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## Clinical Research

## Aortic valve replacement for aortic stenosis: Influence of centre volume on TAVR adoption rates and outcomes in France

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## INFO ARTICLE

## Historique de l'article :

Reçu le 20 novembre 2023

Reçu sous la forme révisée

le 19 février 2024

Accepté le 20 février 2024

Disponible sur Internet le xxx

## Keywords :

Aortic stenosis

Aortic valve replacement

Outcome

Centre volume

## ABSTRACT

**Background.** – Transcatheter (TAVR) has supplanted surgical (SAVR) aortic valve replacement (AVR).**Aim.** – To evaluate whether adoption of this technology has varied according to centre volume at the nationwide level.**Methods.** – From an administrative hospital-discharge database, we collected data on all AVRs performed in France between 2007 and 2019. Centres were divided into terciles based on the annual number of SAVRs performed in 2007–2009 (“before TAVR era”).**Results.** – A total of 192,773 AVRs (134,662 SAVRs and 58,111 TAVRs) were performed in 47 centres. The annual number of AVRs and TAVRs increased significantly and linearly in low-volume (< 152 SAVRs/year; median 106, interquartile range [IQR] 75–129), middle-volume (152–219 SAVRs/year; median 197, IQR 172–212) and high-volume (> 219 SAVRs/year; median 303, IQR 268–513) terciles, but to a greater degree in the latter (+14, +16 and +24 AVRs/centre/year and +16, +19 and +31 TAVRs/centre/year, respectively;  $P_{ANCOVA} < 0.001$ ). Charlson Comorbidity Index and in-hospital death rates declined from 2010 to 2019 in all terciles (all  $P_{trend} < 0.05$ ). In 2017–2019, after adjusting for age, sex and Charlson Comorbidity Index, there was a trend toward lower death rates in the high-volume tercile ( $P = 0.06$ ) for SAVR, whereas death rates were similar for TAVR irrespective of tercile ( $P = 0.27$ ). Similar results were obtained when terciles were defined based on number of interventions performed in the last instead of the first 3 years. Importantly, even centres in the lowest-volume tercile performed a relatively high number of interventions (150 TAVRs/year/centre).**Conclusions.** – In a centralized public healthcare system, the total number of AVRs increased linearly between 2007 and 2019, mostly due to an increase in TAVR, irrespective of centre volume. Progressive declines in patient risk profiles and death rates were observed in all terciles; in 2017–2019 death rates were similar in all terciles, although lower in high-volume centres for SAVR.© 2024 L'Auteur(s). Publié par Elsevier Masson SAS. Cet article est publié en Open Access sous licence CC BY (<http://creativecommons.org/licenses/by/4.0/>).

Abbreviations: ANCOVA, analysis of covariance

AP-HP, Assistance publique-Hôpitaux de Paris

AVR, aortic valve replacement

IQR, interquartile range

PMSI, Programme de Médicalisation des Systèmes d'Information

SAVR, surgical aortic valve replacement

TAVR, transcatheter aortic valve replacement

TVT, transcatheter valve therapy.

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Adresse e-mail : [DMessika-zeitoun@ottawaheart.ca](mailto:DMessika-zeitoun@ottawaheart.ca) (D. Messika-Zeitoun).<https://doi.org/10.1016/j.acvd.2024.02.007>1875-2136/© 2024 The Author(s). Published by Elsevier Masson SAS. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

## 1. Background

Over the past decade, transcatheter aortic valve replacement (TAVR) has become a well-established and extensively used technology. The results of randomized controlled trials, together with technology enhancements, have made TAVR the recommended procedure for aortic valve replacement (AVR) in selected populations with severe symptomatic aortic valve stenosis [1,2]. Originally proposed for high-risk, surgically prohibited patients, TAVR indications have expanded to intermediate-risk patients, and low-risk patients [3–12]. Real-life data on TAVR implementation, its impact on surgical aortic valve replacement (SAVR) and their respective outcomes are available from large registries in the USA and Europe [13–19]. These studies showed a significant increase in AVR, mainly due to the wide availability and adoption of TAVR, whereas the number of SAVRs has declined. However, the influence of centre volume on TAVR adoption at the nationwide level has not been evaluated specifically.

The rapid expansion of TAVR across institutions with different levels of experience in transcatheter procedures raises concern about whether there exists an appropriate balance between access to new technology and procedural quality. Previous studies have demonstrated better outcomes, including lower death rates, in high- versus low-volume hospitals in the USA [20–22]. However, the healthcare system in the USA is unique, and whether the TAVR volume-outcome relationship is observed in other western countries with different and often more centralized healthcare organizational models – such as France – remains uncertain.

We previously reported the overall number of AVRs performed, changes over time and TAVR adoption rate up to 2019 in France [18,19]. In the present study, we aimed to compare: the adoption rate of TAVR and its impact on SAVR; temporal changes in the risk profiles of patients undergoing AVR; and temporal changes in TAVR and SAVR outcomes according to centre volume.

## 2. Methods

### 2.1. Study design

Study data were obtained from the *Programme National de Médicalisation des Systèmes d'Information* (PMSI) database as described previously [18,19]. Briefly, the database records all admissions across all healthcare institutions in France, and includes information on the pathology (coded using the International Classification of Diseases 10th Revision [ICD-10]), the patient and the procedures performed during the hospital stay (coded using a French classification, the *Classification Commune des Actes Médicaux* [CCAM]). We included all SAVRs (isolated or combined, i.e. AVR without or combined with any additional intervention, such as coronary artery bypass graft or mitral intervention) and TAVRs performed for aortic stenosis in France in public or in private hospitals between 2007 and 2019. We excluded patients aged  $\leq 18$  years and admissions for aortic regurgitation.

For the present analysis, we excluded institutions that did not develop a TAVR programme or that closed during the study period, as well institutions that opened after 2010. Remaining centres were divided into terciles (low, middle and high) according to the mean annual SAVR volume during the “before TAVR era” (2007–2009).

### 2.2. Patient characteristics and outcomes

Clinical characteristics were extracted directly from the PMSI. The Charlson Comorbidity Index was used to assess patient comorbidities [23]. In-hospital death was defined as that occurring

between the intervention and hospital discharge during the same hospital stay.

### 2.3. Statistical analysis

Continuous variables are expressed as mean  $\pm$  standard deviation or median (interquartile range [IQR]), and categorical variables as number (percentage). Trends in characteristics and outcomes over time were estimated using the Cochrane-Armitage trend test for categorical variables, and the linear-by-linear trend test for continuous variables. Analysis of covariance (ANCOVA) was used to analyse differences in time-series trends, whereas multivariable linear regression was used to adjust for covariates. All tests were two-sided and performed using JMP<sup>®</sup>, version 14.2 (SAS Institute Inc., Cary, NC, USA), XLSTAT (Microsoft<sup>®</sup>, Redmond, WA, USA) or Stata Statistical Software, Release 17 (2021; StataCorp, College Station, TX, USA).  $P < 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Centre characteristics

Among the 64 institutions performing AVR in France during the study period, we excluded 17 from the present analysis: nine surgical centres closed or never developed a TAVR programme; and seven centres opened after 2009. We also excluded the Assistance publique-Hôpitaux de Paris (AP-HP) group, which includes several hospitals of different sizes that we could not individualized accurately from the PMSI (Fig. 1). The remaining 47 centres performed 192,773 AVRs (134,662 SAVRs and 58,111 TAVRs) between 2007 and 2019, which represented 88.3% of all AVRs, 88.3% of all SAVRs and 88.5% of all TAVRs performed in France during the study period. Based on the average annual number of SAVRs performed in the “before TAVR era” (2007–2009), 16 centres were in the low-volume tercile ( $< 152$  SAVRs per year; mean  $103 \pm 31$ ; median 106, IQR 75–129), 16 centres were in the middle-volume tercile (152–219 SAVRs per year; mean  $191 \pm 22$ ; median 197, IQR 172–212) and 15 centres were in the high-volume tercile ( $> 219$  SAVRs per year; mean  $362 \pm 119$ ; median 303, IQR 268–513) (Fig. 1). Baseline characteristics of the population overall and according to volume tercile are presented in Table 1.

