Different types of coronary artery wall injury following cutting balloon angioplasty

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The cutting balloon is a device that enlarges atherosclerotic coronary arteries by a combination of plaque incision and dilation. This peculiar mechanism would account for a better immediate result achieved at the cost of minimal vessel wall trauma. Coronary perforation is however a potential complication. No systematic data have been reported as to which angiographic lesion characteristic may predict the occurrence of complications after cutting balloon angioplasty. This case report study deals with different types of coronary artery wall injury complicating cutting balloon angioplasty and detected by intravascular ultrasound.

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Introduction

The cutting balloon (CB; Intervention Technologies Inc., San Diego, CA, USA) is a percutaneous device that was introduced by Barath et al.[1] in 1991 for the transcatheter treatment of native coronary artery stenosis. The unique feature of this device is the presence of 0.25 mm microblades (3 to 4 depending on the balloon size) bonded longitudinally on the balloon surface. These microatherotomes cut or incise the atherosclerotic plaque during initial balloon inflation, making plaque dilation easier when the balloon is fully inflated. CB angioplasty has been found to be more effective than conventional coronary angioplasty (PTCA) in the treatment of many types of *de novo* coronary lesions[2-5]. Furthermore, the favorable results of CB angioplasty in the treatment of specific coronary anatomical subsets, such as ostial[6,7] and resistant lesions[8,9], small vessel[10,11] and in-stent restenosis[12-16], has recently widened the indications for its use. Although the overall rate of complications following CB angioplasty does not seem to be really increased as compared to PTCA[2,4,17,18], there are no systematic data on which type of coronary lesion is more frequently associated with complications and which test, between angiography and intravascular ultrasound (IVUS), best identifies these lesions.

The aim of this case report study was to describe different types of artery wall injury following CB angioplasty as detected by combined angiographic and IVUS evaluation.

Description of cases

Case 1. A 64-year-old male with chronic effort-induced angina underwent coronary angiography because of a recent worsening in symptoms associated with reversible myocardial ischemia involving the anterior wall at myocardial stress scintigraphy. Left coronary angiography showed a moderate, eccentric stenosis of the mid left anterior descending coronary artery (LAD) distal to the take-off of the second diagonal branch (Fig. 1). IVUS evaluation showed a severe stenosis with a minimal lumen area of 3.4 mm^2 (Fig. 1A, Pre-CB). The plaque was eccentric with an arch of 45° of healthy vessel and was fibrous in composition. The size of the CB was selected on the basis of the IVUS measurements taken at the lesion minimal lumen area: the average of the two orthogonal media-to-media measurements - 0.25 mm. In this case, given an average value of 3.55 mm, a 3.25 mm CB was chosen. A single inflation at 8 atm for 60 s was performed. The post-CB angiographic images showed a patent slightly overdilated vessel. IVUS disclosed a "horseshoe" dissection which was more evident distal to the lesion (Fig. 1B, Post-CB). Probably, the almost circular dissection was the cause of the false optimal angiographic result fol-

