Six-Month Intravascular Ultrasound Follow-up of Coronary Bifurcation Lesions Treated With Rapamycin-Eluting Stents: Technical Considerations

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Introduction and objectives. In vitro studies show that stents deform when dilated laterally to access a side branch. This phenomenon may be avoided by use of a kissing balloon at the end of the procedure. However, to date, no in vivo data are available. Our objectives were to investigate the main vessel stent using intravascular ultrasound (IVUS) at six-month follow-up in 55 patients with bifurcation lesions treated using rapamycin-eluting stents and to examine the effect of technical factors.

Patients and method. All patients were treated using provisional or T stents. At 6 months, IVUS measurements were made in the main vessel at both proximal and distal ends of the stent, in reference segments, immediately below the side branch ostium, and at the points where the lumen was smallest and where stent expansion was greatest.

Results. The lumen area immediately below the side branch ostium was significantly smaller than that at the point of maximum stent expansion (6.7 [1.8] vs 5.1 [1.3] mm^2; *P*<.05). Underexpansion was not influenced by use of a kissing balloon (stent area immediately under the side branch ostium: 5.5 [0.9] vs 5.6 [1.6] mm^2; *P*=NS) and only one patient experienced restenosis at this point. The lumen areas at the proximal and distal edges of the stent were almost identical in patients who did or did not undergo balloon dilation beyond the ends of the stent.

Conclusions. Stent underexpansion below the side branch ostium was frequently found following provisional or T stenting of bifurcation lesions. This minor stent deformity was not prevented by use of a kissing balloon nor by any specific side branch treatment and had no significant impact on the restenosis rate.

Key words: *Rapamycin-eluting stent. Bifurcation lesion. Intravascular ultrasound.*

SEE EDITORIAL ON PAGES 1261-5

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Ecografía intracoronaria durante el seguimiento en la valoración de *stents* liberadores de rapamicina para el tratamiento de las lesiones en bifurcación: implicaciones técnicas

Introducción y objetivos. Los estudios *in vitro* han mostrado que el *stent* se deforma cuando se dilata lateralmente para acceder a un ramo colateral. Así, se han propuesto algunas técnicas para evitar este fenómeno; sin embargo, no hay información *in vivo* disponible. El objetivo es investigar los hallazgos ultrasónicos a los 6 meses en 55 pacientes con lesiones localizadas en bifurcación tratados mediante *stents* de rapamicina.

Pacientes y método. Todos los pacientes fueron tratados con *stent* en el vaso principal y *stent* o dilatación con balón en el ramo colateral. Se analizaron los bordes del *stent,* los segmentos de referencia, el diámetro mínimo de la luz, el punto inmediatamente tras la salida del ramo colateral y el *stent* en el punto de máxima expansión.

Resultados. El área de la luz en el punto inmediatamente tras la salida del ramo colateral fue significativamente más pequeña que en el punto de máxima expansión (6,7 ± 1,8 frente a 5,1 ± 1,3 mm^2; p < 0,05). Esta inexpansión del *stent* no estuvo influida por el uso del inflado simultáneo de balones al final del procedimiento (área del *stent* inmediatamente bajo el origen del ramo colateral, 5,5 ± 0,9 frente a 5,6 ± 1,6 mm^2; p = NS). El área de la luz en los bordes fue prácticamente idéntica entre pacientes con y sin inflado de balón más allá de los límites del *stent.*

Conclusiones. Cierto grado de inexpansión del *stent* inmediatamente después de la salida del ramo colateral fue un hallazgo frecuente en pacientes con bifurcaciones tratados con *stents* en el ramo principal y *stent* provisional en el ramo colateral. Esta deformidad no fue prevenida por variables técnicas y no tuvo un impacto significativo en la incidencia de reestenosis.

