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Brief Communication

In-hospital complications associated with total artificial heart implantation in the United States between 2004 to 2011

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Abstract: Objective: Total artificial heart (TAH) utilization has increased over the recent years. The goal of this study was to evaluate the trend of artificial hearts used in the USA with its associated morbidity and mortality based on a large in-hospital database. Materials and methods: Using a very large nationwide inpatient samples (NIS) database, we used ICD-9 code for a total artificial heart. We evaluated the utilization of this device over the years studied. Furthermore, we evaluated any associated complications and mortality in patients receiving this device. Results: From 2004 until 2011, the rate of total artificial heart implants increased over the years from 5 in 2004 to the highest of 26 in 2011 across the United State. TAH was insesrted in 75 patients. Death was reported in 22 patients (29.3%). Acute renal failure was the most common complication (69.3%). This is followed by post-operative infectious complications (28.0%), acute renal failure requiring dialysis (16%), bleeding complications requiring blood transfusion (14.7%) respiratory complications (6.7%), and stroke/TIA (4.0%). There was no post-operative deep vein thrmobosis or pulmonary embolism. Conclusions: The use of total artificial heart has increased in the United State steadily with substantial morbidity and mortality associated with this device.

Keywords: Artificial heart, transplantation, mortality, complications, total artificial heart, heart transplantation

Introduction

Nearly 5 million people in the United States are diagnosed with heart failure [1]. Heart failure causes approximately 55,000 deaths each year in the United States and accounts for about 5% of all medical admissions [2]. Patients with advanced disease have very limited options for management. Orthotopic heart transplantation is the ultimate therapy of choice. Unfortunately, donor heart supply is limited [3]. As a bridge to transplantation, mechanical circulatory support has been used, decreasing the morbidity as well as mortality in this complicated cohort of patients [4]. Total Artificial Heart (TAH) is used in patients requiring biventricular assist and has proven to be a reliable long-term circulatory support. It is a pneumatic orthotopic cardiac prosthesis that replaces all four-valves, the ventricles, and initial portions of the great vessels. CardioWest TAH was first implanted in 1982 [5] and Abiocore TAH in 2001 [6].

Heart failure is defined as the inability of the heart to supply the body's circulatory demand and is diagnosed based on clinical presentations. Classic symptoms of advanced heart failure are dyspnea at rest or minimal exertion and the presence of orthopnea. Physical examination usually reveals jugular vein distention, bilateral rales on the pulmonary exam, and leg edema. Chest x-ray usually reveals bilateral effusion and pulmonary congestion. Brain natriuretic hormones are usually elevated, and the presence of hyponatremia is very common.

TAH is designed for mechanical circulatory support. Before TAH implantation, native valves and ventricles are removed and replaced by a pneumatically powered TAH. The TAH was initially approved for use in end-stage heart failure

patients as a bridge to heart transplantation. However, with an increasing number of end-stage heart failure patients awaiting heart transplantation far exceeding the number of available hearts, TAH is now used more commonly as the destination therapy for many patients who are not a candidate for heart transplantation. For many patients that have only left ventricular failure without significant valve disease, a left ventricular assist device (LVAD) can be used for destination therapy or bridge to transplantation. However, for patients with the addition of right ventricular failure or other major structural heart conditions prohibiting LVAD placement, TAH is the appropriate therapy.

Major contraindication to TAH implantation includes not being a transplant candidate if not used for destination therapy, lack of psychosocial support, left heart failure only without right-heart involvement, a small thoracic cavity unsuitable to fit the device, and high risk for anticoagulation. The major complications of total artificial heart implantation include strokes, infection, bleeding, thrombosis, renal failure, and chronic anemia. In a study of 101 patients, post-op strokes were reported in 7.9% of patients, 63.4% developed an infection requiring treatment, and 42.6% had bleeding. Post-op mediastinitis occurred in 3% of patients with high rates of mediastinal bleeding requiring mediastinal exploration in 24.7% of patients. Thirty days mortality was 44%.

Long term prognosis of TAH is acceptable. A single center outcome data was published in 2014. From April 2006 through July 2012, 66 patients were implanted with a TAH with a median support duration of 87.5 days. Total of 76% were successfully transplanted. Fifteen percent were discharged home on a portable driver and 11% remained on the device awaiting transplantation with 14% mortality.

