ORIGINAL ARTICLE

Impact of a Heart Team in patients with aortic stenosis who are candidates for transcatheter aortic valve replacement

Impacto de un Heart Team en pacientes con estenosis aórtica candidatos a reemplazo percutáneo

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ABSTRACT

As transcatheter aortic valve implantation (TAVI) for aortic stenosis (AS) became widespread, the need for a Heart Team (HT) arose to choose the best treatment. There are few reports regarding its usefulness.
Objectives: To analyze treatment outcomes in patients with AS evaluated by a HT for 10 years.
Methods: Consecutive enrollment of all patients with AS who were candidates for TAVI between January 2012 and July 2021 to choose the best treatment, including surgical aortic valve replacement (SAVR) and conservative medical management (CMM).
Results: Out of 841 patients, 455 were assigned to TAVI (53%), 213 to SAVR (24%), and 183 to CMM (23%). The percentage assigned to TAVI has increased from 48% to 62% over time ($p<0.05$). Patients who underwent TAVI versus those who underwent SAVR were older (86 ± 7 vs. 83 ± 7 years), had a higher EUROSCORE II (6.2, 95% CI 5.7-6.6 vs. 5.6; 95% CI 4.4-6.5) and were frailer (1.62 ± 1 vs. 0.91 ± 1), in all cases $p<0.01$. Actuarial survival (95% CI) at 1 and 2 years was 88% (84-91%) and 82% (77-86%) for TAVI, 83% (76-88%) and 78% (70-84%) for SAVR, and 70% (60-87%) and 59% (48-68%) for CMM, respectively ($p<0.001$).
Conclusions: For the first 10 years after a Heart Team was established for AS decision-making, approximately half of the patients were assigned to TAVI, and the rest were equally assigned in halves to either surgery or observation. Survival for patients who received interventions was similar at 2 years and higher than in those who did not.

Keywords: Aortic stenosis - Transcatheter aortic valve implantation - Prosthetic heart valves.

RESUMEN

La difusión del reemplazo valvular aórtico percutáneo (TAVI) en la estenosis aórtica (EAo) generó la creación de un *Heart Team* (HT), para elegir el mejor tratamiento. Existen pocos reportes sobre su utilidad.
Objetivos: analizar los resultados del tratamiento de los pacientes con EAo evaluados por un HT durante 10 años
Material y métodos: Inclusión consecutiva de todos los pacientes con EAo candidatos a TAVI entre enero del 2012 y julio del 2021 para seleccionar el mejor tratamiento, incluyendo además Cirugía de Reemplazo Valvular Aórtico (CRVA) y Tratamiento Médico Conservador (TMC).
Resultados: De 841 pacientes, se asignaron a: TAVI 455 (53%), CRVA 213 (24%) y TMC 183 (23%). El porcentaje asignado a TAVI aumentó con el tiempo de 48 a 62% ($p<0,05$). Los pacientes que fueron a TAVI, con respecto a los enviados a CRVA eran mayores (86±7 vs 83±7 años), con mayor EUROSCORE II (6,2, IC95% 5,7-6,6 vs 5,6, IC95% 4,4-6,5) y más frágiles (1,62±1 vs 0,91±1), en todos los casos $p<0,01$. La sobrevida actuarial (IC 95%) a 1 y a 2 años fue, para TAVI 88% (84-91%) y 82% (77-86%), para CRVA 83% (76-88%) y 78% (70-84%) y para TMC 70% (60-87%) y 59% (48-68%) respectivamente ($p<0,001$).
Conclusiones: Durante los primeros 10 años de establecido un *Heart Team* para la toma de decisiones en EAo, se asignaron a TAVI aproximadamente la mitad y el resto se asignó por mitades a cirugía u observación. La sobrevida de los pacientes intervenidos fue similar a 2 años y mayor que la de los no intervenidos.

