Letter by Chalmers Regarding Article “Nitinol Stent Implantation Versus Balloon Angioplasty for Lesions in the Superficial Femoral Artery and Proximal Popliteal Artery: Twelve-Month Results From the RESILIENT Randomized Trial”

To the Editor:

The authors of the RESILIENT trial have adopted a trial design that by their own admission is controversial. They have randomly assigned patients to either percutaneous transluminal angioplasty (PTA) or stent placement but have then analyzed the outcomes using different primary end points for each group. This is surely more than controversial: It is a travesty of scientific method.

The authors have determined that all patients in the PTA arm of the trial who cross over to stent placement during the index procedure are classified as reaching the primary end point (and having target lesion revascularization), whereas those in the primary stent arm of the trial (who have undergone an identical procedure) are not. Thus, 40% of the PTA arm have “failed” from day 0. This bias predetermines the outcome of the trial.

In routine practice, it is entirely normal to place a stent when there is an inadequate result from balloon angioplasty alone. Thus, PTA with bailout stenting is the current standard of practice in the superficial femoral artery. This should be compared with the experimental condition, namely, routine stent placement. This comparison is provided only as a post hoc analysis, and the results are much less convincing, with no significant difference between the treatment groups for target lesion revascularization and borderline significance for primary patency.

At first glance, the implication of this trial is that the use of stents for intermediate-length lesions of the superficial femoral artery should be mandatory. This could have a substantial impact on the cost of treatment. Closer examination of the data indicates that the evidence is at best borderline and in itself does not yet merit a wholesale switch from selective to routine use of stents in these lesions.

Disclosures

None.

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Reference

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