Single-arm Meta-analysis of Argentine Studies Reporting 30-Day Mortality After Transcatheter Aortic Valve Implantation in Intermediate-Risk Patients

Metaanálisis sobre los resultados a 30 días del implante valvular aórtico transcatéter en pacientes con riesgo intermedio en Argentina

RAÚL A. BORRACCI[1] (iD) , EUGENIA AMREIN[2], CLAUDIO C. HIGA[2]

ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) has proved to be beneficial in intermediate-risk patients; however, there is no analysis reporting overall TAVI results in our country.
Objectives: The aim of this investigation was to conduct a meta-analysis of single-arm local studies reporting in-hospital TAVI outcomes in intermediate-risk patients in Argentina.
Methods: A systematic review was performed including observational TAVI studies identified in MEDLINE, Embase, SCOPUS and Cochrane to August 2019.
Results: Among 59 articles identified through the database search, only 4 local observational studies reported 30-day mortality and complications after TAVI in moderate-risk patients, with Society of Thoracic Surgeons (STS) score ranging between 4% and 7%. In 494 patients, 30-day mortality was 4.8%. Weighted pooled estimates of the studies were: stroke 2.7%, myocardial infarction 1.0%, need for definitive pacemaker 24.8%, moderate or severe periprosthetic leak 16.7%, and major bleeding 5.5%.
Conclusions: The proven efficacy of TAVI is expanding its indication to intermediate and low-risk patients. However, this shift should be supported by local evidence of its benefit over traditional valve surgery. This single-arm meta-analysis of Argentine studies presents 30-day mortality and complications after TAVI in intermediate-risk patients. The updated information of local TAVI outcomes will serve as a standard in our setting.

Keywords: Aortic valve stenosis - Transcatheter aortic valve implantation - Meta-analysis - Argentina

RESUMEN

Introducción: El implante valvular aórtico transcatéter (TAVI) ha mostrado ser beneficioso en los pacientes con riesgo intermedio; sin embargo, no existe ningún análisis del conjunto de los resultados del TAVI en nuestro país.
Objetivos: Realizar un metaanálisis de estudios de grupo único locales sobre los resultados hospitalarios del TAVI en pacientes de riesgo intermedio en Argentina.
Métodos: Se realizó una revisión sistemática utilizando estudios observacionales de TAVI identificados en MEDLINE, Embase, SCOPUS y Cochrane hasta agosto de 2019.
Resultados: De 59 estudios identificados a través de la búsqueda en bases de datos, solamente 4 artículos observacionales locales comunicaron la mortalidad a 30 días y las complicaciones posteriores al TAVI en pacientes de riesgo moderado con puntaje STS (Society of Thoracic Surgeons) ente 4% y 7%. En 494 pacientes, la mortalidad a 30 días fue 4.8%. Las estimaciones ponderadas del conjunto de estudios fueron: accidente vascular cerebral 2.7%, infarto de miocardio 1.0%, necesidad de marcapasos definitivo 24.8%, fuga paravalvular moderada o grave 16.7% y sangrado mayor 5.5%.
Conclusiones: La eficacia demostrada del TAVI está generando una expansión de su indicación a pacientes con riesgo intermedio y bajo; sin embargo, este avance debería estar apoyado por evidencia local de su beneficio sobre la cirugía valvular tradicional. Este metaanálisis de estudios de grupo único argentinos presenta la mortalidad a 30 días y las complicaciones posteriores al TAVI en pacientes de riesgo intermedio. La información actualizada de los resultados locales del TAVI servirán como un estándar en nuestro medio.

Palabras clave: Estenosis valvular aórtica - Implantación transcutánea de la válvula aórtica - Metaanálisis - Argentina

[1] Biostatistics, School of Biomedical Sciences, Universidad Austral, Argentina
[2] Cardiology Service, Herzzentrum, Hospital Alemán, Buenos Aires, Argentina

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has proved to be beneficial in patients at high risk for conventional aortic valve replacement surgery. (1-3) In addition, recent controlled clinical trials in intermediate-risk patients [Society of Thoracic Surgeons (STS) score between 4% and 7% for expected 30-day mortality with surgery] as well as low-risk patients (STS <4%) have demonstrated the non-inferiority or superiority of TAVI compared with conventional surgery at 1 or 2-year follow-up. (4-8) Based on this initial evidence, the 2017 European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines suggest a series of indications for TAVI or surgery, but do not detail an unequivocal list of recommendations. (9) Therefore, each cardiology center should develop its own recommendations and decision-making processes within the heart-team, based not only on the individual patient but also on the experience and results of each particular center.

