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**Clinical Evaluation of Siddha Medicine Perumpadukku
Pittu in the Treatment of Pitha Perumpadu
(Dysfunctional Uterine Bleeding)**

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Abstract

Dysfunctional uterine bleeding (DUB) is one of the most common reasons patients seek the opinion of a gynecologist. Women's throughout the globe constantly relies on modern conventional medicine for clinical management of DUB. The main drawback of the current medical therapy is it offers several side effects upon long-term usage. WHO survey clearly states that nearly 80 % of the people around the world depend on traditional medicines for their health care needs. Siddha system of medicine is pioneer among other Indian system of traditional medicines. It not only cures the disease rather alters the basic elemental physiology responsible for such debilities. Perumpadukku Pittu (PP) is one of the best herbal formulation has been mentioned in siddha literature Athmarachamirthamennumvaithiyasarasangirdam for the treatment of DUB. The present study aimed at clinical investigation of PP and its therapeutic efficacy against DUB in 40 subjects reported with this clinical condition. Treatment with the formulation PP reveals the significant clinical improvement (Arresting /Reduction of menstrual blood flow) observed at the end of the first and second menstrual cycle. Hence it was concluded from the present study that the siddha formulation PerumpadukkuPittu may act as a first line medicine in the clinical management of DUB.

Keywords: Dysfunctional Uterine Bleeding, Traditional medicines, Siddha, Perumpadukku Pittu, Menstrual cycle.

1. Introduction

Dysfunctional Uterine Bleeding (DUB) is a term used to describe abnormal uterine bleeding for which no apparent cause can be discerned. The abnormal bleeding in DUB is attributed to disturbances in the ovaries rhythmic production of hormones. The

symptoms are very typical. The most common complaint is continuous, painless vaginal bleeding. Excess bleeding may lead to anemia. Medications play an important role in the treatment; however, research suggests that diet also plays a significant role in recovering from continuous uterine bleeding & weakness [1].

Siddha system of traditional medicine provides differential diagnostic techniques which aid in proper identification of DUB and to initiate the therapy at the earliest. Siddhars have detailed about various types of female ailments in their text, the one is Perumbadu which means great suffering of women. Yugimuni Siddhar who classified perumbadu as four types. Pitha Perumpadu is one among them challenging to medical practitioners of both allopathy and siddha field. Added that it affects mentally, physically and economically.

The signs and symptoms of *Pitha Perumpadu* can be correlated to the Dysfunctional Uterine Bleeding [Dub] because the signs and symptoms of the both are more similar. DUB is more common around the menarche and pre menopause. 1 in 20 women aged 30-49 years consult their GP each year for menstrual disorders. Menstrual disorders are the second most common

gynecological condition to be referred to hospital, accounting for around 12% of all gynecological referrals [2].

The currently available drugs for menorrhagia had many side effects and play a major role in the hormone cycle and alter the regular hormonal secretion of the body. Surgical intervention is the only choice in other system of medicine [3]. In this juncture siddha medicine treatment is a boon to the society to skip surgical procedure. Perumpadukku Pittu (PP) is a novel siddha formulation has been mentioned in siddha literature Athmarachamirthamennumvai thiyasarasangirdam for the treatment of DUB [4]. Hence the main aim of the present study it to clinically investigate the effect of PP against DUB in 40 subjects reported with this clinical condition.

