International Journal of Cardiology 177 (2014) 448–454

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

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

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http://dx.doi.org/10.1016/j.ijcard.2014.09.025

ARTICLE INFO

Article history:
Received 18 June 2014
Accepted 16 September 2014
Available online 28 September 2014

Keywords:
Anaesthesia
Transcatheter aortic valve implantation
Aortic valve stenosis
Outcome

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).

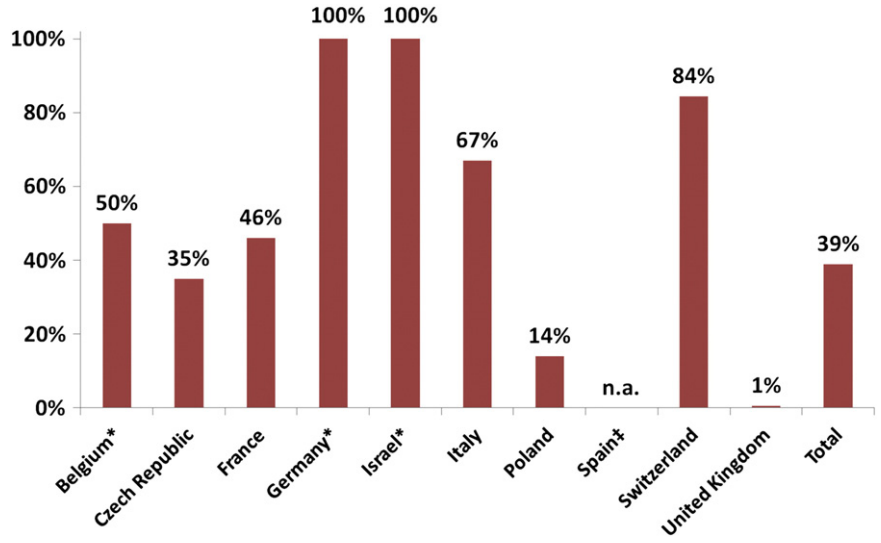

Fig. 1. Local anaesthesia use in the participating European countries. Asterisks indicate the three countries (Belgium, Germany and Israel) where the number of patients and centres was insufficient to be representative of national practice in the study period. Data from Spain are not available.

3.1. Patient characteristics

Baseline characteristics are reported in Table 1. Patients treated under LA/CS were older and more often suffered from hypertension than patients receiving GA. The latter group had higher Log-EuroSCORE, more patients on renal replacement therapy (hemodialysis) and in NYHA functional class III–IV at presentation. The prevalence of previous myocardial infarction (MI), percutaneous coronary intervention (PCI), previous CABG and burden of CAD was also significantly higher in patients treated under GA. Patients in the LA/CS-group had less neurological disorders, reported as a composite of TIA/stroke and dementia. GA was the preferred management strategy in urgent/emergency procedures.

3.2. Echocardiographic evaluation

Table 2 summarizes echocardiographic data. Baseline parameters were similar between groups, with the exception of those few patients with pre-TAVI moderate/severe aortic regurgitation who were more often treated using LA/CS.

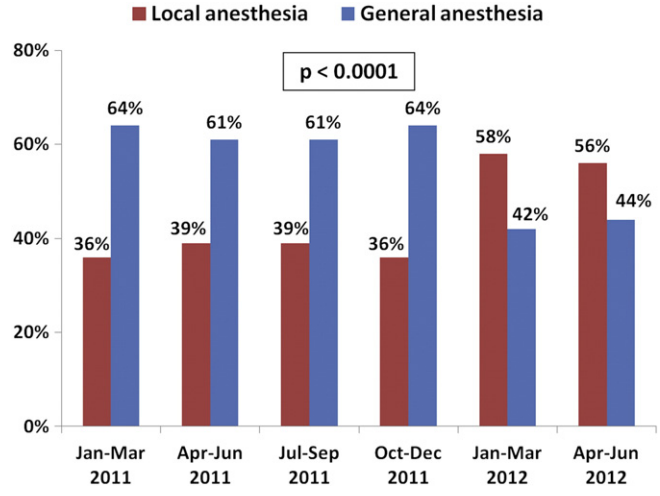

Fig. 2. Anaesthetic practice over time. Population grouped every three month. Percentages are absolute values in each period.

3.3. Procedural results

Table 3 displays procedural data. Patients treated under LA/CS received a CoreValve or Edwards Sapien-XT prosthesis in equal number (50%), whilst in the GA group the Sapien-XT valve was implanted in 54% of cases.

