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Risk-Adjusted Control Charts: Theory, Methods, and Applications in Health

Athanasios Sachlas[1,2] · **Sotirios Bersimis**[1] · **Stelios Psarakis**[2]

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Abstract

Control charts, the most popular tool of statistical process control, appeared in the literature to ensure that an industrial process is operating only with natural variability, i.e., under statistical control. In the last decades, control charts have been also widely used to assess the quality of non-industrial processes, such as medicine and public health. Mainly in the last two decades, a modification of standard and advanced control charts appeared in the bibliography to improve the monitoring mainly of medical processes. This is the *risk-adjusted* control charts which take into consideration the varying health conditions of the patients. These charts are used to monitor certain medical processes such as surgeries, mortality, and doctors' experience. In this paper, we have tried to present all the risk-adjusted control charts presented in the literature appropriately categorized. The risk-adjusted charts have been grouped into three categories: control charts for continuous variables, control charts for attributes (non-continuous variables), time-weighted control charts. The application of risk-adjusted control charts in practical medical processes is also discussed. This review paper highlights the value of the risk-adjusted control charts.

Keywords Control charts · Risk-adjustment · Statistical process monitoring · Systematic review

✉ Athanasios Sachlas
asachlas@unipi.gr

Sotirios Bersimis
sbersim@unipi.gr

Stelios Psarakis
psarakis@aueb.gr

[1] Department of Statistics & Insurance Science, University of Piraeus, 80 Karaoli & Dimitriou str., 185 34 Piraeus, Greece

[2] Department of Statistics and Laboratory of Statistical Methodology, Athens University of Economics and Business, 76 Patission Str., 10434 Athens, Greece

1 Introduction

Control charts (CCs) are a tool of statistical process control (SPC) mainly used to monitor whether industrial processes operate under statistical control. A control chart is a graphical representation of an appropriate function of the sample values of a variable measuring the quality of the final product versus the sample number or time. The main components of a control chart are the central line and two other lines—the lower control limit and the upper control limit. If the depicted points are between the control limits, the process is declared to be under statistical control.

The use of CCs involves two phases: I and II (see, e.g., Montgomery [56]). In phase I, the researcher collects a set of process data and analyzes them retrospectively, constructing trial control limits in order to determine if the process has been in control over the period of time during which the data were collected. In phase II, the researcher uses the CC in order to monitor the process by comparing the sample statistic for each successive sample as it is drawn from the process to the control limits.

A typical CC consists of a center line (CL) and two control limits: the upper and the lower control limits (UCL and LCL, respectively). The CL represents where this characteristic under study should fall if there are no unusual sources of variability present. The two control limits are determined, usually, from some simple statistical considerations [56]. An example of a typical CC, taken from Sasikumar and Devi [68], is presented in Fig. 1. The CL represents the average HemoglobinA1C (HbA1C) level of Type 2 diabetic patients. The average HbA1C level for the first period is above the UCL (this is usually depicted a star), which means that the process is out of control.

In the last decades, SPC techniques, and mainly the control charts, have been widely used to monitor non-industrial processes [14,15]. In this context, in the last two decades, several researchers applied and modified control charts for monitoring medical processes (see among others Woodall [87]; Thor et al. [83]; Woodall et al. [88]; Bersimis et al. [16]). In industrial processes the observations are usually homogeneous in nature. However, in medicine patients can vary greatly with respect to their health and this may affect the outcome. To more effectively assess and monitor

