"A COMPARATIVE STUDY TO ASSESS THE EFFECTIVENESS OF *LECITHINUM* AND *HOMOEOPATHIC INDIVIDUALIZED MEDICINE* IN ANAEMIA OF CHILDREN FROM 5 TO 11 YEARS AGE GROUP"

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ABSTRACT:
Background: Anaemia in children is one of the most common problems. Worldwide 39.8% of childrenwere considered to be anaemic.

Objectives: To evaluate the improvement in anaemia by comparing haemoglobin concentration in the group prescribed ***Lecithinum***. To evaluate the improvement in anaemia by comparing haemoglobin concentration in the group prescribed ***Individualized homoeopathic medicine***. To compare the improvement in both the groups.

Study design: Interventional, Parallel Arm Comparative study.

Methodology: 70 diagnosed cases of Anaemia were selected on the basis of inclusion and exclusion criteria. All the cases were further divided into two groups, Group A '*Homoeopathic Individualized Medicine'* and Group B was '*Lecithinum'* both having 35 cases each. After calculating the droupouts Group A was having 32 cases and Group B was having 30 cases, a total of 62 completed the study. Assessment and reassessment were done using Haemoglobin values.

Result: Anaemia was found commonly in 10 years of age; male children were more affected. Maximumbelonged to middle-income group family and were from rural area. After 8 drop outs, 62 cases were analysed and seen that 51 (Group A-27 & Group B-24) had improvement in terms of increased Hb taking'*Lecithinum' and Homoeopathic Individualized Medicine'.*

Conclusion: It was found that there is statistically significant difference in before and after treatment of Hb receiving '*Lecithinum*' as well as '*Homoeopathic individualized medicine''* whereas no significant difference in the mean between both the group were found, hence it was concluded that both were moreor less equally effective in cases of anaemia.

KEYWORDS: Anaemia, *Lecithinum,* Haemoglobin, *Homoeopathic IndividualizedMedicine,* Paediatrics.

INTRODUCTION: Anaemia is a significant global health problem. Anaemia is the most common haematological disease of the paediatric age group.[1] There are researches in homoeopathy on anaemia done using many homoeopathic medicines but no research found on 5 to 11 years of age group and lecithinum in dilution whereas our literature says it helps in nutritive condition and hence its use in anaemia.[2]

Objectives:

◗ To evaluate the improvement in anaemia by comparing haemoglobin concentration in the groupA prescribed ***Homoeopathic Individualized Medicine***.

◗ To evaluate the improvement in anaemia by comparing haemoglobin concentration in the groupB prescribed ***Lecithinum***.

◗ To compare the improvement in anaemia by comparing haemoglobin concentration in both the

groups.

MATERIALS AND METHODS:

1.Study Setting: The study was conducted at O.P.D./ I.P.D. of Dr. Girendra Pal Homoeopathic Hospital & Research Centre, Homoeopathy University, Saipura,Sanganer, Jaipur.

2.Study Duration: The study was undertaken from February2021 to November 2021. Due to unpredictable event of lockdown during COVID-19 pandemic, the follow up of the cases after were maintained telephonically.

3.Selection of Samples: 70 cases were enrolled in the study after the screening of cases

according to the inclusion and exclusion criteria. Justification: At confidence interval 95% and margin of error 5%, the approximate sample size for the study is 62. Considering approx. 10% dropouts, 70 was considered the appropriate sample size.

4.Inclusion Criteria:
➢ AGE GROUP: 5 to 11years of Age.
➢ SEX: Both sexes.
➢ Cases with haemoglobin level of 8 to 11.4g/dL
➢ Cases with given consent were included

