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Atherectomy and Specialty Balloons in Percutaneous Coronary Intervention

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Abstract

Purpose of review Interventional cardiologists are increasingly being called upon to perform complex revascularization in patients who are deemed not to be candidates for surgical revascularization and, until recently, many of these patients would have only been offered medical management. Further, changing demographics have resulted in an increasingly elderly and frail population with diabetes and chronic kidney disease being referred for revascularization. Owing to the increasing prevalence of coronary artery calcification and the importance of achieving complete revascularization, advanced tools and techniques are required to safely revascularize this patient population.
Recent findings Coronary artery calcification is a marker for increased periprocedural complications and worse long-term outcomes in percutaneous intervention. Its presence may mandate advanced revascularization strategies to facilitate safe revascularization. Several studies have highlighted the importance of intracoronary imaging and there have been iterative changes and new devices that have been developed that can facilitate revascularization in the setting of significant coronary artery calcification.
Summary Successful coronary revascularization is increasingly dependent on the rational use of intraavascular imaging, specialized balloons and atherectomy to overcome complex coronary artery disease and calcification. A rational strategy for the safe use of advanced techniques and tools is presented here.

Introduction

The past decade has seen significant evolution in the field of interventional cardiology. The refinement in interventional equipment, techniques, plaque modification, and pharmacologic strategies has resulted in percutaneous revascularization being attempted in increasingly complex coronary artery disease. This trend has increased owing to a variety of factors, better evidence of success, and an increasing proportion of patients that represent prohibitive operative risk owing to frailty or co-morbidities. Despite these trends, certain lesion characteristics pose a greater challenge to the interventionalist and worse prognosis for the patient. One such characteristic is coronary calcification.

Coronary artery calcification (CAC) is associated with vessel dissection, perforation, difficulty in-stent delivery, polymer disruption of drug-eluting stents, impaired drug delivery, and stent under-expansion. This results in increased frequency of periprocedural complications, stent thrombosis, and high rates of restensosis [1]. However, coronary angiography only detects the presence of CAC in approximately 30% of cases undergoing PCI. Intracoronary imaging identifies CAC in 70% and also provides information on the depth and arc of CAC, information that can be invaluable for procedural planning [2]. Nevertheless, intracoronary imaging remains an under-utilized modality and is only used in 25% of cases in the USA [3]. This failure to routinely use intracoronary imaging may partly explain the inferior revascularization in CAC; it is impossible to reliably prepare the lesion prior to stent implantation. Therefore, there are higher rates of stent deformation, under-expansion, and mal-apposition. Consequently, patients with unrecognized CAC may not realize the benefit of revascularization resulting in this population having higher rates of target lesion revascularization (TLR), restenosis, and major adverse cardiovascular events (MACE) [1, 4–6, 7••]. This may also explain the observed association between intracoronary imaging and lower rates of TLR, death, MI, and stent thrombosis as compared to conventional angiography in isolation [7••, 8, 9].

Importantly, the ULTIMATE trial which randomized a population of 1448 all-comers to IVUS vs standard angiography to PCI with a second-generation drug-eluting stent (DES) demonstrated significant improvement in mean stent diameter (3.15 ± 0.42 vs 2.99 ± 0.38, $p < 0.001$) and a reduction in target vessel failure at 12 months 2.9% vs 5.4%, $p = 0.019$ [7••]. Although a priori planned atherectomy use was exclusion criteria for the trial, atherectomy was used at the discretion of the operator and was used more commonly in those who underwent IVUS-guidance. Further, while 30% of this study population had diabetes, 66% had American Heart Association B2 or C lesions and while not statistically significant, there was a trend for increased benefit in those with more complex lesions. Furthermore, while the ILUMIEN III trial excluded patients with calcification, it found that optical coherence tomography (OCT) or IVUS use resulted in similar mean stent area with both offering improvements compared to angiography alone [9]. While plaque-rich areas can obscure calcification, OCT has the advantage of deeper vessel penetration in the setting of CAC, allowing for a better understanding of the depth of CAC which can impact the revascularization strategy. Given that an increasing proportion of patients who are sent for revascularization are frail, elderly, hypertensive, diabetic or have renal disease, or small diameter coronaries, an even lower threshold for intracoronary imaging should be applied as these patient groups are more likely to have severe CAC [1, 10]. Indeed, observational data confirm that intracoronary imaging use is increasing, but is used in a minority of PCI cases and with substantial institutional variation. Preliminary data on the inpatient utilization of intracoronary imaging from the National Inpatient Sample (NIS) Healthcare Utilization Project (HCUP) suggests OCT and IVUS are performed in less than 5% of total inpatient PCI procedures in the USA. [11] Despite the limitations of observational data, its findings are consistent with randomized trial data indicating that intracoronary imaging use is associated with reduced in-hospital mortality (OR = 0.77; 95% CI 0.71–0.83) [12]. This argues strongly for the case that revascularization strategy is informed by intracoronary imaging and that this superior visualization of the lumen and CAC improves outcome. While there is a paucity of randomized clinical data to guide the appropriate selection of techniques, we suggest escalating the plaque modification strategy (Fig. 1) depending on the calcification pattern, local expertise, and resource availability.

