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Research Article

A RANDOMIZED CONTROLLED CLINICAL STUDY OF *CHANDRASHOORPAYAS* (GARDEN CRESS SEED PORRIDGE) AS DIETARY SUPPLEMENT FOR LACTATING MOTHERS

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ABSTRACT

In India many dietary supplements are given to lactating mothers for sustained and ample milk to nourish their baby. *Chandrashoora Payas* (Garden cress seeds porridge) is one such recipe given to nursing mothers to increase lactation. **Objective:** This study is planned to assess the role of *Chandrashoor Payas* as a dietary supplement in lactation deficiency (*Stanyakshaya*), taking control group of *Shatavari* Powder and milk to ascertain which is better. *Shatavari* powder is taken as a control group since it is a clinically proven galactagogue medicine in Ayurveda. **Material and Methods:** Total 64 lactating mothers diagnosed with lactation deficiency were screened for clinical trial, out of which 60 patients fulfilled the inclusion criteria and included in the trial. Selected patients were divided randomly in two groups by a simple random method. Study group was administered *Chandrashoora Payas* 100ml in morning; and the control group was with 5gm *Shatavari* powder with 100ml milk for 45 days. Follow up visit was on every 15th day. Estimation of milk production and infant weight gain were assessed by comparing difference in grades.

Observations and Results: Study revealed that both *Chandrashoorapayas* and *Shatavari* and milk produced significant improvement $p < 0.001$ in most of the variables and were comparable in reliving all the symptoms of lactation deficiency. On comparison both the drugs show similar effect.

Conclusion: No adverse effects were observed in the trial group, as safety parameters were within normal limit during the study and overall compliance to the treatment was good. Both the interventions were comprehensively effective in management of lack of lactation. *Chandrashoorapayas* is a dietary supplement which gives similar results as *Shatvari* which is a medicine.

KEYWORDS: Lactation, Dietary supplement, *Chandrashoorapayas, Shatavari,* lactational deficiency, *Stanyakshaya*.

INTRODUCTION

The basic tripod of health in Ayurveda *is Ahar, Nidra* and *Brahmacharya*. (Diet, sleep and celibacy)[1]. Out of three, diet is considered of utmost importance. Diet can be a causative factor for disease as well as management of disease. Diet is said to be *Mahabhaishajya* or supreme medicine by Acharya Kashyapa.[2] In new born babies breast milk is the ideal nourishment till the age of 6 months. Breast feeding apart from nourishment promotes emotional and physical bonding in mother and child. It also improves immunity, promotes intelligence and psychomotor functions. Approximately 300ml of lactation daily is considered as adequate by 5th day and 480ml by 10th day. If it is in fewer amounts then baby will not get nourishment adequately and such condition is clinically considered as lactation deficiency. In Asian countries prevalence of this problem is around 30 to 40%[3].

Shatavari is a proven galactagogue drug mentioned in Ayurvedic texts[4]. It is prescribed by Ayurveda practitioners regularly to improve lactation. No other milk is compared to mother's milk.[5] Ten medicinal herbs like roots of *Virana, Shali, Shshtika, Ikshuvalika, Darbha, Kushakasha, Gundra, Itkatakand* and *Trina* are mentioned in *Stanyajanana* (Lactation stimulant) group[6]. In *Shodhala Nighantu, Chandrashoora* (Garden cress seed) is considered as lactation stimulant.[7] However, in many parts of India many recipes are included in nursing mothers diet to improve and sustained lactation. *Payas*

recipe[8] similar like porridge is prepared and included in post-natal diet. To name a few, Porridge are prepared of *Bajra* or Rice or Poppy seeds or *Chandrashoora* (seeds of Garden cress) also known as *Haliv* in Marathi. In *Bhavprakasha, Chandrashoora* is explained as strength promoter.[9] Various animal and clinical studies for galactagogue activity of *Shatavari* are carried out over a period of time proving its lactogenic activity[10-13]. In one analytical study *Chandrashhoor* (Garden cress seeds) were quantitively analyzed in different forms for macro and micro nutritional principles[14]. Till date no clinical study has been conducted to evaluate the galactagogue property of *Chandrashoor*. Hence it is necessary to collect documentary evidence of these dietary supplements to study galactagogic activity clinically. Present study is a step to collect evidence based data of *Chandrashoorpayas* in lactation deficiency clinically.

