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Intramuscular Vitamin B12 Injections for Treating Chronic Low Back Pain

Johanna M. Rooijakkers
Pacific University

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Abstract

Background: Low back pain is a common problem worldwide, but especially in westernized countries. It can often create a great financial burden to society due to people missing workdays or having work limitations. Back pain is also one of the most common symptoms people are seen for by their primary care provider and one of the top 5 causes of surgery. Recent studies have shown a correlation between vitamin B12 injection and a decrease in low back pain. This systematic review takes a look at the efficacy of intramuscular vitamin B12 injection in the treatment of chronic low back pain.

Method: An exhaustive literature search was conducted using OVID (medline), CINAHL, PubMed, and Google Scholar with the search terms “low back pain,” “methylcobalamin,” and “vitamin B12.” Articles that met the inclusion and exclusion criteria were further evaluated with the GRADE method.

Results: Two studies met inclusion and exclusion criteria and were included in this systematic review. Both studies were double-blinded, randomized, placebo controlled trials. They each included 60 participants and showed significant improvement in low back pain and function with the intramuscular vitamin B12 injections as compared to the placebo groups.

Conclusion: Intramuscular vitamin B12 injections appear to be of benefit in the reduction of chronic low back pain and also improve associated disability. However, further research is necessary to study the possible long term adverse reactions of these intramuscular injections.

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Vitamin B 12, low back pain, methylcobalamin

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Intramuscular Vitamin B12 Injections for Treating Chronic Low Back Pain

Johanna M. Rooijakkers

A Clinical Graduate Project Submitted to the Faculty of the

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Faculty Advisor: Dr. Pedemonte

Clinical Graduate Project Coordinator: Annjanette Sommers, PA-C, MS

BIOGRAPHY

Johanna was born in the Netherlands and moved to the United States in late 2000. There she resided in Indiana where she attended Indiana University Purdue University Fort Wayne (IPFW) She obtained her bachelor degree in Fine Arts in 2007, and an associate degree in Radiographic Technology in 2010. The next two years she spent working as a radiologic technologist at Parkview Hospital before starting PA school in 2012 at Pacific University in Oregon. Initially, she will likely pursue a career in Family Medicine.

ABSTRACT

Background: Low back pain is a common problem worldwide, but especially in westernized countries. It can often create a great financial burden to society due to people missing workdays or having work limitations. Back pain is also one of the most common symptoms people are seen for by their primary care provider and one of the top 5 causes of surgery. Recent studies have shown a correlation between vitamin B12 injection and a decrease in low back pain. This systematic review takes a look at the efficacy of intramuscular vitamin B12 injection in the treatment of chronic low back pain.

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LIST OF ABBREVIATIONS

WHO	World Health Organization
NSAIDs	Non-steroidal anti-inflammatory drugs
TENS	Transcutaneous Electrical Nerve Stimulation
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
RCT	Randomized Control Trial
BMI	Body Mass Index
ODI	Oswestry Disability Index
VAS	Visual Analogue Scale
IM	Intramuscular
DQ	Disability Questionnaire

Intramuscular Vitamin B12 Injections for Treating Chronic Low Back Pain

BACKGROUND

Low back pain is a common complaint with anywhere from 70-85% of people worldwide dealing with back pain at some point during their life, especially in industrialized nations.[1] This number slightly changes depending on the article or study. However, one thing is certain; low back pain is a major health concern and financial burden wherever you go. According to the WHO (World Health Organization), low back pain causes a high economic burden due to the effects this often chronic problem has on work productivity, such as high rates of missed workdays and activity limitations.[2] Because the age range of the majority of the workforce in industrialized countries, ages 30-65, is also the same age range of the majority of patients suffering from low back pain this leads one to believe that the type of work done or work environment has something to do with the onset and even the increase incidence of low back pain.

Among Americans 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.[1] Chronic low back pain is frequently encountered with great dislike by many providers. Not only is back pain often a difficult symptom to treat, it's also very subjective and can be used inappropriately to gain access to narcotics. Initially, low back pain is often treated with anti-inflammatories including non-steroidal anti-inflammatory drugs (NSAIDs) and oral steroids, muscle relaxants, and narcotics. Persistent back pain is further treated with physical therapy, TENS units, massage, epidural steroid injections, and surgery, just to name a few. Treatment is different for every

patient; it is based on the nature of the problem, personal preference, and economic status. The majority of people with low back pain recover within 12 weeks, while the remaining 10-20% continues to experience low back pain past this time period, even with treatment.[1] Since the burden of low back pain is so large it is essential to be able to treat it well. The more treatment options available, the larger the likelihood low back pain can be treated. It appears that vitamin B12 could be one of those additional treatment options.

