Impact of Changes in Left Ventricular Ejection Fraction on Survival After Transapical Aortic Valve Implantation

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Background. This single-center retrospective study assessed the variation of left ventricular ejection fraction (LVEF) after transapical transcatheter aortic valve implantation and its effect on survival. We also evaluated the effect of sheath diameter on LVEF.

Methods. We analyzed data of all consecutive patients who underwent transapical transcatheter aortic valve implantation with the Sapien (Edwards Lifesciences, Irvine, CA) device (and its evolutions) between 2009 and 2015. We analyzed the difference between preoperative LVEF and LVEF at discharge (ΔEF = LVEFpost-op – LVEFpre-op) and considered its interquartile range (±5%) as the cutoff. Patients were divided in three groups: (1) improved LVEF (ΔEF ≥ +5%); (2) unchanged LVEF (ΔEF –5% to +5%), and (3) worsened LVEF (ΔEF ≤ –5%). Survival was evaluated with Kaplan-Meier analysis, and logistic regression multivariable analysis was used to determine independent predictors of LVEF improvement.

Results. Data of 122 patients were analyzed. Patients in the three groups were distributed as follows: (group 1) 27 patients (22.1%), (group 2) 69 (56.6%), and (group 3) 26 (21.3%). The mean ΔEF was 12.7% ± 4.7% in group 1 and –10.8% ± 3.9% in group 3. The ΔEF was more likely to improve in patients with preoperative LVEF of less than 0.35 ($p = 0.014$). There were no significant differences in survival ($p = 0.41$), rehospitalization ($p = 0.472$), and New York Heart Association Functional Classification ($p = 0.307$) among the groups. The use of the smallest available sheath (18F) was not associated with a significant change of ΔEF.

Conclusions. LVEF worsened in a small number of patients after transapical transcatheter aortic valve implantation, but this change was not associated with worse postoperative outcomes. Patients with a low LVEF showed better improvement. The progressive reduction of sheath diameter does not have a significant effect on LVEF changes.

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Transcatheter aortic valve implantation (TAVI) is now a well-established procedure [1, 2] for inoperable or high-risk patients with severe symptomatic aortic valve stenosis. It has been demonstrated to be not inferior to surgical aortic valve replacement and better than optimal medical treatment (including balloon aortic valvuloplasty) [3, 4]. Of the available accesses, transfemoral (TF) and transapical (TA) are the most widely used [4]. In particular, TF-TAVI is frequently considered as the first choice because it is completely percutaneous and can be performed without general anesthesia.

Although most studies report no differences in survival between the two accesses [5–7], there is concern about the effect of apical purse string sutures and apical puncture on left ventricular (LV) function after TA-TAVI [8, 9]. However, the relationship between the apical access and a potential loss of LV function has not been clearly demonstrated.

One of the most frequent complications of TF-TAVI is related to vascular injury [10, 11], but the constant evolution of technology has led to the reduction of sheath diameters and, consequently, of vascular damages [12]. Similarly, also for TA-TAVI, companies have tried to reduce apical traumatism by reducing sheath diameters, but the positive effects of this evolution have not been demonstrated yet.

The aim of this single-center retrospective study was to evaluate changes of LV ejection fraction (LVEF) after TA-TAVI and their effect on survival and clinical status. We

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also analyzed the relationship between sheath diameter and variations of LVEF after TA-TAVI.

Patients and Methods

We analyzed data of all patients who underwent TA-TAVI at our institution since the beginning of this program in March 2009 through March 2015 with the balloon-expandable Sapien device and its evolutions Sapien-XT and Sapien-3 (Edwards Lifesciences, Irvine, CA). The analysis excluded patients who underwent TA-TAVI with other devices or those undergoing valve-in-valve procedures (aortic and mitral). To evaluate the real clinical effect of apical surgical manipulation (apical purse strings, apical puncture) we excluded patients who died within 30 days and patients who needed extensive ventricular repair for major apical complications that developed.

