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Education & Clinical Resources

Clinical Evidence Summary

# Specialty Balloons: Inclusive of Cutting, Scoring & Lithotripsy Balloons for Coronary & Peripheral Vasculature

This Clinical Evidence Summary was developed to provide a synopsis of the current clinical literature and study data specific to products available in the United States for ***Cutting, Scoring & Lithotripsy Balloons for Coronary & Peripheral Vasculature***.

Plain old balloon angioplasty (POBA) balloons inflate and exert pressure against plaque and the arterial wall. In heavily calcified lesions, or in the case of in-stent restenosis (ISR), dilation may result in asymmetric vessel expansion. Cutting balloons (CB) are non-compliant and equipped with microatherotomes to incise plaque for better control and improve dilatation.[1] Scoring balloons are semi-compliant with a spiral nitinol scoring element to assist with vessel expansion and reduce the risk of balloon slippage and dissection or perforation.[2] Serrated balloons have multiple serrated metal strips that cause interrupted lines of scoring in the vessel wall allowing low-pressure angioplasty with minimal injury.[3]

Lithotripsy is a relatively new technology for treatment of heavily calcified lesions. A lithotripsy balloon is semi-compliant and delivers pulsatile mechanical energy to crack/fracture plaque via miniaturized emitters placed along the length of the balloon.[2]

## Professional Society Statements

In the 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention (PCI)[4] recommendations for Adjunctive Therapeutic Devices:

- Cutting balloon angioplasty might be considered to avoid slippage-induced coronary artery trauma during PCI for in-stent restenosis or ostial lesions in side branches. (Class IIb; LOE C)
- Cutting balloon angioplasty **should not** be performed routinely during PCI. (Class III: No Benefit; LOE A)

The 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease makes no recommendations regarding the use of cutting or scoring balloon angioplasty.[5]

## Clinical Evidence

The Randomized PREPARE-CALC Trial compared high-speed rotational atherectomy (RA) versus modified balloons (MB) (cutting or scoring) prior to DES implantation in severely calcified coronary lesions. There were 200 patients randomized 1:1 to either high-speed RA or MB lesion preparation. Primary end points were successful stent delivery and

### Summary

- Specialty balloons were developed for use as adjunctive therapy to treat calcified vessels and/or in-stent restenosis.
- Current cardiovascular guidelines support use of cutting balloon angioplasty during PCI to treat in-stent restenosis or ostial lesions in side branches.
- Current peripheral guidelines have no recommendations regarding their use.
- Current evidence supports the use of rotational atherectomy over cutting balloon angioplasty, however, it also supports drug coated balloons or stents over both for treatment of ISR.
- HealthTrust Physician Advisors report cutting balloons may be appropriate for specific situations and the deliverability of the device is a factor in selection.

expansion with less than 20% in-stent residual stenosis with TIMI 3 flow and in-stent late lumen loss at nine months. Successful stent delivery strategy was significantly more common in RA than in MB preparation, albeit with longer fluoroscopy times. Late lumen loss was not significantly different between the two groups.[6]

A subgroup analysis of the PREPARE-CALC trial looked at the impact of lesion preparation on side branch compromise in severely calcified coronary bifurcation lesions.[7] They analyzed 47 bifurcation lesions treated with MB and 68 lesions treated with RA. There were significantly more coronary dissections as well as compromised side branches observed in the MB group than the RA group. Side branch compromise was also associated with higher periprocedural myocardial injury.

A meta-analysis of 31 randomized controlled trials regarding the efficacy of various percutaneous interventions for in-stent restenosis (ISR) concluded that balloon angioplasty, bare metal stents, cutting balloons, rotational atherectomy and excimer laser atherectomy were all inferior to drug coated balloons or drug coated stents in the treatment of ISR.[8]

ADAPT-DES enrolled 8,582 patients who had PCI with DES; of those 2,644 had calcified target lesions. A sub-group analysis of these patients included 150 patients who underwent RA and 53 who underwent CB pretreatment. In a 2-year follow up looking at the primary end-point of target vessel failure (TVF), defined as death, MI or target vessel revascularization, there was no statistical difference in the two arms. TVF was common in both study groups.[9]

A 2020 meta-analysis of seven case reports and retrospective studies regarding the safety and efficacy of lithotripsy in the management of calcified coronary artery stenosis concluded that it could safely disrupt calcium deposits without damaging the vessel.[10]

## Physician Feedback

HealthTrust Physician Advisors with specialties in the fields of interventional radiology and interventional cardiology provided input into this evidence summary and expertise from their clinical practice. Here is a summary of their feedback.

- Cutting balloons are felt to be useful when a standard compliant balloon is slipping or watermeloning through a lesion or for difficult lesions.
- Deliverability of the device is a factor in device selection.

## Considerations

This category includes a multitude of products. Physician preference may play a strong role in uptake for specific suppliers. Engaging with your surgeons in the value analysis process may be beneficial and would assist in ensuring compliance in this category.

*This category has a number of suppliers with various features available on each system. HealthTrust members have exclusive access to a product features document. It can be found within the contract package on the Member Portal. If you do not have access to the Member Portal, contact your local supply chain administrator or HealthTrust Account Manager to request a copy of product features document.*

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