

**Heart valve replacement:
update searches and screening
for
Universitätsklinikum Schleswig-Holstein/Campus Kiel**



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1. PROJECT OBJECTIVES

A key aim of the research project “Making SDM a reality” is to inform patients as part of shared decision making (SDM).

Kleijnen Systematic Reviews (KSR) Ltd has prepared an evidence report with a synthesis of the evidence of heart valve replacement.

2. METHODS

LITERATURE SEARCHES

Literature searches were conducted to identify systematic reviews and evidence-based guidelines about heart valve replacement to update the 2019 evidence report.

The search strategies were developed specifically for each database and the keywords adapted according to the configuration of each database. Searches were limited by date range for systematic reviews and guidelines to 2018-2021. Searches were not limited by language or publication status.

Systematic reviews and guidelines

The following systematic review and health technology assessment specific databases were searched:

- Cochrane Database of Systematic Reviews (CDSR) (Wiley): Issue 10 of 12, October 2021
- KSR Evidence (Internet) (<https://ksrevidence.com/>): 2019-6.10.21
- Epistemonikos (Internet) (<https://www.epistemonikos.org/>): 2019-6.10.21
- International HTA Database (INAHTA) (<https://database.inahta.org/>): 2019-6.10.21

The following guidelines resources were searched:

- Guidelines International Network (GIN) (Internet) (<https://www.g-i-n.net/home>): up to 2019-6.10.21
- NICE Evidence (Internet) (www.evidence.nhs.uk/): 2019-6.10.21
- NICE Guidance (Internet) (<https://www.nice.org.uk/guidance>): 2019-6.10.21
- ECRI Guidelines Trust (Internet) (<https://guidelines.ecri.org/>): 2019-6.10.21
- Trip Database (<https://www.tripdatabase.com/>): 2019-6.10.21
- Canadian Agency for Drugs and Technologies in Health (CADTH) (www.cadth.ca): 2019-6.10.21

Full details of all search strategies are presented in Appendix 1.

Handling of citations

References identified from the searches were downloaded into EndNote bibliographic management software for further assessment and handling.

Supplementary searches

The bibliographies of included studies and review articles were also checked for additional relevant articles.

PRIORITISATION

During formal screening of titles and abstracts, studies were subject to a prioritisation process whereby the recency e.g., to most up-to-date clinical practice guidelines (CPG), methodological quality e.g., Cochrane systematic review (CSR), quality of the analyses per outcome (e.g., ratio of RCTs to observational studies), the number of included RCTs, the breadth of the timepoints reported etc. were considered to further prioritise which studies would be used to inform analyses. Studies were categorised into the following three categories: '1' = German, American, European or similar CPG; '2' = CSR or similar quality SR; '3' = potentially lower/other quality SR.

3. RESULTS

The original KSR searches were conducted on 14 and 15 January 2019; and of the 2,318 references screened, 16 studies were deemed eligible. In the current update, a total of 3,191 records were retrieved from the electronic literature searches (Appendix 1). After the removal of duplicate records 2,306 titles and abstracts were screened by two reviewers. One hundred and forty-five records were found to be potentially eligible and were longlisted after a consensus. Of those, five were short-listed and included in the analyses (Table 1).¹⁻⁵ See also Table 2 for an overview of primary studies included in the identified SRs.

UPDATE – Concluding Assessment by SHARE-TO-CARE Evidence Team (06/04/22)

Based on the update searches conducted by KSR Ltd in November 2021, we want to highlight the following aspects: Two recently published CPGs (Beyersdorf et al., 2021; Otto et al., 2021) emphasise the importance for shared decision making concerning the choice of a prosthetic valve. They give different recommendations regarding age thresholds for mechanical versus bioprosthetic valves and further distinguish between aortic or mitral replacement. Against this background, it seems reasonable to stick to the statements made in the current version of the decision aid while highlighting their debatable character and the need for a shared decision making process between physicians and patients. The systematic review and meta-analysis by Diaz et al. 2019 was already factored in for the evidence body of the 2019 evidence report.

Conclusion regarding the evidence report: No evidence update required. The present evidence report (March, 2019) remains valid until further notice.

Table 1 Evidence sources

Study/year	Evidence type	Primary studies	Number of studies	Intervention(s)	Comparator(s)	Outcome(s)	Date searched	Conclusions
Vahanian 2021 ¹	CPG	CPG,SR,RCT	18*	Bioprosthetic valve	Mechanical valve	Multiple	N/M	Please refer to recommendations on page 765. “A mechanical prosthesis should be considered in patients aged <60 years for prostheses in the aortic position and aged <65 years for prostheses in the mitral position.” “A bioprosthesis should be considered in patients aged >65 years for a prosthesis in the aortic position or aged >70 years in a mitral position.”
Otto 2021 ²	CPG	SR,OS	8*	Bioprosthetic valve	Mechanical valve	Multiple	March 1, 2020	“Shared decision-making about the choice of prosthetic valve type is influenced by several factors, including patient age, values, and preferences; expected bioprosthetic valve durability, avoidance of patient–prosthesis mismatch, and the potential need for and timing of reintervention; and the risks associated with long-term VKA anticoagulation after a mechanical valve replacement.”

