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CLINICAL RESEARCH

Transcatheter aortic valve implantation: The road to a minimalist ''stent-like'' procedure

TAVI, la voie vers une procédure minimaliste de type «stent»

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KEYWORDS
Aortic stenosis;
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Summary
Background. — Since the first-in-man implantation of a transcatheter aortic stented valve in April 2002 in Rouen, the procedure has expanded worldwide. In our centre, all transfemoral procedures have been performed using local anaesthesia without transoesophageal echocardiographic monitoring.
Aim. — To report our experience of transfemoral arterial transcatheter aortic valve implantation (TAVI) over the last 2 decades, following the evolution of devices, practices and indications.
Methods. — Between 2002 and 2021, 2097 consecutive patients had a TAVI procedure in our centre. Among them, 1780 underwent transfemoral arterial aortic valve implantation, and were subdivided into three groups according to the time period: before 2009; 2009—2014; and 2014—2021.

Abbreviations: AS, aortic stenosis; FIM, first-in-man; NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation; TOE, transoesophageal echocardiography.

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Results. — Median age was 85 years, and remained unchanged over time. The mean logistic EuroSCORE gradually decreased over time (28% before 2009 vs 15% for 2009—2014 vs 11% since 2014; $P < 0.001$). Predilatation was performed almost systematically before 2009 (93%), but was rarely performed in the last period (14%; $P < 0.001$). Thirty-day all-cause mortality decreased over time, and was only 1.4% in 2021. Length of stay decreased considerably, with a median duration of only 2 days after the procedure, and > 70% of patients were discharged home within 72 hours. Similarly, procedural duration, X-ray time and contrast volume decreased over time.
Conclusion. — Transfemoral aortic valve implantation, performed as a minimalist ''stent-like'' procedure using only local anaesthesia, is feasible in the vast majority of patients, with excellent outcomes.

MOTS CLÉS
Rétrécissement aortique ;
Valve aortique percutanée ;
TAVI

Résumé
Contexte. — Depuis la première implantation chez l'homme d'une valve aortique percutanée en avril 2002 à Rouen, la procédure s'est considérablement développée dans le monde entier. Dans notre centre, toutes les procédures trans-fémorales ont été réalisées sous anesthésie locale.
Objectif. — Nous rapportons ici notre expérience du TAVI artériel transfémoral au cours des 2 dernières décennies.
Méthodes. — Entre 2002 et 2021, parmi les 2097 procédures TAVI réalisées dans notre centre, 1780 ont été réalisées par voie artérielle transfémorale et ont été subdivisés en 3 groupes selon la période: avant 2009; entre 2009 et 2014; et entre 2014 et 2021.
Résultats. — L'âge médian était de 85 ans. L'EuroSCORE logistique moyen a progressivement diminué au fil du temps (28 % avant 2009 vs 15 % entre 2009 et 2014 vs 11 % depuis 2014; $p < 0{,}001$). La prédilatation quasi systématique avant 2009 (93 %) ne l'a été que rarement (14 %) depuis 2014 ($p < 0{,}001$). La mortalité toutes causes à 30 jours a diminué au fil du temps et n'était que de 1,4 % en 2021. La durée de séjour a considérablement diminué, avec une médiane de 2 jours après l'intervention et plus de 70 % des patients sortis à domicile dans les 72 heures. De même, la durée de la procédure, le temps de scopie et le volume de contraste ont été réduits.
Conclusion. — L'implantation d'une valve aortique par voie artérielle trans-fémorale, réalisée de façon minimaliste « stent-like », sous anesthésie locale uniquement, est réalisable chez la grande majorité des patients avec d'excellents résultats.

Background

On 16 April 2002, the first-in-man (FIM) implantation of a transcatheter aortic stented valve was performed in Rouen, France, in a 57-year-old male patient presenting with severe aortic stenosis (AS) and cardiogenic shock [1]. Since then, the procedure has been performed worldwide in more than 50 countries and more than 1500 centres, with over 1,500,000 patients treated and thousands of lives saved. The outstanding scientific evaluation of transcatheter aortic valve implantation (TAVI) led, in 2021, to the extension of indications to low-risk patients in Europe [2] and the USA [3]. Alain Cribier's idea to implant a valve using a transcatheter technique under local anaesthetic for the treatment of inoperable patients with AS has surpassed his expectations. Since the FIM implantation, and consistent with the original concept (i.e. offering a less invasive aortic valve replacement to the elderly), all transfemoral procedures performed in our centre have been done under local anaesthetic, without invasive transoesophageal echocardiographic (TOE) monitoring. This strategy was long considered by all as unfeasible, but is now used worldwide, and represents the gold standard for transfemoral TAVI procedures.

