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Clinical Evaluation of Siddha Herbomineral Formulation Nayuruvi Nei in the Treatment of Varal Moolam (First-Degree Internal Hemorrhoids)

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Abstract: Nayuruvi nei is a medicated ghee formulation mentioned in Siddha literatures for management of Varal Moolam (First-Degree Internal Hemorrhoids). For its scientific validation this drug was studied for its therapeutic effectiveness in Varal Moolam patients. Its well-designed protocol was approved by Institutional Ethics Committee and the study been enrolled in Clinical Trial Registry of India. The clinical study was conducted as a Prospective, open label clinical trial in OPD of Ayothidoss Pandithar Hospital of National Institute of Siddha Chennai. Based on the inclusion criteria 30 Varal Moolam patients (First-Degree Internal Hemorrhoids) were enrolled in this study. Informed consent was obtained from each patient before study initiation. Nayuruvi nei of 1.6 g dose was administered orally morning a day for a period of 48 days (10 days Medicine 5 days drug holiday without medicine) and advised to follow the prescribed dietary regimen. All the baseline data, Laboratory investigations were recorded in the prescribed Case Report Form of each patient. The clinical assessment was recorded. Student t test was employed to test the significance of treatment using before and after treatment data on Hemorrhoids symptoms score, Clinical symptoms and Proctoscopic examination. The level of significance probability 0.05 was used to test the treatment difference and the values are statistically extremely significant with score ($p < 0.0001$).

Keywords: Varal Moolam, First-Degree Internal Hemorrhoids, Clinical trial, Siddha medicine

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Introduction

In Siddha system of medicine, Sage Yugi mentioned 21 types of Moolam in his text Yugi Vaithiya Chinthamani-800 (Yugi Muni, 2005).

Varal Moolam is a one of the types of Moolam. In Moola noi, increased keelvaikanal stimulates Vatha humour which in turn stimulates pitha

humour resulting in Moolam which is characterized by Constipation, bleeding during defecation, Painful defecation, Pain in anal region as per Saint Yugi. In the treatment aspect, to suppress vatha humour and Pitha humour, prescribe cooling agents to suppress keelvaikanal. As per Siddha, Siddhars notify moolatharam is a seat of kundalini Sakthi (Energy point). Any irregular practice of yoga, food and lifestyle modification may disturb the moolatharam there by kundalini and results in a disease called Moolam (Kuppuswamy, 2004).

An epidemiologic study reported a prevalence ranging from 4.4% in adults in the United States to over 30 % in London's general practice. A peak in incidence is seen between 45 and 65 years of age, while hemorrhoids progress before 20 is uncommon. It is estimated that 50-85% of people around the world had hemorrhoids. In India, 75% of the population was affected (Suma, 1994).

In the text of Agathiyar Vaithiya Valladhi -600, the medical formulation Nayuruvi Nei, a Siddha formulation, has been indicated explicitly for Varal Moolam (First Degree Internal Hemorrhoids). The main ingredients of the above said formulation are Sivantha Nayuruvi (*Achyranthes aspera*), Kodiveli (*Plumbago zeylanica*), Sivathai (*Operculina turpethum*), Serangottai (*Semecarpus anacardium*), Aayil (*Chukrasia tabularis*), Chukku (*Zingiber officinale*), Milagu (*Piper nigrum*), Thippili (*Piper longum*), Thandri (*Terminalia bellerica*), Munnai (*Premna integrifolia*), Kadukkai (*Terminalia chebula*), Nellikai (*Phyllanthus emblica*), Musuttai (*Rivea ornata*), Vetti ver (*Vettiveria zizanioides*), Pungu (*Pongamia pinnata*), Suthitha valam (*Croton tiglium*), Puliyananai verkizhangu (*Cissus setosa*), kanjori (*Tragia involucrate*), Kattu karunai (*Tacca pinnatifolia*), Pirandai (*Cissus quadrangularis*), Kasthoori manjal (*Curcuma aromatica*), Marul (*Sansevieria roxburghiana*), Kattu karunai (*Tacca pinnatifolia*), Indhuppu, Parai uppu, Cow ghee and Cow milk (Mohan, 2001; Murugesu, 2002; Pillai, 2007). This study

records its therapeutic efficacy clinically in Varal moolam patients.