Study/year	Evidence type	Primary studies	Number of studies	Intervention(s)	Comparator(s)	Outcome(s)	Date searched	Conclusions
Diaz 2019 ³	SR	RCT,OS	5*	Bioprosthetic valve	Mechanical valve	Long term survival, reoperation rate, bleeding, stroke	March 2018	“Compared with biological aortic valves, mechanical valves are associated with a long-term survival benefit for patients between 50 and 70 years”
Takagi 2019 ⁴	SR	RCT,OS	28*	Bioprosthetic valve	Mechanical valve	All cause-mortality, aortic regurgitation, new permanent pacemaker implantation	September 2018	SAPIEN 3 was the best effective for a reduction in early postprocedural all-cause mortality and the second best effective for decreased ≥ moderate aortic regurgitation and permanent pacemaker implantation
Macherey 2021 ⁵	SR	RCT,OS	18*	Valve-in-valve transcatheter aortic valve replacement	Surgical aortic valve replacement	Stroke incidence, all cause-mortality	July 1, 2020	“This review is the first one comparing the risk for stroke and mortality rates in valve-in-valve transcatheter aortic valve replacement procedures with native transcatheter aortic valve replacement approach and contributes substantial data for the clinical routine.”
* = pertains to the number studies published after 2015. CPG = clinical practice guideline; N/M = not mentioned; OS = observational study; RCT = randomised controlled trial; SR = systematic review.								

Table 2 Overview of primary studies included in the identified SRs/CPGs

Study/year	Primary study(ies)	Reference (first author & journal)
Vahanian 2021 ¹	CPG,SR,RCT*	1. Tam DY, Vo TX, Wijeysondera HC, Dvir D, Friedrich JO, Fremes SE. Transcatheter valve-in-valve versus redo surgical aortic valve replacement for the treatment of degenerated bioprosthetic aortic valve: a systematic review and meta-analysis. <i>Catheter Cardiovasc Interv</i> 2018;92:14041411. 2. Deharo P, Bisson A, Herbert J, Lacour T, Etienne CS, Porto A, Theron A, Collart F, Bourguignon T, Cuisset T, Fauchier L. Transcatheter valve-in-valve aortic valve replacement as an alternative to surgical re-replacement. <i>J Am Coll Cardiol</i> 2020;76:489499 3. Gozdek M, Raffa GM, Suwalski P, Kolodziejczak M, Anisimowicz L, Kubica J, Navarese EP, Kowalewski M, SIRIO-TAVI group. Comparative performance of transcatheter aortic valve-in-valve implantation versus conventional surgical redo aortic valve replacement in patients with degenerated aortic valve bioprostheses: systematic review and meta-analysis. <i>Eur J Cardiothorac Surg</i> 2018;53:495504 4. Capodanno D, Petronio AS, Prendergast B, Eltchaninoff H, Vahanian A, Modine T, Lancellotti P, Sondergaard L, Ludman PF, Tamburino C, Piazza N, Hancock J, Mehili J, Byrne RA, Baumbach A, Kappetein AP, Windecker S, Bax J, Haude M. Standardized definitions of structural deterioration and valve failure in assessing long-term durability of transcatheter and surgical aortic bioprosthetic valves: a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (EAPCI) endorsed by the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). <i>Eur Heart J</i> 2017;38:33823390 5. Shim CY, Seo J, Kim YJ, Lee SH, De Caterina R, Lee S, Hong GR; Explore the Efficacy and Safety of Edoxaban in Patients after Heart Valve Repair or Bioprosthetic Valve Replacement (ENAVLE) study group. Efficacy and safety of edoxaban in patients early after surgical bioprosthetic valve implantation or valve repair: a randomized clinical trial. <i>J Thorac Cardiovasc Surg</i> 2021;doi: 10.1016/j.jtcvs.2021.01.127 6. Dvir D, and VIVID Investigators. Standardized definition of structural valve degeneration for surgical and transcatheter bioprosthetic aortic valves. <i>Circulation</i> 2018;137:388399 7. Chakravarty T, Sondergaard L, Friedman J, De Backer O, Berman D, Kofoed KF, Jilaihawi H, Shiota T, Abramowitz Y, Jorgensen TH, Rami T, Israr S, Fontana G, de Knecht M, Fuchs A, Lyden P, Trento A, Bhatt DL, Leon MB, Makkar RR, Resolve, SAVORY Investigators. Subclinical leaflet thrombosis in surgical and transcatheter bioprosthetic aortic valves: an observational study. <i>Lancet</i> 2017;389:23832392. 8. De Backer O, Dangas GD, Jilaihawi H, Leipsic JA, Terkelsen CJ, Makkar R, Kini AS, Veien KT, Abdel-Wahab M, Kim WK, Balan P, Van Mieghem N, Mathiassen ON, Jeger RV, Arnold M, Mehran R, Guimaraes AHC, Norgaard BL, Kofoed KF, Blanke P, Windecker S, Sondergaard L, GALILEO-4D Investigators. Reduced leaflet motion after transcatheter aortic-valve replacement. <i>N Engl J Med</i> 2020;382:130139

