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EFFECTIVENESS OF PROCTEN® CREAM IN THE TREATMENT OF HEMORROIDARY DISEASE

The haemorrhoidal disease determines vivid painful symptoms, hemorrhage and often correlates with a symptomatic sequela such as to cause serious limitations to the patient's quality of life.

The treatment of internal and external haemorrhoids involves a well-defined sequence: pharmacological treatment (per os and topical use), minimally invasive therapies (sclerotherapy and elastic ligation), surgical therapy. For a few years, the support of technology has enriched the therapeutic choice with ultrasound scalpels, lasers and many innovative devices. Nevertheless, the pharmaceutical purpose that has always been aimed at innovation (enclosing in a single topical product the multiple actions required so that having a therapeutic effect on the sequence of pathophysiological events that determine the typical symptoms of haemorrhoidal disease; outcome and limit the "discomfort" of the therapy to the patient).

Aim of the study

Pharmacological treatment involves the use of different drugs (flavonoids, cortisone, soothing drugs regenerating, etc.) which aim is to limit and resolve painful symptoms, stop bleeding events, make defecation adequate.

Many reports exist in the literature but none of the studies published in the pharmacological treatment of the hemorrhoidal crisis is currently considered the "Gold Standard".

The aim of our study is to highlight the effictiveness of PROCTEN® CREAM with Ozoile® in the treatment of haemorrhoidal disease, making the analysis of the data in our possession irrefutable using questionnaires, pain assessment and therapeutic effects achieved with PROCTEN® CREAM also by means of Vas scale.

The scientific rationale of the study was based on the composition of the product (Ozoile®, cera alba, arginine, ribes nigrum, hyaluronic acid, glycerretic acid, melaleuca alternifolia leaf oil etc.), which translates into multiple therapeutic effects (action on the inflammatory state, soothing effect,

bio-oxidant action on microorganisms, tissue re-epithelialization and regeneration, protection of the anorectal mucosa, restructuring of the connective tissue, vasotonic and vasoprotective action, reduction of sphincter tone and endoanal pressure, etc.). In particular, the formulation claims the association of Ozoile® with Cera alba to form a natural protective barrier.

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

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

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

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

Ozoile® has a broad-spectrum microbicidal action due to its high affinity towards the lipoprotein components of the bacterial and fungal wall and for the oxidative action of bioperoxides.

In PROCTEN® CREAM, Ozoile® is associated not only with cera alba, but also with other components already mentioned, of which certain functions are widely known. This preparation represents the unmissable opportunity to include in a single product for topical use all the properties sought in the treatment of the pathophysiological sequelae related to haemorrhoidal disease.

Materials and methods

60 patients (34 males and 26 females) with internal and external hemorrhoids (grade II, III, IV) were enrolled in our study.

Patients enrolled in the study underwent treatment with PROCTEN® CREAM at a dosage of 40 ml in two weeks divided into three daily administrations.

The following parameters were taken into consideration:

Clinical evidence before and after treatment; analysis and comparison of the Vas scale administered to the patient before and after treatment; degree of satisfaction expressed by the patient with the prescribed therapy.

Analysis of the results

Regression of acute symptoms sustained by haemorrhoids was observed in 53 out of 60 patients (88.4%) during treatment. At the end of the 14 days of treatment, 91.7% of patients (55 out of 60) reported the remission of painful symptoms; 53 out of 60 patients (88.4%) reported the absence of bleeding.

The analysis of the Vas scale at 14 days after treatment reported disappearance (Vas 0 scale) or the presence of mild and sporadic symptoms, not deserving of use of painkillers (Vas scale 2), in 90.0% of patients (54 out of 60).

All patients enrolled in the study tolerated the therapy well and completed the controls and the proposed therapeutic course in the absence of adverse reactions.

Scientific discussion

The analysis of the data from our study clearly highlights the effectiveness of PROCTEN® CREAM in the treatment of hemorrhoids regardless of the degree of hemorrhoidal disease. In 88.4% of treated patients, resolution of the haemorrhoidal crisis was observed within a few days of starting therapy. At 14 days after treatment, the painful symptoms were well-controlled (Vas 0-2 scale) in 91.7% of patients. Residual bleeding at 14 days of therapy was reported occasionally, only by 7 patients (11.7%).

Conclusions

From the analysis of our preliminary experience, PROCTEN® CREAM has proved to be a highly effective product, well tolerated and able to contain in a single topical product all the desired therapeutic "effects" in haemorrhoidal disease, regardless of the degree of the disease.

The therapeutic effect is observed with very short latency from the start of therapy; at 14 days, only a few patients present mild and "intermittent" residual symptoms, which are easy to manage. It is likely that in this sub-set of patients (11.7%) suffering from advanced haemorrhoidal disease, such as to configure a cluster of patients deserving of surgical treatment, the treatment with PROCTEN® CREAM was able to relieve the symptoms (making it minimal, non-disabling and manageable) and to "accompany" patients to surgical treatment in ideal clinical conditions for elective treatment.

Furthermore, the preparation proved to be well tolerated, completely devoid of side effects, allowing all patients to complete the therapeutic cycle.

In our experience, PROCTEN® CREAM must certainly be considered a first choice preparation in the treatment of haemorrhoidal disease.

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