AVIATOR: An open international registry to evaluate medical and surgical outcomes of aortic valve insufficiency and ascending aorta aneurysm

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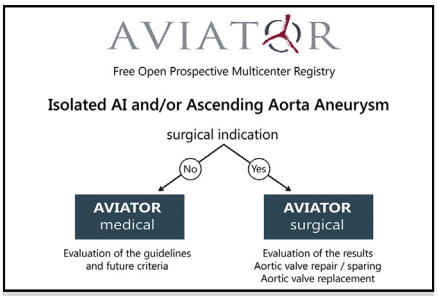
ABSTRACT

Objectives: Current national registries are lacking detailed pathology-driven analysis and long-term patients outcomes. The Heart Valve Society (HVS) aortic valve (AV) repair research network started the Aortic Valve Insufficiency and ascending aorta Aneurysm InternATiOnal Registry (AVIATOR) to evaluate long-term patient outcomes of AV repair and replacement. The purpose of the current report is to describe the AVIATOR initiative and report in a descriptive manner the patients included.

Methods: The AV repair research network includes surgeons, cardiologists, and scientists and established an online database compliant with the guidelines for reporting valve-related events. Prospective inclusion started from January 2013. Adult patients (18 years or older) who were operated on between 1995 and 2017 with complete procedural specification of the type of repair/replacement were selected for descriptive analysis.

Results: Currently 58 centers from 17 countries include 4896 patients with 89% AV repair (n = 4379) versus 11% AV replacement (n = 517). AV repair was either isolated (28%), or associated with tubular/partial root replacement (22%) or valve-sparing root replacement (49%) with an in-hospital mortality of 0.5%, 1.7%, and 1.2%, respectively. AV replacement was either isolated (24%), associated with tubular/partial root replacement (17%) or root replacement (59%) with an in-hospital mortality of 1%, 2.6%, and 2.0%, respectively.

Conclusions: The multicenter surgical AVIATOR registry, by applying uniform definitions, should provide a solid evidence base to evaluate the place of repair versus replacement on the basis of long-term patient outcomes. Obtaining data completeness and adequate representation of all surgery types remain challenging. Toward the near future AVIATOR-medical will start to study natural history, as will AVIATOR-kids, with a focus on pediatric disease. (J Thorac Cardiovasc Surg 2018;■:1-10)



AVIATOR includes the whole disease trajectory of patients with AI and/or AscAo Aneurysm.

Central Message

The AVIATOR currently contains data on 4896 patients with 89% aortic valve repair—isolated (28%), with tubular replacement (22%) or valve-sparing root replacement (49%)—and 11% valve replacement.

Perspective

The AVIATOR is a unique registry open to any center taking care of patients with ascending aorta aneurysm and/or isolated aortic valve insufficiency. It will address key epidemiology questions, stimulate uniform reporting to evaluate the guidelines for surgical indication, and define the place of aortic valve repair versus replacement on the basis of long-term patient outcomes.

See Editorial Commentary page XXX.

The prevalence of aortic regurgitation (AR) is difficult to assess because it is well tolerated for a long period before symptoms emerge.[1] Results from the population-based study in Framingham gave some insight: trace or mild AR was seen in 8.5% of women and in 13% of men.[2,3] Within a hospital-based cohort the Euro Heart Survey

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Abbreviations and Acronyms

AR = aortic regurgitation
AV = aortic valve
AVIATOR = Aortic Valve repair InternATiOnal Registry
CRF = Case Report Form
HVS = Heart Valve Society
PID = patient-identifiable data

Scanning this QR code will take you to the article title page to access supplementary information.

program observed that 10.4% of the patients with valvular heart disease presented with moderate to severe AR (grade 2-4), of whom 1.7% underwent aortic valve (AV) repair.[4] AV repair started 3 decades ago with valve-sparing root replacement using either the reimplantation or remodeling technique.[5,6] Both techniques have evolved during the years.[7-11] A recent analysis of the Society of Thoracic Surgeons database reported that 14% of patients with dystrophic bicuspid or tricuspid AR receive a valve-sparing procedure whereas 80% receive a composite graft–valve replacement (Bentall procedure).[12,13] Some patients of the latter group could actually be candidates for repair.

In the current era, relative risk-adjusted mortality of valve-sparing aortic root replacement appears comparable with composite graft replacement in low- and high-risk subgroups.[14] A recent meta-analysis indicated that AV repair seems a safe and feasible alternative to AV replacement in selected patients with aortic root aneurysm with or without AR.[15,16] However, generalization of published results is still difficult because of the heterogeneity or inadequate description of the populations studied. Furthermore, loss to follow-up and incomplete or inadequate reporting of valve-related events makes interpretation of the results difficult. As a result, patients are treated according to guidelines on the basis of 30-year-old evidence.[17,18] To achieve a real breakthrough in treatment of AR, collaboration of cardiologists and surgeons is needed because they both treat the same patients at different time points during the course of the disease. Including the complete time span of AR from diagnosis through intervention until death within a longitudinal cohort is essential to investigate key epidemiological questions. Solid evidence-based guidelines cannot do without complete and long-term follow-up. From here starts the international Aortic Valve repair InternATiOnal Registry (AVIATOR) initiative. The main objectives are to enhance uniform scientific reporting, to optimize multidisciplinary patient care, to assess quality of care, and to update and improve guidelines. The purpose of the current report is to present the registry design and to describe the characteristics of the first enrolled patients.

AVIATOR REGISTRY

The AVIATOR initiative is a longitudinal observational cohort study enrolling patients with ascending aorta aneurysm and/or AR. The registry contains 2 separate entities: (1) AVIATOR medical registry to evaluate the natural history of nonoperated patients; and (2) AVIATOR surgical registry to evaluate long term outcomes after surgical treatment. Both registries will have an adult and a pediatric counterpart (AVIATOR-kids). The adult surgical database is established and is enrolling patients. AVIATOR medical and AVIATOR kids are in progress and enrollment will follow in the near future.

Inclusion Criteria

The AVIATOR includes all patients with AR and/or ascending aorta aneurysms (Figure 1). Adult patients with AR grade >1 (mild AR)—inclusive of congenital mixed AV disease—and/or an aortic diameter ≥40 mm are eligible for the medical registry. Patients who are operated on because of AR (including congenital mixed AV disease) and/or aortic aneurysm (root or tubular ascending aorta) are eligible for the surgical database. Patients operated on for aortic dissection (type A) are eligible as well. Both patients who undergo AV repair including valve-sparing root replacement as well as AV replacement—including composite graft replacement—are eligible. Centers without an AV repair program are encouraged to join the AVIATOR initiative as well. It is important to enroll all consecutive patients within a center, and not only the successful repairs. Operative correction of an aneurysm of the ascending aorta can be either root and/or supracoronary aorta replacement. Excluded are patients with pure aortic stenosis, whereas patients with mixed disease (AR and aortic stenosis) are eligible. This is because of the incidence of mixed disease in the population of individuals with bicuspid and unicuspid valves, who could either have repair or replacement.

