Pak Heart J

CALCIFIED CORONARY LESION: IS IT STILL THE ACHILLES' HEAL OF PERCUTANEOUS CORONARY INTERVENTIONS?

Tariq Ashraf[1], Nauman Naseer[2]

1. Professor of cardiology, National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan
2. Professor of Cardiology, King Edward Medical University/Mayo Hospital, Lahore, Pakistan

Address for Correspondence:
Tariq Ashraf
Professor of Cardiology, National Institute of Cardiovascular Diseases (NICVD), Karachi, Pakistan
Emails: tariqash45@gmail.com

Contribution
TA conceived the idea of editorial. Literature review and manuscript writing was done by TA and NN. All the authors contributed equally to the submitted manuscript.

All authors declared no conflict of interest.

Percutaneous Coronary Intervention of heavily calcified coronary lesions still represent a great challenge for interventional cardiologist, resulting in an increased risk of immediate and long term complications due to stent under expansion and malapposition.[2] Multi-modality imaging can help understand the characteristics of calcium, and along with that the use of new armamentarium specifically designed for dealing with moderate to heavy calcification, in making optimal lesion preparation before stent implantation.

Coronary artery calcification (CAC) is seen in patients mostly with advanced age, renal disease and diabetes. Severe CAC is seen in patients between 6% and 20% treated with PCI.[3] Conventional angiography usually misses and has low sensitivity for CAC. Intravascular ultrasound (IVUS) have shown that CAC is missed in nearly half of the cases undergoing angiography.[4] IVUS helps in semiquantitative grading of calcium distribution, localisation length, but deep calcium is hidden by acoustic shadowing. OCT (Optimal Coherence Tomography) provides much better resolution than IVUS, with the additional ability of seeing the depth of calcium and seeing microcalcifications. However, unlike IVUS it requires contrast dye and has limited depth penetration. A lot of patients also have had a coronary CT before their procedure. This can also serve as useful tool to better define CAC characteristics to better plan for lesion intervention. Proper assessment of CAC is important in making a strategic plan for use of different tools of ablation in lesion preparation.

Optimal lesion preparation helps in appropriate stent deployment. The first tool used for dilating coronary lesions is with plain old balloon angioplasty (POBA). Non-Compliant (NC balloons) are meant for more uniform balloon expansion and applying high pressure in a focal segment of a coronary vessel that prevent dumbbell deformation resulting in high pressure at the edges as a resulting edge dissection/perforation. OPN NC - Super High Pressure PTCA balloon has twin-layer technology which permits very high pressures with minimal diameter increase. From limited experience they have been shown to have treated >90% of undilatable lesions compared to a conventional NC balloon with a 0.9% rate of coronary perforation.[5]

The chances of unsuccessful expansion with NC balloons with moderate to heavy calcifications can be high. Further modification in balloon developed in 1991 as cutting balloon dilation device. The structure consisted of blades mounted longitudinally on a noncompliant balloon. It causes three or four endovascular

radial incisions through fibrocalcific tissue without balloon slippage and results in large luminal gain. The results were more effective in aorto-ostial lesions.[6] The CAPAS trial[7] and Cutting Balloon Global Randomized trial[8] showed no difference in outcomes at six months between cutting balloon angioplasty (CBA) and POBA, except that there was an increase in rate of perforation with CBA. This high rate of perforation led to the development of the scoring balloon. It is basically a semi-complaint nylon balloon surrounded by external nitinol spiral scoring wires, which provides focal force concentration without balloon slippage. The feasibility trial[9] showed an increase in rate of dissection with no device related perforation. This balloon was used in ISR and calcified lesions. For lesion preparation to address undilatable stenosis, specially calcified lesion dilating strategy can be adopted resulting in plaque modification.

The advantages of primary atherectomy are multiple and includes decrease procedural and fluoroscopy time, contrast volume and number of predilation balloon catheter used.[10] There are two form of atherectomy i.e. rotational and orbital. Rotational provides differential cutting and orbital differential sanding. Atherectomy alters plaque morphology, creates fractures in calcified lesions and causes an increase in luminal gain. All these parameters help in dilating and optimal stent expansion.

