Controlled Exponentially Weighted Moving Average Chart in Cardiac Surgery: A Simulation Study Across 9 Italian Cardiac Centers

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Application of statistical process charts has led to consistent quality production improvement in the industrial sector. Aim of this simulation study is to assess if the use of exponentially weighted moving average chart with control limits (CL) could help to identify mortality trends in a cardiac surgery scenario. Mortality rate of 9 cardiac centers has been continuously monitored by a central clinical governance unit since 2010; prospectively collected monthly mortality rate of calendar year 2013-2014 from each center was used to retrospectively build an exponentially weighted moving average chart; mortality level was set at 4% as per threshold defined by the Italian Ministry of Health recommendation; upper CLs were set as 1.5 standard deviation from the specified level; lowest mortality rate (2.6%) was observed during calendar year 2012-2013, hence that was considered the center of the chart. All centers were considered as 1 entity and consecutively plotted in the chart following a geographic distribution, from North to South. A total number of 4049 operations were performed; 108 patients died while in hospital (2.6%). Different mortality trends that consisted of minor and major out-of-control process defined as a point of the chart outside the upper CLs were demonstrated. In conclusion, mortality trends could have been potentially identified at earlier time points before reaching the 4% limits of mortality; exponentially weighted and controlled chart may facilitate clinical governance units to their monitoring role.

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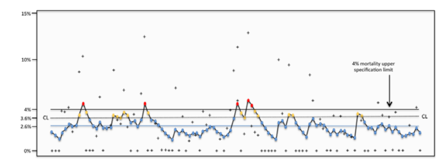

Statistically process control chart depicting the production flow of 9 cardiac units.

Central Message

Controlled modified exponentially weighted moving average chart may be an important quality tool in a cardiac surgery context.

Perspective Statements

In a cardiac surgery scenario, modified statistical process chart such as exponentially weighted moving average chart may help to depict mortality and detect unfavorable mortality trend. Exponentially weighted and controlled chart may facilitate clinical governance units to their monitoring role.

See Editorial Commentary pages 259-260.

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INTRODUCTION

There are different statistical process charts to monitor performance in cardiac surgery, with different pros and cons. During the past years, exponentially weighted moving average chart (EWMA) have gained popularity for 2 main reasons as assigns a greater weight to the more recent data, whereas includes all the data in its calculations[1] and differently from the moving average, EWMA charts work in a way that outcomes from recent patients are more relevant to estimating current failure or improvement rate.[2] As cardiac surgery indicators such as mortality can show more volatility than others, EWMA charts may be particularly efficient to detect a trend without extreme fluctuation[3] around a given mean (center) and these particular features may help to identify variations with a lower number of "false alarms" compared with the conventional superimposed *x*-bar chart. To detect an out-of-control process

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before it reach a maximum given boundary, control limits (CL) have to be set. Theoretically, a productive process with fluctuation inbetween 1.5 standard deviation (SD) below the specification limits (4.5 SD above and below the mean) is in perfect control with virtually no defect.[1] Ministries of Health from different European countries[4] have put as priority to improve quality of health care. The Italian Ministry of Health proposed that mortality for isolated coronary artery bypass grafting (CABG) and isolated valve repair and replacement should be below 4%.[5,6] The aim of this study was to compute a EWMA chart taking into account cardiac surgery Italian mortality rate limits recommended, and to apply CL at 1.5 SD below this given upper specification of 4% and to retrospectively analyze the behavior of the 2013-2014 mortality rate of GVM Care & Research cardiac centers considered as "one single center," to understand if the EWMA chart may help to depict mortality trend.

MATERIAL AND METHODS

GVM Care & Research[7] is a private group that works in partnership with the Italian central and regional National Health System. In total, 9 cardiac centers of GVM Care & Research are differently scattered throughout the Italian territory and they roughly represent the 10% of the Italian cardiac surgery workload (Fig. 1). A central clinical governance unit (CGU) and a data management team were established in early 2010, and as then mortality and morbidity are constantly reviewed. Figure 1 shows geographic collocations of the centers, number of cases performed in the calendar year 2013-2014, and raw mortality.

