**Mini-CAT- Fall 2019**

**Clinical Question:**

Scenario: A 64 years old male with past medical history of aortic stenosis, hyperlipidemia, and goat c/o palpitation, and chest pain and feeling faint with activity. Echo shows severe aortic stenosis. Cardiac team suggests aortic valve replacement.

Clinical question: In adult patients with severe aortic stenosis at intermediate surgical risk, how effective and safe is transcatheter aortic valve replacement (TAVR) when compare to surgical aortic valve replacement (SAVR) in mortality rate, incidence of stroke, and need for permanent pacemaker implantation?

**PICO Question:**

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| **P** | **I** | **C** | **O** |
| Severe aortic stenosis  | Transcatheter aortic valve replacement | Surgical aortic valve replacement  | Mortality rate |
| Severe aortic stenosis with intermediate surgical risk | TAVR | SAVR | Risk of stroke |
|  | transcatheter aortic valve implantation (TAVI) |  | Need for permanent pacemaker implantation |
|  |  |   | Risk of aortic regurgitation/incompetence |
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**Search Strategy:**

Key words used: Transcatheter aortic valve replacement, surgical aortic valve replacement, intermediate surgical risk, severe aortic stenosis, mortality rate

Database: PubMed

Results found:

Transcatheter aortic valve replacement severe aortic stenosis intermediate risk / limits: human, publications dates 10 years🡪 188

Transcatheter vs surgical aortic valve replacement severe aortic stenosis intermediate risk / limits: human, publications dates 10 years🡪49

Database: New England Journal of Medicine

Results found:

Transcatheter vs surgical aortic valve replacement severe aortic stenosis intermediate risk / limits: publications dates 10 years🡪 7

Database: Cochrane

Results found:

Transcatheter vs surgical aortic valve replacement severe aortic stenosis intermediate risk / limits: academic article, publications dates 10 years🡪 22

**How do I narrow down my articles?**

First of all, I tried to find articles that are reviewed articles; published in 10 years; the higher level of evidence, such as systemic review, meta-analysis, and RCTs; based on large sample size; and indexed for MEDLINE. Secondly, I read through abstract quickly and include articles that are published recently and a higher level of evidence, and intervention and control, the outcome of study must match my clinical questions. Especially, articles that match PICO search terms, for example, intervention with transcatheter aortic valve replacement and surgical aortic valve replacement and outcomes of mortality rate, risk of stroke, other complications, such as aortic regurgitation, and need for permanent pacemaker. For the selection of articles, systemic review and meta-analysis are my first choice, but lots of them reviewing low surgical risk or high surgical risk patients. I tried to include those systemic reviews which evaluated intermediate surgical risk and included RCTs studies. The first two systemic reviews are the most precise systemic review I can find that compare transcatheter aortic valve replacement and surgical aortic valve replacement in aortic stenosis. I include 2 RCTs, which also compare transcatheter aortic valve replacement and surgical aortic valve replacement.

**Articles Chosen**:

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| **Title**  | **Transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients With Severe Aortic Stenosis: A Systematic Review and Meta-Analysis.** [Singh K](https://www.ncbi.nlm.nih.gov/pubmed/?term=Singh%20K%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)1, [Carson K](https://www.ncbi.nlm.nih.gov/pubmed/?term=Carson%20K%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)2, [Rashid MK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Rashid%20MK%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)3, [Jayasinghe R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Jayasinghe%20R%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)2, [AlQahtani A](https://www.ncbi.nlm.nih.gov/pubmed/?term=AlQahtani%20A%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)3, [Dick A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Dick%20A%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)3, [Glover C](https://www.ncbi.nlm.nih.gov/pubmed/?term=Glover%20C%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)3, [Labinaz M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Labinaz%20M%5BAuthor%5D&cauthor=true&cauthor_uid=28473216)3. [Heart Lung Circ.](https://www.ncbi.nlm.nih.gov/pubmed/28473216) 2018 Feb;27(2):227-234. doi: 10.1016/j.hlc.2017.02.032. Epub 2017 Apr 12. |
| **Abstract**  | AbstractBACKGROUND:Recent data from randomised and observational studies have reported non-inferior outcomes for transcatheter aortic valve implantation (TAVI) compared to surgical aortic valve replacement (SAVR) in intermediate-risk patients. We performed a systematic review to evaluate the mortality of TAVI compared to SAVR in intermediate-risk patients.METHODS:A comprehensive search of four major databases (Embase, Ovid MEDLINE, PubMed, and Google Scholar) was performed from their inception to 29 April 2016. We included original research studies reporting data on TAVI and SAVR in intermediate-risk patients. We compared the outcomes of TAVI to SAVR.RESULTS:A total of 2,375 and 2,377 intermediate-risk patients underwent TAVI and SAVR respectively. The 30-day all-cause (p=0.07), 30-day cardiac (p=0.53), and 12-month all-cause mortality (p=0.34) was similar between the two groups. However, TAVI through transfemoral access had a significantly lower mortality than SAVR (OR 0.58, p=0.006). The incidence of ≥moderate aortic incompetence (p<0.00001) and pacemaker implantation (p<0.0001) was higher in the TAVI group.CONCLUSIONS:In the intermediate-risk patients, the 30-day and 12-month mortality are similar between TAVI and SAVR. Increased operator experience and improved device technology have led to a significant reduction in mortality in intermediate-risk patients undergoing TAVI. PMID: 28473216[Indexed for MEDLINE] |
| **Study**  | Systemic review / Meta-analysis  |
| **Link** | **Link**: <https://www.ncbi.nlm.nih.gov/pubmed/28473216> |
| **PDF** |  |

