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Trends in the Outcomes of High-risk Percutaneous Ventricular Assist Device-assisted Percutaneous Coronary Intervention, 2008-2018

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Trends in the Outcomes of High-risk Percutaneous Ventricular Assist Device-assisted Percutaneous Coronary Intervention, 2008-2018

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Percutaneous ventricular assist devices (pVAD) are frequently utilized in high-risk percutaneous coronary intervention (HR-PCI) to provide hemodynamic support in patients with complex cardiovascular disease and/or multiple comorbidities who are poor candidates for surgical revascularization. Using the National Inpatient Sample we identified pVAD-assisted PCI (excluding intra-aortic balloon pump) in patients without cardiogenic shock from January 2008 to December 2018. We evaluated the trends in patient and procedural characteristics, and complication rates across the 11-year study period. A total of 26,661 pVAD-PCI was performed. From 2008 to 2018 there has was a 27-fold increase in the number of pVAD-PCIs performed annually. There has also been an increase in the proportion of procedures performed in small to medium sized hospitals. The use of atherectomy, image-guided PCI, FFR/iFR, drug-eluting stents, and multi-vessel intervention has significantly increased. Patients undergoing pVAD-PCI had a higher burden of comorbidities, without a significant difference in mortality over time. There were decreased rates of acute stroke and blood transfusions over time, while vascular complications and acute kidney injury (AKI) requiring dialysis remained mostly unchanged. In conclusion, the use of pVAD for HR-PCI has increased significantly, along with adjunctive PCI techniques such as atherectomy, intravascular imaging, and physiologic lesion assessment. With increasing use of this device, there appeared to be lower rates of peri-procedural stroke, and blood transfusions. Despite a higher burden of comorbidities, adjusted mortality remained stable over time. **(Am J Cardiol 2021;156:65−71)**

Patients with multi-vessel coronary artery disease (CAD), and/or unprotected left main coronary artery stenosis, with reduced ejection fraction have been historically treated with coronary artery bypass grafting (CABG) surgery.[1] Previous studies evaluating the use of adjunctive mechanical circulatory support devices during high-risk percutaneous coronary intervention (HRPCI), have reported mixed results. The BCIS-1 trial demonstrated that IABP use led to fewer major procedural complications during HRPCI but there was no difference in the primary endpoint of major adverse cardiovascular events (MACE) at 28 days. Similarly, the CRISP AMI trial failed to demonstrate any improvement in the primary objective of decreased infarct size at 6-months, with the routine use of IABP in patients with anterior STEMI without shock.[2,3] The PROTECT II trial, which evaluated the use of Impella 2.5 compared to IABP demonstrated trends toward reduced MACE with Impella at 90 days but failed to show differences in MACE at 30 days.[4,5] None of these trials have been powered to evaluate differences in overall survival with the use of mechanical circulatory support. The purpose of this study was to evaluate trends in the utilization and outcomes of pVAD assisted PCI.

Methods

The study cohort was derived from the National Inpatient Sample (NIS), a publicly available database of all-payer hospital inpatient stays developed by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project. The NIS contains all-payer data on hospital inpatient stays from States participating in the Healthcare Cost and Utilization Project. The NIS database is a sample of discharges from the U.S and contains data on 7 to 8 million admissions per year. National estimates were obtained using sampling weights provided. We queried the NIS database from January 2008 to December 2018. A detailed explanation of all the variables in the NIS is available online (https://www.hcup-us.ahrq.gov/db/

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nation/nis/nisdde.jsp). This study was deemed exempt by the Institutional Review Board as the NIS is a publicly available database that contains de-identified patient information.

