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Complications and Health Care Costs Associated With Transvenous Cardiac Pacemakers in a Nationwide Assessment

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ABSTRACT

OBJECTIVES The aim of this study was to retrospectively characterize transvenous pacemaker (TVP) complications and associated health care costs in a large-scale U.S. patient cohort.

BACKGROUND TVP complications have previously been shown to affect more than 1 in 10 patients but may be underestimated. Pacemakers are widely implanted across community and urban hospitals by operators of varying specialization and experience.

METHODS Truven Health MarketScan databases track U.S. health care claims and encounters of private or Medicare supplemental insurance. Patients implanted with de dual- and single-chamber TVPs between April 2010 and March 2014 and over 1 year of pre-implantation MarketScan enrollment were identified. International Classification of Diseases-Ninth Revision and Current Procedural Terminology codes were used to extract relevant comorbidities and complications. Incremental adjusted cost analysis was performed for acute complications, defined as those occurring within 30 days of implantation.

RESULTS Among 72,701 TVP implantations (mean age 75 ± 12 years, 55% men, 13% single chamber) with 1.5 ± 1.1 years of follow-up, acute complications (0 to 1 month) occurred in 7.7% of single- and 9.1% of dual-chamber TVPs and long-term complications (1 to 36 months) in 6.4% and 5.9% of single- and dual-chamber TVPs, respectively. The net 3-year event rates were approximately 15% and 16%. The incidence and incremental cost of complications are considerable. Most common acute complications include thoracic trauma (3.71%, $70,114), leads requiring revision (3.51%, $9,296), and infection (1.15%, $80,247). Long-term complications are attributed to leads (2.84%), infection (2.42%), and pocket (0.96%).

CONCLUSIONS Claims data suggest that TVP complications are more common than previously reported, affecting nearly 1 in 6 patients by 3 years and contributing to considerable incremental U.S. health care cost. (J Am Coll Cardiol EP 2017;3:1296–305) © 2017 by the American College of Cardiology Foundation.

Acute and long-term complications involving transvenous pacemakers (TVPs) remain a significant problem despite considerable technological advancements (1–3). Multicenter U.S. and European data from the MOST (Mode Selection in Sinus Node Dysfunction Trial) and FOLLOWPACE (Cost-Effectiveness of Routine Follow-up Visits in Patients With a Pacemaker) studies report 30- and 60-day complication rates of 4.8% and 12.4%, respectively, and 3-year and 5-year complication rates of

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7.5% and 19.7%, respectively (1,2). Acute complications commonly include lead dislodgement, thoracic trauma, vascular injury, pocket hematoma, and infection and consistently account for the majority of adverse events (1-6). Operator experience, technique, and a number of patient-specific parameters have been associated with acute pacemaker complications (1,2,4-7). Long-term pacemaker complications requiring transvenous lead extraction commonly include lead conductor fractures, abnormal lead sensing or pacing values, insulation failures, device header or connector problems, premature battery depletion, and pocket infection (3). Serious adverse events directly related to transvenous lead extraction procedures, including death, range from 1.4% to 5.6% (3,8). In addition, pacemaker complications are known to easily double the cost of an uncomplicated procedure (5).

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It is not known if prior studies have accurately characterized the scope of pacemaker complications, as most published reports have been limited to single-center or multicenter data at predominantly academic or tertiary medical care centers (1-8). Pacemakers are implanted across the United States by operators of varying specialization and experience in both community and urban hospitals (9). Analysis of deidentified claims data can potentially capture a broader clinical account by tracking billed encounters rendered for the diagnosis and treatment of pacemaker-related complications across medical practice, while obviating the need for voluntary reporting (10). In the present analysis, we used claims data to characterize the acute and long-term TVP complications and their associated costs across the U.S. health care system.

METHODS

DATABASE. Data were extracted from the Truven Health MarketScan Research Databases, which contain more than 120 million patient claim records, with more than 20 billion deidentified person-specific health insurance claims. The data are derived from approximately 350 U.S. private-sector payers, including large employers, health plans, and government and public organizations (11). In this analysis, we used 2 of the MarketScan databases from April 2009 through March 2014. The first was the Commercial Claims and Encounters database, which contains data from active employees, dependents, and early retirees covered by employer-sponsored health plans. The second was the Medicare Supplemental database, which contains data from Medicare-eligible retirees with employer-sponsored Medicare supplemental plans.

