DOI: 10.1002/pul2.12374

RESEARCH ARTICLE

Pulmonary Circulation | PVRI | WILEY

Nationwide trends of balloon pulmonary angioplasty and pulmonary thromboendarterectomy for chronic thromboembolic pulmonary hypertension (2012–2019)

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Funding information
Michael Work Heart Foundation; New York Cardiac Center Inc.; Weill Cornell Medical Center Alumni Council

Abstract

Chronic thromboembolic pulmonary hypertension (CTEPH) is a sequela of a pulmonary embolus that occurs in approximately 1%–3% of patients. Pulmonary thromboendoarterectomy (PTE) can be a curative procedure, but balloon pulmonary angioplasty (BPA) has emerged as an option for poor surgical candidates. We used the National Inpatient Sample to query patients who underwent PTE or BPA between 2012 and 2019 with CTEPH. The primary outcome was a composite of in-hospital mortality, myocardial infarction, stroke, tracheostomy, and prolonged mechanical ventilation. Outcomes were compared between low- and high-volume centers, defined as 5 and 10 procedures per year for BPA and PTE, respectively. During our study period, 870 BPA and 2395 PTE were performed. There was a 328% relative increase in the number of PTE performed during the study period. Adverse events for BPA were rare. There was an increase in the primary composite outcome for low-volume centers compared to high-volume centers for PTE (24.4% vs. 12.1%, $p = 0.003$). Patients with hospitalizations for PTE in low-volume centers were more likely to have prolonged mechanical ventilation (20.0%% vs. 7.2%, $p < 0.001$) and tracheostomy (7.8% vs. 2.6%, $p = 0.017$). In summary, PTE rates have been rising over the past 10 years, while BPA rates have remained stable. While adverse outcomes are rare for BPA, patients with hospitalizations at low-volume centers for PTE were more likely to have adverse outcomes. For patients undergoing treatment of CTEPH with BPA or PTE, referral to high-volume centers with multidisciplinary teams should be encouraged for optimal outcomes.

KEYWORDS
balloon pulmonary angioplasty, chronic thromboembolic pulmonary hypertension, pulmonary thromboendoarterectomy

INTRODUCTION

Chronic thromboembolic pulmonary hypertension (CTEPH) is a rare sequela of pulmonary embolism that leads to pulmonary vascular remodeling, progressive pulmonary hypertension, and right heart failure.[1,2] In prospective cohort studies, the incidence of CTEPH has ranged from 0.57% to 3.8% after an acute pulmonary embolism,[3–6] though the true incidence is likely higher given a substantial proportion of individuals are diagnosed in the absence of an acute presentation. Pulmonary thromboendarterectomy (PTE) is the treatment of choice for symptomatic patients who are considered operable,[1] with registry data showing 3-year survival for operated patients of 89% compared to only 70% for not-operated patients.[7]

Operability continues to be a source of debate but is dependent on a number of patient, physician, and institutional factors. These include the site of anatomic obstruction, hemodynamic severity, and patient comorbidities, including degree of right heart failure. Furthermore, surgical expertise and institutional resources are important in the multidisciplinary treatment approach.[1,8,9] For operable patients at high-volume centers, studies have shown periprocedural mortality of less than 4% with a mean decrease in pulmonary vascular resistance of 564 $dyn/s/cm^{-5}$.[8] However, international registry data shows that up to 37% of patients are considered inoperable with up to 15% of patients having postoperative pulmonary hypertension.[7,10] Furthermore, a recent meta-analysis suggests wide variation in rates of in-hospital mortality between centers.[11]

In recent years, balloon pulmonary angioplasty (BPA) has emerged as an attractive option for inoperable patients, as well as for those with persistent pulmonary hypertension after surgery.[1] Small, single-center studies have showed significant hemodynamic improvements with the use of BPA with low mortality rates.[12–16] However, no studies evaluate the nationwide trends and outcomes of these procedures over time. Our study will describe the contemporary trends, characteristics, and in-hospital outcomes of patients undergoing both PTE and BPA in the United States, highlighting differences in hospital characteristics and patient outcomes for high- and low-volume centers.

