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Contemporary procedural trends of Watchman percutaneous left atrial appendage occlusion in the United States

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Abstract

Objective: To determine trends in real-world utilization and in-hospital adverse events from Watchman implantation since its approval by the Food and Drug Administration in 2015.

Background: The risk of embolic stroke caused by atrial fibrillation is reduced by oral anticoagulants, but not all patients can tolerate long-term anticoagulation. Left atrial appendage occlusion with the Watchman device has emerged as an alternative therapy.

Methods: This was a retrospective cohort study utilizing data from National In-patient Sample for calendar years 2015–2017. The outcomes assessed in this study were associated complications, in-hospital mortality, and resource utilization trends after Watchman implantation. Trends analysis were performed using analysis of variance. Multivariable adjusted logistic regression analysis was performed to determine predictors of mortality.

Results: A total of 17 700 patients underwent Watchman implantation during the study period. There was a significantly increased trend in the number of Watchman procedures performed over the study years (from 1195 in 2015 to 11 165 devices in 2017, $p < .01$). A significant decline in the rate of complications (from 26.4% in 2015% to 7.9% in 2017, $p < .01$) and inpatient mortality (from 1.3% in 2015% to 0.1% in 2017, $p < .01$) were noted. Predictors of in-hospital mortality included a higher CHA_2DS_2-VASc score (odds ratio [OR]: 2.61 per 1-point increase, 95% confidence interval [CI]: 1.91–3.57), chronic blood loss anemia (OR: 3.63, 95% CI: 1.37–9.61) and coagulopathy (OR: 4.90, 95% CI: 2.32–10.35).

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SUPPORTING INFORMATION

Additional Supporting Information may be found online in the supporting information tab for this article.

Conclusion: In contemporary United States clinical practice, Watchman utilization has increased significantly since approval in 2015, while complications and in-patient mortality have declined.

Keywords

complications; mortality; national trends; Watchman

1 | INTRODUCTION

Atrial fibrillation (AF) is the most commonly encountered sustained cardiac arrhythmia in clinical practice and responsible for more than 20% of all embolic strokes.[1,2] AF-associated strokes tend to have worse morbidity and mortality when compared to strokes not related to AF.[3,4] The left atrial appendage (LAA) is the location for thrombus formation in more than 90% of patients with nonvalvular AF.[5] Coumadin and direct oral anticoagulants (DOACs) are the gold-standard therapy for reducing stroke risk in AF patients with risk factors for stroke. However, their utilization is often limited by lack of patient compliance and adverse effects.[6–8] Left atrial appendage occlusion (LAAO) using an endocardial Watchman device has shown promising results in mitigating stroke risk when utilized in selected AF patients.[9] The landmark PROTECT AF (percutaneous closure of the LAA vs. warfarin therapy for prevention of stroke in patients with atrial fibrillation) trial showed the Watchman device to be noninferior to coumadin in terms of the primary efficacy end-point of stroke, systemic embolism and cardiovascular/unexplained death.[10] Subsequently, the PREVAIL (prospective randomized evaluation of the Watchman LAA closure device in patients with atrial fibrillation vs. long-term warfarin therapy) trial confirmed these results and also showed a reduced rate of short-term complications.[11] The results of these two trials eventually led to Food and Drug Administration (FDA) approval of the Watchman device in March of 2015. Since FDA approval of the Watchman device, there has been limited real-world data on trends in utilization, complications, and in-hospital mortality from the procedure in contemporary practice.[12] The aim of the present study is to assess these parameters from a comprehensive, national United States population database.

2 | METHODS

2.1 | Study data

For the purpose of the current analysis, data were derived from the National Inpatient Sample (NIS) for calendar years 2015–2017. The NIS is made possible by a Federal-State-Industry partnership sponsored by the Agency for Healthcare Research and Quality (AHRQ). The NIS is derived from all States for national estimates of healthcare utilization, costs, and outcomes.[13] NIS data are compiled annually and therefore the data can be used for analyses of disease trends over time. The NIS approximates 20% of all discharges from all US nonfederal hospitals and provides discharge weights that are used for computation of national estimates. The discharge weights are calculated with in each sampling hospital as the ratio of discharges in the universe (derived from data collected from American Hospital Association survey for non-Health care cost and utilization project [HCUP] hospitals and State Inpatient Databases for HCUP hospitals) to the discharges in the sample hospital. The discharge weight is uniform throughout the sample hospital which implies that estimates

of sample means are consistent for both weighted and unweighted encounters. Institutional Review Board approval and informed consents were not required for this study given the deidentified nature of the NIS data set and public availability.

2.2 | Study population and study design

We analyzed NIS data from January 2015 to December 2017. The study population was selected by using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes. We selected patients 18 years of age and above for the purpose of our study. Age was further divided into three groups, <65, 65–74, and ≥75. Patients implanted with a WATCHMAN were identified by ICD-9 code of 37.90 and ICD-10 code of 02L73DK. Baseline characteristics and key complications were identified (ICD codes for complications provided in supplement), as previously described.[14] Hospital outcomes including inpatient mortality, discharge disposition, length of stay (LOS) and cost of hospitalization (inflation adjusted) were derived. For the computation of hospitalization costs, cost-to-charge ratio files from NIS were utilized.

Complication rate trends were analyzed over the study years. The primary outcome of the study was the prevalence of Watchman implantation over our study period. Additional outcomes analyzed including associated complications, in-hospital mortality and resource utilization (including LOS, cost of stay, and discharge disposition to home, short term care, long-term care, or home with institutional care or home health).

