Comparison of Cutting Balloon vs Stenting Alone in Small Branch Ostial Lesions of Native Coronary Arteries

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Angioplasty of small vessels is associated with a higher rate of restenosis, even in the ostium. The present study compared the acute, late results of cutting balloon vs those of stenting alone in small branch ostial lesions of native coronary arteries and the effect on the parent vessel. The study group comprised 61 patients with successful angioplasty of smaller branch ostial lesions in native coronary arteries. The reference vessel diameter was between 2.5 and 3.0 mm. Patients were divided into 2 groups: group I (cutting balloon, n=30) and group II (stenting alone, n=31). After intervention, patients in group II achieved significant acute lumen gain, larger minimal lumen diameter (MLD) and less diameter stenosis. At 3-month follow-up, the MLD and diameter stenosis of the 2 groups were almost identical; however, late loss was lower in group I. At the 6-month follow-up, the cumulative restenosis rate was 41% (11/27) in group I compared with 63% (19/31) in group II (p=0.05), and the target lesion revascularization was also lower in the cutting balloon group [29% (8/27) vs 53% (16/30) p=0.05]. In group I, the MLD of the parent vessel did not change before, after cutting balloon or at follow-up. In contrast, there were significant reductions in parent vessel MLD following stenting alone and at follow-up. Plaque shift did not occur in the cutting balloon group. Cutting balloon angioplasty is a feasible approach for the treatment of small branch ostial lesions and does not cause significant narrowing of the parent vessel.  

Key Words: Cutting balloon; Ostium; Stent

The treatment of native coronary ostial stenosis with balloon angioplasty (PTCA) has been associated with lower rates of procedural success, higher risk of serious complications, suboptimal dilatation because of elastic recoil and spasm, and a higher rate of restenosis. Attempts to overcome this problem with laser-based systems or by rotational atherectomy have also been disappointing, particularly with regard to the rate of restenosis. Intracoronary stents have significantly altered the outcome of percutaneous intervention for ostial lesions. Coronary stenting reduces restenosis in focal de novo lesions, compared with balloon angioplasty; however; restenosis in ostial lesions, especially small branch ostial lesions, remains a problem. The cutting balloon is useful for ostial lesions as compared with plain old balloon angioplasty and might be a better option than conventional balloon for revascularizing vessels smaller than 3 mm in diameter. Cutting balloon angioplasty followed by stent insertion is also a feasible technique for the treatment of aorto-ostial lesions. The purpose of this study was to evaluate and compare the acute and follow up results of stenting alone vs cutting balloon with stent support for the treatment of small branch ostial lesions of native coronary arteries.

Methods

Study Population
From January 1998 through 2001, we performed cutting balloon angioplasty in 220 de novo lesions, 50 of which were ostial stenosis, and 30 branch ostial lesions in 30 patients were regularly followed up. During the same time, 896 stents were delivered in de novo lesions and 115 lesions were ostial in origin; of these, 31 branch ostial lesions in 31 patients were regularly followed up. A branch ostial lesion was defined as a lesion ≥70% diameter stenosis involving the coronary ostium and arising within 0.3 cm of the bifurcation of a large epicardial coronary artery. The patients were recruited according to these criteria: (1) both of the following: 2.5 mm ≤ reference diameter ≤ 3.0 mm and diameter stenosis ≥70% (2) no myocardial infarction within the previous week; and (3) clinical or functional evidence of ischemia. Angiographic follow-up was requested at 3 and 6 months. The lesions had to be judged suitable for both angioplasty techniques and the initial assigned strategy was according to the surgeon’s decision. Two groups of consecutive patients with small (diameter between 2.5 and 3.0 mm) branch ostial disease were compared: Group 1 comprised patients treated with cutting balloon with or without adjunctive balloon or stent, and Group 2 comprised patients treated with stent alone. Neither debulking nor cutting balloon was done before stenting.

Definitions

Procedural Success residual stenosis < 50% without cardiac complications.

Angiographic Restenosis > 50% diameter stenosis at the treated site at follow-up.
Procedural Details

The size of the cutting balloon (Interventional Technologies, Europe) was selected according to an estimated diameter cutting balloon/reference artery ratio between 1:1 and 1.0. The length of the cutting balloon, 10 or 15 mm, was chosen on the basis of the length of the target stenosis. The cutting balloon was advanced over a 0.014-inch guidewire and then gradually inflated to reach 6–10 atm. Adjunctive balloon or stent was delivered if the cutting balloon failed to dilate the lesion and 8/30 (26%) lesions were stented because of suboptimal or failed treatment by cutting balloon.

Quantitative Coronary Angiographic Analysis

Coronary angiography was performed after intracoronary administration of nitroglycerin. Using the guiding catheter for magnification calibration, off-line computerized quantitative coronary angiographic measurements were performed with the CMS system (version 4.0, MEDIS). The percent diameter stenosis, minimal luminal diameter (MLD) and reference vessel diameter were measured before and after the intervention and at follow-up from diastolic frames in a single, matched view showing the smallest luminal diameter.