Study/year	Primary study(ies)	Reference (first author & journal)
		9. Barbanti M, Costa G, Zappulla P, Todaro D, Picci A, Rapisarda G, Di Simone E, Sicuso R, Buccheri S, Gulino S, Pilato G, La Spina K, D'Arrigo P, Valvo R, Indelicato A, Giannazzo D, Imme S, Tamburino C, Patane M, Sgroi C, Giuffrida A, Trovato D, Monte IP, Deste W, Capranzano P, Capodanno D, Tamburino C. Incidence of long-term structural valve dysfunction and bioprosthetic valve failure after transcatheter aortic valve replacement. <i>J Am Heart Assoc</i> 2018;7:e008440 10. Head SJ, Celik M, Kappetein AP. Mechanical versus bioprosthetic aortic valve replacement. <i>Eur Heart J</i> 2017;38:21832191. 11. Malik AH, Yandrapalli S, Aronow WS, Panza JA, Cooper HA. Oral anticoagulants in atrial fibrillation with valvular heart disease and bioprosthetic heart valves. <i>Heart</i> 2019;105:14321436. 12. Duan L, Doctor JN, Adams JL, Romley JA, Nguyen LA, An J, Lee MS. Comparison of direct oral anticoagulants versus warfarin in patients with atrial fibrillation and bioprosthetic heart valves. <i>Am J Cardiol</i> 2021;146:2228. 13. Pasciolla S, Zizza LF, Le T, Wright K. Comparison of the efficacy and safety of direct oral anticoagulants and warfarin after bioprosthetic valve replacements. <i>Clin Drug Investig</i> 2020;40:839845. 14. Russo V, Carbone A, Attena E, Rago A, Mazzone C, Proietti R, Parisi V, Scotti A, Nigro G, Golino P, D'Onofrio A. Clinical benefit of direct oral anticoagulants versus vitamin K antagonists in patients with atrial fibrillation and bioprosthetic heart valves. <i>Clin Ther</i> 2019;41:25492557. 15. Siontis KC, Yao X, Gersh BJ, Noseworthy PA. Direct oral anticoagulants in patients with atrial fibrillation and valvular heart disease other than significant mitral stenosis and mechanical valves: a meta-analysis. <i>Circulation</i> 2017;135:714716. 16. Diaz R, Hernandez-Vaquero D, Alvarez-Cabo R, Avanzas P, Silva J, Moris C, Pascual I. Long-term outcomes of mechanical versus biological aortic valve prosthesis: systematic review and meta-analysis. <i>J Thorac Cardiovasc Surg</i> 2019;158:706714.e18. 17. Goldstone AB, Chiu P, Baiocchi M, Lingala B, Patrick WL, Fischbein MP, Woo YJ. Mechanical or biologic prostheses for aortic-valve and mitral-valve replacement. <i>N Engl J Med</i> 2017;377:18471857 18. Mazine A, Rocha RV, El-Hamamsy I, Ouzounian M, Yanagawa B, Bhatt DL, Verma S, Friedrich JO. Ross procedure vs mechanical aortic valve replacement in adults: a systematic review and meta-analysis. <i>JAMA Cardiol</i> 2018;3:978987.
Otto 2021 ²	SR,OS*	1. Goldstone AB, Chiu P, Baiocchi M, et al. Mechanical or biologic prostheses for aortic-valve and mitral-valve replacement. <i>N Engl J Med</i>. 2017;377:1847–57. 2. Glaser N, Jackson V, Holzmann MJ, et al. Aortic valve replacement with mechanical vs. biological prostheses in patients aged 50–69 years. <i>Eur Heart J</i>. 2016;37:2658–67.

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		- Buratto E, Shi WY, Wynne R, et al. Improved survival after the Ross procedure compared with mechanical aortic valve replacement. <i>J Am Coll Cardiol.</i> 2018;71:1337–44. - Martin E, Mohammadi S, Jacques F, et al. Clinical outcomes following the Ross procedure in adults: a 25-year longitudinal study. <i>J Am Coll Cardiol.</i> 2017;70: 1890–9. - Buratto E, Shi WY, Wynne R, et al. Improved survival after the Ross procedure compared with mechanical aortic valve replacement. <i>J Am Coll Cardiol.</i> 2018;71:1337–44. - Tuzcu EM, Kapadia SR, Vemulapalli S, et al. Transcatheter aortic valve replacement of failed surgically implanted bioprostheses: the STS/ACC registry. <i>J Am Coll Cardiol.</i> 2018;72:370–82. - Coylewright M, Forrest JK, McCabe JM, et al. TAVR in low-risk patients: FDA approval, the new NCD, and shared decision-making. <i>J Am Coll Cardiol.</i> 2020;75: 1208–11. - Mazine A, El-Hamamsy I, Verma S, et al. Ross procedure in adults for cardiologists and cardiac surgeons: JACC state-of-the-art review. <i>J Am Coll Cardiol.</i> 2018;72:2761–77.
Diaz 2019 ³	RCT,OS*	- Glaser N, Jackson V, Holzmann MJ, Franco-Cereceda A, Sartipy U. Aortic valve replacement with mechanical vs biological prostheses in patients aged 50–69 years. <i>Eur Heart J.</i> 2016;37:2658–67. - Sakamoto Y, Yoshitake M, Matsumura Y, Naruse H, Bando K, Hashimoto K. Choice of aortic valve prosthesis in a rapidly aging and long-living society. <i>Ann Thorac Cardiovasc Surg.</i> 2016;22:333–9.
Takagi 2019 ⁴	RCT,OS*	- Akodad M, Lattuca B, Agullo A, Macia JC, Gandet T, Marin G, Lemmi A, Vernhet H, Schmutz L, Nagot N, Albat B, Cayla G, Leclercq F (2018) Prognostic impact of calcium score after transcatheter aortic valve implantation performed with new generation prosthesis. <i>Am J Cardiol</i> 121:1225–1230 - Asch FM, Vannan MA, Singh S, Khandheria B, Little SH, Allocco DJ, Meredith IT, Feldman TE, Reardon MJ, Weissman NJ (2018) Hemodynamic and echocardiographic comparison of the lotus and corevalve transcatheter aortic valves in patients with high and extreme surgical risk: an analysis from the reprise iii randomized controlled trial. <i>Circulation</i> 137:2557–2567 - Eitan A, Witt J, Stripling J, Haselbach T, Rieß FC, Schofer J (2018) Performance of the Evolut-R 34 mm versus Sapien-3 29 mm in Transcatheter aortic valve replacement patients with larger annuli: Early outcome results of Evolut-R 34 mm as compared with Sapien-3 29 mm in patients with Annuli ≥26 mm. <i>Catheter Cardiovasc Interv</i> 5:5. https://doi.org/10.1002/ccd.27588 - Enríquez-Rodríguez E, Amat-Santos IJ, Jiménez-Quevedo P, Martín- Morquecho I, Tirado-Conte G, Pérez-Vizcayno MJ, Gómez de Diego JJ, Arnold R, Aldazábal A, Rojas P, de Agustín A, Del Trigo M, Gutiérrez H, San Román JA, Macaya C, Nombela- Franco L (2018) Comparison of the hemodynamic performance of the balloon-expandable