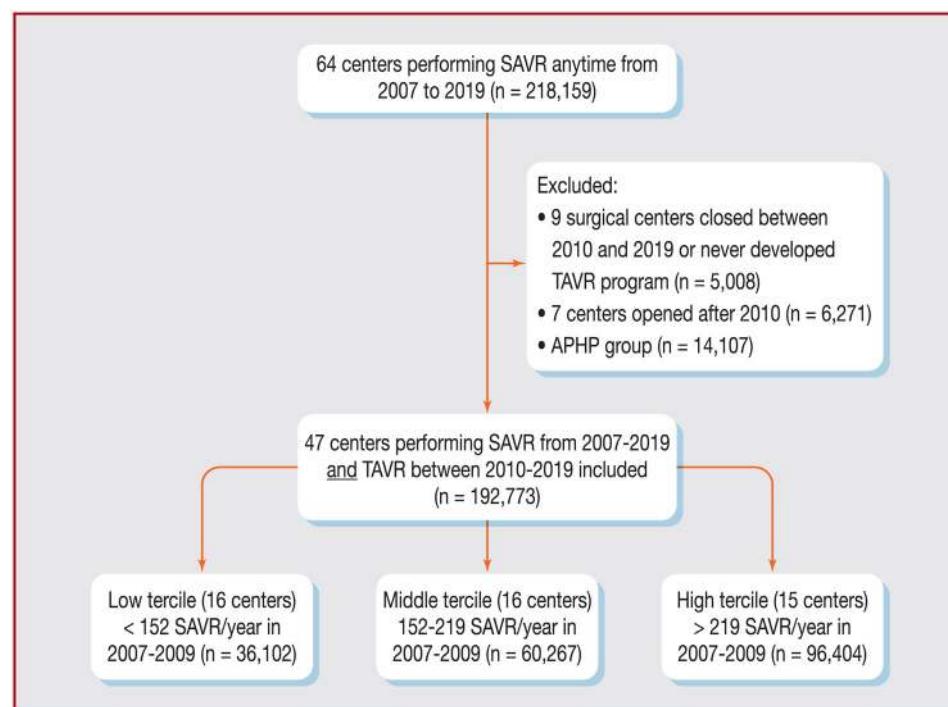
### 3.2. TAVR adoption and impact on SAVR

#### 3.2.1. All AVRs

The number of AVRs increased linearly from 2007 to 2019 in the low-tercile group (+14 AVRs/centre/year [94–275 AVRs/centre/year];  $P_{\text{trend}} = 0.0006$ ), middle-tercile group (+16 AVRs/centre/year [171–382 AVRs/centre/year];  $P_{\text{trend}} = 0.0006$ ) and high-tercile group (+24 AVRs/centre/year [342–656 AVRs/centre/year];  $P_{\text{trend}} = 0.0005$ ), with the fastest increase seen in the high-volume tercile ( $P_{\text{ANCOVA}} < 0.001$ ) (Fig. 2A and Table A.1). Although statistically significant ( $P < 0.001$ ), the proportion of all AVRs performed according to volume tercile changed only minimally from 2007–2009 to 2017–2019. In 2007–2009, low-volume centres performed 16% of all AVRs, medium-volume centres 30% and high-volume centres 54%. In 2017–2019, the percentages were 21%, 31% and 48%, respectively (Fig. 3).

#### 3.2.2. SAVRs

In all terciles, the number of SAVRs performed per year increased slightly up to 2013–2015, but then remained stable or decreased thereafter up to 2019 (Fig. 2B).



**Fig. 1.** Flow chart of excluded centres (with reason for exclusion) and included centres by volume tercile, based on annual volume of surgical aortic valve replacements (SAVRs) performed in 2007–2009 (before the transcatheter aortic valve replacement [TAVR] era). APHP: Assistance publique–Hôpitaux de Paris.

**Table 1**

Baseline characteristics of the overall population according to volume tercile.

	Overall population (n = 192,773)	Low-volume tercile (n = 36,102)	Middle-volume tercile (n = 60,267)	High-volume tercile (n = 96,404)	P <sup>a</sup>
<b>SAVR</b>					
Number of interventions	134,662	24,300	42,051	68,311	< 0.0001
Age (years)	71 ± 10	71 ± 10	72 ± 10	72 ± 10	< 0.0001
Male sex	86,501 (64.2)	15,690 (64.6)	26,769 (63.6)	44,042 (64.4)	0.01
CCI	0.86 ± 1.26	0.89 ± 1.30	0.86 ± 1.26	0.85 ± 1.24	0.07
CCI ≥ 2	28,603 (21.2)	5370 (22.0)	8668 (20.6)	14,565 (21.3)	< 0.0001
In-hospital deaths	4520 (3.4)	987 (4.1)	1447 (3.4)	2086 (3.1)	< 0.0001
Pacemaker implantation	6255 (4.6)	1044 (4.3)	2152 (5.1)	3059 (4.5)	< 0.0001
<b>TAVR</b>					
Number of interventions	58,111	11,802	18,216	28,093	< 0.0001
Age (years)	83 ± 7	83 ± 7	83 ± 7	83 ± 7	< 0.0001
Male sex	28,918 (49.7)	5794 (49.1)	9012 (49.5)	14,112 (50.2)	0.07
CCI	0.87 ± 1.22	0.77 ± 1.15	0.81 ± 1.17	0.94 ± 1.26	< 0.0001
CCI ≥ 2	13,440 (23.1)	2397 (20.3)	3821 (20.1)	7222 (25.7)	< 0.0001
In-hospital deaths	1890 (3.3)	345 (2.9)	665 (3.6)	880 (3.1)	0.0008
Pacemaker implantation	8797 (15.1)	1746 (14.8)	2782 (15.3)	4269 (15.2)	0.49

Data are expressed as mean ± standard deviation, number or number (%). CCI: Charlson Comorbidity Index; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.

<sup>a</sup> P value for difference between any terciles.

### 3.2.3. TAVRs

Most of the increase in AVRs was due to an increase in the number of TAVRs performed in all three terciles. As with the total number of AVRs, the number of TAVRs increased in all three terciles, although more rapidly in the high-volume tercile (+16 TAVRs/centre/year in the low-volume tercile, +19 TAVRs/centre/year in the middle-volume tercile and +31 TAVRs/centre/year in the high-volume tercile;  $P_{ANCOVA} < 0.001$ ; Fig. 2C). The proportion of TAVRs performed between 2010 and 2019 increased in the three terciles (from 8% to 60%, 10% to 57% and 11% to 55% in the low-, middle- and high-volume terciles, respectively), and TAVR became the predominant AVR strategy, representing ≥ 50% of all AVRs in the three terciles in 2017–2018 (Fig. 4).

