

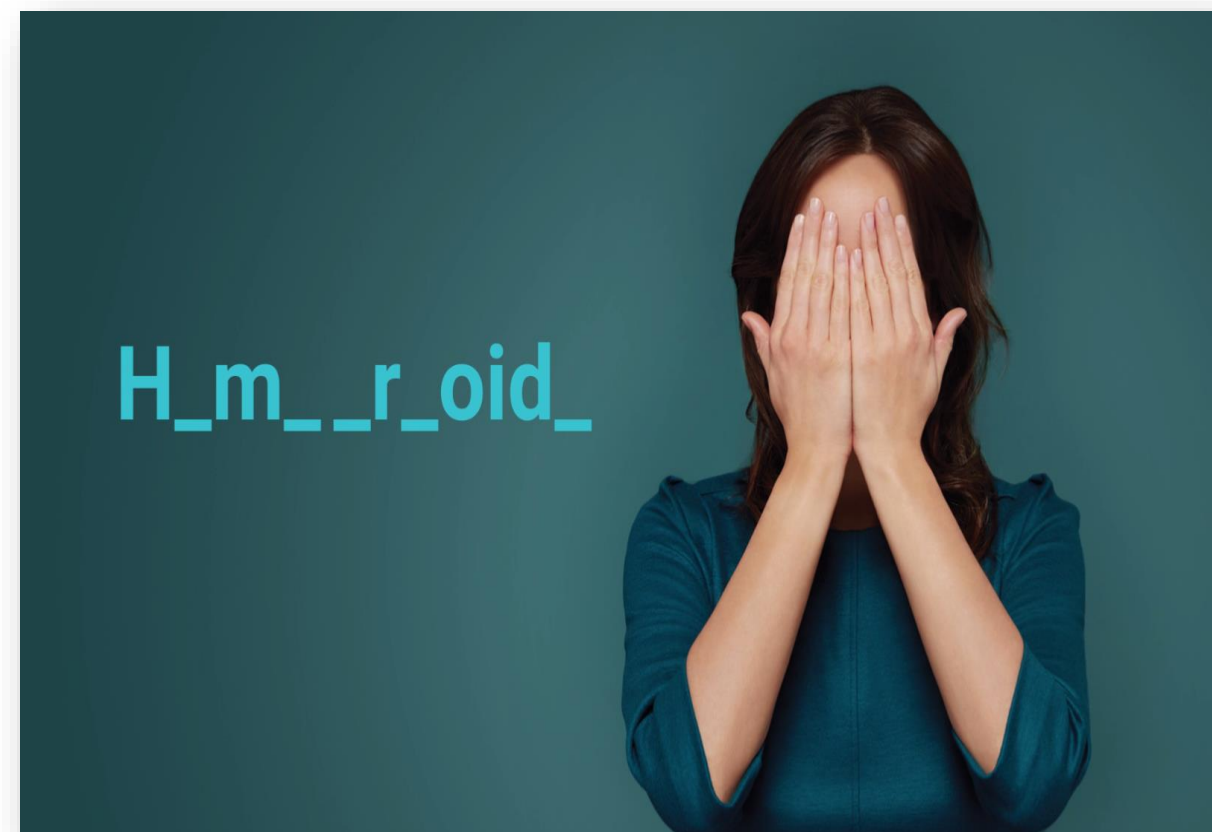
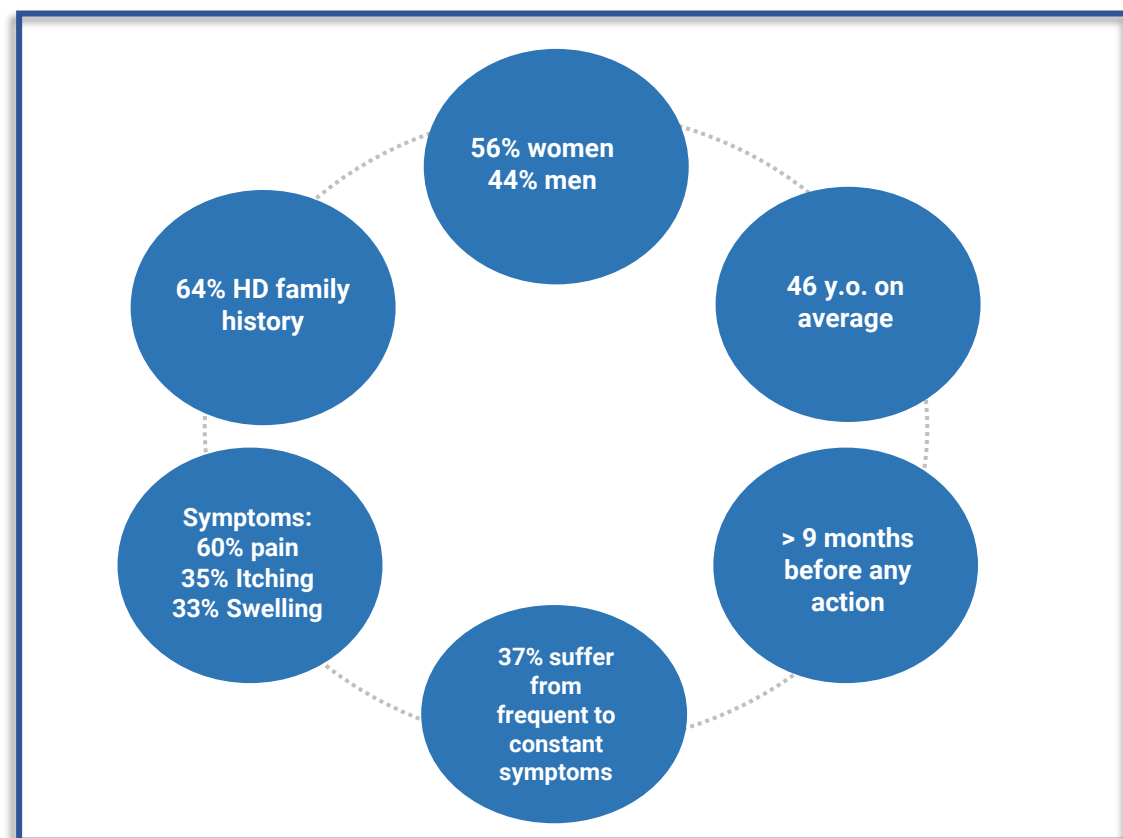