This was a simulation study structured in a way that all 9 centers were considered as "one large factory," consecutively generating "a flow of production" ("goods" as cardiac operations of different case mix). Prospectively collected monthly mortality rates of calendar year 2013-2014 of all 9 cardiac units were used to compute a modified EWMA; cardiac units were plotted in the modified chart following a geographic regional distribution, from North to South in a way that each month (from January onward) for each center was consecutively represented in the x-axes of the chart (Fig. 2A). There were no missing data points.

STUDY METRICS

Definition of Mortality

In hospital raw mortality included all deaths within 30 days of operation irrespective to where the death occurred and all deaths in hospital after 30 days among patients who had not been discharged after the index operation.

EWMA chart parameters and Six-Sigma (SS) level.

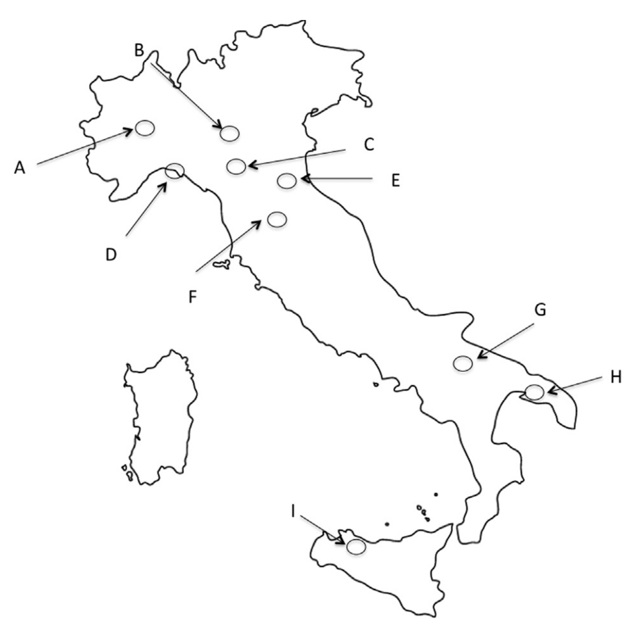

Figure 1. GVM Care & Research cardiac units, geographic distribution and calendar year 2013-2014 raw mortality and number of cases—(A) (Piemonte), 4.6%, $n = 351$; (B) (Emilia Romagna), 1.2%, $n = 27$; (C) (Emilia Romagna), 0.9%, $n = 343$; (D) (Liguria), 4.3%, $n = 392$; (E) (Emilia Romagna), 2.3%, $n = 922$; (F) (Tuscany), 1.9% $n = 368$; (G) (Puglia), 2.6%, $n = 637$; (H) (Puglia), 1.6%, $n = 483$; and (I) (Sicily), 4.1%, $n = 318$. (Color version of figure is available online.)