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		SAPIEN 3 versus self-expandable evolut R transcatheter valve: a case-matched study. <i>Rev Esp Cardiol (Engl Ed)</i> 71:735–742 5. Giannini C, De Carlo M, Tamburino C, Ettori F, Latib AM, Bedogni F, Bruschi G, Presbitero P, Poli A, Fabbiochi F, Violini R, Trani C, Giudice P, Barbanti M, Adamo M, Colombo P, Benincasa S, Agnifili M, Petronio AS (2017) Transcatheter aortic valve implantation with the new repositionable self-expandable Evolut R versus CoreValve system: a case-matched comparison. <i>Int J Cardiol</i> 243:126–131 6. Gomes B, Geis NA, Chorianopoulos E, Meder B, Leuschner F, Katus HA, Bekerredjian R (2017) Improvements of procedural results with a new-generation self-expanding transfemoral aortic valve prosthesis in comparison to the old-generation device. <i>J Interv Cardiol</i> 30:72–78 7. Gonska B, Seeger J, Baarts J, Rodewald C, Scharnbeck D, Rottbauer W, Wöhrle J (2017) The balloon-expandable Edwards Sapien 3 valve is superior to the self-expanding Medtronic CoreValve in patients with severe aortic stenosis undergoing transfemoral aortic valve implantation. <i>J Cardiol</i> 69:877–882 8. Husser O, Kim WK, Pellegrini C, Holzamer A, Walther T, Mayr PN, Joner M, Kasel AM, Trenkwalder T, Michel J, Rheude T, Kastrati A, Schunkert H, Burgdorf C, Hilker M, Möllmann H, Hengstenberg C (2017) Multicenter comparison of novel self-expanding versus balloon-expandable transcatheter heart valves. <i>JACC Cardiovasc Interv</i> 10:2078–2087 9. Jarr KU, Leuschner F, Meder B, Katus HA, Bekerredjian R, Chorianopoulos E (2017) Initial single-center experience with the fully repositionable transfemoral lotus aortic valve system. <i>J Invasive Cardiol</i> 29:30–35 10. Jatene T, Castro-Filho A, Meneguz-Moreno RA, Siqueira DA, Abizaid AAC, Ramos AIO, Arrais M, Le Bihan DCS, Barretto RBM, Moreira AC, Sousa AGMR, Eduardo Sousa J (2017) Prospective comparison between three TAVR devices: ACU RAT E neo vs. CoreValve vs. SAPIEN XT. A single heart team experience in patients with severe aortic stenosis. <i>Catheter Cardiovasc Interv</i> 90:139–146 11. Kalogeras K, Kabir T, Mittal T, Mirsadraee S, Skondras E, Rahman Haley S, Zuhair M, Vavuranakis M, Tousoulis D, Dalby M, Panoulas V (2018) Real-world comparison of the new 34 mm self-expandable transcatheter aortic prosthesis Evolut R to its 31 mm core valve predecessor. <i>Catheter Cardiovasc Interv</i> 5:5. https://doi.org/10.1002/ccd.27862 12. Landes U, Bental T, Barsheshet A, Assali A, Vaknin Assa H, Levi A, Orvin K, Kornowski R (2017) Comparative matched outcome of Evolut-R vs CoreValve transcatheter aortic valve implantation. <i>J Invasive Cardiol</i> 29:69–74 13. Mauri V, Kim WK, Abumayyaleh M, Walther T, Moellmann H, Schaefer U, Conradi L, Hengstenberg C, Hilker M, Wahlers T, Baldus S, Rudolph V, Madershahian N, Rudolph TK (2017) Short-term outcome and hemodynamic

Study/year	Primary study(ies)	Reference (first author & journal)
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Study/year	Primary study(ies)	Reference (first author & journal)
		replacement for degenerative bioprosthetic surgical valves: insights from the VIVID registry. <i>Eur Heart J</i>. 2018;39:687–695. 3. Scholtz S, Piper C, Horstkotte D Valve-in-valve transcatheter aortic valve implantation with CoreValve/Evolut R((c)) for degenerated small versus bigger bioprostheses. <i>J Interv Cardiol</i>. 2018;31:384–390. 4. Huded CP, Tuzcu EM, Krishnaswamy A, Mick SL, Kleiman NS, Svensson LG, Carroll J, Thourani VH, Kirtane AJ, Manandhar P, et al. Association between transcatheter aortic valve replacement and early postprocedural stroke. <i>JAMA</i>. 2019;321:2306–2315. 5. Tchetché D, Chevalier B, Holzhey D, et al. TAVR for failed surgical aortic bioprostheses using a self-expanding device: 1-year results from the prospective VIVA postmarket study. <i>JACC Cardiovasc Interv</i>. 2019;12:923–932. 6. Stankowski T, Aboul-Hassan SS, Seifi-Zinab F, Herwig V, Kubikova M, Harnath A, Fritzsche D, Perek B, et al. Severe structural deterioration of small aortic bioprostheses treated with valve-in- valve transcatheter aortic valve implantation. <i>J Card Surg</i>. 2019;34:7–13. 8. Ejiofor JI, Yammine M, Harloff MT, McGurk S, Muehlschlegel JD, Shekar PS, Cohn LH, Shah P, Kaneko T, et al. Reoperative surgical aortic valve replacement versus transcatheter valve-in- valve replacement for degenerated bioprosthetic aortic valves. <i>Ann Thorac Surg</i>. 2016;102:1452–1458. 10. Santarpino G, Pietsch LE, Jessl J, et al. Transcatheter aortic valve-in- valve implantation and sutureless aortic valve replacement: two strategies for one goal in redo patients. <i>Minerva Cardioangiol</i>. 2016;64:581–585. 11. Silaschi M, Wendler O, Seiffert M, Castro L, Lubos E, Schirmer J, Blankenberg S, Reichenspurner H, Schäfer U, Treede H, et al. Transcatheter valve-in- valve implantation versus redo surgical aortic valve replacement in patients with failed aortic bioprostheses. <i>Interact Cardiovasc Thorac Surg</i>. 2017;24:63–70. 12. Spaziano M, Mylotte D, Thériault-Lauzier P, De Backer O, Søndergaard L, Bosmans J, Debry N, Modine T, Barbanti M, Tamburino C, et al. Transcatheter aortic valve implantation versus redo surgery for failing surgical aortic bioprostheses: a multicentre propensity score analysis. <i>EuroIntervention</i>. 2017;13:1149–1156. 13. Grubitzsch H, Zobel S, Christ T, Holinski S, Stangl K, Treskatsch S, Falk V, Laule M, et al. Redo procedures for degenerated stentless aortic xenografts and the role of valve-in- valve transcatheter techniques. <i>Eur J Cardiothorac Surg</i>. 2017;51:653–659. 14. Stundl A, Rademacher M-C, Descoups C, Weber M, Sedaghat A, Grube M, Hammerstingl C, Mellert F, Vasa-Nicotera M, Welz A, et al. Balloon post-dilation and valve-in- valve implantation for the reduction of paravalvular leakage with use of the self-expanding CoreValve prosthesis. <i>EuroIntervention</i>. 2016;11:1140–1147.

