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Evolution of TAVI patients and techniques over the past decade: The French TAVI registries

Abbreviated title: Evolution of TAVI over the past decade

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Summary

Background. – The French transcatheter aortic valve implantation (TAVI) registries, linked with the nationwide administrative databases, have collected data on TAVI procedures from the first experience to current practices.

Objective. – To investigate changes over the past decade in patient and procedural characteristics, major complications and mortality after TAVI.

Methods. – Data from the France TAVI and FRANCE 2 registries, collected between 2010 and 2021, were linked using a probabilistic algorithm to the French national health single-payer claims database (SNDS). The algorithm created patient profiles from TAVI procedures in SNDS, matching them as closely as possible to the profiles in the registry databases.

Results. – A total of 84,783 TAVI patients were included during the study period. The median age was 83 years (quartile 1, 79 years; quartile 3, 87 years) and remained stable over time. The median EuroSCORE 1 surgical risk score was 12.8 (quartile 1, 7.9; quartile 3, 21.0), and decreased over time. The number of procedures increased linearly, from 1556 in 2010 to 14,114 in 2021. The prevalence of iliofemoral access increased, whereas use of the other approaches decreased. Rates of in-hospital, 30-day and 1-year mortality per year were lower in patients undergoing TAVI after 2015, regardless of the surgical risk score. Finally, hospital length of stay decreased progressively, from 8 days in 2010 to 4 days in 2021.

Conclusion. – The TAVI registries provide the cornerstone for recording changes in TAVI. Over the past decade, patient profiles have improved whereas their age has remained stable. Simplification of the procedure reduced rates of death and major complications as well as length of hospital stay.

Résumé

Contexte. – Les registres français de TAVI, reliés aux bases de données administratives nationales, ont recueilli des données sur les procédures de TAVI depuis la première expérience de TAVI jusqu'à la pratique actuelle.

Objectif. – Nous étudions ici l'évolution dans le temps des caractéristiques des patients, des procédures, des complications majeures et de la mortalité après TAVI.

Méthodes. – Les données des registres France TAVI et FRANCE 2 ont été reliées, à l'aide d'un algorithme probabiliste, à la base de données des demandes de remboursement du système national

de santé français à payeur unique (SNDS), de 2010 à 2021. L'algorithme a créé des profils de patients à partir des procédures TAVI dans le SNDS, en les faisant correspondre aussi étroitement que possible aux profils des bases de données des registres.

Résultats. – Pendant la période d'étude, 84,783 patients bénéficiant d'un TAVI ont été inclus. L'âge médian était de 83 ans (quartile 1, 79 ans ; quartile 3, 87 ans) et est resté stable dans le temps. Le score médian de l'Euroscore 1 était de 12,8 (quartile 1, 7,9 ; quartile 3, 21,0), et a diminué au fil du temps. Le nombre d'interventions par an a augmenté de façon linéaire, passant de 1 556 en 2010 à 14 114 en 2021. La prévalence de l'accès ilio-fémoral a augmenté au fil du temps, tandis que les taux des autres approches ont diminué. La mortalité intra-hospitalière, à 30 jours et à 1 an pour chaque année d'implantation était plus faible chez les patients subissant un TAVI après qu'avant 2015, quel que soit le score de risque chirurgical initial. Enfin, la durée de séjour a diminué progressivement, passant de 8 jours en 2010 à 4 jours en 2021.

Conclusion. – Les registres TAVI sont incontournables pour enregistrer l'évolution du TAVI dans le temps. Au cours de la dernière décennie, le profil des patients s'est amélioré et l'âge est resté stable. La simplification de la procédure a permis de réduire la mortalité, les complications majeures et la durée du séjour.

