

Cobalamin Injection: Is it Useful in Lumbosacral Diseases?

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Abstract

Background: Low back pain is an everyday problem worldwide. It can lead to a great financial burden to society due to absenteeism or having work limitations.

Back pain is one of the most common symptoms for seeing primary care physicians and one of the top 5 causes of surgery.

Objectives: The purpose of this study is to examine the usefulness of cobalamin injection in lumbosacral disc disease in patients with mechanical or irritative lumbago.

Methods: Over 4 years hundred and twenty patients with Lumbosacral disease were enrolled in the study. Patients' ages ranged between 18 to 65 years. The patients were divided randomly into treatment and control group. Both groups received relative bed rest, NSAID's and daily injection of vitamin B12 for the treatment group and sterile water for the control group. The duration of treatment lasted for three weeks, and the concentration of vitamin B12 was 1000 mg/ml. Patients were seen initially and at the end of treatment.

Results: Both treatment groups experienced a sharp decrease in pain and disability. However, comparison between groups at the end of the treatment period showed a statistically significant difference in favour of the active treatment both for pain, paraesthesia, and nocturnal pain. Consumption of paracetamol proved significantly higher in the placebo group than in the active treatment ($p < 0.0001$).

Conclusions: Intramuscular vitamin B12 injections seem to be effective at ameliorating nonspecific chronic low back pain as compared to placebo. Vitamin B12 injections also have exhibited only minimal side effects. There is a need for a larger study with longer duration that spans several years to assess the long term side effects, especially as long term effects can possibly be serious.

Key words : Vitamin B12, low back pain, paracetamol

Introduction

For decades B12 injection, has been given to patients with a variety of symptoms without documented cobalamin deficiency(1). Vitamin B12 is essential for the health of our nervous system and blood cells, and vitamin B12 replacement is known for its role in the treatment of peripheral neuropathy and megaloblastic anemia (1).

Vitamin B12 is one of the body's main building blocks, assisting it to make DNA and keep nerves and blood tissue vigorous. Vitamin B12 is present in animal products, including beef, seafood, milk and cheese. Therefore, vegetarians run the risk of having vitamin B12 deficiencies. Vitamin B12 is essential for prime health. Even in the absence of deficiency, shots of the vitamin have been considered recently as an alternative therapy for chronic conditions, including back pain.

Traditionally vitamin B12 had been used to treat anemic elderly patients and as an adjuvant in sport nutrition. It was considered as a painkiller since 1950 in some countries. Lately studies have shown that vitamin B12 plays a major part in the normal functioning of the brain and nervous system and the formation of blood. Vitamin B12 is generally implicated in several metabolisms such as DNA synthesis and regulation, fatty acid synthesis, and energy production. Vitamin B12 has some analogs including cyanocobalamin (CNCbl), methylcobalamin (MeCbl), hydroxocobalamin (OHCbl), and adenosylcobalamin (AdoCbl). In mammalian cells, CNCbl and OHCbl are inactive forms and AdoCbl acts as a coenzyme of methylmalonyl Co-A mutase in mitochondria. However, vitamin B12 was not used directly in the human body, and it should be translated into activating forms such as MeCbl or AdoCbl. MeCbl differs from vitamin B12 in that the cyanide is replaced by a methyl group (2). It is a coenzyme of methionine synthase, which is needed for the formation of methionine from homocysteine in the methylation cycle which includes methylation of DNA or proteins (3-6). Compared with other analogs, MeCbl is the most effective one in being uptaken by subcellular organelles of neurons. Therefore, MeCbl can provide better treatments for nervous disorders through effective systemic or local delivery.

Multiple Clinical Studies reported improvement of patients with vertebral pain to Intramuscular injection of vitamin B12 (7-9). The purpose of this study is to examine the usefulness of cobolamin injection in lumbosacral disc disease.

