Sponsored by Boston Scientific Corporation

Economic Analysis Supporting the Use of Drug-Eluting Technologies in the Femoropopliteal Artery

These evolving modern therapies are showing promise in reducing health care costs while offering better outcomes.

BY KONSTANTINOS KATSANOS, MSc, MD, PhD, EBIR

Drug-eluting stents (DESs) and drug-coated balloons (DCBs) are increasingly being used in the femoropopliteal artery based on solid evidence from several large-scale, multicenter, randomized studies investigating local delivery of paclitaxel to inhibit neointimal hyperplasia and improve clinical outcomes of infrainguinal interventions.[1,2] Contrary to the sirolimus family of drugs and its analogues that have dominated percutaneous coronary interventions, paclitaxel has become the mainstay drug for inhibition of postangioplasty vascular restenosis in the above-the-knee arteries.[2,3] DESs combine drug delivery with a metal scaffold that eliminates vessel recoil and maximizes immediate lumen gain and are best suited for the treatment of complex occlusive disease, whereas DCBs offer a balloon-based drug delivery option for the treatment of simpler disease without leaving any permanent implants behind.[3]

CLINICAL AND COST-EFFECTIVENESS ANALYSES

Some analyses have recently been published exploring the impact of wider adoption of drug-eluting technologies on the budgets of government-funded health care systems. For the case of the National Health System in the United Kingdom, one model involved pooling of 28 clinical studies encompassing 5,167 femoropopliteal artery lesions (mostly claudicants; critical limb ischemia in 15%–20%) with a time horizon of 2 years.[4] As expected, a significant reduction in the rate of target lesion revascularization (TLR) up to 24 months was noted with the use of drug-eluting technologies, driving TLR rates

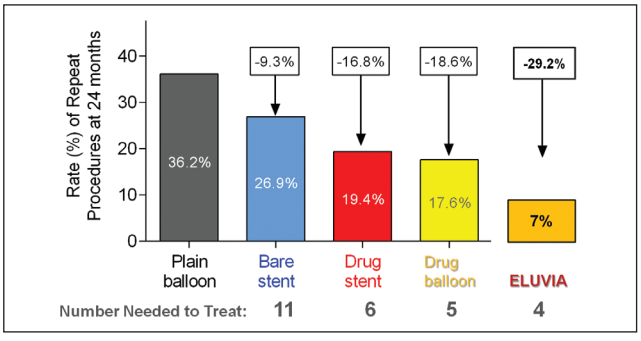

Figure 1. Comparing reduction of repeat limb procedures with DESs versus DCBs. TLR rate reduction calculated according to 24-month aggregate data.[4] Eluvia results at 2 years from cumulative TLR events reported (4 of 57 cases). Number needed to treat to avoid one TLR event up to 2 years.

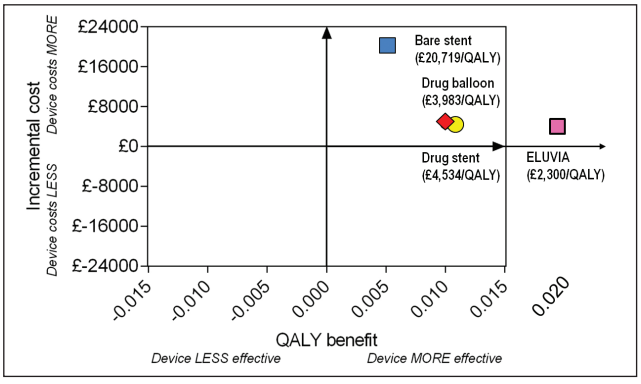

Figure 2. Incremental cost effectiveness of DESs compared to DCBs. Eluvia results calculated according to an approximate 10% TLR rate at 2 years to allow for sampling uncertainty.

