



Research Article

A Single Blind Clinical Study on Evaluation of effect of Amalaki Choorna and Kulatha Choorna in PCOS

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Abstract

Introduction: Polycystic Ovary Syndrome (PCOS) is a prevalent endocrine disorder affecting approximately 2.2% to 26% of women worldwide, primarily in the adolescent and reproductive age group (18–45 years). PCOS is a multi factorial condition that impacts reproductive, metabolic, endocrine, and psychological systems. Due to its complex and heterogeneous presentation, comprehensive management remains challenging. In *Ayurveda*, no single disease entity is directly comparable to PCOS. However, certain clinical manifestations resemble *Granthibhoota Artava Dushti*, which, if left untreated, may progress to a clinical picture similar to PCOS. **Aim:** To evaluate the effect of *Amalaki Choorna* and *Kulatha Choorna*, in patients of PCOS. **Materials and Methods:** A single-blind, (patient-blinded) Quasi experiment (before & after) clinical study was conducted on 70 diagnosed PCOS patients. **Intervention:** *Amalaki Choorna* – 10 gm daily in divided doses for 90 days **Anupana:** Honey (*Madhu*) with warm water (*Ushnodaka*) *Kulatha yusha* (Prepared from *choorna*) – 10 gm daily in divided doses for 90 days **Advised in the form of Yusha (gruel)** **Outcome Measures:** Subjective and objective parameters were assessed, including: Irregularity of menstrual cycle ($P = 0.003$), Quantity of menstrual blood ($P = 0.001$), Dysmenorrhea ($P = 0.001$), Ultrasonographic assessment of ovarian cyst size ($P = 0.001$). **Results:** Patients showed statistically highly significant improvement in menstrual regularity, menstrual blood quantity, and pain during menstruation. Ultrasonography demonstrated a significant reduction in ovarian cyst size after treatment. **Conclusion:** *Amalaki Choorna* with *Madhu* and *Kulatha Yusha* may help to reduce symptoms of PCOS, Regulate menstruation and ovulation, Improve haemoglobin levels, Modulate hormonal parameters such as LH, FSH, TSH.

Keywords: PCOS in *Ayurveda*, *Amalaki Choorna*, *Kulatha yusha*, *Honey*

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Introduction

PCOS is a common female endocrine disorder with prevalence ranging from 2.2% to 26%.⁽¹⁾ Most reports have studied adult women with age ranged from 18 to 45 years which is an adolescence and reproductive age group mainly due to the adoption of westernized culture.⁽¹⁾

Poly cystic Ovarian Syndrome (PCOS) is a physiological disorder that causes many negative effects involving a variety of systems in

the body, such as the endocrine, metabolic, psychological, and reproductive systems.

The complex symptomatology of PCOS makes very difficult to treat as a whole. Women with PCOS have a 30-50% of risk of miscarriage, which is 3 times higher than normal women, and also may cause inhibition of follicular development, micro-cysts in the ovaries, an-ovulation, and menstrual alteration⁽²⁾. Research suggests that 5% to 10% of females 18 to 44 years of age are affected by PCOS, making it the most common endocrine abnormality among women of reproductive age in the U.S. Women seeking help from health care professionals to resolve issues of obesity, acne, amenorrhea, excessive hair growth, and infertility often receive a diagnosis of PCOS. Women with PCOS have higher rates of endometrial cancer, cardiovascular disease, dyslipidemia, and type-2 diabetes mellitus. ⁽³⁾

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In *Ayurveda* no disease can be compared directly with PCOS. The *Artava* term is also used to represent ovum and hence among the 8 *Artavadushti* which leads to *Abeejata* (anovulation), *Granthibhoota Artavadushti* have the features like *Granthila artava* can be correlated with the termination of follicle maturation and became cystic in nature. This prevents proper growth of follicle to release a mature ovum as in poly cystic ovary.

