ACURATE™ Aortic Valve System Publication Compendium

TABLE OF CONTENTS:

INTRODUCTION

PUBLICATIONS LISTED IN THIS COMPENDIUM ARE BOSTON SCIENTIFIC SPONSORED, INVESTIGATOR SPONSORED OR INDEPENDENTLY LED ANALYSES WHICH INCLUDE THE ACURATE™ AORTIC VALVE SYSTEM (ACURATE Prime, ACURATE *neo2* AND ACURATE *neo*).

THE SAFETY AND EFFECTIVENESS OF THE ACURATE™ AORTIC VALVE PLATFORM FOR TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR) IN SUBJECTS WITH SEVERE NATIVE AORTIC STENOSIS IS ASSESSED VIA THE ACURATE IDE TRIAL – SEE FULL ACURATE IDE DETAILS AT CLINICALTRIALS.GOV.

EACH PUBLICATION ENTRY INCLUDES (IF AVAILABLE) ITS FULL REFERENCE, AND A LINK TO THE FULL ARTICLE (THIS LINK MAY REQUIRE THE READER TO PAY FOR THE FULL CONTENT). BOSTON SCIENTIFIC SPONSORED TRIALS INCLUDE PUBLICATION ABSTRACT.

THIS DOCUMENT WILL BE UPDATED AS FUTURE PUBLICATIONS BECOME AVAILABLE.

ACURATE PUBLICATIONS ARE COLOR CODED BY PLATFORM THROUGHOUT THIS DOCUMENT

ACURATE Prime™
Aortic Valve System Publication

ACURATE *neo2*™
Aortic Valve System Publication

ACURATE *neo2*™ and ACURATE *neo*™
Aortic Valve System Publication

ACURATE *neo*™
Aortic Valve System Publication

BOSTON SCIENTIFIC SPONSORED CLINICAL TRIALS

Outcomes and performance of the ACURATE neo2 transcatheter heart valve in clinical practice: one-year results of the ACURATE neo2 PMCF Study.

Kim WK, Tamburino C, Möllmann H, Montorfano M et al., EuroIntervention. 2023 Nov 19:EIJ-D-23-00823. doi: 10.4244/EIJ-D-23-00823. Epub ahead of print. PMID: 37982152.

Abstract:

Background: Transcatheter aortic valve implantation is an effective treatment for patients with aortic stenosis; however, complications related to paravalvular leakage (PVL) persist, including increased risk of mortality, cardiovascular mortality, and rehospitalisation.

Aims: We sought to evaluate the clinical outcomes and valve performance at 1 year in patients with severe aortic stenosis treated with the ACURATE neo2 valve in a post-market clinical setting.

Methods: Valve Academic Research Consortium-2 safety events were assessed up to 1 year. Independent core laboratories evaluated echocardiographic measures of valve performance and hypoattenuated leaflet thickening (HALT; as measured by four-dimensional computed tomography).

Results: The study enrolled 250 patients (64% female; mean age: 81 years; baseline Society of Thoracic Surgeons risk score: 2.9±2.0%); 246 patients were implanted with ACURATE neo2. All-cause mortality was 0.8% at 30 days and 5.1% at 1 year. The 1-year rates for stroke and disabling stroke were 3.0% and 1.3%, respectively. Overall, HALT of >50% leaflet involvement of at least one leaflet was present in 9% of patients at 30 days and in 12% of patients at 1 year. No association was observed between the presence of HALT and 1-year clinical or haemodynamic outcomes. Early haemodynamic improvements were maintained up to 1 year (mean aortic valve gradient: 47.6±14.5 mmHg at baseline, 7.6±3.2 mmHg at 1 year; mean aortic valve area: 0.7±0.2 cm2 at baseline, 1.7±0.4 cm2 at 1 year). At 1 year, 99% of patients had mild or no/trace PVL (<1% had moderate PVL; no patient had severe PVL).

Conclusions: The study outcomes confirm favourable performance and safety up to 1 year in patients treated with ACURATE neo2 in routine clinical practice.

Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study.

Kim WK, Tamburino C, Möllmann H, Montorfano M et al., EuroIntervention. 2022 Nov 27;19(1):83–92. doi: 10.4244/EIJ-D-22-00914. Epub ahead of print. PMID: 36440588; PMCID: PMC10173758.

Abstract:

Background: The next-generation ACURATE neo2 transcatheter aortic valve was designed for simplified implantation and to mitigate the risk of paravalvular leak (PVL) compared to the earlier device.

Aims: To collect clinical outcomes and device performance data, including echocardiography and 4-dimensional computed tomography (4D-CT) data, with the ACURATE neo2 transcatheter heart valve in patients with severe aortic stenosis (AS).

Methods: ACURATE neo2 PMCF is a single-arm, multicentre study of patients with severe AS treated in routine clinical practice. The primary safety endpoint was all-cause mortality at 30-days. The primary imaging endpoint was hypo-attenuated leaflet thickening (HALT), measured by core laboratory-adjudicated 4D-CT at 30 days. Secondary endpoints included VARC safety endpoints, procedural success, and evaluation of valve performance via core laboratory-adjudicated echocardiography.

Results: The study enrolled 250 patients at 18 European centres (mean age: 80.8 years; 63.6% female; mean STS score: 2.9±2.0%); 246 (98.4%) were successfully treated with ACURATE neo2. The 30-day rates for mortality and disabling stroke were 0.8% and 0%, respectively. The new permanent pacemaker implantation rate was 6.5%. HALT >50% was present in 9.3% of patients at 30 days. Valve haemodynamics improved from baseline to 30 days (mean aortic valve gradient: from 47.6±14.5 mmHg to 8.6±3.9 mmHg; mean aortic valve area: from 0.7±0.2 cm2 to 1.6±0.4 cm2). At 30 days, PVL was evaluated as none/trace in 79.2% of patients, mild in 18.9%, moderate in 1.9%, and severe in 0%.

Conclusions: The study results support the safety and efficacy of TAVI with ACURATE neo2 in patients in routine clinical practice.

The ACURATE neo2 valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes.

Möllmann H, Holzhey DM, Hilker M et al., Clin Res Cardiol. 2021 Dec;110(12):1912-1920. doi: 10.1007/s00392-021-01882-3. Epub 2021 Jun 20. PMID: 34148125; PMCID: PMC8639565.

Abstract:

Background: Transcatheter aortic valve implantation (TAVI) has become standard treatment for elderly patients with symptomatic severe aortic valve stenosis. The ACURATE neo AS study evaluates 30-day and 1-year clinical and hemodynamic outcomes in patients treated with the ACURATE neo2 valve.

Methods: The primary endpoint of this single-arm multicenter study is 30-day all-cause mortality. Other key endpoints include device performance, echocardiographic measures assessed by an independent core laboratory, and VARC-2 clinical efficacy and safety endpoints through 12 months.

Results: The study enrolled 120 patients (mean age 82.1 ± 4.0 years; 67.5% female, mean baseline STS score 4.8 ± 3.8%). The VARC-2 composite safety endpoint at 30 days occurred in 13.3% of patients. All-cause mortality was 3.3% at 30 days and 11.9% at 1 year. The 30-day stroke rate was 2.5% (disabling stroke 1.7%); there were no new strokes between 30 days and 12 months. The rate of permanent pacemaker implantation was 15.0% (18/120) at 30 days and 17.8% (21/120) at 1 year. No patients required re-intervention for valve-related dysfunction and there were no cases of valve thrombosis or endocarditis. Patients demonstrated significant improvement in mean aortic valve gradient (baseline 38.9 ± 13.1 mmHg, 1 year 7.8 ± 3.5 mmHg; P < 0.001 in a paired analysis). In the overall population, paravalvular leak was evaluated at 1 year as none/trace in 60.5%, mild in 37.0%, and moderate in 2.5%; no patients had severe PVL.

