RESEARCH PAPER

Effect Of *Lashuna Churna* And *Shatapushpa Ghana Vati* In Pcos – An Open Label Randomized Comparative Clinical Study

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ABSTRACT

Introduction:

Polycystic ovarian syndrome is the common health hazard amongst women of reproductive age. It is characterized by oligo-ovulation or anovulation, features of androgen excess and ultrasound appearance of polycystic ovary. PCOS affects more than 80% of women who report with signs of androgen excess. In Ayurveda classics there are no direct references of this disease rather, symptoms are found under various diseased conditions at various references, like menstrual irregularities described under the Ashtaartavadushti , Pushpaghni, Jataharini mentioned in Kashyapa Samhita Revati Kalpa Adyaya bears similar features of hyperandrogenism like Vruthapushpa(anovulation), Sthoola(obesity), Lomaganda(hirsutism).

Aims and Objective: To evaluate the efficacy of Lashuna Churna in PCOS.

Material and Method: In the study 40 Subjects were selected based on fulfilling the criteria for diagnosis and inclusion visiting OPD and IPD of Dept of Prasuti Tantra and Stree Roga, JSS Ayurveda Medical Hospital, camps and other referrals was selected for the study. Lashuna Churna Capsules were procured from GMP certified pharmacy. Shatapushpa Ghana Vati were prepared at GMP certified pharmacy. Subjects were assessed based on subjective and objective criteria.

Result: when the comparative effect of Lashuna Churna capsule (Group-A), Shatapushpa Ghana Vati (Group-B) was done by applying the Wilcoxon's Sign Rank test and Mann Whitney U test were used to interpret the data in group. In Group A, It shows p value < 0.001 in the parameters- Interval of cycle, acne, endometrial thickness, size of follicle, ovarian volume.

Conclusion:

- Lashuna Churna shows significant improvement in menstrual cycle regularity and reduction of acne, indicating its beneficial role in the management of PCOS.
- Shatapushpa Ghana Vati shows mild improvement in menstrual cycle regularity and acne in the management of PCOS.
- Lashuna Churna shows more effective than Shatapushpa Ghana Vati in the management of PCOS...

Keywords: Lashuna Churna, Shatapushpa Ghana Vati, Artavadushthi, PCOS, menstrual irregularity, Hyperandrogenism..

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INTRODUCTION

The PCOS first described by Stein and Leventhal in 1935. The condition, polycystic ovarian syndrome is a relatively common endocrine disorder amongst women of reproductive age group[1]. It is associated with oligo-ovulation or anovulation, features of androgen excess and ultrasound appearance of polycystic ovary, obesity, infertility, hypersecretion of luteinizing hormone (LH)[2]. It is characterized by the presence of many minute cysts in the ovaries and excessive production of androgens. The prevalence of PCOS, it is a common female endocrine condition has been found to range from 2.2% to 26% globally and from 3.7% to 22.5% in India, depends on the diagnostic criteria utilized[3]**.** PCOS is associated with weight gain, acne, hirsutism and impaired fertility due to chronic oligo-anovulation. Diagnosis of PCOS is made through ultrasound or diagnostic laparoscopy. Blood levels of hormone such as luteinizing hormones (LH), follicle stimulating hormone (FSH), androgens and serum hormone-binding globulins (SHBG). FSH levels are low or normal and LH levels are often raised, resulting in a raised LH/FSH ratio[4]. The treatment available in contemporary science like Hormonal therapy, OC pills, Insulin therapy, prolonged usage end up with other metabolic disturbances, weight gain, acne, skin discoloration (acanthosis nigricans)

and serious complications like Pulmonary thrombosis, Genital carcinoma, renal failure [5,6].