Materials and Methods

The clinical study was conducted using a standard protocol, after obtaining the approval of the Institutional Ethical Committee (IEC) NIS/IEC/2019/D-1- 12.09.2019. The trial was registered in clinical trial registry of India with Reg.no CTRI/2020/02/023354 (Registered on date: 14/02/2020). It is an open clinical trial conducted at Ayothidoss Pandithar Hospital OPD.NO.1 Dept of Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai.

Subject Selection:

Patients reporting at OPD of Ayothidoss Pandithar Hospital with symptoms of inclusion criteria will be subjected to a screening test and documented using screening Performa. After screening of 70 patients diagnosed as Varal Moolam, 30 cases were selected in this trial. Before enrollment into the trial the informed consent and Proctoscopic examination willing consent was obtained from all the study participants.

Inclusion Criteria:

Patients who have the following were included in the study:

- Age: 14- 60 Years
- Sex – Male, Female, and Transgender
- Patients with appropriate symptoms like bleeding during defecation, Constipation,
- Pain in the anal region (Lalta, 2013),
- Willing to give blood samples for the investigation when required.
- Patient willing to Proctoscopy examination
- Willing to sign in the informed consent form.

Exclusion Criteria:

The patients who have the following criteria were excluded from this study:

- Pregnant and lactating mothers

- Second-degree Hemorrhoids
- External Hemorrhoids
- Fistula in Ano
- Fissure in Ano
- Diabetes mellitus
- Hypertension
- Rectal tuberculosis
- Rectal cancer
- Cardiac diseases (Suma, 1994; Chowdri and Parry, 2016)

Withdrawal Criteria:

- Intolerance to the drug and development of any serious adverse effects during the trial If ADR (Adverse Drug Reactions) reported, the patient was directed to RPC (Rules of Professional Conduct))
- Increase in severity of symptoms (Varut, 2012).

Conduct of the Study:

All the patients were given unique registration card having patient's Registration number of the study, Address, Phone number and doctor's contact number etc. All the baseline findings, vitals, clinical signs and symptoms, laboratory data (Hematology, Blood biochemistry, Lipid profile, LFT and RFT, Urine analysis), proctoscopy examination and in siddha aspect En vagai thervugal were done on the 0 day and 49th day of the trial.

- On 1st day the patients were asked to take an oil bath with Seeraga thylam (required quantity)
- On day 2nd the patients were advised to take purgative medication Agasthiyar kuzhambu-1 kundri (130 mg) with inji surasam (Ginger juice) on an early morning empty stomach.
- On 3rd day the patients were advised to take rest (without medication) (Thiyagarajan, 1968),

- From 4th day the trial drug "NAYURUVI NEI" was given at a dose of 1.6 gm once a day (morning) with Thiripala Ash 1.5 g for 48 days.

OPD patients, visited the hospital once in 7 days. At each visit, the patient's vitals and clinical assessments were recorded in the case report form by the doctor.

Statistical Analysis:

All collected data were entered MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions, and cross-tabulations have performed. The quantity variables are expressed as Mean $\pm$ Standard Deviation and qualitative data as a percentage. A probability value of <0.05 has considered indicating statistical significance. t-test was performed for determining the significance between before and after treatment.

Results

30 patients of both sexes were selected for this study among them 21 (70%) were Male and 9 (30%) were female (Table 1).

Out of 30 cases, 1 patient (3%) was affected in 14-20 years, 8 patients (27%) were affected in 21-30 years, 17 patients (57%) were affected in 31-40 years, 1 patient (3%) was affected in 41-50 years and 3 patients (10%) were affected in 51-60 years (Table 2).

Out of 30 cases, 8 patients (27%) were drivers, 3 patients (10%) were Teachers, 2 patients (7%) were Businessmen, 6 patients (20%) were Students, 7 patients (23%) were Housewives, 4 patients (13%) were Bank managers (Table 3).

Out of 30 cases, 27 patients (90%) were Literate and 3 Patients (10%) were Illiterate (Table 4).

Out of 30 cases, 28 Patients (93%) were Non-vegetarians and 2 Patients (7%) were Vegetarians (Table 5).

