An analysis of real-world cost-effectiveness of TAVI in South Africa

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Abstract

Objectives: Transcatheter aortic valve implantation (TAVI) has become the standard of care for inoperable patients with severe aortic stenosis and is an alternative to conventional surgery for high-risk aortic valve replacement (AVR) patients. There is a positive correlation between severity of pre-operative patients and hospital costs. The aim of this study was to compare empirically derived costs of the two therapies in South Africa.

Methods: The cost-comparison analysis was performed with a MediClinic database including 239 conventional isolated AVR (cAVR) and 75 TAVI cases. All costs are given in 2011 ZAR. The subset of cAVR patients were derived from the relevant and available information in the database and their costs were compared with TAVI costs.

Results: From the 75 available subjects, mean TAVI costs were ZAR 335.5k ± 47.9k, (median ZAR 326.5k) with a mean (median) ICU and hospital length of stay (LoS) of 2.7 (2.0) and 7.6 (6.5) days, respectively. The mean cAVR cost was lower at ZAR 213.9 ± 87.5k (median ZAR 193.6k) but this included the entire population costs (i.e. low to high surgical risk). When estimating cAVR costs, defined by LoS of more than six and 13 days in the ICU and hospital, respectively, and being over 75 years of age, the estimate increased to ZAR 337.9k, which was above the TAVI mean costs. In-hospital mortality was 5.3 and 7.9% for TAVI and the entire cAVR group, respectively. When considering the subset of cAVR patients most likely to be high risk, it increased to 21.4%.

Conclusions: Within the context of limited clinical data we performed the first attempt at cost-effective analysis of TAVI vs cAVR in South Africa. Treatment of aortic stenosis with cAVR in a post hoc defined high-risk patient segment was more expensive than TAVI in South African centres. Despite common perceptions on costs, adoption of TAVI as an alternative, less-invasive therapy that has been clinically proven and recommended by an FDA advisory panel (Partner A) to be at least as effective as cAVR, has a viable economic argument in appropriate patients.

Keywords: TAVI, cost effectiveness, interventional cardiology, cardiac surgery, aortic stenosis, aortic valve

Surgical replacement of defective aortic valves has become almost commonplace in recent years with good outcomes expected. A substantial number of patients suffering from severe aortic stenosis are considered inoperable due to existing co-morbidities not allowing a conventional surgical aortic valve replacement (cAVR) intervention. In the latest Euro Heart survey, the estimated prevalence of inoperable patients with severe aortic stenosis was 31.8%.

The Partner Cohort B trial randomly assigned patients considered unsuitable candidates for surgery into two groups: standard therapy (including balloon aortic valvuloplasty) or a transcatheter aortic valve implantation (TAVI) via the transfemoral approach. The difference in rate of death from any cause was considerable, with an absolute 20 and 24.7% difference favouring TAVI at one and two years, respectively. TAVI has subsequently emerged as a new standard of care for these patients and is considered one of the most innovative breakthroughs in medicine in recent years.

The Partner Cohort A trial randomly assigned high-risk patients and aimed to compare conventional surgery with TAVI (via a transfemoral or transapical approach). Non-inferiority was met and TAVI showed similar clinical benefit – absolute reduction of death from any cause of 2.5% (p = 0.45) and 1.1% (p = 0.78) at one and two years, respectively. The clinical trade off appeared to be between major vascular complications (more frequent with TAVI) and major bleeding (more frequent surgically). Myocardial infarction at two years, haemodynamics (mean gradient and EOA), anaesthesia and procedure time, recovery (assessed by ICU and hospital length of stay: LoS) were secondary endpoints that also improved with TAVI.

Only limited cost-effectiveness studies with TAVI have been published so far. Reynolds et al. and Watt et al. looked at the cost-effectiveness of TAVI versus medical management for patients ineligible for cAVR, based on the Partner Cohort B trial, from the perspective of the US and UK environments, respectively. The incremental cost-effectiveness ratio (ICER) for TAVI in the US study was estimated at $50 200 per year of life gained or $61 889 per quality-adjusted life years (QALY) gained, and in the UK study at £16 100 in the base case. Both were well within the acceptable threshold.

Gada et al. used a Markov model, also based on the Partner trial and derived the outcomes and costs from 10 000 simulations. They found TAVI and cAVR cost effective when compared with medical management, with incremental cost-effectiveness ratios (ICERs) of $39 964/QALYs and $39 280/QALYs, respectively. TAVI was associated with a QALY gain of 0.06 compared with cAVR but with a greater cost ($59 503 vs $56 339), yielding an ICER of $52 773/QALYs.

We attempted to assess a cost-effective analysis of TAVI versus cAVR in South Africa. TAVI has not yet been fully embraced in the South African market, largely because of concerns on the initial cost of the device, without considering the potential cost