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Resheathing of self-expanding bioprosthesis: Impact on procedural results, clinical outcome and prosthetic valve durability after transcatheter aortic valve implantation

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ABSTRACT

Background: New transcatheter aortic valves were recently developed, enabling to resheath and reposition the prosthesis. The aim of the present study was to investigate whether the resheath manoeuvre did not impair the outcome of patients and the bioprosthesis durability after transcatheter aortic valve implantation (TAVI).

Methods and results: On the 346 consecutive patients (84 ± 7 yrs-old, mean STS 6.7 ± 5%) undergoing a transfemoral TAVI in our institution since January 2008, 170 patients were implanted using a self-expanding valve (SEV). Among those, 39 (Group 1) required resheathing to achieve a successful implantation, while 131 did not require it (Group 2, N = 131). A balloon-expanding valve (BEV) was used in 176 patients (Group 3). Baseline characteristics were similar between groups. Device success was 98%, the rate of in-hospital death was 2%, and the number of procedural complications was similarly low, with no significant difference between groups. The follow-up was complete in 337 of 338 patients undergoing a successful TAVI (781 patients-year). Kaplan-Meier analysis showed that overall survival was 80 ± 2% and 42 ± 3% at 1 and 5 years respectively, with no difference between groups. On multivariate analysis, acute kidney injury, post-dilatation, pulmonary hypertension, porcelain aorta and STS score, but not resheath, were independant predictors of death after TAVI. The annual event rate of structural valve deterioration was 0.6% patients-year, and similar between groups.

Conclusions: Our study shows that SEV resheath did not impair the procedural results, the outcome of patients nor the valve durability at short term after TAVI.

1. Introduction

Transcatheter aortic valve implantation (TAVI) is a valuable therapeutic option for patients with aortic valve stenosis [1,2,3,4,5,6]. Suboptimal positioning could explain some complications like paravalvular leak and conduction disorders, still unresolved issues after TAVI [7,8]. Recently, new devices were developped, enabling to resheath and reposition the prosthesis during the deployment [9,10,11,12,13,14,15]. As compared with the first generation of prosthesis, they showned an improved clinical outcome with a reduced rate of major vascular complications, major bleeding, and moderate to severe regurgitation [16,17].

The recapture manœuvre increases the interaction between the stent frame of the prosthesis and the calcium of the native valve leaflets, that may favor dislodgment of calcific particles, risk factor for embolic cerebrovascular events after TAVI [18,19]. During the resheating of the prosthesis, the leaflets are crushed and folded before repositioning and re-attempt of deployment. That may induce some tissue damage, resulting in potential intrinsic change of the pericardial leaflets [20] and finally leading to structural valve deterioration [21].

The aim of the present study was to investigate whether the resheath manoeuvre has an impact on the procedural results, the clinical outcome of patients and the prosthetic valve durability after TAVI.

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2. Methods

2.1. Patients

Since January 2008, all consecutive patients with severe aortic stenosis undergoing a transfemoral TAVI after heart-team discussion in our institution, were prospectively included in the study.

Demographics, baseline characteristics, comorbidities, risk scores, echocardiographic data, procedural details, periprocedural adverse events, antithrombotic medications, clinical and echocardiographic follow-up were prospectively collected in a dedicated database. An informed consent was obtained from each patient and the study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.2. Devices and procedure

The devices changed over time when they became available: balloon-expanding valves (BEV) were Sapien, Sapien XT and Sapien 3 (Edwards Lifesciences, Irvine, CA), whereas self-expanding valves (SEV) were Corevalve, Evolut-R (Medtronic Inc., Minneapolis, MN) and Portico (St Jude Medical/Abbott, Santa Clara, CA). The vascular access was obtained by a surgical cut-down between January 2008 and April 2010. Then we changed for a percutaneous approach using one Prostar XL or two Proglides (Abbott, Santa Clara, CA) under local anesthesia and conscious sedation.

2.3. Definitions

Events were defined according to the Valve Academic Research Consortium-2 (VARC-2) and the grade of paravalvular leak was assessed by transthoracic echocardiography according to the VARC-2 guidelines [22].

