Cost of single-vessel and multivessel coronary drug-eluting stenting: comparison to the DRG funding level

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Background. **Large-scale utilization of drug-eluting stents (DES) presents significant economic limitations, related to the current high cost of the device and the absence of adequate reimbursement from the health care system. The aim of the study was to evaluate the cost of single-vessel and multivessel drug-eluting stenting and to compare it with the DRG funding level.**

Methods. **Between November 2003 and May 2004, we studied 100 consecutive patients who underwent a percutaneous coronary intervention (PCI) with DES, 50 single-vessel and 50 multivessel procedures, in order to evaluate the real procedure costs of DES. The cost fields calculated in the analysis included: costs for the materials and drugs used in each procedure, costs related to medical personnel and staff, costs for equipment depreciations, and costs for total hospitalization based on the length of stay in the coronary care unit and/or in the cardiology ward.**

Results. **With regard to the 50 patients with single-vessel disease, 63 lesions were treated with 58 DES. With regard to the 50 patients with multivessel disease, the average number of treated vessels was 2.3 and of lesions 2.8. An average of 2.7 DES per patient was implanted; glycoprotein IIb/IIIa inhibitors were used in 70% of cases. The multivessel procedure necessitated an average of 1.62 guide catheters, 1.86 guides, 1.36 balloons, and 475 ± 124 ml of contrast medium; the average endoscopy time was 16 ± 8 min while the total procedural time was 106 ± 37 min. The procedural success rate was 100% for both groups. The post-PCI hospital stay was 2.1 ± 1.7 days for patients with single-vessel disease and 2.8 ± 2.6 days for patients with multivessel disease; the total was 4.7 ± 2.8 and 6 ± 3.2 days respectively. The mean total cost of hospital stay for PCI and DES was €6390 ± 2274 for single-vessel PCI and €9828 ± 3026 for multivessel PCI, split as follows: materials €2915 ± 963 and €5294 ± 1177, procedural costs €404 ± 55 and €446 ± 99, costs of hospital stay €3070 ± 2024 and €4089 ± 2517 respectively for single-vessel and multivessel PCI.**

Conclusions. **The mean total cost of a single-vessel PCI with DES falls within the DRG 112 reimbursement level for coronary angioplasty of €7006, while that of multivessel PCI with multiple DES is about 40% above the same reimbursement level. Interestingly, the multivessel PCI cost with multiple DES does fall within the reimbursement amount related to DRG 107 for bypass surgery procedures (€14 322).**

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Introduction

Over the past decade, coronary disease care has continued to evolve with the introduction of new treatment tools and methods. Functional and technological innovations have rendered the evaluation of their impact, both at a clinical and economic level, necessary.

The more recent launch of drug-eluting stents (DES) has emerged as a valid alternative not only to bare metal stents, but also to traditional coronary artery bypass graft (CABG) surgery. Randomized trials have demonstrated clinical benefits for the use of DES compared to bare metal stents, and ongoing trials are now comparing DES to CABG in patients with multivessel disease[1-5].

Despite the higher cost of the materials, positive clinical 1-year outcomes have proved DES to be comparable to other accepted interventional techniques[6].

While clinical experience may hint toward a wide adoption of the new technology, the decision-making factor for many Italian hospitals is closely linked to local funding issues. In Italy, hospitals are funded through a DRG system; administrators need to keep this in consideration when allowing for the use of new therapeutic choices. Only by evaluating the cost of the procedure can hospital directors efficiently allocate their financial resources. In some cases, the international literature on clinical outcomes may be used to make a convincing argument in favor of increased funding for a new technology.

The Catheterization Unit at the Ravenna Department of Cardiology has previously conducted a study on the cost of percutaneous coronary intervention (PCI) procedures with bare metal stents[7], revealing that the DRG reimbursement was sufficient to cover the procedure costs. The following study tackles a similar objective: to compare the real costs of two treatments with DES, single-vessel and multivessel PCI, with the DRG payment level. It is a pilot-study forming part of a wider project whose aim is to evaluate the real costs and the cost-efficacy ratio between multiple DES implants and surgical revascularization in patients with multivessel coronary disease.