KEYWORDS

Transcatheter aortic valve implantation;

Evolution over time;

Outcomes

Abbreviations: AS, aortic stenosis; CepenDC: Centre d'Epidémiologie des Causes Médicales de Décès; CNAM, Caisse Nationale d'Assurance Maladie (National Health Insurance Fund); DRG, diagnosis-related group; ICD, International Classification of Diseases; NYHA, New York Heart Association; PMSI, Programme de Médicalisation des Systèmes d'Information; SNDS, Single-payer National health Data System; SNIIR-AM, Système National d'Information Inter-régime de l'Assurance Maladie; TAVI, transcatheter aortic valve implantation; TVT, Transcatheter Valve Therapy registry

Background

Transcatheter aortic valve implantation (TAVI) was initially indicated for symptomatic patients with aortic stenosis (AS) for whom conventional surgical management with aortic valve replacement could not be proposed due to comorbidity. Since the first percutaneous implantation in humans, the scientific validation of TAVI, conducted step by step in randomized trials, has considerably changed the management of patients with symptomatic AS. The most recent European guidelines position TAVI as first-line treatment (Class I, Level A) for older patients (≥ 75 years) with severe symptomatic AS regardless of risk score, and for patients at high risk or who are ineligible for surgery [1].

In addition to randomized trials, it is fundamental to analyse real-life data. In France, since the beginning of the TAVI experience, patients have been included in large national registries. The aim of the present study was to trace the changes in TAVI over the past decade in terms of patient profile, procedure, major in-hospital complications and death.

Methods

French TAVI Registries

Designed as all-comer registries, FRANCE 2 and France-TAVI prospectively included patients undergoing TAVI for severe AS. The FRANCE 2 registry included all implanted patients in France from January 2010 to January 2012 [2,3]. The France-TAVI registry was launched in January 2013 and included all patients who underwent TAVI in 48 of the 50 active TAVI centres in France until December 2021 [4]. These large, national, multicentre, prospective registries were designed to provide baseline characteristics of the patients as well as TAVI procedural aspects. As previously described, the decision to perform TAVI, choice of access and type of device were made based on assessment by multidisciplinary heart teams. Procedures and post-procedural management were performed in accordance with each site's routine protocol. The dataset was collected using a dedicated web-based interface managed by the French Society of Cardiology, which implements regular data quality checks, including range checks and assessments of internal consistency.

All patients provided written informed consent for anonymous processing of their data. The institutional review board of the French Ministry of Health approved the registry. All data are the property of the French Society of Cardiology and were collected with the participation of the French Society of Thoracic and Cardiovascular Surgery.

Study design

In France, the single-payer national health data system (SNDS) provides access to data on national health insurance payments. It covers almost 99% of the French population (more than 66 million people), making it one of the world's largest continuous homogeneous health-claim databases [5]. SNDS was created in 2015 by a merger of the SNIIRAM (Système National d'Information Inter-régime de l'Assurance Maladie) (national anonymous claims database), PMSI (Programme de Médicalisation des Systèmes d'Information) (hospital activity database), national diagnosis-related group (DRG) database and CepiDC (Centre d'Epidémiologie des Causes Médicales de Décès) (national registry of causes of death).

A linking algorithm was developed to match patients in TAVI registries with data from SNDS. The linkage process employed a probabilistic approach, based on matching SNDS data as closely as possible to the profiles in the registry databases. SNDS entries with failure of probabilistic linkage, false patient data (wrong date of birth, wrong admission date, multiple dates of death or duplicate data) were excluded from the analysis. All data were analysed anonymously. Each individual record in SNDS was randomly assigned a numerical identity that did not include any information on patient or centre identity. This number was used in the present analysis, with no reverse identification possible. As all patient data were extracted from registries, informed consent and ethical clearance had already been obtained, and a specific authorization from the national data protection commission (CNIL) was received for the SNDS linkage.

Baseline and procedural characteristics and length of stay were collected from TAVI registries from 2010 to 2021. In-hospital TAVI complications, mortality (30-day, 1-year) and stroke rates were collected from TAVI registries linked to the SNDS from 2010 to 2019 (Fig. 1). In addition, 1-year mortality was reported from 2010 to 2019, as patients implanted in 2020 and 2021 had not yet been linked to SNDS.

