

Comparison of Health Related Quality of Life in Transcatheter Versus Surgical Aortic Valve Replacement: A Meta-Analysis



Tomo Ando, MD^{a*}, Hisato Takagi, MD, PhD^b,
Alexandros Briasoulis, MD, PhD^c, Cindy L. Grines, MD^d,
Luis Afonso, MD^a

^aDivision of Cardiology, Wayne State University/Detroit Medical Center, Detroit, MI, USA

^bDivision of Cardiovascular Surgery, Shizuoka Medical Center, Shizuoka, Japan

^cDivision of Cardiology, University of Iowa Hospitals and Clinics, IA, USA

^dDivision of Cardiology, North Shore University Hospital, Hofstra Northwell School of Medicine, Manhasset, NY, USA

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Background	Data on the effects of transcatheter aortic valve replacement (TAVR) compared to surgical aortic valve replacement (SAVR) on health-related quality of life (HRQOL) outcomes are limited. To assess the comparative HRQOL outcomes between TAVR and SAVR, we performed a systematic review and meta-analysis.
Methods	PubMed and EMBASE databases were searched for articles that compared the HRQOL scores, Kansas City Cardiomyopathy Questionnaire (KCCQ), Medical Outcomes Study Short-Form Health Survey 12 or 36 (SF-12/36), or the EuroQoL 5 Dimension score (EQ-5D) at 30 days and 1 year between TAVR and SAVR. Mean difference (MD) and 95% confidence interval (CI) was calculated with inverse variance statistical method and random-effects model.
Results	A total of four studies with 4,125 patients (1268 transfemoral [TF]-TAVR, 1261 Non-TF TAVR [transsubclavian, transapical or transaortic], and 1,596 SAVR) were included in the studies. KCCQ overall summary scores and its subscales, SF-12/36, and EQ-5D were significantly higher in TF-TAVR compared to SAVR but were similar in non-TF TAVR vs. SAVR at 30 days. At 1-year follow-up, TF-TAVR and non-TF TAVR conferred similar HRQOL scores in KCCQ overall summary and subscales scores, SF-12/36, and EQ-5D compared to SAVR.
Conclusions	Transfemoral-TAVR achieved better HRQOL at 30 days but similar HRQOL at 1 year compared to SAVR. Non-TF TAVR resulted in similar improvements in HRQOL at both 30 days and 1 year compared with SAVR.
Keywords	Meta-analysis • Surgical aortic valve replacement • Transcatheter aortic valve replacement • Quality of life

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*Corresponding author at: Detroit Medical Center, Division of Cardiology, 3990, John R, Detroit, MI, 48201, USA. Tel.: +1 313 745 2620, Fax: +1 313 745 8643., Email: andotomo@hotmail.co.jp

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Transcatheter aortic valve replacement (TAVR) has been shown to offer similar mortality benefits compared to surgical aortic valve replacement (SAVR) in both randomised control trials and real-world cohorts for intermediate and high-surgical risk patients with symptomatic, severe aortic stenosis [1–4]. Although TAVR and SAVR both result in significant mortality reduction, morbidity and mortality rates remain high after TAVR due to advanced age, significant comorbidities, and clinical events such as stroke, myocardial infarction and heart failure. The 5-year follow-up from the Placement of Aortic Transcatheter Valves (PARTNER) trial showed 67.8% mortality and even the most recent Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI) trial showed 11.4% of mortality at 2-year follow-up [1,4].

In these patients with high mortality risk after aortic valve replacement, health-related quality of life (HRQOL) is an important outcome to assess the effectiveness of the procedure. Past studies have mainly focussed on the improvement in HRQOL pre and post TAVR or SAVR, with significant improvements of post-procedural HRQOL [5–7]. However, little is known about the comparative effects of TAVR (transfemoral [TF] or non-TF, i.e. transcarotid, transsubclavian, transapical or transaortic) vs. SAVR on HRQOL. Transcatheter aortic valve replacement could potentially offer a higher degree of HRQOL improvement because of its minimally invasive nature.

Therefore, we performed a systematic review of HRQOL differences between TAVR and SAVR.

Materials and Methods

This systematic review and meta-analysis was performed in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses). A literature search was conducted through PubMed and EMBASE from inception to 25 October 2017. Two independent reviewers (TA and HT) performed the search separately. The search terms were the following: aortic valve AND (percutaneous OR transcatheter OR transluminal OR transarterial OR transapical OR transaortic OR transcarotid OR transaxillary OR transsubclavian OR transiliac OR transfemoral OR transiliofemoral OR “Transcatheter Aortic Valve Replacement” [Mesh]) AND (quality of life OR QOL OR quality OR life OR health). Articles were screened by two-stage strategy. First, articles extracted through the initial search were screened on the basis of title or abstract based on inclusion and exclusion criteria. Second, full manuscripts were reviewed for detailed evaluation whether to include for systematic review based on the pre-defined inclusion and exclusion criteria. Additionally, review articles and references of full manuscript articles included in this systematic review were also investigated for additional relevant articles. Articles were restricted to those published in peer-reviewed scientific journals in English. Conference abstracts were

excluded. Any disagreements were resolved by the third author (LA).

