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Clinical evaluation of *Nilavagai Chooranam* in *moolam* (Grade I-III internal hemorrhoids): A single-arm pre-post study

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Abstract:

Moolam (Grade I-III internal hemorrhoids) remains prone to recurrence after conventional treatment, highlighting the need for effective traditional therapies. Therefore, it is of interest to evaluate the *Nilavagai Chooranam* in 30 patients treated with 1.375 g twice daily for 48 days (CTRI/2024/04/066321). Clinical assessment showed a significant reduction in HSS scores from 8.43 ± 1.55 to 3.13 ± 1.38 ($p < 0.001$). All moderate and severe cases improved to mild severity and proctoscopy showed reduction in pile mass in all participants. Thus, data show the clinical evidence that *Nilavagai Chooranam* is associated with significant reductions in Hemorrhoid Symptom Severity (HSS) scores and pile mass in patients with Grade I-III internal hemorrhoids, supporting its potential as a Siddha therapeutic intervention warranting further evaluation in randomized controlled trials.

Keywords: *Nilavagai Chooranam*, *siddha*, *moolam*, internal hemorrhoids, poly herbal formulation

Background:

Haemorrhoids are one of the most common anorectal disorders worldwide, representing a significant source of morbidity and healthcare expenditure. The burden of this disease is particularly pronounced in the Indian subcontinent, where clinical surveys suggest that up to 75% of the adult population may experience symptomatic hemorrhoids at some point in their lives [1]. It is characterized by symptomatic enlargement and distal displacement of anal cushions [2]. They present clinically with rectal bleeding, pain, pruritus and discomfort, significantly affecting quality of life [3]. The condition is associated with multiple risk factors including chronic constipation, low dietary fiber intake, sedentary lifestyle, obesity and pregnancy. Despite the availability of conventional treatments such as dietary modification, pharmacotherapy and surgical interventions, recurrence remains a significant concern, with reported rates ranging from 0% to 26% depending on the procedure [4, 5]. However, surgical modalities carry their own distinct limitations and morbidities. Conventional excisional hemorrhoidectomy, while providing definitive anatomical correction, is universally associated with excruciating postoperative pain, prolonged convalescence, extended hospital stays and a tangible risk of severe complications such as anal stenosis, wound infection and fecal incontinence. Recent Trial Sequential Analyses (TSA) and meta-analyses comparing the two surgical approaches reveal that stapled hemorrhoidopexy is associated with a markedly higher risk of long-term recurrence specifically, a 3.28 times higher risk of prolapse-related recurrence compared to conventional hemorrhoidectomy [6]. There is an increasing need for alternative therapeutic approaches that can effectively manage symptoms, reduce recurrence and improve patient outcomes without significant adverse effects. The Traditional Siddha Medicine (TSM), one of the oldest medical systems in India, offers a holistic approach to disease management. In Siddha literature, haemorrhoids is described as "*Moolam*," primarily attributed to the derangement of *Vatham* (one of 3 humors) and *Pitham* (one of 3 humors) [7]. Classical texts describe various internal medicines and external therapies aimed at correcting humoral imbalance, improving digestive function and alleviating symptoms. These approaches emphasize not only treatment but also prevention through dietary and lifestyle modifications [8]. *Nilavagai Chooranam*, a polyherbal Siddha formulation, has been traditionally used in the management of

anorectal disorders. Its therapeutic properties are believed to include laxative, anti-inflammatory and haemostatic effects, which may be beneficial in relieving constipation, reducing bleeding and shrinking haemorrhoidal mass [9]. Therefore, it is of interest to evaluate the therapeutic effectiveness of the Siddha herbal formulation *Nilavagai Chooranam* in the management of internal haemorrhoids (*Moolam*) among an adult outpatient population attending a tertiary care Siddha hospital-National Institute of Siddha.

Materials and Methods:**Study design:**

Drug Interventional study (Open labelled, non-randomized Clinical Study). This was a pilot study conducted as part of a doctoral dissertation at the National Institute of Siddha under institutional research guidelines.

Study setting:**Study place:**

Maruthuvam OPD – Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai – 600047

Study period: 12 Months**Sample size:**

30 Patients (determined as per institutional dissertation guidelines of Tamilnadu Dr. MGR Medical University; no formal a priori power calculation was performed). Participant flow diagram is provided in **Figure 1**.

Selection criteria:**Inclusion criteria:**

Participants aged 18–60 years of any gender (male, female, or transgender) with Grade I-III hemorrhoids and a Hemorrhoid Symptom Score (HSS) of 5 or higher are eligible. They must be willing to undergo proctoscopic examination, provide blood samples for required investigations and sign informed consent.