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.[4] There is a possible role of vitamin B12 injections in the relief of low back pain. This systematic review evaluates the efficacy of intramuscular vitamin B12 injections in the treatment of chronic low back pain.

METHOD

An exhaustive literature search was conducted by using the following search engines: OVID (medline), CINAHL, PubMed, and Google Scholar. Articles of interest were then found by using the search terms “low back pain,” “methylcobalamin,” and “vitamin B12.” The reference lists of included studies were also searched. Non-English and non-human studies were excluded. Inclusion criteria included studies that enrolled adults over the age of 18 years old with low back pain greater than 6 months in duration. Grading of Recommendations Assessment, Development and Evaluation (GRADE) was used to evaluate the quality of the included studies.[7]

RESULTS

Results following the initial search, using the above mention search strategies, produced 81 articles. After duplicates were removed 78 records were screened. Out of those, a total of 8 full-text articles were assessed for eligibility. A total of 2 studies,[5,6] both RCTs, met inclusion and exclusion criteria (see Table 1).

CHIU et al

This randomized, double-blinded, placebo control study[5] was conducted to evaluate both the efficacy and safety of intramuscular methylcobalamin injections for treatment of chronic low back pain. Certain eligibility criteria were used for selection of the patient population. Included were patients who were between 20-65 years old and who had a history of low back pain, which had to be nonspecific in nature, for greater than 6 months in duration. Exclusion criteria included patients who are pregnant women, on neurotoxic medications, with severe comorbidities, who had a known vitamin B12 allergy, with megaloblastic anemia, who had a specific cause of their back pain, and who did not want to discontinue other forms of treatment. Sixty patients were selected based on the above criteria. This number was chosen to achieve a study power of 80% with 95% confidence interval. Computerized software was used to randomize participants; the treatment group consisted of 33 patients and the placebo group had 27 patients. Both control and intervention groups started with the same prognosis; groups were homogenous when it came to gender, age, body mass index (BMI), Oswestry Disability Index (ODI) scores and VAS scores. The groups were prognostically balanced during the entire duration of the study and at the completion of the study. Only two patients, one from each group, discontinued the study prior to completion. At the end of the two week study the remaining patients were analyzed in the groups to which they were first assigned.[5]

This study took place in Malaysia at the Orthopaedic Specialist Clinic of Hospital Tuanku Jaafar during the time period of August 2006-April 2007. The placebo group received normal saline injections, while the treatment group received intramuscular injections containing methylcobal (500 μg of parenteral methylcobalamin in 1-mL ampules). On day 1, 3, and 5 of week 1 and 2, patients received an intramuscular injection, for a total of 6 during a 2-week period. Participants in both the placebo and treatment group were also allowed to take a maximum dose of 3 g/day of paracetamol in addition to the injections they received. Pain severity and disability were scored with the VAS and ODI. Scoring was done once at the initiation of the study and once at the study completion, 2 months later.[5]

At the study's completion neither disability nor pain was significantly reduced in the placebo group. However, in the treatment group they found a marked decrease in both disability and pain. These conclusions were based on the ODI and VAS scores taken 2 months after initiation of treatment, see Table 2. In addition, the participants in the placebo group consumed significantly higher doses of paracetamol as compared to the participants in the treatment group; mean paracetamol consumption (in grams) was 87.6 ± 57.3 in the placebo group, 65.7 ± 75.2 in the treatment group. Treatment with intramuscular (IM) methylcobalamin had very few side effects, including hematoma and pain at the injection site. Due to the short follow up period of only 2 months, it is uncertain whether there are any long term effects from IM methylcobalamin injections.[5]

MAURO et al

In this randomized, double-blinded, placebo control study[6] the authors studied the efficacy of vitamin B12 in treating low back pain. Participants included in the study had to be

between 18 and 65 years old with medical evidence of 6 months to 5 years of mechanical low back pain or sciatic neuritis. They also had to have at least 60 out of 100 on the VAS pain intensity scale at the start of the study. Patients who required surgery were excluded. So were participants who were pregnant, took neurotoxic medications, had severe comorbidities, and were intolerant to paracetamol. A total of 60 patients were selected, all of which came from the outpatient clinic of the Department of Orthopaedics of Palermo University Hospital. Patients were randomly assigned to either the placebo or the treatment group. However, the method of randomization was not discussed by the authors and can therefore not be verified. Treatment designation was not discussed with the assessors, so group allocation stayed concealed for both the participants and the examiners. The authors do not mention any participants discontinuing treatment prior to the study's completion.[6]

