A CONTROLLED TRIAL ON LEPTADEN IN WEIGHT GAIN OF INFANTS AND AS A GALACTAGOGUE IN LACTATION CASES

By

Dr. N.R. BHANDARI, M.D. (Paed.), M.A.M.S., F.I.A.P.,
Professor & Head of Paediatric Dept. Dr. S.L. SONI, M.B.B.S., D.C.H., Post-Graduate
In Paediatrics Gandhi Medical College, Bhopal, (M.P.)
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SELECTION OF PATIENTS:

BREAST MILK is an ideal natural food for the child and superior to all artificial feeds and breast-feeding exerts a salutary influence on child-mother relationship.
It is claimed that Leptaden the herbal drug, which consists of Leptadenia reticulata (Jeevanti) and Breynia patens (Kamboji), when given to post-natal cases of lactation, results in increased milk secretion, with initiation, then discharge of secreted milk through nipple and then in maintenance of breast milk, though the exact mechanism of their actions are not known.
The usefulness of Leptaden in lactation cases was first reported by Trivedi.[1] In 1962, Malati Deshpande et.al[2] studied the effects of Leptaden on selected lactation cases. They reported that this drug stimulated lactation with no side-effects to the mother or the child. Kusum Gupta et.al reported that Leptaden could be recommended routinely in normal failure of lactation as they found good response in such cases. Jyoti Kathari & Meena Kothari showed that routine administration of Leptaden was effective in decreasing the number of cases of lactational failure.
Habibi Akhtar & Sita Ratna found that Leptaden established lactation within 8 to 24 hours of administration, and 75% of cases showed good response and 21% of cases showed satisfactory response.

MATERIAL & METHODS

242 cases taken from the post-natal Clinic, Children's O.P.D. & Children's ward were included in this study, out of which 210 cases formed the Trial or the Leptaden Group and 32 cases formed the Control Group. No mother or infant with acute or any other illness was taken up for study. Mothers were taken from different socio-economic groups and included, primiparas and multiparas. All the children were under the age of nine months: The cases were taken at random during the period July 1977 to Sept. 1978.
In the Trial Group, Leptaden was given for four weeks. Observations were made before starting Leptaden to mothers, and then once a week for four weeks, as' to the condition of the breast and details of Milk flow. Infants were weighed before starting the Study and then once a week regularly for four weeks. Similar observations were recorded in. the mothers of the control Group and their children. Control group did not receive any drug during the course of this study.

OBSERVATIONS

Parity: Out of 242 cases taken for Study, 94 cases (38.8%) were primipara and 148 cases (61.2%) were multipara. The details are given in Table I.

Table I

Para	Leptaden Group	Control Group	Total	%
Primipara	82	12	94	38.8%
Multipara	128	20	148	61.2%
Total	210	32	242	100%

SOCIO-ECONOMIC STATUS

Out of 242 cases taken for study, 144 cases (59.5%) belonged to Poor class, 95 cases (38.3%) belonged to Middle class and 3 cases (1.2%) belonged to Upper class. The details are given in Table II.

Table II

SOCIO-ECONOMIC STATUS

Status	Leptaden Group	Control Group	Total	%
Poor Class	125	19	144	59.5%
Middle Class	82	13	95	39.3%
Upper Class	3	-	3	12%
Total	210	32	242	100%

INFANTS IN DIFFERENT AGE GROUPS

Out of 242 cases taken for study, 138 infants (57.0%) were in the age group of 0-2 months; 48 infants (19.8%) were in the age group of 2-4 months; 30 infants (12.4%) were in the age group of 4-6 months; 26 infants (10.8%) were in the age group of 6-9 months. The details are given in Table III.

Table III

NUMBER OF CASES IN DIFFERENT AGE GROUPS

Age group	Leptaden Group	Control Group	Total	%
0-2 months	122	16	138	57.0%
2-4 months	40	8	48	19.8%
4-6 months	26	4	30	12.4%
6-9 months	22	4	26	10.8%
Total	210	32	242	100%

DOSAGE OF LEPTADEN

210 Mothers, were given Leptaden 2 tabs. three times a day for 15 days, followed by 2 tabs, two times a day for the next 15 days. 32 cases of Control Group did not receive any drug. The condition of lactation in both Leptaden and Control Groups was recorded once a week for four weeks. Infants of both the groups were weighed once a week for four weeks.

