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Coronary Aneurysms After Drug-Eluting Stent Implantation

Clinical, Angiographic, and Intravascular Ultrasound Findings

Fernando Alfonso, MD, Maria-José Pérez-Vizcayno, MD, Miguel Ruiz, MD, Alfonso Suárez, MD, Miguel Cazares, MD, Rosana Hernández, MD, Javier Escaned, MD, Camino Bañuelos, MD, Pilar Jiménez-Quevedo, MD, Carlos Macaya, MD

Madrid, Spain

Objectives This study sought to assess clinical, angiographic, and intravascular ultrasound (IVUS) findings in patients developing coronary aneurysms (CANs) after drug-eluting stent (DES) implantation.

Background The long-term safety of DES remains unsettled.

Methods This study analyzed 1,197 consecutive patients with late angiographic evaluation after DES implantation. In 15 patients (1.25%, 95% confidence interval: 0.58 to 1.93), CANs developed at follow-up. Analyses included quantitative angiography and volumetric IVUS.

Results DES developing CANs were more frequently implanted during acute myocardial infarction and were longer than those without this outcome. The elapsed time from DES implantation to CAN diagnosis was 313 ± 194 days. Angiographically, maximal CAN diameter measured 5.1 ± 1.2 mm. On IVUS, CAN external elastic lamina area was 32 ± 13.1 mm^2 and incomplete apposition area was 12.1 ± 8.6 mm^2. Two patients presented with acute myocardial infarction secondary to DES thrombosis. Four additional patients presented with unstable angina and underwent CAN aggressive dilation (3 were also treated for concomitant in-stent restenosis). Dual antiplatelet therapy was recommended in the remaining 9 patients who were asymptomatic at CAN diagnosis, but 1 of them eventually died of cardiogenic shock after a CAN-related myocardial infarction. After a mean follow-up of 399 ± 347 days, the 1-year event-free survival was 49 ± 14% and was related to CAN size on IVUS. In 2 patients, CANs disappeared at repeated late angiography and IVUS showed abluminal CAN thrombosis.

Conclusions After DES implantation, CANs are rare and may be detected in asymptomatic patients. However, CANs are frequently associated with adverse clinical events as a result of DES restenosis and DES thrombosis. Further studies are required to determine the implications of this distinct new entity. (J Am Coll Cardiol 2009;53:2053–60)
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The use of drug-eluting stents (DES) during coronary interventions has exploded in recent years because of their dramatic ability to inhibit neointimal proliferation (1–3). However, DES may affect the normal healing process of the vessel wall after vascular injury, resulting in delayed endothelization (4,5), and currently, prolonged dual antiplatelet therapy is recommended in these patients (6,7). Furthermore, the pharmacological effects of DES may influence the remodeling process and lead to late incomplete stent apposition (8–11).

The appearance of angiographic coronary aneurysms (CANs) after coronary interventions is very rare (12). The occurrence of angiographic CAN after DES has generated great interest but, to date, this finding has only been marginally reported in large-scale clinical trials or described in anecdotal case reports (13–16). Although CAN may develop as a result of exaggerated positive remodeling of the vessel wall (13–16), the underlying pathophysiology remains unknown. In some patients, this phenomenon has been linked to hypersensitivity reactions (15), bacterial arteritis (17–21), or other rare predisposing factors such as Kawasaki disease (14). Finally, it has also been suggested that DES-related CAN might predispose to DES thrombosis (15,18). Currently, however, the clinical implications of angiographic CAN remain uncertain.

The aim of the present study was to systematically assess clinical, angiographic, and intravascular ultrasound (IVUS) findings in patients developing angiographic CAN after DES implantation.

From the Interventional Cardiology Unit, Cardiovascular Institute, Clínico San Carlos University Hospital, Madrid, Spain.

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Abbreviations and Acronyms

CAN = coronary aneurysm
CI = confidence interval
DES = drug-eluting stent(s)
IVUS = intravascular ultrasound

Methods

Patient selection and study design. From the clinical and angiographic databases of the Cardiovascular Institute, Clínico San Carlos University Hospital (Madrid, Spain), 1,197 consecutive patients with late angiographic evaluation after DES implantation were identified and analyzed. This represents an angiographic follow-up rate of 71% in the initial 1,685 patients treated with DES in our institution. Fifteen of these patients (1.25%) had CANs at repeated angiographic evaluation. Once the diagnosis of CAN was established, patients were prospectively surveyed according to a specific protocol. The study was an investigator-driven initiative. All patients gave written informed consent to the study protocol that was approved by the institutional ethical review board.