Methods

Study population. All patients who underwent single-vessel PCI or multivessel PCI with DES between November 2003 and May 2004 at the Ravenna Department of Cardiology were identified. Multivessel stenting was defined as the placement of ≥ 1 coronary stents in ≥ 2 major epicardial coronary arteries (or their major branches) during a single procedure or staged procedures. Patients with multivessel PCI were excluded if the implantation of DES was believed not to be appropriate (reference diameter > 3.6 mm, lesions in side branches with limited distribution, etc.).

Operating since October 1999, the cath lab is situated within the Cardiology Division of the Ravenna Hospital and is used for both catheterization and electrophysiology procedures. It is open 5 days a week and serves the hospitals of Ravenna, Faenza, and Lugo. The center's distinctiveness is the routine application of *ad hoc* PCI during hospitalization[8]; specifically, 95% of PCIs are carried out directly after coronary angiography. Elective outpatients with an indication to coronary angiography are treated on a day hospital basis with previous evaluation by the hemodynamist and pretreated for a possible PCI with double antiplatelet aggregation. In 2003 the volume load of the center was 1158 patients, for a total of 651 PCIs, 23% of which were multivessel PCIs.

Determination of treatment costs. For each patient, a series of data was gathered including: general patient information, type of examination, procedural time, material used, and length of hospital stay. The following cost categories were identified: materials used, procedure (including personnel and equipment amortization) and hospital stay. On the basis of the sizing of a previous study[7], a sample of 50 patients for each group (single and multivessel procedure) has been considered as yielding sufficient power for cost analysis.

All continuous variables are expressed as mean ± SD. Comparisons between costs were performed using a two-tailed Student's t-test. A p value < 0.05 was considered as statistically significant.

Materials. For each procedure, every material used was recorded (including the hemodynamic kit, diagnostic catheters, guiding catheters, guide wires, balloon catheters, stents, medications, and contrast volume). The cost of each item was calculated on the basis of the purchasing cost provided by the hospital pharmacy including 20% VAT (4% for coronary prostheses). The cost of DES (Cypher and Taxus), agreed at a regional level, was €1800 in 2003 and €1650 after-tax for the first months of 2004. Patients with multivessel disease were treated with multiple Taxus stents; with regard to this, the provider Boston Scientific (Milan, Italy) agreed on a discounting pricing scheme for consecutive stents placed in the same patient.

Procedural costs. These include personnel expenses and equipment depreciation. The average cost per examination was calculated on the basis of the expenses during the first 4 months of 2003. An assumption was made that an elective PCI would include this average examination cost, while a session with both coronary angiography and PCI was equal to 1.5 times the average examination cost.

Personnel, staff fees, and mean salaries were referenced from tables compiled by the Health Administration. The following assumption for the number of staff present during the procedure was applied to all cases: 2 cardiologists, 2.5 hospital attendants, 1 radiology technician, and 0.5 ward nurse.

Total equipment amortization was calculated according to data provided by the "Ufficio Patrimonio". A depreciation rate of 12.5% was applied for all the equipment used exclusively by the catheterization lab (polygraph, oximeter, coagulometer, counterpulsator, intravascular ultrasound), and 50% of the amortization cost was applied to equipment also used by the electrophysiology laboratory (angiograph, defibrillator, external pacemaker, respirator, and electrocardiograph).

Hospital stay. The cost per patient stay in the cardiology ward was derived from the Ravenna ASSR data tables[9] and equaled €428/day. Similar data were not available for the cost per patient stay in the coronary care unit (CCU) and hence this was calculated on the basis of data reported in the reference literature. Three references were found for hospitals in other Italian regions that included both the cost of a general ward and that relating to the CCU stay[10-12]. The calculation of the mean relative cost between the ward types resulted in a factor of 1.9 (CCU higher than the cardiology ward). This factor was then applied to the Ravenna cardiology ward cost in order to calculate the cost of a Ravenna CCU ward which was €813/day.

