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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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Running title: impact of TAVI on pacemaker implantations

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Abstract

In this study, we assessed the temporal rates of permanent pacemaker implantations (PPMI) in France from 2008 to 2018 using data from the Echantillon Généraliste de Bénéficiaires administrative database, a representative sample of the French population. Additionally, we evaluated the impact of transcatheter aortic valve implantations (TAVI) on the overall pacemaker implantation rate. Our data suggest that the incidence of PPMI in France increased significantly only in patients ≥ 80 years old, with post-TAVI implantations accounting for at least two-thirds of this increase.

Over the years, a trend of increasing permanent pace maker 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 following 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 Echantillon Généraliste de Bénéficiaires (EGB) administrative database. The EGB consists of a 1/97th randomly selected sample of the Système National des Données de Santé (SNDS), the French national electronic healthcare database, and is considered a representative sample of the French population (7,8). We identified all patients with de novo PPMI and/or TAVI during 2008-2018, before the discontinuation of the EGB database in 2019. All re-interventions, generator replacements, device upgrades, and defibrillator implantations were excluded. PPMI occurring within 30 days following a TAVI were considered procedural complications and were defined as post-TAVI PPMI. We initially calculated the crude annual PPMI and TAVI rates, which are reported as cases per 100,000 individuals. Three separate age groups (60-70, 70-80 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 (≥ 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 PPMI was observed, from 283 cases in 2008 to 407 cases in 2018. Similarly, TAVI procedures increased from just 11 cases in 2010 to 77 cases in 2018, with a marked increase noted from 2013 onwards. The annual PPMI rate increased only in patients ≥ 80 years old, 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 60-70 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 2008-2018 was divided into a reference period (2008-2012) with no or very few TAVI procedures and an index period (2013-2018) with a marked increase in TAVI. For the index period, the expected number of PPMI was estimated based on PPMI rates from the reference period with indirect standardization for age and sex. The standardized incidence ratio (SIR) was calculated as the ratio of the observed to the expected number of PPMI, with 95% confidence intervals (CI). In the overall population, 2199 cases of PPMI were observed during the index period, compared with 2194.4 expected cases (SIR=1.00, 95% CI, 0.95 - 1.04). A significant SIR was found only in patients ≥ 80 years old: 1242 PPMI were observed, compared with 1171.3 expected cases, corresponding to a SIR of 1.06 (95% CI, 1.01 - 1.12) and an excess of 71 PPMI. In the remaining age groups, SIR was not statistically significant, being 0.93 (95% CI, 0.78 - 1.02) in patients 60-70 years old and 0.98 (95% CI, 0.90 - 1.05) in patients 70-80 years old. To determine whether TAVI procedures have influenced 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 non-significant SIR of 1.01 (95% CI, 0.95 - 1.06) was found. However, in the small subgroup of patients ≥ 80 years old with TAVI (n=253), 66 PPMI were observed, 51 of which could be classified as post-TAVI, resulting in 1 PPMI for every 5 TAVI procedures. When compared to 1.7 expected cases, the above number of observed PPMI led to a SIR of 38.3 (95% CI, 29.6 - 46.6) and 64 excess PPMI. 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 ≥ 80 years old (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 carried out, this effect cannot