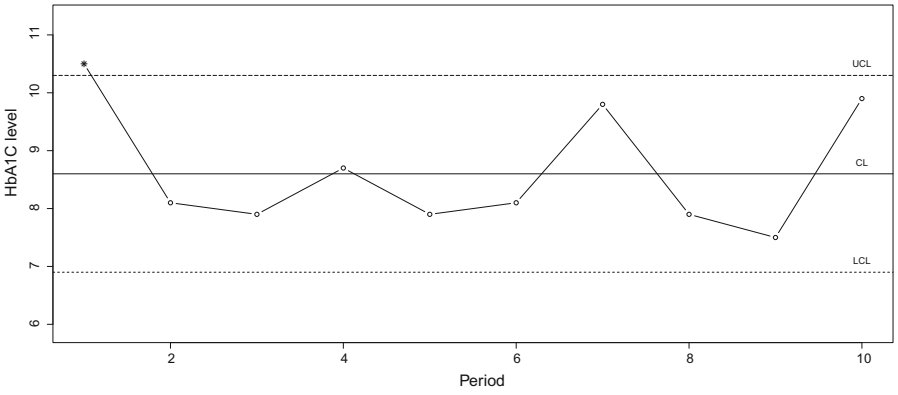

Fig. 1 An example of a typical control chart

the performance of medical processes (such as surgeries), the risks that each patient encounter should be taken into account. Thus, a new class of modified typical control charts appeared in the bibliography, under the name *"risk-adjusted" methods* in order to take into account the different risks and characteristics of the patients. In other words, risk adjustment (RA) is a statistical technique for reducing the effects of confounding factors that a patient may bring to a health care encounter [36].

Hendryx et al. [39] developed and tested risk-adjustment outcome models in publicly funded mental health outpatient programs. Such models improve quality by enabling the straightforward and fair comparison of outcomes across agencies. No mention to control charts was made in this paper. Benneyan and Borgman [13] briefly discussed risk-adjusted sequential probability ratio tests and longitudinal surveillance methods and noted the contribution of the risk-adjusted methods to the better monitoring and assessment of health processes and outcomes. Murtaugh et al. [59] developed risk-adjustment models (i.e., logistic regression models) to improve the effectiveness of home health quality measures. However, they did not use control charts.

Winkel and Zhang [86] devoted the second part of their book, which deals with statistical development of quality in medicine, on risk adjustment. Especially the sixth section presents several risk-adjusted control charts. Grigg and Farewell [31] provided an overview of risk-adjusted charts, with examples based on real data. The review paper of Cook et al. [23] is a good introduction to the use of risk-adjustment methods to track mortality rates. The book of Iezzoni [41] presents the basic principles and concepts of risk adjustment for measuring healthcare outcomes. It also explains why risk adjustment is a crucial instrument for measuring quality. Devoted to development and use of RA SPC methods for monitoring and improvement of clinical outcomes in Interventional Cardiology is the doctoral thesis of Smith [74]. Koetsier et al. [47] conducted a simulation study to evaluate the performance of RA control charts to monitor in-hospital mortality of intensive care unit patients.

Recently, Zeng [90] reviewed the main developments concerning the two basic problems involved in RA: *performance monitoring* establishing risk-adjustment models, which includes identifying the appropriate performance measures to monitor and associated patient risk factors, constructing statistical models that characterize the dependency of the performance measures on the risk factors, and *change detection* based on the established models, which includes estimating baseline parameters of the risk-adjustment models and detecting deviations from them.

Steward and Rigdon [80] addressed the problem of RA monitoring as a change-point problem with several possible change-point models. This Bayesian approach generalizes previous RA charts in that they look for changes in any of the parameters. However, they did not propose a new RA control chart. The aim of the present paper is to present theory and applications of risk-adjusted control charts.

In this paper, we systematically reviewed the advances concerning the risk-adjusted control charts presented in the literature. We categorized the papers included in the review to RA variable control charts, RA control charts for attributes, time-weighted RA control charts, multivariate RA control charts, and applications of RA control charts. The above categorization was selected in order to follow the typical classification of data on quality characteristics as attributes or variables data (see, e.g., Montgomery [56]). When we refer to variables data we usually mean continuous

Table 1 Number of published papers

Category	# of papers
RA CCs for variables	5
RA CCs for attributes	7
Time-weighted RA CCs	35
Multivariate RA CCs	1
Applications of RA CCs	23
Total	71

measurements, while when we refer to attributes data we usually mean discrete data. Control charts for variables and attributes plot single data points over time while time-weighted CCs use previous values.

The paper is organized as follows: Sect. 2 describes the literature search strategy. Section 3 deals with risk-adjusted control charts for continuous variables, while Sect. 4 deals with risk-adjusted control charts for attributes (i.e., non-continuous variables). Section 5 presents time-weighted risk-adjusted control charts. Sections 3–5 are divided into two subsections: the first one presents the advances on RA CCs while the latter presents a typical example. Section 6 is devoted to applications of risk-adjusted control charts. The last section discusses several open problems on the field of risk-adjusted process monitoring.

