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Role of Vitamin B-12 in chronic low backache: A comparative study.

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Abstract

Background: Chronic low backache is a commonly affecting problem in our population; it has an economic impact due to the consumption of health expenses in its treatment and rehabilitation. Backache interferes with daily activities of life without discriminating age, gender or race, etc. Our study aimed to determine the role of vitamin B-12 in relieving chronic low backache.

Methodology: A comparative study was conducted at Baqai University and Fatima Hospital, Karachi, from May 2019 to April 2020. A total of 496 patients were enrolled and divided into two groups; group I was treated with vitamin B-12 (n=256), and group II (n=240) did not receive vitamin B-12 treatment. Pre-treatment Visual Analog Scale (VAS) score and Oswestry Disability Index (ODI) scores were evaluated. Group II was given calcium supplements and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) for one month, while group I was given intramuscular injections of vitamin B-12 (500 mcg) on an alternate day for a month along with calcium supplements and NSAIDs.

Results: Pre-treatment mean VAS and ODI scores were 6.68 ± 1.45 and 30.11 ± 12.7, while post-treatment VAS and ODI scores were subsequently 3.50 ± 2.07 and 17.73 ± 12.7, respectively. At the end of treatment, a remarkable decrease in ODI and VAS scores was observed after treatment with vitamin B-12 ($p<0.05$).

Conclusion: Concurrent use of vitamin B-12 in the treatment of chronic backache had a better impact in relieving backache symptoms than those treated without vitamin B-12.

Keywords

Visual Analog Scale, Oswestry Disability Index, Vitamin B-12, Chronic Backache.

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Introduction

Lower Back Pain (LBP) has become a common prevailing reason for seeking medical attention. Not only does the patient become a victim of agonizing pain, but they also suffer at the expense of limited mobility, decreased quality of life, and the expensive treatments that come along as collateral damage. About 80% of patients with the asymptomatic complaint of lower back pain do not appear to have a specific etiologic pathology and are labeled non-specific low back pain[1].

Non-specific lower back pain is described as a pain occurring in the posterior aspect of the trunk from the level of the first lumbar vertebrae to the gluteal sulcus that could or could not be radiating to the leg, which on assessment, can't be traced back to a specific underlying physical or anatomical pathology, i.e., tumor, nerve compression, disc herniation, trauma, etc. In fact, it appears as a symptom of indistinct condition[2]. Back pain can be a burden not only psychologically and also financially due to the disabling nature of the disease. Chronic low backache has a multifactorial effect on affected population activity of life, like pain and limitation of daily activity, a hindrance to performing their professional works, not only a burden on their carer but also the economic burden. Enormous financial effect further creates challenging situations for the affected population because of medical care cost, use of health care resources, loss of productivity and employee-related issues.[3]

In a world of scientific evolution and deepened understanding of human physiology and its response to different interventions, today is available a wide range of options for an individual with back pain to opt, each in its respect has clinically proven to be beneficial[4]. By understanding the body's response to pain and kinesiology of the human body, some physicians have proven clinically that cognitive-behavioral family therapy (CB-FT) has better prognostic outcomes than manual therapy and exercise[5]. On the contrary, many countries follow the guideline recommending NSAIDs, Analgesics, Opioids, and Antidepressants either in combination or separately along with exercise[6]. While other approaches, such as spinal manipulation, nerve root blocks, are also available, but disc surgery remains the last resort to seek comfort because of unsatisfactory results[7].

Vitamin B-12 comes in various forms, cyanocobalamin (CNCbl), methylcobalamin (MeCbl), hydroxocobalamin (OHCbl), and adenosylcobalamin (AdoCbl). Among these is the form that is inactive and thus cannot be directly introduced to the body. For a reason stated, methylcobalamin is a choice for direct introduction into the human body. It differs from other forms in that methylgroup[8] replaces the cyanide group. Initially, the role of B-12 was known for the maturation of DNA and was found to be of key importance in terms of normal blood cell and nerve cell growth, maturation, and their function. But now, as with the progress to understand a clearer role of vitamin B-12, it has come forth that there is a beneficial effect of Vitamin B-12 in the treatment of different conditions[9].

Despite the dispute over which approach better manages back pain, all the medical experts coincide on one aim that is oriented towards not eliminating the pain, rather managing it in ways that could improve one's quality of life. And this here is the goal of our study as well[10].

However, we aimed to study the efficacy and safety of B-12 in LBP in synergist with NSAIDs and calcium supplements and evaluate the prognosis. The main purpose for using vitamin B-12 as a tool against pain is two folds. First, B-12 is cheap and readily available in the market, so even patients with socioeconomic disadvantage can still choose this course of treatment. Second, to assess its effectiveness in ameliorating pain, in conjunction with other standardized drugs (NSAID, muscle relaxant, and calcium supplement), and minimize disability to improve their quality of life. Among the driving factors to conduct the study about the effects of vitamin B-12 in lower back pain, the fact that such a study has never been conducted in our country before is too grave to be overlooked.

Methodology

A comparative interventional study was conducted at Baqai University Fatima Hospital in Karachi from May 2019 to April 2020. After taking written and informed consent, a total of 496 patients were enrolled and divided into two groups; vitamin B-12 treatment was given to group 1 (n=256), and group 2 (n=240) did not receive vitamin B-12 treatment. The sample size was calculated using Open epi online software, keeping the significance level at 0.05 and power of 80% with a confidence level of 95% and margin of error set at 7%. The sampling technique was a non-probability type, and randomization was done by the chit method. Group I or II was mentioned in a chit and placed in a sealed envelope by the principal investigator. After that, participants were invited to pick one envelope and handed it over to the data collector. The data collector opens the chit and labels the participant in the mentioned group as on the chit. It was a single-blinded study, so the participants were not aware in which group he/she will be assigned.

