

Transapical minimally invasive aortic valve implantation; the initial 50 patients[☆]

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Abstract

Objective: To evaluate the feasibility of minimally invasive transapical beating heart aortic valve implantation (TAP-AVI) for high-risk patients with aortic stenosis. **Methods:** TAP-AVI was performed via a small anterolateral minithoracotomy in 50 patients from February 2006 to March 2007. A balloon expandable transcatheter xenograft (Edwards SAPIENTM THV, Edwards Lifesciences, Irvine, CA, USA) was used. Mean age was 82.4 ± 5 years and 39 (78%) were female. Implantation was performed in a hybrid operative theatre using fluoroscopic and echocardiographic visualization. Average EuroSCORE predicted risk for mortality was $27.6 \pm 12\%$. Seven (14%) patients were re-operations with patent bypass grafts. **Results:** TAP-AVI (13 patients 23 mm and 37 patients 26 mm) was successfully performed on the beating heart under temporary rapid ventricular pacing in 47 (94%) patients, and implantation was performed completely off-pump in 34 (68%) patients. Three patients required early conversion; two of them were successfully discharged. There was no prosthesis migration or embolization observed. Echocardiography revealed good hemodynamic function in all and minor incompetence in 23 patients, mostly paravalvular, without any signs of hemolysis. Mortality was due to the overall health condition and non-valve related in all patients. Actuarial survival at 1 month, 6 months and 1 year was $92 \pm 3.8\%$, $73.9 \pm 6.2\%$ and $71.4 \pm 6.5\%$, respectively. **Conclusions:** Transapical minimally invasive aortic valve implantation is feasible using an off-pump technique. Good results have been achieved in the initial 50 patients, especially when considering the overall high-risk profile of these patients.

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1. Introduction

Aortic stenosis is the most frequently acquired heart valve lesion, usually occurring in the elderly and commonly caused by a degenerative, calcific pathology. Surgical valve replacement has become the gold standard therapy for these patients, with more than five decades experience, as reflected in recent guidelines [1]. Good perioperative and long-term outcomes after conventional valve replacement have been proven by data from national databases as well as by multiple longitudinal studies [2–8]. In addition, good outcomes have recently been published regarding octogenarians with 30-day mortality rates between 9% and 10% [9–12].

Despite guideline recommendations, there may be patients that are not being referred for surgical intervention, because of high-risk profiles that are presumed prohibitive for conventional surgery [13]. However, non-surgical management of these high-risk patients also portrays a grave prognosis [14]. Therefore, there is a need to further develop minimally invasive strategies to adequately treat high-risk patients with symptomatic aortic stenosis. Minimization of periprocedural risk may be accomplished by avoiding conventional sternotomy and by performing off-pump beating heart aortic valve implantation. Transfemoral (TF) and transapical (TAP) approaches have recently been introduced into clinical practice using the CoreValveTM (CoreValve, Paris, France) and the Edwards SapienTM (Edwards Lifesciences Inc., Irvine, CA, USA) prostheses.

In this context the aim of the present study was to analyze the results of the initial 50 patients receiving TAP aortic valve implantation (AVI) at a single center.

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2. Material and methods

2.1. Inclusion criteria and patient enrolment

Fifty consecutive patients with symptomatic, severe aortic stenosis and high perioperative risk were included in this study between February 2006 and March 2007. Inclusion criteria were patient age ≥ 75 years and an increased perioperative risk profile as defined by ≥ 9 points according to the EuroSCORE risk calculator. In addition the patients needed to meet 'technical' inclusion criteria, which included an aortic annulus diameter of ≤ 24 mm as measured on transthoracic and transesophageal echocardiography. This allowed for systematic oversizing of the implanted prosthesis. Patients with an aortic annulus diameter of ≤ 21 mm received 23 mm and patients with an aortic annulus diameter between 22 and 24 mm received 26 mm prosthesis, respectively. All referred patients suitable for the transapical approach according to the previously mentioned inclusion criteria were screened and judged for conventional surgery as well. During the study period, a total of 33 moribund patients were denied any therapy. All other patients who met the inclusion criteria were accepted into the study. Extensive discussions of all available therapeutic options were presented to each patient and their family members. All patients gave informed consent. The study protocol was approved by the local ethics committee (registration number 226–2005).

