The minimum in-stent lumen diameter is a predictor of restenosis. Stent dimensions provided by manufacturers are derived from in vitro tests. The aim of this study was to compare actual stent dimensions obtained by angiography and intracoronary ultrasound with dimensions that would be expected theoretically for a given inflation pressure in a cohort of 100 non-complex lesions suitable for direct stenting. Significant differences were found between the theoretical diameters and those observed by angiography and ultrasound. The actual-to-theoretical diameter ratio was 0.83 (0.09) when measured using angiography and 0.78 (0.10), using intravascular ultrasound. In lesions without severe calcification, stent dimensions were significantly smaller than indicated by the manufacturer. Nominal figures should not be used as reference values for stent implantation.

**Key words:** Stent. Intracoronary ultrasound. Coronary angiography.

**INTRODUCTION**

In-stent restenosis is a problem that results in repeated treatment procedures and additional related costs. In 1992, Kuntz et al. showed that the most important predictor of restenosis is post-stenting minimum lumen diameter (MLD).

Stent manufacturers provide tables to correlate stent diameter to pressure, as determined from in vitro experiments. These tables are often used in clinical practice to calculate the implant pressure. Data are available regarding the inconsistencies between the theoretical and actual measurements by quantitative coronary angiography (QCA) following stent implantation. However, no intravascular ultrasound studies have been conducted to investigate this discrepancy. The purpose of this study was to compare the expected data in noncomplex lesions with the actual post-stenting dimensions obtained by QCA and IVUS.

**METHODS**

**Design**

A prospective cohort study developed from the results of another published study, which compared...
direct stent deployment with predilatation and concluded that there were no differences between the methods. The inclusion and exclusion criteria and the description of the procedure have been described previously.

For the current study, the 100 lesions were grouped into a cohort and the stent dimensions indicated by the manufacturer were compared to the actual dimensions obtained by QCA and IVUS. The influence of stent diameter on these differences and the correlation between angiographic restenosis at 6 months and the three parameters investigated was then analyzed.

Definitions

Calcification (Assessed by Fluoroscopy)

- Mild: single or multiple circumscribed, nonlinear calcium densities, located in the treated lesion.
- Moderate: linear calcium density located on a single side of the treated lesion and not visible on the still image obtained by fluoroscopy.
- Severe: linear calcium density located on both sides of the treated lesion and visible on fluoroscopy, including the still image.

Restenosis

Stenosis >50% on follow-up by QCA.

Statistical Analysis

Continuous variables are expressed as mean ± standard deviation and qualitative variables, as absolute value and percentage. Student’s t test was used to compare continuous variables. Linear regression analysis was performed to assess the influence of vessel size on the differences between theoretical and actual measurements, and the correlation between the incidence of restenosis and the three measurement parameters studied was analyzed. P-values <.05 were considered to be statistically significant.

RESULTS

The data correspond to 82 patients and 99 lesions; in 1 patient who had undergone dilatation of 2 lesions, IVUS was unsuccessful because of a tortuous vessel. Table 1 describes the patient characteristics, lesions, and procedural data.

Table 2 indicates the diameters and areas determined by IVUS. Despite the high pressures and a ratio of 84% between the theoretical diameter and external elastic membrane, an average expansion of only 66% was achieved in the membrane.

Table 3 shows the actual diameters determined by QCA and IVUS, as well as the theoretical values. On average, the diameter achieved no higher than 83% and 78% of the theoretical diameter measured by QCA and IVUS, respectively; hence, the theoretical versus actual measurements were overestimated (y=1.56+0.71x, R²=0.5; P<0.000). The best correlation between the theoretical and actual measurements are related to lumen diameter, and are higher at larger diameters (y=0.27+0.16x; P<0.026). The correlation between the incidence of restenosis and each of these parameters was obtained with post-percutaneous coronary intervention (post-PCI) MLD by IVUS (Table 4).
As a result, in our series, the difference between the theoretical and actual diameters was based on vessel size, and was significantly greater in larger vessels. This contrasts with the results of Hehrlein et al who reported an inverse relationship between the reference diameter and the differences found.

The differences found in our series could be greater in other contexts. The lesions in our particular study were not complex. The main obstacle to stent deployment is calcification, and therefore the differences could be more pronounced in cases with greater calcification. In addition, the stents were tubular. Recoil figures of 21% ± 11% have been found in nitinol stents and 8% ± 7% in tubular models. Thus, the differences found might have been greater with modular or coil stents.

**DISCUSSION**

The main finding of this study was that the actual measurements were significantly lower than expected, and the differences were more pronounced with IVUS than QCA. In addition, the differences were more evident in larger vessels.

The figures provided by the manufacturer are taken from tests performed in water at 37°C with manual calibrators. In addition, it is usually not clear if the distensibility is only from the balloon or from the entire device. In the Hehrlein et al study with Multilink Duet and NIR stents, the first model provides data on the stent as well as balloon, whereas the second only gives data on the balloon. In this study, the QCA analysis obtained comparable actual versus theoretical measurements in only 6% of cases, whereas the QCA analysis showed that the difference was 14–18%. In another study, with implant pressures of 14-16 atm, the actual area was only 62% of theoretical, and in another, the MLD was 72% of the expected value. At lower pressures, the differences would be even greater.

In our series, the diameters measured by IVUS and QCA were an average of 78% and 83% of the theoretical diameter, respectively. The ratio between the theoretical maximum diameter and that of the external elastic membrane was 84%. Hence, the results do not seem to be influenced by an inadequate choice of stent size, but rather that precisely due to the inconsistency between the vessel dimensions will be smaller and will have an affect on restenosis.

**REFERENCES**


Lozano I et al. Comparison Between Theoretical and Actual Intracoronary Stent Dimensions