Hemorrhoids , A new complete disease Management Strategy



Challenging situation

A very common patient who doesn't want to talk about his/her disease

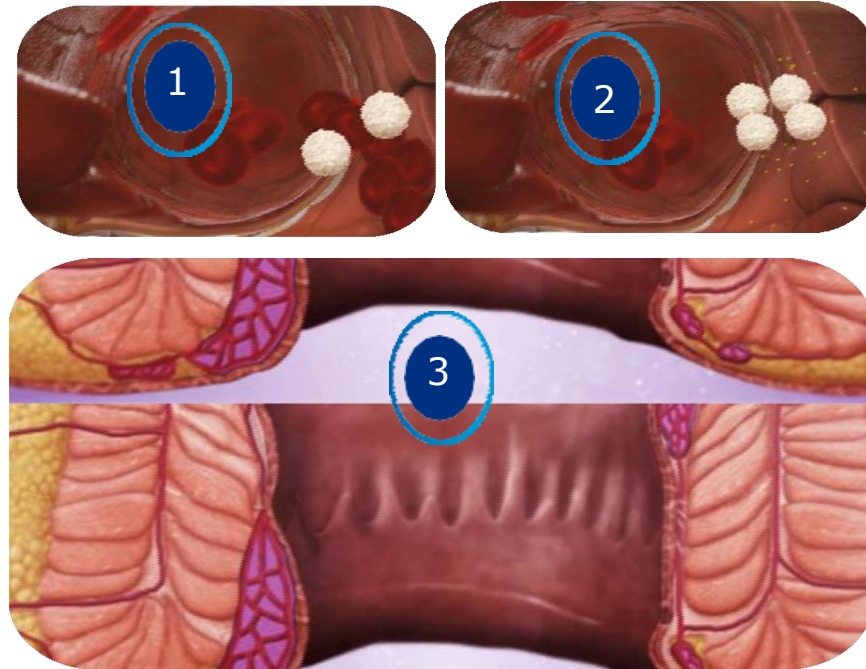


Source: Patient Pathway - Feb18 - Harris Interactive. 16,015 responders, 8 countries (Czech Republic, France, Italy, Brazil, Russia, Hungary, Spain, Romania)

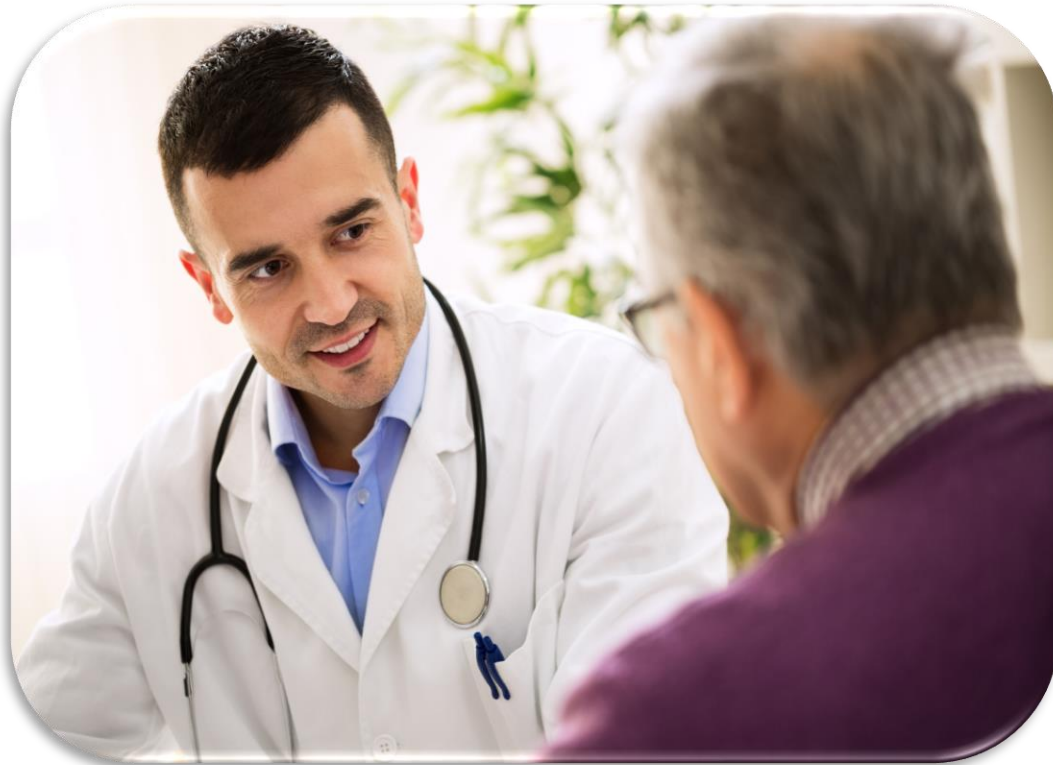
- https://www.forumsalute.it/community/forum_66_chirurgia_colonproctologica/thrd_235722_preparazione_all_intervento_di_emorroidi_bis_purtroppo_1.html#postcount4925140
- <http://club.passion.ru/zhenskoe-zdorove/gemorroy-prohodit-t186533.html>

Inflammation and stagnation lead to macrovascular dysfunction

- 1 Stagnation of blood in the venules and loss of venous tone
- 2 Activation of the leucocytes and Release of inflammatory mediators
- 3 Symptoms:
bleeding (edema, pruritus , tenesmus, discharge, proctitis, erythema), and prolapse



