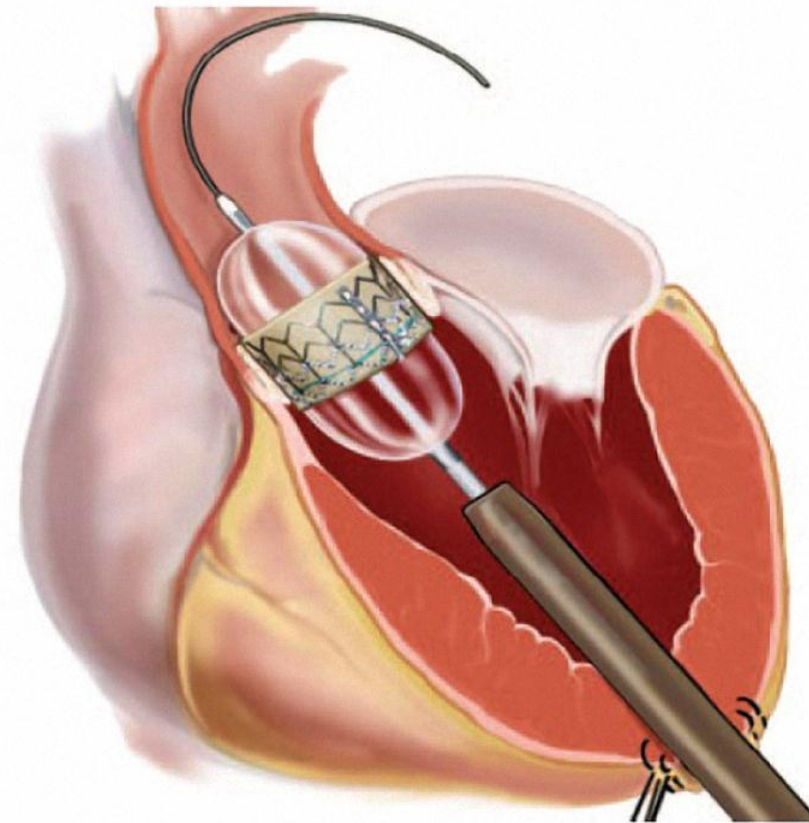
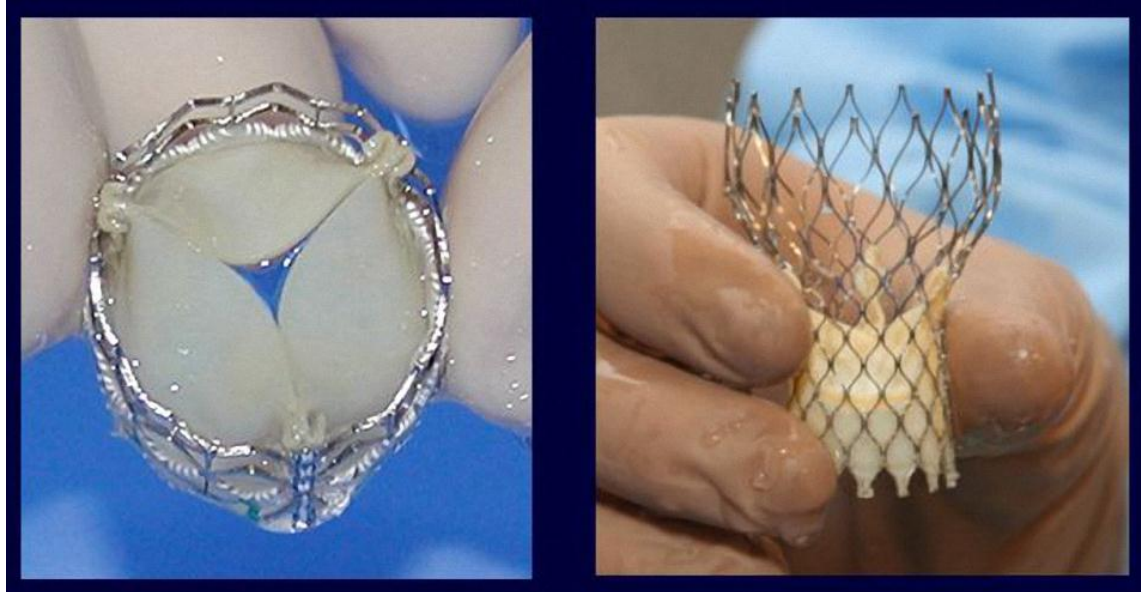


Health Technology Assessment of Transcatheter Aortic Valve Implantation (TAVI) —Evaluation the Methods of Effectiveness and Safety

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Background: TAVI is usually performed using transvascular approach through transfemoral approach (TFA) or transsubclavian approach (TSA), or through transapical approach (TAA). There are, however, no systematic data concerning the comparison of the methods of TAVI.

Objectives: We performed a systematic review to assess the safety and effectiveness of TAVI, and identify factors which have effects on important outcomes.

Methods: We searched studies systematically in 7 databases from January 2000 to December 2011. We assessed the risk of bias of included studies and extracted data of safety and efficacy. Unadjusted odds ratio (OR), mean difference (MD) and their corresponding 95% CI were pooled to assess the effectiveness and safety of TAVI. The statistic for multiple linear regression included the number of studies ≥ 3 and the difference is significant.

Results: We identified 12 primary publications (derived from 247 citations) for TAVI that fulfilled the inclusion criteria. The comparison between TVA and TAA, safety indication: 30 days renal failure RR = 0.35 (0.23-0.53, n = 1487); 30 days MACCEs RR = 2.34 (1.57-3.48, n = 1225); Post-operation conversion to SAVR RR = 0.47 (0.22-0.99, n = 1107). Effectiveness indication: post-operation mortality RR = 0.37 (0.14-0.99, n = 231); 30 days mortality RR = 0.54 (0.39-0.75, n = 1606); 1 year mortality RR = 0.63 (0.52-0.76, n = 1408); post-operation gradient change MD = 11.66 (9.24-14.09, n = 119); hospitalization times (days) MD = 2.60 (3.30-1.91, n = 417). 30 days renal failure inverse proportion with the ratio of women (p = 0.002) and PVD (p = 0.040); Pre-operation conversion to SAVR inverse proportion with CABG (p = 0.000); 30 days MACCEs inverse proportion with renal complication (p = 0.000) and CAD (p = 0.000); Post-operation mortality inverse proportion with lung disease (p = 0.000); 30-day mortality inverse proportion with CAD (p = 0.000); 1 year mortality inverse proportion with age (p = 0.000), and direct proportion with Log EuroSCORE (p = 0.000) and PCI (p = 0.000); Post-operation gradient changes inverse proportion with LVEF % (p = 0.000) and the ratio of women (p = 0.000); hospitalization times inverse proportion with CAD (p = 0.000), MI (p = 0.000), age (p = 0.000) and the ratio of women (p = 0.000).

Conclusions: Based on the current available comparative data, TVA demonstrates the safety and effectiveness compared with TAA; there is no significant difference of efficacy and safety outcomes for 2 methods of TVA. However, the sample size of included studies is small, need more high quality research to prove the effectiveness and safety.

Keywords: TAVI, systematic review, effectiveness evaluation, safety evaluation

