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STUDYING THE ROLE OF HOMEOPATHY AS AN ADD-ON THERAPY IN YOUNG PATIENTS WITH TRANSFUSION DEPENDENT BETA THALASSEMIA ON IMPROVING HEALTH-RELATED QUALITY OF LIFE - AN EXPERIMENTAL UNCONTROLLED STUDY

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1. Abstract:

Inherited disorders of haemoglobin are the commonest genetic disorders in the world and constitute a major health problem. The Thalassaemias are a group of inherited disorders of Haemoglobin production in which there is impaired synthesis of alpha or beta globin chains.Beta thalassemia major presents with severe anaemia,poor growth,skelelatal abnormalities and requires lifelong blood transfusions which further causes iron overload related complications and are fatal.

The purpose to conduct the study using Individualized Homeopathic Medicines is to see whether they improve Health Related Quality of Life ,improve parameters like Hb,Serum ferritin and reduce transfusion frequency in Thalassemia patients and this can be assessed with TranQol Questionnaire.

OBJECTIVES:

Primary:.To study the role of Homoeopathy as an Add on therapy in patients with transfusion dependent Beta Thalassemia on improving health related quality of life.

Secondary:.To study the role of Homoeopathy in reducing the frequency of blood transfusion and

in improving blood parameters like Hemoglobin percentage and Serum Ferritin levels in transfusion dependent Beta Thalassemia.

MATERIALS AND METHODS:

20 cases of Thalasssemia Major from age group 10-24 were selected for an experimental uncontrolled study from opd,IPD,camps,Thalassemia centres.Medicines were prescribed after repertorization,based on totality of symptoms and final differntiation from materia medica.Data was analysed using Paired t test for the Quality of life scores and using Wilcoxon sign rank test for parameters like Hb,serum ferritin and trasfusion cycles.

RESULT:

The P value was significant at 95 % confidence interval for the improvement in Quality of life of Thalassemia patients using the paired t test.Homoeopathy played a role in reducing the frequency of blood transfusion and improving the blood parameters like Haemoglobin percentage and Serum Ferritin levels in transfusion dependent Beta thalassemia based on Wilcoxon Sign rank test Statistics.

CONCLUSION:

This study provides preliminary evidence that Homoeopathy as an add on therapy may offer benefits in managing thalassemia symptoms,including improvement in Quality of life and reduction in transfusion needs.

2. Keywords: *Thalassemia major, blood transfusion, iron-overload.*

3. Introduction:

Hemoglobinopathies, particularly Thalassemia, represent a significant global public health challenge. It is estimated that over 270 million individuals are carriers of this genetic disorder worldwide, with approximately 10,000 to 15,000 babies born annually in India with Thalassemia Major. Thalassemia is an autosomal recessive inherited disorder that results from a deficiency or abnormal synthesis of beta-globin chains, leading to an excess accumulation of alpha-globin chains. This imbalance causes hemolysis, red blood cell precursor destruction, and a reduced lifespan of erythrocytes.[1-5]

The breakdown of hemoglobin (Hb) in these patients results in the formation of reactive oxygen species, which can damage vital organs such as the heart, liver, and endocrine systems. Clinically, the disorder manifests with insidious onset, often presenting as microcytic hypochromic anemia, pallor, growth retardation, splenomegaly, frontal bossing of the skull, pathological fractures,

delayed menarche, and impaired development of secondary sexual characteristics. Early and accurate diagnosis is typically confirmed through Hb electrophoresis.[1-5]

Currently, the only definitive cure for Thalassemia Major is hematopoietic stem cell transplantation (HSCT), also known as bone marrow transplantation (BMT).

However, this treatment option is limited by factors such as high costs, a shortage of BMT centers, and the difficulty in finding suitable HLA-matched donors. As a result, regular blood transfusions and iron chelation therapy remain the cornerstone of treatment. While blood transfusions alleviate the symptoms of anemia, they lead to iron overload, which can result in severe complications, including impaired growth, delayed sexual maturity, endocrine disruption, and damage to the heart, liver, kidneys, and bones. These complications significantly affect the patient's quality of life (QoL) and pose substantial long-term health risks.

In terms of cost, a cost-benefit analysis conducted in Northern Israel estimated the treatment cost for a single Thalassemia patient over their expected lifetime at approximately $2,000,000. In India, the annual cost for blood transfusion and iron chelation therapy for a 30 kg child was estimated at Rs. 200,000 in 2008. These substantial costs underscore the need for integration of alternative treatment and better management strategies.

Recent studies have highlighted the negative impact of Thalassemia on the Health-Related Quality of Life (HRQoL) of affected children, with reductions in physical, social, and mental capabilities ranging from 14% to 23%. Literature reviews suggest that Thalassemia significantly impacts not only the patients' physical health but also their psycho-social well-being and economic stability, affecting both the patients and their families. Furthermore, research has shown that homeopathic treatments, particularly individualized homeopathic medicines, may help reduce the frequency of blood transfusions in some patients, with reports indicating a decrease in transfusion demands by 25% to 75%.[13,14]

The purpose of this study was to evaluate benefits of Individualized Homeopathic Medicines in improving the HRQoL(Health related Quality of life) of children with Thalassemia. Additionally, the study assessed whether these treatments can improve clinical parameters such as hemoglobin (Hb) levels, serum ferritin, and reduce the frequency of blood transfusions. The impact of these interventions was measured using the TranQol questionnaire, a widely used validated tool for assessing quality of life in Thalassemia patients.[12]

Integrating Homoeopathy into mainstream medical practice could provide a more holistic approach to managing Thalassemia, improving not only the clinical outcomes but also the overall

quality of life for patients. Such an approach may offer an adjunctive treatment strategy, ultimately benefiting Thalassemia patients and addressing a critical gap in current management practices.