Some of clinical symptoms of PCOS may simulate *Kapha & Vata dusti Artava* (*Granthibhoota Artava dushti*), there is a increase of *Kapha dosha and meda dhatu*. (4) *The pathology* (Samprapti) of *sthouly (Obesity) and PCOS is similar; the selected Amalaki choorna and Kulatha yusha are mentioned as a line of treatment* (Chikitsa) for *sthouly* (5) (*Obesity*) as the pathology is similar the selected medicines will treat this condition, and if this condition is not treated early, may lead to the complication of PCOS.

Amalakichoorna has high amount of vitamin C, regulating glucose metabolism (*Pramehagna*) Antidiabetic Hypolipidemic agent (*Medahara*), and helps to mitigate the *Kapha dosha* and *Medha datu*.

As it is best anti oxidant, rejuvenator, has good effect on Hyperlipidemia (*sthouly*). (6)

Kulathachoorna high in iron, calcium, and protein. In fact, horse gram has the highest calcium content among pulses and is one of the richest vegetarian sources of protein, low in fat and high in carbohydrate content, low in lipid and sodium content, and its slow digestible starch make ideal for diabetic and obesity patients. Hence this combination of these drugs will give the best result on PCOS. (7)

Objectives of the study

1) To evaluate the *Medahara* effect of *Amalakichoorna* and *Kulathachoorna yusha* in PCOS.

2) To see the Hormonal effect of *Amalakichoorna* and *Kulathachoorna yusha*.

Study Design: A single blind (Patients were blind) Clinical study 70 Diagnosed case of PCOS were selected for the study.

Patients coming to the OPD and IPD of BLDEA'S AVS AMV Hospital & Research centre Vijayapur and Patients coming to the OPD and IPD of Shri B.M.Patil Medical Hospital & Research centre Vijayapur were selected.

Inclusive criteria:

Diagnosed patients of PCOS, Irregular menses / scanty menses due to anovulatory cycle and Age group 18yrs to 45yrs.

Exclusive criteria: Cervical tumour, Polyp, Ca cervix, Uterine fibroid, Congenital anomalies in female genital tract, Tubercular endometriosis, Congenital adrenal hyperplasia, HIV/VDR/L/HbsAg positive, Malignant diseased patients and cytotoxic patients, Other gynecological disorder.

Objective parameters

a. Haematological investigations- CBC, LH, FSH, T3, T4, TSH, Testosterone.

b. Ultrasonography (USG)

Subjective Parameters-

- Duration of Bleeding (*Kala of Rakthasrava*).
- Irregular menstruation (*Aniyamita artava pravrat*)
- Quantity of Menstrual blood (*Pramana of Rakthasrava*)
- Pain during Menstruation (*Vedana*)

Table1: Diagnostic criteria

SI No	Criteria	Normal value	Abnormal value
1	Duration of Bleeding (<i>Kala of Rakthasrava</i>)	3-5 days	<3 & > 5 days
2	Irregular menstruation (<i>Aniyamita artava pravrat</i>)	26- 32 days	<26 & > 32 days
3	Quantity of Menstrual blood (<i>Pramana of Rakthasrava</i>)	3 normal size pads per day = 15	1 pad or no pad per day & more than 3pads.
4	Pain during Menstruation (<i>Vedana</i>) (VAS Scale)	0	1-7
5	Obesity (<i>Sthaulya</i>)	AS per BMI calculation.	
6	Hirsutism and male pattern balding consistent with hyperandrogenism		

Product quality Parameters –

Amalaki Choorna - (*Phyllanthus emblica*)

Organoleptic Characters like – Colour, Odour, Taste, Appearance and Texture.

