

PICO Search Assignment Worksheet

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Brief description of patient problem/setting (summarize the case very briefly)

74M, with history of CAD, HLD, DM, and HTN, presents is admitted to the hospital for chest pain. Patient is deemed to have severe aortic stenosis. When informed he will undergo TAVR, the patient responds, “So you are not going to open me up?” “What are the outcomes of this new method of valve replacement years from now?”

Search Question:

In patients diagnosed with severe aortic stenosis, is TAVR (transcatheter aortic valve replacement) associated with better long-term outcomes compared to or SAVR (surgical aortic valve replacement)?

Question Type: What kind of question is this? (boxes now checkable in Word)

- Prevalence Screening Diagnosis
- Prognosis Treatment Harms

Assuming that the highest level of evidence to answer your question will be meta-analysis or systematic review, what other types of study might you include if these are not available (or if there is a much more current study of another type)? **Please explain your choices.**

Since my question is related to a treatment method, RCTs would be studies that I would look for. Prospective studies as well as retrospective studies would also be taken into consideration although quality of evidence not as high as the others mentioned above.

PICO search terms:

P	I	C	O
Severe aortic stenosis	TAVR	SAVR	Increased survival
Aortic stenosis	Transcatheter aortic valve replacement	Surgical aortic valve replacement	Decreased rates of survival
Adults			Similar rates of survival
			Valvular outcomes

Search tools and strategy used:

Database	Terms	Filter	# of Articles
PubMed	Aortic stenosis TAVR SAVR	Medline, last 10 years	384
	Aortic stenosis Transcatheter aortic valve replacement Surgical aortic valve replacement	Medline, last 10 years	2,015

ScienceDirect	Aortic stenosis TAVR SAVR	Last 10 years, research articles	476
	Aortic stenosis Transcatheter aortic valve replacement Surgical aortic valve replacement	Last 10 years, research articles	1,952
Cochrane Library	Aortic stenosis TAVR SAVR	Last 10 years	70
	Aortic stenosis Transcatheter aortic valve replacement Surgical aortic valve replacement	Last 10 years	1

The search results yielded lots of articles. Many of them were very specific to an aspect about TAVR/SAVR that did not necessarily relate to my PICO question which was probably do to using the complete spelling of the procedures as opposed to the acronym. Had to sort through articles that related to health outcomes and not other aspects such as cost, etc.

Results found:

Article 1

Citation:

Siontis, G. C. M., Praz, F., Pilgrim, T., Mavridis, D., Verma, S., Salanti, G., ... Windecker, S. (2016). *Transcatheter aortic valve implantation vs. surgical aortic valve replacement for treatment of severe aortic stenosis: a meta-analysis of randomized trials*. *European Heart Journal*, 37(47), 3503–3512. doi:10.1093/eurheartj/ehw225

<https://pubmed.ncbi.nlm.nih.gov/27389906/>

Article Type:

Meta Analysis

Abstract:

Aims: In view of the currently available evidence from randomized trials, we aimed to compare the collective safety and efficacy of transcatheter aortic valve implantation (TAVI) vs. surgical aortic valve replacement (SAVR) across the spectrum of risk and in important subgroups.

Methods and results: Trials comparing TAVI vs. SAVR were identified through Medline, Embase, and Cochrane databases. The primary outcome was death from any cause at 2 years. We performed random-effects meta-analyses to combine the available evidence and to evaluate the effect in different subgroups. This systematic review and meta-analysis is registered with PROSPERO (CRD42016037273). We identified four eligible trials including 3806 participants, who were randomly assigned to undergo TAVI (n = 1898) or SAVR (n = 1908). For the primary outcome of death from any

cause, TAVI when compared with SAVR was associated with a significant 13% relative risk reduction [hazard ratio (95% CI): 0.87 (0.76-0.99); P = 0.038] with homogeneity across all trials irrespective of TAVI device ($P_{\text{interaction}} = 0.306$) and baseline risk ($P_{\text{interaction}} = 0.610$). In subgroup analyses, TAVI showed a robust survival benefit over SAVR for patients undergoing transfemoral access [0.80 (0.69-0.93); P = 0.004], but not transthoracic access [1.17 (0.88-1.56); P = 0.293] ($P_{\text{interaction}} = 0.024$) and in female [0.68 (0.50-0.91); P = 0.010], but not male patients [0.99 (0.77-1.28); P = 0.952] ($P_{\text{interaction}} = 0.050$). Secondary outcomes of kidney injury, new-onset atrial fibrillation, and major bleeding favoured TAVI, while major vascular complications, incidence of permanent pacemaker implantation, and paravalvular regurgitation favored SAVR.

Conclusion: Compared with SAVR, TAVI is associated with a significant survival benefit throughout 2 years of follow-up. Importantly, this superiority is observed irrespective of the TAVI device across the spectrum of intermediate and high-risk patients, and is particularly pronounced among patients undergoing transfemoral TAVI and in females.

