



Outcomes following port-a-catheter placement in the Medicare population



Syed I. Khalid, MD^{a,b,*}, Samantha Maasarani, MPH^c, Rachyl M. Shanker, BS^c, Aaron Lee Wiegmann, MD^{a,b}, Rita Wu, BS^c, Nicholas J. Skertich, MD^{a,b}, Samantha L. Terranella, MD^{a,b}, Laura DeCesare, MD^{a,b}, Edie Y. Chan, MD^{a,b}

^a Department of Surgery, Rush University Medical Center, Chicago, IL

^b RCOR (Rush Cook County Center for Outcomes Research), Chicago, IL

^c Chicago Medical School, Rosalind Franklin University, North Chicago, IL

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ABSTRACT

Background: We aimed to evaluate the long-term complication profile associated with port-a-catheter placement.

Methods: Patients undergoing port-a-catheter placement from 2007 to 2012 with 5-year follow up were identified. Descriptive statistics, χ^2 tests, and multivariate regression models were analyzed.

Results: Any complication occurring within 5 years postoperatively was common (59.04%, n = 53,353). Arrhythmogenic (32.66%, n = 30,625) and thrombovascular (36.80%, n = 34,499) complications were more common than infection (17.86%, n = 16,745) and mechanical (10.31%, n = 9,670) complications. Multivariate analysis demonstrated that history of atrial fibrillation is a risk factor for developing any complication (odds ratio 7.99, 95% confidence interval 7.29–8.77).

Conclusion: Patients with history of atrial fibrillation have increased odds of developing infectious, thrombovascular, mechanical, and arrhythmogenic complications with port-a-catheter placement. This study is the first to show that postprocedure arrhythmias occur at significant rates within the 5-year follow-up period. We caution that development of new arrhythmia should be monitored throughout a prolonged follow-up period. We hope our analysis encourages multidisciplinary coordination of patients with ports so that implants are promptly removed when they are no longer needed to avoid these complications.

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INTRODUCTION

A key component of modern therapeutic chemotherapy is safe and repeated access to the venous system for delivery of drugs, fluids, and blood products [1]. Long-term chemotherapy with repeated venipuncture often results in the rapid destruction of peripheral veins [2]. With advances in chemotherapy leading to increased numbers of patients undergoing longer-term treatment, usage of implantable central venous ports has increased each year [3–11].

Since its introduction by Pharmacia U.K. in 1982, the “Port-a-cath” system has become a commonly used long-term venous access devices. A port-a-catheter is a totally implantable vascular access device where a central venous catheter is attached to a subcutaneous injection port. Between injections, the system is bathed in heparinized saline, which

requires flushing the port every 6 weeks. Otherwise, minimal maintenance or dressing is required [12].

Previous studies have documented the various indications and complications associated with the usage of port-a-catheters in the early postoperative period [13–15]. However, few studies have evaluated factors associated with developing complications and the long-term outcomes in patients with these implants. This study aimed to evaluate the long-term complication rates associated with port-a-catheters and the risks of complications associated with present comorbidities in patients covered by Medicare Parts A & B in the United States.

METHODS

This study was undertaken with institutional review board approval. Medicare Standard Analytic Files derived from Medicare parts A & B from 2007 to 2012 containing inpatient and outpatient facility records billed to Medicare were retrospectively analyzed. Only patients undergoing port-a-catheter placement between 2007 and 2012, as defined by Current Procedural Terminology code 36561, with an active record

* Corresponding author at: 1653 W Congress Pkwy, Jelke, Suite 769, Chicago, IL 60612. Tel.: +1 312 942 1614.

E-mail address: syed.khalid@me.com (S.I. Khalid).

for 5-year follow up were included. Exclusion of a large proportion of patients was due to an incomplete insurance status for the designated 5-year time period.