2. Materials and Methods

2.1. Ingredients

The ingredients of the Perumpadukku Pittu are

- | | |
|--------------------------------------------------------------------------------------|--------------------|
| 1. Bark of <i>Ziziphus mauritiana</i> , Lam (<i>Ilandapattai</i>) | - 1 palam(35gms) |
| 2. Bark of <i>Lannea coromandelica</i> (<i>Houtt</i>)Merr (<i>Othiyampattai</i>) | - 1 palam(35gms) |
| 3. Bark of <i>Syzygium cumini</i> , Linn (<i>Naavalpattai</i>) | - 1 palam(35gms) |
| 4. Bark of <i>Ficus racemosa</i> . Linn (<i>Athipattai</i>) | - 1 palam(35gms) |
| 5. Bark of <i>Ficus religiosa</i> .Linn (<i>Arasapattai</i>) | - 1 palam(35gms) |
| 6. Bark of <i>Mangifera indica</i> . Linn (<i>Mampattai</i>) | - 1 palam(35gms) |
| 7. Bark of <i>Acacia nilotica</i> . Linn(<i>Velampattai</i>) | - 1 palam(35gms) |
| 8. Raw rice powder (<i>pacharasimaavu</i>) | - 7 palam(245gms) |
| 9. Palm jaggery (<i>panaivellam</i>) | - 7 palam (245gms) |

2.2. Collection and authentication of Raw Materials

The required raw drugs were collected from kaveri farm Virudhachalam. The raw drugs were b authenticated by the Asst. Professor Medicinal botany in NIS Chennai. The raw drug was purified and the medicine will be prepared as per SOP in Gunapadam laboratory of National Institute of siddha.

2.3. Purification and Formulation

The ingredients from 1 to 7 listed above will be purified by scrubbing the outer skin as per the siddha text Marundu Seilyalumkalaiyum [5]. Further it was been pulverized and filtered to which raw rice powder and palm jaggery was added. Finally the mixture was subjected to baking procedure.

2.4. Dosage and Dispensing

The medicine Perumpadukku Pittu (120gms) was given to the patients in air tight glass container.

2.5. Study design

An open clinical trial study comprises of 40 subjects with the clinical symptoms of Dysfunctional uterine bleeding called by its name "*PITHA PERUMPADU*" was chosen for the individualized in-depth evaluation. The entire study was conducted on Out-patient department of Ayothidass Pandithar Hospital (OPD), National Institute of Siddha, Tambaram Sanatorium, Chennai-47, Tamil Nadu, India. Institutional ethical committee clearance was obtained for this study [IEC approved no: NIS/IEC/8-14/5-26-08-2014] with the total study period of 12 months.

2.6. Inclusion criteria

- Age: 16-45 years
- Patient having the symptoms of increased menstrual bleeding.
- Blood clots seen in the menses bleeding
- Patient willing to undergo routine blood investigation.
- Patient willing to participate in trial and signing in consent form.
- Usg Abdomen(to rule out the fibroid etc)

2.7. Exclusion Criteria

Patients with the following indications was excluded from the study which includes Hypertension, Diabetes mellitus, Cardiac disease, Renal disease, Pregnancy and lactation, Thyroid dysfunction, Recent hormone therapy (past one year), Fibroid uterus, Endometriosis, Adenomyosis, Cancer uterus, Endometritis.

2.8. Withdrawal criteria:

- Intolerance to the drug and development of adverse reactions during the drug trial.
- Poor patient compliance & defaulters.

2.9.2. Siddha assessment

- Patients turned unwilling to continue in the course of clinical trial
- Patient will not take medication regularly
- Increase in the severity of the symptoms i.e excess menstrual bleeding

2.9. Diagnostics Methods

2.9.1. Clinical assessment

- Bleeding or spotting from the vagina between periods.
- Periods that occur less than 28 days apart or more than 35 days.
- Time changes between every menstrual periods.
- Excessive bleeding (such as passing large clots, needing to change protection during the night, soaking through a sanitary pad or tampon every hour for 2 - 3 hours in a row)
- Bleeding lasts for more than 7 days
- Hot flashes
- Mood swings
- Tenderness and dryness of the vagina
- Tired and fatigue

Thinai (Living Place)	Paruvakaalam (Season):	Poripulankal:
Kurinchi (Hill Areas)	KaarKaalam Koothir Kaalam Munpani Kaalam Pinpani Kaalam Elavenil Kaalam Muthuvenil Kaalam	Mei (Skin)
Mullai (Forest)		Vaai (Tongue)
Marutham (Fertile Land)		Kan (Eye)
Neithal (Costal land)		Mooku (Nose)
Paalai (Desert)		Sevi (Ear)