In *Ayurveda* classics there are no direct reference of this disease rather, symptoms are found under various diseased conditions at various references, like menstrual irregularities described under the *Ashtaartavadushti*, *Pushpaghni, Jataharini* mentioned in *Kashyapa Samhita*. *Revati Kalpa Adhyaya* [7] bears similar features of hyperandrogenism like *Vruthapushpa* (anovulation), *Sthoola*(obesity), *Lomaganda*(hirsutism). *Sushruta Samhita* gives the reference in *Shukrashonitashuddhi Adhyaya* about *Nasthartava* [8] (amenorrhea) due to aggravated *Kapha, Vatta Dosha*. In *Doshadhatumalakshayavrudhi Adhyaya* there is reference about *Artavakshaya Lakshanas* like *Yathochitakala Adarshanam Alpadarshana*(scanty flow). In *Charak Samhita* many scattered references are available in 5 different chapters. In *Garbhavakranti Shareera*, there is mention of *Beejadusht* [9] which is characterised by *Nashtartava* (secondary amennorhea) and *Santarpanottha Vikara* in the context of *Sthoulya* has been described. In *Ashtanga Sangraha Putarakameeeyaadhyaya* there is description of *Anartava* [10].

It may understand on the basis of *Doshadushti* involvement of *Dushya, Shrotas, Ama, Agani, Adhishthana* and *Vyadhi Laxanas*. Metabolic process is correlated with *Dhatuagni Vikara*. Therefore the drug selected for this study is *Lashuna* and *Shatapushpa* [11] has been mentioned in *Kashyapa Samhita*. The drug possesses *Katu Rasa, Usna Virya, Laghu Tikshna Guna, Katu Vipaka* and *Vatakapha Hara*, which acts as *Artava Pravartaka, Yonishodhana, Vrushya, Garbhajanana, Deepana, Pachana Karma*.

Aims and ObjectiveS:

To evaluate the efficacy of *Lashuna Churna* in PCOS.

To evaluate the efficacy of *Shatapushpa Ghana Vati* in PCOS.

To compare the efficacy of *Lashuna Churna* and *Shatapushpa Ghana Vati* in PCOS.

Material and Methods:

Selection of subjects: Subjects fulfilling the criteria for diagnosis and inclusion visiting OPD and IPD of Dept of *Prasuti Tantra and Stree Roga,* JSS Ayurveda Medical Hospital, camps and other referrals will be consider for the study.

Drug source: *Lashuna Churna* capsules were procured from GMP certified pharmacy.

Shatapushpa Ghana Vati was prepared at GMP Certified Pharmacy.

Selection criteria: The subjects fulfilling the criteria for diagnosis and inclusion with written informed consent were selected for the study.

Diagnostic criteria: Subjects of PCOS fulfilling the Rotterdam criteria, based on the presence of any two of the following

Oligo and/ or anovulation.

Hyperandrogenism(clinical and /or biochemical)

Ultrasonography (USG) evidence of polycystic ovaries

Inclusion criteria:

Subjects with signs and symptoms of PCOS.

Subjects aged between 18- 40 years.

Exclusion criteria:

Subjects already on another drug treatment for PCOS like (OC pills)

Subjects with other functional and structural pathology of reproductive organs.

Subjects with known cases of systemic disorders like renal disorders, and metabolic disorders like thyroid dysfunction and gastritis.

Assessment criteria:

Subjective Parameters:

Regularity of cycle

Assessment of acne (according to acne grading)

Assessment of hirsutism (on the basis of site)

Assessment of acanthosis nigricans

Interval of cycle

Criteria	Grade
22 - 35 days	1
36- 60 days	2
61- 90 days	3
> 90 days	4

Acne

Criteria	Grade
No black head and white head	0
Mild inflammation, frequent breakout	1
Mild inflammation, frequent breakout and papules	2

Nodule/Pustule/Cyst	3

Hirsutism

Criteria	Grade
Hair growth over the lips or chin or both	1
Hair growth over the lips, chin and face border	2
Hair growth over lips and chin, face border, Upper arm and chest	3
Hair growth over lips and chin, face border, Upper arm and chest Abdomen and thighs	4

Acanthosis nigricans

Criteria	
Present	**Absent**

TREATMENT PROTOCOL:

	Group A	Group B
NO. OF SUBJECTS	20	20
MEDICINE	*Lashuna Churna* Capsule	*Shatapushpa Ghana Vati*
DOSE	500 mg	500 mg
ANUPANA	*Jala*	*Jala*
TIME OF ADMINISTRATION	1-0-1	1-0-1
MODE OF ADMINISTRATION	Oral	Oral
DURATION OF MEDICATION	For 3 consecutive months from 1st day of intervention. Medicine was discontinued during cycles.	For 3 consecutive months from 1st day of intervention. Medicine was discontinued during cycles.