A meta-analysis of local studies reporting aortic valve replacement outcomes in low-and intermediate-risk patients has been recently published in Argentina. In the absence of controlled clinical trials, the authors have proposed using this information as a reference point to compare with the performance of TAVI in our setting. (10) Since there is no analysis of overall TAVI results in our country, the aim of this work was to perform a meta-analysis of local single-arm studies of in-hospital TAVI outcomes in intermediate-risk patients in Argentina. Only intermediate-risk studies were considered since at the moment there are no local publications of TAVI carried out in low-risk patients.

METHODS

A systematic review strategy was carried out using controlled clinical trials and observational studies identified in MEDLINE, Embase, SCOPUS and Cochrane until August 31, 2019. Studies with patients classified as moderate risk according to the STS score and undergoing either isolated or combined with coronary angioplasty TAVI in Argentina were included in the meta-analysis, while those that did not report in-hospital or 30-day mortality or complications as endpoints were excluded from the analysis. Publications were limited to articles in Spanish or English. The search strategy included the terms: "aortic valve" AND "transcatheter aortic valve implantation" OR "transcatheter aortic valve replacement" AND "Argentina [Affiliation]" as keywords or MeSH terms. All data was retrieved from article texts, tables and figures. Two researchers (R.A.B and E.A.) independently reviewed citations and collected data, and all discrepancies were resolved by consensus. Study quality assessment was done using the Dutch Cochrane Center systematic review guidelines proposed by MOOSE. (11)

Statistical analysis

A proportion meta-analysis of single-arm studies was performed for the primary endpoints of 30-day all-cause mortality and post-procedural complications. Categorical data were compared with the chi-square test or Fisher's exact test as appropriate. The proportions of each endpoint with their 95% confidence intervals (CI) and forest plots were calculated with MedCalc Statistical Software, version 18.6 (MedCalc Software bvba, Ostend, Belgium; http: //www.medcalc.org; 2018) using fixed and random-effect models. Heterogeneity between studies was analyzed using Cochran's Q test and the Higgins I^2 test (I^2 values of 25%, 50% and 75% were interpreted as low, moderate and high heterogeneity). Funnel plots were used to identify studies that affected heterogeneity and to assess publication bias. Because only 4 studies were included in the meta-analysis, we avoided using the Begg method as it was expected to have low power to detect bias.

Ethical considerations

The protocol was assessed and approved by the Institutional Review Board which waived the need for informed consent to use the data.

RESULTS

Among a total of 59 studies identified through the database search, only 4 observational articles reported 30-day mortality and post-TAVI complications in moderate-risk patients according to the STS score. (12-15) Baseline characteristics of the studies included in the meta-analysis are shown in Table 1. Overall study analysis showed that 47.4% of the patients were male, with a weighted mean age of 80.7 years (standard deviation: 7.1), and 87.0% had undergone isolated aortic valve replacement. According to the Dutch Cochrane Centre and Moose guidelines, the intra-study risk of bias assessment showed that the four selected studies were considered to be of high quality. Visual inspection of funnel plots (not shown) did not reveal significant asymmetry for the rates of all-cause death and some complications. These results suggest that publication bias had no significant influence, except in the rates of major bleeding and need for permanent pacemaker implantation. Figure 1a shows the forest plot and pooled analysis of the four studies reporting 30-day mortality after TAVI in intermediate-risk patients. In 494 patients, 30-day mortality was 4.8%, while heterogeneity between studies was low.

Meta-analyses summarizing post-TAVI complications are shown in Figures 1b, 2, and 3. The weighted pooled estimate of stroke was 2.7% (Figure 1b). Post-procedural infarction and need for definitive pacemaker implantation were 1.0% (Figure 2a) and 24.8% (Figure 2b), respectively. Finally, the weighted pooled rate of moderate or severe para-valvular leak was 16.7% (Figure 3a), and major bleeding 5.5% (Figure 3b). Regarding complications, the evaluation of heterogeneity between studies was low for stroke, myocardial infarction and major bleeding, and high for pacemaker implantation and paravalvular leak after the procedure. The p values for the Cochran Q test and the I^2 percentages for the Higgins test were associated with each forest plot.