Conclusions: One-year outcomes from the ACURATE neo AS study support the safety and performance of TAVI with the ACURATE neo2 valve.

Keywords: Aortic valve stenosis; Paravalvular regurgitation; Transcatheter aortic valve replacement; Transfemoral aortic valve implantation

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The SAVI-TF Registry: 1-Year Outcomes of the European Post-Market Registry Using the ACURATE neo Transcatheter Heart Valve Under Real-World Conditions in 1,000 Patients.

Kim WK, Hengstenberg C, Hilker M et al., JACC Cardiovasc Interv. 2018 Jul 23;11(14):1368-1374. doi: 10.1016/j.jcin.2018.03.023. PMID: 30025731

Abstract:

Objectives: The SAVI-TF (Symetis ACURATE neo Valve Implantation Using Transfemoral Access) registry was initiated to study the ACURATE neo transcatheter heart valve in a large patient population treated under real-world conditions.

Background: The self-expanding, supra-annular ACURATE neo prosthesis is a transcatheter heart valve that gained the Conformité Européene mark in 2014, but only limited clinical data are available so far.

Methods: This prospective, multicenter registry enrolled 1,000 patients at 25 European centers who were followed for 1 year post-procedure.

Results: Mean patient age was 81.1 ± 5.2 years; mean logistic European System for Cardiac Operative Risk Evaluation I score, European System for Cardiac Operative Risk Evaluation II score, and Society of Thoracic Surgeons score were 18.1 ± 12.5%, 6.6 ± 7.5%, and 6.0 ± 5.6%, respectively. At 1 year, 8.0% (95% confidence interval [CI]: 6.3% to 9.7%) of patients had died, 2.3% (95% CI: 1.3% to 3.2%) had disabling strokes, and 9.9% (95% CI: 8.1% to 11.8%) had permanent pacemaker implantations. Through 1 year, 5 reinterventions (0.5%; 95% CI: 0.1% to 1.0%) were performed: 3 valve-in-valve and 2 surgical aortic valve replacements. Mean effective orifice area was 1.84 ± 0.43 cm2, mean gradient was 7.3 ± 3.7 mm Hg, and greater than mild paravalvular leakage was observed in 3.6% of patients.

Conclusions: Transfemoral implantation of the ACURATE neo prosthesis resulted in favorable 1-year clinical and echocardiographic outcomes with very low mortality and new pacemaker rates.

Real-world experience using the ACURATE neo prosthesis: 30-day outcomes of 1000 patients enrolled in the SAVI TF registry.

Möllmann H, Hengstenberg C, Hilker M et al., EuroIntervention. 2018 Feb 2;13(15): e1764-e1770. doi: 10.4244/EIJ-D-17-00628.

Abstract:

Aims: The aim of the SAVI TF registry was to assess the safety and performance of the self-expanding ACURATE neo transfemoral transcatheter heart valve in a large patient population with severe aortic stenosis and to investigate whether the outcomes obtained in the CE-mark cohort can be replicated in an unselected all-comers population.

Methods and results: From October 2014 until April 2016, 1,000 patients were enrolled in this prospective, European multicentre registry. Patients were 81.1±5.2 years and had a logistic EuroSCORE II and STS score of 6.6±7.5% and 6.0±5.6%, respectively. Pre-dilatation was performed in 96.1% of patients and post-dilatation in 44.8%. Procedural and device success were both obtained in 98.7%; failure comprised nine valve-in-valve procedures, three conversions to surgery, and one aborted procedure. The primary endpoint was 30-day mortality, which was observed in 14 patients (1.4% [95% CI: 0.7-2.1]).

Disabling stroke was seen in 1.2% (95% CI: 0.5-1.9) and new pacemaker implantation in 8.3% (95% CI: 6.6-10.0). At discharge, mean effective orifice area was 1.77±0.46 cm^2 and mean gradient 8.4±4.0 mmHg; 4.1% of patients had a more than mild paravalvular leak.