Calculation of DRG levels. The DRGs were identified on the basis of the corresponding clinical indications and types of exams performed. Their respective fund-

ing levels were those reported in the "Tariffario Emilia Romagna"[13]. DRG 112 for PCIs is valued at €7006; DRG 107 used for CABG procedures is valued at about €14 322; DRGs 122, 124 and 125, related to cardiovascular diseases*, correspond to €4314, €3348, and €2111 respectively.

Results

Patient population. A total of 100 patients were evaluated, 50 who underwent single-vessel stenting and 50 multivessel stenting. The mean patient age was 65 years (62 ± 11 years for patients with single-vessel disease and 69 ± 8 years for patients with multivessel disease). The majority of patients were male (76 vs 24% female). The male to female ratio was similar in the two treatment groups. The patient groups were also similar in terms of numbers of patients with diabetes, hypertension, and dyslipidemia. There was also no difference in the patient population in terms of those who had previous PCI procedures, even though of 6 patients with a previous CABG, 4 were in the single-vessel group. The majority of patients (66%) presented with a primary indication relating to unstable disease (classified as unstable angina, non-Q wave acute myocardial infarction, recent myocardial infarction). This trend held true in both treatment groups. Table I summarizes the clinical characteristics of the two groups.

Table I. Demographic and clinical characteristics.

	Single-vessel PCI (n=50)	Multivessel PCI (n=50)
Age (years)	62 ± 11	69 ± 8
Male	39 (78%)	37 (74%)
Ex-/smoker	28 (56%)	19 (38%)
Diabetes	7 (14%)	9 (18%)
Hypertension	32 (64%)	31 (62%)
Hypercholesterolemia	30 (60%)	30 (60%)
Previous myocardial infarction	10 (20%)	10 (20%)
Previous PCI	6 (12%)	10 (20%)
Previous CABG	4 (8%)	2 (4%)
Unstable disease	29 (58%)	37 (74%)
Stable disease	19 (38%)	12 (24%)
Acute myocardial infarction	2 (4%)	1 (2%)
Diseased vessels		
One vessel	23 (46%)	0
Two vessels	13 (26%)	16 (32%)
Three vessels	14 (28%)	34 (68%)

CABG = coronary artery bypass graft; PCI = percutaneous coronary intervention.

* DRG definition Health Care Financing Administration v. 19: DRG 122: circulatory disorders with acute myocardial infarction without major complication, discharged alive; DRG 124: circulatory disorders except acute myocardial infarction, with cardiac catheterization and complex diagnosis; DRG 125: circulatory disorders except acute myocardial infarction, with cardiac catheterization without complex diagnosis.

With regard to the group with single-vessel disease, 63 lesions (1.11/patient) were treated with 58 DES. With regard to the 50 multivessel procedures an average of 2.3 vessels and 2.8 lesions were treated with 2.7 DES per patient. Figure 1 shows the lesion distribution between the two groups.

In the group with multivessel disease, owing to specific anatomic reasons, 6 lesions were treated with balloon coronary angioplasty only and 5 with bare metal stents. All patients but one had at least one lesion in the left anterior descending coronary artery treated, with 4 patients presenting with a stenosis in the left main; all patients with multivessel disease presented indications for CABG. Only 7 of 50 patients with multivessel disease were submitted to a staged revascularization deferring the treatment of non-culprit lesions. Table II shows the procedural characteristics and the allocation of resources with both types of treatment.

The procedural success was 100% for both groups. Specific complications included: 1 non-Q wave acute myocardial infarction and 1 subacute thrombosis with a re-PCI in the group with single-vessel disease, and 2 non-Q wave acute myocardial infarctions and 2 retroperitoneal hematomas in the group with multivessel disease. Seventy percent of the latter patients were treated with glycoprotein IIb/IIIa inhibitors. The post-PCI hospital stay was 2.1 ± 1.7 days for the patients with single-vessel disease and 2.8 ± 2.6 days for those with multivessel disease; the total mean hospital stay was 4.7 ± 2.8 and 6 ± 3.2 days in the two groups respectively.