Adult Surgical Database

The following information concerns the adult surgical database, which has been open for patient enrollment since January 2013. Data for patients operated on before that can be uploaded retrospectively, and follow-up will be continued prospectively according to AVIATOR standards. Collected data include: baseline patient characteristics including risk factors for operative mortality (EuroSCORE), procedural information with detailed valve analysis and repair procedure, in-hospital outcomes,

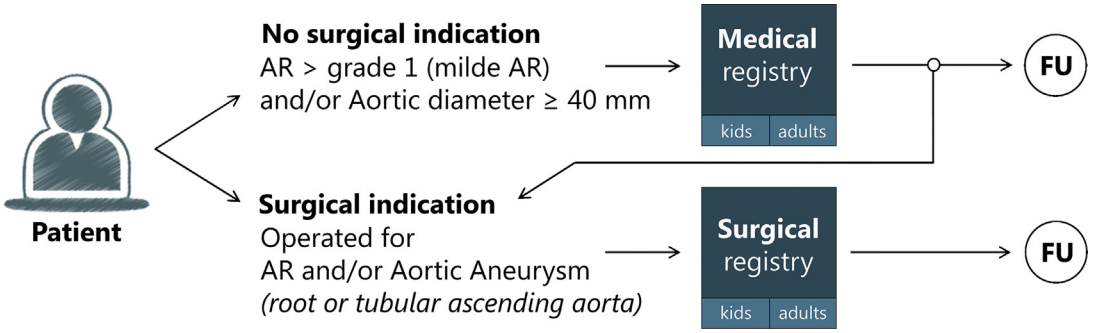

FIGURE 1. Inclusion flow chart. Operations registered in the surgical registry contain: isolated aortic valve (AV) repair/replacement; tubular aorta replacement with or without AV repair/replacement; partial root replacement with or without AV repair; valve-sparing root replacement with or without AV repair; root and valve replacement (Bentall). Patients of 18 years or older are eligible in the adult registry. Younger patients can be enrolled in the pediatric counterpart. *AR*, Aortic regurgitation; *FU*, longitudinal follow-up.

longitudinal measurement of echo parameters, and valve-related events during at least yearly follow-up according to the guidelines of reporting mortality and morbidity after cardiac valve interventions.[19] See Figure E1 for the Case Report Form (CRF) containing all variables. There is room for individual center-initiated substudies linked to the core AVIATOR database, for example. a Quality of Life Questionnaire on the basis of the SF36 with extra valve specific questions. This sub-CRF is not mandatory and can be switch on or off. Data entry is possible directly online (patient by patient), but if a center has a good local database, it is possible to use the upload facility.

Clinical Tool

The AVIATOR registry is designed to be of added value for physicians. Besides data analysis and research it can be used as a clinical tool in daily practice because there is the possibility to generate a ''clinical summary'' on the patient level. It summarizes all relevant information of that particular patient including echo tables. In addition, the application will allow to filter and select specific subgroups.

DATA ANALYSIS

Data Ownership and Online Analysis

The AVIATOR registry is the property of the Heart Valve Society (HVS) that therefore endorses the responsibility of the database, including any multicenter publication originated from it (validated by the scientific committee). Each individual center is the owner of its own submitted data and is responsible for their content. Online extractions can be performed whenever desired. Within the online application, reports and graphs will be developed. Individual center data are not visible for any other center. In a report with summary statistics single-center data will be presented aside with aggregated results of the entire database. Data of centers other than your own are only visible for the central data management group for the purpose of data validation to enhance data quality.

Single-Center Analysis

Each center can extract its own submitted data for local analysis. Each center is asked to acknowledge the AVIATOR project when single-center results on the basis of this registry are presented or published. For analysis of multicenter data a scientific research proposal is needed. Applications should be submitted to the scientific committee.

Multicenter Analysis

The scientific committee will review and facilitate initiatives for multicenter analysis. Research proposal submission to the scientific committee is possible twice a year. Submitted proposals will be discussed in detail during the AVIATOR meetings at the Annual Meeting of the HVS and European Association for Cardio-Thoracic Surgery. Proposals are validated when most of the participants during the meeting agree. Each center that can participate in the study will be notified about the accepted proposals and their data will be used automatically (non-opposition procedure). If a center does not agree, the objections should be justified to the scientific committee. The research team will receive an anonymous data set. After data extraction, the team will be given a deadline of 6 months to perform the analysis and write a draft publication that should be presented at the next meeting. When the deadline is exceeded, the topic can be passed on to another group. First and second authorship is for the person who executed the project (ideally young investigators). Last authorship is for the principal investigator of the proposal. Authors in between are those who contributed to the data analysis and included data to the specific research question. Data selection from the AVIATOR database will take into account data completeness. Follow-up completeness will be represented with the C* ratio: the total observed follow-up years divided by the total potential follow-up years (taking the observed death rate into account).[20] Each selected center can propose at least 1 author for the studies using its data. Authors will

be listed on the basis of their ranking in data completeness multiplied by volume (from high to low). The number of authors will depend on journal requirements. Ideally, all participating centers in the research data set will be represented. In case there is limit, centers with the highest ''quality data × volume factor'' will come first.

Data Safety

Data are entered on a Web-based CRF through a secure data entry system. Telemedicine Technologies hosts the database application (CleanWeb) in Boulogne-Billancourt, France.[21] The data system is set up according to Good Clinical Practice guidelines, is United States Food and Drug Administration-compliant (21 CFR part 11), and meets the criteria of European legislation (EU Directive 2001/20/EC/Directive 2005/28/EC, Annex 11, cGMP).

Patient-Identifiable Data

CleanWEB offers the possibility to enter patient-identifiable data (PID) like the last and first name of a patient for practical use in clinic and for future projects enabling collection of patient-reported outcomes measures. Each center can decide if it wishes to enter PID or not, and should inform their institutional review board before enrolling patients. The patient name is subject to special protection regulations. The PID is stored encrypted and is saved on a server separate from the medical parameters. The PID is only visible within the own site. For all other personnel their value will be set to *****. The PID will never be included in extraction files outside its own center.

Organizational Structure

The Aortic-valve-repair-Research-Network organizes project meetings during the annual meeting of the HVS, European Association for Cardio-Thoracic Surgery, and AV repair summit, to which all participants are invited. A project update is given as well as outcome of research and/or audit originating from the registry. Besides the members there is a technical support group of the database, a functional support group of the project, and a scientific committee. The scientific committee consists of 7 members, including at least 2 cardiologists, 2 surgeons, and 2 scientists. Members of the committee will serve for 3 years. After their term they have to wait 3 years before they can apply again. The scientific committee reviews research proposals and scientific reports originating from the registry, interacts with other HVS working groups, and advises the HVS board.