The periprocedural major adverse events (MAE) were collected from the day zero (TAVI procedure) up to discharge. Survival and clinical events occuring after discharge, ie during the follow-up period, were determined by review of medical records or phone contact of patients undergoing a successful TAVI. Structural valve deterioration was defined according to the European consensus [21].

The resheathing manœuvre was defined as when, after a partial stent frame deployment, the valve was retrieved back into the delivery catheter in order to restart the delivery and optimize the positioning. A full resheath was when the valve was completely retrieved into the delivery catheter with the intent to recross the native aortic valve (usually when the valve has fully migrated in the ascending aorta); a partial resheath was when only part of the valve was recaptured before a new attempt of deployment (usually when the valve was still below or at the level of the native annulus).

2.4. Statistical analysis

Continuous variables are presented as mean ± 1 standard deviation when normally distributed and as median and range when non-normally distributed. Normality was assessed using the Shapiro-Wilk test. Categorical variables are presented as counts and percentages. Continuous variables were compared among groups using ANOVA when normally distributed or else using the Kruskall-Wallis test. Categorical variables were tested using chi-square or Fisher's exact test when appropriate. Univariate and multivariate analysis was carried out using the Cox proportional hazards method. Variables with a $p < 0.10$ at univariate analysis were included in the backward stepwise multivariate analysis. Estimates for freedom from the composite of death and MAE were obtained by the Kaplan-Meier estimation method. A p-value < 0.05 was considered statistically significant. Analyses were performed using the XLSTAT software (version 2016, Addinsoft, France).

3. Results

3.1. Patients

On the 346 consecutive patients undergoing a transfemoral TAVI in our institution between January 2008 and December 2018 (Fig. 1), 170 patients were implanted using a SEV. Among those, 39 (Group 1) required resheathing and repositioning to achieve a successful implantation of the device (8 Portico and 31 Evolut R), while 131 did not require it (Group 2, N = 131: 20 Corevalve/88 Evolut R/23 Portico). A BEV was used in 176 patients (Group 3, including 35 Sapien/120 Sapien XT/21 Sapien 3).

Baseline characteristics are listed in Table 1.

Porcelain aorta was less frequently observed among patients receiving a BEV than a SEV which is a device technically more appropriate to this complex anatomy (18%, 12% and 3% in group 1, 2 and 3 respectively; p = 0.008).

Left ventricular ejection fraction was significantly higher in group 1 than in group 2 (66 ± 10% vs 59 ± 12%; p < 0.001), suggesting that a greater contractility of the left ventricle may favor the pop-up of the valve during the deployment and the subsequent need for resheathing.

The other comorbidities were similar between groups.

3.2. Procedural characteristics and in-hospital oucome

Procedural characteristics and in-hospital outcome were described in the Table 2.

Device success was high, ranging between 98 and 100% and the rate of in-hospital death was low (2%; range: 0.7 to 3%), not different between groups (p = 0.93 and p = 0.67, respectively).

Causes of in-hospital death were: annulus rupture (N = 2), sudden death (N = 2), myocardial infarction (N = 1), heart failure (N = 2), and cerebral trauma after a fall (N = 1).

Resheath manoeuvre was done in 39 patients (11% of the total cohort and 23% of the SEV) and was successful in all of them. The device was recaptured one time in 27 cases, two times in 11 patients and 4 times in only one patient. A full resheathing was required in 17 procedures while it remained partial in 22 cases. The outcome was similar between patients requiring partial versus full resheath and between those undergoing multiple versus only one recapture manœuvre.

The peak gradient dropped from 50 ± 23 to 5 ± 4 mmHg, the delta baseline-post procedure was similar between groups (49, 51 and 49 mmHg respectively, p = NS).