Conclusions: In this initial experience, treatment with the ACURATE neo prosthesis resulted in good clinical outcomes with very low complication rates.

Transcatheter Aortic Valve Implantation with ACURATE neo: Results from the PROGRESS PVL Registry.

Won-Keun Kim, Holger Thiele, Axel Linke et al., J Interv Cardiol. 2022 Jun 25;2022:9138403. doi: 10.1155/2022/9138403.

Abstract:

Objectives: The PROGRESS PVL registry evaluated transcatheter aortic valve implantation (TAVI) in patients treated with ACURATE neo, a supra-annular self-expanding bioprosthetic aortic valve.

Background: While clinical outcomes with TAVI are comparable with those achieved with surgery, residual aortic regurgitation (AR) and paravalvular leak (PVL) are common complications. The ACURATE neo valve has a pericardial sealing skirt designed to minimize PVL.

Methods: The primary endpoint was the rate of total AR over time, as assessed by a core echocardiographic laboratory. The study enrolled 500 patients (mean age: 81.8 ± 5.1 years; 61% female; mean baseline STS score: 6.0 ± 4.5%) from 22 centers in Europe and Canada; 498 patients were treated with ACURATE neo.

Results: The rate of ≥ moderate AR was 4.6% at discharge and 3.1% at 12 months; the rate of ≥ moderate PVL was 4.6% at discharge and 2.6% at 12 months. Paired analyses showed significant improvement in overall PVL between discharge and 12 months ($P < 0.001$); 64.6% of patients had no change in PVL grade, 24.9% improved, and 10.5% worsened. Patients also exhibited significant improvement in transvalvular gradient ($P < 0.001$) and effective orifice area ($P=0.01$). The mortality rate was 2.2% at 30 days and 11.3% at 12 months. The permanent pacemaker implantation (PPI) rate was 10.2% at 30 days and 12.2% at 12 months.

Conclusions: Results from PROGRESS PVL support the sustained safety and performance of TAVI with the ACURATE neo valve, showing excellent valve hemodynamics, good clinical outcomes, and significant interindividual improvement in PVL from discharge to 12-month follow-up.

Transfemoral TAVI using the self-expanding ACURATE neo prosthesis: one-year outcomes of the multicentre "CE-approval cohort".

Möllmann H, Walther T, Siqueira D et al., EuroIntervention. 2017 Oct 13;13(9): e1040-e1046. doi: 10.4244/EIJ-D-17-00187. PMID: 28804056

Abstract:

Aims: The aim of this study was to assess the safety and performance of the ACURATE neo transcatheter heart valve and its transfemoral delivery system.

Methods and results: The prospective, multicentre "CE-approval cohort" consists of a prospective series of the first 89 patients implanted with the ACURATE neo prosthesis. The primary endpoint was all-cause mortality at 30 days. Mean patient age was 83.7±4.4 years and logistic EuroSCORE I was 26.5±7.7%. Procedural success was obtained in 84 patients (94.4%). At 30 days, three patients had died, and two major strokes and one reintervention for a ventricular septal defect occurred, leading to a major adverse cardiac and cerebrovascular event (MACCE) rate of 6.7%. Eight patients (10.3%) received a permanent pacemaker. At one year, 20 patients (22.5%) had died and the MACCE rate was 27%. Effective orifice area was 1.76±0.34 cm2, and mean gradient 7.5±2.8 mmHg. Only three patients (4.5%) had moderate paravalvular regurgitation. NYHA Class III/IV was present in 94.4% of patients at baseline, in 9.9% at 30 days and in 4.5% at one year post procedure.

Conclusions: This first-in-human experience with a novel self-expanding heart valve showed low rates of procedural mortality, major stroke and pacemaker implantation, and good performance outcomes.

First results from the ACURATE Prime XL human feasibility study.

Gooley R, Murdoch D, Modolo R et al., Cardiovasc Revasc Med. 2023 Jun 30:S1553-8389(23)00673-5. doi: 10.1016/j.carrev.2023.06.028. Epub ahead of print. PMID: 37429793.

