

A Learning Curve in Bentall and De Bono Procedure with the Use of the Risk-Adjusted Cumulative Sum Analysis Based on the Japan SCORE

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ABSTRACT

Objective: The risk-adjusted cumulative sum analysis of an individual surgical learning curve for the Bentall and De Bono procedure on aortic root pathologies was used to monitor and enhance quality control.

Methods: From April 2004 to March 2009, 20 consecutive patients were operated upon by a single surgeon for aortic root pathologies by means of the Bentall and De Bono procedure. Operative variables, mortality, and major morbidities were analyzed. The learning curve was calculated using descriptive statistics and cumulative sum failure observed minus expected failure rate derived from the Japan SCORE calculator.

Results: In this series, the Japan SCORE calculator expected $3.91\% \pm 5.14\%$ of 30-day operative mortality rate and $16.74 \pm 13.47\%$ of 30-day operative mortality and morbidity. In reality, there was no operative and in-hospital death. Major postoperative morbidity rate was 15.0% (3 patients). The risk-adjusted cumulative sum analysis revealed that the learning curve of mortality was downward below the lower 95% confidence interval throughout all the patients and that of morbidity was upward till the seventh case and remained downward thereafter. The polynomial approximation coefficient analysis revealed a significant negative correlation between aortic cross-clamp time, cardiopulmonary time, and operation time and case load.

Conclusions: The Bentall and De Bono procedure for aortic root pathologies was performed at the professionally permissive level from the beginning, even in a low-volume environment. It showed one good example of a learning curve. The risk-adjusted cumulative sum analysis based on the Japan SCORE was a very useful tool for monitoring the performance.

Received April 17, 2011; received in revised form May 22, 2011 accepted June 21, 2011.

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INTRODUCTION

Aortic root pathologies include acute type A aortic dissection, aortic annuloectasia and aortic insufficiency, and aortic root aneurysm due to Marfan syndrome. The Bentall and De Bono procedure (BDBP) has been the gold standard operation for those diseases, and its long-term durability has been well proven [Bentall 1968; Kouchoukos 1986]. With the introduction of new valved composite grafts, BDBP has become a straightforward but meticulous operation, and it takes time and experience for an independent cardiac surgeon to attain appropriate proficiency in reproducible results of BDBP.

During 2005, 1526 new cases of BDBP or valve-sparing aortic root replacement procedure (VSRR) were operated upon in Japan [Ueda 2007]. In Japan there are 550 hospitals to which cardiovascular surgeons belong, and 1911 cardiovascular surgeons are practicing as board-certified cardiovascular surgeons [Ueda 2007]. On average, one hospital experiences 2.77 cases of BDBP or VSSR per year, and one cardiac surgeon experiences 0.80 cases of BDBP or VSSR per year.

In recent years, there has been a large increase in the level of clinical audit of cardiovascular surgery. Aortic root pathologies are obviously curable diseases by appropriate operation, and the only alternatives are bleak. Such life-saving surgery is highly demanding but shall be of professional performance. The profession itself has come to recognize clinical audit as a valuable means for improving professional standards and reducing complication rates.

The usefulness of the sequential probability cumulative sum (CUSUM) technique to analyze surgical performance has been shown in recent publications [Novick 2002; Rogers 2004; Holzhey 2007]. It allows for detection of changes in perioperative mortality and morbidity during the patient care process. It provides almost real-time monitoring of surgical performance if updated after each procedure. CUSUM analysis acknowledges the importance of individual experience in monitoring performance and allows for easy charting of a learning curve with regard to the incidence of perioperative complications.

We have been working on the issue of learning curve and have reported literature dealing with coronary artery bypass grafting [Song 2005], aortic arch replacement [Song 2007a], and launching of a new cardiac surgery unit [Song 2008b].

Patient Demographics and Results*

Patient Demographics	
Age, y (range)	53.8 ± 11.1 (39–70)
Men, n (%)	14 (70%)
NYHA, mean	1.8 ± 0.4
Marfan, n (%)	3 (15%)
Takayasu, n (%)	1 (5%)
Root/Valsalva diameter, mm	60.3 ± 5.45
Operative results	
Mortality, n (%)	0 (0%)
Morbidity, n (%)	3 (15%)
ACC time, min (range)	143.4 ± 42.3 (100–262)
CPB time, min (range)	193 ± 71.5 (120–414)
OR time, min (range)	380.4 ± 131.6 (245–692)
Prosthesis used	
CarboSeal, n (%)	10 (50%)
Valsalva graft and Carbomedics mechanical valve, n (%)	10 (50%)

*Data are presented as mean ± standard deviation unless indicated otherwise.

We have shown that there was a cut-off number of cases sufficient to ensure optimal outcomes. In this study, we aimed at constructing a risk-adjusted learning curve of a single surgeon on BDBP surgery in Japan where case-volume was very small per hospital and per surgeon.

