

## Paediatrics

**KEYWORDS:** Cyanocobalamin, Parenteral route, Oral route, Supplementation, Vitamin B12 and Deficiency.

## EFFECTIVENESS OF ORAL VS PARENTERAL TREATMENT FOR VITAMIN B12 DEFICIENCY



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**Abstract**

Vitamin B12 deficiency may result from various inherited or acquired disorders. The recommended minimum daily requirement for cyanocobalamin is approximately 2.4 micrograms. Conventionally, vitamin B12 deficiency has been treated by parenteral (intramuscular route) supplementation with cyanocobalamin. The present study aimed to assess the effectiveness of oral vs parenteral treatment for Nutritional vitamin B12 deficiency in children age (6month -17year). A total of 60 children were analyzed for comparative efficacy of oral (30 children) and parenteral (30 children) vitamin b12 using different parameters. It was observed that post- treatment Hb was significantly higher in both the groups as compared to pre- treatment Hb (p-value <0.05) but no significant difference was found in post- treatment levels of Hb between the two groups. The mean post-treatment MCV in fl 76 ± 9 and 81 ± 10 was comparable between oral and parenteral groups respectively. This study emphasized that no significant difference was seen in post- treatment Vitamin B12 levels between Oral and Parenteral groups. The study concluded that the Oral Vitamin B12 supplementation is equally efficacious as Parenteral supplementation for treatment of Vitamin B12 deficiency in children.

**INTRODUCTION**

Vitamin B12 also known as cobalamin, comprises a number of forms including cyano-, methyl-, deoxyadenosyl- and hydroxycobalamin. The cyano form, which is used in supplements, is found in trace amounts in food. The daily recommended requirement for cyanocobalamin is approximately 2.4 micrograms (1).

Vitamin B12 deficiency may result from various inherited or acquired disorders(2). The majority of patients with vitamin B12 deficiency are asymptomatic(3). The vitamin B12 deficiency can result in megaloblastic anemia. The observed most common hematological manifestations in children with vitamin B12 deficiency were leukopenia, followed by macrocytosis and thrombocytopenia.

Conventionally, vitamin B12 deficiency has been treated by parenteral (intramuscular route) supplementation with cyanocobalamin. However growing evidence suggests that oral vitamin B12 may be as good an option, regardless of the cause of vitamin B12 deficiency (4).

**AIMS AND OBJECTIVES**

The present study aimed to assess the effectiveness of Oral vs

Parenteral treatment for Nutritional vitamin B12 deficiency in Children age (6 month -17 year)

**MATERIAL & METHODS**

This randomized controlled trial was conducted in the Department of Paediatrics at Shri Maharaja Gulab Singh (SMGS) Hospital, Government Medical College, Jammu, over a period of one year w.e.f from 1st November, 2020 to 31st October 2021 after obtaining the institutional permission from concerned authority for treating vitamin B12 deficiency in children age group (6month-17year).

**Inclusion criteria:**

- Children age between 6 months and 17 years.
- Children with low vitamin B12 level (<200pg/ml).
- Patients whose parents or guardian agreed to participate in study by giving informed consent

**Exclusion criteria:**

- Patient receiving vitamin B12 supplementation.
- Patient with a history of allergic reaction to vit B12
- Patient who was seriously ill with any immunodeficiency disease or some other chronic disease.

A total of 60 children were randomly categorized into two groups, group I consist of 30 patients who received oral supplementation and group II consist of 30 patients who received parenteral supplementation of vitamin 12 formulations. Tests for complete blood counts and red cell indices were performed and a review of the peripheral smear for red cell size, fragmented cells, morphologic abnormalities was done.

Statistical analysis was performed by using SPSS version 17 (IBM SPSS Statistics, Chicago, IL). Quantitative variables were associated using independent t test with vitamin B12 deficiency and Qualitative variables were associated using Chi square test/Fisher Exact test. A p-value of <0.05 was considered statistically significant.

