

Clinical evaluation of odhiyampattai kudineer (herbal decoction) a siddha drug for vadha perumpadu (menorrhagia) - as pilot study

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Abstract - The present pilot study was designed to evaluate the clinical efficacy of Odhiyampattai kudineer for the treatment of Vadha Perumpadu(Menorrhagia). The study was conducted at National Institute of Siddha, in the Department of Kuzhandhai Maruthuvam(sool and magalir maruthuvam opd), Tambaram,Chennai. The author recruited 10 patients in the study based on inclusion and exclusion criteria one by one on the day 1 of their mensus. Then they were given Odhiyam pattai kudineer 65 ml thrice a day, until the cessation of bleeding ie maximum for 7 days. The results were assessed by Pictorial Bleeding Assessment Chart. Study outcome was based on the reduction in usage of pads, reduction in passage of clots in during bleeding, improvement persisting at least 3 months. There was reduction in bleeding during menstrual cycle, irrespective of age and chronicity of the complaint. Passage of clots and usage of pads reduced. Around 7 out of 10 were completely convinced comparing their past cycles. In the follow up for the period of 3 months, in most of the cases there was reduction in the flow. Finally, it was concluded at this herbal decoction has a anti stytic activity, very cost effective, has a good clinical improvement after administration and recurrence of heavy bleeding in further cycles also have been controlled.

Key words: Menorrhagia, Odhiyampattai, Herbal decoction, Perumpadu

I. INTRODUCTION

Menorrhagia is defined as a 'complaint of heavy cyclical menstrual bleeding occurring over several consecutive cycles'. Objectively it is a total menstrual blood loss equal to or greater than 80 ml per menstruation. It is estimated that approximately 30% of women complain of menorrhagia. [1]

Siddha system of medicine is one of the ancient traditional medical practices which has its own uniqueness in its diagnosis and treatment methodology. According to the text of Yugi Vaithiya Sinthamani an amazing siddha text, perumpadu is classified into 4 types. Vadha perumpadu is one among them. The symptoms of vadha perumpadu are distended abdomen with reddish black menstrual bleeding, headache,abdominal pain,low back ache,hyperpigmentation of the body.[2] Menorrhagia is the common gynaecological condition where the women are highly disturbed both physically,mentally and needs hospitalization.Among 20 women aged 30 years to 40 years who consult the doctor for increased bleeding during mensus 40% to 60% of them have no pathology and diagnosed as dub (dysfunctional uterine bleeding)[5].Excessive menstrual bleeding is a common cause of iron deficiency anemia.More than two third of patients who have excessive menstrual bleeding also suffer from anemia.In NIS opd a considerable number of female patients are recorded with symptoms of vadha perumpadu and due to this monthly or unpredictable issue they cannot do their daily duties and the entire family members are put in to trouble especially the kids.Their financial status also sounds bad since the working women are affected most.In gunapadam mooligai vaguppu , ODHIYAMPATTAI KUDINEER is exclusively specified for perumpadu which is in practice.The ingredient of ODHIYAMPATTAI KUDINEER is only odhiyampattai{*lannea coromandellia*} which is well known for its astringent property which is purely herbal,and a single herbal preparation which is not taken in trial before .Hence i have selected odhiyampattai kudineer for my pilot study.

II. 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/10/2016-17/32 -20.05.2016). 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/2018/02/011798 09/02/2018.

III. CONDUCT OF TRIAL

The required raw drugs will be purchased from a well reputed indigenous drug shop.The raw drugs will be authenticated by the Asst Professor medicinal botany in NIS Chennai. The raw drugs will be purified and the medicine will be prepared as per sop in gunapadam laboratory of NATIONAL INSTITUTE OF SIDDHA.

Bark of *lannea coromandelia(houtt)merr (odhiyampattai)* is the only ingredient.

The ingredient will be purified by scrubbing the outer skin as per mentioned in the text Marundu Sei Iyalum Kalaiyum[6]. The bark is then made in to coarse powder by grinding and stored in an air tight container. The purified bark powder. 170 gm is taken and mixed with 1500 ml of water. The above contents are boiled thoroughly and condensed to 1/8 of its total quantity and filtered[4] and dispensed to the patient in a clean container.


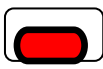




subject selection: Patients reporting at OPD of SOOL MAGALIR MARUTHUVAM with the symptoms of inclusion criteria will be subjected to screening test and documented using screening proforma.

The trial drug ODHIYAMPATTAI KUDINEER will be given for 7 days fro day 1 of the mensus. The trial drug will be given by the investigator in the Ip department of Sool magalir maruthuvam, NIS, chennai. The patients will be monitored in the Ip department. The clinical assessment will be recorded in the prescribed proforma by the investigator in the Ip department. At the end of the trial the patients will be advised to come for follow up for 3 months for observation.

IV. STUDY OUTCOME

It is assessed by the reduction of menstrual bleeding with Pbac score.

