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coordinatori del progetto

Sabrina Trippoli – Valeria Fadda – Dario Maratea – Andrea Messori

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Clinical and hemodynamic outcomes of "all-comers" undergoing transapical aortic valve implantation: results from the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA).

D'Onofrio A, Rubino P, Fusari M, Salvador L, Musumeci F, Rinaldi M, Vitali EO, Glauber M, Di Bartolomeo R, Alfieri OR, Polesel E, Aiello M, Casabona R, Livi U, Grossi C, Cassese M, Pappalardo A, Gherli T, Stefanelli G, Faggian GG, Gerosa G.

OBJECTIVE: The aim of this study was to assess clinical and hemodynamic outcomes of transapical aortic valve implantation (TA-TAVI) in patients enrolled in the Italian Registry of Trans-Apical Aortic Valve Implantation (I-TA).
METHODS: From April 2008 until November 2010, 504 patients from 20 Italian centers were enrolled in the I-TA registry. Mean logistic EuroSCORE and Society of Thoracic Surgeons score were 24% ± 16% and 11% ± 4%, respectively. Mean follow-up was 9.2 ± 6.5 months (range, 1-26 months). Outcomes were analyzed according to intraoperative complications, procedural volume (high-volume centers, >20 cases; low-volume centers, < 20 cases) and learning curve (first 50% cases vs second 50% cases of each center).
RESULTS: All-cause overall mortality was 8.3% (42 patients). Device success was 99% (500/504 patients). Intraoperative severe complications occurred in 24 (4.8%) patients. Overall 2-year survival was 71.5% ± 6.2%. At discharge, peak and mean gradients were 16.4 ± 11.2 and 8.7 ± 4.1 mm Hg, respectively, and effective orifice area was 1.67 cm(2). These values remained stable at 3, 6, and 12 months after surgery. Independent risk factors for mortality after TA-TAVI were as follows: New York Heart Association class III and IV (odds ratio [OR], 4.43; 95% confidence intervals [CI], 1.28-15.40; P = .02); logistic EuroSCORE greater than 20 (OR, 1.83; 95% CI, 1.02-3.29; P = .04); creatinine concentration greater than 200 μmol/L (OR, 2.56; 95% CI, 1.07-6.15; P = .03), and intraoperative complications (OR, 5.80; 95% CI, 2.68-12.55; P < .001). There were no significant differences in outcomes between high- and low-volume centers and between the first and the second 50% of cases.
CONCLUSIONS: TA-TAVI represents a safe and effective alternative treatment for patients who are inoperable or at high risk for surgery. The occurrence of an intraoperative complication significantly affects survival. Procedural volume and learning curve have no impact on patient survival.

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Sex differences in neointimal hyperplasia following endeavor zotarolimus-eluting stent implantation.

Nakatani D, Ako J, Tremmel JA, Waseda K, Otake H, Koo BK, Miyazawa A, Hongo Y, Hur SH, Sakurai R, Yock PG, Honda Y, Fitzgerald PJ.

Inconsistent results in outcomes have been observed between the genders after drug-eluting stent implantation. The aim of this study was to investigate gender differences in neointimal proliferation for the Endeavor zotarolimus-eluting stent (ZES) and the Driver bare-metal stent (BMS). A total of 476 (n = 391 ZES, n = 85 BMS) patients whose volumetric intravascular ultrasound analyses were available at 8-month follow-up were studied. At 8 months, neointimal obstruction and maximum cross-sectional narrowing (CSN) were significantly lower in women than in men receiving ZES (neointimal obstruction 15.5 ± 9.5% vs 18.2 ± 10.9%, p = 0.025; maximum CSN 30.3 ± 13.2% vs 34.8 ± 15.0%, p = 0.007). Conversely, these parameters tended to be higher in women than in men receiving BMS (neointimal obstruction 36.3 ± 15.9% vs 27.5 ± 17.2%, p = 0.053; maximum CSN 54.3 ± 18.6% vs 45.6 ± 18.3%, p = 0.080). There was a significant interaction between stent type and gender regarding neointimal obstruction (p = 0.001) and maximum CSN (p = 0.003). Multivariate linear regression analysis revealed that female gender was independently associated with lower neointimal obstruction (p = 0.027) and mximum CSN (p = 0.004) for ZES but not for BMS. Compared to BMS, ZES were independently associated with a reduced risk for binary restenosis in both genders (odds ratio for women 0.003, p = 0.001; odds ratio for men 0.191, p<0.001), but the magnitude of this risk reduction with ZES was significantly greater in women than men (p = 0.015). In conclusion, female gender is independently associated with decreased neointimal hyperplasia in patients treated with ZES. The magnitude of risk reduction for binary restenosis with ZES is significantly greater in women than in men.