Treatment costs. The treatment costs for the two groups were significantly different. For the group with single-vessel disease the total mean cost (including PCI with DES implantation and hospital stay) was €6390 ± 2274; with regard to multivessel treatment it was €9828 ± 3026 ($p < 0.001$). The material, procedure, and hospital stay mean cost differences were statistically significant ($p < 0.001$, $p = 0.012$, and $p = 0.028$ respectively) with the largest notable difference in the cost of materials. This was expected as, by definition, more material is used to treat a patient with multivessel disease. Table III shows the detailed and total costs for the two groups.

Subgroup analysis. *Diabetes.* The mean cost relating to the 16 diabetes patients (7 with single-vessel and 9 with multivessel disease) was further analyzed to understand any differences in this generally high-cost group. The total diabetes population had mean material, procedure, and length of stay costs of €4585, €419, and €3445 respectively, with a total mean cost of €8449 ± 2762.

The non-diabetic population had overall mean material, procedure, and length of stay costs of €4013, €426, and €3605 respectively, with a total mean cost of €8044 ± 3258. There was no statistically significant difference in the mean cost within each of the groups;

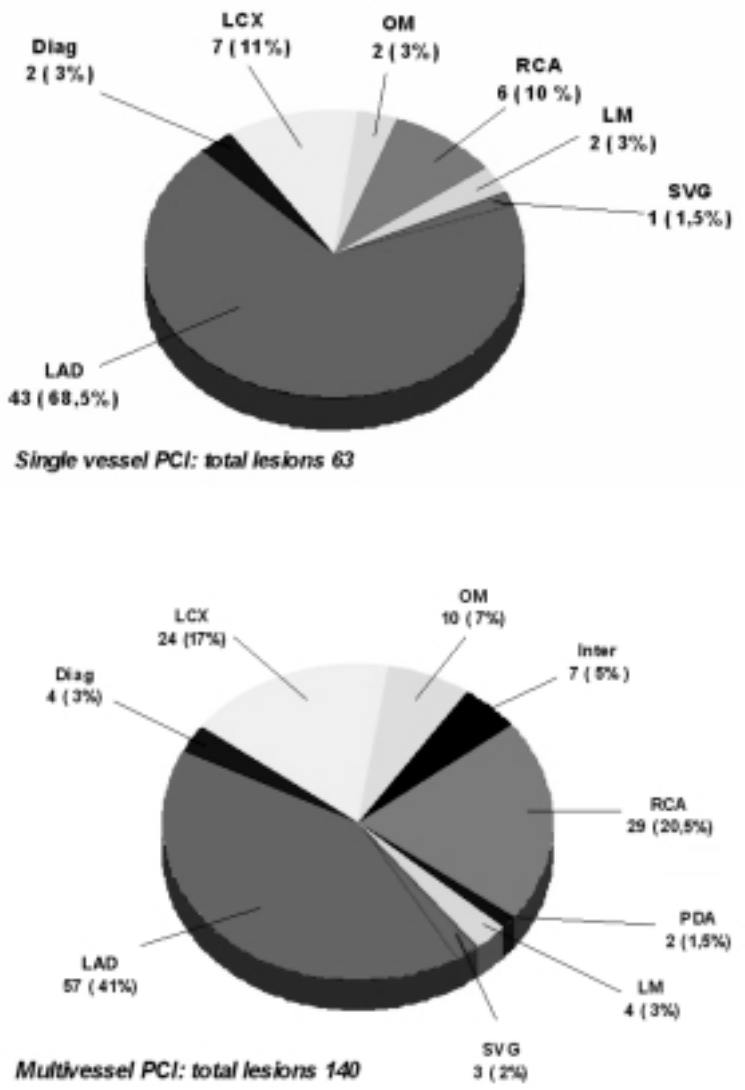

Figure 1. *Vessel distribution of the treated lesions in the two groups. Diag = diagonal branch; Inter = ramus intermedius; LAD = left anterior descending coronary artery; LCX = left circumflex artery; LM = left main; OM = obtuse marginal branch; PCI = percutaneous coronary intervention; PDA = posterior descending artery; RCA = right coronary artery; SVG = saphenous vein graft.*

this also held true when comparing diabetic vs non-diabetic patients with single-vessel disease and diabetic vs non-diabetic patients with multivessel disease.

