

Letters to the Editor

Consensus Document on Polypill and Secondary Prevention. Does It Include Patients With Stents?



Documento de consenso del policomprimido en prevención secundaria. ¿Incluye a los pacientes con stent?

To the Editor,

We have read with interest the consensus document on the use of the polypill¹ and the editorial by González-Juanatey et al.² The authors should be congratulated for their initiative in producing a document that helps to increase our knowledge of this therapy and, moreover, defines the situations in which its use can be beneficial. The European Society of Cardiology indicates that reducing the frequency of administration is the most effective way to improve treatment adherence, and it reportedly could reduce cardiovascular events by 75%. However, in our opinion, this document does not deal with an aspect that we consider of vital importance in secondary prevention. Both the consensus document and the editorial underline the need to control hypertension and cholesterol, stressing high-risk patients, but make no mention of patients with coronary stents. We feel that they should include some comment on this subject, especially concerning drug-eluting stents, therapeutic devices used in most patients with acute coronary syndrome,³ since we consider that the currently available data are insufficient.

In our center, there was a recent case of very late definite thrombosis of an everolimus stent, implanted 16 months earlier in a patient who, 1 year after the procedure, had been taken off clopidogrel and aspirin in their individual forms and had started polypill therapy.⁴ Although an absolute cause and effect relationship cannot be established, we believe that this case should prompt reflection. We wish to highlight that we have found no data on patients with stents either in the patient information leaflet on the drug or in studies conducted to date, with the exception of a study by Castellano et al.⁵ who excluded patients during the first year after implantation of a drug-eluting stent. However, that report does not mention the number or percentage of patients with bare-metal stents included during the first year after implantation or of those with drug-eluting stents beyond the first 12 months. Although the polypill undoubtedly contributes a great deal to improving adherence, some authors have indicated that it may not reach the same level of efficacy as its 2 components separately, and that the bioavailability, pharmacokinetics, and possible interactions should be tested in each of the formulations. Moreover, although the effects of the components are assumed to be additive, this assumption

should be demonstrated with studies performed with each formulation.⁶ This could be particularly important for high-risk patients. The present consensus document mentions patients at higher risk, but only to refer to the possible lack of hypercholesterolemia and hypertension control, when we believe that the most important aspect of the risk and, moreover, over a much shorter term, is the possibility of stent thrombosis. For all these reasons, until studies are conducted that include patients with drug-eluting stents in the first year after implantation, we consider, on the one hand, that the use of the polypill from the time of hospital discharge, as proposed, should not be recommended and, on the other hand, that some comment on the absence of published data on their use in this specific type of patients should be included.

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Available online 17 August 2016

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Documento de consenso del policomprimido en prevención secundaria. ¿Incluye a los pacientes con stent? Respuesta

To the Editor,

We appreciate the comments by Lozano et al.¹ on the consensus document and editorial published in the *Revista Española de*

Cardiología about the use of the polypill.² This consensus document made some recommendations based on current evidence and, when no evidence was available, the consensus opinion of the authors. As a possible use of the polypill, the consensus mentions patients with a recent coronary event who, given their characteristics, may have a low adherence to therapy. Lozano et al.¹ question basic aspects of clinical use of the polypill: bioequivalence of acetylsalicylic acid and the results with this new therapeutic strategy after thrombosis in patients with recent coronary stent placement, particularly, when a new drug-eluting stent was used.