Minimally Invasive Redo Aortic Valve Replacement: Results From a Multicentric Registry (SURD-IR)

Giuseppe Santarpino, MD,* Paolo Berretta, MD,* Utz Kappert, MD, PhD, Kevin Teoh, MD, Carmelo Mignosa, MD, Bart Meuris, MD, PhD, Emmanuel Villa, MD, PhD, Alberto Albertini, MD, Thierry P. Carrel, MD, PhD, Martin Misfeld, MD, PhD, Gianluca Martinelli, MD, Kevin Phan, MD, Antonio Miceli, MD, PhD, Thierry Folliguet, MD, PhD, Malak Shrestha, MD, Marco Solinas, MD, Martin Andreas, MD, PhD, Carlo Savini, MD, PhD, Tristan Yan, MD, PhD, Theodor Fischlein, MD, and Marco Di Eusanio, MD, PhD

Città di Lecce Hospital, GVM Care & Research, Lecce, Italy; Cardiovascular Center, Paracelsus Medical University, Nuremberg, Germany; Cardiac Surgery Unit, Department of Experimental and Clinical Medicine-University "Magna Graecia" of Catanzaro, Catanzaro, Italy; Cardiac Surgery Unit, Department of Experimental and Clinical Medicine, Polytechnic University of Marche, Ospedali Riuniti, Ancona, Italy; Department of Cardiac Surgery, University Heart Centre Dresden, Dresden, Germany; Southlake Regional Health Centre, Ontario, Canada; Department for the Treatment and Study of Cardiothoracic Diseases and Cardiothoracic Transplantation, IRCCS-ISMETT, Palermo, Italy; Gasthuisberg, Cardiale Heelkunde, Leuven, Belgium; Poliambulanza Foundation Hospital, Brescia, Italy; Cardiovascular Surgery Unit, Maria Cecilia Hospital, GVM Care & Research, Cotignola, Italy; Department of Cardiovascular Surgery, University of Bern, Bern, Switzerland; University Clinic for Cardiac Surgery, Leipzig Heart Center, Leipzig, Germany; Cardiovascular Department, Clinica San Gaudenzio, Novara, Italy; The Collaborative Research (CORE) Group, Sydney, Australia; Istituto Clinico Sant'Ambrogio, Clinical & Research Hospitals, IRCCS Gruppo San Donato, Milan, Italy; Henri Mondor Hospital, University of Paris, Paris, France; Hannover Medical School, Hannover, Germany; Pasquinucci Heart Hospital, G. Monasterio Foundation, Massa, Italy; Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria; Cardiac Surgery Department, Sant'Orsola Malpighi Hospital, University of Bologna, Italy; and Macquarie University, Sydney, Australia

Background. **Reoperation for aortic valve replacement can be challenging and is usually associated with an increased risk for complications and mortality. The study aim was to report the results of a multicenter cohort of patients who underwent minimally invasive reoperative aortic valve replacement with a sutureless or rapid-deployment prosthesis.**

Methods. **From 2007 to 2018 data from 3651 patients were retrospectively collected from the Sutureless and Rapid-Deployment Aortic Valve Replacement International Registry. Of them, 63 patients who had previously undergone cardiac surgery represented the study population. In-hospital clinical and echocardiographic outcomes were recorded.**

Results. **Mean age of the selected 63 patients was 75.3 ± 7.8 years and logistic EuroSCORE 10.1. Surgery was performed by ministernotomy in 43 patients (68.3%) and by anterior right thoracotomy in 20 (31.7%); 31 patients (49.2%) received the Perceval valve (Livanova PLC, London, UK) and 32 (50.8%) the Intuity valve (Edwards Lifesciences, Irvine, CA). Mean cross-clamp time was 57.8 ± 23.2 minutes and cardiopulmonary bypass time 95.0 ± 34.3 minutes. Neither conversion to full sternotomy nor in-hospital deaths occurred. Postoperative events were ischemic cerebral events in 3 patients (4.8%), need for pacemaker implantation in 2 (3.6%), bleeding requiring reoperation in 5 (8.9%), and dialysis in 1 (1.6%). Median intensive care unit stay was 1 day, and median length of hospital stay was 10 days. On echocardiographic evaluation 1 patient showed a significant postoperative aortic regurgitation.**

Conclusions. **Minimally invasive reoperative aortic valve replacement with a sutureless or rapid-deployment prosthesis is a safe and feasible treatment strategy, resulting in fast recovery and improved postoperative outcome with no mortality and an acceptable complication rate.**

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Reoperation (redo) for aortic valve replacement (AVR) can be challenging and is usually associated with an

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*Drs Santarpino and Berretta contributed equally to this work.

