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CLINICAL EVALUATION OF SIDDHA DRUG VELVANGA PARPAM IN THE TREATMENT OF BLEEDING HAEMORRHOIDS (ISTDEGREE HAEMORROIDS)

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ABSTRACT

Siddha system is an ancient and unique system, have plenty of medicines which cures many disease without side effects. The present clinical study was carried out to evaluate the efficacy and safety of siddha mineral formulation 'Velvangaparpam' in the treatment of bleeding haemorrhoids. Haemorrhoids are a dilatation of superior, middle, inferior veins of the anal canal. They are 4 grades of haemorrhoids. A clinical trial was conducted in 40 patients with 1st degree haemorrhoids in Arignar Anna Government Hospital of Indian Medicine and Homeopathy, Chennai. The trial drug Velvangaparpam was administered in all patients at the dose of 100mg twice a day with ghee, treatment period is 48 days. The clinical improvement shown by cases treated with Velvangaparpam was significant. Before drug administration to patients, the haematological, protoscopical observation are noted. Administration of Velvangaparpam remarkably ($P<0.001$) restored. The clinical symptoms of bleeding per rectum, constipation, are removed. Overall results revealed that out of 40 patients 24 patients had good improvement, 10 had moderate relief, 6 patients showed poor response. The results clearly have shown that the Velvangaparpam treated to bleeding haemorrhoids gave good results and reliving the symptoms. There were no new or unexpected symptoms noticed during the course of treatment.

KEYWORDS

Bleeding haemorrhoids, Bleeding per rectum, Siddha medicine and Velvangaparpam.

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INTRODUCTION

Haemorrhoids are dilated veins within the anal canal. They are divided into two types, internal and external Haemorrhoids. The external variety is covered by skin, while the internal variety lies beneath the anal mucous membrane. The veins which form internal haemorrhoids become engorged as anal lining descends and is gripped by the anal sphincters. The two varieties may coexist and the condition is called intero-external Haemorrhoids.

Dilatation of the vein at the anal verge is sometimes seen in persons of secondary life particularly during staining. Peri anal hematoma or thrombosis external haemorrhoids-A small in the peri anal subcutaneous tissue can be seen superficial to ani muscle. This condition is due to back pressure on the anal venue consequent upon straining a stool, coughing or lifting heavy weight. [1]Now- a- days people inconsiderate symptoms like constipation, which later on may produce, haemorrhoids, prolapse and fissure-in-ano. The prevalence of the disease in the United Kingdom [UK], haemorrhoids was reported to affect 13% - 36% of the general population. Independent variables include baseline characteristics, sociodemographic data, and health status. Out of 976 participants, 380 patients (38.93%) were suffered from haemorrhoids. In 277 patients (72.89%), haemorrhoids were classified as Grade I, in 70 patients in 2012. A recent prospective study of screening colonoscopy patients revealed the presence of haemorrhoids in 38.9% with 44.7% of those patients suffering from haemorrhoidal symptoms. In India, Prevalence 10-20% 4.2-7.9%. [2]Bleeding is the earliest symptom of haemorrhoids. It is bright red in colour, painless and occurs during defecation. It may continuously or intermittently as a result for months or years. In this condition that bleeds but does not prolapsed outside the anal region, it is called first degree haemorrhoids. Prolape is a lateral symptom. Haemorrhoids can be divided into four types. First degree Haemorrhoids does not come out of the anus. Second degree Haemorrhoids only comes out during defecation and is reduced spontaneously after defecation. Third degree Haemorrhoids only comes out during defecation and does not return by themselves, but need to be replaced manually and they stay reduced. Fourth degree Haemorrhoids that are permanently prolapsed. [3]The traditional siddha drugs have anti haemorrhoidal properties. The interventional drug Velvangaparpam has been quoted by Agathiyar paripooranam 400 pg.no: 40. Tin, known as '*Vangam*' in traditional literature has demulcent and antiseptic properties. Velvangam (*STANNUM)* is the oxide form of tin metal, which is widely used in the treatment of uro-genital infections and dyspepsia[4]. It also has good styptic properties. [5]Karpoorasilajith have haemostatic, astringent properties. [6]Limestone water also has astringent properties. [7]The focus here was the most common disease of bleeding haemorrhoids(1st degree haemorrhoids) was cured by Velvangaparpam(VP), because the animal studies have shown that the trial drug Velvangaparpam possess successful styptic activity. So the present study was undertaken to determine the clinical efficacy of VP in adults and the safety of the drug in continuous administration.