Exclusion criteria:

Participants are excluded if they are pregnant or lactating, have Grade IV hemorrhoids (protruding or irreducible), uncontrolled diabetes mellitus ($HbA1c > 7-8\%$), or severe hepatic, renal, or cardiovascular disorders. Those with anorectal infections,

anorectal malignancies, fistula in ano, fissure in ano, or external hemorrhoids are also excluded.

Withdrawal criteria:

Participants will be withdrawn from the study if they choose not to continue, show poor compliance (e.g., not taking the medication for more than a week), or develop drug intolerance or adverse reactions during the study.

Intervention:

Treatment plan:

- [1] **Day 1:** Oil bath is advised (*Seeraga thailam* (Quantity: 100 ml)).
- [2] **Day 2:** Gentle Laxative is advised (*Moolakudara thailam* – 10-15ml with luke warm water, OD, at early morning in empty stomach)
- [3] **Day 3:** Complete rest (No medications)
- [4] **Day 4:** Study drug “*Nilavagai Chooranam*” was given at a dose of *Verukkadi alavu* (1.375g) twice a day (morning and evening) after food, for 48 days.

Outcome measures:

- [1] **Clinical data assessment:** General examination, anorectal examination, haemorrhoid symptom scoring (HSS) [10].
- [2] **Siddha assessment:** Assessment of *Envagai Theruvu*, *Udal*, *Uyir Thadhukkal*, *Kanmendhriyam*, *Kanmaavidayam*, *Aasayangal* and *Kosangal*.
- [3] **Laboratory values assessment:** Complete blood count – haemoglobin.
- [4] **Special investigation:** Proctoscopy.

Statistical analysis:

All the data was entered into computer using MS Excel software and logical errors were manually cross checked. Then the data was exported to SPSS software for univariate /multivariate analysis. Paired ‘t’ test was performed for determining the significance between before and after values.

Effect Size:

Cohen’s d (paired samples):

- [1] Cohen’s d = Mean Difference / Standard Deviation of Differences
- [2] Cohen’s d = 5.30 / 1.725 = 3.07

Interpretation:

- [1] $d \approx 0.2 \rightarrow$ small
 - [2] $d \approx 0.5 \rightarrow$ medium
 - [3] $d \geq 0.8 \rightarrow$ large
- Here, $d = 3.07$, indicating an extremely large treatment effect.

Effect size (r) calculation:

- [1] Effect size (r) = $Z / \sqrt{N}$
- [2] $r = 4.78 / \sqrt{30} \approx 0.873$

Interpretation:

- [1] $r \approx 0.1 \rightarrow$ small
- [2] $r \approx 0.3 \rightarrow$ medium

- [3] $r \geq 0.5 \rightarrow$ large

This confirms a large non-parametric effect size, consistent with the t-test findings.

Ethical approval:

Ethical clearance (IEC approval: NIS/25/IEC/2023/Dis/8) and CTRI registration (CTRI/2024/04/066321) were obtained. OVID-19 regulations were strictly followed throughout the study. The proctoscopy procedure was explained and performed at the Karanool Unit under sterile and aseptic conditions. Blood samples were collected using disposable syringes and gloves, with proper sterilization of laboratory equipment to prevent infection. Patients were informed about the treatment and procedures in their vernacular language and written informed consent was obtained prior to enrolment. No medications other than the study drug were administered during the study period and patient rights were fully respected. In cases of serious adverse reactions, appropriate alternative treatment was provided at the OPD - Department of Maruthuvam, National Institute of Siddha. Patient data were maintained confidentially. Treatment was provided free of cost and participants were allowed to withdraw from the study at any time.

Haemorrhoidal disease in siddha perspective:

Moolatharam is the home to the *kundalini* i.e. the body’s vital energy centre according to TSM. It has been provided the highest significance in the storage and dispersion of energy. *Anila pitha thondhamalathu Moolam varaathu* (*Anilam-Vaatham, Pitha-Pitham*) [11]. According to *Siddhar Theraiyar*, alterations in diet and behaviour leading to *Moolam* which might also be caused by derangement of *Vatham* and *pitha* humour. The primary *pitha* and *vatha* humours are impacted in the pathogenesis of *Moola noi* (Figure 2). *Vatham* (one of 3 humors) and *Pitham* (one of 3 humors). This condition is also called in other names such as *Arippu noi*, *Mulai noi* and *Moola noi*. According to a verse in *Agathiyar 2000*, the promontory symptoms of the disease are, burning sensation in the anus, itching, sudden onset of bleeding and protrusion of mass from the anus following pallor of body, excessive salivation; acid reflux due to indigestion, thirst, bloating of abdomen, burning sensation of the abdomen, constriction of eyeballs and constipation [12].

