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Original

15 years outcomes following bioprosthetic versus mechanical aortic valve replacement in patients aged 50–65 years with isolated aortic stenosis☆

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ABSTRACT

Objectives: To investigate long term survival (15 years) and major morbidity in patients aged 50–65 years undergoing primary isolated aortic valve replacement with bioprosthetic or mechanical valves.
Methods: A single center retrospective analytical study of all patients aged 50–65 years with severe aortic stenosis who underwent surgery between 2000 and 2015 was performed ($n = 200$). Two groups, mechanical ($n = 117$) and biological ($n = 83$) were obtained. Propensity score matching was performed for analysis. Primary outcome was survival, secondary outcome was major adverse cardiovascular complications (30-day mortality, stroke, any prosthesis-related reoperation and major bleeding).
Results: Mean age was 60 ± 4 years, 33% female, mean follow up was 8.2 ± 3 years (range 0–17 years). Matched overall survival was similar between groups, 65% at 15 years [Log Rank $p = 0.71$, hazard ratio 0.87 (95% CI, 0.41–1.82)]. After matching, mechanical prosthesis presented a trend toward of more major adverse cardiovascular complications (30% versus 15%, $p = 0.07$) with more major bleedings (15% versus 6.3%, $p = 0.06$), stroke 11% versus 7.6% ($p = 0.44$), and cardiac-related rehospitalization (33.7% versus 21.5%, $p = 0.06$). Reoperation was nonsignificant between groups (2.5% mechanical versus 6.3% bioprosthesis, with only 2 cases of structural valve degeneration). Follow up mean transprosthetic gradients were higher in the mechanical group (18 ± 6 versus 15 ± 7 mmHg, $p = 0.01$).
Conclusions: Among propensity matched patients there were no differences in survival between groups at 15 years. The mechanical prosthesis presented a trend toward twofold more major adverse cardiovascular complications specially due to major bleeding. Studies with larger sample sizes are needed to confirm these results.

Resultados a 15 años tras sustitución valvular aórtica con bioprótesis o prótesis mecánicas en pacientes de 50 a 65 años con estenosis aórtica severa aislada

Palabras clave:
Sustitución valvular aórtica
Supervivencia a largo plazo
Bioprótesis
Válvulas mecánicas
Puntuación de propensión

RESUMEN

Objetivos: Investigar la supervivencia a largo plazo (15 años) y la morbilidad en pacientes de 50 a 65 años sometidos a reemplazo valvular aórtico aislado con válvulas bioprotésicas o mecánicas.
Métodos: Estudio analítico retrospectivo unicéntrico, de pacientes de 50-65 años con estenosis aórtica severa que se sometieron a cirugía entre 2000-2015 (n = 200). Se obtuvieron 2 grupos, mecánico (n = 117) y biológico (n = 83). Se realiza puntuación de propensión para el análisis final. El objetivo primario fue la supervivencia a largo plazo y como objetivos secundarios las complicaciones cardiovasculares mayores (mortalidad a 30 días, ictus, reintervención protésica y hemorragia grave).
Resultados: La edad media fue 60 ± 4 años, un 33% mujeres. El seguimiento medio fue de $8,2 \pm 3$ años. La supervivencia global fue similar, del 65% a los 15 años (log rank p = 0,71, hazard ratio 0,87 [IC 95%: 0,41-1,82]). Después del pareado las prótesis mecánicas presentaron una tendencia hacia más complicaciones cardiovasculares mayores (30% vs 15%, p = 0,07) con más hemorragias mayores (15% vs 6,3% p = 0,06), ictus (11% vs 7,6%, p = 0,44) y rehospitalización de causa cardíaca (33,7% vs 21,5%, p = 0,06). La

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reintervención no fue significativa entre grupos (2,5% mecánicas vs 6,3% bioprótesis, 2 casos de degeneración valvular estructural). Los gradientes transprotésicos fueron mayores en el grupo mecánico (18 ± 6 vs 15 ± 7 mm Hg, p = 0,01).

Conclusiones: No hubo diferencias en la supervivencia a 15 años. Las prótesis mecánicas presentaron una tendencia al doble de complicaciones mayores, especialmente debido a sangrado mayor. Se necesitan estudios con mayor tamaño muestral para confirmar estos datos.

