



Effect of Amalaki Rasayana on Vitamin B₁₂ Deficiency – Polyneuropathy : A Case Series

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ABSTRACT

Vitamin B₁₂ deficiency is believed to be widespread in population of India; a case series were conducted to determine the effect of Amalaki rasayana, an ayurvedic single proceeded drug on vitamin B₁₂ deficiency. Amalaki rasayana contains Amla (*Phyllanthus emblica* L.) one of the Indian citrate fruits and it does not contain vitamin B₁₂ constitute. The study was conducted to evaluate effect of Amalaki Rasayana in cases of vitamin B₁₂ deficiency. Nine cases of Vitamin B₁₂ deficiency poly-neuropathy were included in the study. Subjects were treated with 500mg Amalaki rasayana tablets for 8 weeks. Subjective and objective assessment was done on basis of improvement in Aids control trial group (ACTG) peripheral neuropathy symptoms and changes in serum B₁₂ values. Amalaki rasayana shows significant increase in serum B₁₂ values and improvement in symptoms. Amalaki rasayana helps to increase serum B₁₂ values, though it is not recognized as source of vitamin B₁₂. Amalaki rasayana treat the secondary causes with its activity like, Antioxidant, Cytoprotective, Gastro protective etc. Amalaki rasayana should be encouraged for the treatment for vitamin B₁₂ and related disease.

Keywords: Vitamin B₁₂, Amla, Indian gooseberry, Vitamin C, Neuropathy, *Phyllanthus emblica*

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INTRODUCTION

Vitamin B₁₂: A vitamin is an organic molecule that is an essential micronutrient which an organism needs in small quantities for the proper functioning of its metabolism. Among vitamins, vitamin B₁₂ is essential for normal functioning of nervous system and blood formation. It is a water-soluble vitamin which is also called as cobalamin, thermos-stable red crystals [1]. It is synthesized in nature only by micro-organisms; plants and animals acquire it from them. Vitamins absorbed in the body via different organs and different parts of Gastro intestine track (GIT). Vitamin B₁₂ is present in food as protein conjugates and is released by cooking or by proteolysis in stomach facilitated by gastric acid. Intrinsic factor (a glycoprotein, MW 60,000) secreted by stomach forms a complex with B₁₂-attaches to specific receptors present on intestinal mucosal cells and is absorbed by active carrier mediated transport. This mechanism is essential for absorption of vitamin B₁₂ ingested in physiological amounts. So here, Vitamin B₁₂ is absorbed via active process, within four steps 1) intact stomach, 2) intrinsic factor (glycoprotein), 3) pancreatic sufficiency 4) normally functioning terminal ileum. When deficiency of vitamin developed, it's due to either insufficient intake of source/food or unable to absorbed in body and due to some diseases. Cause of vitamin B₁₂ deficiency is outlined in table 1.

Table 1. Common causes of vitamin B₁₂ (cobalamin) deficiency.

Cause	
Low vitamin B ₁₂ intake	Vegetarianism, chronic alcoholism and older people.
Autoimmune	Pernicious anemia and Sjogren's syndrome
Food bound cobalamin malabsorption	Atrophic gastritis, chronic gastritis and helicobacter pylori associated gastritis
Surgery	Post gastrectomy and iliac resection

Malabsorption	Small intestine bacterial overgrowth, chronic pancreatic exocrine insufficiency, Crohn's disease, celiac disease and achlorhydria
Obstetric/gynecological	Oral contraceptive, hormone replacement therapy and pregnancy
Genetic	Transcobalamin II deficiency
Drugs	Metformin, proton pump inhibitors, histamine H ₂ receptor antagonist.

Neurological complications are present in 75 to 90 percent of individuals with clinically observable B₁₂ deficiency and may, in about 25 percent of cases, be the only clinical manifestation of B₁₂ deficiency [2]. Since vitamin B₁₂ supports the sheathing that coats the nerve cells, people with vitamin B₁₂ deficiency often suffer from peripheral neuropathy.

Amalaki rasayana:

Amalaki Rasayana, an Ayurvedic formulation used in Indian traditional system is single drug formulas which is made by *Amla* (*Phyllanthus emblica L.*) and proceed by its own fresh juice by a procedure called *bhavana* (trituration), which made the drug highly potent. *Amla* (*Phyllanthus emblica L.*) primarily contains tannins, alkaloids, phenol compounds, amino acids and carbohydrates. Its fruit juice contains the highest vitamin C (478.56 mg/100 mL). The fruit when blended with other fruits boosted their nutritional quality in terms of vitamin C content [3]. Average percentage composition of the fruit pulp of *Amla* (*Phyllanthus emblica L.*) [4] are outline in Table 2 and Chemical constitute found in *Amla* (*Phyllanthus emblica L.*) are mentioned in Table 3.

