A novel method of coronary stent sizing using intravascular ultrasound: Safety and clinical outcomes

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CB Wong, ND Hansen. A novel method of coronary stent sizing using intravascular ultrasound: Safety and clinical outcomes. *Int J Angiol* 2009;18(1):22-24.

OBJECTIVES: The use of intravascular ultrasound (IVUS) in guiding coronary stenting has increased in recent years. The feasibility, safety and clinical outcomes of a novel method of sizing coronary stents using IVUS have not been established. The main end points of the current study are the incidence of acute and short-term complications, and the need for target vessel revascularization at six months.

METHODS: Eighty-six patients underwent coronary stenting using IVUS imaging during the procedure. The optimal size of the stents was determined by using a novel method (the 'aggressive IVUS method'), ie, measuring the media-to-media dimensions of the coronary vessels

The use of intravascular ultrasound (IVUS) in guiding coronary interventions has increased over the past decade. The impact on short-term and mid-term clinical outcomes has been controversial (1-5). Despite multiple past clinical studies, the safety and clinical outcomes of aggressive coronary stent sizing using IVUS guidance are unclear. Few studies have addressed this issue (6). In busy hospitals in the United States, it remains difficult to recommend a routine IVUS-guided stenting strategy given the time and cost constraints (7). In recent years, drug-eluting stents were introduced for the prevention of restenosis. However, subacute and late stent thrombosis remain important issues (8,9) that probably occur secondary to inadequate stent expansion, late malapposition, premature interruption of dual antiplatelet agents and lack of complete endothelialization. The first two issues may potentially be mitigated by the use of IVUS during the initial stent implantation, particularly when using the 'aggressive IVUS method'. We hypothesized that aggressive sizing of the stents using the novel method with IVUS guidance was feasible and safe and would lead to a favourable clinical outcome.

METHODS

The present retrospective study followed 86 patients who underwent coronary stent implantation.

IVUS imaging was performed before coronary stent implantation between August 1, 2003, and July 31, 2006, at Conroe Regional Medical Center (Conroe, Texas, USA). All ultrasound imaging was performed using a 3.5 Fr monorail catheter with a 35 MHz transducer proximal to its tip. To prevent coronary vasospasm, 100 µg to 200 µg of intracoronary nitroglycerin was administered before intravascular imaging. The transducer was connected to an imaging console. The IVUS catheter was

at the site of the lesions using IVUS. A six-month follow-up chart review was performed following the initial stenting.

RESULTS: At six months, there were two noncardiac deaths in the group. There were no acute, subacute or late stent thromboses. Target vessel revascularization and major adverse cardiac event rates remained low – at 5.8% and 9.3%, respectively. The mean ($\pm$ SD) IVUS-derived coronary stent size (3.89 ± 0.98 mm) using the aggressive IVUS method was significantly different from the mean IVUS-derived coronary stent size (3.46 ± 0.96 mm) using the 'traditional IVUS method'.

CONCLUSION: Aggressive sizing of the coronary stents by IVUS guidance is feasible and safe, and is associated with a favourable clinical outcome.

Key Words: *Coronary artery disease; Intravascular ultrasound; Stenting*

advanced over the wire into the vessels. Images were recorded on compact discs as the catheter was slowly withdrawn through the lesion. Positional changes, lumen dimensions and media-to-media dimensions were recorded.

The optimal stent size was determined by measuring the media-to-media dimensions (or the maximum external elastic membrane diameter) in an orthogonal manner within the coronary lesion. The mean ($\pm$ SD) of these dimensions was taken as the optimal coronary stent size (aggressive IVUS method). At the same time, the proximal and distal reference lumen diameters of the coronary arteries were measured using IVUS. The larger of these measurements would have been the coronary stent size if the 'traditional IVUS method' was adopted.

Clinical follow-up

A six-month chart review was conducted after stent implantation for target vessel revascularization (TVR) and major adverse cardiac events (MACEs). Hospital and computerized records were reviewed, and 90% of the patients were followed by the operator. For the rest of the patients, telephone follow-up was obtained to ensure continued survival and to determine whether MACEs had occurred.

Statistical analysis

Continuous variables were compared using Student's *t* test. *P* < 0.05 was accepted as being statistically significant.

