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Specialty Balloons and Vessel Prepping in Peripheral Artery Disease

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Abstract

Peripheral Artery Disease (PAD) is a global disease that affects more than 200 million individuals worldwide with an ever-increasing prevalence rate from year to year. Peripheral Artery Disease treatments include everything from lifestyle interventions to surgical revascularization or percutaneous angioplasty (PTA). Percutaneous Angioplasty (PTA) has become the primary treatment for this disease with the use of focal force and scoring balloons for vessel prepping. The practice of vessel prepping looks to limit the effect of angioplasty on vessel dissection and recoiling in the infrainguinal region during the treatment of plaque buildup in the vessel. Plaque morphology and rise in incidence of in-stent restenosis can determine which balloon device is best used when restoring a vessel. Some of the different brands we review in this chapter include Peripheral Cutting Balloons by Boston Scientific, Chocolate PTA by Medtronic, Angiosculpt balloon by Philips, and VascuTrak by BARD. In review of Angiosculpt balloon by Philips: The study concluded that the one-year data supports the notion that the AngioSculpt Scoring Balloon is an effective and safe treatment option for infrapopliteal, atherosclerotic lesions in patients with critical limb ischemia. Whereas: Peripheral cutting balloons (PCBs) by Boston Scientific have been used for in-stent restenosis, resistant lesions, small vessels, bifurcations, aorta-ostial lesions, and saphenous vein graft lesions. This chapter will discuss different focal force and scoring balloon devices available to treat different plaque morphology and usefulness for in-stent restenosis resolution. We will review the evidence associated with each brand of device and the factors that should be accounted for before making a decision on which to use for your patient.

Keywords

Peripheral Artery Disease, Vessel Prepping, Percutaneous Angioplasty

1. Introduction

Peripheral Artery Disease (PAD) is a global disease that affects more than 200 million individuals worldwide with an ever-increasing prevalence rate from year to year [1]. The most significant risk factors that cause this disease include habits such as poor diet, uncontrolled blood pressure, smoking and uncontrolled diabetes [1]. Treatment can range from non-surgical approaches (lifestyle changes, preventative medications) to the popular surgical revascularization, referred to as percutaneous angioplasty (PTA). PTA, followed by stenting over the lesioned area has shown to have some benefits in the lower extremities, but is a controversial topic until more data shows a clear need for the stent post angioplasty [2].

Vessel prepping, a term used in the endovascular surgical community, follows the leave-nothing-behind approach, and reduces the risk of dissections, maximizes the luminal gain, and prepares the vessel bed for stents, vascular mimetic implants, and/or local drug delivery [3]. In the midst of vessel prepping, the interventionalist must also account for the plaque morphology that has occluded the vessel of interest.

Plaques that contain a soft lipid-rich core and thin cap are homogenous plaques. They're unstable, associated with acute occlusions, prone to rupture and usually identifiable by their low echogenicity [4]. However, heterogenous plaques that consist mainly of fibrin and collagen, are more stable, and have a high echogenicity [4]. A patient may additionally have calcific plaques that deposit along with phosphate in the intima of the artery. Calcific plaques tend to align with patients that suffer from chronic renal insufficiency and diabetes [5].

This chapter will discuss different focal force and scoring balloon devices available to treat different plaque morphology and usefulness for in-stent restenosis resolution. We will review the evidence associated with each brand of device and the factors that should be accounted for before making a decision on which to use for your patient.

2. Methods

This study is comprised of multipurpose balloon devices or devices that have extended past their original design intent in the interest of better patient care. Inclusion criteria consisted of balloon devices studied that provide evidence of versatility. Exclusion criteria were devices that adequate study information could not be found. These were discarded during the preliminary search for which would be investigated. Articles were found via PubMed, when an adequate amount of information and evidence was acquired through this search engine, exact dimensions, and usage of techniques unique to each device was then extracted from the company website. Potential biases were examined for each device along with the articles used to present its quality of versatility and was stated within the devices section. Achievement of pairing each device with a peer reviewed research article to prove or disprove its versatility in vascular disease treatment was successful.

Revascularization with balloon angioplasty with focal force balloons:

Balloon angioplasty devices expand within the vessel to apply an outward circumferential force with the intent of increasing the lumen size for maximum blood flow. The disease-free areas of the vessel are the targets for maximum pressure coming from the balloon due to better compliance, followed by transitional points between plaque zones and healthy vessel zones [6]. Elastic recoil occurs when the healthy zones of vessel return to normal shape due to the over-expansion during the angioplasty procedure. Dissection of the vessel occurs when the angioplasty places too much stress on the weaker diseased areas of the vessel causing it to rupture. Focal force and scoring balloons are built to propagate a controlled expansion of the vessel by targeting pressure through a smaller surface area on the plaque instead of the elastic vessel. Many designs have been used for this strategy by various device makers.