Statistical analysis

Absolute numbers, percentages and mean \pm standard deviation (SD) were computed to describe the populations. For mortality analysis, two periods were defined to analyse the evolution of mortality over time: patients undergoing TAVI before 2015 and from 2015. Two Kaplan-Meier mortality curves were

traced for the time periods and for each surgical risk level (EuroSCORE: low, $1 \leq 10$; medium, $>10 / < 20$; and high, ≥ 20). The curves were truncated at 3.5 years due to the small number of patients at 4 years in the group who underwent TAVI after 2015. Statistically significant differences are defined as $P < 0.05$. Comparison between groups used the log-rank test.

Results

From 2010 to 2021, 84,783 patients were included for analysis of baseline and procedural characteristics. After the exclusion of patients without follow-up at 2020 and 2021, 47,410 were linked to SNDS TAVI subjects (with an 82.8% rate of matching) and were included in the analysis of in-hospital TAVI complications and mortality (Fig. 1).

The overall median age was 83 years (quartile 1, 79 years; quartile 3, 87 years), and remained stable over time (Fig. 2). The overall median EuroSCORE 1 surgical risk score was 12.8 (quartile 1, 7.9; quartile 3, 21.0), and decreased over time (Fig. 3). Preprocedural New York Heart Association (NYHA) functional status showed a decreasing prevalence of class III or IV compared with class II (Fig. 4). In patients with a history of coronary disease, the rate of previous angioplasty was 29.3% and remained constant over time, whereas the rate of previous coronary bypass was 8.1%, and decreased from 20.3% in 2010 to 2.4% in 2021. The rate of preprocedural creatinine concentration exceeding $200 \mu\text{m}$ was 4.6% and remained stable.

The number of procedures per year increased linearly, from 1556 in 2010 to 14,114 in 2021 (Fig. 5). Fig. 6 shows changes in the use of local and general anaesthesia in TAVI, with iliofemoral access reported from 2010 to 2021. The prevalence of iliofemoral access increased over time, whereas use of the other approaches, especially transapical, decreased (Fig. 7). The rate of pacemaker implantation after TAVI remained stable, from 12.9% in 2013 to 14.6% in 2019 (Fig. 8).

Annual rates of in-hospital, 30-day and 1 year mortality are reported in the Table. At 3.5 years, the mortality rate for TAVI patients was lower before 2015 in each class of surgical risk ($P < 0.0001$) (Fig. 9). The respective mortality rates at 3.5 years were: 35.5% (95% confidence interval [CI] 33.9, 37.1) before 2015 and 27.3% (95% CI 25.7, 28.9) after 2015 for low surgical risk; 38.7% (95% CI 37.5, 40.0) before 2015 and 31.1% (95% CI 29.7, 32.5) after 2015 for medium surgical risk; 47.9% (95% CI 46.5, 49.3) before 2015 and 44.7% (95% CI 42.8, 46.6) after 2015 for high surgical risk. The in-hospital stroke rate (all strokes) after TAVI remained stable, at 0.63% overall (Fig. 10).

Median hospital stay was 5 days (quartile 1, 3 days; quartile 3, 7 days) over the study period. Length of stay decreased progressively from 8 days in 2010 to 4 days in 2021 (Fig. 11).

Discussion

In these large French TAVI registries, the main changes over time from 2010 to 2021 were: 1) the annual number of TAVI procedure increased linearly, from 1556 to 14,114; 2) age remained stable whereas EuroSCORE 1 surgical risk score decreased; 3) the procedure was simplified, with greater use of femoral access and local anaesthesia; 4) mortality decreased regardless of the surgical risk score; and 5) length of stay after the procedure decreased.

