

An open non randomized clinical trial to evaluate the effectiveness of *Tachyspermum ammi* powder - *Oma chooranam* in the management of *moolam* (Internal hemorrhoids) among out-patients attending Ayothidoss Pandithar Hospital, National Institute of Siddha, Chennai

Research Article

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Abstract

Background: Hemorrhoid disease is the fourth leading out-patient gastrointestinal diagnosis in world wide. It arises from congestion of the internal and/or external venous plexuses around the anal canal. **Aim:** The aim of this study was to evaluate the therapeutic effectiveness of siddha herbal formulation *Oma chooranam* in the management of *moolam* (Internal Hemorrhoids) patients. **Materials and Methods:** This study was an open clinical trial and it was conducted after getting Institutional Ethics Committee clearance (25/11/2021;NIS/IEC/2021/MP-2). It was registered prospectively in the Clinical Trail Registry of India (CTRI Reg No: CTRI/2022/02/039973). Patients (N=10) diagnosed with *moolam* (internal haemorrhoids) using proctoscopy results, were enrolled in the study based on the inclusion criteria. Each patient received 3grams of *Oma chooranam* mixed in warm water twice a day after food, for 24 days and patients were followed up for 2 months. The main outcome measure of this study was measured by using Haemorrhoid Symptom Severity scores(HSS Score) on Day-0 and Day 25. **Result and conclusion:** Statistical analysis done for HSS Score showed that the trail drug *Oma chooranam* is effective and significant ($p<0.05$). There was significant reduction in clinical symptoms and hence "*Oma chooranam*" is effective for the management of hemorrhoid.

Keywords: *Oma chooranam*, *Internal hemorrhoids*, *Tachyspermum ammi powder*, *Siddha*, *Bleeding piles*, *Moolam*.

Introduction

Hemorrhoids is a commonest anorectal disease treated by general practitioners and surgeons in India. It is found that about 50% of the population would have haemorrhoids atleast once within 50 years of age. Aproximately 5% population suffer from haemorrhoids at any given point of time(1). Hemorrhoids if left, untreated can cause severe sufferings and complications to the patients. It can affect any age groups and may occur equally in all genders. Prevalence of hemorrhoids all over the world is about 50-85%. In India it is about 75% of the population (2).

According to *Siddha* medicine, derangement of 3 major humors namely *Vatham*, *Pitham* and *kabam* causes disease. One among them is *Moolam*. There are 21 types of *moolam* mentioned in *Yugi Vaithiya Chinthamani-800* (3). As per *Siddhar Yugi*, the causes of *moolam* are excessive intake of tubers (except slender yam), pungent spicy food intake, prolonged sitting, horse riding, improper yogic postures lead to

derangement of *Vatham* humor (*Abana vaayu – kil nokkumkal*) and *Pitham* humor resulting in the genesis of 21 types of *moola noigal* (4). As per *pothu maruthuvam*, etiology of *moolam* is exposure to too much of warmth and chillness, irritability, impatience, depression, scolding the old aged people (5). As hemorrhoids give huge personal suffering, it needs a research attention. Treating and managing the first and second degree hemorrhoids will prevent the progress of disease to next degrees. The trial drug *Oma chooranam* (6) is indicated for *moolam* (Internal hemorrhoids). It contains *Omam* (*Tachyspermum ammi*&*Hook.f*). The trial drug is having Anti hemorrhoidal (9), Anti – inflammatory (7), laxative activities (8) which makes it a good option for the management of *moolam*.

Aims and Objectives

To evaluate the therapeutic effectiveness of siddha herbal formulation *Oma chooranam* in the management of *moolam* (internal hemorrhoids) patients.

Materials and methods

Ethics committee approval

The study comprised of precise protocol and proforma. Approval was obtained from Institutional Ethics Committee (25/11/2021;NIS/IEC/2021/MP-2) and was registered prospectively in the Clinical Trial

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Registry of India (CTRI Reg No: CTRI/2022/02/039973).

Study methodology:

- **Study design:** An open Clinical trial
- **Study setting:** Out -patient department of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai-47.
- **Study period :** 6 months.
- **Sampling technique :** Not applicable
- **Sample size :** 10 patients
- **Trial drug :** *Oma Chooranam*.