METERIALS AND METHODS

A clinical trial-phase II was designed to study the clinical efficacy of Velvangaparpam (VP) with bleeding haemorrhoids (1st degree haemorrhoids). This study was carried out from the out-patient departments at Government siddha medical college hospital, Arumbakkam, Chennai from April2014 to January 2015. Trial period is one year, follow up is 48 days. This study was approved by the Institutional Ethical Committee (IEC); The IEC approval no is GSMC-CH-ME-2/010/2013. The pre-clinical study was approved and carried out by the Institutional Animal Ethical Committee of K.K College of pharmacy, Chennai-122, the IAEC approval No. KKCP/2013/013. All patients were treated as out-patients, and were monitored for their medical care by the author. The nature, properties, therapeutic effect and duration of treatment period of trial drug VP were informed consent (both in English and Tamil) was obtained from all the patients.

PRE-STUDY SCREENING AND BASELINE EVALUATION

All patients with administration criteria of bleeding haemorrhoids (1st degree) were selected. In a screening phase, demographic features, medical history, physical examination and haematological parameters are recorded. 15 patients are anaemia due to loss of blood during defecation. The clinical assessment was done initially, at the end of 7 days, 14days, 21days, and 48 days during treatment and at

end of 48 days follow up was done. Protoscope and haematological parameters are analysed before and at the end of the study period. Occupational history, exposure to any infections, past and personal history, dietary habits were recorded. Safety of the trial drug was monitored carefully at each visit.

INCLUSION CRITERIA

The inclusion criteria are Age between 18 to 60 years. Patients with appropriate symptoms like, bleeding during defecation, Constipation, Loss of appetite Anaemia, tiredness, Patients who are all willing to give blood samples at subsequent visit are involved in this study.

CRITERIA FOR EXCLUSION

The exclusion criteria is Pregnant and lactating women, External heamorrhoids, Fissure in ano, Second degree heamorrhoids, Fistula, CA Rectum.

WITHDRAWAL CRITERIA

Intolerance to the drug and development of any serious adverse effects during the trial (If ADR is reported the patient will be directed to RPC). Patients turned unwilling to continue in the course of clinical trial. Poor compliance. Any other acute illness which need rescue medication.

DRUG FORMULATION AND DOSAGE REGIMEN

The trial drug Velvanga parpam was prepared as per the siddha literature Agathiyar paripooranam 400.

Velvangam (*stannum),*Vaalairasam (*hydragyrum),* Karpoorasilajith (*asphaltum),* Karchunnam *(Limestone*), these drugs are authenticated by Shakila, Research officer, Chemistry dept., Siddha Central Research Institute,

Velvangam (*stannum),* Vaalairasam (*hydragyrum),* Karpoorasilajith (*asphaltum*) these ingredients are ground with karchunna theli neer and calcinated. Then again ground the mixture with chunna theli neer for 6 hrs, calcinate the mixture; finally make it as a powder form. The drug is stored in clean and dry air tight container[8]. The drug is given 100mg bd with ghee. The drug dose was selected on the basis of animal study. All out-patients were requested to attend O.P every week. During each visit, patients were asked for occurrence of any untoward effect, and improvement in the signs and symptoms observed and recorded. The patients were instructed to follow, fiber content food green leafs, fruits and vegetables, eat easily digestive foods, drink plenty of water. The patients were advised to avoid spicy foods, junk foods, preservative food.

PHYSICAL EXAMINATION

General examinations like temperature, body weight, pulse rate, blood pressure, respiratory rate were noted. Paleness of the tongue also noted. At every visit, clinical examination was carried out the signs and symptoms and complaints like constipation, bleeding while defecation, pruritis ani and loss of appetite.

SPECIFIC EXAMINATION

Protoscopy done in all patients in this study.

