

## **Clinical Evaluation of PIL-28, a Herbal Formulation in the Management of Hemorrhoids**

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### **ABSTRACT**

*Fifty patients of either sex aged between 22 and 63 years entered in the study for the evaluation of safety and efficacy of PIL-28. PIL-28 is a formulation of herbs and minerals designed for the management of hemorrhoids. In the group that entered the study, 31 had external hemorrhoids, 10 had internal hemorrhoids and 9 of the patients had both internal as well as external hemorrhoids. The patients were given PIL-28 at a dose of 1 tablet, twice daily for 6 weeks. At the end of the 6 weeks treatment, the patients were evaluated for efficacy and tolerability of PIL-28 tablets. The results revealed that response to PIL-28 was very good in 56.25 % of patients and good in 37.50% of the patients, showing a marked improvement in general health along with a gross reduction of associated symptoms. There were no side effects observed during the treatment and follow-up period.*

### **INTRODUCTION**

Internal hemorrhoids arise from the superior (internal) hemorrhoidal vascular plexuses, above the pectinate line; they are covered by mucosa (Mazier *et al.*, 1995). External hemorrhoids are dilatations of the inferior external hemorrhoidal plexuses; they lie below the pectinate (dentate) line and are covered by anoderm and perianal skin. As the two plexuses freely form anastomoses, many patients have a combination of both types i.e., interoexternal or mixed hemorrhoids (Corman, 1993; Gordon and Nivatvongs, 1991).

Bleeding is a prominent feature, but many patients find the discomfort of persistent discharge the main symptom. This results in the soreness of the adjacent skin and irritation. There is always considerable confusion and much difference of opinion in the treatment of any disease of obscure origin and etiology. The range of oral medicines, suppositories, conservative and operative measures for controlling the symptoms of hemorrhoids bear testimony to this confusion.

PIL-28 contains powders of *Balsamodendron mukul*, Shilajeet (purified), *Melia azadirachta* and extracts of *Berberis aristata*, *Emblica officinalis*, *Terminalia chebula*, *Terminalia belerica*, *Cassia fistula*, *Bauhinia variegata* and *Mesua ferrea*. Processed in *Commelina salicifolia*, *Mimosa pudica*, *Acorus calamus*, *Blumea lacera*, *Caesalpinia bonducella* and *Amorphophallus campanulatus*.

*Commiphora wightii* (Guggulu) is an astringent antiseptic with anti-inflammatory and demulcent properties that help to reduce the pain and inflammation of hemorrhoids (Nadakarni, 1996a). *Emblica officinalis* (Amalaki) has laxative action, which is important in

relieving constipation in hemorrhoids (Kirtikar and Basu, 1981). Its antibacterial and astringent properties prevent infection and help in healing of ulcers (Nadakarni, 1996b). *Mimosa pudica* (Lajjalu) has anti-inflammatory, antiseptic and healing properties. It helps in shrinking pile mass and shrinking varicose veins (Kirtikar and Basu, 1987; Nadakarni, 1976). Shilajeet (Mineral pitch) has astringent and anti-inflammatory properties and is used in the treatment of painful, bleeding hemorrhoids and varicose veins (Nadakarni, 1996c). *Terminalia chebula* (Haritaki) acts as a gentle laxative and helps in smooth evacuation (Warrier *et al.*, 1997). *Berberis aristata* (Daruharidra) is found to be a laxative and is useful in hemorrhoids.

## **MATERIALS AND METHODS**

Fifty patients were enrolled in this study, which include 43 males and 7 females. The patients were grouped as external hemorrhoids (31 patients), internal hemorrhoids (10 patients), and external and internal hemorrhoids (9 patients). All the patients were administered PIL-28 at a dose of 1 tablet twice daily for 6 weeks. Periodical follow-up was done fortnightly. Concomitant medications with other hemorrhoidal preparations were not allowed during the study period.

Patients were evaluated by a proctoscopic examination before and at every follow-up for six weeks of treatment. Signs and symptoms evaluated as reduction in the size of the hemorrhoidal mass, pain during defecation, bleeding during defecation, anal pruritus, straining bowel and loss of appetite. The intensity of the signs and symptoms were graded on 4 point scale, i.e., absent: 0; mild: 1; moderate: 2 and severe: 3. At the end of the treatment, both patients and physician evaluated the efficacy of the treatment on the following scale: *Very Good, Good and Not Effective*.

## **RESULTS**

Thirty two patients completed the treatment, hence only 32 patients were considered for therapeutic evaluation. Remaining 18 patients did not return for follow-up. All the patients who completed the treatment showed positive compliance to the drug. Following was the therapeutic assessment with PIL-28.

PIL-28 was very good in 18 (56.25%) patients, good in 12 (37.50%) patients and 2 (6.25%) patients did not show any significant clinical response.

## **DISCUSSION**

Some physicians adopt oral while some recommend local applications of styptics. Earlier commonly used treatment was an injection of sclerosing solution of 5% phenol in almond oil injected into submucosa around the pedicle. This treatment is not suitable for larger or prolapsed hemorrhoids.

Another form of treatment for hemorrhoids is cryotherapy, where freezing is done with nitrous oxide to  $-90^{\circ}\text{C}$ . The disadvantages however are discomfort, edema, discharge, pain and expensive treatment.

The clinical trial with PIL-28 showed marked improvement in general health of the patient and significant reduction in symptoms of hemorrhoids like pain and bleeding. The polyherbal formulation, PIL-28 has astringent, and antiseptic, anti-inflammatory and demulcent properties that help to reduce the pain and inflammation of hemorrhoids. PIL-28 also possesses laxative property, which is important in relieving constipation associated with hemorrhoids. This is beneficial for elderly patients, where severe strain during constipation may produce systemic complications. The antibacterial and astringent properties of PIL-28 are useful in preventing infection and were shown to help in healing of ulcers. PIL-28 also helps in shrinking hemorrhoidal mass. Thus, PIL-28 was recommended at a dose of 1 tablet, twice daily for mild to moderate hemorrhoids. The dosage may be modulated depending upon the severity of the symptoms and associated risk factors. During the trial period, no observable side effects were noticed. Although this has been an open clinical trial in small population of patients, this can be further confirmed in the larger population of clinical trials.

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