Valve Academic Research Consortium-2 recommends that HRQOL evaluation post-TAVR should include both a heart failure-specific instrument (i.e. Kansas City Cardiomyopathy Questionnaire [KCCQ] or Minnesota Living with Heart Failure Questionnaire) and one or more generic measure (such as Medical Outcomes Study Short-Form Health Survey 12 or 36 [SF-12/36], or the EuroQoL 5 Dimension score [EQ-5D]) measured at early (2 weeks, 1 month, and 3 months) and at later time points (1–5 years) [8]. We therefore adopted KCCQ as an instrument for heart failure-specific and SF-12/36 and EQ-5D for generic health status measurement. Briefly, KCCQ is a 23-item questionnaire that quantifies physical limitations, symptoms, self-efficacy, social interference, and quality of life. Scores for KCCQ summary and its subscales range from 0 to 100 with higher scores indicating better health status [9]. The KCCQ has demonstrated its validity to measure symptoms, functional status and quality of life in cohorts with severe, symptomatic aortic stenosis [10]. SF-36 is a clinical tool developed to survey health status, assessing eight health domains including physical, pain, and emotional problems [11]. SF-12 was a 12-item physical and mental component summary derived from the original SF-36 using regression methods and has shown good correlation with the SF-36 [12]. Both instruments have been studied in the context of cardiovascular disease [13,14]. EQ-5D is a widely used, self-administered questionnaire to assess the generic health status and HRQOL not specific to disease. It is composed of health state description and evaluation. Health state description is assessed by five dimensions: mobility, self-care, usual activities, anxiety/depression, and pain/discomfort. In the evaluation section, patients use a visual analogue scale to evaluate their overall health status from a scale of 0 to 100 with a higher score corresponding to better health status [15].

Inclusion criteria were 1: Studies that assessed the improvement of HRQOL score by either KCCQ, SF-12/36, or EQ-5D between TF or non-TF (transsubclavian, transcarotid, transapical or transaortic) TAVR and SAVR group at short (30 days) or 1-year follow-up. 2: Mean difference (MD) of HRQOL scores and its 95% confidence interval (CI) between TAVR and SAVR (calculated as HRQOL score of TAVR minus HRQOL score of SAVR at 30 days or 1 year) were reported. Exclusion criteria were 1: studies that evaluated the chronological assessment of HRQOL in only single-arm cohort. 2: Scores other than KCCQ, SF-12/36, or EQ-5D were used to evaluate HRQOL.

The included endpoints were mean difference in KCCQ overall summary score and its subscales (physical limitations, total symptoms, quality of life, and social limitations), SF-12/36 (physical and mental), and EQ-5D between TAVR (TF or non-TF) and SAVR at 30-days and 1-year follow-up.

All statistical analyses were performed with Review manager (RevMan) Version 5.3 (Nordic Cochrane Centre, The Cochrane Collaboration, 2012, Copenhagen, Denmark). An inverse variance statistical method and random-effects

model was used to synthesise continuous data and calculate MD and 95% CI. Heterogeneity of the studies was quantified with I^2 index, which indicates 25%, 50% and 75% as low, moderate and high heterogeneity, respectively. Publication bias was evaluated with visual inspection of the funnel plot for asymmetry and subsequently with Egger's test when 1: asymmetry of funnel plot was observed 2: when ≥ 10 studies were included in a meta-analysis (<http://handbook.cochrane.org>). A p-value of <0.05 was considered significant.

Results

A total of four studies [16–19] were identified and included in our quantitative meta-analysis. Details of study selection flows are summarised in the supplemental material. Reynold et al. reported outcomes from PARTNER [16], Arnold et al. from CoreValve U.S. pivotal trial [17], and Baron et al. from PARTNER 2 trial [19]. Gada et al. compared HRQOL scores between transapical-TAVR from non-randomised continued access registry of the PARTNER trial and SAVR cohort of the randomised PARTNER trial [18].

In total, there were 4,125 patients (1268 TF-TAVR, 1,261 Non-TF TAVR, and 1,596 SAVR) included in the studies. Patients were overall elderly with high comorbidities and male gender was approximately half of the entire cohort. While PARTNER and CoreValve studies included patients at high surgical risks, the PARTNER 2 trial included patients at intermediate risk. Baseline patient demographics, KCCQ score, SF-12/36, and EQ-5D were overall well matched between TF-TAVR and SAVR as well as for Non-TF TAVR and SAVR. A summary of patient demographics and baseline health status scores is in Table 1.

All of the KCCQ components including KCCQ overall summary (MD 13.73, 95%CI 10.65-16.81, $p < 0.001$, $I^2 = 48\%$), physical limitations (MD 14.18, 95%CI 11.13-17.22, $p < 0.001$, $I^2 = 27\%$), total symptoms (MD 9.08, 95%CI 7.21-10.94, $p < 0.001$, $I^2 = 0\%$), quality of life (MD 14.01, 95%CI 9.61-18.42, $p < 0.001$, $I^2 = 65\%$), and social limitation (MD 17.61, 95%CI 11.41-23.81, $p < 0.001$, $I^2 = 70\%$) scores at 30-days was higher in TF-TAVR compared to SAVR (Figure 1A). Similarly, SF-12/36 physical (MD 3.95, 95%CI 2.39-5.52, $p < 0.001$, $I^2 = 69\%$) and mental (MD 5.63, 95%CI 4.63-6.62, $p < 0.001$, $I^2 = 0\%$) as well as EQ-5D (MD 0.08, 95%CI 0.05-0.09, $p < 0.001$, $I^2 = 61\%$) at 30-days all favoured TF-TAVR compared to SAVR (Figure 1B, 1C).