Intervention period: 3 consecutive cycles.
Assessment schedule: Assessment was done every 30 days once after intervention for 3 consecutive cycles.
Follow up: Follow up was done for 2 consecutive months after completion of the intervention.

OBSERVATION AND RESULT:
Table no: distribution of patients based on age

Age	Group-A	Group-B	Total	Percentage %
18-23	7	7	14	35%
24-29	11	11	22	55%
30-35	2	1	3	8%
36-40	0	1	1	3%

Table no: distribution of patients according to Regularity of cycle

Regularity	Group-A	Group-B	Total	Percentage %
Absent	0	0	00	0.00
Present	20	20	40	100%

Table no **:** distribution of patients according to Acne

Acne	Group-A	Group-B	Total	Percentage %
Absent	15	16	31	77%
Present	5	4	09	23%

Table no: distribution of patients according to Chief complaints Hirsutism

Hirsutism	Group--A	Group-B	Total	Percentage %
Absent	16	14	30	75%
Present	4	6	10	25%

Table no: distribution of patients according to Acanthosis nigricans

Acanthosis nigricans	Group-A	Group-B	Total	Percentage %
Absent	20	20	40	100%
Present	0	0	00	00%

RESULT

Interval of cycle

Parameter	Group	Mean(BT-AT2)	% Improvement	T test value	P Value	Remarks
Interval Cycle	Group A	1.62	52%	-5.82	0.001	Significant
	Group B	2.14	31%			

The analysis shows that Group A had a mean reduction of 1.62 days in interval cycle with 52% improvement, and this change was statistically significant (t = –5.82, p = 0.001). In Group B showed a mean reduction of 2.14 days with 31% improvement. Overall, Group A demonstrated a more effective and statistically reliable improvement compared to Group B.

Acne

Parameter	Group	Mean(BT-AT2)	% Improvement	Mann Whitney U test value	P Value	Remarks
Acne	Group A	0.24	20%	2.69	0.01	Significant
	Group B	0.18	50%			

The comparison of acne scores between the groups shows that Group A had a mean reduction of 0.24 (20% improvement), while Group B had a reduction of 0.18 (50% improvement). The Mann–Whitney U test (U = 2.69, p = 0.01) indicates that the difference was statistically significant suggest that Group A shows more reliable improvement compared to Group B.

Hirsutism

Parameter	Group	Mean(BT-AT2)	% Improvement	T test value	P Value	Remarks
Hirsutism	Group A	0.20	00%	NA	NA	NA
	Group B	0.45	00%			

The table shows the effect of treatment on **hirsutism** between Group A and Group B. The mean difference (BT–AT2) was 0.20 in Group A and 0.45 in Group B, but both groups showed **0% improvement**, indicating no change from baseline to after treatment. Since there was no improvement, statistical analysis (t-test and p-value) was not applicable, and therefore no significant difference could be established between the groups.

Endometrial thickness

Features	**Group**	**Mean**	**Mean Difference**	**SE**	**t Value**	**P value**	**Result**
Endometrial Thickness BT	**A**	6.48	-.885	.607	-1.459	.153	NS
	B	7.37					
Endometrial Thickness AT	**A**	7.46	-.225	.443	-.508	0.614	NS
	B	7.68					

A significant difference was not observed in endometrial thickness between the groups at baseline (6.48±1.678 Vs 7.37 ± 2.132; t = -1.459, p = 0.153) and after treatment (7.46 ± 1.52 vs 7.68 ± 1.26; t = -0.508, p = 0.614), indicating no improvement in Group A compared to Group B. Endometrial thickness, however, was no significantly in Group A compared to Group B.

Size of follicle

Parameters assessed	Z value	Mann Whitney U Value	p Value between group	Result
Size of Follicle BT	-0.685	175.50	0.493	NS
Size of Follicle AT	-0.338	188.00	0.735	NS

Size of Follicle were not significantly different at baseline (Z = –0.685, p = 0.0.493). Post-treatment, not significant differences were observed (Z = –0.338, p =0.735) indicating no reduction in Group B.