The present study implemented a unique methodology, combining data from large prospective French TAVI registries with and without SNDS data linkage. In this way, each individual could potentially be identified in the SNDS, while maintaining anonymity. This linkage between person- or event-specific data from one source, with additional data for the same people or events from another source, improved the quality and completeness of the registries' data. Additionally, there was no loss to clinical follow-up for patients linked to SNDS, which covers 99% of the population. In addition, SNDS data are not restricted to the PMSI hospital activity database but also include the SNIIRAM health insurance data on patient treatments and the CépIDC epidemiological data on cause of death. However, patients implanted in 2020 and 2021 had not yet been linked to SNDS, as data were not forwarded by the CNAM National Health Insurance Fund, which would have provided information on differences in population size.

Over the past decade, patients' mean risk level halved, with a consistent median age close to 80 years. These data are in concert with a German registry [6]. In the present study, logistic EuroSCORE 1 was analysed, being the only variable that had been used from the beginning in the French registries. However, surgical risk scores developed for coronary surgery do not include some additional comorbidities such as frailty, cirrhosis, porcelain aorta and hostile chest. There is undeniably a shift in TAVI use towards patients with lower surgical risk; however, this is not necessarily associated with shift toward younger patients, because AS remains a pathology of elderly subjects.

Over time, preprocedural NYHA functional status III or IV became less prevalent, in favour of class II. We can speculate that TAVI is being proposed earlier in the management of patients with

severe AS. In addition, in accordance with recent European guidelines, TAVI is no longer recommended in patients with severe comorbidities when intervention is unlikely to improve quality of life or prolong survival beyond 1 year [1].

The trend is towards a more simplified TAVI procedure. Two major shifts involve anaesthesia and vascular access. The rate of local anaesthesia for the femoral approach was 50.8% in 2010, reaching 94.6% in 2021. Alternatives to the femoral approach have changed considerably, with nearly complete disappearance of apical and transaortic access and progression of the carotid approach, which is a French particularity. The femoral approach continues to progress, at a level similar to those reported in other registries (6, 7). Femoral TAVI is becoming a “stent-like” procedure.

Yearly mortality declined dramatically. In-hospital mortality decreased from 10.1% in 2010 to 2.2% in 2019; 30-day mortality from 10.0% in 2010 to 2.7% in 2019; and 1-year mortality from 22.0% in 2010 to 11.0% in 2018, similar to the rates reported in German and US registries [6,7]. Of note, 1-year mortality rates for 2019 to 2021 are not available (data extracted only from SNDS). The reduction in mortality rate over time could primarily be attributed to the lower risk profile of TAVI patients, progression of implantation techniques and better preprocedural cardiac tomography assessment.

Permanent pacemaker rates did not differ from those in the early TAVI experience, but remained stable and similar to those in the German registry [6]. Linkage with SNDS makes it possible to count new permanent pacemakers accurately as these data are not declared by the centres.

The twofold decrease in length of stay, from 8 days in 2010 to 4 days in 2021, was most likely enabled by an improvement in patient profiles, procedural simplification, optimization of the patient pathway and reduction in major complications. In these elderly patients undergoing TAVI, early discharge is key to reducing the iatrogenic effects of hospitalization.

Study limitations

The present linkage method may not be as reliable as clinical event adjudication and does not exclude potential bias related to the use of coding to define clinical events. Moreover, mortality data from 2019 to 2021 were extracted only from SNDS and prevented estimation of 1-year mortality over this period. As the end of enrolment into the FRANCE 2 registry was January 2012, with only 224 patients for this year, we cannot exclude potential bias in analyses for this year. Finally, we are unable to exclude the

risk of potential selection bias for in-hospital TAVI complications and mortality, related to the lack of matching in 17% of the TAVI population.

Conclusions

The TAVI registries are essential for monitoring the evolution of TAVI at a national level. Over the past decade, patient profiles improved whereas age remained stable. Simplification of the procedure may have led to reductions in mortality, major complications and length of stay.

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Disclosure of interest

None.