2.2. Patient characteristics

All patients included had a high perioperative risk profile with a mean mortality risk score of 27.6 ± 12.2 according to the logistic EuroSCORE and of 15.8 ± 9.1 according to the STS scoring system. Detailed patient characteristics are demonstrated in Table 1. Other contributing risk factors are listed in Table 2. Four patients were in a critical preoperative state, all with severely decompensated aortic stenosis. In addition, polycythemia and leukemia (1), cardiac decompensation with inotropic support (1), severe respiratory dysfunction with scoliosis and bilateral phrenic palsy (1) and extreme obesity with a body mass index of 44.1 (1) were each encountered as well.

Table 1
Patient demographics

| | Mean | Range |
|-------------------------------------|-----------------|--------|
| Total (n) | 50 | |
| Female | 39 | 78% |
| Age (years) | 82.4 ± 4.6 | 65–93 |
| Body weight (kg) | 68 ± 13 | 43–120 |
| Body surface area (m ²) | 1.7 ± 0.2 | 1.4–2 |
| NYHA class | 3.3 ± 0.5 | 3–4 |
| Ejection fraction (%) | 53 ± 14 | 15–75 |
| Aortic incompetence ^a | 28 | 56% |
| EuroSCORE (points) | 11.3 ± 1.6 | 9–15 |
| Logistic EuroSCORE (%) | 27.6 ± 12.2 | 11–61 |
| STS score (%) | 15.8 ± 9.1 | 5.6–40 |

NYHA: New York Heart Association; STS: Society of Thoracic Surgeons.

^a Mild-to-moderate aortic valve incompetence at preoperative echocardiography in conjunction with severe aortic valve stenosis.

Table 2
Additional risk factors present in the initial 50 patients

| | n | (%) |
|---|----|-----|
| Chronic pulmonary disease | 21 | 42 |
| Pulmonary hypertension | 16 | 32 |
| Neurological dysfunction | 12 | 24 |
| Peripheral vascular disease | 8 | 16 |
| Renal dysfunction (creatinine > 200 $\mu\text{mol/l}$) | 7 | 14 |
| Previous cardiac surgery ^a | 5 | 10 |
| Critical preoperative state | 4 | 8 |

^a With patent bypass grafts.

2.3. Transcatheter aortic valve

All patients received a pericardial xenograft fixed within a stainless steel, balloon expandable stent (Edwards SAPIEN™ THV, Edwards Lifesciences, Irvine, CA, USA). Immediately prior to implantation, the valve was rinsed and crimped upon the balloon catheter under sterile conditions in the operative theatre. Additional details have been previously published [15].

2.4. Perioperative setup and valve implantation

All procedures were performed in a hybrid operating theatre, as demonstrated in Fig. 1. All patients were treated under general anesthesia using short-acting intravenous medications, with the intention of early extubation, if possible. Each patient was positioned supine with the left chest slightly elevated anteriorly. Our most recent protocol consists of percutaneous insertion of a femoral venous guidewire and a 6 Fr femoral arterial sheath to ensure femoral access in case of emergency cannulation for cardiopulmonary bypass (CPB). A pigtail catheter was placed via the femoral arterial sheath into the aorta, and left just above the level of the aortic valve for aortic root angiography.

An anterolateral minithoracotomy was performed in the 5th intercostal space to expose the left ventricular apex.



Fig. 1. Hybrid operative theatre including high quality angiographic system, transesophageal echocardiography and heart lung machine if required.