METHODS

Data sources

Data were obtained from the National Inpatient Sample (NIS), a publicly available and nationally representative sample of hospitalizations from US community hospitals. The data set is administered by the Healthcare Cost and Utilization Project (HCUP) through the Agency for Healthcare Research and Quality.[17] For the years included in our study (2012–2019), the NIS includes a 20% stratified sample of hospitalizations from all US community hospitals, excluding rehabilitation and long-term acute care hospitals. Sample weights are provided, which can be used to determine national estimates. Each hospitalization includes all reported diagnosis and procedure codes using the *International Classifications of Disease, Ninth Revision, Clinical Modification* (*ICD-9-CM*) from January 2012 to September 2015 and *International Classifications of Disease, Tenth Revision, Clinical Modification* (*ICD-10-CM*) from October 2015 to December 2019. Additional patient-level data includes age, race, gender, and median household income.

Study population

Hospitalizations that included BPA or PTE between January 1, 2012, and December 31, 2019, were included in the study. We selected for hospitalizations with either PTE (ICD-9-CM 38.15 and ICD-10-CM 02CP0ZZ, 02CQ0ZZ, or 02CR0ZZ) or BPA (ICD-9-CM 39.50 and ICD-10-CM 027P34Z, 027P3DZ, 027P3ZZ, 027Q34Z, 027Q3DZ, 027Q3ZZ, 027R34Z, 027R3DZ, or 027R3ZZ) with a diagnosis of CTEPH (ICD-9-CM 416.2 or ICD-10-CM I27.24 or I27.82) using ICD-9-CM and ICD-10-CM codes. Patients admitted with a diagnosis of acute pulmonary embolism were excluded.

Study characteristics and outcomes

Hospitalizations were characterized by age, sex, and race. Comorbidities were identified using Elixhauser Comorbidity Software to identify a comprehensive list of comorbidity measures.[18] For ICD-9-CM data, 29

TABLE 1 Baseline characteristics of patients undergoing balloon pulmonary angioplasty and pulmonary thromboendarterectomy.

Baseline characteristics	Balloon pulmonary angioplasty ($n = 870$)	Pulmonary thromboendarterectomy ($n = 2395$)	p Value
Age, mean years (SD)	58.6 (13.96)	54.0 (14.50)	<0.001
Female gender, N (%)	455 (52.3)	1195 (49.9)	0.587
Race, N (%)			0.571
White	535 (61.5)	1495 (62.4)	
Black	200.(23.0)	490 (20.5)	
Hispanic	45 (5.2)	185 (7.7)	t
Primary payor, N (%)			<0.001
Medicare	490 (56.3)	815 (34.0)	
Medicaid	105 (12.1)	340 (14.2)	
Private insurance	215 (24.7)	995 (41.5)	
Self-pay	20 (2.3)	70 (2.9)	
Length of stay, mean days (SD)	8.3 (13.21)	15.0 (14.85)	<0.001
Comorbid conditions, N (%)			
Congestive heart failure	60 (6.9)	190 (7.9)	0.660
Valvular disease	[***]	75 (3.1)	0.062
Diabetes mellitus	105 (12.1)	200 (8.4)	0.150
Hypertension	500 (57.5)	1125 (47.0)	0.018
Liver disease	[***]	15 (0.6)	0.941
Chronic lung disease	165 (19.0)	495 (20.7)	0.632
Obesity	110 (12.6)	740 (30.9)	<0.001
Renal failure	175 (20.1)	75 (3.1)	<0.001
Metastatic cancer	50 (5.7)	[***]	<0.001

Note: Rows may not add up to 100% due to omitted data.

***Healthcare Cost and Utilization (HCUP) regulations prohibit reporting cell counts less than or equal to 10 due to the risk of identification of individual patients. These cells have been omitted to comply with HCUP regulations.

measures were identified using diagnosis codes. For ICD-10-CM, three measures were added, five measures were expanded to create 12 more specific measures, and one measure was removed. Since our analysis used both ICD-9-CM and ICD-10-CM data, only measures present in both sets of comorbidities were used. Hospitals were identified through unique codes in the NIS. Due to a lack of hospital identifiers, hospitals could not be followed longitudinally through multiple years. Hospitals were characterized as small, medium, and large based on specific thresholds based on region, urban–rural status, and teaching status.[17] The primary outcome was a composite in-hospital mortality, myocardial infarction (MI), stroke, tracheostomy, and prolonged mechanical ventilation (defined as greater than 96 h). Secondary outcomes included the components of the primary composite outcome, procedural bleeding, acute kidney injury, and need for extracorporeal membrane oxygenation (ECMO) by ICD-9-CM and ICD-10-CM codes (see Supporting Information S1: e-Table 1 for a full list of ICD-9-CM and ICD-10-CM codes).