Become a Participant

The AVIATOR network is open to any cardiologist, radiologist, surgeon, and scientist interested in the field. Participation in the AVIATOR registry is free of charge. By signing the participation agreement one automatically becomes a member of the HVS Aortic-valve-repair-Research-Network group and is welcome to visit group meetings. At least 1 surgeon and/or cardiologist per center should be an official member of the HVS. The AVIATOR initiative aims to set up an international research network, in which all participants can be in close contact with their peers, to learn from each other, and to contribute together to improve patient outcomes. Contact: heartvalvesociety.org/AVIATOR or via E-mail at: AVIATOR@HeartValveSociety.org.

METHODS

Data were extracted on April 4, 2018. For the analysis all patients between 1995 and 2017 were selected. Patients younger than 18 years or

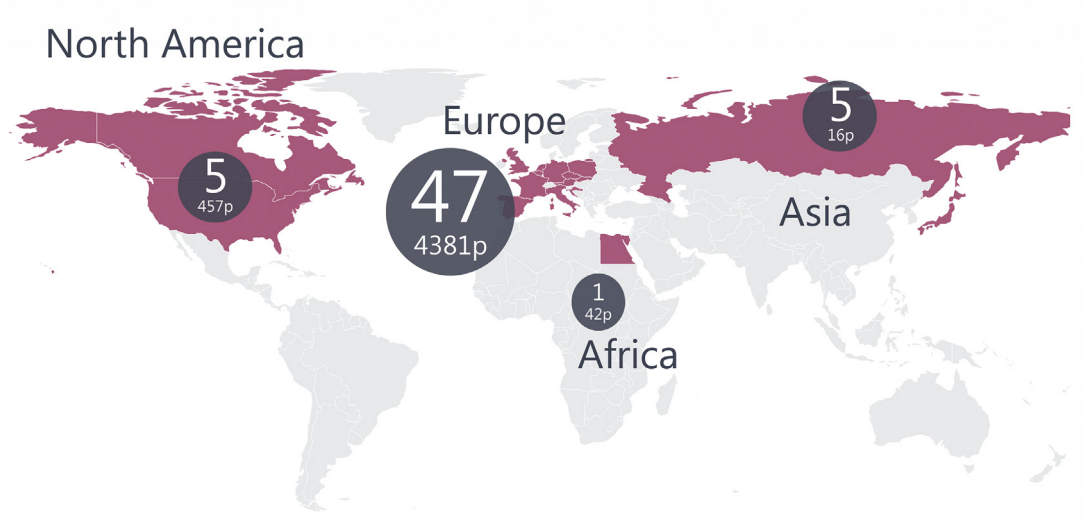

FIGURE 2. Participating cardiothoracic centers, April 2018. Number of participating centers and patients per continent: Africa 1 center with 42 patients (0.9%), Asia 5 centers with 16 patients (0.3%), Europe 47 centers with 4381 patients (89.5%), North America 5 centers with 457 patients (9.3%).

without a registered operation date or procedural specification were excluded (n = 288; 5.6%). This resulted in 4896 patients for analysis. Variables that were added after the initial start of the registry did not reach sufficient data completeness and were therefore not included in the analysis.

RESULTS

Prospective patient enrolment started in August 2013. Currently 58 cardiothoracic surgery centers participate of which 51 are actively enrolling patients. Fifteen centers enrolled more than 50 patients and were responsible for 91% of the cohort (Figure 2). Besides prospective data collection, centers uploaded historical data before 2013: approximately half of the patients (n = 2581; 52.7%) were operated on before 2013. See Figure 3 for the distribution of patients over the years divided by the procedure performed. The AVIATOR registry originated in Europe and especially European centers are enrolling patients at this stage. They are responsible for the inclusion of 4381 (89.5%) patients, followed by North America with 457 (9.3%) patients, Africa with 42 (0.9%) patients, and Asia with 16 (0.3%) patients. Valve repair was the dominant operation with 89% versus 11% replacements. The reconstructive surgery consisted of 28% isolated valve repair, 22% partial root or tubular aorta replacement with valve repair, and 49% valve-sparing root replacements. The replaced valves included 24% isolated valve replacement, 17% tubular aorta with AV replacement, 59% root with valve replacement (Bentall; Table 1). The mean age of the total AVIATOR population is 52 (±16) years and median age of 53 (interquartile range, 41-65) years. Patients who underwent isolated AV repair were younger ($P < .001$) than the patients who underwent AV replacement: 48 (±16) and 56 (±16) years, respectively. Comparing the 3 main procedural groups between repair and replacement did not show differences in sex. Patients with active endocarditis were more likely to undergo isolated aortic replacement compared with isolated AV repair ($P < .001$). Patients who underwent valve-sparing root replacement had a dissection in 7.1% compared with 5.5% of the patients who underwent a Bentall procedure. In the latter group completeness was only 65%. Postoperative (in-hospital) outcomes are presented in Table 2. In-hospital mortality was 0.5% and 1.0% for isolated AV repair and replacement, respectively; 1.7% and 2.6% for partial root and/or tubular aorta replacement with valve repair and replacement, respectively; and 1.2% and 2.0% for valve-sparing root replacement and Bentall procedure, respectively.

DISCUSSION

The AVIATOR initiative is a unique effort in sharing data worldwide. It has grown exponentially the past 5 years from its birth in 2013 until now. The first descriptive analysis of the AVIATOR population shows the variation of patients and reveals potential biases within the registry (eg, repair vs replacement, high- vs low-volume centers, and European countries vs other regions). This overview is vital to address the current imperfections and to head forward. The registry contains detailed information of the valve anatomy, and the currently applied repair techniques and patch materials used in cusp repair. Although AV repair has reached a degree of maturity there are still ongoing debates: at which cut-off value for aortic annulus diameter is circumferential annuloplasty recommended, and leads symmetrical commissural orientation to better outcomes in bicuspid valve repair, or should AV repair be avoided

