Structural Heart 6 (2022) 100001

Articles and Issues Available at ScienceDirect

Structural Heart

journal homepage: www.structuralheartjournal.org

Original Research

Debunking the July Effect in Transcatheter Interventions in Structural Heart Disease: Truth or Myth?

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ARTICLE INFO

Article history:
Submitted 25 July 2021
Revised 7 October 2021
Accepted 24 November 2021
Available online 17 March 2022

Keywords:
Clinical training
July effect
MitraClip
Outcomes
TAVR

ABSTRACT

Background: The “July effect”, the perception of worse outcomes in the first month of training, has been previously demonstrated in critical care medicine and general surgery. However, the July effect in the context of structural heart interventions (i.e., transcatheter aortic valve replacement [TAVR] and MitraClip) remains unknown.
Methods: All adult patients undergoing TAVR or MitraClip in the 2012-2016 National Inpatient Sample were included. Outcomes were compared by procedure month and academic year quartiles (i.e., between the first academic year quartile [Q1] vs. the fourth quartile [Q4]). Outcomes between teaching and nonteaching hospitals were compared using risk-adjusted logistic difference-in-difference regression.
Results: During the study period, 94,170 TAVR (Q1: 25,250; Q4: 23,170) and 8750 MitraClip (Q1: 2220; Q4: 2150) procedures were performed. In-hospital mortality did not vary as per academic year quartiles for either procedure, even after risk adjustment. These findings persisted in sensitivity analysis by procedure month and newer device era (2015-2016; all $p > 0.05$). In the subgroup analysis, the unadjusted and adjusted Q1 vs. Q4 in-hospital mortality between teaching and nonteaching hospitals were similar for either procedure. In-hospital mortality also did not vary by procedure month when stratified by hospital teaching status for both procedures. However, postprocedural complication rates appeared to be improving among the TAVR teaching hospitals for stroke, major bleeding, and vascular complications (all $p < 0.05$).
Conclusions: In this large, nationwide study, the July effect was not evident for structural heart interventions. With increasing interest and growth in transcatheter procedures, early resident and fellow teaching can be achieved with appropriate supervision.

ABBREVIATIONS

AHRQ, Agency for Healthcare Research and Quality; AKI, acute kidney injury; CI, confidence interval; FDA, Food and Drug Administration; ICD-X-CM, International Classification Of Disease Clinical Modification; ICU, intensive care unit; LOS, length of stay; MR, mitral regurgitation; NIS, National Inpatient Sample; OR, odds ratio; SAVR, surgical aortic valve replacement; TAVR, transcatheter aortic valve replacement.

Meeting Presentation: This was presented at American College of Cardiology's 69th Annual Scientific Session Together With the World Congress of Cardiology, March 28-30, 2020, in Chicago, IL.

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https://doi.org/10.1016/j.shj.2022.100001

Introduction

The management of patients with aortic and mitral valve disease has dramatically evolved within the last decade, particularly with the advent of transcatheter therapies. For patients with symptomatic aortic stenosis, transcatheter aortic valve replacement (TAVR) is now approved by the US Food and Drug Administration in all risk profiles, including high- and extreme-risk, intermediate-risk, and, most recently, low-risk patients.[1–5] Likewise, in patients with mitral regurgitation, the MitraClip system (Abbott Laboratories, Abbott Park, Illinois) is Food and Drug Administration–approved for use in prohibitive-risk patients with primary mitral regurgitation and supported by the guidelines for use in high surgical risk.[6,7] As both of these technologies become widely adopted clinically, there is growing interest across institutions to determine innovative ways to complement trainee clinical training in the era of competency-based training.

The "July effect", sometimes referred to as the July phenomenon, is a perceived increase in the risk of patient complications and medical errors in the setting of house-staff turnover at the beginning of every academic year.[8–13] Although a few studies have demonstrated the existence of the July effect in critical care medicine and general surgery, most contemporary findings have been mixed.[11,13] Recent studies in cardiac surgery have debunked the myth of adverse outcomes in the first months of training;[8,14] however, in the context of structural heart interventions (i.e., TAVR and MitraClip), existing literature is lacking. Henceforth, understanding the impact of the July effect is vital in the current era of scrutinized outcomes of TAVR and MitraClip procedures as well as in the discussion of dedicated structural fellowships approved by the Accreditation Council for Graduate Medical Education. Moreover, this information will be critical for the patients undergoing these procedures as well as their supporting families. In this nationally representative study, we aimed to examine whether patient outcomes following structural heart interventions were affected by academic year quartiles.