2.1. Peripheral Cutting Balloon by BOSTON SCIENTIFIC

How it Works:

Peripheral cutting balloons (PCBs) are equipped with microsurgical blades called atherotomes, upon inflation they score the arterial disease allowing for plaque displacement [7]. The balloon is first inflated to 2 atmospheres (atm) in order to set the blades, once it makes contact with the plaques the balloon is inflated to the nominal pressure of 6 atm to incise the plaque.

How it is designed:

The PCB is available in two configurations including, an over the wire, and a Monorail quick exchange catheter system. It is available in two lengths 15 mm and 20 mm. The PCB diameters range from 5.0 mm to 8.0 mm on the larger PCB and 2.0 mm to 4.0 mm on the smaller PCB. The catheter has a working length ranging from 50 cm - 137 cm (Over-the-wire), and 142 cm (Monorail).

Evidence for use:

A prospective randomized study of cutting balloon angioplasty versus conventional balloon angioplasty for the treatment of hemodialysis access stenosis was done. This study showed that cutting balloon angioplasty was a safe and effective treatment of graft-to-vein anastomotic stenosis and presented significantly higher patency than that of conventional balloon angioplasty [8]. The study randomized 623 patients into two groups, assisted primary patency for the cutting balloon was significantly higher at 6 months and 1 year (86% and 63%) than that for conventional PTA (56% and 37%, respectively; $P = 0.037$) [8].

The PCB is a versatile balloon that can help treat difficult lesions but is not necessarily a replacement for stenting. The evidence for this balloon in the lower extremities is not concrete due to the lack of research data available. An interventionalist may decide to use this balloon for complex lesions that aren't its label designation, however discernment of plaque morphology and experience are key factors to consider when doing so. This balloon has been used for in-stent restenosis, resistant lesions, small vessels, bifurcations, aorta-ostial lesions and saphenous vein graft lesions [7].

2.2. Chocolate PTA Balloon by MEDTRONIC

How it Works:

This semi-compliant balloon is surrounded by a nitinol-constraining cage that allows for 1:1 vessel sizing. The cage and balloon expand together, allowing the cage to prevent the balloon from catching on lesions and causing torsional stress and dissection [9]. Once inflated, the balloon-cage relationship forms segmented pillows, which apply force to the plaque and cause small dissections. The grooves relieve the dissection stress to inhibit propagation.

How it is designed:

The Chocolate Balloon is the only nitinol-caged balloon with controlled dilatation and is available from a 2.5 - 6.0 mm diameter, with balloon lengths of 40 - 120 mm, and working length between 120 and 150 cm. The device has an over the wire design and is compatible with 0.014- and 0.018-inch guidewires.

Evidence for use:

In a study focused on the treatment of severely claudicant patients, 81 patients (84 limbs) with a Rutherford category (RC) 3, were treated for superficial femoral artery (SFA) and popliteal arterial (PA) disease. Of the 84 limbs treated, 55 (65.5%) presented chronic total occlusion (CTO). In 18 limbs the CTO was longer that 150 mm. All patients completed the 30 day follow up and primary patency (PP) was at 100%. The mean follow up after that was at 12.3 months and overall PP was 98.8% and secondary patency (SP) was 98.8%. No significant difference was found between stenosis and CTO upon the use of the chocolate balloon at mid-term analysis, but ABI at 12 months was significantly higher with respect to preoperative values ($p < 0.001$) [10]. The study concluded that the balloon was safe to use in SFA and PA lesions of claudicant patients with satisfactory 12-month results [10].

This device demonstrates success in the treatment of PAD in the iliac and infra-inguinal regions as shown by this study and others. The balloon is also well designed for lesions near bifurcation sites. The plaque tends to not shift when receiving force from this balloon upon inflation. A drug-coated version of this balloon is being studied extensively in the United States to confirm safety and efficacy as well.

2.3. Angiosculpt Balloon by PHILIPS

How it Works:

This semi-compliant balloon fitted with a tapered tip for enhanced delivery has three helical nitinol struts. The struts encircle the balloon and score the plaque on contact when inflated focusing the stress caused by the balloon on these scoring elements. The balloon has minimal device slippage or "watermelon seeding" due to the locking of the rectangular scoring edges on to the plaque [11]. The struts then create the luminal expansion needed for stent implantation.

How it is designed:

The Angiosculpt balloon is available from a 2.0 - 8.0 mm diameter with bal-

loon lengths from 10 - 40 mm, and a working length of 90 - 155 cm. The device is compatible with a 0.014, and 0.018 in guidewire, and is compatible with 5 - 6 F sheaths.