Symptoms leading patients to consult their doctors



Bleeding



Itching



Anal discomfort



Burning



Prolapse (depending on grade of hemorrhoids)

Optimal Hemorrhoids Management Strategy

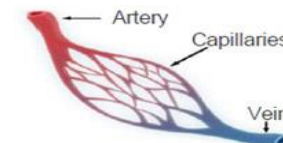
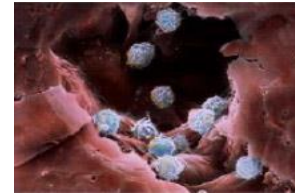
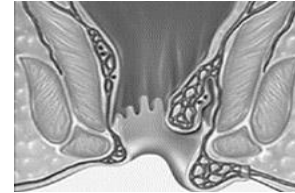


Reference treatment ,
act the core of the disease

Daflon 500 is the first-line treatment

Medication – MPFF, venoactive drugs

acts at the root of the disease,
on vein inflammation



Increase venous
tone



Reduce vein
inflammation



Reduce severity and
duration of acute
hemorrhoidal symptoms



GUIDELINES

MPFF /Daflon is the reference treatment

European Society of
Colo Proctology



2019

VAD/flavonoids are recommended **at all HD grades in the 1st step** for symptomatic relief as part of the basic treatment, and also considered in patients with thrombosed hemorrhoids.

Russian
Association of Coloproctology



MPFF: recommended for **the treatment of HD** (grade B- evidence level 1a) & for **thrombosed hemorrhoids**.

American Society of Colon and
Rectal Surgeons



VAD/flavonoids: recommended as **first-line treatment for grade I-III hemorrhoids** (grade 2B)

The Association of Colon & Rectal
Surgeons of India



2017

MPFF: recommended as a **first-line treatment in grade I-II and selected/minor grade III HD;** also as an **effective adjuvant to surgery and other procedures**.

French Society of
Colo-Proctology



2016

VAD(**MPFF**): for **acute symptoms of HD (bleeding and pain)** (level 1) (grade A)

Efficacy of MPFF / daflon[®] proven in a 2020 meta-analysis

In acute Hemorrhoids

the only veno-active drug with efficacy on HD proven with meta-analysis.

11 clinical studies with 1991 patients with Acute HD



Bleeding
($P < 0.001$)



Pain ($P = 0.06$)



Anal Discharge
($P < 0.001$)



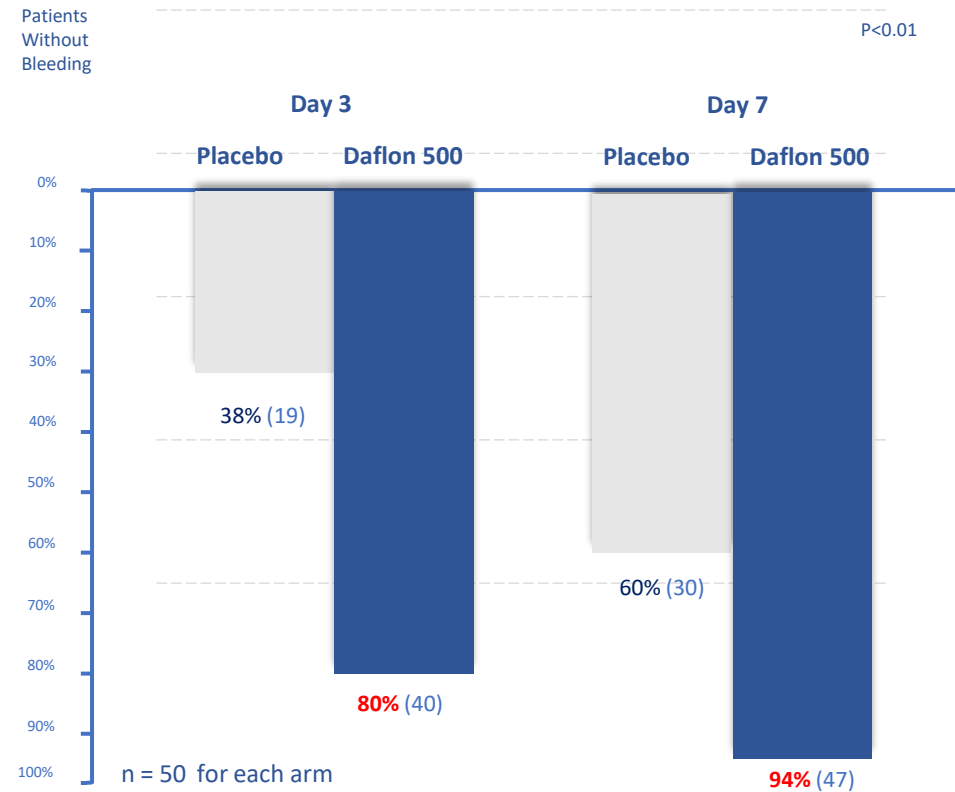
Overall improvement of symptoms
($P < 0.001$)

MPFF / daflon[®] provides fast symptom relief in acute HD

- Assess the Effective and rapid non-invasive control of acute bleeding. 90-day randomized, double-blind study
- 100 patients with acute HD received either MPFF 500 mg or placebo for 7 days
- daily dose of MPFF: **6 tab for 4 days then 4 tab for 3 days**
Symptom improvement was graded from 0 to 3.