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Figure Legends

Figure 1. Overview of the study methodology: flow chart of data collected from TAVI registries and from TAVI registries linked to SDNS.

CepiDC, national registry of causes of death (Centre d'Epidémiologie des Causes Médicales de Décès); PMSI, hospital activity database (Programme de Médicalisation des Systèmes d'Information; SNDS, single-payer national health data system; SNIIR-AM, national anonymous claims database (Système National d'Information Inter-régime de l'Assurance Maladie); TAVI, transcatheter aortic valve implantation.

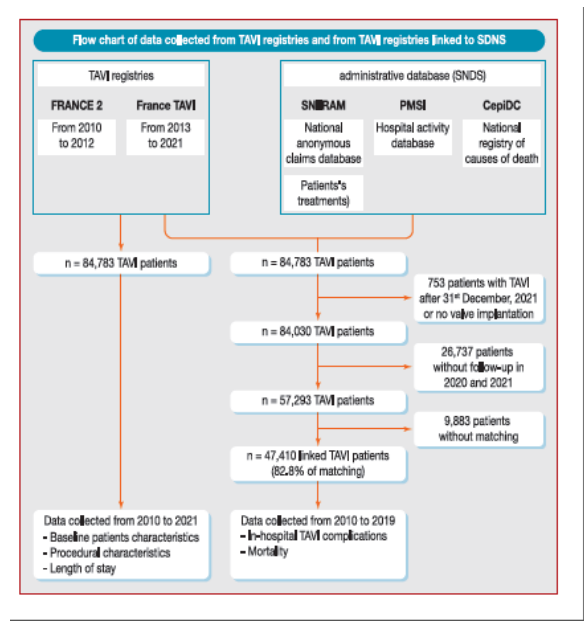


Figure 2. Change in median age of TAVI patients ($n = 84,783$) over time. Vertical lines indicate interquartile range. *Based on data from 224 patients.

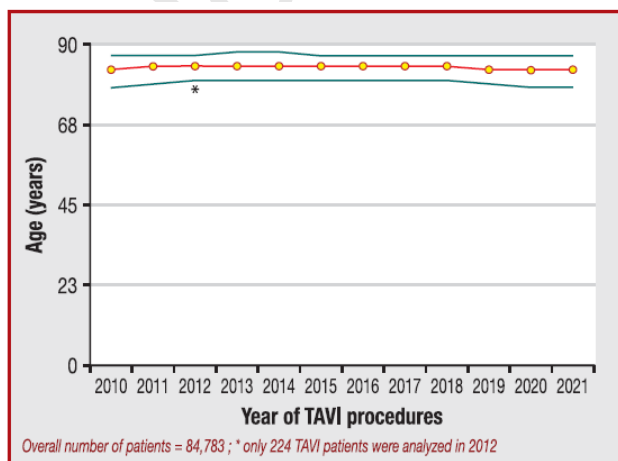


Figure 3. Change in median EuroSCORE 1 of TAVI patients ($n = 84,783$) over time.

Vertical lines indicate interquartile range. *Based on data from 224 patients.

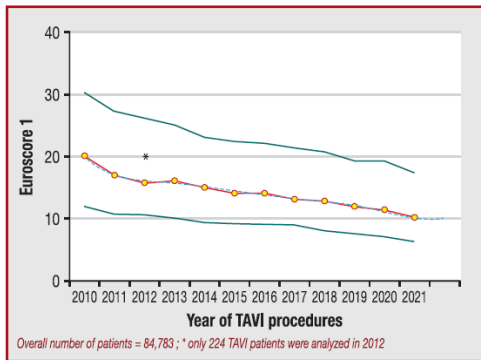


Figure 4. Change in New York Heart Association (NYHA) preprocedural clinical status of TAVI patients ($n = 84,783$) over time. *Based on data from 224 patients.

