Limited Balloon Expansion Through the Struts of the Palmaz-Schatz and NIR Stents Compared With the Multi-Link Stent

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After placing a stent in the main vessel of a bifurcation lesion, it is sometimes necessary to perform further balloon inflation in order to treat an ostial lesion in a side branch. The stent struts may prevent full balloon expansion at the ostium of a side branch, resulting in residual ostial stenosis. The degree of completeness of balloon inflation may vary significantly depending on the stent design and structure. A model of a bifurcation lesion with an angle of 45° was created from acrylic resin. The diameters of the main vessel and the side branch were both 3.5 mm. Deployment of the Palmaz-Schatz stent (n=5), NIR stent (n=5) or Multi-Link stent (n=5) was performed in the main vessel with a 3.5-mm balloon catheter inflated to 12 atm. A 3.5-mm balloon catheter was then inflated to 12 atm through the stent struts of the main vessel and into the ostium of the side branch. The degree of completeness of balloon inflation (% balloon expansion) was calculated as (smallest diameter of balloon catheter/reference diameter of balloon catheter)×100%. The minimal lumen diameter (MLD) and cross-sectional area (CSA) at the ostium of the side branch created with the stent struts were also measured. Limited balloon expansion through the struts was observed with the Palmaz-Schatz stent and the NIR stent, but almost full balloon expansion was observed with the Multi-Link stent (% balloon expansion: Palmaz-Schatz stent 80%, NIR stent 60%, Multi-Link stent 94%, p<0.01). The MLD and CSA of the dilated struts, representing the ostium of the side branch, of the Palmaz-Schatz stent (2.2±0.1 mm, 4.5±0.3 mm²) and the NIR stent (1.8±0.1 mm, 3.1±0.3 mm²) were significantly smaller compared with those of the Multi-Link stent (3.0±0.2 mm, 8.4±0.6 mm²) (p<0.01). The struts of the Palmaz-Schatz stent and the NIR stent deployed in the main vessel of a bifurcation prevent full expansion of a balloon catheter inflated at the side branch ostium. In contrast, almost full balloon expansion through the struts of the Multi-Link stent is achieved. (Jpn Circ J 2000; 64: 883–885)

Key Words: Angioplasty; Bifurcation; Coronary artery disease; Stent

Because randomized studies have shown a lower restenosis rate in focal coronary artery lesions with coronary stenting compared with conventional balloon angioplasty; indications for stenting are expanding to include complex lesions.4

One of the most complex and challenging cases where stents are now utilized is the bifurcation lesion.4 After stenting in the main vessel of a bifurcation lesion, balloon inflation through the stent struts may sometimes be necessary in order to treat an ostial lesion in a side branch.5 However, the stent struts may prevent full balloon expansion at the ostium of a side branch, resulting in residual ostial stenosis. Various stent types are used in treating bifurcation lesions and when balloon inflation is performed through the stent struts, the degree of completeness of balloon inflation may depend in no small part on the design and structure of the stent. The present study compared the degree of completeness of balloon inflation through the struts of the Palmaz-Schatz, NIR and Multi-Link stents.

