Journal of the Society for Cardiovascular Angiography & Interventions 3 (2024) 101189

JSCAI

The official journal of the Society for Cardiovascular Angiography & Interventions

Editorial

Plain Old Perfusion Balloon Angioplasty: Can We Do Without Stents?

Paul Bamford, MBChB [a,b,*], Cindy L. Grines, MD [c]

[a] School of Medicine and Public Health, University of Newcastle, Newcastle, Australia; [b] Cardiology Department, Leeds General Infirmary, Leeds, United Kingdom; [c] Cardiology Department, Northside Hospital Cardiovascular Institute, Atlanta, Georgia

Since the advent of coronary stents more than 20 years ago, the established treatment of acute coronary syndrome has changed little. Despite design iterations, there remain ongoing concerns regarding stent thrombosis and restenosis (especially where atherosclerosis is diffuse or involves small vessels or bifurcations) that place patients at risk of reinfarction. While some of this risk has been mitigated through increased potency of dual antiplatelet therapy, a cohort of these patients will subsequently suffer a major bleeding complication. Addressing this challenge has been investigated in multiple trials to determine the optimal duration of antiplatelet therapy without risking stent thrombosis.

In this issue of *JSCAI*, Fukuoka and colleagues[1] describe a novel stentless approach to acute coronary syndrome utilizing an old technology that shifts the paradigm away from the established revascularization strategy. Perfusion balloons were invented in the 1980s for prolonged inflations required to "tack up" dissection planes but fell out of favor with the introduction of bare metal stents.[2,3] Unlike the semicompliant and noncompliant balloons used in angioplasty, perfusion balloons allow distal coronary perfusion while dilating a lesion; thus, prolonged inflations are better tolerated. More recently, with the advent of drug-coated balloons, investigators have turned their attention back to balloon angioplasty to determine whether a stentless strategy can deliver the same procedural result without complications related to stents and prolonged dual antiplatelet therapy.[4]

Fukuoka and colleagues report results from a single-arm, single-institution, proof-of-concept study in which 30 patients were treated with prolonged inflation (over 10 minutes) with a perfusion balloon (Ryusei, Kaneka Medical) prior to paclitaxel drug-coated balloon inflation.[1] Intravascular imaging during the procedure and predischarge coronary computed tomography angiography (CCTA) were performed in all patients. After treatment, if recoil ≥30%, dissection ≥type C, or residual stenosis ≥50% was observed, bailout stenting was performed. Twenty percent required bailout stenting, with these lesions demonstrating higher plaque volume and increased deep-walled calcium. Procedural success was high, with only 1 patient unable to advance the Ryusei balloon and 1 type C dissection without abrupt closure. Dual antiplatelet therapy use in the stentless strategy was 45 days, which is far shorter than the 12 months (or 6 months for high bleeding risk) recommended in current American College of Cardiology/American Heart Association guidelines (2021) for acute coronary syndrome patients, regardless of stenting technique.[5] The primary end point was target vessel failure at 2 years determined by either invasive coronary angiography or CCTA. Twenty percent of those in the stentless group and 16% in the bailout stent group showed target lesion restenosis. Two patients had recurrent myocardial infarction in the target vessel, which perhaps might have been prevented by stenting or prolonged dual antiplatelet therapy.

The authors should be commended on the refinements to the perfusion balloon technique. Compared with traditional balloon dilatation, gradual inflation to the intravascular imaging-guided vessel size likely resulted in reduced dissection and elastic recoil. Further research trialing this strategy with both drug-eluting balloons and drug-eluting stents is clearly needed. Indeed, at present, the applicability of the perfusion balloon is questionable. The population was highly selective, with 70% of patients excluded due to lesion characteristics (including bifurcation lesions and those over 20 mm) and cardiogenic shock. Similarly, despite limited evidence, aspiration thrombectomy was used in almost half the population. There is further concern that the reduced coronary blood flow through small perfusion balloons might lead to the operator choosing more aggressive anticoagulation, exacerbating any bleeding. Lastly, procedural time was 102 minutes, which might sound beyond the pale to many interventionalists when treating a "type A" lesion or an after-hours ST-elevation myocardial infarction. Despite this, this repurposed old technology might yet become part of cardiologists' armamentarium in treating those at high bleeding risk in addition to those with coronary perforation.

DOI of original article: https://doi.org/10.1016/j.jscai.2023.101175.

Keywords: acute coronary syndrome; dual antiplatelet therapy; perfusion balloon; stentless.

* Corresponding author: paul.bamford@health.nsw.gov.au (P. Bamford).

https://doi.org/10.1016/j.jscai.2023.101189
Received 20 September 2023; Accepted 21 September 2023
Available online 13 October 2023

Peer review statement

Associate Editor Cindy L. Grines had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to Editor-in-Chief Alexandra J. Lansky.

Declaration of competing interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding sources

This editorial did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

References

1. Fukuoka R, Kawasaki T, Umeji K, et al. Novel stentless strategy with perfusion and drug-coated balloons for treating acute coronary syndrome. *J Soc Cardiovasc Angiogr Interv.* XXX.
2. Erbel R, Clas W, Busch U, et al. New balloon catheter for prolonged percutaneous transluminal coronary angioplasty and bypass flow in occluded vessels. *Cathet Cardiovasc Diagn.* 1986;12(2):116–123. https://doi.org/10.1002/ccd.1810120211
3. Görge G, Erbel R, Haude M, et al. Continuous coronary perfusion balloon catheters in coronary dissections after percutaneous transluminal coronary angioplasty: acute clinical results and 6-months follow-up. *Eur Heart J.* 1994;15(7):908–914. https://doi.org/10.1093/oxfordjournals.eurheartj.a060609
4. Mangner N, Farah A, Ohlow MA, et al. Safety and efficacy of drug-coated balloons versus drug-eluting stents in acute coronary syndromes: a prespecified analysis of BASKET-SMALL 2. *Circ Cardiovasc Interv.* 2022;15(2):e011325. https://doi.org/10.1161/CIRCINTERVENTIONS.121.011325
5. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(3):e18–e114. https://doi.org/10.1161/CIR.0000000000001038