Transapical Aortic Valve Implantation: Learning Curve With Reduced Operating Time and Radiation Exposure

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Background. The purpose of this study was to test whether, and in which terms, the cumulative institutional experience in the field of transapical transcatheter aortic valve implantation (TAVI) might impact upon operative time and radiation exposure.

Methods. This was a retrospective, single-center, observational cohort study of prospectively collected data from all 500 consecutive high-risk patients undergoing transapical TAVI at our institution between April 2008 and December 2011. Differences during the study period in baseline characteristics, procedural and postprocedural variables, and survival were analyzed. Nonparametric correlation and linear regression analyses were used to identify changes in operative time, contrast agent use, and radiation exposure according to institutional cumulative experience.

Results. Median operating time was 90 minutes (interquartile range 75–115 min) and fluoroscopy time was 6.7 minutes (4.8–10.3 min). Combined planned percutaneous coronary intervention was performed in 57 (11.4%) patients. There was a significant correlation between operating time, fluoroscopy time, and institutional experience. A 5% reduction in operating time (95% CI 3% to 8%, \( p < 0.0001 \)) and 15% reduction in radiation exposure time (95% CI 12% to 18%, \( p < 0.0001 \)) was reported per 100 procedures performed.

Conclusions. After introduction and implementation of a structured training program for transapical TAVI, operating time and radiation exposure are contained and reduced over the entire observation time in 500 consecutive patients.

The recent introduction and popularization of transcatheter aortic valve implantation (TAVI) has exposed the surgical community to the use of radiologic instrumentation and interventional cardiology tools that had been, in the past, only rarely used in the standard cardiac surgery practice. For this reason, even very simple data concerning radiation exposure and contrast agent use during TAVI have been rarely specifically investigated and are often lacking in the present surgical literature. The purpose of this study was to test whether, and in which terms, the cumulative institutional experience in the field of transapical TAVI might impact upon operative time, contrast agent use, and radiation exposure during the procedure.

Material and Methods

Study Design

This was a retrospective, observational, single-center, cohort study of prospectively collected data from all patients who underwent transapical TAVI at the Deutsches Herzzentrum Berlin (Berlin, Germany), from the beginning of the clinical introduction of transapical TAVI in April 2008 until December 2011. The study was approved by our Institutional Review Board.

Patient Selection and Procedural Criteria

All 500 consecutive high-risk patients with aortic valve stenosis who underwent transapical TAVI at our institution were operated on by the same heart team and were included in the study ("study cohort"). All procedures were performed according to our structured training program and our TAVI checklist [1]. All patients or their representatives gave informed consent.

Patient selection, preoperative evaluation, assessment of the diameter of the aortic annulus, valve size selection, and procedural technique have been described in detail previously [2, 3] and are summarized as the institutional clinical policies [1].
Procedures and Device
Transapical TAVI was performed in the hybrid operating room by the same TAVI team using a principal surgical technique with some modifications according to the institutional policies [1–6]. Balloon-expandable transcatheter stent-prosthetic xenograft valves with their delivering systems (both Edwards Lifesciences LLC, Irvine, CA) were used in all patients. The Edwards Sapien (ES) transcatheter heart valves (sizes 23 or 26 mm) were used from April 2008 to August 2011 and ES XT valves (sizes 23, 26 or 29 mm) from March 2011 until the end of the study period in December 2011.

Radiation and Contrast Agent Use
Fluoroscopy was used at the following predefined stages: (a) pig-tail catheter positioning in the ascending aorta; (b) selection of ideal angulation for valve release; (c) guidance during valvuloplasty and prosthesis release; and (d) control after prosthesis release. Contrast agent was administered in amounts of 10 to 20 mL per injection at predefined stages: (1) selection of ideal angulation before valve release; (2) monitoring during valvuloplasty; (3) prosthesis positioning in the native annulus before release; (4) prosthesis release (2 to 3 injections); and (5) checking after prosthesis release.

Assessment of the Institutional Learning Curve
The effect of the learning curve was assessed by the procedural outcome (the incidence of complications and survival) [6] and by the time effectivity of the procedure focusing on operating time, contrast medium use, and fluoroscopy time.

Statistical Analysis
Continuous variables are presented as mean ± standard deviation or median with interquartile range (IQR). Categoric variables are described as numbers and percentages. The 30-day rates during the study period are presented as percentage with the 95% Wilson confidence interval (CI). Changes during the study period were analyzed with the consecutive number of the procedure as independent variable. Trends of binary variables during the study period were compared between groups using the Mann-Whitney test. Trends of continuous variables are tested by nonparametric Spearman rank correlation (rho) with number of procedure. Linear regression was used to quantify the trends over time. Not normally distributed variables were log transformed. To improve readability, the odds ratios are presented for changes over 100 procedures.

