Research Article

Effect of Nutritional Supplement on Haemoglobin Level and Fatigue Score in Female Anemic Patients

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Abstract

Objective: The aim of this study was to determine the effect of 3 months consumption of Medical Nutrition Supplement (MNS) in adult anemic females. **Background:** Globally, anemia affects 1.62 billion people, whereas in India 53.2% of non-pregnant women and 50.4% of pregnant women were found to be anemic in 2018, as per the NFHS. Proper balanced daily nutrition is important for women, which includes adequate levels of essential high-quality proteins, amino acids and complex carbohydrates to help meet adult nutritional needs. Therefore, in the present study, the short-term effects of MNS rich in proteins, hemo-nutrients and biotin in anemic women were studied. **Design:** This was a retrospective observational study where MNS (Maxvida®) was given to 226 anemic female subjects between 1st March to 30th May 2019 and evaluated for their clinical data (age, weight, and BMI), Modified Fatigue Impact Scale (MFIS) and Hand-Held Dynamometry (HHD) at 3 months. **Results:** The mean (SD) age of patients was 31.1 (8.9) years in this study. A significant improvement in BMR was observed from baseline 21.7 ± 0.3 to 22.6 ± 035 at 3 months (p=0.013). Weight was found to increase from baseline 51.3 ± 0.7 to 53.9 ± 0.6 kg at 3rd months, respectively (p=0.001). Statistically significant increase in Hb levels was observed from baseline 9.0 ± 0.1 to 11.0 ± 0.1 at 3 months (p=0.001) due to MNS intake. There was a significant reduction in MFIS score from baseline 51.1 ± 1.1 to 28.9 ± 1.3 at 3 months (p=0.0001), and improvement in HHD score from 17.3 ± 0.4 to 22.0 ± 0.5 at 3 months (p=0.001). No serious adverse effects were noticed during consumption. **Discussion:** Anemic condition in females is increasing throughout the world as the population in most of the countries continues to age, impacting their BMI. This study evaluated the efficacy and safety pattern of consuming an MNS. Overall, Hb levels increased by 2.0% (from 9.0 to 11.0 g/dl) at the end of 3 months with overall statistical increase in BMR. There was also statistical increase in HHD showing increase in muscular response and improvement from fatigue. **Conclusion:** MNS was found to be efficacious in improving the anemic conditions in female subjects with no deleterious effects.

Keywords: Medical nutrition supplement; Modified fatigue impact scale; Hand-held dynamometry; Nutritional supplement; Hemoglobin level; Fatigue score; Female anemic patients

Introduction

Balanced diet is essential, particularly in women, for the prevention of micronutrient deficiencies and anemia. [1] To prevent this, the nutrition needs of women must be adequately met which can be achieved with the help of a diet that contains adequate levels of essential high-quality proteins with suitable Protein Digestibility Corrected Amino Acid Score (PDCAAS), essential amino acids, and complex carbohydrates. [2,3] Intake of high-quality proteins has been associated with an increase in serum iron concentration through an increase in the absorption of iron from the gastrointestinal tract and improvement in its deposition in the liver. The deficiency of certain amino acids such as tryptophan has been associated with high risk of iron deficiency anemia. [4]

Anemia is a major public health issue, which is associated with poor birth outcomes and increased morbidity and mortality in women. Globally, 1.62 billion individuals have been diagnosed with anemia with iron deficiency being the primary cause in almost 50% of the cases. [5,6] Nutritional deficiency of iron is a primary contributing factor in most of these cases, which can be attributed to low dietary consumption of iron-rich foods or the presence of inflammatory conditions that hinder the absorption and use of iron by the body.

Women in the reproductive age group are at an elevated risk of

How to Cite this Article: Agarwal P, et al. Effect of Nutritional Supplement on Haemoglobin Level and Fatigue Score in Female Anemic Patients. Ann Med Health Sci Res. 2021;12:1-5.

poor health outcomes due to anemia pertaining to the menstrual loss of blood and issues faced during pregnancy and lactation. Further, in middle- and low-income countries such as South East Asian countries, the prevalence of anemia has found to be significantly higher in women. In India, approximately 53.2% of non-pregnant women and 50.4% of pregnant women were found to be anemic in the year 2018, as per the National Family Health Survey 4. [7] The risk of anemia is even more pronounced among individuals following a vegetarian diet regime because of the lack of vitamin B12 in the diet and lower absorption of iron through the vegetarian food sources. [8] Vegetarians have thereby been recommended to increase their dietary intake of iron by 80% to compensate for lower bioavailability or iron from vegetarian food sources (10% *vs.* 18% from meat sources). The use of Medical Nutrition Supplement (MNS) is one such strategy to increase the intake of iron.

