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Local and general anaesthesia do not influence outcome of transfemoral aortic valve implantation

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ABSTRACT

Background: There is great variability for the type of anaesthesia used during TAVI, with no clear consensus coming from comparative studies or guidelines. We sought to detect regional differences in the anaesthetic management of patients undergoing transcatheter aortic valve implantation (TAVI) in Europe and to evaluate the relationship between type of anaesthesia and in-hospital and 1 year outcome.
Methods: Between January 2011 and May 2012 the Sentinel European TAVI Pilot Registry enrolled 2807 patients treated via a transfemoral approach using either local (LA-group, 1095 patients, 39%) or general anaesthesia (GA-group, 1712 patients, 61%).
Results: A wide variation in LA use was evident amongst the 10 participating countries. The use of LA has increased over time (from a mean of 37.5% of procedures in the first year, to 57% in last 6 months, $p < 0.01$). MI, major stroke as well as in-hospital death rate (7.0% LA vs 5.3% GA, $p = 0.053$) had a similar incidence between groups, confirmed in multivariate regression analysis after adjusting for confounders. Dividing our population in tertiles according to the Log-EuroSCORE we found similar mortality under LA, whilst mortality was higher in the highest risk tertile under GA. Survival at 1 year, compared by Kaplan–Meier analysis, was similar between groups (log-rank: $p = 0.1505$).
Conclusions: Selection of anaesthesia appears to be more influenced by national practice and operator preference than patient characteristics. In the absence of an observed difference in outcomes for either approach, there is no compelling argument to suggest that operators and centres should change their anaesthetic practice.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is widely used to treat patients with severe symptomatic aortic stenosis (AS) who are inoperable or at high surgical risk [1,2]. Candidates for TAVI are generally characterized by a combination of old age, left ventricular dysfunction and comorbidities such as coronary artery disease (CAD), neurological disorders, chronic obstructive pulmonary disease (COPD) and renal dysfunction [3–6]. Frailty affects about one fifth of elderly patients and correlates with outcome after coronary artery bypass grafting (CABG), valve surgery or TAVI [7–9]. General anaesthesia is part of the overall risk of aortic valve implantation (AVR) [10]. With transcatheter approaches, a logical step to reduce the invasiveness of the procedure is to perform it under local anaesthesia [11].

In the first report from the European TransCatheter Valve Treatment-(TCVT) Sentinel Pilot Registry marked national differences in the anaesthetic management of patients receiving TAVI were observed [12]. This is mainly due to the lack of a general consensus or evidence for superiority for either general anaesthesia (GA) or local anaesthesia/conscious sedation (LA/CS) [13,14]. In this study we sought to correlate type of anaesthesia with clinical and peri-procedural characteristics, in-hospital and late outcome in a large patient population from a multinational registry.

2. Methods

2.1. Study design, enrolment criteria and definitions

The TCVT-Registry enrolled 4571 patients who underwent TAVI between January 2011 and May 2012 in 137 centres in 10 European countries. Registry design, eligibility criteria, study devices and endpoints have been described elsewhere [12].

The national Cardiology Societies collaborated for suitable centre selection. Ten national coordinators, members of the Registry Steering Committee, in conjunction with the local investigators, obtained for each centre the approval of the Ethics Committee and/or national review boards for this survey. Data were collected via web-based CRFs or electronic transfer of a national database, subsequently cleaned through generated queries managed by the Heart House of the European Society of Cardiology. Whenever possible and consistent with the practice of existing databases, the Valve Academic Research Consortium definitions were applied [15]. The registry collected all consecutive patients who underwent TAVI in the participating centres after providing written informed consent for the procedure and data processing. This study has been performed according to the ethical guidelines of the Declaration of Helsinki.

Two CE-approved devices were available: the Sapien-XT (Edwards Lifesciences Inc., Irvine, CA, USA) and the CoreValve (Medtronic Inc., Minneapolis, MN, USA). We excluded procedures implanted via a transapical and direct/trans-aortic route because these approaches are almost exclusively performed under GA, as well as those via a trans-subclavian access, more often under GA. In our subgroup analysis we only included the percutaneous femoral or surgical retroperitoneal iliac approaches. Closure devices (Prostar Percutaneous Vascular Surgical System, or two Perclose ProGlide Suture-Mediated Closure System, Abbott Vascular, Santa Clara, CA, USA) with the help of controlled hypotension or of a contralateral cross-over balloon were frequently used.

Data from published single centre experiences shows that GA usually consists of a combination of an anaesthetic agent, an opioid and sometimes a muscle relaxant, whilst LA/CS is given by a 1% Lidocaine (or equivalent) subcutaneous injection at the vascular access site, along with a target-controlled intravenous infusion of an anaesthetic or opioid [16,17].

2.2. Aims

The aims of this study are to detect regional differences in the anaesthetic management of patients undergoing transfemoral TAVI in Europe and to evaluate the relationship between type of anaesthesia and baseline characteristics, procedural features, peri-implantation results, in-hospital and 1 year outcome in a high risk population with severe aortic valve stenosis.

2.3. Statistical analysis

Univariate analysis was applied to both continuous and categorical variables. Continuous variables are reported as mean ± standard deviation and compared using the Kruskal–Wallis test. Categorical variables are presented as absolute number and percentage and their comparisons are performed by the X^2 test or Fisher's exact test if any expected cell count was less than five. Significant variables were included in a multivariate regression analysis to explore whether mortality rate could have been biassed by baseline differences, after running a multiple input procedure needed to overcome the limitation caused by missing data. Rubin's multiple imputation procedure replaces each missing value with a set of plausible values, then analysed by using standard procedures for complete data and combining the results from these analyses, using the programme R (http://www.R-project.org/.) [18] and the package Hmisc (http://CRAN.R-project.org/package=Hmisc) [19]. We planned to evaluate relationship between anaesthesia and in-hospital mortality according to patients' risk profile assessed by tertiles of Logistic EuroSCORE (the lowest risk group defined as a Log-EuroSCOREs <10.4%, the intermediate between 10.4 and 25.6%, and the higher >25.6%). Survival curves were calculated and represented by Kaplan–Meier analysis. A two-tailed P value <0.05 was considered statistically significant.

3. Results

Of 4571 patients enrolled in the pilot TCVT registry, 3390 (74%) underwent transfemoral TAVI. We excluded 583 patients with incomplete anaesthesia data, obtaining a study population of 2807 patients, subsequently divided according to management strategy into the LA/CS-group (1095 patients, 39%) and the GA-group (1712 patients, 61%).

Wide variation in LA/CS use was evident amongst the 10 European countries. Fig. 1 shows such variation ranging from more than 50% of LA/CS in Italy and Switzerland to less than 15% in Poland and 1% in the UK. Comparing types of anaesthesia over time, we found a higher initial use of GA with progressive adoption of LA/CS as time passed and operator experience increased (Fig. 2).