Covered Stents versus Bare-Metal Stents in Chronic Atherosclerotic Gastrointestinal Ischemia (CoBaGI): a multicenter randomised controlled trial

Louisa J.D. van Dijk¹,², Désirée van Noord¹,³, Marco J. Bruno*¹, Adriaan Moelker*²

– on behalf of the Dutch Mesenteric Ischemia Study group (DMIS)

*Both authors contributed equally

Department of ¹Gastroenterology and Hepatology and ²Radiology, Erasmus MC University Medical Center, Rotterdam, the Netherlands and ³Gastroenterology and Hepatology, Franciscus Gasthuis & Vlietland, Rotterdam, the Netherlands
Disclosure

Speaker name:
Louisa J.D. van Dijk

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
Introduction

- Chronic Mesenteric Ischemia (CMI) is mostly caused by atherosclerotic stenosis of the celiac artery, superior mesenteric artery and/or inferior mesenteric artery

- Revascularisation is needed:
  - To relief symptoms
  - To prevent acute-on-chronic mesenteric ischemia

- Endovascular revascularisation therapy of choice

- Bare-metal stents are standard care
Comparison of covered stents versus bare metal stents for treatment of chronic atherosclerotic mesenteric arterial disease

Gustavo S. Oderich, MD, Luke S. Erdoes, MD, Christopher LeSar, MD, Bernardo C. Mendes, MD, Peter Gloviczki, MD, Stephen Cha, MS, Audra A. Duncan, MD, and Thomas C. Bower, MD, Rochester, Minn; Bethesda, Md; and Chattanooga, Tenn

To prospectively assess the patency of covered versus bare-metal stents in patients with atherosclerotic CMI
Methods - 1

- Inclusion: patients with occlusive CMI based on atherosclerosis

- Patient and investigator-blinded randomisation:
  - bare-metal (Palmaz Blue - Cordis)
  - versus
  - covered stent (Atrium Advanta V12 - Maquet)

- Follow-up 6, 12 and 24 months after stent placement:
  - CT-angiography
  - Questionnaires:
    - Quality of life
    - Cost-effectiveness
Methods - 2

- Primary outcome: stent patency rate

- Secondary outcomes:
  - Freedom of restenosis
  - Freedom of symptom recurrence
  - Freedom of re-intervention
  - Quality of life
  - Cost-effectiveness

- Sample size: 84 patients
Status

- Erasmus MC
- Maasstad Hospital
- Medical Spectrum Twente
- St. Antonius Hospital

Map of the Netherlands with markers indicating hospital locations and dates:
- May/15
- Jul/15
- Sep/15
- Nov/15
- Jan/16
- Mar/16
- May/16
- Jul/16
- Sep/16
- Nov/16

Legend:
- Erasmus MC (Erasmus MC)
- Maasstad Hospital (Maasstad Hospital)
- Medical Spectrum Twente (Medical Spectrum Twente)
- St. Antonius Hospital (St. Antonius Hospital)
Conclusion

- Prospective assessment of the patency of covered versus bare-metal stents is needed in patients with CMI.

- CoBaGI study is a Dutch multicenter RCT of covered stents versus bare-metal stents in patients with occlusive CMI based on atherosclerosis.
Participants

2. **Maasstad Hospital**: Bram Fioole, Dammis Vroegindewej.
3. **Medical Spectrum Twente**: Robert H. Geelkerken.
4. **St. Antonius Hospital**: Daniel A. van den Heuvel, Jean-Paul P.M. de Vries.
5. **Jeroen Bosch Hospital**: Jan Willem Hinnen.
6. **Bernhoven Hospital**: André S. van Petersen.
Covered Stents versus Bare-Metal Stents in Chronic Atherosclerotic Gastrointestinal Ischemia (CoBaGl): a multicenter randomised controlled trial

Louisa J.D. van Dijk¹,², Désirée van Noord¹,³, Marco J. Bruno*¹, Adriaan Moelker*²

– on behalf of the Dutch Mesenteric Ischemia Study group (DMIS)

*Both authors contributed equally

Department of ¹Gastroenterology and Hepatology and ²Radiology, Erasmus MC University Medical Center, Rotterdam, the Netherlands and ³Gastroenterology and Hepatology, Franciscus Gasthuis & Vlietland, Rotterdam, the Netherlands