Quality Control and the Learning Curve of Transcatheter Aortic Valve Implantation

With the introduction of transcatheter valves, the cardiologists and cardiac surgeons have been faced with a new challenge, that is, to keep efficacy and safety competitive in relation to conventional surgery while implementing a new therapeutic strategy that requires the acquisition of new skills and the close cooperation between different specialties. In this complex scenario, the strict monitoring of the overall and individual performance appears mandatory. The paper by Alli et al. (1), recently published in JACC: Cardiovascular Interventions, represents a commendable attempt to characterize the learning curve of transcatheter aortic valve implantation (TAVI) in terms of number of procedures needed to become proficient with this technique, and to gain insight into the steps that are critical for the successful initiation of a TAVI program.

The paper by Alli et al. (1), however, is based on the retrospective analysis of outcome data arbitrarily divided into tertiles. This rather traditional approach takes an average performance over time; it may hide clusters of failure and may limit our understanding of the learning process. A more appropriate statistical tool, in our opinion, would be represented by time series analysis, and specifically by the cumulative sum (CUSUM) analysis. These methods report graphs of changes in outcome rates over time, and allow for the real-time monitoring of the individual and team performance, representing a particularly promising tool for monitoring learning effect and performance (2).

During the last decade at our institution, there has been a dramatic shift toward minimally invasive approaches for mitral and aortic valve surgery. The CUSUM analysis has been routinely used to monitor the performance of the surgeons introduced to this new technique with excellent results (3,4). It was, therefore, natural to employ this methodology to assess the performance of the TAVI team. It is interesting to observe that, similar to what was reported by Alli et al. (1), the analysis of our first 70 patients showed that “proficiency” was obtained after performing about 30 cases. In particular, the lower boundary line (the line on the CUSUM chart indicating a complication rate equal or inferior to the “accepted failure rate”), was crossed at Patient #29.

The real strength of the CUSUM charts is that they allow one to identify easily and quickly the ongoing trend. If the trend suggests that the procedure is going out of control, the monitored process can be analyzed in detail, and the right countermeasures can be instituted. The failure of a TAVI procedure may be due to several factors, many of which are not directly related to the operative technique itself: by allowing the early identification of negative trends, the CUSUM charts may prompt internal audits aimed to the identification of the causes of failure, helping to take the procedure back into control (2).

With the growing rate at which new techniques and technologies are introduced in cardiac surgery and interventional cardiology, quality control will become a key issue in the near future. For this reason Alli et al. (1) deserve merit for their pioneering paper. However, we believe that time series analysis could be an excellent means to analyze the performance of the TAVI teams, and we would strongly suggest adopting this methodology to monitor the learning curve for TAVI.

*Alfredo Giuseppe Cerillo, MD
Michele Murzi, MD
Mattia Glauber, MD
Sergio Berti, MD

*Operative Unit of Cardiac Surgery
“G. Pasquinucci” Hospital
“G. Monasterio” Foundation
Via Aurelia Sud
54100 Massa
Italy
E-mail: acerillo@yahoo.com

doi:10.1016/j.jcmi.2012.02.005

REFERENCES

Reply

We thank Dr. Cerillo and colleagues for their thoughtful and insightful comments on our paper (1). In their letter, they have highlighted the benefit of using time series analysis to assess learning curve and quality control, and we generally agree with their comments. The traditional method of assessing surgical results is the retrospective analysis of outcome data as used in our study. Statistical testing in this regard is an appropriate way of assessing the learning curve when the interest is in determining whether or not a difference has reached a magnitude of statistical...
significance. However, when a plateau is reached, and/or formal testing is of less interest than detection, a time series analysis, and in particular the cumulative sum (CUSUM) analysis, may be a more appropriate tool for this analysis.

We believe that a combination of both statistical approaches provides complementary information on the learning curve of individuals and teams performing transcatheter aortic valve implantation (TAVI). Such a combined approach would be to use the traditional method to assess the learning curve of new centers/teams performing TAVI to establish proficiency and then to apply the CUSUM analysis in a prospective fashion once these centers have established proficiency, and standards for performance measures have been established. The advantage of such an approach as highlighted by Cerillo et al. would be the ability to capture and identify easily and quickly the ongoing trend. The early detection of negative outcomes often leads to audits that may allow identification of the causes of failure. Another value of the CUSUM analysis was illustrated in the study by Murzi et al. (2); they showed that clusters of failure that happened after a surgeon had gained proficiency in performing a right anterior minithoracotomy were not due to poor surgical technique/lack of proficiency, but resulted from treating a sicker patient population as the surgeon grew in confidence with the technique. This shows both the sensitivity of this monitoring technique, as well as the need to be careful to take all relevant variables into account when trying to understand trends or deviations.

Finally, we would like to suggest the adoption of both approaches by centers looking to establish and ensure proficiency in TAVI procedures as this would lead to optimal quality control and improved outcomes for our patients.

*Oluseun Alli, MD
Jeffrey Booker, MD
Ryan Lennon, MD
Kevin Greason, MD
Charanjit S. Rihal, MD
David R. Holmes, Jr, MD

*Mayo Clinic
Division of Cardiovascular Diseases
Department of Internal Medicine
200 1st Street South West
Rochester, Minnesota 55905
E-mail: alli.oluseun@mayo.edu

doi:10.1016/j.jcin.2012.02.009

REFERENCES