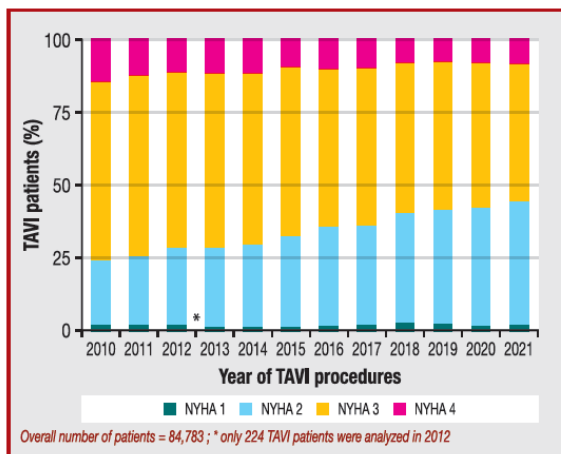


Figure 5. Change in number of TAVI procedures over time.

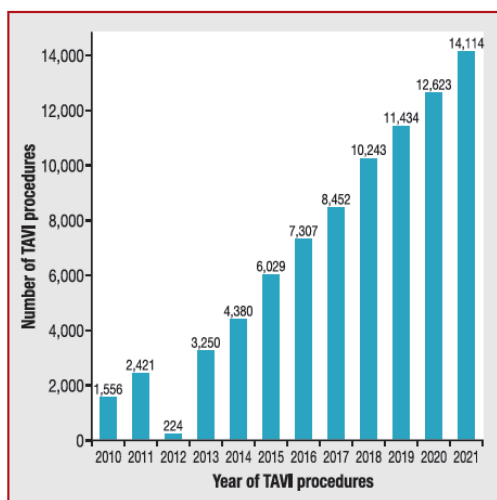


Figure 6. Change in use of local and general anaesthesia for iliofemoral TAVI procedures over time in TAVI patients ($n = 84,783$). *Based on data from 224 patients.

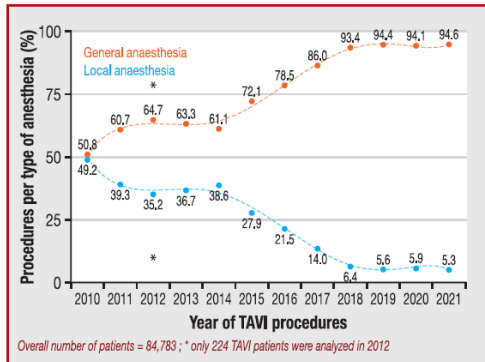


Figure 7. Change in use of access sites over time. *Based on data from 224 patients.

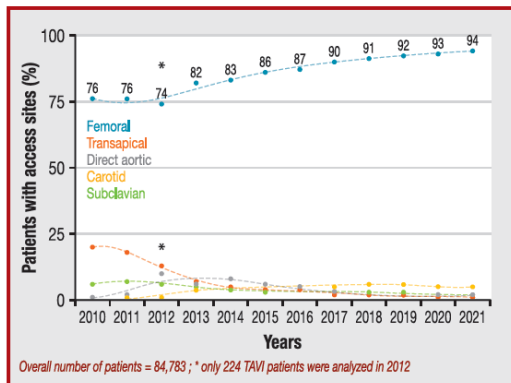


Figure 8. Rate of in-hospital pacemaker implantation over time.

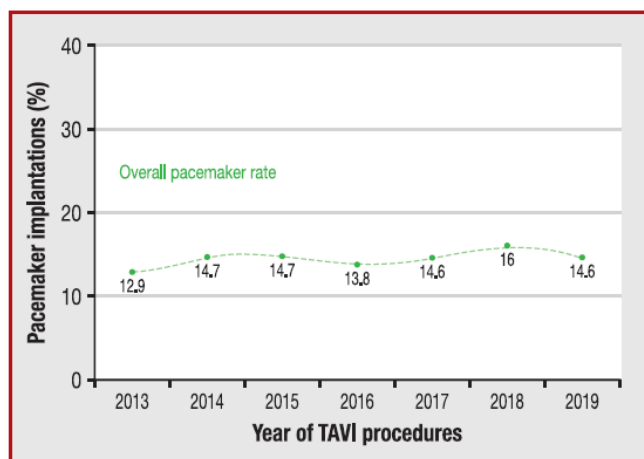


Figure 9. Kaplan-Meier mortality curves for TAVI patients treated before and from 2015, according to low, medium, and high surgical risk score.