The study population was identified using the International Classification of Diseases, Ninth and Tenth Edition, Procedure Coding System (ICD-9-PCS and ICD-10-PCS) codes for percutaneous ventricular assist device (pVAD) (including Impella and Tandem Heart) and percutaneous coronary intervention (PCI). We included only hospitalizations that underwent PCI and pVAD on the same day and excluded those with cardiogenic shock (N = 22,583) *(Supplemental Figure 1).* IABP is not included in our sample as a pVAD and for our study purpose, we define HR-PCI as pVAD-assisted PCI. NIS does not identify individual patients; therefore, we refer to our sample as number of hospitalizations or procedures, nonetheless, patient characteristics are reported in the database and can be used to describe comorbidities, age, gender, and race. Baseline patient characteristics, such as age, gender, race, and relevant comorbidities were collected. The severity of co-morbid conditions was defined using a validated Deyo modification of Charlson Co-morbidity Index (CCI).[6,7] Other characteristics such as teaching status of the hospital, hospital bed size, hospital region, median household income, and insurance status were also included.

The primary outcome was the change over time of procedural characteristics in HR-PCI, which included atherectomy, image-guided PCI, use of fractional flow reserve (FFR) or instant wave-free ratio (iFR), type of stent used (bare-metal or drug-eluting stent), and use of right heart catheterization. Secondary outcomes included rates of procedural complications, such as in-hospital mortality, acute kidney injury requiring dialysis, vascular complications, blood transfusions, acute ischemic stroke, daily hospital costs (calculated as hospital costs and/or length of stay and adjusted for inflation[8]) and length of stay. The ICD-codes used to define the study outcomes are listed on the *Supplemental Table 1.*

Univariate differences were evaluated using Pearson chi-square tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. The Cochran−Armitage test and multivariate Poisson regression analysis were used for trend analysis. We adjusted in-hospital mortality, acute kidney injury requiring dialysis, vascular complications, blood transfusions, and acute ischemic stroke using the following covariates: age, gender, race, procedural characteristics (such as atherectomy, image-guided PCI, use of FFR/iFR, and multivessel PCI), Charlson comorbidity index, myocardial infarction on admission, and elective admission. Statistical analysis was performed with STATA 14 and a p-value less than 0.05 was considered significant for all the analyses.

Results

From 2008 to 2018, a total of 26,661 pVAD-PCI procedures were performed in patients without cardiogenic shock. There was a 27-fold increase in the number of pVAD-PCI performed from 2008 to 2018 (Figure 1*),* and patients undergoing pVAD-PCI in the later years have a higher number of comorbidities when compared to previous years. Table 1 shows a complete description of the baseline and hospital characteristics. Significant differences in the trends in time over the 11-year period were seen in comorbidities such as hypertension, smoking, peripheral arterial disease, and atrial fibrillation. The percentage of patients with a Charlson comorbidity index ≥3 was significantly larger over time. There has also been a significant increase in the number of patients with a primary discharge