Data were prospectively collected in our institutional TAVI-dedicated database and retrospectively analyzed. Severe symptomatic aortic valve stenosis was present in all patients, and they were deemed inoperable or at high surgical risk by the heart team, which consisted of a cardiac surgeon, a clinical and an interventional cardiologist, and an anesthesiologist. Patients gave their informed consent for the procedure and for data collection. The local Ethic Committee approved data collection and analysis.

The TA-TAVI procedure was performed according to the conventional technique [1]. In particular, 2 concentric apical purse string sutures with 2-0 MH polypropylene (Ethicon, Somerville, NJ) were used since the beginning of the program until the introduction of the new Certitude (Edwards Lifesciences) sheath, together with the Sapien-3 valve. Then, we switched to 2 horizontal mattress sutures with 3-0 JB polypropylene. This choice was guided by the reduction of sheath diameter that occurred with the last Sapien-3 valve. A 24F sheath was used for Sapien and Sapien-XT sizes 23 mm and 26 mm. A 26-mm sheath was used for Sapien and Sapien-XT 29-mm size. An 18F sheath was used for Sapien-3 23-mm and 26-mm sizes, and a 21F sheath was used for Sapien-3 29-mm size.

All patients underwent clinical and echocardiographic evaluation at hospital admission, before discharge, 1 to 3 months postoperatively, and then yearly in a TAVI-dedicated outpatient clinic. Patients with a low preoperative LVEF underwent dobutamine stress echocardiography to evaluate contractile reserve. All echocardiographic examinations at discharge were performed by the same echocardiography laboratory, with two-dimensional and three-dimensional evaluation in all patients. For patients unable to return to our hospital for the follow-up evaluation, we performed telephone interviews and asked for a copy of the most recent echocardiographic examination.

Preoperative clinical characteristics were defined according to European System for Cardiac Operative Risk Evaluation (EuroSCORE) definitions, and postoperative outcomes were defined according to the updated Valve Academic Research Consortium 2 definitions [13]. Echocardiographic parameters were graded in accordance with American Society of Echocardiography/European Association of Echocardiography guidelines [14], and in particular, LVEF was calculated with the Simpson biplane method.

We evaluated the difference between postoperative (discharge) LVEF and preoperative LVEF (ΔEF = LVEFpost-op − LVEFpre-op). The probability of postoperative worsening, stability, or improvement of EF was based on the interquartile range of the observed ΔEF ($\pm 5\%$). A 5% LVEF variation as the cutoff for study group creation had the advantage to identify even small LVEF changes but, at the same time, allowed to reasonably overcome physiologic deviations due to the operator-dependency of echocardiography.

We used this cutoff value to divide our population into three groups: (1) improved LVEF ($\geq +5\%$), (2) unchanged LVEF (ΔEF -5% to $+5\%$), and (3) worsened LVEF ($\Delta EF \leq -5\%$). The assessment of the effect of sheath diameter on LVEF was estimated by the analysis of ΔEF variation according to the following formula: ΔEF variation = (LVEFpost-op − LVEFpre-op)/LVEFpre-op $\times$ 100.

Statistical Analysis

Continuous data are summarized with means $\pm$ SD, and categoric data are presented as frequency and percentage. Change of EF occurring after the surgical procedure and discharge was measured in 122 echocardiographic evaluations and was analyzed with a multilevel mixed-effects linear regression (Mixed procedure) using Stata 13 software (Stata Corp LP, College Station, TX). The probability of postoperative worsening, stability, or improvement of the EF was calculated using conservative cut points for stability ($\pm 5\%$) and was analyzed with a multilevel mixed-effects ordered logistic regression (Meologit procedure in Stata 13) to exclude confounding effects due to random variability among patients and time-related repetitive examination. Comparisons among the groups were made using the *t*-test, the Wilcoxon–Mann-Whitney test, the χ^2 test, or the Fisher exact test, as appropriate. Determinants of LVEF improvement were selected with bootstrap bagging of Cox proportional hazard model among all of preoperative variables listed in Table 1. All tests were two-tailed. A value of p of less than 0.05 was considered significant. Statistics were analyzed with Stata 13 software.

