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Local Anesthesia for Surgical Repair of TF - TAVI Access - Site Lesions

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Abstract

Aim: We evaluated the impact of the anesthesiologic approach on the outcome of patients in need of surgical repair of the access - site after transfemoral transcatheter aortic valve implantation (TF-TAVI).

Methods and Results: In this retrospective study we included 26 patients, who required surgical repair for femoral access-site complications after TF-TAVI. This collective was divided into two groups: First group, where surgical repair was performed under general anesthesia (GA, n=11), and a second group receiving surgery in local anesthesia and conscious sedation (LAS, n=15). The groups were analysed regarding complications and mortality.

There were no significant differences for patient characteristics between the two groups. GA patients received significant more vasopressors and were in higher need for transfusion of blood products. As a result they spent significant longer time on intensive care units (192.7 ± 150.9 *vs*. 35.0 ± 41.2 hrs; P=0.0012). One-year mortality was significantly higher in the GA group (54.5% *vs*. 7.7%; P=0.0233). The Kaplan Meier analysis of survival also revealed a significant benefit for LAS (P=0.0052).

Conclusion: Repair of femoral access-site complications after TF-TAVI in LAS appears the superior alternative to GA, since it has less effect on the haemodynamic stability of these fragile patients. We were able to demonstrate that this approach is associated with significant improved survival.

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Introduction

Since the first human case reported in 2002 [1], Transfemoral Transcatheter Aortic Valve Implantation (TF - TAVI) has become a widely accepted alternative to traditional surgical aortic valve replacement especially in patients whose comorbidities bear unacceptable surgical risk. More than 100,000 successful TAVI procedures have been reported since then with comparable outcomes to conventional aortic valve surgery [2,3]. Even though several alternative approaches have been developed, transfemoral is the least invasive and most common applied [4,5]. While initially femoral access and closure required surgical cut-down and arteriotomy, today closure devices enable us to perform this procedure percutaneous [6]. Nevertheless, TF-TAVI is still associated with vascular complications resulting in significant impact on periprocedural morbidity and mortality [7,8]. Since TAVI is a relatively new and evolving technology, there are many ongoing controversies concerning its practical implementation. One issue at stake regards the anesthetic management. While the early procedures were performed exclusively under General Anesthesia (GA) with invasive monitoring and transesophageal echocardiography, a conscious sedation approach supplemented by local or regional anesthesia (LAS) has become popular recently [9,10]. The use of LAS is supposed to minimize periprocedural cardiovascular and pulmonary complications. It has been shown to be effective to reduce Intensive Care Unit (ICU) and hospital stay [10]. Still though, there are voices calling for GA in TAVI, because of easier management of surgical complications [11]. Therefore,

Table 1: Demographics and baseline characteristics.

Characteristic	GA group (n = 11)	LAS group (n = 15)	P value
Age (yrs)	80.73 ± 5.1	79.07 ± 8.6	0.4971
Gender (% female)	54.5	33.3	0.4259
Body Mass Index (kg/m^2)	27.22 ± 4.6	26.54 ± 7.3	0.3366
Hypertension (%)	100	93.3	1
Diabetes mellitus (%)	18.2	33.3	0.6576
Dyslipidemia (%)	81.8	86.7	1
Current smoking (%)	18.2	40	0.3945
Chronic renal insufficiency (%)	0	16.7	0.4986
Atrial fibrillation (%)	54.5	56.3	1
History of myocardial infarction (%)	22.2	7.8	1
History of CABG (%)	0	15.4	0.4857
History of PCI (%)	55.6	46.7	1
Chronic obstructive pulmonary disease (%)	27.3	20	1
Peripheral artery disease (%)	55.6	33.3	0.3964
History of stroke/TIA (%)	22.2	26.7	1
History or active malignancy (%)	11.1	15.4	1
Haemoglobin level pre-TAVI (g/dl)	11.51 ± 1.6	11.65 ± 2.3	0.9289
ASA score	3.9 ± 0.5	3.7 ± 0.5	0.4946

we evaluated the feasibility and outcome of surgical revision of inguinal access-site complications in LAS compared to GA. To test the hypothesis that surgical repair of the access-site following transfemoral transcatheter aortic valve implantation was associated with higher mortality in patients receiving GA compared to patients receiving LAS, we assessed the EVERY-TAVI registry retrospectively for corresonding patients. The primary endpoint of our analysis was 1-year mortality.