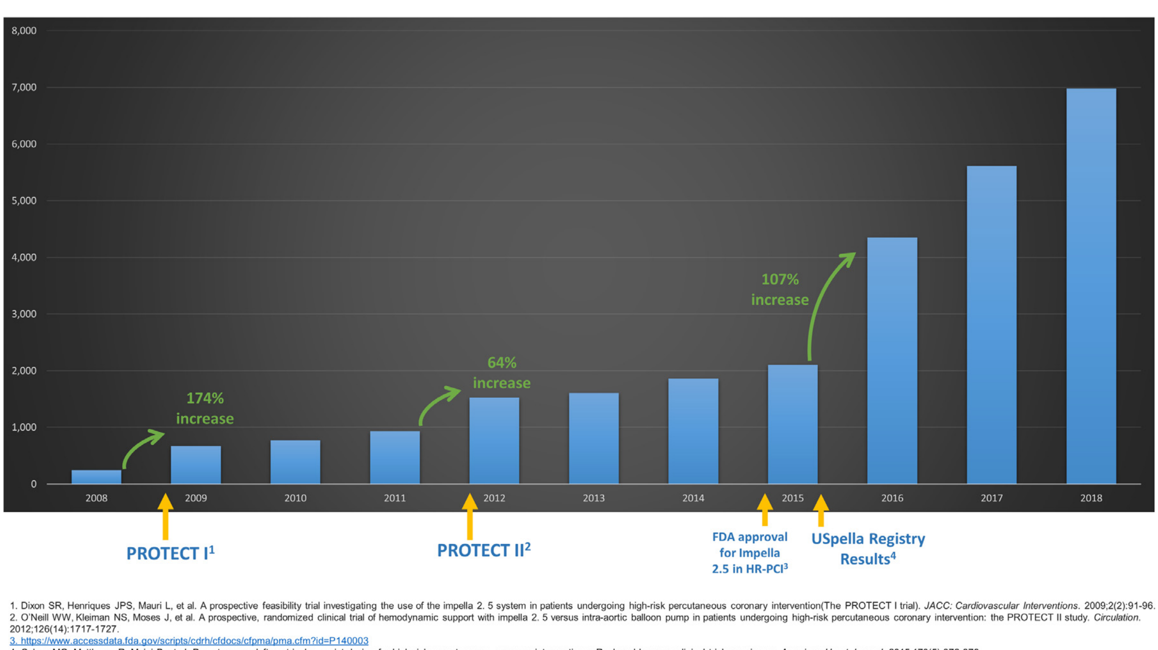

Figure 1. Increase in the number of pVAD-PCI procedures and correlation with published data. There has been a 27-fold increase in the number of pVAD-PCI procedures from 2008 to 2018, which reflects positive published data on safety and feasibility of this high-risk procedure.

Table 1
Baseline characteristics for high-risk pVAD-PCI admissions from 2008 to 2017.

