Original Article

The efficacy of diet supplemented with *Lepidium sativum (Chandrashoor)* on expressed breast milk volume in hypogalactic mothers – An open-label noncross-over randomized trial

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Abstract

Background: Hypogalactia is the common condition, especially in preterm deliveries. Some herbs in Indian medicines such as *Lepidium sativum L.* (*L. sativum*) have galactogogeus effects. The galactogogeus effect of *L. sativum (Chandrashoora)* has not been quantified in randomized control trials in humans till date. We intend to study the galactogogeus effects of *L. sativum* in hypogalactic mothers through an open-label noncross-over trial. **Materials and methods:** The target population were women who had delivered infants <32 weeks gestation with no lower limit to gestational age and their babies admitted in neonatal intensive care unit for prematurity. Participants who were taking specific drugs as a result of their primary illnesses, such as chemotherapy, sedatives, or antiseziure medications, were excluded. The randomization was achieved with computer-generated random number table. The experimental group ($n = 23$) received 2.5 g of *L. sativum (Chandrashoora*) seeds each day, soaked in luke warm water for half an hour in the morning, along with instructions about how to take the seeds. The control group did not receive any medication ($n = 23$). According to the institutional procedure, participants were trained to express breast milk six times using a breast pump. The amount of milk extracted was measured every day for 28 days. The difference in milk production between the two groups at 28 days was the primary endpoint. The secondary endpoint was to asses if any of the trial medicines had any adverse drug effects. **Results:** A total of 46 participants completed the study till 28 days. In both groups, demographic factors were comparable. The study group surpassed the control group in terms of breast milk volume slowly and reached statistical significance ($P = 0.00002$) after 28 days of therapy. No adverse drug effects were reported by the participants. **Conclusion:** There was statistically significant improvement in breast milk production at 28 days in hypogalactic mothers in the experimental group. *L. sativum* can be used as cheap alternatives to costly medicines to improve lactation with minimal costs and no adverse drug reactions.

Keywords: *Balya, Chandrashoora,* hypogalactia, *Lepidium sativum* seeds, *Pushtivardhaka, Stanyakshaya*

Introduction

Breast milk is extremely vital in a child's development. It serves as a nutritional link between the mother and the child.[1,2] For a period of time, the newborn infant thrives only on the mother's milk. Hypogalactia is a condition in which a woman has difficulty producing enough milk for her baby, and it is commonly found in premature deliveries. Hypogalactia has been found to be prevalent in 16%–49% of premature births in several studies. A report published by the WHO titled "Born Too Soon: The Global Action Report on Preterm Birth" showed India having burden of 24% of global preterm births.[3] The majority of these new-borns can be saved if they are breastfed properly, and hypogalactia is a hindrance to this. *Lepidium sativum* has *Bruhaniya* property (nourishing)

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as it is called *Balapushtivardhanam*.[4] It is utilized in many Indian families during the postnatal period to increase the quality and quantity of breast milk produced by new mothers. *L. sativum* has *Katu and Tikta Rasa (pungent and bitter taste), Katu Vipaka (pungent transformation), Ushna Veerya (hot potency), Snigdha, Picchila Guna (unctuous and viscous property). With all these properties, it acts as Balya () and Vatashamaka* (), so it is used in *Prasutiuttara Avastha* (postnatal period). It has a high nutritional value as it is also rich in iron and proteins and used in the postnatal period for new mother as it gives her strength and stamina which eventually increases the breast milk production.[5] The galactogoggue effect of *Lepidium sativus* seeds has not been quantified in randomized control trials in humans till date. In this context, we propose to study the galactogogeus effect of *L. sativum* seeds in postnatal mothers through an open-label non crossover trial.

Materials and methods

This study was conducted in association with tertiary care medical college hospital between September 2020 and December 2020. The inclusion criteria were women who had delivered infants <32 weeks gestation with no lower limit to gestational age and their babies admitted in neonatal intensive care unit for prematurity. The exclusion criteria were women who could not breast fed her babies in view of associated medication use (chemotherapy, sedatives, and anti-seziure medications). Written, valid and informed consent was obtained from all participants. The protocol of the study was approved by the Institutional Ethics Committee as well as Clinical Trial Registry with number CTRI/2020/11/029185. The raw trial drug was purchased online from www.ayurvedacart.com in the form of *Chandrashoora* raw herb. The herb was processed in accordance with GMP guidelines. It passed purity test with heavy metal content <4 PPM according to the manufacturer data.

Study design

It was an open-label trial. The research included parturient who had preterm infants (<32 weeks gestation) with hypogalactia. The randomization was done using a computer-generated random number table and preterm deliveries were sorted into experimental group and control groups as the deliveries occurred at the institution over a period of time. The participants were divided in two groups consisting 23 participants in each group: Group A (control group) and Group B (experimental group). The research substance was known to both the primary investigator and the participants. The study medicine was not administered to the control group.