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| **Title**  | **Efficacy and safety of transcatheter aortic valve replacement in intermediate surgical risk patients: A systematic review and meta-analysis.** [Khan AR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Khan%20AR%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)1, [Khan S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Khan%20S%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)2, [Riaz H](https://www.ncbi.nlm.nih.gov/pubmed/?term=Riaz%20H%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)3, [Luni FK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Luni%20FK%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)4, [Simo H](https://www.ncbi.nlm.nih.gov/pubmed/?term=Simo%20H%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)2, [Bin Abdulhak A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bin%20Abdulhak%20A%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)5, [Bavishi C](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bavishi%20C%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)6, [Flaherty M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Flaherty%20M%5BAuthor%5D&cauthor=true&cauthor_uid=26946091)1. [Catheter Cardiovasc Interv.](https://www.ncbi.nlm.nih.gov/pubmed/26946091) 2016 Nov 15;88(6):934-944. doi: 10.1002/ccd.26465. Epub 2016 Mar 4. |
| **Abstract**  | AbstractBACKGROUND:The efficacy of transcatheter aortic valve replacement (TAVR) in aortic stenosis patients at high surgical risk has been established. The data on patients with intermediate risk is not conclusive. We performed a meta-analysis of studies which compared TAVR with surgical aortic valve replacement (SAVR) in patients at intermediate surgical risk.METHODS:Several databases searched from inception to February 2015 yielded 7 eligible studies with 2,173 participants. The measured outcome of efficacy was all-cause mortality. Data on safety included stroke, permanent pacemaker implantation (PPI), aortic regurgitation (AR), vascular access complications, and major bleeding. Outcomes were pooled and relative risk (RR) was calculated with the Mantel-Haenszel method.RESULTS:There was no difference in either short-term (RR, 1.02; 95% CI: 0.63-1.63; P = 0.94; I2  = 0%) or medium to long-term all-cause mortality (RR, 0.99; 95% CI: 0.81-1.21; P = 0.91; I2  = 0%). There was increased incidence of stroke (RR, 2.96; 95% CI: 0.87-10.09; P = 0.08; I2  = 0%), AR (RR, 3.59; 95% CI: 2.13-7.19; P < 0.00001; I2  = 2%), PPI (RR, 6.53; 95% CI: 1.91-22.32; P < 0.003; I2  = 0%) and vascular access complications (RR, 3.84; 95% CI: 0.65-22.76; P < 0.14; I2  = 48%) in patients with TAVR. There was a small, albeit increased risk of major or life threatening bleeding with SAVR as compared to TAVR (RR, 1.36; 95% CI: 1.04-1.80; P < 0.03; I2  = 0%).CONCLUSIONS:In this meta-analysis we found that TAVR may be an acceptable alternative to SAVR in patients with intermediate risk for surgery. However, we must await evidence from the current large randomized trials before widespread adoption of this procedure is undertaken.  |
| **Study**  | Systemic review / Meta-analysis |
| **Link** | **Link:** <https://www.ncbi.nlm.nih.gov/pubmed/26946091> |
| **PDF** |  |

