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Cutting Balloon Versus Conventional Balloon Angioplasty for the Treatment of In-Stent Restenosis

Results of the Restenosis Cutting Balloon Evaluation Trial (RESCUT)

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OBJECTIVES The aim of this trial was to compare cutting balloon angioplasty (CBA) with conventional balloon angioplasty (i.e., percutaneous transluminal coronary angioplasty [PTCA]) for the treatment of patients with coronary in-stent restenosis (ISR).

BACKGROUND Retrospective studies suggest CBA might be superior to conventional PTCA in the treatment of ISR.

METHODS The Restenosis Cutting Balloon Evaluation Trial (RESCUT) is a multicenter, randomized, prospective European trial including 428 patients with all types of ISR (e.g., focal, multifocal, diffuse, proliferative).

RESULTS In both groups, the majority of ISR lesions were shorter than 20 mm. The length of restenotic stents was similar (CBA: 18.6 ± 9.7 mm; PTCA: 18.3 ± 8.7 mm). The number of balloons used to treat ISR was lower in the CBA group: only one balloon was used in 82.3% of CBA cases, compared with 75% of PTCA procedures ($p = 0.03$). Balloon slippage was less frequent in the CBA group (CBA 6.5%, PTCA 25%; $p < 0.01$). There was a trend toward a lower need for additional stenting in the CBA group (CBA 3.9%, PTCA 8.0%; $p = 0.07$). At seven-month angiographic follow-up, the binary restenosis rate was not different between the groups (CBA 29.8%, PTCA 31.4%; $p = 0.82$), with a similar pattern of recurrent restenosis. Clinical events at seven months were also similar.

CONCLUSIONS Cutting balloon angioplasty did not reduce recurrent ISR and major adverse cardiac events, as compared with conventional PTCA. However, CBA was associated with some procedural advantages, such as use of fewer balloons, less requirement for additional stenting, and a lower incidence of balloon slippage. (J Am Coll Cardiol 2004;43:943–9) © 2004 by the American College of Cardiology Foundation

With the rapid explosion in-stent use, in-stent restenosis (ISR) has become a significant clinical problem (1). Redilation using a conventional percutaneous transluminal coronary angioplasty (PTCA) balloon remains the most commonly used approach to treat ISR (2–5). However, the recurrence rate remains high, especially in the subgroup of patients with diffuse and/or severe ISR (1,3,5–8). Intravascular ultrasound (IVUS) studies have shown that ISR is due to neointimal hyperplasia (9). Thus, debulking techniques that use different devices have been studied for its treatment (1,10,11). However, all these atheroablative technologies remain difficult to handle, and they are costly. In addition, a recent randomized, multicenter study (12) has failed to demonstrate the superiority of rotational atherectomy over conventional PTCA in the treatment of ISR. Another device proposed for treatment of ISR is the cutting balloon (Boston Scientific Corp., InterVentional Technologies Europe Ltd., Letterkerry, Ireland) (13), a special balloon catheter with three or four microsurgical blades bonded longitudinally to its surface, suitable to incise and facilitate redistribution of the ISR plaque. Retrospective studies (14,15) suggest that cutting balloon angioplasty (CBA) might be superior to conventional PTCA in the treatment of ISR. The aim of this randomized study was to compare CBA with conventional PTCA.

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METHODS

Study design and objectives. The Restenosis Cutting Balloon Evaluation Trial (RESCUT) was a prospective, randomized, multicenter trial performed at 23 centers in Europe (Appendix) to evaluate the immediate and seven-month results of CBA compared with conventional PTCA for the treatment of all types of ISR. The primary end point was angiographic restenosis (≥50% diameter reduction) of

Abbreviations and Acronyms

CABG	= coronary artery bypass graft surgery
CBA	= cutting balloon angioplasty
CK	= creatine kinase
%DS	= percent diameter stenosis
ISR	= in-stent restenosis
IVUS	= intravascular ultrasound
MACE	= major adverse cardiac events
MLD	= minimum lumen diameter
PTCA	= percutaneous transluminal coronary angioplasty
QCA	= quantitative coronary angiography
RESCUT	= Restenosis Cutting Balloon Evaluation Trial

the target lesion, as assessed by quantitative coronary angiography (QCA) at seven-month follow-up in the two treatment arms. Secondary end points were the occurrence of major adverse clinical events (MACE) at 30 days and seven-month follow-up in the two treatment arms, the need for additional stent implantation in each arm, and the pattern of restenosis recurrence.

