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BEST EVIDENCE TOPIC

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Is the quality-of-life improvement after transcatheter aortic valve implantation equivalent to that achieved by surgical aortic valve replacement?

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Abstract

A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was 'is the quality-of-life (QoL) improvement after transcatheter aortic valve implantation (TAVI) equivalent to that achieved by surgical aortic valve replacement (sAVR)?' Literature search revealed 189 papers with reference to QoL after TAVI, of which 7 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers were tabulated. QoL plays a crucial role in the decision-making process for procedures such as TAVI and sAVR. Current evidence included and analysed in this review have shown a clear improvement in QoL after both TAVI and sAVR. TAVI offers a rapid improvement of QoL, evident within the first 30 days. There is no difference in QoL at 2- and 5-year follow-up between TAVI and sAVR. There are currently paucity of data on long-term QoL and the potential impact of structural valve degeneration following TAVI.

Keywords: Aortic valve replacement • Transcatheter • Transcatheter aortic valve implantation • TAVR • Quality of life • Surgical aortic valve replacement • Outcomes

INTRODUCTION

A best evidence topic was constructed according to a structured protocol. This is fully described in *ICVTS* [1].

THREE-PART QUESTION

In patients with [severe aortic stenosis], is [QoL improvement] superior following [TAVI or sAVR]?

CLINICAL SCENARIO

A 70-year-old male patient requires aortic valve replacement for symptomatic severe aortic stenosis (AS). He has no comorbidities and accepted to receive surgical aortic valve replacement (sAVR) but cannot have his operation due to the impact of COVID-19 pandemic upon cardiac surgical services. The multidisciplinary team has decided to offer the patient the option of transcatheter aortic valve implantation (TAVI). The patient is unsure of the impact of TAVI on his quality of life (QoL).

SEARCH STRATEGY

Medline using PubMed interface:

[(outcomes) AND (quality of life) AND (transcatheter aortic valve implantation or TAVI or TAVR) AND (surgical aortic valve replacement or sAVR or aortic valve stenosis surgery)].

SEARCH OUTCOME

Our literature search revealed 189 publications, all of which were screened for relevance and level of evidence in relation to the clinical scenario. From these, 7 papers reported findings from big randomized controlled trials with level of evidence I (Table 1) and were included in this paper. All other publications with reference to QoL after TAVI and sAVR that were not randomized