### 3.3. Changes in baseline characteristics and risk profiles

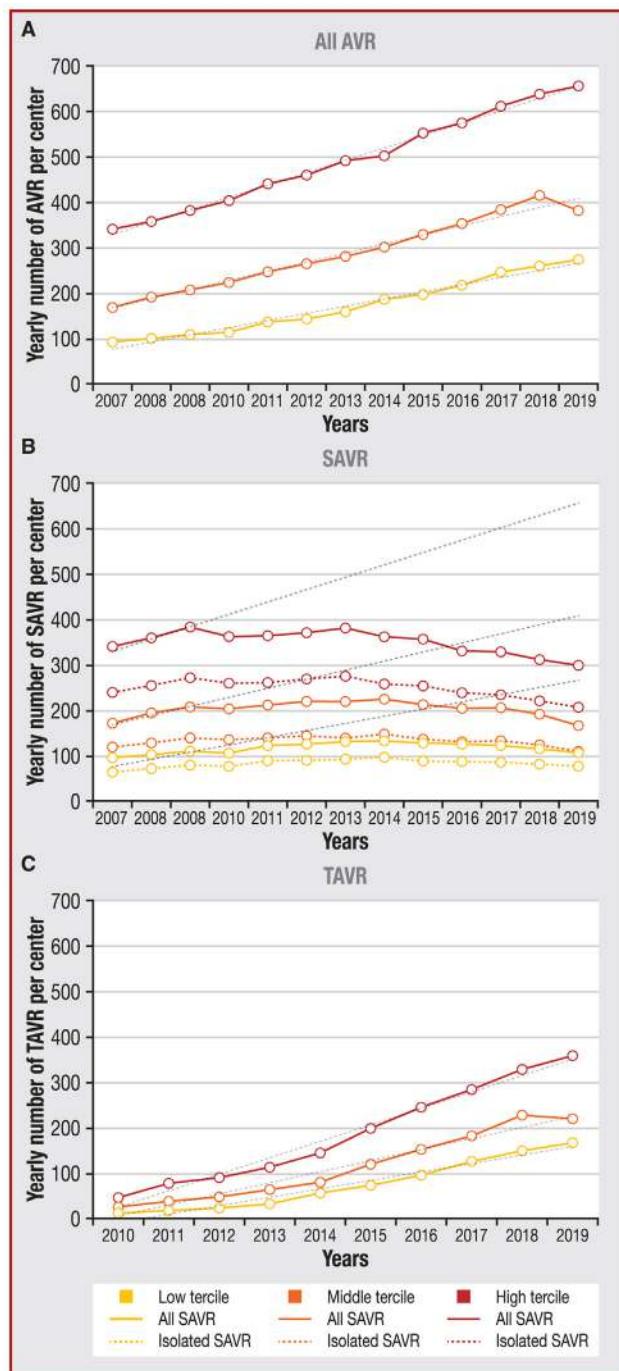
#### 3.3.1. SAVRs

The mean age of the patients who underwent all SAVRs decreased from 2007 to 2019 in the three terciles (from 72 ± 10 to 69 ± 9 years [ $P_{trend} = 0.004$ ], from 72 ± 10 to 69 ± 9 years [ $P_{trend} = 0.004$ ] and from 73 ± 10 to 69 ± 7 years [ $P_{trend} = 0.0019$ ] in the low-, middle- and high-volume terciles, respectively;  $P_{ANCOVA} = 0.83$ ). Similar trends were noted for isolated SAVRs (Table 2). The Charlson Comorbidity Index also decreased between 2007 and 2019 in the three terciles for all SAVRs (from 1.15 ± 0.57 to 0.69 ± 0.31 [ $P_{trend} = 0.003$ ], from 1.18 ± 0.43 to 0.64 ± 0.26 [ $P_{trend} = 0.004$ ] and from 1.14 ± 0.38 to 0.65 ± 0.24 [ $P_{trend} = 0.003$ ] in the low-, middle- and high-volume ter-

**Table 2**  
Changes in baseline characteristics and outcomes according to volume tercile, from 2007 to 2019, for surgical (total and isolated) and transcatheter aortic valve replacement.

