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Exploring the learning curve for minimally invasive sutureless aortic valve replacement

Michele Murzi, MD, PhD, Alfredo Giuseppe Cerillo, MD, Danyar Gilmanov, MD, Giovanni Concistrè, MD, Pierandrea Farneti, MD, Mattia Glauber, MD, and Marco Solinas, MD

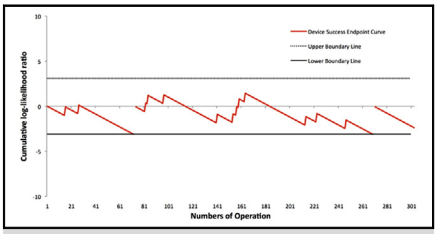
ABSTRACT

Objective: The study objective was to assess the learning process and quality of care of right minithoracotomy aortic valve replacement with a sutureless bioprosthesis at a single institution.

Methods: We performed an analysis of the first 300 consecutive patients (aged 76 ± 6 years; logistic European System for Cardiac Operative Risk Evaluation 9 ± 6) who underwent sutureless valve implantation via a right minithoracotomy by 6 surgeons at the G. Pasquinucci Heart Hospital between 2011 and 2015. The learning curve was analyzed by dividing the study population into tertiles of 100 patients each. Departmental and individual learning curves were calculated using sequential probability cumulative sum failure analysis. Quality indicators were 2 composite end points reflecting the technical success and 30-day complications.

Results: The overall mortality was 0.7% (2 patients). No significant differences were noted in terms of mortality and complications between tertiles. The sutureless valve was implanted successfully in 99% of patients (298/300). Cumulative sum analysis failed to identify any significant learning effects for technical success. Nevertheless, surgeons A, B, and C had a small initial learning curve, and surgeons D, E, and F did not, reflecting a trend toward a positive effect of cumulative institutional experience on the individual learning curve. The 30-day complications analysis revealed a cluster of failures at the beginning of the experience. This cluster prompted an internal audit and modification of the patients' selection process. Consecutively, the procedure returned in control.

Conclusions: Right minithoracotomy sutureless valve implantation can be performed safely without learning curve effects. Cumulative sum analysis is a valuable tool to describe and monitor the learning process. The analysis can identify periods of less than expected performance and alert the team to react. (J Thorac Cardiovasc Surg 2016;■:1-10)



Overall institutional CUSUM curve for device success end point.

Central Message

Right minithoracotomy sutureless AVR provides excellent outcomes. The learning curve can be mitigated quickly with experience.

Perspective

Right minithoracotomy AVR with a sutureless valve provides excellent short-term outcomes with low mortality and perioperative morbidity. No significant learning curve is associated with the procedure, and optimal results have been obtained since the beginning of the experience. With adequate training and supervision, the procedure can be taught to all the surgical staff.

ACQ

Minimally invasive aortic valve replacement (MIAVR) has been increasingly accepted in the surgical community as a potential alternative to conventional sternotomy. Potential advantages of MIAVR arise from the concept that patient morbidity and potential mortality can be reduced without compromising the excellent results of the conventional procedure and include improved cosmetic results, less postoperative bleeding, fewer blood transfusions, lower intensive care unit and in-hospital stays, and the absence of sternal wound infection.[1,2] On the other hand, the limited visibility and the difficulties of managing deviations from the normal course of intervention usually results in longer cardiopulmonary bypass (CPB) and crossclamping times compared with standard sternotomy aortic valve replacement (AVR).[3]

From the Fondazione Toscana Gabriele Monasterio, G. Pasquinucci Heart Hospital, Massa, Italy.

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Address for reprints: Michele Murzi, MD, PhD, G. Pasquinucci Heart Hospital Via Aurelia Sud, 100, 54100 Massa, Italy (E-mail: michele.murzi@ftgm.it).

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Abbreviations and Acronyms

AVR = aortic valve replacement
CPB = cardiopulmonary bypass
CUSUM = cumulative sum analysis
MIAVR = minimally invasive aortic valve replacement
RAMT = right anterior minithoracotomy
TAVI = transcatheter aortic valve implantation

The recently introduced Perceval S sutureless aortic valve bioprosthesis (Sorin Biomedica Cardio Srl, Saluggia, Italy) represents a new valve design that aims to maintain the native anatomy of the aortic root, aortic sinuses, and sinotubular junction. Similar to other sutureless bioprosthetic valves, the Perceval S is a self-expanding valve (only short exposition under a balloon inflation may be needed) and has the potential to shorten the implantation time, thus facilitating minimally invasive AVR.[4-6] In 2010, we initiated our own series of Perceval S AVR at the G. Pasquinucci Heart Hospital, and in April 2011, we started to systematically implant the Perceval S via a right anterior minithoracotomy (RAMT) (Figure E1). Before embarking on our clinical experience, we decided to assess our learning curve and monitor the surgical performance prospectively using a time series analysis. Among these, we have used cumulative sum analysis (CUSUM), which is a visual method that allows the user to easily establish whether a production process is ''in control'' or has become ''out of control.''[7] The graphical presentation of CUSUM results permits rapid assessment of competence and readily demonstrates the acquisition of skill at a given task simply by assessing the slope of the curve. In the present study, we report our experience with control charts to monitor individual surgeons and departmental performance of the Perceval S RAMT performed at the G. Pasquinucci Heart Hospital over a 4-year period by 6 surgeons.

