Drug-eluting coronary stents (DESs) are widely used and entail sizeable Medicare hospital expenditures. However, the overall cost impact of DESs has not been well quantified. A clear understanding of how new technologies like DESs affect health care expenditures can provide insight into national trends in health care cost growth, of which new technology is presumably the leading driver. New technology may not only increase costs by being more expensive than previous treatments, but also by changing the patterns of care for chronic disease. Accordingly, we sought to assess the overall impact of DESs on Medicare expenditures in a nationally representative cohort of Medicare beneficiaries with coronary artery disease (CAD).

Methods. Because DESs were introduced in 2003, we calculated mean annual payer-perspective costs among patients with CAD during 2002 through 2006 (including 2002 costs as a baseline), in each US Hospital Referral Region (HRR) using a 5% random sample of fee-for-service Medicare beneficiaries, excluding patients younger than 66 years and older than 85 years (DES use declines markedly at older ages). Calculations were separately performed on each of 3 CAD subcohorts categorized annually by clinical events: patients with acute myocardial infarction (AMI), patients with acute coronary syndrome (ACS) but no AMI, and patients without ACS. We did not assume that DES-associated health care cost growth was confined solely to DES recipients; thus, cohorts included all patients with CAD regardless of treatments received. Costs included all facility and health care provider Medicare payments, including noncardiovascular costs, inflated to 2006 dollars using the consumer price index. This design captured costs downstream of major cardiovascular procedures and events, as patients were retained in the cohort through December 31, 2006, or until death. Annual DES rates within each HRR and subcohort were also calculated.

Substantial geographic variation in DES use across HRRs enabled measurement of the relationship between higher DES use and higher health care costs. Multivariable regression models were estimated, predicting annual HRR-level health care costs among patients with CAD as a function of the local DES rate, HRR “fixed effects” that controlled for time-invariant differences in costs across HRRs, and time-varying controls such as an annual HRR-specific medical cost index (controlling for geographic variability in health care inflation), patients’ mean DxCG Risk Score (Verisk Health Inc, Waltham, Massachusetts) (predicting comorbidity-associated costs), and general time trend controls. Models were estimated separately for each subcohort.

To fully describe the national expenditure implications of the per-patient DES cost increases estimated by regression models, we computed the total change in national expenditures attributable to DESs by multiplying the total number of Medicare beneficiaries nationwide in each CAD subgroup by the per-patient 2002-2006 cost increase predicted by the models.

Results. Calculations were derived from 1 981 088 Medicare beneficiaries with CAD, of whom 4.5% had a recent AMI, 3.4% had a recent noninfarction ACS, and 92% had no recent ACS. Between 2002 and 2006, DES use increased from 0% in all subcohorts to 23% among patients with AMI, 29% among patients with noninfarction ACS, and 1.1% among patients without ACS. Inflation-adjusted cost increases during 2002 through 2006 among CAD subcohorts ranged from 4.7% to 11.7%. Multivariable regressions indicated that each 1% increase in DES use was associated with a $28 mean per-patient cost increase ($ = .009) among patients with AMI, a $35 increase ($ < .001) among patients with noninfarction ACS, and a $133 increase ($ = .003) among patients without ACS. These estimates implied a DES-attributable increase in annual expenditures on patients with AMI of $657, on patients with noninfarct ACS of $999, and on patients without ACS of $146 (Table). Because most patients with CAD were non-ACS cases, this subgroup composed the largest portion of DES-attributable national cost growth.

Since the Food and Drug Administration approved the use of DESs for discrete, new (ie, previously untreated) partial blockages in patients’ native coronary arteries (ie, not in bypass grafts), and only in relatively large vessels, and the Centers for Medicare and Medicaid Services simultaneously approved payment, the increase in use of DESs has been meteoric. By 2005, DESs were over 90% of all first stents placed. It is estimated that more than 60% of DESs are placed for off-label indications and these patients have higher adverse event rates than on-label usage. Groeneveld et al analyzed Medicare data on almost 2 million beneficiaries from 2002 through 2006 and found that the cost of DESs is staggering, adding $1.37 billion to our national health care bill paid by taxpayers. It is time to clearly define what the value of this extraordinary investment has been in terms of patient benefits and study the harms and determine if we are getting good value for this outlay.

Rita F. Redberg, MD, MSc

Editor’s Note
Table. Patient-Level and Subgroup-Level Costs Attributable to DESs

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Cost, 2002, $</th>
<th>Cost, 2006, $</th>
<th>Cost Change Attributable to DESs, $</th>
<th>Per National CAD Subgroup, Annualized</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patients, No. (in Millions)</td>
<td>Patients Receiving DESs in 2006, No. (in Thousands)</td>
</tr>
<tr>
<td>AMI</td>
<td>35 815</td>
<td>37 345</td>
<td>567</td>
<td>0.36</td>
</tr>
<tr>
<td>Noninfarct ACS</td>
<td>26 418</td>
<td>28 278</td>
<td>999</td>
<td>0.27</td>
</tr>
<tr>
<td>Non-ACS</td>
<td>10 244</td>
<td>11 667</td>
<td>146</td>
<td>0.70</td>
</tr>
<tr>
<td>Total CAD</td>
<td>11 952</td>
<td>13 398</td>
<td>198</td>
<td>7.93</td>
</tr>
</tbody>
</table>

Abbreviations: ACS, acute coronary syndrome; AMI, acute myocardial infarction; CAD, coronary artery disease; DESs, drug-eluting coronary stents.