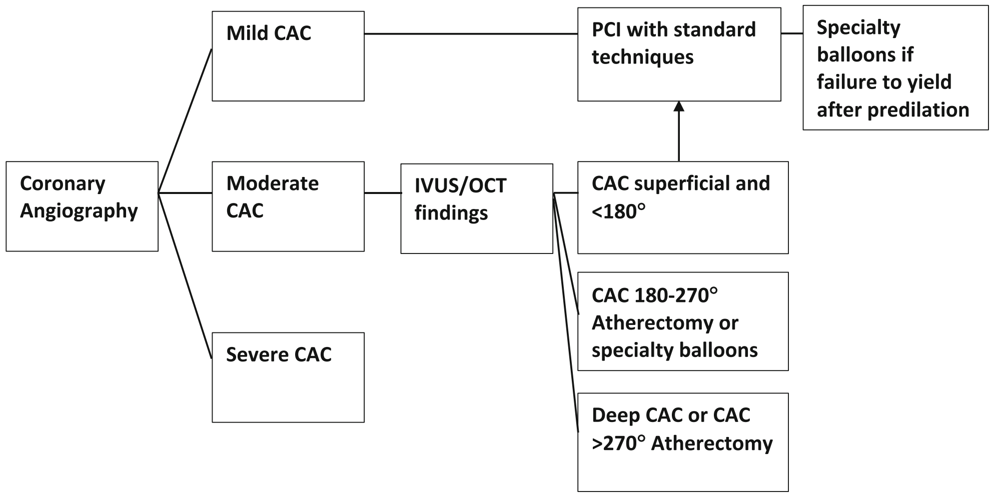

Fig. 1. Algorithm for strategy escalation for coronary calcification. CAC coronary calcification, IVUS intravascular ultrasound, OCT optical coherence tomography.

Specialized balloons

Conventional angioplasty has three main shortcomings with respect to calcified coronary lesions. First, balloon expansion is random; second, balloon expansion is directed towards the most compliant vessel wall; and third, the balloon may be unable to grip the lesion resulting in "melon seeding" to non-diseased vessel segments. Cutting balloons and scoring balloons have been specifically designed to overcome each of these shortcomings. By incorporating longitudinally orientated blades or wires onto the balloon surface, forces are directed in a predictable and focused location. This results in symmetric expansion of the balloon with relatively predictable dissection planes within the vessel wall. This prevents asymmetric expansion caused by failing to fracture an arc of calcium within the vessel wall. Should this shortcoming not be recognized, stent deformity can result during stent placement. Further, the blades/wires of the modified balloons tend to grip the vessel intima preventing "melon seeding" or "geographic miss." Given the mechanism of these balloons, they should be sized in a 1:1 ratio to the vessel lumen.