Table 1: Summary of the studies analysed in this BET

Author, date, journal and country Study type (level of evidence)	Patients (included/total) Groups (mean age) Questionnaire Name of the trial Primary end point	Outcomes	Key results	Comments
Reynolds *et al.* (2012), J Am Coll Cardiol, USA [2] RCT (level I)	628/699 - TF-TAVI cohort 446 [TF 230 (83.8 yo)/sAVR 216 (84.6 yo)] - TA-TAVI cohort 182 [TA 98 (82.6 yo)/sAVR 84 (83.2 yo)] KCCQ EQ-5D SF-12 PARTNER 1 trial (high-risk patients) Primary end point: extent of improvement from BS after both TAVR and AVR at different points during the first year of FU	Improvement between BS and 6- and 12-month FU	TF cohort 1 month KCCQ EQ-5D SF-12 *P*-value TAVI 23.7 0.08 5 sAVR 12.1 0.02* 2.6 6 months TAVI 29.8 0.10 6.7 sAVR 26.9 0.09 7.2 1 year TAVI 28.7 0.09 6.3 sAVR 26.8 0.08 6.1 TA cohort 1 month KCCQ EQ-5D SF-12 *P*-value TAVI 12.5 -0.02* 2.8 sAVR 12.5 0.01* 7 6 months TAVI 23.8 0.04* 0.5* sAVR 27.3 0.06 7.0 1 year TAVI 29.6 0.06 7.1 sAVR 21.6 0.05* 4.5 Results expressed as mean difference versus BS and all yielded statistically significant *P*-values unless '*' next to the number suggesting a non-significant change	- TAVI: more rapid improvement in the KCCQ than AVR, with a significant benefit at 1 month (mean adjusted difference 5.5, 95% CI 1.2–9.8; *P* = 0.01) but no significant difference at either 6/12 months - PATNER trial was not blinded - Very early experience with TA - Fewer patients were randomized within the TA-TAVI cohort
Adams *et al.* (2014), N Engl J Med, USA [3] RCT (level I)	795/871 - TAVI 394 (83.2 yo) - sAVR 401 (83.5 yo) KCCQ SF-12 COREVALVE trial (high-risk patients) Primary end point: rate of death from any cause at 1 year	Changes in functional class and QoL	Change from BS to 1 year: - TAVI: 23.2 ± 25.5 - sAVR: 21.88 ± 26.5 QoL was non-inferior with TAVI (*P* = 0.0063)	- More patients declined surgery post-randomization - Rate of death within 30 days (4.5%) was lower than the estimated rate (≥15%), suggesting that the population was lower risk than intended
Reardon *et al.* (2017), N Engl J Med, USA [4] RCT (level I)	1660/1746 - TAVI 864 (79.9 yo) - sAVR 796 (79.6 yo) KCCQ SURTAVI trial (intermediate-risk patients) Primary end point: death from any cause or disabling stroke at 24 months	Health-related QoL changes from BS	Change from in KCCQ from BS: 1 month - TAVI: 18.4 ± 22.8 - sAVR: 5.9 ± 27.0 95% CI for difference in change from BS (10.0–15.1) 6 months - TAVI: 21.8 ± 22.3 - sAVR: 21.3 ± 22.3 95% CI for difference in change from BS (-1.9 to 2.8) 1 year - TAVI: 20.9 ± 22.2 - sAVR: 20.6 ± 22.2 95% CI for difference in change from BS (-2.2 to 2.9)	- Previous CABG 17.2% of the patients in the sAVR group - TAVI 25.9% rate of PPM implantation - TAVI 6% major vascular complication - The next-generation Evolut R bioprosthesis was used in <20% of the patients - Long-term follow-up is needed
Baron *et al.* (2017), JAMA Cardiol, USA [5] RCT (level I)	1833/2032 - TAVI 950/1011 (81.5 yo) - sAVR 883/1021 (81.7 yo) KCCQ	Early improvement in QoL and at 2 years of follow-up	Rates of substantial improvement (%): - TF cohort: 1 month *P* < 0.01 - TAVI: 43.8 - sAVR: 26.9	- sAVR patients having more extensive procedures than isolated AVR - sAVR: 9.1% concomitant procedures (aortic endarterectomy,