Evidence for use:

A study looking at the one-year outcomes of patients with critical limb ischemia from infrapopliteal lesions using this balloon was done on 31 patients, they had a RC of 4 - 5 and single vessel runoff to the ankle. Complication free survival at 1 month was the safety endpoint, which came out to be 96.8%. PP and limb salvage were the efficacy endpoints evaluated at the 1-year mark, which are 61% and 86.3% respectively. The study concluded that the one-year data supports the notion that the AngioSculpt Scoring Balloon is an effective and safe treatment option for infrapopliteal, atherosclerotic lesions in patients with critical limb ischemia [12].

This device, which was designed for use in treating coronary artery stenosis, has shown promise in other regions of the body. More studies need to be conducted in the infrapopliteal region to have an abundance of data for the use of this balloon in this region [12].

2.4. VascuTrak by BARD

How it Works:

This balloon is a semi-compliant balloon device, with two external wires attached. When expanded, a force is transmitted through the wire to break the vessel plaque in a controlled manner. The device has flexible wires for agility within the vasculature.

How it is designed:

The device is available with a balloon diameter from 2 - 7 mm, balloon lengths from 20 - 300 mm, the working length varies from 80 - 140 cm. The device is compatible with a 0.014- and 0.018-inch guidewire and has a sheath size from 5 - 7 F.

Evidence for use:

The VascuTrak balloon has very limited research for the use in all areas. Although, it was shown to be a useful alternative to conventional balloon angioplasty in patients with autogenous arteriovenous fistula dysfunction (AVF) [13]. 51 patients with AVF treatment, following a previously failed conventional balloon approach, underwent a procedure with the VascuTrak. The VascuTrak was successful in fully dilating under pressure and was significantly better than the conventional catheters on one-time dilation rates ($p < 0.0001$). There was also a significant improvement in the degree of pain felt by the patient during the procedure with this device ($p < 0.0001$). PP was 74.5% at one year [13].

VascuTrak success with AVF cases does not necessarily mean it should be used for lesions in PAD, but it adds another tool into the interventionalist toolbox in case a balloon with more agility is needed for a case. More research is needed on this balloon in PAD to fully endorse its use in lower extremity vascular lesions.

3. Discussion

Cases of PAD present are various ways, with differing disease plaque features in vessels of interest. With consideration of plaque morphology, an interventionalist is better suited to make decisions on instrumentation, and overall have better outcomes with their patients. Each focal force balloon is designed for certain lesions. With this being said, many of the devices have been shown to help treat lesions beyond their original design. It is important for the interventionalist to maintain their flexibility and creativity with these devices to maximize the agility of technology today, while keeping with the standards of patient safety.

The PCB for instance is a versatile balloon that can help treat difficult lesions but is not necessarily a replacement for stenting. This balloon has been used for in-stent restenosis, resistant lesions, small vessels, bifurcations, aorta-ostial lesions and saphenous vein graft lesions. [4] The chocolate balloon is well designed for lesions near bifurcation sites. The plaque tends to not shift when receiving force from this balloon upon inflation. A drug-coated version of this balloon is being studied extensively in the United States to confirm safety and efficacy as well. The AngioSculpt Scoring Balloon is a great choice for infrapopliteal atherosclerotic lesions. The study concluded that the one-year data supports the notion that the AngioSculpt Scoring Balloon is an effective and safe treatment option for infrapopliteal, atherosclerotic lesions in patients with critical limb ischemia. [12] The VascuTrak is a great option for those in need of a device to dilate under pressure and patients with autogenous arteriovenous fistula dysfunction (AVF) [13].

4. Conclusions

Vessel prepping with specialty balloons aims to reduce the need for additional stenting and restore blood flow, while diminishing elastic recoil or dissection in the artery. The balloons function by selectively applying a force to engage and modify plaque buildup in the vessel to alleviate obstructed blood flow and make way for stents. Each balloon engages the plaque and vessel wall differently and more studies are needed to ensure adequate knowledge of device superiority for their users, as well as to see which devices can be used for other lesions. The stents discussed in this chapter have been shown to offer success and agility when it comes to treating a multitude of lesions. However, they're not perfect devices and can still require more extensive procedures for the patients after a poor outcome. With proper balloon usage, knowledge of plaque morphology and extensive research into the appropriate uses of these specialty balloons, the number of poor outcomes should fall even more than their already diminished numbers.

The development of drug-coated balloons (DCBs) allows for an alternative nonstent method in the percutaneous treatment of atherosclerotic lesions [14]. Currently, drug-eluting stents (DES) are the treatment of choice, but DCBs have potential applications in the treatment of de novo lesions, in-stent restenosis, bifurcations, and PAD [14]. With conflicting data related to the use of paclitaxel

devices in PAD, additional research is needed to further the development and usefulness of DCBs safely for future patients.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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