Updates in SFA Atherectomy and Thrombectomy

New tools are emerging, but what about data?

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The superficial femoral artery is the most frequently diseased segment in patients with lower extremity artery disease.[1] Although conventional angioplasty is considered first-line treatment, long-term patency is poor in calcified segments due to decreased vessel compliance requiring higher-pressure balloon inflation, which results in more frequent flow-limiting dissections.[2] Stents placed for dissections are difficult to keep patent due to the mechanical forces on the vessel, as well as the stent, that promote in-stent restenosis (ISR). The primary goals of atherectomy therefore are to debulk calcium/plaque to improve vessel compliance, reduce the need for high-pressure angioplasty, and decrease the incidence of dissections and bailout stenting.

Despite the potential benefits of atherectomy when combined with percutaneous transluminal angioplasty (PTA), a 2014 Cochrane meta-analysis did not find enough high-quality evidence to support atherectomy plus PTA over PTA alone with respect to primary patency.[3] More recent trials have also failed to show improved freedom from target lesion revascularization (TLR) with directional or orbital atherectomy with PTA compared to PTA alone.[4,5] However, the same authors found an association with lower balloon inflation pressures after atherectomy and fewer bailout stents.

Despite the paucity of level 1 evidence, there are encouraging data from retrospective, prospective single-arm, and postmarket registry studies. Types of available atherectomy devices are shown in Table 1.

DIRECTIONAL ATHERECTOMY

Directional atherectomy uses side-cutting blades with a reservoir in the tip of the device to capture excised plaque. FDA-approved devices include the SilverHawk, TurboHawk, and HawkOne (all Medtronic). The DEFINITIVE LE registry found 12-month primary patency of 78% and a bailout stent rate of 3%.[6] These devices have better 12-month primary patency with de novo disease, compared to restenosis and ISR.[7] Outcomes are also better with Trans-Atlantic InterSociety Consensus (TASC) A and B lesions versus TASC C and D lesions, as well as with claudicants versus patients with critical limb ischemia (CLI).[8]

Another directional atherectomy device is the Pantheris (Avinger, Inc.), which features built-in optical coherence tomography (OCT) to characterize plaque and minimize fluoroscopy. The VISION study showcased 6-month freedom from TLR of 94% with 83% of patients reporting an improvement in Rutherford classification.[9]

ROTATIONAL ATHERECTOMY

Rotational atherectomy devices use front-cutting blades to debulk calcium. Offerings include the Phoenix (Philips), Jetstream (Boston Scientific Corporation), RotaLink (Boston Scientific Corporation), and Rotarex (BD Interventional). All of these products except the RotaLink also perform thrombectomy to limit distal embolization. The Phoenix uses an Archimedes screw to extract debulked plaque, whereas the Jetstream and Rotarex actively aspirate plaque.

The EASE trial evaluated the Phoenix and found a 6-month freedom from TLR of 88%, with 75% of patients reporting an improvement in Rutherford classification.[10] Even in patients with CLI, the Phoenix 500 registry found a 12-month freedom from TLR of 83%, with 77% of patients reporting an improvement in Rutherford classification.[11] Longer-term data for the Phoenix have not been published.

The JET registry for the Jetstream found a 12-month freedom from TLR of 83%, with 64% of patients reporting an improvement in Rutherford classification despite long lesion lengths.[12]

The RotaLink was one of the first peripheral atherectomy devices and adapted technology designed for coronary atherectomy to the periphery. The device uses a front-cutting diamond burr and uses a proprietary solution to lubricate the device and flush microemboli into the circulation.[13]

The Rotarex single-use rotational excisional atherectomy device has recently entered the United States market, having been previously studied in Europe. It combines

TABLE 1. ATHERECTOMY DEVICE TYPES AND EXAMPLES		
Type	**Description**	**Examples**
Directional	Use side-cutting blades with a reservoir to capture excised plaque. The Pantheris also has optical coherence tomography to identify plaque	SilverHawk, TurboHawk, HawkOne, Pantheris
Rotational	Use front-cutting blades to debulk calcium. All devices allow thrombectomy except the RotaLink	Phoenix, Jetstream, RotaLink, Rotarex
Orbital	Use diamond-coated crown mounted eccentrically to debulk a larger diameter than the device	Diamondback 360
Laser	Use laser pulses to vaporize plaque. The Auryon uses an Nd:YAG laser. The Turbo-Elite, Turbo-Power, and DABRA use an excimer laser. The DABRA is not over-the-wire. The Turbo and Auryon lasers are indicated for in-stent restenosis	Turbo-Elite, Turbo-Power, Auryon, DABRA

atherectomy with aspiration to limit embolization and is reportedly utilized in different lesion types including thrombus. More recently, a French retrospective multicenter study noted 12-month freedom from TLR of 80% in 128 patients with ISR in which the device was used.[14]

