Aspirex®S in iliofemoral DVT: The Dijon experience

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Disclosure

Speaker name:
Romaric LOFFROY

I have the following potential conflicts of interest to report:

☒ Consulting: Straub Medical, Guerbet, Medtronic, Cook
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Early clot removal options

- Thrombolysis
  - Local
  - CDT
- Manual aspiration
- Thrombus fragmentation
  - Trerotola®
- PMT or lysis-assisted MT
  - EKOS® = US-enhanced lysis
  - Trellis® = pharmaco-MT
  - AngioJet® = rheolytic pharmaco-MT
- Pure mechanical thrombectomy
  - Indigo® = aspiration MT
  - Aspirex®S+++ = rotational MT
Purpose

- To assess the safety, technical success and clinical efficacy of percutaneous mechanical thrombectomy (PMT) for acute symptomatic iliofemoral deep vein thrombosis (DVT) using the Aspirex® S device (Straub Medical AG, Wangs, Switzerland)
Study population

• Single-center retrospective study

• Period of inclusion
  – December 2015 - July 2019

• 30 patients
  – 23F/7M

• Mean age
  – 45.5±19.9 yrs (range: 17-76)

• History
  – DVT history: 15/30 (50%)
  – Thrombophilic abnormality: 6/30 (20%)
  – Malignancy: 4/30 (13.3%)
  – IVC surgery: 1/30 (3.3%)

• Treatment before diagnosis
  – Anticoagulants = 8/30
  – Antiplatelets = 4/30

• Symptomatic ilio-femoral DVT
  – Swelling & pain
    • All patients
  – Additional PE
    • 3 patients

• Pre-intervention imaging
  – US & CT: 100%
DVT characteristics

• Side involved
  – Left = 25/right = 4
  – Bilateral=1

• Localisation
  – LET 3 = 25/30 (83.3%)
    • Involvement of popliteal vein=6/25
  – LET 4 = 5/30 (16.7%)

• Duration of symptoms before treatment
  – Mean = 5.5 days (range: 2-11)

• Etiology
  – May-Thurner syndrome: 20/30 (66.7%)
  – IVC surgery: 1/30 (3.3%)
  – Other or unknown: 9/30 (30%)
Procedural data

- Local anesthesia/sedation
- Cook Flexor 10-Fr long sheath
- Endovascular approach
  - Jugular: 7
  - Popliteal: 19
    - Unilateral: 13
    - Bilateral: 6
  - Both: 4
- Aspirex®S catheter 10-Fr 110 cm
- Self-expandable stents (10-16 mm)
  - Sinus-XL Flex Stent or Sinus Superflex-635 +++
    - Optimed, Ettlingen, Germany
  - Protégé GPS
    - eV3-Covidien, Plymouth, MN
- Bolus of 100UI/kg of heparin every 45 min
- Temporary « ALN » IVC filter
  - 11/30
- Systematic exams at day 1
  - Chest CT scan
  - Duplex US
- Post-operative medication for 3 months
  - Anticoagulants
    - 1 mo: LMWH
    - 2 mo: NOAC
  - Antiplatelets
    - 3 mo
  - Then according to guidelines

Bolus of 100UI/kg of heparin every 45 min
Temporary « ALN » IVC filter
11/30
Systematic exams at day 1
Chest CT scan
Duplex US
Post-operative medication for 3 months
Anticoagulants
1 mo: LMWH
2 mo: NOAC
Antiplatelets
3 mo
Then according to guidelines
Aspirex®S technical data

<table>
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<th>Length cm</th>
<th>GW</th>
<th>OD mm</th>
<th>rVD mm</th>
<th>Rotation rpm</th>
<th>MAC ml/min</th>
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Immediate results

- **Technical success = 100%**
  - Restoration of proximal ilio-femoral blood flow
  - Residual thrombus < 20%

- **No lytic therapy infusion**
  - Additional IV bolus of r-tPA (10 mg) in 5 of 30 patients

- **Stenting rate**
  - 100%
  - Iliac and/or femoral

- **Implanted stents**
  - Mean = 2.3/patient
  - Range: 1-4

- **Number of Aspirex runs**
  - Mean = 2.6/patient
  - Range: 2-4

- **Volume aspirated**
  - Mean = 307.8±66.1 mL
  - Range: 190-410 mL

- **Mean procedural time**
  - PMT run
    - 4.9±0.99 min (range: 3.2-6.7)
  - Total procedure
    - 107.3±33.9 min (range: 70-180)

- **Mean scopy time**
  - 20.2±7.7 min (8-44)
Outcomes

- **Clinical success**
  - Relief of acute symptoms within 3 days
  - 27/30 = 90%

- **Complications**
  - No MAE (bleeding, PE)
  - 2 minor
    - 1 wire lost: snared
    - 1 helix broken outside the patient

- **Hospital stay**
  - Mean = 2.6 days (range: 1-6)
  - Discharge ≤ 2 days in 83.3%
  - No ICU stay

- **Follow-up**
  - Mean: 22.3±14.2 mo
  - Range: 6-48 mo

- **Survival**
  - 96.7% (1 death from cancer)

- **Patency rate at 6-months**
  - Primary: 27/30 = 90%
    - Early in-stent re-thrombosis within 1 week in 3 patients
  - Secondary: 26/30 = 86.7%
    - Failure of recanalization: 2
    - No recanalization attempt: 2
  - PTS at 6 months
    - Low: 22/30 = 73.3%
    - Moderate: 8/30 = 26.7%
Why is pure MT cost-effective?

- Fast thrombus removal
- No ICU stay
- No angiographic control
- No lytics required
- No bleeding complications
- Outpatient procedure

- Catheter cost
LET 4 IF-DVT in a 36 yo woman

9:20 am: angiologist call
1:30 pm: CT scan
2:10 pm: angio-suite entrance
3:20 pm: angio-suite exit
5:15 pm: go home
10:40 pm (day 1): US
Study limitations

- Retrospective nature
- Small series of patients
- Heterogeneity of DVT
- Absence of medico-economic data
- No long-term follow-up results
On-going P-Max study

Clinical follow-up study with the ASPIREX®S Endovascular System
to investigate the safety and effectiveness in the treatment of
DVT patients and special patient groups

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<tr>
<th>STUDY DESIGN</th>
<th>Open, multicentric, international, prospective, post-market clinical follow-up study</th>
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<tr>
<td>NUMBER OF SUBJECTS</td>
<td>In total: up to 120</td>
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Investigators
Dr Thomas HELLER (Rostock, Germany)
Dr Michael LICHTENBERG (Arnsberg, Germany)
Pr Romaric LOFFROY (Dijon, France)
Dr Gerard O’SULLIVAN (Galway, Ireland)

Inclusion criteria
Acute thrombotic or thrombo-embolic occlusion (onset of pain < 14 days)

Follow-up
Up to 24 months

Endpoint
Assessment of the effectiveness and safety of the ASPIREX®S catheter
MAE, QoL, CEAP, VCSS
Conclusion

• Thrombectomy using the Aspirex®S device is a safe, fast and effective therapeutic option in patients presenting with acute symptomatic iliofemoral DVT:
  – Effective in venous thrombus removal +++
    • Fast relief of acute symptoms
  – Restores vein patency in lower limb +++
  – Has low risk and less side effects +++
    • No ICU stay
    • End it in the angiolab
    • No need for lytic infusion
    • No bleeding complications
  – Prevention of PTS ++
  – Preserves valve function...?