Materials and Methods

Data Source

The National Inpatient Sample (NIS) is the largest publicly available all-payer database of hospitalized patients in the United States and is sponsored by the Agency for Healthcare Research and Quality (AHRQ) as a part of the Healthcare Cost and Utilization Project. It is composed of more than 45 state databases and includes anonymized data on discharge diagnoses and procedures on about 8 million hospitalizations from about 1000 hospitals sampled annually.[15] Although the NIS data set constitutes a 20% stratified sample of US hospitals, it provides reliable sampling weights to calculate robust national estimates that represent more than 95% of the US population. This study adhered to best practices required by the AHRQ for design and conduct of research using the NIS[16] and followed recommendations for reporting statistics that are based on Healthcare Cost and Utilization Project data with a mixture of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Tenth Revision, Clinical Modification (ICD-10-CM) codes.[17] Since this study did not involve human subjects, informed consent was waived by the institutional review board (approval # 2021P002317).

Study Population

We included all adult patients aged ≥18 years who underwent either a TAVR or MitraClip procedure between 2012 and 2016. The ICD-9-CM and ICD-10-CM diagnoses and procedure codes that were used to identify these patients are included in Supplemental Table 1. Patients who underwent nontransfemoral access TAVR were excluded because the ICD coding is not specific and has not been previously validated. Patients undergoing any concomitant procedures during the index hospitalization were also excluded.

Patient and Hospital Characteristics

Patient demographics queried included age, sex, race, payer, and median household income quartile (Supplemental Tables 2 and 3). The presence of comorbidities was assessed using the Elixhauser categories supplied by the AHRQ and previously validated ICD-based diagnosis codes for clinically relevant comorbidities such as prior percutaneous coronary intervention and prior coronary artery bypass grafting.[18,19] Admission characteristics included weekend vs. weekday admission, elective vs. urgent/emergent admission status, and transfer status. Hospital factors included bed size (categorized as small, medium, and large), control/ownership of the hospital (government, private nonprofit, and private invest-own), and region (Northeast, Midwest, South, and West).

Outcomes

The primary outcome was in-hospital mortality. The secondary outcomes included postprocedural complications such as stroke, acute kidney injury (AKI), major bleeding, permanent pacemaker implantation, and vascular complications. The lengths of stay and total inpatient charges, adjusted for inflation to 2019 US dollars, were also compared. Patient disposition following their hospitalization was categorized into routine discharge, transfer to a short-term hospital, transfer to a skilled nursing facility/intermediate care facility/rehabilitation, or home health care.

Statistical Analysis

Utilizing survey analysis procedures, we generated weighted national estimates and variances that accounted for clustering of outcomes within hospitals and sampling variation across strata (region and year) as recommended by the AHRQ. For the first analysis, the overall cohort was stratified into academic year quartiles, i.e., July-September (first academic year quartile or Q1) vs. April-June (fourth academic year quartile or Q4) admission for each procedure type. Patients admitted during the other academic months were excluded from this analysis since our aim was to compare time periods with the least (Q1) and most (Q4) experienced trainees. Patient demographics, hospital characteristics, and in-hospital outcomes were compared between Q1 and Q4 admission for each procedure type using the chi-squared test for categorical variables and t-tests for continuous normally distributed variables. For each procedure type, the impact of Q1 admission on in-hospital mortality and the secondary outcomes of interest was also evaluated, after adjusting for all patient and hospital characteristics using a multivariable logistic regression model.

The rationale for comparing outcomes by academic year quartiles was 2 fold: First, to increase the power of our analysis and second, to account for the fact that some trainees may not be able to do the structural heart cases in July given that these are relatively new procedures compared to the cardiac surgical cases. The latter is particularly true for MitraClip procedures since most of the operators were also still learning the implant techniques during this study period. Thus, to account for possible lack of early trainee exposure in July as well as the learning curve for both procedures, we performed 2 additional sensitivity analyses: First, we examined in-hospital outcomes by procedural month, and second, we compared in-hospital outcomes restricted to the era of newer devices (2015-2016).

