

## The Discovery of VB-Gy Filmogen Glycerol Should Revolutionize Hemorrhoidal Treatment in the Future

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### SUMMARY

Hemorrhoids result from dilation of the submucosal vascular tissue in the distal anal canal. These dilated blood vessels may remain inside the anal canal (internal hemorrhoids) or may protrude outside the anus (external hemorrhoids). Persistent vascular dilation may lead to severe inflammation with associated pain and discomfort. Anti- and pro-inflammatory cytokines flood hemorrhoidal surface but if vascular oedema is not removed, inflammation persists and hemorrhoids become chronic. Theoretically, it should not be difficult to reduce vascular oedema and the concentration of pro-inflammatory cytokines from the hemorrhoidal surface, but even modern medicine is not capable of finding a drug which can act simultaneously on vascular oedema, inflammation, pain, and hydration without serious side effects. A few scientists in France imagined using a non-irritant and highly osmotic liquid solution as a topical film over the hemorrhoidal surface to drain out oedema fluid and to clean the hemorrhoidal surface with the outgoing liquid flow. They observed that minimizing oedema and cleaning away inflammatory cytokines through a mechanical and totally safe process produces excellent results within a few days. Being topical, such a treatment cannot induce any side effects. The authors are convinced that such a simple, safe, and multi-target therapeutic approach should revolutionize future treatment of hemorrhoids.

Hemorrhoids are a frequent pathological condition with a considerable burden [1]. Although not a life-threatening disease, the manifestation of hemorrhoids is associated with significant discomfort, having a huge impact on the normal day-by-day routine of the patient. It even has historical relevance since it might be the reason why the French emperor, Napoleon Bonaparte, lost the battle of Waterloo in 1815 [2]. Indeed, he had severe hemorrhoidal pain on that day.

Hemorrhoids occur when the veins of the rectum or anus become dilated or enlarged. Depending on the location of these oedematous blood vessels in relation to the anal dentate line, they classify as internal (essentially above the dentate line) or external (mostly below the dentate line).

External hemorrhoids are most uncomfortable, because the overlying skin becomes irritated and erodes. Eventually, a blood clot forms inside an external hemorrhoid, causing sudden and severe pain. If the clot dissolves, the remaining excess skin might cause itch or become irritated [3,4]. Internal hemorrhoids are also associated with pain during bowel movements, as well as an inevitable rectal bleeding.

So far, therapeutic options are diverse, ranging from dietary and lifestyle modifications to operating-room procedures. However, surgery is only contemplated for advanced stages of disease and it can be associated with appreciable complications, counteracting its efficacy. On the other side, pharmacological or non-operative treatments are, in fact, symptomatic treatments often associated with disappointing chances of success and may have side effects [5,6]. In the absence of any curative treatment, hemorrhoids tend to become chronic and inflamed, leading to, among other things, the formation of edematous vascular sinusoids, tissue destruction and pain.

The authors believe that the understanding of the pathophysiology underlying the manifestation of internal or external hemorrhoids is key to finding the ideal treatment. During the initial phase of hemorrhoid disease, anti-inflammatory cytokines are secreted, particularly on the hemorrhoidal surface, to suppress inflammation but, if the process continues, then, pro-inflammatory cytokines are produced to maintain the inflammation [4]. After a few weeks, pro-inflammatory cytokines dominate an inflammatory cascade, and healing becomes extremely difficult [7,8].

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The authors surmised that the best therapeutic strategy should act on the origin of the disease and, subsequently, allow the recovery of all the symptoms. In other words, the ideal approach should enhance the elimination of the edema, a crucial step to minimize the size of the hemorrhoids and to normalize tissue physiology. Concomitantly, it should allow the natural decrease of inflammation to ease pain, irritation, itching, and bleeding. Healing of damaged tissue further requires keeping the tissue hydrated and infection-free. In order to avoid systemic effects, topical route is more desirable.

Nevertheless, it is practically impossible for a single drug to fulfill all these basic requirements at a time, which explains why an efficient pharmacological treatment is lacking [9]. In addition, due to the differences in anatomical structure, location, and physiopathology of internal and external hemorrhoids, the treatment strategies must also be different. For example, in the specific case of internal hemorrhoids, the location of lesions challenges the use of any long-acting topical medication, while, in the case of external hemorrhoids, a topical treatment is desirable.

NATURVEDA SAS conceived and patented a glycerol-based hypertonic filmogen solution (VB-Gy), 18 times more osmotic than sea water yet not irritant. It is capable of creating a highly osmotically active film over the hemorrhoidal surface, attracting hypotonic liquid from any live semi-permeable biological membrane, and thus acting as a strong anti-edematous bandage for topical application [10]. The hemorrhoidal wall is a semi-permeable and distended with excessive hypotonic liquid. Therefore, the treatment of this condition would benefit from a solution that could attract hypotonic liquid from the inner parts of the hemorrhoids, reducing their volume and keeping the outer hemorrhoidal surface hydrated, helping to relieve the pain, irritation and itching. In the case of internal hemorrhoids, however, VB-Gy eventually gets diluted due to the strong hypotonic liquid outflow it generates. Consequently, VB-Gy *per se* might fail to exert the required osmotic pressure on the surface to provoke exudation of hypotonic liquid from the hemorrhoidal mucosa. Therefore, the strategy adopted was to render the VB-Gy filmogen, flexible and resistant to dilution, by adding a small quantity of natural polymeric ingredients and essential oils, and reducing its water content.

The innovation underlying this treatment is the fact that the conceived and patented VB-Gy-based formulations exert a mechanical rather than a pharmacological effect over the hemorrhoidal mucosa, constituting a new generation of multi-target, anti-edematous, topical treatment. This treatment ultimately produces symptomatic relief and creates a proper environment for healing. Moreover, Glycerol is a common and natural food ingredient, non-toxic (orally and topically) and several tests showed that it is non-irritant,10, attributing to VB-Gy a desirable safety profile, devoid of severe adverse effects.

The therapeutic potential of this new approach to treat hemorrhoids was nicely corroborated by clinical studies [11]. Indeed, it was recently demonstrated that the topical application of hypertonic, osmotically active VB-Gy to patients diagnosed with hemorrhoids provided a clear and fast improvement of the symptomatology. It is remarkable the decrease of hemorrhoids' size as a consequence of the exudation of the liquid accumulated in the hemorrhoid lesion and the relief of pain and overall discomfort (e.g. itching, irritation). More importantly, the beneficial effect exerted by VB-Gy topical application persisted beyond the treatment period (usually 14 days), as confirmed by the follow up consultation on day 21 after the beginning of the treatment (i.e. after 14 days of treatment followed by 7 days without treatment).

This is an innovative and yet simple and logical approach that represents an outstanding achievement, raising a big hope for those dealing with the pain and distress of hemorrhoid manifestation.

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