Nilavagai chooranam:

Nilavagai Chooranam is traditionally indicated in anorectal disorders and is hypothesised to act through its multifactorial pharmacological actions. Its laxative and purgative effects relieve constipation and reduce straining, a key etiological factor. The formulation demonstrates potent anti-inflammatory (33.3%) and analgesic (22.2%) activities, alleviating pain, swelling and mucosal irritation. Vasoactive and astringent properties help control bleeding and promote shrinkage of hemorrhoidal masses, while antioxidant constituents protect vascular integrity. Additionally, carminative and digestive stimulant actions improve gut motility and correct underlying metabolic disturbances. Collectively, these synergistic effects provide

comprehensive relief by addressing both symptoms and the pathophysiology of haemorrhoids [9].

Results:

Analytical characterization of study drug *Nilavagai Chooranam* (Table 1) underwent intense scrutiny at a NABH-accredited laboratory utilizing modern analytical techniques. Physicochemical analysis confirmed optimal moisture content (loss on drying at 2.187%), ensuring the prevention of bacterial proliferation during storage. Advanced High-Performance Thin-Layer Chromatography (HPTLC) fingerprinting at 254 nm, 366 nm and 520 nm generated distinct, reproducible chromatograms, confirming the presence of expected phytochemical constituents. Furthermore, safety screening confirmed that the total bacterial and fungal counts were well within permissible limits and below detectable limits of specific pathogens such as *E. coli*, *Salmonella* and *Staphylococcus aureus*. Heavy metal screening by biochemical analysis confirmed the absence of toxic accumulation and fluorometric assays not detected Aflatoxins (B1, B2, G1 and G2) as per analytical protocol [9]. The study population predominantly comprised patients aged 26–50 years (n=25, 83.3%), followed by 51–60 years (n=3, 10%) and 18–25 years (n=2, 6.7%) (Table 2). Among the 30 participants, 22 (73.3%) were male and 8 (26.7%) were female (Table 3). Occupational distribution revealed that drivers, IT professionals and office workers each accounted for 5 (16.7%) patients, followed by homemakers and tailors with 3 (10%) patients each. Machine operators and unemployed individuals each accounted for 2 (6.7%) patients, while janitors, photographers, salespersons, security personnel and vendors each represented 1 (3.3%) patient (Table 4). Dietary assessment showed that 28 (93.3%) participants were non-vegetarians and 2 (6.7%) were vegetarians (Table 5). Fifteen (50%) patients reported low daily water intake and 19 (63.3%) reported inadequate dietary fibre consumption (Table 6). The duration of illness ranged from 1 month to more than 1 year, with 10 (33.3%) patients reporting symptoms for more than one year, followed by 9 (30%) patients with a duration of 1–3 months, 6 (20%) with 7–12 months and 5 (16.7%) with 4–6 months (Table 7). A positive family history of haemorrhoids was present in 7 (23.3%) patients (Table 8). Evaluation of Siddha diagnostic parameters showed that 12 (40%) patients were *Vaatha Thegi*, followed by *Pitha Thegi* - 8 (26.7%), *Thontha Thegi* - 7 (23.3%) and *Kaba Thegi* - 3 (10%) patients (Table 9). Assessment of *Udal Kattugal* showed *Saaram* (unable to perform routine activities) involvement in 24 (80%) patients and *Senneer* (bleeding defecation) involvement in 5 (16.7%) patients (Figure 3). Among the *Uyir Thathukkal*, *Abanan*

