Apical-access-related complications associated with trans-catheter aortic valve implantation

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Abstract

Objective: The left-ventricular trans-apical access has become well established for trans-catheter aortic valve implantation, especially for patients in whom a retrograde trans-arterial implantation is contraindicated. We report on the short- and long-term implications of the apical-access-site-specific complications. Methods: Between June 2007 and August 2010, 143 patients were scheduled for trans-apical aortic valve implantation (mean age 80±6 years, n=116 females, mean logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation) 21±13%). The patients are followed up at 30 days, 6 months, and then annually. Results: Severe apical bleeding complications occurred in 10 patients (7%). In three of these patients, the procedure was terminated, and no valve was implanted. In the remaining, the bleeding was controlled with cardiopulmonary bypass support (n=3), via median sternotomy (n=1), or both (n=1) ± later re-exploration. Two additional patients required postprocedural re-exploration for apical bleeding. An apical pseudo-aneurysm developed in two patients (2%), one of whom was treated by surgical revision. Survival was significantly impaired when either apical bleeding, aneurysm, or re-exploration occurred (75%±0.082 survival at 30 days and 59%±0.122 at 1 year vs 94%±0.023 and 80%±0.043 in patients without apical complications, p=0.012). Twelve patients (8%) experienced secondary wound healing. An apical hypo- or akinesia was detected in 18/54 (33%) patients at 6 months’ echocardiographic investigation, and in 11/30 (37%) 1 year after the procedure. Conclusions: The trans-apical access for trans-catheter aortic valve implantation might be challenging in elderly patients with fragile tissue. Severe bleeding complications or aneurysm formation significantly impairs survival. The clinical impact of subsequent apical hypo- or akinesia has to be further followed up.

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1. Introduction

The trans-apical approach for trans-catheter aortic valve implantation (TA-TAVI) is widely used for patients with significant peripheral arterial disease that excludes retrograde trans-arterial access. Since the first human TA implantation in 2006 [1], more than 5000 patients have undergone TA-TAVI worldwide. As opposed to the transfemoral approach, which is mainly performed by interventional cardiologists, the TA-TAVI procedure still lies within the surgical domain. Although surgeons argue that venting of the left ventricle or commissurotomy of the mitral valve via an apical incision [2,3] can be managed safely, the high or prohibitive surgical risk patients currently undergoing TA-TAVI may not tolerate extensive blood loss. Furthermore, the thinned and friable cardiac muscle associated with aging increases the risk for complications during apical access and closure.

At the author’s institution, a TAVI program was initiated in 2007, where the same interdisciplinary team performs TAVI through both the antegrade and retrograde access routes with a ‘transfemoral first’ concept. Hence, the TA access is only chosen when no trans-arterial implantation route is available, and consequently, the patient population is invariably sicker [4]. On the other hand, TA-TAVI is a more invasive procedure than the trans-arterial approach, as it requires general anesthesia, thoracotomy, and apical suturing, which may suggest that outcome results might be worse, especially in the face of complications occurring upon implantation. We therefore reviewed our series of TA procedures in 143 patients with special attention to complications directly related to the left-ventricular apical access.

2. Methods

All patients signed an informed consent. The study was approved by the local ethics committee (2234/08). Between

## Keywords

Minimally invasive surgery; Complications; Valve disease

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* Conflicts of Interest. R. Lange is member of the advisory board at Medtronic Inc.; R. Bauernschmitt and D. Mazzitelli are proctors for Medtronic Inc. and Edwards Lifesciences.

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June 2007 and August 2010, 460 patients underwent TAVI at the German Heart Center, Munich. Of these, 143 patients were scheduled for a TA approach, 269 for a transfemoral, 31 for a transsubclavian, and six for a transaortic approach. The patient characteristics of the study cohort that underwent TA-TAVI are summarized in Table 1.

2.1. TAVI

All patients were operated in a surgical hybrid suite. The procedures were performed under general anesthesia. Heparin 5000 IE was administered intra-operatively. Arterial and venous guide wires for potential emergent femoral cannulation were placed into the femoral vessels. Access was achieved through a left anterolateral minithoracotomy along the fifth or sixth intercostal space. A transient pacemaker wire was placed transvenously. The pericardium was then incised, or in case of severe adhesions in redo patients, left in place. Two pledgedot purse-string sutures with 2/0 Prolene were placed under respect of the left anterior descending (LAD) artery within the muscular tissue slightly above the true apex of the heart. After ventricular punc- ture and placement of a stiff guide wire, a balloon aortic valvuloplasty was performed through a 14-F sheath under rapid ventricular pacing (160–200 beats per min); this was true except for patients with pure aortic insufficiency associated with a degenerated bioprosthesis. The 14-F sheath was then replaced by a 26-F sheath. Under fluoroscopic control, the delivery catheter with the crimped prosthesis was placed in the aortic annulus. The CoreValve prosthesis was deployed in a controlled and stepwise fashion on the beating heart, while the Edwards Sapien prosthesis was deployed during rapid ventricular pacing. Prosthesis function was assessed by angiography and intra-operative transesophageal echocar-}

