Immediate and Chronic Results of Cutting Balloon Angioplasty: A Matched Comparison with Conventional Angioplasty

TAIZO KONDO, M.D., KATSUHIRO KAWAGUCHI, M.D., YOSHIFUMI AWAJI, M.D., MITSUHIRO MOCHIZUKI, M.D.

Department of Cardiology, Komaki City Hospital, Komaki City, Aichi Prefecture, Japan

Summary

Background: At the initial stages of percutaneous transluminal coronary angioplasty (PTCA), several studies reported on the feasibility of coronary artery incision and dilatation leading to the extension of the PTCA technique.

Hypothesis: This study was designed to determine the immediate and chronic results of cutting balloon (CB) angioplasty.

Methods: This procedure was performed on 127 lesions in 110 patients (male 83%, age 61.8 ± 9.3 years).

Results: The overall procedural success rates for the CB were 93.7% (119 lesions) and 92.7% (102 patients), while solitary CB without pre- and/or postdilatation was 76.4% (91 lesions). There was one major in-hospital complication (Q-wave myocardial infarction, 0.9%), but there were no deaths or emergency coronary artery bypass graftings. Significant angiographic dissections ($\geq$ grade C) occurred in four patients, and coronary perforation occurred in one. The successfully treated CB group (95 lesions) was matched with the successful conventional angioplasty group (PTCA group) for chronic result assessment in regard to reference vessel size and lesion characteristics. In the CB group, postprocedural minimal luminal diameters were significantly larger and the percentage of stenosis at the stenotic site was significantly lower compared with the PTCA group. Restenosis occurred in 22 lesions (23.1%). This showed a significantly lower restenosis rate

compared with the PTCA group (42.1%). In addition, the restenosis rate of the CB without inclusion of the pre- and/or postdilatation-treated lesions was 19.7%.

Conclusions: (1) Cutting balloon angioplasty procedures can be performed with high success rates with few major in-hospital events. (2) The restenosis rate in the CB group was significantly lower compared with the PTCA group.

Key words: percutaneous transluminal coronary angioplasty, cutting balloon angioplasty, restenosis

Introduction

At the initial stages of percutaneous transluminal coronary angioplasty (PTCA), Lary¹ reported on the feasibility of coronary artery incision and dilatation leading to the extension of the PTCA technique. In 1991 Barath *et al.*² reported on animal experimentation using a cutting balloon (CB) having one to four cutting-edged metal blades (0.1–0.4 mm) mounted on the surface of balloon catheters. They concluded that the potential advantages of the cutting balloon were the following: (1) by cutting deeply into the media, restitution of vascular tone was decreased, resulting in decreased dilatation time and pressure; (2) with a sharp surgical incision, less medial smooth muscle cell stretching led to less growth factor expression and less intimal proliferation.

New devices presently employed to compensate for faulty conventional angioplasty may cause damage to the intima, resulting in increased restenosis rates.³ The first clinical results of the CB suggested its capacity to cause less intimal damage, leading to reduced restenosis.⁴ In this study we demonstrated the efficacy of the CB in (1) decreasing dilatation time, (2) lessening of restenosis, and (3) reducing vascular injury due to severe dissection.

Methods

Study I

This study was designed to determine the immediate results of CB angioplasty. Cutting balloon angioplasty was applied to

Address for reprints:

Taizo Kondo, M.D.
Department of Cardiology
Komaki City Hospital
1-20, Jobushi
Komaki City
Aichi Prefecture
485, Japan

Received: October 14, 1996

Accepted with revision: February 13, 1997

110 patients with 127 lesions that matched the criteria defined below. They were selected from 345 patients with 494 lesions at Komaki City Hospital from November 1994 through February 1996. Of all interventions at Komaki City Hospital between 1993 and 1995, 85% were performed by conventional balloon angioplasty. Directional coronary atherectomy came into use in May 1993, and the Palmaz-Schatz stent has been employed since January 1994. Most of the Barath CB angioplasty technique was conducted in a standard manner using the Judkins approach following right femoral artery puncture. The CB (balloon length 15 mm, or 10 mm, balloon diameter 2.5–4.0 mm) was applied with an 8F guiding catheter and a 0.014" stiff guidewire which straightened the target vessel and resulted in smooth advancement of the balloon. When the CB could not cross the lesion, predilatation was performed with a 1.5 or a 2.0 mm balloon. Postdilatation with the same size balloon as the CB was employed after coronary dissection (NHLBI $\geq$ B) occurred or when the lesion was insufficiently dilated. Exclusion criteria of lesions were severely calcified lesions, chronic total occlusions, vessel diameters < 2.0 mm, and acute myocardial infarction (TIMI 0 or 1).