Clinically, given the mechanism of action of cutting balloons (e.g., Flextome & Wolverine Cutting Balloon; Boston Scientific Corp, Natick, MA), they are able to achieve a larger luminal gain than conventional lesion preparation in aorto-ostial lesions [13]. Indeed, cutting balloons have continued to be commonly used in this scenario owing to their ability to cause increased disruption of the muscular layer of the media resulting in increased luminal gain in this location. However, there has been evolution in the use of these devices in other locations. Originally, there was also some expectation that these devices could minimize trauma to the vascular endothelium by causing predictable and longitudinal dissection planes as opposed to multiple, random dissection planes as seen with plain old balloon angioplasty (POBA). It was thought that this capability would thereby minimize restenosis as compared to POBA in smaller (< 3 mm) vessels. This was examined in the Cutting Balloon Global Randomized trial of 1238 patients. This trial found no difference in the rates of restenosis at 6 months (31% vs 30%, $p = 0.75$) for cutting balloons vs POBA and there was a greater rate of perforation (0.8% vs 0%, $p = 0.03$) with cutting balloon use [14]. This finding may bias the interpretation of a small study of 61 Japanese patients that found that use of cutting balloons prior to stent implantation was associated with a larger minimal luminal diameter and lower restenosis rate as compared to conventional lesion preparation [15]. The relevance of this finding with modern lesion preparation and routine use of third-generation drug-eluting stents is questionable. Given the small increased rate of perforation and no convincing signal of widespread benefit to its use, cutting balloons have largely been reserved for selected cases with at least mild to moderate calcification. Severe calcification and tortuosity have until recently been the domain of other devices owing to the bulkiness and rigidity of the cutting balloon which can make delivery challenging. However, a new iteration of the Flextome Cutting Balloon (Wolverine Cutting Balloon) is now available in some markets. This device is less bulky, has a lower profile, is more flexible, and has a re-designed tip which is more deflectable. These changes make the device more deliverable in calcified and tortuous vessels making it more feasible for use in patients with more extensive CAC.

The AngioSculpt (Spectranetics, Colorado Springs, CO, USA) device operates using a similar principle to the cutting balloon. It is composed of a semi-compliant nylon balloon covered with three scoring nitinol wires arranged in a spiral pattern. While there are no randomized trials of this device as compared to a cutting balloon, anecdotally it appears more deliverable than the cutting balloon and functions similarly. In an observational study of direct stenting vs conventional pre-dilation vs pre-dilation with an AngioSculpt balloon prior to stenting, AngioSculpt use was associated with a 30–50% larger luminal gain that either conventional pre-dilation or direct stenting [16]. In a registry of left main interventions, use of an AngioSculpt resulted in a greater luminal gain as compared to conventional LM preparation, no perforations, and a suggestion of improved MACCE at 12 months (12.5% vs 15.4%, $p = 0.39$) [17]. However, despite the realized promise of improved short-term outcomes of a more predictable and controlled injury of the vessel wall, less flow-limiting dissections as compared to POBA and improved luminal gain, rates of neointimal proliferation, and restenosis are similar [18]. Therefore, further modifications to the AngioSculpt are under study. Early work has demonstrated promising results with a paclitaxel-coated scoring balloon. It is hypothesized that this modification may facilitate the penetration and delivery of the anti-proliferative drug and that this modification may be more effective than either strategy used in isolation. In a study of 61 patients with severe in-stent restenosis of a previously placed bare-metal stent in-stent, treatment with a drug-coated scoring balloon compared to a conventional scoring balloon resulted in lower rates of restenosis (7% vs 41%, $p = 0.004$), MACE (6% vs 32%, $p = 0.016$) restenosis, and TLR (3% vs 32%, $p = 0.004$) [19]. Recently, one patient had two de novo complex coronary lesions treated with this device in isolation with no procedural complications [20]. Angiographic follow-up at 4 months showed persistent good angiographic result. While these results are very preliminary, they are encouraging and suggest that this may be a promising strategy in the future or in selected patient populations.

Given that there are no randomized trials to inform clinical use between cutting and scoring balloons, we tend to use scoring balloons in situations where there is heavy tortuosity and moderate calcification, particularly in de novo lesions. Where there is more extensive calcification, ISR lesions, or in left main lesions, we tend to use cutting balloons while ensuring that it is sized 1:1 to the vessel diameter.

Atherectomy

Initially, atherectomy was hypothesized to reduce the rates of restenosis by reducing the plaque burden at the lesion site [21]. This hypothesis was refuted by multiple trials that demonstrated that routine atherectomy was associated with increased periprocedural myocardial infarction, did not improve long-term outcome, and was associated with increased TVR [22]. Therefore, use of atherectomy became more selective, reserved as a means to facilitate stent delivery and maximal expansion by altering plaque morphology and changing lesions compliance. In those with heavy CAC, conventional lesion preparation resulted in a 6% delivery failure and a twofold increased rate of failure to deploy a stent [23]. In this population, use of atherectomy persisted because of its ability to reduce procedural and fluoroscopy times, contrast volume, and the number of pre-dilation balloon catheters used as compared to bail-out atherectomy in patients with CAC [24].

