Title

Editorial comment: Do you need IVUS guidance for coronary stent deployment?

Journal

Catheterization and Cardiovascular Interventions, 37(4)

ISSN

1522-1946

Authors

Tobis, Jonathan M

Colombo, Antonio

Publication Date

1996-04-01

DOI

10.1002/(sici)1097-0304(199604)37:4<360::aid-ccd2>3.0.co;2-9

Catheterization and Cardiovascular Diagnosis 37:360–361 (1996)

Editorial Comment

Do You Need IVUS Guidance for Coronary Stent Deployment?

Jonathan M. Tobis, MD
University of California, Irvine
Irvine, California
University of California, Los Angeles
Los Angeles, California

Antonio Colombo, MD
Cardiac Catheterization Laboratories
Colombus Hospital
Milan, Italy
Department of Interventional Cardiology
Lenox Hill Hospital
New York, New York

Our knowledge and appreciation for the capabilities of intracoronary stents is advancing at a rapid pace. Coronary stents improve immediate results, as well as decrease restenosis associated with balloon angioplasty [1,2]. Intravascular ultrasound (IVUS) imaging has played a significant role in enhancing our knowledge about how stent deployment can be optimized [3,4]. As exemplified by the article of Sankardas et al. [5], interventionalists are now questioning whether there is a continued need for IVUS to enhance stent insertions.

As stents became more readily available between 1985–1992, it was apparent that they could significantly improve the immediate results of balloon angioplasty, or salvage a severe dissection from progressing to acute occlusion. Despite their impressive immediate angiographic and clinical success, coronary stents were plagued by a high incidence of subacute thrombosis occurring 1–3 weeks postprocedure. These episodes were associated with a high rate of infarction or death. The hypothesis at that time was that the metal content of the stent increased the propensity to thrombosis; therefore, aggressive anticoagulation regimens were devised to protect against this event. However, despite the use of dextran, heparin, aspirin, and coumadin, there was still a high incidence of subacute thrombosis. Because stents were not readily available in the United States, in October 1992 we began working in Milan, Italy, on a protocol to assess the usefulness of intravascular ultrasound as a guide to performing multiple coronary interventions. At that time, stents were being used predominantly in bailout situations when there was acute or threatened closure following balloon angioplasty or atherectomy. During this period we noted that in patients who had coronary stents, the result by intravascular ultrasound was significantly discordant with the excellent-appearing lumen diameter based on angiography. The five major observations obtained with intravascular ultrasound were: 1) that stents frequently had poor apposition against the arterial wall, 2) asymmetric expansion, 3) underexpansion, 4) that there were frequently other unrecognized lesions, either proximal or distal to the stent, and 5) that there could be inlet or outlet stenoses at the shoulder of the stent, or dissections that extended beyond the stent borders. Based on these ultrasound observations, we decided to use either larger balloons or higher pressures to further expand the stents. When the balloons had a larger than 1.2 balloon-to-lumen ratio, the minimum lumen diameter increased (3.44 ± 0.54 mm) and the incidence of subacute thrombus decreased (<1%), but there was an increased incidence of complications (from 3% to 8%), such as rupture of the artery at the edge of the stent. Therefore, our protocol was altered to use higher pressure inflations (mean of 16 atmospheres) which produced a larger minimum lumen diameter, a lower subacute thrombosis rate, and a lower angiographic restenosis rate at 6 mo, but without the increased complications associated with the larger balloons.

Based on the impressive immediate and 6-mo angiographic and clinical results with this method of intravascular ultrasound-guided stent deployment, we decided to stop using coumadin because we felt the risk associated with the bleeding complications of coumadin was greater than the chance of subacute thrombosis [6]. From the intravascular ultrasound-guided high-pressure balloon method, the cross-sectional area of the stents was increased anywhere between 50–300%. It appeared that the previous high incidence of subacute thrombosis was due to the relatively narrow residual lumen, and not to any predisposition to thrombosis from the metallic stents. In addition, more recent evidence has suggested that there may actually be a procoagulant effect of this aggressive anticoagulation regimen [7]. Based on the reports from our clinical studies with intravascular ultrasound-guided stent deployment, most laboratories throughout the world have adopted the technique of high-pressure balloon inflations with or without intravascular ultrasound guidance, and report similar immediate and 6-mo results.

