ISSN: 2322 - 0902 (P)
ISSN: 2322 - 0910 (O)

International Journal of Ayurveda and Pharma Research

Research Article

A COMPARATIVE STUDY ON THE EFFECT OF TWO INDIGENOUS AYURVEDIC FORMULATIONS ON LACTATION

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ABSTRACT

A clinical trial was conducted to compare the lactogenic properties of two indigenous formulations, the trial drug mentioned in *Arogyakalpadrumam* and control drug- some selected drugs from Chikithsamanjari, the efficacy of which was already proved. The study was carried out in the outpatient section of the Department of Prasuthi and Sthreeroga, Govt. Ayurveda college Hospital for women and children, Poojappura, Thiruvananthapuram during 2013-2014. Lactating mothers, complaining of reduced breast milk even after 2 weeks from delivery were screened and grouped into two groups each containing of 15 patients. Data were collected by interviewing mothers using a pre-structured questionnaire with a scoring system. Study drug and control drug are given to each group, in a dose of 6gm powder with 24ml milk twice daily 1hr before food for three months. Evaluations of all the parameters were done at an interval of 30 days in each group. Differences in the score values were noted. Assessment of growth and development of children using Anthropometric parameters and CDC chart were recorded. The data were analyzed using the most appropriate statistical tests. Significant changes were obtained in the clinical parameters in the study group used for assessment such as number of feeds per day, interval between feeling of fullness of breasts, duration of feeds, sleep habits of the baby. There was no statistical significance in increasing number of feeds during night time in both groups. Both drugs have lactogenic properties. All children in both groups attained their natural growth and development. There was a small statistical significance in increasing birth weight in study group when compared with the control group. In the study group poor and moderate response was 0% while in control group they were 13.3%. Good response in the study group was 86.7% while it in the control group was 60.1%. There was a very good response in both groups which was 13.3%.

KEYWORDS: Chikithsamanjari, Lactogenic properties, Arogyakalpadrumam, CDC chart.

INTRODUCTION

Motherhood is the most pristine point of womanhood. The very definition of mother is selfless service to another. The most important symbol of love and sacrifice is undoubtedly, the mother keeping her child at the breast. Breast milk is a complete nutrition that is easy for the baby to digest, which promotes the child eating more often due to faster digestion. The immunological value of breast milk cannot be matched by any other kind of food. Approximately 0.25-0.5gm/day secretory IgA antibodies pass to the baby via the breast milk. It also contains anti infective factors such as bile salt stimulated lipase which protect against amoebic infections and lactoferrin which inhibits the growth of intestinal bacteria.

Breast milk production and breastfeeding is a process that is physically taxing but emotionally satisfying to the mother. It involves interplay of many factors–physical, psychological, social, cultural and economic. Modern medicine has studied the various aspect of breast milk including its production, composition, advantages and methods of feeding. But problems like deficient lactation in which the mother's milk is not sufficient to meet the baby's need are not considered in much detail. The management of this condition is limited to the use of formula feeds or bottle feeds.

In Ayurvedic classics there is detailed description regarding breast milk and breastfeeding. There is much more details regarding qualities of breast milk[1-5], causes for deficient lactation[6-9] and management of deficient lactation in classics. According to Susrutha, the measures that increase *Kapha* will increase the *Sthanya bhavas*

(characteristics of breast milk) and cause *Sthanyajanana*[10] (galactogogue). According to Arogya Kalpadruma, *Apana vata* is also a factor for *Sthanyakshaya* (deficient lactation). So drugs which cause *Vatanulomya* (favourable direction of *Vata*) can also be applied.[11] *Sthanya* (breast milk)is considered to be *Soumya* (gentle) because it is formed from *rasa* (initial body tissue). It gets its white colour by the action of *Kapha*. Its nutritive effects are also due to *Kapha*. Hareetha has considered *Sthanya* to be *Agnisomathmaka*[12] (fiery and gentle in nature). This can be used to explain its *Laghu* (light) and *Deepana* (carminative) properties.

