[4] Ewen S, Zivanovic I, Böhm M, Mahfoud F. CardioPulse. Catheter-based renal denervation for hypertension treatment: update 2015. Eur Heart J 2016 Mar 21;37(12):930–3.
[5] Sakakura K, Ladich E, Cheng Q, et al. Anatomic assessment of sympathetic periarterial renal nerves in man. J Am Coll Cardiol 2014;64(7):635–43.
[6] Kandzari DE, Böhm M, Mahfoud F, et al. Effect of renal denervation on blood pressure in the presence of antihypertensive drugs: 6-month efficacy and safety results from the SPYRAL HTN-ON MED proof-of-concept randomised trial. Lancet 2018;391(10137):2346–55.
[7] Osborn JW, Foss JD. Renal nerves and long-term control of arterial pressure. Compr Physiol 2017;7(2):263–320.
[8] Banek CT, Knuepfer MM, Foss JD, et al. Resting afferent renal nerve discharge and renal inflammation: elucidating the role of afferent and efferent renal nerves in deoxycorticosterone acetate salt hypertension. Hypertension 2016;68(6):1415–23.
[9] Foss JD, Wainford RD, Engeland WC, Fink GD, Osborn JW. A novel method of selective ablation of afferent renal nerves by periaxonal application of capsaicin. Am J Physiol Regul Integr Comp Physiol 2015;308(2):R112–22.
[10] Kopp UC, Cicha MZ, Smith LA, Mulder J, Hökfelt T. Renal sympathetic nerve activity modulates afferent renal nerve activity by PGE2-dependent activation of α1- and α2-adrenoceptors on renal sensory nerve fibers. Am J Physiol Regul Integr Comp Physiol 2007;293(4):R1561–72.
[11] DiBona GF, Kopp UC. Neural control of renal function. Physiol Rev 1997;77(1):75–197.
[12] Kopp UC. Neural control of renal function (colloquium series on integrated systems physiology: from molecule to function). San Rafael, California: Morgan & Claypool Life Sciences; 2011.
[13] Katholi RE. Renal nerves in the pathogenesis of hypertension in experimental animals and humans. Am J Physiol 1983;245(1):F1–14.
[14] Lusch A, Leary R, Heidari E, et al. Intrarenal and extrarenal autonomic nervous system redefined. J Urol 2014;191(4):1060–5.
[15] Sakakura K, Ladich E, Cheng Q, et al. Anatomic assessment of sympathetic periarterial renal nerves in man. J Am Coll Cardiol 2014;64(7):635–43.
[16] Heuser RR, Mhatre AU, Buelna TJ, Berci WL, Hubbard BS. A novel non-vascular system to treat resistant hypertension. EuroIntervention 2013;9(1):135–9.
[17] Heuser RR, Sievart H, Schlaich M. Renal denervation: a new approach to treatment of resistant hypertension. London, UK: Springer; 2014.
[18] Vink EE, Goldschmeding R, Vink A, Weggemans C, Bleijs RL, Blankestijn PJ. Limited destruction of renal nerves after catheter-based renal denervation: results of a human case study. Nephrol Dial Transplant 2014;29(8):1608–10.
[19] Mahfoud F, Schlaich M, Kindermann I, et al. Hypertension effect of renal sympathetic denervation on glucose metabolism in patients with resistant hypertension: a pilot study. Circulation 2011;123:1940–6.
[20] Narkiewicz K, Somers VK. Sympathetic nerve activity in obstructive sleep apnoea. Acta Physiol Scand 2003;177(3):385–90.
[21] Rundqvist B, Elam M, Bergmann-Sverrisdottir Y, Eisenhofer G, Friberg P. Increased cardiac adrenergic drive precedes generalized sympathetic activation in human heart failure. Circulation 1997;95(1):169–75.

Letter by Dérimay et al. regarding the article, "A randomized trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds – The Absorb Bifurcation Coronary (ABC) trial" by Rampat et al.☆

We read with great interest the study by Rampat et al. [1], comparing two stent sizing strategies (proximal vs. distal) in coronary bifurcation provisional stenting with ABSORB bioresorbable vascular scaffolds (BVS) (Abbott Vascular). In 37 patients, they concluded that stent sizing according to the proximal vessel leads to less stent malapposition, and advised this strategy. However, we disagree with these conclusions.

In classic metallic stents, a distal sizing is clearly recommended, to decrease the risk of distal dissection and/or carina shifting [2]. This strategy involves correcting the systematic proximal malapposition due to fractal geometry [3]. A proximal post-dilatation or Proximal Optimization Technique (POT) demonstrated perfect apposition and side-branch ostium optimization [4]. However, the specific mechanical properties of bioresorbable poly-L-lactic (PLLA) are its viscoelasticity and low elongation at break (with scaffold fracture risk) [5]. These properties could put in doubt the strategy proposed by Rampat et al. Foin et al. [6], however, demonstrated that BVS can be post-dilated up to 1 mm beyond the nominal diameter without fracture. In a bifurcation bench study, we confirmed that a provisional strategy with distal BVS sizing followed by POT provided excellent mechanical results without significant fracture on micro-CT analysis [7]. The ABC trial excluded left main coronaries, so the physiological stepwise differences between proximal and final vessels were systematically all <1 mm [8]. In fact, the only case of BVS fracture occurred after a kissing balloon inflation with balloon juxtaposition that probably exceeded this threshold.

