



Monitoring surgical quality: the cumulative sum (CUSUM) approach

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Abstract: Monitoring the quality of new or ongoing surgical activities is a necessity. Several Statistical Process Control (SPC) tools are available to professionals. Among them, Shewhart charts and cumulative sum charts (CUSUM charts) are useful methods to provide visual feedback before significant quality issues arise. In this paper, we discuss both methods based on our current approach. On Shewhart charts, one variable value is plotted on a time-series line. This method provides information about every single determination. Random variations of the values appear and by adjusting the adequate control limits it is possible to know whether those variations are random or out-of-control. Although large variations are easily detected, small but relevant changes are not. On the contrary, CUSUM charts have the capability of detecting small changes quickly. CUSUM is defined as a statistical tool that graphically represents the sequential monitoring of cumulative performance of any dichotomized or continuous variable under assessment. It emphasizes failures penalizing them against the correct performance when individual risk is adjusted. This makes CUSUM especially sensitive to negative changes. CUSUM can be created without the need of a specific sample size and grow with every new case included. Besides the variable under control (with specific definitions of acceptable and unacceptable outcomes), the type I and II errors for the defined parameter and the individual risk of acceptable or unacceptable outcomes must be included in the chart. Graphical representation of these three parameters is easy and intuitive to read making CUSUM graphs a reliable tool to understand the trending of the parameter under control. If performance is considered inadequate: analysis, discussion and implementation of agreed measures should be taken. Despite its limitations, CUSUM analysis is considered the best tool for quality control in health care domain.

Keywords: Cumulative sum chart (CUSUM chart); statistical process control (SPC); quality control; risk-adjusted CUSUM; quality improvement methodology; Shewhart chart

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Introduction

Recognizing the social demands of professional responsibility, all medical activities, and surgical ones are not the exception, are currently under strict internal monitoring of their results, usually by risk-adjusted analysis of outcomes (1) facilitating the adoption of required corrective measures. Also, external audits (2) and benchmarking projects (3) have

been implemented by scientific societies. Public reporting of outcomes adds a sense of transparency and security to patients and facilitate adequate financial resources to health care institutions (4).

Surgical performance can be improved comparing local outcomes to historical large databases through solid risk models which are constructed on multi-institutional high-

quality records. At the time of implementing new surgical programs, no risk-adjusted models are available and, depending on the nature of the innovation, a close follow up in a case by case basis can be necessary. In those cases, close follow-up of outcomes must be implemented on time series analysis either by simple Shewhart chart or CUSUM analysis. This paper aims to review both Statistical Process Control (SPC) tools in health care and to provide some examples based on our own surgical experience.

The SPC tools

SPC tools are mathematical instruments originally developed for the industry to monitor the quality of manufacturing processes (5). Among SPCs, Shewhart charts, exponentially weighted moving average (EWMA) chart, G-chart, Funnel plots and CUSUM plots are the most relevant (6,7). All of them are based on time series analysis of specific results or outcomes.

Choosing the right tool

Difficulties identifying the most appropriate statistical chart for quality control has limited its use in clinical settings (8). Depending on the characteristics of the variable to be measured, one or another tool should be used. When the variable “counts” the number of similar items in a single category, something that is represented as yes/no, passed/failed,... or *Attribute data*, different types of Shewhart charts (p-chart, np-chart, c-chart, u-chart) are specific tools for its analysis and EWMA chart, CUSUM chart, real time contrast charts or time series model can also be used. When analyzing the values resulting from the measurement of continuous variable or *Variables Data*, again different types of Shewhart charts (X-bar and R chart, X-bar and S chart, ImR chart or XmR chart), three-way chart and regression control chart are the appropriated ones. EWMA chart, CUSUM chart, real time contrast charts or time series modeling can also be used for *Variables data's* analysis (9). Despite this difficulty, the Shewhart p-chart, the simplest of all the instruments, is increasingly used to monitor Plan-Do-Study-Act (PDSA) cycles in healthcare (10).

Setting the control limits

Even in the so-called stable processes (6), variations can be observed that do not require any corrective intervention. Without statistical control limits, overinterpretation of the

results can lead to inappropriate decisions to normalize outcomes that do not require any intervention (7). Different methods have been developed to establish the limits (11). In clinical settings, values derived from previous large series analysis (12) or based on expert agreement should be used. For instance, Je *et al.* (13) evaluated the performance of three residents while training on endotracheal intubation after agreeing that 90% of successful intubation was the goal to achieve and considering 80% as inadequately low. No matter which is the value you choose, it must make clinical sense.