and *Samanan* (constipation, tiredness, bleeding defecation) were affected in *Vaatham* in all 30 (100%) patients (Figure 4). *Pitham* assessment showed involvement of *Analagam* (loss of appetite) in 1 (3.3%), *Ranjagam* (bleeding defecation) in 23 (76.7%) and *Saathagam* (unable to perform routine activities) in 27 (90%) patients (Figure 5), while *Kabam* assessment demonstrated *Klethagam* (loss of appetite) involvement in 6 (20%) and *Santhigam* (pain in all limbs) involvement in 5 (16.7%) patients (Figure 6). *Envagai Thervu* findings showed *Vaatha-Pitham Naadi* in 14 (46.7%) patients and *Pitha-Vaatham Naadi* in 16 (53.3%) patients. Pallor of the tongue (*Naa*) was observed in 6 (20%) patients, while constipation (*Malam*) was present in all 30 (100%) patients (Table 10). *Neikuri* examination demonstrated *Vaatha Neer* in 26 (86.7%) patients and *Pitha Neer* in 4 (13.3%) patients (Table 11). Proctoscopic examination before treatment showed that pile masses were located at the 3 o'clock position in 1 (3.3%) patient, 7 o'clock in 6 (20%), 11 o'clock in 8 (26.7%), two positions in 14 (46.7%) patients and all three positions in 1 (3.3%) patient (Table 12). After treatment, marked reduction in pile mass size was observed in 6 (20%) patients, moderate reduction in 14 (46.7%) and mild reduction in 10 (33.3%) patients. Comparison of clinical symptoms before and after treatment demonstrated improvement across all major symptoms (Table 13, Figure 7). Bleeding after defecation reduced from 23 (76.7%) to 4 (13.3%) patients, constipation from 30 (100%) to 2 (6.7%), anal pain from 28 (93.3%) to 17 (56.7%), anaemia from 2 (6.7%) to 1 (3.3%), pain in all limbs from 3 (10%) to none, and pruritus ani from 15 (50%) to 3 (10%). One patient (3.3%) continued to have discharge of pus and mucus after treatment. Haemoglobin estimation showed that before treatment, 3 (10%) patients had haemoglobin levels below 10 g/dL, 8 (26.7%) had levels between 10 and 12 g/dL, 12 (40%) had levels between 12 and 14 g/dL, and 7 (23.3%) had levels above 14 g/dL. Following treatment, no patient had haemoglobin levels below 10 g/dL, while 9 (30%) patients had levels between 10 and 12 g/dL, 12 (40%) had levels between 12 and 14 g/dL, and 9 (30%) had levels above 14 g/dL (Table 14). Assessment of haemorrhoidal symptom severity showed that, before treatment, 3 (10%) patients had severe symptoms and 27 (90%) had moderate symptoms. Following treatment, all three severe cases improved, and 27 (90%) patients achieved mild HSS scores (≤3), whereas only three patients had post-treatment HSS scores >3 (Figure 8). Symptoms such as pain, bleeding and prolapse showed marked reduction after treatment, with many patients attaining near-complete symptom resolution (HSS score ≤2) (Figure 9).

Table 1: Ingredients of Nilavagai Chooranam

Nilavagai (<i>Cassia senna</i> , Linn.)	10 palam (35 grams)	Sivadhai (<i>Operculina turpethum</i> , Linn.)	¼ palam (8.75g)
Milagu (<i>Piper nigrum</i> , Linn.)	¼ palam (8.75g)	Thalisapathiri (<i>Abies spectabilis</i> , Mirb)	¼ palam (8.75g)
Kadukkai (<i>Terminalia chebula</i> , Retz)	¼ palam (8.75g)	Jaadhikkai (<i>Myristica fragrans</i> , Houtt)	¼ palam (8.75g)
Thaanrikkai (<i>Terminalia bellerica</i> , Roxb)	¼ palam (8.75g)	Kiraambu (<i>Syzygium aromaticum</i> , Linn.)	¼ palam (8.75g)
Seeragam (<i>Cuminum cyminum</i> , Linn.)	¼ palam (8.75g)	Thippili (<i>Piper longum</i> , Linn.)	¼ palam (8.75g)
Vaaluluwai (<i>Celastrus paniculatus</i> , Willd)	¼ palam (8.75g)	Seviyam (Root of <i>Piper nigrum</i> , Linn.)	¼ palam (8.75g)
Sirunaagapoo (<i>Mesua nagassarium</i> , Kostermm)	¼ palam (8.75g)	Indhuppu (<i>Sodii chloridum impura</i>)	¼ palam (8.75g)
Elam (<i>Elettaria cardamomum</i> , Maton)	¼ palam (8.75g)	Koogaineeru (<i>Maranta arundinacea</i> , Linn.)	¼ palam (8.75g)
Ilavangapattai (<i>Cinnamomum verum</i> , Presl)	¼ palam (8.75g)	Sukku (<i>Zingiber officinale</i> , Rosc)	¼ palam (8.75g)
Kadugurogini (<i>Picrorhiza scrophulariiflora</i> , Pennell)	¼ palam (8.75g)	Seeni Sarkkari (<i>Saccharum officinarum</i> , Linn.)	7.25 palam (253.75g)

Table 2: Case distribution by age

Age	No of cases	Percentage
18 - 25 years	2	6.7%
26 - 50 years	25	83.3%
51-60 years	3	10%
Total	30	100%

