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## Incremental costs of new permanent pacemaker implantation (PPMI) after transcatheter aortic valve replacement (TAVR)

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## Research Letter

In recent years, transcatheter aortic valve replacement (TAVR) has become the predominant treatment modality for aortic valve replacement [1]. New permanent pacemaker implantation (PPMI) occurs within 30 days of 6%–17% of TAVR cases, and these rates are generally lower with the use of a balloon-expandable TAVR device versus self-expanding device [2,3].

While some studies have demonstrated an increase in index hospitalization costs and length of stay related to PPMI following TAVR, the evidence is limited to earlier time periods, cost-to-charge approximations of cost, or single center studies [4–7]. In one such study, Doshi et al. studied the cost associated with PPMI post-TAVR using the National Inpatient Sample data between 2012 and 2014 and found that PPMI contributed to a significantly longer length of stay, translating to an unadjusted average incremental index hospitalization cost of \$6620 based on cost-to-charge approximations [5]. However, there is a lack of contemporary and multicenter evidence on the direct and indirect costs associated with PPMI post-TAVR, which has meaningful implications for the economics of TAVR procedures. Hospital accounting practices of direct and indirect costs measure per-case profitability, which informs decision-making for hospital investment in new or expanded TAVR programs [8]. Therefore, we sought to use a contemporary, multicenter dataset (2016–2020) to

assess the impact of PPMI implantation following TAVR on total, direct, and indirect hospitalization costs. In addition, our study also provides granularity by reporting the incremental direct and indirect costs by hospital cost centers, such as intensive care unit (ICU), imaging, medical/surgical, and others.

We conducted a retrospective, population-based cohort study of patients who underwent a TAVR procedure and had no pacemaker at admission, between January 2016 and December 2020 in the BIOME database. The BIOME database is a multicenter data repository combining clinical and financial data from 18 U.S. hospitals with TAVR programs. (BIOME Analytics, Sausalito, CA). Hospitals were primarily located in California ( $n = 14$ ) and most facilities conducted over 50 TAVR procedures per year ( $n = 16$ ), with half performing over 100 TAVRs annually ( $n = 9$ ) and one-sixth performing over 200 TAVRs annually ( $n = 3$ ). Patients were assigned to the new PPMI group or the no new PPMI group and costs and healthcare utilization were measured for the two cohorts. Separate generalized linear models with multiple data considerations for total cost, direct cost, length of stay (LOS), ICU utilization, discharge status, and all-cause 30-day readmissions were generated for PPMI versus No-PPMI and adjusted for patient and facility characteristics. Direct costs are costs directly attributable to delivering patient care, such as costs of physician services, supplies and devices, implants, and medications. Indirect costs are allocated costs that

Abbreviations: PPMI, Permanent pacemaker implantation; TAVR, Transcatheter aortic valve replacement; ICU, Intensive care unit; LOS, Length of stay; PACU, Post-anesthesia care unit; STS, Society of Thoracic Surgeons.