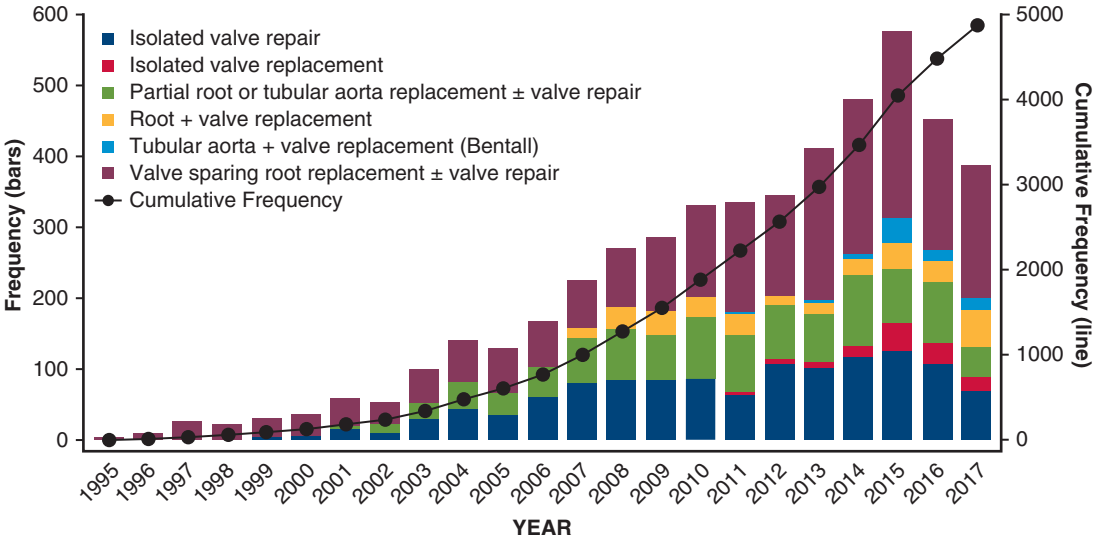

FIGURE 3. Inclusions between 1995 to 2017. Inclusions per year are shown on the left axis. The bar colors reflect the different operative procedures. The right axis shows the cumulative inclusion frequency (*black line*).

TABLE 1. Perioperative patient characteristics according to procedure type

	Isolated AV surgery					Partial root and/or tubular aorta replacement with AV surgery					Root replacement with AV surgery				
	Repair (n = 1228)		Replacement (n = 126)		*P*	Repair (n = 984)		Replacement (n = 86)		*P*	Repair (n = 2168)		Replacement (n = 305)		*P*
	n	%	n	%	value	n	%	n	%	value	n	%	n	%	value
Age															
Total	1226	100%	125	99%		982	100%	85	99%		2148	99%	302	99%	
Mean ± SD	48	±16	56	±16	<.001	58	±15	57	±14	.23	52	±14	53	±14	.135
Median (IQR)	47	35-61	59	48-67		60	48-71	59	44-67		29	27-32	27	25-29	
Age categories					<.001					.014					.343
18-30 Years	203	17%	13	10%		58	6%	0	0%		165	8%	22	7%	
31-50 Years	456	37%	22	18%		218	22%	27	32%		735	34%	89	29%	
51-65 Years	337	27%	49	39%		280	29%	29	34%		785	37%	124	41%	
Older than 65 y	230	19%	41	33%		426	43%	29	34%		463	22%	67	22%	
Sex															
Total*	1224	100%	124	98%		980	100%	84	98%		2153	99%	302	99%	
Female	214	17%	31	25%	.043	367	37%	24	29%	.105	374	17%	40	13%	.073
Dissection															
Total*	1218	99%	125	99%		975	99%	84	98%		2155	99%	199	65%†	
Yes	3	0.2%	1	0.8%	.502	98	10%	5	6.0%	.224	153	7.1%	11	5.5%	
Endocarditis															
Total*	1223	100%	125	99%		971	99%	83	97%		2155	99%	199	65%†	
Yes	34	2.8%	19	15%	<.001	1	0.1%	2	2.4%	.017	7	0.3%	16	8.0%	
AV leaflets					<.001					<.001					<.001
Total*	1228	100%	125	99%		977	99%	82	95%		2163	100%	296	97%	
Tricuspid	547	45%	88	70%		534	55%	34	41%		1344	62%	147	50%	
Bicuspid	579	47%	32	26%		367	38%	35	43%		779	36%	120	41%	
Unicuspid	91	7.4%	2	1.6%		75	7.7%	13	16%		38	1.8%	27	9.1%	
Quadricuspid	11	0.9%	3	2.4%		1	0%	0	0%		2	0%	2	0.7%	
Previous cardiac surgery															
Total*	1095	89%‡	124	98%		887	90%	83	97%		1883	87%‡	194	64%†	
Yes	85	7.8%	18	14.5%		23	2.6%	13	15.7%		117	6.2%	20	10.3%	
Preoperative LVEF															
Total*	1100	90%	121	96%		858	87%‡	79	92%		1892	87%‡	291	95%	
Good (>50%)	822	75%	94	78%		725	84%	69	87%		1545	82%	242	83%	
Moderate (31%-50%)	254	23%	25	21%		106	12%	9	11%		307	16%	39	13%	
Poor (21%-30%)	21	1.9%	2	1.7%		11	1.3%	1	1.3%		20	1.1%	10	3.4%	
Very poor (≤20%)	3	0.3%	0	0%		16	1.9%	0	0%		20	1.1%	0	0.0%	
Preoperative AR															
Total*	1169	95%	90	71%†		880	89%‡	62	72%†		1911	88%‡	277	91%	
Grade 0 (none or trivial)	3	0%	3	3.3%		44	5.0%	4	6.5%		145	7.6%	16	5.8%	
Grade 1 (mild)	60	5.1%	4	4.4%		206	23%	5	8.1%		306	16%	31	11%	
Grade 2 (mild to moderate)	137	12%	7	7.8%		258	29%	16	26%		404	21%	61	22%	
Grade 3 (moderate to severe)	662	57%	52	58%		284	32%	26	42%		767	40%	98	35%	
Grade 4 (severe)	307	26%	24	27%		88	10%	11	18%		289	15%	71	26%	
COPD															
Total*	1105	90%	124	98%		896	91%	83	97%		1889	87%‡	197	65%†	
Yes	29	2.6%	8	6.5%	.027	62	6.9%	4	4.8%	.465	71	3.8%	5	2.5%	

(Continued)

TABLE 1. Continued

	Isolated AV surgery					Partial root and/or tubular aorta replacement with AV surgery					Root replacement with AV surgery				
	Repair (n = 1228)		Replacement (n = 126)		*P* value	Repair (n = 984)		Replacement (n = 86)		*P* value	Repair (n = 2168)		Replacement (n = 305)		*P* value
	n	%	n	%		n	%	n	%		n	%	n	%	
IDDM															
Total*	1102	90%	123	98%		893	91%	82	95%		1889	87%‡	301	99%	
Yes	16	1.5%	8	6.5%	.002	14	1.6%	5	6.1%	.017	38	2.0%	6	2.0%	
Cross-clamp time, minutes															
Total*	1213	99%	123	98%		969	98%	84	98%		2136	99%	297	97%	
Median (IQR)	53	32-85	74	57-105	<.001	60	44-90	114	88-163	<.001	111	76-148	110	88-152	.063
Additional procedures															
Total*	1227	100%	125	99%		981	100%	85	99%		2164	100%	202	66%†	
Yes	413	34%	49	39%	.213	648	66%	41	48%	.001	1248	58%	82	41%	
CABG	118	9.6%	14	11%	.721	110	11%	9	11%	.005	200	9.2%	18	8.9%	
Aorta	3	0.2%	0	0.0%	.783	316	32%	20	24%	.004	418	19%	20	9.9%	
Mitral valve	200	16%	13	10%	.023	38	3.9%	5	5.9%	.002	82	3.8%	8	4.0%	
Maze	88	7.2%	5	4.0%	.349	49	5.0%	3	3.5%	.005	89	4.1%	7	3.5%	
Other	257	21%	27	22%	.486	546	56%	17	20%	<.001	1033	48%	50	25%	