Post Procedure Management and Follow-up

Therapy with aspirin (80 mg/day) and ticlopidine (300 mg/day) was begun before and continued after the procedure in both groups. Patients were asked to return for angiographic follow-up at 3 and 6 months.

Statistics and Data Management

Statistical analyses were performed using the SPSS Windows statistical package (SPSS Inc, Chicago, IL, USA). Categorical variables, given as counts (percentage) were assessed by chi-square or Fisher’s test (when the expected frequency of a cell was <5). Continuous variables were expressed as mean ± SD was compared using unpaired Student’s t test. Within-group comparisons of continuous variables were obtained using Student’s paired t test. A p<0.05 was considered significant.
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Results

Demographics and Clinical Characteristics (Table 1)
There were more, but not significantly, men in the cutting balloon group (70% vs 58%, p=0.10), and there were more patients with diabetes mellitus not significantly involved in the cutting balloon group. Other clinical characteristics were compatible between the 2 groups. In the cutting balloon group, a stent was delivered in 8 lesions (26%).

Quantitative Angiography (Table 2)
The reference vessel diameter and lesion length before intervention were comparable between the 2 groups. The MLD was smaller in the stenting alone group (0.53±0.33 vs 0.65±0.20 mm, p=0.14) and the diameter stenosis was higher in the stenting alone group (13.7±10.4 vs 9.3±9.4). Larger inflation pressure was used in the stenting alone group (2.57±0.64 vs 2.56±0.67 atm, p=0.002). After intervention, the stenting alone group had significant acute lumen gain (2.09±0.51 vs 1.61±0.61 mm, p=0.007), larger minimal lumen diameter (2.62±0.49 vs 2.27±0.58 mm, p=0.01) and less diameter stenosis (7.7±12.9 vs 17.0±19.6%, p=0.03). At 3 months follow-up, the cutting balloon group had less late loss (0.70±0.71 vs 1.23±0.74 mm, p=0.006) and a lower loss index (0.45±0.47 vs 0.62±0.40, p=0.14).

Restenosis and Target Lesion Revascularization Rate (TLR): 3 and 6 months Follow-up (Table 3)
Regarding the angiographic and clinical outcomes, the cutting balloon group had a restenosis rate of 37% (11/30) compared with 55% (17/31) in the stenting alone group (p=0.15) and had a TLR rate of 27% (8/30) compared with 45% (14/31) in the stenting alone group (p=0.13) at 3 month follow-up. During the 6 months follow up, 2 cases in the stenting alone group developed delayed restenosis.

The cumulative restenosis rate was 41% (11/27) in Group I compared with 63% (19/31) in the Group II (p=0.05), and the TLR was also lower in the cutting balloon group [29% (8/27) vs 53% (16/30) p=0.05].

Influence of Procedure on Parent Vessel or Another Side Branch
There were 9 cases in Group I and 10 cases in group II with stenosis in another side branch ostium. The influence of the treatment of the branch ostium on another side branch or parent vessel was studied after excluding the aforementioned cases; the results of the analysis are shown in Table 4 and Fig 1. In the cutting balloon group, the MLD of the other side branch or parent vessel did not change before, after or at follow up (pre-intervention 2.61±0.62 mm; post-intervention 2.57±0.64 mm; follow-up 2.56±0.67 mm, p=NS). In contrast, there was a significant reduction of the MLD of the other side branch ostium or parent vessel following stenting alone (pre-intervention 2.52±0.42 mm; post-intervention 2.28±0.58 mm; follow-up 2.04±0.74 mm, p=0.01). There were 5 cases of plaque shift after stent placement in the stenting alone group, but plaque shift did not occur in the cutting balloon group (p=0.02).

Cutting Balloon Alone vs Combined Cutting Balloon and Stenting
Stents were delivered in 8/30 (26%) lesions because of suboptimal or failed treatment after cutting balloon. At 3

Table 3 Three and 6 Months Follow-up of Branch Ostium Lesions

<table>
<thead>
<tr>
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<th>Cutting balloon</th>
<th>Stent alone</th>
<th>p value</th>
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<tbody>
<tr>
<td>3 month follow-up</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>30</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Restenosis</td>
<td>11 (37%)</td>
<td>17 (55%)</td>
<td>0.15</td>
</tr>
<tr>
<td>TLR</td>
<td>8 (27%)</td>
<td>14 (45%)</td>
<td>0.13</td>
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<tr>
<td>6 month follow-up</td>
<td></td>
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<tr>
<td>Cumulative N</td>
<td>27</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Cumulative restenosis</td>
<td>11 (41%)</td>
<td>19 (63%)</td>
<td>0.05</td>
</tr>
<tr>
<td>Cumulative TLR</td>
<td>8 (29%)</td>
<td>16 (53%)</td>
<td>0.05</td>
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</table>

TLR, target lesion revascularization.

