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ORIGINAL RESEARCH

Factors associated with early cardiac complications following transcatheter aortic valve implantation with transapical approach

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Vasileios Patris[1]
Konstantinos Giakoumidakis[1]
Mihalis Argiriou[1]
Katerina K Naka[2]
Efstratios Apostolakis[3]
Mark Field[4]
Manoj Kuduvalli[4]
Aung Oo[4]
Stavros Siminelakis[3]

[1]Department of Cardiac Surgery, "Evangelismos" General Hospital of Athens, Athens, Greece; [2]Department of Cardiology, Medical School, University of Ioannina, Ioannina, Greece; [3]Department of Cardiothoracic Surgery, University of Ioannina, Ioannina, Greece; [4]Department of Cardiothoracic Surgery, Heart and Chest Hospital of Liverpool, Liverpool, UK

Purpose: To estimate the incidence of postprocedural early cardiac complications among patients undergoing transcatheter aortic valve implantation, through transapical approach (TA-TAVI), and to identify factors independently associated with the occurrence of them.

Patients and methods: A retrospective cohort study of 90 patients, who had undergone TA-TAVI in a tertiary hospital of Liverpool, UK, during a 5-year period (September 2008–October 2013), was conducted. Data on patient demographics, periprocedural characteristics and cardiac complications presented within 30-day post TA-TAVI were collected, retrospectively, using the hospital's electronic database.

Results: The overall 30-day incidence of cardiac complications was estimated at 18.9% (n=17/90). The rate of new onset of atrial fibrillation (AF), atrioventricular block requiring permanent pacemaker implantation, shockable cardiac arrest rhythm and cardiac tamponade was 11.1%, 3.3%, 2.2% and 2.2%, respectively. Bivariate analysis found that absence of preoperative AF (p=0.01), receiving of oral inotropes preprocedurally (p=0.01), intravenous inotropic support postprocedurally (p=0.01) and requirement for postprocedural tracheal intubation (p=0.001) were the main factors associated with increased probability for patient cardiac morbidity.

Conclusion: It seems that patients with absence of AF and oral inotropic support preprocedurally and those with post TA-TAVI mechanical ventilatory and intravenous inotropic support have greater probability to develop cardiac complications. This knowledge allows the early identification of high-risk patients and supports clinicians to apply both preventive and therapeutic interventions for the optimum patient management and care. In addition, administrators could allocate the health care system resources effectively.

Keywords: aortic valve stenosis, complications, retrospective studies, transcatheter aortic valve replacement

Introduction

Transcatheter aortic valve implantation (TAVI) is a well-documented, through high-quality randomized controlled trials, therapeutic option for patients with symptomatic aortic stenosis,[1] consisting not only the treatment of choice for inoperable patients[2] but also a feasible alternative to surgery in patients at high[1] and intermediate surgical risk.[3,4]

It is estimated that during the 3-year period (2011–2014), more than 26,000 TAVI procedures had been performed at 348 centers in the USA with satisfactory patient outcomes.[5] However, despite the high safety and effectiveness of TAVI procedure in appropriately selected patients groups,[6] this therapeutic option has several periprocedural complications, including stroke, bleeding, vascular complications, acute kidney injury, requirement for permanent pacemaker (PPM) implantation, myocardial

Correspondence: Konstantinos Giakoumidakis
Department of Cardiac Surgery, "Evangelismos" General Hospital of Athens, 45-47 Ipsilantou Street, Athens 10676, Greece
Tel +30 697 379 3489
Fax +30 213 204 1987
Email kongiakoumidakis@gmail.com

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infarction, valve malposition, paravalvular leak and heart block.[7,8] In the currently available published research, several patient and technical-related factors have been associated with postprocedural complications such as advanced age, female gender, diabetes mellitus, poor left ventricular ejection fraction, peripheral arterial disease, access route, size of the delivery system, history of stroke, prior and/or a new-onset atrial fibrillation (NOAF), baseline severe aortic regurgitation, severity of calcifications on the valve and the aortic arch.[7,9]

The literature review reveals that TAVI complications have mainly evaluated as risk factors for patient mortality in several patient series,[10–13] and few are known to regard the periprocedural factors independently associated with TAVI complications, which could allow the early identification of patients at high risk for morbidity after TAVI. Moreover, this literature deficit is more apparent among those receiving TAVI through the transapical access, a patient subgroup with poorer outcome, compared with the most widely used and first choice approach, the transfemoral one.[6,9,14] The purpose of the present study was to investigate the periprocedural parameters associated with early cardiac complications in patients after TAVI procedure through the transapical approach. Our study intents to contribute new data to TAVI complications prognosis limited body of knowledge in this specific transapically treated patients' subgroup.

