

PREVENTION

Polycap reduces CVD risk

A polypill that contains three blood pressure lowering agents, aspirin and a statin in low doses has the potential to reduce the incidence of cardiovascular disease (CVD) by 62% and stroke by 48%, according to the investigators of the Indian Polycap Study (TIPS).

“...replacing multidrug regimens with a single pill could simplify risk factor reduction...”

The concept of a polypill was first proposed in 2003 by Wald and Law, who estimated that more than 80% of cardiovascular events could be prevented if such a polypill was taken by every adult over the age of 55 years and by all patients with known CVD. The agents used in such a polypill have proven efficacy for reducing CVD risk when used individually, but “many people find that taking several pills every day, some more than once a day, for an indefinite period [is] burdensome” explains Professor Koon Teo, one of the authors of TIPS. “Many do not take the medications at all, or gradually stop taking them, particularly if they do not have symptoms.” The investigators believe that replacing multidrug regimens with a single pill could simplify risk factor reduction and improve patients’ adherence to medication.

TIPS was a multicenter, double-blind, randomized, proof-of-principle trial conducted in India. The researchers

recruited 2,053 individuals aged between 45 and 80 years, who had one cardiovascular risk factor but no previous CVD. The Polycap (Cadila Pharmaceuticals, Ahmedabad, India) contains 12.5 mg hydrochlorothiazide, 50 mg atenolol, 5 mg ramipril, 20 mg simvastatin and 100 mg aspirin. Participants were randomly assigned to receive the Polycap, or another single capsule containing one of eight different combinations of Polycap constituents, once daily for 12 weeks. This design was used to investigate whether the Polycap was as effective as the additive effect of each constituent drug given separately.

The investigators found that mean blood pressure reduction was similar among individuals who received the Polycap (7.4 mmHg systolic and 5.6 mmHg diastolic) and those given a capsule containing three blood pressure lowering agents (6.6 mmHg systolic and 4.8 mmHg diastolic), but greater than in those taking only one (2.2 mmHg systolic and 1.3 mmHg diastolic) or two (4.7 mmHg systolic and 3.6 mmHg diastolic) drugs. By contrast, participants who received a capsule containing simvastatin alone, derived greater benefit in terms of lowering LDL cholesterol (0.83 mmol/l versus 0.70 mmol/l). Heart rate was reduced to a similar extent in the groups who received the Polycap and atenolol alone (7 bpm). A subgroup analysis indicated that the Polycap might



be more effective in high-risk individuals, such as those with diabetes, than in those with fewer risk factors for CVD. The Polycap was well tolerated and there were no differences in the number of drug-related adverse events between the treatment groups.

The promising results from TIPS have laid the groundwork for future research on the Polycap. “The next step is to carry out a long-term clinical trial evaluating the effect of the polypill in reducing the risk of major vascular events,” says Professor Teo. Assuming the findings from TIPS are confirmed, the concept of a polypill will have a huge effect on clinical practice.

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