Stent Optimization Using Adjunctive Balloon Dilatation in the Era of Second-Generation Drug-Eluting Stents

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Percutaneous coronary intervention (PCI) using both balloon angioplasty and coronary stents has markedly reduced adverse cardiac events in patients with ischemic heart disease. Drug-eluting stents (DES) could further decrease the incidence of target vessel revascularization (TVR) to 5%-10% compared to bare-metal stents (BMS) or balloon angioplasty alone.1) Despite its clinical benefits, stent failure including stent thrombosis or in-stent restenosis (ISR), is the major concern after coronary stenting; it is associated with worse clinical outcomes in patients who received PCI using coronary stents. Among mechanisms of ISR and stent thrombosis, stent under-expansion and stent mal-apposition are important mechanical factors which can cause stent failure.2) For BMS, it is accepted that good apposition and full stent expansion are associated with reduced risk of ISR and stent thrombosis.3) However, few studies have investigated whether adjunctive balloon dilatation after DES implantation could reduce the incidence of stent-related complication or failure. Brodie suggested that adjunctive balloon post-dilatation following deployment of first-generation DES should be used in the majority of patients to reduce stent thrombosis and TVR.4) Romagnoli et al.5) determined through an analysis of the literature that achieving adequate stent expansion (both BMS and DES) during PCI is important to reduce restenosis, the need for TVR and stent thrombosis. Although suboptimal stent expansion frequently occurs after DES deployment in 24%-28% of all cases, routine post-dilatation is not cost-effective, thus imaging devices such as intravascular ultrasound (IVUS) are recommended.6) There is also lack of data regarding post-dilatation after second-generation DES implantation.

Hong et al.7) reported that adjunctive balloon dilatation was not associated with a reduction in major adverse cardiac events (MACEs: composite of cardiac death, target lesion-related myocardial infarction [MI], or ischemia-driven target-lesion revascularization [TLR]) at 1-year among patients requiring long everolimus-eluting stent (EES) implantation. They analyzed 1,671 patients treated with long EES (defined as length of implanted stent ≥28 mm) from 2 randomized trials. After propensity-score matching, there were comparable clinical outcomes in terms of MACEs (hazard ratio [HR] for adjunct balloon dilation, 1.01; 95% confidence interval [CI], 0.60-1.69; p=0.972), cardiac death (HR, 0.76; 95% CI, 0.17–3.39; p=0.718), target-lesion related MI (HR, 1.01; 95% CI, 0.06–16.16; p=0.994), ischemia-driven TLR (HR, 1.10; 95% CI, 0.63–1.91; p=0.749), or stent thrombosis (HR, 0.33; 95% CI, 0.04–
3.21; p=0.319) between the 2 groups. The authors suggested that post-stent adjunct balloon dilation might be necessary for patients requiring long EES implantation who present with stable angina pectoris or for lesions with small vessels in subgroup analysis. However, there were no significant differences in MACEs between the 2 groups in subgroup analyses (stable angina [HR, 0.56; 95% CI, 0.25–1.22; p=0.135] and reference vessel diameter <3 mm [HR, 0.67; 95% CI, 0.36–1.26; p=0.213]). Therefore, the authors’ mention of the need for post-stent balloon dilatation in patients with stable angina or small vessel disease is possibly misleading. A strong point of this study is the study population. All patients received PCI using EES, a second-generation DES. The second-generation DES have more biocompatible polymer and thinner stent struts compared to first-generation DES. Among these, EES was the safest stent in terms of lower risk for stent thrombosis or TVR than other first or second-generation DES and BMS. Thus, stent type in this study might have influenced study outcomes.

The limitations of the current study include its retrospective design and that performing adjunctive balloon dilatation after stenting was at the operators’ discretion. As the authors mentioned in the manuscript, one study investigated 12-month clinical outcomes between routine post-stent dilatation and selective post-stent dilatation. The incidence of MACEs was significantly lower in patients who received routine post-stent dilatation than the selective group. Although about half of the study population received first-generation DES and the sample size was small, angiography-guided routine post-dilatation with non-compliant balloons improved clinical outcomes with DES. However, routine angiography-guided post-dilatation has some procedural risks: stent edge dissection which was not detected by angiography, the risk of the no-reflow phenomenon by plaque debris or microemboli, and the risk of coronary perforation. Real-world data from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) showed that post-dilatation might increase the risk of restenosis. Although these data included a large number of patients treated with BMS, the risk of routine post-dilatation should be considered in each patient. We recommend the use of adjunctive balloon dilatation in these circumstances: 1) obvious stent under-expansion by angiography; 2) stent mal-apposition by intravascular imaging; 3) highly calcified lesions; or 4) implantation of bioreabsorbable vascular scaffolds. When applying adjunctive balloon dilatation, operators should endeavor to reduce the risk for mechanical complications. The use of intravascular devices is warranted to achieve optimal stent apposition and expansion. Post-dilatation in patients with acute coronary syndrome, especially in acute myocardial infarction (AMI), is also problematic. The effect of this practice in AMI remains to be clarified and it was associated with the no-reflow phenomenon because of thrombus and plaque debris embolization. In cases of AMI, routine high-pressure adjunctive balloon dilatation is not recommended.

In conclusion, the approach for post-stent balloon dilatation should be individualized. Despite its clinical benefits, routine adjunctive balloon dilatation should be used carefully, and the risk for stent edge dissection, the no-reflow phenomenon and coronary artery perforation should be taken into consideration. As far as we know, the current study is the first to investigate the clinical outcomes of adjunctive balloon dilatation after second-generation DES. Although the results are negative, adjunctive balloon dilatation after DES implantation is still important for minimizing the risk of ISR and stent thrombosis. Randomized controlled trials and large-sized registry data using various DES including second-generation DES or biodegradable polymer newer-generation DES are needed to confirm the role of post-stent balloon dilatation.
REFERENCES