5.Exclusion Criteria:
➢ Cases with more than 11.4g/dL and below 8g/dL.
➢ Cases with other severe systemic illness were excluded from the study.
➢ Patient pursuing other treatment and were not willing to leave it.
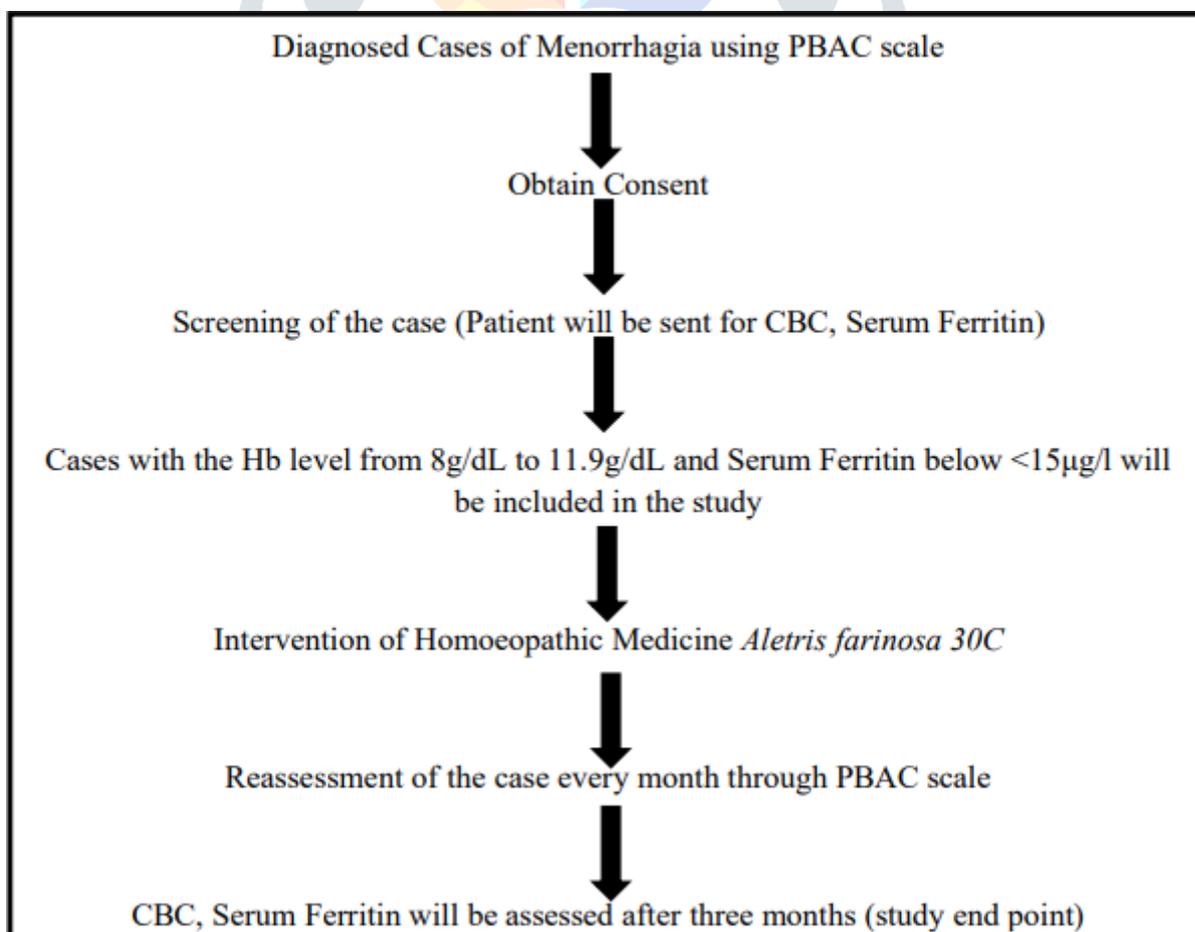➢ Cases without consent were excluded from study

Dropped Out: 8 Cases were dropped out in the study. Main reason was irregular follow ups or some patients denied of post treatment investigations due to their financial issues. Some patients did not return back due to Covid-19 pandemic. Many follow ups were maintained telephonically.

6.Study Design & Brief of Procedure:
Study design: Interventional, Parallel Arm Comparative study

Brief of Procedure:
Table 1:

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            Diagnosed Cases of Menorrhagia using PBAC scale
                              ↓
                        Obtain Consent
                              ↓
        Screening of the case (Patient will be sent for CBC, Serum Ferritin)
                              ↓
    Cases with the Hb level from 8g/dL to 11.9g/dL and Serum Ferritin below <15µg/l will
                          be included in the study
                              ↓
          Intervention of Homoeopathic Medicine Aletris farinosa 30C
                              ↓
           Reassessment of the case every month through PBAC scale
                              ↓
        CBC, Serum Ferritin will be assessed after three months (study end point)
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7.Intervention:

➢ Homoeopathic individualized medicine in group A and Lecithinum in group B was prescribed to the patients in group A and Group B.

➢ Frequency and Repetition: As per the Hahnemannian guidelines in 5th edition of Organon of Medicine.

➢ Medicine dispensing: Medicine were dispensed in globule form (size 30) orally from dispensing unit of Dr. Girendra Pal Homoeopathic Hospital and research centre, Jaipur (Rajasthan) by a certified pharmacist

➢ Manufacturer: Medicine were obtained from a GMP certified company

➢ Follow Up: The follow–ups of the cases were done at an interval of 7-14 days, as per gravity of the case for the duration of minimum 3 months.