Table 2. Composition of *Amla* (*Phyllanthus emblica L.*)

1	Moisture	81.2%
2	Protein	0.5%
3	Fat	0.1%
4	Mineral matter	0.7%
5	Fiber	3.4%
6	Carbohydrate	14.1%
7	Calcium	0.05%
8	Phosphorous	0.02%
9	Iron	1.2mg/100gm
10	Nicotinic acid	0.2mg/100gm
11	Vitamin C	600mg/100gm

Table 3. Chemical constitutes found in *Amla* (*Phyllanthus emblica L.*)

Tannins	Carbohydrates	Chebulinic acid	Gallic acid	Citric acid
Alkaloids	Vitamin C	Quercetin	Emblicanin-B	Ellagotanin
Phenolic compounds	Flavonoids	Chebulagic acid	Punigluconin	Trigallay glucose
Amino acids	Ellagic acid	Emblicanin- A	pedunculagin	Pectin

From the ayurvedic prospective *Amalaki rasayana* has qualities like *Tridosahara*, *Rochana*, *Dipana*, and *Anulomana* which may help indigestion, absorption, and motility of digestive materials in the gut [5].

To evaluate efficacy of *Amalaki rasayana* in the management of vitamin B₁₂ deficiency poly-neuropathy.

MATERIAL AND METHODS

Total 09 patients (08 female, 01 male) of vitamin B₁₂ deficiency, with poly-neuropathy were selected from out-patient department of *Kayachikitsa*, Parul Ayurved Hospital, and Parul University. Patients were showing symptoms of poly-neuropathy-Pain, numbness, tingling sensation, burning sensation in feet. Duration of symptoms may vary from six months to one year. After thorough detailed clinical history, physical examination and estimation of vitamin B₁₂ level in serum. Patients were selected on the basis inclusion exclusion criteria.

Inclusion Criteria

Patients of either gender, between age group of 20 to 60 years.

Clinical features of vitamin B₁₂ (cobalamin) deficiency poly-neuropathy like numbness, burning sensation, pricking pain etc.

Low levels of serum B₁₂ ≤ 150 pmol/L (200 pg/mL).

Exclusion Criteria

Vitamin B₁₂ deficiency due to any secondary systemic illness/disease like Malabsorption syndrome, Crohn's disease, Uncontrolled systemic diseases like Diabetes Mellitus & Hypertension, Pregnant and lactating women, Patients receiving any other vitamin supplementation. Immunocompromised patients such as HIV.

CRITERIA FOR ASSESSMENT

The assessment was done on the basis of following parameters.

On the basis of improvement in ACTG peripheral neuropathy symptoms before and at the end of the study and changes in serum B₁₂ values before and at the end of the study.