ORBITAL ATHERECTOMY

Orbital atherectomy comprises the Diamondback 360 platform (Cardiovascular Systems, Inc), which uses a diamond-coated crown mounted eccentrically to debulk a larger diameter than the device itself. The CONFIRM registry found improved outcomes with calcified plaque compared to soft plaque. The particles created are smaller than a red blood cell and are flushed distally into the vasculature.[15]

A post hoc analysis of the LIBERTY 360 data evaluated orbital atherectomy in patients with Rutherford class 5 and 6 CLI. At 12 months, the authors found that 47% of patients improved to Rutherford class 0 or 1 and wounds completely healed in 71% of patients. The rate of major amputation at 12 months was only 10%.[16]

LASER ATHERECTOMY

The class of laser atherectomy devices includes the Turbo-Elite and Turbo-Power (Philips), which use an excimer laser to deliver pulses of short-wavelength energy for decreased tissue penetration. Excimer lasers can therefore vaporize plaque without injuring deeper layers of tissue.[17] Notably, saline must be continuously infused to prevent contrast or blood from increasing the heat absorbed by tissue from each laser pulse. Of all the trials comparing atherectomy to PTA, the EXCITE ISR trial showed the greatest difference in outcomes. At 6 months, freedom from TLR was 74% in the laser with PTA group versus 52% in the PTA only group.[18] The CELLO registry provided midterm data with 12-month freedom from TLR of 77%.

A new laser atherectomy device is the Auryon (AngioDynamics, Inc.), which is designed with an Nd:YAG laser as well as a front-cutting blade. The single-arm pivotal trial showed 6-month freedom from TLR of 97%. The Nd:YAG laser emits higher-energy pulses and has higher affinity for plaque than normal tissue when compared to the excimer laser. No dissection was seen in the pivotal trial.[19]

The newest offering is the Destruction of Arteriosclerotic Blockages by laser Radiation Ablation (DABRA) atherectomy system (Ra Medical Systems, Inc.), which uses an excimer laser to cross lesions without a wire. The pivotal trial showed a 6-month freedom from TLR of 100% and no adverse events.[20]

The INTACT trial is an ongoing study evaluating treatment for ISR. This French multicenter randomized controlled trial will compare conventional angioplasty to drug-coated balloons (DCBs) to DCB with laser atherectomy. Although the primary outcome is cost-effectiveness, secondary outcomes include a variety of clinical metrics.[21]

The Turbo-Elite, Turbo-Power, and Auryon lasers are FDA approved to treat ISR.

ATHERECTOMY PLUS DCB

The desire to avoid stenting when possible has been part of the attraction to atherectomy, as well as leading to the development of DCBs, which have shown improved patency versus PTA alone. However, Fanelli et al found reduced primary patency when using DCBs in calcified arteries.[22] More recently, the ILLUMENATE Global trial showed a 12-month freedom from TLR of 94% despite 41% of patients with severe calcifications.[23] Nonetheless, atherectomy can debulk calcium to potentially improve paclitaxel deposition into the vessel wall by DCB.

However, the data are mixed. Neither directional nor orbital atherectomy improved 12-month freedom from TLR despite decreased rates of flow-limiting dissection, decreased rates of bailout stenting, and increased concentration of paclitaxel.[24,25]

The JET-SCE study found that Jetstream with DCB is superior to Jetstream with PTA, with 12-month freedom from TLR of 94% versus 69%.[26] A trial comparing Jetstream with DCB to DCB alone is currently enrolling.

EMBOLIC PROTECTION

Manufacturers of atherectomy devices recommend using an embolic protection device (EPD) except for RotaLink, Diamondback 360, and laser atherectomy devices, which are thought to create microemboli too small to capture. The consequences of distal embolization depend on the size and burden of debris but can range from asymptomatic microscopic debris with no impact on runoff to macroscopic debris resulting in occlusive emboli and acute limb ischemia. However, the benefits of EPDs are unclear since studies show the presence of debris captured by devices more easily than the impact on clinical outcome. EPDs also come with some risk, such as causing dissection or spasm.

It is also important to note that not all atherectomy devices have the same potential for embolization. The NAV6 (Abbott) was used with Jetstream in a study by Banerjee et al, showing a 2% incidence of distal embolization in the filter group versus 8% in the no filter group.[27] In contrast, the PROTECT registry and the DEFINITIVE LE study using the SpiderFX with SilverHawk found debris in up to 100% and 88% of cases, respectively.[28,29]

Although no head-to-head comparisons are available, it is important to consider the risk of distal embolization during atherectomy and employ appropriate preventive strategies.