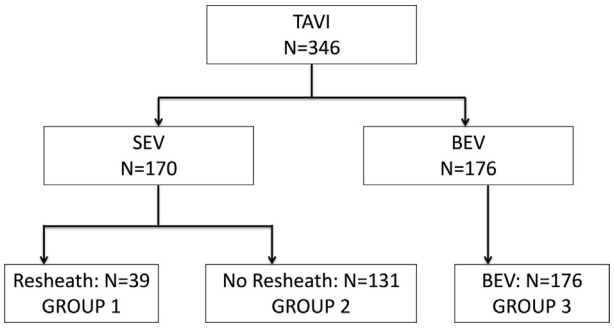


Fig. 1. Flowchart of the patients. TAVI = Transcatheter aortic valve implantation; SEV = Self expanding valve; BEV = Balloon expanding valve.

Table 1
Baseline characteristics.

Characteristics		All N = 346	Group 1 *SEV resheath* *N = 39*	Group 2 *SEV no resheath* *N = 131*	Group 3 *BEV* *N = 176*	*p* value
Age (years)	mean ± sd	84 ± 7	84 ± 6	83 ± 8	85 ± 6	0.7
Gender	M/F	162/184	16/23	58/73	88/88	0.8
Body Mass Index	mean ± sd	26 ± 5	27 ± 5	26 ± 5	26 ± 5	0.08
STS score	mean ± sd	6.7 ± 5	5.3 ± 2.6	6.2 ± 6.4	7.4 ± 5.9	0.15
Sherpa score	mean ± sd	5.6 ± 2.4	4.6 ± 2	4.8 ± 2.1	5.6 ± 2.3	0.26
Coronary artery disease	n (%)	206 (60)	23 (59)	71 (54)	112 (64)	0.59
History of myocardial infarction	n (%)	96 (28)	9 (23)	33 (25)	54 (31)	0.8
Prior coronary arterial by-pass graft	n (%)	57 (16)	5 (13)	18 (14)	34 (19)	0.71
Prior percutaneous coronary angioplasty	n (%)	124 (36)	14 (36)	43 (33)	67 (38)	0.92
Diabetes mellitus	n (%)	63 (18)	7 (18)	23 (17)	33 (19)	0.99
Cerebrovascular disease	n (%)	54 (16)	9 (23)	19 (14)	26 (15)	0.72
Atrial fibrillation	n (%)	131 (38)	12 (31)	51 (39)	68 (39)	0.9
Carotid artery disease	n (%)	50 (14)	5 (13)	21 (16)	24 (14)	0.97
Peripheral vacular disease	n (%)	62 (18)	4 (10)	19 (14)	39 (22)	0.3
Chronic obstructive pulmonary disease	n (%)	95 (27)	12 (31)	34 (26)	49 (28)	0.98
Porcelain aorta	n (%)	29 (1)	7 (18)	16 (12)	6 (3)	0.008
Mediastinal radiotherapy	n (%)	24 (0.7)	3 (8)	7 (5)	14 (8)	0.93
Serum creatinine (mg/dl)	mean ± sd	1.3 ± 0.9	1.4 ± 0.8	1.2 ± 1.2	1.2 ± 0.7	0.63
History of pace-maker	n (%)	67 (19)	9 (23)	30 (23)	28 (16)	0.59
Prior valvular surgery	n (%)	25 (7)	3 (8)	11 (8)	11 (6)	0.97
Echocardiography data						
Aortic valve area (cm2)	mean ± sd	0.6 ± 0.2	0.7 ± 0.1	0.7 ± 0.2	0.6 ± 0.1	0.45
Peak gradient (mmHg)	mean ± sd	75 ± 23	79 ± 18	76 ± 22	74 ± 25	0.64
Mean gradient (mmHg)	mean ± sd	45 ± 15	48 ± 12	46 ± 14	44 ± 16	0.34
Left ventricular ejection fraction (%)	mean ± sd	56 ± 15	66 ± 10	59 ± 12	52 ± 15	<0.001
Pulmonary hypertension > 60 mmHg	n (%)	88 (25)	9 (23)	26 (20)	53 (30)	0.36

Table 2
Procedural characteristics and in-hospital outcome.