Patients and methods

Study design and participants

We carried out a retrospective cohort study of 90 consecutive patients with severe aortic valve disease, who were admitted to a cardiothoracic surgery center of Liverpool, UK, for TAVI procedure, through a transapical approach, under general anesthesia, during a 5-year period (September 2008–October 2013). All patients were implanted with the Edwards SAPIEN-XT valve (Edwards Lifesciences Inc., Irvine, CA, USA). On the basis of our a-priori set study inclusion criteria, our sample included only patients with successful valve implantation, without requirement for conversion of TAVI procedure to an open surgical aortic valve replacement. Conversion to surgery was necessary in 1 patient, due to pericardial tamponade.

Data collection

Data collection was performed in November 2014, using the hospital's structured database (e-cardiac), which included demographic and periprocedural patient data. Specifically, patients' age, gender, weight, height, logistic EuroSCORE, comorbidity (diabetes mellitus, chronic renal insufficiency and hypercholesterolemia), cardiac patient history (Q wave myocardial infarction, previous cardiac surgery, preoperative coronary angiography, preoperative cardiac rhythm, oral inotropes and left ventricular ejection fraction), smoking status, preoperative serum creatinine (Cr) levels, duration of both the postprocedural tracheal intubation and the postprocedural intravenous inotropic support, postprocedural volume of blood loss and postprocedural cardiovascular complications occurred within 30 days post valve implantation.

We recorded the 30-day cardiac morbidity post TAVI, considering the following end points as cardiac complications: new atrioventricular block requiring PPM implantation, NOAF, cardiac arrest rhythms, including pulseless ventricular tachycardia (VT) and/or ventricular fibrillation (VF) and cardiac tamponade diagnosed echocardiography when patient condition allows or by emergency mediastinal re-exploration when patient hemodynamics were very tenuous. We considered NOAF as the occurrence of AF in patients who had sinus rhythm preprocedurally. Finally, we defined as postprocedural tracheal intubation the invasive patient ventilatory support through an endotracheal tube after TAVI procedure completion.

Statistical analysis

We presented continuous variables as median and interquartile range, while categorical variables are depicted as numbers and percentages. Continuous variables were converted into binary variables using their median values as the criterion for separation (cut-off point). However, for body mass index and serum Cr levels the relevant cut-off points were the values of 24.9 kg/m^2 and 1.4 mg/dL, respectively.[15] Chi square test, Fisher's exact test, chi square trend test and student's *t*-test were performed for bivariate associations and p-values <0.01 were defined as significant, aiming to reduce error type I. The IBM SPSS 21.0 for Windows software (IBM Corporation, Armonk, NY, USA) was used for our statistical analysis purposes.

Ethics

Taking into account our study design and methods (retrospective observational study, with no randomization and therapeutic interventions), there was no need for ethical approval by the ethics committee of the "Heart and Chest Hospital" of Liverpool, UK, according to the hospital practice. In addition, to review their medical records, patient consent was not required by the ethics committee, based on the hospital practice. Precautions were taken to ensure the confidentiality of patient data during the data collection process. Research

was conducted in conformity with the ethical standards of both the responsible institutional committee for human experimentation and the Declaration of Helsinki.

Results

The median (interquartile range [IQR]) age of our cohort was 83 (10) years and we had an equal number of males and females in our sample. The median (IQR) logistic EuroSCORE was 20 (18.5)%. The main demographic, clinical and periprocedural patient characteristics are summarized in Table 1. In addition, as shown in Table 2, the overall incidence of cardiac postprocedural complications was estimated at 18.9% (n=17/90). Specifically, 3 patients (3.3%) developed atrioventricular block requiring PPM implantation, 10 of them (11.1%) had an NOAF, 2 patients (2.2%) presented a shockable cardiac arrest rhythm (pulseless VT and/or VF) and the remaining 2 (2.2%) developed cardiac tamponade.

