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ORIGINAL ARTICLE

Transcatheter Aortic Valve Implantation in Nonagenarians: Procedural Outcome and Mid-term Results

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Background For nonagenarians with symptomatic severe aortic stenosis transcatheter aortic valve implantation (TAVI) has become a feasible therapeutic option. Therefore, the aim of this study was to evaluate the procedural outcomes and mid-term follow-up in this patient group and compare this to octogenarians.

Methods From 1359 patients who underwent TAVI at our institution between March 2009 and February 2016, 82 patients were nonagenarians and 912 were octogenarians. In nonagenarians, mean age was 91.9 ± 1.4 years and compared to octogenarians showed a significantly higher logistic EuroScore (27.7 ± 14.8% vs. 23.1 ± 14.4, p = 0.005) and STS Score (8.5 ± 4.8% vs. 6.3 ± 6.7, p = 0.001).

Results There were no significant differences with regard to stroke rate, pacemaker implantation rate and major vascular complications between the two groups. Thirty-day mortality was 9.8% in nonagenarians and 4.1% in octogenarians (p = 0.04). At one year, all-cause mortality increased to 30.9% vs. 18.6% (n.s.).

Conclusion Nonagenarians showed an increased periprocedural mortality during TAVI and higher mortality in follow-up compared to octogenarians. Age alone is not a predictive factor but indication for treatment should be carefully evaluated by the heart team on an individual basis.

Keywords Nonagenarians • TAVI • Aortic stenosis

Introduction

Q5 Falling birth rates and increasing life expectancy have led to a constantly ageing population. The World Health Organization estimated an increase of the population aged more than 65 years, from 524 million in 2010 to 1.5 billion in 2050. The oldest population profiles are present in industrialised countries, but the most rapidly ageing populations are found in the developing countries. The ''oldest old'', above 85 years of age, constitute 8% of the world's 65-and-older-population. Life expectancy at birth now exceeds 81 years in developed countries, 83 years for women and 78 years for men. In Germany, the ''residual'' life expectancy of an 80-year-old female is additional 9.3 years, 7.8 for males, respectively [1].

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The global number of centenarians is projected to increase 10-fold between 2010 and 2050 [2].

As a result of the ageing population, there is an increase in chronic and degenerative diseases such as aortic stenosis. Aortic valve sclerosis is very common in the elderly, involving about 25% of the population over 65 years and about 48% of the population over 85 years. Aortic valve stenosis makes up to 9% in the population over 65 years and approximately 4% in the population over 85 years [3].

Aortic stenosis (AS) is a chronic and progressive disease with poor prognosis if symptomatic. According to the historical paper from Ross and Braunwald, the survival rate was about 50% at two years and decreased further to only 20% at five years [4]. Patients with severe AS who refused the recommended valve replacement had a median survival of 18 months [5]. The more recently published data from PARTNER I trial revealed an all-cause mortality at five years in the standard/medical treatment group as high as 93.6% compared to 71.8% in the TAVI group suggesting that TAVI must be considered in non-surgical candidates for aortic valve replacement to improve functional status and prognosis [6]. Surgical aortic valve replacement (SAVR) is still the gold standard for definite therapy of aortic stenosis and can be performed at low risk with mortality rates between 1.5 to 3% [7,8]. Nonagenarians are rarely considered for SAVR. In a prospective survey age was the major factor for not accepting patients for SAVR, and patients >90 years were not accepted at all for surgery [9]. After a decade of experience with TAVI, and decreasing periprocedural mortality, this procedure now offers the only feasible therapeutic alternative for such patients. Still little is known about midterm outcome. Thus, we report the immediate outcome and midterm results of our TAVI experience in nonagenarian patients.

Material and Methods

Patient Cohort

Patients were considered for TAVI based on the presence of symptomatic AS with an echocardiographic mean gradient ≥40 mmHg or a residual aortic valve area of ≤0.9 cm^2 while being at high risk for conventional surgery due to comorbidities, age or porcelain aorta. All cases were discussed and the indication approved by the institutional heart team.

From a total number of 1,359 patients who underwent TAVI procedure between March 2009 and February 2016, 82 patients presented with an age 90 years or above. Their data were compared with patients aged between 80 and 89 years (n = 912). All patients had coronary angiography and, in the case of significant coronary artery disease, percutaneous coronary intervention was performed prior to TAVI. Multislice computed tomography (MSCT) was part of the screening in all patients. The computed tomographic (CT) data set was analysed by a dedicated software (3Mensio Structural Heart, Pie Medical Imaging, Maastricht, Netherland) in order to determine type and size of the prosthetic valve as well as the access. EuroSCORE I, EuroSCORE II and STS score were calculated in all patients to estimate the procedural risk. All patients gave written informed consent and the study was approved by the institutional ethical committee.

Transcatheter Aortic Valve Implantation

Procedures were performed either by transfemoral or transapical approach in a hybrid operating room equipped with a Siemens Artis Zeego imaging system. The transfemoral cases were conducted in conscious sedation and local anaesthesia under fluoroscopic guidance. The following valve types were implanted: Medtronic CoreValve and Evolute R (Medtronic, Minnesota, USA), Edwards Sapien XT and S3 (Edwards Lifesciences, Irvine, CA, USA), Direct Flow Medical (DFM Inc., Santa Rosa, California, USA). Depending on the valve type the sheath size varied from 14 F to 18 F. Vascular closure devices were used to seal the puncture site in the femoral artery. If appropriate, balloon predilation of the native aortic valve was performed under rapid pacing in the early stage of our TAVI program. Since 2012, in Edwards and CoreValve/Evolute R cases, the device was implanted into the native valve without predilation. Haemodynamic measurements were obtained before and directly after valve implantation. Final angiogram with 30 ml contrast at a flow rate of 15 ml/sec documented the final valve position and residual paravalvular leakage. Heparin was administered at the beginning to keep the activated clotting time above 250 sec throughout the procedure and was antagonised by protamine at the end of the procedure. All patients were on acetyl salicyl acid 100 mg/day and patients with Medtronic CoreValve and Direct Flow Medical implants received 75 mg clopidogrel/day additionally for three months following the procedure. Transapical cases were performed in a similar manner under general anaesthesia via a left lateral mini-thoracotomy as access. Valve types used in the transapical cases were Edwards Sapien XT/S3, Symetis Acurate (Symetis SA, Ecublens, Switzerland), JenaValve (JenaValve Technology GmbH, Munich, Germany) or Engager (Medtronic, Minnesota, USA). Procedural success and adverse events were evaluated according to Valve Academic Research Consortium – 2 (VARC-2) criteria [10].

Follow-up

Patients were re-evaluated at 3 and 12 months after TAVI procedure. Clinical and echocardiographic findings were recorded. In all cases, patients were followed up every year up to the third year by a standardised telephone interview documenting their general health status and cardiovascular events.

Statistical Analysis

All data concerning baseline characteristics, procedural outcomes and follow-up were entered into a dedicated database. Continuous variables were described using means ± standard deviation (SD) or medians with interquartile range if appropriate. Categorical variables are presented as numbers and percentages. The cumulative incidences of follow-up

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