Table 1: Gender Distribution

GENDER DISTRIBUTION	NO OF CASES	PERCENTAGE
Male	21	70%
Female	9	30%

Table 2: Age Distribution

AGE DISTRIBUTION	NO OF CASES	PERCENTAGE
14-20 years	1	3%
21-30 years	8	27%
31-40 years	17	57%
41-50 years	1	3%
51-60 years	3	10%

Table 3: Occupational Distribution

OCCUPATIONAL DISTRIBUTION	NO OF CASES	PERCENTAGE
Driver	8	27%
Teacher	3	10%
Business Man	2	7%
Student	6	20%
Housewife	7	23%
Bank Manager	4	13%

Table 4: Educational Status

EDUCATIONAL STATUS	NO OF CASES	PERCENTAGE
Literate	27	90%
Illiterate	3	10%

Table 5: Food Habits Distribution

FOOD HABITS	NO OF CASES	PERCENTAGE
Vegetarian	2	7%
Non-Vegetarian	28	93%

Table 6: Less intake of water distribution

LESS INTAKE OF WATER	NO OF CASES	PERCENTAGE
Yes	21	70%
No	9	30%

Table 7: Less intakes of fibre content foods distribution

LESS INTAKE OF FIBRE CONTENT FOODS	NO OF CASES	PERCENTAGE
Yes	21	70%
No	9	30%

Table 8: Treatment History Distribution

TREATMENT HISTORY	NO OF CASES	PERCENTAGE
Yes	4	13%
No	26	87%

Table 9: Marital Status Distribution

MARITAL STATUS	NO OF CASES	PERCENTAGE
Married	23	77%
Unmarried	7	23%

Out of 30 cases, 21 patients (70%) had less water intake AND 9 Patients (30%) had more water Intake (Table 6).

Out of 30 cases, 21 patients (70%) were having less intake of Fiber content foods and 9 Patients (30%) were taking fibre content foods very well (Table 7).

Out of 30 cases, 26 patients (87%) had other system treatment history and 4 Patients (13%) had a treatment history for Hemorrhoids (Table 8).

In this study, 77% of patients were married and 23% of patients were unmarried (Table 9).

Among this study, 10% had a family history of Hemorrhoids and 90% had no family history (Table 10).

In this study, all the cases had a history of Constipation (Table 11).

Among this study, 97% had pain in the anal region and 3 % had no pain in the anal Region (Table 12).

Table 10: Family History Distribution

FAMILY HISTORY	NO. OF CASES	PERCENTAGE
Yes	3	10%
No	27	90%

Table 11: History of constipation distribution

HISTORY OF CONSTIPATION	NO. OF CASES	PERCENTAGE
Yes	30	100%
No	0	0%

Table 12: Pain in anal region distribution

PAIN IN ANAL REGION	NO. OF CASES	PERCENTAGE
Yes	29	97%
No	1	3%

Table13: Tenderness in anal region distribution

TENDERNESS IN ANAL REGION	NO. OF CASES	PERCENTAGE
At the Beginning	23	77%
During the Course	7	23%

Table 14: Mode of onset distribution

MODE OF ONSET	NO. OF CASES	PERCENTAGE
Sudden	0	0%
Gradual	30	100%

Table 15: Duration of illness distribution

DURATION	NO. OF CASES	PERCENTAGE
0-3 Months	18	60%
4-6 Months	4	13.5%
7-9 Months	1	3%
9-12 Months	4	13.5%
More Than 1 Year	3	10%

Among this study, 77% had Tenderness in anal region during the course and 2% had Tenderness in anal region at the beginning of Defecation (Table 13).

In this study, 100% of cases had a Gradual onset of Hemorrhoids and no cases were

reported with sudden onset (Table 14).

Among 30 cases, 0-3 months Chronicity of illness was found in 18 cases (60 %) 4-6 months Chronicity of illness in 4 cases (13.5%), 7-9 months Chronicity of illness in 1 case (3%), 9-12 months Chronicity of illness in 4 cases (13.5%)

Table 16: Psychological status distribution

PSYCHOLOGICAL STATE	NO OF CASES	PERCENTAGE
Normal	7	23%
Occupational Stress	16	53%
Depression	5	17%
Anxiety	2	7%

Table 17: Thegi Distribution

THEGI	NO OF CASES	PERCENTAGE
Vatham	5	17%
Pitham	2	7%
Kabam	1	3%
VathaPitham	8	27%
VathaKabam	1	3%
PithaVatham	10	33%
KabaVatham	3	10%