Ovarian volume

Parameters assessed	Z value	Mann Whitney U Value	p Value between group	Result
Ovarian Volume BT	-0.157	194.50	0.875	NS
Ovarian Volume AT	-1.363	157.0	0.162	NS

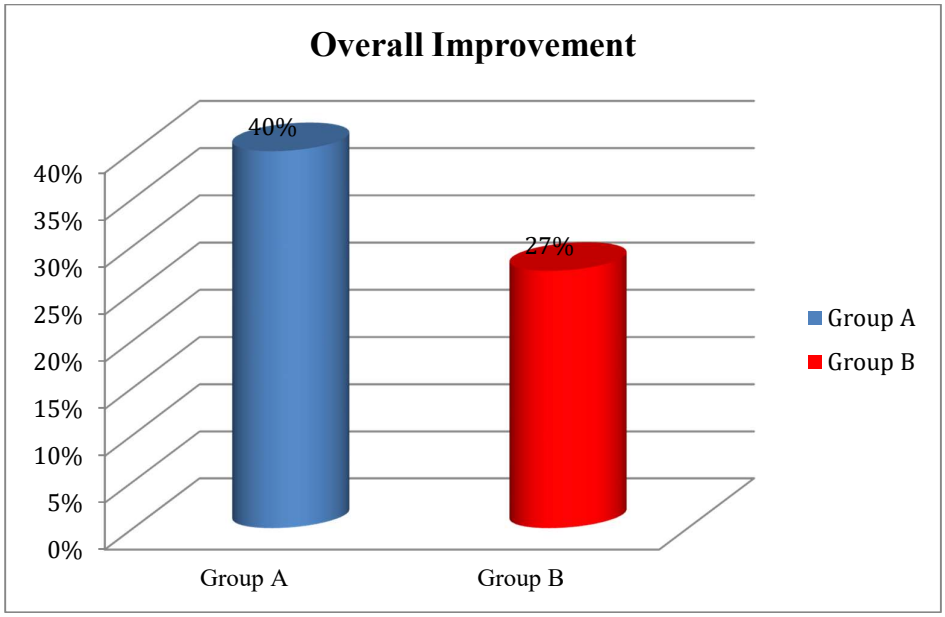
Ovarian Volume at baseline did not differ significantly (Z = –0.157, p = 0.875), but after treatment, Group B showed a not significant reduction compared to Group A (Z = –1.363, p = 0.162).

Antra follicular count

Parameters assessed	Z value	Mann Whitney U Value	p Value between group	Result
AFC BT	0.00	2000	1.00	NS
AFC AT	-1.433	180.00	0.152	NS

AFC: AFC BT were not significantly different at baseline (Z = 0.00, p = 1.00), not significant differences were observed for BT (Z = –1.433, p =0.152) AFC AT, indicating no significant difference were observed for AT.

Overall improvement



The graph shows the overall improvement between the two groups. Group A demonstrated a higher improvement rate (40%) compared to Group B (27%). This indicates that the intervention given to Group A was more effective in producing positive outcomes compared to Group B, suggesting better treatment response in Group A.

DISCUSSION

Polycystic Ovarian Syndrome is a relatively common endocrine disorder in women of reproductive age group. Women with PCOS may have infrequent or prolonged menstrual periods, ovaries may have numerous small collections of follicles

and fail to ovulate (anovulation). Anovulation leads to Infertility or excess male hormone (androgen) levels leads to dermatological problem (hirsutism, acne & acanthosis nigricans) and metabolic problems(insulin resistance, obesity).Thus, drug should have *Artavajanana* (effect on hormone level)*, Srotovishodhana, Vatanulomana, Deepana*, *Lekhana, Chedana,* properties along with specific action at the reproductive site which helps to restore the female menstruation by regularization of HPO axis, rebalancing hormones and promoting the growth and development of follicles leading to ovulation. Hence *Lashuna* and *Shatapushpa* selected for the trial. As it is having properties like *Madhura, Lavana, Katu, Tikta, Kashaya Rasa, Snigdha, Guru, Tikshna, Ushna, Pichila Guna, Ushna Veerya ,Katu Vipaka does Deepana Pachana, Vatanulomana* and *Sroto Shodhana.* Thus regulates normal function of *Jatharagni Agni* and *Dhatwagni* leads *Samyak Rasadi Dhatu Utpatti* and *Samyak Upadhatu Utpatti.* Hence there will be *Samyak Artava Utpattti amd Beejoutsarga.*

