Dual-therapy stent technology for patients with coronary artery disease

A great catch?

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Chapter 9

One year clinical performance of COMBO stent versus Xience stent in all-comers patients with coronary artery disease

On behalf of the REMDEEE Registry investigators and AIDA investigators.


*authors contributed equally
RESEARCH LETTER

The novel COMBO dual-therapy stainless-steel coronary stent (DTS, OrbusNeich BV, The Netherlands) is a device that combines a sirolimus-eluting layer with a pro-healing layer with anti-CD34+ antibodies, that attracts circulating endothelial progenitor cells (EPC’s). These EPC’s can differentiate into endothelial cells, promoting rapid endothelialisation. This device has not yet been compared to the well-established cobalt-chromium Xience everolimus-eluting stent (Abbott Vascular, USA) in an all-comers population. Our aim is to evaluate clinical outcomes after the use of COMBO DTS or Xience in a balanced all-comers patient population.

The REMEDEE Registry enrolled 1000 patients treated with COMBO stent. (1) The randomized AIDA trial compared patients treated with Xience versus Absorb bioreabsorbable vascular scaffold (Abbott Vascular, USA). (2) Both trials are investigator-initiated, prospective, multicentre all-comers studies, and used the same endpoint definitions. A propensity-matched analysis was performed for COMBO DTS versus Xience, using 13 baseline variables: age, gender, (insulin treated)-diabetes mellitus (IT)-(DM), hypertension, previous myocardial infarction (MI), previous percutaneous coronary intervention (PCI), previous bypass surgery, acute coronary syndrome (ACS), number of treated lesions, target vessel location, stent length and diameter and ACC/AHA classification. The method of matching has been described previously. (3) In short, patients were 1-to-1 greedy matched using the nearest-neighbour method. The calliper was set at 0.2. Cox-regression analyses were used to compare clinical outcomes between both stent types. P-values <0.05 were considered statistically significant. Target lesion failure (TLF), a composite of cardiac death, target vessel-myocardial infarction (Tv-MI using the third universal definition of myocardial infarction (4)) and any target lesion revascularization (TLR) was the primary endpoint of this analysis. Also, the separate endpoints of TLF were analysed. Definite and probable stent thrombosis (ST) were evaluated with the ARC criteria for stent thrombosis. (5)

The analysis yielded 674 patients-pairs. All baseline characteristics were well balanced between both groups, as presented in Figure 1A. Number of treated lesions did not differ between both groups (p=0.68) and AHA/ACC lesion classification distribution was the same (p=0.42). TLF occurred in 5.5% of patients treated with COMBO DTS and in 5.3% of patients with Xience, (HR 1.05, 95%-CI: 0.66-1.76, p=0.82), Figure 1B. Rates of cardiac death were 1.3% in both COMBO DTS and Xience patients (HR 1.68, 95%-CI: 0.4-2.51, p=1.00). Tv-MI occurred in 0.8% patients (N=6) with COMBO DTS and 2.2% patients with Xience (N=15)(HR 0.4, 95%-CI: 0.15-1.02, p=0.06). TLR was numerically higher in
patients with COMBO 4.5% (N=30) versus 2.7% (N=18) patients with Xience (HR 1.68, 95%-CI: 0.93-3.00, p=0.08). Definite or probable ST occurred 0.7% of both groups (N=5 in COMBO DTS and N=5 in Xience), HR 1.00, 95%-CI: 0.29-3.46, p=1.00.

Xience is currently widely used as a workhorse stent. This analysis shows that COMBO DTS shows similar results in clinical outcomes compared with Xience in a complex all-comers patient population. The added value of the pro-healing layer is currently being investigated in the REDUCE trial (NCT02118870), which evaluates 3 versus 12 months of dual-antiplatelet therapy after ACS in patients treated with COMBO DTS. The HARMONEE trial (NCT02073565) is a prospective study in patients with ischemic coronary disease and non-ST elevated MI, randomizing patients to Xience or COMBO stent. Although results are currently awaited, the HARMONEE patient population is not an all-comers population. This analysis is the first to compare clinical performance between COMBO DTS and Xience stent in all-comers patients. No significant differences between the two devices were found.

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Target lesion failure (TLF) in COMBO 5.5%, 5.3% in Xience, HR 1.05 (95%-CI: 0.66-1.76) p= 0.82. DM= diabetes mellitus. CABG= coronary artery bypass graft. PCI= percutaneous coronary intervention. MI= myocardial infarction. RCA= right coronary artery.

REFERENCES