Continued

Table 1: Continued

Author, date, journal and country Study type (level of evidence)	Patients (included/total) Groups (mean age) Questionnaire Name of the trial Primary end point	Outcomes	Key results	Comments
	EQ-5D SF-36 PARTNER 2 trial 2-year FU (intermediate-risk patients) Primary end point: health status benefits		2 year *P* = 0.04 - TAVI 47.6 - sAVR: 46.1 - TA cohort: 1 month *P* = 0.32 - TAVI: 29.6 - sAVR: 27.8 2 year *P* = 0.36 - TAVI: 44.4 - sAVR: 47.4	aortic-root enlargement or replacement and mitral valve or tricuspid valve repair or replacement) Once randomized and procedure initiated: - sAVR: 14.5% underwent CABG - TAVI: 3.9% underwent PCI - QoL in the surgical cohort was also assessing complex operations other than isolated sAVR
Mack *et al.* (2019), N Engl J Med, USA [6] RCT (level I)	950/1000 - TAVI 496 (73.3 yo) - sAVR 454 (73.6 yo) KCCQ PARTNER 3 trial (low-risk patients) Primary end point: composite of death from any cause, stroke or rehospitalization at 1 year	Improvements in QoL at 30 days and at 1 year	Increase in KCCQ from BS (*P* < 0.001): 1 month - TAVI: 37.8 - sAVR: 12.8 1 year - TAVI: 39.7 - sAVR: 38.7	- More patients in the surgery group than in the TAVI group withdrew from the trial - Missing data from the KCCQ - Does not address the problem of long-term survival or structural valve deterioration
Popma *et al.* (2019), N Engl J Med, USA [7] RCT (level I)	1403/1468 - TAVI 725/734 (74 yo) - sAVR 678/734 (74 yo) KCCQ EVOLUT trial (low-risk patients) Primary end point: composite of death from any cause or disabling stroke at 24 months	Change of KCCQ score from BS at 30 days, 6 and 12 months	Increase in KCCQ [mean ± SD (*n*)] BS - TAVI: 68.7 ± 21.8 (722) - sAVR: 69.3 ± 20.7 (674) 30 days - TAVI: 88.7 ± 14.2 (714) - sAVR: 78.6 ± 18.9 (637) 95% CI for difference in change from BS (8.6–13.2) 6 months - TAVI: 90.3 ± 13.4 (633) - sAVR: 90.2 ± 13.8 (547) 95% CI for difference in change from BS (-1.0 to 3.8) 1 year - TAVI: 90.3 ± 12.7 (429) - sAVR: 90.8 ± 12.4 (349) 95% CI for difference in change from BS (-1.6 to 4.3)	- Significant loss of follow-up (40–50%) in just 1 year - Excluded patients with bicuspid aortic valves and candidates for mechanical valves - Different models/generation of valve used in the study
Makkar *et al.* (2020), N Engl J Med, USA [8] RCT (level I)	2032 - TAVI 920/1011 (81.5 yo) - sAVR 831/1021 (81.7 yo) (Data available at 5 years) KCCQ PARTNER 2 trial 5-year FU (intermediate-risk patients) Primary end point: death from any cause or disabling stroke	Improvements in health status at 5 years	BS - TAVI: 54.2 - sAVR: 53.9 1 month - TAVI: 70.2 - sAVR: 58.6 1 year - TAVI: 76.3 - sAVR: 76.7 5 year - TAVI: 73.8 - sAVR: 74.4 *KCCQ score (no *P*-value reported)	- sAVR patients having more extensive procedures than isolated AVR (please see PARTNER 2 comments) - QoL in the surgical cohort was also assessing complex operations, other than just isolated sAVR - More reinterventions, rehospitalizations and at least mild paravalvular leaks in the TAVI cohort at 5 years

AVR: aortic valve replacement; BS: baseline; CI: confidence Interval; EQ-5D: EuroQol 5D; FU: follow-up; KCCQ: Kansas City Cardiomyopathy Questionnaire; QoL: quality of life; RCT: randomized controlled trial; sAVR: surgical aortic valve replacement; SF-12: Short-Form 12 Health Survey Questionnaire; SF-36: Short-Form 36 Health Survey Questionnaire; TA: transapical; TAVI: transcatheter aortic valve implantation; TF: transfemoral.

controlled trials (lower level of evidence) were excluded from this analysis. Non-randomized controlled trial publications also reported retrospective and observational data from small cohorts of patients with high attrition bias.

RESULTS

Reynolds *et al.* [2] studied the PARTNER 1 trial population at 1, 6 and 12 months after randomization using balloon-expandable TAVI prosthesis. They divided a high-risk cohort of patients with severe AS into two subgroups, namely transfemoral-TAVI versus sAVR and transapical-TAVI versus sAVR and have shown similar 12-month survival. The assessment of the QoL using Kansas City Cardiomyopathy Questionnaire (KCCQ) has shown more rapid improvement with TAVI, however, both groups have shown a similar improvement in QoL at 6 and 12 months, with a mean difference versus baseline of more than 20 points. Similarly, QoL assessment using EuroQol 5D has shown an increase from 0.08 at baseline to 0.10 at 6 and 12 months for both TAVI and sAVR patients. Short-Form 12 Health Survey Questionnaire physical scores have also shown an improved of QoL from baseline by at least 4.5 points for both treatment groups at 6 and 12 months. Health status improvement was compared after TAVI or sAVR between baseline and at 1-year follow-up and identified a better early QoL improvement in the transfemoral-TAVI but not in the transapical-TAVI. However, fewer patients were randomized in the transapical-TAVI group while in the sAVR cohort there were patients receiving more extensive procedures, other than just isolated sAVR.

Adams *et al.* [3] examined in the COREVALVE trial also high-risk patients with severe AS, randomized to either TAVI or sAVR using self-expanding TAVI valve and have shown a significant survival benefit at 1 year in favour of the TAVI cohort. Improvement in QoL following TAVI was found to be non-inferior to the improvement in QoL observed following sAVR. In this study, a large number of patients declined surgery post-randomization and the death rate was found to be lower than estimated, suggesting that the population enrolled was of lower risk than intended.