Longer total procedure and fluoroscopy times were seen with GA. Elective surgical vascular closure and transoesophageal echo (TOE) were rarely used in patients under LA/CS. In this series, the immediate procedural success rate was higher in the GA-group, whilst the incidence of peri-procedural complications (i.e. permanent pacemaker implantation [PM], cardiac tamponade and bailout PCI) was significantly lower.

3.4. In-hospital and 1 year outcome

Duration of hospital stay was shorter in the LA/CS-group (Table 4). Despite patients treated under LA/CS were more often diagnosed with acute kidney injury, a requirement for transient or permanent renal replacement therapy was more frequent in the GA-group.

MI and major stroke were equivalent between groups. In-hospital death rate was numerically higher in the LA/CS-group; however this difference was not significant (7.0% vs 5.3% for GA, $p = 0.053$). A multivariate logistic regression analysis adjusted by baseline characteristics confirmed that the type of anaesthesia was not independently associated with in-hospital mortality (OR 1.25; 95% C.I. 0.90–1.74).

When comparing in-hospital outcome according to risk profile and type of anaesthesia, we did not find a significant difference between tertiles under LA/CS; however in those patients treated with GA the clinical outcomes were worse in the high risk group (Fig. 3).

One year follow-up was available in 2574 patients (91.7%), whilst data were missing in 126 patients of the LA/CS-group (11.5%) and in 107 of the GA-group (6.3%). Kaplan–Meier curves (Fig. 4) showed a similar 1 year survival (log-rank: $p = 0.1505$).

Out of 583 initially excluded patients due to incomplete anaesthesia data, at 1 year 404 were alive, 83 patients were dead, and 96 patients were lost to follow-up.

4. Discussion

This substudy of a large, multinational registry, independent of industry sponsorship, depicts the contemporary anaesthetic practice in patients receiving TAVI. We focus on the transfemoral approach

Table 1
Baseline clinical characteristics.

Variable	Total $n = 2807$	Local anaesthesia $n = 1095$ (39%)	General anaesthesia $n = 1712$ (61%)	p
Age, years	81.7 ± 8.0	82.5 ± 7.0	81.4 ± 7.1	<0.01
Age > 80	1831 (65.2)	761 (69.5)	1070 (62.5)	<0.01
Male	1331 (47.4)	498 (45.5)	833 (48.7)	0.10
Height, cm	162.7 ± 9.2	163.1 ± 8.7	163.7 ± 9.3	0.11
Weight, kg	70.8 ± 14.8	69.9 ± 14.2	71.5 ± 15.5	0.02
BMI, kg/m^2	26.7 ± 5.0	26.2 ± 4.9	26.5 ± 5.0	0.18
BMI > 30 kg/m^2	489 (17.6)	187 (16.9)	467 (18.1)	0.53
Diabetes mellitus	706 (25.3)	278 (25.5)	428 (25.1)	0.80
Hypertension	1629 (72.5)	813 (74.7)	816 (70.4)	0.02
Former smoker	388 (14.6)	69 (6.9)	319 (19.2)	<0.01
COPD	706 (25.3)	259 (23.8)	447 (26.3)	0.14
NYHA I-II	603 (21.6)	261 (24.0)	342 (20.1)	0.02
NYHA III–IV	2189 (78.4)	828 (76.0)	1361 (79.9)	
Logistic EuroSCORE, %	19.6 ± 13.0	19.7 ± 12.9	20.9 ± 13.8	0.03
Creatinine, mg/dl	1.2 ± 0.7	1.2 ± 0.6	1.3 ± 0.8	0.27
GFR < 60 ml/min	288 (65.6)	74 (60.9)	77 (69.2)	0.07
Dialysis	163 (6.9)	5 (0.5)	158 (12.2)	<0.01
Significant CAD	407 (20.8)	75 (11.2)	332 (25.8)	<0.01
Previous MI	451 (16.1)	139 (12.7)	312 (18.3)	<0.01
Previous PCI	221 (19.0)	52 (15.4)	169 (20.5)	0.046
Previous CABG	455 (16.4)	134 (12.4)	321 (19.0)	<0.01
Previous valve intervention	73 (7.1)	23 (9.5)	50 (6.3)	0.09
Atrial fibrillation/flutter	419 (20.1)	221 (21.6)	198 (18.7)	0.10
Previous neurological disease	332 (11.9)	109 (9.6)	367 (13.3)	<0.01
Elective procedure	1073 (92.3)	331 (98.2)	742 (89.8)	<0.01
Urgent/emergency procedure	90 (7.7)	6 (1.8)	84 (10.2)	

Continuous variables are expressed as mean ± SD; categorical variables as number (%). BMI: body mass index; CABG: coronary artery bypass graft; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; EF: ejection fraction; GFR: glomerular filtration rate; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention.