2.3 | Statistical analysis

Descriptive statistics are presented as frequencies with percentages for categorical variables and as means with standard deviations for continuous variables. Baseline characteristics were compared using a Pearson χ^2 test and Fisher's exact test for categorical variables and independent samples *t*-test for continuous variables. Trends analysis was performed using analysis of variance. Linear regression was used to predict trends over calendar years. Logistic regression was performed to estimate odds ratios (ORs) with 95% confidence intervals (CIs) to determine predictors for mortality. Initially, a binomial logistic regression model was used to identify variables from demographic data (Table 1) that were significantly associated with patient mortality ($p < .10$). These variables were then subsequently utilized in a multivariable logistic regression model to identify statistically significant predictors of mortality. In the final model, $p < .05$ was used as cutoff for stepwise forward entry for logistic regression. A type I error rate of <0.05 was considered statistically significant. All statistical analyses were performed using statistical package for social science (SPSS) version 26 (IBM Corp). Discharge weights provided by NIS were used for computation of national estimates. All analyses were done on a weighted sample.

3 | RESULTS

A total of 17 700 patients underwent Watchman implantation from January 2015 to December 2017. The mean age of patients implanted was 75.6 (SD ± 8.2) years. The mean age increased over the study years (74.2 years in year 2015 vs. 75.8 years in year

2017, $p < .01$). Overall, women constituted 40.1% ($n = 7095$) of the study cohort, and the majority of patients 86.0% ($n = 14\ 650$) were White. Baseline characteristics of the study population are shown in Table 1. Between 2015 and 2017, patients undergoing LAAO in later calendar years were on average older, more commonly female, and more commonly electively admitted for the procedure.

Overall, there was a significant increase in the number of Watchman LAAO procedures in the United States (from 1195 device implants in year 2015 to 11 165 device implants in year 2017, $p < .01$, Figure 1). Peri-procedural complications associated with Watchman implantation are depicted in Table 2. There was a significant decrease in the rate of complications over the study period (26.4% in year 2015 vs. 7.9% in year 2017, $p < .01$). The largest decrease in complications over the study years occurred with cardiovascular and neurological complications, with a decreased rate of any cardiovascular complication from 13.8% in year 2015% to 4.7% in year 2017 ($p < .01$), while the rate of any neurological complication decreased from 7.9% in year 2015 to just 0.9% in year 2017 ($p < .01$). There were very low rates of device related thrombus at discharge or device embolization during the study period ($n < 10$ patients; <0.1%). Overall, in-hospital mortality was low at 0.3% ($n = 45$ patients), and mortality decreased each year from 1.3% in 2015% to 0.1% in 2017 (Figure 2).

Multivariable adjusted predictors of mortality for patients undergoing Watchman implantation are shown in Figure 5. A higher CHA_2DS_2-VASc score (OR: 2.61 for each 1 point increase in score [95% CI: 1.91–3.57], $p < .01$), chronic blood loss anemia (OR: 3.63 [95% CI: 1.37–9.61], $p < .01$) and coagulopathy (OR: 4.90 [95% CI: 2.32–10.35], $p < .01$) were associated with a higher mortality, whereas a more recent calendar year of implant (OR: 0.28 per year increase [95% CI: 0.19–0.43], $p < .01$) and history of hypertension (OR: 0.28 [95% CI: 0.14–0.56], $p < .01$) were associated with a lower odds of mortality at discharge.

As seen in Table 3, the majority of patients were discharged home or with home healthcare. Both LOS and cost of hospitalization demonstrated a declining trend over the study period (Table 3 and Figures 3 and 4).

4 | DISCUSSION

The main findings of our current investigation are[1]: Over the study period from 2015 to 2017, there has been a significant increase in the number of Watchman device implantation procedures in the United States (from 1195 in year 2015 to 11 165 devices in year 2017, $p < .01$).[2] There has been a decline in the rate of complications over the study period primarily driven by lower rates of cardiovascular and neurological complications.[3] Overall mortality continues to be low during the study period, with an even lower trend towards reduced mortality over the study years (1.3% in year 2015 vs. 0.1% in year 2017, $p < .01$).[4] The total LOS and hospitalization costs after Watchman implantation declined over the study period.

Percutaneous LAAO with the Watchman device provides a viable alternative to oral anticoagulation in select patients based on randomized trials that have shown efficacy and

safety of utilizing this approach for stroke risk reduction.[10,11] The FDA approved the device for commercial use in United States in March of 2015 and the Watchman implant procedure currently carries a class IIb recommendation in patients with nonvalvular AF at risk for stroke per the latest American College of Cardiology guidelines.[15] Our analysis of a contemporary, real-world, national database sampling U.S. practice since FDA approval of Watchman showed consistent increased utilization of device procedures suggesting gradual assimilation of this device implantation procedure in clinical practice. Additionally, our analysis also showed that complications and inpatient mortality associated with implantation of Watchman devices continued to show a downward trend.

Our study showed a significant decline in the overall complication rate over the study period (26.4% in year 2015 vs. 7.9% in year 2017, $p < .01$). This downtrend was primarily driven by a reduction in cardiovascular and neurological complications over the study period. Cardiac perforation complications including cardiac tamponade were encountered in the landmark PROTECT AF trial where its prevalence was approximately 4.3%.[10] Subsequently, with improved operator experience, the incidence of this complication was lowered to 1.9% in the PREVAIL trial, 1.4% in CAP (Continued Access to PROTECT AF), 1.9% in CAP2 (Continued Access to PREVAIL), and 0.3% in EWOLUTION registries.[11,16,17] The overall rate of cardiac tamponade in the current study of contemporary Watchman patients was 0.8%. This rate is similar to post-FDA approval study led by Reddy et al. in which the authors reported a nearly similar rate of cardiac tamponade at 1%; still higher than the European EWOLUTION registry which reported cardiac tamponade rate of 0.3%.[18] It is also similar to a recently published contemporary registry of Watchman implantations from National Cardiovascular Data Registry which analyzed nearly 38 000 patients.[19] It may be expected that with more widespread availability of the Watchman device in U.S. practice that the rate of cardiac tamponade may continue to decline over the coming years. The rate of ischemic stroke/transient ischemic attack (TIA) was 1% in our study cohort with most cases reported in 2015 and a significant downtrend since that time (0.7% in year 2016% and 0.4% in year 2017, $p < .01$). Vuddanda et al. have shown nearly similar ischemic stroke/TIA rates of about 0.5% when analyzing Watchman implants from year 2016.[14] These strokes are presumed to be due to inadvertent air or clot embolization from the transseptal sheath and enhanced physician training should continue to mitigate this risk.