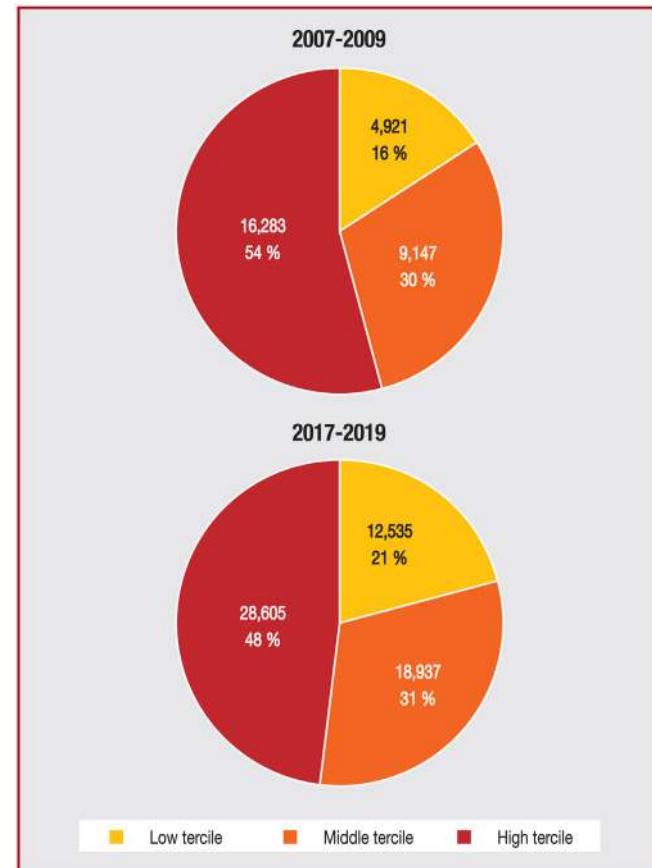
	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
<b>All SAVRs</b>													
Age (years)													
Low-volume	72 ± 10	72 ± 10	73 ± 10	72 ± 10	72 ± 10	72 ± 11	72 ± 10	72 ± 10	71 ± 10	70 ± 10	70 ± 9	69 ± 9	69 ± 9
Middle-volume	72 ± 10	72 ± 10	73 ± 10	73 ± 10	72 ± 11	73 ± 10	72 ± 10	73 ± 10	72 ± 10	71 ± 10	70 ± 10	69 ± 9	69 ± 9
High-volume	73 ± 10	73 ± 10	73 ± 10	73 ± 10	73 ± 10	73 ± 10	73 ± 10	72 ± 10	72 ± 10	71 ± 10	70 ± 10	70 ± 9	69 ± 7
CCI													
Low-volume	1.15 ± 0.57	1.29 ± 0.66	1.29 ± 0.55	1.19 ± 0.52	0.93 ± 0.30	0.81 ± 0.26	0.78 ± 0.33	0.76 ± 0.31	0.74 ± 0.25	0.78 ± 0.29	0.83 ± 0.31	0.69 ± 0.22	0.69 ± 0.31
Middle-volume	1.18 ± 0.43	1.22 ± 0.50	1.27 ± 0.47	1.17 ± 0.48	0.76 ± 0.30	0.74 ± 0.24	0.70 ± 0.21	0.70 ± 0.24	0.72 ± 0.28	0.70 ± 0.29	0.72 ± 0.27	0.70 ± 0.28	0.64 ± 0.26
High-volume	1.14 ± 0.38	1.19 ± 0.35	1.21 ± 0.40	1.14 ± 0.41	0.82 ± 0.22	0.77 ± 0.24	0.76 ± 0.21	0.74 ± 0.21	0.75 ± 0.22	0.75 ± 0.25	0.80 ± 0.28	0.72 ± 0.27	0.65 ± 0.24
In-hospital death rate													
Low-volume	6.7	5.9	6.3	5.3	3.8	4.5	2.9	4.0	2.8	3.2	2.7	3.2	1.9
Middle-volume	4.6	4.0	5.3	3.2	3.9	3.4	3.3	3.1	3.4	2.7	3.1	2.3	2.0
High-volume	4.6	4.6	4.4	3.3	3.3	3.3	3.3	2.7	2.5	2.2	2.4	2.2	1.6
PPM													
Low-volume	2.7	2.5	3.4	4.1	3.9	4.5	4.7	5.3	5.1	4.5	3.8	4.6	5.5
Middle-volume	4.5	4.8	4.6	4.0	3.5	3.9	4.7	5.6	6.0	5.7	6.5	5.9	5.3
High-volume	4.5	4.4	4.7	4.4	4.7	4.3	4.5	4.7	5.1	4.8	4.2	4.4	4.7
<b>Isolated SAVRs</b>													
Age (years)													
Low-volume	71 ± 11	72 ± 11	72 ± 11	72 ± 11	71 ± 11	71 ± 11	71 ± 11	71 ± 11	71 ± 11	69 ± 10	69 ± 10	69 ± 10	68 ± 9
Middle-volume	72 ± 11	71 ± 11	72 ± 11	71 ± 11	72 ± 11	72 ± 11	72 ± 10	71 ± 11	70 ± 10	70 ± 10	68 ± 9	68 ± 9	68 ± 9
High-volume	72 ± 11	72 ± 10	73 ± 11	72 ± 11	72 ± 11	72 ± 11	72 ± 11	72 ± 10	71 ± 10	70 ± 10	69 ± 10	69 ± 10	68 ± 9
CCI													
Low-volume	1.02 ± 0.55	1.15 ± 0.55	1.21 ± 0.50	1.10 ± 0.46	0.81 ± 0.26	0.72 ± 0.24	0.72 ± 0.34	0.70 ± 0.29	0.67 ± 0.24	0.67 ± 0.27	0.75 ± 0.29	0.65 ± 0.23	0.66 ± 0.30
Middle-volume	1.08 ± 0.40	1.13 ± 0.51	1.15 ± 0.48	1.06 ± 0.42	0.70 ± 0.30	0.66 ± 0.22	0.62 ± 0.18	0.61 ± 0.23	0.71 ± 0.41	0.62 ± 0.25	0.70 ± 0.33	0.63 ± 0.26	0.58 ± 0.25
High-volume	1.05 ± 0.37	1.08 ± 0.34	1.11 ± 0.37	1.05 ± 0.41	0.76 ± 0.21	0.70 ± 0.23	0.69 ± 0.18	0.70 ± 0.20	0.69 ± 0.22	0.69 ± 0.22	0.75 ± 0.27	0.68 ± 0.24	0.59 ± 0.19
In-hospital death rate													
Low-volume	5.9	4.2	5.0	3.8	2.6	3.5	2.3	3.2	2.3	1.9	1.7	2.3	1.4
Middle-volume	4.2	2.9	4.3	2.3	3.2	2.6	2.2	2.1	2.6	1.8	2.7	1.5	1.1
High-volume	3.6	3.4	3.6	2.6	2.6	2.7	2.7	2.3	1.7	1.7	1.9	1.5	0.8
PPM													
Low-volume	2.7	2.7	3.3	4.2	4.3	4.3	5.0	5.5	4.6	4.1	3.1	4.4	4.3
Middle-volume	4.6	5.6	4.6	4.0	3.7	3.8	4.0	5.9	6.0	5.2	6.3	4.8	4.9
High-volume	4.8	4.4	5.1	4.8	5.0	4.2	4.4	4.5	5.0	4.6	3.8	4.2	4.4
<b>TAVRs</b>													
Age (years)													
Low-volume	—	—	—	83 ± 6	83 ± 6	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	82 ± 7
Middle-volume	—	—	—	82 ± 7	83 ± 7	83 ± 6	84 ± 6	84 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7
High-volume	—	—	—	82 ± 7	82 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7	83 ± 7
CCI													
Low-volume	—	—	—	1.56 ± 0.50	1.21 ± 0.73	1.22 ± 0.64	0.91 ± 0.56	0.91 ± 0.43	0.90 ± 0.37	0.82 ± 0.34	0.83 ± 0.37	0.66 ± 0.25	0.69 ± 0.27
Middle-volume	—	—	—	1.14 ± 0.39	0.92 ± 0.29	0.94 ± 0.59	1.04 ± 0.41	0.91 ± 0.26	0.99 ± 0.33	0.90 ± 0.34	0.81 ± 0.30	0.75 ± 0.28	0.61 ± 0.18
High-volume	—	—	—	1.55 ± 0.48	1.28 ± 0.52	1.22 ± 0.52	1.28 ± 0.56	1.14 ± 0.43	1.00 ± 0.41	0.91 ± 0.37	0.88 ± 0.36	0.79 ± 0.46	0.79 ± 0.43
In-hospital death rate													
Low-volume	—	—	—	9.3	6.2	5.1	5.6	8.3	2.3	3.6	2.1	2.8	1.8
Middle-volume	—	—	—	8.4	10.5	10.4	7.1	6.0	3.5	3.6	2.5	2.1	2.2
High-volume	—	—	—	9.0	8.3	5.9	6.3	4.0	2.9	2.6	2.2	1.8	1.8
PPM													
Low-volume	—	—	—	—	4.9	10.2	13.0	15.0	14.2	12.8	15.7	16.8	16.4
Middle-volume	—	—	—	—	12.3	15.5	15.2	16.3	15.5	15.8	15.7	15.0	14.5
High-volume	—	—	—	—	11.9	12.3	13.2	14.5	15.6	14.0	15.8	17.5	17.1

Data are presented as mean ± standard deviation or percentage. CCI: Charlson Comorbidity Index; PPM: permanent pacemaker; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement.



**Fig. 2.** Changes in the absolute annual number of aortic valve replacements (AVRs) per centre according to volume tercile between 2007 and 2019. A. All AVRs. B. Surgical aortic valve replacements (SAVRs). C. Transcatheter aortic valve replacements (TAVRs).

ciles, respectively;  $P_{\text{ANCOVA}} = 0.67$ ) and for isolated SAVRs (from  $1.02 \pm 0.55$  to  $0.66 \pm 0.30$  [ $P_{\text{trend}} = 0.004$ ], from  $1.08 \pm 0.55$  to  $0.58 \pm 0.25$  [ $P_{\text{trend}} = 0.004$ ] and from  $1.05 \pm 0.37$  to  $0.59 \pm 0.19$  [ $P_{\text{trend}} = 0.003$ ] in the low-, middle- and high-volume terciles, respectively;  $P_{\text{ANCOVA}} = 0.66$ ) (**Table 2** and **Fig. 5**). In 2017–2019, the Charlson Comorbidity Index was similar in the low-, middle- and high-volume terciles for all AVRs ( $0.74 \pm 0.25$ ,  $0.68 \pm 0.24$  and  $0.73 \pm 0.26$ , respectively;  $P = 0.80$ ) and for isolated SAVRs ( $0.69 \pm 0.23$ ,  $0.64 \pm 0.24$  and  $0.67 \pm 0.22$ , respectively;  $P = 0.85$ )