We report here our experience of transfemoral arterial TAVI over the last 2 decades, following the evolution of devices, practices and indications, and the impact on 30-day and 1-year outcomes.

Methods

Patient selection

Between April 2002 and April 2021, 2097 consecutive patients were hospitalized for TAVI in our centre, and were included in a prospective single-centre registry. Among them, 1780 had transfemoral arterial implantation, and were included in the analysis. The distribution of the different approaches is described in Table A.1. The first ever transfemoral arterial implantation was performed in October

2003, after an initial series of 36 patients treated using the venous transeptal approach imposed by French regulations after the FIM implantation. All procedures were performed using local anaesthesia and without TOE monitoring. To compare 30-day and 1-year outcomes using various generations of prostheses/practices, patients were separated into three groups, defined by time periods: (1) 2003—2009 (exclusive use of SAPIEN valves [Edwards Lifesciences, Irvine, CA, USA], using surgical cut down, systematic balloon aortic predilatation and rapid pacing using the right ventricular lead); (2) 2009—2014 (use of the new-generation balloon-expandable prostheses SAPIEN XT [Edwards Lifesciences] and CoreValve [Medtronic, Minneapolis, MN, USA], with a shift to a pure percutaneous technique with preclosing, using ProStar XL or ProGlide systems [Abbott, Chicago, IL, USA], no systematic predilatation and rapid pacing using the right ventricular lead); and (3) 2014—2021 (use of the third-generation valves SAPIEN 3 [Edwards Lifesciences] and EVOLUT CoreValve [Medtronic]).

All patients selected by our multidisciplinary team had severe, degenerative symptomatic AS, and were included with respect to the inclusion criteria of successive French and European trials and registries. All patients gave written informed consent. The screening process included transthoracic echocardiography, selective coronary angiography, aortography and iliofemoral angiography; TOE was not performed. Computed tomography became a systematic component of the screening process in 2006.

The procedure

Procedures were performed in a conventional cardiac catheterization laboratory with sterile precautions or in a hybrid room. For the surgical arterial cutdown approach (first period), the team in the room was composed of two interventional cardiologists, a cardiac surgeon and two nurses. Since 2009 and the use of a true percutaneous approach, the cardiac surgeon and the echocardiographer were not present in the room, but were immediately available in case of any complications. An echocardiography machine was systematically present in the room.

All transfemoral procedures were done under local anaesthetic, even when surgical cutdown was used. Conscious sedation was used systematically in the first two periods, and only on demand in the last period. As procedures were performed under local anaesthetic, there was no anaesthesiologist in the room.

The selected femoral artery was cut down (Group 1) or ''preclosed'' (Groups 2 and 3). Controlateral arterial and venous access was obtained systematically. If necessary, predilatation was performed using a balloon, in accordance with the valve size. Valve positioning was based on fluoroscopy with serial (5 mL) supra-annular aortography to validate the position of the valve during right ventricular pacing. For SAPIEN-type valves, the prosthesis was delivered using right ventricular pacing. The femoral arteriotomy was closed surgically and, since 2009, by using suture devices. In the absence of atrioventricular block, the pacing lead was removed at the end of the procedure. Patients were monitored in the intensive care unit for a minimum of 24 hours after valve implantation.

Data collection and endpoint definitions

Clinical and transthoracic echocardiogram variables were obtained at baseline, discharge and 1 month, and annually thereafter, and the data were entered into our institutional database and the French national registries. Demographic, echocardiographic and procedural characteristics, outcomes and complications were evaluated in hospital, at 30 days and at 1 year, in the overall population and in the three subgroups. All complications were reported according to the Valve Academic Research Consortium (VARC) classification [4]. Procedural success was defined as: (1) successful access, delivery of the device and retrieval of the delivery system; (2) correct positioning of the device; (3) freedom from death; and (4) freedom from surgery or intervention related to the device or to a major vascular or cardiac complication.