Table 2 shows the comparison between the results of the present study and a local meta-analysis of aortic valve replacement in intermediate-risk patients.

Table 1. Baseline characteristics of the studies included in the meta-analysis

| Study	Number of centers	Period	Risk score	Reported risk	Mean age	TAVI alone
Fava et al.[12]	single center	2009-2018	STS	intermediate	80 years	85%
Raleigh et al.[13]	single center	2009-2016	STS	intermediate	80 years	100%
Abud et al.[14]	single center	2009-2016	STS	intermediate	83 years	100%
Cigalini et al.[15]	single center	2009-2016	STS	intermediate	80 years	100%

TAVI: Transcatheter aortic valve implantation. STS: Society of Thoracic Surgeons risk score.

Fig. 1. Meta-analysis of local single-arm studies showing 30-day mortality (a) and stroke (b) after transcatheter aortic valve implantation in intermediate-risk patients.
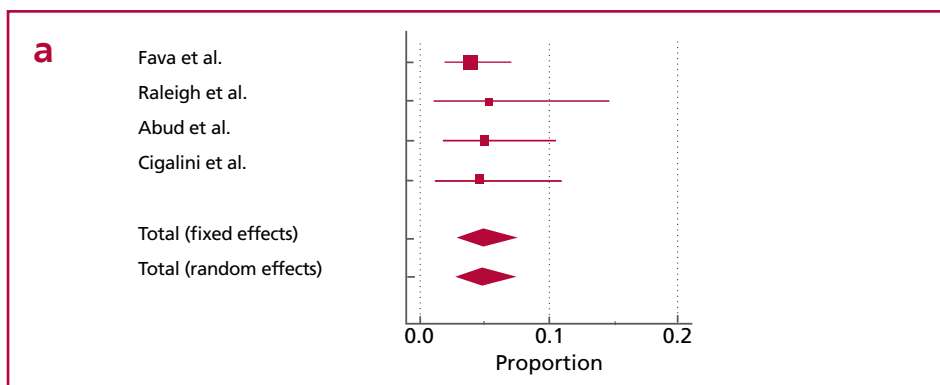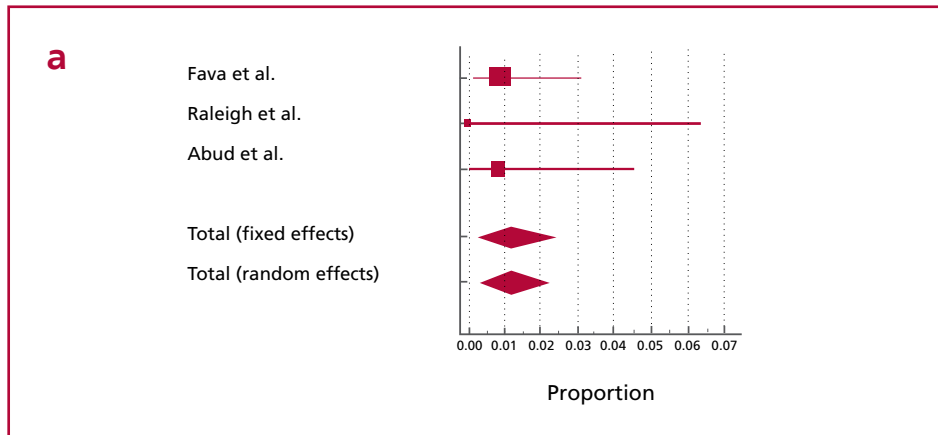

Study	Sample	Mortality	Proportion (%)	95% CI
Fava et al.[12]	229	9	3.93	1.81 to 7.33
Raleigh et al.[13]	56	3	5.36	1.12 to 14.9
Abud et al.[14]	121	6	4.96	1.84 to 10.5
Cigalini et al.[15]	88	4	4.55	1.25 to 11.2
Total (fixed effects)	494	22	4.79	3.09 to 7.05
Total (random effects)	494	22	4.79	3.09 to 6.83

