Assessing the Economic Impact of Peripheral Interventions

The difficulties in weighing cost-effectiveness in treatment algorithms remain.

BY YANN GOUËFFIC, MD, PHD, AND VALÉRY-PIERRE RICHE

Algorithms for the endovascular treatment of femoropopliteal lesions still suffer from a lack of head-to-head comparison between devices. In 2014, Katsanos et al reported a meta-analysis that compared balloon angioplasty against drug-coated balloons (DCBs), drug-eluting stents (DESs), covered stents, and bare-metal stents; all investigated treatments showed reduced restenosis rates and target lesion revascularization against standard balloon angioplasty, with DCBs and DESs as the most efficient.[1]

Bailout stenting rates vary considerably across DCB studies. In randomized controlled trials such as BIOLUX P-I, IN.PACT SFA, LEVANT 2, or ILLUMENATE, bailout stenting ranged from 2.5% to 7.3%.[2-5] In all-comer registries such as BIOLUX P-III, ILLUMENATE Global, LUTONIX Global SFA registry, and IN.PACT Global, the bailout stenting rates range from 15% to 25.2%.[6-9]

Although drug-eluting therapies such as DESs or DCBs appear as a promising strategy to treat femoropopliteal lesions, few data are available to assess the impact of these devices on health care expenditure.

HEALTH CARE EXPENDITURE ASSESSMENT

Health care costs continue to escalate, with innovation often increasing the overall cost of treating patients, while hospital budgets are under pressure to reduce hospital stays and treatment cost. Cost utility or effectiveness analyses are needed to compare the costs and outcomes of different medical strategies during a defined time. For instance, cost utility analysis evaluates outcomes of an intervention in terms of the quality and the quantity of life lived, or quality-adjusted life-years (QALYs). A QALY of 0 is death, and a QALY of 1 equates to 1 year in perfect health.

The most common option for assessing quality of life in patients with peripheral artery disease is the EuroQol 5-dimensions questionnaire (EQ-5D), a standardized instrument for measuring generic health status focusing on mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The EQ-5D is available in 171 languages; however, the questionnaire lacks specificity. For this reason, other questionnaires have been developed for patients with peripheral artery disease, such as the Walking Impairment Questionnaire (WIQ). The WIQ assesses self-reported walking capacity for claudicants and includes subscales for walking distance, speed, and stair climbing. It is widely used and validated as a self-administrated tool; however, it is not validated in all countries and could be relatively complex to use for some patients. Some authors believe that the overall WIQ score only moderately correlates with mean walking distance, even after correction.[10]

The incremental cost-effectiveness ratio (ICER) is an economic evaluation comparing two medical strategies by calculating the cost differential divided by the differential of outcomes (Figure 1). A four-part cost-effectiveness plan diagram helps visualize an ICER by highlighting whether a treatment is worth pursuing when the cost and outcomes are balanced (Figure 2). The best scenario includes a less expensive and more effective medical strategy compared to the current alternative treatment.[11]

$$\text{ICER} = \frac{\text{COST 1} - \text{COST 2}}{\text{QALYs 1} - \text{QALYs 2}}$$

$$\text{ICER} = \frac{\text{COST 1} - \text{COST 2}}{\text{Patency 1} - \text{Patency 2}}$$

Figure 1. The ICER compares cost-effectiveness of two treatments by dividing the cost differential by the outcome differential (eg, QALY, patency, etc).

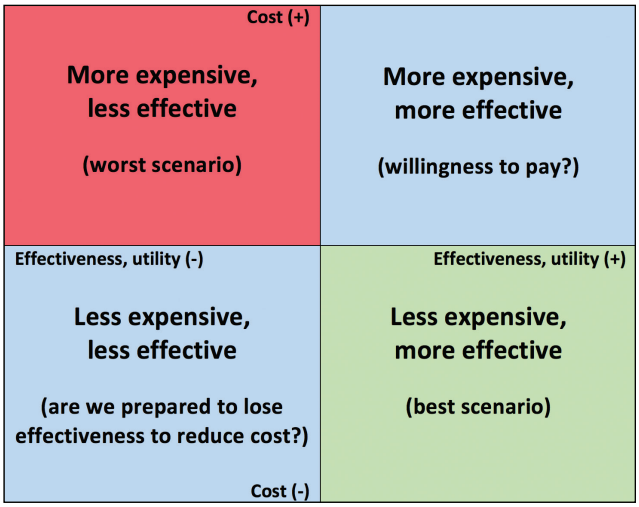

Figure 2. Visualization of an ICER with a cost-effectiveness plan diagram.