Statistical analysis

Categorical data are reported as counts and percentages and continuous data as medians (interquartile ranges). Comparison of quantitative continuous variables was performed with the Wilcoxon rank sum test and the Kruskal-Wallis rank sum test. Comparison of categorical variables used Pearson's χ^2 test or Fisher's exact test.

The Kaplan-Meier method was used to plot the survival curves, which were compared with the log-rank test. All statistical tests were two sided. Differences were considered statistically significant at P values ≤ 0.05. All data were analysed using R software, version 4.0.0 (R Project for Statistical Computing, Vienna, Austria).

Results

Results are presented for the overall population, and for each of the three groups (before 2009, 2009—2014 and 2014—2021).

Baseline characteristics

Baseline clinical characteristics are shown in Table 1. The median age of the treated population was > 85 years, and did not vary over time. However, history of chronic obstructive pulmonary disease, atrial fibrillation, myocardial infarction, balloon aortic valvuloplasty and coronary artery bypass graft, and creatinine concentration decreased significantly over time, indicating fewer co-morbidities. As a consequence, the mean logistic EuroSCORE gradually decreased over time (28% before 2009 vs 15% between 2009 and 2014 vs 11% since 2014; $P < 0.001$). Conversely, the number of patients with a history of hypertension and high body mass index values increased. The majority of patients were severely symptomatic (New York Heart Association [NYHA] class III or IV). All other variables were similar over time.

Baseline transthoracic echocardiogram data are shown in Table 2. There was no major difference regarding the severity of AS. However, the proportion of patients with significant aortic regurgitation, pulmonary hypertension and altered left ventricular ejection fraction decreased significantly over time.

Table 1 Baseline characteristics.

	Overall population	Group 1 (before 2009)	Group 2 (2009—2014)	Group 3 (2014—2021)	P[a]
	(n = 1780)	(n = 60)	(n = 388)	(n = 1332)	
Age (years)	85 (81—88)	84 (80—88)	86 (81—89)	85 (81—88)	0.2
Male sex	806 (45)	28 (47)	167 (43)	611 (46)	0.6
BMI (kg/m^2)	26.6 (23.6—29.7)	24.6 (22.4—27.4)	26.2 (23.4—29.4)	26.7 (23.8—29.8)	0.006
Diabetes mellitus	517 (29)	16 (27)	111 (29)	390 (29)	0.9
Hypertension	1353 (76)	44 (73)	273 (70)	1036 (78)	0.01
Atrial fibrillation	628 (35)	25 (42)	157 (40)	446 (33)	0.023
Previous PCI	422 (24)	18 (30)	90 (23)	314 (24)	0.5
Previous MI	180 (10)	26 (43)	47 (12)	107 (8.0)	< 0.001
Previous CABG	120 (6.7)	17 (28)	38 (9.8)	65 (4.9)	< 0.001
Previous BAV	181 (10)	36 (60)	76 (20)	69 (5.2)	< 0.001
TAVI in TAVI	1 (< 0.1)	0 (0)	0 (0)	1 (< 0.1)	> 0.9
TAVI in surgical bioprosthesis	88 (4.9)	0 (0)	8 (2.1)	80 (6.0)	< 0.001
Stroke	127 (7.1)	4 (6.7)	23 (5.9)	100 (7.5)	0.6
Pacemaker	207 (12)	10 (17)	42 (11)	155 (12)	0.4
COPD	197 (11)	21 (35)	75 (19)	101 (7.6)	< 0.001
PAD	158 (8.9)	9 (15)	40 (10)	109 (8.2)	0.10
Creatinine (μmol/L)	92 (74—119)	118 (96—148)	94 (80—126)	90 (73—116)	< 0.001
Neoplasia	329 (18)	17 (28)	65 (17)	247 (19)	0.10
Logistic EuroSCORE (%)	12 (8—19)	28 (22—35)	15 (11—22)	11 (8—17)	< 0.001
NYHA class III—IV	1019 (57)	53 (88)	280 (72)	686 (52)	< 0.001

Data are expressed as median (interquartile range) or number (%). BAV: balloon aortic valvuloplasty; BMI: body mass index; CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; MI: myocardial infarction; NYHA: New York Heart Association; PAD: peripheral artery disease; PCI: percutaneous coronary intervention; TAVI: transcatheter aortic valve implantation.
[a] Kruskal-Wallis rank sum test; Pearson's χ^2 test; Fisher's exact test.

Table 2 Baseline echocardiographic characteristics.