Address correspondence to Dr Berretta, Cardiac Surgery Unit, Ospedali Riuniti di Ancona, Polytechnic University of Marche, Via Conca 71, 60126 Ancona, Italy; email: p.berretta@icloud.com.

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increased risk for adverse outcome (morbidity and mortality), particularly in specific settings (eg, endocarditis).[1] Moreover, given the increasing life expectancy of the population and the wide use of bioprostheses over the past years, redo surgery is becoming more frequent.[1-3] As a general trend in cardiac surgery in the era of transcatheter aortic valve implantation (TAVI), surgical strategies are moving toward minimization of surgical trauma also in redo settings.[4,5] Redo surgery is often associated with increased operative risk,[6,7] particularly in patients with previous patent coronary artery bypass grafts or endocarditis,[6-9] In patients undergoing reintervention (re-AVR or redo cardiac surgery) for isolated AVR, previous experience suggested minimally invasive surgical approaches as an alternative to conventional sternotomy, mostly with the adoption of an upper right "J-shaped" ministernotomy.[7-10] These studies support the safety and potential advantages of minimally invasive strategies for isolated AVR in patients without previous cardiac surgery.[11]

However only limited data are available on the feasibility of minimally invasive approaches in redo patients. In particular the adoption of minimally invasive AVR techniques remains questionable in patients with patent left internal mammary artery to left anterior descending coronary artery bypass in whom the use of a "no-dissection" strategy does not allow the conventional management of a patent graft, isolation and clamping, to provide myocardial protection.[7-10] Minimally invasive techniques allow for less extensive mediastinal dissection and minimize surgical trauma, thus reducing the risk for operative bleeding, procedure-related complications, and graft injury associated with sternal reentry.[7,10]

The Sutureless and Rapid Deployment International Registry (SURD-IR) was established by a consortium of research centers, through the International Valvular Surgery Study Group, to provide more robust data on the use of sutureless or rapid-deployment prostheses.[12] The aim of the present subanalysis from the SURD-IR is to evaluate perioperative outcomes in terms of morbidity and mortality in patients undergoing redo surgery for isolated AVR with an upper right "J-shaped" ministernotomy or by anterior right thoracotomy and the use of sutureless or rapid-deployment prostheses.

Material and Methods

From 2007 to 2018 data from 3651 patients were collected from the SURD-IR at 18 referral centers in Europe, Australia, and Canada. The registry includes all patients who received 1 of 3 sutureless or rapid-deployment prosthetic models currently or recently available on the market (Perceval S [Livanova PLC, London, UK], Intuity/Intuity Elite [Edwards Lifesciences, Irvine, CA], and Enable 3F [Medtronic, Minneapolis, MN]). Ethics approval was obtained at each participating center.

Participating SURD-IR centers enrolled between 40 and 735 patients and collected information on demographics, patient comorbidities, functional status, imaging studies, surgical data, postoperative course, and clinical and hemodynamic outcomes. More than 190 variables were collected for each patient and saved in a centralized database, as previously described.[11] Isolated variables reported by less than 25% of centers were excluded from the analysis. Definitions of the main variables are described in the Supplemental Appendix.

Sixty-three patients who had previously undergone cardiac surgery were treated with an upper right "J-shaped" ministernotomy or with an anterior right thoracotomy and represented the study population. Both techniques (ministernotomy and minithoracotomy) make it possible to avoid surgical dissection of the heart but only require the preparation of the tissues necessary for aortic clamping and aortotomy. In some cases for patients who had previously undergone coronary artery bypass grafting, preparation of previous grafts and clamping of the mammary artery were not necessary.