REACT APPROACH

The BIOTRONIK REsponse Adapted Combination Therapy (REACT) treatment algorithm begins with a predilatation of the target lesion with standard balloon angioplasty, followed by the Passeo-18 Lux DCB (Biotronik). Angiography is then performed in at least two planes to assess the DCB's technical success (Figure 3). If residual stenosis (> 30%) or a flow-limiting dissection are present and persist after prolonged inflation of the DCB (≥ 5 minutes), stenting of the lesion will be performed, where needed, with the Pulsar-18 bare-metal stent (Biotronik).

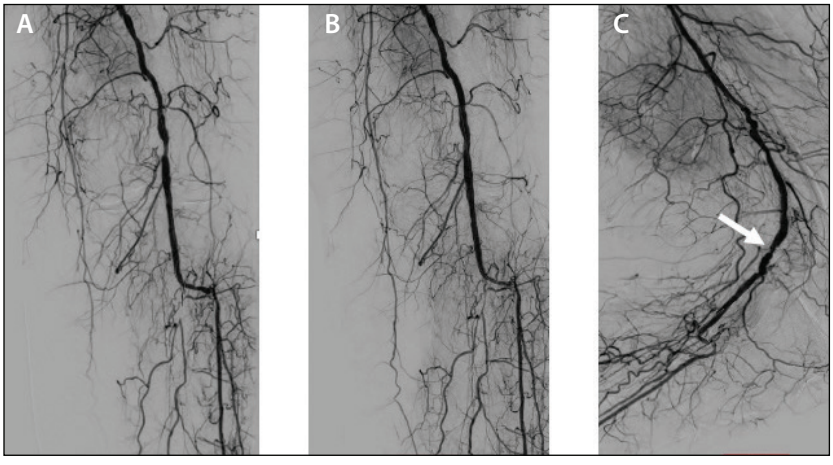

Figure 3. An 83-year-old woman underwent successful vessel preparation (A) before being treated with a DCB for a popliteal lesion. In a first angiogram assessment (B), the morphologic result seemed correct, but a second angiogram assessment at a 45° angulated view showed a residual stenosis > 30% (C), demonstrating the importance of assessing outcomes on at least two planes.

The REACT treatment concept aims to minimize metal burden and the associated foreign body reaction, risk of stent fracture, and possibility of an inhomogeneous drug transfer to the arterial wall due to DES malapposition, as well as maintaining opportunities for subsequent reintervention later. On the other hand, stenting—whether it is focal or not—increases procedural cost due to the combined use of DCBs and stents.

Angiography, even with additional projections, is sometimes insufficient to clearly determine if a dissection is flow-limiting and whether subsequent stenting is needed. There is currently no definition nor validated method to define flow-limiting dissection for peripheral arteries. For this reason, adjunctive procedural assessments (eg, intravascular ultrasound) could be used to assess DCB morphologic intraoperative results. Of course, the incremental use of several adjunctive procedural assessments could increase time and cost procedure and therefore alter health care expenditure. However, the potential increase of the procedure cost and time must be balanced with a presumed reduced usage of stents, as well as the cost and poor outcome of reintervention for in-stent restenosis.

BIOREACT PILOT STUDY

The main objective of the BIOREACT pilot study (NCT03547986) is to assess the incremental value of several intraoperative diagnostic methods (procedural duplex ultrasound, intra-arterial pressure measurement alone or associated with intravascular ultrasound, optical coherence tomography, and quantitative vascular angiography) added to biplanar angiography to identify flow-limiting dissections. As a secondary objective, BIOREACT will identify valuable health care costs of adjunctive procedural assessments. The protocol is based on the REACT approach, and EQ-5D and WIQ will be used to define the QALYs and help characterize the health economic aspect of the REACT approach.

CONCLUSION

It is not yet known which treatment strategy for peripheral intervention has the best cost-effectiveness profile. Additional intraoperative assessments may be a key benefit in identifying the proper treatment protocol on a case-by-case basis, saving valuable costs long term by reducing subsequent

reinterventions or making reinterventions less burdensome. ■

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