Institutional Ethics committee approval was obtained on 11/04/2015 vide letter no. AY/PG/149/ 2014-15/IEC

AIM

1. To assess the role of *Chandrashoorpayasa* as a dietary supplement for lactating mothers.

OBJECTIVES

1. To observe the role of *Chandrashoorpayasa* as a dietary supplement *(Pathyakalpana)* in lactating mothers
2. To collect the detail information about *Chandrashoor*, *Payasakalpana*, from Ayurveda and modern literature.

MATERIALS AND METHODS

Study design: The recruitment and randomization of participants for randomized controlled trial based on consolidated standards of reporting (CONSORT) guidelines. 64 lactating mothers were screened for eligibility. Out of which 4 were excluded as they did not meet inclusion criteria. Included females were divided by simple randomization and single blinding into two groups irrespective of cast and religion.

Informed consent was obtained and randomly assigned in either in study group or in control group. Study group received *Chandrashhorapayas* 100ml for 45 days and controlled group received *Shatavari* powder 5gm with 100ml milk for 45 days.

Ethics committee approval was taken before enrolling the subjects.

Informed consent- Written valid, Informed consent of the patient was taken prior to the commencement of the clinical trial.

Materials

Intervention group: *Chandrashoor beej* (Garden Cress seeds)

Latin name: Lepidium= resembling cress or pepper wort Sativum= cultivated

Vernacular name: Marathi- *Haliv*, English name – Garden cress

Properties as per Ayurved: Taste: Bitter, Pungent

Potency: Hot

After digestion taste: Pungent

Effect on *Doshas*: Pacifying *Vata* and *Kapha*

Effect on *Dhatus*: *Rasa, Rakta, Mamsa, Meda* and *Shukra* aggravating.

Chemical composition: Garden cress contains significant amount of Iron, Calcium and Folic acid in addition to Vitamin A and C. It contains higher amount of protein (25%). Most abundant amino acid is glutamic acid among essential amino acids, flavonoids, sterols as chief phytochemical constituents, they contain phytochemical's which mimic estrogen to some extent. Intake of these seeds stimulates milk production in lactating mothers.[15]

Control drug: *Shatavari*

Latin name: Asparagus racemosus

Properties as per Ayurved: Taste: sweet, Bitter

Potency: cold

After digestion taste: sweet

Effect on *Doshas*: Pacifying *vata* and *pitta*

Effect on *Dhatus*: *Rasa, Rakta, Mamsa, Meda* aggravating,

Chemical composition: The major bioactive constituents of *Asparagus* are a group of steroidal saponins. This plant also contains vitamins A, B_1, B_2, C, E, Mg, P, Ca, Fe, and folic acid. Other primary chemical constituents of *Asparagus* are essential oils, asparagine, arginine, tyrosine, flavonoids (kaempferol, quercetin, and rutin), resin, and tannin. *Shatavari* alsoc ontains Albuminous matter, mucilage and cellulose, chlorides, acetate and phosphate of potash, malate's etc. Roots are highly nutritive, tonic, demulcent, galactagogue, aphrodisiac and antispasmodic [15].

Method of preparation of *Chandrashoora Payas* (Garden cress Porridge): ½ tablespoon of Garden cress seeds roasted in 1 teaspoon of cow's ghee till they give nice aroma. Then 200ml of cow's milk was added to it and boiled to reduce it to half the quantity. 1 teaspoon sugar was added to it. Fresh *Payas* was prepared every day[16]. Mode of administration of the drug was given in Table No:1.

Patients were given the drug orally in the following way.

