



Clinical evaluation of efficacy of Pilief Tablet and Pilief Ointment in the treatment of Piles

Mote D^{1*}, Supugade V², Shinde G³, Shevale M⁴

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^{1*} Dnyaneshwar Mote, Principal Investigator, Vidnyanam Clinic, Katraj-Kondhwa Road, Katraj, Pune, Maharashtra, India.


² Vikram Supugade, Co-Investigator, Pharate Patil Ayurvedic Medical College, Pune, Maharashtra, India.

³ Gurudatta Shinde, Co-Investigator, Pharate Patil Ayurvedic Medical College, Pune, Maharashtra, India.

⁴ Madhukar Shevale, Co-Investigator, Pharate Patil Ayurvedic Medical College, Pune, Maharashtra, India.

Hemorrhoidal disease (piles) is a highly prevalent condition affecting a substantial proportion of the population, often presenting with painful symptoms that significantly compromise quality of life. Despite the availability of conventional treatment modalities, a growing interest in alternative therapies, particularly herbal medicine is well noticed these days. The present study is aimed to evaluate the efficacy of a combined Pilief Tablet and Ointment in the treatment of piles. A total of 100 participants, diagnosed with mild to moderate piles were enrolled into the study and randomized to either of the study group or the control group. The study group was administered with the Pilief Tablet and Ointment combination for six weeks and the control group was supplemented with placebo. The primary outcome included the reduction of symptoms, measured through a standardized symptoms score, and secondary outcomes encompassed any incidence of adverse events and quality of life assessment. Results indicated a significant reduction in symptoms and improvement in quality of life among participants. This study underscores the therapeutic efficacy of Pilief Tablet and Pilief Ointment as viable treatment modalities for the management of hemorrhoids.

Keywords: Piles, haemorrhoids, herbal medicine, Pilief tablet, ointment, efficacy, randomized placebo controlled trial

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Introduction

Piles (haemorrhoids) are vascular structures located in the lower rectum and anal canal in three columns which on inflammation cause discomfort, pain, and bleeding. With a prevalence ranging from 4.4% to 36.4 % of the general population and a peak prevalence occurrence between the age group of 45- 65 years, it is estimated to affect about a third of the population[13,14].

Traditional treatment modalities often include analgesics, topical treatments, and surgical procedures. However, there is a growing trend towards the use of herbal formulations due to their perceived safety and effectiveness. This study investigates the efficacy of a novel herbal Pilief Tablet combined with Pilief Ointment in alleviating the symptoms of piles, both Manufactured by Charak Pharma Pvt. Ltd. The Study was carried out at Out Patient Dept. Vidnyanam Clinic, Pune.

Materials and Methods

The study was designed as randomized, two-arm, double blind, placebo controlled trial, where 100 participants are randomized to receive either the study intervention or placebo for a period of six weeks. Participants were recruited from outpatient clinics, and eligibility criteria included adults aged 18-65 diagnosed with mild to moderate piles.

Study Design: Randomized Double Blind Placebo Controlled Trial

Sample Size: 100 Participants

Test Group: 50 participants (received herbal treatment)

Placebo Control Group: 50 participants (received placebo)

Duration: 6 weeks

Randomization and Blinding

Participants were randomly assigned to either the herbal treatment group or a placebo group. Both groups received the treatment twice daily. Blinding was maintained throughout the study, with outcomes assessed by independent evaluators.

Trial Sites: Vidnyanam Clinic, Pune and Paharate Patil Ayurvedic Hospital, Daund, Pune.

Intervention:

Pilief tablet contained standardized blend of Extracts of Neem Leaves (*Melia azadirachta*), *Khair Chhal* (*Acacia catechu*), *Aloe barbadensis*, *Terminalia chebula* & *Chitrakmool* (*Plumbago zeylanica*), Guar Gum (*Cyamopsis tetragonoloba*) powder known for their anti-inflammatory & soothing properties. Ointment comprised Neem Leaves (*Melia azadirachta*), *Khair Chhal* (*Acacia catechu*), *Aloe Barbadensis*, *Yasthimadhu* (*Glycyrrhiza glabra*), *Haridra* (*Curcuma longa*) which are recognized for their topical analgesic & anti-inflammatory effects.

Dosage:

Subjects in Test Group Received 1 Pilief Tablet of 600mg twice daily after meals for 6 weeks and Placebo Control Group Received 1 Identical Tablet with Corn Starch of 500mg twice daily after meals for 6 weeks. Subjects in Test Group were given Pilief ointment QS for Local application twice daily for 6 weeks and Placebo Control Group were given Identical Base ointment without actives QS for Local application twice daily for 6 weeks.

Outcome Measures

Primary outcome measures included changes in total symptom score based on pain, itching, and bleeding assessed on a 10-point scale. Secondary outcomes were assessment of any adverse effects reported and quality of life measured using EQ-5D scale. Measured at Baseline and at End of 6 weeks.

Statistical Analysis

Data were analysed by independent t-tests and Chi-square tests were empl. as appropriate & p-value of <0.05 was considered statistically significant.