AV, Aortic valve; *SD*, standard deviation; *IQR*, interquartile range; *LVEF*, left ventricular ejection fraction; *AR*, aortic regurgitation; *COPD*, chronic obstructive pulmonary disease; *IDDM*, insulin-dependent diabetes mellitus; *CABG*, coronary arterial bypass grafting. *The complete cases for that particular variable. †More than 20% missing values. ‡Ten percent to 20% missing values. When >10% was missing in one group no statistical tests were performed.

in cases of multiple large fenestrations[22]? The AVIATOR registry could contribute to these debates.

STRENGTHS AND WEAKNESSES

Data Completeness

The AVIATOR registry is a voluntary registry and leans on the effort participants are willing to put in. Data completeness can be at risk especially for: (1) registration of detailed valve cusps characteristics; (2) longitudinal event, survival, and echo follow-up; (3) selection of complete cohort in 1 center; (4) enrollment of consecutive cases; and (5) uniform reporting. (1) The registration must contain valve details to be of an additive value to national registries. These details comprise, for example, a description of the phenotype of each individual cusp assessed intraoperatively. The effective and geometric height can be registered as well. To make prospective data collection possible this information needs to be adapted in the local data collection logistics, for example as standard items in the operative notes for patients with AR. (2) One of the main outcome measures is the recurrence of AR over time. After discharge from the hospital, the care for the patient is frequently transferred to the cardiologist. When the cardiologist is not situated in the same hospital, it is likely that these patients get out of sight. It is important that echo results of all patients must be requested at a regular base (thus also from regional hospitals) to make longitudinal follow-up possible. The same holds for major events and survival. Follow-up completeness could be one of the validation criteria before selecting center data in research projects and publications. (3) The AVIATOR project is a longitudinal observational cohort study, meaning it attempts to follow all patients with AR or dystrophic aorta in time and to describe the patient characteristics, therapeutic interventions performed, and events down the track, whether they will be operated on or not, and whether they will undergo AV repair or replacement. It will take more effort to select the patients with AR who receive AV replacement. To gain more solid evidence for future guidelines, this patient group is vital. When the latter group is under-represented in the AVIATOR registry, it could easily be overcome by establishing partnerships in scientific projects with registries that complement the replaced valves. (4) By signing the participation agreement one confirms to enroll consecutive patients in that particular center. Only sending in the successful cases will lead to biased estimates of outcome and this will disadvantage future patients. The AVIATOR project objective is not to benchmark individual centers, but to improve patient care and future guidelines. In online reports it will be possible to see a center's own results against the complete cohort, as a tool to assess the center's position and to offer tools for improvement. Center-identifying data will be kept confidentially and will only be used for data validation purposes. (5) One of the main objectives of the AVIATOR initiative is to enhance uniform reporting but this is challenging. Take for example the echo parameters: are these measurements done the same in each institution? Probably not, and interinstitutional

TABLE 2. Postoperative in-hospital outcomes

	Isolated AV surgery				Partial root and/or tubular aorta replacement with AV surgery				Root replacement with AV surgery			
	Repair (n = 1228)		Replacement (n = 126)		Repair (n = 984)		Replacement (n = 86)		Repair (n = 2168)		Replacement (n = 305)	
	n or median	% or IQR	n or median	% or IQR	n or median	% or IQR	n or median	% or IQR	n or median	% or IQR	n or median	% or IQR
Postoperative aortic regurgitation												
Total*	971	79†	100	79†	754	77†	59	69†	1612	74†	236	77†
Grade 0 (none or trivial)	410	42	72	72	394	52	55	93	1070	66	204	86
Grade 1 (mild)	441	45	27	27	313	42	4	7	493	31	31	13
Grade 2 (mild to moderate)	105	11	0	0	45	6	0	0	44	3	1	0
Grade 3 (moderate to severe)	13	1.3	1	1.0	2	0.3	0	0	5	0.3	0	0
Grade 4 (severe)	2	0.2	0	0	0	0	0	0	0	0	0	0
AV-related reintervention												
Total*	1212	99	102	81‡	953	97	75	87‡	2130	98	289	95
Yes	47	3.9	0	0	14	1.5	0	0	38	1.8	1	0
Structural valve dysfunction	16	1.3	0	0	3	0.3	0	0	8	0.4	1	0
Nonstructural valve dysfunction	0	0	0	0	0	0	0	0	1	0	0	0
Unknown valve dysfunction	30	2.5	0	0	11	1.2	0	0	29	1.4	0	0
Interval between both procedures, d	6	1-28	–	–	6	0-8	–	–	9	0-14	8	8-8
Reoperation (non–AV-related)												
Total*	1213	99	100	79†	952	97	74	86‡	2131	98	290	95
Yes	26	2.1	5	5.0	40	4.2	5	6.8	118	5.5	23	7.9
Vascular thromboembolic event												
Total*	441	36†	101	80‡	444	45†	75	87‡	1184	55†	285	93
Stroke	1	0.2	0	0	8	1.8	0	0	15	1.3	3	1.0
TIA	1	0.2	0	0	4	0.9	0	0	3	0.3	1	0.3
Peripheral embolism	2	0.5	0	0	1	0	0	0	6	0.5	1	0.3
Pacemaker implantation												
Total*	1207	98	100	79†	943	96	75	87‡	2116	98	204	67†
Yes	9	0.7	2	2.0	9	1.0	4	5.3	27	1.3	9	4.4
Other complication												
Total*	1210	99	99	79†	947	96	75	87	2119	98	259	85‡
Yes	218	18	25	25	252	27	25	33		0.0		0.0
Status at discharge												
Total*	1217	99	103	82‡	964	98	77	90	2132	98	297	97
Death	6	0.5	1	1.0	16	1.7	2	2.6	25	1.2	6	2.0
LOS, d												
Total*	436	36†	111	88	328	33†	77	90	1106	51†	279	91
LOS	8	7-10	8	7-16	8	7-11	8	7-11	8	6-11	9	7-13

Non–AV-related reoperation regardless of the reason, included bleeding/tamponade, mediastinitis, cardiac (other than AV-related) and noncardiac reoperation. *AV*, Aortic valve; *IQR*, interquartile range; *TIA*, transient ischemic attack; *LOS*, length of stay. *The complete cases for that particular variable. †More than 20% missing values. ‡Ten percent to 20% missing values. When >20% was missing in one group no statistical tests were performed.

variation is likely. Here lays a potential role for standardized analysis by core echo labs in the future.