STUDY POPULATION. The study population consisted of patients 18 years and older implanted with de novo single- or dual-chamber pacemakers, regardless of device manufacturer. Single-chamber pacemaker patients were identified as those having International Classification of Diseases-9th Revision (ICD-9) procedure code 37.81 or 37.82 or Current Procedural Terminology code 33207 (code descriptions are listed in Online Table 1). Dual-chamber pacemaker patients were identified by ICD-9 procedure code 37.83 or Current Procedural Terminology code 33208. Patients were excluded from the analysis if they were not continuously enrolled in MarketScan for at least 1 year immediately prior to implantation or had evidence of prior cardiac device utilization on the basis of the presence of any prior implantable rhythm management device-related codes (Online Table 2).

BASELINE COMORBIDITIES. To characterize baseline comorbidities in the study population, relevant inpatient and outpatient diagnostic and procedure codes were identified over the entire available time period prior to implantation. Codes that indicated a history of atrial fibrillation, hypertension, diabetes, coronary artery disease, vascular disease, or tricuspid valve disease were included in the baseline characterization (comorbidity codes are listed in Online Table 3).

PACEMAKER-RELATED COMPLICATION RATES. Pacemaker-related complications were identified using inpatient and outpatient codes recorded from the day of implantation onward. Complication codes were compiled into the following categories: 1) infection, including endocarditis and other device-related infection; 2) thoracic trauma, including pneumothorax and hemothorax attributed to lead insertion; 3) pocket complication, including hematoma and pocket revision; 4) generator complication requiring removal or replacement; 5) lead complication requiring revision; 6) venous embolism or thrombosis; and 7) cardiac perforation and its downstream clinical manifestations. The complete list of complication codes for each category is provided in Online Table 4.

To avoid overestimating complication rates, multiple codes from the same complication category that occurred on the same or consecutive dates were counted as a single event. In cases when pacemaker implantation and a complication occurred on the

ABBREVIATIONS AND ACRONYMS

CCI = Charlson comorbidity index

ICD-9 = International Classification of Diseases-9th Revision

TVP = transvenous pacemaker

TABLE 1 Baseline Patient Characteristics at the Time of Pacemaker Implantation

	Single-Chamber (n = 9,376)	Dual-Chamber (n = 63,325)	Both (n = 72,701)
Male	56.8	54.6	54.9
Age, yrs	80.4 ± 9.5	74.4 ± 12.3	75.1 ± 12.1
1-yr comorbidity history			
Atrial fibrillation	84.8	37.2	43.3
Atrioventricular block	8.6	17.7	16.5
Chronic pulmonary disease	41.4	31.7	33.0
Coronary artery bypass graft	2.7	3.2	3.2
Coronary artery disease	57.5	51.2	52.0
Dementia	8.7	5.0	5.5
Diabetes	37.6	34.8	35.1
Endocarditis	2.4	1.7	1.8
Heart failure	49.6	28.2	31.0
Hyperlipidemia	51.1	55.4	54.9
Hypertension	86.1	81.5	82.1
Myocarditis	0.1	0.1	0.1
Percutaneous coronary intervention	6.9	7.9	7.8
Renal disease	20.7	16.2	16.7
Sick sinus syndrome	29.0	28.5	28.6
Stroke	20.1	15.6	16.2
Tricuspid valve disease	7.4	5.2	5.5
Vascular disease	27.1	20.8	21.6
Venous embolism/thrombosis	4.7	3.4	3.5

Values are % or mean ± SD.

same date, the implantation was assumed to have preceded the complication.

Pacemaker-related complications were classified as short or long-term relative to device implantation. Acute complications were defined as occurring within 1 month post-implantation. Long-term complications were defined as those occurring beyond 1 month post-implantation and exclusive of any acute complications within the first month. Thoracic trauma, cardiac perforation, and venous embolism or thrombosis were omitted as long-term complications, because they were less likely to be pacemaker related beyond 1 month post-implantation. Complications were identified until the time of device upgrade, removal, replacement, or withdrawal from MarketScan (codes listed in Online Table 2). Results are reported until 36 months post-implantation, beyond which <10% of the initial cohort was available for analysis.

Complication rates were quantified by the number of single- or dual-chamber pacemaker patients who experienced at least 1 instance of a particular complication, distinguishing between the acute and long-term time frames. Percentages were calculated relative to the total number of single- or dual-chamber pacemaker patients available for each time frame. Time to first complication was quantified by the median and interquartile range (25th and 75th percentiles) of the number of post-implantation days.