Objectives:

Primary objective

To study the role of Homoeopathy as an Add on therapy in patients with Transfusion dependent Beta Thalassemia on improving health related Quality of life.

Secondary objective

To study the role of Homoeopathy in reducing the frequency of blood transfusion and in improving blood parameters like Hemoglobin percentage and Serum Ferritin levels in transfusion dependent Beta Thalassemia.

4. Materials and Methods:

1. Study Setting: 20 cases from the Thalassemia Center, attached homoeopathic hospital OPD's and IPD and peripheral OPD's and through Health checkup Camps and Health Services.
2. Study design: Experimental uncontrolled.

Selection of Samples: Patients fulfilling the inclusion criteria and who have given consent to participate during the duration of study were included until the desired sample was achieved.

Inclusion Criteria:

i. Known cases of Transfusion dependent Beta Thalassemia

ii. Young age group (10-24years)

iii. All genders

Exclusion Criteria: All other types of Anaemias were excluded.

Withdrawal criteria:

Patients not willing to be a part of the study and at any given point of time wish to withdraw themselves from the study.

3. Selection of tool:

i. Detailed Homoeopathic Case taking

ii. TranQol Questionnaire

iii. Clinical Assessment

4. Operational definition:Young patients of 10-24 age group of all genders suffering from Thalassemia and requiring blood transfusion will be considered for assessment of Quality of Life and other parameters like Hb and Serrum Ferritin levels . Reduction in the frequency of Transfusion cycles.The outcome assessment done using the TranQol Questionnaire.

5. Brief of Procedures:20 cases of Thalassemia Major in the age group of 10-24 years were selected after detailed case taking and medicine was prescribed on the basis of symptom similarity. Proper potency and dose were selected according to principles of homoeopathic posology. Follow up of the patients was done for maximum up to 12 months (see Figure :5.2)

6. Outcome Assessment: TRANQOL SCALE (see Table 5.1),Serrum Ferrin Levels,Hb levels and Transfusion Frequency.

7. Data Collection:Detailed Homoeopathic Case taking,TranQol Questionnaire and Clinical Assessment.

8. Ethical issues: The consent and Assent of the patients was taken after explaining the details about the purpose of the study and course of treatment. No adverse reaction was seen in patients. Ethical clearance was taken from the Institutional Ethical Committee.

9. Statistical Technique and data analysis: Paired t test and wilcoxson sign rank test was used was used for statistical analysis. Data was analyzed with the help of Excel Sheet, Pie chart,line diagram and bar diagram. Data of the TranQol Questionnaire at the beginning of treatment and at the end of the treatment is analyzed using paired T test.Other parameters like frequency of transfusion cycles,Haemoglobin Percentage,Serrum Ferritin levels are analyzed using Wilcoxon Sign rank test.

10. Additional points for all experimental studies: Intervention

A Homoeopathic similimum based on totality of symptoms after repertorizing with Synthesis Repertory was found out and prescribed according to the requirement of the case.Medicines were given orally in the form of globules moistened with liquid potency.

Potency, repetition and change of medicine were decided on the basis of principles of Homoeopathic susceptibility and posology.Medicine from the sealed bottles from the same batch and from a GMP certified standard pharmacy was administered orally.

OUTCOME ASSESSMENT SCALE

SR. NO	TRANQOL	Never	Almost never	Some-times	Often	Always
1	I had trouble sleeping...	☐	☐	☐	☐	☐
2	I was free of pain or discomfort...	☐	☐	☐	☐	☐
3	Pain prevented me from doing what I needed to do	☐	☐	☐	☐	☐
4	I had enough energy for daily activities	☐	☐	☐	☐	☐
5	I was limited in my ability to do the kind of moderate work I take part in	☐	☐	☐	☐	☐
6	I was limited in my ability to do the kind of vigorous work I take part in	☐	☐	☐	☐	☐
7	I felt too tired to do the things I enjoy doing... (i.e. hobbies, crafts, sports, playing musical instruments, etc.)	☐	☐	☐	☐	☐
8	I found it hard to keep up with people of my age	☐	☐	☐	☐	☐
9	My health allowed me to participate in as many social activities as I would have liked	☐	☐	☐	☐	☐
10	My treatments prevented me from doing the things I wanted to do	☐	☐	☐	☐	☐
	We would like to know something about **your emotional health**	☐	☐	☐	☐	☐
11	I felt sad	☐	☐	☐	☐	☐
12	I worried about getting an infection from the blood I receive	☐	☐	☐	☐	☐
13	I worried about my health becoming worse	☐	☐	☐	☐	☐
14	I felt angry	☐	☐	☐	☐	☐
15	I felt anxious	☐	☐	☐	☐	☐
16	I was hopeful about my future	☐	☐	☐	☐	☐
17	I felt comfortable telling someone close to me about my condition	☐	☐	☐	☐	☐
18	I worried Thalassaemia might lead to an earlier death	☐	☐	☐	☐	☐
19	I worried about painful tests	☐	☐	☐	☐	☐
20	I worried about being able to have children	☐	☐	☐	☐	☐