Overall, study groups were fairly similar with respect to known prognostic variables: age, sex, pain, and functional disability. Baseline pain and disability, measured with the VAS and Disability Questionnaire (DQ) respectively, were more severe in the treatment group. The mean age was slightly different between both groups, but not of any significance according to the Mann-Whitney U test. The treatment group was composed of 8 males and 22 females, whereas the place group contained 3 males and 27 females. The Chi-square test was used to detect a potential significant variance in gender between the two groups, which was not detectable.[6]

Once daily, for a 2-week period, treatment was delivered intramuscularly in both the treatment and placebo group. The treatment group received Tricortin® 1000 2mL ampoules containing 1000 mg vitamin B12, whereas the placebo group only received 2 mL ampoules of an

unspecified injection. Pain was evaluated with the VAS, a test in which the participants scored their pain on a scale of 0-100, where 0 meant no pain at all, and 100 was the worse pain one can have. Pain was also evaluated based on how much paracetamol the patient took during the 2 week treatment period. Disability was evaluated by using the DQ, a test that is made up of 24 questions and is then scored on a 0-24 scale. Safety was also measured during the entirety of the study, by means of vital signs obtained prior to initiation of treatment and shortly after treatment.[6]

Pain and disability improved in both the treatment and the placebo groups. In the placebo group the VAS score declined from 70.63 ± 7.9 to 36.83 ± 27.4, whereas in the treatment group it declined from 75.53 ± 8.9 to 9.53 ± 16.5. Similarly, in the placebo group the DQ score decreased from 11.53 ± 2.2 to 5.80 ± 3.3 and in the treatment group it decreased from 13.27 ± 2.7 to 2.43 ± 2.6. However, when compared there was a more statistically significant improvement in the treatment group. Paracetamol was consumed less in the treatment group versus the placebo group, also indicating that vitamin B12 treatment as compared to placebo is effective in treating low back pain. Patients in the placebo group as well as patients in the treatment group had no changes in vital signs or any adverse effects throughout the entire study, indicating that an IM injection of vitamin B12 is safe in the short term. However, long term effects of IM injections of vitamin B12 were not examined nor discussed in this study.[6]

DISCUSSION

Chronic pain is a common complaint, causing those who suffer to be up to five times more likely to seek medical care as compared to those people without chronic pain.[8] Lumbago,

or low back pain, is a common cause of chronic pain. In studies of patients with this pain estimates conclude that up to one-third of people will experience lumbago within a year period.[3] It has also been estimated that around 80% of people might have low back pain at some point during their life.[1] Fortunately, the majority (90%) of low back pain without related neurological symptoms improves within 3 months.[10] However, that means that the remaining 10% suffers from pain on a chronic basis. These are the people who are a challenge to many healthcare providers, not only because chronic low back pain is difficult to treat, but also because of the associated psychological issues. These issues can include anxiety, depression, job dissatisfaction, poor body image as a result of exercise limitations, and the likelihood of somatization, where one has multiple physical symptoms with no physical cause to explain them.[1]

Unfortunately, therapeutic options for low back pain are very limited. The only medications that have been shown to improve low back pain are NSAIDs, tramadol-acetaminophen combinations, non-SSRI antidepressants, and glucocorticoids or local anesthetic applications to the spine.[9] These drugs can have some serious side effects, especially if used on a more chronic basis. For example, NSAIDs can cause kidney dysfunction, acetaminophen can cause liver dysfunction and glucocorticoids can cause weight gain, insomnia, and Cushing syndrome. Not only can these side effects be problematic it also has been shown that out of those options, only NSAIDs appear to improve function.[9] However, these reviewed studies[5,6] have shown that injectable cobalamin might also be a favorable treatment option for lumbago and its associated dysfunction. Several studies, including animal studies[11-14] as well as clinical studies[15-17], have additionally indicated that large doses of vitamin B12 in combination with

NSAIDs can have an enhancing effect on the analgesic properties of NSAIDs, therefor potentially reducing NSAID dosing.

Currently, oral and injectable vitamin B12 are mostly used for treatment of vitamin B12 deficiency, which is often due to malabsorption, insufficient dietary intake, pernicious anemia, gastric surgery, GI disease, and particular medications.[18] If long term effects of injectable large doses of vitamin B12 prove to be minimally harmful, vitamin B12 could be a valuable treatment option for low back pain, especially for those who are opposed to taking synthetically made drugs and would rather take natural substances. Additionally, as mentioned before, NSAIDs and acetaminophen, two of the main medications currently used for treatment of lumbago, have a limited use in certain populations that already have kidney or liver dysfunction. For those people who are more vulnerable to developing liver or kidney disease, such as the elderly population, vitamin B12 could be a safer option, again given that the long term effects are minimal.