RESULTS

During the study period, 86 patients who underwent IVUS during coronary stenting were followed. Baseline demographics and clinical data are shown in Table 1. The proportions of men

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TABLE 1**Baseline demographic and clinical data**

Characteristics, n=86	n (%)
Age, years, mean $\pm$ SD	63 $\pm$ 11.2
Sex	
Male	45 (52)
Female	41 (48)
Smoking	39 (45)
Diabetes mellitus	41 (48)
Hypertension	85 (99)
Dyslipidemia	85 (99)
Renal failure	2 (2.3)
History of myocardial infarction	29 (34)
Angina	84 (98)
Left ventricular ejection fraction, %, mean $\pm$ SD	45.8 $\pm$ 5.6
Previous coronary artery bypass graft	20 (23)
Bifurcation lesions	5 (5.8)

and women were nearly equal in the study group. A high percentage of patients had diabetes mellitus (48%) and myocardial infarction (34%), indicating a high-risk cohort. Renal failure was present in 2.3% of patients. Stents were implanted in all lesions. The procedural success rate was 97.7%. High-risk interventions, including left main coronary artery stenting (2.3%), bifurcation lesions (5.8%) and saphenous vein graft interventions (5.8%), were present in a proportionate number of patients. Of these patients, 70.9% received drug-eluting stents (Table 2).

The mean ($\pm$ SD) size of the stent was determined by IVUS using the media-to-media measurements of the coronary lesions (aggressive IVUS method) and was 3.89 $\pm$ 0.98 mm. In contrast, the mean size of the lumen determined by the traditional IVUS method using the larger of the proximal and distal reference lumen diameters was 3.46 $\pm$ 0.96 mm ($P=0.005$). Only nine of 86 patients had coronary artery dimensions obtained by the aggressive IVUS method that were smaller than the dimensions obtained by the traditional IVUS method. Therefore, in a majority of patients (92%), hyperexpansion of the stents occurred.

Clinical outcomes are shown in Table 3. Acute complications occurred in 3.5% of the patients. One patient required emergency bypass surgery because of retained balloon material trapped within the stent struts following high-pressure balloon dilation. This may have been the result of a defective balloon. Another patient developed transient left main coronary artery spasm after IVUS imaging that resolved with the administration of nitroglycerin. The third patient developed limited coronary perforation following semicompliant balloon dilation at high pressure. The perforation was self-limiting and resolved with conservative management. The patient was discharged home without any further complications. It was retrospectively deemed that perforation may have been avoided if high-pressure balloon dilation after stent implantation had been strictly limited to noncompliant balloons.

None of the patients suffered cardiac death in the subsequent six months, nor did any patient develop subacute or late stent thrombosis. Acute creatine kinase MB elevations greater than three times the baseline levels occurred in 2.3% of the patients. No patient suffered a Q wave myocardial infarction. The revascularization rate of the target vessel was 5.8% with a

TABLE 2**Angiographic and intravascular ultrasound results**

Interventional lesions, n=86	n (%)
Left anterior descending artery	26 (30)
Right coronary artery	40 (47)
Circumflex artery	13 (15)
Left main coronary artery	2 (2.3)
Saphenous vein graft	5 (5.8)
Length of stents, mm, mean $\pm$ SD	24.4 $\pm$ 30.2
Final balloon pressures, atm, mean $\pm$ SD	18.4 $\pm$ 5.42
Use of drug-eluting stents	61 (70.9)

TABLE 3**Clinical outcomes**

Clinical outcomes, n=86	n (%)
Procedural success rate	84 (97.7)
Acute in-hospital complications	3 (3.5)
Flow-limiting dissections at the end of the procedure	0 (0)
Acute, subacute and late stent thrombosis	0 (0)
Non Q wave myocardial infarction (in hospital)	2 (2.3)
Deaths in subsequent 6 months	2 (2.3)
Cardiac deaths in subsequent 6 months	0 (0)
Target vessel revascularization in subsequent 6 months	5 (5.8)
MACEs in subsequent 6 months	8 (9.3)

MACE Major adverse cardiac event

MACE rate of 9.3% in the subsequent six months. Two patients died in the subsequent six months, one from complications arising from end-stage kidney disease, and the other from a massive spontaneous intracerebral hemorrhage, probably from uncontrolled hypertension.