Conversely, Non-TF TAVR showed similar improvement in the KCCQ overall summary (MD -0.62 , 95%CI -5.51 - 4.26 , $p = 0.80$, $I^2 = 51\%$), physical limitations (MD 0.31, 95%CI -3.68 - 4.30 , $p = 0.88$, $I^2 = 0\%$), total symptoms (MD 0.67 , 95%CI -4.56 - 3.22 , $p = 0.73$, $I^2 = 30\%$), quality of life (MD 0.32, 95%CI -5.13 - 5.76 , $p = 0.91$, $I^2 = 48\%$), and social limitation (MD 2.77, 95%CI -2.67 - 8.22 , $p = 0.32$, $I^2 = 17\%$) scores at 30 days (Figure 2A). In addition, improvement in SF-12/36 physical (MD 0.93, 95%CI -0.28 - 2.15 , $I^2 = 0\%$) and mental (MD -1.31 , 95%CI -3.13 - 0.52 , $p = 0.16$, $I^2 = 22\%$) as well as

EQ-5D (MD 0, 95%CI -0.03 - 0.03 , $p = 0.89$, $I^2 = 0\%$) were also similar between non-TF TAVR and SAVR (Figure 2B, 2C).

At 1 year, KCCQ overall summary (MD 0.04, 95%CI -1.76 - 1.84 , $p = 0.97$, $I^2 = 0\%$) and subscales of physical limitations (MD 0.05, 95%CI -2.19 - 2.28 , $p = 0.97$, $I^2 = 0\%$), total symptoms (MD -0.94 , 95%CI -2.69 - 0.80 , $p = 0.29$, $I^2 = 0\%$), quality of life (MD -0.03 , 95%CI -2.06 - 2.00 , $p = 0.98$, $I^2 = 0\%$), and social limitation (MD 0, 95%CI -2.67 - 2.67 , $p = 1.00$, $I^2 = 0\%$) scores were comparable between TF-TAVR and SAVR (Figure 3A). Similarly, SF-12/36 physical (MD -0.60 , 95%CI -1.45 - 0.24 , $p = 0.16$, $I^2 = 0\%$), mental (MD 0.62, 95%CI -0.33 - 1.57 , $p = 0.20$, $I^2 = 0\%$), and EQ-5D (MD 0, 95%CI -0.02 - 0.07 , $p = 0.77$, $I^2 = 39\%$) were also similar at 1-year follow-up (Figure 3B, 3C).

Non-TF TAVR also demonstrated similar scores in KCCQ overall summary (MD -0.08 , 95%CI -3.18 - 3.02 , $p = 0.96$, $I^2 = 0\%$), physical limitation (MD -1.34 , 95%CI -5.19 - 2.51 , $p = 0.49$, $I^2 = 0\%$), total symptoms (MD -1.22 , 95%CI -4.22 - 1.77 , $p = 0.42$, $I^2 = 8\%$), quality of life (MD -0.58 , 95%CI -4.35 - 3.18 , $p = 0.76$, $I^2 = 8\%$), and social limitation (MD 4.61, 95%CI -0.02 - 9.24 , $p = 0.05$, $I^2 = 0\%$) scores at 1 year (Figure 4A). Improvement was also similar in SF-12/36 physical (MD 0.37, 95%CI -1.12 - 1.86 , $p = 0.63$, $I^2 = 0\%$), mental (MD -0.67 , 95%CI -2.22 - 0.87 , $p = 0.39$, $I^2 = 0\%$), and EQ-5D (MD 0, 95%CI -0.02 - 0.03 , $p = 0.77$, $I^2 = 39\%$) at 1-year follow-up.

Publication bias was not assessed as there were less than 10 studies included for meta-analysis.

Discussion

In this systematic review and meta-analysis, we found that 1: HRQOL scores were higher for TF-TAVR compared to SAVR for both heart failure specific and generic health assessment tools, but were similar for non-TF TAVR vs. SAVR at 30-days and 2: TF and non-TF TAVR both conferred similar HRQOL scores in both heart failure specific and generic health assessment tools at 1-year follow-up.

There are several potential explanations for the higher HRQOL score in TF-TAVR compared to SAVR at 30 days. These would include, but are not limited to, early mobilisation, less coronary care unit stay, less pain, and less sedative use in TF-TAVR. Transfemoral-TAVR was associated with lower event rates of new-onset atrial fibrillation, major bleeding, and a trend towards lower cerebrovascular events but increased vascular events compared to SAVR in the PARTNER 1 and 2 trials [20,21]. Despite increased vascular event rates, all HRQOL scores and their subscales were significantly improved after TF-TAVR. The greatest benefit was observed in the subscale of social limitation at 30 days (MD 17.61) while improvement of total symptoms was less pronounced (MD 9.06). Interestingly, although the findings were not specific to aortic valve replacement, Soto et al. reported that risk for all-cause mortality increased by 11.2% per 10-point decrease in KCCQ overall score [22]. Moreover, Chan et al. reported that each five-point decrease in KCCQ score

Table 1 Summary of included studies.