Heterogeneity tests: Cochran Q=0.514, p=0.916; I^2 = 0.0% (95% CI 0.00 to 24.7).
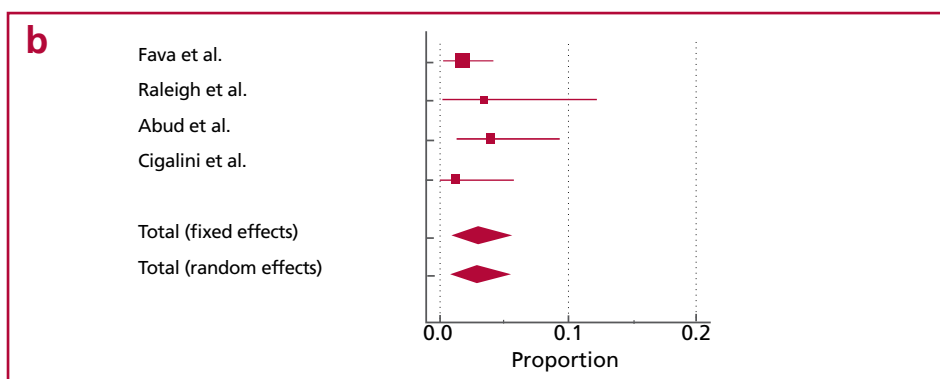
Study	Sample	Stroke	Proportion (%)	95% CI
Fava et al.[12]	229	4	1.75	0.48 to 4.41
Raleigh et al.[13]	56	2	3.57	0.44 to 12.3
Abud et al.[14]	121	5	4.13	1.36 to 9.38
Cigalini et al.[15]	88	1	1.14	0.03 to 6.17
Total (fixed effects)	494	12	2.67	1.44 to 4.49
Total (random effects)	494	12	2.67	1.44 to 4.26

Heterogeneity tests: Cochran Q=2.666, p=0.446; I=0.0% (95% CI 0.00 to 85.5).

Fig. 2. Meta-analysis of local single-arm studies showing the proportion of myocardial infarction (a) and need for definitive pacemaker (b) after transcatheter aortic valve implantation in intermediate-risk patients.

Study	Sample	Infarction	Proportion (%)	95% CI
Fava et al.[12]	229	2	0.87	0.15 to 3.12
Raleigh et al.[13]	56	0	0.00	0.00 to 6.38
Abud et al.[14]	121	1	0.83	0.02 to 4.52
Total (fixed effects)	406	3	1.00	0.28 to 2.52
Total (random effects)	406	3	1.00	0.27 to 2.20