21	I was bothered by my transfusion	□	□	□	□	□
22	I was bothered by my iron removal treatment	□	□	□	□	□
23	I felt guilty about missing my treatments	□	□	□	□	□
24	I felt different from other people	□	□	□	□	□
25	I was satisfied with my sex life or(skip this question)	□	□	□	□	□
	We would like to know something about **your family**	□	□	□	□	□
26	I received enough support from my family	□	□	□	□	□
27	I received enough support from my friends	□	□	□	□	□
28	Thalassaemia negatively affected my family	□	□	□	□	□
	I worried about paying for my medication/equipment	□	□	□	□	□
	My treatments posed a financial strain for me/my family... (i.e. transportation to/from hospital, medical equipment, time off work)	□	□	□	□	□
	We would like to know something about **your studies and career**					
31	I had trouble keeping up with my studies	□	□	□	□	□
	or I am not currently studying □					
32	I was bothered because I missed out on my studies	□	□	□	□	□
	or I am not currently studying □					
33	I was bothered because I missed out on my studies	□	□	□	□	□
	or I am not currently studying □					
34	I had trouble keeping up with my work	□	□	□	□	□
	or I do not currently work □					
35	I was bothered because I missed work	□	□	□	□	□
	or I do not currently work □					
36	Thalassaemia limited my career opportunities	□	□	□	□	□

Table 5.1: Outcome Assessment scale TranQol.

FLOW DIAGRAM OF THE STUDY

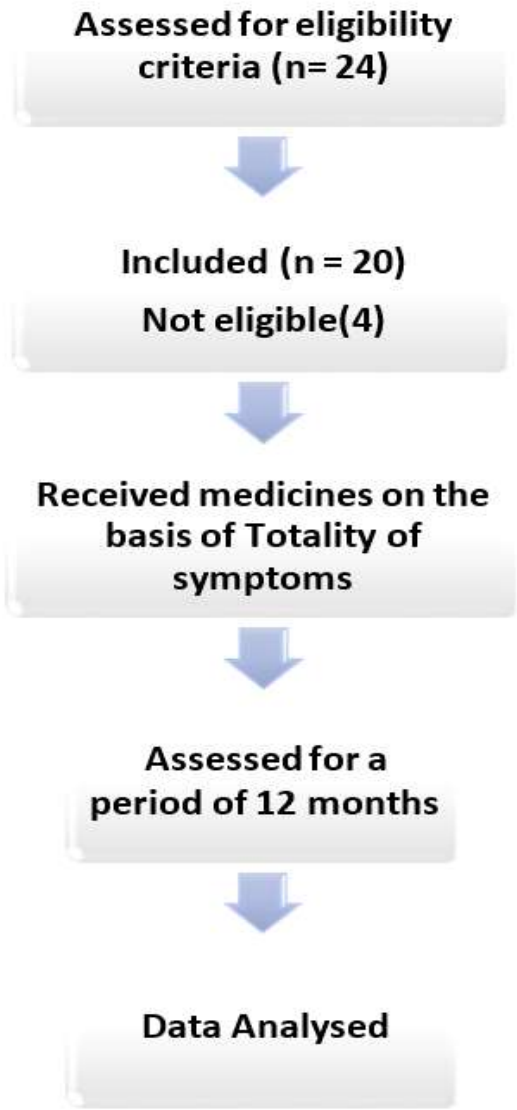

Figure 5.2 – Flow chart of study.

5. Results:

The present study includes a sample of 20 patients suffering from Beta-Thalassemia Major. All these 20 cases were followed up for a period of 12 months and were considered for statistical study. The description of data collected from 20 cases using tables and charts are described in this section. The demographic data includes 13 female and 7 male patients (see Figure 6.1). Maximum patients belong to the age group of 10–15 years (see Figure 6.2). The most frequently prescribed medicine found was Carcinosinum, followed by Natrum muriaticum, Pulsatilla nigricans, and Ceanothus americanus. Figure 6.4–6.7 shows the before and after values of quality

of life scores assessed using the TranQol Questionnaire, haemoglobin levels, serum ferritin levels, and transfusion frequency, respectively.

