

A PILOT STUDY OF GANDHAGA RASAYANAM (INTERNAL) AND THIRIPALA KUDINEER PEECHU(EXTERNAL) FOR THE TREATMENT OF VELLAI NOI. (LEUCORRHOEA)

A.M.Amala hazel ¹, P.Alarmel mangai ², K.Vennila ³, M.Amala⁴, Banumathi.V ⁵

1. Lecturer ,Department of kuzhandhai maruthuvam National Institute of Siddha Chennai

2. Assistant Medical Officer Government Hospital Seynamvilai Kanyakumari

3. Lecturer ,Department of kuzhandhai maruthuvam National Institute of Siddha Chennai

4. PG Scholar (2015-2018) Department of kuzhandhai maruthuvam National Institute of Siddha Chennai

5. Director, National Institute of Siddha Chennai

Abstract

Objective: The present pilot study was designed to evaluate the effect of Gandhaga rasayanam a Traditional Siddha medicine internally and Thiripala kudineer peecheu externally for patients suffering from leucorrhea.

Method: This study was conducted at the National Institute of Siddha, Tambaram, Chennai, India. The investigator recruited 10 patients with an inclusion and exclusion criteria. The patients were given oil bath on first day and treated with 100 mg *Agasthiar kuzhambu* with hot water on the second day. For the next fourteen days the patients were given 5 grams of GANDHAGA RASAYANAM twice a day with milk as its adjuvant and alternate days with thiripala kudineer vaginal wash. Dietary regimen was advised for the patients. Study outcome was studied based on the improvement in the reduction of vaginal discharge assessed by leucorrhea assessment scale, clinical improvement and prevention of vaginal discharge for at least 2 months.

Results: Clinical symptoms such as white discharge per vagina, pruritis in the vaginal region, low back ache, abdominal pain were relieved during the treatment. There were no adverse events reported during the study and no recurrence of white discharge was noticed in 4 patients who were completely cured, during the follow up period of up to 2 months were reported and in all the other patients the white discharge was reduced.

Conclusion: Results suggest that the trial drug gandhaga rasayanam (internal) and thiripala kudineer peecheu(external) is effective and safe for the management of for the treatment of vellai noi. (leucorrhoea) and in alleviating recurrences.

Key words : Leucorrhea, Gandhaga rasayanam, Vellai noi, Thiripala kudineer peecheu.

Introduction

Siddha system of medicine is an old and traditional Indian medical practices which is very efficient and unique in its treatment and management forms.

Reproductive tract infections form one of the major burdens of disease in developing countries, and include infections caused due to any (or combination) of the three factors: iatrogenic, endogenous, and sexually transmitted. While there are many symptoms that define the disease, the most commonly reported among the women is that of abnormal vaginal discharge (or Leukorrhea). Various community based studies in developing countries have revealed that this morbidity and general ill health has been endured silently by women, due to various factors like gender inequalities, cultural restrictions, lack of women autonomy, poor awareness, lack of proper infrastructure, and focussed counselling services (3, 4, 5, and 6,7,8).

Leucorrhoea is a condition in which there is a whitish discharge from the vagina outlet. Leucorrhoea is physiological when associated with various phases of menstrual cycle. It is considered that changes in the vaginal epithelium, changes in the normal bacterial flora and pH of the vaginal secretion predispose to leucorrhoea. The causes for vaginal discharge have been described by women to be environmental heat, eating particular kind of food, weakness, tension, while biomedical causes like unsafe delivery, copper-T insertion, abortion, multiple partners have also been reported (3,6). It often occurs normally, but if the discharge is excessive it may be a symptom of infection. Sometimes it can be thick, viscid and foul smelling but differs from person to person. Leucorrhoea can also be classified as cervical leucorrhoea or vaginal leucorrhoea i.e., according to the place of its origin – cervix or vagina. In the case of advanced, chronic inflammatory conditions of these organs, it leads to discharge with offensive in odour and colour varying from cream to yellow or light green.

Most of the patients presents with the following symptoms.

- Lower abdominal pain.
- General tiredness due to loss of vital fluids as discharges.
- Irritability and lack of concentration in work due to consciousness of discharges.
- Low Backache and pain in the leg, especially thigh and calf muscles.
- Soreness and burning in the genital tract.
- Burning micturition and frequent urge to pass very little urine.
- Loss of libido

In our Sool Magalir Maruthuvam OPD of NIS, we are receiving more number of patients of vellai noi which is the driving force behind to select this topic. Siddha formulations not only treat the disease but also strengthen the uterus, vagina and corrects the deranged pitham without any undesirable side effects, according to siddhar texts this kind of disease is due to deranged pitha humor and it is the first reason for vellai noi. For neutralising the pitham, bitter, sweet and pungent taste will be given. For this reason, bitter and pungent taste presenting Gandhaga rasayanam and pungent taste presenting Thiripala kudineer is taken for this trial. As a combined effect of Gandaga Rasayanam internal and with external treatment THIRIPALA KUDINEER PEECHU would be more effective in curing the disease in short term, but there were no definitive clinical document evidence to prove the efficacy of the same. Hence, it is the need of the hour to evaluate clinical efficacy of commonly prescribing Gandaga rasayanam with Thiripala kudineer peecheu in the treatment of Vellai Noi.