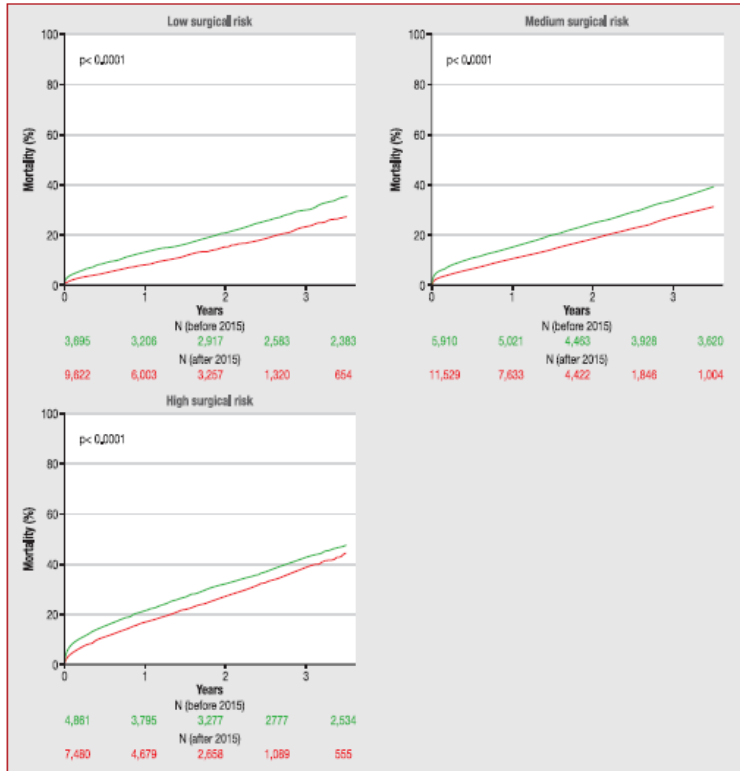


Figure 10. Rate of in-hospital stroke over time. *Based on data from 224 patients.