According to Charaka, *Rasa dhathu* (initial body tissue-plasma) nourishes *Sthanya*[13] (breat milk). Sargadhara consider *Sthanya* (breast milk) as *Upadhathu* (secondary tissue) of *Rasa dhathu* [14] (initial body tissue). In Ashtanga samgraha, while describing *Garbhaposhana* (foetal nourishment) it is said that from the *Ahararasa* (essence of diet) itself *Sthanya* (breast milk) is formed.[15] *Raja* (menstrual blood) and *Sthanya* (breast milk) both are derived from the essence part of *rasa* (initial body tissue) and *Sthanya* (breast milk) is the *Upadhathu* (secondary tissue) of *Rasadhathu* [16] (initial body tissue).

Increase and maintenance of lactation after delivery is essential for the proper growth of the baby. Many medical formulations have also been indicated in this regard. The practical wisdom of traditional physicians in Kerala has been compiled into many books*. Arogyakalpadrumam* is one of the most popular among them. After studying the preparations mentioned in Arogyakalpadrumam[17] for increasing and maintaining lactation, this formulation is selected. The present study is intended to compare the effect of this formulation with one another –some selected drugs from *Chikithsamanjari*, the efficacy of which was already proved.

MATERIALS AND METHODS

Aims and objectives

1. To compare the effect of two Ayurvedic formulations on lactation.
2. To assess the growth and development of the infant up to 3 months.

Ethical considerations

Ethics are principles of right conduct. Ethical principles always represent basic human values. Efforts are made to maximise the benefits to the subjects (beneficence) and subject should suffer no harm in the present study.

DRUG SELECTION

Trial drug

The specific formulation is mentioned in Arogyakalpadrumam for increasing lactation. The properties of the drugs are analysed and are found to be *Sthanya vardhaka* (breast milk promoter) in nature. So the combination becomes an ideal drug for increasing lactation.

Raw materials for the preparation of the trial drugs were procured from a reputed raw drug shop, at Thiruvananthapuram. The drugs were cleaned, dried and powdered in a micro pulveriser by maintaining the standards. The powder is kept in air tight containers and patients were requested to take it along with milk.

Control drug

Seven selected drugs from *Chikitsamanjari*, which are having *Sthanyajanana* (galactogogue) property and the efficacy of which were proved already was taken as control drug. The raw drugs for the preparation of control drug were collected from a reputed raw drug shop at Thiruvananthapuram. The drugs were cleaned, dried and powdered in a micro pulveriser by maintaining the standards. The powder is kept in air tight containers and patients were requested to take it along with milk.

Research population

Outpatient section of the department of Prasuthi and Sthreeroga at Govt. Ayurveda College Hospital for Women and Children, Poojappura, Thiruvananthapuram was selected as the research setting considering the fact that a number of lactating mothers complaining of reduced breast milk after delivery attend the Ayurveda OPD for better management.

Inclusion criteria

Lactating mothers complaining of reduced breast milk from 15th day to 90 days after delivery.

Exclusion criteria

Patients with breast pathologies like Abscess, Fibro adenoma, Retracted nipple, Carcinoma breast.

Time and duration of the study

Study was started on December 2012 and completed by January 2014 with duration of 14 months. For each patient it took 3 months as study period.

Technique of data collection

As per inclusion criteria, the lactating mothers suffering from reduced breast milk were selected and the details about her breastfeeding habits were noted according to a pre-structured questionnaire and a definite score values are given for each patient. The patient is evaluated on the basis of these scores at an interval of one month during the study period. Score values are compared before and after the treatment to evaluate the study.

Treatment schedule

The subjects satisfying inclusion criteria were recruited randomly into two groups for trial, the study group and control group; were made identical in all aspects except for the intervention. Both the groups were followed for a period of 1 month after the scheduled course of intervention. Duration of the treatment was three months.

In the study group, the powdered drug was given 6gm twice daily along with 24ml of milk one hour before food for three months. The amount of breast milk was assessed using the pre-structured questionnaire which was given below. The differences in the score values were noted. Similarly the control group is also given with 6gms of the powdered drug twice daily along with 24ml of milk one hour before food for three months. This group was also evaluated in the same way.

Parameters used to assess lactation

Assessment of process like lactation which is very subjective in nature is not easy. Some parameters were fixed on the basis of findings seen in women during this time. Since both the mother and the child have to be a part of such assessment, the most common practical findings were tabulated as follows and evaluation done on that basis. Scores were given to different grades and cases classified on their basis into mild, moderate and severe.