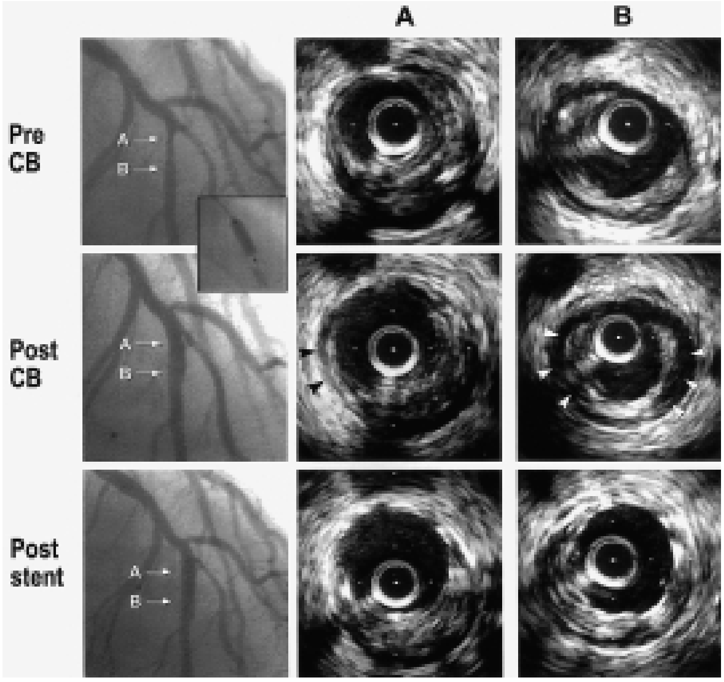

Figure 1. *Angiographic* (left side) *and intravascular ultrasound* (middle and right side) *images of case 1, pre- and post-cutting balloon (CB) angioplasty, and post-stenting. For each step, intravascular ultrasound images* A *and* B *correspond to points A and B of the angiogram. In the post-CB intravascular ultrasound images, the* white *and* black arrows *indicate the "horseshoe" dissection.*

lowing PTCA. A 3.5 × 13 mm BX Velocity stent (Cordis Europe, LJ Roden, The Netherlands) successfully sealed the dissection (Fig. 1A-B, Post-stent).

Case 2. Six months after stent implantation on the mid LAD, a 70-year-old male was admitted to the hospital because of angina pectoris. Left coronary angiography showed a patent stent with minimal in-stent hyperplasia and a critical LAD stenosis (the lesion was moderate at the time of initial stenting) distal to the second diagonal (D2) take-off (Fig. 2). IVUS pullback showed, immediately after the LAD-D2 bifurcation, an eccentric, fibrocalcific plaque with a minimal lumen area of 2.4 mm^2 (Fig. 2A, Pre-CB) and extending downstream for 5 mm (Fig. 2B, Pre-CB). The average of the media-to-media measurements was 3.45 mm. A 3.25 mm CB was selected and a single inflation at 8 atm for 30 s was performed. Post-CB angiography showed a wide, overdilated lumen at the lesion site. No leakage of contrast medium was seen. Post-CB IVUS evaluation showed an increased lumen area (8.8 mm^2) that was mainly the result of a deep cut into the healthy vessel wall reaching the adventitia (Fig. 2A-B, Post-CB). No stent was deployed. The early clinical follow-up was uneventful.

Case 3. A 65-year-old male was referred for coronary arteriography because of stress-induced myocardial ischemia without symptoms. A severe stenosis at the mid LAD was found (Fig. 3). IVUS evaluation showed an eccentric fibrous plaque with a 45° arch of deep calcium and a minimal lumen area of 2.4 mm^2 (Fig. 3A, Pre-CB). The average of the media-to-media measurements was 4.0 mm. A 3.75 mm CB was selected and inflated at 8 atm for 60 s. Post-CB angiography showed a wide, overdilated vessel. No leakage of contrast medium was detected. Post-CB IVUS evaluation showed a 7.7 mm^2 minimal lumen area and a 5 mm length dissection with an intramural hematoma at the level of the healthy vessel wall (Fig. 3A-B, Post-CB). Since the lumen area was acceptable and the hemodynamic and electrocardiographic conditions were stable, no stent was deployed. The early clinical follow-up was uneventful.

Case 4. A 67-year-old woman was admitted to our hospital because of a low threshold effort-induced angina pectoris. She was found to have a single intermediate stenosis of the mid LAD. The left circumflex and right coronary arteries were normal. A 3.0, 20 mm long Worldpass™ balloon (Cordis Europe, LJ Roden, The Netherlands) was initially inflated up to 14 atm, without success (persisting balloon indentation) (Fig. 4A-B). IVUS showed an eccentric lesion with a minimal lumen area of 3.0 mm^2. A 60° arch of calcium was present (Fig. 4C). Due to calcium shadowing, only a single plane media-to-media measurement was obtained (4.0 mm). A 3.5 mm CB was selected and a single inflation at 8 atm for 60 s was performed. After CB deflation, the patient experienced severe chest pain with ST-segment elevation in the anterior leads. Angiography showed a grade II contrast extravasation (Fig. 4D). The CB was quickly reinflated at a low pressure (2-3 atm) to close the perforation without re-exposing the microblades. Since the

