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Methylcobalamin in Clinical Practice

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In this comprehensive article, DR SANJAY AGRAWAL discusses methylcobalamin, which is used to treat vitamin B12 deficiency, and its role in neurological disorders.

Vitamin B_{12}, an indispensable water-soluble vitamin, plays a crucial role in the production of red blood cells, DNA synthesis, and neurological functions. It is predominantly found in animal-based foods such as meat, fish, milk, dairy products and eggs. Plant foods typically do not contain a substantial amount of vitamin B12.

Vitamin B12 is essential for three enzymatic processes: the conversion of homocysteine to methionine, the conversion of methylmalonic acid to succinyl coenzyme A, and the conversion of 5-methyltetrahydrofolate to tetrahydrofolate, which is necessary for DNA synthesis and red blood cell production.

The term vitamin B12 includes several chemical compounds that contain a common corrinoid group centred on the mineral cobalt and various ligands, such as cyano, methyl, adenosyl, and hydroxyl ligands. Methylcobalamin and 5'-deoxyadenosylcobalamin are the active vitamin B12 moieties utilised in the human body to catalyse specific enzymatic reactions.

Methylcobalamin: An active form of vitamin B12

Methylcobalamin is also known as mecobalamin or methyl B12. Methylcobalamin is a potent and active form of vitamin B12.

Methylcobalamin is the most bio-available type of Vitamin B12. Results of three human studies found lower tissue retention of B12 as a result of supplementation with cyanocobalamin rather than with methyl, adenosyl or hydroxyl cobalamins. The urinary excretion of cyanocobalamin was also higher than that of others.

The researchers concluded that the lower bioavailability of cyanocobalamin was due to its lower efficiency in cellular uptake. Few researchers have shown concerns about cyanide accumulation in human tissues from long-term intake of cyanocobalamin from supplements and/or fortified foods. These findings suggest that supplementation with any of the natural bioidentical forms of B12 (MethylCbl, HydroxyCbl or AdenosylCbl) is preferred instead of the use of cyanocobalamin, owing to their superior bioavailability and safety.

Methylcobalamin is the only form of vitamin B12 that can cross the blood-brain barrier without biotransformation. Its methyl group stimulates serotonin secretion, a neurotransmitter responsible for mood enhancement, and protects the brain from damage from excitatory neurotransmitters.

Beneficial actions of Methylcobalamin

A number of laboratory and clinical studies have shown that methylcobalamin has the following beneficial actions:

- Promotes synthesis of healthy myelin
- Helps regeneration of injured nerves
- Analgesic action: Relieves nerve pain associated with nerve degeneration, nerve

compression, nerve inflammation
- Anti-oxidant action
- Anti-inflammatory action

Clinical evidence of Methylcobalamin

Methylcobalamin has been in clinical use since the 1990s. Methylcobalamin therapy is found to be useful in the prevention as well as treatment of vitamin B12 deficiency.

A number of clinical studies have demonstrated the efficacy of methylcobalamin in the treatment of the following neurological disorders:

- Diabetic peripheral neuropathy
- Chronic low back pain
- Radicular pain such as sciatica
- Carpal tunnel syndrome
- Post-herpetic neuralgia
- Trigeminal neuralgia
- Bell's palsy
- Amyotrophic lateral sclerosis
- Autism

Role of methylcobalamin in various neurological disorders

A number of clinical trials have been conducted to study the role of methylcobalamin in the treatment of DPN, either alone or in combination with other treatments. A meta-analysis of such clinical trials concluded that methylcobalamin effectively decreases pain scores, neuropathic disability score and the neuropathic total symptom score in patients with diabetic peripheral neuropathy.

Herpetic neuralgia: In a randomised controlled trial, patients with herpetic neuralgia received either 500 µg of methylcobalamin or lidocaine subcutaneously in four separate locations on the affected dermatome or oral methylcobalamin 500 µg three times a day. While lidocaine and oral methylcobalamin had small but significant effects on pain, daily injections of methylcobalamin reduced pain by half or more in 60% of subjects.