Unstable. Patients were classified as either stable or unstable, depending on their original diagnosed indication. Stable patients were defined as those affected by stable angina, silent ischemia, and postmyocardial infarction. Unstable patients were defined as those with acute coronary syndrome (unstable angina, non-Q wave acute myocardial infarction, acute and recent myocardial infarction). Stable single-vessel treatment patients were compared to unstable single-vessel treatment patients. The same analysis was done to compare stable vs unstable patients with multivessel disease. In both analyses, there was a statistically significant difference in the total cost due exclusively to the length of stay. In the single-vessel treatment group, the total mean cost for stable and unstable patients was €4796 ± 2079 and €7287 ± 1870 respectively ($p < 0.001$). In the multivessel treatment group, the total mean cost for stable and unstable patients was €7575 ± 1694 and €10 539 ± 3017 respectively ($p = 0.002$).

Staged. In some cases with multivessel treatment, the stenting procedure has been staged over two visits. This is often done when there is concern for the patient's safety. The 7 staged patients were similar in that none ever had had a previous myocardial infarction, PCI or CABG, all were unstable patients, and all were treated for three-vessel disease. Their mean material, procedure, and hospitalization costs were €7205, €685, and €6451 respectively with a total mean cost of €14 340 ± 3100. Not surprisingly, the cost of treating these patients with staged procedures is much higher than the cost for patients with multivessel disease treated in one stage (mean total cost €9093 ± 2316, $p = 0.003$). Their corresponding DRG funding level will be discussed be-

Table II. Procedural characteristics in the two groups.

	Single-vessel PCI (n=50)	Multivessel PCI (n=50)
Treated vessel (no./pt)	1	2.3
LAD	38 (76%)	49 (43%)
LCX	6 (12%)	36 (31.5%)
RCA	4 (8%)	25 (22%)
LM	2 (4%)	4 (3.5%)
Treated lesions	63 (1.26/pt)	140 (2.8/pt)
Drug-eluting stents	58 (1.16/pt)	136 (2.7/pt)
Guide catheters (no./pt)	1.04	1.62
Guidewires (no./pt)	1.3	1.86
Balloon catheters (no./pt)	0.74	1.36
GP IIb/IIIa inhibitors	25 (50%)	35 (70%)
Contrast media (ml)	321 ± 104	475 ± 124
Rx exposition time (min)	8 ± 5	16 ± 8
Procedural time (min)	78 ± 19	106 ± 37
Procedural success (%)	100	100
Post-PCI hospital stay (days)	2.1 ± 1.7	2.8 ± 2.6
Total hospital stay (days)	4.7 ± 2.8	6.0 ± 3.2
CCU	1.3 ± 1.5	1.9 ± 2.3
Cardiology ward	3.4 ± 2	4.1 ± 2.5

CCU = coronary care unit; GP = glycoprotein; LAD = left anterior descending coronary artery; LCX = left circumflex artery; LM = left main; PCI = percutaneous coronary intervention; RCA = right coronary artery.

Table III. Single determinant and total hospital costs (€) for single-vessel and multivessel percutaneous coronary intervention (PCI) with drug-eluting stents.

	Single-vessel PCI (n=50)	Multivessel PCI (n=50)	p
Material	2915 ± 963	5294 ± 1177	< 0.001
Procedure	404 ± 55	446 ± 99	0.012
Hospital stay	3070 ± 2024	4089 ± 2517	0.028
Total	6390 ± 2274	9828 ± 3026	< 0.001

low, and in the next phase of the study their outcome-related costs will be studied in more detail.

Comparison of cost to DRG level. The corresponding DRG for PCI in the region of Emilia Romagna is DRG 112, which has a funding level of €7006; the corresponding DRG for CABG, DRG 107, has a funding level of €14 322. While the funding level appears appropriate for the average patient with single-vessel disease treated with DES (total mean cost of €6390), efficiency problems for the hospital may occur with patients that fall beyond the mean cost.