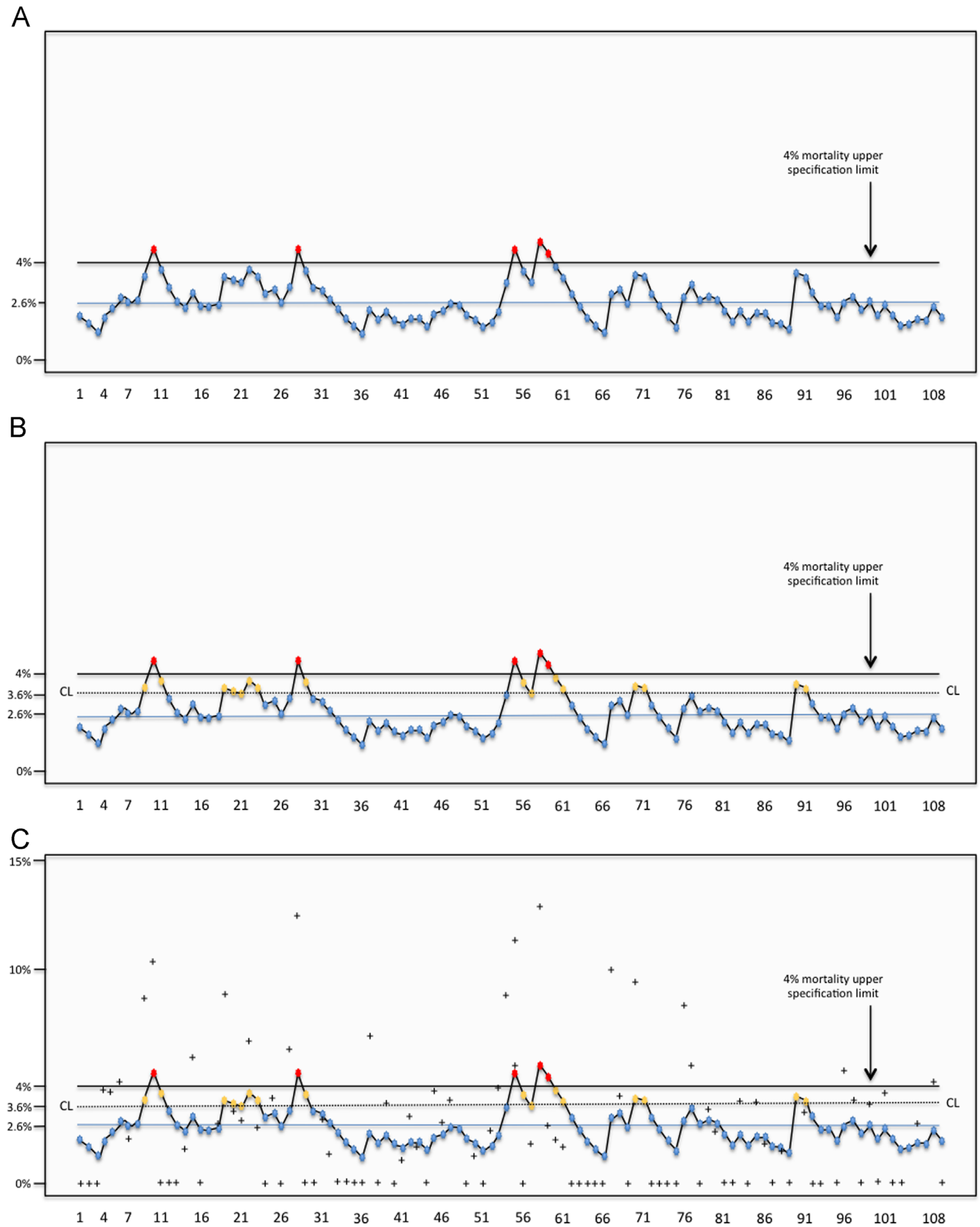

Figure 2. (A) "Flow of production"—modified EWMA showing calendar year 2013-2014 mortality rate fluctuation of 9 cardiac centers GVM Care & Research considered as "one large factory" producing the goods "cardiac surgery." *X*-axes—months (12 months "sentinel point" each of the 9 center, 108 points of observation; eg, 1-9 represents January, 10-18 February and so on). *Y*-axes—mortality frequencies (%). Continuous blue line: indicates the center = 2.6% (mean = 2012-2013 mortality which was the lowest mortality observed in GVM Care & Research group since 2012, hence was use as benchmark). Arrow shows the 4% upper specification limit, established by the Italian Ministry of Health as maximum mortality rate limit permitted. Red-dots—major (above 4% specification level) out-of-control process. Blue-dots—process below the upper specification limit of 4%. (B) CL—control limit (dotted line) set as 3.6% that represent 1.5 SD below the upper specification level of 4%. Yellow-dots—minor (between CL and 4% specification level) out-of-control process. (C) "+ marks" = represents superimposed *x*-bar chart or nonweighted mortality. (Color version of figure is available online.)

