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Temporal Trends in Pacemaker Implantations Over the Past Decade in France: Impact of Transcatheter Aortic Valve Implantations



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In this study, we assessed the temporal trends of permanent pacemaker implantations in France from 2008 to 2018 using data from the Échantillon Généraliste de Bénéficiaires (EGB) administrative database, a representative sample of the French population. Additionally, we evaluated the impact of transcatheter aortic valve implantations on the overall pacemaker implantation rate. Our data suggest that the incidence of permanent pacemaker implantations in France increased significantly only in patients ≥ 80 years old, with post-transcatheter aortic valve implantations accounting for at least 2/3 of this increase. © 2023 Elsevier Inc. All rights reserved. (Am J Cardiol 2023;203:403–405)

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Over the years, a trend of increasing permanent pacemaker implantation (PPMI) rates has been observed, especially in older patients.¹ Recently, transcatheter aortic valve implantation (TAVI), a procedure known to carry a potential short-term risk for conduction disorders,^{2,3} has emerged as a standard therapy for certain elderly patients with severe aortic valve stenosis.^{4,5} Although many studies have explored the incidence, timing, and outcomes of PPMI after TAVI,⁶ data on the impact of TAVI on temporal PPMI trends are scarce at a nationwide scale. We sought to examine the temporal trends in PPMI over the past decade in France and evaluate the extent to which they have been affected by TAVI procedures.

This observational, cross-sectional study was based on data from the Échantillon Généraliste de Bénéficiaires (EGB) administrative database. The EGB consists of a 1/97th randomly selected sample of the Système National des Données de Santé, the French national electronic health care database, and is considered a representative sample of

the French population.^{7,8} We identified all patients with de novo PPMI and/or TAVI from 2008 to 2018, before the discontinuation of the EGB database in 2019. All reinterventions, generator replacements, device upgrades, and defibrillator implantations were excluded. PPMIs occurring within 30 days after a TAVI were considered procedural complications and were defined as post-TAVI PPMIs. We initially calculated the crude annual PPMI and TAVI rates, which are reported as cases per 100,000 individuals. Three separate age groups (60 to 70, 70 to 80, and ≥ 80 years old) were defined for further subgroup analysis.

In 2008, the EGB database included 503,578 individuals, reaching 576,160 in 2018. The number of elderly patients (≥ 80 years old) increased by 42%, from 23,822 in 2008 (4.7% of the total sample) to 33,752 in 2018 (5.9% of the total sample, $p < 0.001$). In the overall population, an increase in the absolute number of PPMIs was observed, from 283 cases in 2008 to 407 cases in 2018. Similarly, TAVI procedures increased from only 11 cases in 2010 to 77 cases in 2018, with a marked increase noted from 2013 onward. The annual PPMI rate increased only in patients aged ≥ 80 years, from 546/100,000 in 2008 to 676/100,000 in 2018, whereas the corresponding rates were much lower in younger patients, even showing a slightly decreasing trend in patients 60 to 70 years old (Figure 1). In addition, TAVI rates also increased in patients ≥ 80 years old, from 31/100,000 in 2010 to 157/100,000 in 2018.

To examine the effect of TAVI on PPMI rates, the decade from 2008 to 2018 was divided into a reference period (2008 to 2012) with no or very few TAVI procedures and an index period (2013 to 2018) with a marked increase in TAVI. For the index period, the expected number of PPMIs was estimated on the basis of PPMI rates from the reference period with indirect standardization for age and gender. The standardized incidence ratio (SIR) was

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See page 405 for Declaration of Competing Interest.

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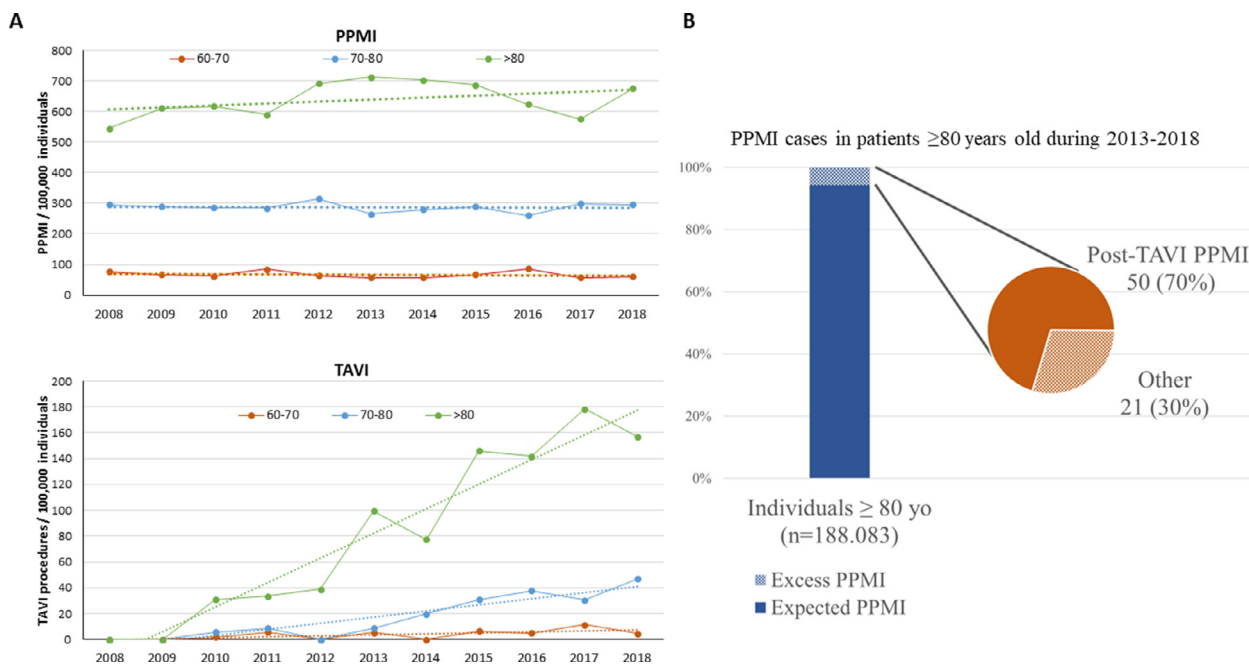