Table 1 Demographic, clinical and periprocedural patient characteristics

Variables	Median (±IQR)
Age (years)	83 (10)
Logistic EuroSCORE (%)	20 (18.5)
Postprocedural intubation time (hours)	0 (3)
Creatinine levels (mg/dL)	1.1 (0.6)
Postprocedural blood loss volume (mL)	23 (200)
Gender, n (%)	
Male	45 (50.0)
Female	45 (50.0)
Diabetes, n (%)	20 (22.2)
Chronic renal insufficiency, n (%)	21 (23.1)
BMI (kg/m^2), n (%)	
≤24.9	31 (34.4)
>24.9	59 (65.6)
Oral inotropic agents, n (%)	16 (17.8)
Active smoking	52 (57.8)
Q wave infarction history	12 (13.3)
Statin therapy	71 (78.9)
Previous cardiac surgery	37 (41.1)
Hypercholesterolemia	70 (77.8)
Preprocedure cardiac rhythm	
SR	65 (72.2)
AF	21 (23.3)
Pacemaker	4 (4.4)
Preprocedural coronary angiography	79 (87.8)
LV ejection fraction	
Good	53 (58.9)
Moderate	28 (31.1)
Poor	9 (10.0)
Duration of postprocedural inotropic support (hours)	
0	72 (81.8)
<12	7 (8.0)
12–24	3 (3.4)
>24	6 (6.8)

Abbreviations: AF, atrial fibrillation; BMI, body mass index; IQR, interquartile range; LV, left ventricular; SR, sinus rhythm.

Table 2 Thirty-day incidence of cardiac complications post TAVI

Cardiac complications	n (%)
Overall	17 (18.9)
AV block requiring PPM implantation	3 (3.3)
Cardiac tamponade	2 (2.2)
NOAF	10 (11.1)
Pulseless VT and/or VF	2 (2.2)

Abbreviations: AV, atrioventricular; NOAF, new-onset atrial fibrillation; PPM, permanent pacemaker; TAVI, transcatheter aortic valve implantation; VF, ventricular fibrillation; VT, ventricular tachycardia.

Table 3 provides the main associations between patient characteristics and cardiac complications resulting from bivariate analyses. Bivariate analysis revealed that sinus and pacemaker preprocedural cardiac rhythm, post TAVI tracheal intubation and receiving of oral inotropic agents preprocedurally and intravenous inotropes postprocedurally were the main risk factors for cardiovascular complications after transapical TAVI. Specifically, patients who were intubated postprocedurally (36.4% vs 8.8%, p=0.001) and those receiving inotropic agents, either orally during the preprocedural phase (43.8% vs 13.5%, p=0.01) or intravenously during the post TAVI period (43.8% vs 13.9%, p=0.01), are characterized by significantly greater probability for postprocedural cardiac morbidity. However, patients with preexisting AF had significantly lower incidence of cardiac complications compared with those on sinus or pacemaker rhythm (0% vs 24.6%, p=0.01).

Discussion

The main findings of our study were both the estimated (overall and complication type) incidence of cardiac complications following transapical TAVI procedure and the identification of four patient-related variables as the main predictors of cardiac complications among recipients of transapical TAVI. The need for tracheal intubation postprocedurally, the absence of preexisting AF, receiving of oral inotropes preprocedurally and the need for postprocedural intravenous inotropic support were significantly associated with the higher incidence of cardiac complications after TAVI.

Not surprisingly, parameters such as the prolonged postprocedural mechanical ventilatory and intravenous inotropic support, along with oral inotropic therapy, prior TAVI are risk factors for patient morbidity, probably reflecting a worse general postprocedural clinical status of these patients. Besides, research on TAVI patient series, has consistently found that patients who require mechanical ventilatory support,[16,17] and

Table 3 Bivariate analyses between independent variables and cardiac complications

