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Efficacy of Inj. Methylcobalamin in patients of chronic non-specific low back pain, A Randomised Single Blind Placebo Controlled Study

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ABSTRACT-

Objective- The objective of this study was to evaluate the efficacy of inj. methylcobalamin (1500 mcg) as compared to placebo (normal saline) in patients with chronic low back pain presenting to a tertiary care hospital.

Methods- 100 patients of either sex aged between 18 to 70 years were enrolled in the study after excluding any red flag signs and any surgical need thereafter. Patients presented to the outpatient department with lower back pain of more than 3 months duration with no prior medical intervention. The evaluation was done according to Visual Analogue Scale. Tablet paracetamol 500mg was allowed for breakthrough pain.

Results- Although both groups showed a decrease in mean VAS score at the end of treatment, the Group with inj. Methylcobalamin had a statistically significant decrease with a p-value >0.001. A statistically significant difference was noted in the consumption of tablet paracetamol in the placebo group.

Conclusion- positive effectiveness was confirmed for inj. methylcobalamin (1500 mcg) to be used for relieving symptoms in patients with chronic low back aches and reducing the consumption of tablet paracetamol during the treatment period.

Keywords – low back ache, inj. Methylcobalamine, tab. Paracetamol.

INTRODUCTION

Low back pain, a leading cause of disability, interferes with quality of life and work performance and is one of the most common complaints with which patients present to the outpatient department.[1] It can be defined as pain localized between the costal margins and inferior gluteal folds, with or without leg pain. [2]

Clinical practice guidelines typically categorize patients with LBP into3 groups: LBP associated with a specific underlying disease (1 – 2% of cases); neuropathic LBP (about5%), which is back pain associated with a neurological condition; and nonspecific LBP (more than 90%)[3]Low back pain can be classified into 3 types according to the duration of onset: acute <6 weeks, subacute 6-12 weeks and chronic >12 weeks.[4]

The impact of LBP on the individual can cause loss of health status in the form of symptoms and loss of function related to pain in the back; limitation of daily, leisure, and/or strenuous activities; and disability. LBP is one of the leading causes of absence from work.[2]

To reduce the impact of chronic nonspecific low back pain (CNLBP) on adults, drug therapy is the most frequently recommended intervention.[5]

Besides that, the therapeutical benefits of B vitamins given in high doses, and in particular vitamin B12, in painful disorders of spinal nerve roots in the absence of typical signs of a nutritional deficiency have already been demonstrated. This compound, after conversion into co-enzymatic forms such as methylcobalamin, is involved in the synthesis of nucleic acid and protein, based on the transmethylation reaction, as well as the metabolism of phospholipids and catecholamines. The methyl group is used in the synthesis of methionine from homocysteine as well as the synthesis of phosphatidyl choline, a

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phospholipid important in the cell membrane structure. Part of phosphatidyl choline becomes choline and is used in the synthesis of acetylcholine, a notableneurotransmitter.[6]

From a clinical standpoint, several studies have documented the positive influence of B vitamins on painful symptoms due to degenerative disorders of the lumbar spine, and have indicated that fewer nonsteroidal anti-inflammatory drugs (NSAIDs) are needed for pain relief when combined with B vitamins. [7, 8]

MATERIALS & METHODOLOGY

Our study was a prospective randomized controlled trail, done at the Department of Orthopaedics, Government Medical College and Guru Nanak Dev Hospital, Amritsar. 100 patients presenting to outpatient departments of either sex, aged between 18 to 70 years were enrolled in the study after getting clearance from Institutional Ethics Committee. Patients were debriefed about the study and proper written consent was obtained.

Inclusion- patients with a history of undiagnosed low back ache since last 3 months or more having received no formal treatment, having pain of more than 5 on the VAS score.

Exclusion criteria - patients with red flag signs, the requirement for surgical management, pregnancy, ongoing treatment with drugs known to have neurotoxic adverse reactions, severe coexisting illness, and intolerance to paracetamol.

Patients after qualifying for inclusion criteria were randomly divided into 2 groups of 50 each without disclosing the mode of treatment assigned.