Comorbidities. Comorbidities were accessed utilizing the past year's (2006) *International Classification of Diseases, Ninth Revision (ICD-9)*, diagnosis billing codes as seen in Supplementary Table 1. Comorbidities evaluated included smoking, hypertension, hyperlipidemia, diabetes mellitus, depression, and atrial fibrillation.

Complications. Complications were identified by ICD-9 diagnosis codes occurring within our 5-year follow-up period (2007–2012) as seen in Supplementary Table 2. Infection included codes for septicemia, bacteremia, sepsis, and other catheter-associated infection or inflammation. Thrombovascular complications included hemorrhage, phlebitis, thrombophlebitis, postphlebotic syndrome, vein compression, chronic venous hypertension, venous insufficiency, embolism, atheroembolism, ischemia, artery occlusion or stenosis, and other unspecific circulatory system disorders. Mechanical complications included catheter obstruction, migration, fracture, or fragmentation, drug extravasation, and port-chamber defect. Arrhythmogenic complications included atrial fibrillation or flutter, ventricular fibrillation or flutter, premature beats, sinoatrial node dysfunction, and unspecific arrhythmias.

Statistical Analysis. Data were stratified by age, sex, and comorbidities. Descriptive statistics and complication rates were calculated and analyzed with chi-squared tests (R statistical software, version 3.42, 2017, R Project, Vienna, Austria).

Adjusted multivariate logistic regression models were constructed to identify any associations between postoperative complications and age, gender, and comorbidities. These models were constructed with univariate factors with statistically significant *P* values of .05 or less (R statistical software, version 3.42, 2017, R Project, Vienna, Austria).

RESULTS

Between 2007 through 2012, a total of 93,756 patients undergoing port-a-catheter placement were identified (Fig 1). Patient characteristics are summarized in Table 1. Most patients were aged 65–69 years (31.8% $n = 29,821$) and female (69.6%, $n = 65,283$). Patients were found to have the following prevalence of comorbidities: 55.0% ($n = 51,550$) with history of hypertension, 11.1% ($n = 10,380$) with history of smoking, 24.4% ($n = 22,867$) with history of diabetes mellitus, 7.3% ($n = 6,869$) with history of atrial fibrillation, 42.6% ($n = 39,909$) with history of hyperlipidemia, and 2.9% ($n = 2,747$) with history of depression.

Overall, any complication occurring over the 5-year follow-up period was very common (59.0%, $n = 53,353$). There were more