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| **Title**  | **Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients.** [Reardon MJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Reardon%20MJ%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Van Mieghem NM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Van%20Mieghem%20NM%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Popma JJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Popma%20JJ%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Kleiman NS](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kleiman%20NS%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Søndergaard L](https://www.ncbi.nlm.nih.gov/pubmed/?term=S%C3%B8ndergaard%20L%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Mumtaz M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mumtaz%20M%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Adams DH](https://www.ncbi.nlm.nih.gov/pubmed/?term=Adams%20DH%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Deeb GM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Deeb%20GM%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Maini B](https://www.ncbi.nlm.nih.gov/pubmed/?term=Maini%20B%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Gada H](https://www.ncbi.nlm.nih.gov/pubmed/?term=Gada%20H%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Chetcuti S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Chetcuti%20S%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Gleason T](https://www.ncbi.nlm.nih.gov/pubmed/?term=Gleason%20T%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Heiser J](https://www.ncbi.nlm.nih.gov/pubmed/?term=Heiser%20J%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Lange R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lange%20R%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Merhi W](https://www.ncbi.nlm.nih.gov/pubmed/?term=Merhi%20W%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Oh JK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Oh%20JK%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Olsen PS](https://www.ncbi.nlm.nih.gov/pubmed/?term=Olsen%20PS%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Piazza N](https://www.ncbi.nlm.nih.gov/pubmed/?term=Piazza%20N%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Williams M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Williams%20M%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Windecker S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Windecker%20S%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Yakubov SJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Yakubov%20SJ%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Grube E](https://www.ncbi.nlm.nih.gov/pubmed/?term=Grube%20E%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Makkar R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Makkar%20R%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Lee JS](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lee%20JS%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Conte J](https://www.ncbi.nlm.nih.gov/pubmed/?term=Conte%20J%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Vang E](https://www.ncbi.nlm.nih.gov/pubmed/?term=Vang%20E%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Nguyen H](https://www.ncbi.nlm.nih.gov/pubmed/?term=Nguyen%20H%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Chang Y](https://www.ncbi.nlm.nih.gov/pubmed/?term=Chang%20Y%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Mugglin AS](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mugglin%20AS%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Serruys PW](https://www.ncbi.nlm.nih.gov/pubmed/?term=Serruys%20PW%5BAuthor%5D&cauthor=true&cauthor_uid=28304219), [Kappetein AP](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kappetein%20AP%5BAuthor%5D&cauthor=true&cauthor_uid=28304219). [N Engl J Med.](https://www.ncbi.nlm.nih.gov/pubmed/28304219) 2017 Apr 6;376(14):1321-1331. doi: 10.1056/NEJMoa1700456. Epub 2017 Mar 17. |
| **Abstract**  | AbstractBACKGROUND:Although transcatheter aortic-valve replacement (TAVR) is an accepted alternative to surgery in patients with severe aortic stenosis who are at high surgical risk, less is known about comparative outcomes among patients with aortic stenosis who are at intermediate surgical risk.METHODS:We evaluated the clinical outcomes in intermediate-risk patients with severe, symptomatic aortic stenosis in a randomized trial comparing TAVR (performed with the use of a self-expanding prosthesis) with surgical aortic-valve replacement. The primary end point was a composite of death from any cause or disabling stroke at 24 months in patients undergoing attempted aortic-valve replacement. We used Bayesian analytical methods (with a margin of 0.07) to evaluate the noninferiority of TAVR as compared with surgical valve replacement.RESULTS:A total of 1746 patients underwent randomization at 87 centers. Of these patients, 1660 underwent an attempted TAVR or surgical procedure. The mean (±SD) age of the patients was 79.8±6.2 years, and all were at intermediate risk for surgery (Society of Thoracic Surgeons Predicted Risk of Mortality, 4.5±1.6%). At 24 months, the estimated incidence of the primary end point was 12.6% in the TAVR group and 14.0% in the surgery group (95% credible interval [Bayesian analysis] for difference, -5.2 to 2.3%; posterior probability of noninferiority, >0.999). Surgery was associated with higher rates of acute kidney injury, atrial fibrillation, and transfusion requirements, whereas TAVR had higher rates of residual aortic regurgitation and need for pacemaker implantation. TAVR resulted in lower mean gradients and larger aortic-valve areas than surgery. Structural valve deterioration at 24 months did not occur in either group.CONCLUSIONS:TAVR was a noninferior alternative to surgery in patients with severe aortic stenosis at intermediate surgical risk, with a different pattern of adverse events associated with each procedure.  |
| **Study**  | RCT  |
| **Link** | Link: <https://www.ncbi.nlm.nih.gov/pubmed/28304219> |
| **PDF** |  |