Characteristics		All N = 346	Group 1 *SEV resheath* *N = 39*	Group 2 *SEV no resheath* *N = 131*	Group 3 *BEV* *N = 176*	*p* value
Device success	n (%)	340 (98)	39 (100)	128 (98)	174 (99)	0.93
Prosthesis size						
23 mm	n (%)	86 (25)	0	16 (12)	70 (40)	
25 mm	n (%)	10 (3)	4 (10)	6 (4)	0	
26 mm	n (%)	132 (38)	12 (31)	29 (22)	91 (52)	
27 mm	n (%)	6 (2)	3 (8)	3 (2)	0	
29 mm	n (%)	81 (23)	16 (41)	50 (38)	15 (8)	
31 mm	n (%)	16 (5)	0	16 (12)	0	
34 mm	n (%)	15 (4)	4 (10)	11 (8)	0	
Vascular access by Right femoral artery	n (%)	317 (92)	35 (90)	127 (97)	155 (88)	0.09
Vascular access by Left femoral artery	n (%)	29 (8)	4 (10)	4 (3)	21 (12)	0.09
Predilatation	n (%)	306 (88)	35 (90)	107 (82)	164 (93)	0.04
Postdilatation	n (%)	40 (11)	7 (18)	26 (20)	7 (4)	0.001
Peak aortic gradient (mmHg) at baseline	mean ± sd	58 ± 24	59 ± 25	57 ± 24	55 ± 21	0.31
Peak aortic gradient (mmHg) after TAVI	mean ± sd	5 ± 4	5 ± 5	6 ± 5	5 ± 3	0.37
TAV-in-SAV	n (%)	18 (5)	2 (5)	9 (7)	7 (4)	0.86
Fluoroscopy time (min)	mean ± sd	20 ± 10	20 ± 7	18 ± 7	21 ± 12	0.11
Contrast volume (ml)	mean ± sd	232 ± 83	243 ± 93	217 ± 93	241 ± 69	0.009
Complications						
Need for second valve	n (%)	5 (1)	1 (2)	3 (2)	1 (0.5)	0.72
Stroke	n (%)	5 (1)	1 (2)	1 (0.7)	3 (2)	0.91
Myocardial infarction	n (%)	1 (0.2)	0	0	1 (0.5)	0.75
Life threatening/Major bleeding	n (%)	6 (2)	2 (5)	3 (2)	1 (0.5)	0.28
Acute kidney injury stage 2 or 3	n (%)	13 (4)	0	4 (3)	9 (5)	0.62
Need for new dialysis	n (%)	1 (0.2)	1 (2)	0	0	1
Major vascular complication	n (%)	9 (3)	0	2 (0.8)	7 (4)	0.47
New permanent pacemaker	n (%)	43 (12)	10 (26)	21 (16)	12 (7)	0.006
In-hospital death	n (%)	8 (2)	1 (2)	1 (0.7)	6 (3)	0.67

TAV = transcatheter aortic valve; SAV = surgical aortic valve.

The number of procedural complications was similarly low in all groups except for the rate of new pace-maker implantation, significantly higher in group 1 than in group 3 (26 vs 7% respectively; p = 0.006), but with no significant difference between group 1 and 2 (26 vs 16%; p = 0.23).

The amount of contrast (243 ± 93 vs 217 ± 93 ml; p = 0.009) was significantly higher in group 1 than in group 2, but without any impact on the rate of acute kidney injury (AKI) stage 2 or 3 (0 vs 3%; p = NS) nor of new dialysis (2 vs 0%; p = NS).

The fluoroscopy time was not statistically significantly different between group 1 and 2 (20 ± 7 vs 18 ± 7 min; p = 0.11).

Balloon predilatation was more frequently performed among group 3 than in group 2 (93 vs 82%; p = 0.04) but was not different between group 1 and 2 (90 vs 82%; p = 0.32). The need for post-dilatation was similar between group 1 and 2 (18 vs 20%; p = 0.32) but was significantly lower in group 3 (4%; p = 0.001).