Guidelines from the World Health Organization recommend the prescription of Iron and Folic Acid (IFA) supplements for the management of anemia in young pregnant and non-pregnant females. [9] Indian guidelines recommend once daily dosage of IFA (60 mg elemental Iron+500 mcg Folic Acid) during the first and second trimester of pregnancy. [10] However, high-dose IFA supplements are associated multiple adverse effects, especially in low-income settings. In a cross-sectional study, 100 mg daily dosage of iron supplement commonly led to nausea and epigastric pain in 31% of the participants. Increasing the dosage to 200 mg raised the risk of these adverse events to 75%. Side effects such as vomiting were observed within 5 hours of dosage worsening the nutritional status of the participants. [11] In the long-term, high–dose iron supplements have been found to increase the risk of bacterial and protozoal infections including malaria because of their impacts on cellular function. [12]

Nutrient supplementation, on the other hand, involving the use of a lower dose of iron supplement administered within a food-based matrix, does not lead to any such side effects. [13] Fortified foods and nutritional supplements facilitate the alteration of gut microbiota to upregulate the absorption of iron. However, simple micronutrient supplements have found to be ineffective in the prevention and management of anemia in adult female subjects suggesting that MNS containing a variety of nutrients are more effective for the management of anemia. [14] Further, nutrition supplements help in overcoming the primary clinical challenge faced in anemic patients in clinical settings, that is, improvement in weight status of the patients. Most particularly, supplements containing haem-specific nutrients are suitable for the management of iron deficiency, and carbohydrate-containing supplements are useful for promoting weight gain in anemic patients.

The aim of this research is to determine the impact of 3-month consumption of an MNS describing its potential benefits for anemic subjects.

Materials and Methods

Design

The present research is a non-interventional observational study where MNS was administered to female participants who had been diagnosed with anemia based on their Complete Blood Counts (CBCs).

Participants

A total of 226 adult female participants between the age group of 18 to 45 years were recruited for the study during the time period from 1st March to 30th May 2019 at the Matram hospital, Indore, Little Lourdes Mission hospital, Kottayam, Asha hospital, Hyderabad, Jorhat medical college, Assam, Bansal hospital, New Delhi, and All India Institute of Medical Sciences, Patna, India. All the participants selected for the research were evaluated for baseline clinical data. The inclusion criteria comprised a clinical diagnosis of anemia. Non-anemic subjects or participants who were taking any nutritional supplement based on dietary consultation during the past year were excluded from the research. Those undergoing treatment for any metabolic disorder at the time of recruitment as well as individuals with a history of comorbid conditions were also excluded from the study.

Ethical considerations

All ethical permissions related to data collection and researches were sought.

Methodology

All the participants were instructed to consume MNS Maxvida® in a 30 gm dosage in 100 ml of water. They were instructed to take the supplement twice daily during the morning and evening hours along with following a normal, healthy diet for a study period of three months. No other dietary or lifestyle changes had been recommended. The participants were regularly scheduled for assessment and evaluations during the study period at the end of 1, 2 and 3 months during the research duration to record changes in their clinical parameters. Participants were not followed up after the completion of the research.

Data collection

Baseline clinical data including age, weight, and BMI and demographic characteristics were collected for all the research participants. The hemoglobin levels were recorded for defining the inclusion criteria. At the end of 3 months, anthropometric parameters and hemoglobin levels were re-evaluated. The Modified Fatigue Impact Scale (MFIS) and Hand-Held Dynamometry (HHD) were used for collecting data related to fatigue levels, and muscular strength and physical function of the participants. All the data collected during the study was compared with that collected at the baseline.

Data analysis

Data was analyzed with the help of SPSS version (10.1). Relevant tests including t-tests and chi square tests were performed to determine the statistical significance of the results.