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| **Title**  | **Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis.**[Thourani VH](https://www.ncbi.nlm.nih.gov/pubmed/?term=Thourani%20VH%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)1, [Kodali S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kodali%20S%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2, [Makkar RR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Makkar%20RR%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)3, [Herrmann HC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Herrmann%20HC%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)4, [Williams M](https://www.ncbi.nlm.nih.gov/pubmed/?term=Williams%20M%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)5, [Babaliaros V](https://www.ncbi.nlm.nih.gov/pubmed/?term=Babaliaros%20V%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)6, [Smalling R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Smalling%20R%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)7, [Lim S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Lim%20S%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)8, [Malaisrie SC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Malaisrie%20SC%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)9, [Kapadia S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kapadia%20S%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)10, [Szeto WY](https://www.ncbi.nlm.nih.gov/pubmed/?term=Szeto%20WY%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)4, [Greason KL](https://www.ncbi.nlm.nih.gov/pubmed/?term=Greason%20KL%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)11, [Kereiakes D](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kereiakes%20D%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)12, [Ailawadi G](https://www.ncbi.nlm.nih.gov/pubmed/?term=Ailawadi%20G%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)8, [Whisenant BK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Whisenant%20BK%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)13, [Devireddy C](https://www.ncbi.nlm.nih.gov/pubmed/?term=Devireddy%20C%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)6, [Leipsic J](https://www.ncbi.nlm.nih.gov/pubmed/?term=Leipsic%20J%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)14, [Hahn RT](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hahn%20RT%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2, [Pibarot P](https://www.ncbi.nlm.nih.gov/pubmed/?term=Pibarot%20P%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)15, [Weissman NJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Weissman%20NJ%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)16, [Jaber WA](https://www.ncbi.nlm.nih.gov/pubmed/?term=Jaber%20WA%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)10, [Cohen DJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Cohen%20DJ%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)17, [Suri R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Suri%20R%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)10, [Tuzcu EM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Tuzcu%20EM%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)10, [Svensson LG](https://www.ncbi.nlm.nih.gov/pubmed/?term=Svensson%20LG%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)10, [Webb JG](https://www.ncbi.nlm.nih.gov/pubmed/?term=Webb%20JG%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)14, [Moses JW](https://www.ncbi.nlm.nih.gov/pubmed/?term=Moses%20JW%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2, [Mack MJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mack%20MJ%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)18, [Miller DC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Miller%20DC%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)19, [Smith CR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Smith%20CR%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2, [Alu MC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Alu%20MC%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2, [Parvataneni R](https://www.ncbi.nlm.nih.gov/pubmed/?term=Parvataneni%20R%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)20, [D'Agostino RB Jr](https://www.ncbi.nlm.nih.gov/pubmed/?term=D%27Agostino%20RB%20Jr%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)21, [Leon MB](https://www.ncbi.nlm.nih.gov/pubmed/?term=Leon%20MB%5BAuthor%5D&cauthor=true&cauthor_uid=27053442)2. [Lancet.](https://www.ncbi.nlm.nih.gov/pubmed/27053442) 2016 May 28;387(10034):2218-25. doi: 10.1016/S0140-6736(16)30073-3. Epub 2016 Apr 3. |
| **Abstract**  | AbstractBACKGROUND:Transcatheter aortic valve replacement (TAVR) with the SAPIEN 3 valve demonstrates good 30 day clinical outcomes in patients with severe aortic stenosis who are at intermediate risk of surgical mortality. Here we report longer-term data in intermediate-risk patients given SAPIEN 3 TAVR and compare outcomes to those of intermediate-risk patients given surgical aortic valve replacement.METHODS:In the SAPIEN 3 observational study, 1077 intermediate-risk patients at 51 sites in the USA and Canada were assigned to receive TAVR with the SAPIEN 3 valve [952 [88%] via transfemoral access) between Feb 17, 2014, and Sept 3, 2014. In this population we assessed all-cause mortality and incidence of strokes, re-intervention, and aortic valve regurgitation at 1 year after implantation. Then we compared 1 year outcomes in this population with those for intermediate-risk patients treated with surgical valve replacement in the PARTNER 2A trial between Dec 23, 2011, and Nov 6, 2013, using a prespecified propensity score analysis to account for between-trial differences in baseline characteristics. The clinical events committee and echocardiographic core laboratory methods were the same for both studies. The primary endpoint was the composite of death from any cause, all strokes, and incidence of moderate or severe aortic regurgitation. We did non-inferiority (margin 7·5%) and superiority analyses in propensity score quintiles to calculate pooled weighted proportion differences for outcomes.FINDINGS:At 1 year follow-up of the SAPIEN 3 observational study, 79 of 1077 patients who initiated the TAVR procedure had died (all-cause mortality 7·4%; 6·5% in the transfemoral access subgroup), and disabling strokes had occurred in 24 (2%), aortic valve re-intervention in six (1%), and moderate or severe paravalvular regurgitation in 13 (2%). In the propensity-score analysis we included 963 patients treated with SAPIEN 3 TAVR and 747 with surgical valve replacement. For the primary composite endpoint of mortality, strokes, and moderate or severe aortic regurgitation, TAVR was both non-inferior (pooled weighted proportion difference of -9·2%; 90% CI -12·4 to -6; p<0·0001) and superior (-9·2%, 95% CI -13·0 to -5·4; p<0·0001) to surgical valve replacement.INTERPRETATION:TAVR with SAPIEN 3 in intermediate-risk patients with severe aortic stenosis is associated with low mortality, strokes, and regurgitation at 1 year. The propensity score analysis indicates a significant superiority for our composite outcome with TAVR compared with surgery, suggesting that TAVR might be the preferred treatment alternative in intermediate-risk patients.FUNDING:None. |
| **Study**  | observational analysis study |
| **Link** | **Link:** <https://www.ncbi.nlm.nih.gov/pubmed/27053442> |
| **PDF** |  |