For the subgroup analysis, we first assessed whether in-hospital mortality varied by overall procedure month or by academic year quartiles across the entire study period. We also compared in-hospital outcomes by academic year quartiles between teaching and nonteaching hospitals. However, to account for possible residual confounding due to nonteaching hospitals, we compared in-hospital mortality between Q1 and Q4 admission among the teaching hospitals using a risk-adjusted logistic difference-in-difference regression, which included terms for teaching status (yes vs. no), time (Q1 vs. Q4), and an interaction between the 2. There was presence of a July effect if there was 1) a higher in-hospital mortality in Q1 vs. Q4 among the teaching hospitals and 2) a larger difference in Q1 vs. Q4 in-hospital mortality among the teaching hospitals than that among the nonteaching hospitals during the same time period (i.e., if the odds ratio [OR] for the interaction term was >1).

Categorical variables are presented as numbers and percentages, and continuous variables are presented as mean +/− standard error. ORs and 95% confidence intervals (CIs) are used to report regression results. Variables with cell sizes <11 were not reported given NIS reporting guidelines. In total, fewer than 0.5% of eligible patients were removed, combining any missing of ≥1 variable together. Remaining data were analyzed using a complete-case analysis approach. All statistical analyses were performed using SAS, version 9.4, (SAS Institute, Cary, NC) with 2-sided *p*-values < 0.05 as the criterion for significance. The study was reported in accordance with the STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) recommendations, and its checklist is included in the Online Supplement.

Results

Patient Demographics and Characteristics by Academic Quartiles

During the study period, a weighted total of 94,170 TAVR and 8750 MitraClip procedures were performed, including 25,250 (26.8%) and 2220 (25.4%) Q1 admissions, respectively. In general, there were no significant differences in baseline patient demographics, comorbidities, and admission characteristics between Q1 and Q4 admitted patients, except for the following: TAVR patients admitted in Q1 had a lower prevalence of chronic obstructive pulmonary disease (37.7% vs. 40%; $p = 0.02$; Supplemental Table 2), whereas MitraClip patients admitted in Q1 had a higher prevalence of heart failure (84.2% vs. 77.7%; all $p = 0.02$; Supplemental Table 3) than those admitted in Q4, respectively.

In-Hospital Outcomes by Academic Quartiles

Unadjusted in-hospital outcomes, disposition, and hospital factors did not largely vary when comparing Q1 vs. Q4 admissions. For instance, for TAVR patients, rates of in-hospital mortality (2.1% vs. 2.5%) and post-procedural complications, such as stroke, major bleeding, AKI, permanent pacemaker placement, and vascular complications, were not statistically different when compared with those admitted in Q4 (all $p >$ 0.05; Table 1). There appeared to be a trend toward higher vascular complication rates in Q1 in TAVR patients although this did not reach significance. Similar findings were observed for the MitraClip patients (Table 2). After risk adjustment, Q1 admission did not predict in-hospital mortality for TAVR (OR = 0.85, 95% CI: 0.64-1.12) or MitraClip procedure (OR = 0.26, 95% CI: 0.02-3.08). Likewise, for both procedures, Q1 admission did not predict other postprocedure outcomes (Figure 1).

Sensitivity Analysis: In-Hospital Outcomes by Procedure Month and Era of Newer Devices

For TAVR and MitraClip procedures, the in-hospital mortalities in July were 2.3% (monthly mean: 2.4%) and 2.8% (monthly mean: 2.4%),