Methods

Patients

Patients were considered for TAVI if they had severe symptomatic aortic valve stenosis and were classified to be at high risk for conventional open cardiac surgery due to comorbidities. All patients underwent coronary angiography, and if significant Coronary Artery Disease (CAD) was present, percutaneous coronary intervention was performed. Data were collected for all patients who were in need of surgical repair of the access-site following TF-TAVI in our institution between January 2013 and November 2017. Demographics, clinical and procedural data were collected prospectively as part of national quality control requirements and were documented in the dedicated database of our cardiology department as part of the ongoing EVERY-TAVI registry (NCT02289339). No informed consent was required for the institutional registry.

TF-TAVI procedure

All TF - TAVI procedures were performed - as previously described [8] in a cardiac catheter laboratory equipped with a Siemens Artis Zeego imaging system. The percutaneous intervention was perfomed in LAS with anesthetic support. Edwards SAPIENS Valve (Edwards Lifescience, Irvine, CA, USA) and Medtronic Corevalve® (Medtronic, Minneapolis, MN, USA) devices were implanted directly into the native valve without pre-dilation. Access site was closed by application of a Proglide® closure device (Abbott Vascular Inc., Santa Clara, CA, USA) according to the manufactures recommendations. A pressure bandage was applied for 4 hrs to 6 hrs. If the closure device failed immediately after the TAVI procedure, the introducer sheath was replaced in the access site to prevent further bleeding and a vascular surgeon was consulted.

Anesthetic and surgical management

Anesthetist and vascular surgeon decided on bases of their own preference about the anesthetic approach. In cases of GA, induction of anesthesia was performed with etomidate, sufentanil and rocuronium and maintained with sevoflurane. Anesthesia was maintained with sevofluran. The anesthetic approach in the LAS group involved infiltration of the vascular access - site (and towards the iliohypogastric/ilioinguinal nerves) with mepivacain 1% in combination with analgosedation with remifentanil and propofol. The procedure is demonstrated in the video: http://peg-dresden.de/supplement_gaebel.mp4

Post-procedure clinical evaluation

All patients were transferred to the ICU after the TF-TAVI access-site repair. Clinical examinations were routinely performed and included inspection and auscultation of the groin followed by sonography. Following primary end points were assessed: in-hospital mortality, 30-day mortality, 1-year, and overall mortality until end of February 2018. Additionally, the following peri - and post procedural characteristics were determined: duration of operation (in minutes); amount of administred noradrenaline (in µg), crystalloid and colloid fluids, red blood cell transfusions, fresh frozen plasma, thrombocytes (all in ml); intensive care unit (ICU) stay (in hours); hospital stay (in days); periprocedural complications (major: resuscitation, stroke/Transient Ischemic Attack (TIA), in-hospital death; minor: prolonged wound healing, nosocomial infections, malignant dysrhythmia with the need for pacemaker implantation). Subjects were divided into

Table 2: Periprocedural characteristics and results.

Characteristic	GA group (n = 11)	LAS group (n = 15)	P value
Preoperative Haemoglobin level (g/dl)	8.39 ± 2.5	9.91 ± 2.2	0.1305
Haemoglobin decrease since TAVI (g/dl)	3.12 ± 2.5	1.73 ± 1.2	0.1934
Affected femoral artery (% right)	54.5	60	1
Operation time (min)	64.55 ± 39.7	56.47 ± 29.5	0.7498
Amount of noradrenaline (µg)	2.72 ± 2.3	0.43 ± 1.1	< 0.0001
Amount of crystalloids (ml)	1459 ± 576.8	1133 ± 953.7	0.1058
Amount of colloids (ml)	350 ± 530.6	80.0 ± 161.2	0.2542
Fresh frozen plasma (ml)	636.4 ± 816.7	33.3 ± 129.1	0.007
Red blood cell units (ml)	709.1 ± 861.9	60.0 ± 232.4	0.0021
Thrombocytes (ml)	109.1 ± 202.3	0.0 ± 0.0	0.0635
ICU stay (hours)	192.7 ± 150.9	35.0 ± 41.2	0.0012
Hospital stay after procedure (days)	19.91 ± 17.9	12.33 ± 8.8	0.0611
Periprocedural stroke/TIA (n)	2	0	0.1692
New pacemaker implantation (n)	1	1	1
Wound healing complications (n)	1	0	0.4231
Nosocomial infections (n)	3	1	0.2789
Resuscitation (n)	2	0	0.1692
Acute kidney injury (n)	0	0	1
In-Hospital mortality (%)	18.2	0	0.1692
30-day mortality (%)	18.2	0	0.1692
1-year mortality (%)	54.5	7.7	0.0233
Patients with major periprocedural complications (%) (Resuscitation, stroke/TIA, in-hospital death)	27.3	0	0.0635