Figure 1. (A) Annual PPMI (upper panel) and TAVI (lower panel) rates for each age group. (B) Expected and excess PPMI cases in patients ≥80 years old during the index period (2013 to 2018). The pie chart depicts the relative percentage of post-TAVI PPMIs among the overall excess PPMI cases. Post-TAVI PPMI was defined as PPMI occurring within 30 days after a TAVI procedure.

calculated as the ratio of the observed to the expected number of PPMIs, with 95% confidence intervals (CIs). In the overall population, 2,199 cases of PPMI were observed during the index period, as opposed to 2,194.4 expected cases (SIR 1.00, 95% CI 0.95 to 1.04). A significant SIR was found only in patients aged ≥80 years: 1,242 PPMIs were observed, as opposed to 1,171.3 expected cases, corresponding to a SIR of 1.06 (95% CI 1.01 to 1.12) and an excess of 71 PPMIs. In the remaining age groups, SIR was not statistically significant, being 0.93 (95% CI 0.78 to 1.02) in patients aged 60 to 70 years and 0.98 (95% CI 0.90 to 1.05) in patients aged 70 to 80 years. To determine whether TAVI procedures have influenced the PPMI rates in patients ≥80 years old, a further analysis according to TAVI status was conducted. For elderly patients without a TAVI procedure (n = 187,830), a nonsignificant SIR of 1.01 (95% CI 0.95 to 1.06) was found. However, in the small subgroup of patients aged ≥80 years with TAVI (n = 253), 66 PPMIs were observed, 51 of which could be classified as post-TAVI, resulting in 1 PPMI for every 5 TAVI procedures. When compared with 1.7 expected cases,

the previously mentioned number of observed PPMIs led to a SIR of 38.3 (95% CI 29.6 to 46.6) and 64 excess PPMIs. Out of these, 50 could be classified as post-TAVI (Table 1), representing 78% of the excess cases in this group and 70% of the excess cases in the overall group of patients aged ≥80 years (Figure 1).

According to our study, PPMI rates have significantly increased among patients ≥80 years old over the past decade in France. Given that age standardization was applied, this effect cannot be attributed to the expanding elderly population of the EGB database, but rather implies additional contributing factors. The increasing rates of TAVI procedures seem to have played a significant role, as 70% of the excess PPMIs in this group of elderly patients occurred within 30 days after a TAVI. In contrast, among elderly patients without a TAVI, the excess PPMI cases were minimal. The 50 post-TAVI PPMIs observed in excess in patients ≥80 years old in our study correspond to >5,000 cases on a nationwide scale from 2013 to 2018. This rate of approximately 850 post-TAVI PPMIs per year translates to an additional, non-negligible

Table 1
Standardized incidence ratio (SIR) of PPMI for the period from 2013 to 2018 in patients aged ≥80 years according to TAVI status

	Observed PPMIs	Expected PPMIs*	SIR (95% CI)	Excess PPMIs (Observed – Expected)
Patients ≥80 years old (n=188,083)	1242	1171.3	1.06 (1.01–1.12)	71
Patients without TAVI (n=187,830)	1176	1169.6	1.01 (0.95–1.06)	7
Patients with TAVI (n=253)	66 (51 post-TAVI)	1.7 (1 post-TAVI [†])	38.8 (29.6–46.6)	64 (50 post-TAVI)

* The expected number of PPMIs for the period 2013-2018 was calculated based on the PPMI rates of the reference period (2008-2012), after standardization for age and gender.

[†] The expected number of post-TAVI PPMIs was calculated by applying the rate of post-TAVI PPMI resulting from the observed cases (51/66 = 77%) to the expected number of PPMIs for patients ≥80 years old with a TAVI procedure.

PPMI = permanent pacemaker implantation; TAVI = transcatheter aortic valve implantation.

economic burden, as post-TAVI PPMIs are known to significantly increase hospitalization costs.^{6,9} The economic impact of post-TAVI PPMIs on health care systems should thus be anticipated, and future resource demands need to be foreseen.

The expansion of TAVI indications to include lower-surgical-risk patients after 2019¹⁰ and the impact of the COVID-19 pandemic may have influenced PPMI rates after 2018. However, because of the discontinuation of the EGB database in 2019, we were unable to draw any meaningful conclusions regarding this period. Further studies based on national administrative health care databases could offer valuable insights into PPMI rates after 2018. Moreover, as the EGB is an administrative health care database, it was not possible to examine perioperative factors that could potentially affect post-TAVI PPMI rates, such as operators' expertise or the specific type of aortic valve prosthesis used.

In conclusion, over the past decade, the incidence of PPMI in France has significantly increased only in patients aged ≥ 80 years. Post-TAVI PPMIs account for 70% of this increase.

Declaration of Competing Interest

Serge Boveda reports a relationship with Medtronic, Boston Scientific, Microport and Zoll that includes: consulting or advisory. The remaining authors have no competing interests to declare.

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