



EFFECT OF MADHU TAILIKA BASTI AND SHAMANA AUSHADHI IN POLY-CYCSTIC OVARIAN DISEASES

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ABSTRACT

Polycystic ovarian disease (PCOD) is emerging as a main cause of menstrual irregularities, mainly observed in age group of 12-45 yrs of age. Based on present data available, 5-15% of females suffer from this condition that includes symptoms like obesity, irregular menstrual cycle, hirsutism etc. In Ayurveda though exact correlation cannot be ascertained, it can be better explained under *Rasa nimittaja vyadhi*, where the involvement of *Medo dhatu*, *Vata* and *Kapha doshas* are seen. *Madhutailika basti* which carries numerous positive clinical results as per the classical reference based on the various pharmacological properties on *Medo dhatu dustigata vyadhis*, because of its ingredients. Based on the available references, *Madhutailika basti* along with other *Shaman ausudhis* are taken for a pilot observational study at Shri Kalabyraveswaryaswamy Ayurvedic Medical College Hospital & Research Centre Vijayanagar Bangalore. Post approval of the institution ethical committee, *Madhutailika basti* was administered to selected patients for a period of 8 days followed by administration of *Shaman aushadis* for a period of next 3-months. The overall results showed marked improvement in 70%, moderate improvement in 20% of the patients. All patients completed the study successfully without any drop outs.

KEYWORDS: PCOD, *Madhutailika Basti*, *Shamana Aushadis*.

INTRODUCTION

Menstrual irregularity is one of the commonest gynaecological complaints seen in the age group of 12-45yrs. One of the causes for this irregularity is said to be polycystic ovarian disease. The incidence varies from 5-15%. It can be considered as a multifactorial disorder characterised by amenorrhoea or oligomenorrhoea, delayed and irregular periods, hirsutism, hoarseness of voice, obesity etc^[1]. Diagnosis is confirmed by ultra sonography examination and hormonal assay.^[2] This complex disorder is characterized by excessive androgen production leading to increased LH (Luteinising Hormone) hormone associated with raised insulin and decreased FSH (Follicle stimulating hormone). Even the SHBG (Sex Hormone Binding Globulin) appears to be reduced. Due to above mentioned causes the follicular growth is hampered which contributes

towards anovulation, oligomenorrhoea, or hypomenorrhoea.^[3] In *Ayurveda* though exact correlation cannot be made, it can be better explained under *Rasa Nimittaja vyadhi* ^[4] with involvement of *Medho Dhatu*, *Vata* and *Kapha doshas*. Keeping all this in mind *Madhutailika basti* was selected for 8 days duration and *Shamanaushadhis* like *Navaka Guggulu*, *Arogya vardhini vati* and *Asanabilwadi kwatha* was later advised for a period of three months.

MATERIAL AND METHODS

The present study is an observational study with open label study design. All subjects were administered *Madhutailika basti* for a period of 8 days. Later they were given *shaman Aoushadis* like *Navaka Guggulu*, *Arogyavardhini vati*, and *Asanabilwadi kwatha* for a period of three months. *Madhutailika yoga basti* is

prepared as per the description in *Charaka samhita siddhistan*. Other formulated products purchased from the approved pharmacy stores manufactured by approved pharmaceutical manufacturers. For example: *Navaka Guggulu* manufactured by Amrita Pharmacy Hyderabad, *Arogyavardhini vati* by Dhootapapeshwara Mumbai, and *Asanabilwadi kwatha* manufactured by *Shri Dharmasthala Manjunatheshwara Ayurvedic Pharmacy* Hassan.

Subjective Parameter

- Irregular menstruation
- Body weight

Objective Parameter

The following parameters are considered as objective parameter.

- USG revealing polycystic ovaries
- Hormonal assay

Assessment criteria

- Regularisation of the menstrual cycle.
- Change in body weight.
- Ovulation or changes in the size and number of follicles in the ovary.
- Normalisation of hormone level LH, FSH, Testosterone, Fasting insulin SHBG.

