



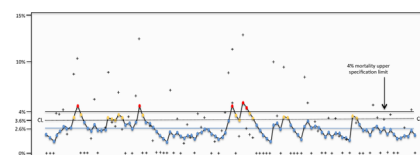
Controlled Exponentially Weighted Moving Average Chart in Cardiac Surgery: A Simulation Study Across 9 Italian Cardiac Centers

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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 calculations¹ 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 fluctuation³ 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

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 countries⁴ 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 & Research⁷ 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.

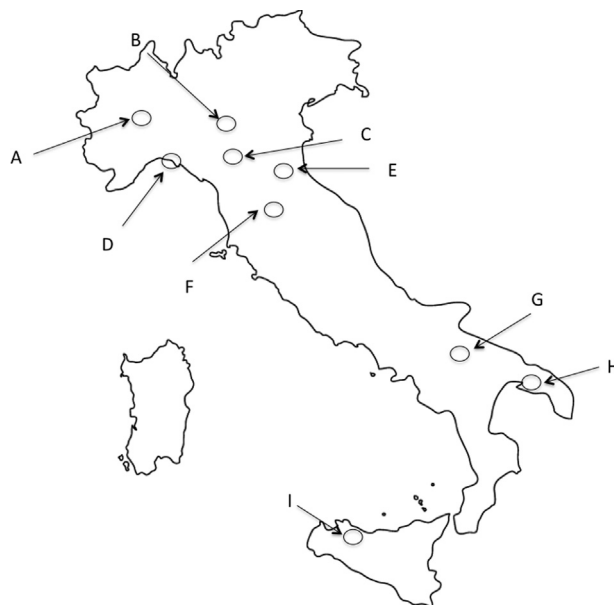


Figure 1. GVM Care & Research cardiac units, geographic distribution and calendar year 2013-2014 raw mortality and number of cases—(A) (Piemonte), 4.6%, $n = 351$; (B) (Emilia Romagna), 1.2%, $n = 27$; (C) (Emilia Romagna), 0.9%, $n = 343$; (D) (Liguria), 4.3%, $n = 392$; (E) (Emilia Romagna), 2.3%, $n = 922$; (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.)

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