Heterogeneity tests: Cochran Q=0.315, p=0.854; I²=0.0% (95% CI 0.00 to 78.7).
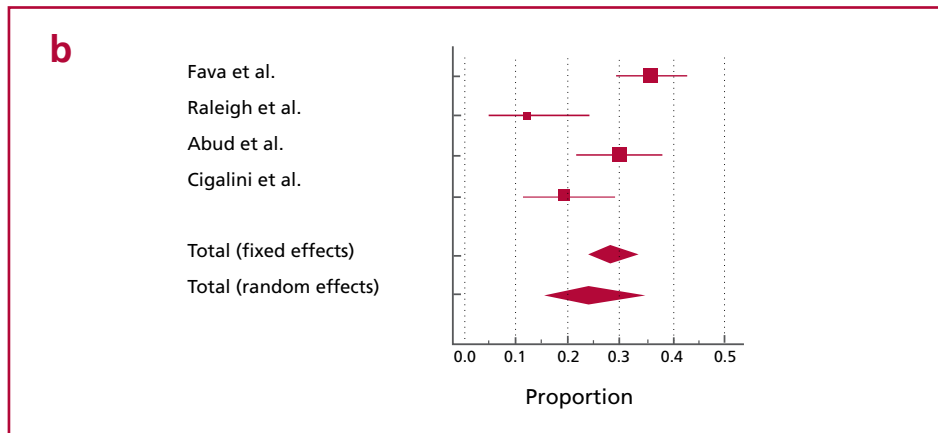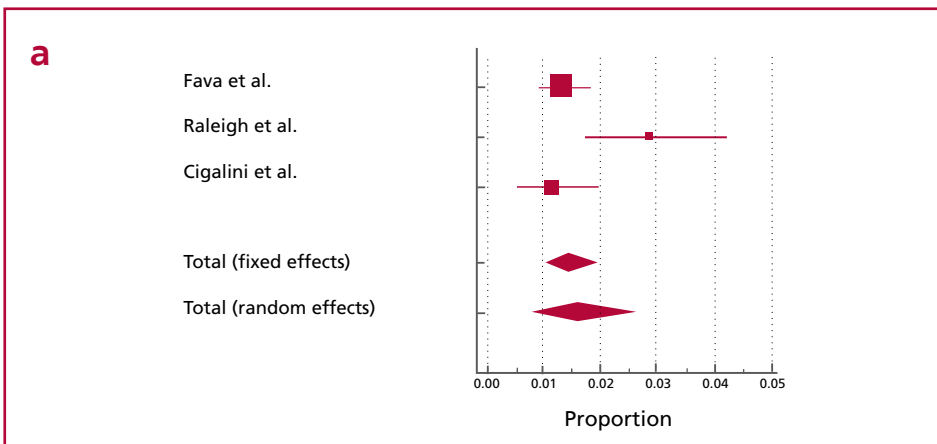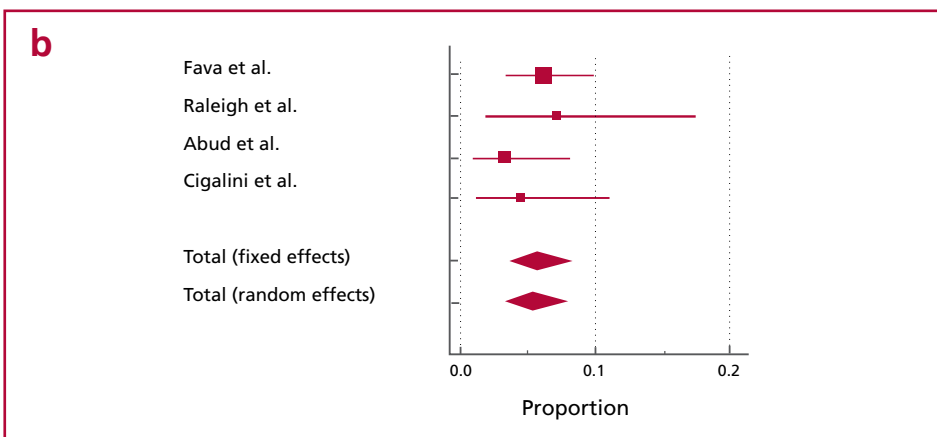

Study	Sample	Pacemaker	Proportion (%)	95% CI
Fava et al.[12]	229	82	35.8	29.6 to 42.4
Raleigh et al.[13]	56	7	12.5	5.18 to 24.1
Abud et al.[14]	121	36	29.8	21.9 to 38.7
Cigalini et al.[15]	88	17	19.3	11.7 to 29.1
Total (fixed effects)	494	142	28.5	24.6 to 32.7
Total (random effects)	494	142	24.8	15.7 to 35.3

Heterogeneity tests: Cochran Q=18.11, p=0.0004; I²=83.4% (95% CI 57.9 to 93.5).

Fig. 3. Meta-analysis of local single-arm studies showing the ratio of moderate to severe residual paravalvular leak (a) and major bleeding (b) after transcatheter aortic valve implantation in intermediate-risk patients.

Study	Sample	Paravalvular leak	Proportion (%)	95% CI
Fava et al.[12]	229	30	13.1	9.02 to 18.2
Raleigh et al.[13]	56	16	28.6	17.3 to 42.2
Cigalini et al.[15]	88	10	11.4	5.59 to 19.9
Total (fixed effects)	373	56	15.0	11.5 to 19.0
Total (random effects)	373	56	16.7	9.20 to 25.8

Heterogeneity tests: Cochran Q=7.982, p=0.019; I²=74.9% (95% CI 16.9 to 92.4.

Study	Sample	Major bleeding	Proportion (%)	95% CI
Fava et al.[12]	229	14	6.11	3.38 to 10.0
Raleigh et al.[13]	56	4	7.14	1.98 to 17.3
Abud et al.[14]	121	4	3.31	0.91 to 8.25
Cigalini et al.[15]	88	4	4.55	1.25 to 11.2
Total (fixed effects)	494	26	5.54	3.70o t 7.92
Total (random effects)	494	26	5.54	3.70 to 7.71

Heterogeneity tests: Cochran Q=1.756, p=0.625; I²=0.0% (95% CI 0.00 a 78.0.