The decision to operate a redo patient with conventional or minimally invasive cardiac surgery (MIC) was made by the operating surgeon. In the same way the decision whether to operate the patient or perform a valve-in-valve (VinV) procedure was made at heart team meetings in all centers participating in the registry. In general the choice of the approach to redo patients with conventional or minimally invasive surgery was dependent on the surgeon's experience with minimally invasive techniques for aortic valve surgery and whether the redo patient was deemed amenable to minimally invasive surgical treatment. Also for the choice of surgery versus VinV-TAVI, the evaluation of the heart team was based on both objective measurements, including risk scores (eg, EuroSCORE), and considerations regarding patients frailty.

Patients who received the off-market Enable 3F valve and patients with incomplete data on the surgical approach were excluded from the analysis. Preoperative and periprocedural parameters and clinical outcomes were analyzed for all patients. A comparison between MIC-redo patients and other patients to allow for subanalyses (eg, vs MIC non-redo) was not performed because of the potential numerical discrepancy between the 2 groups, which would have resulted in unanalyzable results.

Continuous variables are expressed as mean ± SD or as median with interquartile range and categorical variables as percentages. Percentages were calculated using the number of patients with available data as the denominator. Because this was only a descriptive analysis, specific statistical tests were not deemed necessary.

Results

Preoperative characteristics of the 63 study patients are shown in Table 1. Mean age of the study cohort was 75.3 ± 7.8 years, with a median logistic EuroSCORE of 10.1% (6.9%-17.2%). Previous cardiac interventions included isolated AVR (n = 36, 58.1%), mitral/tricuspid valve surgery (n = 9, 14.5%), coronary artery bypass graft (n = 5, 8.1%), and ascending aorta repair with sternotomy (n = 12, 19.4%). Surgery was performed by ministernotomy in 43 patients (68.3%) and by anterior right

Table 1. Patient Demographics (N = 63)

Characteristic	Frequency[a]	Percentage[a]
Male sex	33	52.4
Age, y, mean ± SD	75.3 ± 7.8	
New York Heart Association class		
I	6	10.5
II	19	33.3
III	29	50.9
IV	3	5.3
Hypertension	37	67.3
Obesity	12	20.7
Body mass index, kg/m^2, mean ± SD	27.3 ± 3.8	
Diabetes	14	23.7
Dyslipidemia	26	44.8
Atrial fibrillation	8	15.7
Pacemaker	3	4.9
Bicuspid aortic valve	1	2.2
Cerebrovascular disease	3	5.8
Renal insufficiency	33	57.9
Chronic lung disease	9	15.3
Aortic valve disease		
Aortic valve stenosis	44	71
Mixed aortic valve disease	18	29
Endocarditis	2	3.6
Left ventricular ejection fraction, % median (interquartile range)	60 (50-62)	
>50%	45	72.6
30%-50%	15	24.2
<30%	2	3.2
Aortic valve area, cm^2, mean ± SD	0.67 ± 0.1	
Peak aortic valve gradient, mm Hg, mean ± SD	77.3 ± 33.6	
Mean aortic valve gradient, mm Hg, mean ± SD	53.3 ± 18.8	
Previous cardiac interventions		
Aortic valve replacement	36	58.1
Coronary artery bypass graft	5	8.1
Mitral/tricuspid surgery	9	14.5
Ascending aorta repair with sternotomy	12	19.4
Logistic EuroSCORE, %, median (interquartile range)	10.1 (6.9-17.2)	

[a]Unless otherwise defined.

thoracotomy in 20 (31.7%); 31 patients (49.2%) received the Perceval S valve and 32 patients (50.8%) received the Intuity valve. Mean cross-clamp time was 57.8 ± 23.2 minutes and mean cardiopulmonary bypass time 95.0 ± 34.3 minutes; 4 patients (6.3%) required an associated procedure (Table 2). No patient required a conversion to full sternotomy.