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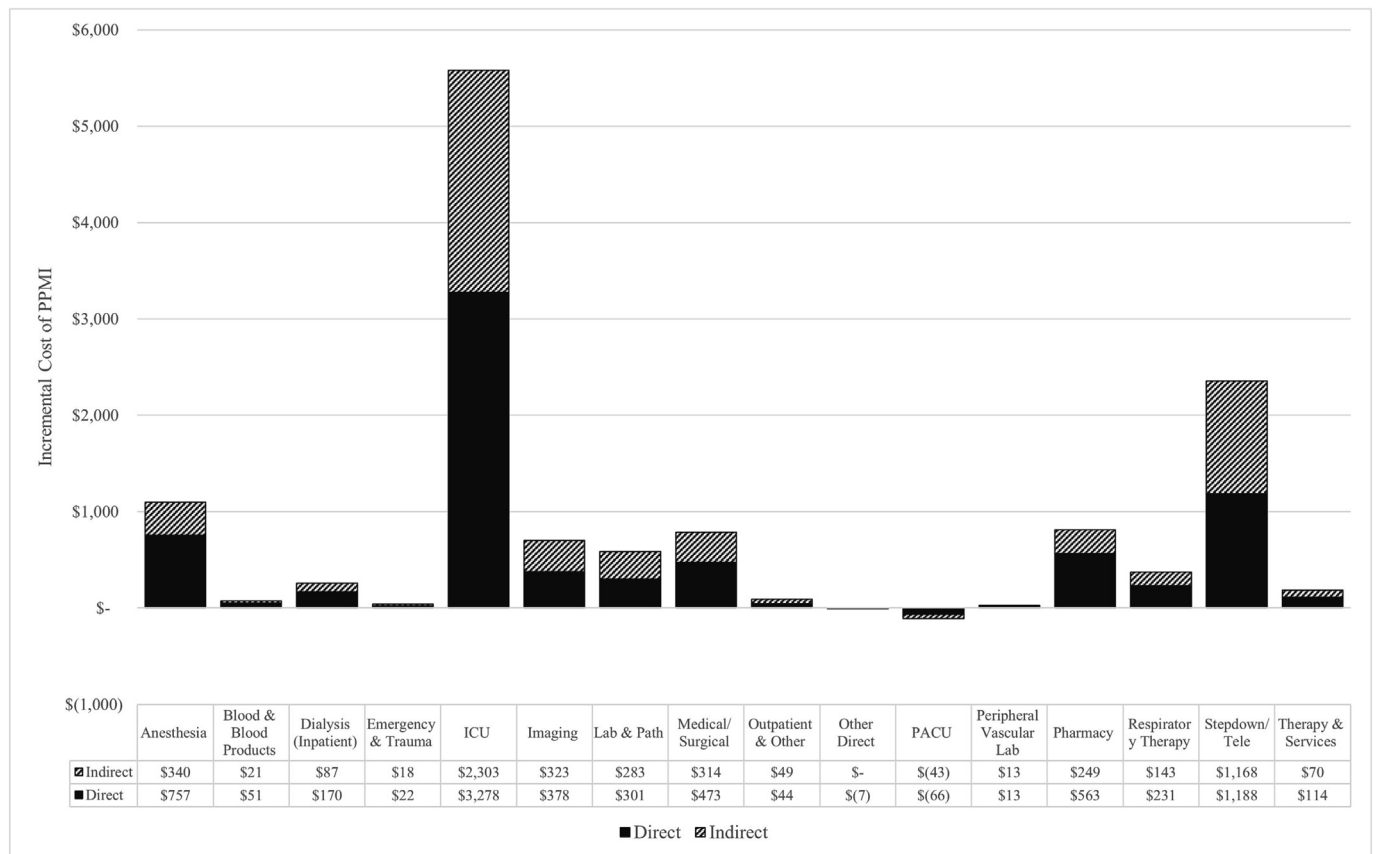


Fig. 1. Mean incremental costs of permanent pacemaker implantation by cost center. Abbreviations: ICU intensive care unit, PACU post-anesthesia care unit, PPMI permanent pacemaker implantation.

are not directly attributed to patient care, such as costs of general administration, information technology, and capital expenses.

Of the 7820 patients in the study, 666 (8.5 %) patients received a PPMI post-TAVR. Most of the sample was of low surgical risk (49.9 %), with the remaining 32.9 %, 13.1 %, and 4.1 % of intermediate, high, and prohibitive surgical risk, respectively. Most patients in the PPMI cohort were male (n = 388, 58.3 %), Caucasian (n = 572, 85.9 %), had an elective admission (n = 530, 79.6 %), with a mean STS score of 6.5, and an average age of 81.7 years. The no-PPMI cohort had a similar distribution of males and race; this group had a higher share of elective admissions (n = 6202, 86.7 %), and a lower mean STS score (5.3). Most of the patients in both cohorts were from facilities in the Western region of the US (PPMI: 79.7 %, no-PPMI: 81.2 %). The average total cost for TAVR patients that received a pacemaker was \$97,224 (+\$38,188) and the average total cost for