Gnanenthiriyam and Kanmenthiriyam:	EzhuUdalKattugal:	EnnVagaiThervu(Eight Diagnostic Methods)
Vaai (Buccal Cavity) Kaal (Lower Limb) Kai (Upper Limb) Eruvaai (Anorectal Region) Karuvaai (Uro- Genital Region)	Saram Senneer Uoon Kozhuppu Enbu Moolai Sukkilam/Suronitham	Naadi Sparisam Naa Niram Mozhi Vizhi Malam Moothiram Neerkuri Neikuri

2.9.3. Routine Investigations

Hb (gms/dl)	Total RBC (million/Cu.mm)	Blood Sugar Level
PCV	Total WBC (cubic mm)	Fasting (mg/dl)
MCV	Differential Count : (%)	Post Prandial (mg/dl)
MCHC	Polymorphs	Random (mg/dl)
MCV	Lymphocytes	
Bleeding Time	Monocytes	
Clotting Time	Esinophils	
Smear Study	Basophils	
	ESR(mm/Hr)	

2.9.4. Special Investigation [6]

PBAC score (pictorial bleeding assessment chart)
Herman MC

2.10. Treatment Schedule [4]

Name Of the drug : PerumbadukkuPittu
Dosage : 30gms/ four times a day after food
Duration : 6 days for 2 consecutive menstrual cycle
(Follow Up For 3 Months)
Vehicle : Butter
Indication : NatpattaPerumbadu
Pathiyam : IchaPathiyam

2.11. Statistical analysis

The statistical analysis was carried by using stata software under the guidance of SRO(stat), NIS. The level of significance will be 0.05 descriptive analysis was made and necessary tables/graphs generated to understand the profile of the patients included in the study. Student't test and chi-square test are proposed to be performed for quantitative and qualitative data.

3. Results

It was observed that out of 40 cases , 8 cases(20%) were in age group 19-25, 6 cases(15%) were in age group 26-30, 5 cases(13%) were in age group 31-35, 5 cases(12%) were in age group 36-40, 16 cases(40%) were in age group 41-45. Further with respect to occupation is concern 18 (45%) working people, 19(47%) non-working people, 3(8%) belongs to student category. In the category of marital status is concern out of 40 cases, 33(82%) were married, 7(18%) were unmarried. It was believed that diet having strong impact on DUB and further literature states that non-vegetarian are more prone to PithaPerumpadu (DUB) than vegetarian. It was observed that out of 40 cases, 37cases (93%) are non-vegetarians and 3cases (7%) belongs to vegetarian category.

From the clinical history, it was noted that 75% of cases had no positive family history of dysfunctional uterine bleeding, 25% of cases related with family history. According to siddha system of classification Pitha Perumbadu affects the people more in the Neidhal 75%, then Mullai 10%, 8% in Marutham , and 7% in Kurinji. There was strong correlation between disease and season variation which was taken as one of the core contributing factor. Out of 40 cases, Disease got worsen at 10 cases(25%) in kaarkaalam, 3 cases (7%) in koothirkaalam, 7 cases(18%) in Munpanikaalam, 4 cases(10%) in Pinpanikaalam, 8 cases(20%) in ilavenilkaalam, 8 cases(20%) in Muthuvenil. Kaalam.

Under the classification of yakkai it was noted that 25%(10) cases were vathapithathegi, 15%(6) cases were vathakabathegi, 35 %(14) cases were pithavathathegi, 15%(6) cases were pithakabathegi, 5%(2) cases were kabavathathegi, 5%(2) cases were kabapithathegi. With respect to Pranamayakosam (mild dyspnoea) was affected in 50% of cases , Vignanamayakosam was affected in 37.5 % of cases. Anandhamayakosam (Excessive menstrual bleeding)) was affected in all cases.

