Off-Label Indications for Trans-Catheter Aortic Valve Implantation

<u>Segev, Amit</u>; Spiegelstein, Danny; Hay, Ilan; Raanani, Ehud; Guetta, Victor Sheba Medical Center, Tel Hashomer, Israel

Background: Trans-catheter Aortic Valve Implantation (TAVI) has emerged as a novel therapeutic approach for patients with severe aortic stenosis (AS) not amenable for conventional surgical aortic valve replacement. Current indications for TAVI consist of symptomatic patients with severe tricuspid native aortic stenosis. We describe herein our initial experience of TAVI in patients with off-label indications.

Methods and Results: 110 patients underwent TAVI in our institution from 2008 to 2010 using trans-femoral, trans-subclavian, trans-apical and trans-aortic approaches. Six patients (5%) underwent TAVI for off-label indication due to: 1) pure severe aortic insufficiency (AI) (n=2), 2) prosthetic valve aortic stenosis (n=2), and 3) bicuspid aortic valve stenosis (n=2).

In all patients implantation of valve was successful: 3 patients received CoreValve (1 transsubclavian, and 2 trans-femoral) and 3 patients received Edwards (all trans-apical). Inhospital mortality was 0%. Valve hemodynamics were excellent except 1 patient who received Edwards valve inside a Mitroflow prosthetic valve in whom trans-aortic gradients remained high. In Al cases, no residual regurgitation was observed.

Conclusions: TAVI is good alternative to surgical AVR in high-risk patients with severe AS. TAVI for off-label indications such as aortic insufficiency, bicuspid and prosthetic valve, is feasible and safe and may be considered in selected patients.