Table 2
Echocardiographic data.

Variable	Total $n = 2807$	Local anaesthesia $n = 1095$ (39%)	General anaesthesia $n = 1712$ (61%)	p
Pre Aortic valve area, cm^2	0.7 ± 0.3	0.7 ± 0.3	0.7 ± 0.3	0.53
Pre aortic mean gradient, mm Hg	49.5 ± 16.5	49.5 ± 16.7	49.3 ± 16.9	0.71
Pre LVEF, %	54.1 ± 13.9	53.5 ± 14.3	53.4 ± 13.5	0.74
Pre AR grade: no/mild	1698 (81.2)	788 (79.5)	910 (82.7)	<0.01
Pre AR grade: moderate/severe	393 (18.8)	203 (20.5)	190 (17.3)	
Pre PAP > 60 mm Hg	178 (11.3)	97 (12.4)	81 (10.2)	0.17
Post aortic mean gradient, mm Hg	11.3 ± 8.1	11.8 ± 9.1	10.9 ± 7.3	0.04
Post AR grade: no/mild	1902 (98.4)	877 (98.3)	1025 (98.5)	<0.01
Post AR grade: moderate/severe	31 (1.6)	15 (1.7)	16 (1.5)	

Continuous variables are expressed as mean ± SD; categorical variables as number (%). AR: aortic regurgitation; LVEF: left ventricle ejection fraction; PAP: pulmonary artery pressure.

Table 3
Procedural data.

Variable	Total $n = 2807$	Local anaesthesia $n = 1095$ (39%)	General anaesthesia $n = 1712$ (61%)	p
Edwards SapienXT	1462 (52.4)	547 (50.0)	915 (54.0)	0.04
Medtronic CoreValve	1327 (47.6)	546 (50.0)	781 (46.0)	
Total procedural time, min	112.2 ± 51.4	87.9 ± 44.2	139.1 ± 53.4	<0.01
Total fluoroscopy time, min	27.3 ± 20.8	23.0 ± 11.9	34.5 ± 28.9	<0.01
TOE	1513 (56.1)	109 (10.9)	1404 (82.8)	<0.01
Manual pressure	75 (2.8)	19 (1.9)	56 (3.3)	<0.01
Surgical closure elective	681 (25.3)	62 (6.2)	619 (36.7)	
Surgical closure bailout	5 (0.2)	5 (0.5)	0 (0.0)	
Device closure	1929 (71.7)	915 (91.4)	1014 (60.0)	
New-onset atrial fibrillation	107 (5.0)	45 (4.3)	62 (5.7)	0.14
Permanent PM implantation	373 (14.2)	179 (17.9)	194 (12.0)	<0.01
Cardiac tamponade	71 (2.6)	35 (3.5)	36 (2.1)	0.03
Cardiogenic shock	15 (1.4)	3 (1.2)	12 (1.5)	0.99
Bailout PCI	8 (0.8)	5 (2.1)	3 (0.4)	0.02
Conversion to surgery	159 (5.7)	69 (6.3)	90 (5.3)	0.24
Procedural success	2632 (97.6)	970 (96.7)	1662 (98.1)	0.03

Continuous variables are expressed as mean ± SD; categorical variables as number (%). PCI: percutaneous coronary intervention; PM: pacemaker; TOE: transoesophageal echocardiography.

Table 4
Outcome data.

Variable	Total $n = 2807$	Local anaesthesia $n = 1095$ (39%)	General anaesthesia $n = 1712$ (61%)	p
Hospital stay, days	9.2 ± 16.4	7.9 ± 6.2	9.8 ± 14.4	<0.01
RBC transfusions	401 (14.8)	153 (15.0)	248 (14.6)	0.80
Bleeding	93 (4.3)	52 (5.1)	41 (3.6)	0.08
Vascular complication requiring surgery	28 (3.0)	4 (2.0)	24 (3.3)	0.34
Acute kidney injury	75 (3.5)	44 (4.4)	31 (2.7)	0.04
New haemofiltration or dialysis	33 (1.2)	6 (0.6)	27 (1.6)	0.02
Second valve implanted	63 (2.3)	19 (1.9)	44 (2.6)	0.24
In-hospital myocardial infarction	6 (1.5)	2 (1.0)	4 (2.1)	0.43
In-hospital major stroke	41 (1.5)	15 (1.5)	26 (1.5)	0.93
In-hospital death	167 (6.0)	77 (7.0)	90 (5.3)	0.053