Study population. Patients fulfilled the following inclusion criteria: 1) angina and/or objective evidence of target vessel-related ischemia by a functional study; 2) target lesions located in native coronary arteries with single or multiple (maximum of three) ISR and with an angiographic percent diameter stenosis (%DS) between 51% and 99% by visual assessment; and 3) lesions that could be focal (<10 mm), multifocal, diffuse (>10 mm), or proliferative (extending outside the stent margins), with a total lesion length ≤25 mm. Patients were excluded for the following reasons: 1) known allergy to the study medication (e.g., heparin, ticlopidine, clopidogrel, aspirin); 2) recent myocardial infarction (<72 h), defined as a serum level ≥2 × the upper limit of normal of creatine kinase (CK) and elevated MB fraction; 3) concomitant PTCA in another vessel during the same procedure or within 30 days; 4) additional brachytherapy after the randomized mechanical treatment of ISR by CBA or conventional PTCA; 5) the lesion was located in an internal mammary artery, saphenous vein bypass graft, or unprotected left main coronary artery; and 6) ISR was in a bifurcated stent. A status of recurrent intrastent restenosis (e.g., second time, third time, and so on) was not considered an exclusion criterion for entry into the study.

Interventional procedures. THE CBA ARM. The cutting balloon device (Boston Scientific Corp.) was a 10- to 15-mm-long cutting balloon selected with the same or 0.25- to 0.5-mm larger diameter than the vessel size. The cutting balloon was positioned at the lesion site (using predilation with a small conventional balloon in case of unsuccessful passage) and inflated to the recommended maximal pressure of 8 to 12 atm.

THE PTCA ARM. The PTCA procedure was done using noncompliant or semicompliant balloons that matched the size of the final balloon used at the time of stent implantation. The balloon was inflated at high pressure (>10 to 12 atm), with the goal of achieving near 0% residual stenosis.

BOTH ARMS. At least three separate, slow balloon inflations were recommended at the lesion site, preferably moving distal to proximal, to fully cover the lesion area to be treated. The occurrence of slippage of the balloon, defined as a forward or backward movement of the balloon of at least 3 mm during its inflation at the lesion site, and dissections outside of the stent after deflation of the balloon were recorded. In case the balloon did not expand, the lesion could be treated with other devices, such as rotational atherectomy (Rotablator, Boston Scientific Corp., Cork, Ireland), directional atherectomy, laser atherectomy, or a different balloon. If the angiographic result was not acceptable with residual stenosis ≥30%, the implantation of an additional stent was recommended. However, the investigators were free to select the more appropriate device for the lesions in which balloon treatment failed.

Coronary angiography. Three coronary angiograms were performed in each patient: one before and one immediately after the procedure and one after seven months from the initial procedure. At least two orthogonal projections of the coronary segment scheduled for coronary intervention were filmed before the intervention. The same projections were repeated after the intervention and at follow-up angiography. Each angiogram was preceded by intracoronary injection of nitrates (100 to 200 μg nitroglycerin or 1 to 3 mg isosorbide dinitrate). The angiographic findings of dissection were recorded and analyzed.

Quantitative coronary angiography. Reference diameter, minimum lumen diameter (MLD), %DS, and lesion length were measured for each lesion from the single view showing the most severe degree of stenosis by the use of a computer-assisted automated edge-detection algorithm (QCA-CMS Version 4.0, MEDIS, Leiden, the Netherlands). Inter- and intra-observer variabilities have been reported to range from 0.07 to 0.10 mm for MLD and 2.7% to 5.1% for %DS, even when using the most precise angiographic systems (16–18). *Acute lumen gain* was defined as the MLD immediately after the procedure minus the MLD before the procedure. *Late lumen loss* was defined as the MLD after the procedure minus the MLD at follow-up. The *late loss index* was defined as the late lumen loss divided by the acute lumen gain. *Restenosis* was defined as ≥50% DS inside the stent or within 5 mm from the stent edges, presenting at least eight weeks after the initial stent implantation or after successful treatment of ISR. In addition, *ISR* was defined as focal (<10 mm in length) or diffuse (≥10 mm in length).