	Overall population	Group 1 (before 2009)	Group 2 (2009—2014)	Group 3 (2014—2021)	P[a]
	(n = 1780)	(n = 60)	(n = 388)	(n = 1332)	
Aortic valve area (cm^2)	0.70 (0.60—0.84)	0.65 (0.50—0.72)	0.67 (0.53—0.79)	0.72 (0.60—0.86)	< 0.001
Mean aortic gradient (mmHg)	44 (36—54)	40 (31—45)	45 (35—57)	44 (37—53)	0.003
AR≥grade 2	355 (20)	26 (43)	91 (23)	238 (18)	< 0.001
PAPS (mmHg)	40 (31—50)	44 (35—52)	41 (34—51)	38 (30—50)	< 0.001
LVEF (%)	62 (52—68)	53 (35—63)	63 (50—70)	61 (53—68)	< 0.001

Data are expressed as median (interquartile range) or number (%). AR: aortic regurgitation; LVEF: left ventricular ejection fraction; PAPS: pulmonary artery systolic pressure.
[a] Kruskal-Wallis rank sum test; Pearson's χ^2 test.

Procedural outcomes

The results are summarized in Table 3. The proportion of patients implanted using the arterial femoral approach increased over time, reaching 93.6% in 2021. At the beginning of our experience, a surgical cutdown was mandatory, in relation to the size of the introducers used with the SAPIEN (24 Fr). From 2009 (when SAPIEN XT and smaller size introducers [18 Fr and 20 Fr] were used, followed in 2014 by SAPIEN 3 with 14 Fr and 16 Fr introducers), a pure percutaneous approach was the default strategy.

The procedural device success rate was very high (93%) in the overall population, and increased over the years. Predilatation was performed almost systematically before 2009 (93%), but decreased over time, and was rarely performed (14%) in the last period ($P < 0.001$). Postdilatation also decreased over time: 10% before 2009 vs 9% for 2009—2014 vs 5.5% since 2014 ($P = 0.018$). Similarly, procedural duration, X-ray time and contrast volume decreased over time. In our centre, the balloon-expandable valve was the most commonly used valve, with the self-expandable device being introduced in June 2013.

Table 3 Procedural outcomes.

	Overall population ($n = 1780$)	Group 1 (before 2009) ($n = 60$)	Group 2 (2009–2014) ($n = 388$)	Group 3 (2014–2021) ($n = 1332$)	P[a]
Surgical cutdown	91 (5.1)	60 (100)	29 (7.5)	2 (0.2)	<0.001
Predilatation	359 (20)	56 (93)	112 (29)	191 (14)	<0.001
Postdilatation	114 (6.4)	6 (10)	35 (9.0)	73 (5.5)	0.018
Device success	1661 (93)	52 (87)	357 (92)	1252 (94)	0.042
Need for second valve	17 (1.0)	0 (0)	2 (0.5)	15 (1.1)	0.7
Procedural duration (minutes)	66 (51–89)	143 (126–176)	90 (60–150)	60 (48–79)	<0.001
X-ray time (minutes)	15 (12–20)	22 (19–29)	18 (15–22)	14 (11–18)	<0.001
Contrast volume (mL)	140 (114–180)	150 (110–175)	180 (141–220)	130 (110–165)	<0.001
Valve					
Model	1544 (87)	60 (100)	381 (98)	1103 (83)	0.001
Balloon expandable	223 (13)	0 (0)	7 (1.8)	216 (16)	
Self expandable	13 (0.7)	0 (0)	0 (0)	13 (1.0)	
Others				0.002	
Size	690 (39)	30 (50)	175 (45)	485 (36)	
≤23 mm	724 (41)	29 (48)	175 (45)	520 (39)	
26 mm	349 (20)	0 (0)	35 (9.0)	314 (24)	
≥29 mm					

Data are expressed as number (%) or median (interquartile range).
[a] Fisher's exact test; Kruskal-Wallis rank sum test; Pearson's χ^2 test.

Postprocedural results at 30 days

Postprocedural results at 30 days are shown in Table 4. In-hospital and 30-day all-cause mortality decreased over time, and the latter was only 1.4% in 2021. The rates of bleeding, vascular complications, acute kidney injury and major complications, such as conversion to emergent cardiovascular or vascular surgery, decreased dramatically over time. In contrast, the incidence of stroke and myocardial infarction was very low, and remained unchanged over time. On the other hand, the pacemaker rate increased gradually over time.