- ✓ MPFF, from day 2, provided significantly greater improvement in bleeding compared with placebo.
- ✓ Patients treated with MPFF reported a significant reduction in bleeding at day 3 80% and at day 7 94%

Bleeding

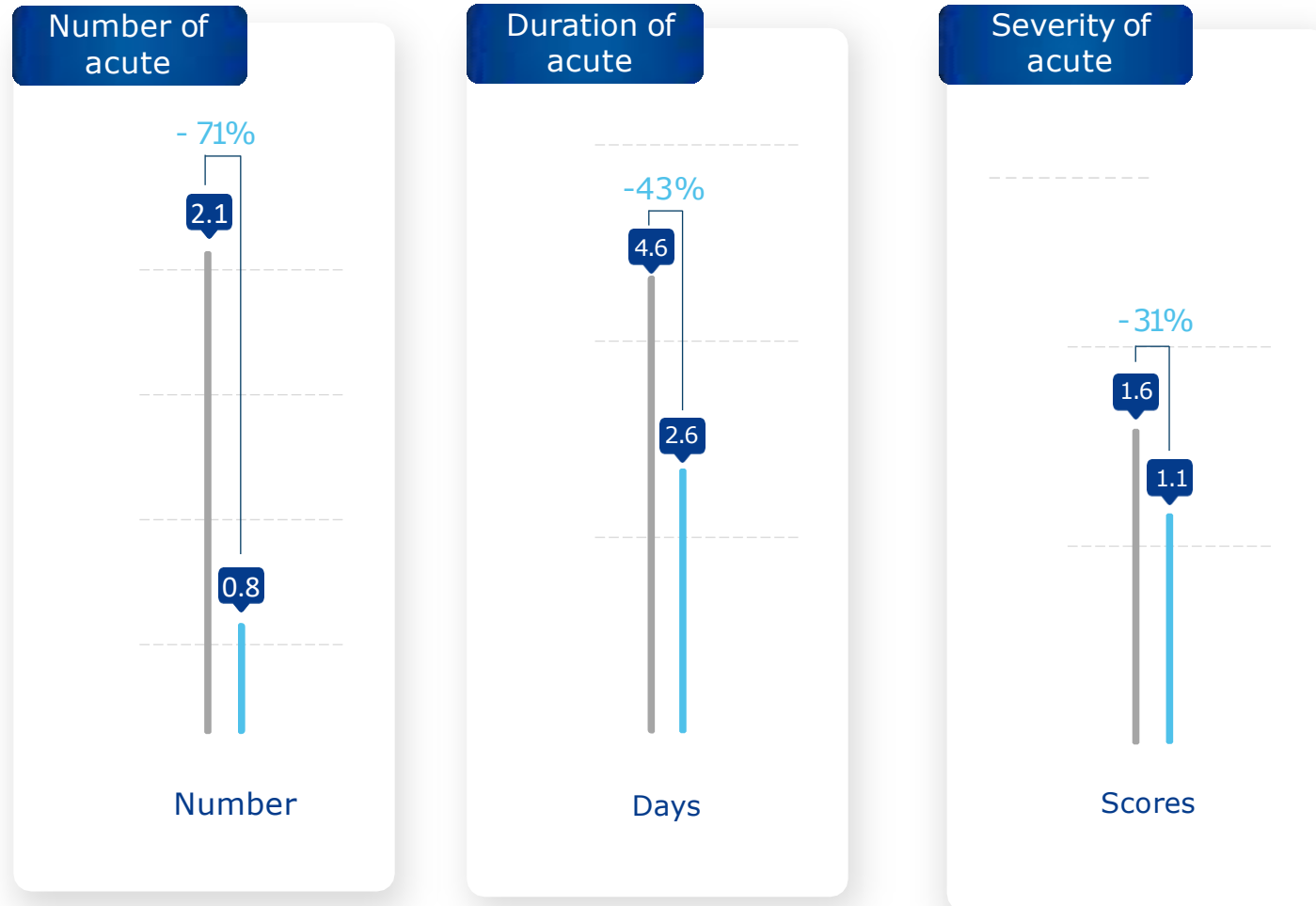


MPFF / daflon[®] prevents acute recurrence of HD episodes and severity

Acute episodes were significantly fewer, shorter, and milder with relapses per patient and the duration and severity of acute attacks decreased with MPFF

● Placebo
● MPFF 500 mg

* $P < 0.01$
n=120
3 month treatment
2 tabs daily



Efficacy of MPFF / daflon[®] in post-hemorrhoidectomy patients

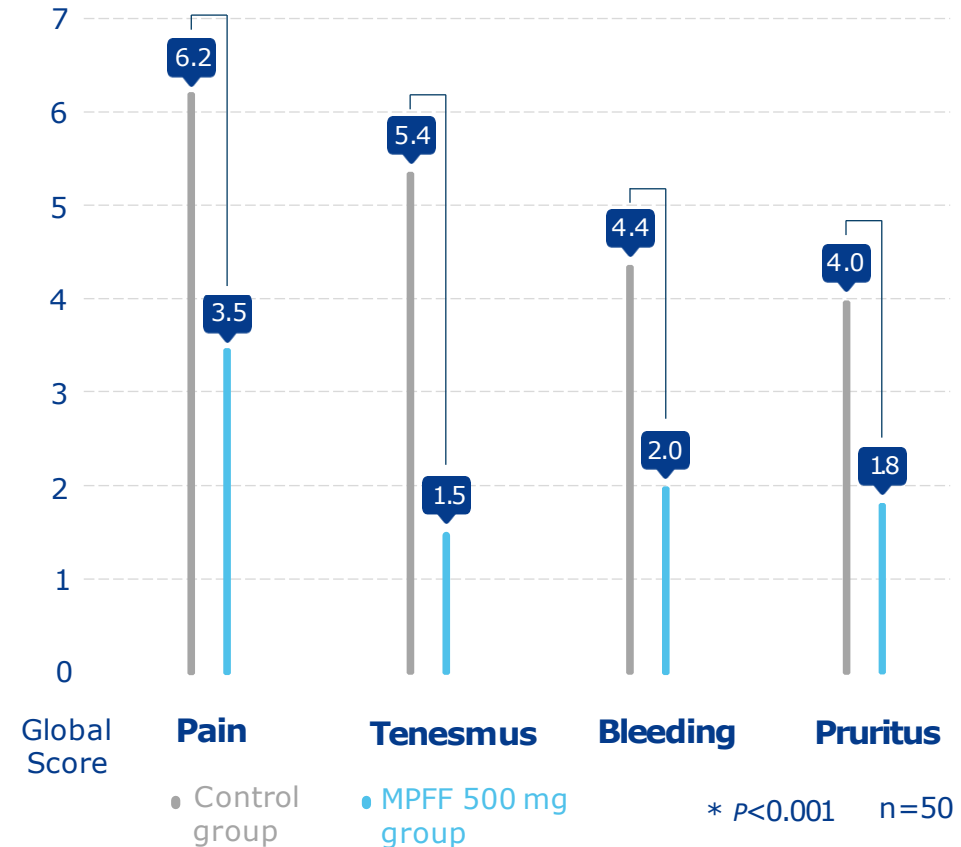
MPFF provides rapid relief from symptoms in patients who have undergone post-hemorrhoidectomy