The majority of data regarding the demographic and complications of TAH comes from selected academic centers and operators with expertise in TAH. There has yet to be reported real-world data regarding complications of TAH. The principal objective of this study was to investigate the demographics of patients undergoing TAH implantation and their in-hospital outcome.

Methods

Data source

The data were obtained from the Nationwide Inpatient Sample (NIS) data base from 2004 to 2011 [7]. Developed by the Agency for Healthcare Research and Quality, the NIS comprises a 20% sample of all inpatient discharges from US hospitals. The database contains de-identified information regarding each hospitalization, including demographic characteristics, admission status, comorbidities, discharge diagnoses, procedures, and outcomes.

Study population and outcomes

The target population consisted of patients who underwent TAH implantation between 2004 to 2011. TAH implantation was defined by the International Classification of Diseases, Ninth Revision, Clinical modification (ICD-9-CM) codes of 37.52. We investigated the acute in-hospital complications in the setting of TAH implantations. Complications studied for this analysis included respiratory complications (pneumothorax, postoperative respiratory failure, and iatrogenic complications); neurological complications (stroke or transient ischemic attack [TIA]); acute renal failure; metabolic derangements' postoperative deep vein thrombosis or pulmonary embolism; postoperative infectious complications; postoperative hemorrhage requiring blood transfusion; and in-hospital death. These complications were selected based on a review of pertinent clinical literature and identified from corresponding ICD-9-CM diagnosis and procedure codes [2-4]. Procedural complications were further 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. Patient Safety Indicators Technical Specifications, Version 5.0, March 2015, was used to identify and define postprocedure respiratory failure, acute renal failure, postoperative deep venous thrombosis or pulmonary embolism, and postoperative infectious complications. We identified other procedure-related complications, which included postprocedural acute renal failure requiring dialysis, post-procedure

Table 1. Baseline patient characteristics

Demographic Variable	Total patients, n (%)
Total No. of TAH Implantations	75
Age	
0-12	2 (2.7%)
13-30	9 (12.0%)
31-40	7 (9.3%)
41-50	17 (22.7%)
51-60	22 (29.3%)
61-70	17 (22.7%)
71-80	1 (1.3%)
≥81	0
Sex	
Male	57 (76%)
Female	18 (24%)
Race	
White	38 (50.7%)
Nonwhite	37 (49.3%)
Comorbidities	
Hypertension	8 (10.7%)
Diabetes Mellitus	8 (10.7%)
Obesity	2 (2.7%)
Liver disease	0
Renal failure	1 (1.3%)
Chronic pulmonary disease	3 (4.0%)
Peripheral vascular disease	0
Neurologic disorder or paralysis	0
Anemia	1 (1.3%)
Coagulopathy	14 (18.7%)

stroke or transient ischemic attack, and post-procedural hemorrhage requiring blood transfusion, using ICD-9-CM codes.

Definition of variables

We used NIS variables to identify patient age, sex, race, and preprocedural comorbidities including hypertension, diabetes mellitus, obesity, liver disease, renal failure, chronic pulmonary disease, peripheral vascular disease, neurologic disorder or paralysis, anemia, and coagulopathy.

Statistical analysis

The weights provided with the NIS were used to generate national estimates of the number of admissions during each year. SPSS statistical program was used for data extraction.

Results

We identified 75 total artificial heart implantation for end-stage heart failure performed between the years 2004 and 2011. **Table 1** summarizes baseline patient characteristics. Most transplants were performed between the ages of 51-60. The majority of the procedures were performed in males (76.0%), and white patients (50.7%), with hypertension (10.7%). Majority of the patients selected to undergo total artificial heart implantation were without diabetes (89.3%), obesity (97.3%), liver disease (100%), renal failure (98.7%), chronic pulmonary disease (96.0%), peripheral vascular disease (100.0%), neurologic disorder (100.0%), anemia (98.7%), or coagulopathy (81.3%).