Introduction

The standard treatment for patients with severe aortic valve disease, aortic valve replacement (AVR), is performed in ∼280,000 patients worldwide every year,[1] and ∼5000 in Spain.[2] Recent 2017 guidelines from the European Society of Cardiology/European Association of Cardiothoracic Surgery (ESC/EACTS) maintain that a bioprosthesis should be considered in patients above 65 years of age.[3] In patients aged between 60 and 65 years, both valve types are considered acceptable options (class IIa indication). According to the recent focused 2017 update American Heart Association/American College of Cardiology (AHA/ACC) guidelines,[4] the choice of prosthetic heart valve should be a shared decision-making process according to patient desire. Below 70 years old, the age range was expanded from age 60–70 to age 50–70 for either a mechanical or bioprosthetic valve choice (class IIa indication).

Recently two great and large observational studies with patients between 50 and 69 years were published with contradictory results after a 15-year follow up. Chiang et al.[5] in an American cohort in 2014, published that bioprosthesis could be considered for patients down to 50 years of age, which is supported by other studies.[6] Glaser et al.,[7] in a Swedish cohort concluded in 2016 that patients aged 50–69 years who received mechanical valves had better long-term survival. The risk of stroke was similar; however, patients with bioprosthesis had a higher risk of reoperation and a lower risk of major bleeding in both studies.

Nevertheless, biologic AVR in patients aged 50–65 years remains controversial,[8] and the expected event rates for both perioperative and long-term valve-related complications have not been clearly determined in this patient subset in a mediterranean population. Our objective was to quantify long term survival (15 years) and major morbidity (rates of stroke, aortic valve reoperation, and major bleeding events) in a group of patients aged 50–65 years undergoing primary isolated aortic valve replacement with bioprosthetic or mechanical valves due to severe aortic stenosis between 2000 and 2015.

Methods

Study design

A single center retrospective analytical study of all patients aged 50–65 years with severe aortic stenosis who underwent primary isolated AVR surgery between 2000 and 2015 was performed. The study was approved by the ethics committee the 27th April 2017 (Comité de Ética de la Investigación Provincial de Málaga, Secretary Gloria Luque). All patients have given informed consent before participation in the study. Exclusion criteria were out-of-state residency, need for concomitant surgery, previous cardiac surgery and infective endocarditis. Two groups, mechanical (M, $n = 117$) and biological (B, $n = 83$) were obtained.

A crude analysis of the data and a posterior paired analysis by propensity score matching with IBM SPSS Statistics 22.0 for Windows (IBM Corp., Armonk, NY, USA) were carried out using a 1:1 "nearest neighbour" matching protocol based on the total number of bioprosthesis, creating a sample size of 166 patients, 83 per group for comparison.

Study endpoints

The primary outcome measure was overall survival. Secondary outcome was a combined endpoint of 4 major adverse cardiovascular events (MACCE): 30-day mortality, stroke, any prosthesis-related reoperation and major bleeding, according. to the Valve Academic Research Consortium 2 (VARC2) definitions.[9]

Preoperative characteristics, deaths and MACCE were identified using the Diraya Health Care medical records software (Servicio Andaluz de Salud, Spain) and the Cardiovascular Surgery Department local database, by searching all hospital admissions and ambulatory or emergency department visits for patient deaths or complications, and confirmed by direct telephone contact with the patient if alive and/or relatives if not.

Patients for whom no stroke, reoperation, or major bleeding event and no date of death were found were censored on December 31, 2016 (last follow-up date).

Echocardiographic data were recorded from same sources, including Cardiology Department local database, using the most recent echocardiogram.

Statistical method

All analysis was performed with the IBM SPSS Statistics 22.0 for Windows software package. Continuous variables are reported as mean ± SD. Categorical variables are expressed as absolute frequencies (n) and proportions (%). Baseline differences between patients receiving bioprosthetic or mechanical prosthetic valves were detected using t test for normally distributed continuous variables and Pearson χ^2 test for categorical variables. In cases where normality cannot be accepted, the corresponding non-parametric test was applied. To adjust for differences in baseline characteristics and selection bias, propensity score matching was performed using by 1:1 nearest neighbor matching protocol without replacement, and a caliper width equal to 0.2 of the SD of the logit of the propensity score. All baseline characteristics (age, sex, logistic EuroScore, body mass index, hypertension, diabetes mellitus, atrial fibrillation, chronic obstructive pulmonary disease, dyslipidemia, previous stroke, previous myocardial infarction, chronic kidney disease, preoperative creatinine value, peripheral arteriopathy, transaortic mean gradients and left ventricular ejection fraction), were included as covariates in the propensity score model.

Kaplan Meier survival curves for the primary end point of survival were constructed for the entire study population as well as the propensity-matched groups. The difference in survival was assessed using the Log-Rank Mantel Cox test and 95% confidence interval hazard ratio was calculated using Cox proportional hazards regression. A sensibility Rosembaum test was performed satisfactorily.