Mechanical debulking of atherosclerotic plaque was introduced in 1988 by David Auth as Percutaneous Transluminal Rotational Atherectomy (PTRA). The mechanistic effect is differential cutting causing ablation of inelastic fibrocalcific plaques while sparing adjacent elastic tissue that deflects away from the ablating burr. The study by Fourier showed an increase in TLR with PTRA vs. balloon.[11,12] STRATAS and CARAT trials used debulking strategy based on the burr to artery ratio lower or higher than 0.7.[13,14] The SARS study showed impact of reducing burr speed during rotation to 140-160 K revolution per minutes (rpm) and avoiding deceleration >3,000 rpm.[15] To reduce effective ablation time and contact of the burr with the plaque i.e. pecking motion.[16]

Other tools for plaque modification is Orbital Atherectomy (OA). Its advantages over RA of having a single size burr, less likelihood of crown entrapment, transient heart block, and no-reflow phenomenon.[17] Moreover as compared to RA, OA result in deeper tissue modification.[18]

Two trials ORBIT I trial (Safety and feasibility of orbital atherectomy for the treatment of calcified coronary lesions), ORBIT II trial (Evaluate the Safety and Efficacy of OAS in Treating Severely Calcified Coronary Lesions) showed safety and efficacy with less complications and MACE[19,20] and three years TLR rate of 7.8%.[21] There has yet to be a large head to head trail comparing OA and RA. Only RA is currently available in Pakistan.

Severe calcification lacks any standard definition. Fluoroscopic presence of visible calcifications on bilateral walls of the vessel without cardiac motion or > 270 degree of calcification on IVUS can help. Some experts recommend upfront atherectomy use in this cases but advise against routine use and others after failed expansion of 1:1 balloon:vessel predilatation. Use of RA, only in the setting of incomplete expansion is a reasonable strategy though predilatation induced dissection may preclude RA should visible dissection result. The ACC/AHA guide lines give RA a class II a recommendation in situations where heavily calcified lesions are difficult to cross or dilate, but advice against routine use.[22] The RA should not be performed on sites without appropriate surgical back up. Whether improved procedural success with RA translates into improved hard outcomes remains to be seen. The practical tips and tricks for RA have been covered very well in the review article by Asim et al.[23] in this issue of the journal.

Intravascular lithotripsy (IVL) a new kid on the block is based on an old technology, which has been used to break up kidney stones for decades. It received CE mark for coronary interventions in 2017. Pulsatile mechanical energy is used to disintegrate selectively amorphous calcium without involving soft tissue. The DISRUPT CAD I and II trials both showed optimal outcomes. The DISRUPT CAD I, primary endpoint (residual diameter stenosis <50% after stent implantation without in-hospital MACE) was achieved in 98.5% of patients and acute luminal gain of 1.7±0.6 mm. There was no major periprocedural complications (no residual dissections/perforation/slow flow).[24] This was followed by DISRUPT CAD II, also a multicenter trial with 120 patients. There was successful delivery of the IVL balloon in all patients (34% facilitated by predilation). The final residual stenosis was 12 ± 5% following DES implantation. Residual stenosis <50% was achieved in all patients, with freedom from in-hospital MACE in 94.2% of patients (including 5.8% with asymptomatic non-Q MI without clinical sequelae).[25] Also multiple single center case series and case reports show that the technique is safe with good procedural success and no major periprocedural complications.[26-28] DISRUPT III and IV trials evaluating IVL have started enrolling patients. Further long term follow up of these patients will shed light on the long term safety of the therapy. There is no data currently available comparing IVL with atherectomy or modified balloons.

Excimer laser coronary atherectomy (ELCA) uses photochemical and photothermal ablation for plaque modification. Its use

is restricted to a limited number of centers internationally. Currently it is not available in Pakistan. It is used currently as 'bail-out' strategy, when lesions are uncrossable for dedicated balloons or for the RotaWire /ViperWire.[29-31]

Despite encouraging data RA and OA, are grossly underutilized (<5%) because of procedural complexity, perceived greater procedural risk and substantial costs. In this scenario, we agree with De Mario et al.[32] that IVL holds promise for more frequent use because it is a balloon based technology which has been successful with low periprocedural complications and no risk of coronary perforation. A reasonable approach would be that for moderate to heavy calcification should ideally consider IVUS/OCT if feasible. If IVUS/OCT shows calcification > 270° or for calcification <270° but associated thickness >0.5 mm or calcium length > 5 mm, should consider lithotripsy as the first choice. Otherwise for less extensive calcification, balloon predilatation options should be considered first. When not crossable atherectomy devices can be used. For both balloon predilatation and atherectomy where there is suboptimal expansion, then also can proceed with IVL.[32] We should make efforts at organizational level to bring IVL to Pakistan at affordable cost.