A total of 75 patients experienced one or more complications, which included death, postoperative respiratory complications, acute renal failure, postoperative DVT/PE, stroke/TIA, postoperative infectious complications, or blood transfusion (**Table 2**). Death was reported in 22 patients (29.3%) Acute renal failure was the most common complication (69.3%). This is followed by post-operative infectious complications (28.0%), acute renal failure requiring dialysis (16%), bleeding complications requiring blood transfusion (14.7%) and respiratory complications (6.7%) and stroke/TIA (4.0%). There was no postoperative DVT/PE. **Figure 1** shows the number of TAH implantation for each year studied.

Discussion

The national inpatient sample (NIS) is one of the largest hospital databases in the United States with its own inherent limitations. We report the basic characteristics of patients undergoing TAH and their complications.

Our study population's gender was similar to previous single-centered studies [8-10]. In contrast to Copeland et al, white patients were about 50% of total patients who underwent transplants [8]. Hypertension was present in about 10% of our patients in contrast to Copeland et al, which was about 26% [11]. Based on our data, one of the patients undergoing TAH implantation had existing renal dysfunction. This is in contrast with the existing studies showing that patients selected for TAH

Table 2. Post-operative complication rate

	Overall (n)	Overall (%)
Any procedural complications		
Death	22	29.3%
Respiratory complications	5	6.7%
Acute Renal Failure	52	69.3%
Acute renal failure requiring dialysis	2	16%
Postoperative DVT/PE	0	0
Stroke/TIA	3	4%
Post-operative infectious complications	21	28%
Blood transfusion	11	14.7%

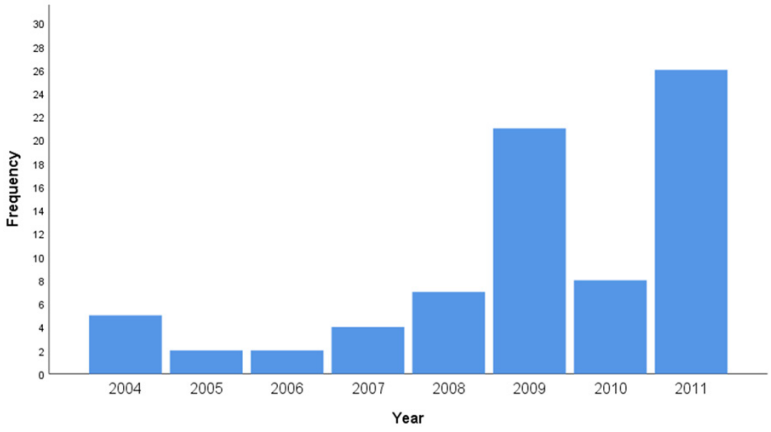

Figure 1. Frequency of total artificial heart implantation in each year studied.

implantation usually have elevated creatinine at baseline [12]. Our study population did not have liver dysfunction. Most of the patients in the previous studies did not have hepatic dysfunction apart from a slight elevation in liver enzymes [9, 11-13].

There are several limitations to our study. The main limitation is related to the use of the NIS administration database. The NIS registry data cannot be used for longitudinal follow-up data. The ICD-9 codes in the registry are impossible to validate as there could be possible oversights in coding. Furthermore, some clinical data is not reported in NIS, which could be of immense importance in reporting the temporal associations. The NIS is also incapable of differentiating between the two different types of total artificial hearts being implanted as only the procedure code is utilized in reporting and is not specific to the type of the artificial heart implanted. NIS is an important research database that retrospectively analyzed the data and can answer important questions which could provide a foundation for a change of practice, however, if a few important clinical variables are added to this database, it could become an extremely powerful tool. The clinical implication of the study is the fact that the use of artificial heart is increasing suggesting more life is saved in patients with severe end-stage heart disease with no viable options but with a cost of high mortality. Furthermore, infection and renal failures are the most occurrences of adverse events after TAH implantation with a persistently high mortality rate.

Conclusions

The use of TAH implantations has increased over the years suggesting a higher chance of survival for patients with severe end-stage heart failure. Mortality and adverse events remain high in this population. Measures focusing on reduction in infection and renal failure could improve survival rates.

Limitations

Complications and outcomes are all based on ICD-9 coding and not based on laboratory data or other variables that are not available in this database for reporting or adjustment limiting our results. Our total number of patients receiving TAH was 75 not large enough to perform multivariate outcome analysis limiting our paper to a descriptive report.

Disclosure of conflict of interest

None.

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