LABORATORY TESTS

Patients under Velvangaparpam were subjected to the following laboratory examinations: blood

TC, DC, ESR, Bleeding time, Clotting time, Blood sugar, Blood urea, Serum cholesterol. Urin, Albumin**,** Sugar**,** Deposits. Motion, Ova, Cyst, Occult Blood. Blood samples were obtained from each patient before and after administration of trial drug VP.

ADVERSE REACTIONS

All patients were carefully observed and monitored for any side effects such as gastro intestinal problem, skin reactions, head ache, insomnia, fever, restlessness, dizziness during the treatment period.

RESULTS AND DISCUSSION

40 patients were included in the study. The patient's gender, age and baseline, clinical features at the time of enrolment were recorded in all patients (Table No. and 2). All patients (40) have both bleeding during defecation and constipation.6 patients (15%) have pruritis ani, 15patients have Loss of appitite

(Table No.3). In this study majority of cases related to occupational status, they are worked in heat atmosphere. 11 patients (27.5%) are labourers, and 12 patients (30%) are home maker (Table No.4) so this is one of the causes of bleeding haemorrhoids. The clinical prognosis shows better result when compared to the before treatment, bleeding during defecation relieved 30 patients, constipation relieved 35patients, (Table No.5). The laboratory investigation shows better improvement in HB levels, about 15 patients (37.5%) 10 patients are improved (Table No.7). The grading results shows 24 patients (60%) shows good improvement, 10patients (25%) had moderate improvement, 6patients (15%) had poor response (Table No.6). The clinical improvement shown by cases treated with VP was quick and significant. The statistic value remarkably less. (P<0.001). So the trial drug Velvangaparpam showed the potent of anti haemorrhoidal property, and the safety, efficacy of drug also good (Figure No.1).

STATISTICAL ANALYSIS

The most popular non-parametric statistical tool, namely, Mc Nemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

Inference

Since the p value is significant in all signs and symptoms. So there is significant reducing of signs and symptoms among the patients for the treatment of Rattha Moolam. Hence it is concluded that the treatment was effective and significant.

Table No.1: Symptoms

S.No	Symptoms	Before Treatment	After Treatment
		n%	n%
1	Bleeding during defecation	40(100)	10(25)**
2	Constipation	40(100)	5(12.5)**
3	Pruritis in ani	6(15)	1(2.5)**
4	Loss of appetite	15(37.5)	4(10)**

Mc Nemat test, C.I: 95%, *P<0.05; **P<0.01**Software:** spss17 version **Number of cases:** 40

Table No.2: Age Distribution

S.No	Age in years	No. of cases	Percentage
1	20-30(Years)	8	20%
2	31-40(Years)	14	35%
3	41-50(Years)	13	32.5%
4	51-60(Years)	5	12.5%

Table No.3: Symptoms

S.No	Symptoms	No. of cases	Percentage
1	Bleeding during defecation	40	100%
2	Constipation	40	100%
3	Pruritisani	6	15%
4	Loss of appetite	15	37.5%

Table No.4: Occupational Status

S.No	Occupation	No. of cases	Percentage
1	Drivers	3	7.5%
2	Labourers	11	27.5%
3	Professionals	7	17.5%
4	Business men	4	10%

Table No.5: Clinical Prognosis

S.No	Symptoms	Before treatment		After treatment	
		No of cases	Percentage	No of cases	Percentage
1	Bleeding during defecation	40	100%	10	25%
2	Constipation	40	100%	5	12.5%
3	Pruritis in ani	6	15%	1	2.5%
4	Loss of appetite	15	37.5%	4	10%

Table No.6: Grading of Results

S.No	Grading of results	No. of cases	Percentage (%)
1	Good Improvement	24	60%
2	Moderate Improvement	10	25%
3	Poor Improvement	6	15%