Results

During the study period, 130 consecutive patients underwent TA-TAVI with the Sapien device for severe symptomatic aortic valve stenosis at our institution. Overall 30-day mortality, defined as according to the updated Valve Academic Research Consortium definitions, occurred in 5 patients (3.9%). Apical rupture with severe bleeding that required extensive surgical repair of the LV occurred in 3 patients (2.3%). The remaining 122 patients represent the population of this study. Preoperative characteristics are reported in Table 1. Mean age was 80.1 $\pm$ 6.1 years, and 61 patients (50%) were male. The

Table 1. Preoperative Variables

Variable[a]	Total (n = 122)	Improved-Group 1 (n = 27)	Unchanged-Group 2 (n = 69)	Worsened-Group 3 (n = 26)	*p* Value
Male sex	61 (50)	12 (44.4)	39 (56.5)	10 (38.5)	0.236
Age, y	80.1 ± 6.1	79.6 ± 6	80.6 ± 6.4	79.4 ± 5.8	0.611
Arterial hypertension	114 (93.4)	26 (96.3)	64 (92.8)	24 (92.3)	0.792
Diabetes	35 (28.7)	7 (25.9)	23 (33.3)	5 (19.2)	0.374
NYHA III-IV	88 (72.2)	18 (66.7)	53 (76.8)	17 (65.4)	0.471
Peripheral vascular disease	77 (63.1)	18 (66.7)	44 (63.8)	15 (57.7)	0.784
COPD	25 (25.5)	9 (33.3)	12 (17.4)	4 (15.4)	0.169
Neurologic dysfunction	10 (8.2)	3 (11.1)	7 (10.1)	0 (0)	0.226
Cardiac rhythm					0.346
Sinus rhythm	77 (63.1)	14 (51.9)	49 (71)	14 (53.8)	
Atrial fibrillation	33 (27)	9 (33.3)	15 (21.7)	9 (34.6)	
PPM	12 (9.8)	4 (14.8)	5 (7.2)	3 (11.5)	
Previous AMI	31 (25.4)	6 (22.2)	16 (23.2)	9 (34.7)	0.364
Previous cardiac operation	28 (22.9)	5 (18.5)	15 (21.7)	8 (30.1)	0.326
CKD (creatinine >2 mg/dL)	13 (10.7)	2 (7.4)	6 (8.8)	5 (19.2)	0.283
EuroSCORE logistic I, %	20.9 ± 12.1	21.6 ± 14.3	21.6 ± 11.5	18.6 ± 11.6	0.545
EuroSCORE II, %	7.1 ± 5.4	5.9 ± 2.9	7.7 ± 6.4	6.8 ± 4.2	0.325
STS Score, %	8.2 ± 7.9	7.3 ± 6.7	8.9 ± 8.2	7.1 ± 8.1	0.499
Aortic gradient					
Max, mm Hg	70.4 ± 21.7	72.8 ± 23.6	70.3 ± 21.5	68.3 ± 20.7	0.745
Mean, mm Hg	42.3 ± 14.4	44.8 ± 16.2	41.8 ± 13.8	40.9 ± 14.3	0.562
AVAi, cm^2/m^2	0.46 ± 0.13	0.47 ± 0.12	0.44 ± 0.1	0.5 ± 0.21	0.161
LVEF	0.545 ± 0.12	0.483 ± 0.108	0.54 ± 0.116	0.622 ± 0.102	<0.001
EDVi, mL/m^2	64.9 ± 16.4	64.4 ± 19.5	67.2 ± 16	59.5 ± 12.3	0.116

[a] Categoric data are presented as number (%). and continuous data are presented as the mean ± SD.