Follow-up and definitions. At our institution, patients undergoing DES implantation are routinely scheduled for a stress test and angiographic evaluation at 9-month follow-up or earlier if clinically indicated. Clopidogrel (75 mg/day) was maintained for 9 months. However, in asymptomatic patients with a negative exercise test result, late angiography may be halted if this is requested by the referring physician. By protocol, however, all patients with recurrent symptoms or with objective evidence of ischemia undergo late angiographic evaluation.

Continuous, prospective, clinical surveillance was indicated in all patients with the diagnosis of CAN to assess long-term outcomes. A pre-defined, structured, detailed questionnaire was used. Major events were verified against source documentation. Clinical events (death, myocardial infarction, target vessel revascularization) were adjudicated by personnel unaware of the intervention results and late angiographic findings. Myocardial infarction diagnosis required 2 of the following: 1) prolonged (>30 min) chest pain; 2) a creatine kinase increase greater than twice the upper normal value (with abnormal MB fraction); and 3) appearance of new pathological Q waves. The Academic Research Consortium definition of definitive or probable stent thrombosis was used (2). Hypersensitivity reactions were specifically sought in every patient including dermatological reactions, anaphylaxis, arthralgia, and fever. Finally, laboratory tests with complete blood cell counts (including eosinophils) and immunoglobulin E titres were performed at CAN diagnosis and at follow-up.

Angiographic analysis. Coronary angiograms (baseline, intervention, follow-up) were carefully analyzed by dedicated personnel at an angiographic core laboratory. On qualitative analysis, CAN was defined as a localized angiographic dilation of the vessel lumen (50% larger than the adjacent reference vessel) at late angiography, closely related to the underlying DES or its edges, that was not present immediately after the procedure (12). Particular attention was taken to identify dissections or extravasation suggestive of contained perforations during the initial intervention. Quantitative coronary angiographic analysis was performed with an automatic edge-detection system (MEDIS, CMS 4.0, Leiden, the Netherlands). The angiographic analysis included the treated segment (lesion site + the treated region + the adjacent [5-mm] vessel on each side). Restenosis was defined as >50% diameter stenosis at follow-up.

IVUS. All IVUS studies (30/40-MHz mechanical transducers) were performed using an automated pullback system (0.5 mm/s) and recorded on sVHS videotapes for subsequent off-line analysis (22,23). Incomplete DES apposition was defined as ≥1 stent strut clearly separated from the vessel wall, with blood speckling behind it, in a vessel segment not encompassing a side-branch exit (8–11). Quantitative IVUS analyses were performed using a previously validated automatic contour detection system (EchoScan, Tomtec, Germany) (22,23). Diameters, areas (every 0.3 mm of DES length), and volumes of lumen, stent, and external elastic lamina were measured. Subsequently, at the segment with incomplete apposition, care was taken to analyze the lumen outside the stent and the maximal depth, area, length, and volume of this lumen. The lumen outside the stent was considered to be part of the effective total vessel lumen (8–11). The extent of incomplete apposition was further evaluated by measuring the arc of malapposition and the number of nonapposed DES struts (8–11). Images suggestive of partial thrombosis of this space were analyzed. The volume of plaque behind the stent was calculated as the external elastic lamina volume minus the sum of the DES volume and the lumen outside the stent volume. On IVUS, CAN was defined as a maximal effective lumen area >50% of reference lumen area (8–11).

Statistical analysis. Data are presented as values and percentages or mean ± SD. Categorical variables were compared with the chi-square test or the Fisher exact test. The Student *t* test was used for the comparison of continuous variables. Event-free survival was estimated by Kaplan-Meier analysis. The SPSS package version 12.0 (SPSS Inc., Chicago, Illinois) was used. A p value of <0.05 was considered statistically significant.

Results

Initial procedural findings. Baseline characteristics of the 15 patients in whom angiographic CANs developed (incidence 1.25%, 95% confidence interval [CI]: 0.58 to 1.93) (Fig. 1) and of the remaining 1,182 cases without CAN are presented in Table 1. Patients who develop CAN had initial procedures more frequently performed during an acute myocardial infarction and in occluded vessels, and more frequently required long DES and multiple DES and had residual dissections as compared with patients in whom CAN did not develop (Table 1). One of these patients had chronic myeloid leukemia, 1 had lung carcinoma, and another required prior surgery for bladder cancer.

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