Defining the stage

Before starting the analysis, a precise definition of the area in which the measure will be implemented is mandatory. In surgical settings, variables related to the surgeon, to the department or any specific part of it, to the hospital or a group of hospitals sharing similar conditions can be analyzed. However, analyzing single surgeon performance is usually not recommended unless measuring very specific procedures highly linked to individual practice (14). Most outcomes are not dependent on the work or the decision of an individual, but the result of a multidisciplinary team action. Therefore, analyzing variables that consider the whole process is recommended. For instance, it can be interesting to analyze different outcomes related to a new treatment in certain tumoral stages (morbidity, mortality, QOL, pain, etc.).

Defining variables and the benchmark value

As mentioned before, SPC tools can work with dichotomized or continuous variables. Of course, these variables can be discrete events or composite scores but always quality indicators of the target outcome. Therefore, systematic literature reviews and formal judgment are necessary to identify the best quality indicators in each situation. In a second step, it is necessary to assess the validity and practicability of the chosen variables. Simple and easy to use variables such as mortality; conversion rates for minimally invasive surgery; requirement of blood transfusion, etc. or in cancer surgery, whether lymphadenectomy was performed or not or whether the standard number of lymph nodes were removed are frequently controlled parameters. Also, composite parameters can be controlled. For instance, aggregates of postoperative complications like the occurrence of type

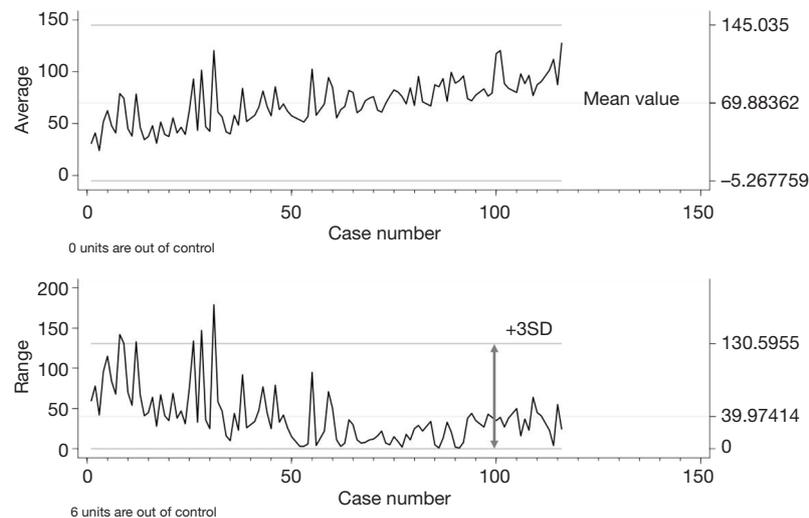


Figure 1 Basic Shewhart charts (X-chart and R-chart) analyzing the surgical length of the procedures. In the average chart (X-chart), the system uses the mean value of the variable for calculations and in the range chart (R-chart) uses the standard deviation based on the range of values. Control limits set at $\pm 3SD$. Note: operative time length of a thymoma series operated on at the Thoracic Surgery Service of the University Hospital of Salamanca from 1995 to 2018. Unpublished data. SD, standard deviation.

IIIa major complications that did not required general anesthesia for its treatment (6,15).

After defining the variable under control, determining the “benchmark” value is mandatory. This value can be determined by the quality manager (13) or can be estimated using the constant value obtained when the process is running correctly. In a dataset with a normally distributed mean, this standard value is the mean obtained when no out-of-the-statistical-limits cases had occurred (16).

The Shewhart control chart

In this simple chart, variable values are plotted against the timeline (*Figure 1*). Up to ten types of Shewhart charts can be identified. Two of them are frequently used and are based on the mean value of the measured variable (X-chart) or on the standard deviation (SD) of the range of values (R-chart). In *Figure 1* both charts show multiple variations. All are within the control limits except for 6 cases in the R-chart. Further analysis of those cases discovered that in all of them local invasion of vascular structures obliged to prolonged surgical times. To note is that not out of control cases occurred in the X-chart while some cases appeared in the R-chart, meaning that both types of charts are complementary.