Hospitals were divided into low and high-volume centers based on the number of procedures performed each year. Hospitals that performed more than five BPAs per year or 10 PTEs per year were considered to have a higher volume for that procedure. Cutoffs were determined based on median procedures performed per year for distributions of procedures per year by hospital. Sensitivity analysis was completed using tertiles instead of medians.

Statistical analysis

Patient-level characteristics were compared between the PTE and BPA groups with a Student *t*-test for continuous variables and a χ^2 analysis for categorical variables. Continuous variables are presented as means, and categorical variables are presented as counts with frequencies. Hospital characteristics and patient outcomes were also compared between low and high-volume centers for PTE and BPA. Incidence of primary and secondary outcomes were compared between low and high-volume centers for both BPA and PTE. All analyses were completed with SAS version 9.4 and R version 4.1.0 at a two-tailed level of significant of $p < 0.05$.

RESULTS

Patient characteristics by procedure

During the study period, there were 870 hospitalizations with BPA (3.1 per million hospitalizations) and 2395 hospitalizations with PTE (8.4 per million hospitalizations). There was a significant increase in the number of PTE performed during the study period (105 [2.9 per million hospitalizations] in 2012 to 449 [12.7 per million hospitalizations] in 2019, $p = 0.005$) and a nonsignificant difference in BPA procedures (150 [4.1 per million hospitalizations] in 2012 to 99 [2.8 per million hospitalizations] in 2019, $p = 0.253$) (see Figure 1). Patients hospitalized with BPA were more likely to be older (mean age 58.6 vs. 54.0, $p < 0.001$), more likely to have Medicare (56.3% vs. 34.0%, $p < 0.001$), and more likely to have systemic hypertension (57.5% vs. 47.0%, $p = 0.018$) and renal failure (20.1% vs. 3.1%, $p < 0.001$). Patients with hospitalizations with PTE were more likely to have private insurance (41.5% vs. 24.7, $p < 0.001$), the longer length of stay (15.0 vs. 8.3 days, $p < 0.001$), and obesity (30.9% vs. 12.6%, $p < 0.001$). There were no differences in gender or race between groups (see Table 1).

Hospital characteristics by procedural volume

Of the hospitals performing BPA, only 57 hospitals (45.6% of hospitals) performed more than five procedures in 1 year. Number of procedures performed by site by year are shown in Figure 2. High-volume centers were more likely to be in the Midwest (28.1% vs. 17.6%) and West (31.6% vs. 16.2%) and less likely in the Northeast

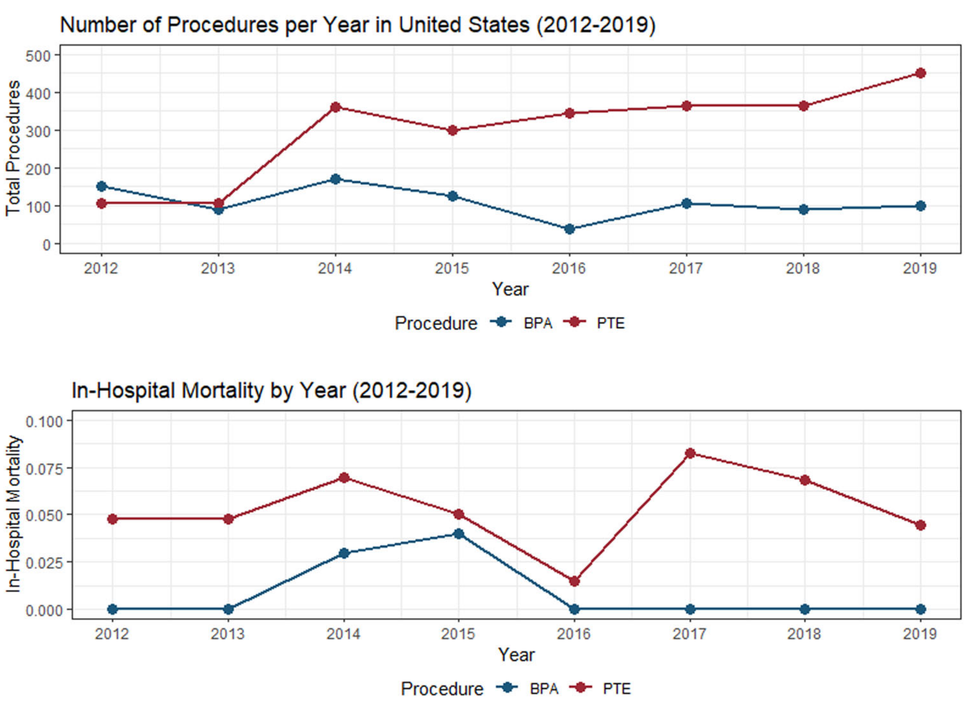

FIGURE 1 Trends in number of procedures and in-hospital mortality by year.