Randomized, controlled study

- 50 patients presenting for a hemorrhoidectomy received
 - MPFF 500 mg + antibiotic/NSAIDs for 30 days
 - Antibiotic/NSAIDs alone : 5 days (daily dose of MPFF: 2g for 10 days then 1g for 20 days)
- Follow-up: 2 months

✓ Global improvement in symptoms were in favor MPFF starting from postoperative day 3 ($P < 0.0001$)

Significant reduction in HD symptoms



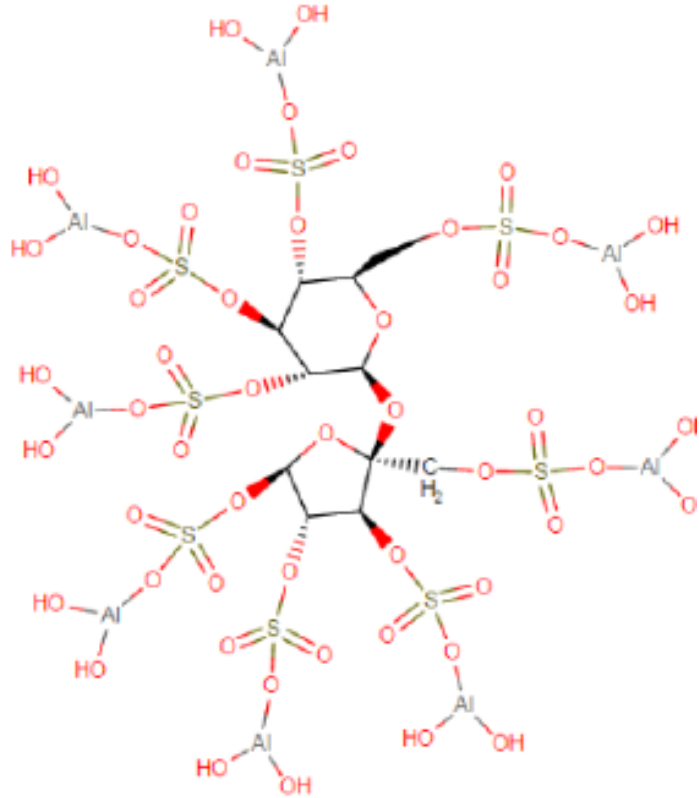
Optimal Hemorrhoids Management Strategy



&



Sucralfate: active ingredient well-known for its protective properties

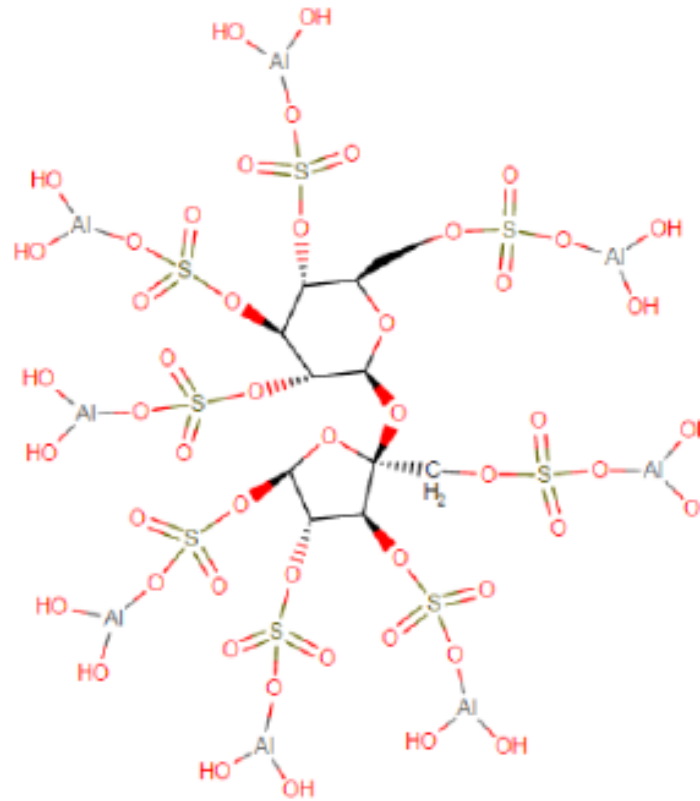


- **Sucralfate** is aluminium hydroxide salt of the disaccharide sucrose octasulfate .
- It was first used as an anti-gastro-duodenal ulcer drug

Form a Mechanical barrier

- Sucralfate bind to proteins on the surface of ulcers, such as albumin and fibrinogen, to form stable insoluble complexes. These complexes serve as protective barriers at the ulcer surface

Sucralfate: active ingredient well-known for its protective properties



Form a Mechanical barrier

➤ increasing the bioavailability of certain growth factors

➤ induction of prostaglandins production

Help & accelerate epithelial wound healing

Masuelli L, Tumino G, Turriziani M, Modesti A and Bei R. Topical use of sucralfate in epithelial wound healing: clinical evidences and molecular mechanisms of action. Recent Patents on Inflammation & Allergy Drug Discovery 2010; 4(1): 25-36.