Table 1
TAVR in-hospital outcomes, patient disposition, and hospital factors

Variable	Q1 admission (n = 25,250)	Q4 admission (n = 23,170)	*p*-value
Vascular complications	640 (2.5)	460 (2.0)	0.08
Stroke	350 (1.4)	295 (1.3)	0.61
Major bleed	8005 (31.7)	7135 (30.8)	0.32
AKI	3430 (13.6)	3255 (14.0)	0.49
PPM placement	2810 (11.1)	2685 (11.6)	0.46
Death	535 (2.1)	585 (2.5)	0.19
Disposition			0.19
Routine	12,240 (48.5)	10,705 (46.2)	
Transfer to a short-term hospital	115 (0.5)	120 (0.5)	
Transfer to SNF, ICF, rehab	5395 (21.4)	5060 (21.8)	
Home health care	6940 (27.5)	6700 (28.9)	
Length of stay, d (mean, SE)	5.8 (0.1)	6.0 (0.1)	0.04*
Total charges, US dollars (mean, SE)	210,983 (3534)	210,484 (3355)	0.827
Hospital factors			
Bed size			0.71
Small	1310 (5.2)	1160 (5.0)	
Medium	4650 (18.4)	4360 (18.8)	
Large	19,290 (76.4)	17,650 (76.2)	
Control/ownership of the hospital			0.57
Government or private	1880 (7.4)	1760 (7.6)	
Government, nonfederal	21,355 (84.6)	19,660 (84.9)	
Private, not-for-profit	2015 (8)	1750 (7.6)	
Region of the hospital			0.19
Northeast	6330 (25.1)	6000 (25.9)	
Midwest	6080 (24.1)	5270 (22.7)	
South	8695 (34.4)	7990 (34.5)	
West	4145 (16.4)	3910 (16.9)	

Notes. Continuous variables are presented as mean (SE) unless indicated as median (interquartile range); categorical variables are summarized as n (%).
AKI = acute kidney injury, ICF = intermediate care facility, PPM = permanent pacemaker, SNF = skilled nursing facility, TAVR = transcatheter aortic valve replacement.
*p-value ≤ 0.05 was considered statistically significant.

Table 2
MitraClip in-hospital outcomes, patient disposition, and hospital factors

Variable	Q1 admission (n = 2220)	Q4 admission (n = 2150)	*p*-value
Vascular	15 (0.7)	30 (1.4)	0.29
Stroke	<11 cell size	<11 cell size	0.97
Major bleed	435 (19.6)	410 (19.1)	0.84
AKI	330 (14.9)	320 (14.9)	0.99
PPM placement	15 (0.7)	30 (1.4)	0.29
Death	11 (0.5)	30 (1.4)	0.09
Disposition			0.47
Routine	1495 (67.3)	1430 (66.5)	
Transfer to a short-term hospital	15 (0.7)	15 (0.7)	
Transfer to SNF, ICF, rehab	235 (10.6)	270 (12.6)	
Home health care	465 (20.9)	405 (18.8)	
Length of stay, d (mean, SE)	5 (0.3)	5.4 (0.5)	0.504
Total charges, US dollars (mean, SE)	190,397 (7357)	196,537 (9056)	0.547
Hospital factors			
Bed size			0.29
Small	115 (5.2)	130 (6.0)	
Medium	400 (18.0)	315 (14.7)	
Large	1705 (76.8)	1705 (79.3)	
Control/ownership of the hospital			0.97
Government or private	245 (11.0)	230 (10.7)	
Government, nonfederal	1745 (78.6)	1690 (78.6)	
Private, not-for-profit	230 (10.4)	230 (10.7)	
Region of the hospital			0.77
Northeast	355 (16)	400 (18.6)	
Midwest	540 (24.3)	520 (24.2)	
South	815 (36.7)	750 (34.9)	
West	510 (23)	480 (22.3)	

Notes. Continuous variables are presented as mean (standard error) unless indicated as median (interquartile range); categorical variables are summarized as n (%).
AKI = acute kidney injury, ICF = intermediate care facility, PPM = permanent pacemaker, SNF = skilled nursing facility.

