Author's response to reviews

Title: A Prospective Evaluation of the Safety and Efficacy of the TAXUS Element Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions: Design and Statistical Methods of the PERSEUS Clinical Program

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Author's response to reviews: see over
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Re: Manuscript Number 1682806832320870

A Prospective Evaluation of the Safety and Efficacy of the TAXUS Element Paclitaxel-Eluting Coronary Stent System for the Treatment of De Novo Coronary Artery Lesions: Design and Statistical Methods of the PERSEUS Clinical Program; Dominic J Allocco, Louis A Cannon, Amy Britt, John E Heil, Andrey Nersesov, Scott Wehrenberg, Keith D Dawkins and Dean J Kereiakes

On behalf of my coauthors, thank you for considering our manuscript for publication in Trials.

Below is a list of changes/responses keyed to the reviewer’s comments. Other than the revisions noted below, the only other changes to the manuscript since the previous submission are the correction of the journal abbreviation in reference 21, and a correction to a footnote in Appendix B, Table 1.

Thank you for your consideration of this manuscript. I look forward to hearing from you at your earliest convenience.

Sincerely,

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Response to Reviewer Comments

We would like to thank Dr. Ulrich Sigwart for reviewing the manuscript and providing helpful feedback. We appreciate the time taken to fully and fairly evaluate our manuscript. We have addressed Dr. Sigwart’s comments and suggestions below.

Comment 1
The units for reporting strut thickness and other dimensions should be metric throughout, not a mix between metric and imperial units (see appendix B, table 1).

Author Reply
Thank you for the suggestion. Units for strut width and thickness have been changed to metric. We have retained use of atmospheres (atm) for nominal and rated burst pressure as that is the unit used most commonly by interventional cardiologists.

Comment 2
I cannot see the point of being so restrictive with left main lesions. Newer guidelines are more relaxed about this.

Author Reply
We agree with Dr. Sigwart that, in light of recent studies, guidelines and practice patterns regarding treatment of PCI lesions with PCI have changed (December 1, 2009 Focused Update of the STEMI and PCI Guidelines, Circulation 2009;120:2271). The decision to exclude left main lesions from PERSEUS was made at the time the study was designed in 2007, at which time there was less comfort in treating left main lesions with PCI. In addition, the exclusion of left main lesions was consistent with other pivotal drug-eluting stent trials of several manufacturers including the historical control group in PERSEUS SV (TAXUS V [2]), as well as the ATLAS [3], SPIRIT [4], and SIRIUS studies [5, 6] in order to facilitate comparison across stent types.

Additionally, as enrollment is complete, we are unable to change the inclusion criteria at this time.
References