Author/Publication, year	Reynold et al., 2012				Arnold et al., 2015			
Study design, used prosthetic valves	Sub-study of the PARTNER trial Sapien, balloon-expandable				Sub-study of the CoreValve U.S. High Risk Pivotal Trial CoreValve, self-expandable			
Patient demographic								
Procedure	TF-TAVR	SAVR	Non-TF TAVR (Transapical)	SAVR	TF-TAVR	SAVR	Non-TF TAVR (Transaortic or transsubclavian)	SAVR
Cohort, (number)	230	216	98	84	315	280	61	53
Age, years	83.8 ± 6.8	84.6 ± 6.5	82.6 ± 7.0	83.2 ± 5.9	83.4 ± 6.9	83.5 ± 6.3	81.9 ± 8.1	83.4 ± 6.5
Male sex, %	60.4	55.6	51.0	59.5	53.3	53.2	50.8	50.9
STS score, %	11.8 ± 3.2	11.5 ± 3.3	11.8 ± 3.7	11.7 ± 3.2	7.3 ± 3.1	7.6 ± 3.2	7.2 ± 2.6	7.7 ± 4.1
Previous MI, %	27.4	24.1	27.6	36.9	22.2	23.9	37.7	28.3
Previous CABG, %	39.1	40.7	51.0	56.0	30.8	30.4	21.3	34.0
CVA, %	22.6	22.7	36.7	29.8	17.1	19.3	*14.8	*32.7
Diabetes, %	NR	NR	NR	NR	**33.0	**43.9	39.3	39.6
PAD, %	35.1	35.7	61.2	62.7	36.9	37.1	62.3	67.9
Chronic lung disease, %	†8.3	†7.4	†11.2	†7.1	44.8	46.1	44.3	34.0
Home oxygen, %	NR	NR	NR	NR	13.7	11.8	8.2	5.7
Frailty, %	16.0	16.6	14.3	18.1	NR	NR	NR	NR
Health status scores								
KCCQ								
Overall summary	39.3 ± 21.7	43.8 ± 22.6	40.3 ± 22.1	46.2 ± 19.8	45.9 ± 23.6	46.0 ± 22.4	51.5 ± 22.1	51.2 ± 21.0
Physical limitation	40.6 ± 26.2	43.4 ± 26.8	40.9 ± 24.1	48.6 ± 23.2	45.7 ± 25.2	45.7 ± 25.1	50.9 ± 22.9	47.9 ± 24.9
Total symptoms	48.9 ± 23.9	52.2 ± 23.8	49.9 ± 23.7	55.5 ± 22.1	55.4 ± 25.0	54.6 ± 24.6	59.9 ± 22.4	61.2 ± 23.6
Quality of life	34.1 ± 22.2	39.2 ± 24.3	34.7 ± 26.9	40.4 ± 22.3	40.7 ± 24.8	42.1 ± 23.7	45.9 ± 24.7	45.1 ± 23.8
Social limitation	32.3 ± 29.3	38.3 ± 28.7	34.6 ± 30.0	40.5 ± 26.9	40.5 ± 30.4	40.5 ± 29.6	48.5 ± 30.9	49.4 ± 28.0
SF-12/36								
Physical summary	29.7 ± 7.7	30.6 ± 8.1	29.4 ± 7.4	31.7 ± 8.5	30.6 ± 9.0	30.7 ± 8.4	31.4 ± 10.1	32.8 ± 9.0
Mental summary	47.0 ± 11.5	47.1 ± 11.0	46.6 ± 11.4	48.7 ± 9.6	47.0 ± 12.3	48.7 ± 11.6	49.5 ± 10.5	46.8 ± 11.7
EQ-5D utility	0.66 ± 0.20	0.66 ± 0.21	0.67 ± 0.19	0.72 ± 0.17	0.73 ± 0.20	0.73 ± 0.17	0.76 ± 0.14	0.72 ± 0.21
Author/Publication, year	Gada et al., 2016				Baron et al., 2017			
Study design, used prosthetic valves	Comparison between NRCA registry TA-TAVR and RCT SAVR from PARTNER trial, Sapien, balloon-expandable				Sub-study of the PARTNER 2 trial Sapien XT, balloon-expandable			
Patient demographic								

Table 1. (continued).

Author/Publication, year	Gada et al., 2016		Baron et al., 2017			
Study design, used prosthetic valves	Comparison between NRCA registry TA-TAVR and RCT SAVR from PARTNER trial, Sapien, balloon-expandable		Sub-study of the PARTNER 2 trial Sapien XT, balloon-expandable			
Procedure	Non-TF TAVR (Transapical)	SAVR	TF-TAVR	SAVR	Non-TF TAVR (Transapical or transaortic)	SAVR
Cohort, (N)	875	80	723	670	227	213
Age, years	*84.6 ± 6.3	*83.4 ± 5.5	81.6 ± 6.7	81.8 ± 6.8	80.6 ± 6.5	80.2 ± 6.9
Male sex, %	47.1	58.8	55.0	55.6	52.4	51.6
STS score, %	12.0 ± 4.2	11.8 ± 3.1	5.8 ± 2.1	5.6 ± 1.7	6.0 ± 2.1	6.3 ± 2.0
Previous MI, %	29.4	36.3	17.4	16.4	20.3	22.5
Previous CABG, %	51.1	57.5	23.1	22.4	*25.6	*35.7
CVA, %	29.9	33.3	8.9	9.3	14.5	13.1
Diabetes, %	*35.0	*48.8	36.8	33.9	42.7	38.0
PAD, %	61.7	63.3	22.0	25.7	48.5	53.1
Chronic lung disease, %	8.7	8.8	†2.8	†2.2	†6.2	†4.7
Home oxygen, %	NR	NR	NR	NR	NR	NR
Frailty, %	NR	NR	NR	NR	NR	NR
Health status scores						
KCCQ						
Overall summary	44.2 ± 21.5	45.4 ± 19.7	53.3 ± 21.9	53.1 ± 21.1	52.9 ± 21.5	52.6 ± 22.0
Physical limitation	*41.6 ± 24.5	*48.1 ± 23.4	55.9 ± 24.1	56.5 ± 24.2	54.1 ± 25.1	53.3 ± 24.3
Total symptoms	55.7 ± 22.8	54.3 ± 21.6	58.1 ± 57.8	57.8 ± 22.0	58.2 ± 21.9	57.8 ± 22.6
Quality of life	40.2 ± 23.6	39.7 ± 22.2	46.7 ± 23.8	46.8 ± 23.2	47.7 ± 23.4	46.9 ± 24.7
Social limitation	37.4 ± 28.2	39.4 ± 26.9	52.3 ± 30.6	50.3 ± 29.6	50.5 ± 30.3	51.9 ± 31.2
SF-12/36						
Physical summary	31.4 ± 8.1	31.8 ± 8.6	36.2 ± 9.0	36.1 ± 8.7	35.5 ± 8.6	35.3 ± 8.9
Mental summary	48.2 ± 11.2	48.4 ± 9.6	48.7 ± 11.2	47.5 ± 11.6	48.9 ± 11.7	48.3 ± 12.1
EQ-5D utility	0.68 ± 0.19	0.72 ± 0.17	0.75 ± 0.17	0.73 ± 0.17	0.74 ± 0.16	0.74 ± 0.17