Data Validation

Data quality is a major concern for voluntary databases. Even when there is no intention to game, data entry could lead to data inaccuracy just by human errors. Data validation should occur at different levels. The online application system contains some simple internal validation rules, like the occurrences of dates in a logical order and build-in ranges for parametric values. Missing values and data completeness should be part of the feedback reports. These reports will be transparent to everyone, enabling social pressure to be complete among participants. The AVIATOR project is planning to define an audit strategy. Data auditing between centers within 1 country or random selection of 5%-10% of data in combination with site visits could be an option. This will allow assessment of data accuracy. To assess if the complete cohort (all consecutive patients) was entered and whether survival data are accurate is more difficult. Linkage to national cardiac surgery registries, including national death registries could be an option. Nevertheless, the feasibility could vary between countries. Because data auditing is costly, it needs to be incorporated in future grants for the AVIATOR project.

Natural History of AR and International Coverage

One of the main strengths of the AVIATOR initiative is the collaboration of surgeons and cardiologists to span the whole trajectory of AR and ascending aorta aneurysm patients from diagnosis, to medical or surgical intervention and beyond. This will improve the fundamental understanding of the natural history, etiology, and mechanisms of AR. Moreover, it will allow to investigate, evaluate, and improve the treatment strategies and ultimately, to provide a solid evidence base for future guidelines. The AVIATOR initiative has brought together many experts in the field of dystrophic AR from all over the world. The registry is open to everyone and the international coverage makes it a unique initiative.

CONCLUSIONS

The international prospective AVIATOR registry already includes 4836 patients. However, because the road toward a perfect representative sample of global clinical practice is a bumpy one, the challenges for the upcoming years are evident. There is a need to focus on data completeness and data quality of the current centers. To avoid cherry-picking, enrollment of consecutive patients need to be monitored, including the replaced valves in all participating centers, and adequate follow-up completeness needs to be established for meaningful analyses. By combining surgical experience from multiple centers, and applying uniform definitions of echo and outcome parameters, it should become possible to provide a solid evidence base to clarify and standardize the place of repair versus replacement in AV surgery and to provide an evidence base for tailored treatment in the individual patient.

Conflict of Interest Statement

Emmanuel Lansac has Consultant Agreements with the company CORONEO, Inc. (www.coroneo.com), in connection with the development of an aortic ring bearing the trade name, ''Extra-Aortic.'' All other authors have nothing to disclose with regard to commercial support.

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Key Words: aortic valve regurgitation, ascending aortic aneurysm, valve surgery, outcome analysis, international registry, long-term echocardiographic follow-up

APPENDIX 1. AORTIC VALVE REPAIR INTERNATIONAL REGISTRY (AVIATOR) SITES AND INVESTIGATORS

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AVIATOR

FORM 1 | HOSPITALIZATION

Version 8.0 (06-12-2016) vB

AVIATOR ID

Gender Date of Birth *or* Age

PREOPERATIVE

Main reason for referral

- ○ AV regurgitation
- ○ Ascending aorta — *if aneurysm:* ○ Root ○ Tubular aorta ○ Arch — Max diameter ____ mm
- ○ AV mixed disease *(congenital)*

AV endocarditis ○ No ○ Yes, active ○ Yes, healed

Aortic dissection ○ No ○ Yes, acute ○ Yes, chronic

Rheumatic disease ○ No ○ Yes

Height and Weight ____ cm ____ kg

NYHA class ○ I ○ II ○ III ○ IV

Rhythm ○ SR ○ AF ○ PM ○ Other

if other, specify:

Previous cardiac surgery ○ Yes ○ No

LVEF ○ Good (>50%) ○ Poor (21%-30%) ○ Moderate (31%-50%) ○ Very poor (20% or less)

Information to connect this patient to the medical registry (AIDA) i.a.

Enrolled in AIDA ○ Yes ○ No ○ Unknown

if yes: AIDA ID

COPD ○ Yes ○ No

IDDM ○ Yes ○ No

Dialysis dependency ○ Yes ○ No

Poor mobility ○ Yes ○ No

Extracardiac arteriopathy ○ Yes ○ No

Recent MI ○ Yes ○ No

Critical state ○ Yes ○ No

Creatinine ____ umol/l ____ mg/dl

Pulmonary hypertension ○ No PAP (<30 mmHg) ○ Moderate (31-55 mmHg) ○ Severe (>55mmHg)

Connective Tissue Disease ○ Yes ○ No

CTD (gene i.a.)

Urgency of operation ○ Elective ○ Urgent

Intention to repair the valve based on pre-op echo findings ○ Yes ○ No ○ Uncertain

OPERATIVE

Date of Surgery

Surgeon

Is there a proctor ○ Yes ○ No

Hegar dilatator size ____ mm

Aortic valve

- ○ Tricuspid
- ○ Bicuspid
- ○ Unicuspid
- ○ Quadricuspid

if bicuspid:

Fused cusps ○ RC - LC ○ RC - NC ○ NC - LC

Raphe type ○ Typo 0 (no raphe) ○ Type 1 (one raphe)

Commissural orientation ____ degrees

Cusp analysis

	Normal	Prolapse	Fenestration	Perforation	Calcification	Retraction	Vegetation	Geometric height (mm)
LC	☐	☐	☐	☐	☐	☐	☐	____
RC	☐	☐	☐	☐	☐	☐	☐	____
NC	☐	☐	☐	☐	☐	☐	☐	____
Fused	☐	☐	☐	☐	☐	☐	☐	
Uni/Res*	☐	☐	☐	☐	☐	☐	☐	____

** Uni = Unicuspid valve; Res = Residual cusp in case of Quadricuspid valve.*

Comments (cusp repair)

Intention to repair (*based on cusp analysis*) ○ Yes ○ No

Valve sparing/repair ○ Yes ○ No

- ○ Isolated valve repair
- ○ Tubular aorta replacement ± valve repair
- ○ Partial root replacement (1-2 sinus) ± valve repair
- ○ Valve sparing root replacement ± valve repair
  - ○ AV reimplantation (David)
  - ○ Root remodeling (Yacoub)

Valve replacement (repl.) ○ Yes ○ No

- ○ Isolated valve repl.
- ○ Tubular aorta + valve repl.
- ○ Root + valve repl.

if valve replacement, specify:

- ○ Mechanical proth.
- ○ Bioprosthesis
- ○ Homograft
- ○ Ross

if graft, specify:

Specify graft type and size ○ Straight graft ○ Sinus graft ____ mm

FIGURE E1. AVIATOR case report form.