be attributed to the expanding elderly population of the EGB database, but rather implies additional contributing factors. The increasing TAVI procedures seem to have played a significant role, as 70% of the excess PPMI in the elderly 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 PPMI observed in excess in patients ≥ 80 years in our study correspond to more than 5000 cases on a nationwide scale during 2013-2018. This rate of approximately 850 post-TAVI PPMI per year translates to an additional, non-negligible economic burden since post-TAVI PPMI are known to significantly increase hospitalization costs (6,9). The economic impact of post-TAVI PPMI on healthcare 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 2019 (10), as well as the impact of the COVID-19 pandemic, may have influenced PPMI rates after 2018. However, due to 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 healthcare databases could offer valuable insights into PPMI rates after 2018. Moreover, as the EGB is an administrative healthcare 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 ≥ 80 years old. Post-TAVI PPMI 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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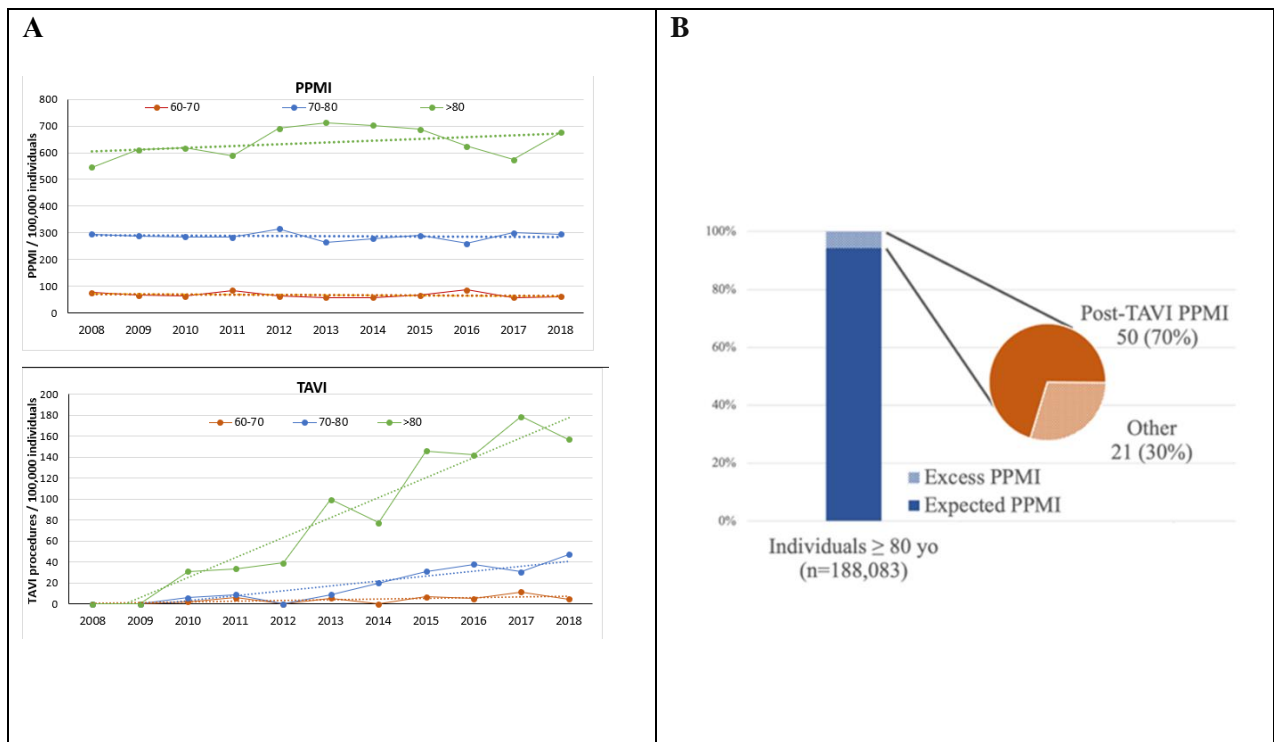


Figure 1: (A) Annual PPMI (upper panel) and TAVI (lower panel) rates for each age group. (B) Expected and excess PPMI cases in patients ≥ 80 years old during the index period (2013 to 2018). The pie chart depicts the relative percentage of post-TAVI PPMIs among the overall excess PPMI cases. Post-TAVI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

Table 1: Standardized incidence ratio (SIR) of PPMI for the period 2013 – 2018 in patients \geq 80 years old according to TAVI status

	Observed number of PPMI	Expected number of PPMI*	SIR (95% CI)	Excess cases of PPMI (Observed – Expected)
Patients \geq 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 PPMI for the period 2013-2018, was calculated based on the reference PPMI rates of the period 2008-2012, after standardization for age and sex.

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

PPMI: permanent pacemaker implantation; TAVI: transcatheter aortic valve implantation