Abbreviations: PARTNER, Placement of Aortic Transcatheter Valves; CABG, coronary artery bypass graft; CVA, cerebrovascular accident; EQ-5D, EuroQoL 5 dimension; KCCQ, Kansas City Cardiomyopathy Questionnaire; MI, myocardial infarction; NR, not reported; NRCA, non-randomised continued access; PAD, peripheral arterial disease; RCT, randomised controlled trial; SF-12/36, Medical Outcomes Study Short-Form Health Survey 12 or 36; S, surgical; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeon; TA, transapical; TAVR, transcatheter aortic valve replacement; TF, transfemoral.

* $P < 0.05$.

** $P < 0.01$.

†Oxygen dependent.

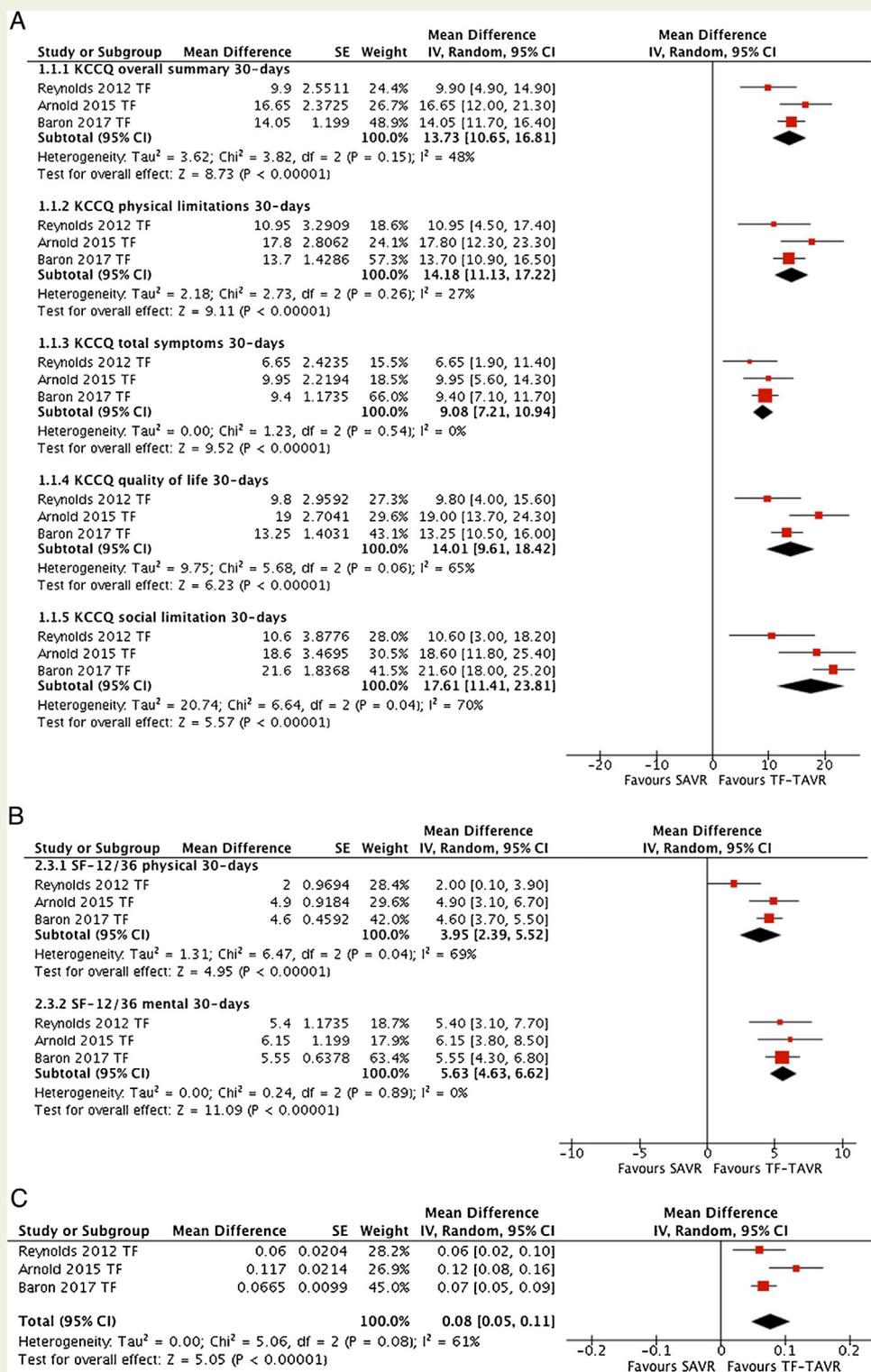


Figure 1 (A) Forest plot for KCCQ between TF-TAVR vs. SAVR at 30 days.

