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Editorial

What are the remaining lessons to be learnt from 1st-generation bioresorbable scaffolds?

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After bioresorbable scaffolds (BRS) were introduced into the percutaneous coronary intervention (PCI) field, they were touted as the next revolution following drug-eluting stents [1]. Although 1st-generation BRSs were immature devices with several limitations, the devices were used much in the same way as contemporary drug-eluting stent (DES). Despite positive results in early studies dealing with relatively simple lesions, a more generalized usage of these devices generated concerns regarding a higher risk of scaffold thrombosis [2,3], and eventually 1st generation BRS disappeared from the front stage.

In this issue of *International Journal of Cardiology*, Wo et al. present one-year angiographic and clinical outcomes of XINSORB bioresorbable sirolimus-eluting scaffold [4]. XINSORB BRS is a 1st-generation BRS with thick struts (160 μm), similar to Absorb BRS, and it was compared to newer generation DES with thinner struts (80 μm). The results show excellent one-year outcomes with XINSORB BRS; in-segment late lumen loss was 0.19 ± 0.32 mm, and 12-months target lesion failure rate of 0.8%. Even though their results are promising, unfortunately they will not be able to affect the current status of BRS. A relatively large number of study patients underwent BRS implantation (200 pts in randomization part and 798 pts in registry part of the study), and therefore it is useful to accumulate clinical data. However, an optimized implantation strategy, which is now considered essential to overcome some limitations of 1st generation BRS [5,6], was not utilized; and notably intravascular imaging was not performed in any of patients. The excellent one-year outcomes reported in this study may be due in part to the simple target lesions (more than 90% type A/B1 lesion) treated. It would also not be surprising if higher event rates occur at longer follow up periods, similar to multiple prior reports. Therefore, the one-year favourable outcome reported provides limited information at present, since longer follow-up is required.

BRS technology is currently in a difficult position and its successful revival will not be easy. At the very least, new generation BRS must overcome the limitations of 1st generation BRS. We see the need for thinner struts, greater radial force, and shorter resorption time with a lesser degree of inflammation secondary to polymer resorption. In fact, new generation devices have been developed in accordance with these concepts [7], but these results are only a first step. The disappearance of a foreign body from a coronary vessel is intellectually pleasing, nevertheless we need demonstration of clinical benefit. Despite some initial positive results, the recovery of vasomotion has not been elucidated in a randomized study [8]. Plaque sealing leading to a stable "golden tube" have been reported as positive features; however, the occurrence of neoatherosclerosis after 5 years of Absorb BRS implantation were unfortunately reported in a number of lesions [9]. Very soon we will see the publication of the long term clinical outcome (over 5 years) of patients treated with BRS in some large randomized studies and the medical community is quite eager to see if there is an impact towards reduction of clinical events.

The road leading to BRS come back is made more difficult by continuous refinement of newer generation DESs that can now be implanted with relatively short durations of dual antiplatelet therapy (DAPT). The need for prolonged DAPT represents a further limitation of BRS. We cannot exclude that a thin strut BRS with short resorption time may partially overcome this limitation, but this consideration needs to be supported by data.

It is our view that these barriers should not limit the search for a better BRS and efforts to revive this field. At the very least: 1) reasonable short to long-term safety/ efficacy (by new generation BRS); and 2) obvious clinical advantages post complete resorption need to be established. If they become a reality in the future, BRS technology could make a comeback.

Disclosures

All authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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