Original Article

COMPARISON OF INJECTION VITAMIN B12 WITH SYMPTOMATIC MANAGEMENT IN CLINICALLY SUSPECTED VITAMIN B12 DEFICENT PATIENTS: AN INTERVENTIONAL STUDY

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ABSTRACT

Objectives: This study was an attempt to evaluate the advantage of empirical use of Injection. Vitamin B 12 versus symptomatic management in clinically suspected Vitamin. B 12 deficient patients.

Methodology: A total of 100 patients over 20 years of age (irrespective of gender) were included in the study. The patients were divided into two groups, one group (n = 50) receiving vitamin B12 injections and the other group (n = 50) received symptomatic treatment.

Results: In clinically suspected vitamin B12 deficient patients after giving empirical therapy of Inj. Vit B 12; generalized fatigue (96%), pareshtesia (93.48%), myalgia (93.75%), loss of appetite (88.89%), confusion (93.75%) and tremor (93.55%) were improved with ($p<0.001$). Labored breathing and depression were also improved with Inj.Vit B 12 as compared to symptomatic management, but this difference was statistically insignificant($p = 0.052$ and $p = 0.201$ respectively).

Conclusion: We conclude and recommend from the study to treat clinically suspected Vit. B 12 deficient patients with empirical Vit. B 12 Injections without the need of costly serum Vit. B 12 estimation

Keywords: Injection Vit. B 12, Symptomatic management.

INTRODUCTION

The term "vitamin B12" is used as a generic descriptor for the cobalamins—those corrinoids (cobalt-containing compounds possessing the corrin ring) having the biologic activity of the vitamin. Some corrinoids that are growth factors for microorganisms not only have no vitamin B12 activity, but may also be antimetabolites of the vitamin. Although it is synthesized

exclusively by microorganisms, for practical purposes vitamin B12 is found only in foods of animal origin, there being no plant sources of this vitamin. This means that strict vegetarians (Vegans) are at risk of developing B12 deficiency. The small amounts of the vitamin formed by bacteria on the surface of fruits may be adequate to meet requirements, but preparations of vitamin B12 made by bacterial fermentation are available. [1]

Recommended Dietary Allowances (RDA) of vitamin B12 for adult males is 2.0 mcg and that for adult females 1 mcg.[2]

Even though the human body can store vitamin B12 to last for up to five years, its deficiency is not very uncommon.[3, 4]

The prevalence of deficient and marginal values is much higher in Asian countries,

70% in Indian adults and elders.[5]

Vitamin B12 deficiency is characterized by megaloblastic anemia, fatigue, weakness, constipation, loss of appetite, and weight loss. Neurological changes, such as numbness and tingling in the hands and feet, depression, confusion state and tremor can also occur.[6] The neurological symptoms of vitamin B12 deficiency can occur without anemia, so early diagnosis and intervention is important to avoid irreversible damage.[7]

Vitamin B12 deficiency is not just a laboratory finding but a clinically relevant issue which needs to be explored. Female gender and vegetarians are at substantial risk to develop B12 deficiency. The magnitude of the prevalence of B12 deficiency estimated in our population strengthens the argument that B12 deficiency is more prevalent in Indians. This study was an attempt to evaluate the advantage of empirical therapy by Inj. Vit B 12 versus symptomatic management in clinically suspected Vit. B 12 deficient patients.

METHODOLOGY

This was an Interventional study conducted during 6 months duration from March to September 2012 in SMIMER Hospital, a tertiary care teaching hospital in Surat city. A total of 100 patients over 20 years of age (irrespective of gender) were included in the study. Patient having at least four of the following symptoms/signs at the time of presentation at OPD were included in the study. These signs/symptoms include generalized fatigue, paresthesia, myalgia, loss of appetite, confusion, tremor, labored breathing, depression.

We had excluded patients having medical and surgical co-morbidities that hinder vitamin B 12 absorption like Sprue or celiac disease, Crohn's disease, pernicious anemia, tuberculosis, epilepsy, autoimmune disorders, long term use of acid reducing durgs, diabetes medication metformin users, parasite infections, chornic alcoholic and people who have undergone certain surgical procedures in the gastrointestinal tract such as surgery to remove all or part of the stomach from our study.

An informed written consent was taken from the eligible patients. Patients not giving written consent were excluded from the study. However they were provided routine management according to the protocol of the hospital.

After selection and written consent, the patients were randomly divided into two groups, one group receiving vitamin B12 injections and the other received symptomatic treatment. Randomly allocation was done with patients selecting a ball (red or blue) from an urn kept in the orthopedic OPD using sampling without replacement technique.