Following placement of pericardial stay sutures, an epicardial ventricular pacing wire and two apical purse-string sutures with teflon reinforcements are placed. Under fluoroscopic visualization, the left ventricular apex was punctured and a soft guidewire was passed in an antegrade fashion across the stenosed aortic valve, along with a 14 Fr introducer sheath. This allows for a wire exchange and anchoring of a 0.035 in. Amplatz superstiff wire (Boston Scientific, Natick, MA, USA) into the descending aorta. The balloon aortic valvuloplasty was then performed with a standard 20 ml balloon catheter under rapid ventricular pacing. The sheath was then exchanged for a 33 Fr sheath, whereby the loader with the prosthetic valve was connected and deaired. Under careful fluoroscopic guidance, the valve was then positioned within the aortic annulus. Valve implantation was performed during a second period of rapid ventricular pacing. After confirmation of good placement with angiography, the sheath and wire were removed, the apex secured with the purse-string sutures and the chest incision was closed in a routine fashion.

2.5. Statistics

Results are expressed in a standard fashion throughout the manuscript. Continuous variables are expressed as mean values \pm SD or as median values when appropriate, and categorical variables are expressed as proportions. Comparisons between subgroups were performed using Student's *t*-test. Survival analysis was performed using the Kaplan–Meier method.

3. Results

All patients received transapical valve implantation as planned using an anterolateral minithoracotomy. Valve size selection was performed according to three repeat perioperative transesophageal echocardiographic measurements of the aortic annulus. A 23 mm prosthesis was selected in the presence of an annulus diameter \leq 21 mm in 13 patients and a 26 mm prosthesis for annulus diameters of \leq 24 mm in 37 patients, respectively. All patients were treated using an oversizing technique. Perioperative details are listed in Table 3. The left ventricular apex was closed securely in all patients with no secondary bleeding problems. Echocardiography revealed good valve function postoperatively as well as at follow-up, as demonstrated in Table 4.

Technically it was possible to implant the valve transapically in all patients. CPB was used in 11 patients by intention; these were the initial seven patients and patient 10, 12, 13 and 23 who were all hemodynamically

Table 3
Perioperative results of the 50 patients

| | Mean | Range |
|----------------------------|----------------|--------|
| Valve size diameter | 25.2 \pm 1.3 | 23–26 |
| Aortic annulus diameter | 22.6 \pm 1.4 | 20–26 |
| Contrast (ml) | 82 \pm 31 | 15–150 |
| Fluoroscopy duration (min) | 6.8 \pm 3.8 | 2.3–24 |

Table 4
Echocardiographic results

| | Postoperative | Follow-up ^a |
|---|---------------|------------------------|
| Transvalvular maximum blood flow velocity (m/s) | 1.8 \pm 0.4 | 1.8 \pm 0.4 |
| Maximum pressure gradient (mmHg) | 15 \pm 7 | 14, 1 \pm 6 |
| Mean pressure gradient (mmHg) | 7.2 \pm 3.9 | 8 \pm 3 |
| Aortic incompetence (severity) | 0.5 \pm 0.5 | 0.6 \pm 0.4 |

^a Six-months follow-up results.

unstable preoperatively. Secondary CPB was applied in five patients, due to need for conversion to sternotomy in three patients, to support apical suturing in one patient and for temporary reperfusion in another patient, respectively. A total of 34/50 patients (68%) were treated completely off-pump.

Early conversion to conventional sternotomy had to be performed in three patients. This was due to proximal valve dislocation at implant in an 85-year-old patient with previous bypass graft surgery (1), aortic root dissection after selective coronary catheterization for temporary functional right coronary artery compromise in a 77-year-old (1) and coronary occlusion in presence of severe calcification and low coronary ostia (1) in a 83-year-old patient. The latter two patients were successfully managed, discharged from the hospital and have survived within the follow-up period, whereas the first patient mentioned died on postoperative day 125 of complications of comorbid illness.

Early extubation was attempted in all patients. A total of 21 (42%) patients were recovered in the post-anesthetic care unit, with a median extubation time of 82 min, without being admitted to the intensive care unit. Temporary renal replacement therapy was required in seven patients postoperatively, whereby three of these patients had pre-existing renal failure. Fortunately, the remaining four of these patients had full renal recovery. Pacemaker implantation was required in two patients due to complete AV-block postoperatively.