Table 3: Case distribution by gender

Gender	No of cases	Percentage
Male	22	73.3%
Female	8	26.7%
Total	30	100%

Table 4: Case distribution by occupation

Occupation	No of cases	Percentage
Driver	5	16.7
Home maker	3	10.0
IT	5	16.7
Janitor	1	3.3
Machine operator	2	6.7
Nil	2	6.7
Office work	5	16.7
Photographer	1	3.3
Sales	1	3.3
Security	1	3.3
Tailor	3	10.0
Vendor	1	3.3
Total	30	100%

Table 5: Case distribution by diet habit

Diet habit	No of cases	Percentage
Veg	2	6.60%
Non-Veg	28	93.30%
Total	30	100%

Table 6: Case distribution by less intake of water and fibre content

Less intake of water	No of cases	Percentage	Less of fibre content	No of cases	Percentage
Yes	15	50%	Yes	19	63.3%
No	15	50%	No	11	36.7%
Total	30	100%	Total	30	100%

Table 7: Case distribution by duration of patients' illness

Duration of illness	No of cases	Percentage
Upto 1 - 3 months	9	30%
Upto 4 - 6 months	5	16.7%
Upto 7 - 12 months	6	20%
More than a Year	10	33.3%

Table 13: Case distribution by clinical symptoms

Clinical symptoms	Before treatment			After treatment		
	No of cases affected	No of cases not affected	Percentage of cases affected	No of cases affected	No of cases not affected	Percentage of cases affected
Bleeding after defecation	23	7	76.7%	4	26	13.3%
Constipation	30	0	100%	2	28	6.7%
Anal pain	28	2	93.3%	17	13	56.7%
Anaemia	2	28	6.6%	1	29	3.3%
Pain in all limbs	3	27	10%	0	30	0%
Pruritis ani	15	15	50%	3	27	10%
Discharge of pus and mucous	1	29	3.3%	1	29	3.3%

Table 16: Paired Samples t-Test

Comparison	Mean Difference	Std. Deviation	Std. Error Mean	95% CI (Lower–Upper)	t	df	p-value
Before vs After	5.30	1.725	0.315	4.656 – 5.944	16.828	29	p < 0.001

Total	30	100%
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Table 8: Case distribution by family history

Family history	No of cases	Percentage
PRESENT	7	23.3
ABSENT	23	76.7
Total	30	100%

Table 9: Case distribution by thegi

Thegi	No of cases	Percentage
Vaatham	12	40%
Pitham	8	26.60%
Kabam	3	10%
Thontham	7	23.30%
Total	30	100%

Table 10: Case distribution by envagai theruvu

Envagai theruvu	No of cases	Percentage
Naadi		
a) Vaatah Pitham	14	46.7%
b) Pitha Vaatham	16	53.3%
Sparisam	0	0%
Naa	6	20%
Niram	0	0%
Mozhi	0	0%
Vizhi	0	0%
Malam	30	100%
Moothiram	0	0%

Table 11: Case distribution by neikuri

Neikuri	No of cases	Percentage
Vaatha neer	26	86.7%
Pitha neer	4	13.3%
Kaba neer	0	0%
Thontha neer	0	0%

Table 12: Case distribution by position of pile mass

Position of pile mass	No of cases	Percentage
3' o clock position	1	3.3%
7' o clock position	6	20%
11' o clock position	8	26.7%
Either 2 positions	14	46.6%
3' 7' 11' o clock positions	1	3.3%

Table 14: Case distribution by haemoglobin level before and after treatment

Haemoglobin Levels (gm/dl)	Before treatment		After treatment	
	No of cases	Percentage	No of cases	Percentage
Below 10	3	10%	0	0%
10 to 12	8	26.66%	9	30%
12 to 14	12	40%	12	40%
Above 14	7	23.33%	9	30%

Table 15: Statistical Analysis of HSS Scores (Pre-Post Comparison)

Variable	N	Mean	Std. Deviation	Std. Error Mean
HSS Score (Before Treatment)	30	8.43	1.547	0.282
HSS Score (After Treatment)	30	3.13	1.383	0.252

Table 17: Wilcoxon Signed-Rank Test (Non-parametric alternative)

Comparison	W	Z value	p-value
HSS Score Before vs After Treatment	0.000	-4.782*	p < 0.001

Table 18: Normality Testing (Shapiro-Wilk Test)

Variable	W	p-value
Before Treatment	0.962	0.351
After Treatment	0.955	0.238
Difference (Before-After)	0.969	0.476