Table 1: Mode of Administration of drug

	Group A	**Group B**
Pathya Kalpana	*Chandrashoor Payasa*	*Shatavari* powder (5gm) with milk
Dose	100ml	100ml
Time of administration	Before meal	Before meal
Duration	45 days	45 days

Assessments and outcomes:

Each patient was followed after every 15 days. Initially all the parameter's- in mothers- lactation failure, lactation cessation, less milk ejection, less breast feeding frequency, breast engorgement and for babies, weight of baby, cry for feeding, sleep, bowel opening were noted thoroughly. Change in the parameters in each follow up were observed and noted in the case paper. Primary and secondary endpoints were described in the following sections.

Outcome measures: A four-point grade scale was used to assess the change in the symptoms of lactation deficiency in mothers and three-point grade scale was used to assess the parameters in babies at base line and the endpoint of 45 days.

Primary outcome

Percentage of females who achieved reliefs in symptoms were assesses at baseline and after 45 days, using a four-point grade scale.

Secondary outcome:

- Relief in symptoms of mother like lactation failure- cessation of milk formation, improvement in milk ejection, breast feeding frequency, breast engorgement were assessed at baseline and after 45 days.
- For baby, improvement in weight, sleep, cries for feeding and ease in bowels were assessed at baseline and after 45 days.

Table 2: Assessment Criteria

Sr. no.	**Subjective parameter**	**Assessment**
	For mother	
1.	Assessment of lactation failure, cessation of milk formation, small size of breast	Three signs are present- it is grade 3 Two signs are present- it is grade 2 One sign present – it is grade 1 No sign present – it is grade 0
2.	Assessment of milk ejection	No ejection- grade0 Drop by drop- grade1 Stream like-grade 2 Force full- grade 3
3.	Assessment of breast-feeding frequency	Feeding 0-2 times/ day-grade 0 Feeding 3-5 times/day-grade 1 Feeding 6-8 times/day-grade 2 Feeding 9-12 times/day-grade3
4.	Assessment of breast engorgement	No engorgement-grade 0 Slight engorgement –grade1 Moderate engorgement- grade2 Severe engorgement with pain- grade3
	For baby	
1.	Baby weight	No weight gain-grade 0 100 to 175gm per week-grade 1 Above 175gm per week-grade 2
2.	Sleep of baby	1-2 hours' sleep-grade 0 2-3 hours' sleep-grade 1 3-4 hours' sleep-grade 2
3.	Cry for demand feeding	Demand feeds before every 2 hrs.- grade 2 Demand feeds after every 2-3 hrs- grade 1 Demand feeds after every 3-4 hrs- grade 0
4.	Bowel opening	Hard stool: grade 2 Watery in consistency :grade 1 Semi solid inconsistency normal color up to 5-6 Times in a day: grade 0

Statistical Analysis

SPSS version 15.0 was used to analyze the data. The Mann-Whitney U-test was applied for detection of intergroup differences and the Wilcoxon test used for intergroup differences for the variable. The results were analyzed statistically and the values of p <0.001 were considered as highly significant.

RESULTS

Socio demographic information of study participants

Table 3: Distribution of patients according to age group

Age in yrs	Trial Group	Control Group	Total	%
20 - 24	5	9	14	23.3
25 - 29	24	21	45	75.0
30 +	1	0	1	1.7
Total	30	30	60	100

Out of 60 patients, number of patients found in age group 20- years were 14 (23.3%). In 25+ age groups they were 45 (75.0%). In 30+ groups there was 1 patient (1.7%).

Table 4: Distribution According to Occupation:

Occupation	Trial Group	Control Group	Total	%
House wife	12	10	22	36.7
Service	12	13	25	41.7
Laborer	6	7	13	21.6
Total	30	30	60	100

Occupation wise 60 patients were found in three groups that is housewife, service and laborer. Out of 60 patients, 22 (36.7%) were in housewife group. 25 (41.7%) were in service group. 13 (21.6%) were in laborer group.