CLASSIFICATION OF IMPROVEMENT

Improvement was classified into the following four categories.

GOOD: Breast engorged and painful; nipple normal; lactation good; good improvement in the amount of weight gain of the infant.

FAIR: Breast not engorged or painful; nipple normal; lactation satisfactory; moderate improvement in the amount of weight gain of the infant.

POOR: Clinically improvement in lactation poor; poor improvement of weight gain of the infant.

NIL: No improvement in lactation. No upward gradient in the increase in weight gain of the infant.

RESULTS:

Weight gain of infants in the Leptaden

The mean increase in weight of the infant per day, during the trial of four weeks, in the Leptaden Group was 31.04 Gms. The largest amount of increase was observed in the youngest age group of 0-2 months with 33.54 Gms. The details are given in Table IV.

Table IV

WEIGHT GAIN OF INFANTS IN LEPTADEN GROUP ACCORDING TO AGE GROUPS (In Gms.)

Age Group	No. of Cases	1st Wk	2nd Wk	3rd Wk	4th Wk	Mean/Week	Mean/Day
0-2 months	122	213.59	241.23	252.80	231.50	234.78	33.54
2-4 months	40	212.30	209.19	220.00	220.00	215.37	30.77
4-6 months	26	203.71	209.62	209.62	209.621	208.14	29.71
6-9 months	22	216.50	209.00	209.00	209.00	210.88	30.12
Total Cases	210						
Mean		211.53	211.26	226.86	271.53	217.53	31.04

RESULTS:

Weight gain of infants in the Control Group

The mean increase in weight of the infant per day, during the trial period of 4 weeks, in the Control Group was 18.48 Gms. As in the Leptaden Group, the largest amount of increase was observed in the youngest age Group of 0-2 months with 20.36 Gms. The details are given Table V.

Table V

WEIGHT GAIN OF INFANTS IN CONTROL GROUP ACCORDING TO AGE GROUPS (In Gms.)

Age Group	No. of Cases	1st Wk	2nd Wk	3rd Wk	4th Wk	Mean/Week	Mean/Day
0-2 months	16	159	140	140	140.8	142.5	20.36
2-4 months	8	140	140	140	140	140	20.00
4-6 months	4	125	125	125	125	125	17.86
6-9 months	4	110	110	110	110	110	15.71
Total Cases	32						
Mean		131.3	128.8	128.8	128.8	129.4	18.48

COMPARISION OF DAILY WEIGHT GAIN IN THE LEPTADEN AND CONTROL GROUPS:

Leptaden Group when compared to the Control Group showed the largest increase in weight in the age group of 6-9 months when compared to the other age groups with an increase of 14.41 Gms. The next in order was the group of 0-2 months with an increase of 13.18 Gms: While the weight increase was the highest in the age group of 0-2 months of both the groups, when we come to the difference in the increase of infant weights between Leptaden & Control Groups, the largest difference was seen in the age group of 6-9 months. This indicates the beneficial action of Leptaden very clearly. The details are given in Table VI.

Table VI

DAILY WEIGHT GAIN IN CONTROL & LEPTADEN GROUPS (In Gms.)

Age Group	Mean Weight gain in control group	Mean Weight gain in leptaden group	Increase in Leptaden group
0-2 months	20.36	33.54	13.18
2-4 months	20.00	30.77	10.77
4-6 months	17.86	29.71	11.88
6-9 months	15.71	30.12	14.41
Total	18.48	31.04	12.56

RESULTS ACCORDING TO PARITY

In the Leptaden group, combining primipara and multipara, the result was Good in 33.33%, Fair in 58.10%, Poor in 7.14% and Nil 1.43%. Primipara showed better response (95.12%) than multipara (89.07%).
Padma Rao' reported good response in multipara, where as in this series primipara showed a slightly better response. Over all satisfactory response (Good + Fair) was 91.43% in the Leptaden Group. In the Control Group, combining primipara and multipara, the result was Poor in 75.0% and Nil in 25.0%. The details are given in Table VII.