ACUTE COMPLICATION COSTS. Cost analysis was limited to acute costs to minimize the potential variability associated with unrelated events or treatments. For each pacemaker-related complication type, patients with either single- or dual-chamber systems who experienced complications within 30 days post-implantation were identified and compared with those who did not experience any complications. To obtain a more balanced comparison, propensity score matching was used to match those who had experienced acute complications with those who did not, using a 1:2 ratio (R version 3.2.5, MatchIt package) (12). The matching was based on age, sex, device type (single- or dual-chamber), 1-year total pre-implantation health care cost, and Charlson comorbidity index (CCI) (13). CCI was calculated on the basis of pre-implantation ICD-9 codes using category mapping, as previously described (14). The matching was conducted separately for each complication type. The total 30-day post-implantation health care cost was then calculated for each patient in the matched subsets. This cost included the total gross payments to all providers who submitted claims for covered services, including physician and facility. Gross payments were composed of net payments made by the insurance as well as the patient's deductible, coinsurance, and any copayment.

Both unadjusted (actual) and adjusted (predicted) acute costs are reported. The unadjusted cost for each complication was the difference between the average cost for patients who experienced the complication and those with no complications. Generalized linear models were used to derive the risk-adjusted costs, controlling for age, sex, device type, CCI, and the presence or absence of the complication of interest. The adjusted cost for each complication was calculated as the difference between the risk-adjusted average cost for patients who experienced the complication and the risk-adjusted cost for those with no complications. To account for skewed cost data, the generalized linear models were fitted using a gamma distribution with a log link function. Because of differences in reimbursement rates, acute costs were analyzed separately for patients under commercial insurance and Medicare supplemental insurance.

RESULTS

PATIENT CHARACTERISTICS AND COMORBIDITIES. A total of 72,701 U.S. patients enrolled in MarketScan were implanted with conventional pacemakers across

TABLE 2 Patients Experiencing Acute and Long-Term Complications

	Acute (0–1 Months)			Long-Term (1–36 Months)		
	Single-Chamber (n = 8,956)	Dual-Chamber (n = 60,902)	Both (n = 69,858)	Single-Chamber (n = 981)	Dual-Chamber (n = 7,856)	Both (n = 8,837)
All	7.68 (688)	9.13 (5,559)	8.94 (6,247)	6.42 (63)	5.88 (462)	5.94 (525)
Infection	1.23 (110)	1.14 (694)	1.15 (804)	2.14 (21)	2.46 (193)	2.42 (214)
Endocarditis	0.84 (75)	0.78 (475)	0.79 (550)	1.94 (19)	2.13 (167)	2.10 (186)
Other (device related)	0.42 (38)	0.44 (269)	0.44 (307)	0.20 (2)	0.46 (36)	0.43 (38)
Thoracic trauma	3.51 (314)	3.74 (2,278)	3.71 (2,592)	–	–	–
Pneumothorax	2.53 (227)	3.01 (1,832)	2.95 (2,059)	–	–	–
Hemothorax	1.45 (130)	1.41 (858)	1.41 (988)	–	–	–
Pocket complication	0.27 (24)	0.26 (160)	0.26 (184)	1.63 (16)	0.88 (69)	0.96 (85)
Hematoma	0.15 (13)	0.08 (47)	0.09 (60)	1.43 (14)	0.56 (44)	0.66 (58)
Pocket revision	0.16 (14)	0.19 (114)	0.18 (128)	0.20 (2)	0.33 (26)	0.32 (28)
Generator complication	0.09 (8)	0.06 (37)	0.06 (45)	0.00 (0)	0.06 (5)	0.06 (5)
Lead complication requiring revision	2.51 (225)	3.66 (2,226)	3.51 (2,451)	2.85 (28)	2.84 (223)	2.84 (251)
Venous embolism/thrombosis	0.35 (31)	0.51 (312)	0.49 (343)	–	–	–
Cardiac perforation	0.25 (22)	0.60 (367)	0.56 (389)	–	–	–

Values are % (n). Numbers denote the numbers of patients with continuous data available for at least 1 month (acute) and 36 months (long-term).

all manufacturers from April 2010 to March 2014. Of those patients, 9,376 (13%) were implanted with single-chamber pacemakers, and 63,325 (87%) were implanted with dual-chamber pacemakers. Patients were continuously followed for 1.5 ± 1.1 years prior to device upgrade, removal, replacement, or MarketScan withdrawal. A requirement of at least 1 year of pre-implantation MarketScan enrollment was imposed, which was used to assess comorbidities (Table 1).