Studies:

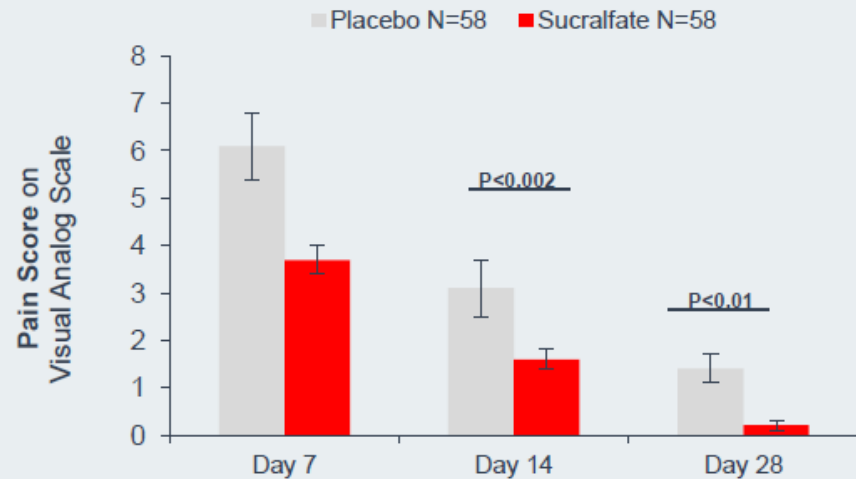
Effect of Topical Sucralfate on Pain & wound healing after Hemorrhoidectomy: *J.Gupta 2008*

Methodology

Randomized, blinded, controlled study

Post Milligan Morgan hemorrhoidectomy, n=116

7% sucralfate or placebo cream 3 times/day on top of Acuwil (tramadol hydrochloride 37.5 mg and acetaminophen 500 mg) 2 tablets/day, metronidazole 2 tablets/day and 30 ml of lactulose/day



KEY INSIGHTS

- PAIN INTENSITY**

Significant decrease in sucralfate group at D7 and D14

- WOUND HEALING**

Significantly faster in sucralfate group 100% wound healing at D41 vs D52 ($P < 0.01$).

Significant wound healing for 82% of patients in sucralfate group vs 55% of patients in placebo group ($P < 0.02$).

- USE OF ANALGESICS**

Decrease of use of Acuwil: 18 tablets in sucralfate group vs 24 tablets at D7

Studies:

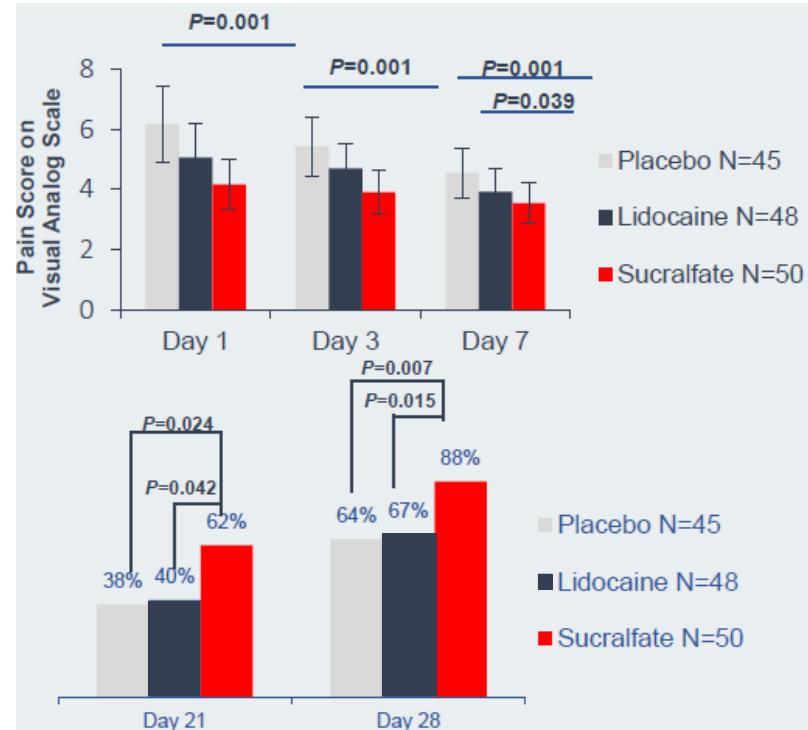
Comparative study between Sucralfate ointment & Lidocaine after Hemorrhoidectomy: *Alkhateep 2017*

Methodology

Double blinded randomized placebo-controlled

Post Milligan Morgan hemorrhoidectomy, n=150

10% sucralfate, 5% lidocaine or placebo ointment every 6 hours; on top of diclofenac sodium every 12 hours and lactulose twice a day



PAIN INTENSITY

- Significant decrease in sucralfate group at D1, D3, and D7.

WOUND HEALING

- Significant increase in sucralfate group.

Take away

- Sucralfate 10% reduces the acute postoperative pain and improves wound healing after hemorrhoidectomy
- Lidocaine 5% decreases significantly pain but without effect on healing.

What is **emoflon**™ ?