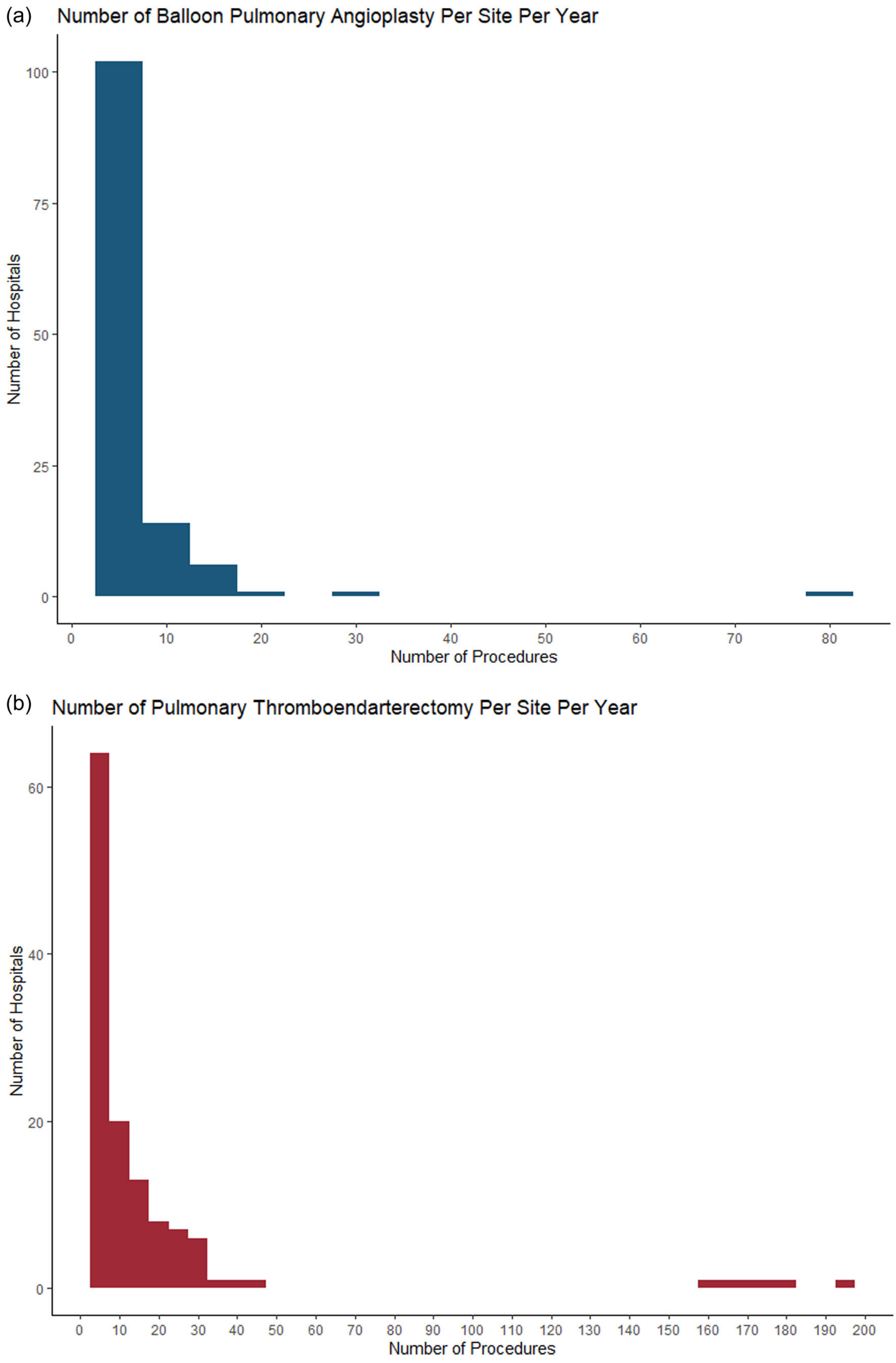

FIGURE 2 Number of (a) balloon pulmonary angioplasty and (b) pulmonary thromboendarterectomy performed yearly across sites.