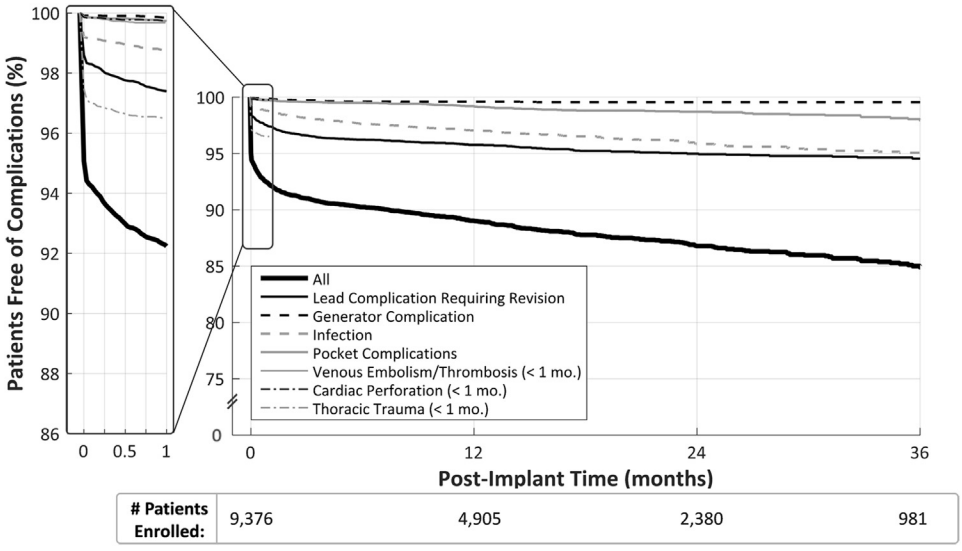
PACEMAKER-RELATED COMPLICATION RATES. The incidence rates of pacemaker complications stratified by complication category, timing in relation to implantation, and pacemaker type are reported in Table 2. Of the 69,858 patients with at least 1 month of continuous MarketScan data, 7.7% of single-chamber patients and 9.1% of dual-chamber patients experienced acute complications within 1 month of pacemaker implantation. Short-term complication rates for single- and dual-chamber devices were highest for thoracic trauma (3.5% and 3.7%, respectively) and lead-related complications requiring revision (2.5% and 3.7%), followed by infection (1.2% and 1.1%), cardiac perforation (0.3% and 0.6%), venous embolism or thrombosis (0.4% and 0.5%), pocket complications (0.3% and 0.3%), and generator complications (0.1% and 0.1%). In addition, lead removals, which constitute 1.4% of all lead-related complications, were preceded or accompanied by infection in 22.9% of the cases.

Of the 8,837 patients with at least 36 months of continuous MarketScan data, 6.4% of single-chamber patients and 5.9% of dual-chamber patients experienced long-term complications from 1 to 36 months after implantation. Long-term complication rates for single- and dual-chamber patients were highest for lead-related complications requiring revision (2.9% and 2.8%, respectively) and infection (2.1% and 2.5%), followed by pocket-related complications (1.6% and 0.9%) and negligible generator complications (0.0% and 0.1%). Occurrences of thoracic trauma, venous embolism or thrombosis, and cardiac perforation-related events beyond 1 month of implantation could not be directly associated with the implantation procedure and thus were not included in the analysis. Note that complication rates quantified individually by ICD-9 code, rather than by category, are provided in Online Table 4.

Patient freedom from complications in the first 3 years after implantation is shown for single-chamber (Figure 1) and dual-chamber (Figure 2) pacemakers. Each trace illustrates the percentage of pacemaker patients who had not experienced complications of each category. In contrast to the complication rates reported in Table 2, patient freedom from complications is illustrated cumulatively from 0 to 36 months post-implantation. Again, thoracic trauma, venous embolism or thrombosis, and cardiac perforation-related events were not included beyond 1 month of implantation.