DISCUSSION

In the present investigation, the pooled analysis of the four observational studies included in the meta-analysis showed updated hospital outcomes of TAVI in intermediate-risk patients treated in high-volume surgical centers of Argentina. Compared with the PARTNER 2A (4) and SURTAVI (6) trials, lower rates of stroke, myocardial infarction and major bleeding were observed in the present meta-analysis; while all-cause mortality, need for permanent pacemaker, and moderate or severe paravalvular leak were higher. Somehow, these data represent the results of real TAVI practice in our local setting. In line with actual practice, in a Sapien 3® implantation registry, Thourani et al. (5) reported a one-year mortality rate of 7.4%, with stroke and paravalvular leak of 2.0%, respectively. Other reviews also based on the real world showed a significant variation of TAVI outcomes in different European countries. (16)

In a recent systematic review of almost 4,800 intermediate-risk patients undergoing TAVI or aortic valve replacement, a similar 30-day mortality was observed with both procedures, although the incidence of need for pacemaker and paravalvular leak was higher with TAVI. Nevertheless, when only the femoral access was analyzed, TAVI had lower in-hospital mortality than surgery. (17) Also, the comparison of immediate TAVI outcomes with respect to another local meta-analysis that included aortic valve replacement in intermediate-risk patients (10), showed similar risk rates of mortality, stroke, infarction and major bleeding, while need for definitive pacemaker and moderate or severe paravalvular leak were significantly higher with TAVI.

Several studies have demonstrated how the operator experience reduces complication rates and mortality in TAVI (18-19); and also, how the number of cases needed in the learning curve varies with the type of prosthesis used. (20) Given that achieving a good degree of proficiency in TAVI could require several dozen cases per operator, it is expected that in the future the current complication rates will be reduced.

Although only immediate outcomes could be assessed in this meta-analysis, so far, only limited evidence has been accumulated on the long-term durability of TAVI. (21-23) In the 5-year follow-up of 50 patients in the PARTNER-1A and -1B trials, no changes in transvalvular gradient or premature structural implant damage were observed. (1, 2) Similar results were found in 174 patients in the CoreValve US Pivotal Trial after a 3-year follow-up. (3) The prevalence of significant structural damage at 5 years increased to 1.4% in an Italian trial that included 353 patients receiving a self-expanding CoreValve prosthesis. (24) Recent data from a TAVI pioneering center that included 378 patients receiving balloon-expandable valves between 2002 and 2012 and were followed up for at least 5 years, showed a structural damage rate of 3.2%, while bioprosthesis failure was 0.58% after a mean follow-up of 8 years. (25) In 241 patients in the UK TAVI registry, the prevalence of moderate structural damage was 8.7%, and that of severe damage 0.4% at a mean follow-up of 5.8 years. (26)

Limitations

The main limitation of the present study is given by the natural restriction associated with a single-arm meta-analysis, which in this case is the lack of a control group for aortic valve replacement. A second limitation is that this pooled analysis does not represent the entire population of patients undergoing TAVI annually in Argentina. Finally, since the cohorts span the period from 2009 to 2018, the learning curve of the early years could have compromised the overall results of the study.

CONCLUSIONS

This meta-analysis of studies conducted in Argentine centers presents in-hospital mortality and postoperative complications after TAVI in intermediate-risk patients. The information provided by this local TAVI evaluation will serve as a reference point to compare results with aortic valve replacement in our setting.

Conflicts of interest
None declared.
(See authors' conflicts of interest forms on the website/ Supplementary material)

Endpoint	Present study (TAVI) n (%)	AVR meta-analysis[10] n (%)	p
Number of patients	494	255	
Average STS score (estimated)	6.3%	5.1%	0.516*
30-day all-cause mortality	22 (4.5)	14 (5.5)	0.596
Stroke	12 (2.4)	4 (1.6)	0.440
Myocardial infarction	3 (0.6)	1 (0.4)	1.000
Definitive pacemaker	142 (28.7)	6 (2.4)	<0.001
Moderate/severe paravalvular leak	56 (11.3)	3 (1.2)	<0.001
Major bleeding/reoperation	26 (5.3)	9 (3.5)	0.287

Table 2. Comparison of the results of the present study with a local meta-analysis of aortic valve replacement in intermediate-risk patients.