Palabras clave: Estenosis aórtica - Reemplazo de la Válvula Aórtica Transcatéter - Prótesis valvulares cardíacas

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INTRODUCTION

Degenerative aortic stenosis (AS) is a disease with an incidence and prevalence that increase at the same rate as life expectancy in the population. (1) In fact, the degenerative etiology has become the most common, replacing rheumatic heart valve disease. (2)

As the population over 80 years old has been increasing, the problem of how to treat degenerative AS in the elderly has increased as well.

Typically considered to be an end-of-life disease and usually associated with other heart and non-cardiovascular (CV) diseases, the emergence and popularization of transcatheter aortic valve implantation (TAVI) has put the focus on a new therapeutic option for these patients, previously left to the natural progression of the disease. (3)

As in many other cases, appearance of a new treatment led to reconsider the usefulness and selection of candidates for traditional treatment i.e., surgical aortic valve replacement (SAVR). The need to select patients for one treatment or the other derived in multidisciplinary team discussions about the best treatment for different conditions. Thus, a Heart Team (HT) or a Valve Team for AS was created (with no equivalent term in Spanish).

HT discussion about the choice of treatment for degenerative AS was quickly incorporated by clinical practice guidelines, (4,5) though with little evidence due to the lack of large and controlled studies that might show its usefulness. However, the need to discuss the best treatment for these complex patients immediately led to its implementation, and it soon became unavoidable and required when planning a TAVI. (6)

Our site has had a Heart Team for 10 years, so we felt the need to analyze its results and compare the characteristics of the patients assigned to each treatment.

METHODS

Design: A retrospective and single site study with consecutive enrollment of all patients with severe AS evaluated by the HT from January 2012 to July 2021. HT referral criteria were the following: 1) cases already selected for TAVI, and 2) uncertain cases when choosing between TAVI, SAVR and conservative medical management (CMM) as the best strategy. TAVI was recommended for symptomatic patients with known severe AS and variables warranting indication, such as increased surgical risk, old age, frailty, and suitability for the procedure, while SAVR was advised in patients with a lower surgical risk, unsuitable for TAVI, or requiring another intervention. Patients who failed to meet intervention criteria, patients for whom invasive treatment was considered futile, patients with a life expectancy of less than 1 year, or patients who refused to receive the procedure continued with CMM.

Severe AS was defined as a valve area ≤1 cm^2 (or ≤0.6 cm^2/m^2), based on the definition of the ESC (European Society of Cardiology) guidelines on valvular heart disease. (4) When in doubt, especially in cases of low-flow, low-gradient AS, the Agatston aortic valve calcium score by computed tomography (CT) was used, where a score over 2000 in men and 1300 in women was considered as severe. (5) All patients under intervention were evaluated by catheter coronary angiography, and a vast majority were also assessed using multi-layer contrast CT.

Members of the HT: The HT was composed of, at least, one cardiovascular surgeon, one interventional cardiologist, one CV imaging specialist, and one clinical cardiologist specialized in valve disease. The HT held weekly meetings (online during the pandemic). In case of disagreement, agreement was reached via a new discussion. The number of evaluated patients, recommended management, and interventions were annually compared over 10 years. Patients under intervention were followed up via personal, telephone or e-mail contact.

Frailty score: The degree of frailty was measured using Fried 1-5 scale assessing mobility, autonomy, handgrip response, etc. (7). A patient with a score ≥ 2 was considered frail according to median values.

Statistical analysis

Quantitative variables were reported as mean ± standard deviation (SD) or median and interquartile range (IQR) based on distribution and were compared using the Kruskal Wallis multiple comparisons test; categorical variables were reported as percentages and compared using the multiple chi-square test. A p value <0.05 was considered to be statistically significant. The STATA 13 statistical package was used.

Ethical considerations

The protocol was sent to the PRIISA platform and approved by the institutional Ethics Committee.

RESULTS

Of 841 evaluated patients, 455 (54%) were assigned to TAVI, of which 385 (85% of those assigned) received treatment; 213 (25%) were assigned to SAVR, of which 183 (86% of those assigned) underwent surgery and 173 (22%) received CMM (Figure 1).