Successful CB angioplasty was defined as final residual stenosis of a target lesion $< 50\%$ without stenting.

Study II

The main object of this study was to evaluate the chronic results of CB angioplasty compared with conventional angioplasty. This evaluation compared the immediate and chronic results of the successfully treated and followed-up lesions. We could not, however, compare the occurrence of complications because cases before stent use were included in the conventional angioplasty group.

Subjects

Cutting balloon (CB) group: In the CB angioplasty group in Study I, 95 lesions in 83 patients were successfully treated and followed up. Twenty-seven patients with 32 lesions were excluded from this study.

Conventional balloon angioplasty (PTCA) group: Successful conventional angioplasty treated and followed-up lesions (95 lesions; 83 patients) matched those in the CB group one-to-one with regard to vessel diameter (reference vessel diameter within ± 0.3 mm), the sites of intervention, and lesion characteristics when possible. Patients were selected from previous cases within the last 5 years before CB procedures came into use.

Measurement of Coronary Stenosis

All vessels were analyzed quantitatively with an automated edge detection system (Cardiovascular Measurement System, Medis Medical Imaging Systems, Nuenen, The Netherlands). The basic method of analysis was described in several reports.^{5,6} Restenosis was defined as $> 50\%$ luminal diameter stenosis of a target lesion at follow-up angiography.

Statistical Analyses

Values are expressed as the mean value ± 1 standard deviation. Statistical analyses were performed by Mann-Whitney U-test, chi-square test, and Fisher's exact probability test. A p value of < 0.05 was considered significant.

Results

Study I

The age of 110 patients was 61.8 ± 9.3 years, and 82.7% were male. The basic angiographic characteristics were as follows: 127 lesions [left anterior descending (LAD) 45, right coronary artery (RCA) 57, and left circumflex (LCx) 25]; AHA/ACC lesion types (A/B1/B2/C; 19/51/50/7); calcified lesions 13; and de novo lesions 74. The number of RCA lesions was slightly higher than the number of other lesions; B1 and B2 lesions occurred most frequently. Procedural success was achieved in 102 patients (92.7%) with 119 lesions (93.7%, Table I). The CB has a 2.7F distal shaft diameter which is relatively larger than the latest conventional angioplasty balloons and predilatation was necessary in 13 lesions (10.2%). Ad-

TABLE I Procedural results

Patient success rate (%)	92.7 (102/110 patients)
Lesion success rates (%)	93.7 (119/127 lesions)
LAD (%)	93.3 (42/45 lesions)
RCA (%)	94.7 (54/57 lesions)
LCx (%)	92.0 (23/25 lesions)
Success rates of ACC/AHA lesion type	
A (%)	19/19 (100)
B1 (%)	50/51 (98.0)
B2 (%)	45/50 (90.0)
C (%)	5/7 (71.4)
Rates of pre- and/or postdilatation	
Predilatation (%)	10.9 (13/119 lesions)
Postdilatation (%)	18.5 (22/119 lesions)
Cutting balloon alone (%)	76.4 (91/119 lesions)
Reasons for failure	
Inability to cross the lesion	3 lesions (LCx 2, RCA 1, type B1 1, type B2 2)
Stenting for dissection	2 lesions (RCA 2, type B2 2)
Inability to dilate	2 lesions (LAD 2, type C 2)
Coronary perforation	1 lesion (LAD 1, type B2 1)
Inflation pressure (psi)	98.4 ± 13.5
Inflation time (s)	250 ± 199
Cutting balloon inflation time (s)	165 ± 73
No. of inflations (times)	1.68 ± 1.05
No. of cutting balloon inflations	1.27 ± 0.5

Abbreviations: LAD = left anterior descending, RCA = right coronary artery, LCx = left circumflex, ACC = American College of Cardiology, AHA = American Heart Association.