DISCUSSION

Uncontrolled clinical studies (1,2) showed that ultrasound-guided coronary stenting leads to a greater initial minimal luminal area with no increase in acute complications. The effects on angiographic and clinical restenosis were controversial (3-5), according to several randomized clinical studies.

In the current era of high-pressure dilation strategy, improved poststenting antiplatelet therapy and improved stent design, most interventionists in the United States shy away from IVUS in view of the cost and time involved. Despite all of the above strategies, the subacute stent thrombosis rate remains at 1%, and may even be higher with the introduction of drug-eluting stents secondary to late stent thrombosis (8).

The current study is one of the few real world studies performed to determine the feasibility, safety and clinical outcome of patients undergoing IVUS-guided stenting in an 'aggressive' manner. A few issues need to be addressed.

'Aggressive sizing' of coronary stents was an adopted strategy. In general, there are two ways to size coronary stents by the IVUS technique. The traditional IVUS method requires measurement of the maximum proximal and distal reference lumen diameters by IVUS. The stent size is selected based on the larger of these measurements. The aggressive IVUS method requires measurement of the media-to-media dimensions in an orthogonal manner within a coronary lesion. The mean of these dimensions is taken as the optimal stent size. Often, the

media-to-media measurement results in significant 'up-sizing' of coronary stents, compared with the sizing of coronary stents by angiographic methods or the traditional IVUS method. The first reason is that the reference segments, whether proximal or distal, are rarely normal. In patients suffering from atherosclerotic heart disease, diffuse atherosclerosis in a given coronary artery is generally a rule rather than an exception. If the stent is sized using the largest reference segment lumen diameter with the least plaque, the measurements will frequently result in a smaller sized stent. Moreover, positive coronary vessel remodelling in response to atherosclerosis is a known mechanism described by Glagov et al (10). This, in turn, makes the media-to-media measurement within the lesion larger than the media-to-media measurement of the reference segments. Therefore, using the traditional IVUS method may result in a smaller stent size. Theoretically, negative coronary remodelling renders the media-to-media measurement at the lesion site smaller than that of the reference segments. Therefore, a smaller stent size may result using the aggressive IVUS method when significant negative remodelling occurs at the lesion site, along with very little atherosclerotic process at the reference segments. However, in most patients, diffuse coronary plaque throughout the whole coronary segment is the major operating factor. Therefore, undersizing of the stent may readily occur if one chooses to measure either the proximal or distal reference lumen diameter by IVUS.

In the current study, the mean stent size measured by the aggressive IVUS method was significantly higher than the stent size obtained by the traditional IVUS method. A low six-month MACE rate, no perioperative deaths, a low stent thrombosis rate and a low perioperative myocardial infarction rate indicated that this strategy was safe and feasible.

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Comparison with other clinical studies

The study by Faulkner et al (7) did not support the added expense of IVUS in community hospitals secondary to the sub-optimal clinical outcome (TVR and MACE), compared with angiography-guided stenting. However, IVUS-guided stent sizing according to the aggressive IVUS method was not adopted in the above study. A study by Iakovou et al (6) demonstrated a lower mortality rate and a lower TVR at one year with the IVUS-guided stent over expansion (final lumen cross-sectional area greater than the reference luminal cross-sectional area) at the expense of higher per-procedure creatine kinase MB release. On the other hand, hyperexpansion of the coronary stents without IVUS guidance has been associated with more occlusions of large side branches and similar rates of MACE at one year compared with the regular stenting strategy (11). The results were not surprising, because a 'blind' hyperexpansion of the coronary stents without determining the actual vessel size using IVUS may be overaggressive, resulting in complications such as dissections and perforations. Hyperexpansion of coronary stents is safe only if the lesion sites of the diseased coronary artery develop positive remodelling, or if diffuse atherosclerosis is present in the reference segments. The above information is not readily available through conventional coronary angiography, again highlighting the value of IVUS.

CONCLUSION

Based on the above observations, we demonstrated that a novel method of aggressive sizing of coronary stents by IVUS guidance is feasible, safe and may be associated with low rates of acute and short-term complications. Further clinical studies are required to define the role of aggressive sizing using IVUS in the era of drug-eluting coronary stents.