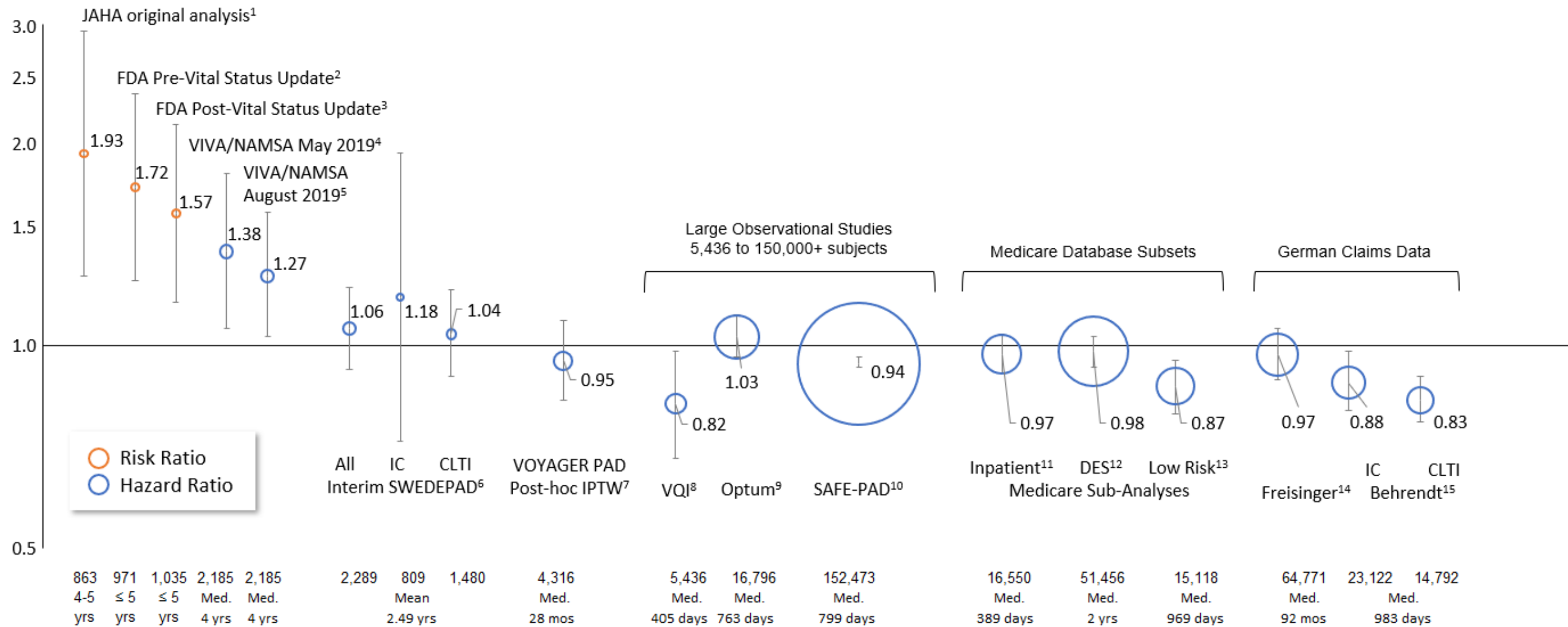


Case Discussion and Key Takeaways



Discussion

Big Data and Paclitaxel Safety: Data Landscape on a Larger Scale Mortality



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Drug-Coated Balloon Data Transparency

IN.PACT Clinical Studies Most Published

	1-Year						2-Year		3-Year		5-Year	
Medtronic IN.PACT™ Admiral™ DCB	IN.PACT IDE	IN.PACT Japan	IN.PACT China	IN.PACT Global	Total IN.PACT	Total IN.PACT All-Comer	IN.PACT IDE	IN.PACT Japan	IN.PACT IDE	IN.PACT Japan	IN.PACT IDE	IN.PACT Safety Meta-Analysis
	IN.PACT Global ISR	IN.PACT Global LL	IN.PACT Global CTO	IN.PACT Global SvB	IN.PACT Global CLI		IN.PACT Global	IN.PACT Health Economics	IN.PACT Global	IN.PACT Gender		IN.PACT Pooled RCT
BD Lutonix™ DCB	LEVANT 2	LEVANT 2 Germany					LEVANT 1 FIH	LEVANT Global				LEVANT Safety Meta-Analysis
Philips Stellarex™ DCB	ILLUMENATE EU	ILLUMENATE US	ILLUMENATE Global				ILLUMENATE EU	ILLUMENATE FIH	ILLUMENATE Safety Meta-Analysis			
Boston Scientific Ranger™ DCB	Ranger FIH	Ranger Global										

Calcium and Lesion Length

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Drug-Coated Balloon Data Transparency

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ILLUMENATE Safety Meta-analysis

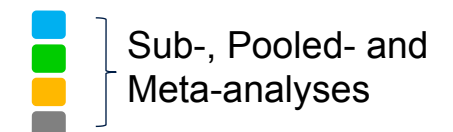
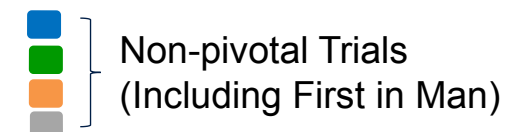
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IN.PACT™ Admiral™ drug-coated PTA balloon catheter

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.

IN.PACT™ Admiral™ drug-coated PTA balloon catheter

Brief Statement

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/arthritis; 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

Reference 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 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.

TurboHawk™ peripheral plaque excision system

Reference 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 TurboHawk peripheral plaque excision system is intended for use in the atherectomy of the peripheral vasculature. The TurboHawk catheter is NOT intended for use in the coronary, carotid, iliac, or renal vasculature.
- The TurboHawk catheter is indicated for use in conjunction with the SpiderFX™ embolic protection device in the treatment of severely calcified lesions (LX-C only).
- **CAUTION:** Federal (USA) law restricts this product for sale by or on the order of a physician.

SilverHawk™ peripheral plaque excision system

Reference 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 SilverHawk peripheral plaque excision system is intended for use in atherectomy of the peripheral vasculature. The 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.

Chocolate™* PTA balloon catheter

Reference 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 Chocolate PTA balloon catheter is intended for balloon dilatation of lesions in the peripheral vasculature, including the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries.

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

TrailBlazer™ support catheter

Reference Statement

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

Indications for Use: TrailBlazer support catheter are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TrailBlazer support catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

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

SpiderFX™ embolic protection device

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:

Lower Extremity (LE) Interventions

The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk™ Peripheral Plaque Excision System, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0 mm and 6.0 mm.

Carotid Interventions

The SpiderFX embolic protection device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

Saphenous Vein Graft (SVG) Interventions

The SpiderFX embolic protection device is indicated for use as an embolic protection system to contain and remove embolic material (thrombus/debris). The device also acts as the guidewire while performing percutaneous transluminal coronary angioplasty or stenting procedures in coronary saphenous vein bypass grafts with reference vessel diameters of 3.0 mm to 6.0mm. The safety and effectiveness of this device as an embolic protection system has not been established in the cerebral vasculature.

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

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