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| **Title**  | **Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients.** [Leon MB](https://www.ncbi.nlm.nih.gov/pubmed/?term=Leon%20MB%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Smith CR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Smith%20CR%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Mack MJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mack%20MJ%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Makkar RR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Makkar%20RR%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Svensson LG](https://www.ncbi.nlm.nih.gov/pubmed/?term=Svensson%20LG%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Kodali SK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kodali%20SK%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Thourani VH](https://www.ncbi.nlm.nih.gov/pubmed/?term=Thourani%20VH%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Tuzcu EM](https://www.ncbi.nlm.nih.gov/pubmed/?term=Tuzcu%20EM%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Miller DC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Miller%20DC%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Herrmann HC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Herrmann%20HC%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Doshi D](https://www.ncbi.nlm.nih.gov/pubmed/?term=Doshi%20D%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Cohen DJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Cohen%20DJ%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Pichard AD](https://www.ncbi.nlm.nih.gov/pubmed/?term=Pichard%20AD%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Kapadia S](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kapadia%20S%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Dewey T](https://www.ncbi.nlm.nih.gov/pubmed/?term=Dewey%20T%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Babaliaros V](https://www.ncbi.nlm.nih.gov/pubmed/?term=Babaliaros%20V%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Szeto WY](https://www.ncbi.nlm.nih.gov/pubmed/?term=Szeto%20WY%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Williams MR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Williams%20MR%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Kereiakes D](https://www.ncbi.nlm.nih.gov/pubmed/?term=Kereiakes%20D%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Zajarias A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Zajarias%20A%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Greason KL](https://www.ncbi.nlm.nih.gov/pubmed/?term=Greason%20KL%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Whisenant BK](https://www.ncbi.nlm.nih.gov/pubmed/?term=Whisenant%20BK%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Hodson RW](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hodson%20RW%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Moses JW](https://www.ncbi.nlm.nih.gov/pubmed/?term=Moses%20JW%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Trento A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Trento%20A%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Brown DL](https://www.ncbi.nlm.nih.gov/pubmed/?term=Brown%20DL%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Fearon WF](https://www.ncbi.nlm.nih.gov/pubmed/?term=Fearon%20WF%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Pibarot P](https://www.ncbi.nlm.nih.gov/pubmed/?term=Pibarot%20P%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Hahn RT](https://www.ncbi.nlm.nih.gov/pubmed/?term=Hahn%20RT%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Jaber WA](https://www.ncbi.nlm.nih.gov/pubmed/?term=Jaber%20WA%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Anderson WN](https://www.ncbi.nlm.nih.gov/pubmed/?term=Anderson%20WN%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Alu MC](https://www.ncbi.nlm.nih.gov/pubmed/?term=Alu%20MC%5BAuthor%5D&cauthor=true&cauthor_uid=27040324), [Webb JG](https://www.ncbi.nlm.nih.gov/pubmed/?term=Webb%20JG%5BAuthor%5D&cauthor=true&cauthor_uid=27040324); [PARTNER 2 Investigators](https://www.ncbi.nlm.nih.gov/pubmed/?term=PARTNER%202%20Investigators%5BCorporate%20Author%5D). [N Engl J Med.](https://www.ncbi.nlm.nih.gov/pubmed/27040324) 2016 Apr 28;374(17):1609-20. doi: 10.1056/NEJMoa1514616. Epub 2016 Apr 2. |
| **Abstract**  | AbstractBACKGROUND:Previous trials have shown that among high-risk patients with aortic stenosis, survival rates are similar with transcatheter aortic-valve replacement (TAVR) and surgical aortic-valve replacement. We evaluated the two procedures in a randomized trial involving intermediate-risk patients.METHODS:We randomly assigned 2032 intermediate-risk patients with severe aortic stenosis, at 57 centers, to undergo either TAVR or surgical replacement. The primary end point was death from any cause or disabling stroke at 2 years. The primary hypothesis was that TAVR would not be inferior to surgical replacement. Before randomization, patients were entered into one of two cohorts on the basis of clinical and imaging findings; 76.3% of the patients were included in the transfemoral-access cohort and 23.7% in the transthoracic-access cohort.RESULTS:The rate of death from any cause or disabling stroke was similar in the TAVR group and the surgery group (P=0.001 for noninferiority). At 2 years, the Kaplan-Meier event rates were 19.3% in the TAVR group and 21.1% in the surgery group (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P=0.25). In the transfemoral-access cohort, TAVR resulted in a lower rate of death or disabling stroke than surgery (hazard ratio, 0.79; 95% CI, 0.62 to 1.00; P=0.05), whereas in the transthoracic-access cohort, outcomes were similar in the two groups. TAVR resulted in larger aortic-valve areas than did surgery and also resulted in lower rates of acute kidney injury, severe bleeding, and new-onset atrial fibrillation; surgery resulted in fewer major vascular complications and less paravalvular aortic regurgitation.CONCLUSIONS:In intermediate-risk patients, TAVR was similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. (Funded by Edwards Lifesciences; PARTNER 2 ClinicalTrials.gov number, [NCT01314313](http://clinicaltrials.gov/show/NCT01314313).). |
| **Study**  | RCT  |
| **Link** | Link: <https://www.ncbi.nlm.nih.gov/pubmed/27040324> |
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| Author (Date) | Level of Evidence | Sample/Setting(# of subjects/ studies, cohort definition etc. ) | Outcome(s) studied | Key Findings | Limitations and Biases |
| Singh K, Carson K, Rashid MK, Jayasinghe R, AlQahtani A, Dick, Glover C, Labinaz M (2018) | Systematic Review/meta-analysis | 8 studies included, with a total of 4752 patients; 2375 patients undergo TAVI, and 2377 patients undergo SAVR | Primary outcomes:-30-day and 12-month mortality rate-Stroke events-Incidences of aortic incompetence-Pacemaker implantation | -Transcatheter aortic valve replacement can be performed successfully with similar mortality rate when compare to surgical aortic valve replacement-For 30-day mortality rate: 3.5% in TAVR group and 4.6% in SAVR group (not statically significant); for 12-month mortality rate: more than 11% death in both groups-There is no significant difference in the stroke events between two groups (4.1% in TAVR group and 4.8% in SAVR group)-Aortic incompetence is higher in the TAVR group (32%) than SAVR group (4.8%); pacemaker implantation rate is significantly higher in the TAVR group (11.6%) than SAVR group (5.1%) | -Do not have patient level data and not all of the studies reported transapical and transfemoral results separately for them to perform the sub-group analysis-In these studies, they combined the results of Edwards SAPIEN and Medtronic Core Valve together for analysis. By combining the two different types of valves may affect the overall mortality, and may can affect the individual complications, such as aortic incompetence and pacemaker implantation rates-No long-term follow-up is done to confirm the TAVI is as effective as SAVR-The impact of mild aortic incompetence and high pacemaker rate on the survival of TAVI patients needs to be assessed before broadening TAVI indications  |