Length of stay

Length of stay in hospital decreased considerably over time, with a median duration of only 2 days after the procedure, and for the last 4 years > 70% of patients were discharged within 72 hours after planned procedures (Table 4; Fig. 1).

Echocardiography at 30 days and 1 year

Echocardiographic variables at 30 days and 1 year are shown in Table 5 and Table 6, respectively. Haemodynamic results were excellent, and the occurrence of paravalvular regurgitation > grade 2 decreased significantly over time ($P < 0.001$).

One-year outcome

One-year outcomes are summarized in Table 7. All-cause mortality decreased gradually from 30% before 2009 to 9.1% after 2014 ($P < 0.001$). After the first 30 days, the number of patients requiring a pacemaker remained very low (0.6% for the overall population). NYHA functional class improved dramatically at 30 days and at 1 year; most patients were in NYHA class I or II after the procedure (Fig. 2). At 1 year, two patients required a reintervention (redo TAVI in one for valve dysfunction (stenosis); and surgical aortic valve replacement in one for symptomatic grade III paravalvular aortic regurgitation). The 1-year incidences of valve thrombosis and endocarditis were extremely low (0.1% and 0.7%, respectively).

Fig. 3 shows the Kaplan-Meier curves for all-cause mortality at 1 year. Mortality rates in the second and third periods were similar, and were significantly better than in the first period.

Discussion

The main findings of our study in patients treated by TAVI with the transfemoral arterial approach are: (1) the feasibility of our strategy using local anaesthesia and exclusive X-ray guiding in transfemoral TAVI procedure; and (2) the constant simplification of the procedure over 2 decades, with better outcomes and a shorter hospital stay.

The idea of using a stented valve to treat AS was in line with Alan Cribier's initial goal to offer a less invasive alternative treatment to the numerous patients with severe AS deemed inoperable in the early 1980s, and without treatment in the short term. Confronted with the evidence of restenosis after balloon aortic valvuloplasty [5], his idea and obsession was to find a viable clinical solution to the devastating challenge of restenosis. His solution was a transcatheter percutaneous stented valve that would use the diseased native valve as a platform to anchor the device. The aim was to perform the procedure in a population of fragile

Table 4 Postprocedural results at 30 days.

	Overall population ($n = 1780$)	Group 1 (before 2009) ($n = 60$)	Group 2 (2009—2014) ($n = 388$)	Group 3 (2014—2021) ($n = 1332$)	P[a]
All-cause mortality during the hospital phase	50 (2.8)	8 (13)	16 (4.1)	26 (2.0)	<0.001
All-cause mortality within 30 days after the hospital phase	24 (1.3)	2 (3.3)	11 (2.8)	11 (0.8)	0.003
All-cause mortality at 30 days	74 (4.2)	10 (17)	27 (7.0)	37 (2.8)	<0.001
Stroke					
Major stroke	26 (1.5)	2 (3.3)	8 (2.1)	16 (1.2)	0.13
Minor stroke	10 (0.6)	1 (1.7)	3 (0.8)	6 (0.5)	0.2
TIA	7 (0.4)	0 (0)	2 (0.5)	5 (0.4)	0.7
Bleeding					
Life-threatening	60 (3.4)	7 (12)	34 (8.8)	19 (1.4)	<0.001
Major	118 (6.6)	12 (20)	38 (9.8)	68 (5.1)	<0.001
Minor	127 (7.1)	1 (1.7)	29 (7.5)	97 (7.3)	0.2
Transfusions	181 (10)	23 (38)	76 (20)	82 (6.2)	<0.001
AKI					
Stage 1	188 (11)	19 (32)	58 (15)	111 (8.3)	<0.001
Stage 2	6 (0.3)	1 (1.7)	1 (0.3)	4 (0.3)	0.2
Stage 3	29 (1.6)	1 (1.7)	1 (0.3)	27 (2.0)	0.029
Vascular complications					
Major	132 (7.4)	11 (18)	58 (15)	63 (4.7)	<0.001
Minor	162 (9.1)	4 (6.7)	29 (7.5)	129 (9.7)	0.3
Other complications					
Conversion to general anaesthesia	19 (1.1)	4 (6.7)	8 (2.1)	7 (0.5)	<0.001
Emergency cardiac surgery	10 (0.6)	3 (5.0)	4 (1.0)	3 (0.2)	<0.001
Emergency vascular surgery	24 (1.3)	6 (10)	6 (1.5)	12 (0.9)	<0.001
Periprocedural MI	24 (1.3)	2 (3.3)	7 (1.8)	15 (1.1)	0.14
New pacemaker	218 (12)	1 (1.7)	27 (7.0)	190 (14)	<0.001
Vasopressors	87 (4.9)	5 (8.3)	21 (5.4)	61 (4.6)	0.3
Days from procedure to CCU discharge	1.00 (1.00—2.00)	1.00 (1.00—3.00)	1.00 (1.00—2.00)	1.00 (1.00—2.00)	0.001
Days from procedure to discharge	3.0 (2.0—5.0)	8.0 (7.0—9.8)	5.0 (3.0—7.0)	2.0 (2.0—4.0)	<0.001
Length of hospital stay $\leq$ 3 days	1032 (58)	1 (1.7)	132 (34)	899 (67)	<0.001

