

Economic Analysis of Drug-Eluting Coronary Stents in Brazil: a Choice for All or Just for a Few Patients?

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Introduction

Modern medicine is going through a restless period, marked by a constant quest for safer, more effective diagnostic tools and therapeutic interventions. In this context, the introduction of percutaneous coronary intervention (from balloon to drug-eluting stents) is considered by many as one of the greatest advances ever made in cardiology^{1,2}. Conversely, escalating health care costs have been a source of growing concern. For a given strategy to be considered optimal, it should be more effective and less costly. This binomial, however, is rare in medicine. The introduction of new diagnostic and therapeutic methods usually entails significant incremental costs. As health care resources are always scarce and finite, the need for studies addressing the economic impact of different strategies in the medical field has been heightened in recent years.

There are two major types of economic analyses used in health care^{3,4}: 1) cost-effectiveness analysis, which usually translates the difference in costs between two interventions (expressed in monetary values) divided by the difference in their effectiveness and expressed in years of life saved (life expectancy) or other less important endpoints, such as prevented complications, non-fatal events avoided, and 2) cost-utility analysis, which uses quality-adjusted life years (QALY) saved as a measure of effectiveness; that is to say, utility weights ranging from 0 (equivalent to death) to 1 (perfect health) are attributed to survival time to express the number of years spent in good health.

Both analyses, therefore, refer to an incremental ratio. In other words, by comparing two (or more) alternative therapeutic methods in a specific condition, they express the incremental cost required to achieve a unit of additional clinical benefit. For example, if a particular treatment costs US\$10,000 and is consistent with 3.5 years of life expectancy at a 0.8 score in quality of life and that of a competitor costs US\$ 20,000 and generates 5.0 years of life expectancy at a 0.7 score in quality of life, the following economic ratios will be produced: cost-effectiveness analysis = $(20,000 - 10,000) / (5.0 - 3.5) = \text{US\$ } 6,667$ per life-year gained using the competitor's treatment; cost-utility analysis = $(20,000 - 10,000) / (5.0 \times 0.7 - 3.5 \times 0.8) = \text{US\$ } 14,286$ per QALY gained.

Key words

Angioplasty, transluminal, percutaneous coronary; stents/economics; National Health System (BR); pharmacologics stents.

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The information used in the economic analyses may be derived from randomized clinical trials or, more frequently, from mathematic models or clinical decision trees based on literature data. Most cost-effectiveness studies, however, have been published in the international literature (USA, Canada, and European countries). Moreover, there are a number of limitations to extrapolating data to other countries, hence the pressing need for economic analyses that reflect the Brazilian reality more accurately.

In this regard, the study by Polanczyk et al⁵, published in this issue, is very timely. The authors used a decision-analytic model to compare the cost-effectiveness ratios of sirolimus-eluting stents (SES) with bare-metal stents (BMS) in Brazil in single-vessel disease patients with stable angina under two perspectives: public (SUS) and nonpublic (health plans and private patients).

Effectiveness analysis was expressed by using less common endpoints (one-year restenosis-free survival), rather than the more frequently used survival free of repeat target-lesion revascularization. The probabilities needed for inclusion in the mathematical model were derived from international literature. As for cost analysis related to index procedures, stents, cardiovascular events, and repeat revascularization in one year of follow-up, this was based on the amounts paid directly to the hospitals by the SUS and health plans/private patients. Cost-utility analysis could not be performed due to the lack of information on the quality of life of patients with chronic coronary artery disease in the Brazilian population.

In the perspective of health plans and private patients, treatment cost in the first year was R\$17,840 using sirolimus-eluting stent and R\$14,024 using bare-metal stent (difference of R\$3,816 favoring BMS). In the perspective of SUS these costs were R\$12,708 and R\$5,788, respectively (a difference of R\$ 6,620 favoring BMS). On the other hand, one-year restenosis-free survival was 92.7% with sirolimus-eluting stent and 78.8% with bare-metal stent (a difference of about 14% favoring SES). As a result, the cost per restenosis avoided in one year was R\$27,403 (R\$3,816/~0.14) for health plans/private patients and R\$47,529 (R\$6,620/~0.14) for the SUS.

Based on international references⁶, which adopt values up to US\$ 50,000 per year of life saved and up to US\$10,000 per revascularization avoided, (in this specific case, percutaneous coronary interventions) using a reasonable amount of health resources, the cost-effectiveness ratios of sirolimus-eluting stent may be considered elevated for the Brazilian reality, according to the model proposed by the authors. It should be noted that with the dollar standing at R\$2,10 (on February 22, 2007), the cost-effectiveness threshold would be R\$21,000 per event avoided.

However, sensitivity analyses have shown that this profile may be somewhat more favorable to certain subgroups of patients, such as those at high risk of restenosis and those presenting high cost of restenosis management, particularly under the nonpublic perspective. A decrease in the cost of drug-eluting stents would improve this cost-effectiveness ratio. Incidentally, the use of the market price for sirolimus-eluting stents in the SUS model (R\$10,320, indeed higher than that specified in its reimbursement table) may have contributed to the more unfavorable results in this health system.

Unfortunately, two other factors might have influenced (this time negatively) the cost-effectiveness analyses, yielding costs even higher for drug-eluting stents, were not taken into account in this study: the need for dual antiplatelet therapy for at least one year (more recently recommended), rather than only the three months assumed, and the greater number of stents per patient, since it seems that a single stent was used per procedure.

Given the current competition among highly complex medical procedures, another aspect that should be taken into account is how feasible it is for the health care system (public and nonpublic) to incorporate new cardiovascular technologies, considering their economic impact, especially in a setting with scant resources.

In another article published in this issue, Araújo *et al.*⁸ evaluated the economic impact of replacing bare-metal stents with drug-eluting stents in the Brazilian public health system (SUS). Using 2003 data, when 30,666 coronary angioplasties with bare-metal stent implantation were performed by the SUS in patients with single and multivessel disease, three hypothetical scenarios were created in order to estimate the budgetary impact of incorporating drug-eluting stents. The

first scenario was characterized by replacement of bare-metal stents with drug-eluting stents in 30% of the cases, the use of 1.3 stents per procedure, and an 80% relative risk reduction (RRR) in repeat intervention for restenosis with drug-eluting stent; the second scenario included 40% of replacement, 1.5 stent per procedure, and RRR of 76.5%; and the third scenario, 50% of replacement, 1.7 stent per procedure, and RRR of 74.5%.

The price of bare-metal stent adopted in the analysis was R\$2,580, equivalent to the amount reimbursed by the SUS to its hospital network at that time. For drug-eluting stent, the amount reimbursed by Medicare (USA) was used, that is, R\$5,166 (dollar at R\$2,87 in June 30, 2003), far lower, therefore, than that used in the study by Polanczyk *et al.*⁵ As far as the use of clopidogrel is concerned, a period of one month was considered for bare-metal stents and of six months for drug-eluting stents, assuming that this drug would be fully supplied to patients by the public health network.

Based on these data, the authors calculated that the (partial) replacement of bare-metal stent with drug-eluting stent (with a one-year follow-up) would incur an approximate additional cost of \$24 million, R\$37 million, and R\$44 million in the first, second and third scenarios, corresponding to a 12.8%, 20.1% and 24.4% increase, respectively, in the SUS budget allocated for that purpose. A non-negligible increase, in my opinion, at least in absolute values. Once more, it stands to reason that these costs would be even higher if clopidogrel was used for a longer period.

In sum, both studies provide converging results, that is to say, not only from the cost-effectiveness standpoint but also in terms of allocation of funds to health care, the use of drug-eluting stents should be restricted to selected cases.

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