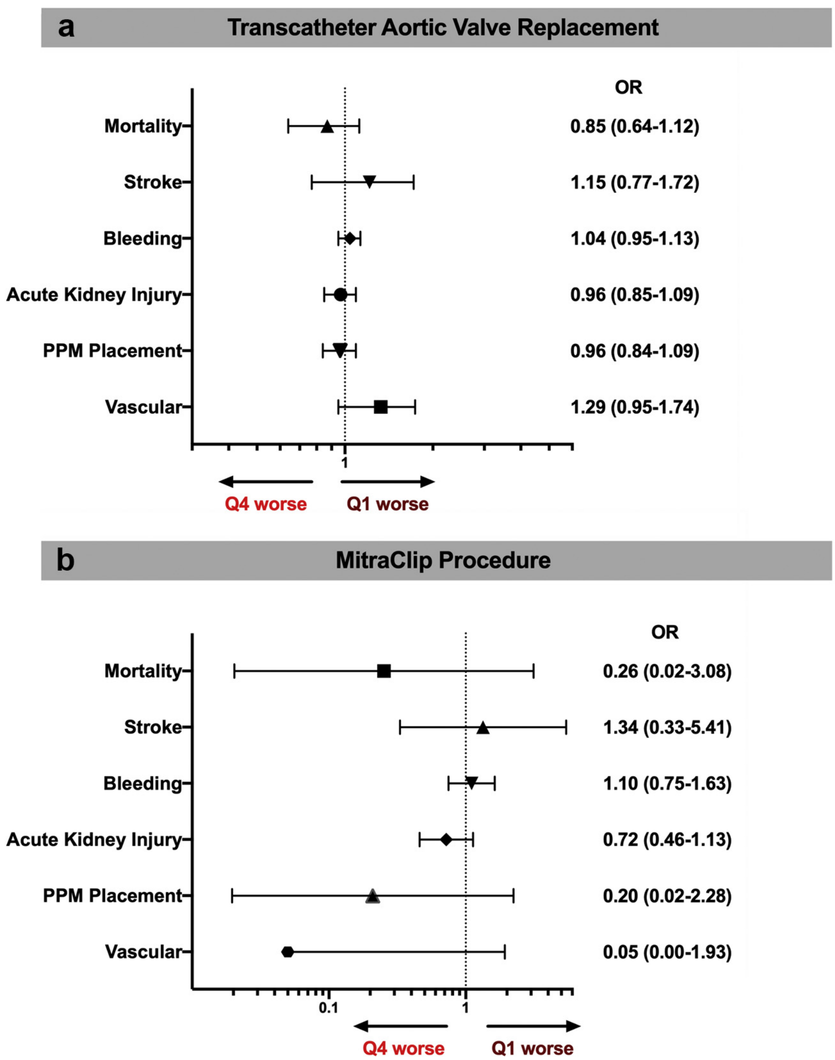

Figure 1. Forest plot of adjusted in-hospital outcomes of TAVR (panel a) and MitraClip procedure (panel b) stratified by academic year quartile (Q1 admission—[July-September] vs. Q4 admission—[April-June]). $p < 0.05$ was considered statistically significant and is denoted by the asterisk (*). After risk adjustment, Q1 admission did not predict in-hospital mortality for TAVR (OR = 0.85, 95% CI: 0.64-1.12) or MitraClip procedure (OR = 0.26, 95% CI: 0.02-3.08).
Abbreviations: CI, confidence interval; OR, odds ratio; TAVR, transcatheter aortic valve replacement.

respectively, and these rates did not vary by procedure month (Figure 2). Likewise, the rates of postprocedural complications did not vary significantly by procedure month for either procedure (both $p > 0.05$). When examining outcomes in the era of newer devices (i.e., 2015-2016), these findings remained consistent. In-hospital mortality did not vary by procedure month for both procedures (both $p > 0.05$; Supplemental Figure 1). However, for TAVR only, in-hospital mortality in Q1 was significantly lower than that in Q4 (1.2% vs. 2.0%; $p = 0.01$; Supplemental Table 4). Other in-hospital outcomes were not statistically different between Q1 and Q4 admission for either procedure (all $p > 0.05$).

Subgroup Analysis: In-Hospital Outcomes by Teaching Status

In-hospital mortality did not vary by procedure month when stratified by hospital teaching status for both procedures ($p > 0.05$; Figure 3). Likewise, there was no apparent evidence of higher in-hospital mortality in Q1 in any calendar year. When unadjusted, there were no significant differences in in-hospital mortality or complications (Q1 vs. Q4) for either TAVR or MitraClip procedure among the teaching hospitals only (all $p > 0.05$; eTable5). In the risk-adjusted difference-in-difference analysis, the temporal (Q1 vs. Q4) comparisons in both teaching and nonteaching hospitals were significant, or the interaction terms were significant (all $p > 0.05$; Supplemental Figure 2). However, post-procedural complication rates appeared to be improving among the TAVR teaching hospitals for stroke, major bleeding, and vascular complications (all $p < 0.05$). This analysis was largely underpowered for the MitraClip procedure although there appeared to be improving AKI rates among the teaching hospitals (Supplemental Figure 3).