Data are expressed as number (%) or median (interquartile range). AKI: acute kidney injury; CCU: coronary care unit; MI: myocardial infarction; TIA: transient ischaemic attack.
[a] Fisher's exact test; Pearson's χ^2 test; Wilcoxon rank sum test.

Table 5 Thirty-day echocardiographic characteristics.

	Overall population ($n = 1780$)	Group 1 (before 2009) ($n = 60$)	Group 2 (2009—2014) ($n = 388$)	Group 3 (2014—2021) ($n = 1332$)	P[a]
Aortic valve area (cm^2)	1.80 (1.56—2.10)	1.80 (1.66—2.00)	1.80 (1.62—2.01)	1.80 (1.50—2.13)	0.9
Mean aortic gradient (mmHg)	10.0 (8.0—13.0)	9.8 (8.0—11.0)	10.0 (7.0—12.0)	11.0 (8.0—14.0)	< 0.001
AR $\geq$ 2	223 (13)	17 (28)	78 (20)	128 (9.6)	< 0.001
PAPS (mmHg)	35 (30—45)	38 (35—48)	37 (30—47)	34 (28—43)	< 0.001
LVEF (%)	62 (55—69)	55 (49—63)	63 (54—70)	62 (55—69)	0.002

Data are expressed as median (interquartile range) or number (%). AR: aortic regurgitation; LVEF: left ventricular ejection fraction; PAPS: pulmonary artery systolic pressure.
[a] Kruskal-Wallis rank sum test; Pearson's χ^2 test; Fisher's exact test.

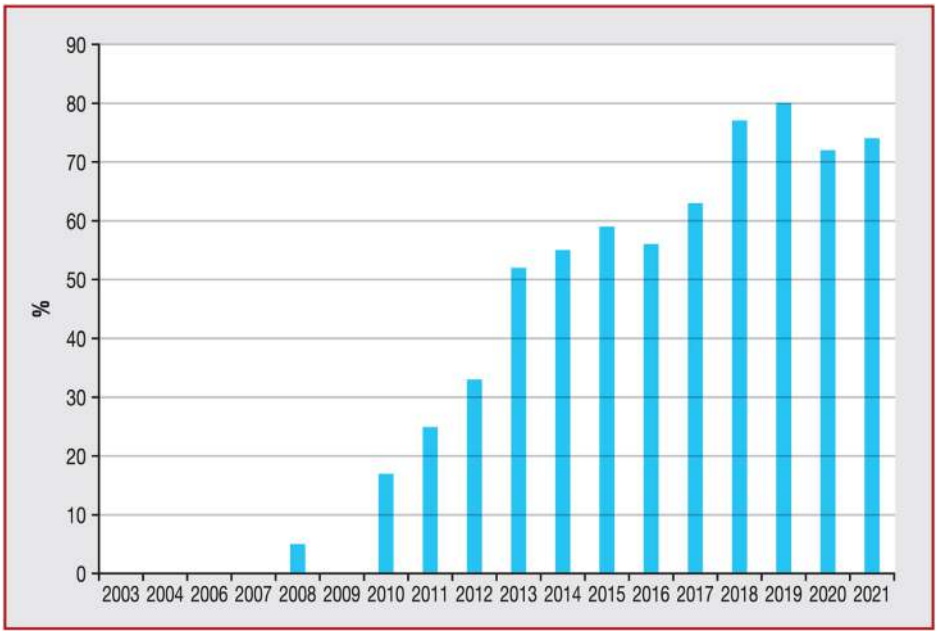

Figure 1. Proportion of patients discharged within 3 days after transcatheter aortic valve implantation, by year.