TABLE II Baseline clinical characteristics in both groups

	CB group	PTCA group	p Value
Age (years)	61.5 ± 9.3	61.4 ± 8.9	NS
Male gender (%)	82.4	82.4	NS
Prior myocardial infarction (%)	42.6	54.0	NS
Prior CABG (%)	4.0	0.9	NS
Diabetes mellitus (%)	34.1	34.4	NS
Hypertension (%)	52.6	51.5	NS
Hyperlipidemia (%)	31.5	36.2	NS
Current smoking (%)	31.5	27.8	NS

Abbreviations: CB = cutting balloon, PTCA = percutaneous transluminal coronary angioplasty, CABG = coronary artery bypass grafting, NS = not significant.

junctive balloon angioplasty was performed in 22 lesions (18.5%) for insufficient dilatation or coronary dissection. Ninety-one lesions (76.4%) were successfully treated by CB alone. Eight patients who were unsuccessfully treated by CB included three patients, in whom the balloons were unable to cross, two patients in whom the balloons were unable to dilate, two patients who received stents, and one patient in whom a coronary perforation occurred. Stenting occurred in two type B2 cases. Major complications occurred in one patient. A Q-wave myocardial infarction occurred when a coronary perforation was treated with conventional angioplasty. After prolonged balloon inflation at the LAD lesion site, extravasation ceased; however, the distal LAD vessel was occluded. The above grade C dissections that occurred after CB angioplasty were treated by stenting and prolonged conventional balloon inflation. Post-CB percent stenosis and minimal luminal diameter (MLD) included patients who were treated with adjunctive balloon.

Study II

Table II shows a comparison of baseline clinical characteristics between the two groups. There were no significant differences in any data, including coronary risk factors. Immediate results in the two groups differ in several points (Table III). The CB size was larger than that of conventional balloons. Accordingly, the balloon/reference vessel ratio was larger in the CB group. Lesion lengths in the PTCA group were significantly longer than those in the CB group. The procedure time was significantly shorter and the inflation times were significantly fewer in the CB group than in the PTCA group.

Follow-up angiography was performed 4 months after the procedure in 95 lesions in each group [mean follow-up intervals (days): 123.4 ± 53.2 for CB and 122.7 ± 74.3 for conventional angioplasty]. Angiographic results (Fig. 1) show that follow-up MLD in the CB group was larger than that in the PTCA group but the difference was not significant ($p = 0.059$); however, follow-up percent stenosis was significantly differ-

TABLE III Angiographic characteristics in both groups

	CB group	PTCA group	p Value
Lesion type (A/B1/B2/C)	16/38/38/3	10/36/43/6	NS
Balloon diameter (mm)	3.40 ± 0.42	3.08 ± 0.45	<0.0001
Reference vessel diameter (mm)	3.02 ± 0.48	2.94 ± 0.49	NS
Balloon/vessel diameter ratio	1.14 ± 0.11	1.06 ± 0.23	<0.0001
Lesion length (mm)	9.77 ± 4.28	12.7 ± 5.46	<0.001
Balloon inflation time (s)	248 ± 202	760 ± 429	<0.0001
Number of inflations	1.7 ± 1.0	4.3 ± 2.3	<0.0001

Abbreviations as in Table II.

ent between the two groups. Figure 2 shows acute gain, late loss, and net gain in the two groups. Acute gain in the CB group was significantly greater than that in the PTCA group; late loss in the CB group was less and net gain in the CB group was greater than that in the PTCA group, though the differences were not significant. A cumulative distribution curve of percent diameter stenosis in the CB group indicated a restenosis rate of 23.1% that was significantly lower than that in the PTCA group (42.1%) (Fig. 3). In the CB group, the restenosis rate of the lesion treated with predilatation and/or adjunctive balloons was 33.3% (8/24 lesions) and that of CB-only treated lesions was 19.7% (14/71 lesions). The restenosis rates according to lesion characteristics in the CB group were type A 31.7% (5/16), type B1 21.1% (8/38), type B2 23.7% (9/38), and type C 0% (0/3), and there were no significant differences among lesion characteristics.

Clarification of the differences of the immediate and chronic results between the two groups may depend on the low balloon/vessel ratio in the PTCA group. We analyzed the correlation between post-percent diameter stenosis and balloon/vessel ratio, and the correlation between follow-up percent di-

FIG. 1 Changes of minimal luminal diameter (MLD) and percent stenosis in both groups. —●— = cutting balloon, —○— = percutaneous transluminal coronary angioplasty.