Criteria		**score**
Number of feeds per day		
Number of feeds per day	Normal	2
Less than 12 feeds per day	Reduced	1
Interval between feeling of fullness of breast		
not exceeding 2 hrs	Normal	2
More than 2 hrs	Reduced	1
Duration of feed		
≥10 – 15 minutes	normal	2
< 10 minutes	reduced	1
Number of feeds at night		
≥5-6	Normal	2
<5-6	Reduced	1

Satisfaction of mother

This was based on the feeling of fullness of breast. This is a subjective feeling which can be understood by breast heaviness, tenderness, prominent veins and a feeling of milk coming down. It was divided into three grades.

breast feel full within half an hour of feed	High	3
breast feel full within 1-2 hrs	Good	2
breast do not feel full even after 2 hrs	Reduced	1

Sleep habits of infant -This was divided into three grades depending on the peaceful or disturbed sleep of the infant and its effect on the mother.

peaceful, undisturbed	3
Satisfactory	2
disturbed	1

Cries of infant between the feeds- This was also divided into 3 grades.

Stops crying immediately after feeding	3
Crying not satisfied by feeding, but by some other distraction	2
Crying continuously	1

Complementary food before treatment period	0
Not using any other feed	1

A score of 7-9 was considered severe, 10-12 moderate and 13-15 mild.

Assessment of response of treatment

The scoring system as specified before was used to assess the response to the treatment. A score of 7-9 was taken as poor response, 10-12 as moderate response and 13-15 as good. Scores above 15 were taken to be very good response.

During the follow up period they were not much dependent on breast feeding during this time. A score of 5-7 was considered as poor, 8-10 moderate and 11 good.

The growth and development of the children in the both groups were evaluated using Anthropometric parameters and CDC chart.

Details related to the age, address, educational status, socioeconomic status, religion, Antenatal history, *Prakruthi* etc were obtained. Qualitative and quantitative data were collected from patients belonging to both groups. Individual treatment chart was prepared and given to the patients for the convenience. Both groups were observed once in every month. Both groups were assessed before treatment, after treatment and after follow up. The findings were entered in the observation sheet, which was meant exclusively for the study.

Assessment criteria

Both the groups were assessed before and after the study by observing

1. Quantity of breast milk assessed by the difference in the score values of pre-structured questionnaire.
2. Growth assessed, by using Anthropometric parameters like height, weight, head circumference etc.
3. Development assessed by CDC chart.

Data analysis

Data were consolidated by using statistical methods. The efficacy of the intervention was evaluated and conclusions were drawn by using statistical tests.

MATERIALS

Trial drug

Baladi yoga, which contains sixteen drugs was administered in study group. The reference of above mentioned formulation is from *Arogyakalpadrumam,* a traditional Ayurvedic paediatric text book. This formulation is having lactogenic property and is also having *Agnivardhana* property. So the above combination is taken in this clinical trial to assess its lactogenic property.

Collection of Raw materials

The ingredients of this formulation include the following drugs.

1. *Bala (Sida retusa)*
2. *Madhuka (Glycyrrhiza glabra)*
3. *Vruscheeva (Boerhaavia diffusa)*
4. *Mudgaparni (Vigna pilosa)*
5. *Mashaparni (Vigna radiata)*
6. *Prisniparni (Pseudarthria viscida)*
7. *Saliparni (Desmodium gangeticum)*
8. *Rasna (Alpinia galanga)*
9. *Aswagandha (Withania somnifera)*
10. *Devadaru (Cedrus deodara)*
11. *Thiktha (Solanum xanthocarpam)*
12. *Nagara (Zingiber officianale)*
13. *Jeeraka (Cuminum cyminum)*
14. *Draksha (Vitis vinifera)*
15. *Priyalamajja (Buchanania lanzan)*
16. *Godhooma (Triticum aestivum)*

All the above drugs are taken in equal quantity. The required amount of raw drug is collected from a reputed Ayurvedic raw drug shop at Thiruvananthapuram. The authenticity of these drugs is then approved by the Department of Dravyaguna at Govt. Ayurveda College, Thiruvananthapuram.

Quantity of Drugs in Study Group

The below mentioned amount of drugs were used for preparing the medicines in the study group.