Table 1. Characteristics of TA-TAVI patients.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD or n (% of 143)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age at time of operation (years)</td>
<td>80.3 ± 6.4</td>
</tr>
<tr>
<td>Gender = female</td>
<td>116 (81%)</td>
</tr>
<tr>
<td>Mean log EuroSCORE (%)</td>
<td>21 ± 13</td>
</tr>
<tr>
<td>Mean STS score (%)</td>
<td>6.1 ± 3.8</td>
</tr>
<tr>
<td>Mean preoperative aortic valve gradient (mmHg)*</td>
<td>47 ± 16</td>
</tr>
<tr>
<td>Mean preoperative aortic valve orifice area (cm²)*</td>
<td>0.67 ± 0.22</td>
</tr>
<tr>
<td>Valve-in-valve procedures after bioprosthetic degeneration</td>
<td>- Aortic 11 (8%) - Mitral 1 (0.7%)</td>
</tr>
<tr>
<td>Implanted valve type</td>
<td>- CoreValve (within the context of the approval study) 5 (4%) - Sapien 135 (94%) - No valve implanted 3 (2%)</td>
</tr>
<tr>
<td>Left-ventricular ejection fraction</td>
<td>&gt;50% 101 (71%) &gt;30% to ≤50% 35 (24%) ≤30% 7 (5%)</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>88 (62%)</td>
</tr>
<tr>
<td>Peripheral vessel disease</td>
<td>58 (41%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>50 (35%)</td>
</tr>
<tr>
<td>Lung disease</td>
<td>27 (19%)</td>
</tr>
<tr>
<td>Renal insufficiency (GFR &lt; 60 ml min⁻¹)</td>
<td>75 (53%)</td>
</tr>
<tr>
<td>Previous cardiac surgery</td>
<td>33 (23%)</td>
</tr>
</tbody>
</table>

* Patients with pure aortic insufficiency (degenerated bioprosthesis) were excluded from this calculation.

3. Results

3.1. Intra-operative data

Procedural data are summarized in Table 2.

Table 2. Procedural data for patients undergoing TA-TAVI.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure time (min)</td>
<td>102 ± 36</td>
</tr>
<tr>
<td>Contrast agent (ml)</td>
<td>100 ± 45</td>
</tr>
<tr>
<td>Fluoroscopy time (min)</td>
<td>13 ± 7</td>
</tr>
<tr>
<td>Dose-area product (µGy cm²)</td>
<td>14291 ± 13623</td>
</tr>
<tr>
<td>Postoperative respiration (h) (survivors only)</td>
<td>9 ± 10 (median 7 h)</td>
</tr>
<tr>
<td>Cumulative postprocedural blood loss (ml)</td>
<td>842 ± 857 (median 650 ml)</td>
</tr>
</tbody>
</table>
refractory cardiac depression and five patients required management of severe apical bleeding.

3.2. Apical-access-related complications

Table 3 summarizes the complications associated with anterolateral minithoracotomy and left-ventricular apical access/closure.

Due to severe apical bleeding, the TA procedure was terminated in three patients, and no valve was implanted. One of these patients died during the procedure from refractory heart failure. Another died on postoperative day 4 (POD 4) from sudden death after apical closure under cardiopulmonary bypass support and having been extubated on POD 1. The third patient had an uneventful recovery and was discharged on day 26.

In five patients after successful TA-TAVI (3%), the apical access closure required cardiopulmonary support with the heart—lung machine (n = 3), a median sternotomy (n = 1), or both (n = 1). The latter two had additional postprocedural re-exploration for bleeding. Two other patients with initially satisfying apical hemostasis underwent re-exploration for apical bleeding.

In 12 patients (8%), the apical incision closure was difficult, but could be performed with several additional stitches without cardiopulmonary support or sternotomy. Concerning the risk for bleeding complications (severe and any apical bleeding), there was a tendency toward a higher incidence of apical bleeding in female patients (18% bleeding complications vs 4% in males, p = 0.076) and in patients aged >80 years (19% bleeding complications vs 12% in patients <80 years, p = 0.354).