Physical constituents (Physicochemical investigation) like-

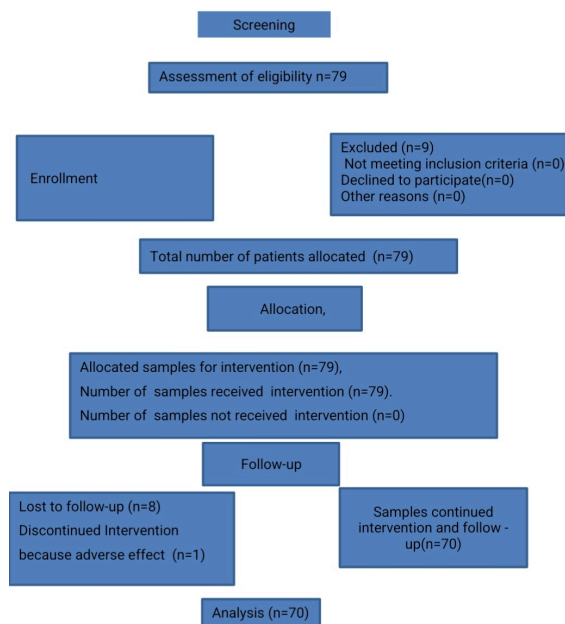
- PH
- Specific gravity
- Ash value
- Acid insoluble
- Water insoluble
- Moisture content
- Solubility test.

Ethical consideration

Ethical consideration was issued, by Ethical Committee of BLDE Deemed to be University Shri B.M.Patil Medical College, Hospital & Research Centre, Vijayapura. Meeting held on Friday, 23rd June, 2023 at 11.30am in the CAL Laboratory Dept of Pharmacology, with IEC reference number BLDE(DU)/IEC/1030/2022-23.

CTRI Registration No: CTRI/2023/09/072765.

Figure 1: Consort flow chart



Sample size - 70

Sample size calculation -Sample size was calculated by a qualified statistician.

With anticipated Proportion of 3% (2.6 to 25%), 95% level of significance and 5% absolute precision, the study would require a sample size of minimum 50 patients.

Formula used is $n = \frac{z^2 \cdot (p \cdot q)}{d^2}$

Where Z= Z statistic at α level of significance; d= Absolute error; p= Proportion rate; q= 100-p

Statistical analysis: Data was represented using Mean \pm SD, percentages and diagrams. Comparison of variables within groups were done using Wilcoxon matched pair test.

- Level of significance will be considered P value < 0.05.

Interventions

A single blind (Patients were blind) Clinical study .70 Diagnosed case of PCOS Patients were selected for the study.

Medicine

- *Amalaki choorna* . 10gms (in two divided doses)
- Duration: 90days.
- Vehicle(*Anupana*) Honey along with Ushnodaka

Pathya

- *Kulatha Yusha* (Patient was advised to take *yusha prepared from 10gms of choorna* in two divided doses)
- Duration: 90days.
- Advised to consume in the form of *Yusha* (Gruel)

Results

Phytochemical results

Table 2: Results of preliminary phytochemical screening of *Amalaki churna*

Test	Inference
Alkaloid	+
Steroid	-
Carbohydrate	+
Tannin	+
Flavanoids	+
Saponins	-
Terpenoid	+
Coumarins	-
Phenols	+
Carboxylic acid	+
Amino acids	+
Resin	-
Quinone	-

Table 3: Phytochemical test and the changes observed

Tests	Color if positive	Aqueous extract
Alkaloids		
Dragendroff's test	Orange red	Orange red
Wagners test	Reddish brown	Reddish brown
Mayers test	Dull white	Dull white
Hagers test	Yellow	Yellow
Steroids		
Liebermann-	Bluish green	No bluish green
Salkowski test	Bluish red to cherry red color in chloroform	No bluish red to cherry red color in chloroform
Carbohydrate		
Molish test	Violet ring	Violet ring
Fehlings test	Brick red	Brick red
Benedicts test	Red precipitate	Red precipitate
Tannin		
With FeCl ₃	Dark blue or	Dark blue
Flavanoids		
Shinoda's test	Red or pink	Pink color
Saponins		
With NaHCO ₃	Stable froth	No stable froth
Triterpenoids		
Tin and thionyl	Pink/ Red color	Red color
Coumarins		
With 2 N NaOH	Yellow	Light green color
Phenols		
With alcoholic	Blue to blue	Blue to blue
Carboxylic acid		
With water and	Brisk	Brisk
Amino acid		
With ninhydrine	Purple colour	No purple color
Resin		
With aqueous	Turbidity	No turbidity
Quinone		
Conc. sulphuric	Pink/purple/red	No Purple / red

Table 4: Phytochemical Analysis of the *Amalaki Churna* compared with Standard values as per API.