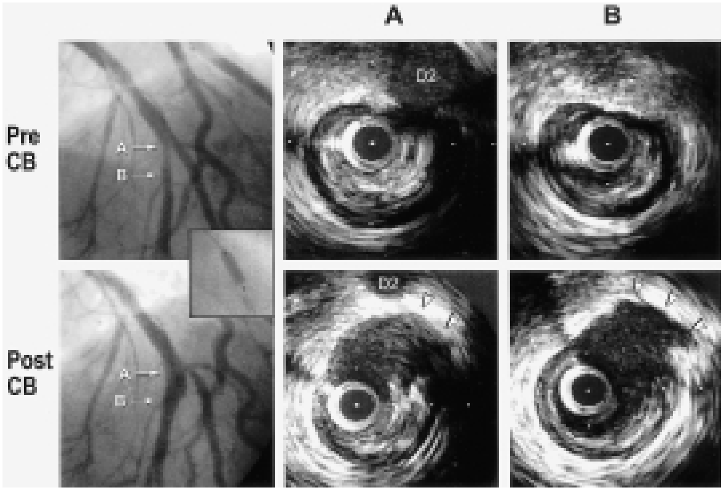

Figure 2. *Angiographic* (left side) *and intravascular ultrasound* (middle and right side) *images of case 2, pre- and post-cutting balloon (CB) angioplasty. For each step, intravascular ultrasound images* A *and* B *correspond to points A and B of the angiogram. In the post-CB intravascular ultrasound images, the* white arrows *indicate a "deep cut with threatened vessel rupture".*

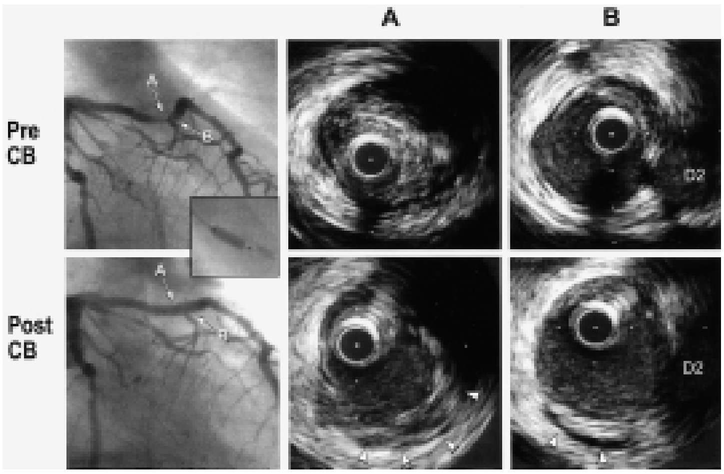

Figure 3. *Angiographic* (left side) *and intravascular ultrasound* (middle and right side) *images of case 3, pre- and post-cutting balloon (CB) angioplasty. For each step, intravascular ultrasound images* A *and* B *correspond to points A and B of the angiogram. In the post-CB intravascular ultrasound images, the* white arrows *indicate vessel dissection with an intramural hematoma.*

coronary perforation was not completely sealed by balloon inflation, a 16 mm PTFE-covered stent (Jostent, Jomed International AB, Helsingborg, Sweden) was hand-crimped onto a 3.0 Worldpass™ balloon (Cordis Europe, LJ Roden, The Netherlands) and was successfully deployed. The stent was post-dilated at high pressure with a 3.5 mm Searider semi-compliant balloon (Nycomed Amersham Medical System, Paris, France). The final angiogram and IVUS images showed complete sealing of the vessel perforation and TIMI 3 flow LAD perfusion. IVUS showed the typical ultrasonographic finding of a PTFE-covered stent (Fig. 4E-F).