AMI = acute myocardial infarction; AVAi = aortic valve area indexed; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; EDVi = end-diastolic volume indexed; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricle ejection fraction; NYHA = New York Heart Association; PPM = permanent pacemaker; STS = The Society of Thoracic Surgeons.

mean logistic EuroSCORE, EuroSCORE II, and The Society of Thoracic Surgeons scores were 20.9% ± 12.1%, 7.1% ± 5.4%, and 8.2% ± 7.9%, respectively, and 88 patients (72.2%) were in New York Heart Association Functional Classification III and IV.

The first-generation Sapien valve was implanted in 37 patients (30.3%), and the evolution Sapien-XT and the last development Sapien-3 were used in 62 (50.8%) and 23 (18.9%), respectively. The preprocedural mean LVEF was 0.545 ± 0.12. According to ΔEF, the three groups were: (1) improved, 27 patients (22.1%); (2) unchanged, 69 patients (56.6%); and (3) worsened, 26 patients (21.3%). As reported in Table 1, groups were comparable in preoperative clinical and echocardiographic characteristics. The only significant difference was preoperative LVEF. Patients of group 1 were more likely to have significantly lower preoperative LVEF than groups 2 and 3 (0.483 ± 0.108, 0.54 ± 0.116, and 0.622 ± 0.102, respectively; $p < 0.001$). Interestingly, all patients with a preoperative LVEF of less than 0.35 were in groups 1 and 2, and those with preserved LVEF were more represented in groups 2 and 3 ($p = 0.014$), as shown in Figure 1. Postoperative LVEF was 0.626 ± 0.104, 0.534 ± 0.114, and 0.498 ± 0.109 in groups 1, 2, and 3, respectively ($p < 0.001$). The mean increase of LVEF of group 1 was 12.7% ± 4.7%, and the mean LVEF reduction in group 3 was –10.8% ± 3.9%. Operative variables, postoperative outcomes, and complications are reported in Table 2.

Valve size distribution and sheath diameters were similar among the groups. A comparison between ΔEF

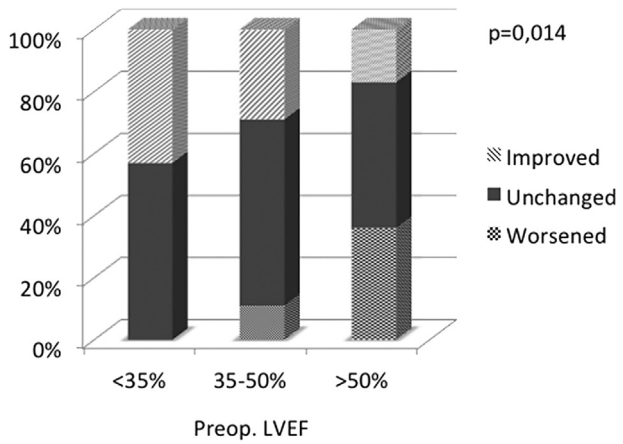


Fig 1. Distribution of patients in the three groups according to the preoperative left ventricular ejection fraction (LVEF). (Preop. = preoperative.)