MATERIALS AND METHODS

From April 2004 to March 2009, 20 consecutive patients were operated upon by a single surgeon (MHS) for BDBP at the Gifu Prefectural Tajimi Hospital (to which MHS belonged before). Clinical charts and operative records were collected for demographic data, preoperative and postoperative morbidities, operative variables, and short-term prognosis. Institutional Review Board approval was obtained for this clinical cardiac surgery database research. The requirement for informed consent was waived by the Institutional Review Board.

The first 3 cases in a row were performed under the strict supervision of a chairman of a cardiothoracic surgery unit at a university hospital who was a mentor when the surgeon under study was a fellow in training. The rest of the 17 cases were performed by the surgeon under study by himself.

Operative Technique

A patient was put in supine position under general anesthesia. The arterial line was monitored at either radial artery. Near infrared rays monitoring was put to frontal head. Opening the chest, the ascending and arch aorta was scanned by epiaortic echo to check the quality of aortic wall. The aortic arch was cannulated for arterial inflow, and the

right atrial appendage was cannulated with double-borne venous drainage. The ascending aorta was cross-clamped, and the aorta was opened distal to the sino-tubular junction. Antegrade selective blood cardioplegia was infused into right and left coronary. We used the manufacturer-made valved composite prosthetic graft in the first 10 patients, and in the remaining 10 patients we used the Valsalva graft sewn and put together with mechanical valve. The detailed technique of proximal suturing was already described [Song 2007b; Song 2008a].

Statistical Analysis

In this study, CUSUM was defined as $S_n = \sum(X_i - X_0)$, where $X_i = 0$ for success, $X_i = 1$ for a failure, and X_0 is the reference or target value. X_0 (the acceptable failure rate) was calculated in every patient according to the Japan SCORE calculator supplied by the Japan Adult Cardiovascular Surgery Database [Ueda 2007]. CUSUM curves were constructed manually according to the published formula, and the 95% confidential intervals were calculated [Rogers 2004].

Numerical data of operation time, cardiopulmonary bypass time, and aortic cross-clamp time were statistically analyzed by the linear and the sixth polynomial approximation equation and coefficient. The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

RESULTS

As shown in the Table, there were 6 female and 14 male patients. Their mean age was 53.8 ± 11.1 years (range, 39–70 years). Three patients had Marfan syndrome, 1 patient had Takayasu arteritis, and the remaining 16 patients had no clear etiology. Thirty-day operative and in-hospital mortality was not observed. Major postoperative morbidity was observed in 3 patients (15.0%), which included re-exploration for bleeding in 2 patients and prolonged mechanical ventilation *due to stroke* in 1 patient. Average aortic cross-clamp (ACC) time was 143.4 ± 42.3 minutes (range, 100–262 minutes), average cardiopulmonary bypass (CPB) time was 193.8 ± 71.5 minutes (range, 120–414 minutes), and average operation (OR) time was 380.4 ± 131.6 minutes (range, 245–692 minutes).

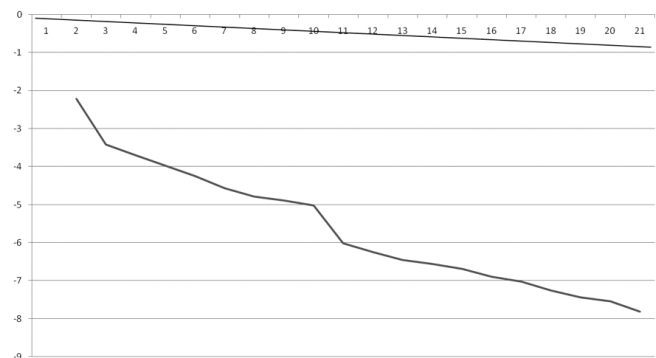


Figure 1. Cumulative Sum of Excess Deaths.

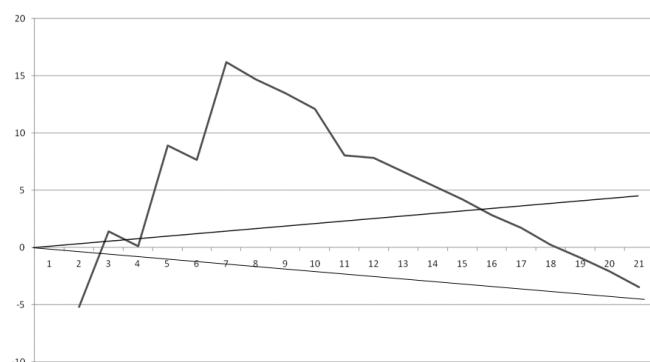


Figure 2. Cumulative Sum of Excess Mortality.

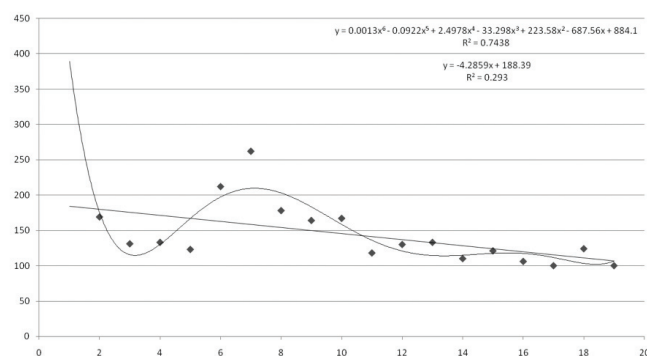


Figure 3. Aortic Cross-Clamp Time over Case Loads.