At 30 days postoperatively four patients (8%) had died, all due to non-valve related causes. Follow-up ranges from 6 to 18 months for these patients and is 100% complete. During the follow-up period, another 10 (21.7%) patients died, all demonstrating good valve function at last echocardiographic examination. Causes of death were related to the underlying comorbidities in all those patients, respectively. Overall survival at 30 days, 6 months and 1 year was 92 \pm 3.8%, 73.9 \pm 6.2%, and 71.4 \pm 6.5%, respectively. A Kaplan–Meier survival curve is demonstrated in Fig. 2.

We performed a subgroup analysis on the initial 25 patients versus the last 25 patients. There were no significant differences in risk profiles between these two subgroups. Mean patient ages were 82 \pm 5 and 83 \pm 4 years with 17 and 22 patients being female. Preoperative risk evaluation was 27 \pm 13% versus 29 \pm 11% according to the logistic EuroSCORE and 15 \pm 10% versus 16 \pm 9% according to the STS score, respectively. Implanted valve sizes were similar in both subgroups. More deaths occurred in the first 25 patients, however, all three sternotomy conversions occurred in the second half of patients. Overall survival at 30 days, 6 months and 1 year were 88 \pm 6.5% versus 96 \pm 3.9%, 68 \pm 9.3% versus

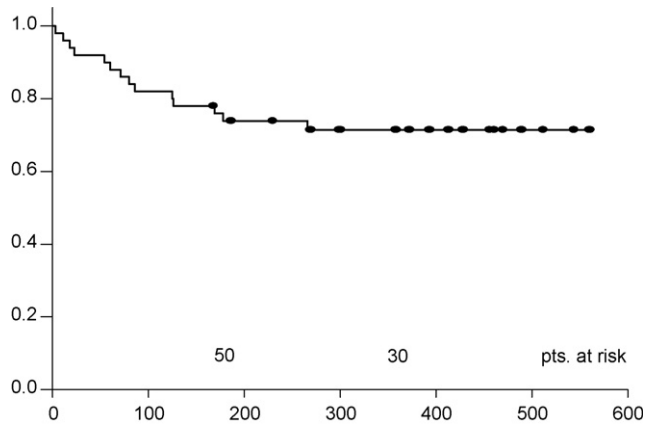


Fig. 2. Survival analysis for the 50 patients. Follow-up duration is shown in days on the x-axis.

$80 \pm 8\%$, and $64 \pm 9.6\%$ versus $80 \pm 8\%$, respectively. Survival analysis for the two subgroups is shown in Fig. 3, the differences did not reach statistical significance.

4. Discussion

Transcatheter aortic valve implantation is a new technique that has been introduced into clinical practice at a few centers recently. The ultimate goal is to reduce the morbidity and mortality of conventional aortic valve replacement while achieving similar good patient outcomes. Initial clinical studies have been approved for TAP-AVI on high-risk surgical patients [15]. Theoretically such high-risk patients may benefit the most from avoiding partial or complete sternotomy, cardiopulmonary bypass and cardioplegic arrest.

The transapical technique has been developed in order to avoid and overcome some of the transfemoral shortcomings, mostly related to small access femoral vessels as well as a rather long and sometimes cumbersome retrograde implantation technique. Initial development of the transapical approach benefited from transfemoral experiences but has further developed more independently during the past 2 years. Our early results demonstrated proof of concept and