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| Khan AR, Khan S, Riaz H, Luni FK, Simo H, Bin Abdulhak A, Bavishi C, Flaherty M. (2016) | Systemic review / Meta-analysis | 7 studies are included with total of 2173 patients with aortic stenosis at intermediate surgical risk; 1100 patients undergo TAVR and 1073 patients undergo SAVR; 4 studies are multi-center in nature and 2 studies are single center | Outcomes:-All-cause mortality-Incidence of stroke-Vascular access complications-Aortic regurgitation-Incidence of permanent pacemaker implantation-Major bleeding-Length of stay in the hospital  | -TAVR may be an acceptable alternative to SAVR since there is no difference in either short-term mortality (RR, 1.02; 95% CI: 0.63–1.63; P=0.94; I2=0%); or medium to long-term all-cause mortality (RR, 0.99; 95% CI: 0.81–1.21; P=0.91;I2=0%)-There was a suggestion of trend toward an increased risk of stroke between TAVR and SAVR groups but it does not reach statistical significance (RR,2.96; 95% CI: 0.87–10.09; P=0.08; I2=0%)-There is threefold increased incidence of aortic regurgitation in patients after TAVR (RR, 3.59; 95% CI: 2.13–7.19; P<0.00001; I2=2%); there is an increased incidence of permanent pacemaker implantation (RR, 6.53; 95% CI: 1.91–22.32; P<0.003; I2=0%); there is more vascular accesscomplications in patients with TAVR (RR, 3.84; 95% CI: 0.65–22.76; P<0.14; I2=48%) | -Not all observational studies included in the analysis have good methodological quality with New-Castle Ottawa Quality Assessment scale (NOS) score >7; the RCTs lack of blinding, which mat affect outcomes between two groups-Differences in the study population and unmeasured confounders may affect results and comparisons of these two groups -The analysis of rare events is associated with its own shortcomings as only few events can change the overall affect estimate  |