Key points:

- Aimed to compare the safety and efficacy of TAVR vs SAVR
- Primary outcome was death after 2 years
- 3,806 patients were included
- TAVR was associated with 13% relative risk reduction
- TAVR: Favored in outcomes including kidney injury, new onset AF, and major bleeding
- SAVR: favored in outcomes including major vascular complications, incidence of permanent pacemaker, and paravalvular regurgitation.

Why I chose this article:

- It was a meta-analysis
- It specifically focused on my PICO question.
- Published 5 years ago
- Focused on outcomes 2 years following procedure

Article 2

Citation:

Deeb, G. M., Reardon, M. J., Chetcuti, S., Patel, H. J., Grossman, P. M., Yakubov, S. J., ... Popma, J. J. (2016). *3-Year Outcomes in High-Risk Patients Who Underwent Surgical or Transcatheter Aortic Valve Replacement*. *Journal of the American College of Cardiology*, 67(22), 2565–2574. doi:10.1016/j.jacc.2016.03.506

<https://pubmed.ncbi.nlm.nih.gov/27050187/>

Article Type:

RCT

Abstract:

Background: In patients with severe aortic stenosis at increased risk for surgery, self-expanding transcatheter aortic valve replacement (TAVR) is associated with improved 2-year survival compared with surgery.

Objective: We sought to determine whether this clinical benefit was sustained over time.

Methods: Patients with severe aortic stenosis deemed at increased risk for surgery by a multidisciplinary heart team were randomized 1:1 to TAVR or open surgical valve replacement (SAVR). Three-year clinical and echocardiographic outcomes were obtained in those patients with an attempted procedure.

Results: A total of 797 patients underwent randomization at 45 US centers; 750 patients underwent an attempted procedure. Three-year all-cause mortality or stroke was significantly lower in TAVR patients (37.3% versus 46.7% in SAVR; $p = 0.006$). Adverse clinical outcome components were also reduced in TAVR patients compared with SAVR patients, including all-cause mortality (32.9% versus 39.1%, respectively; $p = 0.068$), all stroke (12.6% versus 19.0%, respectively; $p = 0.034$), and major adverse cardiovascular or cerebrovascular events (40.2% versus 47.9%, respectively; $p = 0.025$). At 3 years aortic valve hemodynamics were better with TAVR patients (mean aortic valve gradient, 7.62 ± 3.57 mm Hg versus 11.40 ± 6.81 mm Hg in SAVR, $p < 0.001$), although moderate or severe residual aortic regurgitation was higher in TAVR patients (6.8% versus 0.0% in SAVR; $p < 0.001$). There was no clinical evidence of valve thrombosis in either group.

Conclusion: Patients with severe aortic stenosis at increased risk for surgery had improved 3-year clinical outcomes after TAVR compared with surgery. Aortic valve hemodynamics were more favorable in TAVR patients without differences in structural valve deterioration

Key points:

- 797 patients were randomized at 45 different US centers
- 3-year clinical outcomes were obtained as well as echocardiographic outcomes
- 3-year all-cause mortality or stroke: TAVR (37.3%) SAVR (46.7%)
- Adverse clinical outcomes were less with TAVR compared to SAVR
- At 3 years: aortic valve hemodynamics were better with TAVR group
- Moderate to severe aortic regurgitation was higher in TAVR group

Why I chose this article:

- It was a RCT
- It specifically focused on my PICO question.
- Published within the last 5 years
- Measured various outcomes along with all-cause mortality

Article 3

Citation:

Latif, A., Lateef, N., Ahsan, M. J., Kapoor, V., Usman, R. M., Cooper, S., ... Khouzam, R. (2020). *Transcatheter Versus Surgical Aortic Valve Replacement in Patients with Cardiac Surgery: Meta-Analysis and Systematic Review of the Literature*. *Journal of Cardiovascular Development and Disease*, 7(3), 36. doi:10.3390/jcdd7030036

<https://pubmed.ncbi.nlm.nih.gov/32927705/>

Article Type:

Meta-Analysis and Systematic Review

Abstract:

The number of patients with severe aortic stenosis (AS) and a history of prior cardiac surgery has increased. Prior cardiac surgery increases the risk of adverse outcomes in patients undergoing aortic valve replacement. To evaluate the impact of prior cardiac surgery on clinical endpoints in patients undergoing transcatheter aortic valve replacement (TAVR) versus surgical aortic valve replacement (SAVR), we performed a literature search using PubMed, Embase, Google Scholar, and Scopus databases. The clinical endpoints included in our study were 30-day mortality, 1–2-year mortality, acute kidney injury (AKI), bleeding, stroke, procedural time, and duration of hospital stay. Seven studies, which included a total of 8221 patients, were selected. Our study found that TAVR was associated with a lower incidence of stroke and bleeding complications. There was no significant difference in terms of AKI, 30-day all-cause mortality, and 1–2-year all-cause mortality between the two groups. The average procedure time and duration of hospital stay were 170 min less ($p \leq 0.01$) and 3.6 days shorter ($p < 0.01$) in patients with TAVR, respectively. In patients with prior coronary artery bypass graft and severe AS, both TAVR and SAVR are reasonable options. However, TAVR may be associated with a lower incidence of complications like stroke and perioperative bleeding, in addition to a shorter length of stay.