Concomitant medications. All patients received 100 to 325 mg aspirin plus 250 mg ticlopidine twice daily, or 75 mg/day clopidogrel before the procedure. Intraprocedural heparin was given as an intravenous bolus of 70 to 100 U/kg after sheath insertion and then repeated as needed to keep the activated clotting time >200 to 250 s. Glycoprotein IIb/IIIa inhibitors were given at the operator's discretion

only in selected patients. After the procedure, heparin was stopped and the sheath removed. All patients at discharge received 100 to 325 mg/day aspirin indefinitely plus 250 mg ticlopidine twice daily, or 75 mg/day clopidogrel for 1 week. The further use of ticlopidine/clopidogrel for one month was recommended only in patients who required the implantation of additional stents.

Clinical follow-up. In-hospital, 30-day, and cumulative 7-month MACE were defined as death, any myocardial infarction, and/or repeat revascularization (coronary artery bypass graft surgery [CABG]/repeat PTCA). A diagnosis of Q-wave myocardial infarction was made when there was documentation of new pathologic Q waves (>0.04 s) on the electrocardiogram in conjunction with elevation of total CK more than twice the normal value, with a concomitant elevation of the CK-MB. A diagnosis of non–Q-wave myocardial infarction was made when an elevation of total CK to greater than twice the upper limit of normal value, with a concomitant elevation of CK-MB, was documented without development of new pathologic Q waves. Twelve-lead electrocardiograms were recorded before and immediately after the procedure and at hospital discharge, as well as during and after episodes of chest pain. Total CK and CK-MB levels were routinely obtained before and after the procedure and repeated after 6 and 12 h.

Statistical analysis. Based on retrospectively collected data (15), a restenosis rate of approximately 42% could be expected after treatment of intrastent restenosis using a conventional balloon versus 27% using a cutting balloon. Accepting these values, we estimated a sample size of about 420 patients (210 in each arm) to establish a statistically significant difference between the two strategies, with an alpha error of 0.05, a beta error of 0.20, and a two-sided test. A drop-out rate of 20% was also considered. The chi-square test was performed to test for homogeneity of distribution of categorical data, reported as m × n contingency tables; 2 × 2 contingency tables were analyzed according to the Fisher exact test. Analysis of variance was performed for continuous data. Results are expressed as the mean value ± SD. The association between binary restenosis and the potential predictors was assessed via logistic regression methods. Variables with biologic remarkable predictivity (reference vessel diameter before procedure, MLD after procedure, diabetes, unstable angina, previous restenosis of target lesion, time to last stent implantation) and parameters that were statistically significant on univariate analysis (lesion length, number of balloons used, type of lesion) were included in the multivariate analysis. A stepwise selection method according to the maximum likelihood ratio was used to define the predictors of the logistic model. The results were presented as the odds ratio with 95% confidence interval for each variable. A value $p < 0.05$ was considered statistically significant.

Table 1. Demographics and Baseline Characteristics

	CBA (n = 214)	PTCA (n = 214)	p Value
Age (yrs)	61.7 ± 10.6	61.4 ± 9.6	0.78
Male gender	171 (80%)	169 (79%)	0.90
Unstable angina	54 (25%)	46 (21%)	0.84
Diabetes	51 (24%)	58 (27%)	0.44
Elevated cholesterol	151 (71%)	155 (72%)	0.81
Hypertension	137 (64%)	147 (69%)	0.39
Current smoking	24 (11%)	30 (14%)	0.46
Family history of CAD	67 (31%)	79 (37%)	0.26
Previous PTCA*	29 (14%)	19 (9%)	0.18
Previous MI	111 (52%)	104 (49%)	0.56
Previous CABG	26 (12%)	13 (6%)	<0.05
Ejection fraction (%)	56.7 ± 11.8	57.1 ± 10.8	0.78

*Previous conventional percutaneous transluminal coronary angioplasty (PTCA) before stent implantation in the target lesion with actual in-stent restenosis. Data are presented as the mean value ± SD or number (%) of patients.