Independent variables	Cardiac complications n (%)		*P*-value
	No	Yes	
Gender			0.8[a]
Male	36 (80.0)	9 (20.0)	
Female	37 (82.2)	8 (17.8)	
Age (years)	80.8 (7.8)	83.9 (5.2)	0.13[b]
EuroSCORE (%)	21.8 (12.7)	28.4 (14.6)	0.07[b]
Q wave infarction history			0.3[a]
Yes	11 (91.7)	1 (8.3)	
No	62 (79.5)	16 (20.5)	
Previous cardiac surgery			0.1[a]
Yes	33 (89.2)	4 (10.8)	
No	40 (75.5)	13 (24.5)	
Diabetes			0.6[a]
Yes	17 (85)	3 (15)	
No	56 (80.0)	14 (20.0)	
Hypercholesterolemia			0.25[a]
Yes	55 (78.6)	15 (21.4)	
No	18 (90.0)	2 (10.0)	
Statin therapy			0.3[a]
Yes	56 (78.9)	15 (21.1)	
No	17 (89.5)	2 (10.5)	
Active smoking			0.6[a]
Yes	43 (82.7)	9 (17.3)	
No	30 (78.9)	8 (21.1)	
BMI (kg/m^2)			0.6[a]
≤24.9	26 (83.9)	5 (16.1)	
>24.9	47 (79.7)	12 (20.3)	
Creatinine levels (mg/dL)			0.15[a]
≤1.4	47 (77.0)	14 (23.0)	
>1.4	26 (89.7)	3 (10.3)	
Chronic renal insufficiency			0.1[c]
Yes	20 (95.2)	1 (4.8)	
No	53 (76.8)	16 (23.2)	
Preprocedural cardiac rhythm			**0.01**[c]
SR and pacemaker	52 (75.4)	17 (24.6)	
AF	21 (100.0)	0 (0.0)	
Preprocedural coronary angiography			1.0[c]
Yes	64 (81.0)	15 (19.0)	
No	9 (81.8)	2 (18.2)	
LV ejection fraction			0.03[d]
Good	45 (84.9)	8 (15.1)	
Moderate	24 (85.7)	4 (14.3)	
Poor	4 (44.4)	5 (55.6)	
Oral inotropic agents			**0.01**[c]
No	64 (86.5)	10 (13.5)	
Yes	9 (56.3)	7 (43.8)	
Duration of postprocedural inotropic support (hours)			**0.01**[c]
0	62 (86.1)	10 (13.9)	
>0	9 (56.3)	7 (43.8)	
Postprocedural blood loss volume (mL)			0.03[a]
0	39 (90.7)	4 (9.3)	
>0	34 (72.3)	13 (27.7)	
Postprocedural intubation time (hours)			**0.001**[a]
0	52 (91.2)	5 (8.8)	
>0	21 (63.6)	12 (36.4)	

Notes: Continuous variables are presented as mean (SD), while categorical variables are presented as n (%). [a]χ^2 test; [b]Student's *t*-test; [c]Fisher's exact test; [d]χ^2 trend test; Bold entries denote $p \leq 0.01$.

Abbreviations: AF, atrial fibrillation, BMI, body mass index, LV, left ventricular, SR, sinus rhythm.

those at New York Heart Association (NYHA) class III/IV[11] have poorer outcome, with higher morbidity and mortality rates.

Although intravenous inotropic support is suggested as a standard intervention for TAVI patients with low cardiac output and hemodynamic instability, mainly during the early postprocedural phase,[18] literature has not consistently investigated its potential negative effects on patient outcome, in terms of higher incidence of cardiac complications. It seems that the arrhythmogenic adverse effects of inotropic agents could explain the higher incidence of cardiac complications, in terms of rhythm disturbances.[18] However, in other patient series, such as cardiac surgical patients, postoperative support with intravenous inotropic agents is a well-known predictor of poor outcome, including significantly higher incidence of cardiac complications.[19]

However, we found that patients who had sinus or pacemaker rhythm preprocedurally are characterized by significantly greater probability for cardiac complications after TAVI, compared with those with preexisting AF (24.6% vs 0%). Indeed, no one of those with preexisting AF developed any cardiac complication in our patients' series. Other studies have shown that preexisting AF is a well-documented risk factor for poorer mid- and long-term clinical outcome among TAVI patients, even if patient outcome is similar between patients with preexisting AF and those with sinus rhythm during the first 30-day postprocedural period.[12]

The above-mentioned unexpected finding could be explained by our study methods. Specifically, we considered NOAF as the occurrence of AF in patients who had sinus rhythm preprocedurally, excluding apriori the patients with preexisting AF from this cardiac complication type. This limitation, in conjunction with the small sample size of the present study, could justify this seemingly paradox finding.