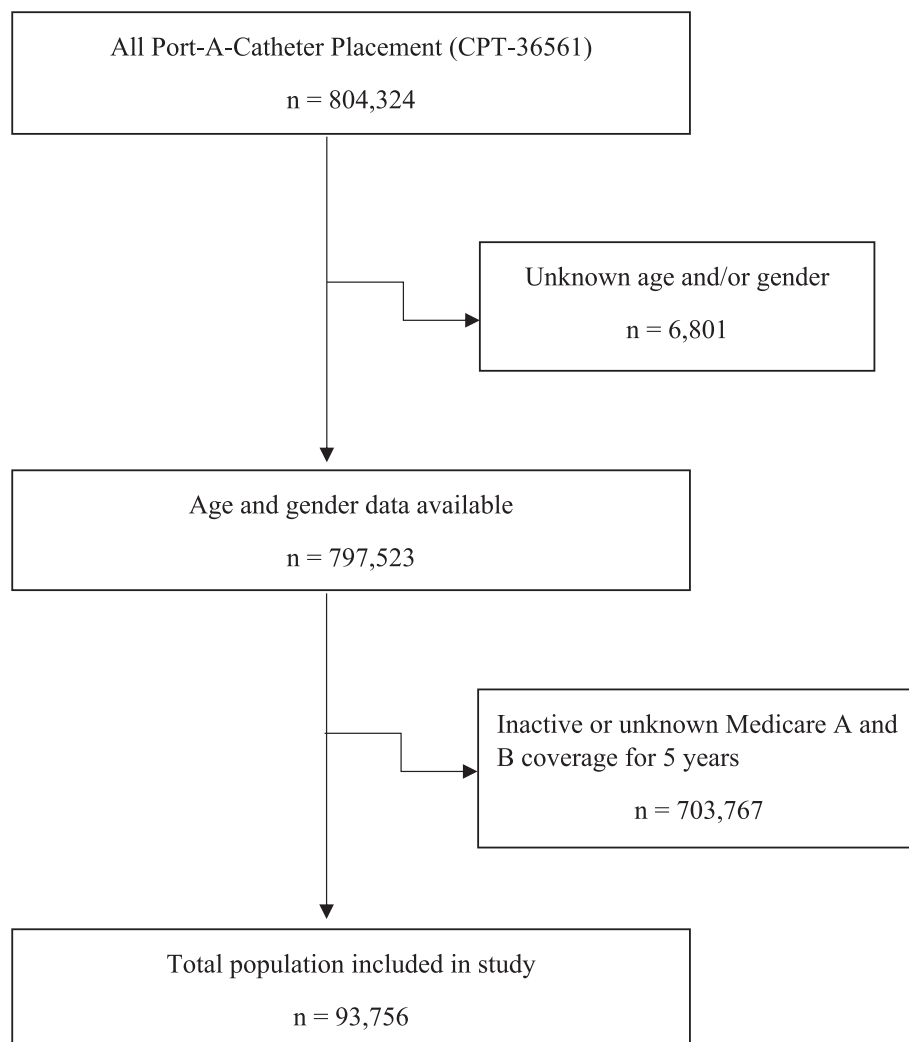


Fig 1. Patient selection flow diagram.

Table 1
Descriptive characteristics for patients undergoing port-a-catheter placement.

	Total n (%)
Age	
64 and under	20,542 (21.9%)
65–69	29,821 (31.8%)
70–74	23,325 (24.9%)
75–79	15,861 (16.9%)
80–84	6,723 (7.2%)
85 and over	1,866 (2.0%)
Gender	
Female	65,283 (69.6%)
Male	28,473 (30.4%)
Comorbidities	
History of smoking	10,380 (11.1%)
History of hypertension	51,550 (55.0%)
History of hyperlipidemia	39,909 (42.6%)
History of diabetes mellitus	22,867 (24.4%)
History of depression	2,747 (2.9%)
History of atrial fibrillation	6,869 (7.3%)

arrhythmogenic (32.7%, n = 30,625) and thrombovascular (36.8%, n = 34,499) complications compared to infection (17.9%, n = 16,745) and mechanical complications (10.3%, n = 9,670) (Table 2).

Multivariate regression models identified risk factors for each postoperative complication included in this study (Tables 3 and 4). Data analysis demonstrated that history of atrial fibrillation is a significant risk factor for any complication (odds ratio [OR] 7.99, 95% confidence interval [CI] 7.29–8.77). Infection was more likely to occur in those aged 64 years and under (OR 2.86, 95% CI 2.73–3.00) and those with a history of depression (OR 1.85, 95% CI 1.70–2.02), history of atrial fibrillation (OR 1.74, 95% CI 1.64–1.85), and history of type 2 diabetes mellitus (OR 1.62, 95% CI 1.56–1.69). Risk factors for thrombovascular complications included history of depression (OR 1.67, 95% CI 1.54–1.81), history of atrial fibrillation (OR 1.60, 95% CI 1.52–1.68), and age 85 years and over (OR 1.54, 95% CI 1.39–1.70). Mechanical complications were more likely to occur in those aged 64 years and under (OR 2.40, 95% CI 2.27–2.54) and those with a history of depression (OR 1.85, 95% CI 1.68–2.02) and history of atrial fibrillation (OR 1.40, 95% CI 1.30–1.51). New-onset arrhythmogenic complications were more likely to occur in those with a history of atrial fibrillation (OR 12.66, 95% CI 11.80–13.59), aged 85 years and over (OR 1.99, 95% CI 1.79–2.21), and with a history of depression (OR 1.56, 95% CI 1.43–1.70).