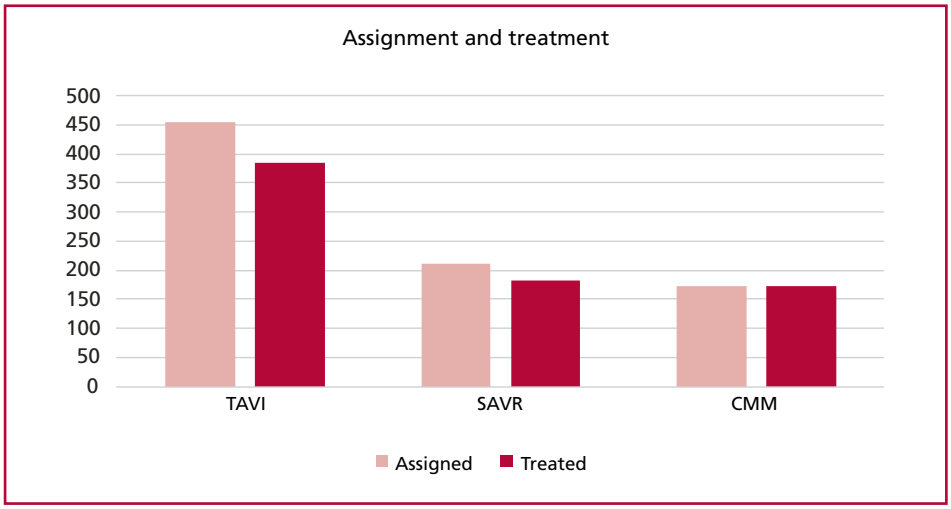
The number of patients evaluated by the HT increased every year, with a marked reduction associated with the COVID-19 pandemic (see Figure 2). The proportion of patients under TAVI also increased from 48% in the first half of the assessed patients to 65% in the most recent half (p <0.05).

The baseline characteristics of the patients assigned to every treatment are summarized in Table 1: the mean age was 85 ± 5 years, 46% were female, the aortic valve area determined by ultrasound was 0.67 ± 0.2 cm^2, the left ventricular ejection fraction (LVEF) was 55 ± 13%, 53% had coronary artery disease, and 46% had comorbidities. Patients assigned to TAVI were older than those assigned to SAVR, had a smaller valve area, had a higher EuroSCORE II, and were frailer. Those assigned to CMM were similar to those who underwent TAVI, except for the larger valve area.

Actuarial survival (95% CI) at 1 and 2 years was 88% (84-91%) and 82% (77-86%) for TAVI, 83% (76-88%) and 78% (70-84%) for SAVR, and 70% (60-87%) and 59% (48-68%) for CMM, respectively, (p <0.001, Figure 3).

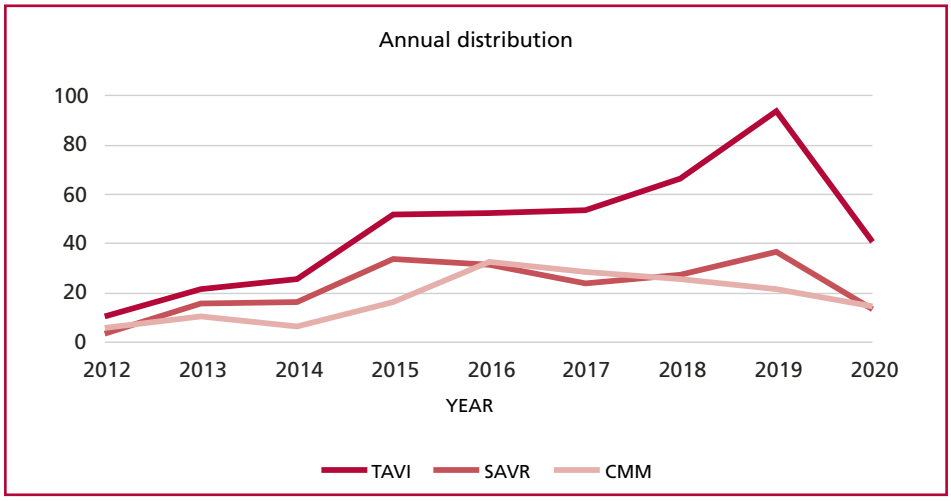
The independent predictors of actuarial mortality are detailed in Table 2.