Table 18: Envagai thervu distribution

ENVAGAI THERVU	BEFORE TREATMENT		AFTER TREATMENT	
	NORMAL	AFFECTED	NORMAL	AFFECTED
Sparisam	100% (30)	0% (0)	100% (30)	0% (0)
Naa	13% (4)	87% (26)	57% (17)	43% (13)
Niram	83% (25)	17% (5)	83% (25)	17% (5)
Mozhi	100% (30)	0% (0)	100% (30)	0% (0)
Vizhi	83% (25)	17% (5)	83% (25)	17% (5)
Malam	0% (0)	100% (30)	90% (27)	10% (3)
Moothiram	100% (30)	0% (0)	100% (30)	0% (0)

Table 19: Naadi Distribution

NAADI DISTRIBUTION	BEFORE TREATMENT	AFTER TREATMENT
Vatha Pitha Naadi	40% (12)	53% (16)
Vatha Kaba Naadi	3% (1)	10% (3)
Pitha Vatha Naadi	57% (17)	37% (11)

and more than 1 year of Chronicity of illness in 3 cases (10%) with the disease (Table 15).

Among 30 cases, Normal Psychological status was found in 7 cases (23%), Occupational stress in 16 cases (53%), Depression in 5 cases (17%), Anxiety in 2 cases (13.3%) with the disease (Table 16).

Among 30 cases, Vatha thegi were 17% (5),

Pithathegi were 7% (2), Kabathegi were 3% (1), Vatha Pithathegi were 27% (8), Vatha Kabathegi were 3% (1), Pitha Vathathegi were 33% (10), and Kaba Vathathegi were 10% (3) with Varal Moolam (Table 17).

Among 30 Cases, Naa was affected in 87% of the cases before treatment, 43% of the cases after treatment. Niram was affected in 17 % of the cases before treatment, 17% of the cases were affected

Table 20: Manikkadai nool distribution

MANIKKADAI NOOL	NO OF CASES	PERCENTAGE
7 ½ Virarkadai	3	10%
7 ¾ Virarkadai	13	43%
8 Virarkadai	4	13.3%
8 ¼ Virarkadai	1	3.3%
8 ½ Virarkadai	8	27%
9 Virarkadai	1	3.3%

Table 21: Pile mass-position distribution

POSITION	NO OF CASES	PERCENTAGE
3' O Clock Position	9	30%
7' O Clock Position	2	7%
11' O Clock Position	9	30%
More Than One Pile; Mass in Various Clock Position	10	33%

Table 22: Clinical symptoms-before and after treatment

CLINICAL SYMPTOMS	BEFORE TREATMENT		AFTER TREATMENT	
	PRESENT	ABSENT	PRESENT	ABSENT
Bleeding During Defecation	100% (30)	0% (0)	10% (3)	90% (27)
Constipation	100% (30)	0% (0)	3% (1)	97% (29)
Anal Pain	97% (29)	3% (1)	47% (14)	53% (16)
Pain in All Limbs	67% (20)	33% (10)	20% (6)	80% (24)
Pruritus in Ani	80% (24)	20% (6)	17% (5)	83% (25)
Discharge of Pus and Mucous in anal region	17% (5)	83% (25)	0% (0)	100% (30)
Irritation and Soreness After Defecation	57% (17)	43% (13)	0% (0)	100% (30)
Anemia	20% (6)	80% (24)	13% (4)	87% (26)

after treatment. Vizhi was affected in 17% before and after treatment. No improvement was observed in Niram and Vizhi. Sparisam, Mozhi, and Moothiram were not affected before and after treatment (Table 18).

Among 30 cases, before treatment 40% of cases had Naadinadai Vathapitha Naadi, 3% of case had Vathakaba naadi, 57% of cases had Pithavathanaadi. After treatment 53% of cases

had Naadinadai Vathapitha Naadi, 10% of cases had Vathakaba naadi, 37% of cases had Pithavathanaadi (Table 19).

Among 30 cases, 10% of cases had 7½ virarkadai, 43% of cases had 7¾ virarkadai, 13.3% of cases had 8 virarkadai, 3.3% of cases had 8¼ virarkadai, 27% of cases had 8½ virarkadai, 3% of cases had 9 virarkadai (Table 20).