Postoperatively no hospital deaths occurred, and main complications included computed tomography–detected nondisabling stroke (n = 3, 4.8%), respiratory insufficiency with need for reintubation due to primary lung problems (n = 3, 4.8%), dialysis (n = 1, 1.6%), and bleeding requiring reexploration without a surgical source (n = 5, 8.9%). A definitive pacemaker was implanted in 2 patients due to new atrioventricular block (3.6%). Median intensive care unit stay was 1 day (interquartile range, 1-2.5), and median length of hospital stay was 10 days (interquartile range, 8-14). Postoperative events and echocardiographic parameters were recorded (Table 3).

Comment

Today redo surgery for AVR is wrongly considered as a "too" high-risk procedure, because TAVI or VinV-TAVI may be offered potentially to "all" patients. However results of redo cardiac surgery clearly demonstrated that outcomes of patients treated in experienced centers are as good as those obtained in patients undergoing a first intervention,[1] even if caution is necessary in particular subsets of at-risk patients (eg, high EuroSCORE II and The Society of Thoracic Surgeons scores, advanced age at surgery, left ventricular ejection fraction < 30%, previous coronary artery bypass graft, severe pulmonary hypertension, or preoperative dialysis) in whom transcatheter techniques can achieve better results.[13-15]

However sutureless and rapid-deployment aortic valve models, which allow a faster procedure, may improve outcome in these patients, particularly when a minimally invasive approach is used.[16-18] Furthermore favorable results seen in low-risk patients are amplified in higher-risk patients.[19] From the combination of the 2 concepts, advantages in performing redos with a minimally invasive approach plus advantages in implanting sutureless/rapid-deployment valves, especially in high-risk patients, regardless of score values, the possibility of using sutureless prostheses for minimally invasive redo has become an attractive treatment option. Here we describe the outcome of patients treated with sutureless or rapid-deployment prostheses in combination with minimally invasive redo AVR.

The results of this multicenter analysis are excellent, with no mortality reported. Results are also interesting because not all redo patients can undergo a safe TAVI or VinV intervention, despite often being at high risk, because of technical reasons (eg, no peripheral vascular access available, too small diameter of the prior implanted bioprosthesis, low coronary takeoff). Conversely all these conditions can be safely managed during open surgery. Patients amenable to this treatment strategy are not few in terms of prevalence, given the increasing adoption of biologic valves in younger patients and the unfavorable results of some biologic models widely implanted in recent years.[19,20]

The extremely low incidence of pacemaker implantations should also be emphasized, driven not only by the operators' experience (to enter into SURD-IR each operator had to have performed at least 100 sutureless prosthesis implantations) but also by the evolution of the implant technique of 1 of 2 sutureless models and the prolonged timing for pacemaker implant (almost 2 weeks from surgery), resulting in a significant improvement in this specific outcome.[21] However with the exception of the

Table 2. Operative Data

Variable	Frequency[a]	Percentage[a]
Ministernotomy	43	68.3
Anterior right thoracotomy	20	31.7
Conversion to full sternotomy	0	0
Associated procedures	4	6.3
Coronary artery bypass graft (proximal right coronary artery)	1	1.6
Tricuspid valve repair	1	1.6
Thoracic aorta repair	2	3.2
Perceval S	31	49.2
Small	4	14.3
Medium	8	28.6
Large	15	53.6
Extra large	1	3.6
Intuity/Intuity Elite	32	50.8
19	4	3.1
21	7	21.9
23	14	43.8
25	6	18.8
27	1	3.1
Valve malpositioning	1	1.6
Cardiopulmonary bypass time, min, mean ± SD	95 ± 34.3	
Clamp time, min, mean ± SD	57.8 ± 23.2	

[a]Unless otherwise defined.

