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"COMPARATIVE PLACEBO CONTROLLED CLINICAL STUDY ON THE EVALUATION OF SHATAVARI GUDA IN ARTHAVA DOSHA WITH SPECIAL REFERENCE TO PRE MENSTRUAL SYNDROME"

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ABSTRACT

PMS is a condition of recurrent physical and psychological symptoms occurring in a cyclic fashion during the 1st to 2nd week period preceding a woman's menstrual period. As many of 85% of menstruating women report one or more mild premenstrual symptoms. Only 10% of women report significant impairment in lifestyle. PMDD, a variant of PMS that entails more severe psychologic symptoms and impairment of functioning, occurs in 2% to 9% of women reproductive age. Serotonin, sex steroids (Allopregnanolone) and GABA receptors, elevated testosterone levels, and a genetic basis are all implicated in the pathogenesis of PMS.60% of PMS patients respond to SSRIs.

Methods: 30 Patients were divided in 2 groups, 15 patients in each. One group is named as Trial group in which prepared drug is given to patients for treatment; another group was named as control group in which placebo tablets are given to patients for treatment. Three follow-ups are taken in both groups for three consecutive cycles each. The study is single blind study.

Results: 100% patients were cured after third follow-up in trial group while 40% were cured and 60% were improved in control group.

Keywords: PMS; PMDD; SSRIs; GABAA.

INTRODUCTION

Premenstrual syndrome (PMS) (also called PMT or Premenstrual Tension) is a collection of physical, psychological, and emotional symptoms related to a woman's menstrual cycle. While most women (about 30 to 80 percent) of child-bearing age have some premenstrual symptoms, women with PMS have symptoms of "sufficient severity to interfere with some aspects of life". Out of them 20-30 percent report moderate to severe symptoms.The National Institute of Mental Health research (U.S.A) compares the intensity of symptoms from cycle days 5 to 10 to the six-day interval before the onset of menses.Women who do not ovulate do not have PMS, and often pregnancy is a welcome relief to the PMS sufferer. Research also shows that PMS tends to be more troublesome at the beginning and ending phases of the reproductive life cycle (puberty and menopause) and in the month immediately following pregnancy and childbirth as the menstrual cycle begins again.

Though there is no doubt that women suffer from PMS, many endure the discomfort and pain in silence or complain only to family and friends because they do not realize that anything can be done to help them. The way PMS is managed depends on identifying specific challenges, when they occur and how severe they are.

MATERIALS AND METHOD:

SELECTION OF THE DRUG :Shatavari Guda. Ingredients of Shatavari Guda with Quantity.

Sr.No.	Drug	Quantity
01	ShatavariSwarasa	2.56Ltr
02	Guda	2.56Kg
03	Gruta	640gm
04	ShuntiChurna	10gm
05	Elachurna	10gm
06	MusaliChurna	10gm
07	PataChurna	10gm
08	GokshuraChurna	10gm
09	SarivaChurna	10gm
10	KrishnaSarivaChurna	10gm
11	UsiraChurna	10gm
12	AjajiChurna	10gm
13	VidariChurna	10gm
14	PipaliChurna	10gm
15	YastimaduChurna	10gm
S16	ShuddaShilajathaChurna	10gm
17	TavakseriChurna	160gm
18	Sugar	160gm

1) STUDY DESIGN: Randomized clinical trial.

2) SAMPLE SIZE: Total 40 patient will be selected

3) DIAGNOSTIC CRITARIA: Patients complaints of any of the symptoms of the PMS.

Group A 20 patients: Placebo capsules DRUG:- Placebo capsules

DOSE:- 10 gm BD with milk in empty stomach. (Morning and Evening Tea Time) DURATION: From 4th day of menstrual cycle to1st day of next menstrual cycle .

Maximum days 45 days for 3 conjugative cycles.

Group B 20 Patients: Shatavari Guda

DOSE:- 10 gm BD with milk in empty stomach. (Morning and Evening Tea Time) DURATION: From 4th day of menstrual cycle to1st day of next menstrual cycle.

Maximum days 45 days for 3 conjugative cycles.

OBSERVATION AND RESULTS

It includes observation of all demographic data with their percentage and graphic presentation of age, sex, occupation etc., lakshanas and results of individual symptoms, followed by overall response of the treatment.

Table showing the individual mean, before and after treatment and their percentage of relief

Abdominal Pain		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	2.25	2.5	0.910465	1.73205080	0.000045	90.00	Sig
	AT	2.1904761	2	0.894427	1.73205080			
GroupB	BT	2.15	2	0.745159	1.73205081	0.000002	72.50	Sig
	AT	1.952381	1	0.825578	1.732051			

Backache		Mean	Median	SD	SE	P-Value	% Change	Result
Group A	BT	1.9	2.0	0.788069	1.414214	0.0000634	85.00	Sig
	AT	1.047619	1	0.825578	1			
Group B	BT	1.85	2	0.87509398	1.41421356	0.000000045	57.50	Sig
	AT	0.238095	1	0.410391	1			

GIT Disturbance		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	1	1	0.725476	1	0.00563366	67.50	Sig
	AT	0.761905	1	0.71635	0			
GroupB	BT	0.65	0.5	0.74516	1	0.0140893	32.50	Sig
	AT	0.142857	0	0.366348	0			

BreastTenderness		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	0.5	0	0.760886	1	0.0092814	35.0	Sig
	AT	0.3333	0	0.4894	1			
GroupB	BT	0.0	0.63	1.03999	0	0.008428	25.0	Sig
	AT	0.142857	0	0.366348	0			