(24.6% vs. 29.4%) or South (15.8% vs. 36.8%). High-volume centers were more likely to be large hospitals (87.7% vs. 66.2%, $p = 0.011$). There was no difference in hospital ownership, teaching status, or rural location (see Table 2). Of the hospitals performing PTE, only 50 hospitals (39.3% of hospitals) performed more than 10 procedures in 1 year. There was no significant difference in region, hospital bed size, hospital ownership, or teaching status of high and low-volume centers for PTE.

Rates of complications by procedural volume

There were higher rates of the primary composite outcome for hospitalization for PTE (24.4% vs. 12.1%, $p = 0.003$) at low-volume centers compared to high-volume centers. There was no significant difference in the primary composite outcome for patients with hospitalizations with BPA, although rates of complications were low. For both procedures, there was no significant difference in death, MI, stroke, other bleeding complications, acute kidney injury, or rates of ECMO (see Table 3). For PTE, there were higher rates of prolonged mechanical ventilation (20.0% vs. 7.2%, $p < 0.001$) and tracheostomy (7.8% vs. 2.6%, $p = 0.017$) in low-volume centers. Similar trends were seen when comparing tertiles of hospital volume (see Supporting Information S1: e-Table 2).

Hospital characteristics and patient outcomes by procedural capabilities

There were 30 hospitals that performed both BPA and PTE in the same year. Compared to hospitals that just performed BPA, hospitals that had both BPA and PTE capability were more likely to be large hospitals (96.7% vs. 69.5%, $p = 0.009$) and urban teaching hospitals (100% vs. 73.7%, $p = 0.007$). Hospitals that performed both BPA and PTE, on average, had higher procedural volumes for BPA (11.7 vs. 5.5, $p < 0.001$) than those that only

TABLE 2 Hospital characteristics by procedural volumes.

Hospital characteristics by procedural volume						
	Balloon pulmonary angioplasty			Pulmonary thromboendarterectomy		
	Low volume centers ($n = 68$)	High volume centers ($n = 57$)	p Value	Low volume centers ($n = 77$)	High volume centers ($n = 50$)	p Value
Procedures per year (mean [SD])	5.00 (0.00)	9.30 (10.67)	0.001	5.84 (1.89)	38.90 (51.22)	<0.001
Region (%)			0.019			0.157
Northeast	20 (29.4)	14 (24.6)		21 (27.3)	18 (36.0)	
Midwest	12 (17.6)	16 (28.1)		14 (18.2)	14 (28.0)	
South	25 (36.8)	9 (15.8)		22 (28.6)	12 (24.0)	
West	11 (16.2)	18 (31.6)		20 (26.0)	6 (12.0)	
Bed size (%)			0.011			0.176
Small	7 (10.3)	4 (7.0)		3 (3.9)	0 (0.0)	
Medium	16 (23.5)	3 (5.3)		5 (6.5)	[***]	
Large	45 (66.2)	50 (87.7)		69 (89.6)	49 (98.0)	
Hospital ownership (%)			0.231			0.296
Government, nonfederal	12 (17.6)	11 (19.3)		18 (23.4)	7 (14.0)	
Private, non-profit	50 (73.5)	45 (78.9)		58 (75.3)	43 (86.0)	
Location and teaching status (%)			0.273			0.675
Rural	3 (4.4)	0 (0.0)		0 (0.0)	0 (0.0)	
Urban nonteaching	12 (17.6)	10 (17.5)		2 (2.6)	0 (0.0)	
Urban teaching	53 (77.9)	47 (82.5)		75 (97.4)	50 (100.0)	

Note: Rows may not add up to 100% due to omitted data.

***Healthcare Cost and Utilization (HCUP) regulations prohibit reporting cell counts less than 2 to identify individual hospitals.

TABLE 3 Patient outcomes by procedural volumes.