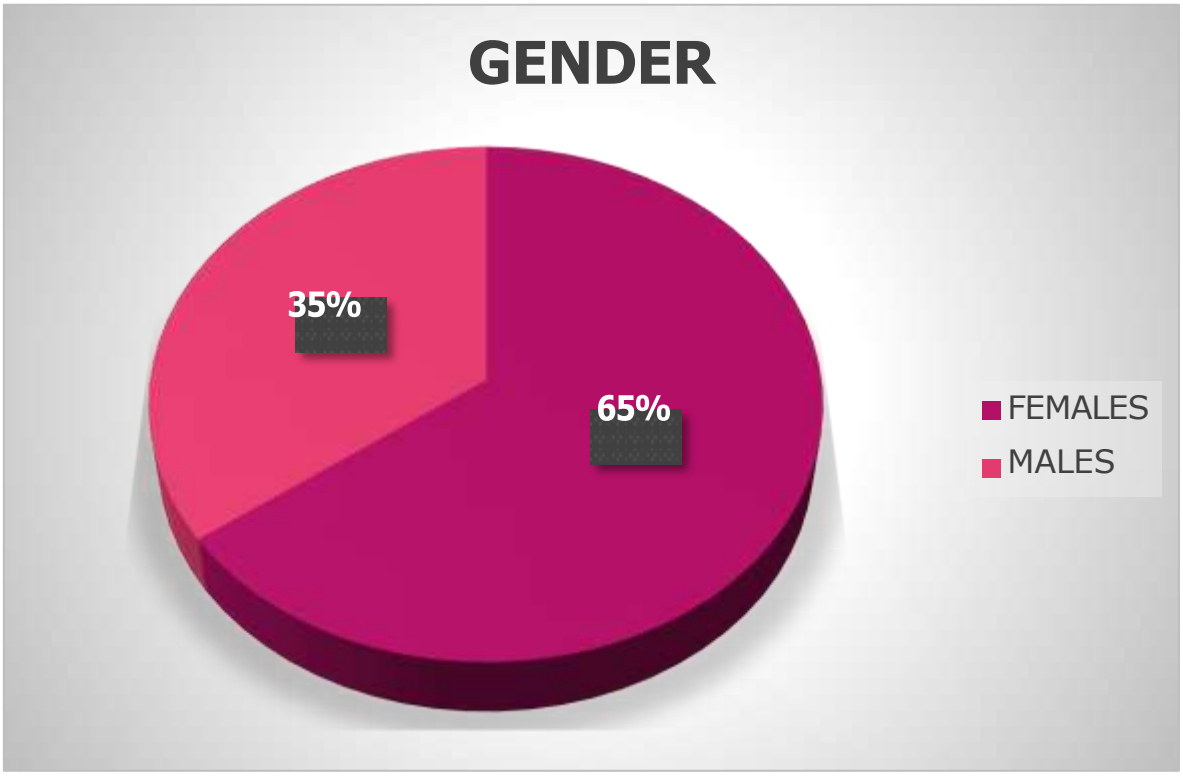

Figure 6.1: Distribution of cases according to gender.