Fig. 1. Heart Team assignment and actual treatment received.



CMM: conservative medical management; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

Fig. 2. Number of patients evaluated by the HT and recommended management. The proportion assigned to TAVI increased significantly over the years. The decrease in 2020 is related to the COVID-19 pandemic.



CMM: conservative medical management; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation.

Table 1. Comparison of patients assigned to TAVI, SAVR and CMM by the HT

	TOTAL: 841	TAVI: 455	SAVR: 213	CMM: 173	p
Age (years), mean + SD	85 ± 5	87 ± 6	83 ± 8	86 ± 8	<0.001*
Male sex (%)	54	54	61	57	<0.05 **
Valve area, cm², median (IQR)	0.67 (0.5-0.8)	0.65 (0.5-0.8)	0.69 (0.6-0.9)	0.70 (0.5-0.8)	<0.05***
LVEF (%), mean + SD	55 ± 13	55 ± 11	55 ± 12	54 ± 12	NS
Comorbidities (%)	46	46	44	49	NS
Coronary artery disease (%)	53	55	57	44	NS
EuroSCORE II, median (IQR)	6.0 (4.2-7.0)	6.1 (3.8-7.8)	5.6 (2.6-6.2)	6.1 (3.8-6.4)	<0.05*
Frailty score, mean ± SD	1.49 ± 1	1.62 ± 1	0.91 ± 1	1.74 ± 1	<0.05*

*SAVR vs. TAVI and CMM; **CMM vs. SAVR and TAVI; ***TAVI vs. SAVR and CMM
CMM: conservative medical management
IQR: interquartile range
LVEF: left ventricular ejection fraction
SAVR: surgical aortic valve replacement
SD: standard deviation
TAVI: transcatheter aortic valve implantation

DISCUSSION

The emergence of a new therapeutic option like TAVI in patients with severe AS –which to a large extent supplements the treatment of patients with high surgical risk– also requires a multidisciplinary approach in the cardiovascular team in charge of these patients.

Thus, there emerged the need to discuss the most appropriate management for each case by interventionists, surgeons, imaging specialists, valve disease specialists, etc. (8)

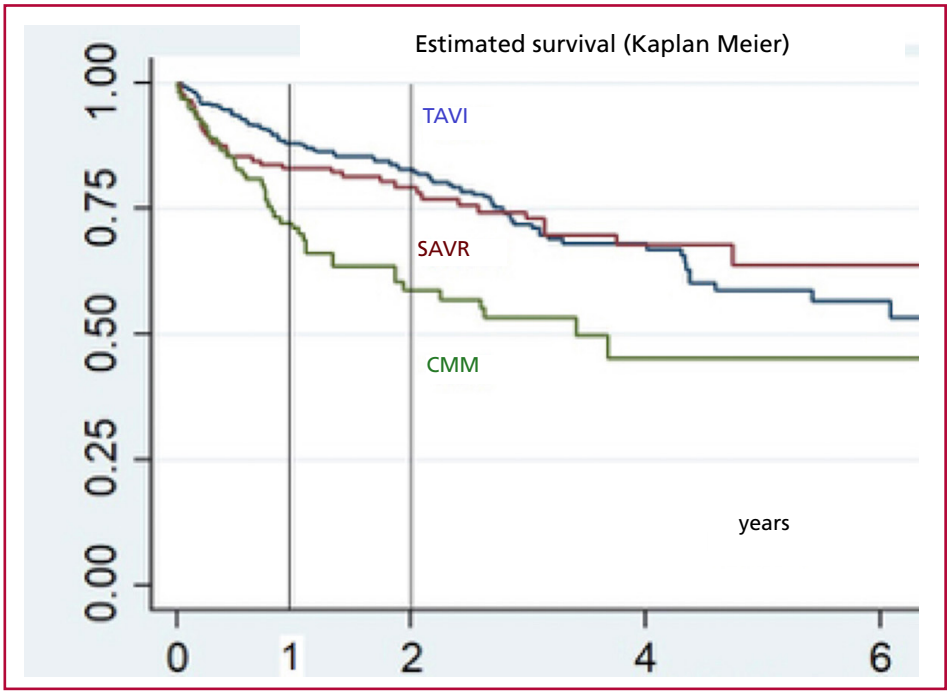
Though recommendations by the scientific societies are unanimous and often required by procedure funders, the lack of publications on the results of the Heart Team (HT) is remarkable both nationally and globally. (9-12).

