fungal wall and for the oxidative action of Bioperoxides. This preparation, therefore, is created to act on tissue regeneration and repair, on the state of inflammation regardless of the cause of origin, exploits the bio-oxidant effect on microorganisms, acts with a vasoprotective effect, brings elasticity to the anorectal mucosa, reduces endoanal pressure rest, thanks to the effect of arginine and nitric oxide. It works by relieving the symptomatologic range generated by the cause and consequences of tenesmus.

Aim of the study

Check the effectiveness of PROCTEN® CREAM in the treatment of the symptoms and many of the underlying causes of anorectal tenesmus.

Materials and Methods

We enrolled 100 patients with anorectal tenesmus in the study.

Considered the wide range of underlying conditions of the anorectal tenesmus, we excluded neoplastic patients, immunocompromised or deserving of surgical treatment (anal fistula) from the study. All patients who recently subject to surgery (50% of patients enrolled in the study) have been inserted in group 1; the remaining 50 patients have been inserted into group 2.

The purpose of the division into groups was to want to objectively evaluate the effect of the preparation we tested on the two clusters of patients separately, and at the same time to avoid losing specificity and significance to the study.

We administered Vas Scale to patients to understand the real efficacy of the preparation in symptomatologic terms with standardized, reproducible and reliable parameters.

We administered 40ml of PROCTEN® CREAM to all patients in 2 weeks, dividing the dosage into three administrations per day.

Results

Two weeks after the administration of PROCTEN® CREAM we observed the following in the two groups:
- all patients enrolled in the study reported of having to complete the prescribed therapy without side effects. No adverse reactions were recorded.

✓ **Group 1**

A high degree of satisfaction with the proposed therapy was observed in patients with postoperative tenesmus. 44 patients (88%) reported the disappearance of tenesmus symptoms within a few days of starting therapy (patients were asked at the end of the day to draw up a Vas scale every day for the two-week duration of treatment) (Vas scale "0"); 2 patients (4%), on the other hand, reported a light and occasional residual symptomatology (Vas scale "2") not deserving of additional pharmacological treatments. Only 4 patients (8%) reported still suffering from symptoms worthy of treatment with painkillers at two weeks (Vas 4-6 scale).
The recrudescence of symptoms was found only in 1 patient (2%) with an onset described in few days after the end of therapy.

✓ **Group 2**

Patients in this group, evaluated 2 weeks after treatment, reported complete resolution of symptoms in 25 cases of 50 (50%) (Vas "0" scale); 22 patients (44%) reported a drastic reduction in symptoms in the absence of the need to resort to painkillers (Vas 2 scale); only 3 patients (6%) described a residual symptomatology two weeks after the treatment such that they still had to resort to pharmacological therapy, even if occasionally (Vas 4 scale).

In this group 3 patients (6%) reported the reappearance of painful symptoms of high intensity (Vas 6-8 scale) with a progressively worsening character a few days after the end of therapy.

Analysis of the results and conclusions

Although for our study it is necessary to implement it through greater sampling, it can clearly be argued that PROCTEN® CREAM proved to be an excellent preparation in the treatment of anorectal tenesmus in both groups examined.

The main aspect of the therapeutic success of PROCTEN® CREAM in anorectal tenesmus is doubtless ascribable to its multiple action on all the pathophysiological mechanisms underlying the determinism of tenesmus (inflammation, irritation, absence of elasticity of the anorectal mucosa, infections, regenerating effect on the epithelium, reduction of endoanal pressure at rest and therefore on hypertonicity and sphincter spasms). The response to the treatment was surprisingly faster in patients in group 1 than in group 2. Furthermore, what was observed suggests that two weeks of therapy with PROCTEN® CREAM at a dosage of 40 ml, represent an adequate time to determine the resolution of the symptoms related to anorectal tenesmus in group 1. Only 1 patient in this group, in fact, experienced a recurrence of symptoms (2%) at the end of the two weeks of therapy. On the other hand, in group 2, at the end of the prescribed therapy, the percentage of patients deserving of new treatment was found to be 6%. In patients with anorectal tenesmus sustained by inflammatory, irritative and steric hindrance processes, our study suggests extending treatment with PROCTEN® CREAM beyond 2 weeks in order to avoid re-ignition of the symptoms. This study suggests the inclusion of PROCTEN® CREAM as a first-line product in the pharmacological treatment of anorectal tenesmus.

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Dott. ANTONIO CANERO
Specialista in
Chirurgia Generale e D'urgenza
Via A. Sabatini, 7 - SALERNO
Tel. 333 3261574
Partita IVA 0444484 065 8