Dutch Iliac Stent trial: COVERed versus uncovered balloon-expandable stents for advanced lesions in the common iliac artery

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Disclosure

Speaker name: Joost Bekken

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☒ I do not have any potential conflict of interest
Rationale
Design
Rationale

- Selective vs. direct stenting
- Self-expanding vs. balloon-expandable stents
- Covered vs uncovered stents
Selective vs. direct stenting

**STAG-trial**

**DIST-trial**

No difference in patency

**STAG: more distal embolization**

Mostly focal, stenotic lesions

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Self-expanding vs. balloon-expandable stents

No randomized trials
Covered vs uncovered stents

COBEST-trial

A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease

Bibombe P. Mwipatayi, MMed (Surg), FCS (SA), FRACS, Shannon Thomas, MBBS (Hons), Jackie Wong, MPH, Suzanna E. L. Temple, PhD, MBA, Vikram Vijayan, MRCS, FRCS, Mark Jackson, MD, FRACS, and Sally A. Burrows, BMath Grad Dip Med Stat, on behalf of the Covered Versus Balloon Expandable Stent Trial (COBEST) Co-investigators, Perth, Western Australia and Gold Coast, Queensland, Australia
Limitations

Common and external iliac arteries
Self-expanding & balloon-expandable stents
TASC-classification
HR 0.748 (95% CI 0.235-2.386); p = .6229

Number at risk
V12 Stent Group  41  40  38  37
Bare Stent Group  56  51  49  46

HR 0.136 (95% CI 0.042-0.442); p = .0056

Number at risk
V12 Stent Group  40  39  38  35
Bare Stent Group  24  18  16  11

V12 Stent  Bare Stent
DISCOVER: Dutch Iliac Stent trial: COVERed balloon-expandable versus uncovered balloon-expandable stents in the common iliac artery: study protocol for a randomized controlled trial

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Inclusion criteria
- Age over 18
- **Symptomatic stenosis <3 cm or occlusion of the common iliac artery**
- Signed informed consent form

Exclusion criteria
- Stenosis with a length of less than 3 cm
- Life expectancy <2 years
- Previous endovascular or surgical treatment of the common iliac artery on the affected side
- Inability or unwillingness to comply with the follow-up schedule or understand the informed consent
- Pregnancy or breast-feeding
- Severe renal failure (e-GFR <30 mL/min/1.73 m2)
- Known allergy to iodinated contrast agents or to PTFE
- Contra-indication for anti-coagulation
- Acute limb ischemia
- Occlusion of the abdominal aorta
- Aneurysm of the abdominal aorta that is not amenable to endograft placement
Endpoints

Primary:
- Freedom from binary restenosis at 2 years

Secondary
- Freedom from occlusion
- TLR
- Technical success
- Clinical success
- Complications
- Mortality
- Major amputation
Sample size calculation

90% vs 72% restenosis rate

Alpha-error: 0.05
Beta-error: 0.2

79 pt’s per group
10% lost to FU
174 patients
Study procedures

Patients with symptomatic CIA stenosis or occlusion → Angiography

- CIA Stenosis > 3cm
  - CIA Occlusion
    - Randomisation
      - Covered BE stent
        - N=87
      - Bare metal BE stent
        - N=87
    - Exclusion
  - CIA Stenosis ≤ 3cm
    - Exclusion
Preoperative

Clinical assessment, Rutherford classification
Ankle-brachial index and treadmill test
Duplex ultrasonography
CT or MR-angiography
Questionnaires regarding disease-related health status, functioning and quality of life
Perioperative

Randomization after guidewire passage and angiography in 2 directions.

5000 units of heparine

Assessment of technical success using angiography in 2 directions and intra-arterial pressure measurement

Unrestricted inflow

Unrestricted outflow through patent deep and/or superficial femoral artery

Statin and acetylsalicylic acid indefinitely, clopidogrel 1 month
Follow-up

Clinical assessment, Rutherford classification
Ankle-brachial index and treadmill test
Duplex ultrasonography
Questionnaires regarding disease-related health status, functioning and quality of life

1, 6, 12 and 24 months

Blinding of patients, vascular laboratorists and clinical investigators.
Current status

6 participating centers
94/174 patients included
21% CLI
78% occlusion
16% hybrid procedures

Inclusion finished in 2017

Maasstad Hospital, Rotterdam
St. Antonius Hospital, Nieuwegein
Rijnstate Hospital, Arnhem
Isala Hospital, Zwolle
Catharina Hospital, Eindhoven
Meander MC, Amersfoort
Questions?
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