Parameters	Results n=3 %w/w	Standard values as per API.	
	Amalaki churna (Avg \pm SD)	Limit	Reference
pH	6.0	3-5%	(App. 2.2.2)
Loss on drying (Moisture content)	7.85 \pm 0.00	6-8%	(App. 2.2.3)
Total ash	3.19 \pm 0.13	Not more than 7%	(App. 2.2.3)
Acid insoluble ash	1.19 \pm 0.01	Not more than 2%	(App. 2.2.4)
Water soluble ash	0.58 \pm 0.02		
Alcohol soluble extractive value	29.51 \pm 0.00	Not less than 40%	(App. 2.2.6)
Water soluble extractive value	60.98 \pm 0.02	Not less than 50%	(App. 2.2.7)
Foreign matter (Including seed and seed coat)		Not more than 3%	(App. 2.2.2)

Result obtained were within the limits specified by the API.

Clinical Study

Table 5: Effect of Treatment on Duration of bleeding in Days (Kaala of Alpa Rakta Srava)

Treatment Duration of Bleeding (Alpa Rakta Srava)	Before Treatment		After Treatment	
	N	%	N	%
Normal	0	0	66	94.3
Mild	0	0	2	2.9
Moderate	13	18.6	1	1.4
Severe	57	81.4	1	1.4
Total	70	100.0	70	100.0

Table 6: Grading for duration of bleeding in Days (Kaala of Alpa Rakta Srava)

Duration	Grade	Score
3-5 days	Noramal	0
1-2 days	Mild	1
1-8 days	Moderate	2
Spotting more than 9 days	Severe	3

Before treatment in 13(18.6%) patients, duration of the bleeding (Kaala of Rakta srava) was moderate ie 1-8 days, in (57 81.4%)patients, duration of the bleeding was severe ie spotting more than 9days. After treatment all 70(100%) patients have shown highly significant result.All 70 (100%)patients got 3-5 days normal PV bleeding.(P=0.001)

Table 7: Effect of Treatment on Less quantity of Menstrual Blood (Alpa Pramana Rakthasrava)

Quantity of Menstrual Blood (Pramana of Rakthasrava alpa rakta srava)	Before Treatment		After Treatment	
	N	%	N	%
Noramal	0	0	0	0
Mild (Pravara +++)	0	0	68	97.1
Moderate (Madyama ++)	11	15.7	1	1.4
Less (Avara +)	59	84.3	1	1.4
Total	70	100.0	70	100.0

Table 8: Grading for less quantity of Menstrual Blood (Alpa Pramana Rakthasrava)

Number of pad/cycle	Grade	Score
15pads	Normal flow	0
12-13pads	Moderate flow (Madyama srava)	1
7-10pads	Light flow (alpa srava)	2
<5pads	Scanty /Stain (Atyalpa srava)	3

Table 12: Effect of Treatment

	Before Treatment		After Treatment		Wilcoxon Signed Ranks Test	P Value
	Mean	Std. Deviation	Mean	Std. Deviation		
Duration of Bleeding (Rakta Srava in days)	2.81	0.392	0.10	0.455	7.717	P=0.001*
Quantity of Menstrual Blood (Pramana of Rakthasrava)	2.84	0.367	1.04	0.266	7.781	P=0.001*
Pain during Menstruation(vedana)	2.83	0.380	1.03	0.239	7.728	P=0.001*
Regularity of Menstruation	2.90	0.302	0.10	0.486	2.943	P=0.003

*: Statistically significant

Before treatment in 11(15.7%) patients, the quantity of bleeding (Rakta Srava pramana) was moderate ie use of 7-10 pads, in 59 (84.3%)patients, the quantity of bleeding was less ie use of less than 5 pads. After treatment all 70(100%) patients have shown highly significant result.

