# New insights into the impact of aortic pathology on TEVAR outcomes: The MOTHER registry

TEVAR has been widely adopted as the first-line therapy for the treatment of thoracic aneurysms and complicated acute type B dissection due to the advantages it confers in regard to early mortality versus open surgery.

Studies evaluating TEVAR or thoracic endografts have historically been characterised by small, single centre series, which are not sufficiently powered for subset analysis. Until recently, the impact of presenting pathology (aneurysm, chronic type B dissection, acute type B dissection) on long-term outcomes had not been well characterised.

A recent study published in *Circulation* (2013;127:24-32) by Benjamin Patterson and Matt Thompson *et al* describe valuable insights from 1,010 patients analysed under the MOTHER database: Medtronic Thoracic Endovascular Registry (Table 1).

Rates of perioperative adverse events, mid-term death and re-intervention were calculated. The MOTHER database demonstrated that mid-term outcomes of endovascular repair of the thoracic aorta can be defined by presenting pathology, associated comorbidities and mode of admission. The MOTHER study also demonstrated that endovascular repair of the thoracic aorta results in midterm protection from aortic-related mortality in each of the pathologies studied.

"The MOTHER database provides important, practical insights into the clinical practice of TEVAR," said Matt Thompson, principal investigator from St Georges Vascular Institute, London, UK. "By stratifying outcomes by indication for intervention, we are able to better understand which patients do best with TEVAR."

"TEVAR offers excellent mid-term protection from aortic-related mortality for both TAA and type B aortic dissection patients," he continued.

## Highlights

Thirty-day observations:

- This study re-affirms that TEVAR for acute and chronic type B dissection offers significant advantages over open surgery with respect to 30-day mortality and major morbidity
- Predictors of mortality across all pathologies at 30-days were age, ASA grade, emergency admission,

Aneurysm patients vs. dissection patients:

- Early outcomes revealed thoracoabdominal aneurysm patients had higher rates of death, stroke and acute spinal cord injuries vs. chronic type B dissection patients.
- Mid-term results demonstrated that the majority of deaths in thoracoabdominal aneurysm patients, who had significant co-morbidities, were due to cardiac, respiratory and other non-aortic causes.
- It appears well established that TEVAR for both acute and chronic type B aortic dissection offers significant advantages over open surgery with respect to 30-day mortality and major morbidity.

"Medtronic is pleased to be able to provide St. George's Vascular Institute with an unprecedented level of thoracic clinical evidence," said Simona Zannetti, vice president of Clinical and Medical Affairs of Medtronic's Endovascular Therapies business. "We believe evidence should drive device use and we want to provide data to physicians to help them optimise patient treatment."

"Clinical evidence matters, and the only way we can continue to develop the field of TEVAR is to continue to invest in Medtronic's strong aortic clinical programme," continued Zannetti. "We are pleased to provide physicians with the largest breadth and depth of clinical evidence, empowering them to make the best decisions for the patients in their practice."

Table 1. Sources of information that comprised the MOTHER database

| Trial | Patients | Device evaluated |
|---|---|---|
| VALOR | 359 | Talent |
| VALOR II | 160 | Valiant |
| Captivia | 68 | Valiant Captivia |
| VIRTUE | 100 | Valiant Xcelerant |
| INSTEAD | 100 | Talent |
| St. George's Vascular Institute | 223 | Talent/Valiant |

MOTHER Database: Patients treated, stratified according to presenting pathology

| Presenting pathology | Patients | Mean follow-up |
|---|---|---|
| Thoracic aneurysm | 670 | 3.1 years |
| Chronic type B aortic dissection | 195 | 2.4 years |
| Acute type B aortic dissection | 114 | 2.2 years |

# Vascular International develops pulsatile arm model for shunt surgeons

Hands-on training with simulation models is designed to help improve further education of vascular surgeons. On the one hand, the surgeons learn stress-free the principles of simple and complex interventions and, on the other hand, they master new industrial implants perfectly. Since 1991 Vascular International has offered systematically structured simulation courses for future vascular surgeons. The models have constantly been further developed under the maxim of highest quality in order to meet the participants' requirements. Since the end of last year a pulsatile arm model, which serves as a training simulator for various access paths for patients in need of haemodialysis, has been developed.

"With the new Vascular International arm model, we can train more than eight different vascular accesses for haemodialysis patients. Besides arteriovenous fistulae, plastic prostheses may be implanted, the implantation of hybrid prostheses can also be trained," explained Matthias K Widmer, Vascular International tutor, Bern, Switzerland.

Widmer has defined the specifications for this all-in-one concept of the arm model. Under the patronage of the European Society for Vascular Surgery he has also offered training courses for young surgeons on specially prepared corpses since 2009. However, these preparations are extremely expensive and not always available. Widmer explained: "As secretary of the Vascular Access Society I have gained some insight as to how great the demand is and how important the training facilities are, so that vascular surgeons – especially in Asian emerging nations or in Saudi Arabia, for example – are able to take care of the ever increasing number of patients with renal insufficiency, who need a dialysis."

The modular arm model serves to reach a high standard of surgery of haemodialysis accesses. Common arteriovenous fistulae and prosthesis shunts as well as hybrid processes can be practised.

## First prototype

Based on Widmer's plans and with the support of Toni Meile, managing director of Vascular International, a first model was produced by Synbone AG in Malans, Switzerland, in December last year. In January a second model was developed, which has been expanded to become the first prototype and will be introduced to the public during the coming weeks. Vascular inlays are integrated in a "basic arm" with prefabricated channels and the arterial vessels are connected to a pulsatile pump. Everything is then covered with a synthetic skin which may – like the vascular inlays – simply be exchanged after use. At the end of March 2013 the first vascular anastomosis was sutured successfully. A few modifications have to be implemented prior to serial production. Atrium/Maquet has played a key role in bearing the development costs of this arm model, which can be transported in a box after use, well protected and ready for the next mission.

# Patients treated with the new Advance Micro 14 ultra low profile balloon catheter

**For the first time, European patients suffering from peripheral arterial disease have been treated with a new ultra low-profile micro-balloon catheter from Cook Medical that allows physicians to treat arterial lesions in the leg below the knee. Cook Medical's Advance Micro 14 percutaneous transluminal angioplasty balloon catheter was introduced to European physicians at the 2013 LINC congress in Leipzig, Germany**

"My first experience using the new Advance Micro 14 balloon catheter from Cook Medical is very positive," said Andrej Schmidt, Leipzig. "The ultra low profile of the balloon allows you to pass lesions from both the antegrade and retrograde approaches with the same device."

To date, patients have been treated with the device at medical centres in Germany, France, Sweden, Belgium, and the UK.

"This is an ultra low profile balloon that was engineered for retrograde pedal approach procedures, but is versatile enough for standard antegrade vascular access procedures, as well," explained Rob Lyles, vice president of Cook's Peripheral Intervention clinical division.

Advance Micro 14 is a dedicated over-the-wire micro balloon with a low crossing profile. The balloon is small enough to fit through a 3F introducer and can even be used through the 2.9F pedal access sheath that is also available from Cook Medical. The device has a tip entry profile as small as a 0.018-inch diameter wire. The Pliaform balloon texture and hydrophilic coating reduce friction during device insertion and retraction compared to uncoated devices. (Pliaform is available on all sizes except the 1.5mm diameter devices.) The device is available in 50, 90 and 150cm shaft configurations to accommodate a variety of access points.

The Advance Micro 14 Ultra balloon catheter will be available soon in many European Union markets.