➢ Reassessment of anaemia through Hb count after 3 months.

➢ CBC after 3 months (study end point)

8.Co-Intervention:

◗ **Dietary Advice:** Rich iron diet like green leafy vegetables, poultry content, beans, cashews,lentils etc for both the groups.

9.Selection of Tools:

➢ A detailed Case Taking Proforma especially designed for the study. (Appendix I)

➢ CBC (Appendix II)

➢ *Lecithinum in potencies 30, 200,1M*

➢ *Homoeopathic Individualized Medicines*

➢ Hompath software

10. Data Collection:

Data was collected after proper follow-ups and maintained in hard copy. A complete history, examination and investigation were done, when required.

➢ **Case taking proforma:** A special case taking proforma was designed for the study with the approval of guide on which case taking was done after screening of the cases according to inclusion and exclusion criteria.

➢ **Diagnostic criteria:** The CBC is used to diagnose Anaemia; indicator for haemoglobin level in blood.

➢ **CBC TEST**- COMPLETE BLOOD COUNT is a blood test which gives us the detailed data about the amount of blood cells present in our body which helps us to diagnose different diseases in our body. Children with low haemoglobin concentration than 11.4gm/dL were considered anaemic and were studied in this research.

➢ **Record:** Centralized data was recorded in approved master chart in proper excel format.

11. Data Analysis:

➢ On the basis of pre and post Haemoglobin reports collecting after recommended follow ups.

➢ On the basis of pre and post anaemic symptom for anaemia after recommended follow ups.

➢ Outcome assessment:

• Improved- Improvement in any of the parameters that is haemoglobin concentration or the symptoms of anaemia.

• Not improved- No Improvement in any of the parameters that is haemoglobin concentration or the symptoms of anaemia.

12. Statistical Techniques:

➢ Data was analysed on the basis of t test (Paired t test) of statistical technique using IBM SPSS 28.0.1.1. version.

➢ Data was analysed on the basis of t test (Independent t test) of statistical technique using IBM SPSS 28.0.1.1. version.

➢ Before and after treatment Hb. values were analysed by using paired t- test

➢ Paired T-test

➢ Independent T-test

13. Ethical Clearance:

➢ Yes, ethical committee has verified the methodology and issued clearance certificate. (Appendix- VII)

➢ Patient information sheet was given to each & every patient where they were sensitized about the study.

➢ Consent of every patient was taken on consent form and confidentiality of their identity was maintained.

RESULTS:

Table 2: Distribution according to age

Age (in years)	No of Cases
5	11 (15.71%)
6	8 (11.42%)
7	10 (14.28%)
8	8 (11.42%)
9	6 (8.57%)
10	14 (20%)
11	13 (18.57%)

Table 3: Distribution of Cases According to sex

Sex	No of cases
Male child	45 (64.3%)
Female child	25 (35.7%)

Table 4: Distribution of Cases According to Socio-economic Status:

Socio-economic Status	No. of Cases (Percentage)
Lower	1 (1.4%)
Middle	69 (98.6%)

Table 5: Distribution according to Area of Residency:

Area of Residency	No. of Cases (Percentage)
Rural	47 (67.1%)
Urban	23 (32.9%)

Table 6: Distribution according to diet:

Diet	No. of Cases (Percentage)
Veg	66 (94.3%)
Non-Veg	04 (5.7%)

Table 7: Frequency of signs and symptoms:

Sign and Symptoms of Anaemia	No. of Cases (Percentage)
Pallor	70 (39.8%)
Fatigue	34 (19.3%)
Weakness	36 (20.5%)
Breathing Difficulty	14 (8.0%)
Dizziness	3 (1.7%)
Lethargy	9 (5.0%)
Cramps in legs	10 (5.7%)

Table 8: Distribution of homoeopathic individualized medicine in Group A

Homoeopathic medicines	No. of Cases (Percentage)
Natrum muriaticum	7 (20%)
Calcarea carbonica	4 (11.4%)
Sepia	4 (11.4%)
Sulphur	6 (17.1%)
Pulsatilla	2 (5.7%)
Zincum metallicum	1 (2.9%)
Nux vomica	1 (2.9%)
Medorrhinum	1 (2.9%)
Phosphorus	5 (14.3%)
Calcarea phosphorica	4 (11.4%)

Table 9: Distribution of cases according to status of patient after treatment in Group A

Status of improvement in Group A	No of cases
Improved	27 (84%)
Not improved	05 (16%)