Parameter with gradation Score

Irregular menstruation

- 0 - 28-32 days menstrual cycle
- 1 - 33-38 days menstrual cycle
- 2 - 39-44 days menstrual cycle
- 3 - above 45 days menstrual cycle

Body weight

- 0 - no change
- 1 - Reduced 1 to 1.5 kgs
- 2 - Reduced 1.6 to 2 kgs
- 3 - Reduced 2.1 to 2.5 kgs

Impact on cyst

- 5 - Reduction in cyst 10%
- 4 - Reduction in 20%
- 3 - Reduction in 40%
- 2 - Reduction in 60%
- 1 - Reduction in more than 80%

Impact on LH Hormone

- 5 - No change
- 4 - Change in 25%
- 3 - Change in 50%
- 2 - Change in 75%
- 1 - Change in more than 75%

Impact on Testosterone

- 5 - No change
- 4 - Change in 25%
- 3 - Change in 50%
- 2 - Change in 75%
- 1 - Change in more than 75%

Impact on serum fasting insulin

- 5 - No change
- 4 - Change in 25%
- 3 - Change in 50%
- 2 - Change in 75%
- 1 - Change in more than 75%

Objective parameters were assessed before treatment and after treatment and the results were assessed using mean value.

Sample Size and Method

- Sample size: 10 without any drop outs.
- Study design : Open level clinical trial
- Number of groups : Single group

Drug schedule and Dosage ^[5,6,7]

- *Madhutailika yoga basti*.
- *Shamana aushadi*:

The following formulations are considered as *Shaman aushadis* for this specific study.

- *Navaka Guggulu* - 2 tab BID internally before food along with hot water for three months
- *Arogyavardhini vati* - 2 tablets BID internally after food along with hot water for three months.
- *Asanabilwadi kwatha* - 20ml BID internally before food along with equal quantity of water for three months.

Duration of Treatment: 8 days *Madhutailika basti* followed by three months of *Shaman aushadis*.

Follow up: Once in a month, i.e. at the end of 1st, 2nd and 3rd months.

Investigations: USG of pelvic cavity, Hormonal assay (LH, FSH, Testosterone, Fasting insulin)

The volunteers for this study enrolled between 01/10/13 to 01/01/14 from the OPD/IPD of department of *Prasuti tantra-evam-Stree Roga* of SKAMCH & RC, Vijayanagar, Bangalore based on the designed protocol which has been approved by the institutional ethical committee. The inclusion and exclusion criteria are followed as per the guidelines and specification provided by Dr. D C Dutta and Dr

Dewhurst's Text book of O & G which is based on the standard accepted guidelines. The volunteers are recruited for the study based on strict follow

up of inclusion and exclusion criteria, adhesion to the guidelines of CRF and follow up protocol as mentioned in the table No. 1

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
With H/O Irregular menstruation for at least previous three cycles with increased body weight.	PCOD associated with any other known or detected genital tract abnormalities including Cx.
Existence of cystic ovary (ies) confirmed by USG not old than 3 months before the date of reporting	PCOD with long term unexplained Menorrhagia / Metrorrhagia
Lab report (not old than 3 months) with evidence of elevated serum:-LH, fasting insulin, & Testosterone.	Patients Suffering with any other systemic illness like chronic liver & kidney failure, heart failure, hepatic insufficiency, allergic to the ingredients used in this formulation, and pace maker.

OBSERVATION AND RESULTS

Out of the (n=10) patients, complaining of irregular menstrual cycle, who diligently followed the prescription the mean value of 2.2 before treatment was reduced to 1.1 post treatment.

Table no. 1 Statistical analysis on relief of Irregular menstruation (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	2.2	1.1	1.1	0.74	0.25	4.472	<0.01

Impact in the Cyst

Out of the (n=10) patients, complaining of polycystic ovaries, who diligently followed the prescription the mean value of 2.5 before treatment was reduced to 0.5 post treatment.

Table 2: Statistical analysis on Cyst reduction (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	2.5	0.5	2	0.82	0.27	7.348	<0.001

Impact in Body Weight

Out of the (n=10) patients, complaining of increased body weight, who diligently followed the prescription the mean value of 2.27 before treatment was reduced to 2.50 post treatment.

Table 3: Statistical analysis on reduction of Body weight (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	2.27	2.50	1.1	0.74	0.25	4.472	<0.01

Impact on LH

Out of the (n=10) patients, complaining of increased LH hormone, who diligently followed the prescription the mean value of 14.43 before treatment was reduced to 12.33 post treatment.

Table 4: Statistical analysis on LH levels (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	14.43	12.33	2.101	3.47	1.16	1.814	<0.1

Impact in the Testosterone

Out of the (n=10) patients, complaining of increased testosterone, who diligently followed the prescription the mean value of 4.98 before treatment was reduced to 0.5 post treatment.

