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CLINICAL RESEARCH

Incidence of, risk factors for and impact of readmission for heart failure after successful transcatheter aortic valve implantation

Incidence, facteurs de risque et retentissement des réadmissions pour insuffisance cardiaque après un remplacement valvulaire aortique percutanée

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KEYWORDS
Transcatheter aortic valve implantation;
Heart failure;

Summary
Background. — The incidence of and risk factors for readmission for heart failure after successful transcatheter aortic valve implantation (TAVI) are unclear.
Aims. — We sought to evaluate the incidence of, risk factors for and clinical impact of readmission for heart failure after successful TAVI in an unselected patient population.

Abbreviations: AF, atrial fibrillation; CI, confidence interval; HR, hazard ratio; TAVI, transcatheter aortic valve implantation.

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Readmission;
Atrial fibrillation

Methods. — All patients who underwent successful TAVI in two high-volume French tertiary centres from February 2010 to December 2016 were included prospectively and followed up for 1 year. A Cox multivariable model was used to assess risk factors for readmission for heart failure and mortality.
Results. — A total of 1139 patients (mean age 82.4 ± 7.7 years; 52.2% male sex) were included. Readmission for heart failure occurred in 99 (9.2%) patients. Risk factors for readmission for heart failure were previous atrial fibrillation (adjusted hazard ratio [$_{adj}$HR] 1.62, 95% confidence interval [CI] 1.09—2.40), diabetes mellitus ($_{adj}$HR 1.67, 95% CI 1.11—2.50), chronic kidney disease ($_{adj}$HR 1.72, 95% CI 1.13—2.62), chronic pulmonary disease ($_{adj}$HR 1.81, 95% CI 1.17—2.81) and left ventricular ejection fraction after TAVI ≤ 35% ($_{adj}$HR 2.12, 95% CI 1.20—3.75). Readmission for heart failure was strongly associated with mortality ($_{adj}$HR 3.11, 95% CI 1.95—4.94), along with increased Society of Thoracic Surgeons' score ($_{adj}$HR 1.07, 95% CI 1.03—1.12), chronic pulmonary disease ($_{adj}$HR 1.45, 95% CI 1.00—2.09), previous atrial fibrillation ($_{adj}$HR 2.11, 95% CI 1.52—2.93) and shock during the index hospitalization ($_{adj}$HR 2.56, 95% CI 1.41—4.65).
Conclusions. — Readmission for heart failure occurs in one in 10 patients after successful TAVI, and is a strong risk factor for mortality. Co-morbidities and left ventricular ejection fraction after TAVI ≤ 35% are the main risk factors for readmission for heart failure.

MOTS CLÉS
Remplacement valvulaire aortique percutané ;
Réadmission ;
Insuffisance cardiaque ;
Fibrillation auriculaire