The experimental group (Group B $n = 23$) participants received 2.5 g *L. sativum* seeds *(Chandrashoora*) daily soaked in Luke warm water for half an hour in the morning every day at 7 am on empty stomach along with instructions to take the seeds. The seeds were supplied to mothers every week till 4 weeks to check compliance. Control group (Group A $n = 23$) patients did not receive *L. sativum* seeds but received breast pump.

Baseline demographic data were collected and recorded (day 0). Mothers were taught to express the breast milk according to institutional practice. They received Pigeon Manual Breast Pump. They stopped milk extraction after last drop, if there was no milk or after 5–10 min. Staff in neonatal ICU supported and trained the mothers about expressing breast milk manually and trained them to keep record daily in provided sheet. Breast milk was extracted 6 times a day in both the groups. The volume of milk extracted was recorded every day till 28 day. The CONSORT flow diagrams summarizes the design, procedures, and stages of the study [Figure 1].

Study end points

The primary endpoint was difference in milk production at 28 days with the administration of intervention drug in the experimental group as compared to the control group.

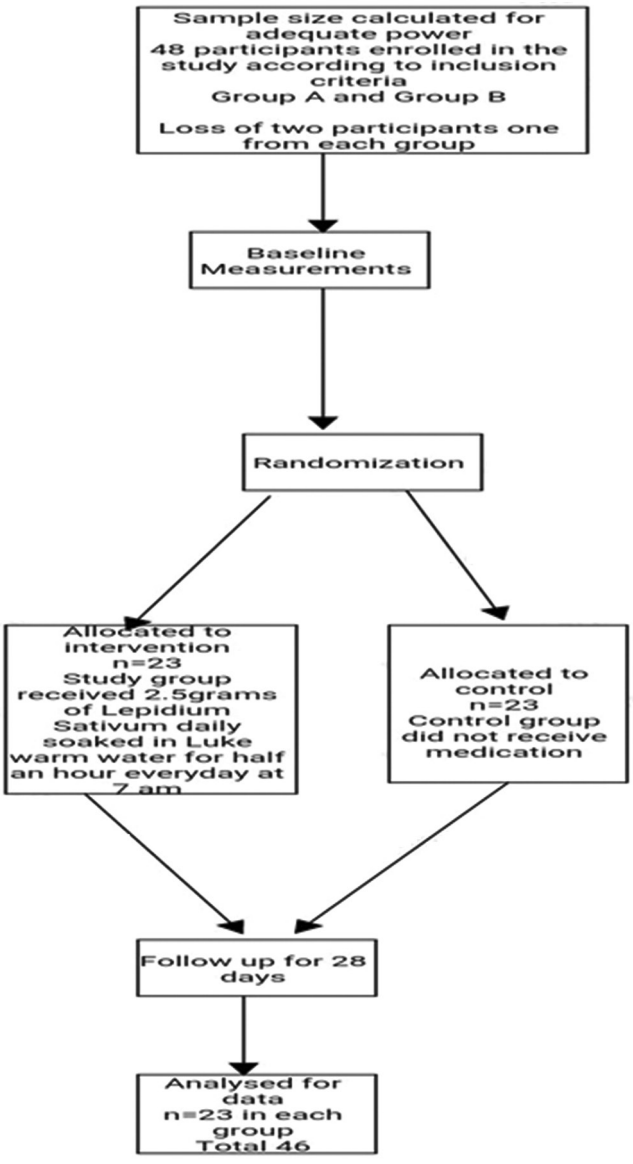

Figure 1: Consort flow chart for the study

The secondary endpoint was the occurrence of any adverse drug reactions associated with study medication.

Sample size calculation

If we set to alpha = 0.05 (one tailed), the type 1 error risk (1-Beta) =0.80 the power of study, and assume variation of milk production has standard deviation of 200, we found out minimum study size of 21 participants per group. Forty-six participants were randomized to 1:1 study drug group and control group.

Statistical analysis

Student's *t*-test for the independent samples was used to test between the difference in variation in milk production between day 0 and days 28. Shapiro–Wilk test was calculated to test the normality of sample population. It was decided to reject the hypothesis of normality when the $P \leq 0.05$. As per secondary endpoint was concerned, they were noted in pro forma handed over to the participants to record any adverse drug reactions if any. The analysis was carried out using the IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp.

Results

A total of 48 participants were enrolled in the study. There was a loss of two participants because of baby death and non-availability of data, one from each group. A total of 46 parturients completed the study as per the protocol. Control group $n = 23$ and study group $n = 23$.

The mean age of parturient in both groups was similar with a nonsignificant *P* value. Nearly 1/3 population in both groups were graduated and above, while 2/3 population were below graduation. It was equally distributed between illiterate, primary, and middle school groups. Most were gravid 2nd and 3rd and there was less prevalence of prematurity in primigravida. The gestational age of parturient was higher in both groups showing mean age in their 30s. Cesarean delivery was there in half population in both groups indicating other diseases complicating pregnancy and needing to terminate the pregnancy, although these data were not documented in the study [Table 1].