Table No.7: Laboratory investigation report of the patients

S. No	Op. No	Name	Age	Before treatment				After Treatment				ESR (mm)				Hb (gms%)		Urine analysis					
				TC (cu/ mm)	DC			TC (cu/ mm)	DC			BT		AT				BT			AT		
					P%	L%	E%		P%	L%	E%	½ hr	1 hr	½ hr	1 hr	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
1	7925	Kamala	38	7800	56	38	6	7800	56	38	6	3	8	3	7	9.8	11.5	N	N	FE	N	N	N
2	5364	Balaji	25	9600	54	42	4	9600	54	48	3	5	16	5	12	13.8	13.8	N	N	N	N	N	N
3	4613	Sanmugasundharam	35	9400	59	32	7	9600	62	32	6	4	8	4	6	9.6	12	N	N	N	N	N	N
4	6196	Vasantha	50	9600	55	39	6	9600	55	39	6	25	50	20	40	9.6	11.7	N	N	FE	N	N	FE
5	7674	Manoj	23	10400	60	34	5	10250	58	35	4	8	16	10	20	14	14	N	N	FE	N	N	FE
6	9817	Kannan	31	8000	61	35	4	8000	61	39	3	5	12	08	20	12.8	13	N	N	N	N	N	N
7	2700	Ravi	50	8700	54	39	2	8700	53	37	4	2	6	3	6	11	12.2	N	N	FE	N	N	FE
8	2705	Sennamal	38	9700	62	35	3	9400	60	38	3	10	25	8	18	12	12.5	N	N	FE	N	N	FE
9	5143	Somasundharam	30	8400	56	36	4	8600	58	40	2	13	22	10	18	9.8	10	N	N	N	N	N	N
10	7352	Uma	40	7600	51	45	4	7600	60	33	4	2	3	2	3	13.6	13.6	N	N	FE	N	N	FE
11	6150	Suganthi	40	9100	58	34	6	9350	56	36	4	4	9	3	8	9.6	11.5	N	N	N	N	N	N
12	8844	Murugana ntham	38	8500	55	41	4	9400	59	33	4	3	7	3	6	12.4	13.2	N	N	FE	N	N	N
13	298	Serif	56	7500	56	40	4	7500	52	35	4	20	23	16	18	10.8	11	N	N	N	N	N	FE
14	197	Javahar	50	8900	51	46	3	8900	51	40	3	2	5	4	6	12	12.3	N	N	FE	N	N	N
15	1642	Loganadhan	27	8300	52	43	5	8300	51	33	3	8	20	9	20	11.6	12	N	N	FE	N	N	N
16	1379	Natarajan	34	7750	55	35	6	7750	54	31	5	10	18	12	26	16.8	16.8	N	N	FE	N	N	N
17	180	Sumathi	33	8200	59	41	5	8400	60	41	4	15	35	16	37	11	11.5	N	N	FE	N	N	N
18	1869	Nisha	34	6800	55	42	3	6800	46	42	10	4	12	18	20	8.6	11.5	N	N	FE	N	N	N
19	1855	Shasadhi	50	9700	55	39	6	9700	55	39	6	6	12	7	12	9.6	11	N	N	FE	N	N	N
20	2303	Sundhari	32	9200	60	38	5	9 400	54	28	6	16	36	13	25	9.8	9.8	N	N	FE	N	N	FE