Résumé
Contexte. — L'incidence et facteurs de risque (FdR) de réadmission pour insuffisance cardiaque après un remplacement valvulaire aortique percutané (TAVI) restent méconnus.
Objectifs. — Décrire l'incidence, FdR, et l'impact clinique d'une réadmission pour insuffisance cardiaque après un TAVI dans un échantillon non sélectionné de patients.
Méthodes. — Tous les patients traités par TAVI dans deux centres tertiaires français entre février 2010 et décembre 2016 ont été inclus de façon prospective et suivi pendant un an. Les FdR de réadmission pour insuffisance cardiaque et de mortalité ont été analysé via un modèle multivarié de Cox.
Résultats. — Un total de 1139 patients (âge moyen 82,4 ± 7,7 ans ; 52,2 % de sexe masculin) ont été inclus. Une réadmission pour insuffisance cardiaque dans l'année post-TAVI a eu lieu chez 99 (9,2 %) patients. Les FdR de réadmission pour insuffisance cardiaque étaient un antécédent de fibrillation atrial (ratio de risque ajusté [$_{adj}$HR] 1,62, intervalle de confiance à 95 % [IC 95 %] 1,09—2,40), un diabète ($_{adj}$HR 1,67, IC 95 % 1,11—2,50), une insuffisance rénale chronique ($_{adj}$HR 1,72, IC 95 % 1,13—2,62), une pneumopathie chronique ($_{adj}$HR 1,81, IC 95 % 1,17—2,81) et une fraction d'éjection ventriculaire gauche post-TAVI ≤ 35 % ($_{adj}$HR 2,12, IC 95 % 1,20—3,75). Une réadmission pour insuffisance cardiaque était associée à un surcroît de mortalité ($_{adj}$HR 3,11, IC 95 % 1,95—4,94), ainsi qu'un score STS élevé ($_{adj}$HR 1,07, IC 95 % 1,03—1,12), une pneumopathie chronique ($_{adj}$HR 1,45, IC 95 % 1,00—2,09), un antécédent de fibrillation atrial ($_{adj}$HR 2,11, IC 95 % 1,52—2,93) et un choc durant l'hospitalisation initiale ($_{adj}$HR 2,56, IC 95 % 1,41—4,65).
Conclusions. — Après un TAVI, une réadmission pour insuffisance cardiaque survient chez un patient sur dix et est associée à un surcroît de la mortalité. Les comorbidités des patients et une fraction d'éjection ventriculaire gauche post-TAVI ≤ 35 % sont les principaux FdR de réadmission pour insuffisance cardiaque.

Background

Transcatheter aortic valve implantation (TAVI) is a recommended alternative to surgical aortic replacement for the treatment of symptomatic severe aortic stenosis. Indications are now expanding towards patients at lower surgical risk [1—7]. Generalization of the transfemoral vascular approach, technological advances and increased operator skills have resulted in higher rates of procedural success and improved short-term and long-term survival [8—11]. Notwithstanding, patients undergoing TAVI remain burdened with frequent co-morbidities, and readmission within 30

days of the index hospitalization has been reported as a common complication [12—15]. Symptomatic heart failure is an important trigger that leads to TAVI [16,17]. Data on the incidence of readmission for heart failure after successful TAVI are scarce [18,19]. Identifying risk factors for readmission of heart failure is paramount to improve quality of care and reduce associated healthcare costs. The purpose of this analysis was to determine the incidence of, risk factors for and impact of readmission for heart failure after successful TAVI in all comers.

Methods

Study design

All patients who entered the nationwide FRANCE-TAVI or FRANCE-2 registries and were discharged alive after successful TAVI at Pitié-Salpêtrière and Nantes University Hospitals in France were considered for the analysis. Indications for TAVI, as well as procedural features, were determined by the local heart teams. Antithrombotic strategy after TAVI was left to the discretion of the physicians in accordance with local standard of care. Clinical follow-up at 1 year was performed by clinical interviews and/or in-person meetings. Each patient provided informed consent according to institutional standard practice, and the study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki. Transthoracic echocardiogram evaluations were performed at hospital discharge, and the mean transprosthesis gradient was determined after measurement of the peak transprosthesis flow velocity by continuous-wave Doppler imaging.

Study endpoint

Readmission was defined as any admission to the hospital ward or to the intensive care unit [18]. Visits to the emergency department were not considered when not associated with admission. Source documents were collected for each readmission. Heart failure was defined as clinical symptoms or worsening heart failure and/or radiological signs of pulmonary acute oedema. The other endpoint of interest was all-cause mortality within 1 year of successful TAVI.

