CLINICAL RESEARCH STUDY

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Percutaneous Aortic Balloon Valvotomy in the United States: A 13-Year Perspective

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ABSTRACT

BACKGROUND: We determined the contemporary trends of percutaneous aortic balloon valvotomy and its outcomes using the nation's largest hospitalization database. There has been a resurgence in the use of percutaneous aortic balloon valvotomy in patients at high surgical risk because of the development of less-invasive endovascular therapies.

METHODS: This is a cross-sectional study with time trends using the Nationwide Inpatient Sample database between the years 1998 and 2010. We identified patients using the International Classification of Diseases, 9th Revision, Clinical Modification procedure code for valvotomy. Only patients aged more than 60 years with aortic stenosis were included. Primary outcome included in-hospital mortality, and secondary outcomes included procedural complications and length of hospital stay.

RESULTS: A total of 2127 percutaneous aortic balloon valvotomies (weighted n = 10,640) were analyzed. The use rate of percutaneous aortic balloon valvotomy increased by 158% from 12 percutaneous aortic balloon valvotomies per million elderly patients in 1998-1999 to 31 percutaneous aortic balloon valvotomies per million elderly patients in 2009-2010 in the United States ($P < .001$). The hospital mortality decreased by 23% from 11.5% in 1998-1999 to 8.8% in 2009-2010 ($P < .001$). Significant predictors of in-hospital mortality were the presence of increasing comorbidities ($P = .03$), unstable patient ($P < .001$), any complication ($P < .001$), and weekend admission ($P = .008$), whereas increasing operator volume was associated with significantly reduced mortality ($P = .03$). Patients who were admitted to hospitals with the highest procedure volume and the highest volume operators had a 51% reduced likelihood ($P = .05$) of in-hospital mortality when compared with those in hospitals with the lowest procedure volume and lowest volume operators.

CONCLUSION: This study comprehensively evaluates trends for percutaneous aortic balloon valvotomy in the United States and demonstrates the significance of operator and hospital volume on outcomes.

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Drs Badheka, Patel, Singh, Shah, and Chothani contributed equally to this manuscript.

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Percutaneous aortic balloon valvotomy was first performed in 1986 as a palliative treatment for elderly patients with symptomatic aortic stenosis at high risk for surgery.[1,2] Despite the initial enthusiasm, the use of percutaneous aortic balloon valvotomy was abandoned for the most part, and the procedure was limited to palliative situations because of nondurability and disappointing long-term survival.[3] With the recognition that symptomatic aortic stenosis remains untreated in 30% to 60% of patients coupled with the development of less-invasive endovascular therapies, including transcatheter aortic valve replacement, there has been resurgence in the use of percutaneous aortic balloon valvotomy in patients who are considered inoperable or at high surgical risk.[4,5] Now, the procedure is used frequently as a bridge to more definitive surgical replacement or transcatheter aortic valve replacement. The aims of our study were to determine the use trend of percutaneous aortic balloon valvotomy; mortality rate and its predictors; complication rates and their predictors; length of stay; and effect of operator volume on outcomes of percutaneous aortic balloon valvotomy in the United States using the nation's largest hospitalization database.

CLINICAL SIGNIFICANCE

- The use rate of percutaneous aortic balloon valvotomy increased by 158%, and the mortality decreased by 23%.
- Multiple comorbidities, unstable patient, any complication, and weekend admission increase in-hospital mortality.
- Patients who were admitted to hospitals with the highest procedure volume and the highest volume operators had a 51% reduced likelihood of in-hospital mortality.

METHODS

Data Source

The Nationwide Inpatient Sample (NIS) is the largest available all-payer database of hospital inpatient stays in the United States. The 2010 NIS contains all discharge data from 1051 hospitals located in 45 states, approximating a 20% stratified sample of US community hospitals. Data from the NIS have been used to identify, track, and analyze national trends in healthcare use, patterns of major procedures, access, disparity of care, trends in hospitalizations, charges, quality, and outcomes.[6,7] Each individual hospitalization is de-identified and maintained in the NIS as a unique entry with 1 primary discharge diagnosis and <24 secondary diagnoses during that hospitalization. Each entry also carries information on demographic details, insurance status, comorbidities, primary and secondary procedures, hospitalization outcome, and length of stay with safeguards to protect the privacy of individual patients, physicians, and hospitals. Annual data quality assessments are performed to ensure the internal validity of the database. To establish the external validity, the database is compared with the following data sources: the American Hospital Association Annual Survey Database, the National Hospital Discharge Survey from the National Center for Health Statistics, and the MedPAR inpatient data from the Centers for Medicare and Medicaid Services.[8,9]

Study Design and Patients

We queried the Healthcare Cost and Utilization Project's NIS between 1998 and 2010 using the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure code of 35.96 for percutaneous valvuloplasty. Only patients aged more than 60 years with aortic stenosis (424.1, 395.0, 395.2, 396.2, 746.3) were included. Patients with concomitant mitral, tricuspid, or pulmonic stenosis were excluded (394.0, 394.2, 396.0, 396.1, 396.8, 397.0, 397.1, 746.0, 746.1, 746.5, 424.2, and 424.3).

Use Rates

Because the NIS represents a 20% stratified random sample of US hospitals, the population at risk forming the denominator was 20% of the US census population of adults aged more than 60 years for any given year.[9,10] Therefore, use rates were calculated by dividing the number of percutaneous aortic balloon valvotomy procedures performed, available in the NIS dataset, in a given year divided by 20% of the US census population aged more than 60 years for that year.

Comorbidities

We defined the severity of comorbid conditions using the Deyo modification of the Charlson Comorbidity Index (CCI).[11] This index contains 17 comorbid conditions with differential weights. The score ranges from 0 to 33, with higher scores corresponding to greater burden of comorbid diseases (**Supplementary Table 1**, online).

Complications

Procedural complications were identified by Patient Safety Indicators, which have been established by the Agency for Healthcare Research and Quality to monitor preventable adverse events during hospitalization. These indicators are based on ICD-9-CM codes and Medicare severity Diagnosis-Related Groups, and each Patient Safety Indicator has specific inclusion and exclusion criteria.[12,13] Patient Safety Indicator individual measure technical specifications (Version 4.4, March 2012) were used to identify and define preventable complications versus postprocedure respiratory failure, postprocedure physiologic, and metabolic derangement, with acute renal failure requiring dialysis studied separately; postprocedure pulmonary embolism or deep venous thrombosis; postprocedure infectious complications, which included postprocedure sepsis and central venous catheter-related bloodstream infection; iatrogenic pneumothorax; complications of anesthesia; pressure ulcers; and accidental puncture or laceration.[12] This methodology has been used in earlier studies.[14]