Methods

A model of a bifurcating vessel with an angle of 45° was created from acrylic resin (Fig 1). The diameters of the main vessel and the side branch were both 3.5 mm. Acrylic resin material was used because this rigid model allowed correct expansion of the stents to the 3.5 mm diameter. A 0.014-inch Balance guidewire (Guidant, Santa Clara, CA, USA) was advanced into the main vessel. The Palmaz-Schatz stent (n=5) (Johnson & Johnson Interventional Systems, Warren, NJ, USA), the NIR stent (n=5) (Medinol, Jerusalem, Israel), and the Multi-Link stent (n=5) (Guidant) were each deployed in the main vessel, using a 3.5-mm Power Press balloon catheter (Terumo, Tokyo, Japan) inflated to 12 atm, in such a way as to cover the ostium of the side branch. When the Palmaz-Schatz stent was deployed, we avoided placing the articulation of that stent over the ostium of the side branch. Another 0.014-inch Balance guidewire was then advanced into the side branch through the stent struts. Under fluoroscopy, a 3.5-mm Power Press balloon catheter was then inflated to 12 atm at the ostium of the side branch for a further 2 min. Cine-film was taken immediately before balloon deflation (Fig 2A-C). Quantitative analysis was performed with an automated computer-based system (CCP310W, Cathex, Tokyo, Japan). The proximal and distal diameters of the inflated balloon catheter were measured as references. The smallest diameter of the balloon catheter at the ostium of the side branch was also measured. Next, the degree of completeness of balloon inflation was calculated as (smallest diameter/mean of references)×100%. After the stent was removed from the model, the dilated stent struts representing the ostium of the side branch (Fig 3A–C) were photographed at ×10 magnification. The minimal lumen

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Fig. 1. Acrylic resin model of a bifurcating vessel with an angle of 45°. The diameter of both the main vessel and the side branch is 3.5 mm.

Fig. 2. Balloon catheter expanded through stent struts. (A) Palmaz-Schatz stent, (B) NIR stent, (C) Multi-Link stent. There is limited balloon expansion through the struts of the Palmaz-Schatz and NIR stents, but almost full balloon expansion through the struts of the Multi-Link stent is observed.

Fig. 3. Stent struts after balloon inflation through the struts. (A) Palmaz-Schatz stent, (B) NIR stent, (C) Multi-Link stent. The diameter and cross-sectional area of the struts of the Palmaz-Schatz and NIR stents are smaller than the Multi-Link stent.

Table 1. Results

<table>
<thead>
<tr>
<th></th>
<th>PS (n=5)</th>
<th>NIR (n=5)</th>
<th>Multi-Link (n=5)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>% balloon expansion</td>
<td>92.4%</td>
<td>60.4%</td>
<td>94.4%</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent struts MLD (mm)</td>
<td>2.2±0.1</td>
<td>1.8±0.1</td>
<td>3.0±0.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Stent struts CSA (mm²)</td>
<td>4.5±0.3</td>
<td>3.1±0.3</td>
<td>8.4±0.6</td>
<td>&lt;0.01</td>
</tr>
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PS, Palmaz-Schatz stent; MLD, minimum lumen diameter; CSA, cross-sectional area.

Results

The results are shown in Table 1. Limited balloon expansion through the stent struts was observed with the Palmaz-Schatz and NIR stents (Fig. 2A, B). In contrast, almost full balloon expansion was observed with the Multi-Link stent (Fig. 2C). The MLD and CSA of the dilated struts, representing the ostium of the side branch, of both the Palmaz-Schatz and NIR stents were significantly smaller compared with the Multi-Link stent (Fig. 3A–C). The original shape of the struts of both the Palmaz-Schatz stent and the NIR stent could be vaguely identified, whereas that of the Multi-Link stent could not and the lumen created by balloon inflation was almost round.

Discussion

Clinical and angiographic restenosis rates in large coronary arteries are reduced with coronary stenting compared with conventional balloon angioplasty. The indications for the types of lesions that may be treated with coronary stenting have expanded significantly to include more complex lesion subsets, such as bifurcation lesions. However, when a bifurcation lesion is treated, the side branch may need balloon angioplasty or stent deployment through the struts of the stent placed in the main vessel. This situation may also be encountered when a stent is placed in a main vessel and causes an obstruction of a side branch by the so-called ‘plaque shifting’. Previous studies have shown rates of side branch occlusion of 14–19% after stenting in the main vessel by high-pressure balloon dilatation. The occlusion of small side branches may be well tolerated but that of one supplying a substantial mass of critical myocardium may result in myocardial infarction or ischemia.