Statistical analyses

Continuous variables are reported as mean ± standard deviation or median (interquartile range), and were compared using the Wilcoxon rank-sum test. Categorical variables are reported as number and percentage (percentages were calculated excluding missing data), and were compared using the χ^2 test or Fisher's exact test, as appropriate. Missing data were not handled. Times to readmission for heart failure and death were analysed using the Kaplan-Meier method. Kaplan-Meier estimate rates at 1 year and their 95% confidence intervals (95% CIs) were presented. Patients without event at 1 year or lost to follow-up were censored. Determinants of readmission for heart failure were assessed using the Cox proportional hazards model. A univariate analysis ($P < 0.2$) was first performed to select potential explanatory variables that were subsequently tested in a multivariable model (stepwise method). Another Cox proportional hazards model was used to assess the risk factors for mortality within 1 year of successful TAVI, with readmission for heart failure evaluated as a time-dependent covariate. Results are interpreted in terms of adjusted hazard ratios (HRs) with their associated 95% CIs. A P-value < 0.05 was considered significant unless otherwise specified. All statistical analyses were performed with the SAS statistical software package, release 9.4 (SAS Institute Inc., Cary, NC, USA).

Results

From February 2010 to December 2016, a total of 1139 out of 1219 (93%) patients were discharged after a successful procedure and were considered for the present analysis, with complete follow-up available for 1133 (99.5%) patients (Fig. A.1). A transfemoral vascular approach was mainly used, with a balloon-expandable device in 60.7% of cases.

Incidence of and risk factors for readmission for heart failure

Readmission for heart failure within 1 year of TAVI occurred in 99 (9.2%) patients (95% CI 7.6—11.1) who presented with more severe dyspnoea at baseline and had more frequent co-morbidities than those without heart failure (Table 1). There was no significant difference between the two groups with respect to in-hospital complications, although a trend towards increased length of stay in the index hospitalization was observed in patients readmitted for heart failure. After multivariable analysis, independent risk factors for readmission for heart failure were chronic pulmonary and kidney disease, diabetes mellitus, previous atrial fibrillation (AF) and LVEF after TAVI ≤ 35% (Fig. 1).

Clinical impact of readmission for heart failure

Overall, 145 (12.9%) patients died (95% CI 11.0—15.0); death was more frequent in patients with versus without readmission for heart failure: 22 (22.2%) patients (95% CI 15.2—31.8) vs 123 (12.0%) patients (95% CI 10.1—14.1), respectively ($P = 0.004$) (Fig. 2). In the multivariable model, readmission for heart failure was strongly associated with mortality within 1 year of TAVI, together with higher Society of Thoracic Surgeons' score at baseline, previous AF, chronic pulmonary disease and in-hospital shock during the index hospitalization (Fig. 3 and Table A.1).

Discussion

Readmission for heart failure occurs in one in 10 patients after successful TAVI, and is strongly associated with mortality within 1 year. Risk factors for subsequent readmission for heart failure included baseline characteristics, such as chronic pulmonary or kidney disease, diabetes mellitus, previous AF and LVEF after TAVI ≤ 35%.

The rates of overall readmission after TAVI in previous observational studies ranged between 3.9% and 27% within 30 days [12—15,20], and between 12% and 53.2% within 1 year [19—24], with heart failure being one of the most frequently reported causes [19]. In the present analysis,

Table 1 Baseline and procedural features.