Drug formulation details

- Drug : *Omam*
- Botanical name : *Tachyspermum ammi.L.*
- *Suvai : kaarpu*
- *Veeriyam:veppam*
- *Pirivu : kaarpu*
- Indication : indigestion, flatulence, *kabha* diseases, diarrhoea and hemorrhoids (6)

Medicine preparation

GMP certified trial drug was purchased from akkaretti company. It was packed and dispensed in zip lock bags each containing 42 grams of trial drug during every visit.

Treatment details

- Sample size : 10
- Treatment : *Oma Chooranam*
- Dose : 3 grams twice a day
- Adjuvant : warm water
- Route of administration : Oral
- Duration : 24 days (1/2 *mandalam*)
- Follow up : 2 months

Selection Criteria

Inclusion criteria

- Patients belonging to 18-60 years of age of all genders
- Patients with symptoms like bleeding during defecation, constipation, pain in anal region
- Those having first and second degree hemorrhoids
- Patients willing to undergo blood investigations and examination using proctoscopy and willing to sign informed consent were included.

Exclusion criteria

- Fissure in ano
- Fistula in ano
- External hemorrhoids
- Known case of rectal tuberculosis
- Known case of rectal cancer

Withdrawal criteria

- Poor patient compliance
- Patients who are not willing to sustain in the full period clinical Study

Diagnostic criteria

Operational definitions

- **Bleeding:** Bleeding is the first and foremost symptom of hemorrhoids. The bleeding is characteristically isolated from the stool and is seen as fresh bleed.
- **Prolapse:** The veins of the anal canal are dilated and bleeds during defecation.
- **Discharge:** Mucosal discharge can cause pruritis in the perianal region.
- **Anal pain:** 4th degree hemorrhoids may become strangulated and present with acute pain.
- **Anemia:** Abundant loss of blood from haemorrhoids very rarely might cause anemia
- **Constipation:** Hemorrhoids is accompanied with secondary to chronic constipation, diarrhea, or prolonged duration of straining to defecate.

Classification

1. First degree – Bleeds only
2. Second degree – spontaneous reduction of the pile mass
3. Third degree – manual reduction of the pile mass
4. Fourth degree – permanent prolapse

Criteria for assessment

Outcome was assessed based on the Improvement of Hemorrhoids Symptoms Severity Scoring before and after treatment published by Karolinska University, Hospital Huddinge Stockholm (10).

Conduct of the study

The study comprised of precise protocol and proforma. Approval was obtained from Institutional Ethics Committee (25/11/2021; NIS/IEC/2021/MP-2) and was registered prospectively in the Clinical Trial Registry of India (CTRI Reg No: CTRI/2022/02/039973). 10 cases were recruited after screening 40 cases as per inclusion criteria. On day 1, all the enrolled patients were given oil bath with *Seeraga thylam* followed by non medicated rest. Day-3 onwards *Oma Chooranam* (Internal) 3g, twice a day with warm water (After food) was given to the patients for a period of 24 days. Blood investigations, Hemorrhoid severity score and proctoscopy examination were done before treatment and after treatment.

Observations and Results

Distribution based on gender reveals that, 8 (80 %) were male and 2 (20 %) were female. Regarding age group, 3 cases (30%) belonged to 20-30 years, 3 cases 51- 60 years (30%), 2 cases (20%) belonged to 18-30 years and 2 cases (20%) belonged to 41-50 years. Regarding occupation, 5 cases (50%) were skilled, 2 cases (20%) were businessmen, 2 cases (20%) were unskilled and 1 case (10%) was semi professional. All the 10 cases (100%) were Non – vegetarian out of which 6 cases (60%) were alcoholic. Out of 10 cases, 7 cases (70 %) took less amount of water and 6 cases (60%) took less amount of fibre content. In this study, *naadi* was *Vathapitham* in 4 cases (40%), *Pithavatham* in 6 cases (60%). Out of 10

cases, in all the cases (100%) *Abanan* was affected before treatment (100%) and 1 case (10%) was improved after treatment. In all the 10 cases (100%) *Ranjakam* was affected in before treatment and 1 case (10%) was improved after treatment. Among 10 cases, 5 cases (50%) had 0-3 months of illness, 2 cases (20%) had 4-6 months of illness, 3 case (30%) had chronicity of illness above 9 months. In this study, bleeding during defecation and anal pain was present in all 10 cases

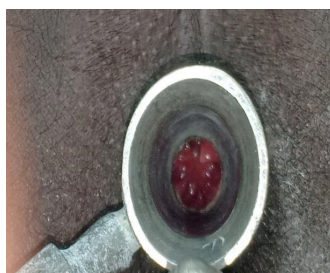
(100%) before treatment and bleeding was arrested in 6 cases (60%) after treatment, pruritic ani was seen in 5 cases (50%) before treatment and 2 cases (20%) improved after treatment.