ADULT

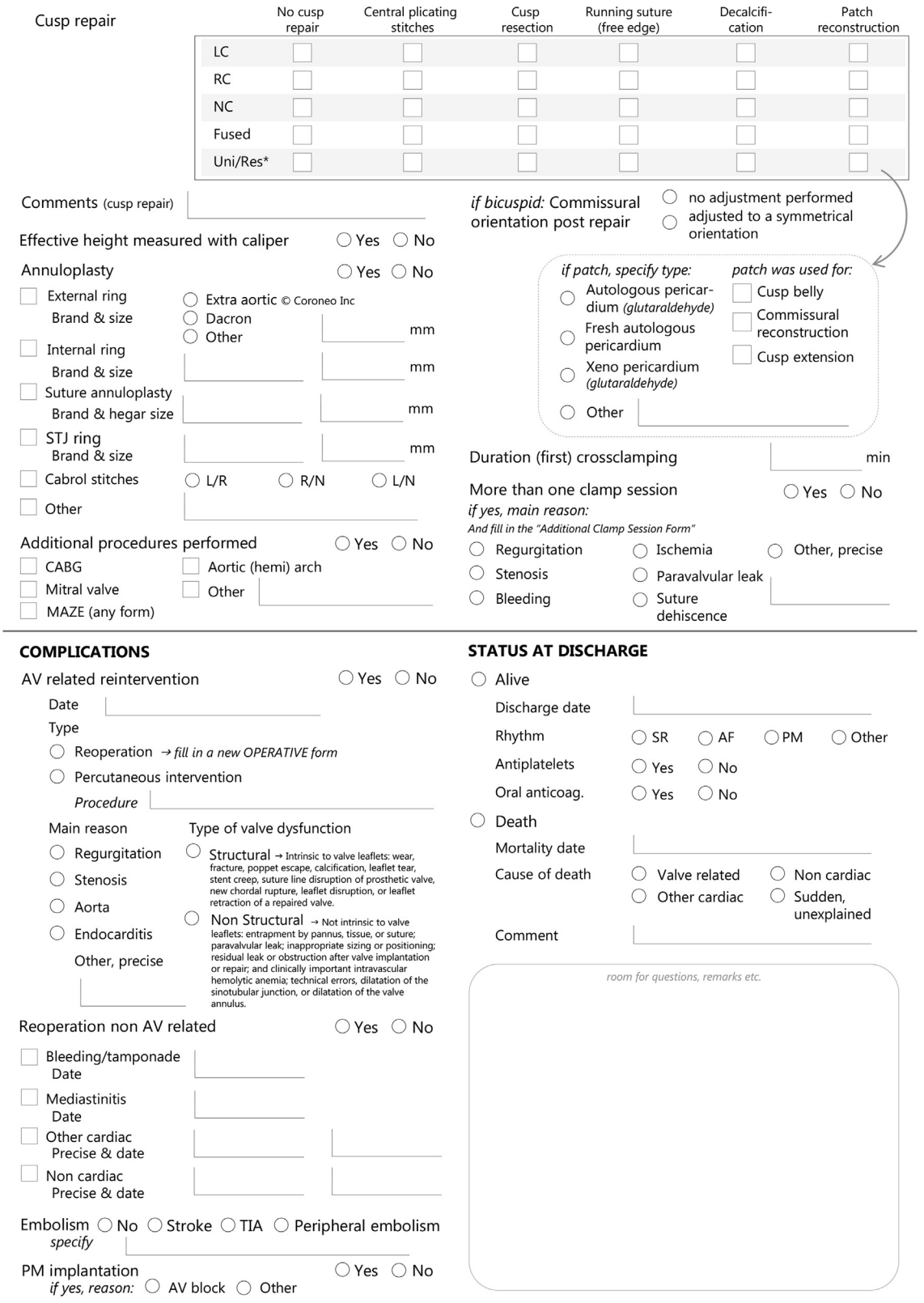

FIGURE E1. (*continued*).

AVIATOR

FORM 2 | ECHO

Version 8.0 (06-12-2016)

AVIATOR ID

Gender | Date of Birth *or* Age

	PRE OP (TTE)	INTRA OP (TEE) pre repair	INTRA OP (TEE) post repair	AT DISCHARGE (TTE)	AT DISCHARGE (TEE)
EF (%) *or*					
LVEF (grade) [1] 1 Good; 2. Moderate; 3. Poor; 4. Very poor.					
LVEDD (mm)					
LVESD (mm)					
Aortic valve regurgurgitation [2] grade 0 / 1 / 2 / 3 / 4					
Jet direction 1 Central; 2. Eccentric;					
Coaptation height / length (mm)					
Effective height (mm)					
Ao mean gradient (mm/Hg)					
Annulus (mm) *Systole*					
Sinus (mm) *Diastole*					
STJ (mm) *Diastole*					
Tubular aorta (mm) *Diastole*					

Footnotes:
1. If the EF was not measured, one of the following grades should be filled in for LVEF:
   1. Good > 50%; 2. Moderate 31%-50%; 3. Poor 21%-30%; 4. Very poor ≤ 20%.
2. The grade of aortic regurgitation should be one of the following categories:
   Grade 0 none or trivial; Grade 1 mild: VC <3, ERO <10, RVol <30; Grade 2 mild to moderate: ERO 10-19, RVol 30-44; Grade 3 moderate to severe: ERO 20-29, RVol 45-59; Grade 4 severe: VC >6, ERO >30, RVol >60.

FIGURE E1. (*continued*).