Patient outcomes by procedural volume	Balloon pulmonary angioplasty			Pulmonary thromboendarterectomy		
	Low volume centers ($n = 340$)	High volume centers ($n = 530$)	p Value	Low volume centers ($n = 450$)	High volume centers ($n = 1945$)	p Value
Primary outcome						
Composite outcome (death, MI, CVA, tracheostomy, prolonged mechanical ventilation) (%)	[***]	[***]	0.652	110 (24.4)	235 (12.1)	0.003
Secondary outcomes						
Death (%)	[***]	[***]	0.751	20 (4.4)	110 (5.7)	0.648
Myocardial infarction (%)	0 (0.0)	0 (0.0)	NA	0 (0.0)	0 (0.0)	NA
Stroke (%)	0 (0.0)	0 (0.0)	NA	[***]	45 (2.3)	0.473
Other bleeding complication (%)	20 (5.9)	15 (2.8)	0.320	15 (3.3)	110 (5.7)	0.373
Acute kidney injury (%)	50 (14.7)	55 (10.4)	0.395	130 (28.9)	435 (22.4)	0.19
Prolonged mechanical ventilation	0 (0.0)	0 (0.0)	NA	90 (20.0)	140 (7.2)	<0.001
Tracheostomy (%)	[***]	[***]	0.751	35 (7.8)	50 (2.6)	0.017
ECMO (%)	0 (0.0)	0 (0.0)	NA	15 (3.3)	45 (2.3)	0.578

Note: Rows may not add up to 100% due to omitted data.

Abbreviations: ECMO, extracorporeal membrane oxygenation; MI, myocardial infarction.

***Healthcare Cost and Utilization (HCUP) regulations prohibit reporting cell counts less than or equal to 10 due to the risk of identification of individual patients. These cells have been omitted to comply with HCUP regulations.

performed one procedure. The rate of complications was low and there was no significant difference between hospitals who only performed BPA compared to those that performed both BPA and PTE (see Supporting Information S1: e-Table 3).

DISCUSSION

In this cross-sectional study, we found that between 2012 and 2019, the rate of PTE performed have significantly increased while the number of BPA performed have remained stable. We found that patients who underwent BPA were older, had more comorbidities, and had shorter lengths of stay than those that underwent PTE. While most procedures continue to occur at high-volume centers, there are many centers that only perform small numbers of BPA and PTE each year. In low-volume centers for PTE, there were higher rates of prolonged mechanical ventilation and tracheostomy, leading to a significant increase in adverse events in the primary composite outcome. This is the first study of which we are aware that compares national trends and outcomes for BPA and PTE in the treatment of CTEPH and helps to establish real-world experience with these procedures.

In recent years, case series of BPA from high-volume centers have shown improvement in surrogate markers (e.g., hemodynamics) with low complication rates.[12–16] However, no studies to our knowledge have looked at the broader use of this procedure outside these centers. Furthermore, there has been a paucity of outcomes studies from centers in the United States,[19,20] further obscuring generalizations about national practice patterns and outcomes. Our study shows that the number of BPA, however, has remained constant, with more than half of all procedures performed at high-volume centers. One explanation for this observation is the relatively slow adoption of BPA as a primary therapeutic intervention for non-operable patients. Interestingly, PTE has had significant increases over the study, despite having been performed since 1960. As of 2008, only 3500 cases of PTE had been performed with more than 2000 at one center alone.[8] Recent increases in the number of these surgeries performed in our study could reflect improved awareness of the expected clinical improvements after this operation.

Our study also examined the volume-outcome relationships for both BPA and PTE. Despite the increase in the number of PTE performed over our study period, the vast majority (more than 80%) of PTE surgeries still occurred in high-volume centers. However, even with fairly conservative definitions of >5 BPA or >10 PTE being defined as high-volume centers, a significant number of hospitals—54.4% and 60.7% of centers, respectively—are performing less than these numbers of procedures. We found that in low-volume centers, patients undergoing PTE were more likely to have prolonged mechanical ventilation (defined as greater than 96 h) and higher rates of tracheostomy compared to those at high-volume centers. We used conservative definitions for high-volume centers compared with other studies.[21] However, our study findings were consistent with sensitivity analysis using tertiles—hospitals in the highest tertile performed about 44 PTE per year. This finding is a signal that supports these procedures should be limited to high-volume centers with multidisciplinary teams of cardiologists, interventional cardiologists, and cardiac surgeons for optimal outcomes.