Table 5: Statistical analysis on Testosterone levels (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	4.98	0.5	4.48	0.613	0.23	2.505	<0.5

Impact in the Fasting Insulin

Out of the (n=10) patients, complaining of increased fasting insulin, who diligently followed the prescription the mean value of 32.542 before treatment was reduced to 26.976 post treatment.

Table 5: Statistical analysis on Serum Fasting Insulin levels (n=10)

NO	Mean (BT)	Mean (AT)	D	SD	SE	T	P
10	32.542	26.976	5.566	5.80	1.93	2.880	<0.01

The overall results were analysed based on the following criteria:

- Pregnancy occurred during or after the treatment.
- Normalization of Hormonal level
- Regularization of cycle post treatment. Present study was carried out to evaluate efficacy of *Madhutailika Basti* and *Shamana aoushadhis* in Poly cystic ovarian disease. The overall results showed marked improvement in 70%, moderate improvement in 20% and improvement in 10% of the patients. Highly significant results were achieved in menstrual irregularity, polycystic ovaries, body weight, fasting insulin, testosterone, and significant results were achieved with regard to level of LH Hormone.

DISCUSSION

Present study is carried out to evaluate the effect of *Madhutailika basti* and *Shamana aushadhis* in PCOD (Poly cystic ovarian disease). It is a multifactorial disease with manifestation of many symptoms like acne, hirsutism, obesity, irregular menstrual cycle, and anovulation.^[11] Though exact pathophysiology of PCOD is not understood following can be the causes:

- Hypothalamic-pituitary compartment abnormality, where an increased pulse frequency of GnRH leads to increased pulse frequency of LH.^[12]
- Androgen excess, here abnormal regulation of the androgen forming enzyme (P450 C17) is main cause for excess production of androgen from ovaries.^[13]
- Obesity is associated with reduced SHGB (Sex hormone binding globuline). It also induces insulin resistance leading to hyperinsulinaemia which in turn increases the gonadal androgen production.^[14] These factors hamper the development of follicles, leading to anovulatory cycle associated with prolonged period of amenorrhoea.

In Ayurveda, it can be better explained under *Rasanimittaja vyadhi*, with involvement of *Medho dhatu*, *Vata & Kapha doshas*. *Acharya Sushruta* has mentioned that *Rasadhatu* is the main cause for *Stoulya*, *Prameha*, and *Karshya* etc. Due to excessive intake of *guru*, *Snigdha*, *Madhura*, *Sheeta abhishyandi aharas* it leads to *Agnimandya* which further leads to *Kapha vriddi* and *Medho dhatu vriddi*. This contributes to *Shrotodusti* and *Avarana* of *Rasadhatu* by *Medhodhatu* which can cause symptoms like *stoulya*. *Artava* is also affected because *Artava* is *Upadhatu* of *Rasa dhatu*. This produces symptoms like *Alpartava*, *Artavakshaya* or *Anartava* which can be seen in PCOD. To correct the *Avarana* as well as *Vata kapha doshas*, and *Medho dhatu dusti* *Madhutailika Basti* was selected, which contains equal quantity of *Madhu* and *Taila*, *Saindhavalavana*, *Shatapushpa*, *Shatavari erandamoola kwatha*. *Madhu* is having *Lekhana guna* which helps to reduce both *Kapha* and *Meda*.^[15] *Tila taila* is having *Artava jananaka* property and *Erandamoola kwatha* acts as *vatahara*.^[16] *Guggulu* having *Lekhana* and *Rasayana gunas* which helps in reduction of increased *Medho dhatu* and *Kapha dosha*. Among them all are having the *karmas* like *Deepana*, *Pachana*, *Srotoshodaka*, and *Medhokaphahara*, which helps to improve the *Jatharagni*, *Dhatwagni* as well as *Rasadhatu*. This intern reduces *Sthoulya* and regularizes the ovulation.

CONCLUSION

PCOD is one of the commonest problems seen in women today. Most of the times, it manifests as oligomenorrhoea or amenorrhoea or delayed and irregular periods along with hirsutism, hoarseness of voice, obesity etc. Based on the properties like *Medhokaphahara* and *Vatahara*, *Deepana*, *Pachana*, and *Srotoshodhaka*, *Madhutailika Basti*, *Navaka Guggulu*, *Arogyavardhini vati*, *Asanabilwadi kwatha* are selected for the study. The overall results showed marked improvement in 70%, moderate improvement in 20% and improvement in 10% of the patients. On statistical analysis, efficacy of

the trial drugs was found to be highly significant in relieving PCOD ($P < 0.001$).

