BRIEF REPORT

Comparison Between Theoretical and Actual Intracoronary Stent Dimensions in Non-Complex Lesions

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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.*

Comparación entre dimensiones teóricas y reales del *stent* intracoronario en lesiones no complejas

El diámetro luminal mínimo intra-*stent* es predictor de reestenosis. Las dimensiones suministradas por el fabricante son el resultado de pruebas *in vitro.* El objetivo del trabajo es comparar las dimensiones reales, mediante angiografía y ultrasonidos, con las teóricas en una cohorte prospectiva de 100 lesiones no complejas susceptibles *a priori* de *stenting* directo. Se encontraron diferencias significativas entre los diámetros teóricos y reales por angiografía y ultrasonidos intracoronarios; la relación diámetro real/teórico por angiografía fue de 0,83 ± 0,09 y por ultrasonidos intracoronarios, 0,78 ± 0,10. Las medidas reales obtenidas en lesiones sin calcificación severa son significativamente inferiores que las teóricas. Las medidas nominales no deberían utilizarse como medida de referencia en el implante.

Palabras clave: Stent. *Ultrasonidos intracoronarios. Angioplastia coronaria.*

INTRODUCTION

In-stent restenosis is a problem that results in repeated treatment procedures and additional related costs. In 1992, Kuntz et al[1] 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.[2] 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

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direct stent deployment with predilatation[3] 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.[3]

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.

TABLE 1. **Baseline Characteristics and Procedure Data***

Ege, y	60.4±10.3
Women	14 (17.1%)
Diabetes mellitus	26 (31.9%)
Ventricular function <45%	13 (15.2%)
Previous MLD, mm	0.73±0.37
Reference diameter, mm	3.01±0.48
Prior stenosis, %	76.23±10.9
Lesion length, mm	10.09±4.05
Moderate calcification	8 (8.1%)
Direct implantation	46 (46.4%)
Inflation pressure, atm	16.5±1.5
Balloon to artery ratio	1.17±0.13

*MLD indicates minimum lumen diameter.

TABLE 2. **Intracoronary Ultrasound Dimensions (n=99)***

Post-PCI MLD, mm	2.73±0.44
Lumen diameter, proximal segment, mm	3.21±.59
Lumen diameter, distal segment, mm	3.05±0.55
Lumen diameter, middle segment, mm	3.13±0.50
Post-PCI mean EEM RD, mm	4.13±0.61
MLD/EEM, %	0.66±0.08
Symmetry index, %	0.89±0.09
In-stent area, mm^2	6.90±2.14
Lumen area, proximal segment, mm^2	9.50±3.83
Lumen area, distal segment, mm^2	8.52±3.40
Lumen area, middle segment, mm^2	9.04±3.27
In-stent area, mm^2/reference area, mm^2	0.79±0.16

*EEM indicates external elastic membrane; MLD, minimum lumen diameter; PCI, percutaneous coronary intervention; RD, reference diameter.

TABLE 3. **Theoretical-to-Actual Diameter***

Theoretical diameter, mm	3.47±0.46
Actual angiographic diameter, mm	2.89±0.43
Actual angiographic-to-theoretical diameter	0.83±0.09
Actual IVUS diameter, mm	2.73±0.44
Actual IVUS-to-theoretical diameter	0.78±0.10
Theoretical-to-average diameter of EEM	0.84±0.10

*EEM indicates external elastic membrane; IVUS, intravascular ultrasound.

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, R^2=0.5; *P*<.000). The differences between the theoretical and actual measurements are related to lumen diameter, and are higher at larger diameters (y=0.27+0.16x; *P*=.028). The best 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).

TABLE 4. **Correlations Between Final Parameters and Angiographic Restenosis Rate***

Parameters	Pearson	*P*
Theoretical MLD-stenosis follow-up	–0.205	.57
Post-PCI MLD angiography-stenosis follow-up	–0.217	.045
Post-PCI MLD IVUS-stenosis follow-up	–0.333	.002
Post-PCI final area-stenosis follow-up	–0.329	.003

*IVUS indicates intravascular ultrasound; MLD, post-PCI minimum lumen diameter; PCI, percutaneous coronary intervention.

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[2] 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 mean 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.[4] At lower pressures, the differences would be even greater.[5] 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 actual and theoretical diameters, the final result does appear to indicate undersizing of the stent compared to the vessel observed.

In our study, the differences are more pronounced with IVUS than QCA. There are several differences between these 2 methods: *a)* QCA has a limited capacity to detect small differences and therefore, IVUS studies require a smaller sample[5]; *b)* visual estimation by angiography in unstented segments tends to overestimate pre-procedure stenosis severity and underestimate it afterwards[6]; *c)* protrusion of the stent struts in the lumen can cause overestimation of the lumen by QCA, particularly at low inflation pressures[6,7]; and *d)* lastly, the vessel dimensions are greater when obtained by IVUS than QCA.[6,8]

In keeping with previous studies, we found a correlation between the incidence of restenosis and the dimensions of the stent. Kasaoka et al[9] showed that the incidence of restenosis decreases by 19% for every mm^2 increase in in-stent area, and, as in previous studies, restenosis by IVUS correlates more closely to the post-PCI measurements than by QCA.[9] As a result, if the manufacturer's tables are used, then the actual dimensions will be smaller and will have an affect on restenosis.

The vessel size influences the results. In smaller vessels, it is easier to obtain diameters and areas near those of the lumen or external elastic membrane.[10] 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[2] who reported an inverse relationship between the reference diameter and the differences found.

The differences between the dimensions studied remained unchanged with the implant pressures used. However, because the implant mean was 16.5±1.5 atm, there were no cases below 14 atm, and 75% were between 16 and 18 atm, we cannot draw conclusions regarding the influence of pressure.

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 calcium,[11] 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.[12] Thus, the differences found might have been greater with modular or coil stents.

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