two groups for analysis: patients who received GA for repair of their access site (GA group) and patients who received LAS (LAS group).

Follow up

Clinical follow - up until end of February 2018 was performed either in our outpatient clinic or with telephone interview documenting their general health status and cardiovascular events. It was available for all included patients at 30 days and for 92.3% of the patients at one year.

Statistics

All patient data are presented as mean ± standard deviation, or as absolute and relative frequency. Baseline data were checked for normal distribution using the Kolmogorov-Smirnov method. Comparisons of categorical data between patient cohorts were performed using the Fisher exact test. Mann - Whitney U test was performed to identify differences in continuous variables between the two groups. Survival curves were calculated using Kaplan - Meier analysis and were compared among groups by means of a Log - rank (Mantel - Cox) test. A two-tailed *P* value <0.05 was considered statistically significant. All statistical analyses were performed using the Graphpad Prism 6.0 statistical package (Graph Pad, La Jolla, CA, USA).

Results

Baseline characteristics

We identified 28 patients who required access - site repair following TF - TAVI. Two patients were excluded from the study. One patient had to be excluded, because both common femoral arteries required surgical repair. The right side was repaired in LAS immediately after TF - TAVI and the left in GA 10 days later due to major bleeding complications at the coronary catheter access - site. In one patient conversion from LAS to GA occurred (6.3%). The patient had received unsuccessful fibrin injections prior to surgery. Due to the fibrin injections local anesthetics could not effect properly and conversion was necessary due to insufficient analgesia and agitation of the patient. Since, we were unsure in which group these patients should be analysed, the patients were excluded. Therefore, data of 26 patients were collected and included, 11 patients received femoral access - site repair in GA and 15 patients in LAS. Patient characteristics are summarized in Table 1. No significant differences were detected between the groups in baseline patient characteristics. The follow up was complete for all patients.

Primary endpoint

Two patients (18.2%) in the GA group died during a complicated course in the hospital within 30 days *vs.* none in the LAS group (P=0.1692). Analysis of the 1-year all - cause mortality resulted in a significant higher mortality for patients of the GA group (54.5% *vs.* 7.7%; P=0.0233; relative risk 7.091). Also, the Kaplan - Meier analysis demonstrated a significant difference in favor of the LAS group for the overall survival (Figure 1).

Procedural characteristics: Twenty one patients (80.8%) required urgent access-site repair immediately after the TF - TAVI procedure.

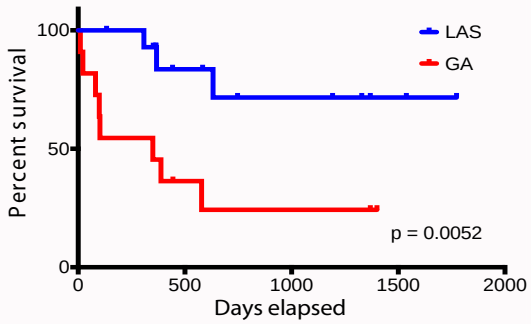

Figure 1: Overall Survival**.** Kaplan-Meier curve for overall survival according to the anesthetic approach (GA: General Anesthesia; LAS: Local Anesthesia and Conscious Sedation).