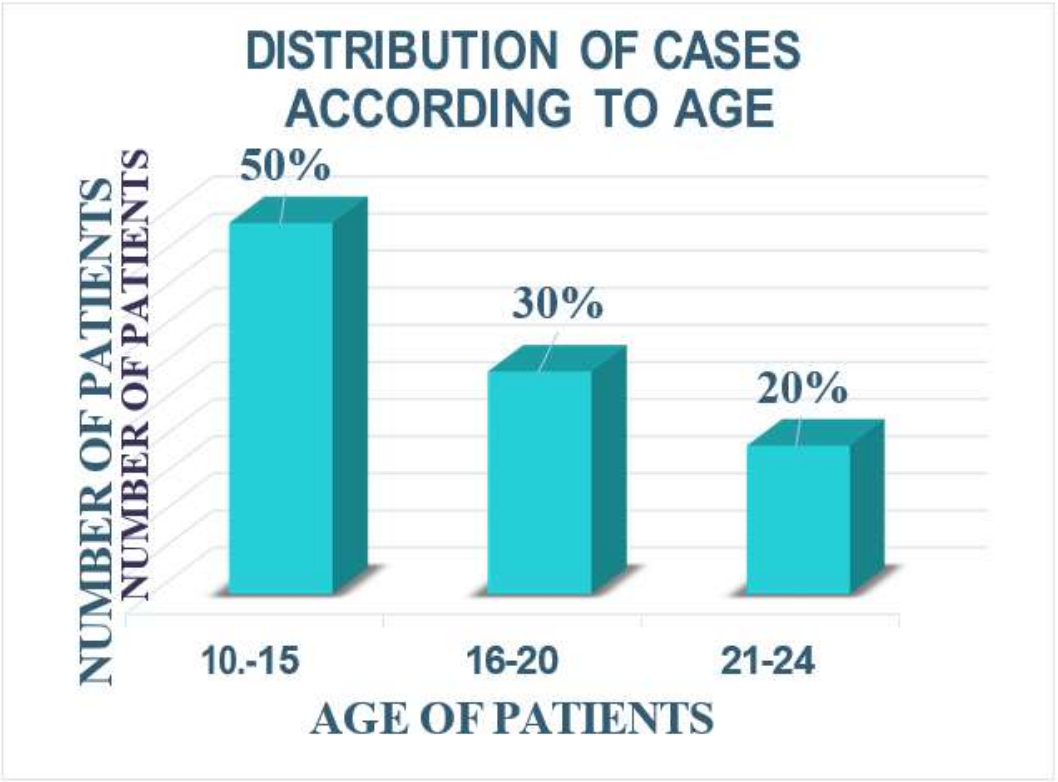

Figure no 6.2: Distribution of cases according to age

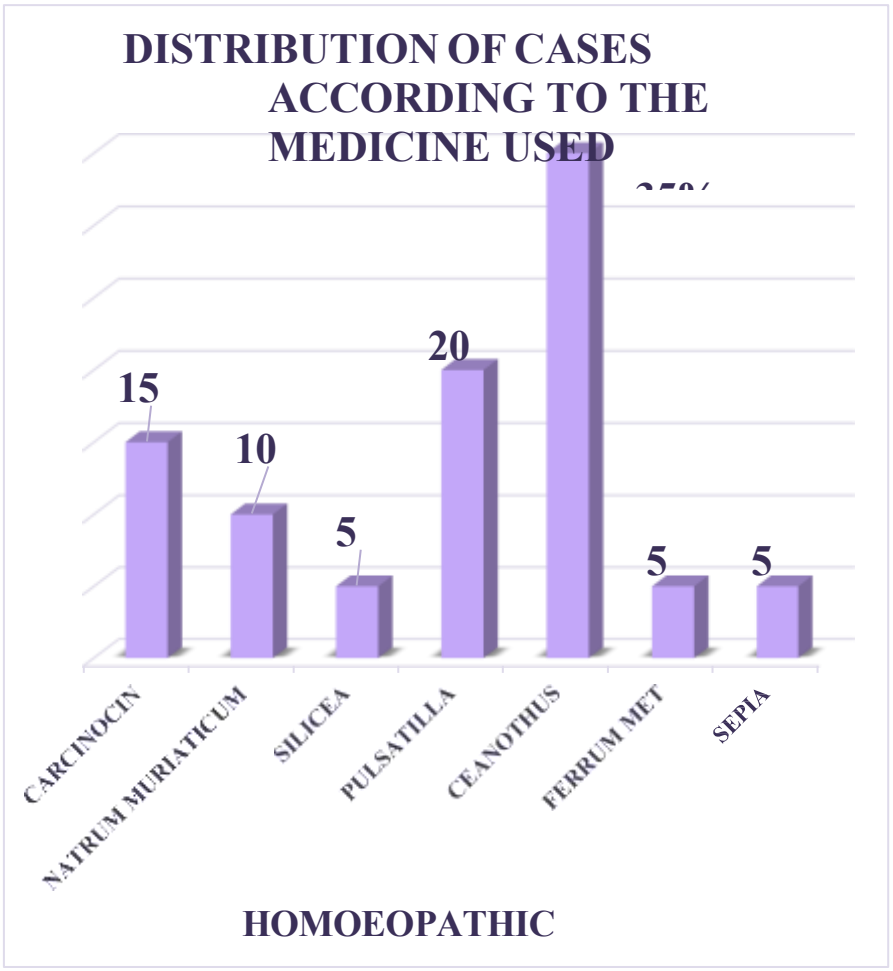

Figure 6.3: Distribution of cases according to Homoeopathic Medicines.

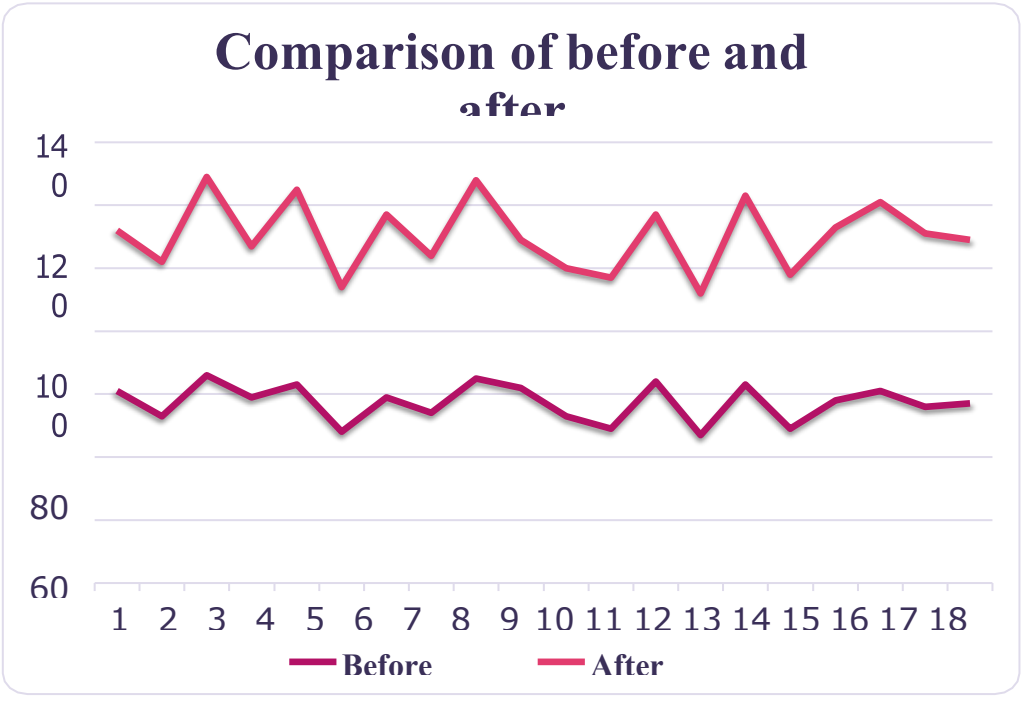

Figure no6.4: Casewise presentation of before and after treatment score of TRANQOL scale.