We will be seeing more calcified lesions with an aging population, diabetes and chronic kidney disease, so it is incumbent upon interventional cardiologists to develop skills to deal with them. With the new dedicated tools for imaging and treatment for calcific lesions, for most cases, it may no longer remain the Achilles' heel it once used to be.

REFERENCES

1.   Parry CH. An Inquiry Into the Symptoms and Causes of the Syncope Anginosa, Commonly Called Angina Pectoris: Illustrated by Dissections. R. Cruttwell; and sold by Cadell and Davies, London; 1799.

2.   Byrne RA, Capodanno D, Mylotte D, Serruys PW. State of the art: 40 years of percutaneous cardiac intervention. EuroIntervention. 2017;13:621-4

3.   Généreux P, Madhavan MV, Mintz GS, Maehara A, Palmerini T, LaSalle L, et al. Ischemic outcomes after coronary intervention of calcified vessels in acute coronary syndromes: pooled analysis from the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) and ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) trials. J Am Coll Cardiol. 2014;63(18):1845-54.

4.   Mintz GS, Popma JJ, Pichard AD, Kent KM, Satler LF, Chuang YC, et al. Patterns of calcification in coronary artery disease: a statistical analysis of intravascular ultrasound and coronary angiography in 1155 lesions. Circulation. 1995;91(7):1959-65.

5.   Secco GG, Buettner A, Parisi R, Pistis G, Vercellino M, Audo A, et al. Clinical experience with very high-pressure dilatation for resistant coronary lesions. Cardiovasc Revasc Med. 2019;20(12):1083-7.

6.   Kurbaan AS, Kelly PA, Sigwart U. Cutting balloon angioplasty and stenting for aorto-ostial lesions. Heart. 1997;77(4):350-2.

7.   Izumi M, Tsuchikane E, Funamoto M, Kobayashi T, Sumitsuji S, Otsuji S, et al. Final results of the CAPAS trial. Am Heart J. 2001;142(5):782-9.

8.   Mauri L, Bonan R, Weiner BH, Legrand V, Bassand JP, Popma JJ, et al. Cutting balloon angioplasty for the prevention of restenosis: results of the Cutting Balloon Global Randomized Trial. Am J Cardiol. 2002;90(10):1079-83.

9.   Fonseca A, Costa JJ, Abizaid A, Feres F, Abizaid AS, Costa R, et al. Intravascular ultrasound assessment of the novel AngioSculpt scoring balloon catheter for the treatment of complex coronary lesions. J Invasive Cardiol. 2008;20(1):21-7.

10.   Kawamoto H, Latib A, Ruparelia N, Boccuzzi GG, Pennacchi M, Sardella G, et al. Planned versus provisional rotational atherectomy for severe calcified coronary lesions: Insights From the ROTATE multi-center registry. Catheter Cardiovasc Interv. 2016;88(6):881-9.

11.   Fourrier JL, Bertrand ME, Auth DC, Lablanche JM, Gommeaux A, Brunetaud JM. Percutaneous coronary rotational angioplasty in humans: preliminary report. J Am Coll Cardiol. 1989;14(5):1278-82.

12.   Reifart N, Vandormael M, Krajcar M, Göhring S, Preusler W, Schwarz F, et al. Randomized comparison of angioplasty of complex coronary lesions at a single center: Excimer Laser, Rotational Atherectomy, and Balloon

Angioplasty Comparison (ERBAC) Study. Circulation.1997;96(1):91-8.

13.   Whitlow PL, Bass TA, Kipperman RM, Sharaf BL, Ho KK, Cutlip DE, et al. Results of the study to determine rotablator and transluminal angioplasty strategy (STRATAS). Am J Cardiol. 2001;87(6):699-705.

14.   Safian RD, Feldman T, Muller DW, Mason D, Schreiber T, Haik B, et al. Coronary angioplasty and Rotablator atherectomy trial (CARAT): immediate and late results of a prospective multicenter randomized trial. Catheter Cardiovasc Interv. 2001;53(2):213-20.

15.   Eeckhout E, Serruys P, Wijns W, Vahanian A, Van Sambeek M, De Palma R. Percutaneous interventional cardiovascular medicine: The PCR-EAPCI textbook. London, UK: Europa. 2012.