**Fig. 3.** Proportion of aortic valve replacements per volume tercile. A. 2007–2009. B. 2017–2019.

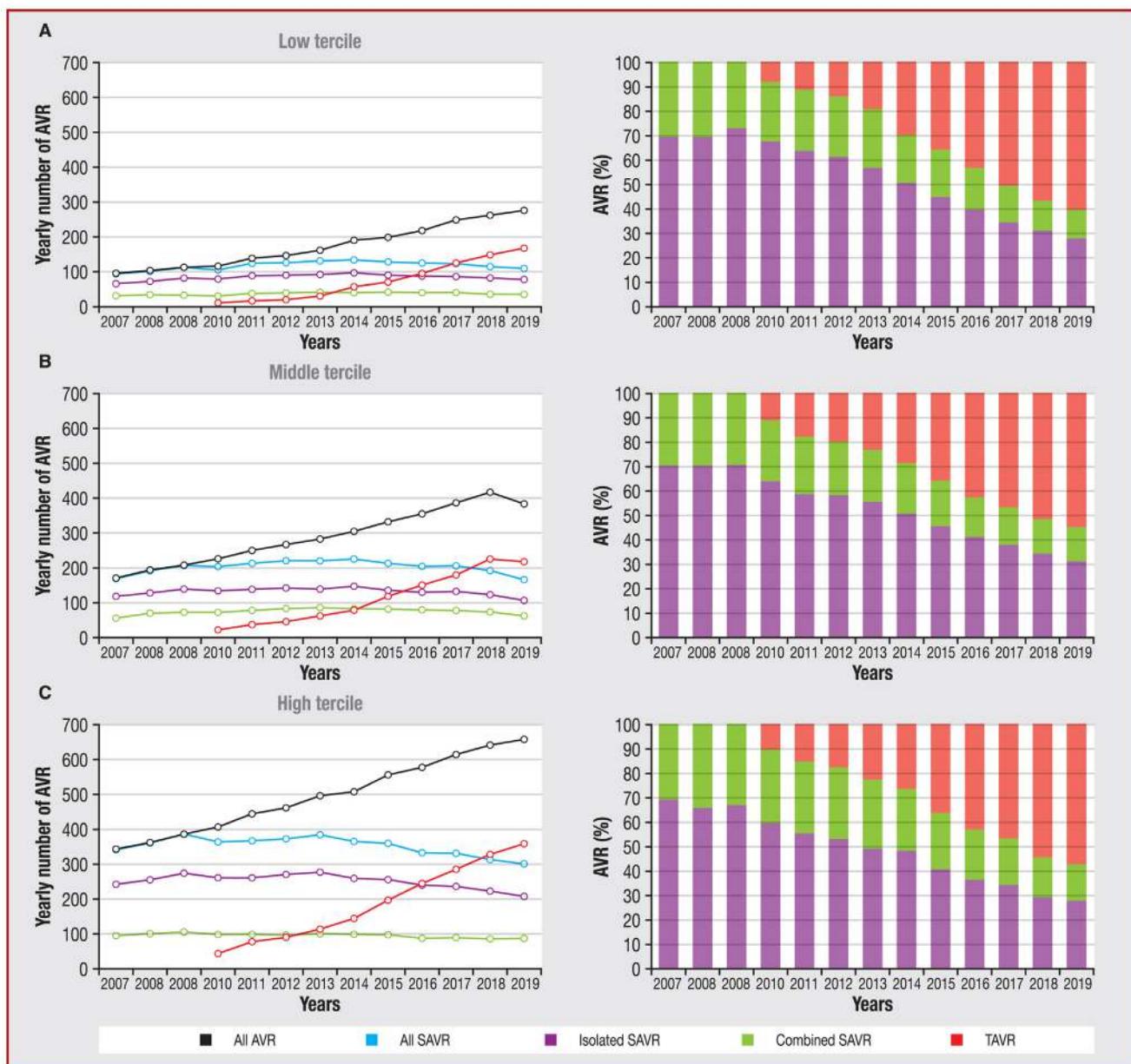
### 3.3.2. TAVRs

Although the age of the patients who underwent TAVR remained largely unchanged between 2010 and 2019 in low-volume ( $83 \pm 6$  to  $82 \pm 7$ ;  $P_{\text{trend}} = 0.24$ ), middle-volume ( $82 \pm 7$  to  $83 \pm 7$ ;  $P_{\text{trend}} = 0.35$ ) and high-volume ( $82 \pm 7$  to  $83 \pm 7$  years;  $P_{\text{trend}} = 0.08$ ) terciles, the Charlson Comorbidity Index declined progressively in the three terciles (from  $1.56 \pm 0.50$  to  $0.69 \pm 0.27$  [ $P_{\text{trend}} = 0.006$ ], from  $1.14 \pm 0.39$  to  $0.61 \pm 0.18$  [ $P_{\text{trend}} = 0.01$ ] and from  $1.55 \pm 0.48$  to  $0.79 \pm 0.43$  [ $P_{\text{trend}} = 0.004$ ], respectively) (**Fig. 5**). The rate of decrease was lower in the high-volume tercile versus the other terciles ( $P_{\text{ANCOVA}} = 0.01$ ). Similar to SAVR, the Charlson Comorbidity Index for TAVR was similar between the three terciles in 2017–2019 ( $0.72 \pm 0.27$ ,  $0.73 \pm 0.25$  and  $0.82 \pm 0.40$ , in the low-, middle- and high-volume terciles, respectively;  $P = 0.60$ ).

### 3.4. In-hospital outcomes

#### 3.4.1. SAVRs

The change in in-hospital death rates over time according to the type of intervention and volume tercile is shown in **Table 2** and **Fig. 6**. In-hospital death rates decreased in all SAVRs in low-volume (from 6.7% to 1.9%;  $P_{\text{trend}} = 0.002$ ), middle-volume (from 4.6% to 2.0%;  $P_{\text{trend}} = 0.003$ ) and high-volume (from 4.6% to 1.6%;  $P_{\text{trend}} = 0.009$ ) terciles, and in isolated SAVRs in low-volume (from 5.9% to 1.4%;  $P_{\text{trend}} = 0.002$ ), middle-volume (from 4.2% to 1.1%;  $P_{\text{trend}} = 0.006$ ), and high-volume (from 3.6% to 0.8%;  $P_{\text{trend}} = 0.001$ ) terciles. There was a faster decrease in death rate in the low-volume tercile compared with the middle- and high-volume terciles for all SAVRs ( $P_{\text{ANCOVA}} = 0.01$ ), but not for isolated SAVRs ( $P_{\text{ANCOVA}} = 0.23$ ). The mean death rate in 2017–2019 was similar across volume



**Fig. 4.** Changes in the absolute annual number of all AVRs, surgical aortic valve replacements (SAVRs), isolated SAVRs, combined SAVRs and transcatheter aortic valve replacement (TAVRs) per centre (left column), and in the proportions of SAVRs and TAVRs (right column) per tercile volume, between 2007 and 2019.

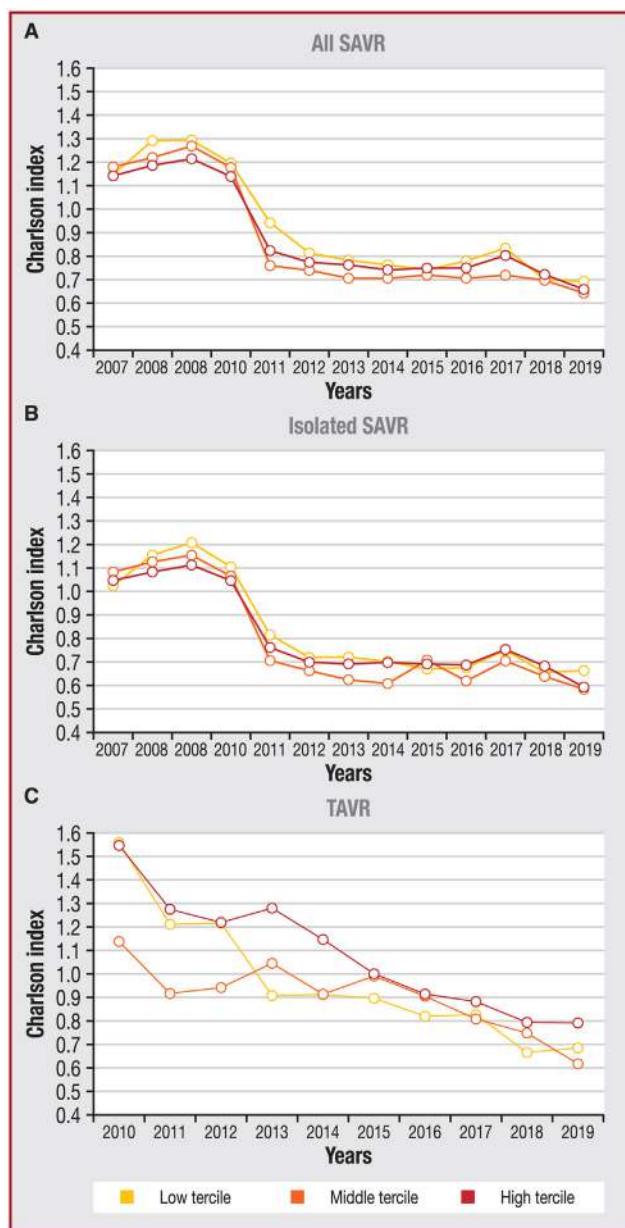
terciles for all SAVRs (2.7%, 2.5% and 2.1% in the low-, middle- and high-volume terciles, respectively;  $P=0.37$ ) and for isolated AVRs (1.8%, 1.9% and 1.4%, in the low-, middle- and high-volume terciles, respectively;  $P=0.19$ ); this persisted after adjustment for age, sex and Charlson Comorbidity Index ( $P=0.23$  for all SAVRs and  $P=0.14$  for isolated SAVRs). When volume terciles were defined based on annual SAVR volume performed in the last 3 years (2017–2019) instead of the first 3 years (2007–2009), we observed a trend towards a lower death rate in the highest tercile for all SAVRs (2.8%, 2.6% and 1.9% in the low-, middle- and high-volume terciles, respectively;  $P=0.06$  [unadjusted] and  $P=0.06$  [adjusted for age, sex and Charlson Comorbidity Index]) and for isolated SAVRs (2.1%, 1.9% and 1.2% in the low-, middle- and high-volume terciles, respectively;  $P=0.08$  [unadjusted] and  $P=0.09$  [adjusted for age, sex and Charlson Comorbidity Index]).