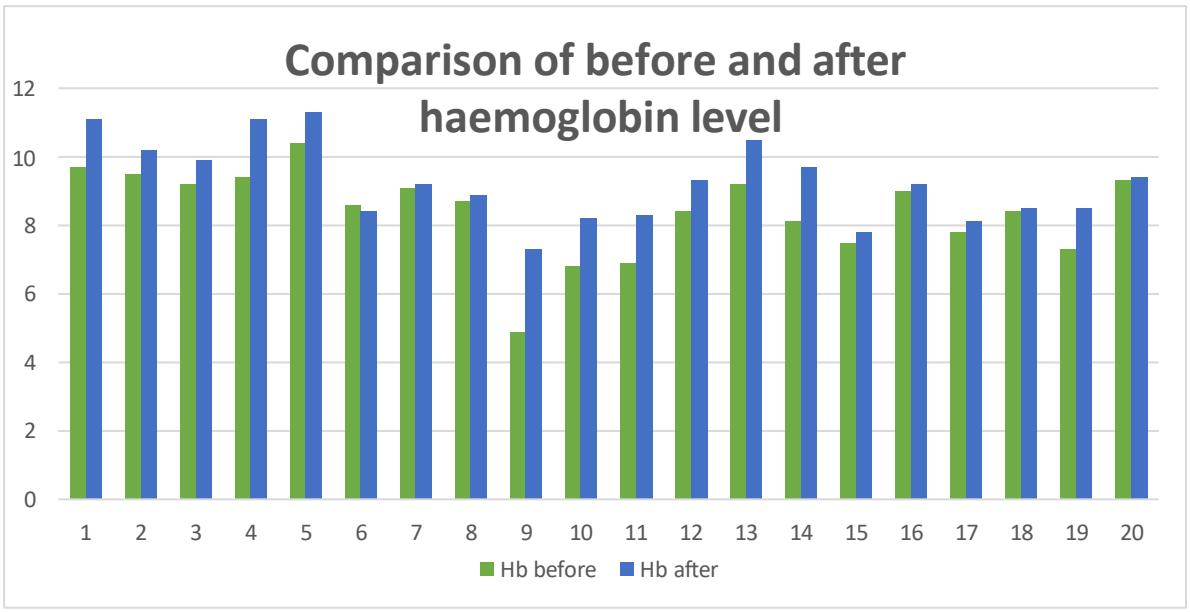

Fig :6.5 Comparison of before and after haemoglobin level

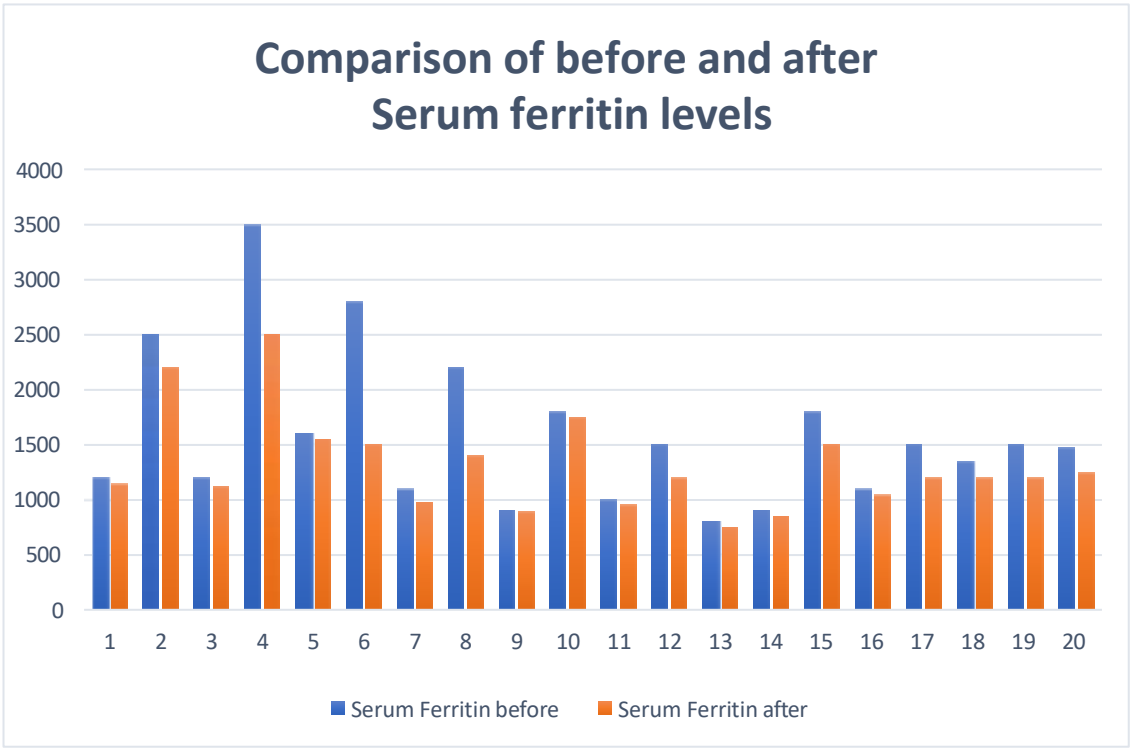

Fig 6.6: Comparison of before and after Serum ferritin levels

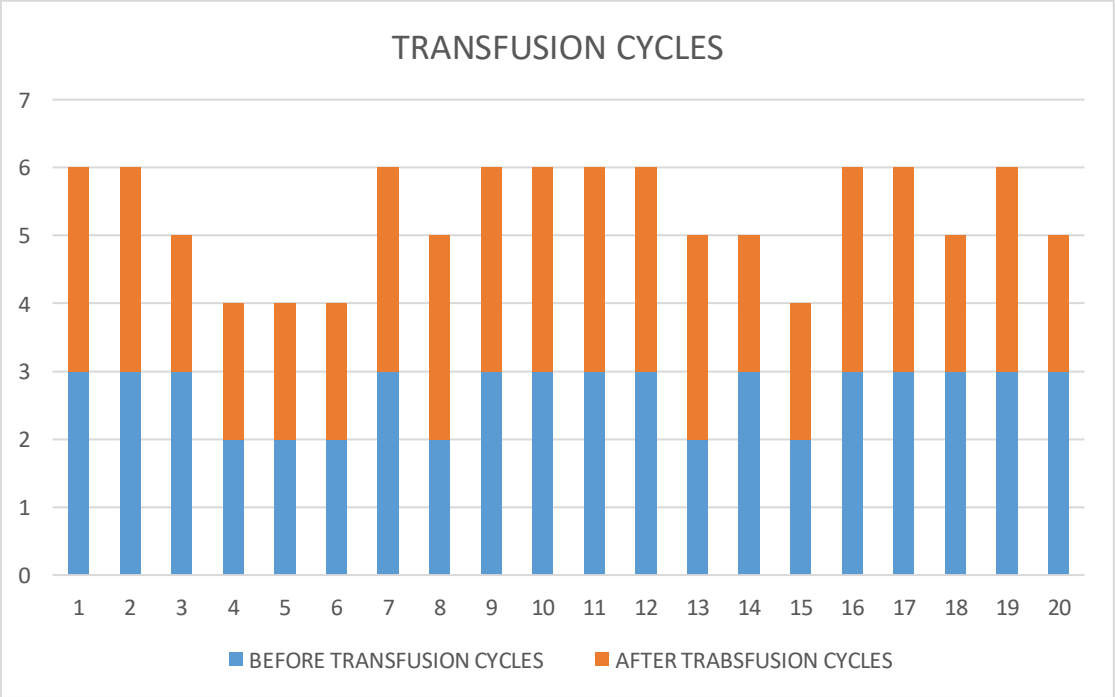

Fig 6.7: Comparison of before and after Transfusion cycles

STATISTICAL ANALYSIS

	Data	**Test used**
Before and after TranQol scores	Normally distributed	**Paired t test**
Before and After Hb levels	Not normally distributed	**Wilcoxon signed rank Test**
Before and after Serum Ferritin	Not normally distributed	**Wilcoxon signed rank Test**
Before and After Transfusion cycles	Not normally distributed	**Wilcoxon signed rank Test**

To determine whether the data is normally distributed or not, Shapiro- wilk test was used. The test showed that the before and after Tranqol score data is normally distributed hence,Paired T test was used.