Complications of all types occurred predominantly on the day of implantation, as shown in the 1-month insets on the left of Figures 1 and 2. Mechanical complications that can be directly associated with insertion and placement of leads, such as tamponade (cardiac perforation), hemothorax (thoracic trauma), and

FIGURE 1 Freedom From Single-Chamber Pacemaker Complications Stratified by Complication Category

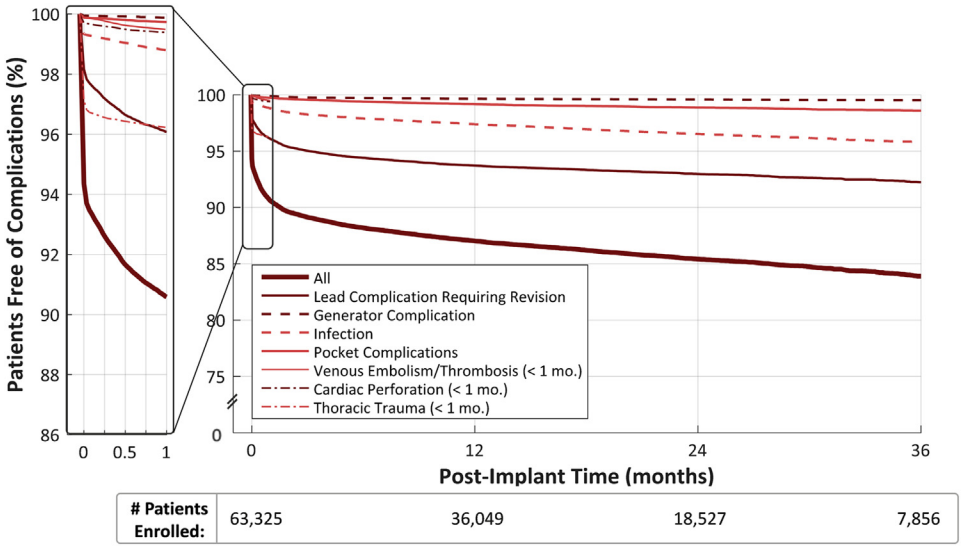


# Patients Enrolled:	9,376	4,905	2,380	981

The first 30 day post-implantation period is depicted in the expanded panel.

dislodgement (lead complication requiring revision), manifested either during or immediately after the procedure. Complications that develop after implantation, such as infection or pocket issues, were identified during the entire 36-month period. Consequently, freedom from these complications consistently diminished over time. Overall, approximately 15% of single-chamber and 16% of dual-chamber pacemaker patients experienced pacemaker-related complications within the first 3 years of implantation.

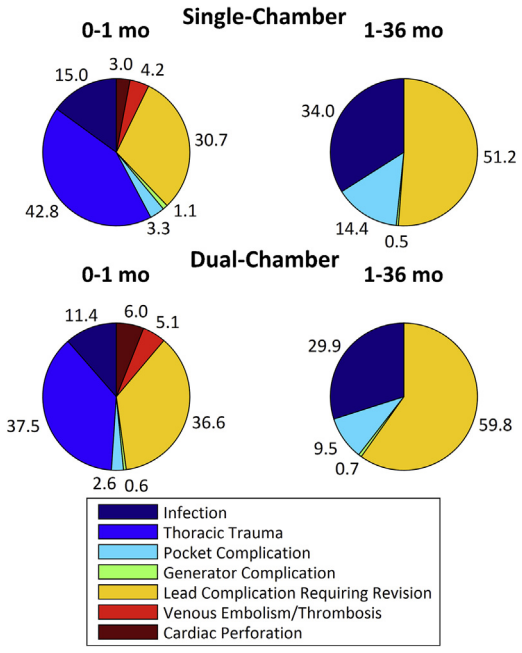
FIGURE 2 Freedom From Dual-Chamber Pacemaker Complications Stratified by Complication Category



# Patients Enrolled:	63,325	36,049	18,527	7,856

The first 30-day post-implantation period is depicted in the expanded panel.

FIGURE 3 Distribution of Pacemaker Complications by Category for Single-Chamber Implants and Dual-Chamber Implants



Acute complications are shown for single-chamber implants **(Top)** and dual-chamber implants **(Bottom)** on the **left side** and long-term complications on the **right side**. Generator complications make up the least of long-term complications.

The distribution of complications across categories was different for acute and long-term time frames. Consistent with the freedom from complications (Figures 1 and 2), infection and pocket complications became relatively more prevalent beyond 1 month post-implantation, as shown in Figure 3.

Complication timelines can also be characterized by the first time they are clinically identified and reported. As shown in Table 3, the first instances of most complication types were reported within 2 weeks of implantation. Generator complications, infection, and pocket complications, however, occurred predominantly in the second month after implantation or beyond.