	Overall ($n = 1139$)	No readmission for HF ($n = 1040$)	Readmission for HF ($n = 99$)	*P*
Baseline characteristics				
Age (years)	82.4 ± 7.7	82.4 ± 7.8	82.1 ± 6.2	0.11
Male sex	594 (52.2)	541 (52.0)	53 (53.5)	0.77
Body mass index (kg/m^2)	26.7 ± 5.4	26.7 ± 5.5	26.8 ± 5.3	0.67
Severe dyspnoea (NYHA 3—4) at baseline	630 (55.3)	565 (54.3)	65 (65.7)	0.03
Angina pectoris at baseline	154 (13.5)	143 (13.8)	11 (11.1)	0.46
EuroSCORE I	17.1 ± 11.7	16.8 ± 11.6	19.3 ± 13.2	0.06
EuroSCORE II	5.2 ± 4.5	5.1 ± 4.5	5.6 ± 4.3	0.03
STS score	4.3 ± 3.1	4.2 ± 3.1	4.8 ± 3.5	0.25
Previous non-CABG cardiac surgery	78 (6.8)	70 (6.7)	8 (8.1)	0.61
Coronary artery disease	512 (45)	40 (44.2)	52 (52.5)	0.11
Peripheral artery disease	309 (27.1)	279 (26.8)	30 (30.3)	0.46
Chronic pulmonary disease	224 (19.7)	196 (18.8)	28 (28.3)	0.02
Diabetes mellitus	304 (26.7)	266 (25.6)	38 (38.4)	0.006
Insulin-dependent diabetes	101 (8.9)	87 (8.4)	14 (14.1)	0.05
Systemic hypertension ($n = 1133$)	894 (78.9)	809 (78.2)	85 (86.7)	0.047
History of bleeding	113 (9.9)	104 (10.0)	9 (9.1)	0.77
Chronic kidney disease	617 (54.2)	551 (53.0)	66 (66.7)	0.009
History of AF	422 (37.1)	374 (36.0)	48 (48.5)	0.01
CHA2DS2-VASc score	4.0 ± 1.3	4.0 ± 1.3	4.2 ± 1.3	0.13
HAS-BLED score	2.9 ± 1.0	2.8 ± 1.0	3.2 ± 1.0	0.003
LVEF (%)	54.8 ± 12.4	55.1 ± 12.3	51.6 ± 13.0	0.007
LVEF ≤ 35%	118 (10.4)	102 (9.8)	16 (16.2)	0.047
Aortic regurgitation ($n = 1089$)	693 (63.6)	636 (64.0)	57 (59.4)	0.36
Pulmonary arterial pressure > 30 mmHg ($n = 1031$)	550 (53.3)	494 (52.6)	56 (60.9)	0.13
Procedural characteristics				
PCI before TAVI	156 (13.7)	144 (13.8)	12 (12.1)	0.63
Critical condition before TAVI	43 (3.8)	37 (3.6)	6 (6.1)	0.26
Urgent procedure	129 (11.3)	114 (11.0)	15 (15.2)	0.21
Vascular approach				0.67
Transfemoral approach	939 (82.4)	859 (82.6)	80 (80.8)	
Transapical approach	68 (6.0)	63 (6.1)	5 (5.1)	
Other approach	132 (11.6)	118 (11.3)	14 (14.1)	
Prosthesis type				0.29
Balloon-expandable	691 (60.7)	626 (60.2)	65 (65.7)	
Self-expanding prosthesis	448 (39.3)	414 (39.8)	34 (34.3)	
Valve-in-valve procedure	54 (4.7)	51 (4.9)	3 (3.0)	0.62
Prosthesis diameter < 29 mm ($n = 1138$)	697 (61.2)	637 (61.3)	60 (60.6)	0.89
In-hospital complications				
Permanent pacemaker implantation	220 (19.3)	202 (19.4)	18 (18.2)	0.77
Stroke	31 (2.7)	28 (2.7)	3 (3.0)	0.75
Major or life-threatening VARC-2 bleeding	122 (10.7)	110 (10.6)	12 (12.1)	0.64
Shock requiring use of catecholamine	42 (3.7)	40 (3.8)	2 (2.0)	0.57
Sepsis	109 (9.6)	102 (9.8)	7 (7.1)	0.38
Hospital discharge characteristics				
LVEF (%)	55.4 ± 10.5	55.7 ± 10.3	52.4 ± 11.6	0.004
LVEF ≤ 35%	81 (7.1)	67 (6.4)	14 (14.1)	0.004
Mean gradient (mmHg) ($n = 1065$)	10.6 ± 5.4	10.7 ± 5.5	9.8 ± 4.2	0.21
Severe aortic regurgitation ($n = 1105$)	7 (0.6)	6 (0.6)	1 (1.0)	0.48
Antiplatelet therapy prescription				0.02
Single antiplatelet therapy	389 (34.2)	355 (34.1)	34 (34.3)	
Dual antiplatelet therapy	488 (42.8)	456 (43.8)	32 (32.3)	
None	262 (23.0)	229 (22.0)	33 (33.3)	