CAD = coronary artery disease; CBA = cutting balloon angioplasty; CABG = coronary artery bypass graft; MI = myocardial infarction.

RESULTS

Patient population and baseline lesion characteristics. A total of 428 patients were randomly assigned to CBA (n = 214 [229 lesions]) or PTCA (n = 214 [237 lesions]). Baseline demographics and clinical characteristics (Table 1) were similar in both arms, except for previous CABG (CBA 12% vs. PTCA 6%; $p < 0.05$). There were no significant differences in baseline stent and lesion characteristics (Table 2), except for a higher rate of multifocal, diffuse, or proliferative lesions in the PTCA group. The majority of ISR was first ISR (CBA 84.6%, PTCA 81.5%; $p = 0.06$) and <20 mm in length (CBA 86.7%, PTCA 83.6%; $p = 0.44$).

Procedural characteristics. Procedural characteristics are presented in Table 3. Failure to cross the lesion using the cutting balloon, known to have a worse profile than traditional balloons, was higher (CBA 5.2%, PTCA 0%; $p < 0.01$). The procedural time was not different between the two devices.

The number of balloons used was significantly lower in the CBA arm (patients treated with CBA required the use of only one balloon in 82.3% of cases vs. 75.4% of PTCA procedures, $p = 0.03$). Balloon slippage was less frequent in the CBA group (CBA 6.5% vs. PTCA 25%; $p < 0.01$). Moreover, the cutting balloon was shorter (due to its shorter length; available lengths of 10 or 15 mm), slightly larger, and inflated at a lower maximal inflation pressure (due to its lower burst pressure; the manufacturer recommends 8 to 10 atm), compared with the longer (usually 20-mm long) and high-pressure conventional PTCA balloons (the manufacturers commonly recommend 14 to 18 atm). Finally, there was a trend toward a lower need for additional stenting in the CBA group (CBA 3.9% vs. PTCA 8.0%; $p = 0.07$), mainly due to a lower frequency of residual stenosis >30% and type D to F dissections in the CBA arm.

Clinical events and angiographic results. As shown in Table 4, there were no differences between the two arms in

Table 2. Baseline Stent and Lesion Characteristics

	CBA (n = 229)	PTCA (n = 237)	p Value
Previous implanted stents			
Slotted tubular stents	81.3%	86.5%	0.18
Implantation interval (months)	10.1 ± 12.4	8.71 ± 11.9	0.22
Stent length (mm)	18.6 ± 9.7	18.3 ± 8.7	0.73
First in-stent restenosis	84.6%	81.5%	0.06
Type of stent restenosis			0.01
Focal (<10 mm in length)	100 (51%)	74 (38%)	
Multifocal/diffuse/proliferative	96 (49%)	120 (62%)	
Lesion length			0.47
<20 mm	170 (87%)	163 (84%)	
>20 mm	26 (13%)	31 (16%)	
Target vessel			0.60
LAD	43%	46%	
LCx	20%	22%	
RCA	37%	32%	

Data are presented as the percentage of patients, mean value ± SD, or number (%) of patients.
LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery; other abbreviations as in Table 1.

clinical events during the hospital stay and at 30-day follow-up since hospital discharge and in cumulative MACE at 7-month follow-up.

Table 5 summarizes the QCA results. There were no differences in MLD before and after the procedure and at seven-month follow-up angiography, which was conducted in 82% of the patients in both arms (CBA: n = 188; PTCA: n = 194). The cumulative distribution curves of MLD are presented in Figure 1. There were no significant differences between the two arms in %DS, late loss, loss index, and angiographic binary restenosis (CBA 29.8%, PTCA 31.4%; p = 0.82), with a similar pattern of restenosis recurrence.

Table 6 shows the predictors of restenosis recurrence that were analyzed. On multivariate logistic regression analysis, a longer baseline lesion length measured by QCA, a shorter time passed since implantation of a currently restenotic target stent, a higher number of balloons used, the presence of unstable angina, and previous restenosis of the target lesion turned out to be independent predictors of restenosis recurrence.