Results

Out of the 226 participants, 198 were a part of the final investigations. The remaining 28 participants had dropped out either during the first, second or third month of the study, and were not followed up by the physicians. Data from the withdrawn participants were not included in the final analysis of the results.

Table 1: Comparison of the average weight, BMI, hemoglobin levels, MFIS and HHD scores of the study participants at baseline and 3 months.

Parameter	Mean observation at baseline	Mean observation at 3rd month	P value
Weight	51.3 ± 0.7 kgs	53.9 ± 0.6 kgs	0.001
BMI	21.7 ± 0.3 kg/m^2	22.6 ± 0.35 kg/m^2	0.013
Hemoglobin levels	9.0 ± 0.1 g/dL	11.0 ± 0.1 g/dL	0.001
MFIS score	51.1 ± 1.1	28.9 ± 1.3	0.0001
HHD score	17.3 ± 0.4	22.0 ± 0.5	0.001

92 out of 198 participants were diagnosed with mild anemia, whereas 106 participants were diagnosed with moderate to severe anemia at the beginning of the study.

The mean age of the participants was 31.1 years (SD=8.9) and their average weight was 51.3 ± 0.7 kg. A high rate of compliance of consuming the MNS was observed during the study since all the included participants followed the guideline of taking the supplement twice a day on each day of the study.

Efficacy

Following the course of this study, a significant improvement in weight, hemoglobin levels and MFIS and HHD scores were observed for the participants [Table 1]. However, the improvement in BMI was statistically non-significant.

Out of all the observed parameters including hemoglobin levels, fatigue reduction and gain in muscular strength, weight gain was the most immediate effect. At the first month, the average weight recorded was 53.3 ± 0.6 kgs, which was maintained during the second month of the research [Table 1].

Safety

Throughout the duration of the study, no adverse effects were observed. There were no deleterious impacts on the normal diet of the participants of the research, and their daily activities were not affected. In fact, a significant improvement in energy levels while pursuing daily activities was reported.

Discussion

The hemoglobin levels of the study participants increased by 2.0 g/dL at the end of research through the consumption of a nutritional supplement. There was also a 2.6 kg weight gain and a significant increase in the HHD (22.0 ± 0.5) recorded after 3 months of intake. At the same time, the MFIS had significantly reduced leading to reduction in overall fatigue [Table 1].

Nutritional supplement for the management of iron deficiency

The efficacy of food-based nutritional supplements in improving hemoglobin levels of anemic women has been evidenced in the literature. In a cluster Randomized Controlled Trial (RCT) of 361 non-pregnant anemic Indian women of the reproductive age group, the mean hemoglobin volume of the subjects had increased by 1.3% over a time period of 90 days. [15,16] At the end of this study, the prevalence of anemia was found to be significantly lower among the participants receiving the MNS when compared with the controls (29.2% *vs.* 98.6%). Further, similar to the present research, no side effects were associated with the use of MNS indicating their safety.

In another double-blinded RCT of 561 female participants, it was observed that nutritional supplements containing iron and micronutrients significantly helped in reducing the incidence of anemia when compared with iron and folic acid supplements. [17] These treatment effects were unaffected by the dietary intake of women, the consumption of a vegetarian diet or being underweight. Further, even in women with a previous history of childbirth and in those who were currently lactating, the intake of MNS was associated with an improvement in hemoglobin levels. Cross-sectional studies have reported that the use of dietary intervention that provide a broad range of nutrients to improve iron status is more effective than dietary supplements that provide single nutrients. [18] This has also been evidenced by clinical studies which reflected the inefficiency of micronutrients in managing iron deficiency when compared to iron supplementation. Hence, MNS with a blend of hemo-nutrients, carbohydrates, fibers, proteins, multivitamins and antioxidants can be established as a suitable therapy for the management of anemia in Indian patients to overcome the issues of under nutrition.

Mechanism of its effects

The effects achieved with the use of a nutritional supplement can be attributed to its nutritional composition containing both hemo-nutrients and carbohydrates. In a clinical study of 74 adult women, it was found that the participants with higher BMI percentile had a lower risk of developing iron deficiency anemia. [19] Further, this risk was reduced with the intake of foods having a high carbohydrate containing or a lower fat: Carbohydrate ratio. Thus, weight gain along with hemoglobin increase achieved with the use of MNS facilitated in the improvement of anemic state of the participants.