FIG. 2 Changes of acute gain, late loss, and net gain in both groups. CB = cutting balloon, PTCA = percutaneous transluminal coronary angioplasty.

ameter stenosis and balloon/vessel ratio in the PTCA group. There was no significant correlation ($r = -0.158$ and $r = 0.04$, respectively) between the two. Therefore, we reasoned that the difference in outcome in the PTCA group compared with the CB group did not necessarily depend on balloon size.

Discussion

Comparison with Other Devices

Cutting balloon angioplasty safety and efficacy procedures were evaluated in Study I. The success rate of conventional angioplasty has recently been gradually raised to $>90\%$.^{7,8} The overall procedural success rate for CB angioplasty was 92.7% for patient success and 93.7% for lesion success; 76.4% of the lesions were successful due to CB alone. These results were approximately the same as those reported for conventional angioplasty and previously released new devices: 89–98% angiographic success for directional coronary atherectomy,^{9,10} 94.7% angiographic success with or without adjunctive balloon angioplasty for rotational atherectomy,¹¹ 95% patient success for transluminal extraction atherectomy.¹² Major complications in our study occurred in only one patient (0.9%) and were fewer than in other new device trials, such as 2.5–5.9% of directional coronary atherectomy,^{9,10} 3.0% of rotational atherectomy,¹¹ and 3.5% of extraction atherectomy.¹² “Bail-out stenting” may make it more difficult to separate CB results with regard to major complications. However, even when “bail-out stenting” cases (2 patients) were included, the major complication rate for CB angioplasty was only 2.7%—the same as recently reported for conventional angioplasty (3.5%).⁸

Procedural Advantage

The likelihood of CB angioplasty decreasing the procedure time became clear in our Studies I and II in comparison with conventional angioplasty. Moreover, new debulking devices, such as directional coronary atherectomy, are more time con-

FIG. 3 Cumulative distribution curve of percent diameter stenosis in the cutting balloon group (A) and in the percutaneous transluminal coronary angioplasty group (B). ○ = pre-angioplasty, △ = follow-up, □ = postangioplasty.

suming and difficult even for the experienced operator.⁹ Cutting balloon angioplasty does not require extensive preparation time and takes less time to treat the lesion than do new debulking devices.

Feasibility of Reducing Restenosis

Conventional angioplasty still has several unsolved problems in spite of improved balloons and advanced techniques. Coronary restenosis within 3 or 4 months after balloon angioplasty remains one of the most important problems. New interventional devices such as directional coronary atherectomy were expected to reduce the restenosis rate by debulking atheroma with resultant larger luminal diameters. However, the clinical results have been disappointing.^{9,10} A major cause of restenosis is neointimal thickening; deeper tissue resection, which stimulates neointimal proliferation, may be associated with higher restenosis.^{13–16} Barath *et al.*² therefore assumed that postcutting dilatation of the lesion leads to less intimal injury and less neointimal proliferation, which may be confirmed in our Study II. The restenosis rate for CB angioplasty was significantly lower than conventional angioplasty. Those cases without predilatation and/or postdilatation had restenosis rates that were considerably lower, and we considered those lesions treated by CB alone to be less damaged. Study II also supports Barath *et al.*'s hypothesis that acute gain in the CB group was significantly larger than that in the

PTCA group, and that late losses at follow-up were virtually identical in both groups.² This resulted in a larger MLD at follow-up in the CB group even though it was not significant. Various stents have recently appeared, and some of their results showed remarkable restenosis rates.⁷ For a few B2 or C lesions, only stent implantation resulted in a larger lumen, and we would expect those restenosis rates to be lower. Multiple stent deployment, however, may preclude future surgical options or jail major side branches, thereby causing difficulties in treatment by balloon. Moreover, deciding on therapy for treatment of restenosis within a stent is difficult. These problems may cause controversy over stenting in de novo lesions even when stents become less thrombogenic. Most lesions, on the other hand, remain good candidates for conventional and CB angioplasty, though severely calcified lesions and small vessels (diameter < 2.0 mm) were difficult to treat with CB angioplasty. When we can anticipate that good results can be obtained with respect to restenosis, without stenting, in type A and B lesions, CB angioplasty should be considered as a first-choice procedure.

Conclusions

The cutting balloon has several clinical limitations. This study, however, suggests that cutting balloon techniques can be substituted for conventional balloon angioplasty. We feel that randomized trials of conventional angioplasty versus cutting balloon now being done in Japan and in the U.S. are both timely and appropriate.