Table 3. In-Hospital Outcomes

Outcomes	Frequency[a]	Percentage[a]
In-hospital mortality	0	0
Stroke	3	4.8
Low cardiac output	0	0
Ventilatory support >72 h	3	4.8
New-onset atrial fibrillation	15	25.4
New atrioventricular block requiring pacemaker	2	3.6
Aortic regurgitation (>2+)	1	2.5
Bleeding requiring revision	5	8.9
Acute kidney injury (> stage 1)	1	1.6
Dialysis	1	1.6
Bacteremia	3	4.8
Wound complications	3	4.8
Intensive care unit stay, days, median (interquartile range)	1 (1-2.5)	
Hospital stay, days, median (interquartile range)	10 (8-14)	
Peak pressure gradient, mm Hg, mean ± SD	24 ± 8	
Pressure gradient, mm Hg, mean ± SD	12.3 ± 4.5	

[a]Unless otherwise defined.

incidence of postoperative atrial fibrillation, we were not able to record the incidence of postoperative conduction disorders that required temporary or no pacemaker.

Current evidence on the use of sutureless prostheses in redo procedures mostly derives from single-center experiences with small sample size.[22-25] Nonetheless available data support the potential advantages of sutureless valves also in specific settings, including degeneration of stentless prostheses or homografts. In a case series of 13 redo patients (of whom 6 with a degenerated aortic valve prosthesis to be explanted), the use of sutureless bioprostheses was associated with a very short cross-clamp time (44 minutes on average).[22] Only 1 study compared sutureless versus VinV implantation, and both procedures were found to be effective and safe in preventing the occurrence of paravalvular leakage but with a better capacity of sutureless prostheses to minimize patient–prosthesis mismatch.[22] These findings seem logical given that previously implanted valves are removed only in surgical patients. However despite the presence of a patient–prosthesis mismatch, no differences were observed in clinical outcome and quality of life at follow-up. Furthermore it should be emphasized that transcatheter VinV implantation has been proposed as a viable option in "all" redo patients, even though it is burdened by significant limitations (eg, for some prosthetic models with biologic leaflets mounted outside the stent).[24] Moreover the VinV results in a significant patient–prosthesis mismatch in almost 50% of patients.[26,27]

In a series of 8 patients receiving a Perceval sutureless aortic valve after removal of a degenerated small Mitroflow valve, neither early mortality nor major complications occurred.[24] The authors concluded that in patients with a degenerated Mitroflow valve (Livanova, Saluggia, Italy), sutureless AVR represents a favorable alternative to conventional redo AVR or transcatheter VinV implantation.[24] Data on redo procedures using a minimally invasive approach have also become available, demonstrating that minimally invasive surgery reduces the overall surgical trauma, which may translate into shorter operation times and lower risk for sternal instability or infection. All these elements contribute to lower operative morbidity and mortality.[7]

Therefore in this perspective we can hypothesize that in the redo setting the use of sutureless/rapid-deployment prostheses, although currently contraindicated, could represent a new frontier given that patients most at risk are those affected by endocarditis. In fact the use of these prostheses in case of endocarditis is currently off-label and still under investigation. Furthermore we do not see any limitations to the use of this technique, even in young patients, except we believe that good experience of the surgeon with the MIC non-redo approach and the knowledge of sutureless prostheses is necessary before performing MIC-redo procedures.

Moreover the decision to operate a redo patient with conventional or MIC was taken by the operating surgeon. In other words only expert surgeons performed this strategy, making learning curves to play a crucial role. This is to highlight the importance of the learning curve for that approach, which was also relevant to the patient who experienced aortic insufficiency in the postoperative

period: This patient received the first implant of a sutureless prosthesis through a minimally invasive reintervention in that cardiac surgery center.

SURD-IR is the largest worldwide sutureless prosthesis registry. However the limited number of patients included represents the main limitation of this study, along with the lack of a control group, allowing for comparisons and of long-term follow-up. Additionally the lack of complete information on the type of cannulation and perfusion performed (anterograde or retrograde) did not allow us to determine whether these factors played a role in the incidence of postoperative stroke.

Moreover it should be underlined that this is a multicenter retrospective registry and some data were not available. Numbers and percentages refer to the available data as reported in the statistics section, and because of this several percentages reported in tables do not meet the denominator of "63."

Larger trials, also addressing postoperative pain, time required for recovery, and quality of life, are needed to better clarify the role of minimally invasive redo AVR.[11] In conclusion minimally invasive redo AVR using a sutureless or rapid-deployment prosthesis is a safe treatment strategy in selected patients, resulting in fast recovery and very promising early postoperative outcome.

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