The current study showed a downward trend in in-hospital mortality suggesting improved safety with the device with more operator experience (from 1.3% in year 2015% to 0.1% in year 2017, $p < .01$). Improvement in mortality rate trends over time seen in the current study of real-world patients was also seen in previous clinical studies, including the CAP2 registry which supplemented the PREVAIL trial and was designed to continue long-term accrual of data, and showed a mortality rate of 0.2% within 7 days of Watchman implant.[16] A subsequent study utilizing National Inpatient Sample database by Vuddanda showed a mortality rate of 0.3% at discharge for combined endocardial and epicardial based approaches for LAA occlusion.[14] In another post-FDA approval analysis of more than 3800 patients undergoing Watchman implantation from March 2015 to May 2016, Reddy et al. demonstrated procedure related mortality of 0.078%.[18] The prospective EWOLUTION registry that enrolled more than 1000 consecutive patients undergoing

Watchman implantation outside the United States also showed low procedure related mortality of 0.1%.[17] These earlier studies along with our more contemporary data suggest that overall implantation of the Watchman device is associated with low absolute rates of mortality that is decreasing over time.

5 | LIMITATIONS

Our study has the following key limitations[1]: The NIS is an administrative claims-based database that utilized ICD codes which may be prone to errors and could introduce information bias due to outcome misclassification. The hard clinical end points, however, are less subjected to error. Additionally, AHRQ quality control measures are routinely instituted that guarantee data integrity.[13] Additionally, the ICD-9 code utilized in this study was not specific to the Watchman device and could be referred for any LAA occlusion procedure. Due to the limited magnitude of other research studies of endocardial devices and any epicardial LAA occlusion procedures performed in the United States during the study period,[14] we believe that application of this code for the purpose of our study was able to mostly characterize Watchman implants.[2] The NIS only captures inpatient admissions and does not provide any information on outpatient encounters. This limitation may result in selection bias; however, our data is well representative of national utilization of Watchman devices performed during in-patient settings; in fact since inpatient hospitalization is often required for reimbursement for the procedure, our results may be more indicative of widespread practice.[3,20] The NIS censors data gathering at discharge so long-term outcomes could not be ascertained from the present data set.[4] Specific data on potential confounders including medications, as well as operator and intraprocedural characteristics could not be examined from the NIS.

6 | CONCLUSION

In conclusion, in this large, nationally representative sample of the United States database, there has been a significant increase in the use of Watchman devices since FDA approval in 2015. Between 2015 and 2017, a significantly reduced rate of procedural complications and in-hospital mortality was noted, which appeared primarily driven by reduction in cardiovascular and neurological complications. In later years, LOS shortened and costs of hospitalization for the procedure decreased.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the first author (MBM) upon reasonable request. The data were extracted from Healthcare Cost and Utilization Project National Inpatient Sample (NIS) database (https://www.hcupus.ahrq.gov/nisoverview.jsp).

ABBREVIATIONS:

AF	atrial fibrillation
LAA	left atrial appendage
DOACs	direct acting oral anti-coagulants
FDA	Food and Drug Administration
LOS	length of stay
OR	odds ratio
NIS	National Inpatient Sample
ICD-9-CM	International Classification of Diseases, 9th Revision, Clinical Modification
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification

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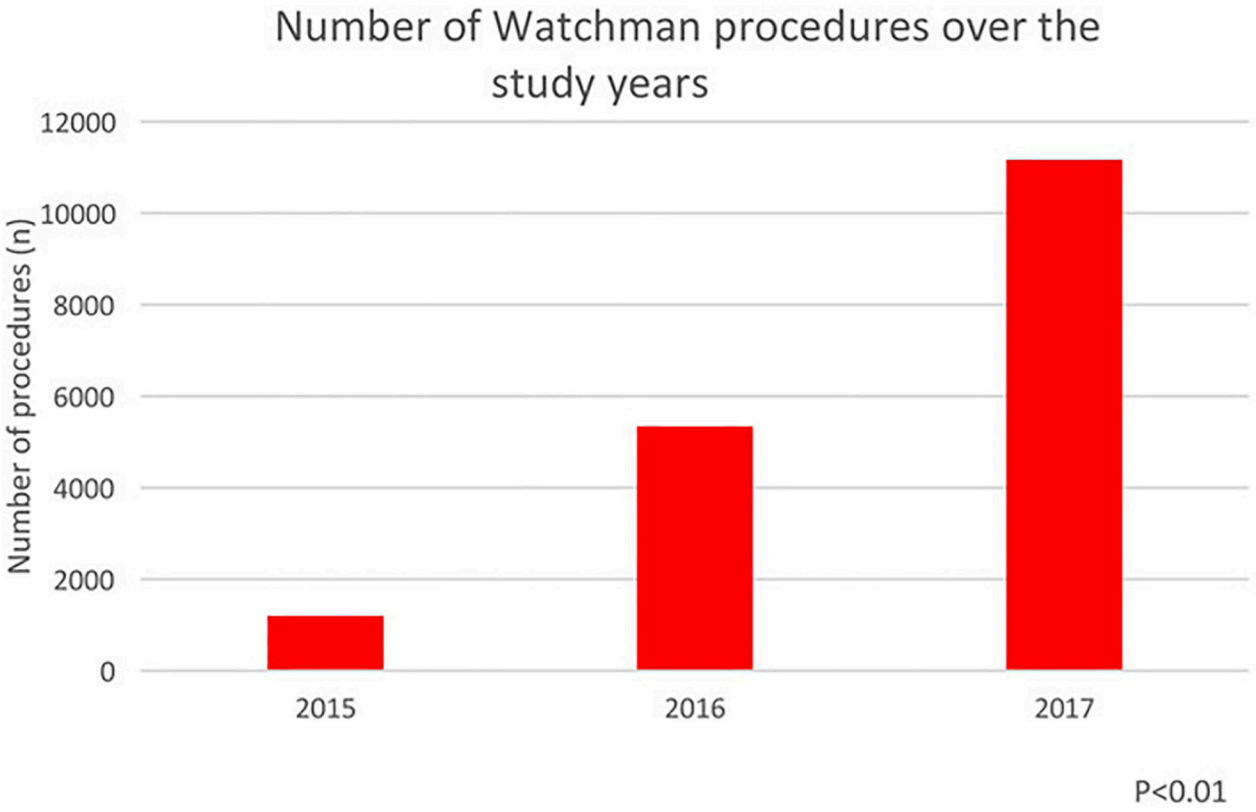

