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.

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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. 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.

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.

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. 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. Eluvia results calculated according to an approximate 10% TLR rate at 2 years to allow for sampling uncertainty.

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). A
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 niti-
nol BMSs (Figure 2). A
A similar budget impact model has been also released for
the United States and German health care systems, report-
ing very similar clinical benefits in terms of reducing the rate
of TLR and marginal cost savings for the health care system. 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). THE ELUVIA STENT SYSTEM
Eluvia (Boston Scientific Corporation) is a new-genera-
tion, 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. Hence, the
relevant economic analysis of Eluvia (assuming a nearly 10%
ratio 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 favor-
able investment for improved clinical outcomes in the
defemoral 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 reimburse-
ment policies.
2. Kitrou P, Karanoulatou D, Katsanos K. Drug-coated balloons are replacing the need for nitinol stents in the superficial
3. Katsanos K, Spiliopoulos S, Karanoulatou D, Katsanos K. Drug-coated balloons are replacing the need for nitinol stents in the superficial
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