LETTERS TO THE EDITOR

Regarding "Outcomes of covered versus bare-metal balloon-expandable stents for aortoiliac occlusive disease"

With interest we have read the paper by Humphries et al, who have performed a retrospective cohort study comparing outcome of bare-metal stents (BMSs) with balloon-expandable covered (CBE) stents.[1] They concluded that BMSs are superior to CBE stents at 3 years in the treatment of aortoiliac occlusive disease. This is in conflict with other studies, including the Covered Versus Balloon Expandable Stent Trial (COBEST), which is the only published randomized trial of CBE stents for aortoiliac occlusive disease to date, and another historical cohort study. Both showed significantly better results in terms of restenosis and reinterventions in the use of CBE stents, especially in more complex lesions.[2,3]

There are a few points that might have biased the results of the present study, both related to clinical decision making. First, the choice of CBE stents or BMSs was decided on a case-by-case basis, without describing why a certain stent was chosen. There were no differences between groups in lesion length or TransAtlantic Inter-Society Consensus (TASC) classification, but that does not exclude differences between groups. Factors such as occlusion vs stenosis and the presence of mural thrombus or calcifications are not included in the TASC classification. The more costly CBE stents are regularly reserved for specific, often more complex indications in which these CBE stents might have a benefit above BMSs, thereby justifying the use of these more expensive stents.

Second, and even more important, they have shown that the primary patency was significantly lower in the CBE stent group. Loss of primary patency was defined as any stent that underwent reintervention to prevent thrombosis or any stent that thrombosed primarily. The decision for reintervention was made, again and unfortunately, on a case-by-case basis. It seems reasonable to assume that an indication for a reintervention on a focal edge stenosis to preserve patency in an expensive CBE stent might have been more attractive than reintervening in a patient with a diffuse in-stent restenosis without clinical symptoms. This may have severely affected the outcome of this study, and it was for that reason that Diehm et al have suggested replacement of the term *patency* with *absence of binary restenosis* and *occlusion* in endovascular studies, as was done in the COBEST.[3,4] This would have excluded the clinical decision-making process as a bias and would have provided real evidence on the performance of CBE stents vs BMSs.

In summary, the result of this study merely reflects the clinical performance of these stents in this particular center, but we agree with the authors that more randomized studies, such as the Dutch DISCOVER trial, are indicated before the use of CBE stents is considered standard care.[5]

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REFERENCES

1. Humphries MD, Armstrong E, Laird J, Paz J, Pevec W. Outcomes of covered versus bare-metal balloon-expandable stents for aortoiliac occlusive disease. J Vasc Surg 2014;60:337-44.
2. Mwipatayi BP, Thomas S, Wong J, Temple SE, Vijayan V, Jackson M, et al. A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease. J Vasc Surg 2011;54:1561-70.
3. Sabri SS, Choudhri A, Orgera G, Arslan B, Turba UC, Harthun NL, et al. Outcomes of covered kissing stent placement compared with bare metal stent placement in the treatment of atherosclerotic occlusive disease at the aortic bifurcation. J Vasc Interv Radiol 2010;21:995-1003.
4. Diehm N, Pattynama PM, Jaff MR, Cremonesi A, Becker GJ, Hopkins LN, et al. Clinical endpoints in peripheral endovascular revascularization trials: a case for standardized definitions. Eur J Vasc Endovasc Surg 2008;36:409-19.
5. Bekken JA, Vos JA, Aarts RA, de Vries JP, Fioole B. DISCOVER: Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents in the common iliac artery: study protocol for a randomized controlled trial. Trials 2012;13:215.

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Reply

Our study concluded that the primary patency of bare-metal stents (BMSs) is superior to that of covered balloon-expandable (CBE) stents,[1] although on the basis of the relatively small number of patients evaluated, this may be an overstatement. Our work describes the bias of vascular specialists to use BMSs rather than CBE stents in treating aortoiliac occlusive disease and supports the lack of sufficient data to change this practice pattern. This work is observational and has inherent biases, but vascular specialists are looking for guidance to support decision making. The Covered Versus Balloon Expandable Stent Trial (COBEST),[2] despite being a randomized controlled trial, does not answer the question of when and for what lesions a CBE stent should be chosen. COBEST has limitations, most notably the use of binary restenosis as the primary end point, the vague criteria for defining restenosis, the absence of data on which imaging modalities were used to diagnose the restenoses and how many of these restenoses where confirmed by angiography, and the lack of power for the subgroup analyses that were performed.

When the design of the COBEST trial is considered, it is important to remember that the trial was designed as a noninferiority trial and that the only conclusion that can be drawn is that CBE stents are no worse than BMSs for the outcome of binary restenosis. Diehm et al[3] have called for standardization of outcomes and argued that restenosis be used as an outcome, rather than patency. Restenosis allows comparison of the technical aspects of how stents perform head to head, but this is not necessarily a meaningful outcome for patients. We do not need another explanatory study to inform us of the safety and efficacy of covered stents. We need more pragmatic studies that look at how these treatments perform in average patients and must face the reality that decisions for reintervention are always made on a case-by-case basis.

An additional limitation of COBEST is the lack of transparency in regard to confirmation of stenosis. It has been well established that in the carotid[4] and mesenteric[5] arteries, velocity criteria to diagnose stenosis of stented arteries can be different from the