Table 5: Distribution of Patients According to Socio Economic Class

Socio Economic Status	Trial Group	Control Group	Total	%
High class	8	6	14	23.3
Middle class	12	12	24	40.0
Low class	10	12	22	36.7
Total	30	30	60	100

Socioeconomically out of 60 patients, 14 (23.3%) patients were from in higher class. 24 (40%), patients were from middle class and 22 (36.7%) patients were from low class.

Table 6: Distribution of patient according to parity

Parity	Trial Group	Control Group	Total	%
Primi	15	15	30	50
Multi	15	15	30	50
Total	30	30	60	100

Out of 60 patients in study maximum patients were found Primi para 15, second para and lastly multipara are 15 patients were found in number.

Statistical observations in clinical symptoms of both the groups

The study group received *Chandrashoorapayas* as intervention which is a dietary supplement and control group received *Shatavari* powder which is established galactagogue drug. The results observed in both the group were as follows:

Table 7: In the symptoms of Lactation failure (cessation of milk formation)

Lactation failure	Day 0		Day 45		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-Trial	2.07	0.640	0.30	0.535	85.5	4.950	<0.001 HS
Group-Control	2.37	0.490	0.13	0.346	94.5	5.002	<0.001 HS

Table 8: Statistical analysis of symptom Lactation failure

Lactation failure	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	1.77	0.57	3.104	0.002 Sig
Group-Control	2.23	0.50		

In Trial group before treatment the mean score was found 2.07 and it came down to 0.30 after treatment, i.e., relief was 85.5% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z).

Similarly, in group-B on before treatment the mean score was found 2.37 and it came down to 0.13, after treatment i.e., relief was 94.5% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z). This indicates treatment given to Trial group is effective but treatment of Control group is more effective.

Table 9: In Milk Ejection Symptom

milk ejection	Day 0		Day 45		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-Trial	0.97	.615	2.67	.547	4.956	<0.001 HS	Group-Trial
Group-Control	0.77	.626	2.80	.484	4.941	<0.001 HS	Group-Control

Table 10: Statistical analysis of symptom milk ejection

Milk ejection	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	1.70	0.53	2.121	0.034 Sig
Group-Control	2.03	0.61		

In group-Trial before treatment the mean score was found 0.97 and it increases to 2.67 on after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z). Similarly in group-Control on before treatment the mean score was found 0.77 and it increase to 2.80 on after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z). This indicates treatment given to Trial group and Control group are equally effective.

Table 11: In breast feeding frequency

Breast feeding frequency	Day 0		Day 45		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-Trial	1.23	.430	2.77	.430	4.932	<0.001 HS	Group-Trial
Group-Control	1.30	.466	2.80	.407	4.930	<0.001 HS	Group-Control

Table12: Statistical analysis of symptom Breast feeding frequency

Breast feeding frequency	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	1.53	0.51	0.256	0.798 NS
Group-Control	1.50	0.51		

In Trial group before treatment the mean score was found 1.23 and it increases to 2.77 on after treatment that is effect was found statistically highly significant by Wilcoxon signed ranks test (Z) Similarly, in Control group before treatment the mean score was found 1.30 and it increase to 2.80 on after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z).

This indicates that treatment given to Trial group and Control group is equally effective.

Table 13: In Breast Engorgement

Breast engorgement	**Day 0**		**Day 45**		**% Relief**	**Wilcoxon Signed Ranks Test Z**	**P**
	Mean score	**Sd**	**Mean score**	**Sd**			
Group-Trial	1.43	.504	0.20	.407	86.0	5.069	<0.001 HS
Group-Control	1.47	.507	0.13	.346	91.2	4.983	<0.001 HS

Table 14: Statistical analysis of symptom Breast engorgement

Breast Engorgement	**Mean difference score**	**Sd**	**Mann-Whitney Z**	**P**
Group-Trial	1.23	0.43	0.852	0.394 NS
Group-Control	1.33	0.48		

In Trial group before treatment the mean score was found 1.43 and it decreases to 0.20 on after treatment i.e., relief was 86.0% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z). Similarly in Control group on before treatment the mean score was found 1.47 and it decrease to 0.13 on after treatment i.e., relief was 91.2% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z). This indicates that treatment given to Trial group is effective and Control group is more effective.