Moodswings		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	1.65	2	1.03999	1	0.0000574	70.0	Sig
	AT	0.71428571	1	0.7326951	0			
GroupB	BT	1.6	2	0.994723	0	0.0000048	52.5	Sig
	AT	0.190476	0	0.410391	0			

Headache		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	0.75	1	0.850696	1	0.000658	35.0	Sig
	AT	0.190476	0	0.5231483	0			
GroupB	BT	0.4	0	0.680557	0	0.030771	17.5	Sig
	AT	0.047619	0	0.223607	0			

Insomnia		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	0.8	1	0.767772	1.414214	0.002095	47.5	Sig
	AT	0.380952	0	0.502625	1			
GroupB	BT	0.6	0	0.753937	1	0.008428	27.5	Sig
	AT	0.095238	0	0.307794	0			

Legcramps		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	1.9	2	0.788069	1.414214	0.000358	75.0	Sig
	AT	1.904762	2	0.788069	1.414214			
GroupB	BT	1.55	2	0.825578	1.414214	0.008428	55.0	Sig
	AT	0.238095	1	0.410391	0			

Foodcraving		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	0.55	0.5	0.604805	1	0.006796	35.0	Sig
	AT	0.190476	0	0.410391	0			
GroupB	BT	0.9	1	0.852242	1.414214	0.001576	15.0	Sig
	AT	0.142857	0	0.366348	0			

Acne		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	1.9	2	1.071153	0	0.000873	82.5	Sig
	AT	1.285714	1	0.978721	0			
GroupB	BT	2.1	2	0.9119	1	0.000492	60.0	Sig
	AT	0.809524	1	0.767772	0			

Activeness		Mean	Median	SD	SE	P-Value	% Change	Result
GroupA	BT	1.7	2	1.031095	1	0.000162	75.0	Sig
	AT	0.952381	1	0.825578	0			
GroupB	BT	1.3	1	0.801315	1.414214	0.000537	55.0	Sig
	AT	0.285714	1	0.444262	1			

Menstrual Bleeding		Mean	Median	SD	SE	P-Value	% Change	Result
Group A	BT	2.15	2	0.9333	0	0.000021	82.5	Sig
	AT	1.261905	1.5	0.966546	0			
GroupB	BT	2.15	2	0.74516	1.414214	0.00000035	72.5	Sig
	AT	0.52381	2	0.510418	1			

OVERALL EFFECT OF TREATMENT

Study status	GroupA	GroupB
	Aftertreatment	Aftertreatment
Status of Pts	No.ofpts	No.ofpts
Cured	01	11
Mild improvement	11	02
Major Improvement	08	07

In the present study, overall effect of treatment showed that, in- group A after follow-up55%patientsexperiencedmildimprovementwhereas40%patientsshowedup major improvements in their symptoms and 5% patients were completely cured. Similarly, in the group B after follow-up 10% patients experienced mild improvement whereas 35% patients showed up major improvements in their symptoms and 55%patientswere completely cured.

DISCUSSION

The only proven risk factor for PMS is ovulatory cycles. Women with prior history of a depressive disorder including post partum depression or with a family history of PMS may represent high risk groups. There appears to be an increased risk with age and increased parity. Dalton proposed that tubal ligation, oral contraceptive use, preeclampsia and absence of dysmenorrhea were associated with increased risk for premenstrual symptoms. However, none of these factors have been shown empirically to have an association. PMS has been reported among women in diverse geographic locations, cultural and ethnic groups and historical periods. Racial, socioeconomic or marital status differences have not been identified. Finally risk factors such as increased imposed stress and specific personality profiles are not helpful in differentiating women with PMS from those without the disorder. The present clinical study entitled “Management of Premenstrual Syndrome with a Shatavari guda” was aimed to evaluate the role of an Shatavari guda in PMS a psychosomatic disorder. In the present clinical study 20 cases had been treated with trial drug after being diagnosed for PMS. The observations were made on the different parameters including clinical findings.

CONCLUSION

There is a single reference related to PMS in ancient literature in the context of Shuddha artava lakshana described by charaka. Rituchakra is a physiological process but due to the extreme variations in doshic

avastha within a very short period of Ritu chakra it causes discomfort either to mind or body. It attains Vyadhisvarupa and attains a disease status which requires medical interference. Ovulatory cycles is a proven risk factor for PMS. Family history of PMS represents high risk group. The most common theories implicated in PMS are serotonergic dysregulation, fluctuating sex steroid levels and genetic predisposition. The symptoms occurring in premenstrual syndrome like; sleep disturbance, irritability, breast tenderness, etc. can be co-related with Vata Pittaja Lakshana. The observations of the study have shown that the said patients fall in the range of 18 – 35 years of age groups. Rasa dhatu dushti and disturbed rajah, tamas and satva guna balance are the main underlying factor in the evolution of psychosomatic symptoms of PMS. Therefore, Rasayana therapy (the trial drug) is useful for the treatment which prevents the long-term effects of premenstrual syndrome. The trial drug possesses significant properties like deepana, pachana, rasayana and vedanasthapana, mootra virechaniya. It also significantly decreases the manas dushti lakshanas. The patients should be followed for a longer period to evaluate the long term effect of the drugs under trial. Increasing number of working female population and the life-style disorders in them is going to be one of the major social and health concerns. Hence this section of population pyramid should be given utmost importance.Pre-menstrual counseling for adolescent girls should be done.

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