Adverse Drug Reaction

No adverse drug reaction were noted during the trial period.

Proctoscopic examination: (Op No:243046)

Before Treatment



After Treatment

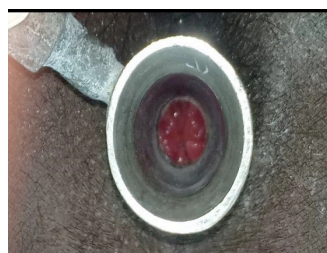


Figure 1 : Intake of water and fibre content

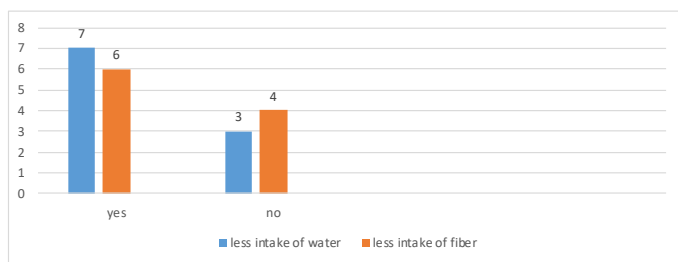


Figure 2 : Clinical features

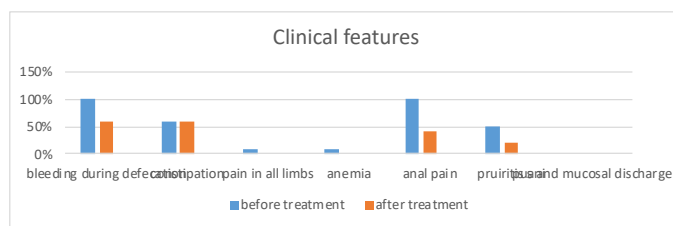


Table 1 : Clinical Symptoms - McNemar Test

Variable	Test	Yes	No	P-Value	Inference
Constipation	Pre Test	60%	40%	0.01	Significant
	Post Test	0%	100%		
Anemia	Pre Test	10%	90%	1.00	Not Significant
	Post Test	10%	90%		
Pain in all Limbs	Pre Test	10%	90%	1.00	Not Significant
	Post Test	10%	90%		
Irritation and soreness after defecation in the anus	Pre Test	0%	100%	Not-Applicable McNemar Test	
	Post Test	0%	100%		
Discharge of pus and mucous from anus	Pre Test	0%	100%		
	Post Test	0%	100%		
Rectal bleeding	Pre Test	60%	40%	0.01	Significant
	Post Test	0%	100%		

Results chart – Statistical analysis

Table 2 : Clinical Investigation - Paired T-Test

Variable	Pre	Post	T-Value	P-Value	Inference
Hb	12.8 ± 1.8	12.7 ± 1.6	1.04	0.32	Not Significant
Total RBC count	4.5 ± 0.5	4.5 ± 0.5	0.72	0.49	Not Significant
ESR(1/2 hr)	6.1 ± 3.8	7.1 ± 3.7	-2.37	0.04	Significant
ESR 1 hr	13.3 ± 8.0	13.6 ± 7.5	-0.63	0.54	Not Significant
Bleeding Time	119.6 ± 28	117.1 ± 29.5	0.62	0.55	Not Significant
Clotting Time	226 ± 42.2	211.8 ± 57.4	1.25	0.24	Not Significant

Table 3 : Statistical analysis (Wilcoxon Signed Rank Test) for Hemorrhoid symptom severity scoring

	Test	Never	Less than once/ week	1-6 times/ week	Everyday/ Always	Z-Value	P-Value	Inference
Frequency of Pain in the anal region	Pre Test	0%	10%	40%	50%	-2.701	0.007	Significant
	Post Test	30%	70%	0%	0%			
Frequency of Itching or Discomfort in the anal region	Pre Test	40%	30%	30%	0%	-2.236	0.025	Significant
	Post Test	60%	40%	0%	0%			
Frequency of Bleeding at stools	Pre Test	0%	-40%	30%	30%	-2.859	0.004	Significant
	Post Test	70%	30%	0%	0%			
Frequency of Soiling of under clothes	Pre Test	100%	0%	0%	0%	0.00	1.00	Not Significant
	Post Test	100%	0%	0%	0%			
Frequency of prolapsed pile mass	Pre Test	0%	40%	20%	40%	-2.414	0.016	Significant
	Post test	30%	50%	20%	0%			