AVR: Aortic valve replacement. TAVI: Transcatheter aortic valve implantation. STS: Society of Thoracic Surgeons risk score
*estimated chi² difference over the total of each group.

REFERENCES

1. Kapadia SR, Leon MB, Makkar RR, Tuzcu EM, Svensson LG, Kodali S, et al. 5-year outcomes of transcatheter aortic valve replacement compared with standard treatment for patients with inoperable aortic stenosis (PARTNER 1B): a randomized controlled trial. Lancet 2015;385:2485-91.http://dx.doi.org/10.1016/S0140-6736(15)60290-2.

2. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, et al. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1A): a randomized controlled trial. Lancet 2015;385:2477-84.http://dx.doi.org/10.1016/S0140-6736(15)60308-7.

3. Deeb GM, Reardon MJ, Chetcuti S, Patel HJ, Grossman PM, Yakubov SJ, et al. 3-year outcomes in high-risk patients who underwent surgical or transcatheter aortic valve replacement. J Am Coll Cardiol 2016;67:2565-74.http://dx.doi.org/10.1016/j.jacc.2016.03.506.

4. Leon MB, Smith CR, Mack MJ,Makkar RR, Svensson LG, Kodali SK, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. N Engl J Med 2016;374:1609-20.http://dx.doi.org/10.1056/NEJMoa1514616.

5. Thourani VH, Kodali S, Makkar RR, Herrmann HC, Williams M, Babaliaros V, et al. Transcatheter aortic valve replacement versus surgical valve replacement in intermediate-risk patients: a propensity score analysis. Lancet 2016;387:2218-25.http://dx.doi.org/10.1016/S0140-6736(16)30073-3.

6. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, et al.; SURTAVI Investigators. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. N Engl J Med 2017;376:1321-31.http://dx.doi.org/10.1056/NEJMoa1700456.

7. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low risk patients. N Engl J Med 2019;380:1695-705.http://dx.doi.org/10.1056/NEJMoa1814052.

8. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic valve replacement with a self-expanding valve in low-riskpatients. N Engl J Med 2019;380:1706-15.http://dx.doi.org/10.1056/NEJMoa1816885.

9. Baumgartner H, Falk V, Bax JJ, De Bonis M, Hamm C, Holm PJ, et al. 2017 ESC/EACTS guidelines for the management of valvular heart disease. Eur Heart J 2017;38:2739-91.http://dx.doi.org/10.1093/eurheartj/ehx391.

10. Borracci RA, Navia DO, Kotowicz V, Machain A, Higa CC. Single-Arm Meta-Analysis of Argentine Studies Reporting In-Hospital Mortality After Aortic Valve Replacement in Low and Intermediate Risk Patients. Rev Argent Cardiol 2019;87:271-80. http://dx.doi.org/10.7775/rac.v87.i4.15693

11. Phan K, Tian DH, Cao C, Black D, Yan TD. Systematic review and meta-analysis: technique and a guide for the academic surgeon. Ann Cardiothorac Surg 2015;4:112-22. http://doi.org/10.3978/j.issn.2225-319X.2015.02.04.

12. Fava C, Gamboa P, Caponi G, Gómez C, Fabián S, Guevara E, et al. Minimalist Approach for Percutaneous Aortic Valve Implantation. Rev Argent Cardiol 2019;87: 265-70. http://dx.doi.org/10.7775/rac.v87.i4.12015

13. Raleigh JV, Agatiello C, Romeo F, Oberti P, Falconi M, Battellini R, et al. Transapical and Transfemoral Aortic Valve Implantation. Impact and General Considerations of both Approaches. Rev Argent Cardiol 2018;86:171-6. http://dx.doi.org/10.7775/rac.v86.i3.10501

14. Abud MA, Nau G, Candiello A, Padilla LT, Piccinini F, Trivi M, et al. Efficacy and Safety of Transfemoral Transcatheter Aortic Valve Replacement under General Anesthesia versus Local Anesthesia with Conscious Sedation. Rev Argent Cardiol 2018;86:33-9. http://dx.doi.org/10.7775/rac.v86.i1.12981

