Vacuum Assisted Catheter Based Thrombo-Embolectomy For Acute Limb Ischemia (ALI): How Does It Work And Results: From The INDIAN Registry

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Conflict of interest

Speaker’s name: Gianmarco de Donato

I have the following potential conflicts of interest to report:

- Research contracts
- Consulting (Endologix, Penumbra)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

From Fogarty to hybrid treatment

The combination of surgical embolectomy and endovascular techniques may improve outcomes of patients with acute lower limb ischemia

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Fogarty embolectomy for acute on chronic ischemia

Possibility & limit of Fogarty embolectomy

From Fogarty to hybrid treatment + vs. Fogarty group Hybrid group (Fogarty + endo)

HYBRID TREATMENT

2 Steps
1. FOGARTY
   - Fibrinolysis through multiple side hole infusion catheter
   - Thrombus fragmentation
   - Aspiration by large guiding-catheter
2. ENDO
   - PTA ± Stenting
   - Covered stenting

Findings at intraoperative angiography (HP group – n=210)

1. Native arterial lesions (stenosis underlying thrombus) n = 30
2. Residual thrombus in IMA & popliteal firmly adherent to the arterial wall n = 14
3. Residual thrombus in BTK vessels (not appropriately reached by the balloon catheter thromboembolectomy) n = 18
4. Vessel injury after intraluminal Fogarty’s balloon catheter manipulation n = 8
From Fogarty to total endovascular solution – The aspiration thrombectomy system

Background from cerebral stroke
Penumbra system has begun the market leader in stroke

- dedicated design for intracranial navigation
- atraumatic tip
- trackability
- aspiration power

Vacuum Assisted Catheter Based Thrombo-Embolectomy For Acute Limb Ischemia (ALI):
How Does It Work

MY FIRST CASE
with percutaneous mechanical thrombectomy system

BACKGROUND OF MY FIRST CASE WITH MECHANICAL THROMBECTOMY SYSTEM BY PENUMBRA

1. Some conflicting results with other mechanical thrombectomy system
2. Very positive feedback from neuroradiologists (Stroke Unit @ University of Siena)
3. Possibility to borrow ACE 64 (neuro catheter from Penumbra)

MY FIRST CASE OF MECHANICAL THROMBECTOMY

- Previous intracranial hemorrhage
- CABG
- Zilver PTX thrombosis
- Tibial embolization
Indigo – Siena experience

Acute on chronic ischemia

Level of application:
- iliac occlusion
- post-EVAR iliac limb occlusion
- in-stent SFA thrombosis
- cardiac embolization in diseased SFA
- popliteal & BTK acute on-plaque occlusion
- tibial & plantar thrombosis in dialysis-dep patient

Tibial & plantar thrombosis in dialysis dependent patient
Tibial & plantar thrombosis in dialysis dependent patient

The Indian registry (The Indigo system in acute lower limb malperfusion)

First investigator meeting on Sept 25, 2017

Indications:
- Any acute lower limb ischemia
- Embolism
- Thrombosis
- Graft or endograft thrombosis
- Distal emboli secondary to preceding intervention
- Incomplete reperfusion after Fogarty or lytics

Exclusion:
- ALI longer 14 days
- ALI Rutherford class III

Vessel patency, evaluated by TIMI score

Any further treatment of the target vessel(s) after thrombus removal is according the physician’s discretion

ClinicalTrials.gov Identifier: NCT03386370

Preliminary data

- 17 centers active (VS, IR, IC)
- 136 pts enrolled
Preliminary data

Thrombus location

Preliminary results

120 patients

The Indian registry
(The Indigo system in acute lower limb malperfusion)

Preliminary results

- Indigo is safe and effective in acute lower limb ischemia
- Technical success is high even in very small arteries (BTK & BTA)
- AEs as bleeding and hemolysis are not reported

INDIGO SYSTEM FOR THE PERIPHERY

1. Flexible,atraumatic tip, large-bore catheter
   - the risk of vessel injury is truly minimized
2. The system is not provided of any rotational components
   - no risk of intravascular hemolysis and acute renal insufficiency
3. No rapid stream of fluid / no hydrodynamic forces
   - Access to any located peripheral arterial or venous thrombosis
The Indian registry (The indigo system in acute lower limb malperfusion)

Further data COMING SOON Indian

The Indian registry (The indigo system in acute lower limb malperfusion)