Pacemaker implantation rate increased in the low-volume tercile (from 2.7% to 5.5%;  $P_{\text{trend}}=0.007$ ) and middle-volume tercile

(from 4.5% to 5.3%;  $P_{\text{trend}}=0.0158$ ), but was stable in the high-volume tercile (from 4.5% to 4.7%;  $P_{\text{trend}}=0.47$ ) ( $P_{\text{ANCOVA}}=0.24$ ).

#### 3.4.2. TAVRs

The in-hospital death rate declined similarly from 2010 to 2019 for TAVR in the low-volume (from 9.3% to 1.8%;  $P_{\text{trend}}=0.01$ ), middle-volume (from 8.4% to 2.2%,  $P_{\text{trend}}=0.006$ ), and high-volume (from 9.0% to 1.8%,  $P_{\text{trend}}=0.004$ ) terciles ( $P_{\text{ANCOVA}}=0.20$ ), with similar death rates across terciles in 2017–2019 (2.4%, 2.0% and 1.9% in the low-, middle- and high-volume terciles, respectively;  $P=0.23$ ). After adjustment for age, sex and Charlson Comorbidity Index, in-hospital death rates remained similar in all three terciles ( $P=0.27$ ). Results remained unchanged after exclusion of the TAVRs not performed using a transarterial approach ( $P=0.24$ ). Defining volume terciles based on TAVR annual volume in the 2017–2019 period also did not change our results, showing similar death rates across terciles (2.4%, 2.0% and 1.8% for low-, middle-

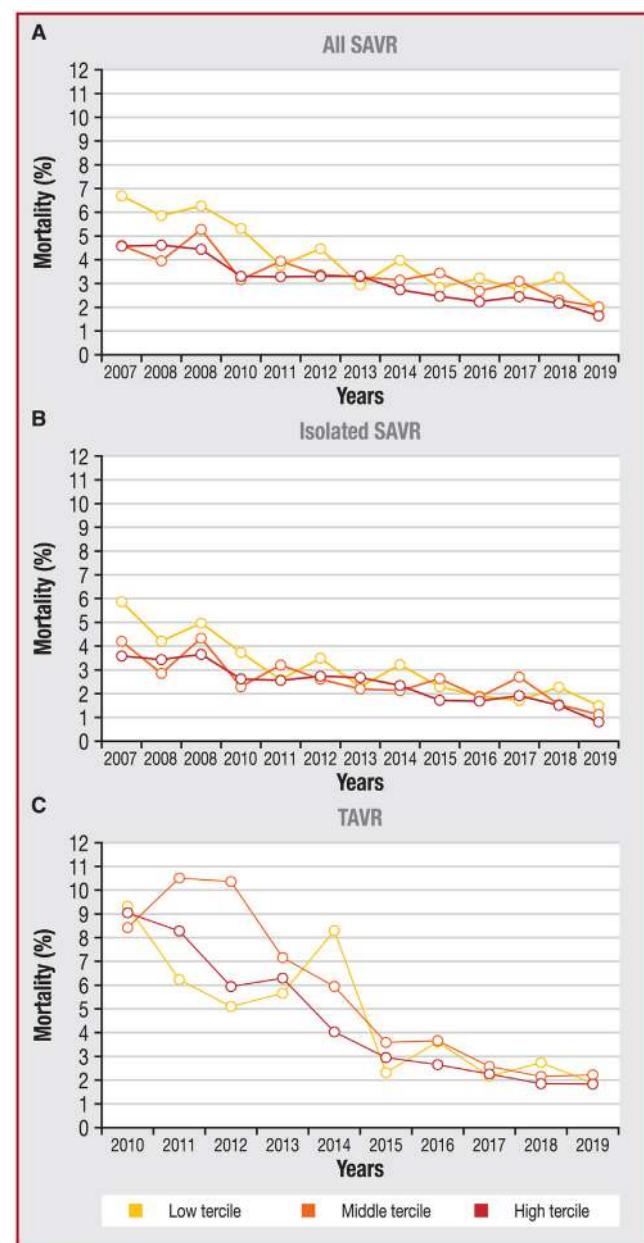


**Fig. 5.** Evolution of the Charlson Comorbidity Index for each type of aortic valve replacement by volume tercile from 2007 to 2019. A. All surgical aortic valve replacements (SAVRs). B. Isolated SAVRs. C. Transcatheter aortic valve replacements (TAVRs).

and high-volume terciles, respectively;  $P = 0.23$  [unadjusted] and  $P = 0.27$  [adjusted for age, sex and Charlson Comorbidity Index]). Pacemaker implantation rates were similar in the last 3 years (16.4%, 15.2% and 16.8%, for low-, middle- and high-volume terciles, respectively;  $P = 0.69$ ).

### 3.5. Excluded centres

Overall, excluded institutions performed 18,105 SAVRs and 7281 TAVRs. The mean age of excluded patients was  $74 \pm 11$  years, and 14,832 (58.4%) were male. The institutions excluded as a result of programme closure during the study period performed a total of 4757 AVRs, with a mean of  $121 \pm 48$  SAVRs/centre/year in 2007–2009, and hence were classified as low-volume centres. The seven centres that opened after 2010 performed a total of 3696 SAVRs (2010–2019) and 2575 TAVRs (2014–2019). The AP-HP



**Fig. 6.** Evolution of in-hospital death rates by volume tercile from 2007 to 2019. A. All surgical aortic valve replacement (SAVRs). B. Isolated SAVRs. C. Transcatheter aortic valve replacements (TAVRs).

group, which gathers institutions of various size, including some that closed during the study period, performed 2754 SAVRs between 2007 and 2009 (918 SAVRs/year). A summary of AVRs performed during the study period at the excluded institutions can be found in Table A.2.

## 4. Discussion

We report the trends in the adoption of TAVR, the impact on SAVR and the changes in clinical presentation and outcomes of AVR at the nationwide level between 2007 and 2019 according to centre volume terciles. The main findings can be summarized as follows. First, the total number of AVRs increased significantly and linearly from 2007 to 2019 due to the wide expansion of TAVR, whereas SAVR numbers have declined since 2013–2015 (following a small increase after TAVR implementation) in all centre volume terciles.