There is significant literature exploring the effect of volume-outcome relationships in various cardiovascular procedures, including percutaneous coronary interventions.[22–26] These data show an inverse relationship between operator or hospital volume and clinical outcomes. Because of this, many professional organizations have recommended either minimum operator volumes[27] or referral to centers that have demonstrated excellence in clinical outcomes for patients treated with that disease.[28] For PTE specifically, studies have shown wide variation in clinical outcomes, with a recent meta-analysis showing estimates for in-hospital mortality ranging from 0.8% to 24.4%.[11] After the introduction of the procedure in the 1970s at the University of California San Diego, there has been a significant and iterative improvement in in-hospital mortality at that institution, from 16.8% to 7.0% to 2.2%.[9] However for our study, we found a mortality rate of 5.7% even at high-volume centers. While this may be in part related to the acuity of patients, with such wide variation in outcomes, similar guideline recommendations may be needed to ensure that patients are treated at a small number of hospitals with the competence, experience, and specialized training to provide optimal outcomes.

This study has several limitations. First, we used administrative data relying on ICD-9-CM and ICD-10-CM codes to identify patients undergoing BPA and PTE for CTEPH. Despite careful selection of codes that specifically look for chronic pulmonary hypertension, given the lack of granularity in coding, we may have captured patients who did not have CTEPH or alternatively not included patients who did. Additionally, administrative codes may fail to capture important BPA complications, leading us to underreport differences in outcomes between low- and high-volume centers. Second, the NIS does not include present on admission indicators for secondary diagnosis. This may limit the ability to identify complications during a hospitalization. Third, our study period occurs during a transition between ICD-9-CM and ICD-10-CM. Some changes in procedural trends could reflect changes in coding practices and not changes in clinical volumes. Further study will be needed to follow these trends to differentiate these effects. Fourth, the NIS only looks at inpatient hospitalizations. Procedures completed in an outpatient or observation encounter are not included. This may bias our population, especially those with BPA, toward a sicker cohort. We utilized peri-admission mechanical ventilation time and tracheostomy rates as surrogate markers for BPA outcomes largely because long-term outcomes data is not available in the NIS data set. Finally, the NIS is a 20% sample of hospitalization from all hospitals. Given the low frequency of these procedures, random variation in sampling could affect hospital volumes.

AUTHOR CONTRIBUTIONS

Adam S. Vohra contributed to the study design, completed the primary data analysis, and wrote the initial draft of the manuscript. Danielle A. Olonoff, Ada Ip, Ajay J. Kirtane, Zachary Steinberg, Evelyn Horn, Udhay Krishnan, Mark Reisman, Geoffrey Bergman, Shing-Chiu Wong, Dmitriy N. Feldman, Luke K. Kim, and Harsimran S. Singh contributed substantially to the study design, data analysis, and the writing of the manuscript.

ACKNOWLEDGMENTS

This work was supported by grants from the Michael Wolk Heart Foundation, the New York Cardiac Center Inc., and the Weill Cornell Medical Center Alumni Council. A. V. is the guarantor of the data.

CONFLICT OF INTEREST STATEMENT

A. V.: Grant funding from the New York Academy of Medicine; A. K.: Institutional funding to Columbia University and/or Cardiovascular Research Foundation from Medtronic, Boston Scientific, Abbott Vascular, Amgen, CSI, Philips, ReCor Medical, Neurotronic, Biotronik, Chiesi, Bolt Medical, Magenta Medical, Canon, SoniVie, Shockwave Medical, and Merck. In addition to research grants, institutional funding includes fees paid to

Columbia University and/or Cardiovascular Research Foundation for consulting and/or speaking engagements in which Dr. Ajay J. Kirtane controlled the content. Personal: Consulting from IMDS; Travel Expenses/Meals from Medtronic, Boston Scientific, Abbott Vascular, CSI, Siemens, Philips, ReCor Medical, Chiesi, OpSens, Zoll, and Regeneron; Z. S.: Consulting feeds from Medtronic and Abbott Vascular. The remaining authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

A. V. had full access to all of the data in the study and takes responsibility for the integrity of the data and accuracy of the data analysis.

ETHICS STATEMENT

Institutional review board approval and informed consent were not required since data was derived from a deidentified administrative database.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Vohra AS, Olonoff DA, Ip A, Kirtane AJ, Steinberg Z, Horn E, Krishnan U, Reisman M, Bergman G, Wong S-C, Feldman DN, Kim LK, Singh HS. Nationwide trends of balloon pulmonary angioplasty and pulmonary thromboendarterectomy for chronic thromboembolic pulmonary hypertension (2012–2019). Pulm Circ. 2024;14:e12374.
https://doi.org/10.1002/pul2.12374