Study/year	Primary study(ies)	Reference (first author & journal)
		15. Huczek Z, Grodecki K, Scisło P, Wilczek K, Jagielak D, Fil W, Kubler P, Olszówka P, Dąbrowski M, Frank M, et al. Transcatheter aortic valve-in- valve implantation in failed stentless bioprostheses. <i>J Interv Cardiol.</i> 2018;31:861–869. 16. Tuzcu EM, Kapadia SR, Vemulapalli S, Carroll JD, Holmes DR, Mack MJ, Thourani VH, Grover FL, Brennan JM, Suri RM, et al. Transcatheter aortic valve replacement of failed surgically implanted bioprostheses: the STS/ACC registry. <i>J Am Coll Cardiol.</i> 2018;72:370–382. 17. Akodad M, Meilhac A, Lefèvre T, Cayla G, Lattuca B, Autissier C, Duflos C, Gandet T, Macia J-C, Delseny D, et al. Hemodynamic performances and clinical outcomes in patients undergoing valve-in- valve versus native transcatheter aortic valve implantation. <i>Am J Cardiol.</i> 2019;124:90–97. 18. Deharo P, Bisson A, Herbert J, Lacour T, Saint Etienne C, Jaussaud N, Theron A, Collart F, Bourguignon T, Cuisset T, et al. Valve-in- valve transcatheter aortic valve implantation after failed surgically implanted aortic bioprosthesis versus native transcatheter aortic valve implantation for aortic stenosis: data from a nationwide analysis. <i>Arch Cardiovasc Dis.</i> 2020; S1875-2136(20)30108-X.
* = only studies published after 2015 were extracted. CPG = clinical practice guideline; OS = observational study; RCT = randomised controlled trial; SR = systematic review.		

REFERENCES

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- [2] Otto CM, Nishimura RA, Bonow R, Carabello BA, Erwin JP, Gentile F, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol* 2021;77(4):e25-e197.
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- [5] Macherey S, Meertens M, Mauri V, Frerker C, Adam M, Baldus S, et al. Meta-analysis of stroke and mortality rates in patients undergoing valve-in-valve transcatheter aortic valve replacement. *J Am Heart Assoc* 2021;10(6):e019512.

APPENDIX 1: SEARCH STRATEGIES

Shared Decision Making: heart valve replacement update (KSR)

Table 3. Systematic reviews and guideline search results

Database	Dates	Results
CDSR	2019-Issue 10 of 12, October 2021	10
KSR Evidence	2019-6.10.21	1376
Epistemonikos	2019-6.10.21	1149
INAHTA	2019-6.10.21	46
NICE Evidence	2019-6.10.21	361
NICE Guidance	2019-6.10.21	5
GIN	2019-6.10.21	0
ECRI	2019-6.10.21	0
Trip	2019-6.10.21	240
CADTH	2019-6.10.21	4
Total		3191
Total after de-duplication		2306
Total after de-duplication with original ENL		2300

Search strategies

Cochrane Database of Systematic Reviews (CDSR) (Wiley): 2019-Issue 10 of 12, October 2021

Date searched: 6.10.21

Records found: 11

- #1 MeSH descriptor: [Heart Valve Prosthesis] this term only 545
- #2 MeSH descriptor: [Heart Valve Prosthesis Implantation] explode all trees 822
- #3 (artificial* near/3 valv*):ti,ab,kw 94
- #4 ((percutaneous* or sternotom* or thoracotom*) near/3 (implant* or replacement* or valv* or prosth*)):ti,ab,kw 507
- #5 ((heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or av) near/3 (prosth* or valv* or heterograft* or hetero-graft* or implant*)):ti,ab,kw 8965
- #6 (lung near/2 arter* near/3 (prosth* or valv*)):ti,ab,kw 5
- #7 ("Transcatheter Aortic Valve" adj2 Replac*) or TAVR):ti,ab 499
- #8 #1 or #2 or #3 or #4 or #5 or #6 or #7 9200
- #9 ((Mechanical* or metallic* or manufactur* or synthetic*) near/3 valv*):ti,ab,kw 16
- #10 MHV:ti,ab 32
- #11 ((stent* near/2 framed) near/3 (replac* or valv* or implant* or prosth*)):ti,ab,kw 0
- #12 ("caged ball" or "ball and cage" or "tilting disk" or "bi-leaflet" or "tri-leaflet or bileaflet or trileaflet"):ti,ab,kw 27
- #13 ("starr-edward*" or "smeloff-cutter" or Hufnagel or bjork-shiley or Bjoerk-shiley or CarboMedics or cryo valve* or cryo-valve*):ti,ab,kw 61
- #14 (ATS near/3 (valv* or "open pivot" or prosthes*)):ti,ab,kw 5
- #15 ((SJM or "St jude Medical") near/3 (valv* or mechanical* or prosth* or regent or bileaflet* or bi-leaflet*)):ti,ab,kw 63

