



# DISCOVER

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

JA Bekken, JA Vos, RA Aarts, JPPM de Vries, B Fioole

# 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

The image features a light blue background with two large, overlapping, curved brush strokes in a slightly darker shade of blue in the upper-left quadrant. The text 'Rationale Design' is centered in the right half of the image.

# 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

ARTICLES

**Randomised comparison of primary stent placement versus primary angioplasty followed by selective stent placement in patients with iliac-artery occlusive disease**

*Eric Tetteroo, Yolanda van der Graaf, Johanna L. Bosch, Andries D van Engelen, Maria G M Hunink, Bert C Eikelboom, Willem P Th M Mali, for the Dutch Iliac Stent Trial Study Group\**

Randomized clinical trial

**Randomized clinical trial of stents *versus* angioplasty for the treatment of iliac artery occlusions (STAG trial)**

*S. D. Goode, T. J. Cleveland and P. A. Gaines on behalf of the STAG trial collaborators\**

*No difference in patency*

*STAG: more distal embolization*

*Mostly focal, stenotic lesions*

# Self-expanding vs. balloon-expandable stents

*No randomized trials*

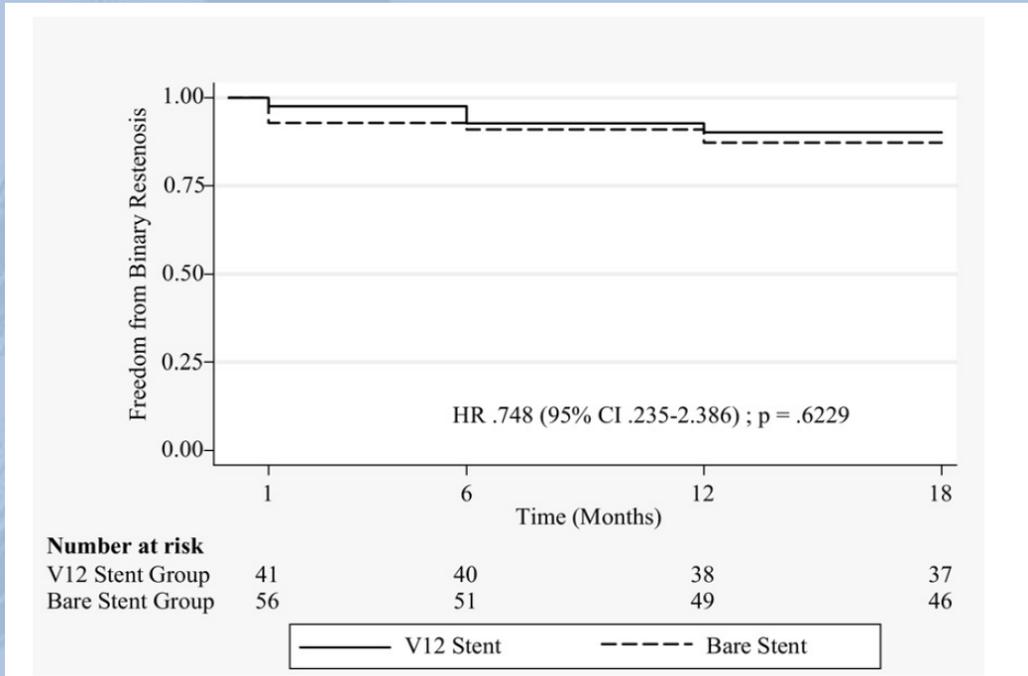
# Covered vs uncovered stents

## COBEST-trial

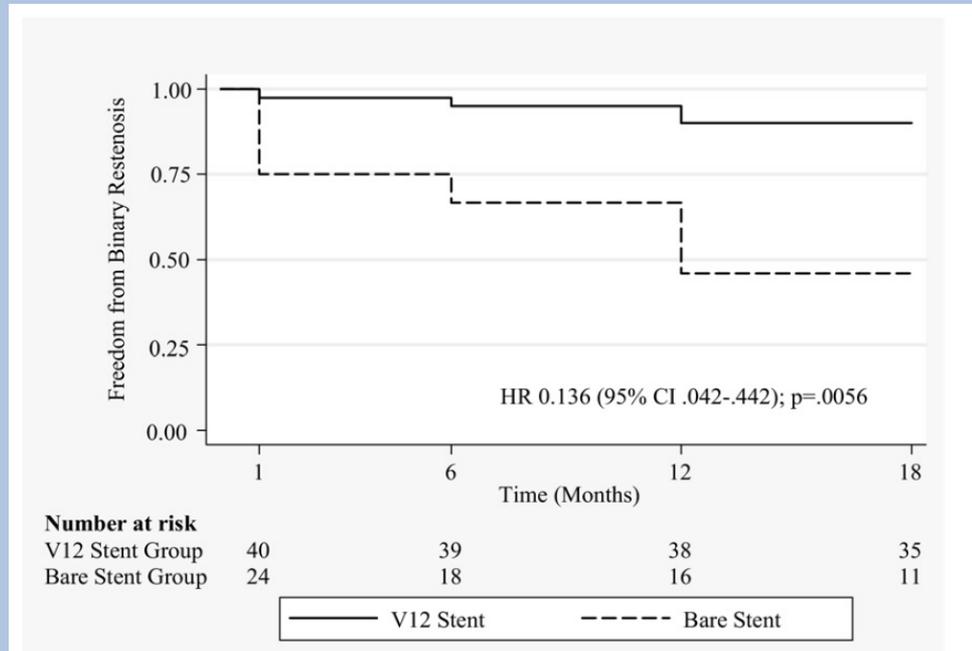
A comparison of covered vs bare expandable stents for the treatment of aortoiliac occlusive disease

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

# TASC B

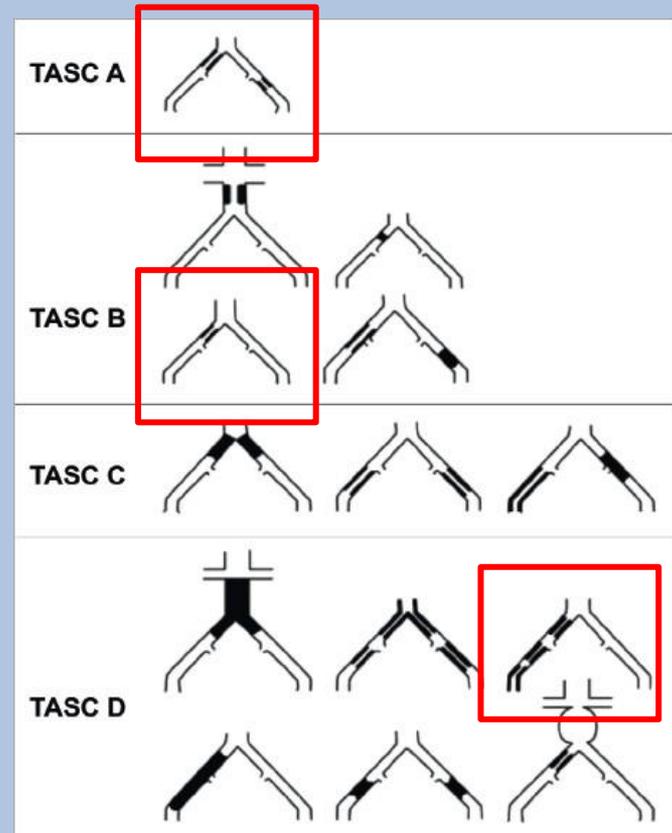
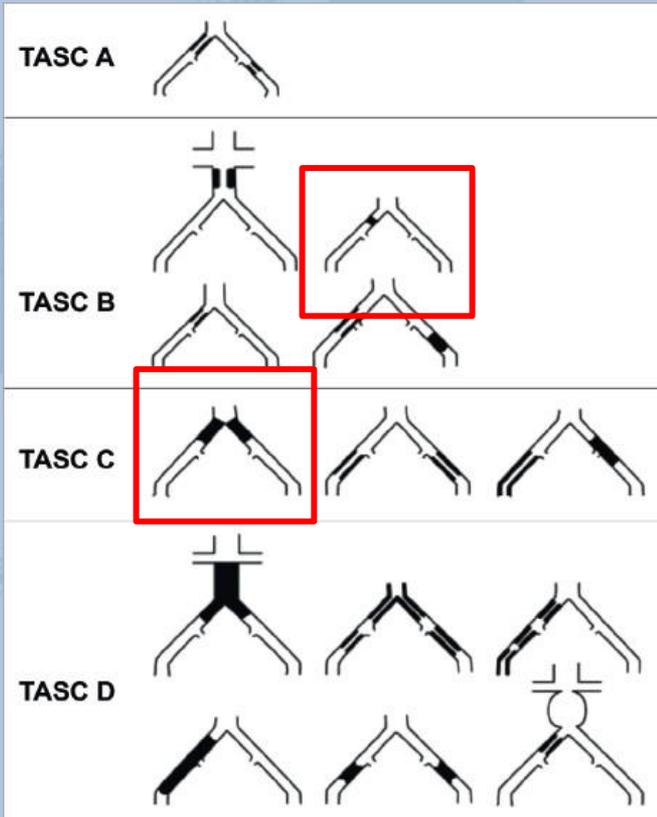