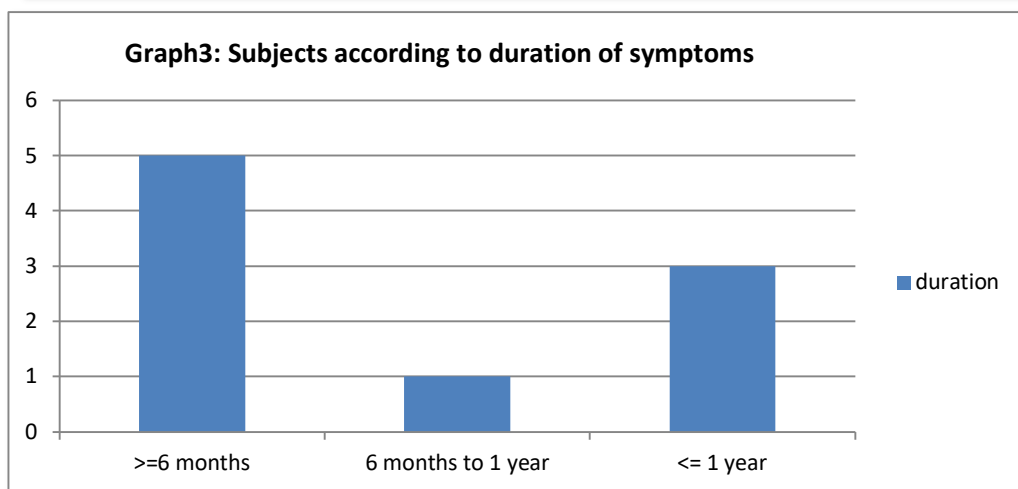
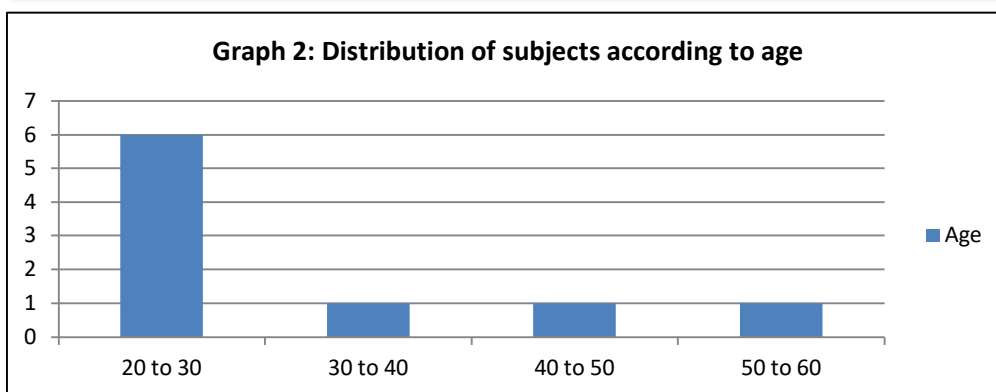
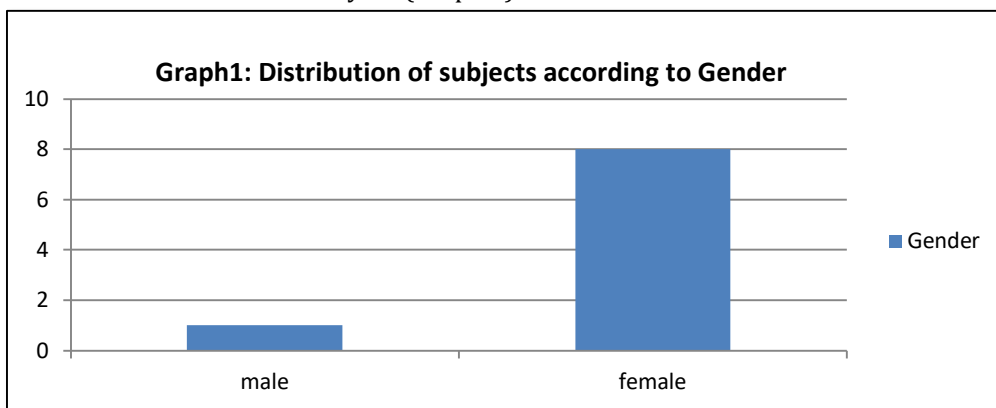
Study Medicine: Patients received three tablets of *Amalaki rasayana* 500mg each, twice a day, before meal, for 8 weeks follows up by 4 weeks.

STATISTICAL ANALYSIS

The data generated in the clinical trial was analyzed using Microsoft excel 2007. Objective parameters were analyzed using student’s’ test. Subjective parameters were analyzed using repeated measures ANOVA. All the parameters were tested at 95 percent confidence level.

RESULT

Out of 9 patient included 8 were female and 1was male (Graph 1). Mean age was 29.77 years while maximum and minimum age was 60 years and 20 years respectively (Graph 2). Duration of symptoms was less than 6months to more than 1 year (Graph 3).



Subjective parameter has been done by ACTG peripheral neuropathy symptoms score. Maximum number of subjects complained of Numbness as the major negative sensory complaint i.e., n= 8, pain as positive sensory complaint i.e. n=2, Pins & needle as positive sensory complaint i.e. n=2, Burning sensation as a positive sensory complaint i.e. n=2, Aching as a primary sensory complaint i.e. n= 2. Objective parameter has been done by serum B₁₂ level before and after the treatment for 8 weeks, as per the criteria all subjects has Low levels of serum B₁₂ ≤ 150 pmol/L (200pg/mL) at the 0 day of trial.

Table 4 Statistical analysis of B₁₂ serum values before and after study.

S.N	Parameter	Before treatment. (Mean ± SD)	After treatment (Mean ± SD)	p- value	Decision
1	B ₁₂ serum value	135.222 ± 40.526	182.556± 19.311	0.0003	Significant

Table 5. Statistical analysis of ACTG values before and after study.