Subjects with complaints of backache for more than 3 months, aged between 18 to 60 years, were included in the study. Pregnant females and all those with a history of neurological deficiency, having received vitamin B-12 supplement either oral or in injection form, any surgical intervention of spine, pathological or traumatic fracture, acute or chronic infections of the spine, and those with diabetes mellitus were excluded.

VAS and ODI scores were evaluated by the investigators pre-treatment. One group was given calcium supplements and NSAIDs for 1 month, while the other group was given intramuscular injections of vitamin B-12 (500 mcg) on an alternate day for a month along with calcium supplements and NSAIDs. The questionnaire was color-coded, and the investigators were unaware of the given treatment. After six weeks of treatment, VAS and ODI were re-assessed.

The risks of intramuscular injections and possible side effects were explained to all the patients. Data were analyzed on SPSS version 17.0, one-way ANOVA and t-test were applied for quantitative data analysis, while for qualitative data, and Fisher test/chi-square test was used, and p-value < 0.05 was considered significant.

Results

At the end of treatment, both groups mean VAS and ODI scores showed statistically significant outcomes, as post-treatment VAS and ODI scores were 2.50 ± 1.85 and 13.41 ± 11.4 in the vitamin B-12 treated group while 4.57 ± 1.77 and 22.33 ± 12.7 in the control group ($p<0.05$). None of the patients had experienced injection site complications. There is a remarkable statistical change in mean VAS and ODI score observed after treatment (Table 1).

Table 1: Mean pre and post-treatment ODI and VAS score of patients in Group I and II

Variables		Group I	Group II
		Mean±SD	
Age		32.16±9.9	33.03±12.07
ODI score	Pre-treatment	28.53±13.4	31.80±11.91
	Post-treatment	13.41±11.4	22.33±12.7
VAS score	Pre-treatment	6.56±1.66	6.80±1.21
	Post-treatment	2.50±1.85	4.57±1.77

A remarkable decrease in ODI and VAS scores was observed after treatment with vitamin B-12 ($p<0.05$), as shown in table 2.

Table 2: Comparison of post-treatment VAS and ODI scores between the study groups.

Variables	Groups		F	p-value
	Group I	Group II		
Post-treatment ODI Score	13.41±11.4	22.33±12.7	8.48	0.005**
Post-treatment VAS Score	2.50±1.85	4.57±1.77	20.1	0.000**

**p<0.05 is considered statistically significant.
Group I – with vitamin B-12; Group II – without vitamin B-12

Discussion

Most of the patients with chronic backache, with no signs and symptoms of radiculopathy, resolved within 12 weeks of period[10]. Between 10%-20% of patients are difficult to manage, and it's become a challenging situation for physicians and surgeons to manage these patients because of other associated issues like depression, somatization, job dissatisfaction, and anxiety. Multiple treatment choices are available to manage chronic backache, but none is free from side effects, especially when used for a long-term basis. Research divulges that among various treatment options, non-steroidal anti-inflammatory drugs pretend to be improving pain and functions[11].

Various studies revealed that the use of vitamin B-12 and non-steroidal anti-inflammatory drugs might enhance its analgesic effect and possibly reduce the frequency and dosage of non-steroidal anti-inflammatory drugs[12-14]. The uses of vitamin B-12 injections for back and neck pain symptoms to alleviate pain, allodynia, and numbness inpatients, or the analgesic effects of vitamin B-12 along with improved nerve conduction velocity and ameliorating neuropathic pain, were already established way back in the 1980s[14, 15].

In different studies revealed that Injectable vitamin B-12 might be beneficial in the treatment of chronic backache. In these studies, a placebo was used to compare with injectable vitamin B-12 to treat chronic low backache. Their results showed that vitamin B-12 reduces chronic low back pain and remarkably ameliorates function. These three known studies have been done to minimize back pain using B-12, showing promising results to decrease the pain. All three of the studies focused on the efficacy and/or safety of B-12 in low back pain, with the control group receiving a placebo[16].

Mauro et al. conducted an RCT in 2000 in which 60 patients were included. Patients were randomized into two groups; one group was given intramuscular vitamin B-12 on an alternate day for two weeks, while the other group was given a placebo 2ml normal saline for two weeks. Results showed marked improvement in pain and decreased requirement for NSAIDs in patients receiving vitamin B-12[17]. Rocha-Gonzales et al. conducted a study in 2004 in which he showed that if vitamin B-12 was given in increased amount, it could lead to decreased use of NSAIDs[13]. Chiu et al. conducted an RCT in 2011 in which he compared the results of vitamin B-12 to a placebo. He showed that vitamin B-12 has a positive role in relieving low back pain[18].

There is limited data available regarding the efficacy of vitamin B-12 in our population. This study shows that vitamin B-12 intramuscular injections can be given safely with minimum to no side effects, and it can be used as an adjunct in the treatment of low back pain.

Conclusion

Concurrent use of vitamin B-12 in the treatment of chronic backache had a better impact in relieving backache symptoms than those treated without vitamin B-12. So we concluded that in the treatment of low backache, vitamin B-12 and the

use of calcium supplement and NSAID provide an early and prompt response.

Conflicts of Interest

The authors have declared that no competing interests exist.

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