Recorded case: with Aspirex™S in Iliofemoral Deep Vein Thrombosis: Tips and Tricks

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Disclosure

Speaker name: **Dr. BRUNO FREITAS**

I have the following potential conflicts of interest to report:

- Consulting for Angiodroid, BD, Boston Scientific, Jotec, Medtronic, Nano Medical, Ortic, Straub Medical

- Employment in Industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest
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The opinions and clinical experiences presented herein are for informational purposes only. The results from this study report may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.

The clinicians have been compensated by Becton, Dickinson and Company to participate in this presentation.
Obstructive Venous Lesions

3 different contexts:
- Acute DVT
- Chronic primary (MTS)
- Chronic post DVT

Treatment
- Medical: mostly insufficient
- Surgical: invasive and poor results*

Potentially all patients with iliofemoral DVT are candidates for early clot removal*

Of these, patients with no calf and fempop vein thrombosis have better outcome following invasive treatment considered “ideal” candidates (present study, 12% of the total cohort)*

About 80,000 ideal candidates for clot removal annually (Europe)**

* Maeseneer et al. Analysis of 1,338 Patients with Acute Lower Limb Deep Venous Thrombosis (DVT) Supports the Inadequacy of the Term “Proximal DVT” Eur J Vasc Endovasc Surg (2016) 51, 415-420
** Mazzolai et al. Diagnosis and management of acute deep vein thrombosis: a joint consensus document from the European Society of Cardiology working groups of aorta and peripheral vascular diseases and pulmonary circulation and right ventricular function. European Heart Journal (2018) 39, 4208-4218
Mechanical Thrombectomy in iliofemoral DVT:
The Maceio experience step-by-step
Some Technical advice

- Enlarge the cathlab's webcam
- Use the chat to make questions and comments
Physical Exam on admission

- Phlegmasia Cerulea Dolens
  - Severe edema
  - Severe cyanosis
  - Bad perfusion
  - Pulses weak (edema)
- Acute Tubular Necrosis with Oliguria
- Hypotension
- Creatinine and Urea elevated
External saphenous vein access
CASE-BASED DISCUSSION
CASE-BASED DISCUSSION

Increase Infusion !!!!
Heparinized saline – contrast mix in action
Long 11-12F Sheath
1F larger than Aspirex™
IVUS – LOWER END OF STENT
Clinical improvement
MECHANICAL THROMBECTOMY IN ACUTE ILIOFEMORAL DVT

Summary of this case:

- Use of the “toc toc” technique allowed for more complete removal of thrombus than simply advancing and retracting Aspirex™ S.
- Use of contrast/infusion mix allowed better visualisation of thrombus in the Iliac veins.
- Rotating the Aspirex™ S catheter during aspiration allowed the 2 diametrically opposed windows to aspirate more thrombus.
**Indications**
Aspirex™ S catheters in combination with the Straub Medical Drive System (REF SRS-Set/80300) are intended for the percutaneous transluminal removal of fresh thrombotic or thromboembolic material from blood vessels outside the cardiopulmonary, coronary and cerebral circulations; native blood vessels or vessels fitted with stents, stent grafts or native or artificial bypasses outside the cardiopulmonary, coronary and cerebral circulations.

**Contraindications**
Vessels of the cardiopulmonary, coronary or cerebral circulations; undersized or oversized vessel diameters; use in stents, stent grafts, or venous caval filters if the guidewire has become threaded at any point in the wire mesh / construction of stent, stent graft, or venous caval filter or the lining of the stent graft; in the fracture areas of broken stents; in patients with haemodynamic instability or shock; in patients with severe coagulatory disorders; if it is impossible to achieve sufficient anticoagulation and platelet aggregation inhibition.