Methods

Over 4 years hundred and twenty patients with Lumbosacral disease were enrolled in the study. A routine medical work up showed that none of the patients had other medical diagnosis. Patients' ages ranged between 18 to 65 years. The patients were divided randomly into treatment and control group. Both groups received relative bed rest, NSAID's and daily injection of vitamin B12 for the treatment

group and sterile water for the control group. The duration of treatment lasted for three weeks, and the concentration of vitamin B12 was 1000 mg/ml. Patients were seen initially and at the end of treatment. A research assistant blinded to the hypothesis of the study assessed patients using their reports of improvement in their symptoms.

Setting

The study was performed in the Abyad Medical Center, a model multispeciality group with 15,000 thousand registered patients. The group is located in the North of Lebanon.

Results

The mean age of the patients was 55 years. Forty percent of the patients were male. Both treatment groups noted a marked improvement (Table 1). However good improvement was statistically more significant in the treatment group.

Both the treatment and placebo group reported decrease in spontaneous pain (Table 2).

Again both moderate and good improvement was statistically more significant in the active treatment group.

As for pain provoked by movement the treatment group was statistically better on the moderate and good improvement category (Table 3).

The comparison of the group at the end of treatment period revealed that nocturnal pain showed a statistical significant difference in favor of the active treatment (Table 4).

At the end of treatment both the control and treatment group report a reduction in nocturnal paraesthesia (Table 5).

Mean consumption of paracetamol was significantly higher in the placebo group than in the active treatment group (45.7+-10.32 vs 14 +-9/21 days; p<0.0001). Fifteen patients in the treatment group did not take any paracetamol tablets vs only 2 subjects in the placebo groups.

Safety was good in both groups. No change in their medical conditions, vital signs, nor any adverse effects at the end of treatment.

Discussion

Chronic pain is a usual complaint, leading the sufferer to be up to five times more likely to pursue medical attention as compared to those people without chronic pain (10). Lumbago, is a main cause of chronic pain. Within a year period one third of patients with this pain will experience lumbago (11). It has also been projected that around 80% of people will have low back pain at some point during their life (12). The bulk of low back pain (90%) without related neurological symptoms improves within 3 months (13).

Table 1: Global Result treatment as reported by patients

| | Treatment group | Control group | P |
|----------------------|-----------------|---------------|------|
| No improvement | 6 | 14 | 0.2 |
| Modest improvement | 10 | 16 | 0.4 |
| Moderate improvement | 16 | 18 | 0.8 |
| Good improvement | 28 | 12 | 0.03 |

Table 2: Spontaneous Pain as reported by patients at the end of treatment period

| | Treatment group | Control group | P |
|----------------------|-----------------|---------------|------|
| No improvement | 4 | 12 | 0.3 |
| Modest improvement | 4 | 18 | 0.05 |
| Moderate improvement | 28 | 20 | 0.4 |
| Good improvement | 24 | 10 | 0.05 |

Table 3: Pain provoked by movement as reported by patients at the end of treatment period

| | Treatment group | Control group | P |
|----------------------|-----------------|---------------|------|
| No improvement | 2 | 18 | 0.02 |
| Modest improvement | 6 | 22 | 0.03 |
| Moderate improvement | 28 | 12 | 0.03 |
| Good improvement | 24 | 8 | 0.04 |

Table 4: Nocturnal Pain as reported by patients at the end of treatment period

| | Treatment group | Control group | P |
|----------------------|-----------------|---------------|------|
| No improvement | 2 | 18 | 0.02 |
| Modest improvement | 18 | 10 | 0.2 |
| Moderate improvement | 12 | 20 | 0.4 |
| Good improvement | 28 | 12 | 0.03 |

Table 5: Nocturnal Paraesthesia as reported by patients at the end of treatment period

| | Treatment group | Control group | P |
|----------------------|-----------------|---------------|------|
| No improvement | 4 | 14 | 0.1 |
| Modest improvement | 4 | 18 | 0.05 |
| Moderate improvement | 20 | 12 | 0.3 |
| Good improvement | 32 | 16 | 0.04 |

The remaining 10% are a challenge to many healthcare providers, not only because chronic low back pain is challenging to manage, and normally linked to anxiety, depression, job dissatisfaction, poor body image and somatization (11).