Among patients who had to undergo surgical re-exploration for postoperative blood loss, 4/11 exhibited a bleeding from the apex (see above), while the others showed bleedings from the chest wall and/or subcutaneous tissue.

Two patients presented with an apical false aneurysm 2 and 9 months after TA-TAVI. In the first patient, there was a perforation into the subcutaneous tissue; therefore, surgical revision was performed and the aneurysm was closed with felt-strip reinforcement under cardiopulmonary support. The second patient exhibited an 8-mm false aneurysm, which did not increase in size over months and was not treated.

Secondary wound healing with or without infection at the thoracotomy incision site occurred in 8% of the patients, and 5/12 patients underwent surgical secondary wound closure after vacuum-assisted wound management.

3.3. Survival and echocardiographic findings

Overall survival rates were 90.4% ± 0.026, 77.5% ± 0.040, and 75.9% ± 0.042 at 30 days, 6 months, and 1 year, respectively. There was a significant impairment in survival in patients exhibiting any intraprocedural apical bleeding, postprocedural re-expansion, or aneurysm formation as a combined end point (p = 0.012); see Fig. 1. The causes of death were valve-related or cardiac in a higher proportion of patients, who experienced an apical bleeding (n = 5 (83%) vs n = 1 (17%) non-cardiac death) compared with patients without this complication (n = 10 (48%) cardiac or valve-related death vs n = 11 (52%) non-cardiac death). This finding was not significant.

Neurological complications occurred in four patients. There was one stroke (0.7%), two transient ischemic attacks (TIAs) (1.4%), and one patient with non-awakening after resuscitation on POD 2. Myocardial infarction occurred in four patients (2.8%). In two patients, coronary occlusion by native calcium masses after valve implantation was treated by main-stem stenting or bypass surgery. One patient had LAD thrombosis after potential LAD occlusion by the apical suture, and one patient experienced postoperative right coronary artery (RCA) embolism, which was treated interventionally.

Echocardiographic data showed a new apical hypo- or akinesia after the TA procedure in 18/54 (33%) patients at 6 months, and in 11/30 (37%) patients 1 year after the procedure. The apical scar led to an impairment of the ejection fraction in 4/54 (7%) patients at 6 months, and in 4/30 (13%) patients at 1 year.

4. Discussion

The TA approach for TAVI is well established within 4 years after its introduction. Among the surgical community, some argue that TA-TAVI could be the approach of first choice for TAVI [6] due to several advantages: reduced stroke rate in most series compared with trans-arterial TAVI, a short distance from the sheath to the annulus facilitating exact positioning, and no access limitation as the apex can be

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Table 3. Apical-access-related complications.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n (% of 143)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe apical bleeding</td>
<td>10 (7%)</td>
<td>n = 3: procedure terminated, no valve implanted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 5: HLM and/or sternotomy + later re-exploration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 2: re-exploration for apical bleeding</td>
</tr>
<tr>
<td>Any apical bleeding</td>
<td>12 (8%)</td>
<td>Challenging apical closure requiring more than one additional felt suture</td>
</tr>
<tr>
<td>Re-exploration for postoperative bleeding</td>
<td>11 (8%)</td>
<td>n = 4: bleeding from apex (see above)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 7: bleeding from chest wall or subcutaneous tissue</td>
</tr>
<tr>
<td>Apical pseudo-aneurysm</td>
<td>2 (1%)</td>
<td>n = 1: surgical revision</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 1: conservative treatment</td>
</tr>
<tr>
<td>Secondary wound healing</td>
<td>12 (8%)</td>
<td>n = 5: surgical secondary closure</td>
</tr>
<tr>
<td></td>
<td></td>
<td>n = 7: conservative treatment</td>
</tr>
</tbody>
</table>

HLM: heart—lung machine.
theoretically exposed in every patient. Until recently, a major anatomical limitation for TA-TAVI was the insufficient availability of valve substitutes for all annulus sizes. Despite surgical experience with the ventricular access in the past, hemostatic control of the apex is a critical step during TA-TAVI.