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| Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, Adams DH, Deeb GM, Maini B, Gada H, Chetcuti S, Gleason T, Grube E, Makkar R, Lee JS, Conte J, Vang E, Nguyen H, Chang Y, Mugglin AS, Serruys PW, Kappetein AP; SURTAVI Investigators. (2017) | RCT  | -Intervention group (TAVR): 864 patients-Control group (SAVR): 796 patients |  Primary outcomes:-Mortality rate-Risk of strokeSecondary outcomes:-Aortic regurgitation-Pacemaker implantation-Transfusion requirement-Afib-Kidney injury |  -TAVR is a statistically noninferior alternative to surgery with respect to death from any cause or disabling stroke-At 24 months, the rate of death from any cause is 11.4% in the TAVR group and 11.6% in the surgery group(95% credible interval for difference, −3.8 to 3.3%); the rate of disabling stroke was also similar in the two groups-Kidney injury, afib, major vascular complications, and permanent pacemaker implantation are more common in TAVR group; and transfusions are more common in the SAVR group | -For the participants, there are more patients in TAVR groups, because a relatively high frequency of unplanned withdrawals occurred in the surgery group-Cannot identify differences inbaseline demographic characteristics among thepatients who undergo the assigned surgeryand those who did not-No long-termfollow-up, a 24-month end-point analysis cannot provides complete information aboutthe life cycle of TAVR as compared with surgicalbioprostheses |

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| Author (Date) | Level of Evidence | Sample/Setting(# of subjects/ studies, cohort definition etc. ) | Outcome(s) studied | Key Findings | Limitations and Biases |
| Thourani VH, Kodali S, Makkar, Herrmann HC, Williams M, Babaliaros V, Kapadia, Whisenant BK, LG, Webb JG, Moses JW, Mack MJ, Miller DC, Smith CR, D'Agostino RB Jr, Leon MB. (2016) | Observational study  | 963 intermediate-risk patients at 51 sites in the USA and Canada get TVAR; 747 patients with surgical valve replacement  | Primary outcomes:-All cause mortality-Strokes-Incidence of moderate or severe aortic regurgitation Secondary outcomes:-Length of hospital stay  | -TAVR in intermediate-risk patients with severe aortic stenosis is associated with low mortality, strokes, and regurgitation at 1 year-TAVR is superior to surgery for the composite endpoint (weighted difference of proportions –9·2%, 95% CI –13·0 to –5·4; p<0·0001), and for the individual outcomes of death (–5·2%, –8·0 to –2·4; p= 0·0003) andstroke (–3·5%, –5·9 to –1·1; p=0·0038)-The median postoperative length of hospital stay was shorter in the TAVR cohort than in the surgical cohort (4 days [range 1·0–122·0] vs 9 days [1·0–77·0]) and a higher percentage of patients went home after the procedure (912 [85%] vs 436 [46%]) | -Patient baseline characteristics are different from two groups. Patients in TAVR group are more frequently male and have more frequent oxygen-dependent COPD; and patients in the SAVR group have higher median STS scores, lower mean gradients and left ventricular fractions, and have more frequent moderate or severe mitral regurgitation, these differences in the baseline can affect analysis -It is not a randomized trial and relevant confounders may not be represented in the risk-adjustment process, which can influence the results |

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| Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D, Cohen DJ, Pichard AD, Moses JW, Trento A, Brown DL, Fearon WF, Pibarot P, Hahn RT, Jaber WA, Anderson WN, Alu MC, Webb JG; PARTNER 2 Investigators (2016) | RCT  | 2032 patients in total; 1011 patients assigned to TAVR, and 1021 to surgery  | Primary outcomes:-All causes of mortality rate-Disabling strokesSecondary outcomes:-Vascular complications -Life-threatening bleeding-Acute kidney injury-New onset of Afib-Repeat hospitalizations -The needed for permanent pacemakers-Endocarditis | -There is no significant difference in the primary outcomes of death from any cause or disabling stroke at 2 years between the TAVR group and the surgery group in either the intention-to-treat analysis (hazard ratio in the TAVR group, 0.89; 95% confidence interval [CI], 0.73 to 1.09; P = 0.25) or the as-treated analysis (hazard ratio, 0.87; 95% CI, 0.71 to 1.07; P = 0.18)- At 30 days, major vascular complications are more frequent in the TAVR group than in the surgery group (7.9% vs. 5.0%, P = 0.008)-Secondary outcomes are less frequent in the TAVR group, life-threatening bleeding (10.4% vs. 43.4%, P<0.001), acute kidney injury (1.3% vs. 3.1%, P = 0.006), and new-onset Afib (9.1% vs. 26.4%, P<0.001)-Two groups are similar in repeat hospitalizations, need for new pacemaker, and endocarditis  | -There is high frequency of unexpected withdrawals inpatients who are scheduled to undergo surgery-Further technological advances may favorably influence the outcomeswith TAVR in the future, and the SAPIEN XT valve that was used in this trial has already been replaced by the SAPIEN 3 valve-In this trial, multislice CT isnot used consistently to assess aortic annulusdimensions for appropriate valve sizing-Long-term assessmentsof the durability of bioprosthetictranscatheter valves are not assessed in this study  |