FIGURE 1.
Number of Watchman procedures over the study years

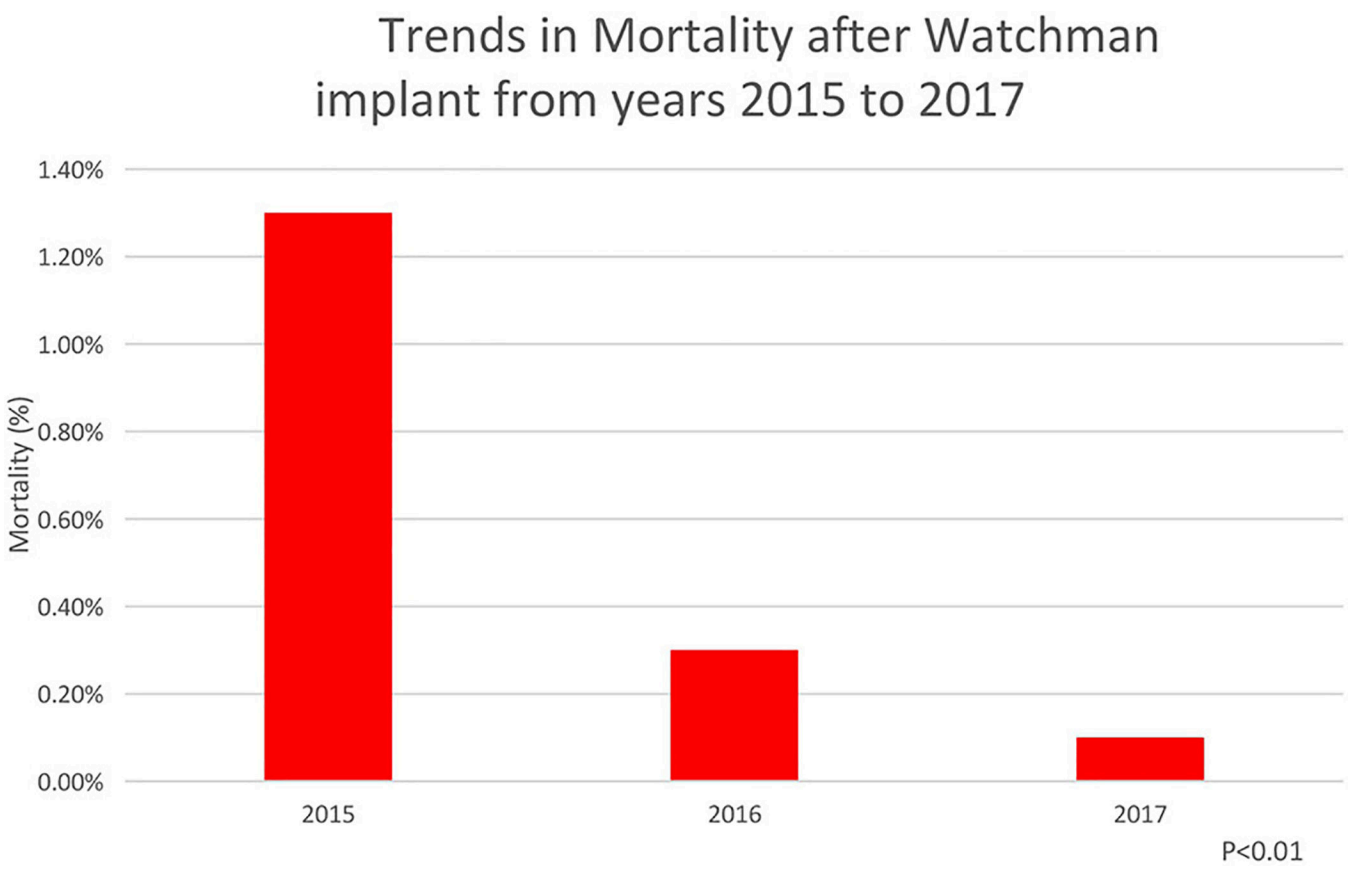

FIGURE 2.
Trends in mortality after Watchman implant from years 2015 to 2017

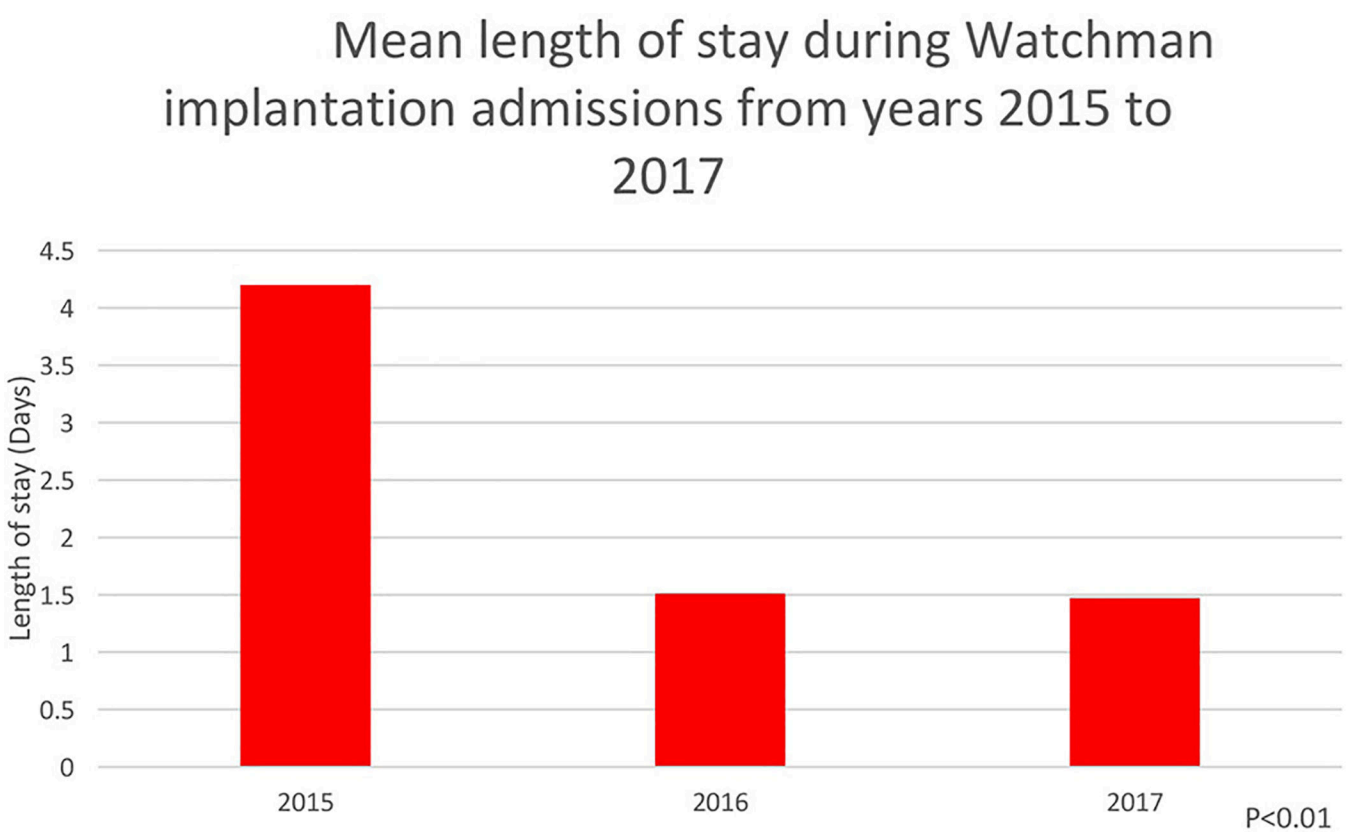

FIGURE 3.