#16 ("3f Enable" or "3f-Enable" or "Aortech Aspire" or Elan or Evolut or "Freedom Solo" or INTUITY or Mitroflow or "PERCEVAL S" or "Prima Plus" or "Soprano Armonia" or "Sorin Pericarbon Freedom" or "Toronto SPV" or "Trifecta valve*"):ti,ab,kw 142

#17 ((Quattro or tiara or bicarbon or mira or "ON-X") near/3 (valv* or prosth* or implant*)):ti,ab,kw 143

#18 ((disk* or disc*) near/3 valv*):ti,ab,kw 79

#19 (Aortech Ultracor or Duromedics or Medtronic Hall or Omnicarbon or TEKNA or CardiAQ):ti,ab,kw 22

#20 #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19500

#21 ((bio-prosth* or biologic* prosth* or bioprosth*) near/3 valv*):ti,ab,kw 1655

#22 (Tissue* near/3 valv*):ti,ab 49

#23 (Tissue* near/3 (heart valv* or cardiac valv*)):ti,ab,kw 917

#24 (biologic* near/3 valv*):ti,ab,kw49

#25 (biologic* near/3 valv*):ti,ab,kw49

#26 (Cardiac Biological near/3 (valv* or prosth*)):ti,ab,kw 15

#27 ((freestyle or mosaic or liotta or Supra-G) near/3 (valv* or implant* or prosth*)):ti,ab,kw 30

#28 (perimount magna near/3 (ease or mitral or valv* or implant* or prosth*)):ti,ab,kw 7

#29 (Epic near/2 Stent* near/3 valv*):ti,ab,kw 0

#30 ("carpentier edwards" near/3 (valv* or implant* or prosth* or bioprosth* or pericardi* or perimount or porcine or supraannular or supra-annular)):ti,ab,kw 35

#31 (Hancock near/3 (valv* or implant* or prosth*)):ti,ab,kw 13

#32 ("Acurate TA" or "Acurate TF" or Centera or "CoreValve ReValving" or "Cribier Edwards valve" or "DirectFlow" or "Edwards SAPIEN valve" or Engager or "Inovare Valve*" or JenaValve or "Lotus Valve*" or "Portico valve*" or Biocor):ti,ab,kw 147

#33 #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 2679

#34 MeSH descriptor: [undefined] explode all trees 0

#35 (Donor* near/3 valv*):ti,ab,kw 4

#36 ((porcine* or pig or pigs* or cow or cows or bovine*) near/3 (valv* or prosth* or bioprosth*)):ti,ab,kw 101

#37 (Ross near/2 procedure*):ti,ab,kw 16

#38 (pulmonary near/3 (autograft* or auto-graft*)):ti,ab,kw 9

#39 (valv* near/3 (Homograft* or Homo-graft* or xenograft* or xeno-graft* or allograft* or allo-graft* or allotransplant* or allo-transplant* or isograft* or iso-graft*)):ti,ab,kw 29

#40 ((allogeneic or homostatic* or homo-static*) near/3 valv*):ti,ab,kw 0

#41 #34 or #35 or #36 or #37 or #38 or #39 or #40 143

#42 MeSH descriptor: [Heart] explode all trees 7018

#43 (heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or av or coronary or aortocoron* or myocard* or valv*):ti,ab,kw 255169

#44 #42 or #43 255194

#45 (Homograft* or Homo-graft* or xenograft* or xeno-graft* or allograft* or allo-graft* or allotransplant* or allo-transplant* or isograft* or iso-graft*):ti,ab,kw 5614

#46 (Donor* near/3 graft*):ti,ab,kw 1048

#47 ((allogeneic or homostatic* or homo-static*) near/3 graft*):ti,ab,kw 110

#48 #45 or #46 or #47 6610

#49 #44 and #48 727

#50 #33 or #41 or #49 3396

#51 #20 and #50 224

#52 #8 or #51 with Cochrane Library publication date Between Jan 2019 and Oct 2021, in Cochrane Reviews, Cochrane Protocols 11