Trigeminal Neuralgia: The pain of trigeminal neuralgia (TN) can be described as agonising, paroxysmal, and lancinating. It may be activated by activities such as chewing, speaking, and swallowing. A clinical trial proved that the pain of TN patients was greatly alleviated in the methylcobalamin group.

Low back pain: In a double-blind, randomised, controlled study, 60 patients with chronic non-

specific low backache were assigned to either the methylcobalamin group or the placebo group. Of the 60 patients, 27 received the placebo injections, and 33 were given methylcobalamin injections (500 mcg of methylcobalamin IM, three times a week) for two weeks. There was a significant improvement in the Oswestry Disability Index and Visual Analogue Scale pain scores in the methylcobalamin group compared to the placebo group ($p < 0.05$). The active treatment reduced the disability score by 27% and the pain score by 31%. The study concluded that Intramuscular methylcobalamin is both an effective and safe method of treatment for patients with non-specific low back pain.

Neck pain: A clinical trial showed that spontaneous pain, allodynia, and paraesthesia in patients with neck pain were improved significantly in the methylcobalamin group, and the analgesic effect was more obvious with continued treatment.

Bell's Palsy: A study suggested that methylcobalamin dramatically increases the recovery time for facial nerve function in Bell's Palsy.

Autism: An open-label trial using 75 mcg/Kg of methylcobalamin twice daily, together with folinic acid, demonstrated improvement in autistic symptoms, glutathione redox status, and expressive communication. Receptive, expressive, and written language showed marked improvements.

Another study reported that a high dose of methylcobalamin, administered in syrup form, ameliorates the clinical and psychological status of autistic individuals, probably due to the improved oxidative status.

Amyotrophic lateral sclerosis (ALS): 373 patients with ALS were randomised to receive a placebo, 25mg or 50 mg of methylcobalamin, for 182 weeks. Post-hoc analyses of methylcobalamin-treated patients diagnosed and entered early (less than 12 months 'duration) showed longer time intervals to the primary event and fewer decreases in the ALSFRS-R score than the placebo group. The study concluded that early treatment with methylcobalamin may prolong survival and retard symptomatic progression of ALS without major side effects.

Few small studies have also reported beneficial effects of methylcobalamin treatment in patients with fibromyalgia, mild cognitive impairment, dementia and dry eye disease.

Methylcobalamin: Dosage_

Methylcobalamin can be administered orally, intramuscularly or intravenously. Positive clinical results have been reported, irrespective of the route of administration.

A therapeutic dose for methylcobalamin varies from 1500 µg to a maximum of 6000 µg per day. No significant therapeutic advantage appears to occur from dosages exceeding this maximum dose. It is likely that beneficial physiological effects of methylcobalamin may occur at dosages as low as 100 µg per day, especially if this dose is given for a long time.

Methylcobalamin has excellent tolerability, whether given orally or parenterally

Clinical studies using doses as high as 25-50 mg, given twice weekly, have shown that it is free from any serious side effects.

Chronic neuropathic pain is closely associated with chronic neuroinflammation caused by nerve injury and impediments to remyelination. Methylcobalamin targets this fundamental aspect of pathophysiology and offers an effective and safe treatment option. It reduces neuroinflammation by regulating NFκB activity in immune cells and neurons, which results in the reduction of TNF-α, IL-1β, and IL-6 levels and an increase in IL-10 levels. It also controls peripheral and ganglionic sensitisation, which affects nerve impulse transmission by inhibiting the ion channel activation in neurons. In addition, it also modulates remyelination.

Finally, Methylcobalamin alone or in combination with other agents produces an analgesic effect in patients suffering from non-specific low back pain, neck pain, diabetic neuropathic pain, subacute herpetic neuralgia, glossopharyngeal neuralgia, and trigeminal neuralgia. Possible mechanisms include improved nerve conduction velocity, promotion of injured nerve regeneration, and inhibition of ectopic spontaneous discharges from peripheral primary sensory neurons.

(Dr Sanjay Agrawal is Scientific Advisor of ALOKMEX GBN USA. The views/opinions in this article are personal.)

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