The rate of stroke ranged between 0.7 and 2% with no difference between groups (p = 0.91).

Fig. 2 compares the periprocedural outcome between groups of patients.

Logistic regression univariate analysis showed that porcelain aorta (OR 2.83 [1.123–7.151]; p = 0.03) and left ventricular ejection fraction (OR 1.06 [1.034–1.098]; p < 0.001) increased the risk of resheath, but predilatation had no impact (HR 1.16 [0.390–3.462]; p = 0.78). The type of valve has no impact on the rate of resheath, which was performed in 24% of the Evolut-R and in 26% of the Portico devices (p = 1).

Resheath was needed more frequently during the first half of Evolut-R implantations (30 vs 14%, p = 0.04) but was equally required for the first and the last Portico valves (12 vs 40%, p = 0.11).

4. Follow-up

4.1. Clinical

The follow-up was complete in 337 of 338 patients undergoing a successful TAVI (99%). The mean duration was 863 days and the median value was 20, 1 months (interquartile range 227–1227 days), resulting in a total of 781 patients-year.

During this period, there were 7 ischemic strokes, 2 major bleedings, 3 AKI stage 3, 1 major vascular complication and 4 new permanent pace-makers, with no differences between groups. A total of 159 deaths occurred at a median time of 658 days after TAVI. Table 3 provides the detailed causes of death, which were mainly non cardiovascular.

Kaplan-Meier analysis showed that overall and event-free survival was 80 ± 2%, 69 ± 3% and 42 ± 3% and 80 ± 2%, 68 ± 3% and 39 ± 3% @ 1, 2 and 5 years respectively, with no difference between groups (Fig. 3).

On multivariate analysis, AKI, post-dilatation, pulmonary hypertension, porcelain aorta and STS score, but not resheath, were independant predictors of death after TAVI (Table 4).

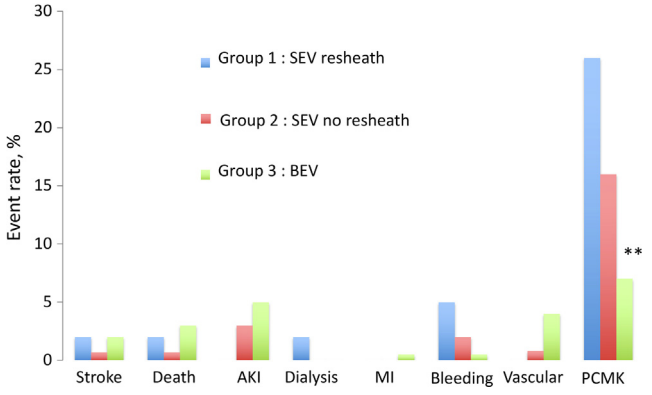


Fig. 2. Periprocedural complications. AKI = Acute kidney injury stage 2 or 3; MI = Myocardial infarction; Bleeding = life-threatening and major bleeding; Vascular = Major vascular complications; PCMK = new permanent pace-maker; **= p < 0.05 between group 1 and group 3.

Table 3
Causes of death at follow-up.

Total	**159**
Cardiovascular	*67*
heart failure	25
limb ischemia	1
pulmonary embolism	2
stroke	6
sudden death	14
tamponnade	1
unknown	18
Non cardiovascular	*92*
renal failure	7
dementia	5
age	14
bleeding	6
bone fracture	4
cancer	20
COPD	4
liver cirrhosis	2
sepsis	29
suicide	1

4.2. Echo

The systematic echocardiographic follow-up (mean duration: 343 days) showed a persistant good function of the valve overtime (peak gradient: 16 ± 10 mmHg, mean gradient: 9 ± 6 mmHg, aortic valve area 1.6 cm^2, no new intra-prosthetic regurgitation) and allowed to detect 5 structural valve deteriorations, observed at a median time of 1196 days (3.2 years) after the procedure (Fig. 4). None of these prostheses (one Sapien, 2 Sapien XT and two Portico) have been resheated. The annual event rate of structural valve deterioration was low (0.6% patients-year) and similar between groups (zero vs 2.1% vs 0.5% respectively, p = 0.24).