For Babies

Table15: Change in weight

Change in weight	**Day 0**		**Day 45**		**% Relief**	**Wilcoxon Signed Ranks Test Z**	**P**
	Mean score	**Sd**	**Mean score**	**Sd**			
Group-Trial	0.47	.507	1.80	.406	4.983	<0.001 HS	Group-Trial
Group-Control	0.43	.504	1.90	.305	4.932	<0.001 HS	Group-Control

Table 16: Statistical analysis of symptom Change in weight of baby

Change in weight	**Mean difference score**	**Sd**	**Mann-Whitney Z**	**P**
Group-Trial	1.33	0.479	1.045	0.296
Group-Control	1.47	0.507		

In Trial group before treatment the mean score was found 0.47 and it increases to 1.8 on after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z) Similarly, in Control group on before treatment the mean score was found 0.43 and it increase to 1.9 on after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z).

This indicate treatment given to Trial group and Control group is equally effective

Table 17: **Regarding bowel opening**

bowel opening	**Day 0**		**Day 45**		**% Relief**	**Wilcoxon Signed Ranks Test Z**	**P**
	Mean score	**Sd**	**Mean score**	**Sd**			
Group-Trial	0.93	.740	0.17	.461	81.7	3.758	<0.001 HS
Group-Control	1.17	.379	0.10	.305	91.5	4.866	<0.001 HS

Table 18: Statistical analysis of symptom bowel opening of baby

Bowel opening	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	0.77	0.77	1.833	0.067 NS
Group-Control	1.07	0.52		

In Trial group before treatment the mean score was found 0.93 and it decreased to 0.17 after treatment i.e., relief was 81.7% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z). Similarly, in Control group before treatment the mean score was found 1.17 and it increase to 0.10 after treatment i.e., relief was 91.5% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z).

This indicates that treatment given to Control group is effective and Trial group is more effective.

Table 19: Sleep of baby

Sleep of baby	Day 0		Day 45		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-Trial	0.33	.479	1.80	.407	4.932	<0.001 HS	Group-Trial
Group-Control	0.47	.507	1.90	.305	4.939	<0.001 HS	Group-Control

Table 20: Statistical analysis of symptom sleep of baby

sleep of baby	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	1.47	0.51	0.257	0.797 NS
Group-Control	1.43	0.50		

In Trial group before treatment the mean score was found 0.33 and it increase to 1.80 after treatment that is effect was found statistically highly significant by Wilcoxon signed ranks test (Z).

Similarly in control group before treatment the mean score was found 0.47 and it increase to 1.90 after treatment i.e., effect was found statistically highly significant by Wilcoxon signed ranks test (Z).

This indicates that that treatment given to Trial group and Control group is effective.

Table 21: Cry of baby

Cry of baby	Day 0		Day 45		% Relief	Wilcoxon Signed Ranks Test Z	P
	Mean score	Sd	Mean score	Sd			
Group-Trial	1.43	.504	0.13	.346	90.9	5.007	<0.001 HS
Group-Control	1.50	.509	0.10	.305	93.3	4.949	<0.001 HS

Table 22: Statistical analysis of symptom Cry of baby

sleep of baby	Mean difference score	Sd	Mann-Whitney Z	P
Group-Trial	1.30	0.47	0.805	0.421 NS
Group-Control	1.40	0.50		

In Trial group before treatment mean score was found 1.43 and it come down to 0.13 after treatment i.e., relief was 90.9% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z).

Similarly in Control group before treatment the mean score was found 1.50 and it come down to 0.10 after treatment i.e., relief was 93.3% and reduction was found statistically highly significant by Wilcoxon signed ranks test (Z). This indicates that treatment given to Trial group and Control group is effective

DISCUSSION

General Socioeconomic observations of present study revealed that most of patients belong to 25-29 yrs. age group (45) which is the child bearing age and were working women (service and laborer 63.3%) with family responsibility, physical work load, stress,

and irregular food regimen. These factors affect their health and probably are the reason for lactation deficiency. Parity wise maximum patients were found to be first para. It is noticed that in such patients, lack of knowledge of breast-feeding, fear and ignorance about the benefits of mother's milk lead to lactation deficiency.