Number of procedures, n (%)	Overall 26,661 (100%)	2008 247 (0.9%)	2009 673 (2.5%)	2010 771 (2.9%)	2011 929 (3.5%)	2012 1,525 (5.7%)	2013 1,605 (6.0%)	2014 1,860 (7.0%)	2015 2,105 (7.9%)	2016 4,350 (16.3%)	2017 5,615 (21.1%)	2018 6,980 (26.2%)
Age (Median [IQR])	71 (62 to 80)	66 (61 to 75)	69 (62 to 79)	71 (62 to 80)	70 (62 to 78)	72 (62 to 81)	72 (62 to 79)	69 (61 to 78)	71 (63 to 80)	71 (62 to 80)	71 (63 to 80)	72 (63 to 80)
Male	71.6%	76.2%	71.8%	76.5%	74.7%	75.1%	76.0%	71.2%	71.7%	72.3%	69.7%	69.8%
Race and/or Ethnicity												
White	72.0%	57.5%	72.0%	74.3%	73.5%	71.9%	69.2%	74.3%	68.7%	71.1%	71.5%	74.1%
Black	9.9%	8.6%	10.2%	8.9%	9.9%	12.5%	12.3%	9.0%	9.3%	10.7%	9.6%	9.0%
Hispanic	20.0%	21.1%	13.7%	6.7%	7.7%	6.1%	8.6%	9.9%	13.8%	8.1%	10.8%	10.6%
Other	8.1%	12.9%	4.1%	10.1%	8.9%	9.6%	9.9%	6.8%	8.3%	10.1%	8.2%	6.3%
Hypertension	82.2%	65.4%	67.5%	65.8%	70.3%	75.1%	78.2%	76.9%	78.4%	83.2%	87.1%	88.0%
Diabetes Mellitus	49.8%	53.1%	37.7%	47.1%	46.8%	47.5%	43.6%	45.4%	47.7%	50.0%	51.0%	53.9%
Heart Failure	68.8%	60.7%	64.9%	70.7%	73.7%	68.9%	73.5%	72.6%	69.6%	69.5%	68.5%	66.0%
Systolic Heart Failure	54.1%	41.0%	42.0%	52.1%	56.2%	52.8%	56.1%	56.2%	53.2%	56.9%	55.9%	51.9%
Dyslipidemia	67.4%	53.0%	55.3%	56.7%	66.8%	63.0%	59.5%	68.0%	66.5%	69.0%	68.0%	71.9%
Previous Pci	19.2%	15.6%	17.8%	16.6%	17.1%	18.4%	18.7%	17.7%	20.2%	20.0%	18.7%	20.1%
Previous Cabg	11.6%	11.6%	11.3%	11.1%	7.1%	8.9%	6.9%	8.9%	10.7%	12.3%	13.2%	13.2%
Obesity	16.0%	8.1%	5.9%	8.3%	13.1%	13.8%	11.8%	15.6%	12.8%	16.1%	17.4%	19.7%
Smoker	40.5%	29.3%	29.7%	26.1%	27.1%	38.0%	36.8%	41.7%	38.5%	40.2%	44.8%	43.8%
Copd	22.5%	17.5%	18.9%	21.4%	22.6%	20.3%	20.9%	19.9%	20.4%	22.0%	24.1%	24.3%
End Stage Renal Disease	8.6%	11.8%	9.7%	6.4%	7.0%	6.6%	6.5%	7.5%	10.2%	9.1%	8.6%	9.2%
Peripheral Artery Disease	16.8%	5.9%	6.1%	9.9%	10.7%	9.8%	14.0%	12.4%	10.7%	23.3%	19.2%	18.8%
Atrial Fibrillation	22.7%	9.9%	16.3%	13.3%	19.8%	20.7%	21.8%	18.6%	23.5%	23.8%	25.6%	23.9%
Charlson Comorbidity Index												
0	3.5%	7.9%	5.5%	5.7%	4.6%	3.3%	3.4%	3.8%	5.9%	2.1%	3.0%	3.2%
1	11.5%	15.6%	22.9%	11.2%	15.9%	18.4%	11.2%	14.5%	11.6%	9.7%	9.4%	10.3%
2	20.4%	25.1%	19.2%	30.2%	21.9%	19.7%	24.3%	21.5%	21.9%	19.7%	20.5%	17.9%
≥3	64.6%	51.5%	52.4%	52.9%	57.6%	58.7%	61.1%	60.2%	60.6%	68.6%	67.1%	68.6%
Discharge Diagnosis												
Acute Coronary Syndrome (Acs)	41.1%	21.5%	35.8%	36.9%	34.2%	36.1%	43.6%	41.4%	37.5%	42.0%	42.7%	43.5%
Non-Acs	58.9%	78.5%	64.2%	63.1%	65.8%	63.9%	56.4%	58.6%	62.5%	58.1%	57.3%	56.5%
Hospital Characteristics												
Teaching Hospital	76.9%	93.2%	61.8%	72.9%	72.4%	69.5%	69.5%	75.8%	75.8%	74.9%	81.7%	80.0%
Hospital Bed Size												
Small	11.9%	4.9%	12.7%	9.8%	5.3%	6.2%	4.4%	9.4%	10.5%	13.5%	14.2%	14.6%
Medium	24.9%	3.8%	6.8%	19.5%	20.9%	23.9%	20.6%	23.9%	24.2%	24.7%	28.9%	27.2%
Large	63.1%	91.3%	80.5%	70.6%	73.8%	69.8%	75.1%	66.7%	65.3%	61.8%	57.0%	58.2%
Hospital Region												
Northe Ast	17.5%	55.6%	30.8%	22.5%	22.4%	16.4%	16.8%	18.6%	15.0%	17.0%	17.1%	15.0%
Midwest	22.9%	12.1%	20.9%	14.8%	22.8%	23.3%	28.7%	18.8%	23.5%	22.8%	23.2%	23.6%
South	38.9%	1.9%	19.4%	46.6%	39.6%	41.3%	36.8%	42.2%	38.0%	38.1%	38.0%	41.8%
West	20.8%	30.4%	28.9%	16.1%	15.2%	19.0%	17.8%	20.4%	23.5%	22.2%	21.7%	19.6%
Other Characteristics												
Elective Admission		50.6%	34.8%	24.4%	25.0%	37.2%	29.1%	34.6%	34.9%	29.6%	28.1%	30.2%

(*continued on next page*)

Table 1 (*Continued*)