In logistic regression univariate analysis, the resheath manœuvre (OR 0.69 [0.036–13.284]; p = 0.81) and anticoagulants at discharge (OR 0.54 [0.029–10.346]; p = 0.68) were not associated with an increased risk for structural valve deterioration at follow-up.

5. Discussion

The salient findings of this study are:

1. Resheating manœuvre of a SEV did not impair the safety nor the efficacy of the TAVI procedure, and has no negative impact on the clinical outcome of patients at follow-up.
2. Resheating manœuvre has no deleterious effect on the valve durability.

5.1. Procedural results and clinical outcome after TAVI

The rate of resheating manœuvre was reported in 23.8% by Manoharan et al with the Portico system [10] and in 22.6% by Popma et al in the Evolut-R US registry [15] but none of them reported an association between this manœuvre and the outcome after TAVI. The rate of resheath was similar in our study (23%) which, to the best of our knowledge, is the first to demonstrate the absence of negative impact of this recapture manœuvre on the procedural outcome. Indeed, the procedural success and the rate of periprocedural complications were similar between patients receiving a SEV implanted with or without need for resheath.

We could have expected a higher number of cerebrovascular events among patients requiring a resheath, due to the greater interaction between the stent frame and the calcium of the native

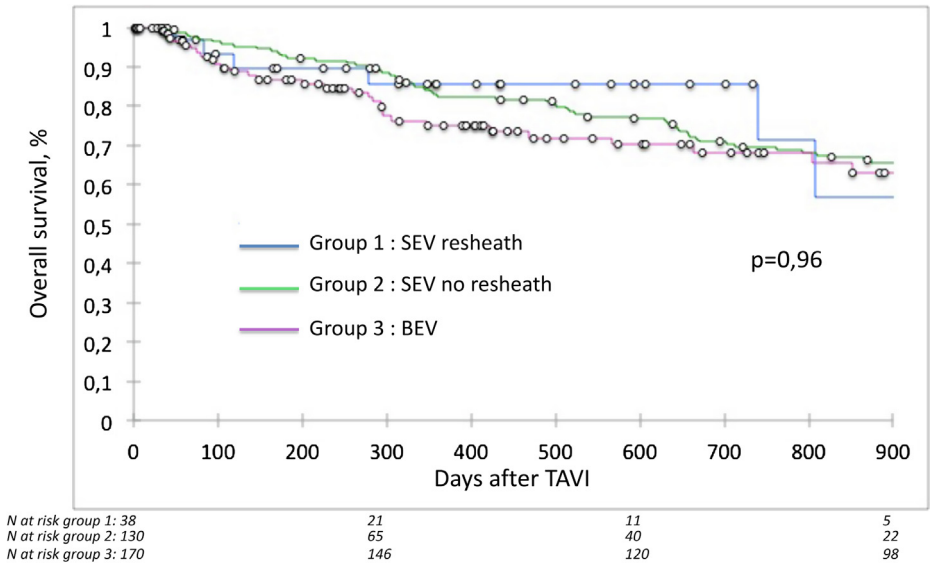


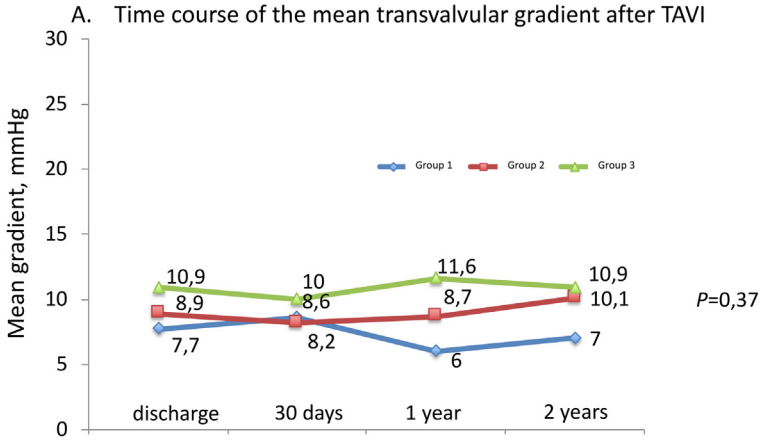
Fig. 3. Kaplan-Meier analysis showing the comparison of the overall survival between groups. SEV = Self expanding valve; BEV = Balloon expanding valve.