Parameter	Pain, Aching & Burning sensation	Pins & Needls	Numbness
Before treatment Mean ±SD	9.22±2.27	10.11±1.83	6.55±1.70
After treatment Mean ±SD	7.77±3.89	9.33±3.31	4.77±2.52
p-value	0.0003	0.0007	0.0003
Decision	Significant	Significant	Significant

Subjective parameters have shown significant relief in many of the symptoms observed by patients. Improvement was seen in poly neuropathy symptoms pain, aching, burning sensation, pin and needle sensation and numbness. Before treatment in pain, aching, burning sensation mean value was 9.22±2.27, in pins and needle mean value was 10.11± 1.83 and in numbness mean value was 6.5 ± 1.70 while after treatment it was found in pain, aching, burning sensation mean value 7.77 ±3.89, in pins and needle mean value 9.33±3.31 and in numbness mean value 4.77±2.52. (Table 5). Objective parameter has shown significant low level of serum B₁₂ value, before treatment Mean serum B₁₂ 135.222 ± 40.526 while after treatment it was found 182.556 ± 19.31(P<0.05). With the result obtained from subjective and objective parameter the effect of *Amalaki rasayana* in B₁₂ deficiency has shown an unbelievable result in this case series study.

DISCUSSION

As explain earlier vitamins are micronutrients a very essential part of metabolism within the body and its deficiency can be manifest either insufficient intake from the food or defect in absorption via GIT. Treatment for deficiency would be reverse of it, and that is to take food which is rich in particular vitamins and to treat secondary causes which are affecting the absorption. In this case series study nine patients has low serum vitamin B₁₂ levels (<150 pmol/L (200 pg/mL) with symptoms of poly-neuropathy and treatment has given *Amalaki rasayana* tablets for 8 weeks, at the end of the study (after 8 weeks) value of serum B₁₂ have been increase and the symptoms improved significantly. *Amalaki rasayana* is having richness of Amla (*Phyllanthus emblica L*). In table no 1 we can see in all composition of Amla(*Phyllanthus emblica L*) vitamin C is higher percentage that is 600mg/100gm and there is no data about vitamin B₁₂ in Amla(*Phyllanthus emblica L*). But in current case series study it was observed that there was statistically significant (p < 0.05) increase of vitamin B₁₂ level without giving any supplement of vitamin B₁₂. These observations has leads us to a question about how a drug without having composition of vitamin B₁₂ treat the deficiency of vitamin B₁₂. In the answer of above question there may be some theories that we have to look upon and may be the answer is hidden behind the action of *Amalaki rasayana*. Research has shown various medicinal activities of *Amalaki rasayana* are mentioned in table 6.

Table no 6: Actions of Amalaki Rasayana [2]

Antioxidant	Immunomodulatory	Antipyretic	Analgesic	Hepatoprotective
Cytoprotective	Antitussive	Gastro protective	Ophthalmic	Antimicrobial
Anti-inflammatory	Radio protective	Chemoprotective	Antitumor	Antiatherogenic
Apoptotic	Antiulcer	Hypolipidemic	Adoptogenic	Antimutagenic
Hypocholesterolemic				

As per the table 6 actions like Cytoprotective activity, gastro protective activity and antimicrobial activity *Amalaki rasayana* has proven that it help to maintain GIT track and improve the absorption furthermore the qualities like *Tridosahara*, *Rochana*, *Dipana*, and *Anulomana* by the ayurvedic perspective also helps in digestion, absorption, and motility of digestive materials in the gut [5]. So here *Amalaki rasayana* treat the secondary cause which are affecting the absorption. As per table 1 various causes of vitamin B₁₂

deficiency can be treated by *Amalaki rasayanas* actions which are given into table 6. Pernicious anemia is treated with *Amalaki rasayana* by its effects of Hepatoprotective activity [6]. Sjogren's syndrome an immune system disorder can be treated with immunomodulatory and gastroprotective activity [7]. Atrophic gastritis, chronic gastritis and *Helicobacter pylori* associated gastritis which is mainly gastric related diseases they can be managed by Gastro protective, Cytoprotective, and Antimicrobial activity [8]. Small intestine bacterial overgrowth where absorption of vitamin B₁₂ hampered due to overgrowth of bacteria can be reduced by Antimicrobial activity [9]. *Amalaki rasayanas* Antioxidant activity will protect GIT from free radicals and maintain the GIT cells longevity [10]. *Amalaki rasayana* treats secondary reasons and maintains the GIT, which is necessary for vitamin B₁₂ synthesis and absorption.

CONCLUSION

Natural products have gained popularity in recent years due to their low side effects, low cost, convenient availability, and high effectiveness. According to the findings of this case series investigation, *Amalaki rasayana*, an ayurvedic single- proceeded medicine, significantly improved vitamin B₁₂ serum value as well as symptoms of polyneuropathy. Because *Amalaki rasayana* contains Amla (*Phyllanthus emblica* L.), which increases vitamin C levels while also increasing vitamin B₁₂ levels in the blood, this one medicine can help with both vitamin deficiencies. These discoveries may be of commercial interest to pharmaceutical companies and research institutes in the development of innovative, effective, and cost-effective medications to treat a variety of human ailments. *Amalaki rasayana* should be encouraged for the treatment for vitamin B₁₂ and related disease.

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