Abstract:

Background/purpose: This prospective, open-label, single-arm study evaluated transcatheter aortic valve replacement (TAVR) in patients with severe aortic stenosis with ACURATE Prime XL, an iteration of the ACURATE neo2 device designed with improved radial force and adaptations for compatibility with a larger annulus diameter (≥ 26.5 mm and ≤ 29 mm based on pre-procedure diagnostic imaging).

Methods: The composite primary device success endpoint was based on Valve Academic Research Consortium (VARC)-2 criteria. The primary safety endpoint was a composite of all-cause mortality and all stroke at 30 days. Aortic valve (AV) performance, including mean AV gradient, AV area, and grade of paravalvular leak (PVL), was assessed by an independent core laboratory.

Results: 13 male patients were enrolled at 3 Australian centers (mean age: 83.1 years; 10 of 13 were considered high/extreme operative risk). 61.5 % of patients met the primary device success endpoint. At 30 days, no patients experienced death or stroke; one patient received a permanent pacemaker. Mean AV gradient improved from baseline (42.7 ± 11.0 mmHg) to discharge (7.7 ± 2.5 mmHg) and through 30 days (7.2 ± 2.3 mmHg). Mean AV area was 0.8 ± 0.1 cm2 at baseline, 1.9 ± 0.3 cm2 at discharge, and 1.7 ± 0.3 cm2 at 30 days. Per core-laboratory adjudication, no patient had moderate or severe PVL at 30 days; 91.7 % had no/trace PVL and 8.3 % had mild PVL.

Conclusions and relevance: In this first-in-human feasibility study of the ACURATE Prime XL valve, there were no safety concerns, and no deaths or strokes within 30 days. Valve hemodynamics were favorable, and no patient had >mild PVL.

INVESTIGATOR SPONSORED RESEARCH

The Early neo2 Registry: Transcatheter Aortic Valve Implantation With ACURATE neo2 in a European Population.

Ruck A, Kim WK, Abdel-Wahab M et al., J Am Heart Assoc. 2023 Aug;12(15):e029464. doi: 10.1161/JAHA.122.029464. Epub 2023 Jul 25. PMID: 37489732; PMCID: PMC10493001.

Paravalvular Leak After Implantation of the ACURATE neo and the ACURATE neo2 Transcatheter Heart Valve.

Stefan Toggweiler, Miriam Brinkert, Mathias Wolfrum, et al., Open Heart. 2020 Nov;7(2):e001391. doi: 10.1136/openhrt-2020-001391. PMID: 33243930; PMCID: PMC7692991.

Safety and efficacy of a self-expanding versus a balloon-expandable bioprosthesis for transcatheter aortic valve replacement in patients with symptomatic severe aortic stenosis: a randomised non-inferiority trial. (SCOPE I)

Lanz J, Kim W-K, Walther T et al., Lancet 2019 DOI:https://doi.org/10.1016/S0140-6736(19)32220-2.

Final 3-Year Outcomes of a Randomized Trial Comparing a Self-Expanding to a Balloon-Expandable Transcatheter Aortic Valve.

Lanz J, Mollmann H, Kim WK et al., Circ Cardiovasc Interv. 2023 Jul;16(7):e012873. doi: ,10.1161/CIRCINTERVENTIONS.123.012873. Epub 2023 Jul 7. PMID: 37417229.

Comparison of Self-Expanding Bioprostheses for Transcatheter Aortic Valve Replacement in Patients With Symptomatic Severe Aortic Stenosis: SCOPE 2 Randomized Clinical Trial.

Tamburino C, Bleiziffer S, Thiele H et al., Circulation. 2020 Dec 22;142(25):2431-2442. doi: 10.1161/CIRCULATIONAHA.120.051547. Epub 2020 Oct 15. PMID: 33054367.

Permanent pacemaker implantation and left bundle branch block with self-expanding valves - a SCOPE 2 subanalysis.