While both the Mauro et al study[6] and the Chiu et al study[5] demonstrate that compared to placebo, vitamin B12 decreases low back pain and improves function significantly, both studies have some limitations. First, both studies were fairly small in size. This caused the confidence intervals to be large and as a result the treatment effect was not precise. Second, the cost of vitamin B12 injections, which can be a major factor, also was not discussed. Although the cost is approximately $26 per 1000 mcg/mL (1 vial, 10 mL).[19] Often cost is the main factor when it comes to deciding which treatment to utilize. Finally and most importantly, neither study looked at or mentioned long term effects of injectable vitamin B12. One study only spanned two weeks and the other only two months.[5,6] Some known long term conditions

have been associated with high serum levels.[20] For example, in one study vitamin B12 serum levels of >1275 pg/mL were associated with hematologic malignancies.[21] Other conditions linked to high serum levels of vitamin B12 are cancer, liver and renal disease, and inflammatory diseases.[20] All of these conditions can seriously limit one's quality of life and eventually lead to an early death. Therefore, the benefits of vitamin B12 in treating low back pain might not outweigh the long term risks that come with it. However, one needs to be mindful of the fact that these studies done to evaluate long term effects of high serum cobalamin levels had their own limitations. For example, in one study[20] it appeared that the older the patient was, the higher the serum vitamin B12 levels. At the same time older people often have multiple comorbidities. Therefore it was difficult to contribute the results of the study to the vitamin B12 levels versus the participants age.[22] Another limitation mentioned in a second study was the fact that vitamin B12 was the only lab value looked at for it's possible relation to cancer development.[23] However, it could be true that another electrolyte abnormality or vitamin deficiency was instead the cause for an increased risk of cancer. Furthermore, we don't know whether the cobalamin doses used in the treatment of low back pain were high enough to cause the high serum vitamin b12 levels discussed in the studies[22,23] mentioned above. Although vitamin B12 appears to have substantial 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 appear to be effective at improving nonspecific chronic low back pain as compared to placebo. Vitamin B12 injections also have shown only

mild short term adverse effects, which include hematoma and pain at the injection site. Unfortunately, the studies are pretty limited. Neither study looked at the cost of intramuscular vitamin B12 injections or had a large enough study population to have precise results. But even more important, neither study had followed study participants long enough to measure any long term effects. Since long term effects can potentially be serious, further long term research is necessary before we can safely say that intramuscular methylcobalamin injections for treatment of low back pain are free of harm. This results in an overall low quality of evidence. A future research study should include a larger group of participants, should look at the cost of vitamin B12 injections as compared to current treatment options, and should span over several years in order to measure long term outcomes and side effects. In the meanwhile, providers can offer vitamin B12 treatments in addition to conventional treatment to carefully selected patients with the potential of long term effects in mind and patients need to be made aware of these possible long term consequences prior to initiation of vitamin B12 treatment.

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Table 1. GRADE Quality Assessment

Quality Assessment							
		Downgrade Criteria					
Study	**Design**	**Limitations**	**Indirectness**	**Imprecision**	**Inconsistency**	**Publication Bias likely**	**Quality**
Chiu et al[5]	RCT	Serious limitations[a]	No serious indirectness	Serious lack of precision[b]	No serious inconsistent results	Publication bias is unlikely	Low
Mauro et al[6]	RCT	Serious limitations[a]	No serious indirectness	Serious lack of precision[b]	No serious inconsistent results	Publication bias is unlikely	Low

[a] Short study durations of 2 months and 2 weeks, respectively

[b] Sample size is small (n=60) and confidence Intervals are wide

Table 2. Summary of Findings

		Pain		Function	
		Baseline	Post treatment	Baseline	Post treatment
Study	Treatment	VAS[c]		ODI[d]	
Chiu et al[5]	Vitamin B12	56.0 ± 18.6	38.6 ± 22.3	64.0 ± 18.3	47.0 ± 22.3
	Placebo	54.8 ± 16.1	51.5 ± 19.4	60.5 ± 15.4	55.3 ± 20.5
Mauro et al[6]		VAS[c]		DQ[e]	
	Vitamin B12	75.5 ± 8.9	9.5 ± 16.5	13.2 ± 2.7	2.4 ± 2.6
	Placebo	70.6 ± 7.9	36.8 ± 27.4	11.5 ± 2.1	5.8 ± 3.3

[c] Visual Analogic Scale (VAS): where 0 means no pain at all, and 100 is the worst pain imaginable (range is 0-100mm)

[d] Oswestry Disability Index Questionnaire Version 2.0 (ODI): Index is scored from 0-100, where 0 is no disability and 100 is max disability

[e] Disability Questionnaire (DQ): consists of 24 questions, with each question corresponding to a single score (range is 0-24)