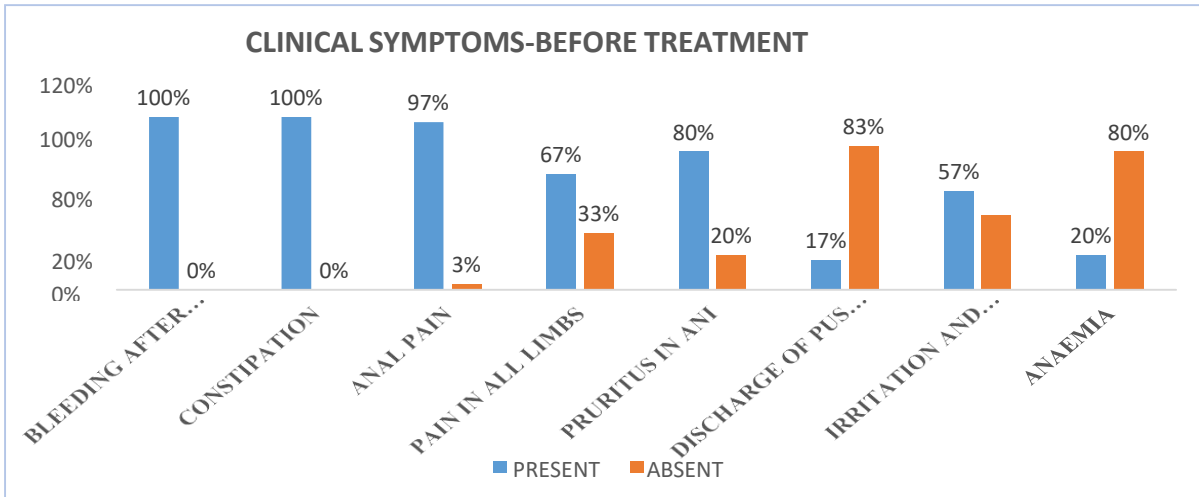


Fig. 1: Clinical symptoms-before treatment.

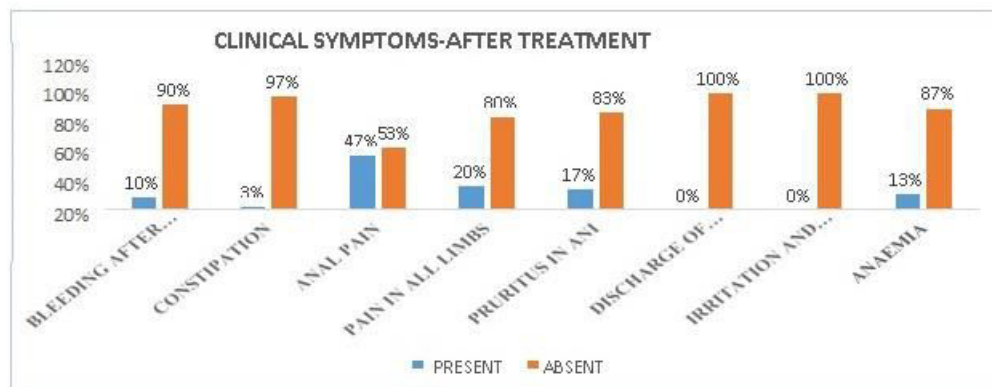


Fig. 2: Clinical symptoms-after treatment.

Among 30 cases, 30% of cases had Pile mass in 3'o clock position, 7% of cases had Pile mass in 7'o clock position, 30% had Pile mass in 11'o clock position, and 33% of cases had more than one Pile mass in various clock position (Table 21).

Among 30 cases affected before treatment, 100% of cases had clinical symptoms of bleeding and Constipation, 97% of cases had Anal pain, 67% of cases had pain in all limbs, 80% of cases had Pruritus in ani, 17% of cases had Discharge of pus and mucous, 57% of cases had Irritation and soreness after Defecation, 20% of cases had Anaemia. After treatment, only 10% of cases had clinical symptoms of bleeding, 3% had Constipation, 47% had Anal pain, 20% had pain in all limbs, 17% had Pruritus in ani, 13% had Anaemia. Moreover, 0 % had no Discharge of pus

and mucous and Irritation and soreness after Defecation (Table 22, Figs. 1, 2).

Prognosis Chart:

Clinical Severity Symptoms by Hemorrhoids Symptoms Severity Score (HSS score) (Varut, 2012), before and after treatment [Score: 0 - Never, 1- Less than once/week, 2-1-6 times/week, 3-Always] (Table 23; Fig. 3).