Month:-----

Day\\	Pads			Tampons			Clots		Floodin g Episode	sco re
	light\\ 1pt each\\	Medium\\ 5pts each	Heavy\\ 20pts each	Light\\ each 1pt	Medium\\ 5pts each	Heavy\\ 10pts each	5cm Size (1 pt Each)	50 cm Size (5 pts Each)		
										
1										
2										
3										
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27										
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30										
31										
									Total	

Each row represents a day of the month count the number of sanitary pads and/or tampons you use each day (24 hour period). Calculate a score for each day, then add up the score at the end of the month.







bleeding between periods - if you also experienced bleeding between periods that required sanitary protection please record this on the relevant days.

clots – if you pass clots, please indicate this on the relevant days and the approximate size (ie. Closer to an australian 5 cent or 50 cent piece).

flooding – if you experience any episodes of ‘flooding’/overflowing/staining of clothing/underwear please indicate the number of episodes on the relevant days.

double protection – if you have used both a pad and tampon simultaneously and both sanitary items were stained with blood don't forget to include both sanitary items on the pbac.

Pbac Scoring System

Pads		
1 point	For each lightly stained pad	
5 points	For each moderately stained pad	
20 points	For each completely saturated pad	
Tampons		
1 point	For each lightly stained tampon	
5 points	For each moderately stained tampon	
10 points	For each completely saturated tampon	
Clots/flooding		
1 point	For each small clot	
5 points	for each large clot	
10 points	For each episode of flooding	

V. MENORRHAGIA CLINICAL ASSESSMENT

PICTORIAL BLEEDING ASSESSMENT CHART- PBAC SCORE

S.NO	NAME AND AGE	OP/IP NO	PBAC SCORE	
			BEFORE TMT	AFTER TMT
1	P.AMUDHA 44	8196	220	116
2	J.BHARATHI 36	H2338	448	255
3	S.LAVANYA 26	8206	116	608
4	A.JANAKI 28	H68226	980	782
5	P.VIJILA 32	G94736	830	650
6	M.MEENA 35	H99641	450	281
7	K.JANSIRANI 36	G71961	720	180
8	N.RAMYA 25	H32306	680	130
9	P.SARANYA 16	I37130	580	132
10	M.LAKSHMI 38	I10336	630	416

VI. RESULTS

Clinical symptoms such as heavy menstrual flow, passage of clots during bleeding were reduced significantly. There were no adverse events reported during the study. Usage of pads during menstrual period reduced moderately.

VII. DISCUSSION

The medicine odhiyam pattai kudineer is a simple and very cost effective siddha drug for management of perumpadu. As a result of this trial, needing to double up on sanitary protection, usage of sanitary napkins during night time and restriction of the daily activities due to heavy flow, absence to schools and colleges were reduced significantly. Patients were highly satisfied with this easily palatable and simple medication for their monthly trouble. A total number of 65 cases were 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 results. Among 10 cases, 5% shows excellent improvement and 3% 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)	578.2 \pm 261.8	364.7 to 791.6	t value – 1.9888
After (10)	355.0 \pm 232.5	179.6 to 530.3	P - 0.081

The mean and standard deviation of clinical symptoms score of Vadha perumpadu before and after treatment were 578.2 \pm 261.8 and 355.0 \pm 232.5 respectively, which is statistically significant. The reduction of clinical symptoms after the treatment is significant. The reduction in the symptom is considerable at the end of the treatment.

Hence the efficacy of the trial drug odhiyampattai kudineer, for the management of vadha perumbadu which is observed clinically and statistically is found to be a good one.

VIII. CONCLUSION

Excessive bleeding is the main presenting complaint in women referred to gynecologists and it accounts for two-thirds of all hysterectomies, and most of endoscopic endometrial destructive surgery. Thus, menorrhagia is an important healthcare problem. Its etiology, investigation, medical and surgical management are described. In approximately 50% of cases of menorrhagia no pathology is found at hysterectomy. [1] Siddha formulations described in traditional texts for the management of menorrhagia are comparatively economical and also clinically effective. The observation both clinically and statistically made during the clinical study explores that the trial drug Odhiyampattai kudineer was clinically effective in the management of Vada perumpadu. This has in turn, provided a golden opportunity for a new combination of drugs established in the management of menorrhagia.

IX. REFERENCE

- [1] <https://www.ncbi.nlm.nih.gov/pubmed/12752071>
- [2] Yugi Vaidhya Senthamani, Yugi Munivar. Edition_ 2nd :Page no_233
- [3] Aathmaratchamirtham Ennum Vaidhya Saara Sangiragam-Kannusamy Mudhaliar Edition Sep 2011 (1st)pg no-51
- [4] Gunapadam mooligai Vaguppu Dr.Thiyagarajan. edition-2nd(2008).
- [5] Howkins And Borne Shaws Text Book Of Gynaecology 14th Edition page no:545.
- [6] Marundu sei iyalum kalaiyum. Page no:283
- [7] www.rch.org
- [8] www.ncbi.com
- [9] Kuppusaamy muhaliyar, Uthamaraayan Siddha vaidhiya thirattu 2nd edition, Indian medicine and homeopathy.