Discussion

Despite the lack of consistent evidence of an increased rate of complications following CB angioplasty as compared to PTCA[2,4,17,18], it is theoretically possible that the CB, by its specific mechanism of dilation-incision, may slightly increase the risk of coronary perforation. Popma et al.[4] reported a 1% rate of coronary perforation after CB as compared to none in the PTCA arm of the Global Randomized Trial (GRT); Fukutomi et al.[18] reported a rate of 0.53% after CB as compared to 0.06% after PTCA. However, a 0% perforation rate was reported in both the CUBA and REDUCE II trials[2] despite patient and angiographic characteristics, which were similar to those reported in the GRT. In the absence of specific angiographic predictors of coronary perforations, the recommendations on the use of the CB are obligatorily tentative.

The present study. This case report study shows that: 1) CB angioplasty may induce a wide spectrum of coronary injuries including significant dissection (case 1)

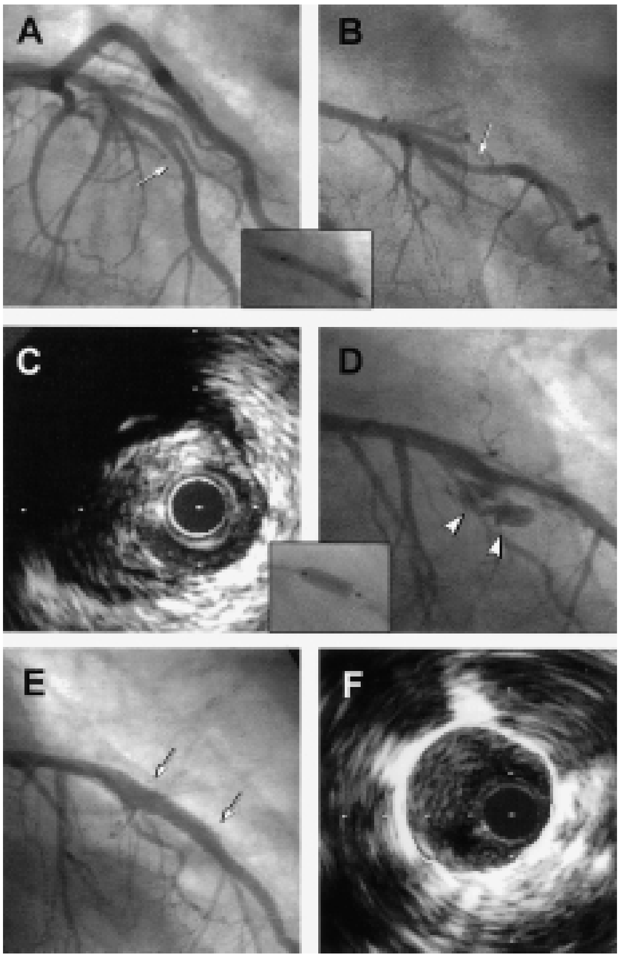

Figure 4. *Angiographic and intravascular ultrasound images of case 4. An intermediate lesion of the mid left anterior descending coronary artery before* (A) *and after* (B) *conventional coronary angioplasty balloon inflation. The lesion intravascular ultrasound image is shown in* panel C. *The post-cutting balloon angiographic result showing coronary perforation with extravasation of contrast medium is shown in* panel D (white arrows). Panels E *and* F *show the angiographic and intravascular ultrasound images following PTFE-covered stent implantation.*

and/or a deep cut with threatened vessel rupture (cases 2 and 3) and perforation (case 4); 2) conventional angiography fails to identify these complications (except for perforation); however, the detection of an overdilated vessel at the target site after CB angioplasty should raise the suspicion of dissection or impending rupture; 3) IVUS is superior to angiography for the correct detection of these complications and to shed light on their possible mechanisms; 4) balloon-to-artery ratio, plaque distribution (lesion eccentricity) and plaque composition (lesion calcification) are procedural and anatomical variables that may play a role in eliciting these types of complications.