The question now remains, as to whether it is the high-pressure balloon technique or the intravascular ultrasound guidance which is responsible for the beneficial result. There is currently at least one randomized clinical trial comparing angiographic guidance without coumadin to intravascular ultrasound guidance without coumadin to determine the actual role of ultrasound imaging. From a review of our own data base of 1,200 patients, we suspect that the subacute thrombosis rate is so low with the high-pressure balloon technique that there will probably be no significant change with or without intravascular ultrasound guidance. However, there may be subsets of lesions that are served better with IVUS guidance. With small vessels, the Multicenter French Registry reports a 10% incidence of complications without IVUS, compared to our 1.8% using IVUS. With bailout stenting, our subacute occlusion rate is similar to the rate for elective cases (<2%), but the French Registry reports an incidence of 6.6%.

The second issue concerns whether intravascular ultrasound will enhance the results obtained by the use of high-pressure balloons so that restenosis is reduced. Our data show a modest improvement in restenosis (21% vs. 27%) in patients who had intravascular ultrasound imaging as distinguished from those who did not. A recent report [8] from the Washington Hospital Center using this technique documents that the target lesion revascularization rate was only 5%. These results imply that previous trials comparing surgery and balloon dilatation are already outdated and need to be redone with optimized stent utilization.

In our laboratories, even when an excellent angiographic result is obtained with the high-pressure balloon technique, subsequent ultrasound imaging provides information which alters our treatment plan in approximately 25% of cases. Whether or not these decisions and this technique will make any difference clinically will depend upon the outcome of randomized clinical trials. But no matter what future clinical trials reveal, there are several provisos that one should keep in mind: 1) Intravascular ultrasound is extremely helpful when angiography in unclear. It will frequently direct one to proceed further and do more dilatations, stent more areas, or stop any further treatment when angiography might suggest that there could be some intraluminal filling defect. 2) Intravascular ultrasound accelerates the learning curve and enhances our understanding of stent deployment in terms of the position of the stent relative to the ostium, side branches, or lesion margins, and in terms of the size of the stented segment relative to the reference lumen. For those interventionalists starting to use stents, we believe that intravascular ultrasound will significantly help your understanding. For those experienced interventionalists who are tackling more complicated cases, intravascular ultrasound can be indispensable for optimizing results. Anyone who is inserting stents, and is dealing with a subacute thrombosis associated with significant clinical complications, will never know the cause of that thrombosis unless intravascular ultrasound imaging has been performed.

REFERENCES

1. Serruys PW, de Jaegere P, Kiemeneij F, Macaya C, Rutsch W, Heyndrickx G, Emanuelsson H, Marco J, Legrand V, Materne P: A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease. Benestent Study Group. N Engl J Med 331:489–495, 1994.
2. Fischman DL, Leon MB, Baim DS, Schatz RA, Savage MP, Penn I, Detre K, Veltri L, Ricci D, Nobuyoshi M: A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease. Stent Restenosis Study Investigators. N Engl J Med 331:496–501, 1994.
3. Goldberg SL, Colombo A, Nakamura S, Almagor Y, Maiello L, Tobis JM: Benefit of intracoronary ultrasound in the deployment of Palmaz-Schatz stents. J Am Coll Cardiol 24:996–1003, 1994.
4. Nakamura S, Colombo A, Gaglione A, Almagor Y, Goldberg SL, Maiello L, Finci L, Tobis JM: Intracoronary ultrasound observations during stent implantation. Circulation 89:2026–2034, 1994.
5. Sankardas MA, McEniery PT, Aroney CN, Bett JHN: Elective implantation of intracoronary stents without intravascular guidance or subsequent warfarin. Cathet Cardiovasc Diagn x:x–x, 1995.
6. Colombo A, Hall P, Nakamura S, Almagor Y, Maiello L, Martini G, Gaglione A, Goldberg SL, Tobis JM: Intracoronary stenting without anticoagulation accomplished with intravascular ultrasound guidance. Circulation 91:1676–1688, 1995.
7. Gallerani M, Manfredini R, Morratelli S: Non-hemorrhagic adverse reactions of oral anticoagulant therapy. Internat J Cardiol 49:1–7, 1994.
8. Wong S, Hong M, Chuang Y, Satler L, Kent K, Pichard A, et al.: The anti-platelet treatment after intravascular ultrasound guided optimal stent expansion (APLAUSE) trial. Circulation/October 92–8:1–795, 1995.