DISCUSSION

To our knowledge, this is the first study to evaluate rates of port-a-catheter placement complications during 5-year follow-up and identifies history of atrial fibrillation as major risk factor for development of any complication. Furthermore, these data support the notion that implanted port-a-catheters are not benign and represent an unnatural physiologic state leading to the progressive development of several complications. Most strikingly, the development of new arrhythmia (traditionally viewed as an acute phase perioperative phenomenon or related to catheter malpositioning/embolization) was the most frequent

Table 2
Complication rates occurring within 5 years postoperatively

Complications	Total n (%)
Any complication	55,353 (59.0%)
Infection	16,745 (17.9%)
Thrombovascular	34,499 (36.8%)
Mechanical complication	9,670 (10.3%)
Arrhythmogenic	30,625 (32.7%)

Table 3
Multivariate regression models—long-term complications occurring within 5 years postoperatively

	All complications OR (95% CI)	Infection OR (95% CI)	Thrombovascular OR (95% CI)
Age			
64 and under	1.73 (1.67–1.80)	2.86 (2.73–3.00)	1.54 (1.48–1.60)
65–69	Reference value		
70–74	1.14 (1.10–1.18)	0.99 (0.94–1.05)	1.12 (1.08–1.17)
75–79	1.40 (1.34–1.46)	1.04 (0.98–1.10)	1.27 (1.22–1.33)
80–84	1.61 (1.52–1.71)	1.18 (1.09–1.27)	1.36 (1.28–1.44)
85 and over	1.89 (1.70–2.11)	1.22 (1.07–1.39)	1.54 (1.40–1.70)
Gender			
Female	Reference value		
Male	1.32 (1.28–1.36)	1.36 (1.31–1.41)	1.11 (1.08–1.14)
Comorbidities			
Hypertension	1.31 (1.27–1.35)	1.23 (1.18–1.29)	1.31 (1.27–1.35)
Hyperlipidemia	1.20 (1.16–1.23)	1.00 (0.96–1.04)	1.24 (1.20–1.28)
Diabetes mellitus	1.40 (1.35–1.45)	1.62 (1.56–1.69)	1.35 (1.31–1.40)
Depression	1.87 (1.70–2.07)	1.85 (1.70–2.02)	1.67 (1.54–1.81)
Atrial fibrillation	7.99 (7.29–8.77)	1.74 (1.64–1.85)	1.60 (1.52–1.68)
Smoking	1.25 (1.19–1.31)	1.17 (1.11–1.23)	1.24 (1.19–1.30)

complication found within the 5-year follow-up period. Furthermore, our analysis suggests a 5-year postoperative complication rate approaching 60% for all patients.

Previous studies have shown iatrogenic complications with pneumothorax and bleeding to be the most common early complications (<30 days) and infection and thrombovascular complications as the most common late complications (>30 days) [16–20]. An early retrospective study by Kock et al of 1,500 subcutaneously implanted venous access systems (417 port-a-catheters and 1,083 updated variations) showed an overall 12.8% complication rate comprised of infection (4.8%), thrombosis (3.2%), catheter malposition (2.4%), and other complications such as portal occlusion, bleeding, necrosis, catheter fracture, disconnection, and pneumothorax (2.4%). A similar study by Burney et al of only 55 port-a-catheters showed an overall complication rate of 16.4%, interestingly consisting mainly of device failures and exit site infection. A later retrospective analysis by Mahmoud et al of 250 patients with ports showed a total complication rate of 11.6% over an average 22-month follow-up [15]. Complications included infection (4%), mechanical failure (2%), neck hematoma (1.6%), and venous thrombosis (1.6%). Our study showed similar rates of complication breakdown,

Table 4
Multivariate regression models—long-term complications occurring within 5 years postoperatively