Number of procedures, n (%)	Overall 26,661 (100%)	2008 247 (0.9%)	2009 673 (2.5%)	2010 771 (2.9%)	2011 929 (3.5%)	2012 1,525 (5.7%)	2013 1,605 (6.0%)	2014 1,860 (7.0%)	2015 2,105 (7.9%)	2016 4,350 (16.3%)	2017 5,615 (21.1%)	2018 6,980 (26.2%)
Median Household Income												
0 - 25th Percentile	33.0%	35.1%	24.8%	40.4%	33.1%	32.2%	35.9%	35.3%	33.5%	34.0%	33.0%	30.9%
26th - 50th Percentile	26.8%	21.6%	25.0%	23.9%	27.3%	26.9%	25.5%	25.5%	23.4%	26.1%	25.3%	30.6%
51st - 75th Percentile	22.7%	27.4%	19.1%	16.8%	17.7%	23.3%	23.9%	22.7%	27.0%	22.2%	24.0%	21.6%
76th - 100th Percentile	17.6%	15.9%	31.1%	18.9%	21.9%	17.6%	14.8%	16.4%	16.0%	17.7%	17.8%	16.8%
Primary Payer												
Medicare	70.8%	58.8%	69.2%	66.8%	66.7%	71.8%	73.2%	65.1%	73.4%	72.2%	70.4%	71.8%
Medicaid	6.3%	15.5%	7.6%	6.5%	8.6%	3.9%	6.5%	7.3%	4.0%	5.8%	6.9%	6.2%
Private Insurance	18.2%	23.8%	20.3%	21.2%	20.1%	18.0%	14.0%	22.3%	19.2%	16.8%	18.1%	17.6%
Self-Pay and/or Other	4.8%	1.9%	3.0%	5.5%	4.7%	6.2%	6.2%	5.4%	3.3%	5.3%	4.6%	4.4%

diagnosis of ACS when compared to non-ACS patients who underwent pVAD-PCI. We observed an increase in the number of pVAD-PCI procedures performed in small to medium size hospitals as well as in hospitals in the Midwest and South.

We observed significant differences in the 11-year period regarding procedural characteristics. There has been a significant increase in the use of image-guided PCI (intravascular ultrasound [IVUS] and optical coherence tomography [OCT]), atherectomy, fractional flow reserve (FFR) and instantaneous wave-free ratio (iFR), and multi-vessel PCI (Figure 2). Despite sicker patients, some clinical outcomes have improved; the rates of acute stroke and blood transfusions have decreased significantly, while the rates of vascular complications and acute kidney injury requiring dialysis have remained unchanged despite yearly fluctuations (Figure 3*)*. In-hospital mortality increased from 4% in 2008 to 8.8% in 2018, however, after adjusting for age, gender, Charlson comorbidity index, myocardial infarction at presentation, and procedural characteristics, this difference was not statistically significant ($p = 0.42$). Moreover, when mortality was analyzed based on hospital bed size, pVAD-PCI performed in large hospitals had a mortality of 7.7% compared to 9.5% in those in small to moderate size hospitals ($p = 0.08$, adjusted for age, gender, Charlson comorbidity index, and year). Lastly, daily hospital costs have remained similar over the 11-year study period, around $10,000 per hospital day (p trend = 0.43) (Figure 4).

Discussion

Using real-world data, we evaluated a large sample of pVAD-PCI procedures in patients without cardiogenic shock in a 11-year period. We reported several important findings (Figure 5) First, there was a 27-fold increase in the use of pVAD-assisted PCI in the United States between 2008 and 2018. This increase correlates with technological advancements, regulatory approval and increasing published data on safety, and efficacy.[4,5] Second, patients undergoing pVAD-PCI in more recent years of the study have a higher number of comorbidities, suggesting a broader acceptance of higher risk patients as well as more complex procedures which may also explain the higher unadjusted mortality observed, which was not significant after adjusting for patient and procedural characteristics. Third, there is a significant increase in the use of image-guided PCI, FFR/iFR, drug-eluting stents, atherectomy, and multi-vessel intervention, which may reflect both increased procedural complexity in addition to improvements in technique. Fourth, there has been a decrease in the rates of acute stroke and blood transfusions; however, other complications such as AKI requiring dialysis and vascular complications have remained mostly unchanged despite the inclusion of more comorbid patients. Finally, hospital costs for pVAD-PCI have remained overall similar, with a median of $10,000 per hospital day.