In this study, the authors concluded that proximal stent sizing was probably better, mostly because proximal apposition was judged worse in case of distal sizing. However, this difference was probably due to technical points more than to the choice of vessel for sizing. In distal sizing, POT balloon diameter and inflation pressure were lower than for proximal sizing. Thus, given the post-dilatation capability of BVSs up to 1 mm, it seems that the malappositions were probably due to stent under-expansion after POT. Moreover, malapposition threshold is threshold defined by summing stent thickness and OCT resolution (<170 μm); in this study, however, the malapposition threshold was higher than usual (300 μm) [9]. This higher threshold could easily underestimate intermediate malapposition (between 170 μm and 300 μm), which are more frequent with proximal sizing. Conversely, the authors observed an unsurprising trend for excess of distal dissection with proximal sizing (which was probably non-significant only because of the small sample size). Moreover, it is interesting to know that the ABSORB 2.5 mm and 3.0 mm models are in fact the same scaffold. A specific analysis taking account of this might change the final interpretation.

Thus, in our opinion, it cannot be concluded that a proximal sizing is preferable for BVS implantation in bifurcations. Given the possibility of BVS post-dilatation up to 1 mm without fracture, it seems that the same strategy as metallic stent with distal BVS sizing and systematic POT could be recommended most of the time to avoid distal dissection. The key point concerning final proximal malapposition is primarily the technical characteristics of the POT. The choice of balloon diameter and pressure, the mechanical properties (compliance or not) and inflation time according to PLLA viscoelasticity are essential factors. We look forward to reading Dr. Rampat's response to the above.

François Dérimay*
Gilles Rioufol
Gérard Finet
Cardiology Department, Cardiovascular Hospital, Lyon, France
INSERM, U-1060 Lyon, France
*Corresponding author at: Fédération de Cardiologie Médicale, Hôpital Cardiologique, 69394 Lyon, France.
E-mail address: fderimay@hotmail.fr.

https://doi.org/10.1016/j.carrev.2018.08.024

☆ Conflict of interest: All authors report no relationships to disclose.

References

[1] Rampat R, Mayo T, Hildick-Smith D, Cockburn J. A randomised trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds – the Absorb bifurcation coronary (ABC) trial. Cardiovasc Revasc Med 2019;20(1):43–9.
[2] Lassen JF, Burzotta F, Banning AP, Lefèvre T, Darremont O, Hildick-Smith D, et al. Percutaneous coronary intervention for the Left Main stem and other bifurcation lesions. The 12th consensus document from the European Bifurcation Club. EuroIntervention 2018;13(13):1540–53.
[3] Finet G, Gilard M, Perrenot B, Rioufol G, Motreff P, Gavit L, et al. Fractal geometry of arterial coronary bifurcations: a quantitative coronary angiography and intravascular ultrasound analysis. EuroIntervention 2008;3(4):490–8.

[4] Finet G, Derimay F, Motreff P, Guerin P, Pilet P, Ohayon J, et al. Comparative analysis of sequential proximal optimizing technique versus kissing balloon inflation technique in provisional bifurcation stenting: fractal coronary bifurcation bench test. JACC Cardiovasc Interv 2015;8:1308–17.
[5] Onuma Y, Serruys PW. Bioresorbable scaffold. The advent of a new era in percutaneous coronary and peripheral revascularization? Circulation 2011;123:779–97.
[6] Foin N, Lee R, Mattesini A, Caiazzo G, Fabris E, Kilic ID, et al. Bioabsorbable vascular scaffold overexpansion: insights from in vitro post-expansion experiments. EuroIntervention 2015;11:1389–99.
[7] Derimay F, Souteyrand G, Motreff P, Guerin P, Pilet P, Ohayon J, et al. Sequential Proximal Optimizing Technique (rePOT) in provisional bifurcation stenting with everolimus-eluting bioresorbable vascular scaffold. Fractal coronary bifurcation bench for comparative test between ABSORB™ and XIENCE Xpedition™. JACC Cardiovasc Interv 2016;7:1397–406.
[8] Huo Y, Finet G, Lefévre T, Louvard Y, Moussa I, Kassab GS. Optimal diameter of diseased bifurcation segment: a practical rule for percutaneous coronary intervention. EuroIntervention 2012;7(11):1310–6.
[9] Derimay F, Finet G, Souteyrand G, Maillard L, Aminian A, Lattuca B, et al. Benefit of a new provisional stenting strategy: the re-proximal optimizing technique. The rePOT clinical study. EuroIntervention 2018;14(3):325–32.