Abbreviations: KCCQ, Kansas City Cardiomyopathy Questionnaire; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

(B) Forest plot for SF-12/36 between TF-TAVR vs. SAVR at 30 days.

Abbreviations: SF-12/36, Short-Form Health Survey 12 or 36; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

(C) Forest plot for EQ-5D between TF-TAVR vs. SAVR at 30 days.

Abbreviations: EQ-5D, EuroQoL 5 Dimension score; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

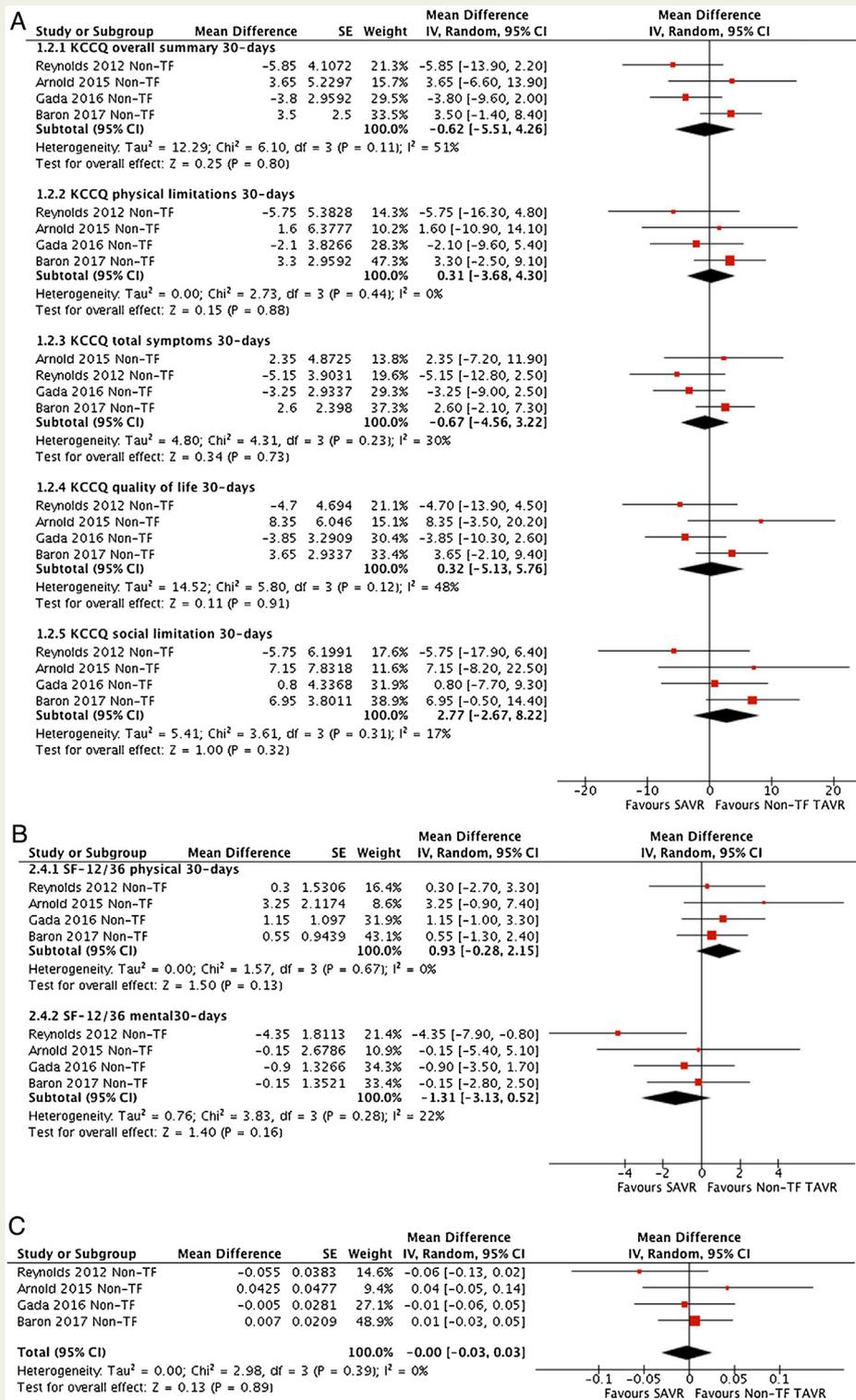


Figure 2 (A) Forest plot for KCCQ between non-TF TAVR vs. SAVR at 30 days. Abbreviations: KCCQ, Kansas City Cardiomyopathy Questionnaire, TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (B) Forest plot for SF-12/36 between non-TF TAVR vs. SAVR at 30 days. Abbreviations: SF-12/36, Short-Form Health Survey 12 or 36; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (C) Forest plot for EQ-5D between non-TF TAVR vs. SAVR at 30 days. Abbreviations: EQ-5D, EuroQoL 5 Dimension score; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