**Observations and Results**

In the present study a total of 60 study subjects were involved among them majority of participants (i.e.38.33%) were ≥15 years of age. Majority of oral group patients were aged <4 years whereas, majority of parenteral group patients were aged more than 15 years. It was evident that majority (65%) of study participants were females. Further, in both the groups' majority of the participants were Hindu and were residing in the rural areas.

It was observed that irritability and decreased appetite were significantly associated with the groups (p<0.05). Moreover, among Pre clinical signs, a significant association of Hepatomegaly (p <0.05) was found with both groups.

**Table 1: Association of laboratory values in Parenteral and Oral**

treatment groups in Pre and Post treatment period (mean±SD)

Laboratory parameters	Pre-Treatment Period		Post Treatment Period	
	Parenteral Group	Oral Group	Parenteral Group	Oral Group
Hemoglobin (g/dL)	5.81±2.06	6.20±2.83	11.92±1.53	11.36±1.18
Platelet count (per mcl)	128400±733 88.58	167700±12 5000.73	274200±125 583.44	266500±101 181.89
MCV	111.77±16.1 2	110.50±18. 04	81.63±10.15	76.80±9.89
Serum Vitamin B-12	97.53±23.6	107.43±30. 13	1070.93±623 .26	1060.57±487. 1018

As seen in table 1, a significant difference was found among both groups in pre-post treatment Hb, platelet count, MCV and serum Vitamin B12. Post-treatment Hb, platelet count, MCV and serum Vitamin B12 was significantly higher in both the groups as compared to pre-treatment Hb (P<0.05).

Table 2 Comparison of Post-treatment levels of HB, MCV and B12

Laboratory parameter	Group	Mean	SD	t
Hb	Oral	11.36	1.18	-1.585
	Parenteral	11.92	1.53	-1.585
Post MCV	Oral	76.80	9.89	-1.869
	Parenteral	81.63	10.15	-1.869
Post Vit B12	Oral	1060.57	487.10	-.003
	Parenteral	1070.93	623.26	-.003

As per Table 2, no significant difference was found in post-treatment levels of HB, MCV and Vitamin B12 (P>0.05).

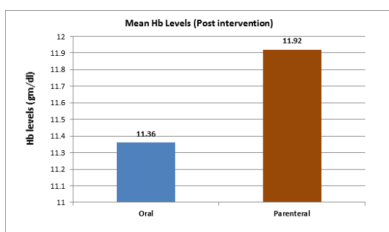


Figure 2. Hb levels between both the groups

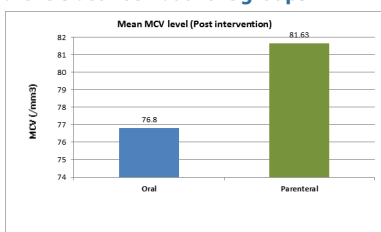


Figure 3. MCV levels between both the groups

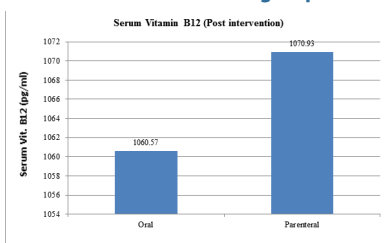


Figure 4. Serum Vitamin B12 levels between both the groups

Discussion

The findings of our study emphasize on comparative efficacy between oral and parenteral management of Vitamin B12

deficiency in children. In this study, Vitamin B12 deficient children were studied in two different groups, one receiving oral and other receiving parenteral Vitamin B12. Thirty children for each group were analyzed for comparative efficacy of oral and parenteral vitamin b12 using different parameters.

The mean age (in years) of oral and parenteral groups were 7.34 (SD=6.49) and 12.69 (SD=5.21) respectively. Majority (50%) of patients in group receiving oral Vitamin B12 were in age group 0-4 years while as in group receiving parenteral Vitamin B12 majority (57%) of patients were in age group of more than 15 years. Similar results were seen in study conducted by Bahadir et al., (2014) where majority (50%) of patients belonged to above 10yr.<sup>5</sup>

Apart from this, the gender wise distribution in oral group involves 33.3% male and 66.7% female. Parenteral group involves 37% male and 63% female patients. Study done by Sezer et al., 2017 showed Vitamin B12 deficiency at median age of 2.5 years with majority of patients (59.5%) as males which is contrary to the findings of this study.<sup>6</sup>

There was no statistically significant difference between the two groups with regards to residences. Also, majority of patients in both the group were residing in rural areas.