Results
Patients’ characteristics, intraprocedural and postprocedural data of this cohort of patients have been already presented in depth in a previous publication [6] and will be herein summarized. The study cohort consisted of 311 (62.2%) female and correspondingly 37.8% (189) male patients. Mean age was 79.5 ± 8.1 years (median 80.6 years, range 28.9 to 98.9, interquartile range [IQR] 75.3 to 84.6 years).

The median logistic European System for Cardiac Operative Risk Evaluation of the study cohort was 30.4%, (IQR 21.0% to 48.5%) and the median The Society of Thoracic Surgeons predicted operative mortality was 12.2%, (IQR 6.7% to 21.6%). There were 28 (5.6%) patients with cardiogenic shock during the study period. The overall 30-day mortality rate for the entire cohort of 500 patients was 4.6% (95% CI 3.1% to 6.8%) with 23 deaths among 500 patients. The 30-day mortality in the entire cohort excluding patients in cardiogenic shock was 4.0% (95% CI 2.6% to 6.2%) [6].

Table 1 reports the average amount of contrast medium, fluoroscopy time, and operating time according to the consecutive number of the procedure (5 groups of 100 patients each). Contrast volume used per procedure was not related to the institutional experience (rho = 0.089, p = 0.053) (Table 2). Fluoroscopy time and operating time decreased significantly during the study period (p < 0.001) (Table 2). At linear regression, a 5% reduction in operating time (95% CI 3% to 8%, p < 0.0001) and 15% reduction in fluoroscopy time (95% CI 12% to 18%, p < 0.0001) was reported per 100 procedures performed (Figs 1, 2).

Comment
Radiation exposure during TAVI has been previously investigated by Signorotto and colleagues [7]. Patient doses for 5,549 diagnostic and therapeutic procedures and 76 TAVI were examined. The average patient dose for TAVI was double that for a percutaneous coronary intervention (PCI) and 6 times higher than for a simple coronary angiogram [7]. There are many factors that theoretically may impact upon radiation exposure and

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<th>Variable</th>
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<th>Mean</th>
<th>SD</th>
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<td>5</td>
<td>97.3</td>
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SD = standard deviation.
contrast agent use, including operator experience, patients’ characteristics, and perioperative findings.

Kempfert and colleagues [8] have described their 4-year learning experience with transapical TAVI. After 150 cases they documented a significant decrease in contrast agent use (from 104 ± 78 to 93 ± 46 mL; p = 0.016) and fluoroscopy time (from 7.1 ± 3.9 to 6.2 ± 3.2 minutes; p = 0.032). More recently a retrospective analysis of the first 44 consecutive patients who underwent transfemoral TAVI as part of the Placement of Aortic Transcatheter Valves trial [9, 10] was performed [11]. Patients were divided into tertiles based on sequence. A significant decrease in contrast volume was seen across the 3 tertiles (median: 180 to 160 to 130 mL, p < 0.003). Similarly significant decreases were also seen in fluoroscopy times, from 26.1 to 17.2 and 14.3 minutes, respectively, from tertiles 1 to 3 (p < 0.001). Concomitant significant decreases in radiation doses were also seen across the 3 tertiles (p < 0.001) [11].

Excessive contrast agent use may lead to renal impairment. As an Institutional policy, we always limit to the minimum the amount of contrast agent used during TAVI. All patients receive preoperative hydration and acetylcysteine (1,200 mg). Whenever a severely impaired renal function is present, we wave the preoperative contrasted computed tomographic scan. We have a 24 hour-7 day nephrology service available to consult upon request. Within this cohort of 500 patients, the requirement for renal dialysis was 3.6% and did not seem to relate significantly to the amount of contrast agent used [6].

In our analysis, operative experience with transapical TAVI seems to impact on fluoroscopy and operating time. As emerging from our data, a learning curve of around 100 patients is sufficient to significantly reduce the total fluoroscopy and operating time. Interestingly, we did not notice a relationship between operative experience with TAVI and contrast agent use. Furthermore, a sub-analysis concerning the single operators has not shown significant differences. This may be due to the fact that all our procedures are performed with the simultaneous participation of surgeons with different TAVI experience and with the constant presence of an interventional cardiologist. An additional important factor was that we used the same predefined angiographic schema throughout the study period [1–6].