DISCUSSION

In contrast to previous reports (14,15,19), in this large, multicenter, randomized study comparing CBA with conventional PTCA for the treatment of ISR, there were no significant differences between the two approaches regarding the study end points of recurrent angiographic binary restenosis at seven-month follow-up, the occurrence of MACE at 30 days and 7-month follow-up, and the pattern of restenosis recurrence.

Table 3. Procedural Characteristics

	CBA (n = 229)	PTCA (n = 237)	p Value
No. of balloons used			0.03
1	82.3%	75.4%	
2	16.0%	19.2%	
≥3	1.8%	5.4%	
Maximal balloon size (mm)	3.18 ± 0.47	3.07 ± 0.48	<0.01
Maximal inflation pressure (atm)	9.9 ± 2.6	12.6 ± 3.9	<0.01
Final balloon length (mm)	11.3 ± 3.2	18.3 ± 4.6	<0.01
No. of balloon inflations per lesion	2.83 ± 1.7	2.75 ± 2.3	0.65
Balloon slippage	6.5%	25.1%	<0.01
Balloon-to-artery ratio (QCA)	1.27 ± 0.20	1.25 ± 0.20	0.27
Additional stent implantation	9 (3.9%)	19 (8.0%)	0.07
For residual stenosis >30%	2 (0.9%)	7 (2.9%)	
For ischemia and dissection type C	2 (0.9%)	2 (0.9%)	
For dissection type D, E, and F	5 (2.1%)	10 (4.2%)	
Dissection post-procedure	4.8%	6.8%	0.48
Procedural time	97 ± 85	89 ± 75	0.28
Failure to cross the lesion	12 (5.2%)	0	<0.01

Data are presented as the percentage of patients, mean value ± SD, or number (%) of patients.
QCA = quantitative coronary angioplasty; other abbreviations as in Table 1.

Table 4. In and Out of Hospital to Seven-Month Follow-Up Major Adverse Cardiac Events* per Patient

	CBA (n = 214)	PTCA (n = 214)	p Value
During hospital stay			
Death	0	0	
MI	1 (0.5%)	2 (0.9%)	0.99
CABG	0	0	
Bleeding or vascular complications	4 (1.8%)	1 (0.5%)	0.37
After 30 days since hospital discharge			
Death	0	0	
MI	1 (0.5%)	0	0.99
CABG	0	0	
Repeat PCI	1 (0.5%)	1 (0.5%)	1
Bleeding or vascular complications	1 (0.5%)	0	0.99
Subacute occlusion	0	0	
Cumulative (in and out of hospital) MACE at 7 months†			
Death	3 (1.4%)	2 (0.9%)	0.99
MI	3 (1.4%)	3 (1.4%)	1
TLR (repeat PCI and CABG)	29 (13.5%)	28 (13.1%)	0.99
Total patients with MACE	35 (16.4%)	33 (15.4%)	0.79

*Death, MI, CABG, and repeat PCI, TLR. †Patients with more than one MACE were counted only one time for the most severe MACE. ‡p values are calculated according to the Fisher exact test. Data are presented as the number (%) of patients.

CABG = coronary artery bypass graft surgery; MACE = major adverse cardiac events; MI = myocardial infarction; PCI = percutaneous coronary intervention; TLR = target lesion revascularization; other abbreviations as in Table 1.

Theoretical advantages of CBA over conventional PTCA for treatment of ISR. Previous IVUS studies suggested a difference in the mechanisms of lumen enlargement after CBA and conventional PTCA. Mehran et al. (20) demonstrated by IVUS that the mechanism of conventional PTCA for the treatment of ISR is a combination of additional stent expansion and tissue extrusion out of the stent: of the total lumen enlargement, 56% is attributable to additional stent expansion, whereas 44% is the result of an apparent decrease (displacement) in neointimal tissue. In addition, a significant tissue re-intrusion shortly after catheter-based treatment of ISR has been reported, which results in early lumen loss (21).