Pellegrini C, Garot P, Morice MC et al., EuroIntervention. 2022 Sep 21:EIJ-D-22-00558. doi: 10.4244/EIJ-D-22-00558. Epub ahead of print. PMID: 36128956.

Transcatheter aortic valve replacement using the iSleeve expandable sheath in small femoral arteries.

Glaser N, O'Sullivan CJ, Saleh N et al., Open Heart. 2021 Oct;8(2):e001703. doi: 10.1136/openhrt-2021-001703. PMID: 34642241; PMCID: PMC8513271.

Accurate commissural alignment during ACURATE neo TAVI procedure. Proof of concept.

Redondo A, Valencia-Serrano F, Santos-Martínez S et al., Rev Esp Cardiol (Engl Ed). 2021 Mar 26:S1885-5857(21)00068-2. English, Spanish. doi: 10.1016/j.rec.2021.02.004. Epub ahead of print. PMID: 33781722.

EXTERNALLY DRIVEN EVIDENCE (BY TOPIC)

HEAD-TO-HEAD COMPARISONS

ACURATE neo2 versus SAPIEN 3 Ultra for transcatheter aortic valve implantation.

Pellegrini C, Rheude T, Renker M et al., EuroIntervention. 2023 Jan 23;18(12):987-995. doi: 10.4244/EIJ-D-22-00164. PMID: 36250307; PMCID: PMC9853033.

Comparison of transcatheter aortic valve replacement with the ACURATE neo2 versus Evolut PRO/PRO+ devices.

Baggio S, Pagnesi M, Kim WK et al., EuroIntervention. 2022 Sep 12:EIJ-D-22-00498. doi: 10.4244/EIJ-D-22-00498. Epub ahead of print. PMID: 36093795.

Multicenter comparison of transcatheter aortic valve implantation with the self-expanding ACURATE neo2 versus Evolut PRO transcatheter heart valves.

Rheude T, Rellegrini C, Landt M et al., Clin Res Cardiol. 2023 Apr 28. doi: 10.1007/s00392-023-02194-4. Epub ahead of print. PMID: 37115228.

Comparison of contemporary transcatheter heart valve prostheses: data from the German Aortic Valve Registry (GARY).

Ruldolph TK, Herrmann E, Bon Dimitria et al., Clin Res Cardiol. 2023 Jul 18. doi: 10.1007/s00392-023-02242-z. Epub ahead of print. PMID: 37462856.

Comparing the Safety and Effectiveness of Five Leading New-Generation Devices for Transcatheter Aortic Valve Implantation: Twelve-Month Results From the RISPEVA Study.

Corcione N, Morello A, Ferraro P et al., Registro Italiano GISE sull'Impiantodi Valvola Aortica Percutanea (RISPEVA) Study Investigators. J Invasive Cardiol. 2021 May;33(5):E320-E329. Epub 2021 Mar 19. PMID: 33739300.

Comparative one-month safety and effectiveness of five leading new-generation devices for transcatheter aortic valve implantation.

Giordano A, Corcione N, Ferraro et al., Registro Italiano GISE sull'impianto di Valvola Aortica Percutanea (RISPEVA) Study Investigators. Sci Rep. 2019 Nov 19;9(1):17098. doi: 10.1038/s41598-019-53081-w. PMID: 31745198

Transcatheter Aortic Valve Replacement With Next-Generation Self-Expanding Devices: A Multicenter, Retrospective, Propensity-Matched Comparison of Evolut PRO Versus Acurate neo Transcatheter Heart Valves.

Pagnesi M, Kim WK, Conradi L et al., JACC Cardiovasc Interv. 2019 Mar 11;12(5):433-443. doi: 10.1016/j.jcin.2018.11.036

Comparison of Self-Expanding RDV Perceval S versus TAVI ACURATE neo/TF.