THROMBECTOMY

In addition to rotational atherectomy devices that perform thrombectomy, dedicated aspiration thrombectomy devices include AngioJet (Boston Scientific Corporation), Jeti (Walk Vascular), Indigo (Penumbra, Inc.), and QuickClear (Philips).

The AngioJet is a pharmacomechanical device that can infuse lytic, as well as perform rheolytic thrombectomy. Side holes in the catheter spray out saline to fragment thrombus and facilitate aspiration. The goal is to remain isovolemic by infusing saline equal to the volume of blood loss. Limitations of the device include risk of hemolysis resulting in hemoglobinuria and acute renal injury, as well as adenosine release from lysed red blood cells and bradycardia.[30,31]

The Jeti system is a mechanical thrombectomy device that also relies on rheolytic thrombectomy.[32] This system is designed to pose less risk of distal embolization because saline is used to fragment thrombus already captured in the tip of the catheter.

The Indigo with separate aspiration pump is a mechanical thrombectomy device system relying on continuous aspiration of thrombus, which may lead to increased blood loss if the thrombus is not fully engaged. Newer iterations such as the Lightning 8 catheter (Penumbra, Inc.) with designs to increase luminal aspiration with decreased blood loss may have benefits for future interventions, although no data are yet available.

The QuickClear (Philips) is the same technology used in the Phoenix atherectomy device but is now sold as a dedicated aspiration thrombectomy device.[33] Although the mechanism is similar to the Indigo, the QuickClear includes the aspiration pump and no additional capital equipment is needed.

Although thrombectomy may not yet have an established role in treating patients with CLI, these devices are necessary in the event of distal embolization causing acute limb ischemia. The Indigo is perhaps the most proven technology in this space, with one trial showing 87% revascularization using only the Indigo device and 92% revascularization after failure of catheter-directed thrombolysis.[34] Additionally, several operators are utilizing mechanical thrombectomy for nonacute limb patients to clear underlying thrombus within a chronic total occlusion lesion to thus limit that actual final length of intervention that may be needed.

LITHOTRIPSY

Neither atherectomy nor thrombectomy, the Intravascular Lithotripsy balloon catheter (Shockwave Medical) is a relative newcomer in the PAD toolbox that holds promise for heavy calcified lesions. The goal of this technology is to apply sound waves to break up calcium within the walls of the peripheral vessels at low atmosphere balloon pressures, which in turn can be used to increase vessel compliance. Theoretically, this could decrease the need for scaffold placement and can be used in conjunction with drug-coated technology. The DISRUPT PAD II prospective, multicenter, nonblinded study evaluated DCB (Lutonix, BD Interventional) alone versus lithotripsy with DCB in the femoropopliteal region, including patients with dissections and a large subset of heavily calcified lesions, and had a 79% TLR rate at 1 year.[35] Recently, DISRUPT III, a larger multicenter study with approximately 400 patients, showed 82% to 93% (depending on lesion length) freedom from TLR in patients with dissection after DCB angioplasty (In.Pact Admiral, Medtronic) at 2 years.[36] The DISRUPT BTK trial will look at similar dissection patients in the infrapopliteal vessels.

INTRAVASCULAR IMAGING

The value of intravascular imaging in the evaluation of PAD is an area of continued exploration. It is believed that angiography underestimates atherosclerotic burden and alternative imaging modalities can help select patients who would benefit from atherectomy. Furthermore, intravascular ultrasound (IVUS) and OCT can provide histologic information on arterial plaques to help choose an appropriate atherectomy device. IVUS and OCT can also be used after interventions to detect angiographically occult dissections that may require stenting.[37,38] Krishnan et al found that IVUS-guided directional atherectomy resulted in a 12-month freedom from TLR of 82% versus 49% for angiography-guided directional atherectomy in patients with ISR.[39] However, to date, no randomized studies exist to help further validate its benefit in routine use.

FUTURE DIRECTIONS

Many of the data sources supporting atherectomy use are single-arm registries, with a notable lack of randomized data. The available data on atherectomy are also heterogeneous with regard to patient characteristics such as Rutherford category, vascular territory, lesion lengths, lesion complexity, and lesion histology. This heterogeneity makes it difficult to compare studies to determine which device to use and when. With so many different atherectomy devices to choose from, head-to-head trials would increase user confidence in device selection and application.

The available studies to date have also enrolled mostly claudicants, whereas most physicians would use atherectomy for patients with CLI. Trials evaluating outcomes in CLI patients are needed, as these patients often have severely calcified arteries with long lesion lengths, which could help define the role of atherectomy and distinguish one device from another. ■

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