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Directional versus orbital atherectomy of femoropopliteal artery lesions: Angiographic and intravascular ultrasound outcomes

Clinical Paper Review
Prepared by PVH Scientific Communications *for Health Care Professionals*

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Purpose

To compare the ability of the HawkOne™ directional atherectomy system (DAS) versus the Diamondback 360™* peripheral orbital atherectomy system (OAS) to modify plaque and augment luminal gain in patients with symptomatic femoropopliteal peripheral arterial disease (PAD), as evaluated by angiography and intravascular ultrasound (IVUS).

Methods

- The DIRECT study is an open-label, single-center, prospective, randomized, controlled trial (NCT03495453).
- The study enrolled 60 patients with symptomatic PAD (Rutherford 1-4) refractory to medical therapy with a femoropopliteal lesion with angiographic stenosis ≥70%.
- Participants were randomized 1:1 to undergo DAS or OAS followed by angioplasty with the IN.PACT™ Admiral™ drug-coated balloon.
- At least 6 passes of the DAS device were made through the lesion in different planes. At least 6 passes of the OAS device were also made (minimum of 2 passes each at the 60,000 rpm, 90,000 rpm, and 120,000 rpm speeds).
- Angiography and IVUS were performed prior to atherectomy, after atherectomy, and after DCB angioplasty. All IVUS images and select angiograms were analyzed by an independent core laboratory.
- The study endpoints were: Treated percent stenosis; luminal gain; IVUS-derived lumen and plaque volume characteristics for atherectomy and balloon angioplasty.
- The current paper presents the acute angiographic and IVUS results. Clinical follow-up to 3 years is planned.

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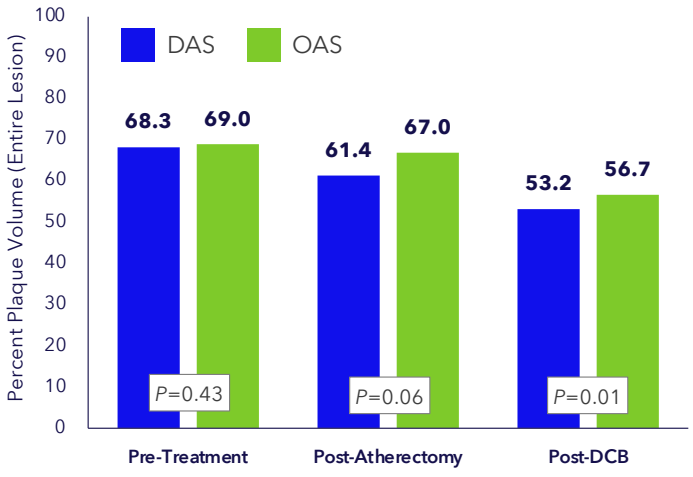
Key baseline patient and lesion characteristics

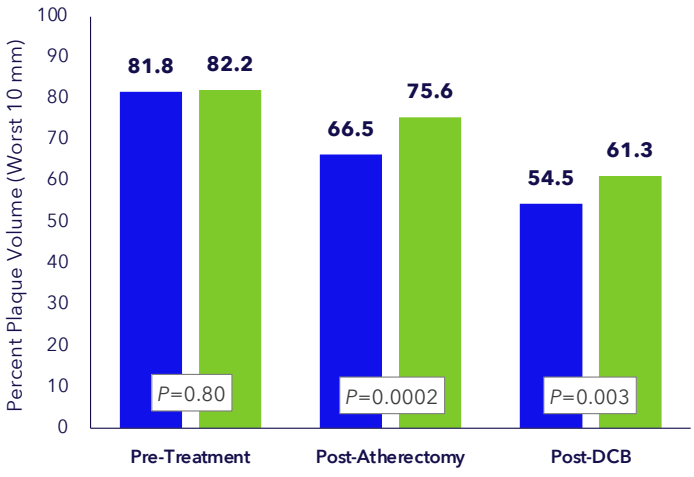
Table 1: Baseline patient and lesion characteristics

Characteristics	DAS (N=30)	OAS (N=30)	*P* Value
Hypertension	29 (97%)	30 (100%)	1.00
Diabetes mellitus	14 (47%)	17 (57%)	0.61
eGFR < 60 mL/min/1.73 m²	8 (27%)	12 (40%)	0.41
Coronary artery disease	22 (73%)	25 (83%)	0.53
Rutherford class	3 ± 0	3 ± 0	1.00
ABI at rest	0.79 (0.75-0.88)	0.86 (0.71-0.91)	0.57
Lesion length (mm)	151.0 ± 51.5	142.0 ± 54.3	0.34
CTO	13 (43%)	13 (43%)	1.00
RVD (mm)	5.5 ± 1.1	5.7 ± 0.6	0.46
Severe calcification	13 (65%)	12 (63%)	0.29†

Values are median (interquartile range), mean ± SD, or n (%). ABI: ankle-brachial index; CTO: chronic total occlusion; eGFR: estimated glomerular filtration rate; RVD: reference vessel diameter.
† *P* value for comparison of mild/moderate/severe.

Key results





- The change in plaque volume from pre- to post-atherectomy was statistically significantly greater in the DAS group for both the entire segment (-5.9 DAS vs. -1.1 OAS, *P*=0.003) and the worst 10 mm segment (-13.0 DAS vs. -3.3 OAS, *P*=0.001).
- This corresponds to a greater increase in total vessel and lumen volume by IVUS for DAS, as well as a reduction in angiographic stenosis post-atherectomy (39.5% DAS vs. 69.8% OAS, *P*<0.001) which persisted post-DCB (16.7% DAS vs. 33.7% OAS, *P*<0.001).
- Device success (≤30% residual stenosis) was 38% in the DAS group vs. 0% in the OAS group.
- Stents were placed in 2 (7%) DAS patients vs. 10 (33%) OAS patients, *P*=0.02.