First group comprising 50 patients were treated with 2ml Intramuscular injection of Vit B 12 1000mcg thrice a week for total ten injections.[8] Fifty patients of second group were treated symptomatically with tab. Paracetamol (500mg thrice a day for first week then as and when required); tab. Diclofenac sodium (50mg twice a day for first week with antacids then as and when required); tab. Amitryptallin (10mg once a day, one hour before sleep for one month); tab. Multivitamin B complex (once daily for two months) [9]; physiotherapy; and dietary modification counseling [10]. Follow up of both groups of patients were done on weekly basis for first month, then every two weekly for next two month and then monthly basis for next three months. The follow up assessment was done only once at two months after the baseline assessment (done on the first contact with the patients).

RESULTS

The mean age of the patients was 41.35 years and S.D was 8.43. In our study 47 patients were

from age 20 to 40 years and 53 patients were from age 41 to 60 years. In our study 39 patients were male and 61 patients were female. (Table 1) There is no significant difference in age and gender in both the group.

It was observed in our study that generalized fatigue was improved with Inj. Vit B12 in 96 % patients as compared to 6.67% with symptomatic management (p <0.001).

Majority of patients (93.48%) with paresthesia were improved with Inj. Vit B 12 as compared to 6.82% with symptomatic management (p<0.001)

Table 1: Age and Genderwise distribution of subjects in both groups

Variable	Group A (Vit. B 12)	Group B (Symptomatic)	P-Value
Age			
20-40	20 (40)	27 (54)	0.161
41-60	30 (60)	23 (46)	
Gender			
Male	21 (42)	18 (36)	0.539
Female	29 (58)	32 (64)	

Figure in parenthesis indicate percentage

Table2: Comparision of symptoms in both groups after therapy

Variable	Status of variable	Vitamin B12 group (%)	Symptomatic group (%)	P-value	Odds Ratio (95% CI)
Generalized fatigue	Improved	48 (96)	3 (6.67)	< 0.001	336 (53.54-2108.30)
	Not improved	2 (4)	42(93.33)		
	Total	50 (100)	45(100)		
Paresthesia	Improved	43(93.48)	3(6.82)	< 0.001	195.88 (37.37-1026.67)
	Not improved	3(6.52)	41(93.18)		
	Total	46(100)	44(100)		
Myalgia	Improved	45(93.75)	2(4,55)	< 0.001	315 (50.12-1979.40)
	Not improved	3(6.25)	42(95.45)		
	Total	48(100)	44(100)		
Loss of appetite	Improved	40(88.89)	9(20.93)	< 0.001	30.22 (9.24-98.84)
	Not improved	5(11.11)	34(79.07)		
	Total	45(100)	43(100)		
Confusion	Improved	15(93.75)	1(12.50)	<0.001	105(5.70-1934.09)
	Not improved	1(6.25)	7(87.50)		
	Total	16(100)	8(100)		
Tremor	Improved	29(93.55)	1(11.11)	<0.001	116 (9.28-1448.78)
	Not improved	2(6.45)	8(88.89)		
	Total	31(100)	9(100)		
Labored breathing	Improved	4(80)	2(25)	0.0529	12 (0.79-180.98)
	Not improved	1(20)	6(75)		
	Total	5(100)	8(100)		
Depression	Improved	7(77.78)	1(16.67)	0.201	17.5 (1.22-250.36)
	Not improved	2(22.22)	5(83.33)		
	Total	9(100)	6(100)		

Myalgia was improved with Inj. Vit B12 in 93.75 % patients as compared to 4.55 % with symptomatic management (p <0.001).

Majority of patients (88.89%) with loss of appetite were improved with Inj. Vit B 12 as compared to 20.93% with symptomatic management (p<0.001)

Confusion was improved with Inj. Vit B12 in 93.75 % patients as compared to 12.50% with symptomatic management (p <0.001).

Majority of patients (93.55%) with tremor were improved with Inj. Vit B 12 as compared to 11.11% with symptomatic management (p<0.001).

Labored breathing and depression were also improved with Inj.Vit B 12 as compared to symptomatic management, but this difference was statistically insignificant(p = 0.052 and p = 0.201 respectively).

DISCUSSION

Vitamin B 12 deficiency is common in our country especially in vegetarian population. Many centers in our country still have no facility to estimate serum Vitamin B 12 and very costly in private health sector. We had seen in our results that after giving Inj. Vit B 12 empirically in clinically suspected vitamin B12 patients, generalized fatigue (96%), pareshtesia (93.48%), myalgia (93.75%), loss of appetite (88.89%), confusion (93.75%) and tremor (93.55%) were significantly improved versus symptomatic management protocols. Labored breathing and depression did not improve after giving vitamin B12 injections.

CONCLUSION AND RECOMMENDATIONS

We conclude and recommend from the study to treat clinically suspected Vit. B 12 deficient patients with empirical Vit. B 12 Injections without the need of costly serum Vit. B 12 estimation.

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