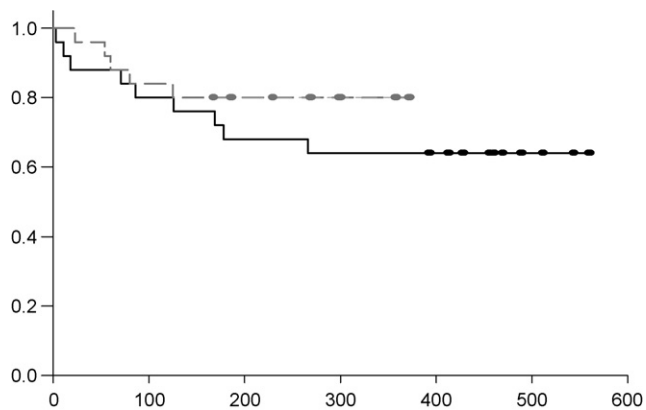


Fig. 3. Survival analysis for the initial 25 (lower curve, solid line) versus the more recent (upper curve, dashed line) patients. Follow-up duration is shown in days on the x-axis.

have enabled the refinement of our technique to their current iteration [15].

The results presented in this manuscript represent the world's largest single center series of transapical valve implantation to date. We attribute our good results not only to excellent preoperative planning, careful patient screening, experience and technical expertise, but also importantly to the collaborative efforts of a specialized team of cardiac surgeons, cardiologists and anesthetists who worked closely together to treat these high-risk patients. Patient screening consists of careful evaluation of all inclusion criteria as well as technical aspects, especially aortic annular dimension as measured on transesophageal echocardiography. However, precise risk assessment may be difficult in some patients. In addition, we believe that it was greatly beneficial to perform all implantations in a well-equipped hybrid operative theatre. Full operative capabilities together with optimal imaging including high quality fluoroscopy and transesophageal echocardiography were essential. Most importantly, the presence of full operative capabilities enabled us to perform sternotomy conversions if required and thus save two out of three patients in the long term. Therefore, we firmly recommend performing all future transcatheter valve implantations using a hybrid operative theatre, which provides the team simultaneously with superior imaging and also the necessary tools to achieve optimal patient safety.

Recently published data supports the feasibility of transcatheter valve implantations using both the transfemoral and the transapical implantation techniques [15–18]. However, transfemoral implantations have reported 30-day mortality rates of 12% with an additional 4–10% of patients suffering new onset strokes [16,17]. In one study, a combined 30-day mortality and stroke rate of 22% reached the predicted risk for the patients when using the logistic EuroSCORE [17]. In comparison, we were fortunate to have achieved a 30-day survival rate of $92 \pm 3.8\%$ for our first 50 patients. Late mortality during follow-up was related to the underlying patient comorbidities, with good prosthetic valve function reported at last echocardiographic assessment. The reduced observed stroke rates with the transapical approach may be attributable to less aortic arch manipulation. Results may change with further experience, however, currently the overall lower stroke risk is a well-accepted advantage of the transapical technique.

When evaluating such outcomes, we recognize that the EuroSCORE may overestimate the surgical risk for patients, particularly for those considered at highest risk. Therefore, continuous risk evaluation should be performed, using the EuroSCORE risk assessment along with other scoring systems. Published results of conventional aortic valve surgery in octogenarians are relatively good in comparison to the new transcatheter techniques [9–12,16–18]. However, these patients may be subject to selection bias with significantly less comorbidities than those patients receiving TAP-AVI. Nonetheless, in presence of relatively good outcomes for low-risk octogenarians with conventional aortic valve surgery, this should remain the standard approach for patients with an acceptable risk profile at present.

Implantation success rates of approximately 90% are currently being reported for transfemoral transcatheter approaches for aortic valve implantation. This is completely

different to the transapical approach where all patients planned were treated as presented in the current results, reaching an implant success rate of 100%. This may well be another advantage of the transapical implantation technique.

It is imperative to evaluate these new techniques stringently, however, no randomized studies comparing transfemoral, transapical and conventional aortic valve replacement has been constructed. This is unfortunate because the efficacy of the transfemoral and transapical techniques can only be established by properly designed, well-powered trials. However, other interests may favor different study designs and early commercialization of the products.