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Summary

- Lesions treated with directional atherectomy demonstrated a greater plaque volume reduction and luminal gain than those treated with orbital atherectomy.
- These differences persisted after DCB treatment.
- There were significantly more stents placed in the orbital atherectomy group post-DCB compared to the directional atherectomy group.
- Overall, DA and OA were both found to be safe with minimal complications.

Authors' Conclusion

Compared to OAS, DAS significantly reduced vessel stenosis and plaque burden, even following DCB treatment. Three-year follow-up is ongoing to determine whether these acute performance measures are associated with improved clinical outcomes.

Funding Source

Investigator-initiated study supported by an institutional grant from Medtronic.

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If you are located in the United States, please refer to the brief statement(s) below to review applicable indications, safety and warning information. If you are located outside the United States, see the device manual for detailed information regarding instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

IN.PACT™ Admiral™ Paclitaxel-coated PTA balloon catheter Brief Statement

Indications for Use:

The IN.PACT™ Admiral™ Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.

Contraindications

The IN.PACT Admiral DCB is contraindicated for use in:

- Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries
- Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy
- Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system
- Patients with known allergies or sensitivities to paclitaxel
- Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure.

Warnings

A signal for increased risk of late mortality has been identified following the use of paclitaxel-coated balloons and paclitaxel-eluting stents for femoropopliteal arterial disease beginning approximately 2-3 years post-treatment compared with the use of non-drug coated devices. There is uncertainty regarding the magnitude and mechanism for the increased late mortality risk, including the impact of repeat paclitaxel-coated device exposure. Physicians should discuss this late mortality signal and the benefits and risks of available treatment options with their patients.

- Use the product prior to the Use-by Date specified on the package.
- Contents are supplied sterile. Do not use the product if the inner packaging is damaged or opened.
- Do not use air or any gaseous medium to inflate the balloon. Use only the recommended inflation medium (equal parts contrast medium and saline solution).
- Do not move the guidewire during inflation of the IN.PACT Admiral DCB.
- Do not exceed the rated burst pressure (RBP). The RBP is 14 atm (1419 kPa) for all balloons except the 200 and 250 mm balloons. For the 200 and 250 mm balloons the RBP is 11 atm (1115 kPa). The RBP is based on the results of in vitro testing. Use of pressures higher than RBP may result in a ruptured balloon with possible intimal damage and dissection.
- The safety and effectiveness of using multiple IN.PACT Admiral DCBs with a total drug dosage exceeding 34,854 µg of paclitaxel in a patient has not been clinically evaluated.

Precautions

- This product should only be used by physicians trained in percutaneous transluminal angioplasty (PTA).
- This product is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.
- Assess risks and benefits before treating patients with a history of severe reaction to contrast agents.
- The safety and effectiveness of the IN.PACT Admiral DCB used in conjunction with other drug-eluting stents or drug-coated balloons in the same procedure or following treatment failure has not been evaluated.
- The extent of the patient's exposure to the drug coating is directly related to the number of balloons used. Refer to the Instructions for Use (IFU) for details regarding the use of multiple balloons and paclitaxel content.
- The use of this product carries the risks associated with percutaneous transluminal angioplasty, including thrombosis, vascular complications, and/or bleeding events.
- Vessel preparation using only pre-dilatation was studied in the clinical study. Other methods of vessel preparation, such as atherectomy, have not been studied clinically with IN.PACT Admiral DCB.
- This product is not intended for the expansion or delivery of a stent.

Potential Adverse Effects

- The potential adverse effects (e.g. complications) associated with the use of the device are: abrupt vessel closure; access site pain; allergic reaction to contrast medium, antiplatelet therapy, or catheter system components (materials, drugs, and excipients); amputation/loss of limb; arrhythmias; arterial aneurysm; arterial thrombosis; arteriovenous (AV) fistula; death; dissection; embolization; fever; hematoma; hemorrhage; hypotension/hypertension; inflammation; ischemia or infarction of tissue/organ; local infection at access site; local or distal embolic events; perforation or rupture of the artery; pseudoaneurysm; renal insufficiency or failure; restenosis of the dilated artery; sepsis or systemic infection; shock; stroke; systemic embolization; vessel spasms or recoil; vessel trauma which requires surgical repair.
- Potential complications of peripheral balloon catheterization include, but are not limited to the following: balloon rupture; detachment of a component of the balloon and/or catheter system; failure of the balloon to perform as intended; failure to cross the lesion.
- Although systemic effects are not anticipated, potential adverse events that may be unique to the paclitaxel drug coating include, but are not limited to: allergic/immunologic reaction; alopecia; anemia; gastrointestinal symptoms; hematologic dyscrasia (including leucopenia, neutropenia, thrombocytopenia); hepatic enzyme changes; histologic changes in vessel wall, including inflammation, cellular damage, or necrosis; myalgia/arthralgia; myelosuppression; peripheral neuropathy.
- Refer to the Physician's Desk Reference for more information on the potential adverse effects observed with paclitaxel. There may be other potential adverse effects that are unforeseen at this time.
- Please reference appropriate product *Instructions for Use* for a detailed list of indications, warnings, precautions and potential adverse effects. This content is available electronically at www.manuals.medtronic.com.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

HawkOne™ directional atherectomy system Brief Statement

Important Information: Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

Indications for Use:

The HawkOne™ peripheral directional atherectomy system is intended for use in atherectomy of the peripheral vasculature. The HawkOne catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions. The HawkOne catheter is NOT intended for use in the coronary, carotid, iliac or renal vasculature.

CAUTION: Federal (USA) law restricts this product for sale by or on the order of a physician.