Table 4
Univariate and multivariate analysis for predictors of survival according to Cox models.

	Univariate analysis		Multivariate analysis	
Parameter	HR (95% CI)	*p* value	HR (95% CI)	p value
Baseline characteristic				
Age (yrs)	0.97 (0.974–1.026)	0.973		
Gender	0.99 (0.56–1.75)	0.97		
Body Mass Index	0.99 (0.964–1.036)	0.962		
STS score	1.034 (1.010–1.058)	0.005	1.030 (1.006–1.054)	0.012
Sherpa score	1.003 (0.920–1.092)	0.952		
Coronary artery disease	0.89 (0.645–1.227)	0.475		
Diabetes mellitus	1.32 (0.885–1.967)	0.173		
Atrial fibrillation	1.35 (0.985–1.856)	0.062	1.069 (0.764–1.496)	0.698
Prior coronary arterial by-pass	0.72 (0.464–1.126)	0.151		
Peripheral vacular disease	1.04 (0.715–1.520)	0.829		
Chronic obstructive pulmonary disease	1.01 (0.710–1.432)	0.964		
Porcelain aorta	1.75 (0.909–3.371)	0.094	2.061 (1.058–4.014)	0.034
Mediastinal radiotherapy	0.74 (0.412–1.345)	0.329		
Serum creatinine (mg/dl)	1.10 (0.954–1.274)	0.188		
History of pace-maker	1.17 (0.785–1.749)	0.439		
Prior valvular surgery	1.15 (0.641–2.086)	0.629		
Aortic valve area (cm2)	0.87 (0.331–2.305)	0.784		
Peak gradient (mmHg)	1.00 (0.994–1.006)	0.995		
Left ventricular ejection fraction (%)	1.00 (0.995–1.017)	0.303		
Pulmonary hypertension > 60 mmHg	1.93 (1.387–2.685)	< 0.0001	1.708 (1.219–2.394)	0.002
Periprocedural characteristic				
Predilatation	1.48 (0.655–3.382)	0.342		
Postdilatation	1.75 (1.089–2.818)	0.021	1.964 (1.210–3.188)	0.006
TAV-in-SAV	0.72 (0.322–1.650)	0.448		
Resheath	0.90 (0.420–1.950)	0.79		
Fluoroscopy time (min)	1.00 (0.992–1.015)	0.562		
Contrast volume (ml)	1.00 (0.998–1.002)	0.959		
Need for second valve	2.10 (0.669–6.640)	0.203		
Stroke	1.51 (0.373–6.123)	0.563		
Life threatening/Major bleeding	1.49 (0.369–6.013)	0.575		
Acute kidney injury stage 2 or 3	4.39 (2.415–8.006)	<0.0001	4.386 (2.383–8.074)	<0.001
Major vascular complication	1.14 (0.537–2.448)	0.725		
New permanent pacemaker	1.38 (0.855–2.244)	0.185		
Anticoagulants at discharge	1.12 (0.773–1.650)	0.530		

leaflets. Kahlert et al [19] shown that high-intensity transient signals at the transcranial doppler were registered predominantly during the positioning and the implantation of the valve, meaning when the interaction between the stent frame and native leaflets is maximal and may favor calcific particles embolization. Nombela-Franco et al [18] reported that 54% of cerebrovascular events occur within the first 24 h after TAVI and that valve dislodgment/embolization was the most powerful predictor of acute cerebrovascular events. In fact, in our study, the rate of stroke was similarly low in all patients (2% in patients with resheath and 0.7% among those with no resheath, p = 0.18). The design of the last generation of TAVI devices could potentially explain the safety of the

