MINI REVIEW

A countrywide research found late stroke following trans catheter aortic valve replacement

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ABSTRACT

The field of Transcatheter Aortic Valve Replacement (TAVR) is expanding quickly. These techniques effectiveness and short term safety have both been thoroughly researched. The long term safety of these gadgets, however, is not well understood. One predicted long term consequence is stroke and guidelines for treating both aortic stenosis and selecting antithrombotic medication following TAVR may be affected by an increase in stroke rates. The main goal was to compare the risk of stroke in the general population with the incidence of stroke up to 8 years following TAVR implantation. Studying late stroke risk variables and post-stroke outcomes were secondary goals. A comprehensive, open label study of patients who underwent TAVR in Sweden between 2008 and 2018 was conducted. The TAVR registry, the stroke registry, and the diagnostic registry were the three national registries on which the study's data was based. Stroke incidence 30 days or more after TAVR implantation was the primary outcome, and it was compared to a standard incidence. In a cohort of individuals with similar ages and sexes, the annual risk for stroke ranged between 2.0% and 3.1% as opposed to 1.5% and 1.9%. Reduced renal function, diabetes, a history of stroke, advanced age, and male sex were risk factors for having stroke. The stroke mortality rate after one year was 44%. The results of this study showed an increased rate of stroke following TAVR, but they also indicated that this may be partially explained by the group's higher prevalence of predisposing risk factors.

Keywords: Aortic valve; Prosthetic valve; Endocarditis; Cerebral infarction; Implantation

INTRODUCTION

Transcatheter Aortic Valve Replacement (TAVR) is a therapy that is being used more and more frequently, and this growth has been supported by numerous well-established randomised trials. These studies have shown that when compared to surgical aortic valve replacement, there are good short and medium term results (SAVR). Due to the growth of TAVR, more patients are being treated despite not meeting the requirements for enrollment, and study follow up periods are being extended for patients. The long-term safety of TAVR valves in a real world environment is therefore of major importance. Life threatening late complications like prosthetic valve endocarditis, stroke, and valve dysfunction are especially important because an increase in late incidence may influence patients with aortic stenosis' choice of treatment [1].

The geometry of TAVR valves is different from surgical valves and includes more stent material that extends to the ascending aorta and Left Ventricular Outflow Tract (LVOT). Additionally, the native valve is immobilised by the stent frame following TAVR implantation, and both of these components may serve as emboli sources. The potential of a rise in late problems must thus be investigated. With 30 day stroke rates ranging from 1.0% to 5.5% in more recent research and 1 year stroke rates ranging from 4.3% to 8.2%, where part of these figures are based on randomised studies and some on actual data, stroke is a well documented complication in the immediate aftermath of TAVR [2].

LITERATURE REVIEW

In Sweden, from January 2008 to September 2018, all patients who undergone TAVR underwent a retrospective, countrywide follow up study. The dataset and its data sources have already been discussed. The national TAVR registry swentry, a part of SWEDEHEART (Swedish Web-system for Enhancement and Development of Evidence based care in Heart Disease Evaluated According to Recommended Therapies), served as the initial data source and contains details on all TAVR operations carried out in the nation. We utilised the first implantation in each case as the index procedure for this analysis because, of the 4336 implantations in the registry, 28 used TAVR in TAVR. The national patient registry and the risk stroke registry were both utilised to confirm the diagnosis of stroke. A nationwide register with a very high coverage rate of all strokes is the risk stroke registry. All hospital admissions in Sweden are recorded in the NPR, and data submission is required by law. The International Classification of Diseases and related health problems (ICD-10) is required for the major discharge diagnosis, and the register permits several secondary diagnoses. The ICD-10 codes I61 (intracerebral haemorrhage) and I63 (cerebral infarction) were chosen as the principal diagnoses for people with stroke. We used national population records along with data from risk stroke for 2017 to calculate a standardised age and sex specific incidence of stroke in the general population. This allowed us to estimate standardised risk for stroke based on age and sex. After that, each patient was given an age and sex specific standard incidence of stroke for each year they participated in the trial using the numbers (with a parallel increase in year for risk category). Due to the inability of this procedure to account for co-morbidities, a control group was created that was almost certainly healthier than the TAVR group. Up to eight years after TAVR, a mean background stroke risk was calculated for each year. To depict cumulative stroke incidence and survival following stroke, Kaplan-Meier curves were utilised. During follow up of 30 days or longer, a cox proportional hazard model was employed to identify predictive characteristics related to stroke. With the exception of five cases, all of the data was complete. These five cases, none of which had a stroke diagnosis, were omitted from the multivariable analysis but were included in the description of the population. Variables were chosen if they were clinically relevant or significant (p 0.1) in a univariable Cox analysis. To remain in the model, a backwards stepwise exclusion was performed with a p-value of 0.1. After 30 days of TAVR, cox regression modelling was started [3,4].