Discussion

This large, comprehensive study is the first to date to explore the notion of the July effect within the context of structural heart interventions. This study had several notable findings: First, for both TAVR and MitraClip procedures, in-hospital mortality was similar by admission quartiles, even after risk adjustment. Similar results were observed in the sensitivity analysis that looked at differences in mortality by procedure month and restricted to operations during the newer device era, i.e., 2015-2016. Second, there were no significant differences in procedural-related complications between Q1 and Q4 admissions, and these findings persisted even after risk adjustment. Finally, in the subgroup analysis, the teaching status did not influence in-hospital mortality for either procedure, and these findings remained robust in our risk-adjusted difference-in-difference regression analysis. Interestingly, post-TAVR complications appeared to be improving among the teaching hospitals. Our findings demonstrated that the July effect is not evident for structural heart interventions despite pre-existing notions. As interest and volume in transcatheter procedures increase, early resident and fellow teaching can be achieved with appropriate supervision.

Existing studies on the July effect have primarily been in the non-cardiovascular literature, but these are largely discrepant in part owing to

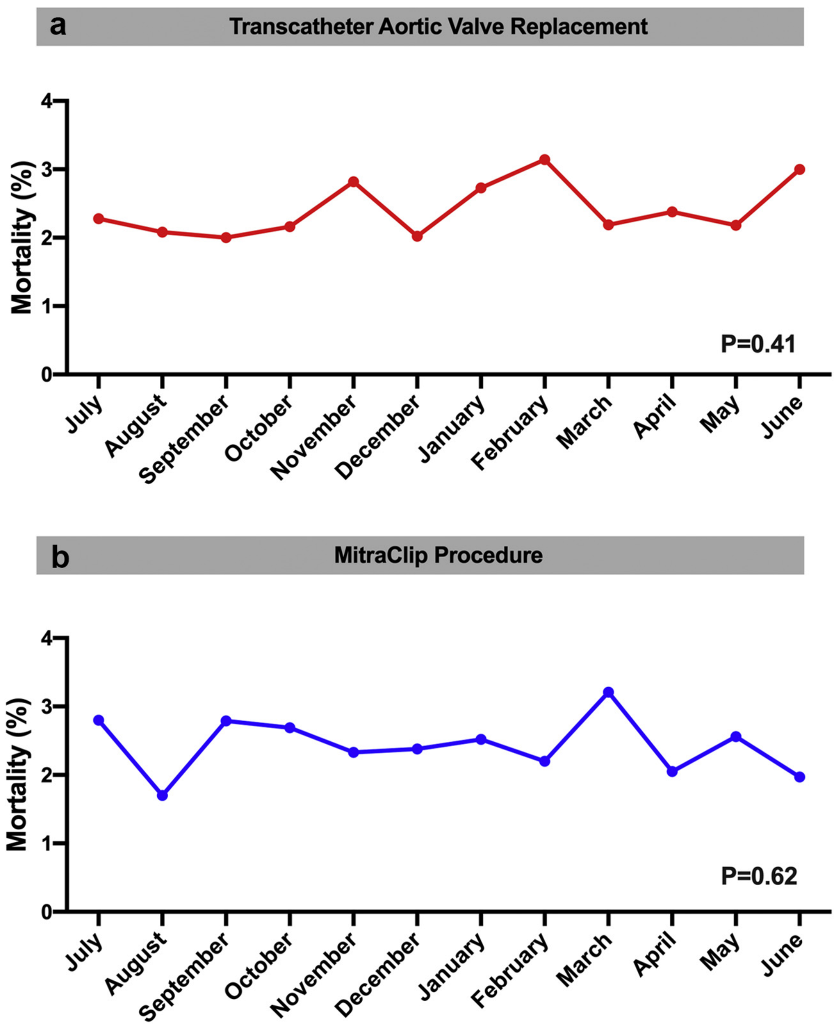

Figure 2. **The July effect and in-hospital mortality for TAVR (panel a) and MitraClip procedure (panel b).** For TAVR and MitraClip procedures, the in-hospital mortalities in July were 2.3% (monthly mean: 2.4%) and 2.8% (monthly mean: 2.4%), respectively, and these rates did not vary by procedure month. Abbreviation: TAVR, transcatheter aortic valve replacement.