The present manuscript presents the results in a cohort of sole transapical TAVI patients. The question about using either a transapical or a transfemoral approach has often arisen. We believe that the best treatment option should be evaluated on the patient’s individual base. Our “TAVI team” is trained to use all TAVI approaches (transfemoral, transapical, right and left transaxillary) and, nowadays, we can perform whatever approach is best for the patient. The simplest criterion to decide between transapical and transfemoral approach is the condition of the vascular access. Whenever the status of the iliac and femoral arteries is favorable, transfemoral implantation should be performed as a primary option. It has to be remarked that transapical TAVI is a more difficult technique than transfemoral and needs a longer learning curve. To achieve excellent expertise in both techniques, we used, first, the transapical route. Vice versa, transapical implantation is a very simple and direct procedure with several advantages over the transfemoral

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<td>Contrast medium (mL)</td>
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<td>Fluoroscopy time (minutes)</td>
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<td>Operating time (minutes)</td>
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(or transaxillary) route. In fact, the transapical approach is independent of the degree of peripheral vascular disease [1–6]. Furthermore, the antegrade crossing of the stenotic aortic valve is quicker and simpler in comparison with the retrograde approach used with transfemoral implantation. A lower risk of neurologic complications should be expected when using the transapical route where there is decreased intravascular instrumentation of the aortic arch. However, the main reason for the exclusive use of the transapical approach at the beginning of our project was the excellent and safe possibility of precise deployment of the prosthesis in the target position by applying our modified valve implantation technique [2]. In the future, the transfemoral approach should be performed more frequently and become the primary way of implantation if results in terms of procedural success could be matched to those we have achieved using the transapical route. In fact, at present we have not yet compared the results of the 2 approaches. Any future evaluation will, in any case, be biased by differences in patients’ selection criteria within the 2 groups.

In our results it emerges that the average amount of contrast used during our procedures is higher than that proposed by other groups. In fact, we consistently perform slow release of the valve to finely correct its final position while concomitantly performing 2 to 3 aortographies [2]. Furthermore, since the beginning of our experience we have performed a high rate of simultaneous TAVI and PCI [12].

The TAVI and concomitant PCI will lead, as expected, to a significantly increased procedural time, radiation dose, and contrast agent used. In a more detailed analysis of our results it emerges that in patients undergoing elective PCI, average contrast agent use reaches 170 mL, fluoroscopy time 16 minutes, and total operating time over 130 minutes [12]. To avoid prolonged procedures and minimize the risk of iatrogenic complications we have developed an institutional strategy aimed at treating with simultaneous PCI only the most significant coronary lesions (in terms of both degree of stenosis and subtended myocardium at risk) that are amenable to a simple percutaneous correction [12]. In fact, in spite of the increased operative time and contrast agent use, perioperative morbidity and mortality of patients treated with simultaneous PCI remain, in our experience, comparable with those of patients treated with sole TAVI [12]. Our philosophy in performing simultaneous PCI and TAVI is to prevent postoperative myocardial infarction without increasing the risk of the procedure [12]. We adopt this approach because one of our first patients experienced acute myocardial infarction after TAVI and was afterward treated with PCI. Therefore, we have decided to treat only the most relevant coronary lesion(s) by PCI simultaneously with TAVI and reduce, in a single-staged fashion, the possible complications from a pathology remaining untreated during the waiting time for the second procedure [12]. Periprocedural renal failure, secondary to administration of additional contrast medium for PCI, is a theoretic complication that, so far, we did not identify as a serious problem. We need to emphasize that, although patients with coronary artery disease have a risk of possible myocardial ischemia during the various phases of TAVI (including rapid ventricular pacing), PCI should not be performed first. In fact, we believe that severe aortic stenosis is “the most proximal coronary artery stenosis because it reduces both systemic and myocardial perfusion” [12]. Abrupt elimination of aortic stenosis and reduction of afterload with TAVI will optimize, immediately, myocardial perfusion even when a concomitant coronary artery stenosis is present. In our experience, when myocardial ischemia occurs during TAVI, it is often secondary to debris microembolization during balloon valvuloplasty rather than a consequence of concomitant coronary artery disease [12].

In conclusion, transapical TAVI can be performed even in very comorbid patients while maintaining an acceptable radiation exposure, operative time, and contrast agent use. We did not note any correlation between risk scores and any of the radiation variables. Concomitant PCI makes the procedure more cumbersome and impacts upon contrast agent use, fluoroscopy, and operating time. Contrast agent use can be limited since the beginning of the learning experience with transapical TAVI. A learning curve of approximately 100 patients seems sufficient to reduce fluoroscopy and operating time during transapical TAVI.

The other members of our TAVI team are Christoph Klein, MD, Ekatarina Ivanitskaia-Kühn, MD, Guna Tetere, MD, Tom Gromann, MD, Katrin Schäfer, and Natalia Solowjowa, MD.

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References


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