

INSTEAD-XL

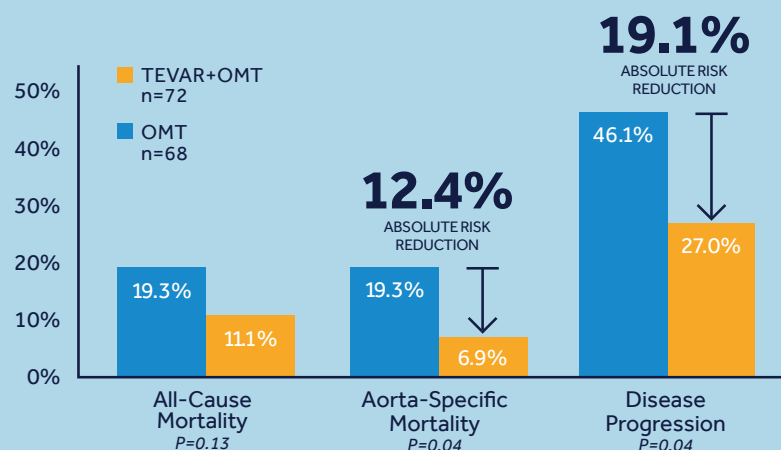
RANDOMIZED
CONTROLLED
TRIAL

The Investigation of Stent Grafts in Aortic Dissection (INSTEAD) Trial 5-Year Long-Term Results

TEVAR COMBINED WITH OPTIMAL MEDICAL THERAPY may emerge as the first line treatment for uncomplicated Type B dissection in patients with suitable anatomy

TEVAR FOR AORTIC DISSECTION Prevents Late Expansion; Encourages Aortic Remodeling

Cumulative Clinical Results: Year 0 Through Year 5



EVIDENCE HIGHLIGHTS

- TEVAR+OMT demonstrated a trend towards reduction in all-cause mortality vs. OMT alone
- TEVAR+OMT achieved 19.1% absolute risk reduction in disease progression, from 46.1% to 27% vs. OMT alone
- Through 5 years, aorta-specific mortality was nearly 3x higher with OMT alone vs. a combined treatment of TEVAR+OMT
- Only 1 incident of retrograde Type A dissection

INSTEAD-XL RANDOMIZED CONTROLLED TRIAL SCORECARD: TEVAR+OMT VS. OMT ALONE IN TYPE B AORTIC DISSECTIONS AT 5 YEARS

Aortic Dissection Treatment Goals	Tevar+OMT (n=72)	OMT (n=68)
Cover Entry Tear ▪ Redirect blood flow through the true lumen	Yes	No
Stabilize Aortic Diameter* ▪ Minimize expansion/rupture risk	Stable aortic diameter (44.1mm vs 44.5mm)	29% increase in aortic diameter (43.6 mm vs 56.4 mm) p < 0.0001
Confirm complete false lumen thrombosis	90.6%	22% p < 0.0001
Maximum true lumen diameter— redirect blood flow to true lumen	32.6mm	18.7mm p < 0.0001
Morphological evidence of remodeling ▪ Sealed entry ▪ Thrombosed false lumen ▪ Shrinking false lumen ▪ Absence of diameter progression	79.2%	10% p < 0.0001

*Based on aortic morphology as assessed at 5Y vs. baseline

PURPOSE

- Characterize long-term outcomes and vessel morphology of stable Type B aortic dissection patients
- Compare outcomes of patients treated with OMT vs. TEVAR+OMT through 5 years follow-up

STUDY DESIGN

- 7 European centers. Enrollment: 2002–2005
- N=140 patients with stable Type B aortic dissection: n=72 TEVAR+OMT vs. n=68 OMT. TEVAR patients received Talent™ thoracic stent grafts¹
- 1° endpoint: all-cause mortality; 2° endpoints: aorta-specific mortality, disease progression

Source: Nienaber, C. et. al. Circ Cardiovasc Inter. 2013 Aug; 6(4):407-16

¹ The Talent™ thoracic stent graft is no longer commercially available in the U.S.

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