B vitamins do not prevent vascular events in stroke patients

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B vitamin supplements are safe, but do not reduce subsequent vascular events (stroke, heart attack, or vascular death) in patients who have had a recent stroke or ischaemic attack, despite a lowering of homocysteine levels. As such, B vitamins should not be recommended to prevent recurrent stroke, according to the first placebo-controlled trial of B vitamins in stroke patients. These are the conclusions of an Article published Online First and in the September edition of The *Lancet Neurology*.

Previous observational studies have suggested an association between raised homocysteine (an amino acid in the blood) levels and increased risk of cardiovascular disease and stroke. Other studies have shown that daily supplementation with B vitamins can reduce homocysteine levels, but whether this improves outcomes is unclear. The potential protective effect of B vitamins in patients who have had a stroke or transient ischaemic attack (TIA) is not known.

The VITAmins TO Prevent Stroke (VITATOPS) trial examined whether lowering levels of homocysteine with a combination of B vitamins (folic acid 2mg, vitamin B6 25mg, and vitamin B12 500µg) would reduce the combined incidence of non-fatal stroke, non-fatal heart attack, and vascular death among patients with recent stroke or TIA over a median 3.4 years of follow-up.

8164 patients with recent stroke or TIA (within the past 7 months) were enrolled from 123 medical centres across 20 countries and randomly

assigned to receive a daily tablet of B vitamins (4089) or placebo (4075) in addition to standard care.

B vitamins were not significantly more effective than placebo in reducing the relative risk for stroke, heart attack, or death from any cause. 616 patients taking B vitamins (15%) experienced a major vascular event compared with 678 patients (17%) in the placebo group.

The researchers also found that the average total homocysteine level was 3.8µmol/L lower in the vitamin group than in the placebo group.

B vitamin treatment was safe and well tolerated with no unexpected serious adverse reactions or significant differences in common side effects between the two groups.

The authors say: "These results are consistent with trials of B vitamins in other patient populations."

They conclude: "The results of ongoing trials and an individual patient data meta-analysis will add statistical power and precision to present estimates of the effect of B vitamins."

In a Comment, Peter Sandercock from the Western General Hospital, Edinburgh, UK, points out that: "If widespread treatment with a simple, inexpensive vitamin pill for a few years among stroke survivors had even a small effect on the risk of subsequent vascular events, the effect on the global burden of vascular disease could be very large."

However, he concludes: "the VITATOPS trial does not provide sufficiently robust evidence to support a policy of giving B vitamin supplements for secondary prevention after transient ischaemic attack or minor stroke. However, there is still a place for further trials of homocysteine-lowering treatment, especially if the intervention can

achieve and sustain large reductions in homocysteine."

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