Results

Participant Characteristics

A total of 100 participants, 50 in treatment group and 50 in placebo group, completed study. Baseline characteristics were similar across both groups with no statistically significant differences.

| Characteristic | Test Group (n=50) | Placebo Group (n=50) | p-value |
|---------------------------------------|----------------------|-------------------------|---------|
| Age (Mean ± SD) | 45 ± 10 | 46 ± 11 | 0.650 |
| Gender (Male/Female) | 30/20 | 28/22 | 0.750 |
| Severity (Mild/Moderate) | 30/20 | 29/21 | 0.860 |
| Baseline Symptom Score (Mean ± SD) | 7.5 ± 1.5 | 7.6 ± 1.4 | 0.820 |

Primary Outcomes

At the end of the six-week period, participants in the herbal treatment group reported a significant reduction in the total symptom score (mean reduction = 7.5) compared to the placebo group (mean reduction = 2.0) ($p < 0.001$).

| Outcome Measure | Test Group (n=50) | Placebo Group (n=50) | p-value |
|-----------------------------------|-------------------|----------------------|---------|
| Mean Total Symptom Score (Week 0) | 7.5 ± 1.5 | 7.6 ± 1.4 | 0.820 |
| Mean Total Symptom Score (Week 6) | 1.5 ± 0.8 | 6.0 ± 1.2 | <0.001 |
| Mean Change in Symptom Score | 6.0 ± 1.2 | 1.6 ± 0.9 | <0.001 |
| Percentage Improvement | 80% | 20% | <0.001 |
| Adverse Effects | 0 (0%) | 0 (0%) | 1 |

Secondary Outcomes

There were no serious adverse effects reported in the treatment group. Additionally, scores on the EQ-5D scale showed a substantial improvement in the treatment group compared to the placebo group ($p < 0.01$).

| EQ-5D Scale | Test Group (n=50) | Placebo Group (n=50) | p-value |
|-------------|-------------------|----------------------|---------|
| (0-10) | 8.0 ± 1 | 5.5 ± 1 | < 0.01 |

Discussion

Ayurvedic medicines are prepared by natural, safe & potent herbs. Combined pharmacology or Mode of action of Ayurvedic multi herbal preparation like Pilief Tablet and ointment can be derived only from the synergic effect of all herbs present in that preparation. Pilief Tablet is the unique combination of drugs with anti-inflammatory, purgative, analgesic, and astringent property. It helps in arresting the haemorrhage and reduces the inflammation thereby shrinking the pile mass.

Anti-Inflammatory Action can be rationalised with Nimbidin present in *Melia azadirachta* suppresses functions of macrophages and neutrophils: relevance to its anti-inflammatory mechanisms[1-3] also the natural, flavonoid mixture in *Acacia catechu* acts via "dual inhibition" of COX and LOX enzymes to reduce production of pro-inflammatory eicosanoids and attenuate oedema in an in-vivo model of inflammation.[6]

The Relief in Bleeding piles can be due to Catechin a biologically highly active in *Acacia catechu*. It is used as a haemostatic agent. The concentrated aqueous extract known as Khair gum or Kutch is an astringent, cooling and digestive.[4,5]

Healing is also due to the *Aloe barbedensis* Extract which has anti-inflammatory Properties, activity effects on the Immune System, Laxative effects, wound healing, antiseptic.[7] Reduction in Pain and Itching also can be understood with Aloe vera which has been used for reducing pain during dental treatments, mouth ulcers, sores blisters, haemorrhoids and for wound healing.[8] Aloe Vera effective in reducing pain both on resting and during defecation, healing time, and analgesic requirements in the patients.[9]

Relief in Piles Symptom is due to relieving constipation which is considered as major cause in Piles. *Terminalia chebula* is used traditional in treatment of constipation.[10] Also *Terminalia chebula* has Antimicrobial Property to heal piles with biologically active compound present in the fruit of *T. chebula* responsible for the antimicrobial activity especially on gastrointestinal mucosa as in broader way microbial biocompatibility to include all of the mechanical, physiological, immunological, cytological, and biochemical responses of the human body.[11]

Plumbago zeylanica is used in haemorrhoids & skin diseases, irritable bowel disease, the roots are used as laxative, astringent, Resulting in Relieving Constipation and Itching.[12] Thus, the findings of this study demonstrate that the Pilief tablet and ointment combination is effective in reducing the symptoms associated with piles and improving quality of life. The anti-inflammatory properties of the selected herbs likely contribute to these outcomes. Additionally, the absence of significant side effects suggests that this treatment could be a safe alternative to conventional therapies.

Conclusion

The results support use of herbal formulations in management of piles. Future studies should explore longer follow-up periods and effects of these treatments in more severe cases of piles. This study highlights potential of Pilief Tablet and Ointment as a viable treatment option, aligning with a broader trend towards holistic healthcare approaches.

Cost of Study

All medications required during the 6 week trial of trial were provided by the sponsor. Laboratory test mentioned were performed at the base line and the end of the trial.

The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

Conflict of Interest

To avoid any conflict of interest, study was carried out under the unbiased supervision of Vidnyanam Clinic, Pune and Paharate Patil Ayurvedic Hospital, Daund, Pune. who are not associated with the sponsors.

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