TABLE 3 Time to First Pacemaker-Related Complication

	Days to First Event		
	Single-Chamber	Dual-Chamber	Both
All	3 (0–74)	4 (0–50)	4 (0–52)
Infection	65 (1–292)	52 (3–271)	53 (3–274)
Thoracic trauma	0 (0–1)	0 (0–0)	0 (0–0)
Pocket complication	223 (29–428)	117 (23–342)	126 (24–365)
Generator complication	46 (21–112)	64 (21–233)	57 (21–207)
Lead complication requiring revision	14 (0–79)	14 (0–82)	14 (0–82)
Venous embolism/thrombosis	4 (0–10)	9 (0–17)	9 (0–16)
Cardiac perforation	0 (0–9)	1 (0–12)	1 (0–12)

Values are median (interquartile range).

ACUTE COMPLICATION COSTS. The unadjusted and adjusted estimates of costs incurred within 30 days post-implantation for each complication are reported in Table 4. All complications in patients with either commercial or Medicare supplemental insurance were significantly associated with acute costs ($p < 0.05$), with the exception of pocket complications and generator complications. The highest adjusted incremental costs were seen with cardiac perforation and infection. The adjusted incremental costs for patients with Medicare were lower than those for patients with commercial insurance for all complication types but showed similar trends. The incremental costs for generator complication were not estimated for the commercial data, because the sample size was too small for cost analysis ($n = 10$).

DISCUSSION

This retrospective study of a large-population, real-world patient cohort revealed that transvenous cardiac pacemaker complication rates are greater than previously reported and contribute to considerable costs to the U.S. health care system. Acute complications occurred in 7.7% of single-chamber and 9.1% of dual-chamber pacemakers. The majority of these complications were attributed to leads, thoracic trauma, and infection. Long-term complications occurred in an additional 6.4% and 5.9% of single- and dual-chamber patients, respectively. More than half of the long-term complications were related to leads. The net 3-year complication event rates were approximately 15% and 16% for single- and dual-chamber implants, respectively.

The dual-chamber patient population studied in the present analysis was analogous in age and sex distribution to previous investigations (2,15,16). However, the single-chamber pacemaker patients were older and more often male than those studied in the MOST multicenter trial, which evaluated more than 2,000 pacemaker patients (16). The proportion of patients with atrial fibrillation was lower compared with MOST in the dual-chamber patients but higher in those with single-chamber devices. We report higher rates of hypertension, diabetes, and coronary artery disease compared with prior trials (2,16). The differences could be attributed to changes in patient

TABLE 4 Healthcare Costs Associated With Pacemaker-Related Complications

	n	Mean Total Actual Cost		Incremental Actual Cost*	Mean Total Predicted Cost		Incremental Predicted Cost, Mean ± SD†	p Value
		With Complication	Without Complication		With Complication	Without Complication		
Commercial insurance								
Infection	232	$119,365	$39,118	$80,247	$120,915	$38,981	$81,933 ± 32,192	<0.001
Thoracic trauma	424	$106,395	$36,280	$70,114	$104,331	$36,758	$67,573 ± 29,223	<0.001
Pocket complication	28	$93,294	$51,284	$42,010	$89,073	$53,530	$35,543 ± 31,559	0.15
Generator complication‡	10	–	–	–	–	–	–	–
Lead complication requiring revision	480	$44,210	$34,914	$9,296	$44,141	$34,948	$9,193 ± 3,842	<0.001
Venous embolism/thrombosis	89	$97,015	$34,352	$62,663	$91,744	$35,603	$56,141 ± 28,658	<0.001
Cardiac perforation	96	$140,706	$38,220	$102,486	$133,014	$39,222	$93,792 ± 35,042	<0.001
Medicare supplemental insurance								
Infection	528	$61,800	$26,032	$35,768	$61,918	$26,018	$35,900 ± 10,048	<0.001
Thoracic trauma	2,061	$48,167	$26,472	$21,695	$47,766	$26,577	$21,190 ± 3,625	<0.001
Pocket complication	137	$36,733	$25,900	$10,833	$36,251	$26,131	$10,120 ± 7,526	0.01
Generator complication	32	$23,181	$19,978	$3,203	$23,986	$19,776	$4,210 ± 7,011	0.27
Lead complication requiring revision	1,828	$34,203	$25,371	$8,832	$34,033	$25,437	$8,596 ± 2,903	<0.001
Venous embolism/thrombosis	229	$39,913	$26,510	$13,403	$38,808	$26,844	$11,964 ± 8,088	0.0033
Cardiac perforation	270	$62,590	$23,541	$39,049	$61,424	$23,755	$37,669 ± 7,939	<0.001