Table 2. Procedural Variables, Outcomes, and Complications

Variable[a]	Total (n = 122)	Improved-Group 1 (n = 27)	Unchanged-Group 2 (n = 69)	Worsened-Group 3 (n = 26)	*p* Value
TAVI device					0.656
Edwards Sapien[b]	37 (30.3)	8 (29.6)	22 (31.9)	7 (26.9)	
Edwards Sapien XT	62 (50.8)	16 (59.3)	34 (49.3)	12 (46.2)	
Edwards Sapien 3	23 (18.9)	3 (11.1)	13 (18.8)	7 (26.9)	
Prosthesis size, mm					0.277
23	37 (30.3)	7 (25.9)	24 (34.8)	6 (23.1)	
26	65 (53.3)	13 (48.1)	38 (55.1)	14 (53.8)	
29	20 (16.4)	7 (25.9)	7 (10.1)	6 (23.1)	
Sheath diameter					0.114
18F	19 (15.6)	3 (11.1)	11 (15.9)	5 (19.2)	
21F	3 (2.5)	0 (0)	2 (2.9)	1 (3.8)	
24F	81 (66.4)	17 (63)	51 (73.9)	13 (50)	
26F	17 (13.9)	7 (25.9)	5 (7.2)	5 (19.2)	
Prosthesis embolization	2[c] (1.6)	2 (7.4)	0 (0)	0 (0)	0.028
Conversion to sternotomy	2 (1.6)	2 (7.4)	0 (0)	0 (0)	0.028
Need for extracorporeal assistance	2 (1.6)	1 (3.7)	1 (1.4)	0 (0)	0.559
Coronary occlusion	0 (0)	0 (0)	0 (0)	0 (0)	-
Aortic dissection	0 (0)	0 (0)	0 (0)	0 (0)	-
AMI	1 (0.8)	0 (0)	0 (0)	1 (3.8)	0.155
Stroke (major)	1 (0.8)	0 (0)	1 (1.4)	0 (0)	0.884
Bleeding (life threatening/major)	5 (4.1)	0 (0)	2 (2.9)	3 (11.5)	0.054
PPM implantation	8 (6.5)	1 (3.7)	6 (8.6)	1 (3.8)	0.831
Need for CVVH	8 (6.6)	2 (7.4)	3 (4.3)	3 (11.5)	0.442
Device success (excluding procedural death)	120 (98.4)	25 (92.6)	69 (100)	26 (100)	0.028
LVEF at discharge	54.6 ± 11.9	62.6 ± 10.4	53.4 ± 11.4	49.8 ± 10.9	<0.001
Discharge AR					0.57
No	68 (55.7)	19 (70.4)	35 (50.7)	14 (53.8)	
Mild	51 (41.8)	7 (25.9)	32 (46.3)	12 (46.2)	
Moderate	3 (2.5)	1 (3.7)	2 (2.9)	0 (0)	
Severe	0 (0)	0 (0)	0 (0)	0 (0)	
Rehospitalization for CV event	20 (16.4)	5 (18.5)	9 (13)	6 (23.1)	0.472

[a] Categoric data are presented as number (%). and continuous data are presented as the mean ± SD. [b] Edwards Lifesciences, Irvine, CA. [c] Both transcatheter valves were removed, and conventional aortic valve replacement was performed.

AMI = acute myocardial infarction; AR = aortic regurgitation; CV = cardiovascular; CVVH = continuous venovenous hemofiltration; LVEF = left ventricular ejection fraction; PPM = permanent pacemaker; TAVI = transcatheter aortic valve implantation.

variation (percentage) for each valve type with its sheath diameter and ΔEF variation of the smallest available sheath (Sapien-3 18F) did not demonstrate significant differences (Table 3). The mean follow-up time was 2 ± 1.3 years, and follow-up was 100% complete.

The changes of LVEF over time in the overall population and in the three groups are shown in Figure 2. Rehospitalization for cardiovascular causes was 18.5%, 13%, and 23.1% in groups 1, 2, and 3, respectively ($p = 0.472$). The differences in New York Heart Association Functional Classification at follow-up among the groups were not significant ($p = 0.307$; Fig 3). The Kaplan-Meier survival analysis did not show significant differences among the groups (Fig 4); in particular, overall survival in groups 1, 2, and 3 at 24 months was 79.5% ± 10.8%, 90.4% ± 4.2%, and 79.7% ± 8.1%, respectively ($p = 0.41$). The multivariable analysis identified preoperative LVEF (odds ratio, 0.93; 95% confidence interval, 0.90 to 0.96; $p < 0.001$) and mean preoperative gradient (odds ratio, 1.02; 95% confidence interval, 0.99 to 1.05, $p = 0.05$) as independent predictors of LVEF improvement after TA-TAVI.

Comment

The main findings of this study are that (1) LVEF variation did not affect survival at follow-up; (2) patients with poor preoperative LVEF have higher probability to improve LVEF after the procedure; and (3) LVEF variation is not modified by the reduction of sheath diameter.

