Economics and Cost Effectiveness of Managing Complex Lesions

Analyzing data on the cost of drug-coated balloons, drug-eluting stents, percutaneous transluminal angioplasty, and bare-metal stents for the treatment of peripheral artery disease.

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t is difficult to engage in a conversation regarding any aspect of health care and avoid terms such as value, cost effectiveness, and net quality impact. The reason is obvious: inflation in the cost of health care has outpaced the economy at large in many Western countries. In the United States, for example, although the rate of health care inflation has slowed over the past 2 decades, it still remains at an unsustainably high rate of 6% to 7% per year, 1 and the operating expenses of United States facilities continue to outpace revenue.² Unfortunately, none of these developments appear to be helping health care consumers obtain consistent quality care. In fact, there is no correlation between cost and quality of care, with some of the highest cost facilities in the United States being among the most mediocre.3 Despite efforts to curb utilization by payers, medical costs continue to rise. Payers and employers are focusing on price control and costs per benefit gained, which is what has led to the age of "value" and efforts to tie reimbursement to outcomes.

The other prevailing trend in the United States is the rapid expansion of office-based labs (OBLs) or ambulatory surgery centers (ASCs) that are entirely or partially owned by physicians.⁴ This ownership has influenced physicians to keep the return on their investment in sharp focus while rendering care. Many physicians practice in environments where the interests of all stakeholders may not always be aligned. Patients expect the best care they can get, physicians want to provide the best treatment available, payers are trying to rein in the costs, and facilities need to operate with reasonable margins to stay financially solvent. Therefore, it is our responsibility to understand what the best available care option for the money is and what is the best "value." How "value" in health care is defined in general and who defines it is outside of the scope of this article. Instead, the focus of this article is on value for patients with peripheral artery disease (PAD) and the endovascular treatment of a symptomatic femoropopliteal segment.

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UNDERSTANDING VALUE FOR PAD

Given the trends discussed previously, a focus on the best value in the treatment of PAD is particularly timely because the annual cost of treating patients with PAD now exceeds that of coronary artery disease or cancer.^{5,6} Fortunately, the literature is fairly clear on this topic. In an analysis of the potential impact of treating superficial femoral artery (SFA) disease on payers and providers in the German and United States health care systems, Pietzsch et al examined the outcome and costs of one of four endovascular strategies of bare-metal stents (BMSs), drug-eluting stents (DESs), percutaneous transluminal angioplasty (PTA), and drug-coated balloons (DCBs).7 Outcome data were derived from a systemic review of the literature and a decision-analytic model was developed to evaluate the economic consequences of the four treatment strategies as index procedures. The average cost per patient over a 24-month period, including the cost of the index procedure and the applicable costs of a possible reintervention, was lowest for the index strategy of DCBs at \$10,214, followed by DESs (\$12,904), PTA (\$13,114), and BMSs (\$13,802). The investigators concluded that DCBs offer the "lowest budget impact and, therefore, the greatest economic value to the payers" in the United States. Similarly, drug-eluting therapies were found to be the least costly strategies to the payers in the German health care system.⁷

In another study, Salisbury et al used the data from the randomized IN.PACT SFA Trial to examine the cost-

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effectiveness of the IN.PACT™ Admiral™ DCB (Medtronic) versus standard PTA.8 Resource utilization data were collected for the index procedure and subsequent hospitalizations for vascular care over a 2-year follow-up, and health utility values were derived from the quality of life data. Although the index procedure costs were higher for DCBs, this was offset by the savings due to fewer repeat procedures over 2-year follow-up. The authors concluded that a strategy of initial DCB angioplasty in the treatment of claudicants with SFA disease is likely to be cost effective (if not economically dominant) compared with standard PTA.8

Katsanos et al adopted a similar approach to Pietzsch et al to estimate the per patient cost impact of various therapies for SFA on the United Kingdom's National Health Service (NHS).⁹ Researchers systematically reviewed 28 studies utilizing various therapies in the SFA on 5,167 lesions. DCBs were estimated to add 0.011 quality-adjusted life years (QALYs) resulting in an estimated incremental cost effectiveness ratio of £3,983 as compared with £4,534 and £20,719 per QALY gained for DESs and BMSs, respectively. The authors concluded that based on currently available data, "DCBs offer the highest clinical and economic value."

Similar conclusions have been reached regarding the cost effectiveness of DCBs from the perspective of the French and Italian NHSs as well as the United States payers. 10-12

DISCUSSION

Despite the consistent conclusions of the literature regarding the cost effectiveness of DCBs, two important aspects of these analyses must be kept in mind. First, the degree of benefit of DCBs over PTA has not been consistent in various randomized studies with variable patency and clinically driven target lesion revascularization

rates. 13-19 Therefore, it is reasonable to assume that not all DCB platforms may prove cost effective to the same extent. Second, analyses based on data from randomized trials are not always applicable to real-world patients who frequently fall outside of the narrow scope of patients included in randomized trials. As such, cost-effectiveness analyses based on the outcome of prospective registries with core lab—adjudicated data that include more complex patients and lesions will be more illuminating.

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