Therefore, the objective of this study was to analyze the results of treatment in patients with AS evaluated by the HT over the first 10 years of its creation.

Notably, during this period some changes occurred both in the prostheses and in the implantation techniques, and experience was gained in terms of diagnosis, patient selection, and therapy. (13) In addition, the acceptance of a new therapeutic approach allowed us to evaluate more patients with no prior intervention. In fact, the annual analysis showed sustained increase in evaluated patients, as well as a larger number of TAVIs, with an average of half the patients under assessment, and there was a significant decrease associated with the COVID-19 pandemic, which reflects the side effect suffered by this population with severe cardiovascular conditions. (14)

About half of the patients were assigned to TAVI (this percentage increased to 60% in the last few years due to the increased acceptance of the procedure), and the rest were equally assigned to surgery or conservative management. These percentages are remarkably similar to those recently presented by the HT from the Italian group of Burzotta et al., for patients with valvular heart disease, with 77% experiencing AS. (15)

Evaluated patients were mostly in their eighties,



CMM: conservative medical management; SAVR: surgical aortic valve replacement; TAVI: transcatheter aortic valve implantation

Fig. 3. Actuarial survival for patients under TAVI (transcatheter aortic valve implantation), SAVR (surgical aortic valve replacement) or CMM (conservative medical management) as recommended by the HT.

	RR	95% CI	p
Age	1.04	1.01–1.06	0.002
LVEF	0.98	0.97–0.99	0.015
Renal failure	1.58	1.16–2.17	0.004
Diabetes	1.52	1.07–2.15	0.018
CMM	1.99	1.41–2.81	0.001

CMM: conservative medical management; LVEF: left ventricular ejection fraction; RR: relative risk

Table 2. Independent predictors of actuarial mortality.

had severe AS (reconfirmed by the HT, a major task of this team), were mostly asymptomatic, had comorbidities and an estimated surgical risk that was at least intermediate, and an EuroSCORE II around 6, on average. The LVEF was near the lower limit of normal, and at least half of the patients had coronary artery disease.

Patients selected for TAVI were comparable to those selected for SAVR, except for a higher estimated surgical risk in the former, who were older and frailer. Actuarial survival at 1 and 2 years (88% and 82% with TAVI, 83% and 78% with SAVR, p = NS) seems to be reasonable with both strategies and suggests an adequate choice of treatment in a setting where access to transcatheter valve implantations is limited by high costs.

Focus should be made on the group under CMM: this is a heterogenous group ranging from a subgroup with less severe valve disease and absence of symptoms i.e., with no intervention indicated at the time of assessment, to a subgroup with no intervention required due to the lack of severe comorbidities, futility or end stage, also including patients who refuse to have the intervention, thus making a comparison difficult.

As observed virtually in every set, patients without intervention show significantly poorer survival (70% and 59% at 1 and 2 years), which supports intervention in candidates. In fact, CMM was the main mortality predictor in a multivariate analysis (see Table 2), with a relative risk near 2: patients under (non-interventional) medical management had twice the mortality rate of those under intervention (either with TAVI or surgery) during the follow-up, beyond other risk predictors.