Our hypothesis was that CBA could have a potential advantage over conventional PTCA for the treatment of ISR because it could lead to less remaining tissue inside the stent. This hypothesis was based on a previous observational study (19) that demonstrated a greater capacity of CBA to extrude fibrous residual neointimal plaque out of the stent struts, compared with conventional PTCA. The micro-

Table 5. Results of Quantitative Coronary Angiography

	CBA (n = 229)	PTCA (n = 237)	p Value
Reference vessel diameter (mm)	2.58 ± 0.47	2.53 ± 0.45	0.23
MLD (mm)			
Before treatment	0.83 ± 0.33	0.84 ± 0.32	0.87
After treatment	2.17 ± 0.45	2.16 ± 0.43	0.78
Acute gain	1.36 ± 0.50	1.32 ± 0.50	0.39
7-month follow-up	188 (82%)	194 (82%)	
MLD (mm)	1.61 ± 0.65	1.55 ± 0.62	0.23
Late loss (mm)	0.56 ± 0.65	0.62 ± 0.61	0.42
Loss index	0.43 ± 0.79	0.45 ± 0.47	0.72
%DS			
Before treatment	68 ± 12	67 ± 11	0.54
After treatment	21 ± 11	21 ± 10	0.60
7-month follow-up	188 (82.1%)	194 (81.9%)	
%DS	39 ± 22	40 ± 21	0.31
Lesion length			
Before treatment (mm)	14.0 ± 7.9	13.4 ± 6.4	0.39
Follow-up (mm)	10.8 ± 6.6	11.3 ± 7.5	0.46
Restenosis (>50% DS)	56 (29.8%)	61 (31.4%)	0.82
Pattern of restenosis recurrence			
Focal (length <10 mm)	12 (23%)	12 (21%)	0.26
Diffuse (length >10 mm)	41 (77%)	44 (79%)	0.55

Data are presented as the mean value ± SD or number (%) of patients.

%DS = percent diameter stenosis; MLD = minimal lumen diameter; other abbreviations as in Table 1.

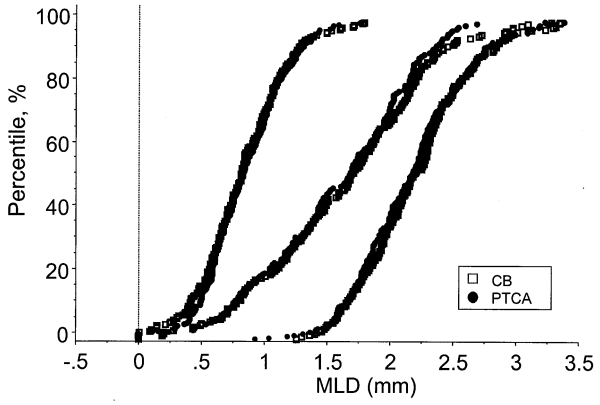

Figure 1. Measurements by quantitative coronary angiography (QCA). Cumulative distribution curves of minimum lumen diameter (MLD). CB = cutting balloon.

blades of the cutting balloon are able to surgically incise the restenotic plaques up to the metallic stent cage, and these incisions could facilitate the maximum extrusion of the neointimal plaque, separated into three or four quadrants. This hypothesis was confirmed by a recent IVUS study (14) that showed a larger lumen area acute gain after CBA (2.5 ± 0.8 mm^2) than after conventional PTCA (1.8 ± 1.0 mm^2), which translated in a lower restenosis rate at 5.4-month follow-up (CBA 24%, PTCA 59%). Cutting balloon angioplasty also has a practical advantage over conventional PTCA for the treatment of ISR: conventional PTCA balloons, especially short balloons, when positioned within restenotic lesions, tend to move forward or backward during inflation into larger segments with lower resistance, because the hyperplastic tissue has a smooth slippery surface; with a cutting balloon, this problem is prevented by the blades, which anchor the balloon to the plaque during balloon inflation, reducing the risk of dissection at the stent margins. This fact could be important when contemplating additional brachytherapy, a setting where there is the need to carefully control the boundaries of the injured segment. In the present trial, the CBA procedure was accompanied by a significantly lower incidence of balloon slippage.