Table VII

RESULTS IN LEPTADEN AND CONTROL GROUPS ACCORDING TO PARITY

	LEPTADEN GROUP						Control (Pri. + Mul)	
Response	Primipara	%	Multipara	%	Total	%	No cases	%
GOOD	33	40.24%	37	28.91%	70	33.3%		
FAIR	45	54.88%	77	60.16%	122	58.1%		
POOR	4	4.88%	11	8.59%	15	7.14%	24	75.0%
NIL			3	2.34%	3	1.43%	8	25.0%
TOTAL	82	100%	128	100%	210	100%	32	100.00%

RESULTS ACCORDING TO SOCIOECONOMIC STATUS

In the Leptaden Group, combining all the Socio-economic groups, result was Good in 33.33%, Fair in 58.10% Poor in 7.14% and Nil in 1.43%. Good result was slightly better in Middle class (41.46%) than the other cases. How ever on the whole, satisfactory response (Good + Fair) was better in Poor class (92.80%) than in the Middle Class (90.24%). In the Control Group, combining all the socioeconomic classes, the result was poor in 75.0% and Nil 25.0%. The details are given in Table VIII.

Table VIII

RESULTS IN LEPTADEN AND CONTROL GROUPS ACCORDING TO SOCIO-ECONOMIC STATUS

	LEPTADEN GROUP										CONTROL GR.	
Response	Poor class	%	Middle class	%	Upper class	%	Total	%	No. of cases (All cases)	Control Gr. %
GOOD	35	28.00%	34	41.46%		33.33%	70	33.33%		
FAIR	81	64.80%	40	48.78%	1	33.33%	122	58.10%		
POOR	8	6.40%	6	7.32%	1	33.33%	15	7.14%	24	75.0%
NIL	1	0.80%	2	2.44%			3	1.43%	8	25.0%
TOTAL	125	100.00%	82	100.00%	3	100.00%	210	100.00%	32	100.00%

STATISTICAL STUDY

Weight gain of infants: Paired 't' Test:

For the purpose of statistical study, weekly observations of weight gain made for four weeks in all the age groups (0-9 months) of the Leptaden Group of Table IV, are compared with similar observations of the Control Group of Table V, as all the conditions of study are identical in both the groups except as to the treatment that each group received. For statistical analysis, the test applied is Paired 't' Test of Differences namely X1-X2= Y

The value as per this test in this study is 22.90 and is much more in value than of the Paried Test Table of Differences for significance at 0.001. Hence it is concluded that the results of the weight gain in infants is highly significant at P<0.001 in the Leptaden when compared to the Control Group. The details are given in Table IX.

Table IX

STATISTICAL STUDY: WEIGHT GAIN IN INFANTS: PAIRED 't' TEST

Period (Stages)	1st Week	2nd Week	3rd Week	4th Week
0-2 months	54.59	101.23	112.80	91.50
2-4 months	12.30	69.19	80.00	80.00
4-6 months	74.71	84.52	84.62	83.14
6-9 months	106.50	99.00	99.00	99.00

T15=22.90 P<0.001

STATISTICAL STUDY: WEIGHT GAIN IN INFANTS: CHI SQUARE TEST:

In the Leptaden Group, as per Table IV, the best results were obtained in weight gain in 122 infants of the age group of 0-2 months with 33.54 Gms. increase in weight per day and the rest of 88 cases are taken as No Improvement for the purpose of this test. In the Control Group, as per Table V, all the 32 cases are taken as No Improvement as the highest mean increase in weight per day was only 20.36 Gms. The total number of cases that showed the best results from both the groups, was 122. Similarly, the total number of cases that did not show any results from both the groups was 120. On the hypothesis that Leptaden has no effect on the lactation of mothers and consequently no appreciable amount of increase in the weight gain of the infant, CHI square test is used. Since the calculated value of this trial is higher than the Table value of 2x2 contingency Tables is the hypothesis is rejected and it is concluded that Leptaden is effective as the result is significant at P<0.001. This also confirms the results by Paired 't' Test as to weight gain in infants. The concerned Table X is given below.