The present research not only reported an improvement in blood parameters associated with anemia but also helped in managing the clinical symptoms as observed through reduction of MFIS score and an improvement in HHD test [Table 1]. Iron deficiency is the primary cause of fatigue and poor muscular function as concluded by a clinical study of 224 participants with 67% female population. [20] Since MNS helped in overcoming fatigue and improving muscular function, it can also be ascertained that it improved the serum iron concentrations of the participants, although this impact was not independently evaluated in the research.

In a recent systematic review and meta-analysis of 18 clinical trials, it was found that iron supplementation in the form of oral or intravenous therapy was effective in improving the serum hemoglobin and serum ferritin levels but did not achieve an overall improvement in physical activity. [21] The use of nutritional supplements and the intake of iron-rich foods were thereby

recommended to overcome the issue of fatigue and reduction in muscular capacity in individuals with iron deficiency, which justifies the observations of the present research. Improvement in symptoms of fatigue and muscular strength and function also concludes that the intake of MNS facilitated improvement in the quality of life of anemic patients.

Recommendations for the use of Maxvida® in anemic patients

High compliance rate observed in this study suggests that the educational strategies utilized for the promotion of the use of Maxvida® among the research participants were effective. In a Quassi-experimental research of 115 mild to moderate anemic female patients, it was observed that nutrition education significantly promoted the intake of iron-rich foods among the research participants facilitating an improvement in hemoglobin levels (0.56 ± 0.40 gm/dl increase in the group receiving nutrition education versus 0.16 ± 0.82 gm/dl increase in the control group). Although no particular dietary or lifestyle changes were recommended as a part of this study, it can be ascertained that combining the use of Maxvida® with nutrition education can maximize its effect. [22]

Multi-interventional approaches including dietary supplementation, food fortification and dietary modification along with nutrition education have been recommended for the management of anemia in Indian patients. [23] It has also been stated that intravenous iron supplements must be reserved as second line treatment agents because of their high risk of side effects when compared with MNS. [24,25] Considering the safety and efficacy of MNS as identified in the present research, it could be prescribed as an MNS in patients with severe anemia alongside the conventional treatment of iron deficiency. In those with mild to moderate anemia, the use of MNS could be sufficient when combined with suitable nutrition education.

Limitations of the Research

The primary limitations of the research are its small sample size and the use of a prospective research design. It was a Multi-centre observational study having a low dropout rate. Further, the participants of the study were not sufficiently followed up in order to determine the long-term clinical benefits associated with the use of MNS. Overall, the research concluded clinically significant improvement in the clinical profile of anemic subjects but did not provide specific data into the percentage of participants in whom these beneficial results were observed. [26] Hence, future research must focus on meeting these drawbacks using a focused prospective research design.

Conclusion

Maxvida® evidenced to be efficacious for the management of anemia in adult female participants. In this research of 226 female participants, the use of MNS significantly improved hemoglobin levels, while at the same time, improving the quality of life of participants by facilitating weight gain, reduction in fatigue and improvement in muscular strength and function. These beneficial effects for anemic subjects using this MNS can be attributed to the presence of multiple nutrients and dietary groups, which has been found to have a better effect as per recent RCTs and cross-sectional studies. Overall, Maxvida® can be prescribed as an MNS for daily use in patients with mild, moderate or severe anemia.

The need for iron supplementation therapy in patients receiving the nutritional supplement must be decided based on hemoglobin levels in these patients. Nutrition education promoting the intake of iron-rich foods is recommended alongside the use of MNS in individuals with iron deficiency for the enhancement of its effect. As opposed to the intervention of iron supplementation, the use of Maxvida® did not result in any adverse events in the present research or in the larger literature concluding it as a safe supplement.

Acknowledgement

The authors acknowledge Dr. Atul Mishra of Signutra® Inc and Dr. Punit Srivastava from Mediception Science Pvt. Ltd, Gurgaon, India (HYPERLINK "http://www.mediception.com" www.mediception.com) for providing writing and editing assistance for this project, and Signutra® Inc for a grant towards medical writing assistance.

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