Hemorrhoid symptom severity scoring

S.NO	OPNO	HSS SCORE: BEFORE TREATMENT					AFTER TREATMENT						
		Freq. of pain in the anal region	Freq. of itching or discomfort in anal region	Freq. of bleeding at stools	Freq. of soiling of under clothes	Freq. of prolapsed pile mass	Total score	Freq. of pain in the anal region	Freq. of itching or discomfort in anal region	Freq. of bleeding at stools	Freq. of soiling of under clothes	Freq. of prolapsed pile mass	Total score
1	243046	1	2	1	0	3	7	1	1	0	0	1	3
2	129361	3	0	1	0	3	7	0	0	0	0	2	2
3	66796	2	0	1	0	3	6	0	0	0	0	0	0
4	241631	3	1	2	0	1	7	0	0	1	0	1	2
5	240040	2	0	2	0	2	6	1	0	0	0	1	2
6	206937	2	1	3	0	1	7	1	0	0	0	0	1
7	242194	3	0	1	0	3	7	1	0	0	0	2	3
8	230617	2	1	2	0	2	7	1	1	0	0	0	2
9	243398	3	2	3	0	1	9	1	1	1	0	1	4
10	238095	3	2	3	0	1	9	1	1	1	0	1	4

Based on the difference of HSS scoring before and after treatment, 2 cases - symptoms reduced well and were improved from severe to Mild, in 7 cases - symptoms reduced well and were improved Moderate to Mild level and in 1 case (10%) - symptoms completely relieved.

Discussion

According to mode of action of *Oma Chooranam*, Alkaloids, Flavonoids, Tannins are present in *Tachyspermum ammi*. These chemical compounds aid in arresting the bleeding in hemorrhoids. It exerts Laxative [8] activity. Hence it relieves constipation. It possess anti-hemorrhoidal [9] activity, Anti inflammatory [7] and Anti-spasmodic activity [14].

From the results, it was found that male are more prone to internal hemorrhoids and all the cases were non vegetarians. Hence dietary habits also play a vital role in the development of internal hemorrhoids. Regarding *naadi* examination, *Vatha pitham* and *pitha vatham* were predominantly observed. Hence it proves the versus "*Anila pitha thonthamalathu moolam*

varathu" which is stated in *pinigaluku mutharkaranam* by the saint *Therayar* (4).

The frequency of symptoms like pain, itching and discomfort in the anal region, bleeding at stool, prolapsed pile mass reduced significantly. From HSS score, it was found that 2 cases showed improvement from severe level to mild level, 7 cases showed good reduction in symptoms improved moderate level to mild level and in 1 case symptoms completely relieved was calculated. Statistical analysis using Wilcoxon signed ranked test of the difference of HSS score before treatment and after treatment showed that $p < 0.05$ which indicates that *oma chooranam* is effective in the management of *moolam* (Internal hemorrhoids). The trial drug possess an advantage that it consists of only one drug. Hence it is highly cost effective and easily available drug. Since there is no significant changes in the laboratory investigations before and after treatment and no adverse drug reactions were noted in the trial period, the trial drug is safe for administration.

In a study conducted by Dr. Anbarasan et al, *Moolaroga chooranam* was studied for the management of *moolam* 22.5% of patients showed good

improvement, 25% of patients showed mild improvement and 47.5% patients showed moderate improvement and 5% of patients showed poor improvement (13). In another trial conducted by Dr. Aishwarya et al, *Kukkilathy chooranam* was studied for the management of *moolam*. In that study it was concluded that 37% of cases showed complete recovery from symptoms and in 64% patients were improved moderate score to mild score (14).

Conclusion

In this study, it can be concluded that *Oma Chooranam* is safe, effective, easily affordable and potent herbal drug for treating hemorrhoids. From the HSS Score, finally out of 10 cases, 1 case (10%) completely recovered from symptoms and in 9 cases (90%) symptoms were reduced well, those patients were improved Moderate to mild score. Statistical analysis shows that $p < 0.05$ which indicates that *oma chooranam* is effective in the management of *moolam* (Internal hemorrhoids). Proctoscopic examination showed significant reduction of internal pile mass size in after treatment. Adverse reaction was not reported in the course of trial. Since the outcome of the study is effective, it should be extended in a larger clinical population for more promising results.

Competing interests: There is no conflict of interest among the authors.

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