All 70 (100%)patients got normal PV bleeding use of 15 pads. (P=0.001)

Table 9: Effect of Treatment on Pain during Menstruation (Vedana)

Pain during Menstruation(vedana)	Before		After Treatment	
	N	%	N	%
Nil (0)	0	0	1	1.4
Mild (1-3)	0	0	66	94.3
Moderate (4-6)	12	17.1	3	4.3
Severe(7-10)	58	82.9	0	0
Total	70	100.0	70	100.0

Table 10: Pain during Menstruation(vedana) (grading was done as per Visual Analog Scale)

Pain	Grade	Score
No pain	Nil	0
Menstruation is painful but daily activities are not affected no need of analgesic	Mild	1-3
Daily activities are affected, need to take analgesic	Moderate	4-6
Daily activities are inhibited, affected continuous after taking analgesic	Severe	7-10

Before treatment in 12(17.1%) patients, the pain during menstruation (Vedanaa) was moderate ie (4-6), in 58 (82.9%)patients, the pain was severe ie (7-10). After treatment all 70(100%) patients have shown highly significant result.All 70 (100%)patients got PV bleeding with mild and moderate pain. (P=0.001).

Table 11. Irregular Menstruation (Aniyamita Artava pravrti)

Mensyrual cycle in days	Grade	Score
28days	Normal	0
28-45days	Mild	1
46-60days	Moderate	2
Above 60days	Severe	3

Before treatment in 4(5.7%) patients, the irregularity of menstruation (Aniyamita Artava pravrti) was moderate ie (46-60), in 66(94.2%)patients, the irregularity of menstruation (Aniyamita Artava pravrti)was severe ie (above 60 days). After treatment all 67(95.71%) patients have shown significant result (P= 0.003).2 (2.85%)patients shown moderate effect (46-60) and 1 patient was not at all responded.

Table: 13.Effect of Treatment

	Before Treatment		After Treatment		Wilcoxon Signed Ranks Test	P Value
	Mean	Std. Deviation	Mean	Std. Deviation		
BT USG Report Size of the cysts RTO	11.150	4.0627	9.209	2.8938	7.717	P=0.001*
BT USG Report Size of the cysts LTO	10.611	3.6347	8.829	2.1517	7.781	P=0.001*
Thinning of the hair	2.79	0.447	0.13	0.448	7.728	P=0.001*
Ludwig scale HB%	12.387	1.281	14.762	14.7257	5.389	P=0.001*
LH	13.409	12.472	14.470	13.667	5.368	P=0.001*
FSH	13.673	62.309	7.618	4.625	7.672	P=0.001*
TSH	2.571	1.717	3.169	4.848	5.560	P=0.001*

*: Statistically significant

The effect of these treatment shown the significant results in reducing the size of the cyst, increment in the Heamoglobin %,repair of thinning of the hair, increment in the level of LH,FSH and TSH P=0.001.

Figure 1

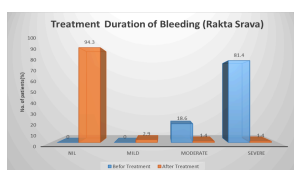


Figure 2

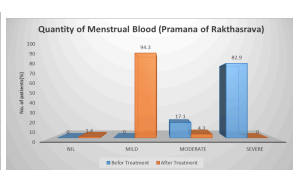


Figure 3

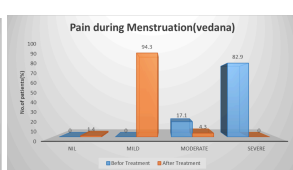


Figure 4

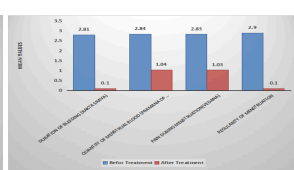
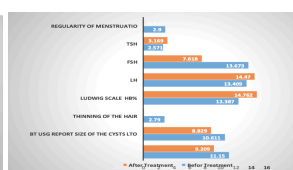