A stent deployed across a side branch results in partial blockade of its ostium by the stent struts, which then restricts access to the side branch ('stent jail'). Even though a guidewire and a balloon catheter can cross the struts into the side branch, they may still prevent full balloon expansion. The design and structure of the stent placed in the main vessel therefore play a major role in the expansion of the struts that affects completeness of balloon inflation at the ostium of a side branch. One in vitro study showed limited...
expansion of the struts of the Palmaz-Schatz and NIR stents after balloon inflation through the struts, but, in contrast, a large lumen after balloon inflation through the struts of the Multi-Link stent\textsuperscript{5} The Palmaz-Schatz diamond-shaped strut site has a perimeter of 7.2 mm\textsuperscript{2} so theoretically the MLD of this diamond is less than 2.3 mm, even after it is dilated maximally by balloon inflation. Thus, the limited CSA of the Palmaz-Schatz stent struts results in limited balloon expansion at the side branch ostium.

The second generation NIR and Multi-Link stents are now widely used, but in the present study, the NIR stent had limited strut expansion capability, which resulted in limited balloon expansion through the stent struts. In contrast, the Multi-Link stent struts were expanded to form a large lumen, which allowed almost full expansion of the balloon catheter. A previous study reported acceptable procedural success rates of balloon angioplasty through the struts of the Palmaz-Schatz stent (86%) and the Gianturco-Roubin stent (78%);\textsuperscript{5} however, in that case the procedure was performed in a relative small vessel that had a reference vessel diameter of 1.98±0.54 mm. When the side branch that the operator wishes to approach is small, the effect of the limited expansion of stent struts on the degree of balloon expansion may be less, and as a result there should be no significant residual stenosis at the ostium of the side branch. However, when a side branch is large, the limited expansion of the diamond of the Palmaz-Schatz stent and the cell of the NIR stent prevents full balloon expansion, possibly resulting in residual stenosis and a subsequently higher likelihood of restenosis. In contrast, if balloon inflation is performed through the struts of the Multi-Link stent, nearly complete balloon expansion can be achieved, the result of which will be less residual stenosis, and subsequently a more favorable late outcome.

The major purpose of this study was to evaluate the degree of completeness of balloon inflation through the struts of the 3 different types of stents. However, there are other concerns associated with the limited expansion of the diamond of the Palmaz-Schatz stent and the cell of the NIR stent. Even though a balloon catheter can cross into a side branch, entrapment after deflation might occur, especially when a balloon catheter that has larger profile is used\textsuperscript{5} Stenting through the struts of the stent deployed in the main vessel may be required in a true bifurcation lesion or a lesion created by plaque shift. Even if predilatation is performed at the side branch ostium, the limited expansion of the stent struts may make it difficult to deliver another stent through the existing stent struts.

Study Limitations

Several limitations should be noted when interpreting the results of this study.

1. This is an in-vitro study; true lesions treated with stents have atherosclerotic plaque. If this in-vitro model had atherosclerotic plaque, higher residual stenosis at the ostium of a side branch could be expected.

2. Balloon catheters in the side branch were inflated to 12 atm. Lower inflation pressure is usual for balloon angioplasty and therefore less balloon expansion through the struts of the Palmaz-Schatz stent and the NIR stent would be observed.

3. Cine-film showing the completeness of balloon inflation was taken from one angle. Because the diamond or cell of the stent is not round, the degree of completeness of balloon inflation from other angles might be different. Nevertheless, differences in the CSA of the dilated struts among the 3 stents were revealed.

4. Because coil stents have less metal, full balloon expansion through the struts of a coil stent might be achieved. In the present study, we did not evaluate coil stents because they are rarely used due to higher restenosis rates.\textsuperscript{11}

Conclusions

The struts of the Palmaz-Schatz stent and the NIR stent deployed in the main vessel of a bifurcation prevent full expansion of a balloon catheter inflated at a side branch ostium. In contrast, almost full balloon expansion through the struts of the Multi-Link stent can be achieved.

References