16.   Barbato E, Carrié D, Dardas P, Fajadet J, Gaul G, Haude M, et al. European expert consensus on rotational atherectomy. EuroIntervention. 2015;11(1):30-6.

17.   Sotomi Y, Shlofmitz RA, Colombo A, Serruys PW, Onuma Y. Patient selection and procedural considerations for coronary orbital atherectomy system. Interv Cardiol Rev. 2016;11(1):33.

18.   Kini AS, Vengrenyuk Y, Pena J, Motoyama S, Feig JE, Meelu OA, et al. Optical coherence tomography assessment of the mechanistic effects of rotational and orbital atherectomy in severely calcified coronary lesions. Catheter Cardiovasc Interv. 2015;86(6):1024-32.

19.   Lee MS, Shlofmitz E, Kaplan B, Alexandru D, Meraj P, Shlofmitz R. Real-world multicenter registry of patients with severe coronary artery calcification undergoing orbital atherectomy. J Interv Cardiol. 2016;29(4):357-62.

20.   Bhatt P, Parikh P, Patel A, Chag M, Chandarana A, Parikh R, et al. Long-term safety and performance of the orbital atherectomy system for treating calcified coronary artery lesions: 5-Year follow-up in the ORBIT I trial. Cardiovasc Revasc Med. 2015;16(4):213-6.

21.   Lee M, Généreux P, Shlofmitz R, Phillipson D, Anose BM, Martinsen BJ, et al. Orbital atherectomy for treating de novo, severely calcified coronary lesions: 3-year results of the pivotal ORBIT II trial. Cardiovasc Revasc Med. 2017;18(4):261-4.

22.   Authors/Task Force members, Windecker S, Kolh P, Alfonso F, Collet JP, Cremer J, et al. 2014 ESC/EACTS guidelines on myocardial revascularization: the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS) developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2014;35(37):2541-619.

23.   Javed A, Khan HS, Azad MAS, Mohsin M, Ahmed S, Ghauri HA. Rotablation (Rotational Atherectomy) Must Know Procedural Aspects. Pak Heart J. 2020;53(02). [PREPRINT]

24.   Brinton TJ, Ali ZA, Hill JM, Meredith IT, Maehara A, Illindala U, et al. Feasibility of shockwave coronary intravascular lithotripsy for the treatment of calcified coronary stenoses: first description. Circulation. 2019;139:834–6.

25.   Shockwave Coronary Lithoplasty® Study (Disrupt CAD II). 2017. Available at: https://clinicaltrials.gov/ct2/show/NCT03328949 [accessed: 16 July 2020]

26.   Ali ZA, Brinton TJ, Hill JM, Maehara A, Matsumura M, Galougahi KK, et al. Optical coherence tomography characterization of coronary lithoplasty for treatment of calcified lesions: first description. JACC Cardiovasc Imaging. 2017;10:897–906.

27.   Wong B, El-Jack S, Khan A, Newcombe R, Glenie T, Cicovic A, et al. Treatment of heavily calcified unprotected left main disease with lithotripsy: the first case series. J Invasive Cardiol. 2019;31:E143–7.

28.   Wong B, El-Jack S, Newcombe R, Glenie T, Armstrong G, Khan A. Shockwave intravascular lithotripsy for calcified coronary lesions: first real-world experience. J Invasive Cardiol. 2019;31:46–8.

29.   Badr S, Ben-Dor I, Dvir D, Barbash IM, Kitabata H, Pendyala LK, et al. The state of the excimer laser for coronary intervention in the drug-eluting stent era. Cardiovasc Revasc Med. 2013;14:93–8.

30.   Bilodeau L, Fretz EB, Taeymans Y, Koolen J, Taylor K, Hilton DJ. Novel use of a high-energy excimer laser catheter for calcified and complex coronary artery lesions. Catheter Cardiovasc Interv. 2004;62:155–61.

31.   Holmes Jr DR, Mehta S, George CJ, Margolis JR, Leon MB, Isner JM, et al. Excimer laser coronary angioplasty: the New Approaches to Coronary Intervention (NACI) experience. Am J Cardiol. 1997;80:99K–105K.

32.   Dini CS, Nardi G, Ristalli F, Mattesini A, Hamiti B, Di Mario C. Contemporary approach to heavily calcified coronary lesions. Interv Cardiol Rev. 2019;14(3):154.