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ORIGINAL ARTICLE

A Clinimetric Approach To The Detection And Management Of Vitamin B₁₂ Deficiency Among A Vegan Group In Rural Coimbatore In Tamilnadu

BHARATWAJ R S*, MUTHUKUMAR K**

ABSTRACT

Introduction: Unfortified plant based foods do not contain Vit B₁₂. The deficiency of the vitamin is markedly under-diagnosed and is widespread in the developing countries. Low B₁₂ levels can have profound effects on the patient's well-being and if this condition is not detected and treated, it can lead to serious irreversible sequelae. There is no gold standard test for diagnosing the B₁₂ deficiency.

Materials and Methods: 121 vegans living as a group were assessed for the deficiency of Vit B₁₂ by using a clinimetric tool. Those who were found positive were given parenteral B₁₂ supplementation and were followed up for a three month period. The results were tabulated and analyzed by tests for the significance of the difference in the proportions.

Results and Discussion: 91(75.2%) of participants were found to be positive for Vit B₁₂ deficiency. The most common (90.1%) presentations were loss of appetite, excess fatigue, mood swings and irritability. The deficiency was significantly higher among the participants who were vegans for more than 5 years. The treatment with parenteral B₁₂ brought about a dramatic improvement in 85.7% of the deficient participants. 93.5% of the participants who were found to be deficient did show a perceptible improvement in well being by the end of three months.

Conclusion: Clinimetric approaches to detect Vit B₁₂ deficiency, a majority of which is sub-clinical, as a primary care tool at least for the high risk groups, would definitely help in alleviating a big magnitude of suffering people in the general population.

Key words: Clinimetry, B₁₂ Deficiency, Vegans, Coimbatore

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Introduction

Vitamin B₁₂ is a water soluble compound that is naturally available for human use only through animal proteins. Unfortified plant based foods do not contain Vitamin B₁₂. [1],[2],[3] Clinical Vitamin B₁₂ deficiency is very rare. Most of the patients are far likely to have a sub clinical deficiency. [4] The deficiency is markedly under diagnosed and widespread in developing countries. [5] A patient characteristic that should raise the index of suspicion is a long term adherence to a vegan diet. [6],[7] The common neurological complaints include paresthesias, weakness, motor disturbances, visual disturbances and a wide range of cognitive and behavioural changes, including dementia, depression and personality changes. Tingling in the hands and feet is the most common neurological complaint. [8] and [9] some frequent gastrointestinal complaints include anorexia, flatulence, diarrhoea and constipation. [10],[11]

Objectives

1. To assess the problem of Vit B₁₂ deficiency among a group of vegans by a pretested symptoms and signs analysis chart.
2. To evaluate the improvement in the condition of those diagnosed through the chart after instituting parenteral B₁₂ therapy for them over a period of three months.

Justification

Low Vit B₁₂ can have profound effects on patient well being, although most do not have overt symptoms and are in a sub clinical stage. If not detected and treated, they are at a risk of serious sequelae. [12]-[18]

There is no gold standard lab test for determining Vit B₁₂ deficiency. [19]

A primary care set up in a developing country like ours, does not have access to costly lab tests for assessing Vit B₁₂ deficiency.

The treatment is safe and remarkably effective. [12]-[18]

Materials and methods

A group of 121 vegans living as a community in Coimbatore, which is situated at 11° 00' N latitude and 77° 00' E longitude of Tamilnadu state, were chosen for the study. All the participants were living as a group for a spiritual

cause and were having a diet of a good nutritious type, except for the total absence of milk, milk products and any type of non-vegetarian diets. Informed consent was obtained from them for their participation in the study. The participants were assessed for Vitamin B₁₂ deficiency by using the symptoms and signs chart which was derived from the Dr Joseph Chandy B₁₂ Patient Support Group, which was made as a result of 28 years of clinical practice by Horden (North East England, UK) caring for, and helping, over 700 people who have benefited from Vitamin B₁₂ replacement therapy.

The data was tabulated and the differences were assessed by tests for the significance of the difference the proportions. Those who were found to be positive for Vit B₁₂ deficiency, based on the chart score (15 and above), were administered parenteral Vit B₁₂ (Four doses of 500 microgram over a period of two weeks intramuscularly (IM), followed by one dose weekly for the next six weeks and then monthly henceforth) and were followed up over a period of 3 months.