Mean breast milk production was low in both groups as was the study protocol. Day 0 breast milk volume was not significantly different in both groups according to *P* value. The treatment was started in the study group and slow progress was seen in volume of breast milk with slightly higher values for breast milk volumes in the study group, although the values were not significant till the 21st day. On the 28th day, the breast milk volumes were significantly differed between the two groups with *P* values as low as 0.0002 [Table 2].

There are a few confounders in this study. The mother's nutrition was not monitored and may not have followed a comparable pattern in both groups. The baby's weight was not taken into account during randomization, which might lead to confounding bias. The third bias might be linked to family stress patterns involving mothers, which could also impact breast milk supply.

Table 1: Demographic data of cases of both groups

Variable	Group A ($n=23$)	Group B ($n=23$)	*P*
Age of the parturient	24.22±2.4	23.22±2.1	0.4 (NS)
Education of the mother			
Illiterate	8	10	0.753 (NS)
Primary	10	6	
Secondary	2	3	
Graduation and above	3	5	
Gravida	2.1	1.8	0.334 (NS)
Gestational age	30.2	31.2	0.5452 (NS)
Cesarean delivery	12	16	0.22628 (NS)#

*NS, all values are in mean±SD, *P* value significant if>0.05, The test used was the Chi-square test for the categorical variables, #*P* value here is calculated from z score for two population proportions. NS: Not significant

The adverse drug events were not observed in both groups. The only issue the research participants mentioned was the exceedingly bland flavor and taste of trial drug, which was occasionally unpleasant.

The data were also analyzed for normality by Shapiro–Wilk Test. The result showed skewness of 0.240 at significance level of 0.5 (alpha) while skewness shape was potentially symmetrical. (Normality $P = 0.093$.)

Discussion

L. sativum (Chandrashoora) is included in *Charturbeeja* (group of four seeds) as it is one ingredient of a compound of four seeds. The seeds of *Chandrashoora* have medicinal properties as stated in Bhavprakash Nighantu.[4] It is said to be "*Balapushtivardhanam"* means it gives strength.

Hypogalactia is a common condition affecting nearly 16%–49% of the population in India and worldwide. There is no association of hypogalactia with socioeconomic status of the population, as suggested by our data. Galactogogeus are medicines that improve milk production in nursing mothers. All these drug act through interaction with dopaminargic receptors and increasing prolactin levels. Many of these drugs have a dramatic side effect profile which needs to be evaluated on continuous basis. There is a constant need to find out cheap alternative which heals the microenvironment of body physiology. In this search of such alternative, *L. sativum (Chandrashoor*) is one herb which is not evaluated for hypogalactia in human subject, although Ayurveda knows this drug since the Vedic period and mentions about its activity in detail. *L. sativum* seeds were studied in animal models. The seeds contain many alkaloids and flavonoids. The increase in mammogenic hormonal levels has been proven in animal models secondary to action of bioactive flavonoids on mammary glands.[5] The animal models prove that the treatment of *L. sativum* seeds leads to growing of the dimension of lobules and an abundance of vesicles[6,7] with branching dilated alveoli for all animals in virgins, pregnant, and lactating rats.

Table 2: Breast milk production in the cases of both groups

Variable	Group A	Group B	*t*	*P*
Breast milk (ml) on day 1	53.0434±14.393	66.333±22.638	1.200	0.12112
Breast milk (ml) on day 7	123.4±17.67	123.2±20.304	−0.272166	0.39391
Breast milk (ml) on day 21	306.041±16.21	305.625±16.82	−0.641198	0.26374
Breast milk (ml) on day 28	485.416±101.736	552.6±138.096	4.934933	0.00002*

*Clinically significant $P>0.05$, The test used was *t*-test for two dependent means. All values of breast milk are in milliliters

There are quite a few animal studies of *L. sativum* where it has been evaluated in animal models producing excellent results.[8-10]

This is probably first of its kind noncross-over parallel group human trial of *L. sativum* seeds for hypogalactia. Our trial shows the effect of *L. sativum* took nearly 4 weeks to act. There are not many human trials about galactogogeus effect of *L. sativum.* In the animal studies done prior, the morphometrical analysis shows increase of acinar diameter, in experimental rats, is most probably reflecting the active condition of mammary gland. When we compare estrous cycle of rat's verses humans, it is self-explanatory to need 28 days duration for the increase in milk production.

Our data show that the drug can be supplemented to routine medication as a galactogogeus.

Limitation of the study

The study contains a few limitations. The first limitation is power, which in our instance was set at 80%. This is a single-center study, and the participants came from a wide range of socioeconomic and cultural backgrounds, as well as different dietary habits. This may have an impact on nutritional status and as a result, breast milk production. Again, a small number of new-borns were retained in intensive care, while a smaller number were discharged after attaining sufficient weight. As a result, infant separation in a few individuals may have an impact on breast milk production.

Conclusion

L. sativum is effective galactogogeus agent. There was statistically significant improvement in breast milk production at 28 days in hypogalactic mothers. *L. sativum* seeds can be one of the cheapest alternatives to costly medicines to improve lactation with minimal costs and without any adverse side effects.

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Conflicts of interest

There are no conflicts of interest.

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