**Warnings**
Before using the Straub Endovascular System and its components, the user must be entirely familiar with the user manuals of the Straub Medical Drive System and Straub rotational catheters; Only use sheaths that are highly resistant to kinking. If used incorrectly, Aspirex™ S catheters and/or the guidewire used can cause vessel perforation; Insert and operate the catheter over the supplied guidewire of the appropriate length only. During the procedure, unforeseen complications of technical or medical origin may make it necessary to carry out unplanned, emergency additional measures, such as, but not limited to, administration of thrombolytic agents or surgical intervention; The products are for single use and must not be reused or resterilized; Do not use the products after the expiration date; Appropriate testing of the patient’s coagulation status is mandatory. Aspirex™ S catheters may only be used in the indicated diameters of target vessels. The catheter must always be guided via the guidewire, which has been correctly positioned according to the instructions for use. Make sure that the flexible tip of the guidewire is placed as distal as possible to the occluded segment to prevent the flexible tip from being aspirated into the catheter head. The guidewire must lie inside the lumen throughout its course from the introducing sheath to its flexible tip. Monitor the correct position of the guidewire throughout the entire process of catheter use. The catheter must never be kinked at any stage. At no point should the catheter ever be exposed to pressure that is sufficient to compress the tube so that it is pressed against the rotating helix. The catheter lumen must be filled with liquid (heparinised isotonic saline or blood) at all times throughout catheter use in the patient. If resistance is experienced, pull the catheter back a little way into the open(ed) segment with the motor continuing to run so that the ablated material can be processed and carried away. Advancing the catheter too quickly increases the risk of this advancement mobilising more material than can be aspirated and carried away, which can cause distal embolization; The internal lumen of the introducer sheath must at least correspond to the external diameter of the catheter. At all times monitor the quantity of blood transported into the collecting bag. Effective anticoagulants at a suitable dose have to be administered before the patient is treated with the Straub Endovascular System in order to achieve an activated clotting time (ACT) > 250 seconds or equivalent values according to other measuring techniques, throughout use of the catheter. If used correctly, embolizations caused by material detached by the catheter head are very rare. Ensure that the catheter lumen is completely filled with solution when the motor is running: The wire adapter must be in the working position (knob pulled out) during use of the catheter. If there is unlikely to be enough natural flow of blood to the catheter head, the supply of liquid to the catheter head can be guaranteed by providing additional appropriate liquid, such as isotonic saline, via a suitable access, such as the side-port of the introducer sheath being used; If the LEDs go out or the alarm is audible, safe functioning of the catheter is no longer guaranteed. Blood and thrombus fragments in the catheter lumen might clot if the helix has stopped. Therefore, if catheter use is interrupted, the catheter must be rinsed immediately in heparinised isotonic saline; Precautions The catheter sets do not contain any parts that need to be maintained or serviced by the end-user. Do not repair or change the configuration of the product. An annual service is recommended for the Straub Medical Drive System (see Straub Medical Drive System user manual) Potential Adverse Events Embolisms, especially distal thromboembolisms; pulmonary embolisms of all degrees of severity; thromboses, especially recurrent thromboses; re-occlusion; vessel wall injury or valve damage; vessel dissection / perforation / rupture; perforation as a result of mural calcium being torn out of the vessel wall; arteriovenous fistula / pseudoaneurysm; haematoma, bleeding, haemorrhage; organ perforation; implants such as stents / stent grafts / bypass grafts getting damaged, caught or dilated; disruption of the catheter and/or guidewire: debris remaining in the body; allergic reactions to catheter material; death; infections or necrosis at the puncture site; allergic reactions; catheter-induced sepsis

Please consult product labels and instructions for use for all indications, contraindications, hazards, warnings and precautions.
VENOVO™ Venous Stent System

Indication for Use
The VENOVO™ Venous Stent System is indicated for the treatment of stenoses and occlusions in the iliac and femoral veins.

Contraindications
The VENOVO™ Venous Stent System is contraindicated for use in:

- Patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum
- Patients who cannot receive recommended antiplatelet and/or anti-coagulation therapy
- Patients who are judged to have a lesion that prevents complete inflation of a balloon dilatation catheter proper placement of the stent or the stent delivery system.

Warnings

The VENOVO™ Venous Stent System is supplied sterile and is intended for SINGLE USE ONLY. DO NOT RESTERILIZE and/or REUSE the device. Reuse, resterilization, reprocessing and/or repackaging may create a risk to the patient or user, may lead to infection or compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness, or death of the patient. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components- are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogenic or microorganisms which may lead to infectious complications or death. • DO NOT use in patients with total venous occlusion that cannot be dilated to allow passage of the guidewire. • DO NOT use the device with contralateral access. • DO NOT use the pouch is opened or damaged. • DO NOT use the device if the "Use By" date specified on the label. • Persons with allergic reactions to nitinol (nickel-titanium) alloy and/or tantalum may suffer an allergic response to this implant. • DO NOT expose the delivery system to organic solvents, e.g., alcohol. • The stent is not designed for repositioning or recapturing. • Stenting across a major branch could cause difficulties during future diagnostic or therapeutic procedures. • If a long lesion needs to be stented consider using the longest available stent rather than overlapping stents. If multiple stents are placed in an overlapping fashion, they should be of similar composition (i.e., nitinol) • The long-term outcomes following repeat dilatation of endothelialized stents are unknown. • The safety and effectiveness of this device for use in the arterial system have not been established.

Precautions

- The device is intended for use by physicians who have received appropriate training. • During system flushing, observe that saline exits at the catheter tip. • The delivery system is not designed for use with power injection systems. • Recrossing a partially or fully deployed stent with adjunct devices must be performed with caution. • Prior to stent deployment, remove slack from the delivery system catheter outside the patient. • If excessive force is felt during stent deployment, do not force the delivery system. Remove the delivery system and replace with a new unit. • Store in a cool, dark, dry place. • Do not attempt to break, damage, or disrupt the stent after placement.

Potential Complications and Adverse Events

Complications and Adverse Events which may occur include, but are not limited to the following: • Allergic/anaphylactoid reaction • Amputation • Anemia • Arteriovenous fistula • Death related to procedure • Dissection • Embolization, venous • Embolization, stent • Extravasation • Fever • Hemorrhage/bleeding requiring a blood transfusion • Hematoma, remote site • Hematoma, puncture site • Hypotension/hypertension • Incorrect positioning of the stent requiring further stenting or surgery • Intimal injury/dissection • Ischemia/infarction of tissue/organ • Local infection • Mal position (failure to deliver the stent to the intended site) • Open surgical repair • Pain • Pulmonary embolism

Pseudoaneurysm • Renal failure • Respiratory arrest • Restenosis • Rupture • Septicemia/bacteremia • Stent Fracture • Stent Migration • Vasospasm • Venous occlusion/thrombosis, remote from puncture site • Venous occlusion/thrombosis, near the puncture site • Venous occlusion/restenosis of the treated vessel.

Please consult product labels and instructions for use for indications, contraindications, hazards, warnings and precautions.

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