4.1. Apical bleeding complications

The difficulty of apical closure in an elderly patient population with potentially friable tissue might be under-reported. For example, patients, who die from apical bleeding before a valve can be implanted, are often not reported at all because they are no 'TAVI' patients. On the other hand, a very difficult apical suture will not be reported, if the outcome was favorable. Some of the largest series published recently do not report apical bleeding complications at all [7—10]. If reported, the authors usually focus on the severe bleeding complications that require cardiopulmonary support, sternotomy, or re-exploration. Such severe bleeding complications occurred in 2—10% of series of 18—175 patients [11—17]. In our retrospective series of 143 patients, we observed 10 patients (7%) with severe apical bleeding complications. Five of these patients died within 4 days of the procedure, while the others had an uneventful postoperative course. The proportion of patients with weak and fragile ventricular tissue was as high as 15%, with a tendency towards female patients and patients aged >80 years. Surgeons must be aware of the increased risk in these patients, and should consider this when obtaining informed consent of the patients.

4.2. Other complications related to the TA access

Surgical re-exploration for postoperative bleeding is reported in approximately 5% of patients after conventional cardiac surgery in octogenarians [18,19], and is 2—10% after TA-TAVI [14,16,17], and was 8% in our series of TA-TAVI. Of note, in 7/11 patients, the bleeding source was not the apical suture, but the chest wall or subcutaneous tissue. The incidence of re-exploration was reduced in the second half of our experience (12—3%, \( p = 0.055 \)), demonstrating a certain learning curve.

A rare complication after TA-TAVI is the development of an apical pseudo-aneurysm [20]. Data from the literature demonstrate a rate of 3—7% [15,21], if reported, and we observed a rate of 1% (two patients). As a combined end point, intraprocedural bleeding, postprocedural re-exploration and aneurysm formation significantly impaired survival in the present patient cohort (Fig. 1). Consequently, all attempts should be made to avoid these complications.

Further sequelae of the left anterolateral incision and apical suture include secondary thoracic wound healing, which occurred in as many as 8% of our patients, leading to prolonged hospitalization, and subsequent apical-wall-motion abnormalities. Our echocardiographic data up to 1 year after the procedure indicate that approximately one-third of the patients develop new hypo- or akinesia of the apex after TA-TAVI, which affected the overall ejection fraction in 7—13% of patients. At present, the long-term impact of these findings is unclear.
4.3. Technical considerations

Several surgical techniques are described for TA-TAVI. After thoracotomy, we recommend the use of a soft-tissue retractor to facilitate the access to the left-ventricular apex. We open the pericardium, if at all possible even in redo patients, to ensure the localization of the LAD. One group aims to puncture the real apex to reduce tension on the suture [15]. Others [22], including the author’s institution, prefer to puncture slightly laterally and above the real apex, where the tissue exhibits more strength and the myocardium is thicker. In any case, epicardial fat should be avoided. We use two 2/0 Prolene purse-string sutures each with three Teflon pledges and place deep bites transmurally covering an area of approximately 1.5 cm in diameter. There is also a description of the use of 3/0 Prolene sutures to make two horizontal mattress sutures [15] or to use numerous pledges and non-penetrating bites into the myocardium with a larger internal diameter of the purse string [22]. Ventricular puncture should be performed centrally within the sutures [15]. During sheath removal and tightening of the purse-string sutures, we install rapid ventricular pacing again to lower the systolic blood pressure below 90 mmHg. Even rapid ventricular pacing with lowering the blood pressure to 20–30 mmHg can be performed (personal communication). In case of bleeding, additional felt-enforced sutures are placed under rapid pacing. As reported above, in some patients, installation of extracorporeal bypass or sternotomy becomes necessary. With regard to aneurysm formation, it may be speculated that if a routinely placed additional suture or closing the pericardium to provide a counter-pressure might prevent this complication, especially in patients under anticoagulation. However, this complication occurred in earlier experience only (patients no. 31 and 40), indicating a potential learning curve. Meticulous control of hemostasis also of the chest wall must be performed to prevent postprocedural extensive blood loss, requiring re-exploration.

4.4. The future of the TA approach

The device that has been used most frequently for TA-TAVI is the Edwards Sapien prosthesis. TA CoreValve implantation was performed in five patients of our series within the context of a feasibility study, but the device is no longer available. Other TA aortic valve substitutes are under exploration, such as the Medtronic Engager [23] prosthesis and the Jena Valve, both of which can be anatomically orientated in the aortic annulus. A TA access is feasible not only for TAVI, but has also been used for pulmonary valve implantation, mitral-valve-chordal insertion, paravalvular leak closure, mitral commissurotomy, valve-in-a-mitral bioprosthesis, or pacemaker-lead implantation.

