Background

In the era of cutting-edge medical breakthroughs, national registries have been implemented to ensure best practices are maintained. In November 2011, the FDA gave approval to the first transcatheter aortic valve (TAVR), Sapien. Given that this valve was so new, radical and expensive guidelines were set by the Centers for Medicare and Medicaid Services (CMS) which included the participation in the NCDR® STS/ACC TVT Registry™. The registry was designed to have a process which allowed clinicians to better understand the device in a real world setting. The goal of this study was to look at the utilization of the STS/ACC TVT Registry for creating benchmarks of quality control.

Methods

294 patients were entered into the registry from 11/5/2012 to 11/27/2013. The key data points required by CMS: mortality, major adverse events and quality of life (QOL) were easily retrieved and displayed in a searchable format. The registry can provide valuable financial analysis by accessing data to determine length of stay, discharge disposition and insurance carrier. The registry allows site to run reports displaying a year of data by quarter in table form.

Results

The interim report showed the data entered from 1/2013 through 9/2013. 79 (8.8 per month) patients were entered. At the discharge period, 34 (43%) patients averaged a length of stay >6 days. 51 (64.5%) of the patients were discharged home, zero cases aborted, zero strokes and 98.8% were alive at discharge. At 30 days 22 (88%) of 56 patients Kansas City Cardiomyopathy Questionnaire (KCCQ) score increased from baseline to 30 days by 2 points and another 22 (88%) increased by 6 points. Overall of the 294 patients entered 157 were females and 137 were males. There were 14 (4.9%) patients who expired prior to discharge. The limitations of the registry include resources needed for training, entering data, maintaining the registry and self-audit. CMS will use the one year data for tracking.

Conclusion

STS/ACC TVT registry can prove to be a valuable asset to monitor the outcomes and success of TAVR programs. Institutions can utilize the registry to assess changes in processes made and make early intervention if necessary.