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Consumer Care



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ASPIRIN UNSURPASSED IN PREVENTION OF HEART ATTACK AND STROKE IN WIDE RANGE OF PATIENTS

CHARISMA Trial Reaffirms Aspirin as Cornerstone Antiplatelet Treatment

LEVERKUSEN, GERMANY, 12 March 2006 – Data from a long-term study released today strengthens aspirin’s cornerstone role in the prevention and treatment of heart attack and recurrent stroke. The results of the Clopidogrel for High Atherothrombotic Risk and Ischaemic Stabilisation, Management, and Avoidance (CHARISMA) trial, which were presented today at the 55th Annual Scientific Session of the American College of Cardiology in Atlanta, Georgia, USA, and published online in an advance issue of the *New England Journal of Medicine*ⁱ, highlight the primacy of aspirin among antiplatelet agents, adding to the robust body of evidence supporting aspirin’s role in cardioprevention. The study showed that there was no benefit to adding clopidogrel to aspirin therapy. Furthermore, the patients who took clopidogrel had an increased risk of moderate-to-severe bleeding, making a strong case against the utility of combination antiplatelet therapy in a wide range of high risk patients.

“These findings reinforce the longstanding history surrounding the benefits of aspirin and enrich our knowledge of its effectiveness in the prevention of heart attack and stroke in patients who have previously suffered an event. The results also add to our knowledge of aspirin’s effectiveness in those high risk patients who have not experienced events,” said Freek Verheugt, MD, professor of Cardiology and head of the Department of Cardiology at the University of Nijmegen, The Netherlands.

As described in the *New England Journal of Medicine*’s accompanying editorial “The Charisma Sub Groups and the Subgroups of CHARISMA. Antiplatelet therapy with aspirin... has earned its rightful place as a cornerstone of treatment for reducing cardiovascular events in patients with established vascular disease.” The authors of the editorial also note, “the absence of a clear benefit in terms of clinical outcome, coupled with the increased rate of bleeding (as well as the economic considerations related to the long-term use of clopidogrel), provides a robust answer to the central question of the trial and argues against the use of dual antiplatelet therapy in this patient populationⁱⁱ.”

These results highlight the importance of redoubling efforts to encourage the broader appropriate use of aspirin to stem the growing tide of cardiovascular disease worldwide. Despite the compelling evidence in support of aspirin's meaningful benefits its use remains suboptimal. "The CHARISMA investigators should be applauded," adds Dr. Verheugt, "for bringing aspirin to the foreground and cementing its unsurpassed role as a highly effective, widely available and inexpensive treatment for a wide variety of patients."

About CHARISMA

The CHARISMA trial is an international, multicentre, double-blinded, placebo-controlled study involving 15,603 patients aged 45 years or older who were at high risk of heart attack, stroke or death from heart disease. The study was designed to assess whether adding clopidogrel (75 mg/day) to aspirin therapy (75-162 mg/day) provided any benefit over aspirin monotherapy in preventing the occurrence of such events in a high-risk population"¹

The study results showed that the addition of clopidogrel to aspirin therapy did not result in a significant lowering ($p=0.22$) of risk of the primary endpoint, the combined risk of heart attack, stroke or cardiovascular death (6.8 percent in the clopidogrel plus aspirin group and 7.3 in the aspirin-only group – a difference that was not statistically significant). Additionally, the rate of moderate bleeding was significantly higher ($p<0.001$) in the patients taking clopidogrel with aspirin (2.1 percent) compared to the rate in those taking aspirin alone (1.3 percent).

The Unsurpassed Efficacy of Aspirin

Aspirin is one of the most studied drugs in history – and the most studied antiplatelet agent – with more than a 100-year track record of efficacy and safety. As the cornerstone antiplatelet therapy for reducing the risk of cardiovascular events, aspirin is well recognized for its benefits as first-line therapy across a wide cardiovascular risk continuum because of its proven efficacy, safety and cost-effectiveness – benefits that have been demonstrated in more than 200 studies involving over 200,000 patients

About Bayer Consumer Care

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ⁱ Bhatt DL, Fox KAA, Hacke W, et al. Clopidogrel and aspirin versus aspirin alone for the prevention of atherothrombotic events. *N Engl J Med* 2006;354.

ⁱⁱ Pfeffer MA, Jarcho JA. The charisma of subgroups and the subgroups of CHARISMA. *N Engl J Med* 2006;354.