In reply to: Letter by Dérimay et al. regarding the article, "A randomized trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds – The Absorb Bifurcation Coronary (ABC) trial" by Rampat et al.

We would like to thank Dérimay et al. for their interest in our study [1].

In line with EBC recommendation, we agree that a distal sizing strategy is preferable when using metal stents to treat coronary bifurcation disease [2]. Such a strategy avoids distal oversizing while allowing correction of proximal malapposition with liberal Proximal Optimisation Technique without incurring a significant risk of damage to the stent. However caution must be exercised with the ABSORB BVS due to the inherent limits of its expansion capacity. In fact, this difference in mechanical properties between stent and scaffold was the main impetus behind our study.

While we appreciate that bench studies have shown a postdilatatory capacity of 1 mm above the nominal diameter without scaffold damage [3], we disagree with the implication that this can therefore safely be performed in vivo. Acute scaffold disruption has even been observed in patients where the post dilatation balloon was same size of the scaffold [4]. The manufacturers of the ABSORB BVS recommend that post dilatation be performed with a balloon no larger than 0.5 mm of the scaffold size. In the interest of safety, we limited our study to bifurcations where the difference between proximal and distal reference diameters would not unduly take us above this threshold. This meant excluding left main bifurcation lesions. In that respect, we accept that our recommendation of a proximal sizing strategy may not be applicable to large bifurcations.

With metal stents, the right sizing strategy aims to achieve the balance between minimising the risk of both distal dissection and proximal malapposition. However, in our opinion, it would be a mistake to treat malapposition and edge dissection equally in the context of BVS implantation. The commercial lifespan of the ABSORB BVS was plagued by its higher risk of thrombosis compared to metal stents. Intracoronary imaging studies have revealed malapposition to be one of the most frequent intravascular findings in cases of ST [5]. We would argue that malapposition is a more hazardous phenomenon in BVS than DES. However not all malapposed struts carry an equal risk and malapposition distance also needs to be taken into account. In a study with drug eluting stents in stable angina, a malapposition distance of >300 μm showed the highest likelihood of delayed strut healing and persistence on follow up imaging [6]. Conversely, another study with metal stents found that struts with a malapposition distance of <270 μm are more likely to be apposed at 9 months [7]. It is not unreasonable to assume that struts with a low malapposition distance are less likely to induce persistent flow disturbance and thus pose a smaller thrombotic risk. Based on these observations, we chose a cut off of 300 μm to define a significantly malapposed strut.

Finally, we did observe a numerically higher but statistically insignificant number of distal dissections with a proximal sizing strategy compared to a distal one. While we recognize that our sample size was not large, it would be erroneous to assume that a larger cohort would have demonstrated statistical significance.

Yours Sincerely,

Rajiv Rampat*
Thomas Mayo
David Hildick-Smith
James Cockburn
*Corresponding author.
E-mail address:rampat@doctors.org.uk (R. Rampat).

2 November 2018

https://doi.org/10.1016/j.carrev.2018.11.002

References

[1] Dérimay F, Rioufol G, Finet G. Letter by Dérimay et al. regarding the article, "A randomized trial comparing two stent sizing strategies in coronary bifurcation treatment with bioresorbable vascular scaffolds – the Absorb Bifurcation Coronary (ABC) trial" by Rampat et al. Cardiovasc Revasc Med 2019;20(1):85.
[2] Lassen JF, Holm NR, Stankovic G, et al. Percutaneous coronary intervention for coronary bifurcation disease: consensus from the first 10 years of the European Bifurcation Club meetings. EuroIntervention 2014;10(5):545–60.
[3] Foin N, Lee R, Mattesini A, et al. Bioabsorbable vascular scaffold overexpansion: insights from in vitro post-expansion experiments. EuroIntervention 2016;11(12):1389–99.
[4] Onuma Y, Serruys PW, Muramatsu T, et al. Incidence and imaging outcomes of acute scaffold disruption and late structural discontinuity after implantation of the absorb Everolimus-Eluting fully bioresorbable vascular scaffold: optical coherence tomography assessment in the ABSORB cohort B Trial (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions). J Am Coll Cardiol Intv 2014;7(12):1400–11.
[5] Sotomi Y, Suwannasom P, Serruys PW, Onuma Y. Possible mechanical causes of scaffold thrombosis: insights from case reports with intracoronary imaging. EuroIntervention 2017;12(14):1747–56.
[6] Foin N, Gutiérrez-Chico JL, Nakatani S, et al. Incomplete stent apposition causes high shear flow disturbances and delay in neointimal coverage as a function of strut to wall detachment distance. Circ Cardiovasc Interv 2014;7(2):180.
[7] Gutiérrez-Chico JL, Wykrzykowska J, Nüesch E, et al. Vascular tissue reaction to acute malapposition in human coronary arteries. Circ Cardiovasc Interv 2012;5(1):20–9.