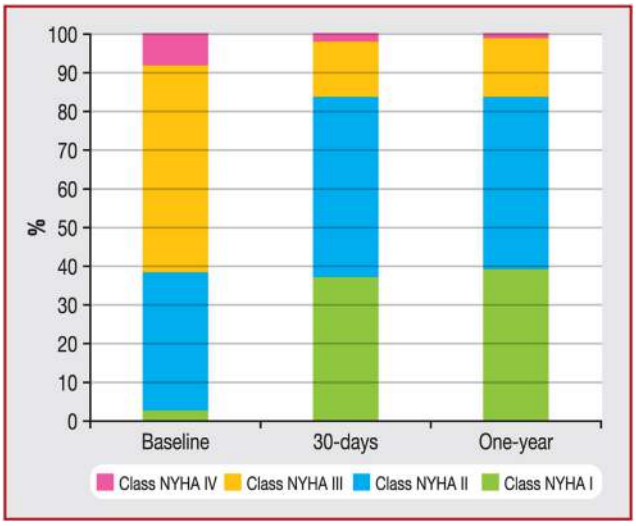

Figure 2. New York Heart Association (NYHA) class changes over time.

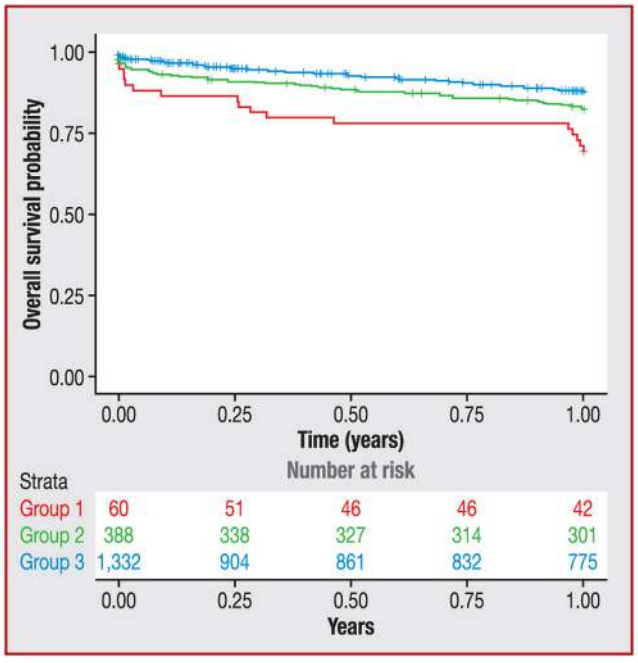

Figure 3. Kaplan-Meier curves for all-cause mortality at 1 year.

and up-to-now inoperable patients, using regular catheter-based techniques and local anaesthesia.

Our study has demonstrated the feasibility of this strategy since the very first case. All patients except one were treated under local anaesthetic, even when surgical cutdown was mandatory because of the large size of the introducer [6]. Our minimalist procedure has avoided the need for intubation/extubation, as well as the deleterious impact of drugs used for general anaesthesia, responsible for hypotension and requiring vasopressors [7]. Other advantages of local anaesthesia were the early detection, by the pain caused, of vascular complications during the early period of very large introducers, and the immediate diagnosis of cerebrovascular events. Thus, we have used this simplified procedure without hesitation from the very beginning of our experience with the transfemoral retrograde approach. This minimalist strategy [8] was limited to our centre for years, despite scientific demonstration of its feasibility; its large acceptance came in the mid 2010s, reaching only in 2019 a 76% rate of local anaesthesia with conscious sedation in the USA [9]. Local anaesthesia without echocardiographic guidance is nowadays predominantly used over general anaesthesia throughout the world.

Predilatation was initially performed systematically, but was progressively abandoned after scientific demonstration of its uselessness [10,11], and nowadays it is performed

Table 6 One-year echocardiographic characteristics.