S.No	Drug	Quantity
1	*Bala*	1 kg
2	*Madhuka*	1 kg
3	*Mudgaparni*	1 kg
4	*Mashaparni*	1 kg
5	*Prisniparni*	1 kg
6	*Saliparni*	1 kg
7	*Rasna*	1 kg
8	*Aswagandha*	1 kg
9	*Devadaru*	1 kg
10	*Thiktha*	1 kg
11	*Nagaram*	1 kg
12	*Jeeraka*	1 kg
13	*Draksha*	1 kg
14	*Priyalamajja*	1 kg
15	*Godhoomam*	1 kg
16	*Punarnava*	1kg

Method of preparation of Drugs in study group

Good quality drugs are collected, cleaned, washed and dried well. These all are made into fine powder and kept in air tight containers. 6gm powdered drug given with 24ml milk one hour before food twice daily for three months.

The control group

Seven selected drugs mentioned in Chikithsa Manjari, which is having the lactogenic properties and the efficacy of which was already proved is taken as control drug. The drugs included in this group are

1. *Sathavari (Asparagus racemosus)*
2. *Vidari (Ipomoea mauritiana)*
3. *Bala (Sida retusa)*
4. *Madhuka (Glycyrrhiza glabra)*
5. *Prisniparni (Desmodium gangeticum)*
6. *Mustha (Cyperus rotundus)*
7. *Patha (Cyclea peltata)*

All the above drugs are taken in equal quantity. The required amount of raw drug is collected from a reputed Ayurvedic raw drug shop at Thiruvananthapuram. The authenticity of these drugs is then approved by the Department of Dravyaguna at Govt. Ayurveda College Thiruvananthapuram.

Quantity of drugs in control group

Drugs	Quantity
Sathavari (Asparagus racemosus)	2kg
Vidari (Ipomoea mauritiana)	2kg
Bala (Sida retusa)	2kg
Madhuka (Glycyrrhiza glabra)	2kg
Prisniparni (Desmodium gangeticum)	2kg
Mustha (Cyperus rotundus)	2kg
Patha (Cyclea peltata)	2kg

Method of preparation of Drugs in control group

Good quality drugs are collected, cleaned, washed and dried well. These all are made in to fine powder and kept in air tight containers. 6gm powdered drug given with 24ml milk one hour before food twice daily for three months.

METHODS

Study type

Therapeutic

Research design

Therapeutic Quasi Experimental study

Sampling

Simple Random sampling was followed in this study. Selected subjects were randomly divided into two groups, study group and control group by using Table of Random Number.

Sampling Element

Lactating mothers are complaining of reduced breast milk from 15th day to 90th day after delivery and having age between 20 to 35 years.

Sampling Fraction

Lactating mothers in the age group 20 to 25 years, 25 to 30 years and 30 to 35 years with reduced breast milk attending the outpatient section of Department of Prasuthi and Sthreeroga, Govt. Ayurveda College, Thiruvananthapuram were the sampling fraction.

Observation Interpretation and Analysis

1) Demographic data

1. In study group and control group 87% are in the age group of 20-30yrs.
2. 80% in the study group and 60% in the control group are either in the middle or in the high income group.
3. 67% in the study group were belonging to joint family and 60% of control group belong to nuclear family.
4. 40% in the study group and 53% in the control group belonged to *Vatha pitha prakruthi.*

2) Clinical picture

1. Most patients in both groups were primi para.
2. Among multipara, 42.9% in the study group and 71.4% in the control group had complaints of reduced breast milk in the previous deliveries.
3. 60% patients in the study group and 66.7% in the control group were psychologically anxious.
4. 86.7% in the study group and 80% in the control group started breast feeding immediately after delivery.
5. 26.7% in the study group and 53.3% in the control group had some kinds of difficulties in antenatal period.
6. 86.7% in the study group and 80% in the control group had normal deliveries.
7. 20% patients in study group and 13.3% in the control group had some difficulties during labor.