considerable variations across surgical specialties, hospital setting, and patient risk profiles.[8–13] In the intensive care unit setting for instance, Barry et al.[10] retrospectively reviewed over 156,000 patients across 38 intensive care units in 28 hospitals in Ohio and found no evidence to support the existence of a July effect, even after stratifying the analysis by surgical and medical patients. In the context of interventional cardiology, a few studies have debunked the existence of the July effect in patients presenting with acute coronary syndrome +/− percutaneous coronary intervention.[20,21] In cardiac surgery, a recent study from our group, which utilized the NIS from 2012 to 2014 and examined outcomes in 111,260 surgical aortic valve replacements and 54,985 mitral valve surgical procedures, found no evidence of the July effect in these procedures.[8] Currently, no study has specifically explored the domain of the structural heart procedures.

The lack of the July effect observed in this study is reassuring both from an educational and patient care standpoint, since mortality outcomes did not differ by academic year quartile or procedural month. What was further reassuring was the fact that the postprocedural complication rates appeared to improve marginally among the teaching hospitals especially for TAVR complications, such as bleeding and vascular complications, and for AKI in the context of MitraClip procedures. The absence of the July effect for structural heart procedures can be related to either increased trainee supervision by senior and/or more experienced physicians during this time or perhaps due to limited autonomy of residents/fellows during the early period of their training. There is also a possibility that the teaching hospitals have higher procedural volume, which has been shown to be inversely related to better outcomes.[22] This aspect could also be potentially contributing toward the improved outcomes during the year.

A notable finding in this study was there appeared to be a trend toward higher vascular complication rates in Q1 for TAVR patients although this did not reach statistical significance. Since there is a significant learning curve to optimal femoral access techniques for large bore sheaths and use of suture-based closure devices and that this is the initial part of the TAVR procedure, it is especially important for this step to be closely supervised in Q1 to ensure optimal outcomes while improving resident autonomy.

Our findings have important implications, particularly with regard to trainee involvement in the emerging field of structural heart interventions. Given the existing treatment landscape for aortic and mitral valve disease, there has been substantial growth in the volume of TAVR and MitraClip procedures nationwide.[22,23] Currently, there are no formal training programs for structural heart interventions accredited by the Accreditation Council for Graduate Medical Education. However, there is a discussion among the specialty societies to establish a dedicated training curriculum to supplement existing trainee needs. Thus, the findings of this study support the concept of early training without compromising patient care.

There are several limitations to this study. First, the NIS is an administrative database and does not contain detailed clinical information on a variety of measures, including patient complexity, anatomic indication, and intraoperative details. Second, only 20% of