Table 10: Distribution of cases according to status of patient after treatment in Group B

Status of improvement	No of cases
Improved	24 (80%)
Not improved	06 (20%)

Statistical Analysis:

Table 11: Paired Sample Statistics of Group A

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Group A	Post A	10.08	30	0.782	0.143
	Pre A	9.64	30	0.509	0.093

Paired Samples Correlations

		N	Correlation	Significance	
				One-Sided p	Two-Sided p
Group A	Post A & Pre A	30	0.643	<.001	<.001

Paired Samples Test

		Paired Differences						T	df	Significance	
		Mean	Std. Deviation	Std. Error Mea n	95% Confidence Interval of the Difference					One-Sidedp	Two-Side d p
					Lower	Upper					
Grou p A	Pos t A - Pre A	0.44	0.599	0.10 9	0.216	0.664		4.02 2	2 9	<.001	<.00 1

Paired sample t-test result to assess the effect of *Homoeopathic Individualized Medicine* on anaemia post treatment (M = 10.08, S.D. =0.78), compared to pre-treatment (M= 9.64, S.D. = 0.50) by Hb count analysis, Lower the Score indicate Hb improved by homoeopathic medicine, difference of mean= 0.44, t (29) = 4.02, *P* = <0.001

Table 12:

Paired Samples Statistics

		Mean	N	Std. Deviation	Std. Error Mean
Group B	Post B	9.91	32	0.592	0.105
	Pre B	9.51	32	0.415	0.073

Paired Samples Correlations

		N	Correlation	Significance	
				One-Sided p	Two-Sided p
Group B	Post B & Pre B	32	0.573	<.001	<.001

Paired Samples Test

		Paired Differences						T	df	Significance	
		Mean	Std. Deviation	Std. Error Mea n	95% Confidence Interval of the Difference					One-Sidedp	Two-Side d p

					Upper				
				Lower					
Grou p B	Pos t B - Pre B	0.397	0.491	0.08 7	0.22	0.574	4.57 4	3 1	<.001	<.00 1

Paired sample t- test result, to assess the effect of *Lecithinum* on anaemia post treatment (M = 9.91, S.D. = 0.59), compared to pre-treatment (M= 9.51, S.D. =0.41) by Hb count analysis lower Score indicates Hb improved significantly by *Lecithinum*, difference of mean= 0.39, t (31) = 4.57, *P* = <0.001

Table 13: INDEPENDENT T TEST

Group Statistics					
	Group	N	Mean	Std. Deviation	Std.Error Mean
Pre	Group A	30	9.64	0.509	0.093
	Group B	32	9.51	0.415	0.073
Post	Group A	30	10.08	0.782	0.143
	Group B	32	9.91	0.592	0.105

Independent Samples Test										
				t-test for Equality of Means						
Levene's Test for Equality of Variances										
									95% Confidence Interval of the Difference	
		F	Sig.	T	df	Significance		Mean Difference	Std. Error Difference	
						One-Sided p	Two-Sided p			Lower	Upper
Pre	Equal variances assumed	0.913	0.343	1.139	60	0.13	0.259	0.134	0.118	-0.101	0.369
	Equal variances not assumed			1.131	56.066	0.131	0.263	0.134	0.118	-0.103	0.371
Post	Equal variances assumed	2.951	0.091	1.009	60	0.158	0.317	0.177	0.175	-0.174	0.528
	Equal variances not assumed			1	53.948	0.161	0.322	0.177	0.177	-0.178	0.532

Independent Samples Effect Sizes					
		Standardize era	Point Estimate	95% Confidence Interval	
				Lower	Upper
Pre	Cohen's d	0.463	0.289	-0.213	0.789
	Hedges' correction	0.469	0.286	-0.21	0.779
	Glass's delta	0.415	0.323	-0.184	0.824
Post	Cohen's d	0.69	0.256	-0.245	0.756
	Hedges' correction	0.699	0.253	-0.242	0.746
	Glass's delta	0.592	0.299	-0.207	0.8

An independent samples t-test was conducted to compare Pre treatment Hb in cases of anaemia for *Homoeopathic Individualized Medicine* (Group A) and *Lecithinum* (Group B). There was not a significant difference in the pre-treatment Hb of Group A [M= 9.64, SD= 0.50] and for Group B [M= 9.51, SD= 0.415] at t (60) = 1.139, p= 0.259.As the p-value is larger than 0.05, we cannot conclude that a significant difference exists between Group A and Group B. An independent samples t-test was conducted to compare Post treatment Hb in cases of anaemia for *Homoeopathic Individualized Medicine* (Group A) and *Lecithinum* (Group B). There was not a significant difference in the post-treatment Hb ofGroup A [M= 10.08, SD= 0.78] and for Group B [M= 9.91, SD= 0.59] at t (60) = 1.009, p=0.317. As

the p-value is larger than 0.05, we cannot conclude that a significant difference exists between Group Aand Group B.