To illustrate this point, we calculated a total cost for the department using the data obtained for the 50 patients with single-vessel disease (€319 514) and the 50 patients with multivessel disease (€491 406) of €810 920. The total funding the department could expect from the current DRG level is €749 708 (which includes 7 patients who were treated over two stages), resulting in a €61 212 loss to the department.

Discussion

New technologies aimed at improving patient care are always welcome, especially if their clinical use is backed by sufficient clinical data. However, with today's increasing concern on the cost of medical care, effectiveness is no longer the primary factor determining their adoption. Rather, medical and non-medical decision-makers within a hospital are forced to consider the impact on their budget by comparing the cost of the new technology vs its funding levels. If it is inadequate, the decision must be made on whether to pursue a change in funding levels.

According to the first randomized studies and the results in the European and Dutch registries[1-4,14,15], DES proved to be unquestionably better than traditional bare metal stents as for medium-term major adverse cardiac events and target lesion revascularization; nevertheless their large-scale utilization is burdened with economic limitations due to the device's current high cost and the absence of a proper reimbursement level.

Clinical studies' cost-efficacy analysis of the RAVEL[16] and SIRIUS[6] DES show a rather moderate additional cost per treated patient and a favorable cost-efficacy ratio due to the decrease in revascularization procedures; nevertheless, by applying the analysis on an empiric model related to non-selected patients with an average stent utilization of 1.3 per single-vessel procedure, the use of DES shows cost savings for patients with an estimated target vessel revascularization > 20% and cost-effectiveness (avoided target vessel revascularization costs < $10 000) for patients with target vessel revascularization > 12% after bare metal stent implantation[17].

Taking in consideration the major predictive factors of restenosis, this model highlights the economic attractiveness of DES for patients who present with a higher risk of restenosis (diabetics or patients with a reference vessel diameter < 3.0 mm and/or lesion length > 15 mm)[18].

The need to accurately select patients who may benefit from this technology is even more justified by the absence of any advantage in terms of the strong endpoints of ischemic heart disease (death or acute myocardial infarction) with benefits limited exclusively to reduced rates of restenosis and reintervention for revascularization.

In the absence of guidelines, a few scientific organizations such as GISE[19] have approved the DES indications that emerge from the first randomized clinical trials[1,2,4,5]. However, the medical community's interest is focused on those patients who present with a higher risk of restenosis[20,21], for whom clinical trials are currently underway.

The Emilia Romagna Regional Health Agency and the Regional Cardiac and Cardiac Surgery Committee have suggested some conditions in which the benefit related to the use of DES is expected to be higher, with

an estimated DES utilization of 30% in PCI procedures; in this context, economic analysis reveals that DES are cost-effective even in patients with high-risk lesions[22].

These considerations focus on the problem from the health care system perspective, while from the hospital point of view, the application of this new technology, besides implying enormous starting costs, produces further deficits due to the decrease in the number of repeat revascularization procedures and the possible substitution of profitable CABG operations with DES-PCI[23,24].

The prompt economic impact of DES on hospital budgets has been acknowledged by the US Health System with the establishment of two new DRGs to reimburse DES-PCI even before the product received Food and Drug Administration approval; this adaptation seems necessary to minimize hospital losses when using DES.

Given the wide use of assumptions and pre-defined models when carrying out cost-efficacy studies, we considered particularly interesting the comparison of the real costs of PCIs with DES to the current DRG reimbursement level, as part of a wider evaluation project between costs and clinical results of multi-DES-PCI compared to CABG in patients with multivessel disease. This real world analysis begins with the important feature that the cost is consistently lower in Italy and Europe; Emilia Romagna, notably, has carried out a negotiation with the supplying companies in order to standardize the cost of the devices for all the hemodynamics centers, negotiating an initial price of €1800, reduced to €1650 in early 2004.