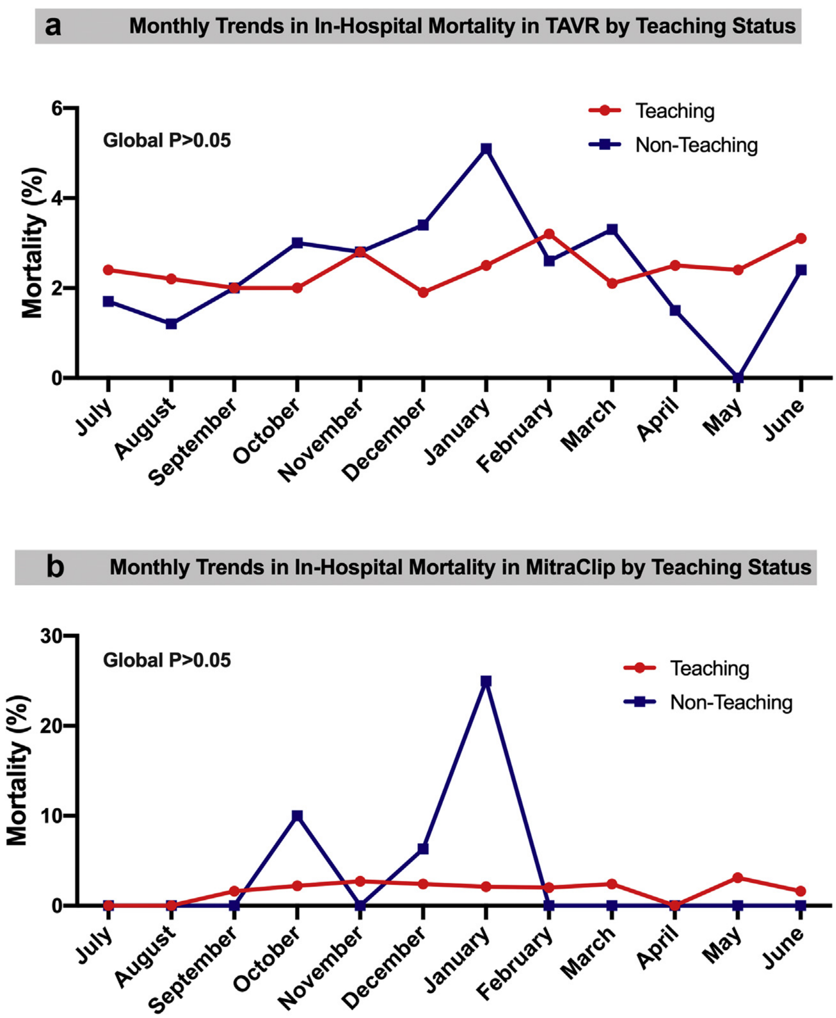

Figure 3. The July effect and in-hospital mortality for TAVR (panel a) and MitraClip procedure (panel b). In-hospital mortality did not vary by procedure month when stratified by hospital teaching status for both procedures.
Abbreviation: TAVR, transcatheter aortic valve replacement.

nationwide institutions are sampled within the NIS; therefore, there exists the potential for limitations in the number of hospitals surveyed that perform comprehensive TAVR or MitraClip procedures. Third, the follow-up did not extend beyond the index hospitalization; consequently, important events or complications that may have occurred after discharge were not captured. Fourth, the use of ICD codes to identify clinical events is imperfect. Nevertheless, it remains a well-established and valid technique.[24] Finally, given the lack of institutional-specific identifiers, we could not control for potential program-specific confounders such as resident/fellow autonomy during the procedure, the extent of attending supervision, and training type or year of the postgraduate level. Since we were unable to determine the extent of trainee involvement during the entirety of the procedure or perioperative care, it is possible that the null findings observed in this study may be related to the fact that trainees are not involved in the care of some of these patients at certain institutions. Thus, many of the limitations in this analysis must be understood in the context of the strengths of the NIS, which include its large size, nationally representative quality, standardized methodology of the survey, and availability of economic endpoints, which are not always possible to obtain from single-center or multicenter registries.

Conclusions

In summary, in this large, nationwide study, we demonstrate that the July effect is not evident for structural heart interventions. With increasing interest and growth in transcatheter procedures, early resident and fellow teaching may be achieved with appropriate supervision.

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Ethics statement

The research reported has adhered to the relevant ethical guidelines. The NIS is a publicly available database. Since this study did not involve human subjects, informed consent was waived by the institutional review board (approval #2021P002317).

Funding

The authors have no funding to report.

Disclosure statement

C.K.Z. is supported by NIH Medical Scientist Training Program Training Grant T32GM007205. She is the PI of an F30 award through the National Institute on Aging F30AG066371 entitled “The ED.TRAUMA Study: Evaluating the Discordance of Trauma Readmission And Unanticipated Mortality in the Assessment of hospital quality.” M.J.R. served as a study investigator, a consultant, and a proctor for Edwards Lifesciences, Boston Scientific, and Abbott. P.O. has been a consultant to Medtronic and Edwards Lifesciences. P.S. reports receiving compensation as a proctor for Edwards and educational grants from Edwards, Medtronic, and Abbott. He also reports that his wife is an employee of Thermo Fisher. T.K. is a speaker for Edwards Life Sciences, Medtronic, Abbott, and Baylis Medical and is a consultant for 4C Medical. There are no other potential conflicts that exist.

Supplementary Material

Supplemental data for this article can be accessed on the publisher's website.

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