KSR Evidence (Internet): 2019-6.10.21

<https://ksrevidence.com/>

Date searched: 6.10.21

Records found: 1376

- 1 artificial* AND valv* in All text 40 results
- 2 (percutaneous* or sternotom* or thoracotom*) AND (implant* or replacement* or valv* or prosth*) in All text 441 results
- 3 (heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or av) AND (prosth* or valv* or heterograft* or hetero-graft* or implant*) in All text 2057 results
- 4 lung arter* AND (prosth* or valv*) in All text 31 results
- 5 "Transcatheter Aortic Valve" AND Replac* in All text 391 results
- 6 TAVR in All text 255 results
- 7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 in All text 2214 results
- 8 (Mechanical* or metallic* or manufactur* or synthetic*) AND valv* in All text 7 results
- 9 MHV in All text 5 results
- 10 "stent framed" AND (replac* or valv* or implant* or prosth*) in All text 0 results
- 11 "caged ball" or "ball and cage" or "tilting disk" or "bi-leaflet" or "tri-leaflet or bileaflet or trileaflet" in All text 1 result
- 12 "starr-edward*" or "smeloff-cutter" or Hufnagel or bjork-shiley or Bjoerk-shiley or CarboMedics or cryo valve* or cryo-valve* in All text 1 result
- 13 ATS AND (valv* or "open pivot" or prosthes*) in All text 1 result
- 14 (SJM or "St jude Medical") AND (valv* or mechanical* or prosth* or regent or bileaflet* or bi-leaflet*) in All text 4 results
- 15 "3f Enable" or "3f-Enable" or "Aortech Aspire" or Elan or Evolut or "Freedom Solo" or INTUITY or Mitroflow or "PERCEVAL S" or "Prima Plus" or "Soprano Armonia" or "Sorin Pericarbon Freedom" or "Toronto SPV" or "Trifecta valve" in All text 25 results
- 16 (Quattro or tiara or bicarbon or mira or "ON-X") AND (valv* or prosth* or implant*) in All text 10 results
- 17 (disk* or disc*) AND valv* in All text 190 results
- 18 "Aortech Ultracor" or Duromedics or "Medtronic Hall" or Omnicarbon or TEKNA or CardiAQ in All text 0 results
- 19 #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 in All text 235 results
- 20 (bio-prosth* or biologic* prosth* or bioprosth*) AND valv* in All text 111 results
- 21 Tissue* AND valv* in All text 41 results
- 22 Tissue* AND (heart valv* or cardiac valv*) in All text 25 results
- 23 biologic* AND valv* in All text 35 results
- 24 "Cardiac Biological" AND (valv* or prosth*) in All text 0 results
- 25 (freestyle or mosaic or liotta or Supra-G) AND (valv* or implant* or prosth*) in All text 4 results
- 26 "perimount magna" AND (ease or mitral or valv* or implant* or prosth*) in All text 0 results
- 27 "Epic Stent*" AND valv* in All text 0 results
- 28 "carpentier edwards" AND (valv* or implant* or prosth* or bioprosth* or pericardi* or perimount or porcine or supraannular or "supra-annular") in All text 2 results
- 29 Hancock AND (valv* or implant* or prosth*) in All text 1 result

30 "Acurate TA" or "Acurate TF" or Centera or "CoreValve ReValving" or "Cribier Edwards valve" or "DirectFlow" or "Edwards SAPIEN valve" or Engager or "Inovare Valve*" or JenaValve or "Lotus Valve" or "Portico valve" or Biocor in All text 12 results

31 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 in All text 173 results

32 "Donor valve" OR "donor valves" OR "Ross procedure" in All text 9 results

33 (porcine* or pig or pigs* or cow or cows or bovine*) AND (valv* or prosth* or bioprosth*) in All text 15 results

34 pulmonary AND (autograft* or auto-graft*) in All text 4 results

35 valv* AND (Homograft* or "Homo-graft*" or xenograft* or "xeno-graft*" or allograft* or "allo-graft*" or allotransplant* or "allo-transplant*" or isograft* or "iso-graft*") in All text 10 results

36 (allogeneic or homostatic* or homo-static*) AND valv* in All text 3 results

37 #32 OR #33 OR #34 OR #35 OR #36 in All text 33 results

38 heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or av or coronary or aortocoron* or myocard* or valv* in All text 21133 results

39 (Homograft* or "Homo-graft*" or xenograft* or "xeno-graft*" or allograft* or "allo-graft*" or allotransplant* or "allo-transplant*" or isograft* or "iso-graft*") in All text 618 results

40 Donor* AND grafts* in All text 102 results

41 (allogeneic or homostatic* or homo-static*) AND graft* in All text 113 results

42 #39 OR #40 OR #41 in All text 802 results

43 #38 AND #42 in All text 84 results

44 #31 OR #37 OR #43 in All text 259 results

45 #19 AND 44 in All text 566 results

46 #7 OR #45 in All text 1376 results

Filtered by: PUBLICATION DATE 2022, 2021, 2020, 2019

Epistemonikos (Internet): 2019-6.10.21

<https://www.epistemonikos.org/en/>

Date searched: 6.10.21

Records found: 1149

(title:((artificial* AND valv*)) OR abstract:((artificial* AND valv*)) OR (title:(((percutaneous* OR sternotom* OR thoracotom*) AND (implant* OR replacement* OR valv* OR prosth*))) OR abstract:(((percutaneous* OR sternotom* OR thoracotom*) AND (implant* OR replacement* OR valv* OR prosth*)))) OR (title:(((heart OR cardiac* OR aort* OR pericardi* OR bicuspid* OR tricuspid* OR atrioventricular OR mitral* OR pulmonary OR av) AND (prosth* OR valv* OR heterograft* OR hetero-graft* OR implant*))) OR abstract:(((heart OR cardiac* OR aort* OR pericardi* OR bicuspid* OR tricuspid* OR atrioventricular OR mitral* OR pulmonary OR av) AND (prosth* OR valv* OR heterograft* OR hetero-graft* OR implant*)))) OR (title:("lung artery" AND (prosth* OR valv*)) OR abstract:("lung artery" AND (prosth* OR valv*)) OR (title:("Transcatheter Aortic Valve" AND Replac*) OR abstract:("Transcatheter Aortic Valve" AND Replac*)) OR (title:(TAVR AND MHV) OR abstract:(TAVR AND MHV)) OR (title:(((Mechanical* OR metallic* OR manufactur* OR synthetic*) AND valv*)) OR abstract:(((Mechanical* OR metallic* OR manufactur* OR synthetic*) AND valv*)) OR (title:("stent framed" AND (replac* OR valv* OR implant* OR prosth*)) OR abstract:("stent framed" AND (replac* OR valv* OR implant* OR prosth*)) OR (title:("caged ball" OR "ball AND cage" OR "tilting disk" OR "bi-leaflet" OR tri-leaflet OR bileaflet OR trileaflet OR "starr-edward*" OR "smeloff-cutter" OR Hufnagel OR bjork-shiley OR Bjoerk-shiley OR CarboMedics OR

