Polypill increases adherence to post MI treatment

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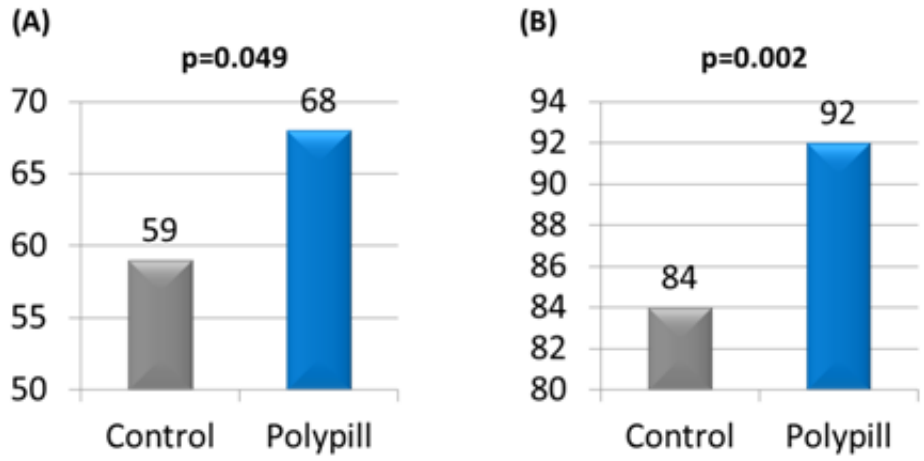

Percentage of post MI patients adhering to treatment with the FDC polypill vs. control (conventional treatment with 3 drugs separately) (A) using Morisky Green Adherence Questionnaire; (B) using pill count.

A new polypill increases adherence to treatment following a myocardial infarction (MI), according to results from the FOCUS Study presented for the first time at ESC Congress 2014 today by principal investigator Dr Valentin Fuster, director of Mount Sinai Heart in New York, US. The novel treatment regime has the potential to prevent more patients having a second heart attack.

Dr Fuster said: "Despite continuous advances in all areas of cardiovascular (CV) medicine, cardiovascular disease (CVD) has

steadily increased in prevalence to become the number one cause of death worldwide. It is estimated that half of the overall reduction in CVD mortality observed over the past 20 years in western countries could be attributed to appropriate use of CV medications for secondary prevention. But lack of adherence to treatment impedes adequate secondary prevention and contributes to the CVD pandemic."

He continued: "The most important factors responsible for a lack of adherence to treatment are the complexity of treatment and the daily number of prescribed pills. The idea of using a polypill for CVD prevention has gained increasing momentum because it could increase adherence and therefore contain the progression of CVD. A polypill could simplify healthcare delivery, improve cost-effectiveness, support the comprehensive prescription of evidence-based cardioprotective drugs, and reach underdeveloped regions of the world."

The Fixed-dose Combination Drug for Secondary Cardiovascular Prevention (FOCUS) study was established to investigate adherence to secondary prevention medication and test a new polypill. The study was conducted in two subsequent phases. FOCUS 1 included post MI patients in a multi-country comprehensive analysis of socioeconomic, comorbidity, and other factors that determine adherence to CV medications. FOCUS 2 was a randomised controlled clinical trial testing the effect of a fixed-dose combination (FDC), the CNIC-FS-FERRER polypill, containing acetylsalicylic acid (ASA) 100 mg, simvastatin 40 mg and ramipril 2.5, 5 or 10 mg, on adherence and control of CV risk factors in post MI patients.

FOCUS 1 included 2 118 patients with a history of MI from five different countries (Spain, Italy, Argentina, Brazil and Paraguay). The degree of adherence to prescribed medications was calculated using the Morisky Green Adherence Questionnaire, a self-reported method with four questions on adherence behaviour. The researchers found an

average baseline adherence level of 45.5%.

The researchers also conducted a descriptive analysis of variables that impede adequate adherence. They found that patients below 50 years of age, those taking more than 10 pills, following a complex regimen (i.e. those taking medications other than orally), current smokers and those with sedentary lifestyles were significantly more non-adherent.

Dr Fuster said: "Importantly, there was a significant trend towards more non-adherence with a higher score of depression (as measured by the PHQ-9 questionnaire). Of the socio-demographic variables, illiteracy level, lower social support and lower percentage of insurance cover showed significantly lower levels of adherence as well as those patients being treated by general practitioners (as opposed to cardiologists) and being treated in a private centre (as opposed to a public health centre)."

In a stepwise forward regression model, FOCUS 1 found that the risk of being non-adherent was independently associated with younger age (under 50 years old), scoring high on the depression scale, and following a complex (administrations other than oral) treatment. On the other hand, the odds of being adherent increased with higher percentage of health insurance coverage, and with optimal levels of social support.

In FOCUS 2, a total of 695 patients were enrolled from four countries and followed for a period of nine months. Patients were randomised to receive either the polypill or the three drugs separately. Adherence was measured with two methods: self-reported adherence using the Morisky Green Adherence Questionnaire as well as a direct method, the pill count. The results after nine months of follow up are shown in figure 1.

Dr Fuster said: "Patients were more likely to take their medication to prevent a heart attack when it was given as a polypill, rather than as three separate pills. We found this using two methods. With the self-reported

questionnaire, 68% of patients in the polypill group took their drugs compared to just 59% of patients in the group assigned to three drugs. With the pill count, we found that 92% of patients in the polypill group were adherent compared to only 84% in the group assigned to separate drugs."

He added: "FOCUS 1 has identified the reasons that impede appropriate adherence to CV medications in a post MI population from five different countries. FOCUS 2 has shown that, compared with the three drugs given separately, the use of a polypill strategy significantly increases self-reported and directly measured medication adherence for secondary prevention following an acute MI. FOCUS 2 is ongoing and will assess whether there are any differences between the two treatment arms in blood pressure, blood cholesterol, safety or costs."

Dr Fuster concluded: "Our results suggest that the polypill has the potential to prevent more patients having a second heart attack. A randomised trial is needed to test whether the improved adherence with the polypill found in FOCUS results in fewer post MI patients having another MI."

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