*For unadjusted (actual) cost, the incremental cost associated with each complication is the average total cost for each complication minus the average total cost of a case with no complications. †For risk-adjusted (predicted) cost, the incremental cost associated with each complication is the average predicted cost for each complication minus the average predicted cost of an uncomplicated case, controlling for age, sex, device type, Charlson comorbidity index, and the complications of interest. ‡The cost comparison and predictions were not performed for generator complication, because of small sample size.

populations that receive pacemakers over time. The MOST study was performed between 1995 and 2001 and the FOLLOWPACE study between 2003 and 2007, while our study included patients between 2010 and 2014. A recent report from a very large national survey illustrates that the population receiving pacemakers has greatly expanded and has become older and sicker (17). Between 1993 and 2009, the overall use of pacemakers has increased by 55.6%, accompanied by increased age and complexity of patients' conditions (17). The proportion of patients with a CCI of more than 2 increased from 14.1% to 45.1% in single-chamber and from 13.5% to 42.4% in dual-chamber pacemaker patients (17). The population described in the present analysis is likely representative of the current U.S. pacemaker population. Greenspon et al. (17) reported that by 2009, the average ages of single- and dual-chamber pacemaker patients in the U.S. were approximately 80.1 and 75.4 years, respectively, which is similar to our study, in which these patients were 80 ± 10 and 74 ± 12 years of age. An even more recent report by Moazzami et al. (15) showed the average age of pacemaker patients to be 75.8 ± 12 years, which is quite similar to our overall average of 75 ± 12 years.

The 30-day complication rates of 7.7% for single-chamber systems and 9.1% for dual-chamber systems exceeded both the 30- and 60-day complication rates previously reported in the MOST study, which reported a complication rate of 4.8% (1). In contrast to MOST and other studies, claims data capture complications occurring across the full spectrum of operators performing pacemaker surgery at U.S. community and urban hospitals and are not limited to the academic or tertiary medical centers with highly experienced operators. Complication rates have previously been shown to be influenced by operator experience and technique (5,18). However, it is not known if this is sufficient to account for the measured differences, and the MarketScan databases do not contain information on operator specialization or experience level. In a Danish registry of approximately 5,000 patients spanning a spectrum of urban and community hospitals, there was a 9.5% rate of acute complications (18), higher than that found in the MOST study but similar to the present study. Another study in which event rates resemble those reported in the present analysis is FOLLOWPACE, which was a clinical trial of 1,517 Dutch patients. The trial found that 12.4% of patients experienced any complication within 60 days of implantation, but only 4.2% of patients had complications that required reoperation (2). Similarly, Wiegand et al. (7) reported a 4.2% rate of complications requiring surgical interventions. The 36-month complication rate of 5.9% in this analysis is similar to the rate previously reported in the MOST trial, (1) but is lower than reported in the FOLLOWPACE study. To avoid

overestimating complications, only long-term complications that could definitively be attributed to a pacemaker were quantified, which could have led to an underestimation. In 1,517 FOLLOWPACE patients, there was 1 perforation that occurred after 2 months, which would not have been captured in our analysis. The rate of perforation found in our study (0.25% single-chamber, 0.60% dual-chamber) is similar to that reported in a recent study of a very large sample of the U.S. population receiving single-chamber, dual-chamber, and biventricular pacemakers, with an overall tamponade rate of 0.28%, which steadily increased from 0.26% in 2008 to 0.35% in 2012 (15).

This study agrees with multiple previous studies that have shown that acute complications are driven by lead dislodgements, thoracic trauma, vascular injury, pocket hematoma, and infection (1,2,7,18–21). Beyond the acute period, the complication profile shifts toward electric and mechanical phenomena involving either the pacing system itself or the electrode-tissue interface (3). Complication rates for claims data and previously published studies appear to have greater discrepancies during the early acute period within 30 days but greater concordance during later periods, which usually correspond to pacing system issues. Similar discrepancies for acute complications have been identified in the field of robotic surgery when comparing legal database queries against complications voluntarily reported to the U.S. Food and Drug Administration (22). The discrepancies between voluntarily and involuntarily reported complication rates merit further investigation.