Pranan (Mild dyspnoea present) was affected in 50% cases. Abanan (excessive menstrual bleeding) was affected in 100% cases. Udhanan (tiredness) was affected in 87.5% cases. Viyanan (Pain present in the upper & lower limb) was affected in 37.5% cases. Samanan was affected in 100%. Kirukaran (polyphagia) was affected in 13% cases and Nagan (burning sensation present in both eyes) was affected in 7.5% cases and Devathaththan (tiredness, anxiety) was affected in 100% cases. Koorman was affected in 2.5% cases.

Among 40 cases Saathagapittham (general tiredness) was affected in 100%(40) cases. Anal pittham (Increased appetite) was affected in 25% of cases(10). Ranjagapittham (Altered blood Hb) was affected in 87.5%(35) cases, Pirasagapittham (Pallor of skin) was affected in 62.5% cases(25). Aalosagapittham (dullness of vision) was affected in 12.5% of cases(5).

Further Avalambagam (breathing difficulty) was affected in 50% (20 cases), kilethagam (increased appetite) was affected in 5% (2 cases), Pothagam was affected in 25% (10 cases), Tharpagam (dullness of vision) affected in 12.5% (5 cases) Santhigam (Joint pain) was affected in 37.5% (15). In UdalThathukkal, Saarm (general tiredness) was affected in 40 cases (100%) & Chenneer (altered blood Hb level) was affected in all cases. Oon (muscular pain) affected in 25 cases (62.5%) Kozhuppu (obesity) was affected in 25% (10) of cases. Enbu (joint pain) was affected in 37.5% (15) of cases. Suronitham (Increased menstrual bleeding) was affected in 100% (40) of cases.

In Naadi is concern 35% of cases are vali azhal, 8% of cases are azhal iyyam, 57% of cases are azhal vali. In Neikkuri 55% of cases are slowly spread, 45% of

cases are fastly spread. Observation pertains to Neikkuri spreading pattern is concern 32% of cases are Aravenaneendathu (vathaneer -lengthening like a snake), 35% of cases are Aazhi pol paraviathu (pithaneer - spreading like a ring), 23% of cases Muththu pol ninrathu (kabaneer - appears like a pearl), 10% of case are other fashions. 40% (16) Patients had the history of this disease less than 6 months only, 35% (14) Patients suffered for 6 months to 1 year, 17% (7) patients for 1-2 years and 8% (3) patients for 2-3 years.

There is an marked improvement observed in the 1st and 2nd visit menstrual phase of the pateints with respect to menorrhagia, volume of blood clot and dysmenorrhoea as listed in table 1 and 2. Further the results of PBAC assesment score were debicted in table 3.

Table 1: 1st Visit Menstrual Phase

S.N	CLINICAL FEATURE	NO. OF CASES			IMPROVEMENT	
		BEFORE	AFTER		BEFORE	AFTER
			No improvement	Improvement		
1	Menorrhagia	40	17	23	100%	57.5%
2	Large Blood Clots	18	9	9	45%	22.5%
3	Dysmenorrhoea					
4	Vaginal Tenderness	15 2	13 2	2 0	37.5% 5%	5% 0%

Table 2: 2nd Visit Menstrual Phase

S.N	CLINICAL FEATURE	NO. OF CASES			IMPROVEMENT	
		BEFORE	AFTER		BEFORE	AFTER
			No improvement	Improvement		
1	Menorrhagia	40	12	28	100%	70%
2	Large Blood Clots	12	7	5	30%	12.5%
3	Dysmenorrhoea					
4	Vaginal Tenderness	15 1	12 1	3 0	37.5% 2.5%	7.5% 2.5%