Mean length of stay during Watchman implantation admissions from years 2015 to 2017

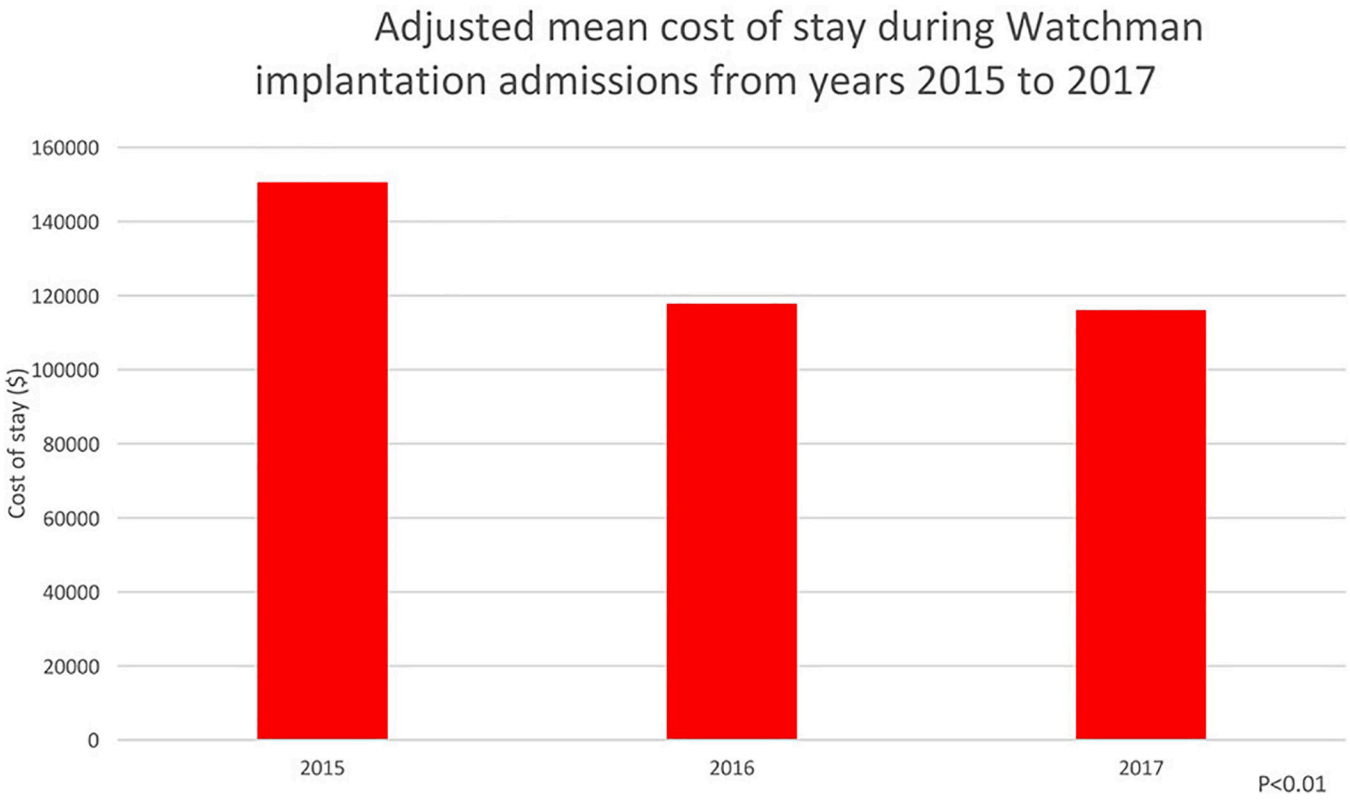

FIGURE 4.
Adjusted mean cost of stay during Watchman implantation admissions from years 2015 to 2017