Notably, patients evaluated by the HT were not all patients with AS but those considered for TAVI. Patients with an indication of conventional surgery or patients for whom no intervention was considered were not evaluated. This is the most common strategy at present and seems to be the future in terms of the HT. (16)

Our study showed 12% mortality at 1 year for TAVI, 17% for SAVR, and 30% for CMM. The Portuguese group from Catia Costa et al. (10) published a similar study of 473 patients evaluated by their HT over 8 years: mortality after a year was 16% for TAVI, 11% for surgery, and 20% for medical management. For the Spanish group from Diego Iglesias et al. (11), mortality at 1 year was 20% for TAVI and 18% for surgery. In addition, this study analyzed the prognostic value of the HT decision in the long term and found that such decision was an independent predictor of long-term mortality. The results from our study can also be compared to those from large studies, such as PARTNER and SURTAVI. (17,18) In our setting, the only publication referring to the usefulness of the HT for AS is the work by Garmendia et al. on new hospitalization predictors. (19)

Limitations

As cited above, our study has a selection bias, as it includes only patients considered to be candidates for TAVI. (20,21) Another limitation is the retrospective nature of data collection, the involvement of only one site (making it difficult to generalize findings), and major financial restrictions in terms of percutaneous valves availability in our setting, especially in the first half of the decade under analysis.

CONCLUSIONS

Ten years after creation of the Heart Team to select patients with AS who are candidates for TAVI, about half of them have been assigned to TAVI, while the rest were divided in two to undergo either surgery or observation. Patients under intervention seem to follow the selection pattern suggested by the team. Survival in patients under intervention seems to be similar up to 2 years with TAVI or SAVR, and is reasonable for both strategies, which suggests an adequate choice of treatment. Worse progression in patients under no intervention supports an invasive strategy in those who are candidates for intervention.

Conflicts of interest

None declared.

(See authors' conflict of interests forms on the web).

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REFERENCES

1. Nkomo VT, Gardin JM, Skelton TN, Gottdiener JS, Scott CG, Enriquez-Sarano M, et al. Burden of valvular heart diseases: a population-based study. Lancet 2006; 368:1005-11. https://doi.org/10.1016/S0140-6736(06)69208-8

2. Braunwald E. Aortic Stenosis: Then and Now. Circulation. 2018;137:2099-100. https://doi.org/10.1161/CIRCULATIONAHA.118.033408

3. Osnabrugge RL, Mylotte D, Head SJ, Van Mieghem NM, Nkomo VT, LeReun CM, et al. Aortic stenosis in the elderly: disease prevalence and number of candidates for transcatheter aortic valve replacement: a meta-analysis and modeling study. J Am Coll Cardiol. 2013;62:1002-12. https://doi.org/10.1016/j.jacc.2013.05.015

4. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al.; ESC/EACTS Scientific Document Group. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2022;43:561-632. https://doi.org/10.1093/eurheartj/ehab395

5. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP 3rd, Gentile F, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: executive summary: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2021;143:e35–e71. https://doi.org/10.1161/CIR.0000000000000932

6. de Jaegere PPT, de Weger A, den Heijer P, Verkroost M, Baan J, de Kroon T, et al.Treatment decision for transcatheter aortic valve implantation: the role of the heart team : Position statement paper of the Dutch Working Group of Transcatheter Heart Interventions. Neth Heart J. 2020;28:229-39. https://doi.org/10.1007/s12471-020-01367-4

7. Fried LP, Tangen CM, Walston J, Newman AB, Hirsch C, Gottdiener J, et al. Frailty in older adults: evidence for a pheno-

type. J Gerontol A Biol Sci Med Sci. 2001;56:M146-56. https://doi.org/10.1093/gerona/56.3.M146