**Conclusion(s):**

Article1 (systemic review) concludes that in patients with severe aortic stenosis of intermediate surgical risk, transcatheter aortic valve replacement can be performed successfully with similar mortality rate when compare to surgical aortic valve replacement. There are no significant differences between two groups in 30-day morality rate, 12-month mortality rate, and stroke events. In addition, aortic incompetence and pacemaker implantation are higher in the TAVR group.

Article 2 (systemic review), TAVR may be an acceptable alternative to SAVR since there is no difference in either short-term or medium to long-term all-cause mortality. There are increased incidence of aortic regurgitation and permanent pacemaker in TAVR group, and there is more major bleeding in the SAVR group.

Article 3 (RCT) concludes that TAVR is a statistically noninferior alternative to surgery with respect to death from any cause or disabling stroke. Kidney injury, Afib, major vascular complications, and permanent pacemaker implantation are more common in TAVR group; and transfusions are more common in the SAVR group.

Article 4 (observational study) concludes that TAVR in intermediate-risk patients with severe aortic stenosis is associated with low mortality, strokes, and regurgitation at 1 year.

Article 5 (RCT) concludes that in intermediate-risk patients, TAVR is similar to surgical aortic-valve replacement with respect to the primary end point of death or disabling stroke. Major vascular complications are more frequent in the TAVR group, but there is less life-threatening bleeding, Afib, and kidney injury in the TAVR group.

Overall, all 5 articles have the same conclusions that TAVR is an acceptable alternative to surgical repair based on the similar mortality rate and incidence of stroke. Only article 4 results show a lower morality rate, strokes and aortic regurgitation in the TAVR group. Article 1, 2, and 3 show TAVR groups have higher need for pacemaker and incidence of aortic regurgitation. Article 3 and article 5 show TAVR group have more vascular complications. And article 2 and article 3 show SAVR groups have higher major bleeding rate and more patients need transfusion.

**Clinical Bottom Line:**

Article 1 is a systemic review, which includes 8 studies, and it is based on a larger sample size with 4752 participants. They measure the 30-day mortality rate and also 12-month morality rate. Article 2 is also a systemic review, it has 2173 patients in total, and it also measures the mortality rate and incidence of stroke. Article 4 is an observation study, it based on 1710 patients and patients are from 51 different sites in the USA and Canada. Article 3 and Article 5 are RCTs exam the efficacy and safety of TAVR. The intervention to TAVR or SAVR, and measure the outcomes and adverse events. They are based on relatively large sample sizes; the experimental study design is a good standard for evaluating efficacy in clinical research and constitute evidence for medical treatments.

Aortic stenosis is the most common valvular heart disease in the developed world. And as we learned, the American College of Cardiology recommends aortic valve replacement to treat severe aortic stenosis. However, some patients are not referred for surgery. Typically, there are some concerns about prohibitive surgical risk, such as frailty, comorbidities, age, and severe left ventricular dysfunction. Transcatheter aortic valve replacement is used as an alternative and less invasive treatment for aortic stenosis.

All five articles reach the conclusion that TAVR is a noninferior alternative to SAVR due to similar mortality rate and similar stroke events. However, 3 articles also show the patients undergo TAVR has higher of complications of aortic incompetence and need for permanent pacemaker implantation; 2 articles show the TAVR group also have higher rate of vascular complications. In conclusion, according to all five articles, when compare to SAVR, TAVR is an effective alternative for patients with severe aortic stenosis at intermediate surgical risk. For my patient, considering complications of TAVR, such as need for pacemaker, risk of aortic incompetence and vascular complications; and patient’s age and less comorbidities, I will still recommend SAVR. Furthermore, more studies should be done to further investigate complications of TAVR in management of severe aortic stenosis.