Results

The age group of the participants was in the range 18-42 years. The number of males was 70 and the number of females was 51. All the participants were teetotalers. The duration of following a vegan diet was for a minimum of three years for all and among these, 72(59.5%) participants were on a vegan diet for 3-5 years, 28(23.1%) were on it for 5-7 years and 21(17.35%) were on it for more than 7 years. None of them was on any medications and none had any currently diagnosed medical problems. Ninety one (75.2%) of the participants were found to be positive for Vit B₁₂ deficiency, based on the symptoms and signs analysis chart. Among those who were found to be positive for a B₁₂ deficiency, 82(90.1%) of them presented with symptoms of loss of appetite, excess fatigue, mood swings and irritability, these being the most common complaints. Fifteen (16.48%) had mouth ulcers, loose motions and tingling/numbness in hands and feet. Two had bladder incontinence, 1 of whom had frank neuropathy (loss of vibration sense in both lower limbs, impaired sensation to touch in both lower limbs and a positive Romberg's sign). Both the people with bladder incontinence as a feature

were on a vegan diet for more than seven years. Among these 91, the proportion of people with Vit B₁₂ deficiency among the vegans who had been on a vegan diet for 5 years and more(85.7%) and 7 years and more(90.4%), was significantly higher than in the group which had been vegan between 3-5 years (66.6%).(p<0.01)[Table/Fig I]

[Table/Fig 1]

	Vegan for 3-5 Yrs	Vegan for 5-7 Yrs	Vegan for > 7 Yrs
B12 Deficiency Present	48	24	19
B12 Deficiency Absent	24	4	2
	72	28	21

p<0.01

Treatment with 500 micrograms B₁₂ Injection IM, four doses within the first two weeks, followed by once weekly for the next six weeks and then monthly henceforth and follow up showed a dramatic improvement in 78(85.7%) in the first two weeks in terms of increased energy levels, less lethargy, more stable mood, less irritability, relieving of mouth ulcers, better appetite and digestion and an enhanced sense of general well being. After one month, seven more participants on therapy showed improvement on similar lines, including the 2 with bladder incontinence reporting a better control of bladder movements. After three months, no more participants showed any significant change. The person with neurological complaints still had impaired sensation and a positive Romberg's, but reported a big improvement in his overall state of well being. At the end of three months, only 6(6.59%) participants who were diagnosed as deficient by the chart, showed no perceptible improvement [Table/Fig II]. All the participants who showed improvement at two weeks and at the end of a month sustained their improvement up to the end of the study. Many of the participants who showed improvement confided of a great sense of psychological comfort and restfulness. A monthly dose of Injection B₁₂ was prescribed as long as they were following veganism.

[Table/Fig II].

	2 weeks	1 month	3 months
Improvement present	78	85	85
No Improvement	13	6	6

Discussion

This study points to the acknowledged fact of a high possibility of B₁₂ deficiency among vegans. Most of the improvement happened within the first two weeks of initiating therapy. The lab tests which were used to confirm the deficiency were not done in this study due to their unreliability, unavailability, as well as cost constraints.[19] The cost of a serum B₁₂ analysis is Rs.730 in a good quality lab, while tests like methyl malonate are not available, even in accredited labs in Coimbatore and hence, it could hardly be expected that such tests would be available in other accessible labs. Moreover, the unreliability of the lab tests in the diagnosis has been already stated. The prevalence of Vit B₁₂ deficiency among those on a pure vegan diet was higher with the duration of the veganism. In India, with B₁₂ food fortification hardly available on a large scale and the increasing trend of veganism, the risk is still higher for a deficiency to happen.

The analysis of the deficiency, based on gender, was not done as no information from the past supports a gender based enhancement the risk of the deficiency.[20] The parental route of therapy was preferred due to economic implications and bioavailability concerns. An oral formulation costs more than Rs. 4 per pill, which has to be taken daily life long, with problems of gastrointestinal absorption and compliance, as compared to Rs. 4 an ampoule for parenteral injection with multi dose vials still cheaper and a near complete bio availability. Excluding the cost of the professional charges of the doctor or the nurse, which in a primary care government set-up are offered free to the patients and considering that there would be no extra charges for giving an injection as compared to just prescribing, it works out per year to a cost of at least R.S 1460 for the oral formulation, as compared to less than R.S 170 (75 for the formulation+95 for the disposable syringes) for a good quality branded parenteral formulation. Moreover, the administration of parenteral B₁₂ has been the standard treatment protocol for decades. Only few side effects have been reported and patient compliance is generally high.[21],[22]

On a primary care level, thus, the use of a chart of this sort as a clinimetric tool by the physician can detect many of the sub clinical cases without any increased load on the system to cater for costly investigations that are still not very reliable or can be made available on a larger scale. Also, Vitamin B₁₂ is considered safe, even at levels which are much higher than the recommended dose. It has not been shown to be toxic or to cause cancer, birth defects, or mutations.[23] So, a nationwide campaign to transfer the simple chart technique to all the physicians can go a long way in preventing a lot of morbidity among a great number of people who are suffering the various consequences of a sub clinical deficiency and can prevent any irreversible complications from happening. Because of the high prevalence of mild, sub clinical cobalamin deficiency in asymptomatic individuals, it is important to remain vigilant, especially with individuals who are at a high risk for vitamin B₁₂ deficiency.

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