Continuous variables are expressed as mean ± SD; categorical variables as number (%). RBC: red blood cells.

where both GA and LA/CS are accepted. Both approaches have advantages and drawbacks and our results suggest that selection is more often influenced by national practice and preference of operators and anaesthetists than patient characteristics. The wide variation observed amongst countries can be explained by the variable composition of the operating team. Whilst everybody recommends the full involvement of the Heart Team in all TAVI procedures, there are countries and centres where surgeons and cardiologists scrub for all procedures independently of the access route. In other centres surgeons are directly performing procedures with surgical access. For percutaneous transfemoral procedures, surgeons remain stand-by ready to treat vascular or cardiac emergencies or for the rare need of surgical conversion. Cardiologists supported by innovative anaesthetists have pioneered this approach working under LA/CS, probably initially prompted by the needs of few patients with important contraindications to endotracheal intubation. This interpretation, with cardiologists used to work in conscious and cardiac surgeons used to GA, is confirmed by the higher rate of elective surgical femoral closure in the GA-group.

Complete information on individual centre policy and selection criteria is not available but the similarity in patient characteristics between the two groups suggests that the observed differences of penetration of the two strategies might be driven by different predetermined policies rather than by different patient selection for TAVI. In fact, the differences observed between the groups appear influenced by the inclusion patterns in countries with a prevalent use of either LA/CS (Italy, France, Switzerland) or GA (UK, Poland, Spain) [20]. It is otherwise counterintuitive that patients receiving GA had worse baseline clinical profiles, higher Log-EuroSCOREs, NYHA functional class, and a greater incidence of pre-existing hemodialysis, neurological disease and history of MI, PCI or CABG. The only patient-based characteristic consistently associated with GA management is the need for urgent/emergency procedures, a very rare event for this procedure. The relative absence of patient-based selection criteria is, in our view, a strength rather than a limitation in this comparison of differences, which are more likely to be driven by type of anaesthesia than by confounders.

The main message is that there is no significant difference between the two groups either with regard to in-hospital mortality, confirmed after adjusting for confounders in multivariate regression analysis, or 1-year mortality. It appears that modern GA, when administered by dedicated cardiac anaesthetists familiar with the frailty and comorbidities of this high-risk population, is not associated with a significant difference in the overall outcomes. Data from previous studies reporting single centre experience suggests that during the "learning curve" of their TAVI experience operators preferred GA [21–25], helping to maintain patient immobility and control respiratory excursion and allowing monitoring with TOE. More recently there is a trend towards the more liberal use of LA/CS for transfemoral TAVI which may be driven by organizational changes rather than by extension of TAVI into higher risk patient groups with absolute contraindications to GA (Figs. 1 and 3).

The equivalence observed in this study in the incidence of MI and major stroke, in-hospital and long term mortality is consistent with most previous studies [13,16,26] with the exception of Tamburino et al. who reported a higher absolute late mortality in the GA-group on univariate analysis. This study was limited to a small population (663 patients), used a single valve type (CoreValve), in one country (Italy) early in the centres' experience (2007–2009). In fact, multivariate analysis didn't show mode of anaesthesia to remain a predictor of mortality [27]. A recent meta-analysis by Fröhlich et al confirmed

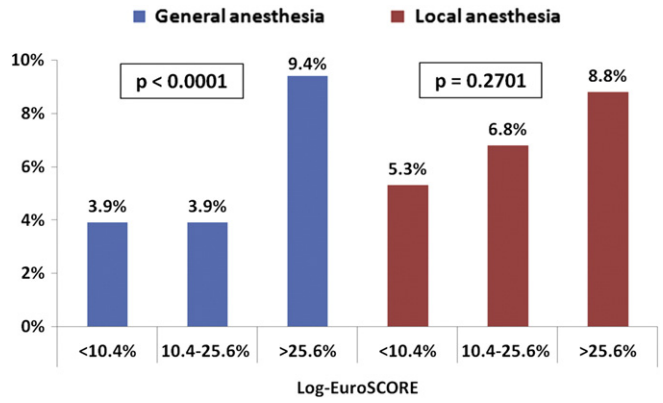

Fig. 3. In-hospital mortality according to anaesthetic management and patients predicted risk. Population divided by tertiles of Log-EuroSCORE (details in "Statistical analysis"). In the GA-group, in-hospital mortality rate was significantly higher in the high-risk tertile.