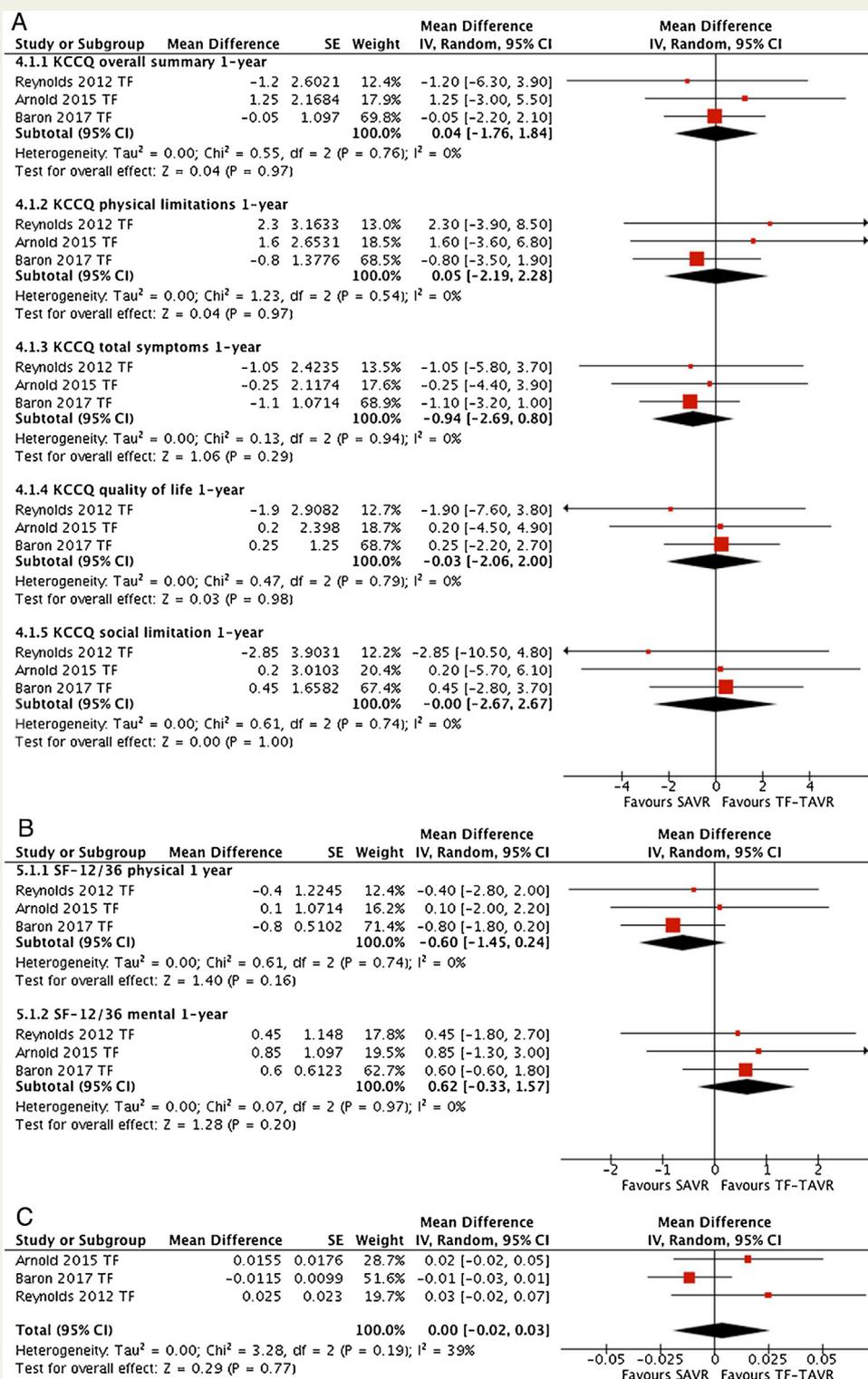


Figure 3 (A) Forest plot for KCCQ between TF-TAVR vs. SAVR at 1 year. Abbreviations: KCCQ, Kansas City Cardiomyopathy Questionnaire, TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (B) Forest plot for SF-12/36 between TF-TAVR vs. SAVR at 1 year. Abbreviations: SF-12/36, Short-Form Health Survey 12 or 36; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (C) Forest plot for SF-12/36 between TF-TAVR vs. SAVR at 1 year. Abbreviations: SF-12/36, Short-Form Health Survey 12 or 36; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

