Editorial Comment

"Full Metal Jacket" Drug-Eluting Stent Implantation: A Reasonable Therapeutic Option for Advanced Coronary Artery Disease?

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Managing advanced coronary artery disease (CAD) is an increasing clinical problem with a growing number of patients with severe CAD [1]. Since the introduction of percutaneous coronary intervention, lesion length has been identified the key factor related to higher rates of restenosis. Until now, patients with very diffuse CAD tend to be treated with aggressive medical therapy because they are not usually suitable for surgical or percutaneous coronary revascularization. Balloon angioplasty or bare-metal stent implantation in these patients is associated with high risk of repeat revascularization, and rarely used in clinical practice. However, drug-eluting stents (DESs) nearly eliminate the risk of restenosis, rapidly expanding the indications for complex and challenging lesions.

Full metal jacket (FMJ) DES implantation (stented length without gaps ≥ 60 mm) is not uncommon in real-world clinical practice, and increasingly used in accordance with the requirement of more complex procedures (5–10% of the total DES implantation, unpublished Korean registry data). For example, percutaneous coronary intervention of chronic total occlusion remains the most challenging area to treat in coronary interventional practice, commonly requiring FMJ stent implantation to cover full coronary artery lesions. It is well demonstrated that DESs provide better long-term clinical outcomes than bare-metal stents in various clinical settings including acute myocardial infarction, diabetes, bifurcation, chronic total occlusions, diffuse long lesions, and etc. However, there is still controversy on the efficacy and safety of FMJ approach. Limited data exist regarding the long-term clinical outcomes after FMJ DES implantation.

In this issue of the Journal, Dr. Basavarajaiah et al. performed extended follow-up in 274 patients with 297 lesions in native coronary arteries, who underwent FMJ DES implantation [2]. During the median follow-up of 6.2 years, the rates of cardiac death, myocardial infarction, and target lesion revascularization were 5.8%, 6.2%, and 27.3%, respectively. The rate of definite and probable stent thrombosis was 3.6%. The most serious concern in using previous DESs was the ongoing hazard of definite stent thrombosis, with a continuing rate of $\sim$0.6%/year for very late stent thrombosis. Given the complexity of lesions treated in this study, however, the rate of definite stent thrombosis was relatively low with 0.25%/year, reassuring the skeptical physicians. Diabetes, smoking, and left ventricular ejection fraction were found to be the independent predictors of major adverse cardiac events. Likewise, smoking and final minimal stent diameter were the independent predictors of target lesion revascularization. These findings show that the long-term clinical outcomes of patients with FMJ procedure are favorable with acceptable rates of hard clinical endpoints, and the major adverse cardiac event is primarily driven by repeat revascularization. Previously, we also reported long-term clinical outcomes and predictors of major adverse cardiac events in 347 consecutive patients with 352 lesions who had been treated with FMJ DES implantation [3]. During the median follow-up of 8 years, the event-free survival rate for cardiac death, cardiac death/myocardial infarction, or cardiac death/myocardial infarction/target lesion revascularization was 90.5%, 85.8%, and 71.6%, respectively. Left ventricular dysfunction (ejection fraction $< 45\%$) was an independent predictor of cardiac death, and left ventricular dysfunction and a stent length > 80 mm were significantly related to cardiac death/myocardial infarction. Intravascular ultrasound was used in 73% of patients. Stent underexpansion is common after the FMJ

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procedure, and therefore intravascular ultrasound guidance during the procedure seems to be especially important to achieve optimal stent expansion (minimum stent cross-sectional area > 5.0 mm^2) and complete strut apposition after the FMJ procedure. Taken together, these studies demonstrate that long-term clinical outcomes regarding the safety and efficacy of FMJ procedure are favorable in patients with very diffuse CAD, and left ventricular dysfunction is a major predictor of poor clinical outcomes. In these two studies [2,3], however, previous DESs (Cypher™ or Taxus™ stents) were only used, which are no longer available in routine clinical practice. Newer-generation DESs are now widely used, and long-term outcomes in patients undergoing FMJ procedure with newer-generation DESs may improve further.

DESs technology has rapidly evolved over the past decade, and newer-generation DESs appear safer than previous DESs [4]. Newer-generation DESs markedly reduced the risk of very late stent thrombosis compared with previous DESs, and long-term clinical outcomes with newer-generation DESs may be better than previous DESs. Finally, the major limitation of FMJ approach is that if the coronary artery is caged with FMJ stents, future bypass surgery is difficult, especially for left anterior descending coronary artery lesions. Bioresorbable vascular scaffold (BVS) is a new approach that provides drug release and vessel patency until it has healed and the stent degrades into nontoxic compounds. BVS allows the restoration of vessel vasoreactivity, late luminal enlargement, late positive remodeling, and non-invasive assessment of coronary artery during follow-up. In a recent randomized trial to compare an everolimus-eluting BVS with an everolimus-eluting metallic stent, the everolimus-eluting BVS showed similar 1-year clinical outcomes to the everolimus-eluting metallic stent, shedding light on this new technology [5]. In addition, BVS can facilitate future coronary percutaneous or surgical revascularization because the stent is completely absorbed from the vessel wall. Therefore, full BVS jacket may be a promising approach to overcome the limitation of current FMJ approach, eventually revolutionizing coronary interventions in this particular field. Further studies are definitely needed to investigate the role of BVS in treating patients with very diffuse CAD.

In summary, the FMJ approach with any DESs may be a reasonable treatment option with favorable clinical outcomes in patients with very diffuse CAD. Intravascular ultrasound guidance during the procedure may be useful to achieve optimal results. Further progress is expected in the era of newer-generation DESs and BVS.

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