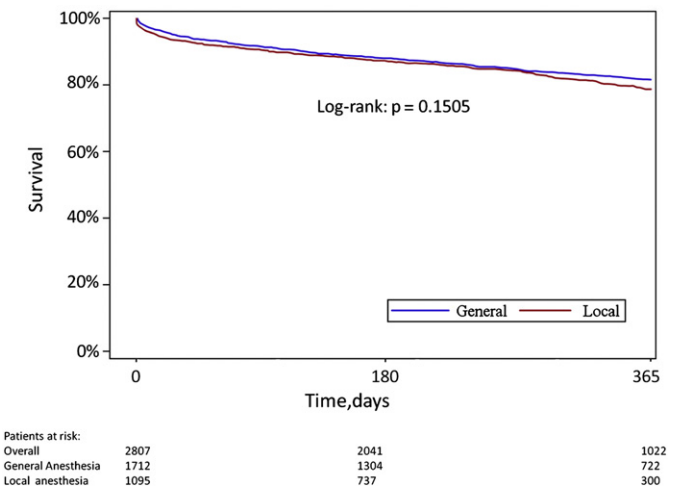

Fig. 4. Kaplan–Meier curves showing 1 year follow-up survival, comparing LA/CS and GA. No difference in survival rate was found between groups at 1 year. The number of patients at risk is reported at days 0, 180 and 365.

the absence of differences in terms of procedure-related and 30-day mortality, stroke and MI rate, between LA/CS and GA [28].

Analysing our population according to predicted surgical risk, LA/CS did not influence clinical outcome, whereas higher mortality was observed in the high Log-EuroSCORE tertile under GA (Fig. 3). Although GA appears technically feasible and safe in the majority of patients undergoing TAVI, this observation may challenge the universal use of GA in very high-risk patients and appears to be in line with data from the EUROSTAR registry, where patients treated by endovascular aortic repair for abdominal aortic aneurysms benefited from loco-regional anaesthesia rather than GA with a reduction in both cardiac and pulmonary complications. In the high-risk group, patients treated with LA had lower mortality [29]. It is not appropriate to suggest that our findings coming from an observational study should alter current practice in the management of high-risk TAVI patients. To support such a change requires a randomized trial to demonstrate the possible superiority of LA/CS.

With GA you may expect a higher rate of renal complications [10], and we have found a slight, but significant increase in patients requiring renal replacement therapy post-TAVI. Kidney injury after TAVI is multifactorial with the use of nephrotoxic contrast dye, debris embolisation during valvuloplasty and valve deployment, hypotensive episodes sometimes triggered by anaesthetic agents but also by rapid right ventricular pacing, along with multiple predisposing factors such as diabetes, hypertension and pre-existing renal impairment [14]. Conversely, you may expect that patients receiving a GA would benefit from greater patient and operator comfort and therefore more accurate valve positioning, resulting in a lower incidence of PM implantation and paravalvular leaks. Patient immobility, greater flexibility in the manipulation of patient haemodynamics and respiration and information acquired from TOE may also reduce the incidence of complications.

Pacemaker implantation is known to be influenced by many factors, starting from the type of valve with self-expanding valves associated to greater incidence [14,30]. In this study the balloon expandable valve was less frequently used in the LA/CS-group where a significantly higher PM implantation rate was observed. Anyway, geographical inequalities in anaesthetic management may have skewed patients receiving LA/CS towards countries more aggressive in their policy of post-TAVI PM implantation.

Patients with GA frequently benefited from the concomitant use of TOE (80%). There is consensus that TOE is no longer mandatory during TAVI. For prosthesis sizing echocardiography has largely been superseded by multislice computed tomography and 3D-TOE, whilst TOE remains of limited value in the critical phase of valve deployment, when the probe interferes with fluoroscopic imaging and the use of a pigtail catheter as a landmark and timely injections of contrast dye can be sufficient [31]. TOE remains, however, a useful tool for the immediate assessment of prosthesis deployment, identifying paravalvular leaks, interference with mitral valve function, and early evidence of cardiac tamponade, thus enabling a prompt treatment [32].