Despite these caveats, evidence of the superiority of atherectomy in CAC remains elusive. In the ROTAXUS trial, 240 patients with complex calcified native coronary lesions were randomized to rotational atherectomy (RA) followed by stenting or conventional lesion preparation followed by stenting. While RA resulted in a higher initial lumen gain (1.56 ± 0.43 vs 1.44 ± 0.49, $p = 0.01$), there was greater lumen loss at 9 months (0.44 ± 0.58 vs 0.31 ± 0.52, $p = 0.04$) [25]. Importantly, there was no difference in binary restenosis, target lesion revascularization, stent thrombosis, and MACE at 9 months. This failure to demonstrate superiority of RA may have been obscured by the 8% higher rate of cross-over to the RA strategy, highlighting the difficulty in obtaining truly randomized data in this population.

Modern registry data highlight that RA is being used with increasing frequency with good short-term outcomes [26, 27]. While RA use in patients with CAC is associated with higher complications than PCI in non-calcified lesions, not using RA in the setting of CAC is associated with even higher rates of complications [26]. In patients with severe CAC, the use of RA was associated with a 1.3% rate of serious complications (in-hospital death, cardiac tamponade, and emergent surgery after RA). Importantly, while the risk of RA is determined by patient factors such as advanced age, kidney disease, previous myocardial infarction, and emergent need for the procedure, institutional volume is inversely associated with complications [27]. Therefore, in situations where there is an unfamiliarity with the use of RA, when possible, the case should be referred for intervention at a high-volume center. In situations where this is not feasible or practical, the PREPARE-CALC trial suggests that there may be a narrow "middle path." In the PREPARE-CALC trial, 200 patients with evidence of severe calcification of the target lesion on standard angiography were randomized to treatment with a cutting/scoring balloon or RA. Crucially, cross-over to RA was only allowed if the lesion could not be crossed by any balloon or adequately expanded with a specialized balloon or a stent could not be delivered after complete balloon expansion. In this study, complications were no different between the two groups; however, use of RA resulted in a higher rate of procedural success (stent delivered with a < 20% residual stenosis without cross-over or stent failure) 98% vs 81%, $p = 0.0001$. There was no difference in late lumen loss at 9 months, nor was there any difference in clinical outcomes at 9 months [28•]. Nevertheless, it must be stressed that RA was always available as a back-up strategy in the event of failure with specialized balloons.

Orbital atherectomy (OA) (Diamondback 360° Coronary Oribital Atherectomy System, Cardiovascular Systems Inc., St. Paul, MN, USA) uses a 1.25-mm eccentrically mounted crown and centrifugal force to ablate hard tissue while flexing away from elastic (healthy) tissue. The device utilizes a single burr size that provides bidirectional ablation of lesions in a 6-Fr capable device. Increasing the time in contact with the lesion, the number of passes or the rotational speed results in larger luminal gain. The small crown size and elliptical orbit allow for continuous perfusion of the distal territory, continual dispersal of the particulate matter, and cooling of the crown, thus reducing the risk of thermal injury, a possible cause of restenosis [29]. It also results in smaller particulate generation, continuous blood flow, and deeper tissue modification as compared to RA, which may result in different outcomes as compared to RA. However, no-large scale randomized head-head trials have yet occurred [30, 31]. Using the weighted averages from the ORBIT I, ORBIT II, and COAST, the incidence of MACE at 30 days was 11.1% largely driven by MI (10.1%). Procedural complications of perforation, dissection, abrupt closure, and no-reflow were 1.9%, 3.9%, 2%, and 1.3% respectively [32]. The benefits of OA seemed to be durable, the 3-year analysis of ORBIT II, which enrolled patients with severe CAC demonstrated MACE of 23.5% and TLR of 7.8% [33]. While the ORBIT II trial did not enroll patients with aorto-ostial lesions, the registry did. In the registry data, there were 59 cases of aorto-ostial lesions that were treated with OA. In this population, there was no difference in the 30-day rates of death, TVR and stroke, or in angiographic complications [34].