Table 1 (*Continued*)

	Overall ($n = 1139$)	No readmission for HF ($n = 1040$)	Readmission for HF ($n = 99$)	*P*
Oral anticoagulant	400 (35.1)	354 (34.0)	46 (46.5)	0.013
In-hospital length of stay (days) ($n = 1129$)	9.0 (7.0—14.0)	9.0 (7.0—13.0)	11.0 (7.0—15.0)	0.06

Data are expressed as mean ± standard deviation, number () or median (interquartile range). AF: atrial fibrillation; CABG: coronary artery bypass graft; CHA_2DS_2-VASc: Congestive heart failure, Hypertension, Age ≥ 75 years (Doubled), Diabetes, Stroke/transient ischaemic attack/thromboembolism (Doubled)—Vascular disease, Age 65—74 years and Sex category (Female); HAS-BLED: Hypertension, Abnormal liver/renal function, Stroke history, Bleeding history or predisposition, Labile international normalized ratio, Elderly, Drug/alcohol usage; HF: heart failure; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation; VARC: Valve Academic Research Consortium.

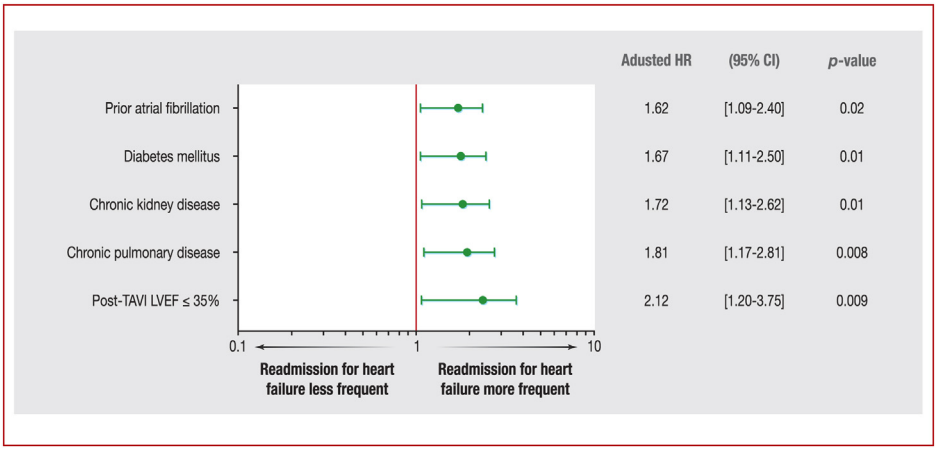

Figure 1. Multivariable Cox model for readmission for heart failure. CI: confidence interval; HR: hazard ratio; LVEF: left ventricular ejection fraction; TAVI: transcatheter aortic valve implantation.