Patient selection is critical for the evaluation of all studies on transcatheter valve implantation techniques. Selection bias may be affecting which patients undergo transfemoral and transapical approaches, potentially affecting the results of each technique greatly. Furthermore, some of the patients are deemed as 'inoperable' [16]. In comparison to this we present results of an all comers study performed according to defined inclusion criteria that have been developed after team discussion and have been approved by the ethical committee. This is a study on referred patients only and we do not know potential overall numbers of high-risk patients with severe aortic stenosis. Patient selection will continue to be the most critical determinant of the overall results, especially after further commercialization of transcatheter valves.

A team approach together with team training will be extremely important when recruiting further centers to perform transcatheter aortic valve implantations. As we are still early in the learning curve, co-operation is paramount between all specialties involved in order to anticipate and mitigate potential disastrous complications.

When comparing the initial versus the more recent 25 patients receiving transapical aortic valve implantations we observed an improvement in outcome more recently. This may be due to increasing experience and especially to a more integrated team approach. However, this may also reflect some differences in patient referral patterns and may in fact reverse when even sicker patients are admitted.

Valve durability will most certainly be sufficient for the elderly high-risk populations. There is a long history of using bovine pericardial xenografts in the aortic position and the currently used tissue is treated according to proven standards including modern anticalcification technology. However, in case of valve degeneration the valve in a valve concept will allow for placement of another one inside the initial stent. For the future further improvements in imaging, namely three-dimensional online transesophageal echocardiography and integrated computertomographic images of aortic root dimensions may be helpful for valve positioning. In addition advanced technology will allow for repositions of the devices to further improve valve positioning.

In summary, transapical aortic valve implantation is a truly minimally invasive technique for beating heart off-pump aortic valve implantation. Results of the initial 50 patients at our single center are excellent when considering the overall high-risk profile and the poor natural history with non-surgical management. Transapical aortic valve implantation

is a relatively easy, safe and straightforward direct technique associated with a low stroke risk. Further long-term evaluation of this exciting technique is warranted.

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Appendix A. Conference discussion

Dr P. Kappetein (Rotterdam, The Netherlands): Several reports in literature state that about 50% of the patients with severe aortic stenosis are not even discussed with a surgeon mainly because surgery is considered to be too high risk. So there is obviously a need for a new therapy, and this transapical implantation technique might be one of these. However, the patients that are treated with this new technique are also a selection of the untreated patient population. Of the 115 patients that we screened for percutaneous valve implantation in my center, 34 patients died during the screening process. And when I spoke with Michael Mack during this meeting, he told me that he had roughly the same figures of the screening process in his center.

So my question is, do you have the same experience, that patients are so sick that they die during the screening process or that patients are so sick that they cannot even have this minimal invasive valve implantation? Should we reduce the screening time from one month to a few days and by doing that could we then save these patients?

Dr Walther: That is a very important point, if there is any registry to register patients who have not been referred so far. Actually all the colleagues who work in that field start with future studies like the PARTNER trial where you need to register all patients.

In this series we didn't do that so far. As I mentioned, three of those patients who were moribund were referred, but we said you are too moribund, you are just lying in bed, you had a hip replacement, you cannot be mobilized, you have very poor pulmonary function. We think you shouldn't receive any operation. But all others are all-comers with the one exception is those we get referred from our in-house cardiologists, they screen the ones they use for a transfemoral approach first. That is a different study that is not being presented here. And those that couldn't do with a transfemoral approach they sent to us. And from our external referring cardiologists, all the patients we were referred to, however, I don't have a clear picture of how many they did not refer at all.

But my understanding at present talking to referring cardiologists is that they get more and more awareness of what we are doing, what other colleagues with this transfemoral approach are doing, and that they are referring more and more of those very sick patients for the future.

Dr D Loisançe (Creteil, France): I think your paper is a very important contribution, and it will help us to understand how we can get step by step from the open techniques to less invasive techniques. You are raising a lot of questions, actually, from patient selection to technical details, including ethical issues. Should we still try to do something on very high-risk patients who are about to die? Many questions, indeed! I will concentrate on a few of them.