Table 3:PBAC (Pictorial Blood Assessment Chart) Score

S.N	Age	PBAC (PICTORIAL BLOOD ASSESSMENT CHART) SCORE			
		1 ST visit menstrual phase		2 nd visit menstrual phase	
		Before Treatment	After Treatment	Before Treatment	After Treatment
1	32	570	0	340	0
2	22	295	55	315	68
3	34	470	96	380	92
4	28	278	0	183	0
5	24	380	128	280	35
6	45	210	0	160	0
7	27	433	105	374	86
8	25	250	13	238	39
9	23	367	77	321	34
10	38	243	0	180	0
11	26	281	0	236	0
12	45	355	0	323	0
13	26	236	0	187	0
14	34	188	0	176	0
15	45	267	0	193	0
16	44	332	0	280	0
17	38	231	0	232	0
18	18	187	27	194	0
19	36	396	43	242	0
20	42	386	0	291	0
21	37	225	0	218	0
22	42	262	0	296	0
23	20	193	63	210	41
24	34	414	128	440	15
25	45	460	0	425	0
26	30	216	92	316	58
27	26	263	18	238	0
28	43	412	0	434	0
29	42	363	16	394	0
30	40	484	126	465	118
31	39	463	39	491	42
32	25	116	0	112	0
33	40	271	0	115	0
34	23	181	0	145	0
35	42	242	0	216	0
36	45	269	0	247	0
37	45	206	0	202	0
38	27	418	16	383	26
39	39	374	61	278	0
40	38	392	10	343	21

4. Discussion

Dysfunctional uterine bleeding (DUB) is the diagnosis given to women with abnormal uterine bleeding in whom no clear etiology can be identified. DUB has been observed in both ovulatory and non-ovulatory cycles. Medical treatments include nonsteroidal anti-inflammatory drugs, oral contraceptive pills, progestins, danazol (a synthetic androgen), GnRH agonists, and antifibrinolytic drugs. The drawback to medical therapy, in addition to side effects, is that the benefit lasts only while the patient takes the medication. Siddha system of medicine is one of the greatest to which western medicine owes much in its earlier stage of development from the sages of Ancient India to mankind. It is one of the world's most ancient medical discipline. It is not only the system of medicine in the conventional sense of curing disease but it is the way of life. Siddha system of medicine treats man as a whole which is a combination of Body, Mind, Soul.

The pathophysiology of dysfunctional uterine bleeding is largely unknown, but it occurs in both ovulatory and anovulatory menstrual cycles. Ovulatory dysfunctional bleeding occurs secondary to defects in local endometrial haemostasis, while anovulatory bleeding is a systemic disorder, occurring secondary to endocrine, neurochemical, or pharmacological mechanisms. Since diagnosis is by exclusion, you must proceed through a logical, stepwise evaluation to rule out all other causes of the abnormal bleeding [7].

Patients usually present first to their family physicians, who can do most of the diagnostic workup and management. Specialist care is sought when first-line medical treatments have failed or specialized testing is required. An approach to diagnosis and management of DUB in women of all ages is, therefore, important for family physicians. Uterine bleeding is the main reason women are referred to gynecologists and accounts for two thirds of all hysterectomies [8].

With the evidence of statistical report, It showed that the significant clinical improvement (Arresting /Reduction of menstrual blood flow) with the percentage of 91.5% was observed at the end of the first menstrual cycle. It is also observed at second menstrual cycle with significant clinical improvement of 93.5 %($p < 0.0001$) Significant degree of clinical improvement between 1st menstrual cycle and 2nd menstrual cycle is present which is increased with the percentage of 12% ($p < 0.0001$). From the comparison between the two age group (above 30 & below 30), the significant clinical response was better among the age group above 30 years than below 30 years ($P < 0.0021$).

5. Conclusion

Present diagnostic methods of DUB offers unnecessary delay in proper identification and initiation of the therapy. In the present investigation siddha method of diagnosis was carried out for all the patients along with modern investigation. Combining traditional methods with modern investigation aids in early and proper identification of the indications which would really benefit the patients requires clinical treatment. Treatment with the formulation PP reveals the significant clinical improvement (Arresting/Reduction of menstrual blood flow) observed at the end of the first and second menstrual cycle. Hence it was concluded from the present study that the siddha formulation Perumpadukku Pittu may act as a first line medicine in the clinical management of Dysfunctional Uterine Bleeding.

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