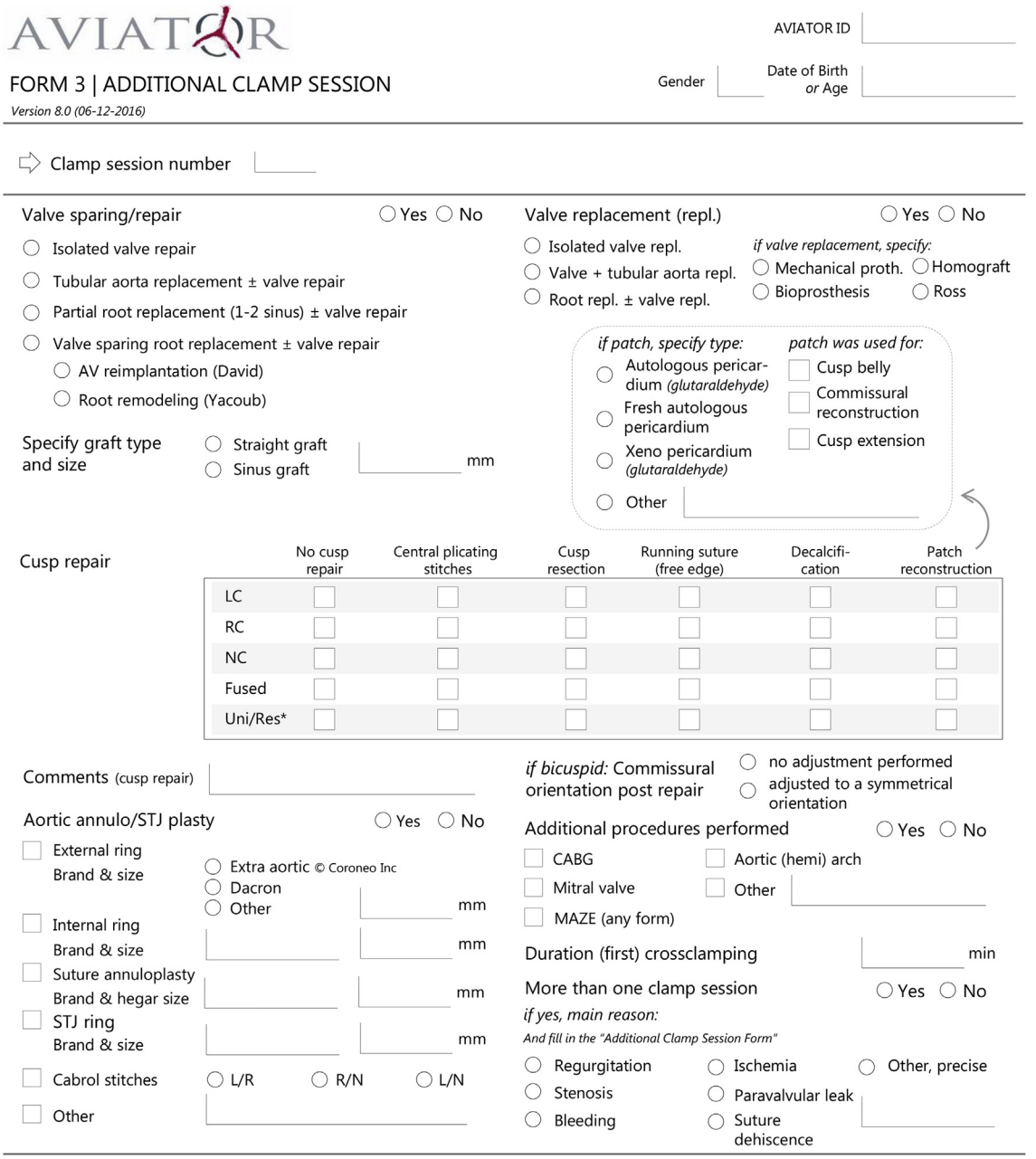

FIGURE E1. (*continued*).

AVIATOR

FORM 4 | FOLLOW-UP

Version 8.0 (06-12-2016)

AVIATOR ID

Gender | Date of Birth *or* Age

Follow-up date

NYHA class ○ I ○ II ○ III ○ IV

Rhythm ○ SR ○ AF ○ PM ○ Other

if other, specify:

Childbirth ○ Yes ○ No

Date

Medication

Antiplatelets ○ Yes ○ No

Oral anticoag. ○ Yes ○ No

COMPLICATIONS SINCE LAST FOLLOW-UP

AV related reintervention ○ Yes ○ No

Date

Type

○ Reoperation → *fill in a new OPERATIVE form*

○ Percutaneous intervention

Procedure

Main reason

○ Regurgitation

○ Stenosis

○ Aorta

○ Endocarditis

Other, precise

Type of valve dysfunction

○ Structural → Intrinsic to valve leaflets: wear, fracture, poppet escape, calcification, leaflet tear, stent creep, suture line disruption of prosthetic valve, new chordal rupture, leaflet disruption, or leaflet retraction of a repaired valve.

○ Non Structural → Not intrinsic to valve leaflets: entrapment by pannus, tissue, or suture; paravalvular leak; inappropriate sizing or positioning; residual leak or obstruction after valve implantation or repair; and clinically important intravascular hemolytic anemia; technical errors, dilatation of the sinotubular junction, or dilatation of the valve annulus.

Other cardiac reoperation ○ Yes ○ No

Date

Precise

Aorta complication *(thoracic or abdominal)* ○ Yes ○ No

Date

Precise

AV endocarditis *(non operated)* ○ Yes ○ No

Date

AV thrombosis *(non operated)* ○ Yes ○ No

Date

Embolism ○ No ○ Stroke ○ TIA ○ Peripheral embolism

Specify

Date

Major bleeding ○ Yes ○ No

Date

PM implantation ○ Yes ○ No

Date

Reason ○ AV block ○ Other

SURVIVAL

Death ○ Yes ○ No

Date

Cause of Death

○ Valve related ○ Non cardiac

○ Other cardiac ○ Sudden, unexplained death

Comment

ECHO

	TTE	TEE
EF (%) *or*		
LVEF (grade) [1] 1 Good; 2. Moderate; 3. Poor; 4. Very poor.		
LVEDD (mm)		
LVESD (mm)		
Aortic valve regurgurgitation [2] grade 0 / 1 / 2 / 3 / 4		
Jet direction 1 Central; 2. Eccentric;		
Coaptation height / length (mm)		
Effective height (mm)		
Ao mean gradient (mm/Hg)		
Annulus (mm) *Systole*		
Sinus (mm) *Diastole*		
STJ (mm) *Diastole*		
Tubular aorta (mm) *Diastole*		

Footnotes:

1. If the EF was not measured, one of the following grades should be filled in for LVEF: 1. Good > 50%; 2. Moderate 31%-50%; 3. Poor 21%-30%; 4. Very poor ≤ 20%.
2. The grade of aortic regurgitation should be one of the following categories: Grade 0 none or trivial; Grade 1 mild: VC <3, ERO <10, RVol <30; Grade 2 mild to moderate: ERO 10-19, RVol 30-44; Grade 3 moderate to severe: ERO 20-29, RVol 45-59; Grade 4 severe: VC >6, ERO >30, RVol >60.

FIGURE E1. (*continued*).

000 AVIATOR: An open international registry to evaluate medical and surgical outcomes of aortic valve insufficiency and ascending aorta aneurysm

Frederiek de Heer, MSc, Jolanda Kluin, MD, PhD, Gebrine Elkhoury, MD, PhD, Guillaume Jondeau, MD, PhD, Maurice Enriquez-Sarano, MD, Hans-Joachim Schäfers, MD, PhD, Johanna J. M. Takkenberg, MD, PhD, and Emmanuel Lansac, MD, PhD, on behalf of the Aortic Valve Repair Research Network Investigators, Amsterdam and Rotterdam, The Netherlands; Bruxelles, Belgium; Paris, France; Rochester, Minn; and Homburg, Germany

The AVIATOR currently contains data on 4896 patients with 89% aortic valve repair—isolated (28%), with tubular replacement (22%) or valve-sparing root replacement (49%)—and 11% valve replacement.