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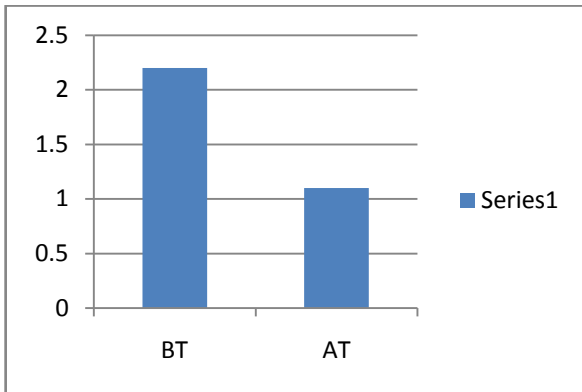
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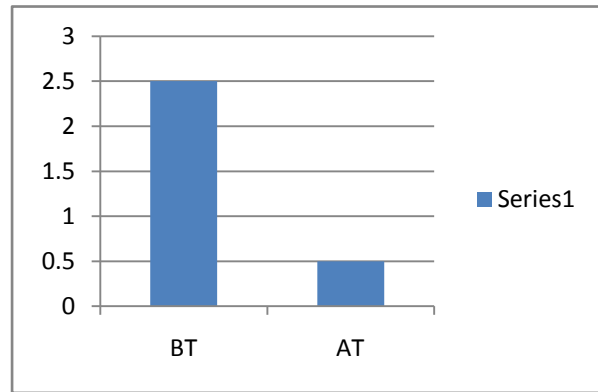
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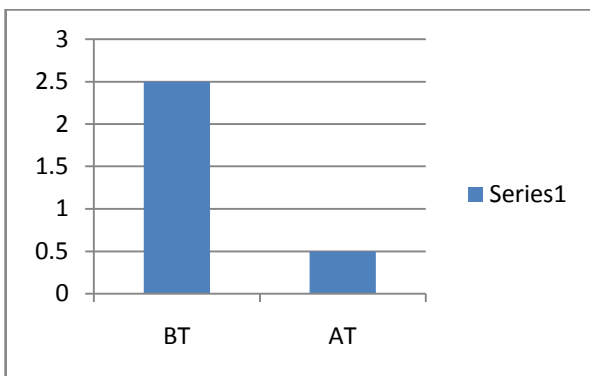
Bio Statistical Graphs



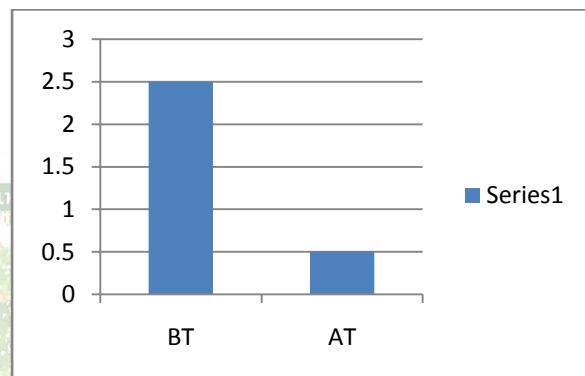
Graph I: Relief in Irregular menstruation



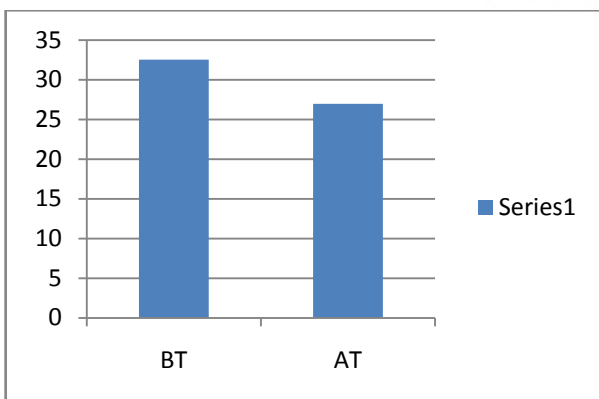
Graph II: Relief in the size of polycystic ovaries



Graph III: Reduction of Body weight



Graph IV: hormone level LH



Graph V: Testosterone hormone levels