Postprocedural atrioventricular block requiring a PPM implantation is the main cardiac complication, which has been widely investigated in the currently published researches,[6,10,20,21] with, contrary to our results, an incidence of 13.4% according to a recently published systematic review involving 11,599 patients.[8] Previous published research has consistently found that procedure-related parameters such as the implantation of a larger prosthesis into a smaller annulus and a deep valve implantation, but also patient-related ones included a pre-existing right bundle block, patient age >75 years, male gender, chronic AF, perioperative bradycardia and high calcification load of the native valve are among the main risk factors for postprocedural heart block.[7,22] The lower incidence of heart block with PPM implantation in our cohort could be explained by its small sample size that could affect the validity of the present study.

NOAF following TAVI procedures is a well-known complication,[23] while transapical approach has been identified as an independent predictor of this patient outcome.[12] It seems that the more invasive character of transapical TAVIs accompanied by epicardial and pericardial injury due to transapical access route could justify this association.[12,24] Several studies have reported a NOAF incidence of 1%–32% postprocedurally,[12,23,25,26] a finding that is consistent with the present study.

As aforementioned, another important cardiac complication in our cohort was the occurrence of malignant ventricular arrhythmias (pulseless VT and/or VF) during the post-TAVI period in 2 patients. Our incidence is similar to the relevant early outcomes of other recently published studies.[27,28] Although the incidence of major ventricular arrhythmias after TAVI is lower than the pre-TAVI rates,[27] post-TAVI conditions such as the aggressive left ventricular remodeling,[28] the higher systolic ventricular overload, the reduced systolic function and the left ventricular hypertrophy[27] could interpret the presentation of ventricular adverse events postprocedurally. In addition, the local tissue injury and edema due to transapical manipulations could trigger the above-mentioned disorders.[29]

According to the findings of our study, 2 patients (2.2%) were developed cardiac tamponade postprocedurally, a major complication that has been associated with high mortality rates.[30] Factors associated with the applied technique and devices, and patient-related conditions, such as calcified aortic annulus and fragile myocardium due to severe ischemic heart disease are the main predisposing factors for hemopericardium and cardiac tamponade after TAVI.[30] Our incidence is in line with the currently available published researches.[30,31] It is worth mentioning that other studies did not give a clear picture on cardiac tamponade incidence as complication post TAVI, considering hemopericardium, surgical re-exploration due to bleeding and cardiac tamponade as the same clinical condition. For instance, Čanádyová et al reported an incidence of 9.7% of surgical re-exploration due to bleeding or cardiac tamponade, without clarification on the size of these patient subgroups.[32] In addition, Margolina et al in their study of 99 patients who underwent TAVI in a single center in Russia stated hemopericardium, with an incidence of 6%, among the main complications after TAVI, without giving information whether this condition led to cardiac tamponade.[33]

Study limitations

The present study adds new data to the current knowledge regarding the periprocedural factors associated with

increased probability for cardiac complications following TAVI, through the transapical approach. However, some limitations should be acknowledged. First, this single-center study, with a relatively small sample size and retrospective design, carries all the limitations adherent to such an investigation and could influence the internal and external validity of the study findings. Second, the small sample size of the present study did not allow us to use multivariate statistical models to analyze our data. Third, mid- and long-term data were not addressed, according to our study design. Finally, patients undergoing TAVI with other than transapical access route were not included in our study sample.

Conclusion

TAVI procedure is an effective and main-stream option for inoperable, high and intermediate surgical risk patients with severe, symptomatic aortic stenosis, characterized by an increasing number of recipients annually, since its introduction into clinical practice in 2002.[8] Despite the documented effectiveness and safety of this procedure, TAVIs are accompanied by, among others, cardiac complications during the postprocedural period, which must be treated immediately and optimally, ensuring the best patient outcome.

Patients remained intubated and under intravenous inotropic support during the postprocedural phase, those with sinus or pacemaker rhythm at baseline and patients who receive oral inotropes preprocedurally have significantly higher probability to develop cardiac complications post TAVI. The early identification of these high-risk patient groups could allow clinicians to have a better patient care planning and to take measures rapidly aiming to manage severe and life-threatening complications. Furthermore, administrators, taking into account the above information, could achieve the optimal allocation of the limited health care system resources. Finally, based on the above-mentioned study limitations, further research, including multi-center, prospective studies, with greater sample size, mid- and long-term follow-up data and multivariate data analysis, is needed.

Disclosure

The authors report no conflicts of interest in this work.

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