Defining the control limits in Shewhart charts

Johnson in 1961 (17) defined a widely used process for statistical calculation of the limit's values. It is widely used due to its simplicity. The basics consist in calculating the SD of the series. Once known, limits are established at $\pm 3SD$ (or 3 Sigma) including 99.7% of the normal fluctuations of any variable. Therefore, any point that exceeds the limits is extremely rare and should be evaluated. It is assumed that control values are stable all along the series and that all points within limits are equal and good meanwhile anything out of limits is bad. Not all of the values are, however, equal. In fact, the closer to the mean, the better the values should be (6). This comes from the non-medical industry in which production must comply with very strict margins and no wide changes are expected. Something that, sometimes, it is not true in health care, although reduction of variability is also a priority in clinical settings.

Despite this limitation, the Shewhart chart has clear advantages over other quality control tools:

- (I) It is intuitive and therefore easy to understand. The R-chart of *Figure 1* shows that performance before case number 35 was irregular and 6 cases were clearly out of standard. After that, performance was much more regular although the series includes cases with different levels of difficulty and

performed by different surgeons. On the other hand, the X-chart does not detect cases out of control but an imaginary line of performance points upward getting close to the upper limit meaning that operative times are increasing. Therefore, in the next cases, a close monitoring of performance would be mandatory to control the trends towards prolonged surgical times, helping to reach a more stable (around the mean value) performance.;

- (II) It provides real time monitoring of the measured event;
- (III) It can be created despite the final population is unknown since the numbers are increasing over time.

Cumulative sum quality control charts (CUSUM charts)

Page proposed the first CUSUM charts in 1954 (18). Since then, several modifications have been introduced (11). CUSUM graphs are intended to monitor the deviations of individual samples results (X values) from a target value. This target value is aim of the process (6). The chart displays a curve that is the result of adding all these deviations, case after case, around 0. Cases appear as dots in the curve organized along the x -axis which is the timeline. Therefore, every point in the curve shows the sequential monitoring of cumulative performance over time. The system rewards the correct or positive outcome(s) (according to the defined variables and binary values of it) and punishes the negative or wrong outcomes (I -s). When the situation is “in control”, the departures caused by random variations cancel each other numerically. In the “out of control” situation, departures from the target value tend to be unidirectional, so that the sum of departures accumulates until it becomes statistically identifiable. Therefore, the curve will display any slow and small but constant change in the quality of the process that depart from the defined benchmark control. In CUSUM charts, curves moving upwards have positive meanings and downwards negative.

Building a CUSUM chart

There are several methods to build a CUSUM chart because there are different types of data distribution. This fact makes possible the analysis of continuous or binomial variables using the same methodology. Independently of the distribution of your data, CUSUM charts will be developed under the same basic concepts but being parameters and

coefficients different depending on your data (16).

Assuming that the data are normally distributed or transformed into normally distributed ones, the requested conditions for designing CUSUM charts include (16):

First, defining the acceptable and unacceptable limits of the variable under evaluation. Both can be defined by the quality manager or calculated after collection of certain amounts of cases. The following must be defined:

- ❖ Mean or benchmark value: the mean value of the variable when everything is “in control” also known as $p0$ or $\mu0$;
- ❖ Mean value of the “out of control”. The value from which outputs are non-acceptable or $p1$ or $\mu1$.

Based on the previous values, the system will calculate the model constant or stable parameter along the process:

- ❖ Standard error (SE): SE or the SD of the mean (in control or benchmark value). When just one set of data is being monitored at the same time, the SE is equivalent to the SD. When several sets of data are being monitored at the same time, SE should be adjusted knowing that $SE = SD/\sqrt{() n}$ where $n =$ total sample size.

Other data that should be defined by the quality manager or accepted using standard values are the following:

- ❖ The average run length (ARL). ARL is defined as the expected average number of consecutive elements required to obtain a false positive alarm when the situation is still “in control” (11). As mentioned in the definition, ARL is equivalent to the false positive rate (FFR) or the type I error (6,11) and it is normally set between 20 and 1,000 in health care systems. The figure depends on the number of data expected to be monitored (11). For instance, for a FFR of 5%, ARL is set at 20 (calculated as $1/0.05$); for $FPR = 0.1\%$, $ARL = 1,000$. Most often, in health care, type 1 error is set at 0.1 (6). It is important to know this value because mathematicians have developed multiple tables to manually calculate the values to build the curves. In those tables, ARL value is key to adjust the rest of the parameters.
- ❖ Type 2 error is usually set at 0.1 (6).