Key points:

- Clinical outcomes were 30-day mortality, 1-2 year mortality, AKI, bleeding, stroke, procedural time, and duration of hospital stay.
- Seven studies were included in the review/analysis
- 8,000+ patients were included
- No difference was seen regarding AKI, 30-day/1/2 year all-cause mortality between the groups
- TAVR: average 170 minutes less procedure time and 3.6 days shorter hospital stay
- TAVR: Lower incidence of stroke and perioperative bleeding as well

Why I chose this article:

- Published last year, very recent
- Large population size

- Focused directly on my PICO question
- Compared various outcomes and not only all-cause mortality

Article 4

Citation:

Abi Khalil, C., Ignatiuk, B., Erdem, G., Chemaitelly, H., Barilli, F., El-Shazly, M., ... Bonaros, N. (2021). Aortic valve function post-replacement of severe aortic stenosis by transcatheter procedure versus surgery: a systematic review and metanalysis. *Scientific Reports*, 11(1). doi:10.1038/s41598-021-91548-x

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8184892/>

Article type:

Meta Analysis and Systematic Review

Abstract:

Transcatheter aortic valve replacement (TAVR) has shown to reduce mortality compared to surgical aortic valve replacement (sAVR). However, it is unknown which procedure is associated with better post-procedural valvular function. We conducted a meta-analysis of randomized clinical trials that compared TAVR to sAVR for at least 2 years. The primary outcome was post-procedural patient prosthesis-mismatch (PPM). Secondary outcomes were post-procedural and 2-year: effective orifice area (EOA), paravalvular gradient (PVG) and moderate/severe paravalvular leak (PVL). We identified 6 trials with a total of 7022 participants with severe aortic stenosis. TAVR was associated with 37% (95% CI [0.51–0.78]) mean RR reduction of post-procedural PPM, a decrease that was not affected by the surgical risk at inclusion, neither by the transcatheter heart valve system. Postprocedural changes in gradient and EOA were also in favor of TAVR as there was a pooled mean difference decrease of 0.56 (95% CI [0.73–0.38]) in gradient and an increase of 0.47 (95% CI [0.38–0.56]) in EOA. Additionally, self-expandable valves were associated with a higher decrease in gradient than balloon ones (beta= 0.38; 95% CI [0.12–0.64]). However, TAVR was associated with a higher risk of moderate/severe PVL (pooled RR: 9.54, 95% CI [5.53–16.46]). All results were sustainable at 2 years.

Key points:

- 6 trials were included which totaled 7,000+ patients
- Primary outcomes was post-procedural patient prosthesis-mismatch (PPM). Secondary outcomes were post-procedural and 2-year: effective orifice area (EOA), paravalvular gradient (PVG) and moderate/severe paravalvular leak (PVL).
- TAVR was associated with 37% decrease in post-procedural PPM (prosthesis opening too small in relation to the patient body size)
- TAVR associated with higher risk of mod/severe PVL

Why I chose this article:

- The study was published this year, very recent
- Focused directly on my PICO question
- Measured valve outcomes after 2 years

What is the clinical “bottom line” derived from these articles in answer to your question?

For adults suffering from severe aortic stenosis, an aortic valve replacement is indicated to treat their symptoms. In today’s medicine, the surgical repair of the aortic valve is seen as an older method of intervention compared to the relatively new method of transcatheter aortic valve replacement, a minimally invasive procedure where a catheter is threaded through the blood vessel in the patient’s leg to deliver and implant the artificial valve into the heart. Based on the articles above, the clinical bottom line here is that TAVR does provide a better outcome compared to the SAVR method. Siontis (2016) et al., concluded that there is a significant survival benefit throughout the 2 year follow up period while Deeb (2016) et al., also concluded TAVR providing a better clinical outcome following 3 years post procedure compared to surgery. Khalil (2021) et al., concluded that there are better valvular outcomes (PPM, orifice area, transvalvular gradients) over surgery. Although Latif (2020) et al., concluded no significant difference in 30-day and 1-2 year all-cause mortality between TAVR and SAVR, there was associated decreased hospital stay and procedural time along with lower incidence of complications (i.e. stroke, perioperative bleeding). TAVR seems to be the preferred intervention for patients suffering from aortic stenosis, however, there was an increased incidence in aortic regurgitation seen with TAVR patients. (Siontis et al., 2016) (Deeb et al., 2016). Although TAVR seems to have the advantage over the surgical valve repair, patients should be aware of the possible adverse effects with the procedure. More research should be done to determine the long-term outcomes of TAVR v SAVR over longer periods of time such as 5 and 10 years post procedure.