In this study Mean pre-treatment hemoglobin in gram per deciliter was 6.20 ±2.83 and 5.81 ± 2.06 in patients receiving oral Vitamin B12 and parenteral Vitamin B12 respectively and no significant difference was found between the two groups. Study done by Sezer et al., 2017 observed Mean pre-treatment hemoglobin (gram %) as 11.6 ± 1.5 and 11.7 ± 1.2 in patients receiving oral Vitamin B12 and parenteral Vitamin B12 respectively.<sup>6</sup>

In this study mean pre-treatment platelet count in lakhs per micro litre (µL) was 1.67 ±1.25 and 1.28 ± 0.77 in groups receiving oral and parenteral Vitamin B12 respectively and there was no significant difference found in platelet count between the two groups. Similar results were observed in study conducted by Verma et al., 2017.<sup>7</sup>

In this study mean pre-treatment mean corpuscular volume (MCV) in femtoliters fL was 110±18 and 111±16 in groups receiving oral and parenteral Vitamin B12 respectively and there was no significant difference found in MCV between the two groups. Butler Cet al., 2006 observed a MCV value of 100±12 and 102±11 in groups receiving oral and parenteral Vitamin B12 respectively.<sup>8</sup>

In this study mean pre-treatment Vitamin B12 level in picogram per ml was 107 ±30 and 97± 23 in groups receiving oral and parenteral Vitamin B12 respectively and no significant association was found between the groups.

Study done by Sezer et al 2017., revealed mean pre-treatment Vitamin B12 level as 183 ± 47 and 175 ± 42 picogram per ml among oral and parenteral groups respectively. Another study conducted by Butler C et al., 2006 observed 93± 46 and 95± 92 as mean pre-treatment Vitamin B12 levels in oral and parenteral groups respectively.<sup>6,8</sup>

Primary outcome of this study i.e. Hb (Hemoglobin) and Serum Vitamin B12 were reassessed at 3 months in both the Oral and Parenteral groups. Mean post-treatment hemoglobin in gram percent was 11.3 ± 1.1 in group who received oral Vitamin B12 while as mean post-treatment Hb in group who were put on parenteral Vitamin B12 was 11.9 ± 1.5 gram percent. Post- treatment Hb was significantly higher in both the groups as compared to pre-treatment Hb (p-value <0.05) but no significant difference was found in post- treatment levels of Hb between the two groups. Similar results were observed in the study done by Sezer et al., 2017 which revealed Mean post-treatment hemoglobin in gram per deciliter as 12 ± 0.9 and 11.8 ± 1.3 in patients receiving oral Vit B12 and parenteral Vit B12 respectively.<sup>6</sup>

In this study mean post-treatment MCV in fl  $76 \pm 9$  and  $81 \pm 10$  was comparable between oral and parenteral groups respectively. Our results were comparable with the study done by Sezeretal., 2017 and study conducted by Butler C et al.,2006.<sup>6,8</sup>

This study emphasized that no significant difference was seen in post-treatment Vitamin B12 levels between Oral and Parenteral groups although post-treatment Serum Vitamin B12 was higher in both the oral and parenteral groups as compared to pre-treatment Serum Vitamin B12 level. However contradicting results were seen in two RCTs by Butler C et al., 2006 where increase in Vitamin B12 levels in oral group was significantly higher than in parenteral group in one RCT while as no significant difference was seen in post-treatment Vitamin B12 levels between the two groups in another RCT.<sup>5</sup>

### CONCLUSION

The study concluded that Vitamin B12 Deficiency in pediatric age group has bimodal distribution as per age group 0-4 year and above 15 year and more common in females. The study further concluded that the Oral Vitamin B12 supplementation is equally efficacious as Parenteral supplementation for treatment of Vitamin B12 deficiency in children.

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