H0 =Homeopathy does not play any role as an Add on therapy in improving health related quality of life in patients with transfusion dependent β Thalassemia.

H1 =Homeopathy plays a role as an Add on therapy in improving health related quality of life in

patients with transfusion dependent β Thalassemia

X1=Score After treatment X2= Score before treatment

N=Total number of Observations d=Mean difference between 2 scores S.D= Standard Deviation

S.E= Standard error of mean

Case no	**X1**	**X2**	**d=(X2-X1)**	**$(d-d^-)$**	**$(d-d^-)^2$**
1.	51	61	10	5.7	32.49
2.	49	53	4	-0.3	0.09
3.	63	66	3	-1.3	1.69
4.	48	59	11	6.7	44.89
5.	62	63	1	-3.3	10.89
6.	46	48	2	-2.3	5.29
7.	58	59	1	-3.3	10.89
8.	50	54	4	-0.3	0.09
9.	63	65	2	-2.3	5.29
10.	47	62	15	10.7	114.49
11.	47	53	6	1.7	2.89
12.	48	49	1	-3.3	10.89
13.	53	64	11	6.7	44.89
14.	45	47	2	-2.3	5.29
15.	60	63	3	-1.3	1.69
16.	49	49	0	-4.3	18.49
17.	55	58	3	-1.3	1.69
18.	60	61	1	-3.3	10.89
19.	55	56	1	-3.3	10.89
20.	52	57	5	0.7	0.49
Total	**1061**	**1147**	**86**		**334.2**

N=20

1) $\sum d$ = 86

2) Therefore, mean of difference

$d^- = \sum d \div N$

Hence, $d^- = 86 \div 20 = 4.3$

3) Degree of freedom Df=N-1=20-1=19

4) Variance

$S^2 = \sum (d-d^-)^2 \div (N-1)$

$= 334.2 \div 19 = 17.59$

5) To find Standard Deviation SD=$\sqrt{variance} = \sqrt{17.59} = 4.19$

6) To find Standard error (S.E)

S.E=S.D $\div \sqrt{N} = 4.19 \div \sqrt{20} = 4.19 \div 4.47 = 0.937$

The given data is quantitative and normally distributed.The sample size is 20,owing to this reasons paired t test was used to determine whether the difference between the meansis significant or not. To find the t value,following steps were followed.

1) Calculate the value of t statistics:-$T_{calculated} = d^- \div$ S.E$= 4.3 \div 0.937 = 4.62$

2) Referring to the t-table' the value of t at 19 degrees of freedom and 95% confidence interval level with 5% limit of significance (P = 0.05) is **2.093**

$T_{tabulated} = 2.093$

3) If $t_{calculated} > t_{tabulated}$ then the null hypothesis is rejected

If $t_{calculated} < t_{tabulated}$ then the null hypothesis is not rejected.

4) Here,from above calculations,

$t_{calculated} > t_{tabulated}$

$4.62 > 2.093$

Hence,the null hypothesis is rejected.

Therefore we accept the alternate hypothesis-Homeopathy plays a role as an Add on therapy in

improving health related quality of life in patients with transfusion dependent β Thalassemia

5) The value of p <0.001.Hence the result is significant at p<0.05 STATISTICS -I

The data (Hb levels,Serum ferrin levels and transfusion Cycles) was not normally distributed; it was checked through Shapiro-Wilk test hence, non-parametric test Wilcoxon signed rank test was applied.

Step 1: Null Hypothesis :There is no difference in before and after Haemoglobin levels Step 2: set the level of significance alpha=0.05

Step3: Wilcoxon Sign rank test statistic

Hb-before	Hb-after	DIFFERENCE	Ascending order	signs	Sum of Positive rank	Sum of negative ranks
9.7	11.1	1.4	0.1	+	2	
9.5	10.2	0.7	0.1	+	2	
9.2	9.9	0.7	0.1	+	2	
9.4	11.1	1.7	0.2	+	5	
10.4	11.3	0.9	0.2	+	5	
8.6	8.4	-0.2	0.2	-		-5
9.1	9.2	0.1	0.3	+	7.5	
8.7	8.9	0.2	0.3	+	7.5	
4.9	7.3	2.4	0.7	+	9.5	
6.8	8.2	1.4	0.7	+	9.5	
6.9	8.3	1.4	0.9	+	11.5	
8.4	9.3	0.9	0.9	+	11.5	
9.2	10.5	1.3	1.2	+	13	
8.1	9.7	1.6	1.3	+	14	
7.5	7.8	0.3	1.4	+	16	
9	9.2	0.2	1.4	+	16	
7.8	8.1	0.3	1.4	+	16	
8.4	8.5	0.1	1.6	+	18	
7.3	8.5	1.2	1.7	+	19	
9.3	9.4	0.1	2.4	+	20	
					205	**-5**

Mean(μ)

μ= n(n+1)/4=20(20+1)/4=105

standard deviation

σW=√n(n + 1)(2n + 1)/24=26.79

2) convert the test statistic to a z score

Z=T-μ/σ=-3.73

Where T=Tstatistic,Mean(μ),σW=standard deviation

3) Find the P value = 0.0002

4) Pvalue < alpha reject the null hypotheisis Summary

Test statistic T	5
Z score z	-3.73
P value	0.0002

Also the critical value is greater than tabulated value

Decision: reject the null hypothesis because p value is < 0.05.Hence, there is significant difference in before and after values of Hb values under Homoeopathic treatment.

