

Comparative Evaluation of Pilex with Daflon in Haemorrhoids

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ABSTRACT

Thirty patients with grade I, II and III haemorrhoids were enrolled in an open clinical trial to compare the efficacy of Pilex tablet and ointment with Daflon tablet. Pilex tablet and ointment were highly effective in patients with Grades I and II haemorrhoids. Ninety percent of patients showed complete relief and recovery. Patients with Grade III haemorrhoids required longer treatment of four weeks to control haemorrhoidal bleeding. The efficacy of Pilex tablet with ointment is comparable to Daflon tablets. Daflon tablets, however takes longer period of 4–6 weeks to control haemorrhoidal bleeding. In patients with Grade I and II haemorrhoids with mild symptoms, Pilex ointment alone may be recommended. However, patients with severe symptoms and Grade III haemorrhoids may require a combination of Pilex tablet with ointment.

Key words: Bleeding, haemorrhoidal plexus, constipation

INTRODUCTION

Haemorrhoidal tissue is found at the distal end of the rectum within the anal canal. These vascular and connective tissue cushions are usually found in the right anterolateral and posterolateral positions and the left lateral position. Internal haemorrhoids are above the dentate line; external haemorrhoids are the vascular complexes under the anoderm of the anal canal. The function of normal haemorrhoidal tissue is to provide protection to the underlying muscle during defecation and allow complete closure of the anal canal during rest.

The pathophysiology of symptomatic haemorrhoids is related to the engorgement of the vascular pedicles in the haemorrhoidal complexes, which then dilate, stretch and cause the cushions to enlarge. The vascular plexuses engorge as pressure is applied to the pelvic floor during straining, lifting or standing. Bleeding occurs from local trauma to the haemorrhoidal plexus, during defecation. Hard stools, prolonged straining, increased abdominal pressure and prolonged lack of supports to the pelvic floor all combined increase the likelihood of abnormal haemorrhoidal tissue development.

Internal haemorrhoids, which are covered by mucosa, typically bleed or prolapse, but do not cause pain. Patients complain of rectal fullness, mucous discharge and bright red blood dripping into the toilet or on the toilet paper. Occasionally, internal haemorrhoids will

incarcerate within the outer ring of the anal canal and develop thrombosis and necrosis. Internal haemorrhoids can be classified as follows: first-degree haemorrhoids, second-degree haemorrhoids and third-degree haemorrhoids which bleed, prolapse and require manual reduction; fourth-degree haemorrhoids that bleed and incarcerate and cannot be reduced may require surgical intervention.

External haemorrhoids beneath the anal skin enlarges over time due to dilatation or repeated thrombosis. The overlying skin may stretch to develop a skin tag, which prevents adequate hygiene. Occasionally, a clot within an external haemorrhoid will cause severe pain and may bleed if the clot erodes through the overlying skin. External haemorrhoids usually cause pain and itching even after a small thrombosis as they are beneath richly innervated skin.

MATERIALS AND METHODS

Thirty patients with grade I, II and III of internal and external haemorrhoids were included in the trial. This was a controlled trial using Pilex tablet and ointment with Daflon tablets. Patients with evidence of rectal prolapse, malignancy and systemic debilitating illness were excluded from the trial. Baseline investigations which included a complete haemogram with stool examination were done in all the patients. All the patients were subjected to clinical history taking and physical examination including the digital and proctoscopic examinations. Patients were divided into two groups of 15 each. Group A patients received Pilex tablets, 2 tablets thrice daily after meals for one week, followed by 2 tablets twice daily for 5 weeks. All the patients were advised to apply Pilex ointment twice daily before and after evacuation of the bowel.

Group B patients received Daflon tablets in the dose of one tablet three times daily for 6 weeks. All the patients were examined at weekly intervals of 6 weeks for subjective evaluation. The subjective evaluation included observations of rectal fullness, bleeding *per rectum*, pain, itching and ease of evacuation of the bowel.

The subjective evaluation was graded as mild, moderate or complete relief with mathematical scores, i.e,

- 1 – Mild relief
- 2 – Moderate relief
- 3 – Complete relief

The objective evaluation was done at the beginning and at 6 weeks on completion of the treatment.

Criteria of anti-inflammatory and wound healing efficacy was determined through the following:

1. Shrinkage of haemorrhoidal mass
2. Control of bleeding *per rectum*
3. Relief from itching
4. Control of pain during defecation

5. Relief from constipation
6. Control of secondary infection

Patients were also interrogated for any side effects occurring during the period of the trial.

RESULTS

GROUP A: Patients treated with Pilex tablet and ointment

Ten patients were suffering from Grade I haemorrhoids, 4 patients were suffering from Grade II haemorrhoids and 1 patient from Grade III haemorrhoid.