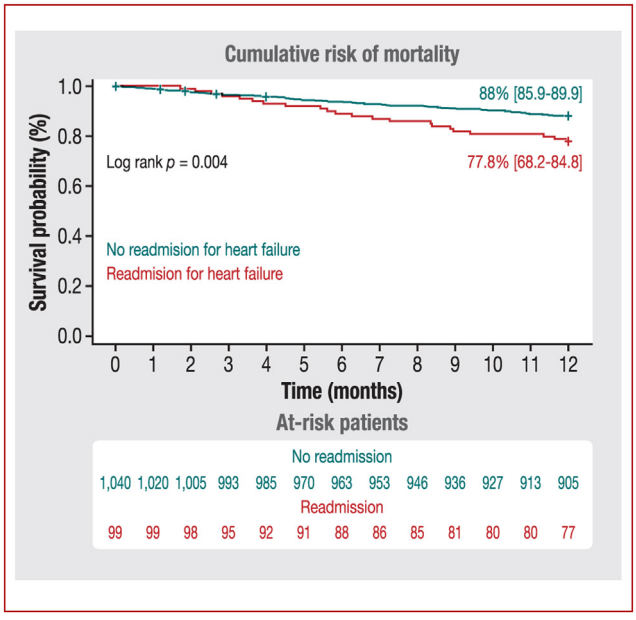

Figure 2. Kaplan-Meier survival curves. Results are given as Kaplan-Meier estimate with 95% confidence interval.

prevalence of readmission for heart failure within 1 year was lower than that recently reported by Durand et al., and closer to the rate of readmission for aortic valve-related disease (8.5% at 12 months) in the randomized SURTAVI trial, the 11.6% rate of readmission for cardiovascular cause in a Canadian observational registry reported by Kamioka et al., and the 14.3% rate in the national FRANCE-2 registry [25—27]. Significant variations in the rate of readmission have been described between and within countries [28]. In a recent large meta-analysis including 20 TAVI cohorts and 109,730 patients, Danielsen et al. reported regional differences in the incidence of 30-day all-cause readmission, with higher rates in the USA than in other countries. These discrepancies may be partly explained by differences in the assessment and definition of readmission [28]. Khera et al. also described an inverse association between hospital TAVI volume and 30-day readmission [29]. Discrepancies in the pattern of discharge medication may also be involved, as a recent report from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapies Registry found that the prescription of renin-angiotensin system inhibitors was associated with a reduced risk of readmission for heart failure [30]. Furthermore, the present analysis included lower-risk patients with a lower prevalence of severely altered LVEF than the previous report

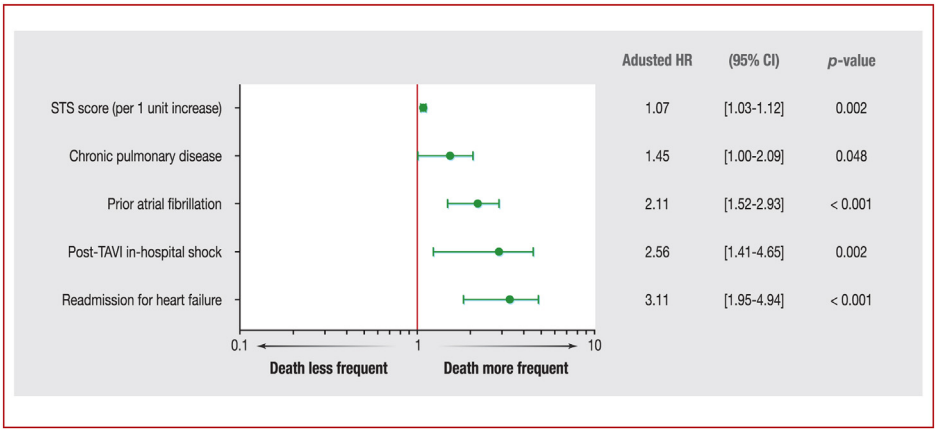

Figure 3. Multivariable Cox model for all-cause death. CI: confidence interval; HR: hazard ratio; STS: Society of Thoracic Surgeons; TAVI: transcatheter aortic valve implantation.

[24]. Finally, discrepancies among published reports may also be partly explained by different study time periods, as improvements in both procedural and long-term outcomes in patients undergoing TAVI more recently have been reported [8,11].