Figure 5



Discussion

Discussion on results

Amalaki helps to stimulate the *agni* (Digestive fire) as it has the predominant *Amla rasa* and helps for *Ama Pachana*, simultaneously corrects the *Dhatwagni*.

Due to its *Rasayana* (Adaptogenic (best rejuvenating herb) *guna* it nourishes the *rasa dhatu*, as *artava* is the *updhatu* of *rasa dhatu*, *artava* also get nourished well and the *pramana* of *artava* became normal. As it alleviates all three *Doshas: Vata, Pitta, Kapha*, and is especially effective for *Pitta Dosha*. *Amalaki* has been considered the best of the *Ayurvedic* rejuvenative herb and used as *Rasayan dravya*, it helps to nourish *adya datu rasa dhatu* and *upadhatu artava*, because of this *niyamita artava prvrati*(*yathochita kaala darshan*) takes place.

The chemical composition like-acid value 12.7, saponification value 185, acetyl value 2.03, iodine value 139.5, unsaponifiable matter 3.81%, sterol 2.70%, saturated fatty acids 7%, linolenic acid (8.78%), linoleic acid (44.0%), oleic acid (28.40%), stearic acid (2.15%), palmitic acid (2.99%) and myristic acid (0.95%) all help to increase the digestive fire.(8)

Due to its *Amala Rasa* (Sour) it helps for *vatanulomana* by this reduces the *Vedana*(pain) during the menstruation. *Kashaya Rasa* (Astringent) and *Ruksha* (Dry) *Guna* it alleviates *Kapha*.(9)

By mitigating the *Kapha dosha* according to the *Ashrayi Ashrayi siddhanta* it mitigates the *medha dhatu* (Hypolipidemic agent) and helps to reduce the *granthi* (Cyst) size of the Cyst has been reduced.

Kapha and *medahara* properties help to reduce the weight. The seed oil is rich in unsaturated fatty acids like linoleic acid (18:2n-6) and oleic acid, helps to reduce the body weight.

As *Amalaki* is best *rasayana nityasevana ahara dravya*, and rich in Vitamin C and Calcium it helps to increase the Heamoglobin %, and hair growth.

Mode of action of *Kulatha, Madhu* and *Sukhoshnodaka*

Rasapanchaka of *Kulatha* (*Dolichos biflorus*Linn)(Ayurvedic pharmacodynamics)

As the drug is predominant of *Kashaya rasa*, and *ushna veerya* (hot potency) *Laghu* (light to digest) *Rooksha* (Dry in nature) *Teekshna*- Pungent, it is *Kapha vata shamaka* (reduces the vitiated *Kapha* and *Vata*) helps in mitigating the *Vedana* (pain during menstruation) helps in mitigating the reduces the size of the *granthi* (Cyst).(10)

“*Kulatha Amlapittajananaanam Shreshtam*” (11) as *kulatha* is *agrya dravya* in *amlapitta janana*,if consumed in appropriate matra it increases *pitaa dosha* (because of its *agni mahabhoota predominance*), hence it helps to *agni deepana* & *amapachana*.The *ushnaveerya teekshna* property of *Kulatha* helps increase the quantity of *artava* “*Artavam tu Agneyam*” *samanya sidhanta*.

Shukragna(Reduces Male hormones) *Ashmarigna* (Reduces the calculi),, *Medohara* (Hypolipidaemic, Hypocholesterolemic), *Gulma*(pseudotumours),*Pramehagna*(Hypoglycaemic) *Rajorodha* (Amenorrhoea) Antihepatotoxic, Antispasmodic(*Vedana hara*), Abortifacient (Causes Abortion).