In 2009, the PROTECT I[5] trial demonstrated that Impella-assisted PCI was feasible and safe in high-risk patients without cardiogenic shock. This led to the PROTECT II[4] trial published in 2012, which compared patients undergoing HRPCI with IABP versus Impella 2.5. The

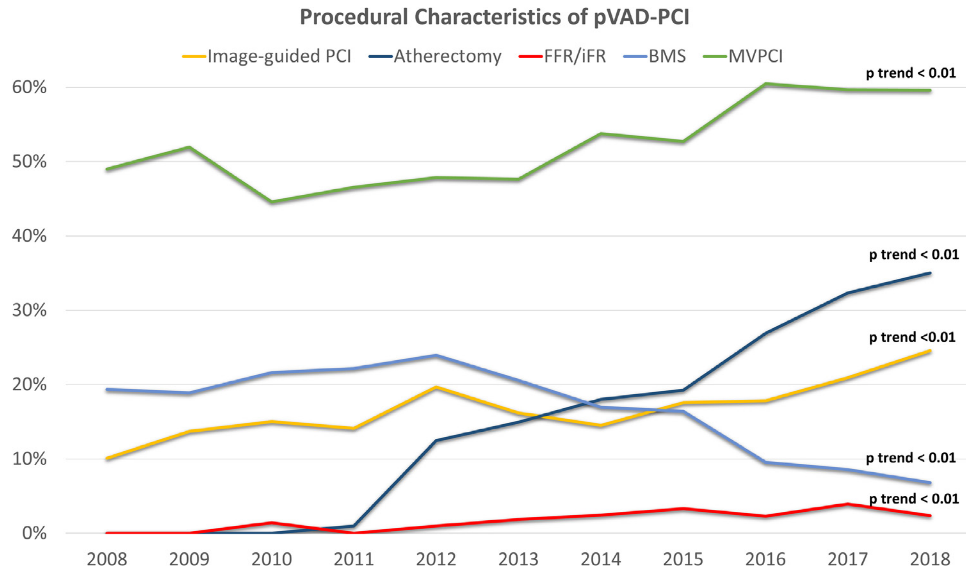

Figure 2. Trend of procedural characteristics. The use of adjunctive PCI techniques such as atherectomy, intravascular imaging, and physiologic lesion assessment has increased significantly over the past 11 years.

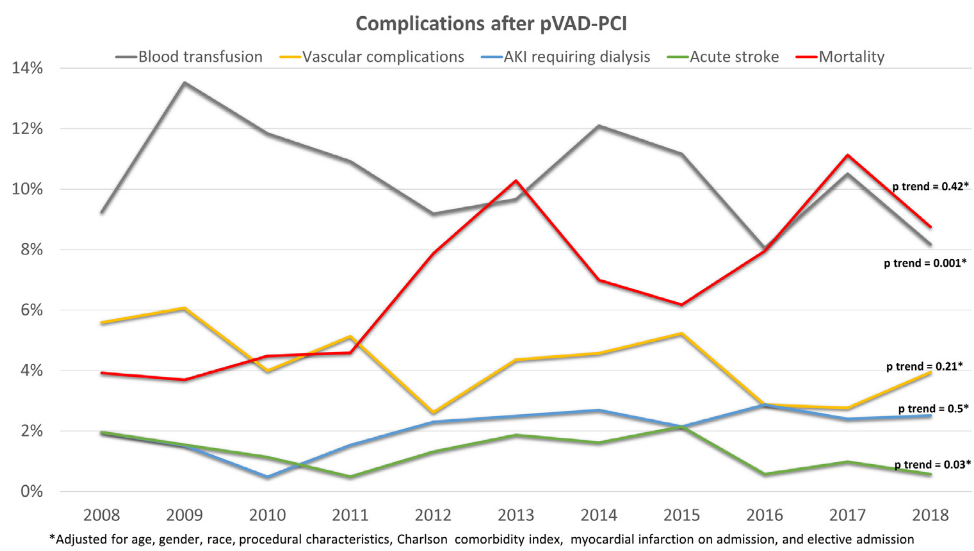

Figure 3. Trend of procedural complications. During the 11-year study period, there are lower rates of peri-procedural stroke and blood transfusions, and despite a higher burden of comorbidities, adjusted mortality and vascular complications remained stable over time.