Distribution of cases according to presenting complaints and associated symptoms

Complaints	Study Group	%	Control Group	%
Lightness of Breast	8	53.3	5	33.3
Abdominal Discomfort	9	60.0	7	46.7
Piles/bleeding	4	26.7	3	20.0
Anemia	3	20.0	4	26.7
Emotional Problems	9	60.0	3	20.0
Lack of Appetite	14	93.3	12	80.0

Response of the treatment

Z test for proportion for number of feeds per day

Group	Feeds per day	Before Treatment		After Treatment		Z-value	p- value
		No	%	No	%		
Study	≤ 12 times	15	100	4	26.7	2.15	<0.01
	> 12 times			11	73.3		
Control	≤ 12 times	15	100	8	53.3	0.36	>0.05
	>12 times			7	46.7		

Z value in the study group- 2.15, Z value in the control group- 0.36

The Z test for rise in the number of patients who had increase in the number of feeds per day in the study group was found to be significant with a Z value of 2.15 and p<0.01. In the control group, this test was not significant with an Z value of 0.36 and p>0.05.

Z test for proportion for effectiveness in increasing the number of feeds per day

Feeds per day	Study Group		Control Group		Z-value	p-value
	No	%	No	%		
≤ 12 times	4	26.7	8	53.3	2.56	<0.01
> 12 times	11	73.3	7	46.7		

Z value -2.56, p<0.01.The Z test for effectiveness in increasing the number of feeds per day was found to be significant at 0.01 with a Z value of 2.56. So the medicine was more effective than control in increasing the number of feeds per day.

Z test for proportion for interval between fullness of breasts

Group	Interval between breast fullness	Before Treatment		After Treatment		Z-value	p-value
		No	%	No	%		
Study	≥ 2 hrs	15	100	3	20	3.28	<0.01
	< 2 hrs			12	80		
Control	≥ 2 hrs	15	100	7	46.7	0.38	>0.05
	< 2 hrs			8	53.3		

Z value in the study group -3.28, p<0.01, Z value in the control group- 0.38, p>0.05

The Z test for rise in number of the patients who felt fullness of breasts in less than 2 hrs was found to be significant in the study group with an Z value of 3.28 and p<0.01. In the control group this was found to be insignificant with a Z value of 0.38 and p>0.05.

Z test proportion for effectiveness in increasing feeling of fullness of breasts

Time for fullness of breast	Study Group		Control Group		Z-value	p-value
	No	%	No	%		
> 2 hrs	3	20.0	7	46.7	2.69	≤0.01
≤ 2 hrs	12	80.0	8	53.3		

The Z test for effectiveness in increasing the feeling of fullness of breast in less than 2 hrs was found to be significant at 0.01 level with a Z value of 2.69. So the medicine was more effective than control in increasing the feeling of fullness in the breast.

Z test for proportion for duration of each feed

Group	Duration	BT	%	AT	%	Z-value	p-value
Study	< 10 min	9	60	3	20	3.28	<0.01
	10-15min	6	40	12	80		
Control	< 10 min	10	66.7	6	40	1.09	>0.05
	10-15min	5	33.3	9	60		

Z value in the study group -3.28, p<0.01; Z value in the control group-1.09, p>0.05

Z test for rise in number of patients who had increased duration of each feed was found to be significant in the study group with an Z value of 3.28, and p<0.01.

Z test for the proportion of effectiveness in increasing the duration of each feed

Time for fullness of breast	Study Group		Control Group		Z-value	p-Value
	No	%	No	%		
< 10 min	3	20	6	40	1.20	0.23
10-15min	12	80	9	60		

Z value- 1.20, p>0.05

Z test for effectiveness in increasing the duration of feed was found to be statistically insignificant with an Z value of 1.20, p >0.05.

Z test for the proportion of number of breast feeds at night

Group	No of times	BT	%	AT	%	Z-value	p-value
Study	< 5 times	12	80	5	33.3	1.83	>0.05
	>= 5 times	3	20	10	66.7		
Control	< 5 times	14	93.3	7	46.7	03.7	>0.05
	>= 5 times	1	6.7	8	53.3		

Z value in the study group-1.83, p>0.05; Z value in the control group-3.7, p>0.05

In the study group, the Z test for rise in number of patients who had increase in the number of feeds at night was found to be insignificant with a Z value of 1.83 and p >0.05. In the control group Z value was 3.7 and the test was found to be statistically insignificant.

Z test for proportion for effectiveness in increasing number of feeds per night

Time for fullness of breast	Study Group		Control Group		Z-value	p-value
	No	%	No	%		
< 5 times	5	33.3	7	46.7	1.28	0.25
≥ 5 times	10	66.7	8	53.3		

Z value-1.28, p>0.05

Z test for effectiveness in increasing the number of feeds per night between the study group and control group was found to be statistically insignificant with n Z value of 1.28 and p>0.05. So the medicine was not effective in increasing the number feeds at night.