References

1. Lary BG: Coronary artery incision and dilatation. *Arch Surg* 1980; 115:1478–1480
2. Barath P, Fishbein MC, Vari S, Forrester JS: Cutting balloon: A novel approach to percutaneous angioplasty. *Am J Cardiol* 1991; 68:1249–1252
3. Waller BF: "Crackers, breakers, stretchers, drillers, scrapers, shavers, burners, welders and melters"—the future treatment of atherosclerotic coronary artery disease? A clinical-morphologic assessment. *J Am Coll Cardiol* 1989; 13:969–987
4. Unterberg C, Buchwald AB, Barath P, Schmidt T, Kreuzer H, Wiegand V: Cutting balloon coronary angioplasty: Initial clinical experience. *Clin Cardiol* 1993; 16:660–664
5. Reiber JHC, van der Zwet PMJ, von Land CD, Koning G, van Meurs B, Buis B, van Voorthuisen ADE: Quantitative coronary arteriography: Equipment and technical requirements. In *Advances in Quantitative Coronary Arteriography* (Eds. Reiber JC, Serruys PW), p. 75. Dordrecht, the Netherlands: Kluwer Academic Publishers, 1992
6. Hausleiter J, Nolte CWT, Jost S, Wiese B, Sturm M, Lichtlen PR: Comparison of different quantitative coronary analysis systems: ARTREK, CAAS, and CMS. *Cathet Cardiovasc Diagn* 1996; 37: 14–22
7. Kimura T, Nosaka H, Yokoi H, Iwabuchi M, Nobuyoshi M: Serial angiographic follow-up after Palmaz-Schatz stent implantation: Comparison with conventional balloon angioplasty. *J Am Coll Cardiol* 1993; 21:1557–1563
8. Ellis SG, Cowley MJ, Whitlow PL, Vandormael M, Lincoff AM, DiSciascio G, Dean LS, Topol EJ: Prospective case-control comparison of percutaneous transluminal coronary revascularization in patients with multivessel disease treated in 1986–1987 versus 1991: Improved in-hospital and 12-month results. *J Am Coll Cardiol* 1995; 25:1137–1142
9. Holmes DR Jr, Topol EJ, Adelman AG, Cohen EA, Califf RM: Randomized trials of directional coronary atherectomy: Implications for clinical practice and future investigation. *J Am Coll Cardiol* 1994; 24:431–439
10. Topol EJ, Leya F, Pinkerton CA, Whitlow PL, Hofling B, Simon-ton CA, Ronald R, Masden RR, Serruys PW, Leon MB, Williams DO, King SB III, Mark DB, Isner JM, Holmes DR Jr, Ellis SG, Lee KL, Keeler GP, Berdan LG, Hinojara T, Califf RM: A comparison of directional atherectomy with coronary angioplasty in patients with coronary artery disease. *N Engl J Med* 1993; 329:221–227
11. Warth DC, Leon MB, O'Neill W, Zacca N, Polissar NL, Buch-binder M: Rotational atherectomy multicenter registry: Acute results, complications and 6-month angiographic follow-up in 709 patients. *J Am Coll Cardiol* 1994; 24:641–648
12. Annex BH, Sketch MH Jr, Stack RS, Phillips HR III: Transluminal extraction coronary atherectomy. *Cardiol Clin* 1994; 12:611–622
13. Schwartz RS, Huber KC, Murphy JG, Edwards WD, Camrud AR, Vliestra RE, Holmes DR: Restenosis and the proportional neointimal response to coronary artery injury: Results in a porcine model. *J Am Coll Cardiol* 1992; 19:267–274
14. Beatt KJ, Serruys PW, Luijten HE, Rensing BJ, Suryapranata H, de Feyter P, van den Brand M, Laarman GJ, Roelandt J, van Es GA: Restenosis after coronary angioplasty: The paradox of increased lumen diameter and restenosis. *J Am Coll Cardiol* 1992; 19:258–266
15. MacLeod DC, Strauss BH, de Jong M, Escaned J, Umans VA, van Suylen R-J, Verkerk A, de Feyter PJ, Serruys PW: Proliferation and extracellular matrix synthesis of smooth muscle cells cultured from human coronary atherosclerotic and restenotic lesions. *J Am Coll Cardiol* 1994; 23:59–65
16. Taylor AJ, Farb AA, Angello DA, Burwell LR, Virmani R: Proliferative activity in coronary atherectomy tissue. *Chest* 1995; 108: 815–820