LVEF Changes and Outcomes

The importance of studying LVEF in TAVI patients derives from the findings of recent studies that have

Table 3. Comparison Between Change in Ejection Fraction Variation for Each Valve Type With Its Sheath Diameter and of the Smallest Available Sheath (Sapien-3 18F)

Prosthesis and Sheath Diameter	ΔEF Variation[a] (%)	*p* Value vs Sapien-3 18F
Sapien[b] 24F	0.07	0.96
Sapien XT 24F	0.4	0.93
Sapien XT 26F	−2.2	0.52
Sapien-3 18F	0.21	…
Sapien-3 21F	3	0.24

[a] Calculated as (LVEFpost-op-LVEFpre-op)/LVEFpre-op × 100. [b] Edwards Lifesciences, Irvine, CA.

ΔEF = change in ejection fraction; LVEF = left ventricular ejection fraction.

demonstrated that LVEF is independently associated with a mortality effect on outcomes after TAVI [15, 16]. Although many studies have demonstrated similar survival between patients undergoing TF-TAVI and TA-TAVI [3, 4, 17], TF-TAVI is frequently considered as the first choice for high-risk or inoperable patients with aortic valve stenosis owing to its lower invasiveness and to the possibility to work on the awake patient. For this reason, TA-TAVI is chosen when TF access is contraindicated by extensive peripheral vascular disease or extreme vascular tortuosity.

Studies report myocardial injury both in TF-TAVI and TA-TAVI, but the latter seems to be more frequently associated with myocardial damage because a higher increase of myocardial enzymes (troponin and creatine kinase-MB) occurs [18, 19]. Myocardial damage in TA-TAVI is not surprising because it requires surgical manipulation and perforation of the LV wall as placement of apical purse string sutures and apical puncture with sheath insertion are performed. Despite the evidence of myocardial damage, its real clinical effect is still debated because the severity of the enzyme increase does not seem to be directly associated with apical dysfunction [20].

We observed a LVEF reduction of more than 5% in 22% of patients, but they did not show worse survival compared with patients with an LVEF that was unchanged or improved postoperatively. This is of great interest, especially if we consider that the three groups had similar preoperative characteristics, except for the preoperative LVEF that was significantly lower in the improved group. This shows that myocardial damage occurring during TA-TAVI is easily overcome by the benefits of overload reduction.

In accordance, the multivariable analysis identified mean preoperative transaortic gradient as an independent predictor of positive LVEF change. Many studies have investigated functional changes of LV wall motion in patients undergoing TAVI through speckle-tracking echocardiography with strain assessment, which is a tool for evaluating myocardial function. Løgstrup and colleagues [21] showed that global longitudinal strain improved in all TAVI patients, independently from the approach, whether TF or TA. Furthermore, Ando and associates [22] performed a study to assess the effect of TA-TAVI on apical longitudinal strain and on global longitudinal strain. They found that equal improvement in myocardial strain was observed in TA and TF-TAVI patients and that preprocedural strain impairment, and not the method of approach, dictated postoperative functional recovery [22].

A recent report by Ribeiro and colleagues [23] reported limited strain improvement as well as small LVEF increases in TA-TAVI patients. Their study evaluated the difference between preoperative LVEF and LVEF at 6 to 12 months; however, correlating surgical manipulation of the apex with late modification of myocardial function is difficult because many other factors, such as ventricular remodeling and the presence and severity of paravalvular leak, may play an important role.