	Mechanical OR (95% CI)	Arrhythmogenic OR (95% CI)
Age		
64 and under	2.40 (2.27–2.54)	1.32 (1.27–1.38)
65–69	Reference value	
70–74	0.92 (0.86–0.98)	1.15 (1.11–1.20)
75–79	0.84 (0.77–0.90)	1.51 (1.44–1.58)
80–84	0.89 (0.80–0.98)	1.75 (1.65–1.86)
85 and over	0.76 (0.62–0.91)	1.99 (1.79–2.21)
Gender		
Female	Reference value	
Male	0.82 (0.78–0.86)	1.40 (1.36–1.44)
Comorbidities		
Hypertension	1.30 (1.24–1.37)	1.30 (1.25–1.34)
Hyperlipidemia	1.05 (1.00–1.10)	1.10 (1.06–1.14)
Diabetes mellitus	1.35 (1.29–1.42)	1.31 (1.27–1.36)
Depression	1.85 (1.68–2.02)	1.56 (1.43–1.70)
Atrial fibrillation	1.40 (1.30–1.51)	12.66 (11.80–13.59)
Smoking	1.24 (1.16–1.31)	1.15 (1.10–1.21)

with prevalence of mechanical complications being the least common and thrombovascular complications as one of the most common. However, our overall complication rates were substantially higher than these studies, which may be attributed to our longer follow-up period.

Although the rates of most complications in our study are generally comparable to those reported in the literature, there are some compelling differences. Previous studies have reported rates of early complications ranging between 1.7% and 20.5% [20–23] and rates of late complications between 0.63% and 55% [16,23–25]. A study by Ballarini et al of 102 subcutaneous port catheters showed an overall complication rate of 8.8% ($n = 9$) during an unspecified follow-up period, with 4.9% ($n = 4$) at 30 days, 5.9% ($n = 5$) at 60 days, and 8.8% at 180 days [25]. Complications included skin necrosis ($n = 1$), pocket infection ($n = 1$), catheter disconnection ($n = 1$), catheter fracture ($n = 3$), catheter occlusion and vein thrombosis ($n = 1$), and systemic infection ($n = 2$). A retrospective study by Lemmers et al of 135 venous access ports for patients with disseminated testicular tumors demonstrated a post-operative complication rate of 31% ($n = 42$) consisting of 9.6% catheter obstruction ($n = 13$), 8.1% thrombosis ($n = 11$), 4.4% infection ($n = 6$), 4.4% catheter defect ($n = 6$), 3.0% extravasation ($n = 4$), and 1.5% local skin necrosis ($n = 2$) [23]. Catheter obstruction and thrombosis comprised the majority of early complications (median days of onset at 40 and 33 days, respectively), infection and extravasation later (median days of onset at 75 and 72 days, respectively), and necrosis and defect latest (median days of onset at 197 and 363 days, respectively).

However, our finding of significantly increased risk of new arrhythmia development is a novel finding and requires careful consideration. Patients with preoperative atrial fibrillation comprised more than 7.33% of the study population, and those patients had a 7.99 increased likelihood of developing any complication—but those complications were not just limited to the perioperative period. Moreover, the patients that developed arrhythmias were newly diagnosed in the postoperative period, so it is less likely that these arrhythmias were preexisting and more likely related to the port placement. Furthermore, when all patients were analyzed regardless of preoperative atrial fibrillation status, rates of new arrhythmia development were significantly increased during the 5-year postoperative period. Proposed mechanisms include considering that mechanical stimulation from the catheter on the heart can lead to atrial and ventricular arrhythmias. Transiently, during insertion, the guidewire frequently induces arrhythmias without significant hemodynamic consequences [26]. Embolization of the catheter has been shown to lead to atrial fibrillation, and positional arrhythmias are frequently reported when peripheral central venous catheters are placed [27,28]. It is possible that postport hemodynamics, mechanical stress, infusion effects on the heart, or a combination of each is responsible for this finding. Regardless of the pathophysiology, this study is the first to suggest that indwelling port-a-catheters lead to the significant development of new arrhythmias up to 5 years after placement. As such, this finding should prompt providers to evaluate the ongoing necessity of the patient's port and to recommend removal as soon as clinically feasible to avoid untoward complications.