We found that readmission for heart failure carried a significant prognostic value, with a strong association with mortality within 1 year of successful TAVI. Similarly, Durand et al. also found a significant increase in 1-year mortality to 24.2% compared with 10.4% in its absence ($P < 0.0001$) [18]. A consistent adverse effect has been demonstrated with all-cause readmission. In the Bern TAVI registry, readmission for any cause was associated with a four-fold increase in the risk of mortality within 1 year [19]. Direct complications of hospitalization, such as nosocomial infection or posthospital syndrome, may partly explain this result [31]. Most of all, the need for readmission for heart failure demonstrates the adverse evolution of the underlying cardiac condition, despite successful TAVI. Hence, these high-risk patients could benefit from early identification, regular clinical evaluation, medical treatment intensification and multidisciplinary management of extracardiac co-morbidities [30].

Risk factors for readmission described in the present analysis are consistent with previous reports. Kolte et al., using the USA nationwide readmissions database, found chronic kidney disease (HR 1.20, 95% CI 1.24—1.73) and pulmonary disease (HR 1.16, 95% CI 1.01—1.34) to be significantly associated with 30-day readmission [14]. Danielsen et al., using six TAVI cohorts, found diabetes mellitus to be a risk factor for 30-day readmission, with odds ratios of 1.13—1.18 [12]. AF, a major cause of heart-failure related hospitalization in the overall population [32], has been previously associated with an increased risk of late (> 30 days) readmission after TAVI [22,33—37]. These co-morbidities may result in specific cardiomyopathy, which would not be improved by successful TAVI. Of note, other variables, previously described as risk factors for overall subsequent readmission after TAVI, such as sex, use of non-transfemoral vascular approach and major or life-threatening bleeding during the index hospitalization, were not significantly associated with readmission for heart failure in our analysis [12,14,15,19]. This discrepancy may be partly explained by the fact that the present analysis specifically evaluated determinant of readmission for heart failure rather than any readmission following TAVI. Our results are complementary to those previously published by Durand et al., as the associations of different variables with the occurrence of readmission for heart failure were evaluated. Particularly, the impact of co-morbidities, such as diabetes mellitus, chronic kidney disease and pulmonary disease, was not evaluated in this previous analysis. Our results also differed regarding the impact of AF and LVEF altered after TAVI, which were both no longer associated with readmission for heart failure after adjustment for other covariates, unlike the present study. These discrepancies between French registries performed in a consistent study period emphasize the complexity of the interaction between the patient's co-morbidities, the severity of the aortic stenosis, the success of the TAVI procedure as estimated by postprocedural echocardiographic results and long-term outcomes following TAVI. Thus, future research is warranted, particularly for the evaluation of specific co-morbidities in this frail population, such as transthyretin cardiac amyloidosis, a disease encountered frequently in elderly patients with aortic stenosis, particularly low-gradient aortic stenosis, as it may require dedicated management and follow-up [38].

Study limitations: We acknowledge several limitations. The multivariable model included measured covariates without missing values, but unmeasured cofounders may have persisted. This registry did not include specific heart failure biological markers, such as B-type natriuretic peptide, medical treatment at discharge, exhaustive echocardiographic evaluation or frailty indexes. As such, our results should be considered only as hypothesis generating. Moreover, only two centres were included, and our results may not be generalized to other centres, although this limitation was mitigated by the relatively large number of enrolled patients. Only data for the first readmission for heart failure were collected, and the impact of subsequent hospitalizations could not be evaluated. We did not include echocardiographic follow-up in the analysis, as we aimed to evaluate risk factors for readmission within 1 year of successful TAVI, following the initial hospital discharge. Finally, follow-up was limited to 1 year, and incidence and risk factors for very-late readmission for heart failure could not be evaluated.

Conclusions

Readmission for heart failure within 1 year after successful TAVI is a frequent complication in all comers, strongly associated with death. Baseline co-morbidities, such as chronic pulmonary and kidney disease, diabetes mellitus, previous AF and LVEF after TAVI $\leq$ 35%, were independent risk factors for readmission for heart failure.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.plantsci.2004.08.011.

Disclosure of interest

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The other authors declare that they have no competing interest.

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