Therefore, the Null hypothesis gets accepted stating that there is no significant difference between the two groups i.e., *Homoeopathic Individualized Medicine* and *Lecithinum* in cases of anaemia in Children.

DISCUSSION:

Age Incidence: Maximum incidence of anaemia was noted in children of age 10 years, i.e., 20% (n=14) while the least incidence was in the age of 9 years, i.e., 9% (n=6). There were 16% (n=11) in 5 years of age, 11% (n=8) in 6 years of age, 14% (n=10) in 7 years of age, 11% (n=8) in 8 years of age, 19% (n=13) in 11 years of age group.

Sex Incidence: It was observed from the study that maximum number of cases suffering from anaemiawere found in male child i.e., 64.3% (n=45) while the least number of cases were in the female child i.e., 35.7% (n=25). In a study done in Sudan on children shows 49% prevalence on male child whereasfemale child was having 51 % of prevalence in anaemia.[3]

Socio-economic Status: Maximum incidence of anaemia was observed in Middle class i.e., 98.6% (n=69) cases and only 1 case was from upper class.

Area of Residence: Maximum incidence of anaemia was observed in the patients of rural area i.e., 67.1% (n= 47), whereas in urban area incidence was 32.9% (n= 23). According to NFHS5

(2019-21)the prevalence in rural area was 72.4 % and prevalence in urban area was 68.3%.[4]

Diet: It was observed that there were 4 patients taking non-vegetarian diet while the maximum were vegetarians i.e., 66. From the study "Prevalence of anaemia in school children by Neeraj Jain and Vibha Mangal Jain" it was found that vegetarian children were found to be more anaemic than the non- vegetarians.[5]

Sign and symptoms of anaemia:
In 70 cases, the variety of sign and symptoms of anaemia were found in the patients. Pallor was the sign found in all the 70 cases which is followed by other symptoms of anaemia like weakness (36), fatigue (34), breathing difficulty (14), cramps in legs (10) lethargy (9) and dizziness (3).

Homoeopathic medicines prescribed in Group A:
Group A were prescribed the individualized homoeopathic medicine on the basis of symptomsimilarity. Maximum cases that is 7 cases were given *Natrum muriaticum* followed by *Sulphur* in 6 cases, *Phosphorus* in 5 cases, *Calcarea carbonica*, *Calcarea phosphoricum* and *Sepia* in 4 cases each,*Pulsatilla* in 2 cases and *Nux vomica*, *Medorrhinum*, *Zincum metallicum* in 1 case each.

Status of patient after treatment:
Among the 70 cases of anaemia, after drop out of 08 cases (Group A-3, Group B-5), improvement was seen in 51 cases (Group A-27 & Group B-24) in terms of increased Hb, and 11 cases (Group A-5, GroupB-6) reported no improvement.Strength of the Study:
This was first study to be done in anaemia in children in 5 to 11 years of age group, generally researchesare done either in under five children or in reproductive age group of females.

Limitations of the Study:
1.There were no data found for reference in 5 to 11 years of age group, this affected the study.
2.This was a very basic study for the age group of 5 to 11 years of age group.

CONCLUSION:
Homoeopathic medicines can help in alleviating symptoms of diseases as well as improve the quality of life of the patients. From the study of **"A Comparative Study to assess the effectiveness of *Lecithinum* and *Homoeopathic Individualized Medicine* in Anaemia of children from 5 to 11 years age group"** various epidemiology, clinical and therapeutic observations have been made. 70 cases were studied and divided in two groups. Patients of group A were prescribed *Homoeopathic Individualized Medicine* andwas found effective while Patients of group B were prescribed *Lecithinum* which was also found to be effective. Comparing results of both the groups, it came to know that both have been found more or less equally effective in cases of anaemia in children. From the results of this study, the conclusion can be drawn that Homoeopathy is effective in both the ways that is therapeutically as well as a individualizedmedicine in cases of anaemic children.

Further recommendations:
• Randomized controlled trial should be done in future.

• This study was conducted with small sample size. So, in future a different population with large sample size is recommended for more reliable results.

• Period of this study was short. So, to confirm the conclusions long term studies are recommended.

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