For TA-TAVI, the TA approach has an established role today. The TA procedure is considered more invasive than the retrograde arterial procedure, and, is therefore chosen, especially in patients who have no arterial route due to diseased vessels [4]. Consequently, the patient population receiving TA-TAVI usually has more severe co-morbidities. Nevertheless, our group demonstrated equal survival data for either TA or trans-arterial TAVI [4]. Despite a number of advantages over the retrograde technique, such as a short distance to the aortic valve, or a low stroke rate as also demonstrated in our series with 0.7%, the control of apical bleeding remains the most critical step during TA-TAVI. Unfortunately, there is no imaging tool to anticipate friable tissue, which occurred in 15% of the patients of our series. Future developments might generate interventional closure devices to control the apex such as muscular ventricular septal defect (VSD) occluders [24], or even percutaneous closure devices [25]. In addition, sheaths for TA prosthesis deployment might become available in smaller sizes, which could reduce fatal bleeding complications and increase the safety of the TA approach.

5. Conclusions

The TA access for TAVI might be challenging in elderly patients with fragile tissue. Severe bleeding complications or aneurysm formation significantly impacts survival. The clinical impact of subsequent apical hypo- or akinesia has to be further followed up.

References

And the second question relates to new apical hypo- or akinesia occurring in approximately 35% of patients. Do you think that this results in a lower ejection fraction than in patients without apical hypo- or akinesia?

**Dr Bleiziffer:** I am sorry, I didn’t get your contact information in advance, so I couldn’t provide you with the paper.

Your first question was whether we could foresee these complications. I analyzed that, and what we see is that female gender and age above 80 seem to be risk factors for these complications, and I don’t think there will be any imaging tool to foresee these complications.

And concerning the apical hypo- or akinesia, so far we have not seen an impairment of left ventricular ejection fraction despite the hypo- or akinesia.

**Dr Walther:** I think I have to make a comment.

I am a bit surprised about the high incidence of apical problems, because I was quoted on the second slide that I think there is no problem over 4 years, and I believe many centers don’t have problems. I just looked up the number I am going to present in the fourth presentation from PREVAIL trans-apical. In 150 patients in more than 10 sites, there is just one patient with an apical problem, one single patient, <1%. So I don’t really have a clue why you had a higher incidence.

**Dr Bleiziffer:** So how do you define here an apical problem?

**Dr Walther:** To abolish the procedure. The definitions may be different, but to abolish the procedure or not to go on with the procedure because of severe bleeding.

**Dr Bleiziffer:** The three patients where we terminated the procedure really had very fragile tissue, every stitch created a new bleeding source, and so we decided not to implant the valve in those patients. And two of those died soon afterwards.

**Dr Walther:** You are using a big needle to bring the purse string through very smoothly and so on?

**Dr Bleiziffer:** We use a 2-0 Prolene suture with quite a large needle, half circle, and we do transmural stitches.

**Dr Walther:** Transmural? Okay. Well, I never do transmural as far as I understand it, and that is what we have published, I think, not to go completely transapically. I don’t know. The additional bite was suggested by Svensson after his first case. I just do that when there is certain additional bleeding.

**Dr Bleiziffer:** We also don’t do it routinely.

**Dr Walther:** But I would be cautious to leave the room with the feeling that the apical approach is unsafe. That was just my comment. Sorry.

**Dr O. Wendler** (London, UK): I have just one comment, and that is, given that the incidence of apical complications in your presentation is much higher than reported in some other reports, I wonder if you do the closure of the apex under rapid pacing? From my own experience and from the proctor experience I have, rapid pacing made a huge difference compared to the past when we have retrieved the device and closed the apex under normal blood pressure. But if you are rapidly pacing during the time of apex closure, and reduce the blood pressure at that time, you have the same advantage that you have with on-pump surgery when you stop the pump for a moment to control a bleeding. So that is maybe one suggestion to reduce the complications if you don’t do it already.

**Dr Bleiziffer:** Yes, we do it routinely in all patients and reduce the systolic blood pressure down to 80 mmHg in all patients.

**Dr Wendler:** But if you do it on rapid pacing, you can get the blood pressure down to a mean of something like 20 or 30.

**Dr Bleiziffer:** We don’t do so high pacing to have no blood pressure anymore. We put it down to 80 not to low cardiac output.

**Dr Wendler:** Well, I do it the same way as you for the deployment of the valve or for the balloon dilatation but just for a very short time period. You have something like 10 seconds of rapid pacing, tie down your purse string, and that usually is something which works quite elegantly. And I don’t know if it would contribute to improving the results, but that is how I teach it and how I have done it for a long time now. For me, it made the biggest difference in terms of preventing apical complications.