While there are no randomized comparisons of OA vs RA, a single center completed a real-world analysis of their use of OA and RA in 184 patients. They found no difference in the rates of periprocedural complications, kidney injury, residual stenosis, or peak cardiac biomarker level in either group [35]. Conversely, an observational study of 546 propensity matched patients from a sample of 907 patients who underwent either OA or RA from five sites between 2011 and 2017 determined that myocardial infarction was higher amongst patients with RA vs OA (13.8 vs 6.7%, $p \leq 0.01$) [36]. This same analysis found no differences in the periprocedural outcomes of dissections, perforation, and tamponade while OA use was associated with reduced fluoroscopy time. Promisingly, they found that OA was associated with a reduction in in-hospital mortality (2.2% vs 0%, $p = 0.01$). They hypothesized that the reduced fluoroscopy time was related to the bidirectional action of OA and that the reduced MI was related to the smaller particulate matter that is generated and the fact that the device maintains distal vessel perfusion. While this data is intriguing and supports the safety of OA, it would be premature to draw firm conclusions based on this observational data and the limitations therein. The ongoing ECLIPSE trial (NCT03108456) is randomizing eligible patients with severe CAC to receive either conventional balloon angioplasty and stenting or orbital atherectomy followed by conventional balloon angioplasty and stenting.

Given the reduced rate of vascular complications associated with radial access, it has become the default vascular access route in all of our cases. The vast majority of patients will accept a 6/7F Glidesheath slender (Terumo, Tokyo, Japan) allowing a 7F guide to be placed which will accept a 1.25-mm OA crown or a RA burr size of up to 2.0 mm, sufficient for the vast majority of RA cases. When using RA, a burr-artery ratio of 0.5–0.7 is maintained owing to the lower rates of procedural complications with preserved long-term outcomes [37, 38]. The burr speed is maintained between 140,000 and 160,000 RPM and a pecking motion is maintained to prevent decelerations of > 3000 RPM for runs of no longer than 30 s to reduce no-reflow and myocardial ischemia. Instead of using pacing, or even using atropine in cases of symptomatic bradycardia, our practice has been to give 100–250 mg IV of aminophylline prior to commencing ablation with RA or OA. This strategy has been successful in preventing the adenosine-mediated bradycardia that is often seen with atherectomy [39].

In our practice, RA is used preferentially over OA for calcified aorto-ostial lesions given the theoretical higher risk of aortic root dissection associated with OA. However, OA may be used cautiously in this anatomic subset if the device can be introduced beyond the lesion and ablation performed in a retrograde fashion at low speed. If this is not possible, the guide must be in a co-axial position and the nose cone placed into the lesion beyond the ostium while keeping the crown 5 mm from the lesion to constrain the orbit of the device and ablation performed under low speeds. If the nose cone cannot be introduced in this manner, RA should be used instead.

A potential shortcoming of atherectomy-based strategies (RA more than OA) is that it transcribes a circular pattern that follows the path of the guidewire. This is a particular concern in tortuous and heavily angulated vessels as the wire bias may result in vessel perforation. Therefore, a novel, balloon-based strategy for CAC, intravascular lithotripsy, has been developed (Shockwave Medical Inc., Fremont, CA). This nascent strategy is based on the well-established treatment of renal calculi using lithotripsy, with the difference that the acoustic emitters are mounted on a balloon catheter. In this manner, transient acoustic circumferential pressure pulses can be delivered to disrupt calcium within vascular plaques. Preliminary data from a study of 31 patients treated with this technique suggested that the calcium fracture occurred throughout the lesion with a mean acute lumen gain of ~ 2.1 mm^2 without any episodes of no-reflow or vessel perforation [40]. The DISRUPT CAD I trial studied the performance and safety of lithoplasty in 60 patients with moderate to severe CAC. The majority of patients were noted to have clinical (95%) and device success (98.3%) defined as effective device delivery and lithoplasty treatment. The 6-month MACE rate was 8.5% which included non-Q wave MI ($n = 3$) and cardiac death ($n = 2$). [41] DISRUPT CAD II (NCT03328949) is now ongoing and is a Prospective Multi-Center, Single Arm Post-Market Study of the Shockwave Medical, Inc. Coronary Lithoplasty® System in Coronary Arteries. In addition, DISRUPT CAD III (IDE number G180146) is the prospective, multicenter single arm global IDE study of the device and is currently recruiting sites. In the future, this strategy may become a part of the arsenal for CAC.

Compliance with Ethical Standards

Conflict of Interest
David W. Allen declares no potential conflicts of interest. Prashant Kaul reports personal fees from Cardiovascular Systems, Inc. and Boston Scientific.

Human and Animal Rights and Informed Consent
This article does not contain any studies with human or animal subjects performed by any of the authors.

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