Grade I: Pilex tablet and ointment was found very effective in controlling bleeding. About 90% of patients reported complete recovery and on proctoscopy after 4 weeks of treatment, the mucosa was normal. Bleeding was checked within 2-3 weeks of treatment. In 80% of cases, shrinkage in pile mass gradually took place over 3-4 weeks.

Grade II: Moderate reduction in size and inflammation on haemorrhoidal mass was reported in patients from Grade II haemorrhoids. Bleeding was controlled in over 90% of cases.

Grade III: Mild reduction in size and inflammation of haemorrhoid mass was reported. However, bleeding stopped within 4 weeks of treatment.

GROUP B: Patients treated with Daflon

Four patients were suffering from Grade I haemorrhoids, 9 patients were suffering from Grade II haemorrhoids and 2 patients from Grade III haemorrhoids.

Grade I: Daflon was very effective in controlling bleeding. Above 90% of patients responded in terms of bleeding *per rectum*. There was a mild reduction in size and inflammation of haemorrhoidal mass.

Grade II: Bleeding was controlled in over 90% of cases. Minimal to mild reduction in size and inflammation of mass was reported after 4-6 weeks of treatment with Daflon.

Grade III: Effective in controlling bleeding. Minimal change in size and inflammation was reported.

DISCUSSION

Pilex tablet is a polyherbal formulation comprising mainly of:

Commiphora mukul (Indian bedellium, Guggul) has astringent, antiseptic and antispasmodic properties and is used in the treatment of haemorrhoids. It is excreted by the mucous membranes of the body, in the course of which it stimulates and disinfects their secretions¹.

Azadirachta indica (Neem, Nimba) is effective against gram-positive and gram-negative bacteria. It relieves constipation and is useful in treating ulcers^{2,3}.

Emblica officinalis (Indian gooseberry, Amalaki) is antibacterial and its astringent properties prevent infection and help in healing of ulcers^{4,5}. It is used as a laxative to relieve constipation in piles⁶.

Terminalia chebula (Chebulic myrobalan, Haritaki) acts as a gentle laxative and helps in smooth evacuation⁷.

Cassia fistula (Indian laburnum, Aragvadha) is used in the treatment of varicose veins. It helps in shrinking engorged veins and has a profound anti-inflammatory activity⁸.

Shilajeet (Mineral pitch) has astringent and anti-inflammatory properties and is used in the treatment of painful, bleeding piles and varicose veins⁹.

Clinical trials conducted on Pilex tablets have shown its anti-haemorrhoidal activity. It helps in shrinking the pile mass, controls bleeding and itching, checks pain and constipation, exerts an anti-inflammatory action and speeds healing. Pilex tablet also helps in shrinking varicose veins^{10,12}.

Pilex ointment is an herbal formulation comprising mainly *Calendula officinalis*, *Mimosa pudica*, *Vitex negundo*, *Eclipta alba* and Yashad bhasma.

Calendula officinalis (Zergul) aids in quicker wound healing especially in cases of fissures and haemorrhoids and controls bleeding. It contains salicylic acid and essential oils which impart analgesic (pain relieving), astringent and styptic properties¹³.

Mimosa pudica (Sensitive Plant, Lajwanthi) leaves are applied in fistula and piles. It has antiseptic and anti-inflammatory properties. The roots and leaves help in shrinking varicose veins^{14,15}.

Vitex negundo (Five-leaved chaste Tree, Nirgundi) leaves are effective in dispelling inflammatory swellings and in controlling bleeding piles. It has a significant astringent activity¹⁶.

Eclipta alba (Thistles, Bhringaraja) has anti-inflammatory and antioxidant properties¹⁷⁻¹⁹.

Yashad bhasma (Zinc Oxide) has astringent and soothing properties. It is used in the treatment of wounds and inflammatory conditions of the skin. It relieves constipation.

CONCLUSION

- a) Daflon tablets and Pilex tablet and ointment are equally effective in controlling bleeding, irrespective of the grade of haemorrhoids. Bleeding was checked in both the groups over a period of 2-3 weeks.

- b) Pilex tablet and ointment are better than Daflon tablet in reducing inflammation and size of haemorrhoidal mass in Grades I and II haemorrhoids. In Grade I haemorrhoids, Pilex tablet and ointment brought complete remission in the majority of cases.
- c) Pilex tablet and ointment have got better efficacy in reducing pain in patients with haemorrhoids, than Daflon, in terms of early recovery.
- d) Neither Pilex nor Daflon have shown any significant role in relieving constipation and do not check secondary infection.

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