Gerfer S, Mauri V, Kuhn E et al., Thorac Cardiovasc Surg. 2021 Aug;69(5):420-427. doi: 10.1055/s-0040-1722692. Epub 2021 Mar 24. PMID: 33761569.

Comparison of latest generation transfemoral self-expandable and balloon-expandable transcatheter heart valves.

Schaefer A, Linder M, Seiffert M et al., Interact Cardiovasc Thorac Surg. 2017 Dec 1;25(6):905-911. doi: 10.1093/icvts/ivx194. PMID: 28655156

Multicenter Comparison of Novel Self-Expanding Versus Balloon-Expandable Transcatheter Heart Valves.

Husser O, Kim WK, Pellegrini C et al., JACC Cardiovasc Interv. 2017 Oct 23;10(20):2078-2087. doi: 10.1016/j.jcin.2017.06.026. PMID: 29050625

Multi-Center Comparison of Two Self-Expanding Transcatheter Heart Valves: A Propensity Matched Analysis.

Blumenstein J, Eckel C, Husser O et al., J Clin Med. 2022 Jul 21;11(14):4228. doi: 10.3390/jcm11144228. PMID: 35887990; PMCID: PMC9318122.

Transcatheter aortic valve implantation with different self-expanding devices-a propensity score-matched multicenter comparison.

Wienemann H, Hof A, Ludwig S et al., J Cardiol. 2023 Mar-Apr;70:1-9. doi: 10.1016/j.hjc.2022.12.006. Epub 2022 Dec 17. PMID: 36538975.

Real-World Multiple Comparison of Transcatheter Aortic Valves: Insights From the Multicenter OBSERVANT II Study.

Costa G, Barbanti M, Rosato S, et al., Cardiovascular Interventions. 2022;15 2022https://doi.org/10.1161/CIRCINTERVENTIONS.122.012294Circulation:

Comparison of latest generation supra-annular and intra-annular self-expanding transcatheter heart valves.

Pellegrini C, Rheude T, Michel J et al., J Thorac Dis. 2020 Nov;12(11):6769-6779. doi: 10.21037/jtd-20-1700.PMID: 33282378

LENGTH OF STAY

Safety of Next-Day Discharge After Transfemoral Transcatheter Aortic Valve Replacement with a Self-Expandable Versus Balloon-Expandable Valve Prosthesis.

Moriyama N, Vento A, Laine M et al., Circ Cardiovasc Interv. 2019 Jun;12(6):e007756. doi:10.1161/CIRCINTERVENTIONS.118.007756. Epub 2019 Jun 6. PMID: 31167602

CONDUCTION DISORDERS

Conduction Disturbance After Transcatheter Aortic Valve Implantation With Self- or Balloon-Expandable Valve According to the Implantation Depth.

Miyashita H, Moriyama N, Sugiyama Y et al., Am J Cardiol. 2023 Sep 15;203:17-22. doi: 10.1016/j.amjcard.2023.05.025. Epub 2023 Jul 19. PMID: 37478637.

Transcatheter Valve SELECTion in Patients With Right Bundle Branch Block and Impact on Pacemaker Implantations.

Husser O, Pellegrini C, Kim WK et al., JACC Cardiovasc Interv. 2019 Sep 23;12(18):1781-1793. doi: 10.1016/j.jcin.2019.05.055.

Relevance of New Conduction Disorders After Implantation of the ACURATE Neo Transcatheter Heart Valve in the Aortic Valve Position.

Brinkert M, Wolfrum M, Moccetti F et al., Am J Cardiol. 2020 Mar 1;125(5):783-787. doi: 10.1016/j.amjcard.2019.11.036. Epub 2019 Dec 14. PMID: 31898969

Predictors of permanent pacemaker implantation after ACURATE neo transcatheter heart valve implantation.

Kim WK, Möllmann H, Walther T et al., CW.Pacing Clin Electrophysiol. 2020 Dec 29. doi: 10.1111/pace.14155. Online ahead of print. PMID: 33373045

Paravalvular regurgitation and permanent pacemaker implantation after TAVR with a next-generation self-expanding device.

