Maria de Almeida Carvalho, Luíza Rodrigues, Sandra de Oliveira Sapori Avelar, Mariana Fernandes, Luciano Rios Scherrer, Fernando Martin Biscione and Silvana Marcia Kelles

Introduction. Severe aortic stenosis with symptoms or left ventricular dysfunction has commonly a poor prognosis and therefore, aortic valve replacement is usually performed for patients aiming at improving their functional class and survival rate.

Methods. This retrospective study evaluated a convenience sample of patients at high risk for open surgery for the correction of aortic valve dysfunction treated with TAVI from 2013 to 2018. Data from a private healthcare organization in Belo Horizonte, Brazil were used to assess all-cause mortality. Continuous variables were expressed as mean and standard deviation. Cox proportional regression model and Log-Rank test were used to adjust the survival curve.

Results. Fifty-two patients were included in the study (mean 83 ± 5.7 years of age, range 67 to 93 years; female 55.8 percent). Patients were characterized by: left ventricular ejection fraction (n = 30; mean 52.9 percent, range 26 to 81 percent); aortic valve area (n = 36; mean 0.68 cm^2, range 0.4 to 1.2 cm^2); left atrium size (n = 14; range 30 to 61 ml/m^2); pulmonary artery pressure (n = 20; mean 53 mmHg, range 31 to 70 mmHg). Death occurred in 19 patients during the follow-up period (mean 8.4 months, range 0 to 60 months). Nine deaths occurred within the first 30 days of follow-up (17.3 percent) and 14 (26.9 percent) in the first year. Stroke occurred in three patients (5.8 percent) in the post-implant period. A pacemaker device was required for nine patients (17.3 percent).

Conclusions. Transcatheter aortic valve implantation (TAVI) has become an alternative to surgical aortic valve replacement for patients at high risk for surgery. Real-world studies might result in a better understanding of the local team expertise on TAVI utilization.

PP58 The Alliance Between Health Technology Assessment And Public Health In National Screening Policies

Leonor Varela-Lema (Avalia-t1@sergas.es), Janet Puñal-Riobóo, Paula Cantero-Muñoz and Maria José Faraldo-Vallés

Introduction. Decision making regarding national population-based prenatal and newborn screening policies is recognized to be highly challenging. This paper aims to describe the formalized collaboration that has been established between the Spanish National Public Health Screening Advisory Committee (PHSAC) and the Spanish Network of Health Technology Assessment (HTA) agencies to support the development of evidence- and consensus-based recommendations to support this process.

Methods. In-depth description and analysis of the strategic and methodological processes that have been implemented within the Spanish National Health System prenatal and newborn screening frameworks, with special emphasis on the role, actions, and responsibilities of HTA agencies.

Results. The role of HTA agencies is threefold: (i) support the PHSAC by providing evidence on safety, effectiveness and cost/effectiveness of the screening tests/strategies, as well as contextualized information regarding costs, organizational, social, legal and ethical issues; (ii) collaborate with the PHSAC in the development of formal evidence- and consensus-based recommendations for defining population screening programs, when required; (iii) analyze real-world data that is generated by piloted programs. This paper will provide real-life examples of how these processes were implemented in practice, with a special focus on the development of the non-invasive prenatal testing (NIPT) policy. Recommendations for NIPT were developed by a multidisciplinary group based on the European network for Health Technology Assessment (EUnetHTA) rapid assessment report and the predictive models that were built using national statistics and other contextualized data.

Conclusions. The current work represents an innovative approach for prenatal and newborn screening policymaking, which are commonly difficult to evaluate due to the low quality of evidence and the confounding public health issues. The paper raises awareness regarding the importance of joint collaborations in areas where evidence is commonly insufficient for decision making.

PP61 Advanced Therapy Medicinal Products Germany: Drugs Or Methods Review?

Elvira Müller, Kurt Neeser and Ilse-Barbara Oelze (ilse-barbara.oelze@certara.com)

Introduction. Advanced Therapy Medicinal Products (ATMPs) comprise medicines for human use based on gene therapy, somatic cell therapy or bioprocessed tissue products. ATMPs are pharmaceutically manufactured drugs and mostly subject to central authorization requirements. In terms of social law, it is an ambiguous situation and more heterogeneously dealt with. ATMPs are assigned to method evaluation as well as to the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) procedure designated for drugs.

Methods. Guidelines from Gemeinsame Bundesausschuss (G-BA), Institute for Quality and Efficiency in Health Care (IQWiG) and respective legislation, consultation results and methods/medical devices (MDs) evaluations according to §137h and for drugs according to AMNOG were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

Results. ATMPs are subject to benefit assessment, with a decision at first on whether to be evaluated as a drug (e.g., Alofisel) or a method/device (e.g., Holoclar). By definition, an ATMP is classified as a treatment method, if the correct administration has at least the same significance for a successful therapy outcome as its mode of action. Depending on the respective decision, an evaluation as method follows or it must undergo the AMNOG

https://doi.org/10.1017/S0266462319002113 Published online by Cambridge University Press