Distribution of sleep habits of the children

	Study Group				Control group			
Sleep Habit	Before treatment	%	After Treatment	%	Before treatment	%	After Treatment	%
Mild	2	13.3	0	0	4	26.6	0	0
Moderate	11	73.4	4	26.6	10	66.7	7	46.7
Good	2	13.3	11	73.4	1	6.7	8	53.3

Before treatment, 13.3 % of children in the study group and 26.6% in the control group had mild sleep. 73.4% in the study group and 66.7% in the control group had moderate sleep habits and only 13.3% in the study group and 6.7% in the control group had good sleep. After treatment 73.4% in the study group and 53.3% in the control group attained good sleep habits.

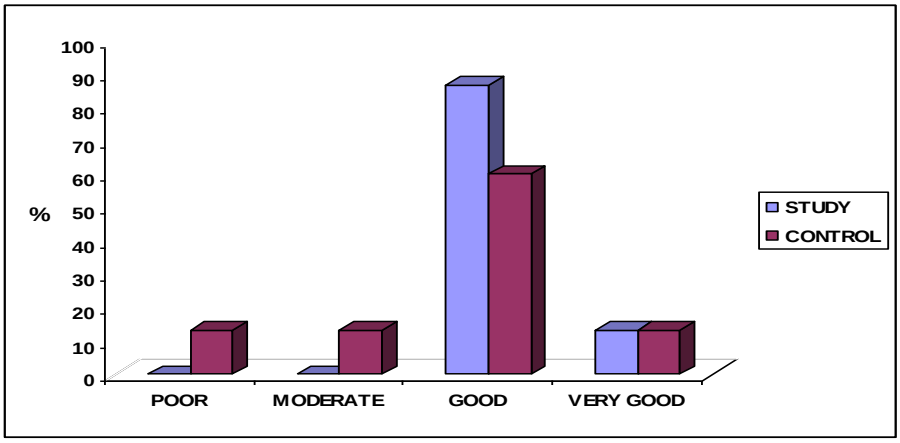
Comparison of Distribution of sleep habits

Distribution of cases according to Overall response of drugs

Difficulty	Study Group		Control Group	
	BT	%	AT	%
Poor	0	0	2	13.3
Moderate	0	0	2	13.3
Good	13	86.7	9	60.1
Very Good	2	13.3	2	13.3

In the study group poor and moderate response was 0% while in control group they were 13.3%. Good response in the study group was 86.7% while it in the control group was 60.1%. There was a very good response in both groups which was 13.3%.

Comparison of overall response of drugs

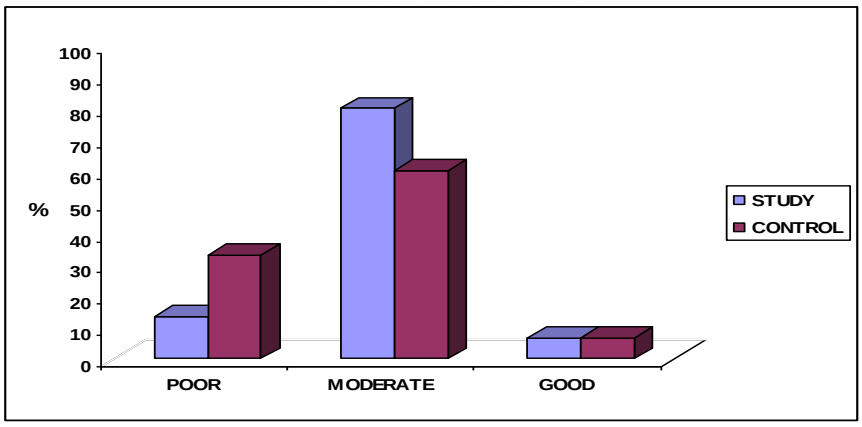


Distribution of cases according to Response after follow-up

Response	Study Group	%	Control Group	%
Poor	2	13.3	5	33.2
Moderate	12	80.0	9	60.1
Good	1	06.7	1	6.7

After follow up period 13.3% in the study group and 33.2% in the control group had poor response. In the study group 80% in the study group had moderate response, while in the control group it was 60.1%. Good response in both group were found to be only 6.7%.