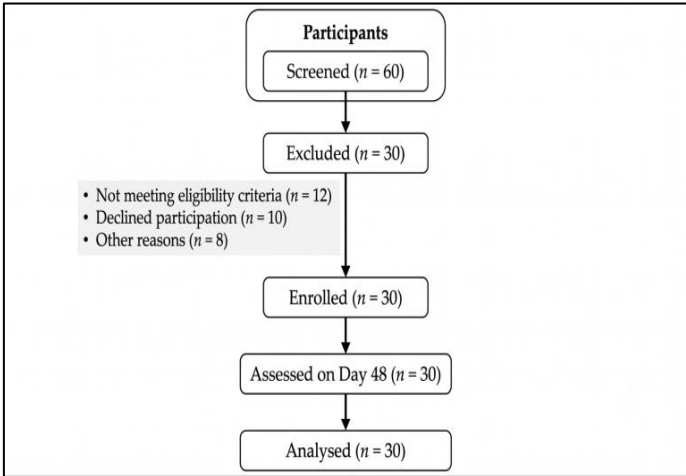


Figure 1: Participant flow diagram

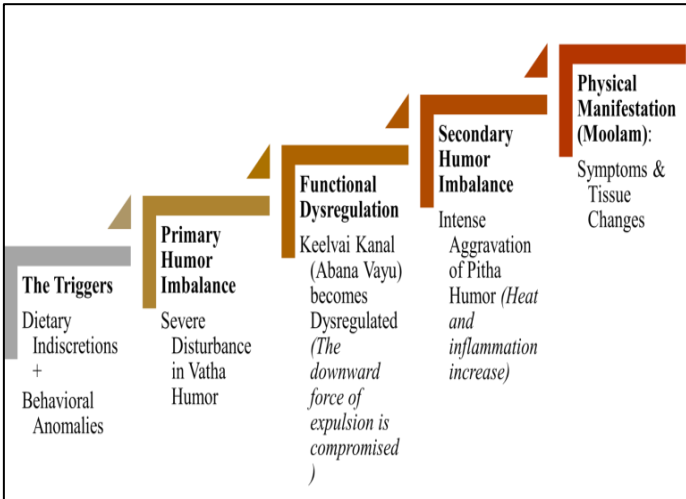


Figure 2: Siddha pathophysiology of Moolam

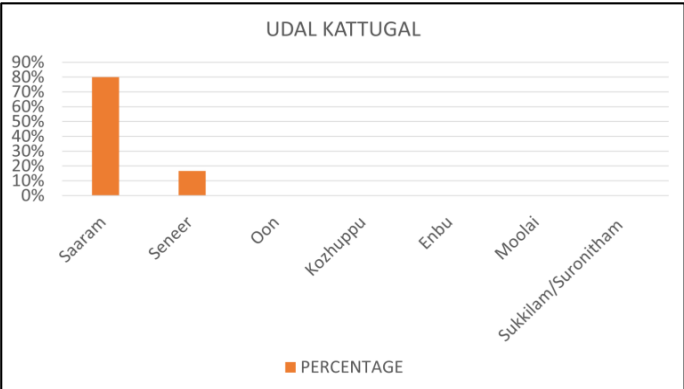


Figure 3: Affected case distribution by udal kattugal

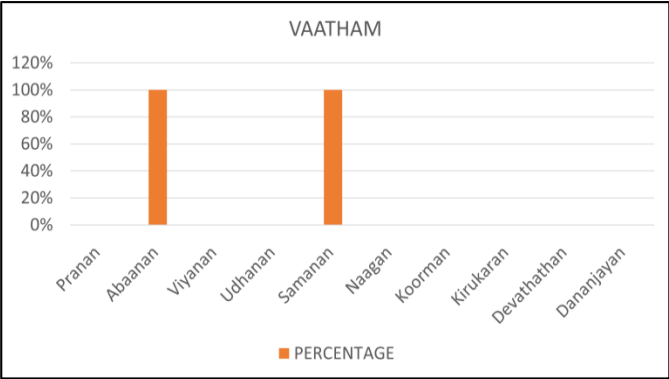


Figure 4: Case distribution by Vatham

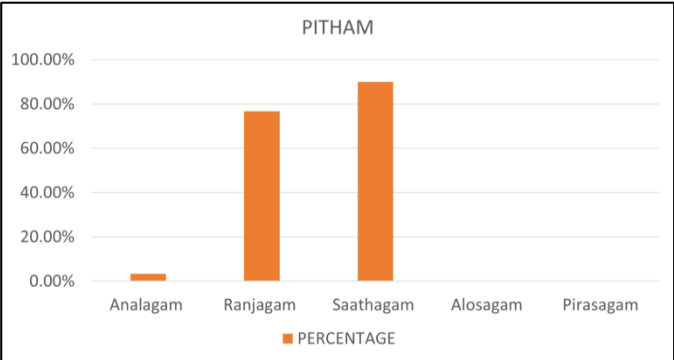


Figure 5: Case distribution by Pitham