study demonstrated similar 30-day MACE in both cohorts and a trend toward improved 90-day outcomes with Impella (40.6% vs 49.3%, p = 0.066 in the intent-to-treat population and 40.0% vs 51.0%, p = 0.023 in the per protocol population, respectively). Real world data from the USpella registry[8] have shown similar favorable outcomes with Impella as compared to clinical trial patients. There has been a steady increase in the utilization of pVAD for high-risk patients undergoing PCI. This is likely explained by a combination of greater clinical familiarity, regulatory approval, growing evidence of device safety and efficacy,[4,5,8] and a decrease in the number of surgical revascularizations, especially in high-risk patients.[9,10] In this series, although unadjusted mortality increased over time, there was a greater burden of comorbidities of patients in the patients undergoing HRPCI over time as well as an increase in the complexity of coronary lesions; After accounting for these confounding factors, adjusted mortality was not significantly different (p = 0.42). As reported by Alkhouli et al,[9] PCI mortality has slightly increased over the years; It is interesting to note that we did see a decrease in mortality from 2017 to 2018 that could be explained by better operator familiarity with pVAD and HRPCI.

PVAD-assisted PCI is increasingly utilized to support patients who require complex procedures including left main PCI or atherectomy. Since atherectomy can result in transient and sometimes prolonged reductions in stroke volume,[11] the use of MCS in such patients may prevent significant hemodynamic destabilization and cardiovascular collapse, and allow for adequate time for the operator to properly prepare the lesion for stent implantation This rational may explain the steady increase in this use of atherectomy with the increase number of HR-PCI performed. In pVAD-assisted PCI, atherectomy rates have been reported

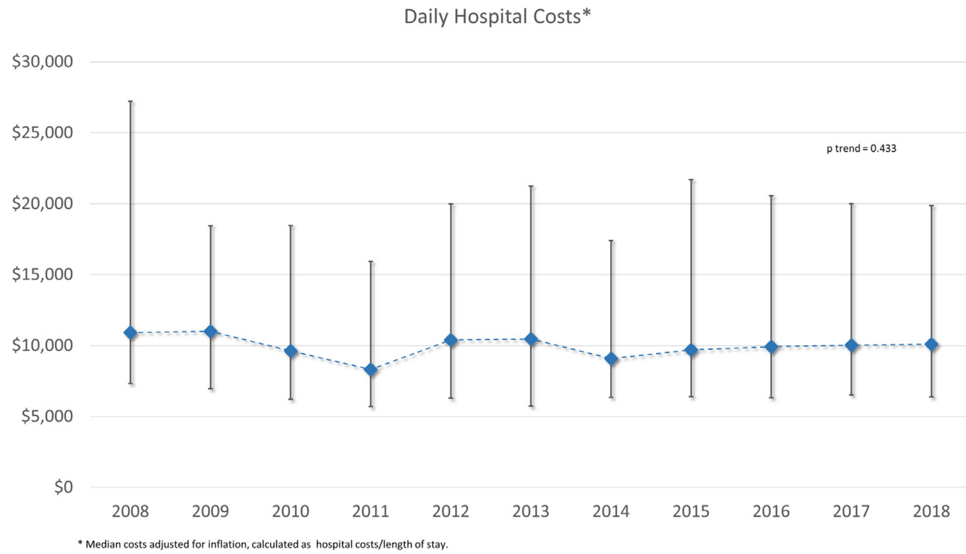

Figure 4. Median daily hospital costs. Median daily hospital costs have remained similar from 2008 to 2018.