Statistical parameters:

- ❖ The reference value k , or the sensitivity of the graphic, is calculated based on $p0$ and $p1$;
- ❖ The decision interval h that will create the limits for raising an alarm is calculated based on ARL or type 1 error, based on type 2 error and k . $h1$ is the interval between unaccepted values and $h0$ is the interval

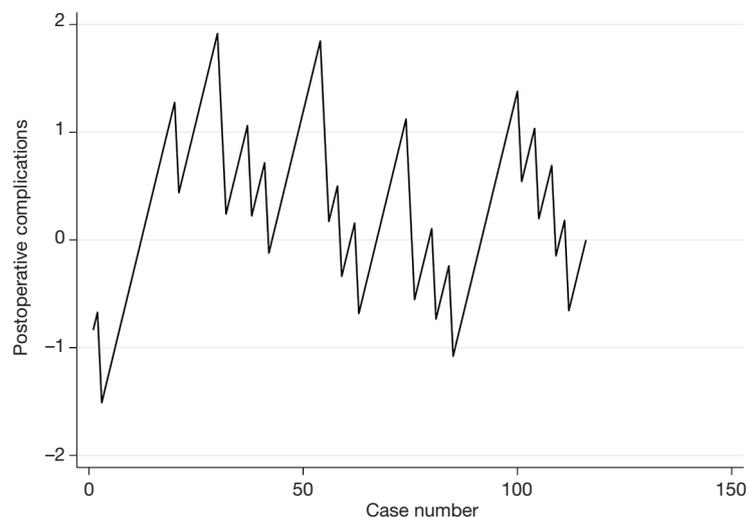


Figure 2 Standard CUSUM chart analyzing any type of postoperative complications after thymectomy. No control limits are set. Note: postoperative morbidity on thymoma series operated on at the Thoracic Surgery Service of the University Hospital of Salamanca from 1995 to 2018. Unpublished data. CUSUM, cumulative sum.

between accepted values. Because both types of error are normally set equally at 0.1, both intervals are equal and only one line (positive and negative) will appear (6).

In the statistical programs that can create CUSUM curves, normally defining p_0 and p_1 , calculating the SE, setting the errors at 0.1 and defining whether it is a binomial or continuous variable are enough to build the curve in most cases. In EXCEL® it is possible to calculate all the variables (19) although the program has the possibility of making it automatically.

There are different types of CUSUM charts. The tabular or algorithmic one is especially interesting because it displays the influence of the negative and positive deviations from the benchmark value in every point of the curve. It plots two one-sided cumulative sums for every point giving a clear information of what was more relevant for the output in a certain point: the positive or the negative cumulative values. Sometimes the information is not presented on lines but in bars (9,20).

Calculating the control or decision limits: what shift from the benchmark value do we want to detect? Where do we want the action limits set?

Because CUSUM curves are easily understandable, in most cases no control limits are shown (Figure 2). This is also known as a standard or non-risk adjusted CUSUM chart

without limits. However, depending on the distribution of your data, different methods should be applied to calculate those limits (16).

The most usual system to build the decision interval is using the h value (16). However, the most sensitive control limits are defined by the V-mask. The V-mask is a V-shape shadowed area drawn in the interest point of the curve, normally the last value. It marks the positive and negative lines of maximum and minimum accepted values along the curve. Frequently, the mask is calculated using the SE of the plotted variable (9) although risk-adjusted limits can be calculated (Figure 3).

Risk adjusted or non-risk adjusted CUSUM chart

In the non-risk adjusted chart, all recorded outputs have the same risk all along the time-series. Due to the cumulative sum of data, the line swings around the 0 value when it is under or “in control”. In this chart, control limits are normally calculated using the h value.