Mode of action of *Lashuna in PCOS*

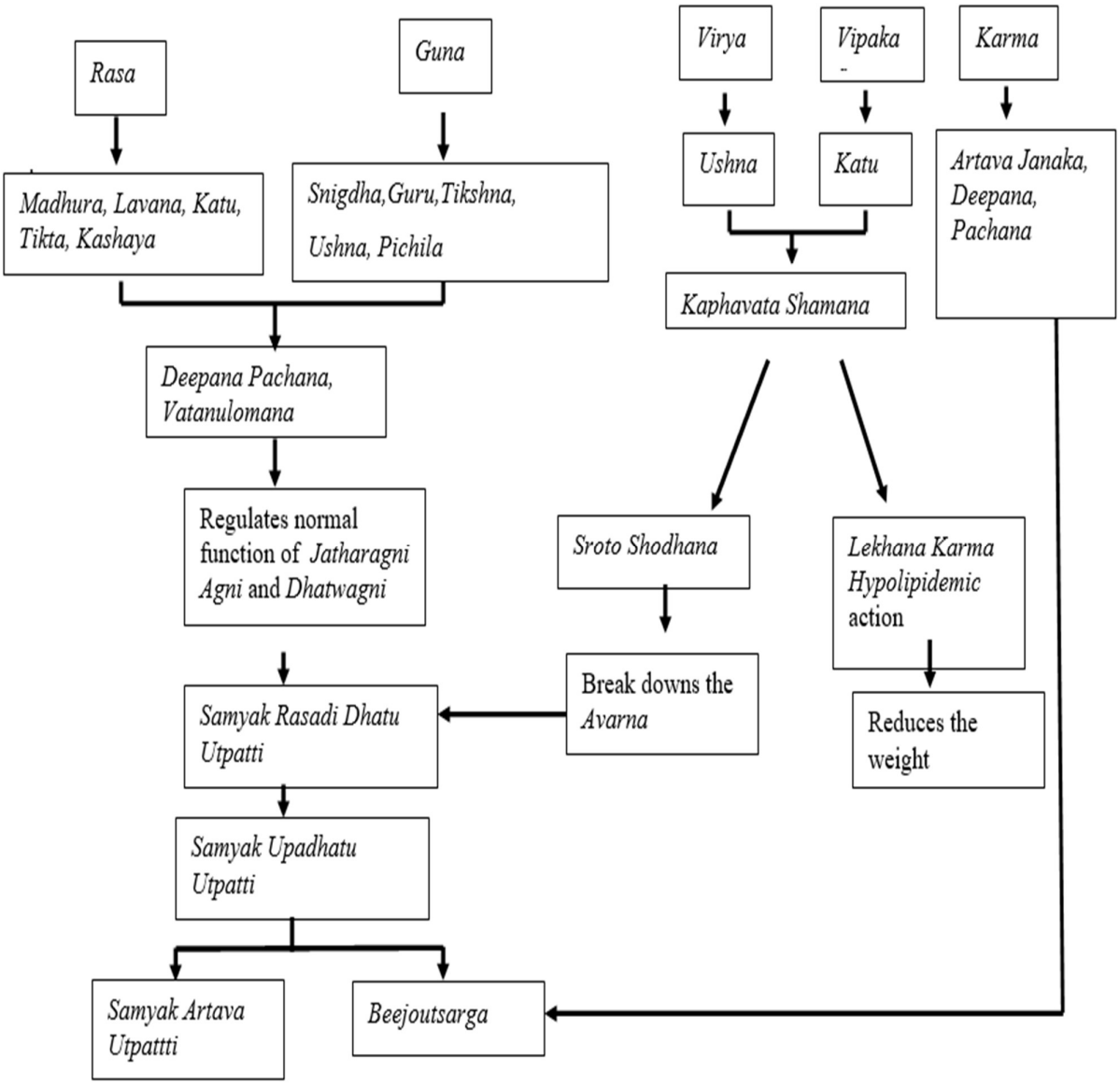


Fig No. 1 Mode of action of *Lashuna* in PCOS

Mode of action of Shatapushpa in PCOS

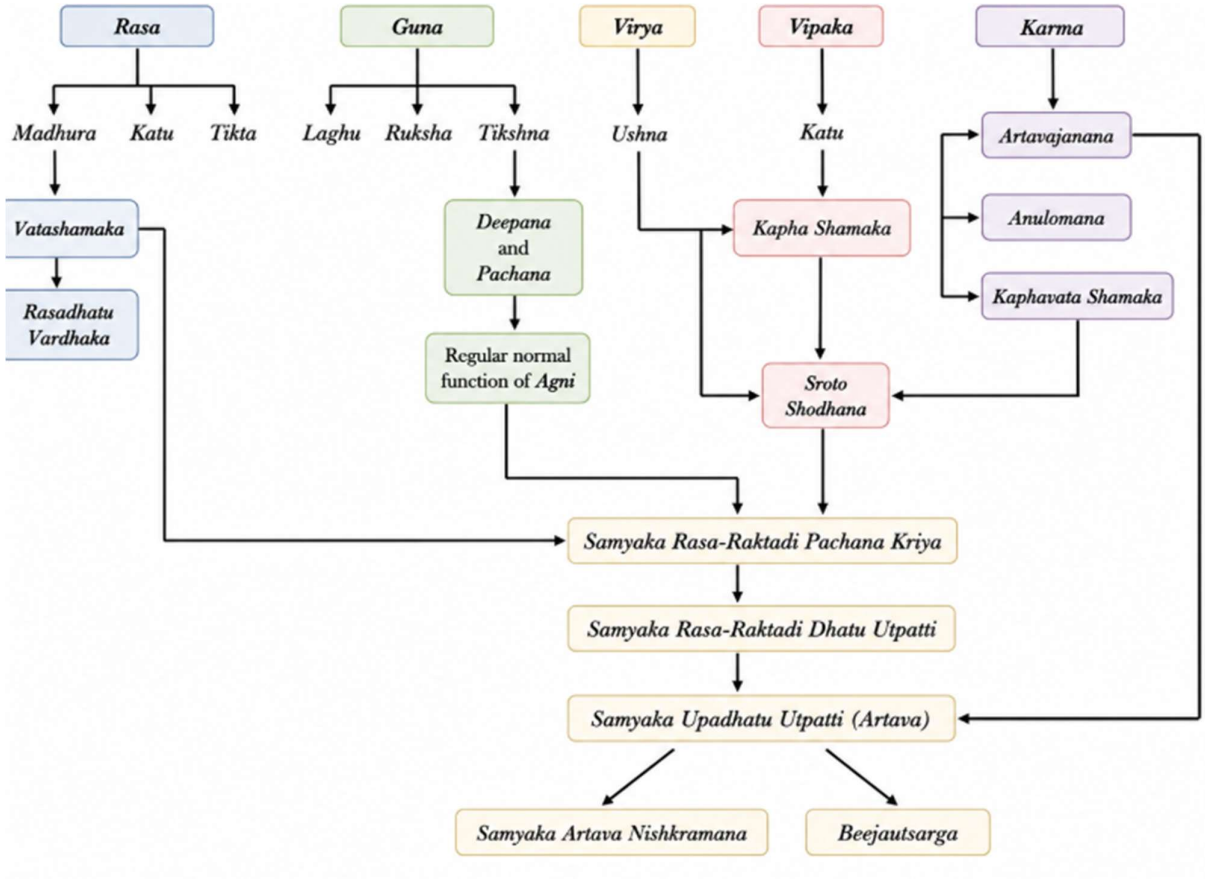


Fig No.2 Mode of action of Shatapushpa in PCOS

CONCLUSION

Thus present case study concludes that the holistic approach of *Ayurveda* system of medicine gives best result in PCOS. *Lashuna Churna* shows significant improvement in menstrual cycle regularity and reduction of acne, indicating its beneficial role in the management of PCOS.

Shatapushpa Ghana Vati shows mild improvement in menstrual cycle regularity and acne in the management of PCOS.

Lashuna Churna shows more effective than *Shatapushpa Ghana Vati* in the management of PCOS.

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