Comparisons of response after follow up



Comparison of growth assessment of children in both groups

1. The children in both groups attained their height according to their age. So the test became statistically insignificant with a p value > 0.05.
2. Children in both groups attained head circumference in normal limit according to their age. So the study becomes statistically insignificant in increasing the head circumference.
3. There is a small increase in the birth weight of children in the study group compared with that of children in the control group. So the study was statistically significant with p value<0.05. Birth weight is statistically significant as compared to the control group

DISCUSSION

Causes of deficient lactation include anatomic, Physiologic, Psychological and socio economic factors. These are described in Ayurvedic classics as- *Swabhava* (intrinsic nature), *Langhana* (attenuation therapy), *Ayasa* (physical excertion), *Sodhana* (purification therapy), *Suklakshaya* (hypo activity of reproductive tissue), *Soka* (worry), *Krodha* (anger), *Avalsalya* (foreign body) etc. The *Dosha* involved in *Sthanyanasa* (destruction of breast milk) is *Vatapitha kopa* (hyper activity of *Vata* and *Pitta)*. The *Saumya* elements of the body are decreased indicating *Kapha kshaya* (hypo activity of *Kapha*) and *Rasakshaya* (hypo activity of Rasa). The quantitative deficiency of *Sthanya* (breast milk) is manifested as *Sthanyakshaya* (diminished breast milk) and qualitative deficiency as *Sthanyadushti* (vitiated breast milk). Medicines for increasing breast milk production should be *Vata pitha samana* (pacifies *Vata* and *Pitta*) and *Kapha vardhana* (increases kapha) and possessing properties like *Madhura rasa* (sweet in taste) *& Vipaka* (metabolic end effect), *guru* (heavy) *–Snigdha guna* (unctuous quality), *Seethe*

veerya (cold potency), *Vrushya* (aphrodisiac), *Balya* (improve strength), *Brihmana karma* (nutritive in action). *Vatanulomana* (favourable direction of *Vata*) and *Agnideepana* (enhances digestive fire) are also needed for *Sthanyajanana* (promote lactation).The increase in breast milk production causing increased number of feeds during the day shows the proper *Saumya parinama* (gentle transformation) of *rasa* (initial body tissue) in to *Upadhathu sthanya* (secondary tissue- breast milk). *Ahara rasa* (essence of diet) has to be formed in proper quantity and quality for its conversion in to *Upadhathu* (secondary tissue). In this combination- the drugs *Saliparni, Devadaru, Thiktha, Jeeraka, Nagara* are *Deepaneeya* (carminative) in nature. Drug *Rasna* has *Amapachana* (digestion of incompletely transformed matter) property also. By all these the *Agni* (digestive fire) of patients were corrected and formation of *Rasa dhathu* (initial body tissue) took place in proper way and therefore the formation of *Sthanya* (breast milk) which is the *Upadhathu* (secondary tissue) of *Rasa* (initial body tissue). In this case *Sara* being *Sthanya* and the transportation of this *Sara* to the breast is carried out by *Vyana vata* whose seat is the *Hridaya* (heart). The *Hridya* drugs in the combination-*Bala*, *Prusniparni, Thiktha, Priyala* can act as cardiotonic and normalise the function of *Vyana vata*. *Anulomana* (sending right direction) drugs like *Punarnava*, *Priyala* and *Saliparni* present in the combination also helps for the proper functioning of *Vata*. *Ojovardhaka* (increases vitality) and *Brihmana* (nutritive) drugs can also increase *Sthanya* (breast milk) by their similar properties. In this *Bala yoga* has *Ojavardhaka* (increases vitality) property and majority of drugs are *Brihmana* (nutritive) in nature. By all these proper *Dhathu parinama* (transformation of tissue elements) takes place and increase in the breast milk production takes place. Majority of drugs in the study group were found to be having *Vata pitha samana* (pacifies *Vata* and *Pitta*) in nature. *Bala* and *Madhuka* were *Sthanyajanana* (galactogogue) in nature. *Bala*, *Madhuka* and *Mudgaparni* were *Rasayana* (rejuvinative) and *Jeevaneeya* (restorative) in nature. *Bala, Saliparni, Prusniparni, Thiktha* was *Vrishyam* (aphrodisiac), *Hrdhyam* (cardiac tonic) and *Brihmaneeyam* (nutritive) in nature. Nagaram, *Jeerakam*, *Devadaru* and *Saliparni* were *Deepaneeyam* (carminative) in nature. *Prisniparni* was *Srotho-sudhikara* (purifies channels). *Rasna* was *Amapacha-nam* (digestion of incompletely transformed matter) in nature.