Breast milk is an integral part of an infant's nutrition. A detailed study of available literature, both in Ayurveda as well as the modern science, was carried out. Varieties of therapies were administered to correct the lactation deficiency. *Charaka*, *Sushruta, Vagbhata* and other ancient texts have mentioned a group of medicinal herbs which increase lactation. They are grouped as *Stanyajanana* (Lactation stimulant*). Shatavari* is included in this group. *Shatavari* has *Madhurarasa* and *Sheetaguna*. It stimulates milk production from an Ayurvedic perspective. It has been studied by many researchers and was observed that its roots are galactagogue. Hence, *Shatavari* improves milk production. The randomized double blind clinical trial by Mradu Gupt and Badri Shaw on lactating mothers exhibited significant galactagogue activity of *Shatavari*[17]. In another study by Swati mohite and others *Shatavari kalpa* proved to be significantly effective in improving breast milk secretion in post caesarian females[18]. The chemical ingredients of *Shatavari*, steroidal saponin have estrogenic activity which results in stimulation of prolactin hormone, which is responsible for lactation. The results obtained from control group of present study justify the objective of taking *Shatavari* as control group medicine. The observations revealed that *Shatavari* Powder with milk is effective in improving breast milk secretion in deficiency or cessation of lactation. It is beneficial in symptoms like breast engorgement, milk ejection, feeding frequency in mothers. It ultimately shows significant effect in babies' weight, demand for feeding, sleep and bowel opening.

On the other hand, Garden cress seeds of *Chandrashoora* were not analyzed for their galactagogue activity till now. In *Sodhal nighantu,* one of the ancient texts of Ayurveda, *Chandrashoor* (Garden Cress seeds) is said to be *Stanyapushtikruta* (Improves lactation). *Chandrashoora* is considered as *Balya* or strength promoting. In one of the analytical studies by Nidhi Agarwal and others, nutritional evaluation of Garden cress seeds was done. It was found to be containing good amount of fat and protein as well as calcium, phosphorous and iron. As per Indian Materia Medica, seeds of Garden cress have properties like demulcent, aphrodisiac, carminative, galactagogue.

Payas Kalpana or porridge is mentioned in *Kritannavarga* (Recipe group). Usually *Payas* is prepared from grains like rice or wheat cooked in milk with added sugar. This is a dietary delicacy which is similar to the recipe of porridge. It is easy to prepare and is highly nutritious. The results of study groups provide evidence supportive to the above mentioned properties. The observations reveals that *Chandrashoora Payas* is similar to *Shatavari* in treating symptoms of lactational deficiency like milk ejection, breast engorgement, feeding frequency in mothers and which subsequently improved symptoms like low weight, inadequate sleep, cry for demand and bowel opening in babies. The results of present study showed that use of *Chandrashhorapayas* as nutritional supplement had a definite positive effect. However, further study is required to assess the effect of this preparation on prolactin levels of blood.

CONCLUSION

In this study *Chandrashoorapayas* showed good results in relieving the subjective parameters in mothers, viz**.** lactation failure, cessation of milk formation, milk ejection, breast feeding frequency, breast engorgement, in babies improvement in weight, sleep of baby, cry for demand feeding, bowel pattern after one and half months. Both the groups showed significant improvement in all the parameters.

However statistical tests states that there is no much significant difference between the groups in relieving the symptoms

No adverse effects were observed in trial group, as safety parameters were within normal limit during the study and overall compliance to the treatment was good. On the basis of above observation, it may be recommended that this diet supplement is safe and effective in the management of lactational deficiency (*Stanyakshaya*). This study provides substantial evidence that *Chandrashoorapayas* can be used as a dietary supplement for improvement of breast milk secretion. However, to see the effect on prolactin secretion further studies are necessary.

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