For this reason we decided to evaluate the differences between preoperative LVEF and LVEF at discharge. Indeed, ventricular remodeling and aortic regurgitation (that in our series, when present, is just mild in the great majority of patients) have only a limited effect on LVEF changes in the acute phase soon after the operation. Myocardial injury after TA-TAVI is limited to the apical segments and occurs in nearly one-third of the population, as shown by Barbash and associates [20]. The same

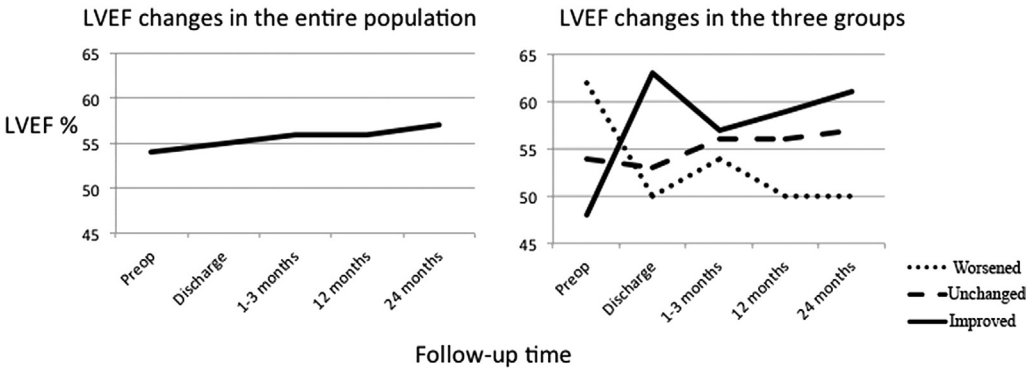


Fig 2. Left ventricular ejection fraction (LVEF) changes (left) in the entire population and (right) in the three groups.

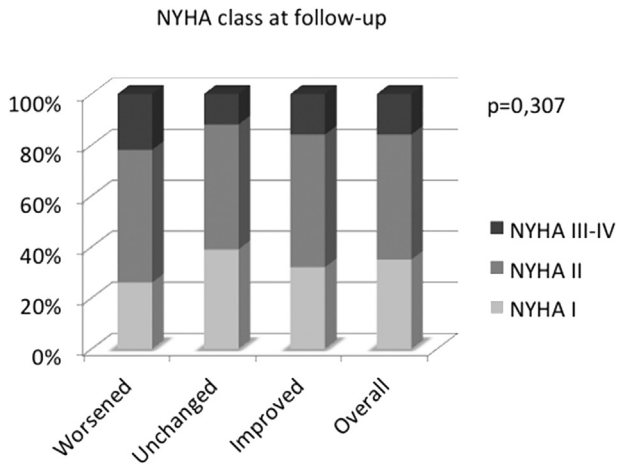


Fig 3. New York Heart Association (NYHA) Functional Classification at follow-up in the entire population and in the three groups.

study also demonstrated that this apical dysfunction is transitory in 50% of patients, with no effect on patient survival.

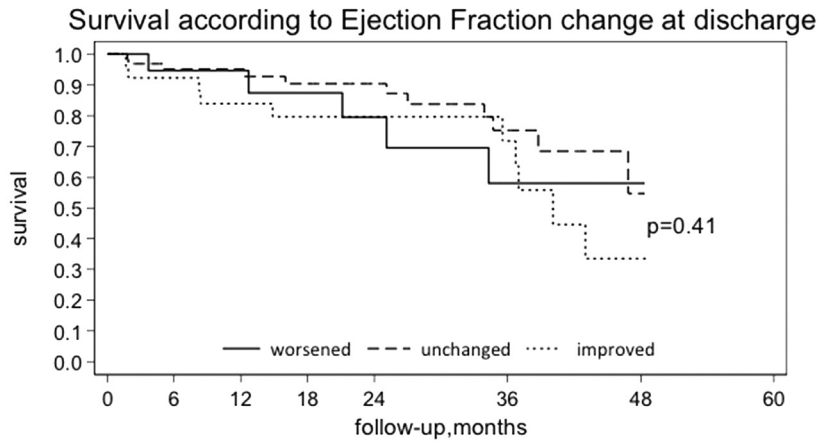
Our finding that patients with poor preoperative LVEF have a higher probability to improve and that poor preoperative LVEF is an independent predictor of LVEF improvement is consistent with previous reports [24, 25]. Furthermore, we did not observe any LVEF reduction in patients with impaired preoperative LVEF. In particular, Unbehaun and colleagues, in a large series of patients with severely depressed LV function (LVEF ≤0.30) undergoing TA-TAVI, found at least 50% and at least 100% improvement in LVEF in 71% and 43% of patients respectively, and they also showed that early improvement was significantly greater in patients with preoperative LVEF ≤0.020 [26]. This further confirms that a poor LVEF should not be considered, per se, as a contraindication to TA-TAVI also given the very low incidence of apical complications requiring extensive surgical repair of the ventricular wall [1, 25].