15. Cigalini IM, Zaidel EJ, Villareal R, Bettinotti M, Sosa Liprandi A, Sztejfman M. In-Hospital and 30-Day Mortality After Percutaneous Aortic Valve Implantation. Usefulness of Different Surgical Risk Scores. Rev Argent Cardiol 2019;87:152-4. http://dx.doi.org/10.7775/rac.v87.i2.10531

16. Krasopoulos G, Falconieri F, Benedetto U, Newton J, Sayeed R, Kharbanda R, et al. European real world trans-catheter aortic valve implantation: systematic review and meta-analysis of European national registries. J Cardiothorac Surg 2016;11:159.

17. Singh K, Carson K, Rashid MK, Jayasinghe R, AlQahtani A, Dick A, et al. Transcatheter Aortic Valve Implantation in Intermediate Surgical Risk Patients With Severe Aortic Stenosis: A Systematic Review and Meta-Analysis. Heart Lung Circ 2018;27:227-34. http://dx.doi.org/10.1016/j.hlc.2017.02.032.

18. Lunardi M, Pesarini G, Zivelonghi C, Piccoli A, Geremia G, Ariotti S, et al. Clinical outcomes of transcatheter aortic valve implantation: from learning curve to proficiency. Open Heart 2016;3:e000420. http://dx.doi.org /10.1136/openhrt-2016-000420.

19. Handa N, Kumamaru H, Torikai K, Kohsaka S, Takayama M, Kobayashi J, et al. Japanese TAVR Registry Participants. Learning Curve for Transcatheter Aortic Valve Implantation Under a Controlled Introduction System- Initial Analysis of a Japanese Nationwide Registry. Circ J 2018;82:1951-8. d http://dx.doi.org /10.1253/circj.CJ-18-0211.

20. Arai T, Lefèvre T, Hovasse T, Hayashida K, Watanabe Y, O'Connor SA, et al. Evaluation of the learning curve for transcatheter aortic valve implantation via the transfemoral approach. Int J Cardiol 2016;203:491-7. http://dx.doi.org /10.1016/j.ijcard.2015.10.178.

21. von Scheidt W, Welz A, Pauschinger M, Fischlein T, Schächinger V, Treede H, et al. Interdisciplinary consensus on indications for transfemoral transcatheter aortic valve Implantation (TF-TAVI): Joint Consensus Document of the Arbeitsgemeinschaft Leitende Kardiologische Krankenhausärzte e.V. (ALKK) and cooperating Cardiac Surgery Departments. Clin Res Cardiol 2019 Aug 13. http://dx.doi.org/10.1007/s00392-019-01528-5.

22. Capodanno D, Petronio AS, Prendergast B, Eltchaninoff H, Vahanian A, Modine T, et al. 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). Eur Heart J 2017;38:3382-90. http://dx.doi.org/ 10.1093/eurheartj/ehx303.

23. Lancelotti P, Martinez C, Radermecker M. The long quest for the holy grail in transcatheter aortic bioprosthesis. J Am Coll Cardiol 2019;73:554-8. http://dx.doi.org/ 10.1016/j.jacc.2018.11.043.

24. Barbanti M, Petronio AS, Ettori F, Latib A, Bedogni F, De Marco F,et al. 5-Year outcomes after transcatheter aortic valve implantation with CoreValve prosthesis. J Am Coll Cardiol Interv 2015;8:1084-91. http://dx.doi.org/10.1016/j.jcin.2015.03.024.

25. Eltchaninoff H, Durand E, Avinée G, Tron C, Litzler PY, Bauer F, et al. Assessment of structural valve deterioration of transcatheter aortic bioprosthetic balloon-expandable valves using the new European consensus definition. EuroIntervention 2018;14:e264-71. https://doi.org/10.4244/eij-d-18-00015

26. Blackman DJ, Saraf S, MacCarthy PA, Myat A, Anderson SG, Malkin CJ, et al. Long-term durability of transcatheter aortic valve prostheses. J Am Coll Cardiol 2019;73:537-45. http://dx.doi.org/10.1016/j.jacc.2018.10.078