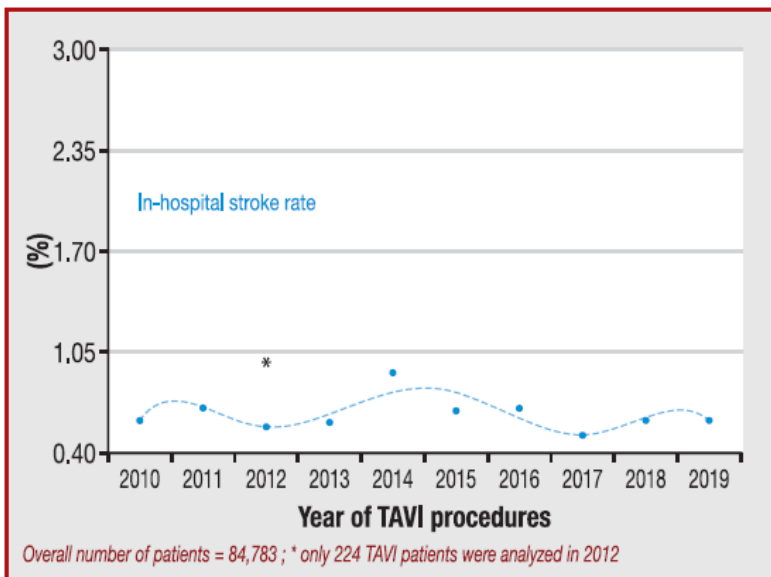
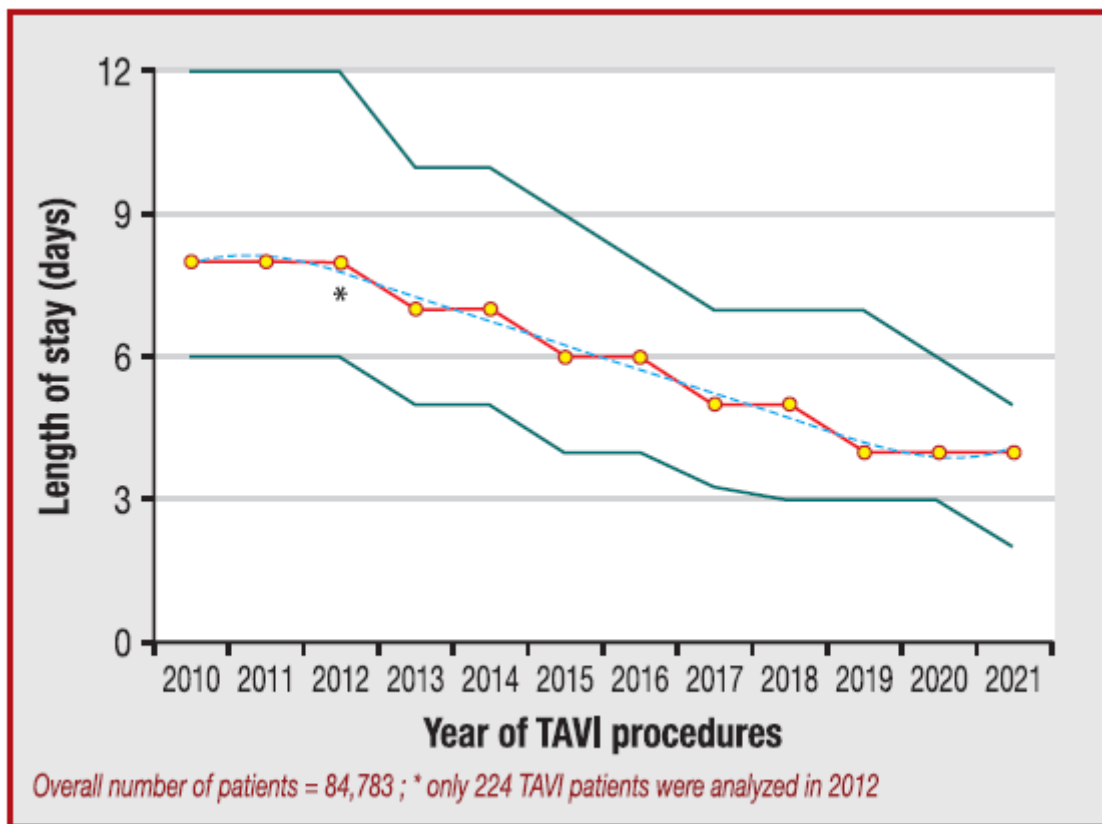


Figure 11. Median length of stay in hospital over time. Vertical lines indicate interquartile range.

*Based on data from 224 patients.



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Table In-hospital, 30-day and 1-year mortality from 2010 to 2019.

Year	In-hospital mortality (<i>n</i> = 47,410)	30-day mortality (<i>n</i> = 46,699)	1-year mortality (<i>n</i> = 38,021)
Overall rate	3.59%	3.98%	13.85%
Rate per year			
2010	10.13%	9.96%	21.97%
2011	9.05%	9.47%	23.36%
2012	7.26%	4.47%	17.88%
2013	5.52%	6.85%	16.44%
2014	5.25%	5.54%	16.12%
2015	3.43%	3.82%	14.04%
2016	3.44%	3.75%	12.96%
2017	2.73%	3.14%	11.99%
2018	2.34%	2.7%	11.04%
2019	2.18%	2.7%	NA