Palabras clave: Stent *de rapamicina. Lesiones coronarias en bifurcación. Ecografía intracoronaria.*

INTRODUCTION

During the percutaneous treatment of a bifurcation lesion, the main vessel stent is necessarily deformed when the side branch (SB) is dilated through the stent struts. Bench studies have been performed[1-3] and certain theoretical considerations may be drawn from them. However, there are no in vivo follow-up studies that focus on the technical strategies that might preserve original main vessel stent geometry, or on the impact the degree of this stent deformation may have on late patient outcome. The purpose of this study is to investigate the 6-month intravascular ultrasound (IVUS) appearance of the parent vessel stent in patients with bifurcation lesions treated in the era of drug-eluting stents as well as the influence of technical factors on IVUS parameters.

PATIENTS AND METHOD

Patients

Our series comprises 55 patients with bifurcation lesions treated by rapamycin-eluting stents (RES) between June 2002 and June 2004 who had 6 month angiographic and ultrasonic re-evaluation. All patients fulfilled the following inclusion criteria: *1*) lesion located in a major bifurcation point regardless of morphology and angulation; *2*) main vessel >2.5 mm diameter; *3*) SB≥2.25 mm diameter; *4*) significant stenosis in both main vessel and SB origin. Patients with diffuse SB lesions were excluded. Written informed consent was obtained from all patients.

Procedure

The technique of RES implantation has been described previously.[4,5] Balloon dilation of the SB or of the both vessels was performed first, followed by RES deployment in the parent vessel. The SB was then re-wired and balloon dilation of the ostium was repeated across the metallic structure of the stent. Whether to stent the SB origin or not was dictated by a randomization process between June 2002 and April 2003, and according to the criteria of the operator in patients treated between June 2003 and June 2004, so all our patients were treated with provisional or T stenting. The decision to perform final kissing balloon or balloon dilation beyond the stent limits was at the discretion of the operator. The same balloon used for stent deployment at the main vessel was also used for the final kissing balloon inflation with a second balloon of the same diameter as the reference SB. The inflation pressure was lower than for stent deployment (6-12 atmospheres). The balloon/artery ratio for each distal branch was close to 1. In the hemodynamic laboratory, patients received a bolus of 1-2 mg/kg of intravenous unfractionated heparin continuing with low-molecular-weight heparin (Fragmin®) 10 000 IU anti–Xa/day, ticlopidine 500 mg/day, and aspirin 150 mg/day for the first month. After this initial regimen, patients continued with clopidogrel and aspirin for 1 year. Protamine was administered at the end of the procedure allowing immediate removal of the femoral sheath. We used the CAAS II version 4.1.1 (Pie Medical Imaging, Maastricht, Netherlands) for quantitative coronary angiography, with the dye-filled catheter as a reference. Quantitative parameters were obtained at baseline condition, immediately post-procedure and at follow-up.

Follow-up Study

Patients were followed up closely by telephone and further cardiac catheterization was scheduled at 6-month evaluation or earlier in the presence of symptoms. Quantitative coronary angiography was performed at follow-up and quantitative measurements were obtained in the same selected view. Restenosis was defined as a >50% stenosis at follow-up.

All IVUS studies were obtained after a bolus (450 µg) of intracoronary nitroglycerin. A 64-element, 3.5 F monorail catheter (EndoSonics®) was used in every study. Intrastent ultrasound-measurements were obtained in the main vessel at the edges, at the minimal lumen diameter, immediately under the SB origin and at the maximal stent diameter. Proximal and distal references were examined at 1 cm from the stent borders. The following measurements were obtained at each site: external elastic lamina area, stent area and lumen area.

Statistics

Data are expressed as mean±standard deviation. A Student-Fisher unpaired *t* test was used to compare quantitative data from different groups of patients. Linear correlation between balloon inflation pressures and IVUS parameters was assessed with the Pearson correlation coefficient (*r*). A value of $P<.05$ was considered statistically significant.

RESULTS

Baseline and Procedural Data

Baseline clinical data are shown in Table 1. Most of patients presented an unstable clinical condition at hospital admission and 26 were diabetics. The bifurcation site was most frequently located at the left anterior descending artery/diagonal branch. The angiographic and procedural characteristics are summarized in Table 2. The use of platelet glycoprotein IIb/IIIa inhibitors at the discretion of the researchers was used in 53% of the patients.