Total procedural and fluoroscopy times were longer under GA and it could be argued that a difference of more than 50 min in favour of LA/CS per procedure will save catheter lab time and reduce the time operators are involved thereby allowing greater overall productivity. In the GA-group the duration of hospital stay was almost 2 days longer, a difference which is statistically but also clinically and economically relevant, especially if we consider that patients treated under GA may be required to stay more often and longer in Intensive Therapy Unit post-procedure. In an elderly population the importance of rapid recovery and early mobilization cannot be sufficiently emphasized [33].

4.1. Limitations

This study is not a randomized trial but represents the retrospective analysis of registry data. We cannot therefore exclude bias due to unmeasured confounding variables. Very frail patients with absolute contraindications to GA may increase the risk of the LA-group but this also benefits from low risk individuals for whom the fastest and simplest LA procedure was adopted. In reality, only few centres and countries made this distinction as they seem to apply their preferred strategy (GA or LA) to most of the patients they treated. Another limitation is the lack of data documenting anaesthetic conversion from LA/CS to GA in cases of intra-procedural complications, with these cases likely to mitigate the real correlation between management and outcome. Alternatives in anaesthetic practice, blurring the boundaries between the two approaches, have not been recorded, such as epidural anaesthesia or ilioinguinal/iliohypogastric nerve blockage for transfemoral route [13,32,34].

Participation in this European registry comes from referral of suitable centres by national Cardiology Societies and national coordinators. Hence, some countries are represented by almost an entire national registry whilst other countries are represented by one or few high-volume centres (on-line Appendix).

4.2. Clinical implications

In the absence of mortality differences, the clinical implications of this study are open to contrasting interpretation. On one side, as GA is not associated with additional risk in the overall population, some investigators may conclude that its use should be continued because it makes the procedure more predictable and patient and operator-friendly. On the other hand, other investigators may argue that LA/CS should be favoured as this approach is associated with lower procedure and fluoroscopy duration as well as hospital stay, moreover in consideration of few but encouraging data coming from the population at highest risk, such as patients with high frailty score, those with COPD or high expected rate of respiratory or renal complications.

4.3. Conclusion

GA and LA were not associated with differences in mortality in patients undergoing TAVI procedures. In the absence of conclusive evidence favouring either approach, this observational study has found no compelling argument to persuade operators to change their current anaesthetic practice.

Funding sources

At the time of the registry, the following companies were supporting the EURObservational Research Programme: GOLD: Abott Vascular, Bayer Pharma, Bristol Myers Squibb (BMS), Pfizer, Boehringer Ingelheim, Daiichi Sankyo Europe, Menarini international Operations, Novartis Pharma, Sanofi-Aventis, Servier International. SILVER: Amgen. BRONZE: Boston Scientific International, Merck & Co. (MSD).

Sponsor had no role in study design, in collection, analysis and interpretation of data, in writing the article.

Disclosures

C. Di Mario has been sponsored by Edwards Lifesciences and Medtronic to participate in courses in Nyon and Tolochenaz as part of the mandatory certification process for the implantation of Sapien and CoreValves. He also receives speakers' fees, grants for clinical trials and sponsorship for the organization of congresses and courses from Medtronic UK and Medtronic Vascular Europe. E. Eltchaninoff receives Proctor fees from Edwards Lifesciences. N. Moat receives lecture fees from Medtronic. G.P. Ussia received Proctorship fees from both Medtronic and Edwards Lifesciences. P. Wenaweser receives lecture, Proctor and Consultant fees from Medtronic and Edwards Lifesciences. G. Nickenig receives lecture fees from Medtronic. B. Iung has received consultant fees from Abbott, Boehringer Ingelheim, Valtech, and speaker's fees from Edwards Lifesciences. B. Prendergast received

speakers' fee from Edwards Lifesciences. S. Windecker received lecture, Proctor and Consultant fees from Medtronic and Edwards Lifesciences. L. Tavazzi receives Consultant fees and/or Committee membership Fees from Servier, St. Jude Medical, Boston Scientific, Vifor Pharma, Cardiorentis and CVIE Therapeutics. The other authors have no conflicts of interest to declare.

Acknowledgements

Data collection was conducted by the EurObservational Research Programme department of the European Society of Cardiology by Gerard Gracia, statistical analyses were performed by Cécile Laroche with the support of Renato Urso, and overall activities were coordinated by Aldo Maggioni, Scientific coordinator EORP, and Thierry Ferreira, Head of Department EORP.

Appendix A. Supplementary data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ijcard.2014.09.025.

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