cryovalve* OR cryo-valve*) OR abstract:("caged ball" OR "ball AND cage" OR "tilting disk" OR "bi-leaflet" OR tri-leaflet OR bileaflet OR trileaflet OR "starr-edward*" OR "smeloff-cutter" OR Hufnagel OR bjork-shiley OR Bjoerk-shiley OR CarboMedics OR cryovalve* OR cryo-valve*)) OR (title:(ATS AND (valv* OR "open pivot" OR prosthes*)) OR abstract:(ATS AND (valv* OR "open pivot" OR prosthes*))) OR (title:((Tissue* AND valv*)) OR abstract:((Tissue* AND valv*))) OR (title:((biologic* AND valv*)) OR abstract:((biologic* AND valv*))) OR (title:("Cardiac Biological" AND (valv* OR prosthe*)) OR abstract:(Cardiac Biological AND (valv* OR prosthe*))) OR (title:((Donor* AND valv*)) OR abstract:((Donor* AND valv*))) OR (title:((porcine* OR pig OR pigs* OR cow OR cows OR bovine*) AND (valv* OR prosthe* OR bioprosthe*)) OR abstract:((porcine* OR pig OR pigs* OR cow OR cows OR bovine*) AND (valv* OR prosthe* OR bioprosthe*))) OR (title:((valv* AND (Homograft* OR Homo-graft* OR xenograft* OR xeno-graft* OR allograft* OR allo-graft* OR allotransplant* OR allo-transplant* OR isograft* OR iso-graft*))) OR abstract:((valv* AND (Homograft* OR Homo-graft* OR xenograft* OR xeno-graft* OR allograft* OR allo-graft* OR allotransplant* OR allo-transplant* OR isograft* OR iso-graft*))) OR (title:((heart OR cardiac* OR aort* OR pericardi* OR bicuspid* OR tricuspid* OR atrioventricular OR mitral* OR pulmonary OR av OR coronary OR aortocoron* OR myocard*) AND valv*)) OR abstract:((heart OR cardiac* OR aort* OR pericardi* OR bicuspid* OR tricuspid* OR atrioventricular OR mitral* OR pulmonary OR av OR coronary OR aortocoron* OR myocard*) AND valv*))

Retrieved 1149 records.

Limits:

Publication year: 2019-2021

Publication type: Systematic review

Cochrane review: No

International HTA Database

<https://database.inahta.org/>

Date searched: 6.10.21

Records found: 46

4	#3 OR #2 OR #1	421
3	(Mechanical* or metallic* or manufactur* or synthetic*) and valv*) OR (MHV) OR ((stent* and framed) and (replac* or valv* or implant* or prosthe*)) OR ("caged ball" or "ball and cage" or "tilting disk" or "bi-leaflet" or "tri-leaflet or bileaflet or trileaflet") OR ("starr-edward*" or "smeloff-cutter" or Hufnagel or bjork-shiley or Bjoerk-shiley or CarboMedics or cryovalve* or cryo-valve*) OR (ATS and (valv* or "open pivot" or prosthes*)) OR ((SJM or "St jude Medical") and (valv* or mechanical* or prosthe* or regent or bileaflet* or bi-leaflet*)) OR ("3f Enable" or "3f-Enable" or "Aortech Aspire" or Elan or Evolut or "Freedom Solo" or INTUITY or Mitroflow or "PERCEVAL S" or "Prima Plus" or "Soprano Armonia" or "Sorin Pericarbon Freedom" or "Toronto SPV" or "Trifecta valve*") OR ((Quattro or tiara or bicarbon or mira or "ON-X") and (valv* or prosthe* or implant*)) OR ((disk* or disc*) and valv*) OR (Aortech Ultracor or Duromedics or Medtronic Hall or Omnicarbon or TEKNA or CardiAQ)	416
2	"Heart Valve Prosthesis Implantation"[mhe]	68
1	"Heart Valve Prosthesis"[mh]	78

Limits:

Publication year: 2019-2021

NHS Evidence: 2019 – 6.10.21
<https://www.evidence.nhs.uk/>

Date searched: 6.10.21

Records found:

(heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or coronary or myocardia*) and (prosthe* or valv* or graft* or implant*) 361

Limits:

Type: Guidance

Date: 2019-2021

NICE Guidelines: 2019 – 6.10.21
<https://www.nice.org.uk/guidance>

Date searched: 6.10.21

Records found: 361

(heart or cardiac* or aort* or pericardi* or bicuspid* or tricuspid* or atrioventricular or mitral* or pulmonary or coronary or myocardia*) and (prosthe* or valv* or graft* or implant*) 361

Limits:

Type: Guidance

Date: 2019-2021

Guidelines International Network (G-I-N): 2019 – 6.10.21
<https://guidelines.ebmportal.com/>

Date searched: 6.10.21

Records found: 0

Search term	Records
Valve	0
Prosthesis	0
Graft	0
Implant	0
TOTAL	0

Limits:

Guideline publication status: Published

Publication year: 2019-2021

ECRI Guidelines Trust: 2019 – 6.10.21
<https://guidelines.ecri.org/>

Date searched: 6.10.21

Records found: 0

Search term	Records
Valve	0
Prosthesis	0
Graft	0
Implant	0
TOTAL	0

Limits:

Clinical area: Cardiology

Publication year: 2019-2021

Trip Database: 2019 – 6.10.21

<https://www.tripdatabase.com/>

Date searched: 6.10.21

Records found: 6

(valve) AND (heart OR cardiac OR coronary OR myocardial)

Limits:

Publication type: Guidelines

Publication year: 2019-2021

CADTH: 2019 – 6.10.21

<https://www.cadth.ca/>

Date searched: 6.10.21

Records found: 4

(valve) AND (heart OR cardiac OR coronary OR myocardial)

Limits:

Project line: Health Technology Review

Last updated: 2019-2021