Nevertheless, increases in TAVR volumes were faster in high-volume centres. The proportion of all AVRs performed according to centre volume remained grossly unchanged, with high-volume centres accounting for approximately one half of all AVRs at the nationwide level in both 2007–2009 and 2017–2019. Second, from 2007 to 2019, the Charlson Comorbidity Index declined markedly for both SAVR and TAVR, irrespective of centre volume tercile. Third, in-hospital death rates declined markedly from 2007 to 2019 for both SAVR and TAVR, irrespective of centre volume tercile. Adjusted for age, sex and Charlson Comorbidity Index, death rates in 2017–2019 tended to be lower in high-volume centres for SAVR, but were similar in all terciles for TAVR. Pacemaker implantation rates after TAVR were similar in all three terciles.

Real-life registries in the USA and Europe have clearly documented the wide expansion of TAVR, which has become the dominant form of AVR in most Western countries [13–19]. However, the rate of adoption of TAVR and the impact on SAVR according to centre volume has received little attention. Indeed, whether a new technology would be similarly adopted irrespective of the volume of the centre remained unclear. The present study addresses this issue by analysing trends and outcomes of more than 190,000 AVR procedures performed in 47 centres in France over the course of more than one decade. We observed that the number of AVRs increased linearly between 2007 and 2019 due to a marked increase in TAVR, irrespective of the centre volume tercile. In contrast, SAVR volume increased mildly up until 2013–2015 and then decreased in all terciles. In 2017–2018, TAVR became the dominant form of AVR in all three terciles. Our results show a similar dissemination of TAVR, irrespective of centre volume, with smaller hospitals embracing the new technology and shifting their activities accordingly. Interestingly, TAVR volume increased more rapidly in high-volume centres than in middle- and low-volume centres, whereas the proportion of all AVRs performed according to centre volume remained essentially unchanged. These results suggest that the introduction of TAVR has not redistributed procedural volumes in France. Importantly, and in contrast to percutaneous coronary intervention, TAVR is performed exclusively in surgical centres in France.

Major changes in clinical presentation were observed over the study period. Whereas the mean age of patients referred for TAVR remained stable, it decreased for SAVR in all terciles, suggesting that, irrespective of centre volume, SAVR was mainly performed in recent years in the younger subset of the aortic stenosis population. Patient risk profiles, as assessed using the Charlson Comorbidity Index, also declined markedly in all volume terciles for both TAVR and SAVR, probably due to the extension of TAVR indications to patients at lower risk. It is worth noting that, in recent years, for both SAVR and TAVR, the Charlson Comorbidity Index was similar in all three volume terciles, suggesting that centres are dealing with patients with a similar burden of co-morbidities. It is critical to acknowledge that our findings are purely descriptive, and that the appropriateness of the decision could not be evaluated in the present study.

In parallel with the decrease in Charlson Comorbidity Index, in-hospital death rates after all AVRs, after SAVR and after TAVR declined markedly in all terciles. This implies that, regardless of centre volume, more patients are being treated and, overall, in-hospital death rates have improved. Interestingly, in the last 3 years (2017–2019), TAVR in-hospital death rates were not different among volume terciles after adjustment for age, sex and Charlson Comorbidity Index. These findings may seem in conflict with previous publications that reported significant differences in death rates between high- and low-volume centres. In the Trans-

catheter Valve Therapy (TVT) registry, an inverse volume-death association was observed for TAVR, with higher (+20%) and more variable death rates in hospitals with low TAVR volumes [22]. However, in the USA, the number of centres per million inhabitants is at least two times higher than in France (more than 750 in 2021). In addition, the use of the low-volume tercile definition might be misleading because it is relative to the healthcare system, with highly variable thresholds across countries and studies. The average TAVR volume per centre in the TVT report was thus markedly lower than in France, with mean annual TAVR volumes per centre of 27 and 143 in low- and high-volume centres, respectively. In 2017–2019, centres in the so called “low-volume” tercile in France performed an average of 150 TAVRs annually, and numbers as reported in the low-volume centres in the USA were almost never observed. In fact, many “high-volume” centres in the USA would have been categorized in the “low-volume” tercile in France. In a recent study from the TVT registry, including 545 sites with more than 90,000 TAVRs, the authors confirmed prior results with better outcomes in high-volume centres, but also showed critically that “expansion of TAVR services in the United States may have had unintended consequences on procedural quality” [21]. Proliferation of TAVR centres occurred disproportionately, clustering in specific urban areas, and was associated with a dilution of TAVR volumes, resulting in worsening outcomes. Like France, TAVR performance in Germany is also concentrated (80% of centres performed more than 100 interventions per year, with these centres accounting for more than 90% of all TAVRs performed in the country), and Germany has implemented a well-developed quality control system. Aggregated data from German hospitals have shown a weak association between in-hospital deaths and centre volume [24]. Altogether, our results, combined with the existing literature, suggest that a more centralized consolidated system, such as in France or Germany, may provide better outcomes at the population level, and support the recommendation of scientific societies in establishing volume thresholds for TAVR centres [25,26], although this present study was not designed to refine the value of such thresholds. Importantly, centre and operator volumes often overlap, but are not equivalent, and deserve further consideration outside the scope of the present study. In addition, apart from volume, specific centres' expertise in valvular diseases and networking with referral centres are highly important [2]. As death rates plateau and become similar across centres, it is critical to develop new quality indicators to benchmark institutions' indicators as the number of days spent alive at home outside of a hospital or a skilled nursing facility for both transcatheter and surgical interventions [27–29].

We observed a trend toward an association between centre volume and death rates after SAVR, with lower in-hospital death rates in the high-volume tercile compared with the low- and middle-volume terciles. Determinants of surgical outcomes are complex and multifactorial, and include not only the expertise of the surgeon, but also the expertise of the intensive care unit and the cardiology and rehabilitation teams. The number and experience of personnel in high-volume centres probably facilitates the recognition and timely treatment of surgical and postoperative issues. Centre volume has also been shown to impact outcome in the setting of SAVR or mitral valve surgery [30–32].