Comment. Drug-eluting coronary stents substantially increased costs for Medicare beneficiaries with CAD. The fraction of DES cost growth attributable to patients without ACS (68%) was much larger than the proportion of DESs received by this subcohort (33%), suggesting that DES use among patients without ACS was particularly cost amplifying (ie, DES introduction changed patterns of care for patients without ACS in a more costly manner than for patients with ACS). This is troubling, since the limited efficacy of percutaneous coronary intervention among patients without ACS, whether or not DESs are used, would not justify sizeable DES-related cost increases among patients without ACS.7,8

This analysis contributes to understanding the cost-increasing effects of technology because the cost effects of DESs were measured beyond the price of the new technology itself. By measuring "global" costs among stable groups of patients over time, we captured temporal changes in both direct and indirect costs related to changing rates of DES use that occurred among patients who actually received the technology as well as nonrecipients.

This observational study could not establish whether the association between increased DES use and cost growth was causal. Use of DESs may be inappropriate in selected patients without ACS and could deliver benefits at acceptable cost.9 Outpatient pharmaceutical costs were not included; these may have amplified or attenuated the DES-associated cost increase.

Drug-eluting coronary stents added $1.57 billion in annual Medicare expenditures among beneficiaries aged 66 to 85 years, with the largest cost increase occurring among patients without ACS.

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Previous Presentation: This study was presented orally at the American Heart Association Quality of Care and Outcomes Forum; May 20, 2010; Washington, DC.
Limitations in the Use of Qualitative Terms to Inform Diagnoses

The use of qualitative terms to describe the probability of disease is a potential source of misunderstanding and inaccuracy, and the use of probabilities has been a main supportive tool to deal with uncertainty in evidence-based diagnosis. Considering this, we have investigated how patients, medical students, and physicians quantify in probabilities the meaning of common terms used to indicate the presence of a disease.

Methods. In a public teaching hospital, volunteers who consented were invited to fill in a form marking in a metric rule (0% to 100%) the probability they would attribute to the use of qualitative terms to describe the probability of disease. Optimal medical therapy with or without PCI for stable coronary disease. N Engl J Med. 2007;356(15):1503-1516.


Results. During a period of 90 days, 167 participants (mean [SD] age, 36 [14] years; 52% male) were interviewed: 45 patients, 44 medical students, 41 medical residents, and 37 hospital practicing physicians, all from radiology, cardiology, and internal medicine wards. Of these, 14 patients were not able to adequately make the proposed quantitative transformation to fill in the form and so were excluded from the analysis.

The distribution of probabilities for each word in the valid sample (n = 153) is shown in the Figure. It is noteworthy that while words conveying ideas related to both extremes of probabilities showed narrower ranges of results, those representing intermediate probabilities showed a marked variability among responders. Moreover, no single term covered adequately the range of probabilities between 20% and 50%.

The mean (SD) probability of all answers was lower in the patients subgroup compared with others (45% [11%] vs 49% [4%]; P < .01). Patients’ answers tended to be closer to 50%, ie, they attributed higher probabilities for “never,” “almost never,” and “unlikely,” and lower probabilities for “compatible with,” “likely,” “very likely,” and “certainly” (all P < .05). We found no significant differences when sample was stratified by sex, age, self-attributed health status, patient origin (inpatient/outpatient), or medical specialty.

Comment. We found a high degree of variability in the way language is used and interpreted to attribute probabilities, particularly in the intermediate range, potentially affecting health care provider–patient communication. This finding could, in some aspects, correctly represent the range of indeterminate results of diagnostic tests or, in the worst case, show a lack in formal medical diagnosis reasoning in common practice.

Patients’ answers tended to be closer to 50% when compared with other groups, which could be inherent to the patient feelings and fears associated with the presence of disease. Furthermore, the very concept of probability of disease was flawed for some of them, representing a real barrier in communication.

Some study limitations should be addressed. Despite the back translation exercise, differences in results among countries and institutions could emerge from native language use and local practices. Subgroup analysis should also be viewed with caution owing to the limited sample size. Unfortunately, we could not go further in additional questions relating to specific cutoffs for each term, multicenter variability, or the reliability of answers.

Although findings such as ours have already been described for decades, no real improvement has been detected yet. We suggest testing a more restrictive categorization for the presence of a clinical condition, such as low, intermediate, and, high probability. This would simplify the interpretation of results for both patients and physicians, as much as it would disclose the importance...