Table X

STATISTICAL STUDY: WEIGHT GAIN

Group Good	Good	Fair + Poor + Nil	Total
Leptaden Group	122	88	210
Control Group	-	32	32
Total	122	120	242

STATISTICAL STUDY: LACTATION IN MOTHER AS TO PARITY & SOCIOECONOMIC STATUS

As per Table VII & VIII Leptaden Group showed Good results in 70 cases and Fair + Poor + Nil results in 140 cases. In the Control Group, all the 32 cases showed Poor + Nil results. Combining both the Groups (242 cases), Good results were seen in 172 cases. This was put to CHI square test to see whether the assumption that Leptaden has no action as a Galactagogue is correct or this assumption is to be rejected. Using 2x2 contingency tables, it is found that the result is significant at P<0.001, and so it is concluded that Leptaden is effective in increasing lactation in mothers. The details are given in Table XI.

Table XI

STATISTICAL STUDY: PARITY & SOCIO-ECONOMIC STATUS

Group Good	Good	Fair + Poor + Nil	Total
Leptaden Group	70	140	210
Control Group	-	32	32
Total : 10	70	172	242

DISCUSSION

The process of lactation consists of secretion of breast milk, discharge and continued maintenance. Galactogenisis is governed by hypothalamus and it may also be influenced by psychological factors. Hypothalamus controls pituitary and indirectly controls the secretary hormone prolactin which initiates lactation. Galactopoisis depends upon many factors including good sucking capacity of the baby and also good nutrition of the mother. Flow of breast milk may be affected by a variety of factors, many of which are not known.

This study has shown that infants of the mothers treated with leptaden showed a daily increase in weight of 31.04 Gms., while those in the Control Group showed only 18.48 Gms.The increase was better in all the age groups. This shows that breast milk of the Leptaden treated mothers had better quality and quantity of breast milk, as reflected on the increase of the weight gain of the infants, than the breast milk of the control group.

Statistical studies have confirmed that the effect of Leptaden is significant at P<0.001.

The difference in weight gain between the Leptaden and Control groups was the highest in the age group of 6-9 months with 14.41 Gms. showing that response was comparatively better in the later part of lactation and will help in prolongation of lactation period and delaying the weaning time.

In our series response was slightly better in primipara when compared to multipara. Poor and middle classes showed better response than the upper class.

While in our study 91.43% of cases showed satisfactory response, Habla Akhtar & Sita Ratna reported satisfactory response in 75% of cases. Padma Rao at.el reported satisfactory response in 86.67%.

SUMMARY & CONCLUSION

Clinical trial with Leptaden was done in 210 lactation cases and 32 cases were taken as Control. The trial period was of four weeks with weekly observations of results. Mothers were evaluated clinically as to their lactation. Children were weighed once a week for four weeks.

Clinically the response to Leptaden was found to be 91.43%, as satisfactory improvement. In the control group, there was no satisfactory improvement and the improvement was either poor or nil.

The clinical improvement in lactation had direct bearing on the quality and quantity of breast milk and if had reflected on the weight gain of the infant. The mean increase per day of weight gain was 31.04 Gms. in the Leptaden Group and it was only 18.48 Gms. in the Control group, that is, Leptaden group showed 12.56 Gms. more increase in weight per day than the Control Group-Response was slightly better in the primipara (95.12%) than in the multipara (89.07%).

Statistical study of the results showed that the effect of Leptaden in lactation cases and the weight gain of the infants whose mothers were treated with Leptaden were statistically significant at P<0.001. This study has shown the good effect of Leptaden in lactation cases both clinically and statistically.

This controlled trial with Leptaden in Postnatal cases of lactation showed that there was appreciable increase in secretion of breast milk. The results are also statistically significant. Leptaden therapy can be recommended to post-natal lactation cases to increase the quantity and quality of breast milk which will help in the increase of weight gain in the breast-fed infants. This is of vital importance in developing countries like India.

No side effects were observed in both the mother and child.

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