STATISTICS -II

The datanot normally distributed; it was checked through Shapiro-Wilk test hence, non-parametric test Wilcoxon signed rank test was applied.

Step 1: Null Hypothesis :There is no difference in before and after Serum Ferritin levels Step 2: set the level of significance alpha=0.05

Step3: Wilcoxon Sign rank test statistic

Serum Ferritin before	Serum ferritin after	DIFFERENCE	Ascending order	signs	Sum of Positive rank	Sum of negative ranks
1200	1150	50	10	+	1	
2500	2200	300	40	+	2	

1200	1120	80	50	+	5.5	
3500	2500	1000	50	+	5.5	
1600	1550	50	50	+	5.5	
2800	1500	1300	50	+	5.5	
1100	970	130	50	+	5.5	
2200	1400	800	80	+	5.5	
900	890	10	130	+	9	
1800	1750	50	150	+	10	
1000	960	40	220	+	11	
1500	1200	300	300	+	12	
800	750	50	300	+	15	
900	850	50	300	+	15	
1800	1500	300	300	+	15	
1100	1050	50	300	+	15	
1500	1200	300	300	+	15	
1350	1200	150	800	+	18	
1500	1200	300	1000	+	19	
1470	1250	220	1300	+	20	
					210	**0**

Mean(μ)

$\mu = n(n+1)/4 = 20(20+1)/4 = 105$

standard deviation

$\sigma W = \sqrt{n(n+1)(2n+1)/24} = 26.79$

2) convert the test statistic to a z score

$Z = T - \mu/\sigma = -3.92$

Where T=Tstatistic,Mean(μ),σW=standard deviation

3) Find the P value = 0.0002

4) Pvalue < alpha reject the null hypotheisis Summary

Test statistic T	0
Z score z	-3.92
P value	0.0002

Also the critical value is greater than tabulated value

Decision: reject the null hypothesis because p value is < 0.05.Hence, there is significant difference in before and after values of Serum Ferritin levels under Homoeopathic treatment.

STATISTICS -III

The data was not normally distributed; it was checked through Shapiro-Wilk test hence, non-parametric test Wilcoxon signed rank test was applied.

Step 1: Null Hypothesis :There is no difference in before and after blood transfusion cycles

Step 2: set the level of significance alpha=0.05 Step3: Wilcoxon Sign rank test statistic

		DIFFERENCE	Ascending order	signs	Sum of Positive rank	Sum of negative ranks
3	3	0				
3	3	0				
3	2	-1	1	-		-1
2	2	0				
2	2	0				
2	2	0				
3	3	0				
2	3	1	1	+	+1	
3	3	0				
3	3	0				
3	3	0				

3	3	0				
2	3	1	1	+	+1	
3	2	-1	1	-		-1
2	2	0				
3	3	0				
3	3	0				
3	2	-1	1	-		-1
3	3	0				
3	2	-1	1	-		-1
					+2	**-4**

T statistic T=Tmin=2 Mean(μ)

μ= n(n+1)/4=20(20+1)/4=105

standard deviation

σW=√n(n + 1)(2n + 1)/24=26.79

2) convert the test statistic to a z score

Z=T-μ/σ=-103/26.79=-3.84

Where T=Tstatistic,Mean(μ),σW=standard deviation

3) Find the P value = 0.0002

4) Pvalue < alpha reject the null hypothesis Summary

Test statistic T	2
Z score z	-3.84
P value	0.0002

Also the critical value is greater than tabulated value

Decision: reject the null hypothesis because p value is < 0.05.Hence, there is significant difference in before and after values of Transfusion cycles under Homoeopathic treatment.

Homoeopathy played a role in reducing the frequency of blood transfusion and in improving blood parameters like Hemoglobin percentage and Serum Ferritin levels in transfusion dependent Beta Thalassemia based on above statistics.

6. Discussion:

Based on the Statistical Analysis P value was Significant at 95% confidence interval for the improvement of Quality of Life Of Thalassemia patients using the paired T test.Statistically significant improvement was seen in blood parameters like Hb and Serrum ferritin along with some reduction in transfusion cycles using Wilcoxon Sign rank test.

The present study shows that Indivisualized medicines when used as an add-on therapy is associated with improvement in Quality of life among Transfusion dependent Beta-Thalassemia patients.Improvent was observed in transfusion frequency and Haematological parameters.

Previous studies have explored the potential benefits of combining homeopathy with conventional treatments. Homeopathic remedies such as **Pulsatilla nigricans**, **Ceanothus americanus**, and **Ferrum metallicum** have shown positive effects in thalassemia patients, including a decrease in serum ferritin levels, an increase in fetal hemoglobin (HbF) levels, and a reduction in spleen size. This combination therapy has demonstrated the potential to reduce transfusion frequency and improve overall health, particularly in developing countries.[12,13]

The Strengths of this study is the use of Validated tool TranQol Questionnaire the assessment of QOL of Thalassemia Patients and the assessment of Objective findings in the Haematological Parameters.However,the Limitation of this study was the lack of control group.

7. Conclusion:

This study provides preliminary evidence that Homoeopathy as an add on therapy may offer benefits in managing Thalassemia symptoms,including improvement in Quality of life and reduction in transfusion needs.However,further research with randomised controlled trials is needed to explore the potential role of Homoeopathy in Thalassemia management.

8. Conflict of Interest: No Conflict of Interest.

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