Among 30 cases, based on this HSS Score, In 14 cases (47%) symptoms were completely relieved and from 16 cases (53%) symptoms were reduced well, those patients were improved from Moderate to mild (Table 24, Fig. 4).

Proctoscopic Images:

3'o clock Position of Pile mass completely

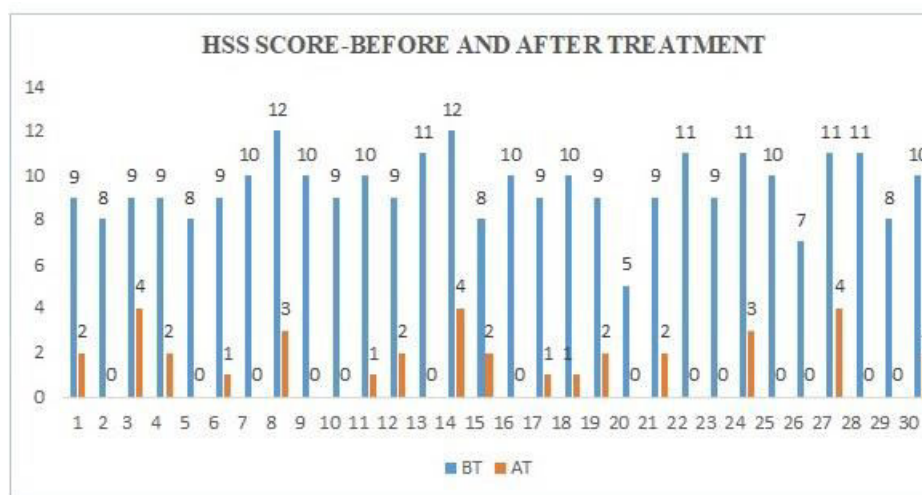


Fig. 3: HSS score-before and after treatment.

Table 23: HSS score-before and after treatment.

S.No	OP No.	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	69179	3	2	3	1	-	9	1	1	0	0	-	2
2	133974	3	2	2	1	-	8	0	0	0	0	-	0
3	133708	3	2	2	2	-	9	2	1	1	0	-	4
4	136503	3	3	2	1	-	9	1	0	1	0	-	2
5	136605	3	0	3	2	-	8	0	0	0	0	-	0
6	82672	3	2	2	2	-	9	0	1	0	0	-	1
7	136244	3	3	2	2	-	10	0	0	0	0	-	0
8	120318	3	3	3	3	-	12	2	0	1	0	-	3
9	132646	3	2	3	2	-	10	0	0	0	0	-	0
10	114185	2	2	3	2	-	9	0	0	0	0	-	0
11	139517	3	2	3	2	-	10	1	0	0	0	-	1

12	123952	3	3	2	1	-	9	1	1	0	0	-	2
13	61075	3	3	3	2	-	11	0	0	0	0	-	0
14	54086	3	3	3	3	-	12	2	2	0	0	-	4
15	45659	2	2	2	2	-	8	1	1	0	0	-	2
16	140295	3	2	3	2	-	10	0	0	0	0	-	0
17	14010	2	2	3	2	-	9	1	0	0	0	-	1
18	122501	3	3	2	2	-	10	1	0	0	0	-	1
19	139183	3	2	2	2	-	9	0	1	1	0	-	2
20	145420	2	2	1	0	-	5	0	0	0	0	-	0
21	127569	3	3	3	0	-	9	1	1	0	0	-	2
22	127093	3	3	3	2	-	11	0	0	0	0	-	0
23	146837	3	3	2	1	-	9	0	0	0	0	-	0
24	147079	3	3	3	2	-	11	1	1	1	0	-	3
25	146789	3	2	3	2	-	10	0	0	0	0	-	0
26	114560	2	2	2	1	-	7	0	0	0	0	-	0
27	127434	3	3	3	2	-	11	2	1	1	0	-	4
28	147678	3	3	3	2	-	11	0	0	0	0	-	0
29	145716	3	2	2	1	-	8	0	0	0	0	-	0
30	147848	3	2	3	2	-	10	1	0	1	0	-	2

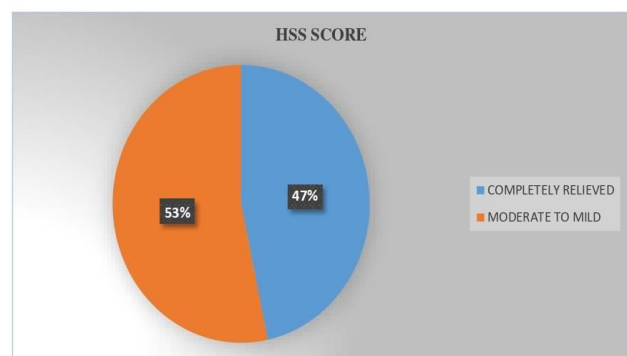


Fig. 4: HSS score.