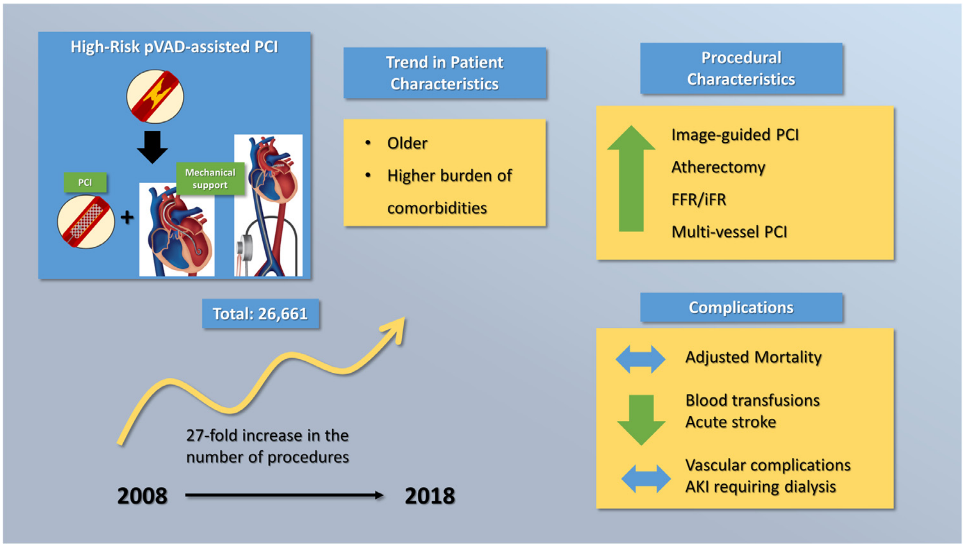

Figure 5. Summary of study findings. The use of pVAD for HR-PCI has increased significantly in recent years, along with adjunctive PCI techniques such as atherectomy, intravascular imaging and physiology. Patients undergoing pVAD-PCI had a higher burden of comorbidities, without a significant difference in mortality over time.

from 16 to 48%.[4,8,12] Similarly, there has been an increase use of image-guided PCI with IVUS or OCT, which was used in 25% of cases in 2018. This trend is likely to continue as recent data continue to demonstrate improved short and long-term outcomes with the use of imaging.[13–15] IVUS and OCT improve operators' ability to identify plaque morphology which can allow for improved vessel preparation including increase utilization of atherectomy. Furthermore, the rates of multi-vessel intervention have also increased, from 50% to 60% in 10 years; pVAD-assisted PCI may permit for more multi-vessel and complex revascularization when clinically indicated.

The rates of vascular complications following MCS vary greatly in the literature, from 2% to 10%.[16] In our study we demonstrated that the rates of vascular complications with pVAD decreased from 6% to 4% over time despite an increasingly comorbid patient population. The decrease in the number of vascular complications is likely multifactorial and explained at least in part by greater operator familiarity with pVADs, increasing education on large bore access management, and closure, and overall greater experience with large bore procedures. This improvement has occurred even as most operators have adopted use of the 14 Fr Impella CP over the first generation 13 Fr Impella 2.5.[17–19] Lastly, transfusion rates have remained stable, around 10%, which is similar to what has been previously reported in the USpella registry (11%) and PROTECT II trial (12.5%). The rates of AKI requiring dialysis and acute stroke remained lower than 2.5% during the 11-year period.

There are several limitations to the present study. The NIS data is based on ICD-9 and 10 codes, and like any administrative database, there is a possibility of coding error. The NIS database also does not contain specific information on the indication for pVAD or decision-making regarding the choice of PCI over CABG or medical therapy. Only the primary discharge diagnosis was used to determine the possible indication. Lack of information regarding laboratory results, medications, hemodynamic state, and imaging findings renders a more comprehensive analysis unfeasible with this database. Despite these limitations, our results provide real world data of contemporary trends of HR-PCI and pVAD use in the United States.

In conclusion, the use of pVAD for HR-PCI has increased significantly in recent years, along with adjunctive PCI procedures such as atherectomy, intravascular imaging and physiology. Patients undergoing pVAD-PCI had a higher burden of comorbidities, without a significant difference in mortality over time.

Disclosures

Dr Basir has the following disclosures: Abbott Vascular, Abiomed, Chiesi, Cardiovascular Systems, and Zoll. Dr Truesdell has the following disclosures: Abiomed. Dr Alqarqaz has the following disclosures: Abiomed. Dr O'Neill has the following disclosures: Abiomed and Abbott. The rest of the authors have nothing to disclose.

Declaration of Competing Interest

None.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.amjcard.2021.06.048.

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