Method

This pilot study was conducted in *Ayothidoss Pandithar* Hospital in the OPD of Sool and Magalir Maruthuvam, National Institute of Siddha, Tambaram Sanatorium, Chennai-47 in accordance with standard protocol after obtaining the approval of the Institutional Ethical Committee (IEC) (NIS/IEC/9/2014-15/36/37-26.08.2015). Before enrollment into the study the informed consent was obtained from the patients, and the study was registered in CLINICAL TRIAL REGISTRY OF INDIA and the register number is CTRI/2018/02/011807 09/02/2018.

Conduct of Trial

The total of 10 patients who are enrolled in the study will be advised to take oil bath followed by purgation with Agasthiyar kuzhambu 100 mg will be given with hot water. The trial drug Gandhaga Rasayanam will be given from NIS dispensary once in 5 days and will be advised to come to the OPD for alternate days for the external treatment Thiripalai Kudineer peecheu (vaginal wash) which would be done by the investigator in the labour room of NIS in an aseptic environment. In every visit the clinical assessment will be recorded in the prescribed Proforma. The laboratory investigation will be done before and after treatment and recorded in the prescribed format. For IP patients the drug will be provided daily and assessment will be done through the prescribed format. The prognosis will be noted daily. At the end of the trial the patients will be advised to come to the NIS OPD once in 10 days as apart of follow

up for the post procedure assessment. This follow up will be for 2 months.

Study Outcome

Study outcome was studied based on the improvement in the reduction of white discharge per vagina and other clinical symptoms, using leucorrhoea assessment scale, clinical improvement and prevention of recurrence of white discharge for at least 2 months.

Results were observed with respect to the following criteria

LEUCORRHEA ASSESSMENT SCALE

s.no	Clinical features	Before tmt	After tmt
1	Discharge in grade		
2	Pruritis		
3	Foul odour		
4	Lower abdominal pain		
5	Low back ache		

DISCHARGE IN GRADE :

G 0 – No discharge

G1 – Mild watery discharge

G 2 – White discharge staining on the inner wear

G 3- White discharge wetting the clothes

CLINICAL ASSESSMENT RESULTS

S.no	Op/Ipno	Name	Age	Discharge in grade		Pruritis		Foul odour		Dysuria		Lower abd.pain		Low back ache		TOTAL	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	F60370	S.SUNDARI	42	3	1	2	0	1	0	0	0	1	0	1	0	8	1
2	H17448	V.RENUGA	32	3	2	3	1	1	0	0	0	1	0	0	0	8	3

3	HI9279	S.VANITHA	43	3	1	3	1	1	0	0	0	0	0	1	1	8	3
4	G85848	S.DATCHAYANI	39	2	1	2	0	1	0	0	0	0	0	1	1	7	2
5	H13491	A.KAVITHA	44	2	2	3	1	0	0	0	0	1	1	0	0	6	4
6	H48101	V.DILLI RANI	40	3	0	1	0	0	0	1	1	0	0	0	0	5	1
7	H26053	E.MALLIGA	45	2	0	3	0	1	0	1	0	0	0	0	0	7	1
8	H29920	S.SARALA	29	3	1	2	1	0	0	0	0	0	0	1	0	6	2
9	H42820	R.LAKSHMI	26	2	2	2	0	1	1	0	0	1	1	0	0	6	4
10	H86183	R.YAMUNA RANI	28	3	1	2	0	0	0	0	0	0	0	0	0	5	1

Results

Clinical symptoms such as white discharge, pruritis, foul odour, low back pain, lower abdominal pain were relieved during the treatment. There were no adverse events reported during the study and no recurrence of white discharge in 4 patients who were completely cured, during the follow up period of up to 3 months four to five cases were reported and in those patients discharge was reduced.

Discussion

The efficient and cost effective simple drug which has been mentioned in Siddha literature for the management of leucorrhoea was used for the trial. Leucorrhoea affects almost 60% of women in their reproductive age and some after menopause also. A total number of 45 cases was screened and 10 cases were recruited and given treatment in the OPD and IPD of Sool and Magalir Maruthuvam OPD. After completion of the study, the patients were advised to visit the OPD of Sool magalir Maruthuvam for 3 months for follow-up. The results obtained provide promising good result. Among 10 cases, 4% shows excellent improvement and 2% shows good improvement. These results were based completely on the clinical improvements.

In the other hand, on the statistical data,

Treatment	Mean \pm Std Dev	95% of C.I	Significance (t, p)
Before (10)	6.6 \pm 1.17	5.7 to 7.43	8.8196
After (10)	2.2 \pm .22	1.3 to 3.07	P 1.0000

The mean and standard deviation of clinical symptoms score of leucorrhoea before and after treatment were 6.6 \pm 1.17 and 2.2 \pm .22 respectively, which is statistically significant. The reduction of clinical symptoms after the treatment is significant (p 1.0000). The reduction in the symptom is 67% at the end of the treatment. Hence the efficacy of the trial drug Gandhaga Rasayanam internal and Thiripala kudineer peecheu external in the management of vellai noi (Leucorrhoea), which is observed clinically and statistically is found to be a good one.

Conclusion

Women are prone to many types of illness, both physiologically and pathologically. Siddha formulations described in traditional texts for the management of leucorrhoea are comparatively economical

and also clinically effective. The observation both clinically and statistically made during the clinical study explores that the trail drug Gandhaga Rasayanam internal and Thiripala kudineer peecheu external, was clinically effective in the management of vellai noi. This has in turn, provided a golden opportunity for a new combination of drugs established in the management of vellai noi.

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