The statistical analysis showed that both drugs were having lactogenic properties. The Z test for effectiveness in increasing the number of feeds per day was found to be significant at 0.01 with a Z value of 2.56. So the medicine was more effective than control in increasing the number of feeds per day. Even though both groups contain *Sthanyajanan* drugs, drugs in the study group were more *Agni deepanam* (enhance digestive fire) and *Vata pitha samanam* (pacifies *Vata* and *Pitta*). *Vrishya* (aphrodisiac), *Rasayana* (rejuvinative) and *Hridya* (cardiac tonic) properties of the combination was responsible for the proper conversion of *Rasa* (initial body tissue) into its *Upadhathu* (secondary tissue).

The Z test for rise in number of the patients who felt fullness of breasts in less than 2 hrs was found to be significant in the study group with an Z value of 3.28 and $P<0.01$ In the control group this was found to be insignificant with an Z value of 0.38 and $P>0.05$.

Z test for rise in number of patients who had increased duration of each feed was found to be significant in the study group with an Z value of 3.28, and $P<0.01$.

In the study group, the Z test for rise in number of patients who had increase in the number of feeds at night was found to be insignificant with an Z value of 1.83 and $P>0.05$. In the control group Z value was 3.7 and the test was found to be statistically insignificant.

Before treatment, 13.3% of children in the study group and 26.6% in the control group had mild sleep. 73.4% in the study group and 66.7% in the control group had moderate sleep habits and only 13.3% in the study group and 6.7% in the control group had good sleep. After treatment 73.4% in the study group and 53.3% in the control group attained good sleep habits. In the study group poor and moderate response was 0% while in control group they were 13.3%. Good response in the study group was 86.7% while it in the control group was 60.1%. Very good response in both groups was 13.3%.

After follow up period 13.3% in the study group and 33.2% in the control group had poor response. In the study group 80% in the study group had moderate response, while in the control group it was 60.1%. Good response in both group were found to be only 6.7%. The action of the drug can be considered as increasing the availability of enough substrates to the *Ahara rasa* (essence of diet) by virtue of its anabolic properties. This action diminished once the drug was stopped.

Number feeds during night did not find any significant change in both groups.

CONCLUSION

- Deficient lactation or *Sthanya kshaya* is caused by combination of *Sareerika* (physical) and *Manasika bhavas* (physiological factors).

- *Nidanas* for *Sthanya kshaya* (deficient lactation) leads to *Vata pitha kopa* (hyper activity of *Vata* and *Pitta*) and *Kapha kshaya* (hypo activity of *Kapha*).
- In Ayurveda classics there is detailed description about the management of deficient lactation.
- A formulation in the Arogyakalpadrumam mentioned as *Sthanya vardhana* (increases breast milk) in nature was selected as study drug and as control some selected drugs from Chikithsamanjari, the efficacy of which was already proved was selected.
- Lack of appetite and abdominal discomfort seen in a major percent of patients were corrected in both groups.
- Even though both drugs were having lactogenic properties, study drug was found to be statistically significant in increasing number of feeds per day, increasing the feeling of fullness of breast and duration of feed.
- Both drugs were effective in improving the sleep habits of the baby.
- The drug was not effective in increasing the number of feeds during night time.
- The overall response of the drug was good or very good in the study group. In the control group it was moderate or good in majority.
- The lactogenic properties of the drugs were maximum while it was being used and decline when it is stopped.
- There is a small increase in the birth weight of children in the study group compared with that of children in the control group. So the study was statistically significant with P value<0.05.
- Growth and development of children in both groups were found to be normal for age.

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Cite this article as:
Binitha P, N.Vijayakumar, Asha Sreedhar. A Comparative Study on the effect of two Indigenous Ayurvedic Formulations on Lactation. International Journal of Ayurveda and Pharma Research. 2018;6(8):27-36.
Source of support: Nil, Conflict of interest: None Declared

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