	Overall population	Group 1 (before 2009)	Group 2 (2009—2014)	Group 3 (2014—2021)	P[a]
	(*n* = 1780)	(*n* = 60)	(*n* = 388)	(*n* = 1332)	
Aortic valve area (cm^2)	1.78 (1.50—2.04)	1.75 (1.65—1.90)	1.71 (1.60—2.00)	1.79 (1.50—2.10)	0.9
Mean aortic gradient (mmHg)	11.0 (8.0—14.0)	9.0 (7.2—10.8)	9.0 (7.0—13.0)	11.0 (9.0—14.0)	<0.001
AR ≥ 2	139 (7.8)	13 (22)	36 (9.3)	90 (6.8)	<0.001
PAPS (mmHg)	35 (29—45)	45 (35—55)	36 (30—47)	33 (27—42)	<0.001
LVEF (%)	62 (56—69)	60 (48—68)	61 (54—67)	63 (58—70)	0.009

Data are expressed as median (interquartile range) or number (%). AR: aortic regurgitation; LVEF: left ventricular ejection fraction; PAPS: pulmonary artery systolic pressure.
[a] Kruskal-Wallis rank sum test; Fisher's exact test.

Table 7 One-year characteristics.

	Overall population	Group 1 (before 2009)	Group 2 (2009—2014)	Group 3 (2014—2021)	P[a]
	(*n* = 1780)	(*n* = 60)	(*n* = 388)	(*n* = 1332)	
All-cause mortality at 1 year	203 (11)	18 (30)	64 (16)	121 (9.1)	<0.001
New pacemaker	11 (0.6)	0 (0)	4 (1.0)	7 (0.5)	0.5
NYHA class III—IV	66 (3.7)	5 (8.3)	29 (7.5)	32 (2.4)	<0.001

Data are expressed as number (%). NYHA: New York Heart Association.
[a] Pearson's χ^2 test; Fisher's exact test.

in < 15% of cases. This may be explained by the predominant use of balloon-expandable devices in our centre, with predilatation performed only in massively calcified valves or when balloon sizing is appropriate. By contrast, predilatation is still generally performed as a first step with self-expandable valves.

Over time, the procedural duration has become shorter, with less X-ray exposure and less contrast used, translating into less renal insufficiency. Increased experience, improved devices, decreased vascular complications, predetermination of the working view by computed tomography scan and less coronary angiography may explain the decrease in contrast used.

Overall, a dramatic decrease in major complications was observed in our series, as well as in randomized trials [12,13] and large registries, with a decrease in the 30-day mortality rate from 7.2% to 2.5% over the years [14]. In our series, the 30-day mortality rate was 2.8% over the last 7 years, and was even as low as 1.4% in 2021, compared with the 17% initially observed. Our contemporary results compare favourably with the more recent results of large randomized trials comparing transfemoral TAVI with surgery in low-risk patients (PARTNER 3 [12] and EVOLUT Low Risk [13]), which reported 30-day mortality rates of 0.4% and 0.5%, respectively.

Taken together, a minimalist procedure performed under local anaesthetic, a lower rate of complications (particularly vascular), preprogramming of the patient pathway and clear information given to the patient and relatives about early discharge allowed for a shorter hospital stay, with a median length of stay of only 2 days since 2014. More than 70% of patients are currently discharged within 3 days in our centre, which represents the shortest length of stay in France [15]. Indeed, in the most recent study evaluating length of stay [16], the median (interquartile range) was 2 (2—4) days, and 72.6% of patients were discharged within 72 hours. Following Rouen registries [17,18], Italian registries [19], FAST-TAVI [20] and the 3 M programme [21], several programmes are ongoing to improve the patient pathway from diagnosis to discharge [22].

The simplification of the procedure, associated with better devices and advanced technology, appears to be the key for better outcomes compared with surgery. Indeed, in the randomized PARTNER 2 [23] and PARTNER 3 [12] trials, the superiority of TAVI over surgery was observed from the first month after intervention.

Study limitations

The main limitations of this study were its observational design and lack of randomization. This prospective study reflects a single-centre experience in a relatively limited number of patients. We compared three different periods, but overlap in the strategies may have occurred, and biased our findings.

Conclusions

Combined with scientific evidence from randomized trials, transfemoral TAVI has demonstrated its superiority over surgery, with equal or even better results at 1 year, and

has led to the extension of indications to low-risk patients with severe AS. Transfemoral TAVI has become the gold standard therapy for most elderly patients with severe AS, and the transfemoral minimalist approach that we have been pioneering has become the default strategy.

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Disclosure of interest

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Online Supplement. Supplementary data

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