Reardon *et al.* [4] performed a randomized trial (SURTAVI trial) comparing TAVI and sAVR in intermediate-risk patients using a self-expanding TAVI valve. They have shown that TAVI is non-inferior to sAVR at 2 years follow-up. The QoL was assessed using the KCCQ and they have shown a significant improvement for both TAVI and sAVR at 24 months of follow-up. However, the TAVI group had higher rate of residual aortic regurgitation and need for pacemaker implantation while 17.2% of the patients enrolled into the sAVR group had re-do sternotomies due to previous CABG surgery.

Baron *et al.* [5] performed a first analysis of the PARTNER 2 cohort of intermediate-risk patients with severe AS who were randomized to either TAVI or sAVR showing that TAVI and sAVR had similar outcomes at 2-year follow-up for death from any cause or disabling stroke. They were able to identify a better but of borderline significance, early (1 month) QoL for the transfemoral-TAVI cohort only. Both TAVI and sAVR were associated with significant improvements in both disease-specific (16–22 points in the KCCQ-OS scale) and generic health status (3.9–5.1 points in the SF-36 physical scale). There were no significant differences between TAVI and sAVR in any health status measures at 1- or 2-year follow-up.

Makkar *et al.* [8] followed up intermediate-risk patients with severe AS from the PARTNER 2 trial [9] for 5 years after TAVI or sAVR and compared changes in their reported QoL. They concluded that both TAVI and sAVR led to no significant difference in death or stroke at 5 years and also a comparable improvement in QoL, despite more reinterventions, rehospitalizations, and at least mild paravalvular leaks in the TAVI cohort.

Popma *et al.* [7] performed a randomized non-inferiority trial (EVOLUT trial) using the self-expanding supra-annular TAVI compared to sAVR with bioprosthetic valves, in low surgical risk patients who had severe non-bicuspid AS. They have shown that TAVI was non-inferior to sAVR for the composite end point of death or disabling stroke at 24 months. In relation to QoL analysis, assessed using the KCCQ, both TAVI and surgery offered similar functional improvement at 12 months, with better early, 30-day recovery observed in the TAVI group.

Mack *et al.* [6] from the PARTNER 3 trial performed an analysis in low-risk patients with severe AS that underwent TAVI versus sAVR. Their primary outcome of death, stroke or rehospitalization at 1 year follow-up was lower for patients treated with TAVI. The improvement reported in QoL was based in changes observed in NYHA class, 6-min walk-test distance and KCCQ score. This analysis was only focused on the first-year post-procedure and has shown that patients who underwent TAVI had more rapid improvement in all the aforementioned metrics than those who underwent sAVR. When interpreting the results from this study, it is important to keep in mind that the mean age of the patients randomized was below 75 and that all patients were of low surgical risk with potentially longer post-procedure life expectancy. This study did not report on mid-term or long-term outcomes for either QoL or valve-related durability of the procedure.

In interpreting the findings from these studies, we recognize that the reported results on QoL derive from the surviving patients only at each time interval, leading to potentially significant survivorship bias.

CLINICAL BOTTOM LINE

Most of the studies reviewed have not stratified their patients by age groups. The questionnaires were not age-weighted, which makes it difficult to quantify and compare answers not only between studies but also between age groups in each study. However, it appears that both TAVI and sAVR have an important positive impact on QoL outcomes. TAVI can offer a faster improvement in QoL when compared to sAVR. There is no difference to the QoL at intermediate 2- and 5-year follow-up. There are no long-term data on QoL (beyond 5 years). Long-term data on QoL are of vital importance to the consent process of offering TAVR or sAVR in intermediate, but most importantly in low-risk patients with severe AS. Further research in the field is required, using standardized tools, to evaluate the QoL and durability of TAVI procedures in the younger cohort of patients and providing this is ethically acceptable, given the excellent long-term outcomes currently available supporting sAVR.

Conflict of interest: George Krasopoulos receives honoraria for being a consultant, advisor and speaker for Medistim ASA and Abbott. Vasileios Panoulas receives honoraria for been a consultant, advisor and speaker for Medronic.

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