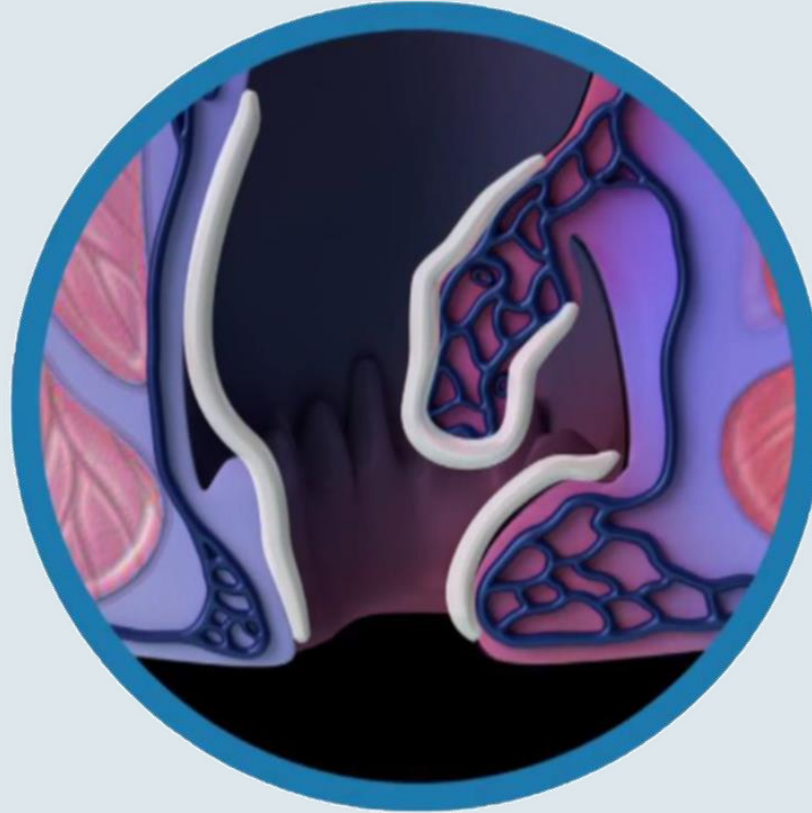


- **Rectal Ointment** intended for the **treatment of symptoms associated with hemorrhoidal disease & its complications** (e.g. eczema & anal fissure).
- **Medical device** (exerts effect mechanically) **Class IIa** (invasive device for short term use)
- **Dose & duration: 1-2 times daily up to 4 weeks**
- **Product form & size: Ointment 25 gm**


NEW Innovation

Patients with Anal conditions

Unique composition
Sucralfate





emoflon® is a class IIa medical device. Manufactured by EGIS Pharmaceuticals PLC.  2409

* Emoflon® Instructions for Use: March 2021. Emoflon® covers and protects the epidermis, provides care to the inflamed, itchy skin, by this means helps to promote skin regeneration. It diminishes the drying out of the skin, hereby helps wound healing, reduces the risk of fissure and injury caused by defecation.

A triple action

PROTECTS the anal mucosa against injury caused by defecation*

RELIEVES
itchy and inflamed
anal mucosa*

Helps **WOUND HEALING**
and to promote **SKIN
REGENERATION***

A unique composition

- ✓ Physical active ingredient **SUCRALFATE**
- ✓ A mechanical barrier to protect the anal mucosa*

Ø CORTISONE -FREE


Contains herbal extracts

Ø LIDOCAINE - FREE

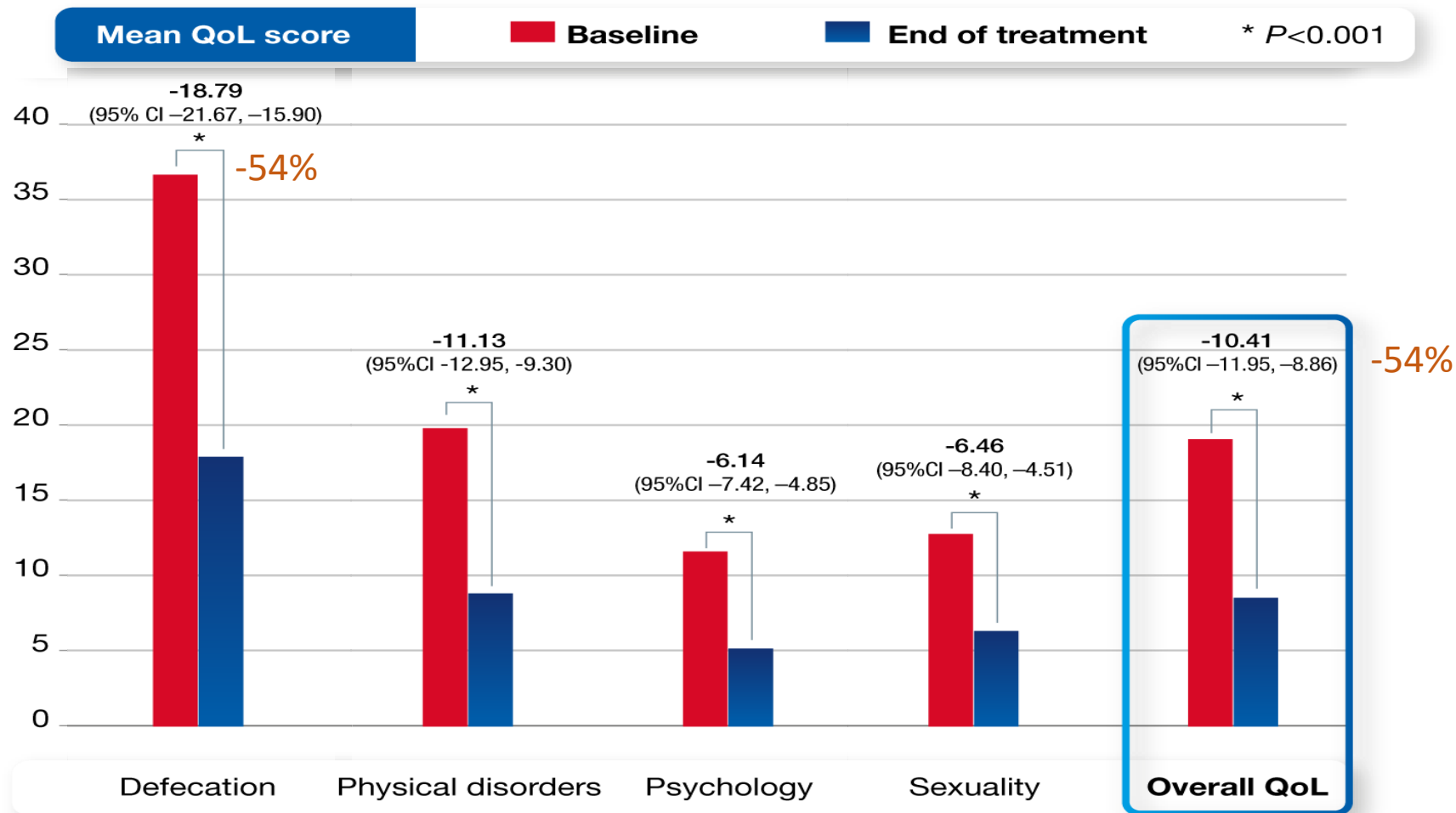
Primary end point:
Change from baseline to end of treatment in mean quality of life (QoL) scores.
A reduction in score indicates an improvement.