Modified exponentially weighted moving average chart was designed according to the formula

$Ei = \lambda xi + (1-\lambda)Ei-1$

The required different parameters are as follows: Ei is the current value of the EWMA chart, xi the current observation, and Lambda (λ) the weight given to the most recent rational subgroup mean; λ must satisfy $0 < \lambda \leq 1$; we set the smoothing parameter $\lambda =$ to 0.2.[8,9] Moreover, upper mortality specification level: was set as per Italian Ministry of Health recommendation (4% mortality rate).[6,10] Width of the CL, CL was set as per 1.5 SD below the upper specification level (4.5 SD above and below the mean). Center is the mean value of the benchmark. We chose 2012 mortality rate (2.61%) because it was the lowest mortality rate observed since 2010 in GVM Care & Research.

For completeness purposes an x-chart ($\lambda = 1$) was superimposed to EWMA chart in Figure 2C.

R project software (www.R-project.com) was used for statistic and modeling purposes.

Definition of "in and out control"

A process is declared to be "in control" if all points charted lie randomly within the CLs, if 1 or more points are beyond limits the process is said to be "out of control."[9]

(1) "Major out-of-control process" was defined as points beyond the upper mortality specification limit level (4%).
(2) "Minor out-of-control process" was defined as points between the upper specification limits and the CL set 1.5 SD below (3.6%).

RESULTS

Modified eEWMA depicting 2013-2014 mortality of 9 centers with major out-of-control processes (red dots) is shown in Figure 2A. In Figure 2B the CL is set (1.5 SD below 4%) to detect the minor out-of-control processes (yellow dots).

A total number of 4049 operations of a different case mix were performed; 108 patients died while in hospital (2.6%). In all, 3 centers had mortality rate above 4% (center A, D, and I—4.6%, 4.3%, and 4.3%, respectively, Fig. 1). A total number of 21 out-of-control processes were observed. Among these 5 were major (beyond 4% mortality, red dots, Fig. 2A) and 16 minor (between 4% and 1.5 SD below 4%, yellow dots, Fig. 2B). In the first part of the chart 3 trends of out-of-control mortality at regular intervals were observed; first trend (9 months) was characterized by minor out-of-control process (Fig. 2B, yellow dot) that eventually led to a major one; second trend (18 months) did not have major out-of-control process, whereas the third (28 months) had 1 major out-of-control process. Fluctuation of the line was steady until another cluster of out-of-control process was observed (54 months) with 3 major out-of-control processes; finally 2 minor out-of-control processes were observed toward the end of the chart (71 and 91 months) that did not evolve into major one. In Figure 2C an x-bar chart showing the nonweighted mortality rate is superimposed.

DISCUSSION

Although the Health Sector is treating patients rather than operating an industrial or manufacturing process, quality control initiatives in medicine have applied methods derived from other industries to assess and improve quality and reliability in service delivery.

Cardiac surgical performance may vary over time because of different reasons eg,: introduction of new technologies such as suture-less valves, steep-learning curve related to minimally invasive technique and other factors. Regarding mortality, an ideal control chart could potentially allow the designed CGU to (1) identify if a trend exists, (2) trigger appropriate responses, and (3) without overreacting with local investigations. Charts should be also easy to be constructed and interpreted, without requiring too many observation points. Finally, they should allow data comparison between the observed populations; consistent reviews were written about use of charts in public health surveillance.[10,11] There are different statistical process chart in use. Shewhart control charts are very practical, however, the decision regarding the state of control of the process at any time would depend solely on the most recent measurement from the process, they depend heavily on the normality assumption and generally detect only large shift.[12] Cumulative sum performance charts, originally used for industrial quality check,[1] have gained popularity in cardiac surgery, however, they lack of clear clinical interpretation and that, ultimately, has limited their use in practice.[13] Variable life-adjusted display[14,15] have been proposed to show differences between expected and actual cumulative mortality; nevertheless, although useful, these risk-adjusted charts may be biased owing to the accuracy limits of the "tool of risk prediction" such as Euroscore II or STS-PROMS or other methods for risk-adjusting mortality[3,16,17] or because of unintentional and intentional misclassification (gaming) of risk factors[18] or because of data entry mistakes.[19]