The excluded risk factors were gradually introduced to the final model after it had been created to check if the model had dramatically changed. A

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Harrell's C-index was employed to gauge model strength, and Martingale residuals were utilised to evaluate the quality of fit. Schoenfeld residuals were used to examine the proportional hazard assumption in the Cox model. Only the initial stroke episode was examined. Depending on how the data were distributed, the student's t-test, *Chi-square* test, or Mann-Whitney U-test was used.

DISCUSSION

In this large scale, registry based, open label research of late stroke after TAVR, we were able to show that the annual stroke rate ranged between 2%-3%. The 30 days mortality was 20%, and the most common type of stroke (89%) was an ischemic stroke. If having a TAVR valve is linked to an increased risk of stroke was one important question that we attempted to answer in this study. Patients who have TAVR are typically older, have risk factors that could make them susceptible to stroke, and as a result, already have a higher baseline risk of stroke. This needs to be taken into consideration in any attempts to answer the question. We used risk stroke to create an estimated standardised incidence for each person and compared it to the actual outcome in this cohort after integrating official population data to determine the number of people for each age and sex. During the follow up, the standardised incidence ratio changed between 1.15% and 1.75%. The goal was to gain perspective on the risk of stroke following TAVR rather than to draw a direct comparison. Directly comparing the outcome to the standardised incidence is ineffective for two reasons. First, there were two sources used to determine the stroke diagnosis in the TAVR cohort, with 3% of patients diagnoses coming from the national patient registry [5,6].

Since the NPR could not be obtained for the full Swedish population, only risk stroke was utilised for the standardised incidence estimation. We discovered a 3% underreporting in the TAVR population, while validation studies have indicated that the registry has between 5 and 11% missing cases. Second, compared to the general population, the TAVR cohort had greater comorbidities. While the same age group in Sweden has an atrial fibrillation prevalence of 21%-24%, 37% of the individuals in the current study had the condition. The group also had a 74% prevalence of hypertension, compared to lower rates in the general population. On the other hand, diabetes was not overrepresented, with a prevalence of 24% as opposed to a prevalence of 21-25% in the general population. We cannot rule out the possibility that the pericardial valve tissue, the stent frame, or native leaflets that have been immobilised influence the stroke rate. This effect is probably not very significant given the finding that there was no difference between low frame valves (BEVs) and valves with frames spreading into the LVOT and ascending aorta (SEVs). Reduced estimated GFR, diabetes, a history of stroke, patient age, and male sex were identified in the current study as predisposing variables for stroke after TAVR. These results are consistent with prior studies outlining stroke risk factors in both the general population and TAVR patients.

It's interesting to note that a valve in valve method was linked to a lower stroke rate. This unexpected result can only be explained by the fact that patients with valve in valve are generally healthier because the bar for approving them for TAVR is higher. The valve in valve group in our cohort was younger, had less peripheral vascular disease, and used steroids less frequently. Another theory is that they were subjected to more potent anticoagulation following the procedure or that there are still confounding variables present. Given the variety of the material, the model's Harrell's C-index of 0.64 should be regarded as reasonably good. Nearly 90% of the patients had ischemic strokes, 10% had hemorrhagic strokes, and one patient had an unidentified form of stroke. Patients with ischemic stroke had more hypertension and were more alert when they arrived for treatment.

Antiplatelet treatment and anticoagulation did not statistically differ between ischemic and hemorrhagic stroke. However, patients with ischemic stroke tended to receive acetylsalicylic acid and clopidrogel more frequently than patients with hemorrhagic stroke, who typically received anticoagulation. 21% of those who had an ischemic stroke were not receiving any antithrombotic medication, compared to 33% of those who had a hemorrhagic stroke. We are unable to do a more in depth analysis since the databases do not contain information on the indication for various antithrombotic treatments or the reason why individuals did not receive treatment. Given these numbers, it is difficult to determine if the present acetylsalicylic acid regimen following TAVR is as suitable as antithrombotic therapy. After a stroke, the results revealed a 20% predicted 30 day mortality rate. The short and long term survival was quite similar to what was observed in prior trials and in the general population of Sweden for a similar age group following stroke. In terms of functional class, 40% of patients could be sent home, while 35% were sent to a nursing home or rehabilitation facility. A significant risk factor for stroke that is also curable is atrial fibrillation. Surprisingly, the multivariate analysis did not reveal this, but the univariate analysis did. This can be explained by the fact that we measure atrial fibrillation at implant time but do not have records of atrial rhythm for all patients when the risk of stroke arises years later. It is conceivable that many patients who received inadequate care after receiving the implant experienced atrial fibrillation.

CONCLUSION

The quantity and caliber of the data at hand restrict a retrospective registry based investigation. The breadth of our study's coverage of all TAVR procedures performed in Sweden throughout the study period and our ability to cross reference the swede heart data with risk stroke and the national patient registry three registries with a high degree of accuracy and completeness are its strongest points. All registry based research has the same main flaw, which is that the data are often missing or inaccurate due to human error. A larger cohort would have produced more reliable data despite the relatively large sample size of 4000+ patients; however, because all procedures in Sweden were included, a larger dataset was not feasible.

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