The raw seeds of *Kulatha* has the ability to reduce postprandial hyperglycemia by slowing down carbohydrate digestion and reduce insulin resistance by inhibiting protein tyrosine phosphatase 1 beta enzyme. *Kulathachoorna* high in iron, calcium, and protein. In fact, horse gram has the highest calcium content among pulses and is one of the richest vegetarian sources of protein, low in fat and high in carbohydrate content,low in lipid and sodium content, and its slow digestible starch make ideal for diabetic and obesity patients.(12)

Puran Madhu: *Madhura rasa* is *Pradhana Rasa*, *Anurasa Kashaya*, *Guna Ruksha Laghu*, *Ruksha*, *Picchila*, *Vishad*,*Sukshma Virya* *Sheeta Vipaka* *Katu Dosghanta alpa Vat karak*, *Kapha pitta nashak* *Tridosh nashak*.

Helps to mitigate the *kapha dosha*, *medadhatu* helps to reduce the *granthi*. consists chiefly of fructose (40-50%), glucose (30-40%), and small amounts of sucrose (0.1-10%), dextrin, formic acid, volatile oil and pollen grains. In addition to these, traces of enzymes, vitamins, proteins, maltose, melezitose, pentosans, gums, trace elements, amino acids, and coloring matter are also present. (13)

Sukhoshnodaka: Warm water as *anupana* helps to easy assimilation the consumed medicine, as *sukhoshna jala* is *agni mahabhoota pradhana* it will help to mitigate the *Kapha, Vata dosha, meda daatu*, acts as *Ama Pachaka* and *agni vardhka*. (14)

As the *Amalaki* and *Kulatha* both have *karshana* property they both help to balance the Thyroid stimulating Hormone. As the size of the cyst get reduced LH and FSH values were become normal.

Samprapti (Pathogenesis)

Mithya Achara, Pradushta Artava, Beeja dosha and *Daiva*, due to these all causative factors, *Tridosha* get aggravated predominantly *Kapha* and *vata* aggravate more, further leads to vitiation of *Agni*, that leads to *Agnimandya* (impairment of metabolism) then formation of *Ama* (metabolic waste products accumulation) takes place. Then it leads to *Dhatwagni mandya* (impairment of metabolism in the cells) *Rasa+ Meda Dhatu* get vitiates further then it leads *Alpa Artava* (Oligomenorrhoea) along with formation of *Granthi*. (15)

“Samprapti Vighatanameva hi Chikitsa” Destroying this pathogenesis is known as *Chikitsa* (Treatment) **“Sankshepatah Kriyayoho Nidana Parivarjana”** the basic first line of treatment is avoiding *Nidan sevana* or avoiding intake of *Nidana* (causative factor). Hence the combination of these drugs help to destroy the *samprapti*. Patients were advised to avoid the intake of causative factors and healthy diet was advised.

Outcome measures

Primary outcome

Among 79 samples, 9 patients were in drop out list because of irregular followup, 1 patient had adverse effect of Amalaki choorna (When taken history, that pt had, allergy towards sour taste). In remaining 70, 10 patients had conceived as this intervention helps for ovulation.

Secondary out come measures,- increment in the Haemoglobin %, repair of thinning of the hair, increment in the level of LH, FSH, TSH and reduction in their body weight.

The future scope of the study- Research work can be taken in *Sthouly Vyadhi* (Obesity), Anovulatory cycle and infertility, with *Amalaki choorna* and *Kulatha yusha*

Conclusion

This study suggests potential future implications of *Amalaki choorna* with *Madhu* and *Kulath yusha* will reduce the PCOS, regulates the Menstruation, Ovulation, Improves the Haemoglobin %, has an impact on LH, FSH and TSH. Further it will help for conception.

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Conflicts of interest: There are no conflicts of interest.

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