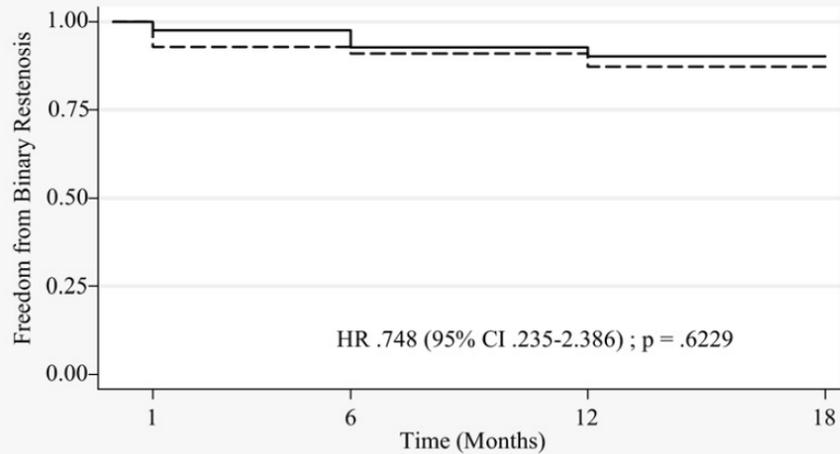
# TASC C & D



# Limitations

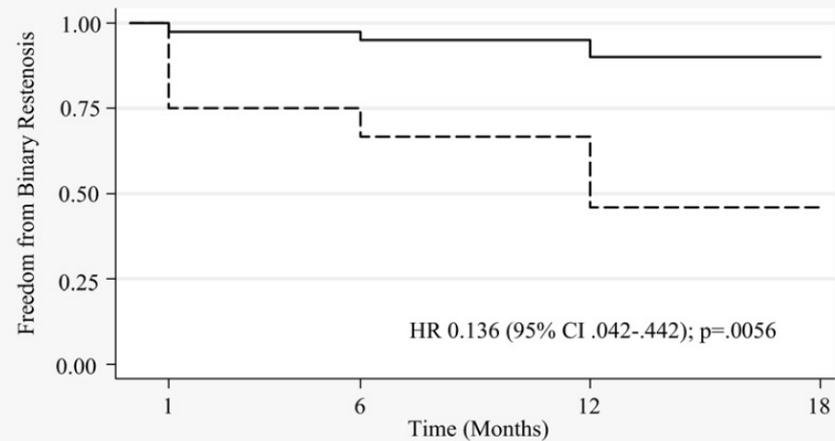
Common and external iliac arteries  
Self-expanding & balloon-expandable stents  
TASC-classification





**Number at risk**

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



**Number at risk**

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





Bekken *et al. Trials* 2012, **13**:215  
<http://www.trialsjournal.com/content/13/1/215>



**STUDY PROTOCOL**

**Open Access**

**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**

Joost A Bekken<sup>1\*</sup>, Jan Albert Vos<sup>2</sup>, Ruud A Aarts<sup>3</sup>, Jean-Paul PM de Vries<sup>4</sup> and Bram Fioole<sup>1</sup>