However, in health science, risk is barely uniform. Thus, a good quality control tool must consider variations. The risk adjusted CUSUM chart introduces the individual risk into the equation. For instance, a thymoma showing evidence of superior vena cava invasion has a higher risk of having an intraoperative bleeding than a non-invasive thymoma (Figure 3). Therefore, if no bleeding occurs during the procedure, the system should reward the absence

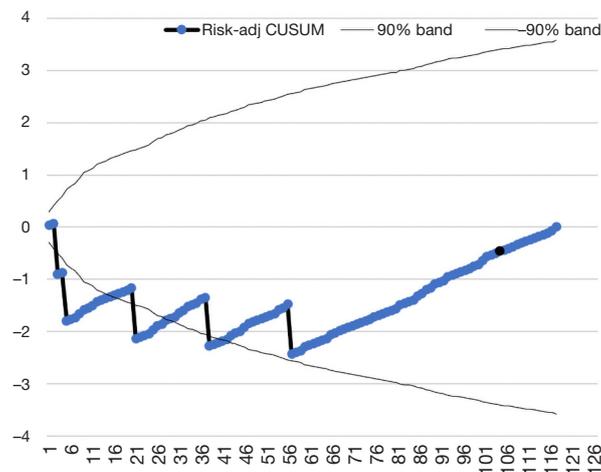


Figure 3 Risk-adjusted V-mask CUSUM chart analyzing the occurrence of postoperative hemorrhage after thymectomy. Control limits were set at 90% risk. The black and blue line is the “events line” displayed along the time series (number of cases in the x-axis). In this chart, every blue dot represents the final value of comparing the probability of having a bleeding complication of the considered case plus what happened previously with the real occurrence of the bleeding in the considered case. It is interesting to see how much the system penalizes the failures [the occurrence of bleeding when it was not expected (black lines)]. The external curved lines or control limits present the 90% probability of having a hemorrhage according to the designed risk model. Note: data of a thymoma series operated on at the Thoracic Surgery Service of the University Hospital of Salamanca from 1995 to 2018. Unpublished data. CUSUM, cumulative sum.

of bleeding. In this type of charts, defining a V-mask is the adequate way to set the decision limits (6). Individual risk can be estimated through risk modelling (21). In the absence of reliable risk models, recruiting some cases and using the h value could be a useful initial approach.

Discussion

A key aspect of continuous quality improving is measurement, analysis, and interpretation of variation (22). SPC are statistical tools that identify the normal variation within a process or common cause variations, and, at the same time, they set alarms when variations in the performance of the process seem to be statistically out of control due to identifiable reasons. Therefore, SPC help us differentiating between variations needing no correction and causes of variation that should be identify and corrected. The control chart is a guide to continuous evaluation (22). The basic element of any SPC is the graphic plotting of a control chart. In any of these charts, the most important lines are the central or benchmark value (most often the mean value of the distribution) and the control limits when they are needed. Although intuitive and apparently simple, an important amount of statistical work is needed to develop any SPC (19).

The Shewhart chart gives information regarding an individual point in the graph; in CUSUM charts, each value summarizes what is happening in the current and all the previous points in the curve. This makes CUSUM charts especially useful for detecting very small changes. Normally, changes in the range of 1 Sigma can be detected but shorter variations between 0.2 to 2 Sigma can be detected through specific adjustments. This makes CUSUM the most powerful tool for quality control of any situation in which minor changes are very relevant as in clinical settings. Furthermore, after mathematical comparison, CUSUM charts (more specifically risk adjusted V-mask CUSUM charts) seem to be more efficient than the rest of the medical quality control tools detecting changes both in rare and frequent events (6,23,24).

Charts have limitations related to defining the decision interval. When creating the Shewhart charts, control limits are fixed on $\pm 3SD$ according to the initial outputs recorded. Although they can be adjusted when data are variable (6), most of the times they are used on a fixed basis. The main limitation for CUSUM charts is the need of a certain number of cases to establish the initial SE to proceed with the analysis and the lack of risk modelling in many instances. That means that before starting a new program, acceptable and non-acceptable standard limits must be clear,

well established and making clinical sense.

Arguably the best way to evaluate a new program should follow three steps. A preliminary evaluation by Shewhart chart is acceptable to analyze the initial cases. After more cases are performed, decision interval can be fixed and non-risk adjusted CUSUM chart expanded. Finally, with a higher number of cases, all the information needed to create the risk-adjusted CUSUM chart can be available.

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