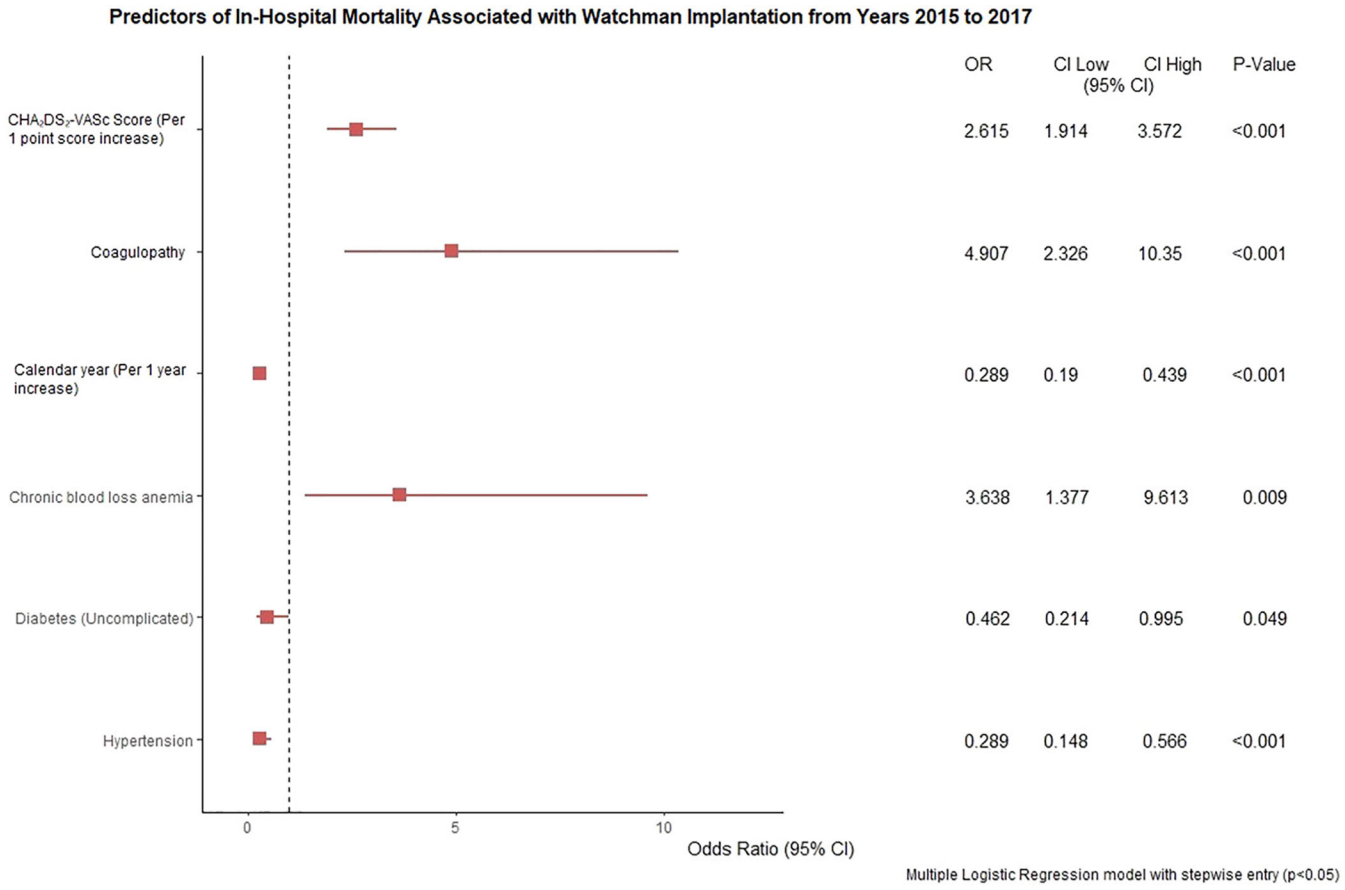

FIGURE 5.

Predictors of in-hospital mortality associated with Watchman implantation from years 2015 to 2017

TABLE 1

Baseline characteristics of the study population of patients undergoing Watchman device implantation, stratified by year of implant from years 2015 to 2017