Group A patients received intramuscular inj. Methylcobalamin 1500 mcg,

Group B patients received 2ml intramuscular inj. Normal saline as a placebo.

10 injections were given at every alternate day, within a period of 3 weeks, and there after assessed and compared with VAS score.

VAS was evaluated according to *Scott & Huskisson* by means of a graduated rule with a total length of 100 mm; absence of pain corresponded to the position at 0 mm and maximum pain to the position at 100mm.[9] Patients were allowed to consume tablet paracetamol 500mg on SOS basis, if they experienced any breakthrough pain during the study period, and was noted using a diary method. It was later evaluated and served as an indirect measure of treatment efficacy within the 2 groups.

RESULTS

The mean age of group A was55 +- 4.6 years and group B was 51 +-7.4 years. There were 23 males and 27 females in group A and 18 males and 32 females in group B, with no statistically significant difference between them. Baseline pain according to the VAS score was noted on day 1. Findings as shown in Table no. 1.

		Group A	Group B	P – Value
Age		55 ± 4.6	51 ±7.4	0.001
Sex	Male	23	18	0.309
	Female	27	32	
Mean VAS score	Day 1	72.31 ± 8.5	78.15 ± 9.7	0.001
	Day 21	24.34 ± 9.45	50.44 ± 8.62	<0.0001
Mean PCM Consumption		8.75 ± 2.45	17.15 ± 5.12	<0.0001

Group A had a mean VAS score of 24.34 ± 9.45 and Group B had mean VAS score of 50.44 ± 8.62 AT Day 21. Both the groups experienced a relief with decrease in VAS score

Mean paracetamol consumption was statistically higher in Group B treated with a placebo of inj. Normal saline with a p-value of <0.0001. There was no linear correlation between the initial VAS score and the consumption of the tab. Paracetamol during the period of follow-up in both groups.

DISCUSSION

Lower back aches are one of the most common complaints prevalent in the general population, accounting for the loss of working days and cause of great discomfort, affecting people from a sedentary lifestyle to manual labour. Over-the-counter medications and informal therapies account heavily for the

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mismanagement in these cases. It's well known of NSAIDs cause an adverse reaction if consumed for a longer duration, although being the therapy of choice in patients managed non-surgically. Vitamin B12 and its congeners have previously demonstrated their role in metabolic polyneuropathy, uremic and diabetic neuropathy. Supplementing our treatment with inj. Methylcobalamin may reduce the need for NSAIDS and help in the early relief of symptoms, thereafter patients could be advised to start with physiotherapy. Although the mechanisms producing these positive effects on nerve damage are not fully elucidated, it has been speculated that the accumulation of exogenous methylcobalamin promotes nerve regeneration or remyelination. Biochemical findings suggest that methylcobalamin acts directly as a methyl donor in DNA metabolism and that high concentrations up-regulate gene transcription, which may increase protein synthesis for nerve regeneration12. Patients also reported a decrease in associated symptoms like burning feet, tingling, and numbness in the lower extremities.

Similar findings were reported by G. Mauro et al. concluding the efficacy and safety of parenteral Vit B12 in alleviating low back pain in patients with no signs of nutritional deficiency. [10]

A study done by Kuhlwein et al. did a double-blind study and concluded the reduced need for diclofenac 75mg showed a positive influence of vit B complex in shortening the treatment time and reducing the daily dosage of diclofenac.[11]

Chiu et al did a randomized double-blinded placebo control study that gave 6 intramuscular injections of methylcobalamin 500mcg on days 1,3 & 5 of 1st and 2ndweeks. Comparable findings were reported stating a decrease in VAS score and minimizing consumption of tablet paracetamol during the follow-up period.[12]

In our study, inj. Methylcobalamin proved its efficacy in relieving symptoms and disability along with decreasing the consumption of paracetamol tablets. Thus, augmenting our treatment of chronic low back ache with inj. Vit B12 could be a cost-effective method for out-patients.

Limitation – a longer-term follow-up is required to see if the benefits are sustainable, a multicentric randomized double-blind study would prove to be a superior study. Pre-treatment serum vitamin B12 was not assessed, therefore difficult to rule out any nutritional deficiency.

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