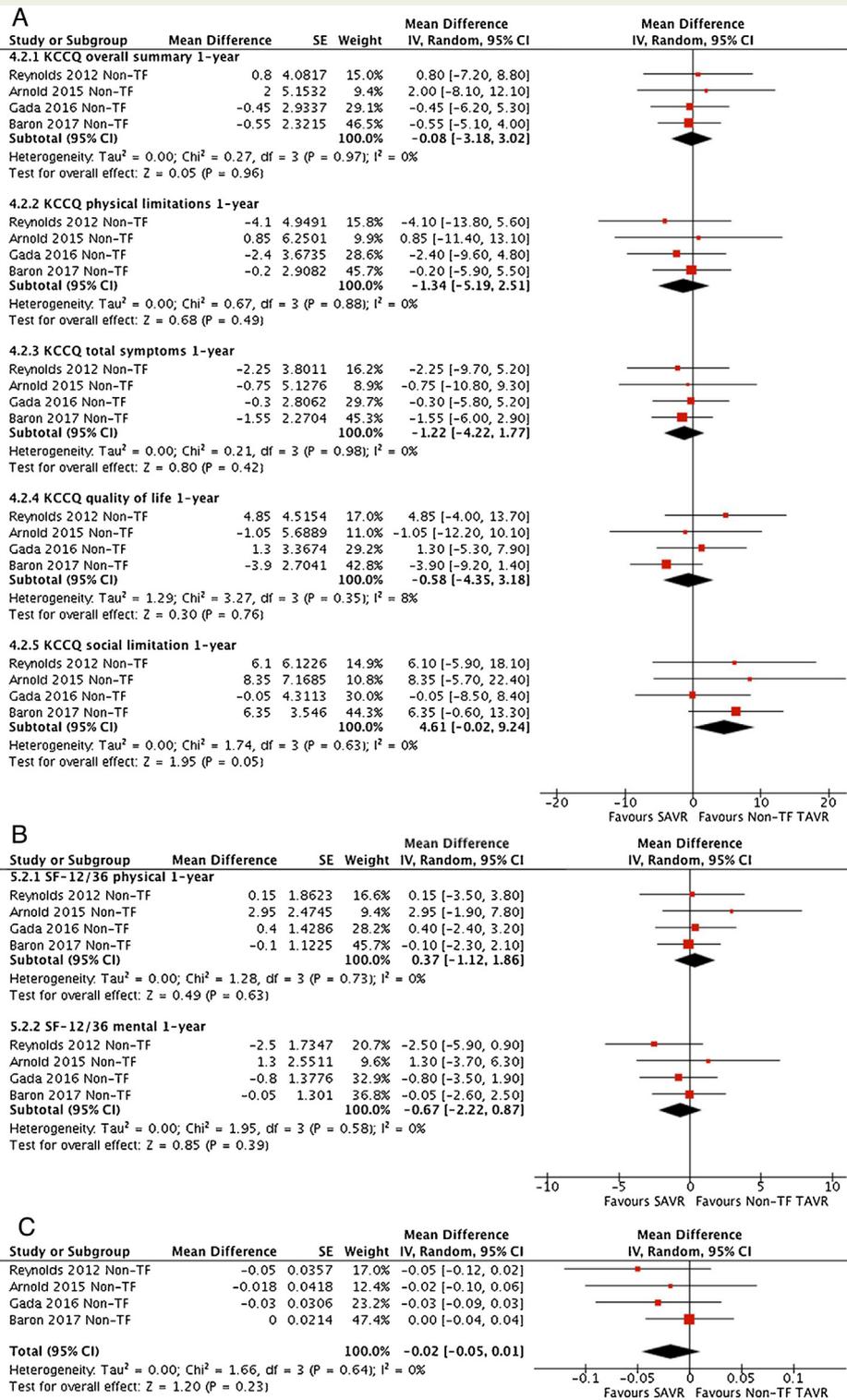


Figure 4 (A) Forest plot for KCCQ between non-TF TAVR vs. SAVR at 1 year. Abbreviations: KCCQ, Kansas City Cardiomyopathy Questionnaire, TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (B) Forest plot SF-12/36 between non-TF TAVR vs. SAVR at 1 year. Abbreviations: SF-12/36, Short-Form Health Survey 12 or 36; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement. (C) Forest plot EQ-5D between non-TF TAVR vs. SAVR at 1 year. Abbreviations: EQ-5D, EuroQoL 5 Dimension score; TF-TAVR, transfemoral-transcatheter aortic valve replacement; SAVR, surgical aortic valve replacement.

was associated with a 4.0% increase in 1-year cost [23]. Based on these observations, the 10-point difference between TF-TAVR and SAVR is of clinical significance. However, the superiority of TF-TAVR was not evident at 1 year of follow-up. This is understandable as most of these benefits from TF-TAVR are derived from the aforementioned perioperative merits in TF-TAVR.

Studies included in this meta-analysis mainly evaluated TAVR vs. SAVR in high surgical risk patients with very impaired baseline HRQOL. A study by Baron *et al.*, which included intermediate risk patients also showed higher HRQOL scores in TF-TAVR over SAVR at 30 days despite less impaired baseline HRQOL status [19]. Further studies are warranted to examine whether there is HRQOL benefit with TF-TAVR at 30 days across all patients regardless of the surgical risk.

Arnold *et al.* reported several factors, including non-TF TAVR, that were independent risk factors for worse health status at 1 year from a large registry [5]. Although non-TF TAVR has been associated with poor health status, both at 30-days and 1-year follow-up, it results in similar HRQOL outcomes compared to SAVR in all scoring tools assessed in this review. Patients undergoing non-TF TAVR typically have a high burden of comorbidities, and their recovery after the procedure is likely to be prolonged and long-term complication rates expected to be higher. Non-TF TAVR is performed less frequently with the advent of the new generation of transcatheter prosthetic valves with smaller diameter sheath sizes and a lower profile delivery system [24].

There are several limitations that need to be mentioned. First, this was a study-level meta-analysis and not patient-level and therefore may be more subject to biases. Second, the study was mainly a sub-study of the major randomised clinical trials with stringent inclusion and exclusion criteria. Patients with end-stage renal disease on dialysis, severe liver disease, severe left ventricular dysfunction, and low-flow low-gradient symptomatic severe aortic stenosis were excluded in these studies. Further studies are warranted to address the role of TAVR and SAVR in these unique patients cohorts. Third, we only identified four studies, which could have resulted in limited generalisability of the findings. Lastly, we only included KCCQ, EF-12/36, and EQ-5D for the assessment of HRQOL. Although it is unclear whether the use of other scores and more objective measures to assess HRQOL would lead to different results, we analysed the recommended instruments for assessment of HRQOL post-TAVR by the Valve Academic Research Consortium 2 [8].

In conclusion, TF-TAVR achieved better HRQOL at 30 days but similar HRQOL at 1 year compared to SAVR. Non-TF TAVR resulted in similar improvements in HRQOL at both 30 days and 1 year compared with SAVR. Further study is warranted to clarify patient populations who would obtain the maximum HRQOL benefit from TF-TAVR.

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Disclosures

None.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.hlc.2018.07.013>.

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