Table 24: Case distribution by HSS score

HSS SCORE	NO. OF CASES	PERCENTAGE
Completely relieved	14	47%
Moderate to mild	16	53%



Fig. 5: Before treatment.

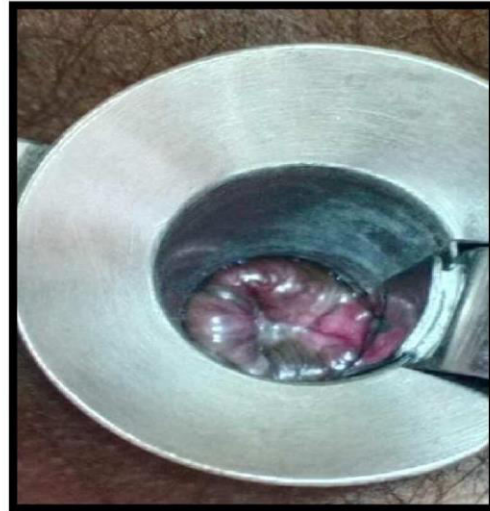


Fig. 6: After treatment.



Fig. 7



Fig. 8

Table 25: Distribution of Mean and Standard Deviation of before and after treatment in Clinical symptoms

SYMPTOMS - PRESENT	Mean	Standard Deviation	t value	p-value
BEFORE TREATMENT	0.6725	0.3392323	4.8281	0.0019
AFTER TREATMENT	0.1375	0.1541567		

SYMPTOMS - ABSENT	Mean	Standard Deviation	t value	p-value
BEFORE TREATMENT	0.3275	0.3392323	-4.8281	0.0019
AFTER TREATMENT	0.8625	0.1541567		

Table 26: Distribution of Mean and Standard Deviation of before and after treatment of Hemorrhoid Symptoms Severity Score

HSS SCORE	Mean	Standard Deviation	t value	p-value
BEFORE TREATMENT	9.433333	1.478194	27.9734	0.001
AFTER TREATMENT	1.2	1.374647		

reduced after treatment (Figs. 5, 6). 3'o clock, 7'oclock and 11'o clock Position of Pile mass size completely reduced after the treatment (Figs. 7, 8).

The Clinical symptoms presenting in before and after treatment were 0.6725 and 0.1375 respectively, following Clinical symptoms absenting in before and after treatment were 0.3275 and 0.8625 (Table 25).

Before and After treatment, presenting and absenting of clinical symptoms has been significantly reduced ($p=0.0019$) (Table 25).

The Hemorrhoids Symptoms Severity Score in before and after treatment Mean value were 9.433333 and 1.2 respectively (Table 26). Before and After treatment of Hemorrhoids Symptoms Severity Score has been significantly reduced ($p=0.001$).

Discussion

Varal Moolam is one of the 21 types of classification of Moolam mentioned by Sage Yugi, Varal Moolam, which in Siddha literature correlated with First-degree internal hemorrhoids. varal moolam is characterized by first-degree internal hemorrhoids like Constipation, Bleeding per Rectum drop by drop, Pile mass present inside, Dryness of body, General weakness in chronicity. The trial was the clinical evaluation of Siddha medicine Nayuruvi Nei in treating Varal Moolam (First-degree internal hemorrhoids). All the components of the trial drug were well known for its anti-inflammatory Astringent, Antispasmodic, Anthelmintic, Laxative activities, Carminative and Styptic actions (India Pharmacopeia, 2014). Hence, the medicine possesses all these activities and acts as a whole some drug in the