Mauri V, Deuschl F, Frohn T et al., Clin Res Cardiol. 2018 Aug;107(8):688-697. doi: 10.1007/s00392-018-1235-1. Epub 2018 Apr 17. PMID: 29667013

Predictors of Need for Permanent Pacemaker Implantation and Conduction Abnormalities with a Novel Self-expanding Transcatheter Heart Valve.

Pellegrini C, Husser O, Kim WK et al., Rev Esp Cardiol (Engl Ed). 2019 Feb;72(2):145-153. doi: 10.1016/j.rec.2018.01.011. Epub 2018 Mar 16. PMID: 29551701 English, Spanish.

Very low pacemaker rate following ACURATE neo transcatheter heart valve implantation.

Toggweiler S, Nissen H, Mogensen B et al., EuroIntervention. 2017 Dec 20;13(11):1273-1280. doi: 10.4244/EIJ-D-17-00252. PMID: 28870877

Impact of Interventricular membranous septum length on pacemaker need with different Transcatheter aortic valve implantation systems.

Thijmen W.H, Maarten P.vanW, J F. O et al., International Journal of Cardiology March 02, 2021DOI:https://doi.org/10.1016/j.ijcard.2021.02.080

Development of atrioventricular and intraventricular conduction disturbances in patients undergoing transcatheter aortic valve replacement with new generation self-expanding valves: A real world multicenter analysis.

Castro-Mejía AF, Amat-Santos I, Ortega-Armas ME et al., Int J Cardiol. 2022 Sep 1;362:128-136. doi: 10.1016/j.ijcard.2022.05.014. Epub 2022 May 10. PMID: 35550389.

SMALL ANNULI

Implantation of contemporary transcatheter aortic valves in small aortic annuli: the international multicentre TAVI-SMALL 2 registry.

Leone PP, Regazzoli D, Pagnesi M et al., EuroIntervention. 2023 Jun 19;19(3):256-266. doi: 10.4244/EIJ-D-22-00843. PMID: 36950893; PMCID: PMC10266383.

Short-Term Outcome and Hemodynamic Performance of Next-Generation Self-Expanding Versus Balloon-Expandable Transcatheter Aortic Valves in Patients With Small Aortic Annulus: A Multicenter Propensity-Matched Comparison.

Mauri V, Kim WK, Abumayyaleh M, et al., Circ Cardiovasc Interv. 2017;10(10)

Procedural Outcomes of a Self-Expanding Transcatheter Heart Valve in Small Annuli.

Eckel C, Sötemann D, Kim WK, et al., J Clin Med. 2022 Sep 9;11(18):5313. doi: 10.3390/jcm11185313. PMID: 36142960; PMCID: PMC9502952.

Transcatheter aortic valve implantation in patients with a small aortic annulus: performance of supra-, intra- and infra-annular transcatheter heart valves.

Voigtländer L, Kim WK, Mauri V,et al., Clin Res Cardiol. 2021 Dec;110(12):1957-1966. doi: 10.1007/s00392-021-01918-8. Epub 2021 Aug 13. PMID: 34387736; PMCID: PMC8639544.

Transcatheter Self-Expandable Valve Implantation for Aortic Stenosis in Small Aortic Annuli: The TAVI-SMALL Registry.

Regazzoli D, Chiarito M, Cannataet al., TAVI-SMALL Investigators. JACC Cardiovasc Interv. 2020 Jan 27;13(2):196-206. doi: 10.1016/j.jcin.2019.08.041. Epub 2019 Dec 25. PMID: 31883714

CORONARY OBSTRUCTION

Risk Assessment Of Coronary Obstruction For The ACURATE Transcatheter Heart Valve.

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OFF-LABEL USE

(SAFETY AND EFFECTIVNESS HAVE NOT BEEN ESTABLISHED IN THESE PATIENT POPULATIONS)

VALVE-IN-VALVE

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ALTERNATIVE ACCESS ROUTE

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