The first one will be about the technique itself. In our experience, we have experienced difficulties to evaluate exactly the position of the aortic annulus, and we still wonder what is the best technique. Is it echo or is it fluoro, and when we are using fluoro, we are worrying about the quantity of contrast media that we are using. I have noticed in your paper that you have observed a very high number of patients with renal insufficiency.

The second question will be about the need of some type of repositioning system. It is hard to know if you are in the correct position. With this type of device you have used, the procedure is a one-shot procedure. You cannot mobilize the stent valve after it is deployed. I am wondering if we should try to develop something which would permit to reposition the stent valve.

I have a comment about the patient selection. You mentioned that we need the collaboration of the cardiologists. I fully agree: we have to work together! But be careful. I think the cardiologists need to make a cultural revolution and become more friendly. For years they have shown us that they are the gatekeepers for cardiac surgery. They pretend to seek a collaboration to actually expand the pool of patients they can treat themselves by the percutaneous techniques. For years they have been extremely critical about the results of valve surgery. You must remember the comments of referral cardiologists when they discover a trivial regurgitation in the postoperative period! Today, they are becoming less critical about the results after placement of a stent valve: they are just going to accept a 40% rate of regurgitation! My feeling today: be careful with the cardiologists!

Dr Walther: Patient selection, I will start with the third one. Of course cardiologists are the gatekeepers and we cannot change them, but I think we change if you work together with them, and we as surgeons have to do two things: first we have to say our conventional results are pretty good, but there is a subgroup which are very high risk. But we have to take part in these new procedures as well. So we need to push in the direction of a transapical access. It has a very low stroke risk. We have zero in this series. I forgot to mention that. There is some stroke risk with the transfemoral approach.

Regarding repositioning, that is a very important issue, and this is the first generation of stent design. I am pretty sure there will be other systems that will allow for repositioning in the future and that will be of some help. If you talk about repositioning, the exact position is the most critical thing of the whole procedure, and actually the annulus position we at present check it by echo, by transesophageal echo. Once you teach your radiologists how to look at the CT, how to exactly measure the annular diameter, he will probably come to the same results. That is what I discussed with our radiologists, that is what I heard from John Webb who did similar in Vancouver. However, at present the echo is the most reliable, and that is a tool you can use yourself as a cardiac surgeon. We do the exact measurement just before valve implantation in the OR. So I do it myself, measure the annulus and say this is the size of valve I want to have.

Regarding renal function, this is on my additional slide, there were seven patients with renal dysfunction. Three of them were on dialysis preoperatively and four required hemofiltration postop due to high amounts of contrast, but all of them recovered, fortunately. So there are no new dialysis patients in the long-term follow-up, so I am happy about that. And I think 80 cc of contrast is pretty acceptable for those patients.

Dr T. Sioris (Helsinki, Finland): This is just an idea, but do you think the results when you follow up the valve will improve with time? Because I can imagine when you crack open the valve and the leaflets and you expose calcium to the bloodstream, so something that is a disadvantage when you do open valve surgery resulting in paravalvular leaks, the exposed calcium dissolving with time. Do you think this mechanism might actually be a help with the calcium little by little going away and you are getting a better fit with the valve in the nitinol expansion, better matching the walls long-term?

Dr Walther: This is an important issue, if you are asking about removing the calcium first before you implant the valve?

Dr Sioris: No, you can't do that, obviously. I am just thinking when you do this, you see the paravalvular leaks to begin with, right, just like the comment was and in quite a few patients, but what I am thinking is when you crack open and you expose the calcium to the bloodstream, maybe it will dissolve.

Dr Walther: Usually we don't see a big change in leaks. Once they are there, they are usually there. This is a steel stent, but even with the nitinol in the recent paper on CoreValves, there is no improvement in paravalvular leak. But the leaks are minor. And these are very high-risk patients. They all have severe aortic stenosis as the leading disease, they have some contributing incompetence, even preop. These are hypertrophied ventricles. We don't have any hemolysis in our series. None of the patients suffer from this minor incompetence. That is not a big issue.

Dr Sioris: Yes, I understand. I was too optimistic.