Our findings highlight the substantial health care costs associated with pacemaker complications. Common "lead complications" resulted in adjusted incremental costs of $9,193 ± 3,842 and $8,596 ± 2,903 for commercial and Medicare supplemental insurance patients, respectively. Overall, the adjusted incremental costs were slightly lower than unadjusted costs, after controlling for patients' age, sex, device type, and comorbidities. The cost associated with the most common complication of lead dislodgement is similar to the cost of a de novo implantation. Uncommon but serious complications, such as pericardial effusion, carry costs that are similar to 4 or 5 de novo implantations. The incremental costs associated with pacemaker-related complications in Medicare patients are higher than those reported in a hospital-based analysis performed on implantable cardioverter-defibrillator patients with Medicare insurance in 2006 (23). The differences could be due to rising health care costs and the study perspective. The costs in this study are presented from the perspective of the payer and include payments to the facility and to the physician. These payments are composed of net payments made by insurance, as well as the patient's deductible, coinsurance, and any copayment. It would also be interesting to examine the financial burden of complications from other perspectives, such as that of the hospital, the patient, the employer, and the greater society.

Recent developments in leadless cardiac pacing technology have shown substantial reductions in overall complication rates over 6 months relative to TVPs (24,25). These novel technologies show promise in eradicating complications related to the lead and pacemaker pocket while presenting few vascular complications. However, such technology is still in its relative infancy compared with the use of transvenous systems, which spans more than 50 years. The former may improve with respect to acute complications, as the LEADLESS II (LEADLESS Pacemaker IDE Study) study encouragingly demonstrated a reduction in adverse event rates from 6.8% to 3.6% after 10 operator implantations (24). Future generations of leadless pacemakers are likely to exhibit improved safety and user experience, as feedback from early users is incorporated into development efforts. In contrast, transvenous pacing may be reaching a plateau, given similar complication rates between the FOLLOWPACE study and those published more recently. Tissue-encapsulated, indwelling transvenous leads connected to pulse generators requiring incisional access are highly vulnerable to complications. Although many questions remain, including end-of-service concerns, the disruptive technological innovation of leadless pacing addresses some inherent problems with TVPs. However, only time will tell if new technology can meet the challenges posed by status quo limitations described in both the present analysis and older single-center and multicenter studies.

STUDY LIMITATIONS. MarketScan databases do not contain a random sample of patient claims data but rather a cohort that is primarily drawn from large employers. Patients who are self-insured and those insured through small and medium employers are underrepresented in the dataset (10). Similarly, patients covered only by public insurance (e.g., Medicaid, traditional Medicare, and Medicare Advantage) could not be included. Also, although reasonable efforts were made to identify only

patients with de novo pacemaker implantations, MarketScan was available only from April 2009, so pacemaker implantations and follow-up performed before that date could not be captured. Therefore, some implantations may have actually been device replacements. In addition, information on operator specialization and experience level, which could help explain some of our findings, was not available. However, we expect that the cohort of operators is representative of that in the general U.S. medical practice.

To avoid overestimating complication rates, multiple diagnostic and procedure codes observed on the same or consecutive service dates were treated as a single occurrence, which could have caused repeat occurrences to be undercounted in some scenarios. Similarly, single complications with codes executed on nonconsecutive service dates could be overcounted. Furthermore, it was not possible to definitively associate every complication with the pacemaker implantation using a retrospective claims database. Some complications may have wrongly been attributed to pacemaker implantations, others may not have been identified if unanticipated claims codes were used, and conditions secondary to pacemaker complications may not have been identified at all.

Finally, because distinct cost information was not available for each complication type in the claims database, patients with multiple complications would have their total costs included in the incremental cost for each complication type. Consequently, this could lead to possible misattribution of the cost of certain complications. Furthermore, patients with Medicare Advantage insurance may have lower incremental costs compared with patients in the present study, which had either private or Medicare supplemental coverage.

CONCLUSIONS

Claims data suggest that TVP complications are more common than previously reported, affecting nearly 1 in 6 patients by 3 years at considerable incremental cost to the U.S. health care system, and remain most commonly related to the leads and pocket.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: TVPs are implanted by operators of varying specialization and experience level. Even though pacemakers are ubiquitous in current clinical practice, complications associated with their implantation and long-term use are common and costly. Precautions should be taken to avoid pacemaker complications.

TRANSLATIONAL OUTLOOK: Much advancement over the past decades has led to the current embodiment of the TVP. In the past few years, a new technology has emerged in the form of leadless pacemakers. Leadless pacemakers are fully implanted in the heart and do not require any leads or pocket, thus avoiding the majority of complications enumerated in this study. Initial trial results have demonstrated ease of implantation and low complication rates of leadless pacemakers. Real-world use of these devices and their technological evolution will be important areas of investigation in the future.

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KEY WORDS complications, pacemaker, transvenous pacemaker

APPENDIX For supplemental tables, please see the online version of this article.