Variable no. (%)	2015 (*n* = 1195)	2016 (*n* = 5340)	2017 (*n* = 11165)	Total (*n* =17700)	*p* Value
Age, mean (*SD*), years	74.2 (8.4)	75.5 (8.5)	75.8 (7.9)	75.6 (8.2)	<.01
Males	780 (65.30)	3140 (58.80)	6685 (59.90)	10 605 (59.9)	<.01
Females	415 (34.70)	2200 (41.20)	4480 (40.10)	7095 (40.10)	
Age					
<65	155 (13.0)	445 (8.3)	830 (7.4)	1430 (8.1)	<.01
65–74	345 (28.9)	1770 (33.1)	3665 (32.8)	5780 (32.7)	
≥75	695 (58.2)	3125 (58.5)	6670 (59.7)	10 490 (59.3)	
Elective admission	960 (81.7)	4625 (86.9)	10170 (91.5)	15 755 (89.5)	<.01
Race and ethnicity					
Caucasian	985 (86.0)	4405 (86.4)	9260 (85.9)	14 650 (86.0)	<.01
African American	45 (3.9)	175 (3.4)	475 (4.4)	695 (4.1)	
Hispanics	60 (5.2)	215 (4.2)	655 (6.1)	930 (5.5)	
Asian or Pacific Islander	30 (2.6)	130 (2.5)	190 (1.8)	350 (2.1)	
Native American	<10[a]	45 (0.9)	30 (0.3)	85 (0.5)	
CHA_2DS_2-VASc score					
0	15 (1.3)	30 (0.6)	35 (0.3)	80 (0.5)	
1	50 (4.2)	165 (3.1)	425 (3.8)	640 (3.6)	<.01
2	210 (17.6)	860 (16.1)	1705 (15.3)	2775 (15.7)	
3	335 (28.0)	1640 (30.7)	3805 (34.1)	5780 (32.7)	
4	340 (28.5)	1565 (29.3)	3405 (30.5)	5310 (30.0)	
5	190 (15.9)	760 (14.2)	1290 (11.6)	2240 (12.7)	
6	40 (3.3)	230 (4.3)	385 (3.4)	655 (3.7)	
7–9	15 (1.2)	90 (1.7)	115 (1.0)	220 (1.2)	
Mean CHA_2DS_2-VASc Score (mean [SD])	3.5 (1.3)	3.5 (1.3)	3.4 (1.2)	3.5 (1.2)	<.01
Anemia (blood loss)	20 (1.7)	100 (1.9)	195 (1.7)	315 (1.8)	.84
Iron deficiency anemia	170 (14.2)	670 (12.5)	1610 (14.4)	2450 (13.8)	<.01
Congestive heart failure	410 (34.3)	1660 (31.1)	3670 (33)	5740 (32.4)	<.01

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Variable no. (%)	2015 (*n* = 1195)	2016 (*n* = 5340)	2017 (*n* = 11165)	Total (*n* =17700)	*p* Value
Chronic pulmonary disease	200 (16.7)	1165 (21.8)	2390 (21.4)	3755 (21.2)	<.01
Coagulopathy	150 (12.6)	200 (3.7)	510 (4.6)	860 (4.9)	<.01
Coronary artery disease	55 (4.6)	405 (7.6)	930 (8.3)	1390 (7.9)	<.01
Diabetes	320 (26.8)	1240 (23.2)	2215 (19.8)	3775 (21.3)	<.01
Diabetes with complications	55 (4.6)	405 (7.6)	1720 (15.4)	2180 (12.3)	<.01
Hypertension	910 (76.2)	4040 (75.7)	6330 (56.7)	11 280 (63.7)	<.01
Liver disease	<10[a]	135 (2.5)	290 (2.6)	435 (2.5)	<.01
Obesity	195 (16.3)	620 (11.6)	1890 (16.9)	2705 (15.3)	<.01
Paralysis	20 (1.7)	195 (3.7)	350 (3.1)	565 (3.2)	<.01
Peripheral vascular disorders	170 (14.2)	555 (10.4)	1245 (11.2)	1970 (11.1)	<.01
Renal failure	240 (20.1)	1030 (19.3)	2540 (22.7)	3810 (21.5)	<.01
Valvular disease	<10[a]	20 (0.4)	15 (0.1)	45 (0.3)	<.01
Hospital Location					
Rural	15 (1.3)	40 (0.7)	160 (1.4)	215 (1.2)	<.01
Urban nonteaching	150 (12.6)	575 (10.8)	1045 (9.4)	1770 (10.0)	
Urban Teaching	1030 (86.2)	4725 (88.5)	9960 (89.2)	15 715 (88.8)	
Bed size of the hospital					
Small	165 (13.8)	575 (10.8)	1175 (10.5)	1915 (10.8)	<.01
Medium	255 (21.3)	1070 (20.0)	2565 (23.0)	3890 (22.0)	
Large	775 (64.9)	3695 (69.2)	7425 (66.5)	11 895 (67.2)	
Census divisions					
New England	<10[a]	180 (3.4)	350 (3.1)	540 (3.1)	<.01
Mid-Atlantic	155 (13.0)	720 (13.5)	1410 (12.6)	2285 (12.9)	
East North Central	195 (16.3)	715 (13.4)	1530 (13.7)	2440 (13.8)	
West North Central	70 (5.9)	330 (6.2)	785 (7.0)	1185 (6.7)	
South Atlantic	235 (19.7)	1040 (19.5)	2565 (23.0)	3840 (21.7)	
East South Central	20 (1.7)	200 (3.7)	600 (5.4)	820 (4.6)	
West South Central	140 (11.7)	620 (11.6)	1335 (12.0)	2095 (11.8)	
Mountain	85 (7.1)	440 (8.2)	1175 (10.5)	1700 (9.6)	
Pacific	285 (23.8)	1095 (20.5)	1415 (12.7)	2795 (15.8)	

Variable no. (%)	2015 (*n* = 1195)	2016 (*n* = 5340)	2017 (*n* = 11165)	Total (*n* =17700)	*p* Value
Payee					
Medicare/Medicaid	1025 (85.8)	4915 (92.2)	10 015 (90.1)	15 955 (90.4)	<.01
Private insurance	150 (12.6)	365 (6.8)	920 (8.3)	1435 (8.1)	
Self-pay	0	<10[a]	60(0.5)	65 (0.4)	
Median income					
0–25th	280 (24)	930 (17.7)	2320 (21.1)	3530 (20.3)	<.01
26–50th	210 (18)	1235 (23.5)	2815 (25.6)	4260 (24.5)	
51–75th	335 (28.8)	1460 (27.8)	3175 (28.9)	4970 (28.5)	
76–100th	340 (29.2)	1630 (31.)	2680 (24.4)	4650 (26.7)	

[a]Less than 10 data were not reported as per HCUP recommendations.