Table 4 Quantitative Angiographic Diameter and Side Effect on Another Side Branch or Parent Vessel

<table>
<thead>
<tr>
<th></th>
<th>Cutting balloon (n=19)</th>
<th>Stenting alone (n=20)</th>
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</thead>
<tbody>
<tr>
<td>Pre-intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference diameter, mm</td>
<td>3.03±0.65</td>
<td>2.78±0.40</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>2.61±0.62</td>
<td>2.52±0.42</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>13.7±10.4</td>
<td>9.3±9.4</td>
</tr>
<tr>
<td>Post-intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference diameter, mm</td>
<td>3.02±0.62</td>
<td>2.95±0.66</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>2.57±0.64</td>
<td>2.56±0.67</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>15.0±10.6</td>
<td>13.5±10.8</td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
<td></td>
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<tr>
<td>Reference diameter, mm</td>
<td>2.81±0.43</td>
<td>2.75±0.47</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>2.28±0.58</td>
<td>2.04±0.74</td>
</tr>
<tr>
<td>Diameter stenosis, %</td>
<td>19.1±14.1</td>
<td>26.7±21.0</td>
</tr>
</tbody>
</table>

MLD; minimal luminal diameter.

Fig 1. Changes in the minimal lumen diameter of the other side branch ostium or parent vessel before intervention (Before), after intervention (After) and at follow up (repeat angiography). The diameter was unchanged by cutting balloon, but was narrowed by stenting alone.
for every given amount of short-term gain in the cutting alone group. Fig 1 shows that the late lumen loss was lower lumen gain, the late loss was also greater in the stenting patency, residual narrowing often remains.

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Discussion

Conventional balloon angioplasty is ineffective in treating ostial lesions because of high rates of immediate recoil and long-term restenosis. The higher concentration of elastic and muscle fibers around the ostium is the cause of the recoil after balloon inflations.

Recent studies have shown that both stenting alone and directional coronary atherectomy achieve superior angiographic results with a higher success rate than PTCA.

However, the larger debulking devices are not suitable for small branch ostial stenoses. The present study confirms that either stenting alone or in combination with cutting balloon for small branch ostial lesions is a safe and effective treatment with acceptable angiographic results. The branch ostial lesions frequently involve the bifurcation, either because the disease extends into the bifurcation or because placement of the stent too proximally may entrap another vessel (That can be confirmed if intracoronary ultrasound (IVUS) is performed post stent deployment.).

Under the guidance of IVUS, the stents can be dilated with a larger balloon or higher pressure, which may result in a larger acute gain of lumen diameter and less residual steno-

sis in the stenting alone group.

The mechanical scaffold of the stent freezes the lumen gain obtained after balloon dilatation, virtually eliminating mural recoil. The outward extrusion of the plaque during balloon dilatation is limited by the mechanical resistance of the fibrous adventitial layers and results in the axial redistribution of plaque. Plaque shift and edge tears are likely to be the major causes of focal restenosis at the stent edges. Another more evident consequence of plaque shift after stenting is compromise of the ostium of side branches originating from the stented segment. This will induce severe narrowing or occlusion of the side branches, especially in the presence of a pre-existing ostial narrowing. Although dilatation through the stent struts may restore side-branch patency, residual narrowing often remains.

Although the stenting alone group could get larger acute lumen gain, the late loss was also greater in the stenting alone group. Fig 1 shows that the late lumen loss was lower for every given amount of short-term gain in the cutting balloon group. Stenting of small coronary arteries is not a generally accepted practice because despite a successful procedure, a higher restenosis rate is expected if the small vessel size limits the achievement of a sufficiently large MLD.

The longitudinal blades on the cutting balloon concentrate the dilatation force, enabling the more resistant stenoses to be overcome. The more organized approach to plaque disruption because of the alignment of the blades can produce the desired increase in luminal cross-sectional area without extensive intraplaque disruption:21 The longitudinal, microsurgical incisions in the vessel wall before the actual dilatation may produce less vessel wall injury and, consequently, less neutrophil activation, which may also reduce restenosis and improve long-term outcomes.22,23

The postprocedural residual stenosis was higher in the cutting balloon group (17.2±21.5% vs 6.4±13.1%, p=0.04). The degree of postprocedural residual stenosis after cutting balloon angioplasty is predictive of late restenosis24 and to decrease the restenosis rate, it is important to optimize the angiographic result after cutting balloon angioplasty with adjunctive balloon or stenting. A case example of cutting balloon used in a branch ostial lesion is shown in Fig 3.

Study Limitations

This study represents a single center, nonrandomized, retrospective study and, therefore, has several limitations. First, the number of patients is relatively small. Second, no other control group using conventional balloon to dilate the ostial lesion was involved in this study. Third, there were 4 cases of CTO in the stenting alone group, which might in-
crease the restenosis rate. Finally, conventional balloon or stent was used after cutting balloon angioplasty to optimize the angiographic result. The ‘pure’ effect of cutting balloon is not known from this study.

References


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