



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

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Piles, or haemorrhoids, are a common affliction that affects a significant portion of the population and is often characterized by painful symptoms that can greatly impact quality of life. Despite the availability of various pharmacological treatments, there is a growing interest in alternative therapies, particularly herbal remedies. This study 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 in a randomized clinical trial and were treated with the Pilief Tablet and Ointment combination for six weeks. Primary outcomes included the reduction of symptoms, measured through a standardized symptoms score, and secondary outcomes included any adverse effects and quality of life assessments. Results indicated a significant reduction in symptoms and improvement in quality of life among participants. This study supports the potential of Pilief Tablet and Pilief Ointment treatments as effective options in managing piles.

**Keywords:** Piles, haemorrhoids, herbal medicine, tablet, ointment, efficacy, clinical trial

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Authors state the presence of conflict of interest

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Yes

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### Note

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## Introduction

Piles (haemorrhoids) are vascular structures that can become pathological leading to discomfort, pain, bleeding, and in some cases, surgical intervention. 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

This was a randomized, double-blind, placebo-controlled trial conducted over 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.

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

### Interventional Drug:

The Pilief tablet contained a standardized blend of Extracts of Neem Leaves (*Melia azadirachta*), *Khair Chhal* (*Acacia catechu*), *Aloe barbadensis*, *Terminalia chebula* and *Chitrakmool* (*Plumbago zeylanica*), Guar Gum (*Cyamopsis tetragonoloba*) powder known for their anti-inflammatory and soothing properties.

The 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 and 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 the total symptom score based on pain, itching, and bleeding assessed on a 10-point scale.

Secondary outcomes were the assessment of any adverse effects reported and quality of life measured using the EQ-5D scale. Measured at Baseline and at the End of 6 weeks.

### Statistical Analysis

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

## Results

### Participant Characteristics

A total of 100 participants, 50 in the treatment group and 50 in the placebo group, completed the 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 $\pm$ 1.5	7.6 $\pm$ 1.4	0.820
Mean Total Symptom Score (Week 6)	1.5 $\pm$ 0.8	6.0 $\pm$ 1.2	<0.001
Mean Change in Symptom Score	6.0 $\pm$ 1.2	1.6 $\pm$ 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 $\pm$ 1	5.5 $\pm$ 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 combination of different properties 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 lack 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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