21	2965	Prabakaran	43	8000	61	35	4	8000	61	39	3	5	12	8	20	12.8	13.1	N	N	N	N	N	N
22	3440	Harikrishnan	22	8300	56	40	4	8300	57	38	3	2	6	8	15	13.2	13.2	N	N	N	N	N	N
23	3761	Renuga devi	60	9700	62	35	3	9400	60	38	3	10	25	8	26	9.6	9.6	N	N	FE	N	N	FE
24	3771	Janagi	42	9200	60	38	5	9 400	54	28	6	16	36	13	25	9.8	9.8	N	N	FE	N	N	FE
25	4196	Venkatnarayanan	48	7900	61	34	5	7900	60	33	5	8	18	12	23	12.8	12.8	N	N	FE	N	N	FE
26	4179	Krishnan	20	8400	56	42	2	8400	50	41	2	3	9	8	15	12	12.2	N	N	N	N	N	N
27	4543	Mahesh	38	7750	55	35	6	7750	54	31	5	10	18	12	26	12.6	12.6	N	N	FE	N	N	N
28	4534	Lakshmi	35	7600	51	45	4	7600	60	33	4	2	3	2	3	10	10.6	N	N	FE	N	N	FE
29	4875	Ponnuramam	43	7800	56	40	4	7800	55	42	3	3	7	12	16	12.2	12.3	N	N	FE	N	N	FE
30	4860	Muhamadesa	44	8400	56	36	4	8600	58	40	2	13	22	10	18	10	10.8	N	N	N	N	N	N
31	5090	Abdul rasidu	24	9600	54	42	4	9600	54	48	3	5	16	5	12	9.6	11.5	N	N	N	N	N	N
32	5091	Aamina	54	7500	56	40	4	7500	52	35	4	20	23	16	18	11.6	11.7	N	N	N	N	N	FE
33	1519	Thanigasalam	48	9700	62	35	3	9400	60	38	3	10	25	8	18	10	10.5	N	N	FE	N	N	FE
34	1808	Mohan	52	8700	54	39	2	8700	53	37	4	2	6	3	6	9.6	9.8	N	N	FE	N	N	FE
35	1884	Mani	52	7500	56	40	4	7500	52	35	4	20	23	16	18	9.6	9.8	N	N	N	N	N	FE
36	2675	Somasankar	45	9200	60	38	5	9 400	54	28	6	16	36	13	25	12	12	N	N	FE	N	N	FE
37	4096	Anthonyraj	30	8100	56	40	4	8100	54	38	4	5	12	8	20	13	13	N	N	FE	N	N	FE
38	4097	Jayanthi	32	7800	62	34	4	7800	60	33	3	2	5	10	15	8.4	11	N	N	N	N	N	N
39	4098	Jayalakshmi	46	7600	57	39	4	7800	55	40	3	6	12	9	18	7.8	11	N	N	FE	N	N	FE
40	5245	Vinayagamoorthy	47	8500	53	44	3	8500	54	43	3	7	15	9	20	10	10	N	N	FE	N	N	FE

BT – Before Treatment, AT – After Treatment, N – Nil, TC – Total Blood Count, DC – Differential Blood Count, P – Polymorphs, L – Leucocytes, E – Eosinophils.
ESR – Erythrocytes Sedimentation Rate, mm – Milli meter, Hb – Hemoglobin, Alb – Albumin, Sug – Sugar, Dep– Deposits, FE – Few Epithelial cells, FP – Few Pus cells, N – Nil.

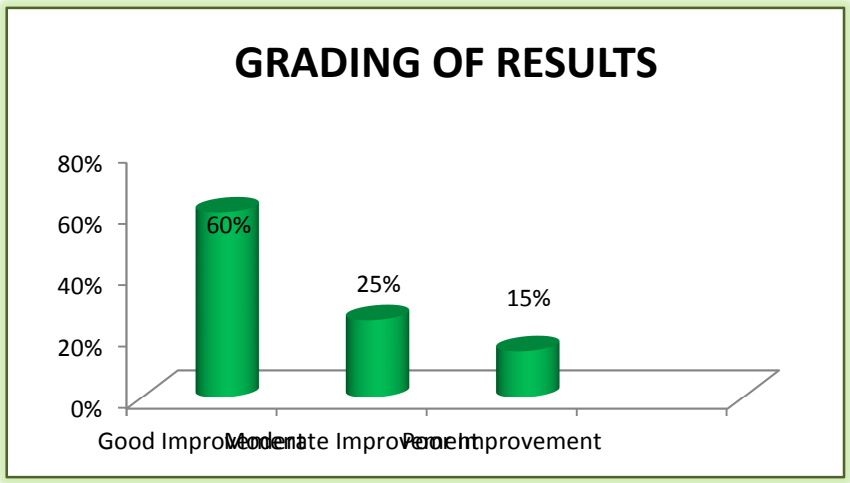

Figure No.1: Grading of Results

CONCLUSION

In siddha system of medicine one of the major disadvantages is lack of scientific evident. So people are not known the medicine values. Now a day's standardization of drug is important. In order to overcome these difficulties, I am sure this paper is useful to know the siddha drug Velvangaparpam had anti haemorrhoidal properties and the clinical improvement of bleeding haemorrhoids. On close observation of results showed velvangaparpam (VP) had significant action. The overall compliance of drug was good. The experimental study has given scientific evidence for the ancient siddha text, the trial medicine VP have safety and efficacy to cure the bleeding haemorrhoids.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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