Sheath Diameter and LVEF Changes

Technical evolution allowed progressive reduction of sheath diameter for both TA-TAVI and TF-TAVI. In particular for TA-TAVI with the Sapien device, the last released "Certitude" sheath features a 30% diameter reduction compared with previous generations that corresponds to almost 2 mm. The positive effects of sheath diameter reduction on outcomes have been already demonstrated in TF-TAVI devices. Mussardo and colleagues [27] found a threefold reduction of major vascular events in patients treated with the Sapien XT (sheath diameters: 18F and 19F) vs the first-generation Sapien valve (24F and 28F). Even better results have been found with the newest Commander sheath (14F and 16F) of the Sapien-3 valve: Nijhoff and colleagues [12] experienced neither major/life-threatening bleeding nor vascular complications associated with its use.

Differently, these benefits have not been demonstrated for TA-TAVI. In this study, although the limited number of patients treated with the new Certitude sheath does not provide sufficient statistical power, we did not find a significant effect of sheath diameter (and its reduction) on LVEF changes. In particular, the smallest available sheath (Sapien-3 Certitude 18F) did not show any advantage in LVEF changes compared with the previous generation's bigger sheaths. A potential advantage of the smaller sheath could be related to the lower incidence of apical complications. Owing to the low incidence of such complications, further larger multicenter studies are needed

Fig 4. Kaplan-Meier analysis of survival in the three groups.



	Baseline	6 months	12 months	24 months	48 months
Pts at risk: Worsened	27	17	14	11	4
Unchanged	69	53	42	32	4
Improved	26	23	21	19	3
Survival(%) Worsened	100	94.7±5.1	94.7±5.1	79.5±10.8	58±15.3
Unchanged	100	95.1±2.7	95.1±2.7	90.4±4.2	54.7±14.5
Improved	100	92.3±5.2	83.9v7.4	79.7±8.1	33.5±14.5

to demonstrate this hypothesis. Although some authors advocate the superiority of retrograde access (TF, transaortic) over TA-TAVI in terms of myocardial injury and survival [19, 28], the higher incidence of paravalvular leak in transvascular TAVI, which is directly associated with worse survival, imposes a careful evaluation of the best access for each patient according to anatomy, LV function, and preoperative risk profile.

Limitations

The limitations of this study are mainly related to its retrospective nature. Because interobserver variability for LVEF echocardiographic assessment has been reported to be as high as 14% [29], a LVEF change of 5% as the cutoff for inclusion in the three groups might be questionable. However, this is an appropriate cutoff in this study for two main reasons: first, the use of three-dimensional echocardiography may reduce interobserver variability to 5% [30], and all our echocardiographic examinations included a three-dimensional evaluation; second, the interquartile range of ΔEF was ±5%, and this makes this value the most appropriate under a methodological point of view. Another limitation is the lack of troponin I serial blood measurements in all patients, which did not allow us to assess the relationship between LVEF variation and troponin values.

Conclusions

According to our data, LVEF changes after TA-TAVI do not seem to have a significant effect on patient outcomes. The chance of LVEF improvement is higher in patients with a severely depressed preoperative LVEF (<0.35). Sheath diameter reduction is not associated with significant LVEF changes. As a result of these findings, concerns about ventricular function worsening after TA-TAVI should be reduced, and the TA access should not be contraindicated in patients with poor LVEF preoperatively.

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