Balloon-to-artery ratio. Vessel rupture during percutaneous intervention is a rare occurrence[19]. Larger balloons have been found to facilitate vessel rupture following PTCA[20]. A balloon-to-artery ratio of 1.1-1.2:1 at quantitative coronary angiography or visual inspection is recommended for CB angioplasty. In previous studies, a somewhat "conservative" approach with a mean balloon-to-artery ratio of 1.15 (range 0.7-1.6) has been used[2-5]. The aim was to avoid deep cuts by the CB microblades into the vessel wall which would have increased the risk of perforation. However, in the GRT, no relationship was found between the balloon-to-artery ratio and the rate of complications[2]. Moreover, a significant inverse relationship was found between the CB-to-artery ratio and the final percent diameter stenosis or minimal lumen diameter both in the short- as well as at long-term evaluation[2,21,22]. Thus, despite a conservative approach to avoid complications, larger CBs were found to be associated with better results.

We selected the CB size on the basis of IVUS. The average of the two orthogonal media-to-media measurements was reduced by 0.25 mm to avoid excessively deep cuts by the device. The mean CB size was 3.31 ± 0.31 mm. This value corresponded to an angiographic balloon-to-artery ratio of 1.22 ± 0.15 (range 1.02-1.38) that is in accordance with the manufacturer's recommendations and previous clinical experience. This would suggest that factors other than the balloon-to-artery ratio may play a role in facilitating vessel injury. The question as to which method, among visual inspection, on-line quantitative coronary angiography and IVUS, one should rely upon when selecting the appropriate CB size should be addressed by further studies.

Plaque distribution. Eccentric lesions carry a moderate risk of complications following PTCA[23]. Asymmetric expansion of the normal vessel wall with only slight changes in the atherosclerotic plaque may induce dissection at the margins of the plaque and in normal segments of the wall[24,25]. This risk may be further increased when using the CB, since the microblades could preferentially cut the healthy vessel wall creating significant artery dissection or perforation (the risk may increase with multiple inflations and with a large-sized CB carrying 4 microblades). Despite this potential risk, in different series the rate of eccentric lesions treated with the CB has been reported to be as high as 79% with no increase in the rate of complications[4,7]. This discrepancy may be explained by the poor accuracy of the angiographic assessment of the plaque distribution when compared with anatomical or ultrasound examinations[26,27]. In our patients, angiography revealed an eccentric lesion in 1 out of 4 cases. However, when evaluated at IVUS all lesions were classified as eccentric on the basis of the presence of an arch of disease-free arterial wall within the lesion[27]. This type of plaque distribution may be more susceptible to dissection/perforation during percutaneous coronary interventions because of the normal vessel wall. The low frequency of this type of lesion (15% of 1446 lesions evaluated at IVUS)[27], may actually explain the relatively low rate of coronary perforations reported in previous studies after CB angioplasty.

Plaque composition. Vessel calcification is an additional relative contraindication to the use of the CB. The presence of calcium, especially if involving a limited arch of the vessel wall, may increase the risk of perforation because the CB is unable to cut the calcified portion of the plaque and may converge the microblade action towards the opposite vessel wall, resulting in different degrees of wall injury including arterial perforation. This is what has probably occurred in case 4. Thus, calcified coronary lesions, especially if eccentric, should be considered as a contraindication to CB angioplasty. Since IVUS is superior to angiography in the evaluation of the plaque distribution and calcification[28], the question regarding the use of IVUS before any CB procedure should be addressed. Although this approach would increase the cost of the procedure, a better understanding of the plaque distribution and composition should allow for the matching of the right device with the right lesion thus improving results and decreasing complications[29,30].

Conclusions. This study showed that the coexistence of many, rather than a single, anatomical and procedural characteristics may increase the risk of vascular complications following CB angioplasty. The lesion eccentricity is probably the most important factor, followed by vessel calcification and a large balloon-to-artery ratio. IVUS evaluation is superior to angiography in identifying both the type and mechanism of complications after CB angioplasty. Interestingly, the appearance, at angiography, of an overdilated vessel after CB angioplasty should raise suspicion of an excessively deep cut of the device.

Limitations. The lack of systematic IVUS data after CB angioplasty in a large patient population does not allow us a precise knowledge of the true incidence of these types of complications and of the predictive role of different patterns of plaque distribution and composition. Since no invasive follow-up was carried out in these patients, no inferences can be drawn about the angiographic and IVUS outcomes of these complications (late perforation?, aggressive restenosis?, aneurysm formation?)[31].

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