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# Efficacy and safety of adjunctive cilostazol to clopidogrel-treated diabetic patients with symptomatic lower extremity artery disease in the prevention of ischemic vascular events

**Statement of the Problem:** Type 2 diabetes mellitus (T2DM) is a risk factor for lower extremity arterial disease (LEAD). Cilostazol expresses antiplatelet, anti-inflammatory and vasodilator actions and improves the claudication intermittent symptoms. We investigated the efficacy and safety of adjunctive cilostazol to clopidogrel-treated T2DM patients exhibiting symptomatic LEAD, in the prevention of ischemic vascular events and improvement of the claudication intermittent symptoms.

**Methodology:** This is a prospective 2-arm, multicenter, open-label, phase 4 trial, in which 794 T2DM patients with intermittent claudication receiving clopidogrel (75mg/day) for at least 6 months, were randomly assigned in a 1:1 ratio, either to continue to clopidogrel monotherapy, without receiving placebo cilostazol (391 patients), or to additionally receive cilostazol, 100 mg twice/day (403 patients). The median duration of follow-up was 27 months. The primary efficacy end point was the composite of acute ischemic stroke/transient ischemic attack (TIA), acute myocardial infarction, and death from vascular causes. Findings: The primary efficacy end point was significantly reduced in patients receiving adjunctive cilostazol compared with the clopidogrel monotherapy group (gender adjusted HR 0.468; 95%CI 0.252-0.870; p=0.016). Adjunctive cilostazol also reduced the secondary efficacy end point of stroke/TIA events (gender adjusted HR 0.38; 95%CI 0.15-0.98; p=0.046). The Ankle-Branchial Index and the pain-free walking distance values in both legs were significantly improved in both patient groups. The improvement in both parameters, was higher in the cilostazol group compared with the clopidogrel monotherapy group (p=0.001 for both comparisons). No significant difference in the bleeding events, as defined by Bleeding Academic Research Consortium (BARC) criteria, was found between the 2 groups.

**Conclusion and Significance:** Long-term treatment with a combination of cilostazol and clopidogrel of T2DM patients who presented with symptomatic LEAD could be an effective therapeutic regimen in these high thrombotic risk patients..

## Biography

Alexandros Tselepis graduated in pharmacy (University of Thessaloniki, Greece) and in medicine (University of Ioannina, Greece). He obtained his PhD in biochemistry from the department of chemistry, University of Ioannina. His research work continued with a postdoctoral fellowship (Fogarty, NIH) in the pathology department, university of texas health science centre, San Antonio, TX, USA. From 1994 to 1999 he took a sabbatical leave (3 months per year) and conducted research work on lipoproteins and atherosclerosis as invited researcher in INSERM U321 Paris, France. He is currently director of the atherothrombosis research centre (http://atherothrombosis.lab.uoi.gr) and president of the interdepartmental postgraduate programme “Medical Chemistry” of the University of Ioannina (http://medchem.ac.uoi.gr). His main research interests concern the role of platelets, and inflammation in the development and progression of atherosclerotic plaque as well as its thrombotic complications. He has supervised 25 PhDs, 35 MSc and 10 postdocs and he has an over than 25 years’ experience in managing international and national research projects. Currently he has 271 publications in peer reviewed journals and more than 9,500 citations, whereas his h-index is 47, according to scopus.

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