## **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 m<sup>2</sup>)
- 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*

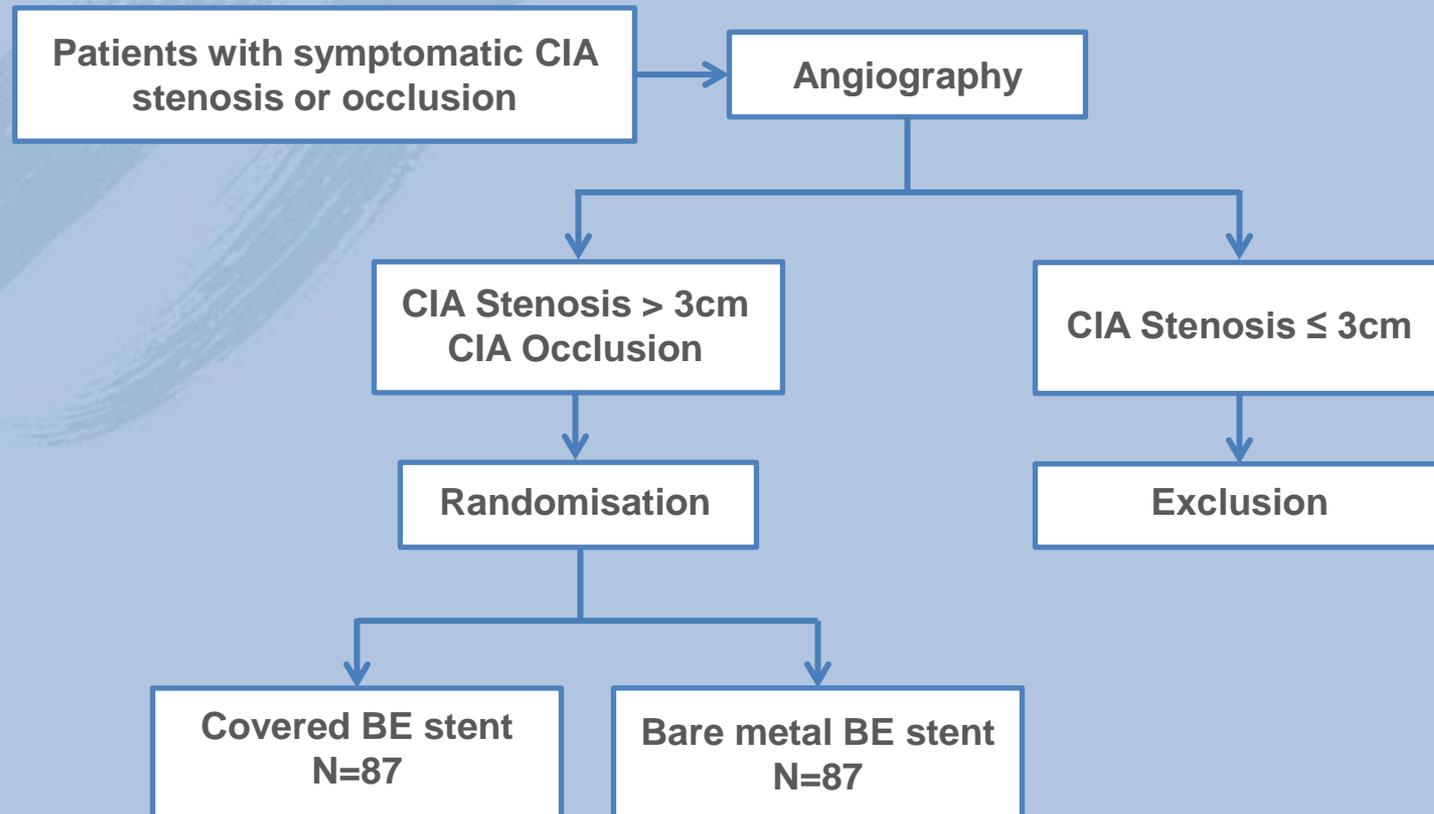
*Beta-error: 0.2*

*79 pt's per group*

*10% lost to FU*

*174 patients*

# Study procedures



# 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

Assesment 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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