management of Varal Moolam. The trial drug is cost-effective and efficacious also. The study found that Varal Moolam affects more men than women. The highest number of cases were found in the age group of 31-40 years. People who have jobs that involve prolonged sitting and stress are more likely to get Varal Moolam. Most of the cases were non-vegetarians and had a high fat consumption. Patients who do not drink enough water are also more likely to have Varal Moolam. Eating foods with fiber can help prevent Varal Moolam. It is important to make lifestyle changes to treat and prevent hemorrhoids. These changes include eating more fibre, following a low-fat diet, and drinking enough fluids every day. In this study, 10% of the people had a family history of hemorrhoids while 90% did not. Even though genetics can cause hemorrhoids, it was not important in this study. The study found that all the cases in this history have had constipation before. Constipation is a factor that can cause the disease. The psychological status of 30 people was examined. Out of these, 7 people (23%) had normal psychological status, 16 people (53%) had occupational stress, 5 people (17%) had depression, and 2 people (13. 3%) had anxiety along with the disease. Stress can cause digestive issues, such as constipation and diarrhea, which may result in hemorrhoid flare-ups. When people feel stressed, they squeeze their sphincter muscle and put pressure on the rectum. This pressure can cause a condition called hemorrhoid flare-ups. Among 30 cases, 33% (10) had a body constitution called PithaVatha thegi, and 27% had a body constitution called Vatha Pitha thegi with Varal Moolam. In a book called Yugi Vaithya Chinthamanai 800, it was mentioned that a disruption in the vatham and pitham humor is the cause for Varal Moolam. The feeling of being tired was seen in most patients. It was caused by dryness, a tongue that looked coated, and being pale. After treatment, some patients still felt tired. The color of the skin was pale in 17% of cases, and there was no improvement after treatment. The eyes were also pale in 17% of cases, and there was no improvement after treatment. All

patients had constipation, but it improved after treatment. The conditions of body odor, speech, and urination were not affected before or after treatment. In varal moolam patients, before treatment, 40% of cases had a specific pulse called Naadi nadai Vathapitha Naadi, 3% had Vathakaba naadi, and 57% had Pithavatha naadi. After treatment, 53% had Naadinadai Vathapitha Naadi, 10% had Vathakaba naadi, and 37% had Pithavatha naadi. In Siddha texts, it has been mentioned that Pithavatha naadi is responsible for Moolam. In Manikadainool to varal moolam patients, 10% had 7 ½ virarkadai, 43% had 7 ¾ virarkadai, 13. 3% had 8 virarkadai, 3. 3% had 8 ¼ virarkadai, 27% had 8 ½ virarkadai, and 3% had 9 virarkadai. In this study, 7 ¾ out of 10 people were more likely to have Varal Moolam. The symptoms of first-degree internal hemorrhoids in these people were as follows: Bleeding was noticed in all cases before treatment, but only 10% of cases were affected after treatment; Constipation was noticed in all cases before treatment, but only 3% of cases were affected after treatment; Anal pain was noticed in 97% of cases before treatment, but only 47% of cases were affected after treatment; Pain in all limbs was noticed in 67% of cases before treatment, but only 20% of cases were affected after treatment; Itching in the anus was noticed in 80% of cases before treatment, but only 17% of cases were affected after treatment; Discharge of pus and mucous in the anal area was noticed in 17% of cases before treatment, but none of the cases were affected after treatment; Irritation and soreness after bowel movements were noticed in 57% of cases before treatment, but none of the cases were affected after treatment; Anemia was noticed in 20% of cases before treatment, and 13% of cases were affected after treatment. During the examination, pile masses were found in different positions: 30% were at the 3'o clock position, 7% were at the 7'o clock position, 30% were at the 11'o clock position, and 33% had more than one pile mass at different positions. Out of the total cases, 47% had their symptoms completely relieved, and

53% had their symptoms reduced from moderate to mild.

Conclusion

Clinical study revealed that the trial drug possessed good clinical improvement, From the Hemorrhoid Symptoms Severity Score it was concluded that clinical symptoms were completely relieved in 14 cases (47%) and clinical symptoms were reduced well in 16 cases (53%) who improved from Moderate to mild level. Before and After treatment, Hemorrhoids Symptoms Severity Score has been significantly reduced in all cases ($p = 0.001$). Therefore, the trial drug *Nayuruvi Nei* is therapeutically effective. Statistical analysis was done for before and after treatment, presenting and absencing of clinical symptoms has been significantly reduced in all cases ($p = 0.0019$). Proctoscopy examination showed a moderate reduction of internal pile mass size after treatment. There was no adverse reaction reported during the trial period. The study may be further carried out with the same drug "*Nayuruvi Nei*" in a larger clinical population because of the promising clinical outcome.

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