TAVR patients that did not receive a pacemaker was \$70,086 (+\$25,048). It is expected that the use of an additional resource would increase the direct cost of care, however the PPMI group also had a significantly higher indirect cost. Compared to the no-PPMI group, the average per-patient cost in the PPMI cohort was \$16,877 higher for direct costs and \$10,261 higher for indirect costs. The ICU, Stepdown/Telemetry, and Anesthesia cost centers were the largest contributors to the cost difference between the PPMI and no-PPMI cohorts, with 41 % of incremental ICU costs, 50 % of incremental Stepdown/Telemetry costs, and 31 % of incremental Anesthesia costs originating from indirect costs (Fig. 1). After adjusting for patient and hospital characteristics, the models estimated significantly higher costs (incremental: total \$23,588, direct \$14,466, and indirect \$9157), significantly longer lengths of stay (1.8 days, p < .0001), significantly more ICU hours (14.9 h, p < .0001), less likely to be

Table 1

Multivariable modeling results for costs, length of stay and hours in the intensive care unit at index for PPMI and no-PPMI cohorts.

Outcome	PPMI	No PPMI	Difference	P-value
Total costs on index <sup>a</sup>	\$93,129	\$69,541	\$23,588	<.0001
Direct costs on index <sup>a</sup>	\$63,665	\$49,199	\$14,466	<.0001
Indirect costs on index <sup>a</sup>	\$28,843	\$19,686	\$9157	<.0001
LOS on index <sup>b</sup>	4.8	3.0	1.8	<.0001
ICU hours on index	31.6	16.7	14.9	<.0001
Outcome	Odds ratio	95 % LCL	95 % UCL	P-value
Discharged home on index	0.60	0.47	0.77	<.0001
Readmitted within 30 days	1.02	0.78	1.32	0.9100

Abbreviations: ICU intensive care unit, LCL lower confidence limit, LOS length of stay, PPMI permanent pacemaker implantation, UCL upper confidence limit.

<sup>a</sup> Patients with cost = 0 were removed.

<sup>b</sup> Patients with LOS = 0 were removed.

discharged home at 30 days (odds ratio 0.60; 95 % CI: 0.47–0.77,  $p < .0001$ ), and no statistically significant difference for readmissions at 30 days, for PPMI compared to the no-PPMI group (Table 1).

Our study demonstrates the serious financial implications of PPMI post-TAVR, with estimated total cost to the US healthcare system being >145 million dollars annually if pacemaker rates are similar to those in our study [1]. We found the mean cost of the pacemaker device itself (\$2421) represented only 17 % of the difference in direct costs associated with PPMI (\$14,466). We provide a novel estimate of the average adjusted incremental indirect cost of new PPMI across TAVR programs (\$9157 per patient), a previously unpublished nonprocedural value that hospitals may look to lower to increase adoption. Our estimate is higher than estimated in Doshi et al. due to its inclusion of indirect costs and the tendency for cost-to-charge approximations of cost to underestimate hospitals' true costs [8]. In addition to the previously demonstrated clinical consequences of PPMI, such as increased mortality, our study finds increased time in the ICU, increased LOS, and a 40 % reduction in the odds of being discharged to home, a patient-centered outcome and finding in line with other literature [6,7,9]. The study is limited by the nature of the data, so we were not able to adjust for unmeasured factors. Because of the overall clinical and cost burden of PPMI post-TAVR, we believe that a focus on reduction of PPMI post-TAVR is of vital importance to the financial solvency of hospital cardiovascular programs nationally. We believe that attention to modifiable ways to reduce PPMI rates is critical, and continued research efforts are important to help clarify best practices to achieve the lowest PPMI possible.

#### CRediT authorship contribution statement

**Christopher Brown:** Writing – review & editing, Writing – original draft, Conceptualization. **Michael P. Ryan:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Soumya G. Chikermane:** Writing – review & editing, Writing – original draft, Project administration. **Marcella A. Kelley:** Writing – review & editing, Writing – original draft, Project administration. **Tara M. Walker:** Writing – review & editing, Writing – original draft, Conceptualization. **Curtiss T. Stinis:** Writing – review & editing, Writing – original draft, Conceptualization.

#### Declaration of competing interest

Curtiss Stinis: Edwards Lifesciences – Consultant, Medtronic – Consultant.

Michael Ryan: receives direct or indirect financial support from Edwards Lifesciences.

Soumya Chikermane: is an employee of Edwards Lifesciences.

Marcella Kelley: is an employee of Edwards Lifesciences.

Tara Walker: is an employee of Edwards Lifesciences.

Christopher Brown: No disclosures.

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