Previous literature has suggested risk factors for port-a-catheter-related complications including type of malignancy, type of chemotherapy, approach, timing of implantation, and duration of treatment [9,18,23,26–33]; however, few studies have evaluated the associated risks of complications with consideration of patient comorbidities. A retrospective study by Nakamura et al of 132 patients with an implantable central venous access port (PowerPort) showed, when comparing sex, age, purpose, port site, disease, and operation time, increased odds of developing postoperative complications with benign neoplasm compared to metastatic neoplasm (OR = 10.03, $P = .0009$) [6]. Ten patients had benign disease, with 3 developing postoperative complications during a 12-month follow-up period. A retrospective study by Hsieh et al of 1,348 totally implantable venous access devices (TIVADs) using a Cox proportional hazard model analysis demonstrated increasing age (hazard ratio = 1.01, $P = .003$),

male gender (hazard ratio = 1.57, $P < .001$), use of open-ended catheters (hazard ratio = 1.69, $P < .001$), and hematogenous malignancy (hazard ratio = 1.50, $P = .016$) as factors for TIVAD failure [3]. In particular, presence of hematogenous malignancy increased rates of catheter-related infection. An early study by Kock et al showed significantly lower rates of infection (2%) in patients with solid tumors compared to patients with hematologic diseases (6%) ($P < .05$) [4]. Our study suggests that all comorbidities, but especially history of atrial fibrillation, play a significant role in the risk of developing infection and thrombovascular, mechanical, and arrhythmogenic complications.

This study has several limitations. Although the use of administrative data allows for access to large numbers of medical data files from hospitals and clinics across the nation, it is limited by the granularity it can provide, as analysis of such data does not allow for control of individual variabilities such as surgeon expertise, procedural methods, and follow-up and treatment protocols, or any insight into patient selection criteria. Various clinical factors, including but not limited to agents infused, heparin flushes, and systemic anticoagulation, are all variables that may further discern differences in complication rates within this cohort that we were unable to assess. Furthermore, we are unable to know if any inciting or organic cardiac events in the postoperative period influenced the large number of new arrhythmias found in this study. Finally, stratification within this cohort based on total time period of port-a-catheter placement may yield more significant results. Such data are typically meant for administrative and financial purposes rather than research, which may subject the data to errors in accuracy due to reliance on interpretation of physician records by a medical reviewer.

In conclusion, port-a-catheter implantations are associated with risk of infection and of thrombovascular, mechanical, and arrhythmogenic complications within a 5-year follow-up period. Patients with history of atrial fibrillation are at increased odds of developing aforementioned complications. This study is the first to show that arrhythmias may be common in this population and can occur at significant rates up to 5 years postoperatively. Although our data are limited by inability to discern time point to complications, we caution that development of new arrhythmia should be monitored throughout a prolonged follow-up period. We hope that our analysis encourages multidisciplinary coordination of patients with ports so that implants are promptly removed when they are no longer needed to avoid these complications.

Author Contribution

All authors were responsible for final approval of the article. SK was responsible for conception/design, data collection, literature search, analysis/interpretation, writing the article, and critical revision. SM was responsible for data collection, literature search, analysis/interpretation, writing the article, and critical revision. RS and RW were responsible for literature search, writing the article, and critical revision. AW, NS, ST, LD, and EC were responsible for critical revision and administrative support of the article.

Conflict of Interest

The authors report no conflicts of interest, including no proprietary or commercial interest in any product mentioned or concept discussed in this article.

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Appendix A. Supplementary data

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