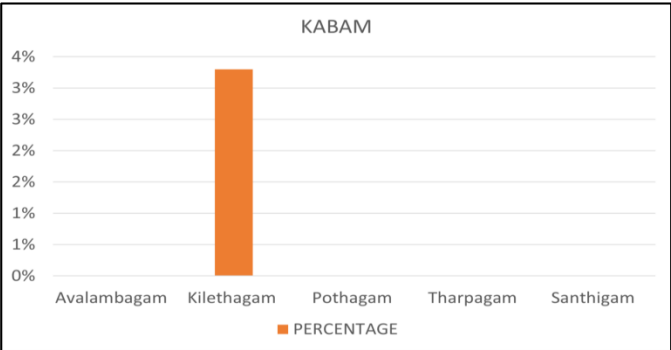
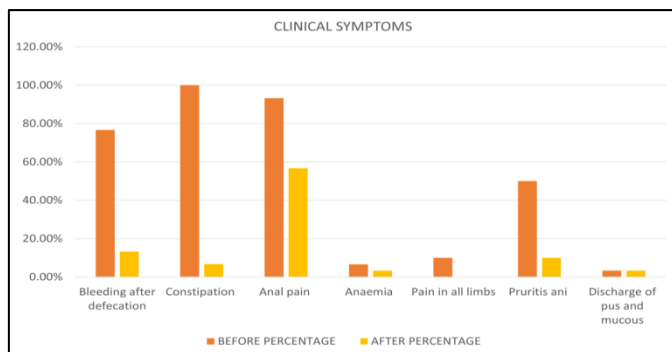
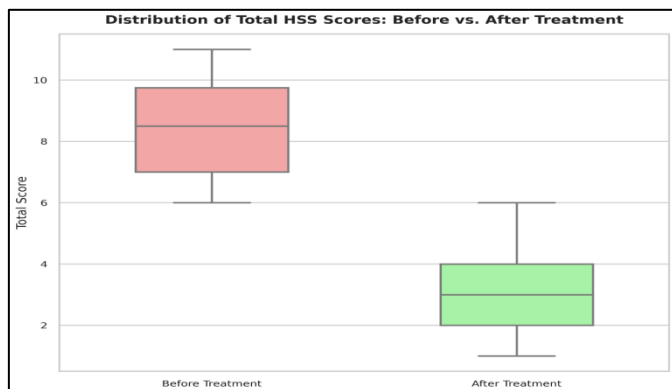
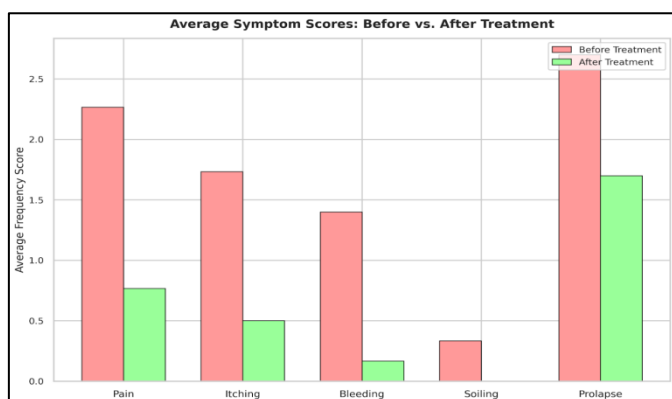


Figure 6: Case distribution by *kabam***Figure 7:** Case distribution by clinical symptoms**Figure 8:** Distribution of total HSS scores: before vs. after treatment**Figure 9:** Average symptom scores: before vs. after treatment

Discussion:

Most patients with *Moolam* in this study were men aged 26–50 years, suggesting that the condition was more common in the economically productive age group. The occupational pattern was dominated by sedentary work or jobs involving prolonged sitting which promote pelvic venous stasis and constipation, key contributors to haemorrhoidal pathology. Most participants also reported non-vegetarian food habits, inadequate water intake,

and low dietary fibre intake, all of which are known to contribute to constipation. In addition, one-third had symptoms for more than one year, and nearly one-quarter had a positive family history of haemorrhoids. Siddha diagnostic assessment showed a predominance of *Vaatha Thegi*. *Abanan* and *Samanan* were involved in all patients among the *Uyir Thathukkal*. The *Vaatha-Pitha Naadi* pattern, *Vaatha Neer* in *Neikuri*, and constipation observed in all participants further indicate that *Vaatham*, along with associated *Pitham* derangement, played a major role in the pathogenesis of *Moolam*. Among the 30 cases, before treatment, 3 patients (10%) had severe symptoms and 27 patients (90%) had moderate symptoms. Following treatment, a marked reduction in HSS scores was observed. Overall, 27 patients (90%) achieved mild HSS levels (score ≤ 3), while only 3 patients (10%) had a post-treatment HSS score > 3 , indicating residual moderate severity or partial improvement. No patient remained in the severe category after treatment. Symptoms such as pain, bleeding and prolapse showed marked reduction across all cases, with many patients reporting near-complete resolution (HSS score ≤ 2) (Table 15, 16) (Figures 8 and 9). There is a statistically highly significant reduction in HSS scores following treatment (paired t-test: $t(29) = 16.83$, $p < 0.001$). Normality assumptions were satisfied (Shapiro-Wilk $p > 0.05$) (Table 18). The magnitude of effect was extremely large (Cohen's $d = 3.07$). Non-parametric analysis using the Wilcoxon signed-rank test also showed a significant reduction ($p < 0.001$) with a large effect size, confirming the robustness of the findings (Table 17). The classical *Nilavagai Chooranam* from *Siddha Vaidhya Thirattu* [13] contains five ingredients and is indicated for *Ushna Vaayu*, abdominal bloating, hiccups, vomiting and bronchial asthma. The study drug selected from *Brammamuni Karukkudai Choothiram* - 380 has twenty ingredients and broader applications, including It has various indications like *Megam* (A sexually transmitted disease classified into 21 types), *Pitham* (One of the three humours), *Malakkattu* (Constipation), *Vaaiyu* (One of the three humours), *Soodu kollal* (Intense heat in pelvic region), *Sori* and *Sirangu* (A kind of itch or scabies), *Moolavaayu* (Accumulation of bowel gas) [14]. It is also considered a bowel cleanser and remedy for ailments arising from the seat of *Moolam*. Though Most ingredients possess *Ushna Veeriyam* (hot potency), they help rectify vitiated *Vadham* and *Pitham* commonly seen in anorectal disorders possibly through the *Oppurai*. These herbs stimulate *Agni* (digestive fire), enhance digestion, prevent *Ama* (undigested toxins) and exert anti-inflammatory effects. Cold potency herbs, though fewer, promote healing and reduce soreness through demulcent action. Pungent herbs dominate, stimulating metabolism, dispersing stagnation and providing antimicrobial and anti-inflammatory effects, while sweet-tasting herbs nourish, regenerate tissues and support hemostatic and anti-ulcer activity. When analyzed through modern phytochemical and pharmacological perspectives, the 20 ingredients of *Nilavagai Chooranam* act through four major, interrelated mechanisms - hypothetically that effectively address the underlying pathology of hemorrhoidal disease Collectively, *Nilavagai Chooranam* works through a multi-targeted approach-relieving constipation, reducing inflammation, controlling bleeding and improving

vascular tone-thereby addressing both the symptoms and root causes of hemorrhoidal disease in an integrated manner. Therefore, the trial drug, *Nilavagai Chooranam* showed significant symptom reduction in this single arm pre-post study in reducing the clinical symptoms of internal haemorrhoids.

Conclusion:

Nilavagai Chooranam administered for 48 days produced statistically significant improvement in patients with Grade I-III internal hemorrhoids in this uncontrolled pre-post study. Patients experienced marked relief from constipation, rectal bleeding and anal pain, with significant reduction in HSS scores ($p < 0.001$), supported by proctoscopic reduction in pile mass. The formulation's laxative, anti-inflammatory and hemostatic properties may underlie its therapeutic effects and no adverse events were observed, indicating a favorable safety profile.

Limitations and future recommendations:

This dissertation mandated study has no control group by study design. No blinding and no QoL instrument were used. The study did not fully adhere to CONSORT 2010 reporting standards and Incorporation of STRICTA or equivalent reporting frameworks for traditional medicine which is recommended to enhance reproducibility. The Hemorrhoid Symptom Severity score has not been validated in an Indian or Siddha clinical context and clinical assessments were largely subjective. Future research should employ validated instruments, standardized proctoscopic grading systems and assess inter-observer reliability to minimize bias. Further large-scale, multi-centre randomized controlled trials are

recommended to validate these results and help establish standardized treatment protocols for broader clinical use.

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