Quality of life results

- ✓ The mean total HEMO-FISS-QoL score significantly improved
- ✓ The mean score for all domains of the scale significantly improved

Giua C et al. The effect of sucralfate-containing ointment on quality of life in people with symptoms associated with haemorrhoidal disease and its complications: the results of the EMOcare survey. *Acta Biomed.* 2021; 92(1).



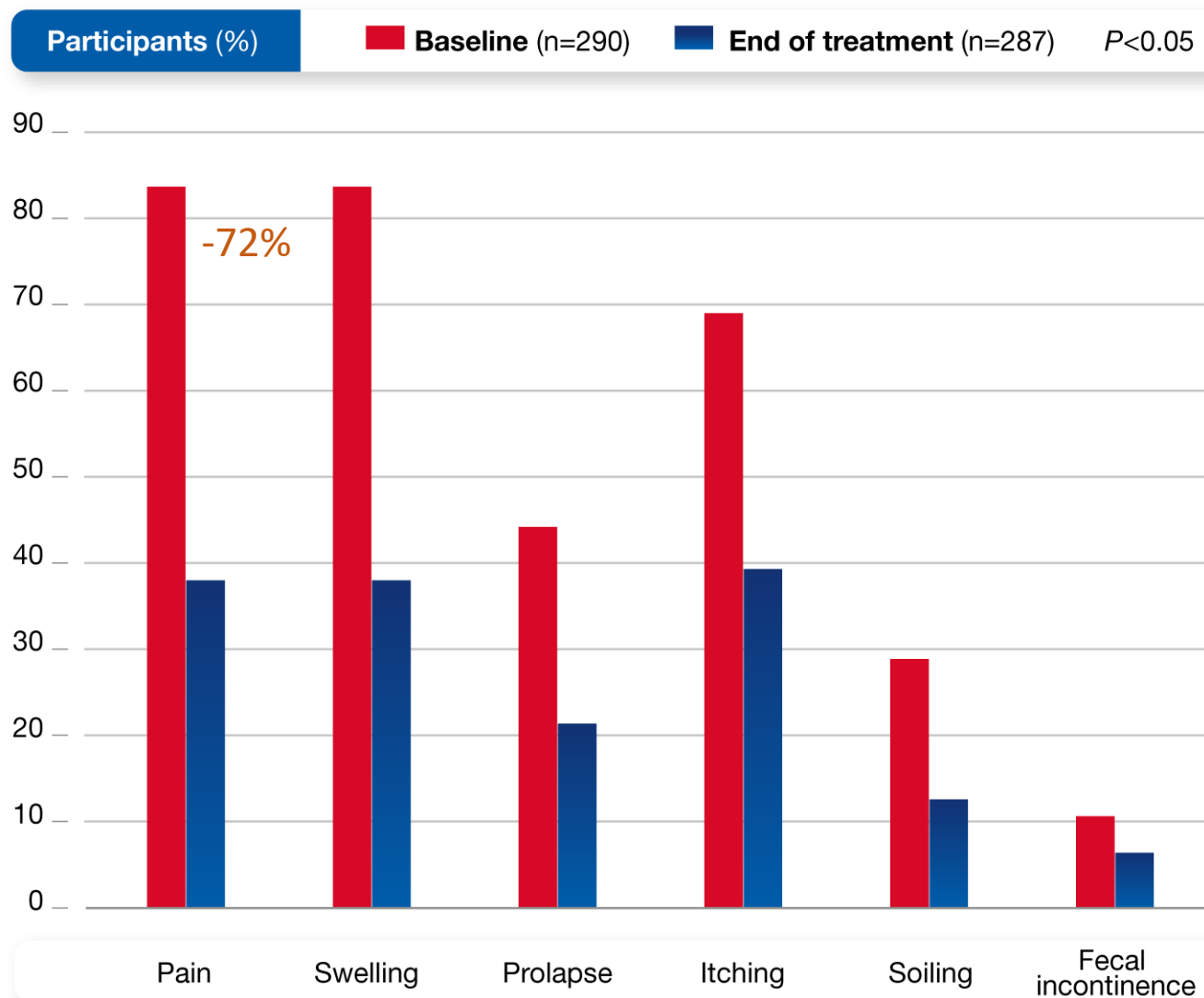
Secondary end point: Change from baseline to end of treatment in the percentage of participants reporting symptoms of any frequency (rarely, sometimes, very often, or always).



Symptom improvement results

- ✓ The proportion of participants reporting any frequency of symptoms was reduced significantly from baseline

Giua C et al. The effect of sucralfate-containing ointment on quality of life in people with symptoms associated with haemorrhoidal disease and its complications: the results of the EMOcare survey. *Acta Biomed.* 2021; 92(1).



Optimal Hemorrhoids Management Strategy



Reference treatment ,
act the core of the disease



the new and innovative
local treatment to relieve
symptoms and wound healing

Optimal HD Management Strategy

SYNERGY WITH **daflon[®]500_{mg}**



The reference
treatment



6

Tabs Daily
for 4 days

4

Tabs Daily
for 3 days

Then

2

Tabs Daily



Thank you