The real costs analysis is conditioned by a few particular characteristics of the specific center, such as the volume of activity, the number of personnel involved in the procedures, the complexity rate and the number of DES per patient, the performance of *ad hoc* PCI, the percentage of complications and finally the average length of hospitalization.

Our experience relates to a center ranked in the middle-high category both at the local and national levels for its quantitative and qualitative parameters.

Given this assumption, the study reveals that the total cost of a single-vessel PCI with the use of 1.16 DES per patient in an epicardial principal vessel, and with a length of hospital stay within the regional average, is €6390 ± 2274, so far well covered by the current DRG 112 reimbursement (€7006); therefore, in this subgroup economic aspects should not limit the use of DES if such a procedure is considered appropriate from an angiographic and/or clinical point of view. Obviously, in this case the DRG is not profit-bearing (unlike plain old balloon angioplasty or to a lesser extent bare metal stents), but simply covers the average global expenses of the operation and hospital stay, proving not even sufficient when patients present with higher costs than the average, as in case of acute coronary syndrome.

In the multivessel PCI group DES were implanted most frequently in the main vessels after having selected patients with possible complete DES revascularization; only 11 lesions out of 140 were treated with plain old balloon angioplasty or bare metal stents because of their location in less developed minor vessels or in anatomic sites theoretically not suitable for DES (kinking, etc.). All our patients with multivessel disease had CABG indications as the alternative to multivessel PCI; treatment with multiple DES proved to be achievable with almost the same complication incidence as single-vessel treatment.

The average total cost of hospitalization for multivessel PCI with multiple DES (2.7/patient) (€9828 ± 3026) exceeded the DRG 112 refunding level by about 40%, even though interestingly it fell within DRG 107 for CABG (€14 322). Only 7 patients out of 50 with multivessel PCI were treated in two steps, the first after coronary angiography and the second 20-30 days later; as this procedure is considered quite risky, this choice was made bearing in mind the patient's safety (first step during acute myocardial infarction, large extension of jeopardized myocardium, particular anatomical complexity).

In case of staged procedures, that are funded by two DRG payments, the real total costs fell within the funding level.

The excess of expenses could be a perverse incentive for treatment choices not necessarily based on the clinical requirements of the patient, with the risk of an excessive split of the revascularization procedure due to economic reasons.

Consequently, DRG 112 for PCI seems unsuited to the current activity in the interventional arena that includes a large proportion of multivessel treatments with multiple stents. The authorities in charge of budgeting and planning health organization should take into consideration that the availability of DES is generating a shift toward PCI procedures thus remarkably reducing the number of CABG procedures; the only study already performed on this subject estimated that this shift is roughly 21%[25].

The cost-efficacy ratio of multivessel PCI with multiple stents must be evaluated in comparison with CABG. The reducing effect of DES on target lesion revascularization must be included in the equation so as to shift the balance in favor of the former procedure as compared with traditional surgery; previous studies showed a contrasting evidence of economic advantage of multivessel PCI with bare metal stents vs CABG[26,27] with equivalent incidence of major clinical events (death, acute myocardial infarction) following the two procedures[27-30].

While international clinical trials are underway and may provide an answer within the next few years, we will continue to evaluate our in-hospital experience. The following phase of our study will be comparing the costs of treatment of patients with multivessel disease

and treated with DES to those of as many patients treated with CABG, including the additional costs of 6 and 12 months of follow-up. This will again be viewed within the context of the corresponding DRG funding levels and bearing in mind the clinical outcomes of the two treatments.

In conclusion, the treatment of patients with single-vessel disease with DES has become more common and, according to this study, is generally covered by the region's DRG funding level. The use of DES in patients with multivessel disease is still evolving, but it is encumbered by a DRG funding level that does not adequately cover its cost. A hospital endorsing the use of DES in patients with multivessel disease should expect higher costs. The case must be made to create a new mechanism for the funding of multivessel treatment with DES. If the cost-efficacy ratio compared to CABG will turn out to be in favor of multi-DES-PCI, a justified and appropriate reduction in the number of surgical procedures will occur, leading to a shift of resources to the latter technique.

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