Why did CBA fail to improve the outcome? There are some possible explanations for this unexpected outcome. First, there is the relatively lower risk of ISR recurrence in the two cohorts, which mostly had lesions shorter than 20 mm and prevalently focal and multifocal lesions. In fact, the recurrence of restenosis after repeat angioplasty for the treatment of ISR is influenced by its pattern (3–6,8,22), with a better outcome for focal than for diffuse ISR lesions, and a prohibitive recurrence rate for total occlusions (1). It can be also speculated that the operators did not perform an appropriate number of cutting balloon inflations. This hypothesis is supported by the observation of a similar mean number of balloon inflations in the two arms, but given the longer length of the conventional PTCA balloons used, there should have been a higher number inflations with the shorter cutting balloons to cover the same lesion length.

Study limitations. A limitation of the present study is the lack of data on IVUS assessment of the treated lesions, so as to better understand the differential mechanisms of CBA versus conventional PTCA in ISR. A downside of the cutting balloon is that it is more costly than standard

Table 6. Predictors of Angiographic Binary Restenosis Recurrence

	Univariate Analysis		Multivariate Analysis	
Variables	**OR (95% CI)**	**p Value**	**OR (95% CI)**	**p Value**
Treatment (random)	0.984 (0.581–1.670)	0.9513		
Clinical				
Gender	0.842 (0.440–1.610)	0.6021		
Diabetes	0.790 (0.440–1.420)	0.4308		
Unstable angina	0.583 (0.319–1.070)	0.0815	0.585 (0.307–1.110)	0.1041
Previous CABG	1.340 (0.473–3.820)	0.5788		
Previous restenosis of target lesion	0.486 (0.210–1.130)	0.0941	0.350 (0.152–0.805)	0.0148
Time to last stent implantation	1.030 (0.992–1.060)	0.1368	1.030 (0.996–1.070)	0.0832
Angiographic				
Segment treated (LAD; other)	1.100 (0.650–1.850)	0.7323		
Baseline lesion length	0.940 (0.906–0.976)	0.0017	0.940 (0.904–0.978)	0.0028
Lesion length (≤20; >20)	1.660 (0.857–3.200)	0.1342		
Reference vessel diameter before procedure	1.030 (0.572–1.860)	0.9209		
MLD after procedure	1.390 (0.738–2.610)	0.3102		
Length of balloon	0.986 (0.939–1.040)	0.5829		
Type of lesion (focal, diffuse)	0.594 (0.345–1.020)	0.0617		
Procedural				
Number of balloons used (1 vs. >1)	0.410 (0.220–0.763)	0.0058	0.417 (0.217–0.799)	0.0094
Maximum balloon size	0.921 (0.502–1.690)	0.7916		
Maximum inflation pressure	0.973 (0.897–1.050)	0.4987		
Diameter of final balloon used	0.994 (0.537–1.840)	0.9857		
Balloon slippage	0.836 (0.396–1.760)	0.6372		
Additional stent implantation	0.477 (0.141–1.620)	0.2369		

CABG = coronary artery bypass graft surgery; CI = confidence interval; LAD = left anterior descending coronary artery; MLD = minimal lumen diameter; OR = odds ratio.

balloons. A cost-benefit analysis was not performed in this trial. Therefore, the issue of whether the increased expense per procedure could be offset by the fewer stents used could not be solved. Only 82% of study groups had seven-month angiographic follow-up. However, as assumed for RESCUT sample size calculation, about 20% of patients are routinely lost to follow-up.

CONCLUSIONS AND FUTURE DIRECTIONS

The results of this study indicate that CBA and traditional PTCA are equally effective in preventing the recurrence of ISR. There were no differences in QCA measurements, recurrence of binary restenosis, or clinical event rates at seven-month follow-up between the two treatments. However, CBA was associated with some advantages: the procedure required fewer balloons and was accompanied by a lower incidence of balloon slippage (containment of trauma, especially useful when combining CBA with brachytherapy). In the CBA group, there was also an almost significantly lower need for additional stent implantation.

The question of the long-term superiority of CBA over conventional PTCA for the treatment of ISR will be also addressed by another ongoing randomized multicenter Japanese study—the Restenosis Reduction by Cutting Balloon Evaluation (REDUCE II).

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APPENDIX

For a list of the Steering Committee, Data and Safety Monitoring Board, Core Laboratories, and Participating Centers of the RESCUT trial, please see the March 17, 2004, issue of *JACC* at www.cardiosource.com/jacc.html.