A. Time course of the mean transvalvular gradient after TAVI



B. Details of the mean gradient per patient with structural valve deterioration

	Type of valve	discharge	30 days	1 year	2 years	3 years	4 years	5 years	6 years	7 years
Patient 1	Sapien 23 mm	10	7	12	8	12	3	8	13	20
Patient 2	Sapien XT 26 mm	8	12	12	11	12	21			
Patient 3	Sapien XT 26 mm	9	16	17	34					
Patient 4	Portico 23 mm	8	9	24						
Patient 5	Portico 29 mm	14	14	12	12	20				

Fig. 4. A. Time course of the mean transvalvular gradient by groups. B. Details of the mean gradient per patient experiencing a structural valve deterioration.

recapture manœuvre: the delivery system offers the ability of gradually absorb the residual energy of the nitinol cage, avoiding a strong jump of the metallic stent frame during recapture. The external skirt reduces the frictions with the calcified native leaflets during positioning and implantation.

The rate of new definitive pacemaker implantation has been shown to be superior after SEV than after BEV implantation [8,17] and it was confirmed in our study; but, among the patients treated by a SEV, the need for new pacemaker was not different if they underwent a resheath of the valve or not (26 vs 16%, p = 0.08).

At follow-up, our data showed that the risk of mortality or adverse events was not predicted by the resheath, which remains a safe manœuvre regarding the long term outcome of patients treated by TAVI.

5.2. Valve durability

Structural valve deterioration is the principal mechanism of bioprosthetic valve dysfunction at long term. It is characterized by permanent intrinsic changes (calcification, pannus deposition, leaflet tear, flail or fibrotic leaflet), leading to stenosis or intraprosthetic regurgitation, that can be detected by an increase of the transvalvular gradient overtime or a new intraprosthetic leak, not described at discharge [21]. Data of long term follow-up after TAVI are scarce because a lot of patients did not survive more than five years after the procedure, due to their comorbidities and/or their old age. A rate of structural valve deterioration was reported at 3.4% by Toggweiler et al and at 4.2% by Barbanti et al at 5 year follow-up, but they use different criteria to define it [23,24]. According to the definition of the European consensus [21], Eltchaninoff et al [25] founded only 9 patients with a structural valve deterioration among the 378 included in the Rouen registry and followed up to 8 years. In our series, we reported 5 restenotic structural valve deteriorations (1 Sapien, 2 Sapien XT and 2 Portico) detected during the systematic follow-up of our 338 patients up to 5 years. None of the patients undergoing a reheath during the deployment of the valve experienced a structural valve deterioration. The resheating of the prosthesis implies that the leaflets are crushed and folded again, before repositioning and re-attempt of deployment. Zegdi et al [20] published pathological microscopic evidence of traumatic injury of the pericardial leaflets in transcatheter valves, consisting in collagen fibers fragmentation and disruption, potentially related to the crimping and ballooning process. As the recapture consists in a reclosing of the partially opened stent frame and a subsequent folding of the leaflets, this manœuvre could potentially induce pericardial injury, leading to premature bioprosthetic dysfunction. Our study, with zero structural valve deterioration observed among the 39 patients needing a resheath, suggests that this manœuvre did not fracture any component of the valve and has no deleterious effect on the bioprosthesis durability at 20-months follow-up.

5.3. Study limitations

This study was performed in a single center, assessing a relatively low number of patients. The duration of follow-up is too short for a long or mid-term (i.e. >5 years) assessment of bioprosthesis durability, but showed mainly an absence of damage in any component of the valve at 20 months follow-up.

Our results should be confirmed in larger series with longer follow-up before final conclusion about the safety of the resheath manœuvre.

6. Conclusion

This study shows that the resheath of SEV is a safe technique that did not impair the procedural results, with no negative impact on the outcome of patients after TAVI nor on the valve durability at follow-up.

Declaration of Competing Interest

For all the authors: there are no conflict of interest. The authors takes responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcha.2019.100462.

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