from 36.2% with plain old balloon angioplasty (POBA), down to 26.9% with bare-metal stents (BMSs) (-9.3%), and further down to 19.4% with DESs (-16.8%) and 17.6% with DCBs (-18.6%). Consequently, the number needed to treat (NNT) to avoid one TLR in 24 months were 10.8, 6.0, and 5.4 with BMS, DES and DCB use (Figure 1), respectively, at an average cost premium per-patient of £112, £44, and £43 (economic comparison included the index procedure and any applicable reinterventions costs up to 2 years).[4] Furthermore, the incremental cost-effectiveness ratio (ICER) was projected to be £4,534 per quality-adjusted life-year (QALY) gained for DESs and £3,983 per QALY for DCBs compared to more than £20,700 per QALY with nitinol BMSs (Figure 2).[4]

A similar budget impact model has been also released for the United States and German health care systems, reporting very similar clinical benefits in terms of reducing the rate of TLR and marginal cost savings for the health care system.[5] Up to 24 months, aggregate patient costs were significantly reduced following a primary DES or DCB treatment strategy for both the United States (DCB: $10,214; DES: $12,904; POBA: $13,114; BMS: $13,802) and the German public health care system (DCB: €3,619; DES: €3,632; POBA: €4,290; BMS: €4,026).[5]

THE ELUVIA STENT SYSTEM

Eluvia (Boston Scientific Corporation) is a new-generation, polymer-based, sustained-release, paclitaxel-eluting stent with promising results seen in early clinical studies. The MAJESTIC single-arm study in the superficial femoral artery (n = 57 patients) has recently released a compelling 92.5% freedom from TLR rate at 24 months, with only four patients out of 53 requiring a reintervention.[6] Hence, the relevant economic analysis of Eluvia (assuming a nearly 10% rate of TLR at 24 months, which is nearly half of the DES rates reported in the aforementioned published budget impact models) would calculate an NNT of only 3.8 cases needed to be treated to avoid one TLR event and a projected ICER of £2,300 per QALY. This makes the Eluvia stent a very favorable investment for improved clinical outcomes in the femoral artery.

CONCLUSION

Clearly, modern drug-eluting technologies are not only associated with a very favorable cost-utility profile but may even produce some cost savings for the taxpayers at up to 2 years, depending on individual government reimbursement policies. ■

1. Katsanos K, Tepe G, Tsetis D, Fanelli F. Standards of practice for superficial femoral and popliteal artery angioplasty and stenting. Cardiovasc Intervent Radiol. 2014;37:592-603.
2. Kitrou P, Karnabatidis D, Katsanos K. Drug-coated balloons are replacing the need for nitinol stents in the superficial femoral artery. J Cardiovasc Surg (Torino). 2016;57:569-577.
3. Katsanos K, Spiliopoulos S, Karunanithy N, et al. Bayesian network meta-analysis of nitinol stents, covered stents, drug-eluting stents, and drug-coated balloons in the femoropopliteal artery. J Vasc Surg. 2014;59:1123-1133.
4. Katsanos K, Geisler BP, Garner AM, et al. Economic analysis of endovascular drug-eluting treatments for femoropopliteal artery disease in the UK. BMJ Open. 2016;6:e011245.
5. Pietzsch JB, Geisler BP, Garner AM, et al. Economic analysis of endovascular interventions for femoropopliteal arterial disease: a systematic review and budget impact model for the United States and Germany. Catheter Cardiovasc Interv. 2014;84:546-554.
6. Müller-Hülsbeck S. MAJESTIC study 2-year results. Presented at CIRSE 2016; September 13, 2016; Barcelona, Spain.

Konstantinos Katsanos, MSc, MD, PhD, EBIR
Assistant Professor, Interventional Radiology
Patras University Hospital
School of Medicine, Rion
Patras, Greece
Honorary Consultant Interventional Radiologist
Guy's and St. Thomas' Hospitals
King's Health Partners
London, United Kingdom
konstantinos.katsanos@gstt.nhs.uk
Disclosures: Receives honoraria and research support from Abbott Vascular, Boston Scientific Corporation, and Medtronic.