

## EDITORIAL COMMENT

# Self-Expanding Stents for Primary Percutaneous Coronary Intervention During Acute Myocardial Infarction

Did We Find the Right Indication . . . at Last!\*

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Most young colleagues may not be aware of the fact that coronary stenting started back in Europe during the late 1980s with the delivery of self-expanding nitinol devices (1). The coronary Wallstent (Boston Scientific, Natick, Massachusetts) was indeed the first stent used in the coronary circulation, be it in grafted saphenous veins or in native coronary vessels of sufficient diameter (2). It is beyond the scope of this editorial to review the history and all the controversies of another age—details can be found in the relevant chapters of the *PCR-EAPCI Textbook of Interventional Cardiovascular Medicine* (3). We will summarize what we have learned and what applies today in relation to the paper by van Geuns et al. (4).

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The rationale for preferring the use of self-expanding to balloon-expandable stents remains the same. Adequate sizing and stent selection that would allow proper expansion still is problematic today. Failure to achieve proper expansion results in the permanent implant of an incompletely deployed, fixed metallic cage inside a dynamic vessel, with increased risk of stent thrombosis and restenosis. The gentle (as opposed to forceful) mechanics of stent expansion have always seemed desirable, aiming at reducing plaque fracture, edge dissections, and distal embolization of thrombus or plaque debris. Even though the original Wallstent and followers, such as the Radius device (Boston Scientific), shared these desirable features, balloon expansion has

reigned supreme ever since. Granted, self-expanding stents were bulkier; some design characteristics were suboptimal; and they are somewhat more delicate to deliver adequately. Above all, it became obvious that restenosis rates were unacceptable, as illustrated in the systematic study by Foley et al. (5), who reported angiographic restenosis rates at 9 months ranging between 25.9% and 67.5% with increasing stent length. Similar to the situation with balloon-expandable stents, initial attempts at eliminating restenosis used beta-radiation-based vascular brachytherapy (6), which was soon followed by drug elution (7), but let us leave this aspect on the side for the moment.

## The STENTYS Device and Its Application to Primary PCI for St-Segment Elevation Myocardial Infarction

It is interesting to note that this new self-expanding device was initially designed to tackle bifurcation lesions and in fact can be used perfectly to treat such vessels and lesion subsets. By design, struts can be disconnected easily by balloon inflation toward a side branch (8), allowing either provisional stenting with final kissing balloon inflation or double stent implantation techniques to be performed readily. The idea of applying the device to primary percutaneous coronary intervention (PCI) procedures was first tested in the APPOSITION I (Assessment of the Safety and Performance of the STENTYS self-expanding Coronary Stent in Acute Myocardial Infarction) trial (9), which demonstrated the safety of the approach, and was soon followed with the currently reported randomized trial (4). The specifics of primary PCI seem ideally suitable for application of self-expanding stents. This became obvious with the advent of intracoronary imaging techniques, such as intravascular ultrasound, and even more so using optical coherence tomography (OCT). Indeed, stent apposition to the wall and its components can now be assessed with exquisite levels of detail and accuracy, at the individual strut level while accounting for strut thickness. Presence of vasoconstriction and a thrombotic milieu are risk factors for malapposition of stent struts initially, as well as later. Initially well-apposed stent struts were shown to become poorly apposed after resolution of thrombus that covered the vessel wall at the time of implantation.

Another brilliant component of the study rationale pertains to the clinical situation, namely the constant desire to minimize myocardial damage during evolving infarction. This can be achieved primarily by reducing all delays to reperfusion, but in those patients who did reach the invasive laboratory in a timely fashion, prevention of reperfusion-associated injury becomes of paramount importance. Among the causes of reperfusion injury and no reflow, distal embolization of disrupted plaque or thrombus debris is amenable to reduced mechanical trauma at

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the time of stent expansion. Therefore, designing a stenting strategy such as the one tested by the investigators of APPOSITION II seems worthwhile, also in view of the poor short- and long-term prognosis that is associated with failure to restore perfusion at the level of the myocardial tissue.

With this background in mind, the strengths and limitations of the current study become obvious. Van Geuns et al. (4) have successfully performed a small step toward their ultimate goal—to contribute to further improving clinical outcomes after primary PCI for ST-segment elevation myocardial infarction, a proven lifesaving indication of percutaneous intervention. This initial step is taking advantage of OCT imaging as an intermediate endpoint allowing the testing of a simple hypothesis, but one that is mechanically relevant to the pathophysiology of reperfusion and reperfusion damage. Rates of strut malapposition after balloon expansion of metallic stents were high, as expected from earlier reports, and much lower with STENTYS (STENTYS, Paris, France). Additional observations, including repeat OCT imaging at 3 days showed continued expansion of the luminal dimensions and further reduction of strut malapposition with the self-expanding, as opposed to the balloon-expandable, device.

The observed changes in diameters and areas over time following implantation were well known from the early days (2). The question that has remained unanswered is whether spontaneous expansion is preferable to additional in-stent post-dilation using balloons. In the present study, the procedural technique did involve immediate post-stent expansion via balloon inflation in 63% of cases randomized to receiving the self-expanding device, as opposed to 24% with initial balloon expansion. The strategy was dependent on site or operator preference, and the investigators do not provide analysis of the pro and cons of either technique. Even pre-dilation was applied more often in the group randomized to self-expanding stent implantation: 60.5% versus 40.5% of cases. It is not mentioned whether limited dilation was applied merely to allow easy passage of the delivery catheter or full dilation of the stenosis was performed to facilitate self-expansion of the device. Conceptually, it may seem that balloon expansion, either pre- or post-stent placement, may jeopardize some of the benefits related to softer self-expansion, but this remains speculative. It is currently not known whether there are any risks associated with a conservative strategy, allowing for spontaneous stent expansion over the first few days after delivery. In this context, a more detailed quantitative analysis of stent underexpansion, as well as a description of “out of round” stent configurations in both study arms, would have been of value. Although this can be seen as a limitation of the present study, one has to admit that the clinical correlates of these measurements, as well as the implications of OCT-determined malapposition rates, remain elusive.

**Study and device limitations.** Obviously, the study is not powered to address differences in clinical metrics. Yet in keeping with the ultimate goal, the reader may require some additional information regarding the procedural outcomes. One may appropriately wonder about the presence of residual thrombus or tissue prolapse at the level of the coronary stent. Likewise, it would be of interest to learn about any differences between randomization groups in TIMI (Thrombolysis In Myocardial Infarction) flow grade or myocardial blush grade at the end of the procedure. Such observations will be much needed to design and size future outcome-based trials.

However, the main limitation of the current effort pertains to the device itself. Restenosis rates of bare-metal self-expanding stents are high, at best. The mean in-stent late loss with STENTYS was indeed high at 0.7 mm, even though the z-shape of the current design differs entirely from the initial Wallstent design. Fortunately, it was proven possible to reduce restenosis rates of similar stents by combining drug elution from bioerodable polymers with self-expanding properties (7) and STENTYS drug-eluting devices are under clinical evaluation. Following the demonstration that drug elution does not compromise vascular healing and preserves the opportunity for adequate late apposition, this technology will be ready for large-scale evaluation in prospective randomized trials to test its potential for incrementally improving the outcome of patients with ST-segment elevation myocardial infarction by reducing reperfusion injury, stent thrombosis, and restenosis, beyond what is already achievable with contemporary balloon-expandable drug-eluting stent.

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