There was no significant difference detectable for emergency repair between the groups (n=9 in GA *vs.* n=12 in LAS; P=1.0). Five patients received inguinal access-site repair with a delay of up to 14 days after less invasive conservative approaches failed. Note able peri - and post procedural characteristics and results are demonstrated in Table 2. We did not observe a difference in duration of the surgical procedure between the groups (GA: 64.55 ± 39.7, LAS: 56.47 ± 29.5 min; P=0.7498). A significant reduction in amount of applicated vasopressors (noradrenaline) was detected in the LAS group (GA: 2.72 ± 2.3, LAS: 0.43 ± 1.1 µg; P<0.0001). Patients receiving LAS also required significantly less transfusion of blood products, while haemoglobin levels or loss of haemoglobin following TF - TAVI did not differ significantly between the groups (Figure 2). There were no significant differences in the incidence of post procedural complications. Three patients (27.3%) in the GA group suffered of major complications (resuscitation, stroke/TIA, in - hospital death) vs. none in the LAS group (P=0.0635). Two of these required prolonged resuscitation due to cardiac arrest during initiation of GA. Both patients died during the further course in the hospital, resulting in an in - hospital mortality rate of 18.2% (*vs.* 0% in LAS; P=0.1692). No patient suffered of acute renal failure in both groups. Two patients suffered of malignant dysrhythmia with the need for pacemaker implantation - one in each group. Both pacemaker implantations were performed in GA. Remarkably, the one patient from the LAS group had thereafter the longest hospital stay in the group (40 days). However, the length of hospital stay was shorter in the LAS group this finding did not reach statistical significance. But, we did observe a significantly reduced length of ICU stay for patients in the LAS group.

Discussion

The current study is the first one reporting the impact of two anesthetic approaches for access-site surgery in a large cohort of consecutive patients with severe aortic stenosis undergoing TF - TAVI. The most important result of this study is that LAS seems to be the preferred regimen for TF - TAVI patients in need for surgical repair of inguinal access-site lesions, since the 1-year mortality was significant lower in this group. It has recently been shown that major vascular complications following TF - TAVI independently predict long-term mortality. Major bleeding according to the VARC-2 criteria [12] is one of the most frequent major vascular complications [8]. In most of these cases there is a need for vascular access - site surgery. Surgery usually is performed in GA. But, with the ongoing development of new TAVI devices including substantial reduction of delivery catheter entry profiles as well as the use of suture-mediated closure devices, the TF - TAVI procedure itself is predominantly performed in LAS

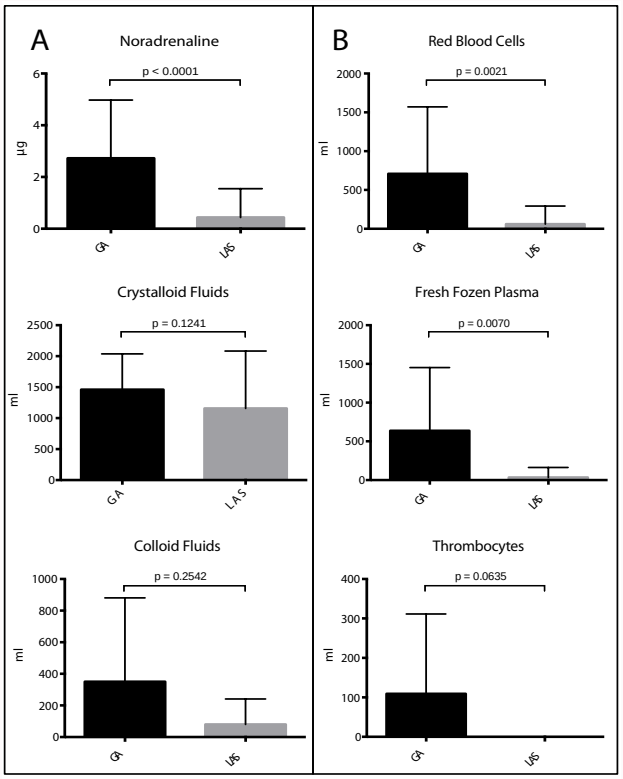

Figure 2: Transfusion demand. Amount of intra-operative administered (A) noradrenaline, crystalloid and, colloid liquids as well as (B) blood products.