Lastly, funnel plots have been used mainly for individual surgeon and surgical team comparison.[20]

Main aim of this study was to understand if the application of EWMA with CLs could help to depict mortality trend. The theoretical rationale of introducing a CL lies to the possibilities to identify minor out-of-control process (yellow dots, Fig. 2B) and potentially to act before the trend trespasses the mortality upper specification level. In terms to "where" to set the CLs we followed the "Six-Sigma" basic principle, based on the notion that if 1 has 6 SDs between the process mean and the nearest specification limit, practically no items would fail to meet specification and, as part of SS general principles, limits of production control must be set 1.5 SD below the upper specification limits (4.5 SD above and below the mean).[21] A productive process with fluctuation in between those limits would have virtually no defect (3.4 defective parts per million opportunities. In our simulation study we retrospectively identified 16 yellow dots (minor out-of-control processes, Fig. 2B) and theoretically those should trigger the CGU intervention. Although our Ministry of Health proposed 4% mortality only for isolated CABG and valve surgery we accepted this limits for all case mix. In terms of statistical process charts, we used a modified EWMA charts, however, a normal *x*-bar chart was superimposed for discretion (Fig. 2C). As a mean (center) of the EWMA chart we decided to select the lowest mortality rate among the GVM Care & Research centers since 2010 (2.6%)[7]; moreover, that was in line with the national Italian mortality rate of the calendar year 2013-2014, 2.4% for CABG and 2.8% for isolated valve; however, GVM Care & Research mortality refers to a more complex case mix rather than isolated surgery.[6] Limit of 4% mortality proposed by the Italian Ministry of Health refers to 30 days from the operation date; however, we included deaths of all patients who had not been discharged after the index operation. Furthermore, we reported raw mortality rather than adjusted to avoid potential bias; also, correctness of our database was below 80% in 2 centers in 2013 (A and E) thereby raw mortality was preferred. Moreover, according to the Italian agency of reporting outcomes in cardiac surgery (Programma Nazionale Esiti)[5] there was a limited difference between adjusted and unadjusted mortality rate.

STUDY LIMITATIONS

This has different limitations. First caveat is the nonnormally distributed patient population included in the analysis; however, it must be said that sigma levels can be determined for process data that has evidence of nonnormality.[21] Secondly, mortality is a volatile outcome and naturally varies in between period and centers assessed. Another limitation lies on the choice of the smoothing parameter λ, that is the weight given to the most recent rational subgroup mean, hence, fluctuation of the line depends on the this value, different Authors have used different values, but there is not a general agreement.[8,9] Moreover, for practical reasons we tracked the mortality rate every calendar months thereby we obtained only 12 points of observation per centers (108 observation points totally), however, use of 4 weeks as a "sentinel point" has been already proposed in epidemiology.[22] A different plot entry in the chart rather than North to South might have changed the EWMA shape. No investigation at this stage was carried out to analyze the components of the out-of-control processes. Definition of quality is somewhat difficult to define; we arbitrarily considered mortality as indicator of quality and no other outcomes were considered. Lastly, our modified EWMA chart was based on raw mortality and no adjusted chart was built.

CONCLUSIONS

This study may contribute to demonstrate that the use of statistical process chart such as modified controlled EWMA may help to monitor mortality trend that ultimately may be identified in advance when they reach the upper CLs. However, to validate such methodology, prospective studies are required.

CONFLICT OF INTEREST

There is no conflict of interest for this research. Giuseppe Speziale is GVM Care & Research vice Chief Executive Officer. Nick Sevdalis delivers team, quality, and patient safety assessment and training interventions to hospitals in England and internationally via the London Safety and Training Solutions Ltd, which he directs.

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