8. Otto CM, Baumgartner H. Updated 2017 European and American guidelines for prosthesis type and implantation mode in severe aortic stenosis. Heart. 2018;104:710-3. https://doi.org/10.1136/heartjnl-2017-312487

9. Dubois C, Coosemans M, Rega F, Poortmans G, Belmans A, Adriaenssens T, et al. Prospective evaluation of clinical outcomes in all-comer high-risk patients with aortic valve stenosis undergoing medical treatment, transcatheter or surgical aortic valve implantation following heart team assessment. Interact Cardiovasc Thorac Surg. 2013;17:492-500. https://doi.org/10.1093/icvts/ivt228

10. Costa C, Teles RC, Brito J, Neves JP, Gabriel HM, Abecassis M, et al. Advantages of a prospective multidisciplinary approach in transcatheter aortic valve implantation: Eight years of experience. Rev Port Cardiol. 2017; 36:809-18. https://doi.org/10.1016/j.repc.2016.11.015

11. Iglesias D, Salinas P, Moreno R, García-Blas S, Calvo L, Jiménez-Valero S, et al. Prognostic impact of decisions taken by the heart team in patients evaluated for transcatheter aortic valve implantation. Rev Port Cardiol 2015;34:587-95. https://doi.org/10.1016/j.repc.2015.03.013

12. Bouleti C, Chauvet M, Franchineau G, Himbert D, Iung B, Alos B, et al. The impact of the development of transcatheter aortic valve implantation on the management of severe aortic stenosis in high-risk patients: treatment strategies and outcome. Eur J Cardiothorac Surg. 2017;51:80-8. https://doi.org/10.1093/ejcts/ezw211

13. Antonides C, Mack M, Kappetein A. Approaches to the Role of The Heart Team in Therapeutic Decision Making for Heart Valve Disease. Structural Heart 2017;1:249-55. https://doi.org/10.1080/24748706.2017.1380377

14. Giordano A, Biondi-Zoccai G, Frati G, Bartorelli AL. Management of Structural Heart Disease and Acute Coronary Syndromes in the COVID-19 Pandemic. Curr Atheroscler Rep. 2020;22:29-35. https://doi.org/10.1007/s11883-020-00849-5

15. Burzotta F, Graziani F, Trani C, Aurigemma C, Bruno P, Lombardo A, et al. Clinical Impact of Heart Team Decisions for Patients with Complex Valvular Heart Disease: A Large, Single-Center Experience. J Am Heart Assoc. 2022;11:e024404. https://doi.org/10.1161/JAHA.121.024404

16. Khan S, Shi W, Kaneko T, Baron SJ. The Evolving Role of the Multidisciplinary Heart Team in Aortic Stenosis. US Cardiology Review 2022;16:e19. https://doi.org/10.15420/usc.2022.04

17. Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al and PARTNER Trial Investigators. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med. 2010;363:1597-607. https://doi.org/10.1056/NEJMoa1008232

18. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients N Engl J Med 2017;376:1321-31. https://doi.org/10.1056/NEJMoa1700456

19. Garmendia CM, Seropian IM, Chiabrando JG, Medina de Chazal H, Cal M, Kotowicz V, y cols. Prevalencia, predictores e impacto clínico de la rehospitalización en pacientes con estenosis valvular aórtica valorados por un Heart Team. Rev Argent Cardiol 2021;89:501-6. http://dx.doi.org/10.7775/rac.es.v89.i6.20459

20. Adams HSL, Ashokkumar S, Newcomb A, MacIsaac AI, Whitbourn RJ, Palmer S. Contemporary review of severe aortic stenosis. Intern Med J. 2019;49:297-305. http://dx.doi.org/10.1111/imj.14071.

21. Youn S, Wong SA, Chrystoja C, Tomlinson G, Wijeysundera HC, Bell CM, et al. Bias estimation in study design: a meta-epidemiological analysis of transcatheter versus surgical aortic valve replacement. BMC Surg. 2021;21:285. http://dx.doi.org/10.1186/s12893-021-01278-0.