in most European centers [9]. In a recent meta - analysis comparing LAS and GA for TF - TAVI it has been demonstrated that LAS has benefits such as increased haemodynamic stability and shorter hospital and ICU stays [10]. Based on these results, we performed a retrospective evaluation of the feasibility and potential benefits of a LAS approach for patients requiring access-site surgery following TF - TAVI. Both groups were similar regarding medical history, frailty, and preoperative haemodynamic conditions. As in previous reports for the TAVI procedure itself [9,13-15], we found that a GA approach was associated with significantly more haemodynamic instability, as suggested by a higher requirement for vasopressor application and higher transfusion volumes. It is unsurprising, as the use of GA leads to reductions in systemic vascular resistance, venous return, and cardiac output in most of these fragile patients. The application of neuromuscular blockade and positive pressure ventilation has disadvantageous effects with respect to changes in intrathoracic blood volume, pre - and afterload, and are a source of haemodynamic modification. The fact, that no patient needed resuscitation in the LAS group vs. two in the GA group refelects the cardiac depressant effects of anesthetic drugs administred in the GA group. Hypotension and bradycardia are side effects of anesthetic drugs that may lead to reduced vital organ perfusion, putting the patient at risk of neurologic deficits, myocardial ischemia and renal impairment [16]. Accordingly, in our study only in the GA group 2 patients suffered of periprocedural stroke/TIA. Even though, we cannot rule out, that embolic events occurred already during the TAVI procedure. In accordance with findings from studies comparing GA and LAS for TF - TAVI implantation, in our study GA resulted in significantly higher vasopressor demand. In terms of catecholamine administration, some authors prefer inotropes over vasopressors, since poor contractility and left ventricular systolic dysfunction are dominating factors in

the genesis of hypotension in TAVI patients [9,10]. But, inotrops are actually not indicated in patients with aortic stenosis, therefore the preferred haemodynamic therapy is vasopressor therapy to adjunct adequate mean arterial pressure for organ perfusion. It should be kept in mind, that most of the TAVI patients are octogenerians and have significant altered physiological changes of their organs, i.e. labile hypotonus, higher sensibility for volume overload as well as diastolic dysfunction. Therefore, these patients are at higher risk for haemodynamic instability and vasopressor support in the induction phase of anesthesia. This means, maintenance of homoestasis of these patients and avoidance of intubation is mandatory and might have a significant impact on the outcome. Similar were the results for the application of blood products. The lower rate of red blood cell transfusion in the LAS group has in earlier studies been explained by the anesthesiologists' increased tolerance of low haemoglobin levels as long as haemodynamic stability is maintained [15]. Our finding of no significant differences in pre - operative haemoglobin values and compareable haemoglobin loss between the GA and LAS group supports this hypothesis. The obsereved shorter length of ICU stay in the LAS group adds an important rational for primarily choosing LAS as anesthetic approach for surgery of vascular access - site complications following TF - TAVI. The prolonged ICU stay may be a result of the rate of periprocedural complications occurring in the GA group. Another reason for the prolonged ICU stay might be the transfer of intubated patients to the ICU, where extubation occurred with some delay after the procedure, as reported by some authors [15,17,18]. ICU admission has been associated with a high risk of nosocomial infections, which is related to both the length of stay and the administration of mechanical ventilation [19]. It has been shown that patients who received LAS for TAVI implantation have a lower risk of infectious complications. This finding was attributed to the avoidance of bladder catheterization, central venous catheter insertion and intubation [20]. However, we could not identify a significant difference in infection rate between the LAS and GA group, possibly due to the low incidence and small number of patients included in our study. The most striking finding of our study is that the survival rate after 1 - year as well as the overall survival was significantly improved in the LAS group. Even though, we analyzed rather small groups. It points out how sensible these fragile patients are to the haemodynamic changes occurring under GA. Therefore, we suggest that patients receiving TF - TAVI in LAS with vascular access-site complications should primarily receive surgical repair in a LAS approach. Our study is limited by its retrospective, non-randomized design. Therefore, selection bias cannot be ruled out. A randomized prospective study would provide a more reliable analysis. Second, our study was performed as a single-center analysis and includes a limited study population. Large - scale studies are required to confirm our findings.

Conclusion

In the present study including 26 patients with vascular access site complications after TF - TAVI, we have demonstrated that an anesthetic approach with LAS resulted in a reduction of transfusion of blood products and significant shorter ICU stays. This approach also helps to further increase mid-term survival rates of patients undergoing TF - TAVI. We recommend that surgical repair of inguinal access-site lesions after TF - TAVI should primarily be performed in LAS. Larger studies are required to validate our promising results.

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