

**Randomized Controlled Trial of
Asparagus racemosus (Shatavari)
as a Lactagogue in Lactational
Inadequacy**

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Secondary lactational failure has been treated with galactagogues, especially metoclopramide, which improves lactation by increasing prolactin (PRL) levels. *Asparagus racemosus* (Shatavari), a herbal drug used for dyspepsia, is reported to have galactogogic effect(1). The present study was undertaken to study its effect on PRL and clinical galactogogic response.

Subjects and Methods

A multicentric, randomized, double-blind, placebo controlled parallel study was designed to observe a rise in serum prolactin (PRL) levels (primary outcome variable). The other variables studied included weight gain of infant, decrease in volume and frequency of supplementary feeds in those mothers who were

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supplementing milk to their breastfed infants. The mother's complaints during therapy were recorded and maternal SGOT, SGPT and alkaline phosphatase were measured before and 4 weeks after therapy.

Patient selection: Mothers who had delivered at term without complications and who, between 14-90 days post-partum, reported lactational inadequacy were screened for selection. Lactation inadequacy was defined as: (i) failure to regain infant's birth weight at 15 days of life, or (ii) infant weight gain of <15 g/day, or (iii) mother supplementing >250 ml/day of milk for infant feeding after 4 weeks of birth. Infants with malformations that could affect feeding or growth, infants with illness or mothers with severe illness or severe malnutrition were excluded from the study. All mothers included with the diagnosis of lactational inadequacy were motivated to exclusively breastfeed, and advised on position and frequency of feeds, adequate rest and nutrition. If after 1 week of exclusive breastfeeding the infant's weight gain was <15 g/day, the mothers were included in the trial. Informed consent was obtained before inclusion in the study.

Randomization: The mothers were randomized to receive either placebo or galactagogue in a dose of 2 tsf twice daily for 4 weeks. Both placebo and the galactagogue had similar color, consistency, taste and packing and were labeled as Drug A and B.

Each 100 g of the galactagogue contained *Asparagus racemosus* (Shatavari) 15.0 g, *Anethum soiva* (Sowa) 1.0 g, *Ipomea digitata linn* (Bidarikand)

1.0 g, *Glycyrrhiza glabra* (Mulethi) 1.0 g, *Spinacia oleracea* linn (Palak) 2.5 g, *Cuminum cyminum* (Safed jeera) 0.5 g, and *Panchatrinamol* 1.0 g. The active principle was Shatavari, root extract of *Asparagus racemosus*.

Prolactin estimation: 5 ml of maternal fasting blood sample was collected pre-nursing between 9 a.m. and noon by venipuncture into a clean vial before and 4 weeks after therapy. The sera was separated and frozen at -20° C and PRL was estimated within 2 months. Before the assay, samples were allowed to come to room temperature and mixed by gentle swirling or inversion. PRL levels were measured by immuno-radio-metric assay (coat-A-count prolactin IRMA) as per instructions of the manufacturers.

Statistical analysis: Data was evaluated using paired 't' and Student's 't' test, Chi-square test and Mann-Whitney U test.

Results

A total of 64 mothers were enrolled into the study; 32 being randomized into each of the two groups. Eleven (17.2%) mothers did not complete the trial.

The two groups were comparable with regard to maternal age, parity, age at entry

into study, birth weight and proportion of infants exclusively breastfed at entry (*Table I*). Twenty six mothers in the galactogogue and 23 in placebo group were offering supplementary feeds to their infants.

Table II provides the comparison of outcome variables for the two groups. The median PRL levels in the two groups before and after therapy were comparable. In both groups the PRL levels declined after therapy, but the decline in both groups were comparable. The frequency and volume of supplementary milk feeds and weight gain velocities were also comparable in the two groups. The within groups changes pre-and post-treatment for all the outcome variables were also comparable.

The groups were stratified by exclusive versus non-exclusive breastfeeding to observe for it's influence on PRL with the use of galactogogue. The median PRL levels post-treatment in galactogogue and placebo groups in exclusively breastfed (24 and 46 ng/ml, respectively) and non-exclusively breastfed groups (45 and 30 ng/ml, respectively) were comparable. There were no biochemical liver cell dysfunctions noted in any of the subjects in either group and nor were any significant side effects reported.

TABLE I—Baseline Characteristics of the Study Sample.

Characteristic	Galactogogue (n=32)	Placebo (n=32)
Maternal age (yrs) (Mean±SD)	24.1±3.9	23.9±4.9
Parity (Median, range)	1 (1-4)	1 (1-4)
Infant's age at entry (days) (Median, range)	50.5 (20-88)	50.5 (10-89)
Birth weight (g) (Mean±SD)	2568±498	2560±606
No. exclusively breastfed at entry (%)	6 (19)	9 (28)

TABLE II—Comparison of Outcome Variables

Variable	Galactagogue (n=32)	Placebo (n=32)
Maternal PRL levels (ng/ml) (Median, range)		
Before therapy	52.5 (8-210)	40.5 (7-220)
After therapy	25 (2-200)	38 (7-156)
Infant weight gain velocity (g/d) (Median, range)		
Before therapy	12 (0-35)	10 (0-41)
After therapy	30 (14-52)	26 (10-75)
Volume of supplemental milk (ml/d) (Mean±SD)		
Before therapy	291.9±144	262.6±118
After therapy	163.2±214	210±242.3

This is probably the first randomized controlled study using *Asparagus racemosus* as a galactagogue. The present study did not document an increase in prolactin levels with the use of the herbal galactagogue. In fact, PRL levels declined 4 weeks after therapy in both the groups. The median PRL levels observed in the study population (pre-nursing) between 50-90 days post-partum were comparable to that reported from other studies(2,3). Stratification for breastfeeding patterns did not influence the outcome results between the placebo and galactagogue groups. In both the groups there was an increase in weight gain and decrease in supplemental feeds, but these were comparable and probably a result of improved breastfeeding techniques as a

result of research staff intervention.

It is concluded that *Asparagus racemose* does not have any lactogenic effect.

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