Back pain is one of the most frequent health complaints. It is a common complaint affecting 70-85% of people worldwide at some point during their life (14). The differential is extensive including cancer, infection, inflammatory disorders, structural disorders of the spine itself and disk herniation, are somewhat more common, and together account for back pain.

According to the WHO (World Health Organization), low back pain leads to a high economic burden due to the

effects this often chronic problem has on work productivity (15). It is one of the most frequent causes behind visiting a primary care provider, and in the top five of the most common reasons for having surgery (12).

Initially, low back pain is usually managed with anti-inflammatories including non-steroidal, muscle relaxants, and narcotics. Persistent back pain is further treated with physical therapy, TENS units, massage, epidural steroid injections, and surgery. Treatment varies depending on the patient. The majority of patients recover within 12 weeks, while 10 to 20% endure low back pain past this time period, even with treatment (11,12).

It emerges that vitamin B12 might be one of those additional treatment options. This study clearly showed the beneficial

effects of the vitamin in low back pain. The advantage of using B12 shots included decreasing the amount of non-steroidal anti-inflammatory drugs (NSAID), such as aspirin and ibuprofen. Vitamin B12 has no known side effects, according to the National Institutes of Health Office of Dietary Supplements, rivaled to long-term NSAID use, which may harm the gastrointestinal system and probably lead to heart attacks and strokes. Vitamin B12 helps nerves repair and regenerate in the back. Additional benefits to treating back pain with B12 shots include the vitamin's low cost, minimal side effects, and ability to get patients back to work and enjoying their lives.

Studies have shown that vitamin B12 shots can successfully decrease back pain (16,17).

One study conducted in 2000 by Italian researchers at the University of Palermo found that vitamin B12 helped to alleviate lower back pain. The study evaluated 60 patients aged between 18 and 65 with proven back pain lasting anywhere from six months to five years.

Study participants were divided into two groups and received either a B12 shot or a placebo. Results showed injections alleviated back pain in patients even if they entered the study with adequate blood levels of vitamin B12 (17).

The therapeutic options for low back pain include NSAIDs, tramadol acetaminophen combinations, non-SSRI antidepressants, and glucocorticoids or local anesthetic to the spine (18). These medications may lead to serious side effects, particularly when used for a long time. NSAIDs, for example can lead to kidney dysfunction, acetaminophen can cause liver dysfunction and glucocorticoids can cause weight gain, insomnia, and Cushing syndrome. Studies revealed that out of the available treatments only NSAIDs seem to ameliorate function (18). Recent studies including this study (16,17) have shown that injectable cobalamin might also be a promising treatment option for lumbago.

Several studies (19-25), have suggested that large doses of vitamin B12 in combination with NSAIDs may lead to heightening effect on the analgesic properties of NSAIDs, therefore possibly decreasing NSAID dosing.

Vitamin B12 is mostly used for treatment of deficiency, which is often due to malabsorption, insufficient dietary intake, pernicious anemia, gastric surgery, GI disease, and particular medications (26). If long term effects of vitamin B12 injection show to be safe, vitamin B12 might be a precious treatment alternative for low back pain. This will be particularly important for the elderly, for patients prone to liver or kidney disease or people interested in natural substances. This study revealed that vitamin B12 compared to placebo, decreases low back pain and improves function significantly.

However there are certain limitations, including small size that leads to large confidence intervals that the possibility that treatment effect was not precise. In addition none of

the studies investigated the long term effects of injectable vitamin B12.

Although vitamin B12 seems to have significant benefit in the treatment of chronic low back pain, further research, with elimination of some of these limiting factors, is needed to study whether the intramuscular vitamin B12 injection doses are indeed harmful in the long run.

Conclusion

Intramuscular vitamin B12 injections seem to be effective at ameliorating nonspecific chronic low back pain as compared to placebo. Vitamin B12 injections also have exhibited only minimal side effects, which include hematoma and pain at the injection site.

There is a need for a larger study with longer duration that spans several years to assess the long term side effects, especially that long term effects can be possibly serious.

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