Figure 1 shows the risk-adjusted CUSUM learning curve of excess deaths, and Figure 2 shows the risk-adjusted CUSUM learning curve of excess morbidity. In mortality CUSUM, the learning curves remained below the 95% lower alarm line from the beginning, which meant the performances were within professionally permissive level as a surgical service provider. In mortality and morbidity CUSUM, the 95% lower alarm line was transgressed at the seventh case, and the CUSUM curve remained below it thereafter.

Scattered graphs regarding ACC time and OR time are shown in Figure 3 and Figure 4. Linear approximation showed weak significant relationships between ACC, CPB, and OR times and case volume. The sixth-degree polynomial approximation showed a strong negative coefficient between ACC, CPB, and OR times and case volume ($R^2 = 0.7438$, 0.6703 , and 0.5875 , respectively). According to the t test of Pearson's coefficient of correlation, each R^2 yielded less than 0.05 significance level, and the null hypothesis that the coefficient of correlation was not statistically significant was rejected even in this sample size of 20 cases.

DISCUSSION

Patients with aortic root pathologies come very infrequently to the board-certified cardiac surgeons in Japan. As mentioned before, on average, one hospital experiences

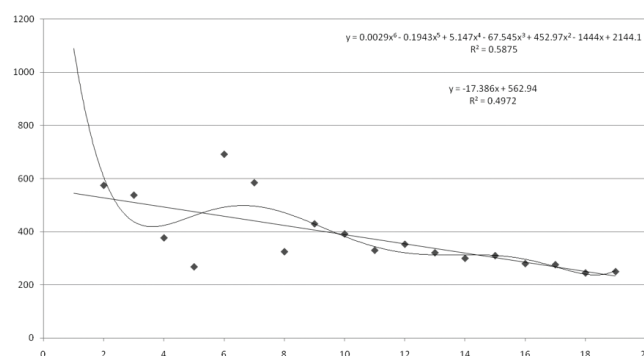


Figure 4. Operation Time and Case Loads.

2.77 cases of BDBP or VSSR per year, and one cardiac surgeon experiences 0.80 cases of BDBP or VSSR per year. In this small-volume situation, we are obliged to attain steady and excellent results of BDBP.

The correlation between surgical volume and quality has been recently investigated intensively. Although some groups reported data that strongly support the positive relationship between case-volume and operative results in coronary artery bypass grafting [Hannan 2003; Shahian 2003], others question the relationship [Rathore 2004; Welke 2005]. Because there have been no data examining the relationship between BDBP and case volume, this study could be one of the clinical examples of the learning curve.

This study inferred 2 facts. First, an independent cardiac surgeon could launch into BDBP surgery with safe results, which was shown in risk adjusted CUSUM analysis below 95% lower alarm line performance. Second, as was anticipated, ACC, CPB, and OR times improved over case loading, which was demonstrated by the sixth-degree polynomial approximation coefficient analysis.

The first fact may be attributed to a superb mentor and uniform BDBP techniques taught at teaching hospitals. Also, we provide careful and meticulous postoperative care not to let the patients die even in patients with complicated stroke. The surgeon examined in this study had spent 12 years of residency and fellowship after graduation of medical school and had performed more than 200 cases of coronary artery bypass surgery and more than 100 cases of valve surgery as an attending-consultant independent surgeon. The first 3 cases were done under strict supervision of the senior attending-consultant surgeon, and the rest of the cases were done by a surgeon under study himself. The nursing staff changed by turns, but perfusionists who run the pump were very much experienced personnel. The second fact was understood very reasonably and was in accordance with the volume-quality relationship. Also, a surgeon has learned crucial stitches and anastomoses in the first 3 cases with the assistance of a mentor in BDBP surgery. They include secure and tight proximal annular anastomosis and posterior anastomosis of graft in which bleeding is very hard to control. The left coronary button must be carefully sewn because it is extremely hard to control the bleeding from there.

A potential limitation of this study is the criticism that 20 cases of BDBP are too few to draw any conclusions. But in very experienced hands, one experienced 12 cases of BDBP per year in Rome [De Paulis 2002], and the other experienced 41 cases of BDBP per year in Toronto at the most [Sioris 2004]. It is unfortunate for us to have very little literature directly dealing with the relationship between case volume and learning curve in BDBP surgery. BDBP comes very infrequently in Japan. CUSUM analysis used in this study is not dependent on case number. Moreover, the t test of Pearson's coefficient of correlation showed that each coefficient of correlation yielded less than 0.05 significance level and null hypothesis that coefficient of correlation was not statistically significant was rejected even in this sample size of 20 cases.

In conclusion, we report the outcome of 20 consecutive patients who have undergone surgery for BDBP by a single surgeon. The risk adjusted CUSUM analysis demonstrated that the learning curve on mortality was always downward and the learning curve on morbidity was initially upward until the seventh case but was downward thereafter. Operative variables improved as case loaded throughout.

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