TABLE 2

Complications in patients undergoing Watchman implantation

Variable no. (%)	2015 (*n* = 1195)	2016 (*n* = 5340)	2017 (*n* = 11165)	Combined (*n* = 17700)	*p* value
Overall complications (%)	315 (26.4)	440 (8.2)	885 (7.9)	1640 (9.3)	<.01
Cardiovascular system					
Any cardiovascular event/complication	165 (13.8)	210 (3.9)	450 (4.0)	825 (4.7)	<.01
Percutaneous coronary intervention	<10 (<1.0)[a]	20(0.4)	<10 (<0.1)	35 (0.2)	<.01
Pericardial effusion/Hemopericardium	65 (5.4)	160 (3.0)	325 (2.9)	550 (3.1)	<.01
Cardiac Arrest/CPR procedure code	<10 (<1.0)[a]	<10 (<0.2)[a]	<10 (<0.1)	20 (0.1)[a]	<.01
STEMI	<10 (<1.0)[a]	<10 (<0.2)[a]	<10 (<0.1)[a]	25 (0.1)[a]	<.01
NSTEMI or type II MI	50 (4.2)	<10 (<0.2)[a]	<10 (<0.1)[a]	65 (0.4)	<.01
Cardiac Tamponade	<10 (<1.0)	30 (0.6)	110 (1.0)	150 (0.8)	.02
Pericarditis	<10 (<1.0)[a]	<10 (<0.2)[a]	45 (0.4)	50 (0.3)	<.01
Need for pericardiocentesis	20 (1.7)	40 (0.7)	145 (1.3)	205 (1.2)	<.01
Cardiogenic Shock	30 (2.5)	15 (0.3)	20 (0.2)	65 (0.4)	<.01
Systemic					
Any systemic complication	<10 (<1.0)[a]	35 (0.7)	45 (0.4)	90 (0.5)	<.01
Anaphylaxis	0	0	<10 (<0.1)	<10 (<0.1)	.23
Arterial thrombosis	0	15(0.3)	<10 (<0.1)	25 (0.1)	<.01
Deep venous thrombosis	<10 (<1.0)[a]	20 (0.4)	20 (0.2)	50 (0.3)	<.01
Septic shock	0	0	<10 (<0.1)	<10 (<0.1)	.05
Vascular complications					
Any peripheral vascular complication	<10 (<1.0)	35 (0.7)	65 (0.6)	105 (0.6)	<.01
AV fistula	0	<10 (<0.2)[a]	15 (0.1)	25 (0.1)	.28
Pseudoaneurysm	5 (0.4)	20 (0.4)	35 (0.3)	60 (0.3)	.73
Retroperitoneal bleeding	0	15 (0.3)	15 (0.1)	30 (0.2)	.03
Neurological complications					
Any neurological complication	95 (7.9)	55 (1.0)	100 (0.9)	250 (1.4)	<.01

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Variable no. (%)	2015 (*n* = 1195)	2016 (*n* = 5340)	2017 (*n* = 11165)	Combined (*n* = 17700)	*p* value
Hemorrhagic stroke	<10 (<1.0)[a]	15 (0.3)	50 (0.4)	70 (0.4)	.28
Ischemic stroke/TIA	90 (7.5)	40 (0.7)	50 (0.4)	180 (1.0)	<.01
Bleeding and Hematological complications					
Any bleeding or hematological complication	155 (13.0)	160 (3)	320 (2.9)	620 (3.6)	<.01
GI bleeding	20 (1.7)	145 (2.7)	300 (2.7)	465 (2.6)	.1
Hemothorax after procedure	<10 (<1.0)[a]	<10 (<0.2)[a]	<10 (<0.1)[a]	15 (0.1)	<.01
Need for blood transfusion	130 (10.9)	70 (1.3)	205 (1.8)	405 (2.3)	<.01
Pulmonary complications					
Any pulmonary complications	70 (5.8%)	45 (0.8%)	95 (0.8)	195 (1.1)	<.01
Pneumothorax	25 (2.1)	<10 (<0.2)[a]	<10 (<0.1)[a]	<10 (<0.1)[a]	<.01
Pleural effusion	25 (2.1)	<10 (<0.2)[a]	55 (0.5)	90 (0.5)	<.01
Pneumonia bacterial	25 (2.1)	20 (0.4)	40 (0.4)	85 (0.5)	<.01
Pulmonary embolism	0	15 (0.3)	0	15 (0.1)	<.01
Device related complications					
Device thrombus	0	0	0	0	
Device Embolization	0	0	<10 (<0.1)[a]	<10 (<0.1)[a]	<.01

Abbreviations: NSTEMI, non-ST segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction; TIA, transient ischemic attack.

[a]Less than 10 data were not reported as per HCUP recommendations.

TABLE 3

Hospital outcomes and resource utilization

Variables no. (%)	2015	2016	2017	total	*p* value
Died at discharge	15 (1.3)	15 (0.3)	15 (0.1)	45 (0.3)	<.01
Discharge disposition					
Routine/self-care	810 (67.8)	4915 (92.0)	10 235 (91.7)	15 960 (90.2)	<.01
Short-term hospital	<10[a]	0	<10[a]	20 (0.1)	
Another type of facility	150 (12.6)	155 (2.9)	285 (2.6)	590 (3.3)	
Home Health Care	210 (17.6)	250 (4.7)	615 (5.5)	1075 (6.1)	
Resource utilization, mean (*SD*)					
Length of stay, days	4.2 (5.6)	1.5 (2.0)	1.5 (1.9)	1.7 (2.5)	<.01
Cost of hospitalization, $	150 370 (131 324)	117 568 (71 736)	115 803 (65 180)	118 676 (73 971)	<.01

Note: Supplementary 1: ICD-9 and ICD-10 codes used for the study cohort and variables entered in logistic regression model.

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