MATERIALS AND METHODS

Patient Selection and Data Collection

All the data presented in the study were prospectively collected and entered into our institutional database, which includes 10 sections that are filled in consecutively by anesthetists, surgeons, perfusionists, and intensive care unit and ward doctors. We analyzed data from 300 consecutive patients with severe aortic stenosis who underwent isolated AVR with the Perceval S sutureless bioprosthesis via a RAMT between April 2011 and April 2015. No cases were excluded from analysis. The 300 operations were performed by 6 surgeons (level of experience ranging from 22 to 130 operations) who gained their first clinical experience with this method at our center. Each of the 6 surgeons had at least 3 years of independent clinical operating experience with at least 100 previous aortic valve operations performed via sternotomy. The number of operations performed by each surgeon was 123 (surgeon A), 44 (surgeon B), 42 (surgeon C), 37 (surgeon D), 32 (surgeon E), and 22 (surgeon D). At the time of the study, surgeon A had extensive experience in RAMT with a sutured valve. Surgeons B and C had little experience with RAMT (<30 cases). The other surgeons had no experience with RAMT and began to perform the procedure with sutureless technology. A learning curve analysis was possible because the cardiac surgery unit was under the same leadership throughout the entire study period, and methods of patient selection, operative technique, and postoperative care were based on institutional protocols that have not changed markedly over time. The study was approved by the clinical audit committee of the G. Pasquinucci Heart Hospital to meet ethical and legal requirements, and individual consent was waived.

Patient Selection and Surgical Technique

It is the policy at G. Pasquinucci Heart Hospital to use a RAMT approach for AVR whenever possible. The criteria for its application have been described by Glauber and colleagues.[3] The Perceval S is a sutureless device designed for AVR, comprising a functional component of 2 superimposed layers of pericardium and mounted in a superelastic alloy metallic cage. The cage is collapsed before implantation and then released in the aortic root. The Perceval S sutureless bioprosthesis currently is available in 4 sizes: small, medium, large, and extra-large (covering annulus diameters ranging from 19-21 mm, 21-23 mm, 23-25 mm, and 25-27 mm, respectively). Our surgical technique for RAMT has been described.[3] Briefly, it consists of a small right thoracotomy in the second intercostal space. CPB is established through direct ascending aorta cannulation and percutaneous femoral vein cannulation. Myocardial arrest is obtained with antegrade warm blood cardioplegia after transthoracic aortic crossclamping. The implantation technique of the Perceval S bioprosthesis included several steps and has been described.[8] After release of the prosthesis from the holder, the guiding 4-0 polypropylene sutures are removed. The operation is completed with the closure of the transverse aortotomy. Intracardiac air is aspirated through catheters in the aortic root and left ventricle, guided by transesophageal echocardiogram. Transesophageal echocardiography is performed during the procedure to evaluate the preimplantation measurements and the prosthetic function.

Data Analysis and Cumulative Sum Analysis Chartings

The learning process was assessed in 2 steps: First the overall institutional experience was divided into tertiles according to procedure order in an effort to evaluate the influence of growing departmental surgical experience. Second, institutional and individual learning curves were generated using the sequential probability CUSUM failure analysis, which has been described in detail.[9,10] A first step toward evaluating the learning curve and quality of care in surgical procedures is to select what is considered a failure and what is considered a success. Perioperative death reflects only a part of a procedural failure; therefore, it is unsuitable for monitoring the performance and learning curve. Thus, we sought more sensitive outcomes, and in advance of any analyses we decided to prospectively evaluate a device success end point, which is a technical composite end point meant to characterize the acute device and procedural factors that underlie the surgical procedure, delivery, and performance of the Perceval S prosthesis and a combined safety end point at 30 days, which is a composite of the most relevant patient-oriented safety end points.

The device success end point was defined as the absence of 1 or more of the following events: (1) intraoperative valve dysfunction with the need to remove and reimplant the Perceval S valve; (2) the presence of moderate or severe paravalvular leak at discharge; (3) the presence of a mean aortic valve gradient 20 mm Hg or greater or peak velocity 3 m/s; and (4) intraoperative conversion to sutured valve implantation.

The combined safety end point at 30 days was defined as the absence of the following events: (1) all-cause mortality; (2) intraoperative conversion to sternotomy; (3) major stroke; (4) acute kidney injury stage 3 (including renal replacement therapy); (5) periprocedural myocardial infarction; (6) reoperation for bleeding; and (7) repeat procedure for valve-related dysfunction during the same recovery (surgical or interventional therapy).

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