#### 4.1. Study limitations

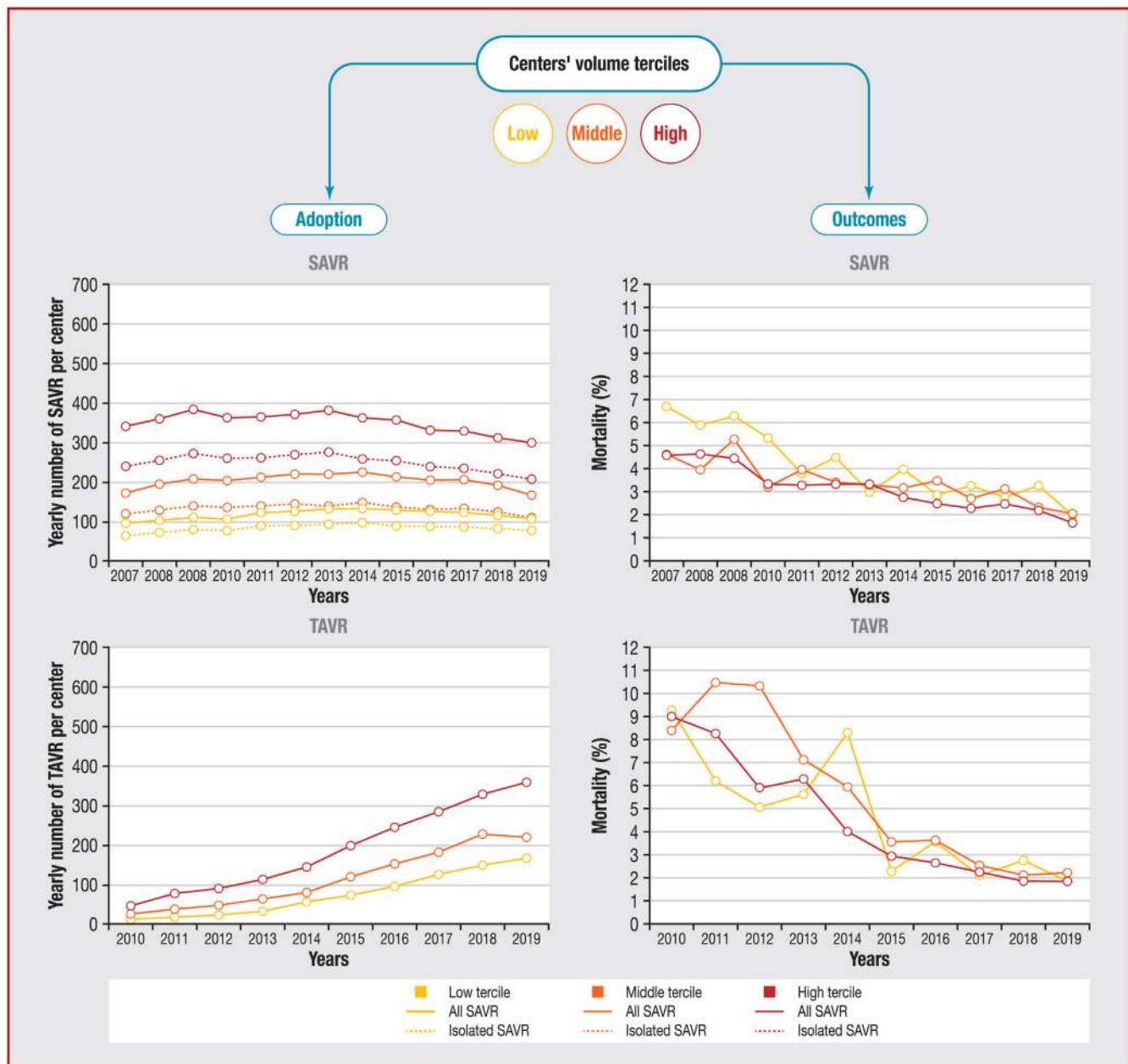
Our study has several strengths and limitations. First, the study was based on an administrative database with the inherent limitations of this data source. Individual coding errors cannot be

excluded, but their impact is largely mitigated by the scale of the database. In addition, variables that were recorded, such as demographics, type of intervention and in-hospital death, leave little room for interpretation. We cannot rule out that some variables used in the calculation of the Charlson Comorbidity Index were omitted, and that the index has been underestimated. However, there is no reason to believe that underestimation might be related to centre volume. Some patients may have also presented with mixed aortic valve disease, and could not be excluded. Coding of complications is linked to reimbursement, and is expected to be of good quality. Second, the PMSI database lacks granularity. Variables such as functional class, frailty, left ventricular ejection fraction and surgical risk-score (e.g. EuroSCORE) cannot be obtained in the PMSI; nor can procedural changes or technical device improvement, which occurred during the study period. Consequently, our adjustment when comparing outcomes across terciles was relatively crude, and residual confounding cannot be excluded. France TAVI, the French nationwide TAVR registry, would have offered a more granular assessment of patients' characteristics and outcomes, but does not collect SAVR. Nevertheless, the PMSI is exhaustive, consecutive and nationwide, and is therefore an ideal tool to analyse nationwide trends and changes in clinical practice. In addition, and in contrast to many other registries, the PMSI is not restricted to one technology or approach and, uniquely, we were able to provide temporal trends for both TAVR and SAVR. Third, only in-hospital deaths are collected in the PMSI. Mid-term and long-term outcomes are not available, but may be accessible with future data linkages. Similarly, procedural results, such as the degree of perivalvular regurgitation, were not available. Pacemaker implantation rates after TAVR could be identified, and were similar in all terciles. Fourth, several institutions were excluded from the present analysis. Centres that closed during the study period or that did not develop a TAVR programme were logically excluded to perform our analysis, but we cannot discount that exclusion of these centres might have contributed, at least partially, to the absence of centre volume impact on TAVR outcome. However, none of the institutions' closures was linked to poor procedural results, but rather to financial and administrative factors. Institutions within the AP-HP group could not be individualized. AP-HP is a heterogeneous group of institutions of various sizes and procedural volumes, including some institutions that closed during the study period. Importantly,

excluded centres accounted for only 12% of the total number of AVRs performed in France during the study period. Fifth, volume terciles were defined based on annual volume of SAVRs performed in 2007–2009, to analyse changes and trends. However, repeating the centre volume analysis based on 2017–2019 annual volume did not change our conclusions, showing similar death rates across terciles for TAVR and a trend toward lower death rates for SAVR in the high-volume tercile. Sixth, our results report the TAVR adoption rates, changes in clinical practice and outcomes observed in France, and may not reflect the experience in other countries, but offer the unique perspective of a centralized publicly funded healthcare system organization. Finally, we are certainly not implying that centre and operator volumes are not critical, but that excellent outcomes can be achieved once certain thresholds are reached, losing their discriminative value, and that volume as a quality indicator should not be considered in isolation. This is fully supported by a recent study from the TVT registry, showing that a modelled strategy based on results instead of purely on volumes significantly improved outcomes [33].

## 5. Conclusions

Using an exhaustive French nationwide database of more than 190,000 AVRs performed in France between 2007 and 2019, we have observed a marked increase in the number of AVRs performed due to the widespread adoption of TAVR with, in the recent years, a decrease in SAVR, irrespective of centre volume. The adoption of TAVR has been greater in high-volume centres; however, the proportion of all AVRs performed according to centre volume has remained essentially unchanged. Patient risk profile and death rates have decreased in all centre volume terciles. However, in the last 3 years, death rates tended to be lower in high-volume centres for SAVR, and similar in all volume terciles for TAVR. These results at a nationwide level are critical to inform policymakers about the dissemination of TAVR resources, suggesting that a centralized healthcare system organized around a limited number of centres all performing a relatively high number of interventions, as in France, is likely to provide the best outcome at the population level, as long as their capacities are appropriately calibrated and that equitable access to care and treatment modalities is provided (Central Illustration).



**Central Illustration.** Aortic valve replacement for aortic stenosis in France: influence of centre volumes on transcatheter aortic valve replacement (TAVR) adoption rate and outcomes. The total number of aortic valve replacements increased linearly, mostly as a result of an increase in TAVRs, irrespective of the centre volume, although with larger absolute volumes in high-volume centres. A decline in death rates was observed in all volume terciles. In 2017–2019, after adjustment for the Charlson Comorbidity Index, death rates tended to be lower for surgical aortic valve replacement (SAVR) in high-volume terciles, and were similar across volume terciles for TAVR.

## Sources of funding

N.W. received salary support from the University of Ottawa Heart Institute. H.E., E.D., B.I. and D.M.-Z. received a grant from the French Government, managed by the National Research Agency (ANR) under the programme “Investissements d’avenir”, with the reference ANR-16-RHUS-0003. H.E. and E.D. were supported by a grant from the GCS G4 (FHU CARNAVAL).

## Acknowledgements

We are indebted to the visionary and pioneering work of Dr Cri- bier who paved the way to the revolution in transcatheter therapy.

## Disclosure of interest

H.E. serves as a proctor for and has received lecture fees from Edwards Lifesciences.

E.D. has received lecture fees from Edwards Lifesciences.

A.C. has served as consultant for Edwards Lifesciences.

D.M.-Z. has received research grants from Edwards Lifesciences. The other authors declare that they have no competing interest.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.acvd.2024.02.007.

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