2 Search Strategy

In order to identify relevant papers, we searched the Google Scholar database using the term "risk adjusted control charts" or combination of these terms like "risk-adjusted" and "control charts". 173 papers were retrieved. All three authors screened the titles and abstracts of the results in order to assess their relevance. All the 173 papers passed the screening procedure. Then we reviewed the full text of the papers to confirm that all inclusion criteria were met. We also reviewed the references of eligible papers to identify additional relevant articles.

Finally, 71 articles were included in this review paper (Table 1). The majority of them (35 papers) are papers about time-weighted RA control charts, 7 papers regard RA control charts for attributes, and 5 papers regard RA variable control charts. Only 1 paper deals with multivariate RA control charts, while 23 papers present applications of RA control charts.

The inclusion criteria were (i) presentation of RA control charts, (ii) application of RA control charts, and (iii) written in English.

The above categorization indicates the structure of the paper, with the difference that the one and only paper about multivariate RA control charts will be incorporated in the time-weighted RA control charts' section, as it is actually an attempt of generalizing a time-weighted RA control chart.

3 Risk-Adjusted Control Charts for Variables

3.1 Theoretical Aspects

Alemi et al. [4], in the context of health care assessment, presented a methodology for adjusting control charts for mortality rates to reflect patients' severity of illness during different time intervals. They demonstrated that risk-adjusting expected patient outcomes can change the assessments of the relative quality of care offered by a health care organization in different time periods. Denoting by n_i the number of cases for a time period, to risk-adjust control chart data the researcher has to follow four steps:

1. Determine the number of expected deaths after risk adjustment in each time period, $\sum_{j=1}^{n_i} P_{ij}$
2. Calculate the expected mortality rate for each time period, $\hat{P}_i = \frac{\sum_{j=1}^{n_i} P_{ij}}{n_i}$
3. Calculate the standard deviation of the expected mortality rate for each time period, $\hat{S}_i = \frac{\sqrt{\sum_{j=1}^{n_i}(\hat{P}_{ij}(1-\hat{P}_{ij}))}}{n_i}$
4. Calculate the risk-adjusted upper and lower control limits for each time period, as $LCL_i = \hat{P}_i - t_{a/2}\hat{S}_i$ and $UCL_i = \hat{P}_i + t_{a/2}\hat{S}_i$, respectively, where $t_{a/2}$ is the $a/2$ critical value of the t distribution. These are called the expected upper control limit and the expected lower control limit, respectively.

To predict outcomes for each patient, a regression model which includes all the patient data is used. Since the model only uses severity of illness variables to predict the number of patients not discharged alive in each of the time periods, this model in effect produces a risk-adjusted estimate of the number of deaths that should have occurred in each time period. Obviously, P_{ij} may be any rate or percentage of interest.

Alemi and Sullivan [3] presented a tutorial on risk-adjusted $\bar{X}$ charts and their applications to measurement of diabetes control. The nine steps for a risk-adjusted $\bar{X}$ chart are presented in Table 2. The assumptions that should be hold are (i) continuous observations, (ii) independent observations, (iii) more than five observations in each time period, (iv) normal distributions, and (v) variances of observations over time are equal. The average of observations for time period i, A_i is calculated as

$$A_i = \sum_{j=1}^{n_i} \frac{A_{ij}}{n_i},$$

where A_{ij} and n_i are the j-th observation and the number of observations in the i-th time period. Then, a scatter plot of averages against time periods can be constructed. The expected (predicted) values E_{ij} are then calculated through a regression model. The average of expected values for time period i, E_i, is calculated as

$$E_i = \sum_{j=1}^{n_i} \frac{E_{ij}}{n_i}.$$

Table 2 The nine steps for a risk-adjusted $\bar{X}$ chart

Step	Description
1	check assumptions
2	determine the average of all observations in each time period
3	create a plot of the averages over time
4	calculate and plot expected values using a severity adjustment tool
5	calculate the expected average for each time period
6	calculate the standard deviation of the difference between observed and expected values for each time period
7	calculate and plot the control limits
8	interpret the findings
9	distribute the chart and the findings

Then, the standard deviation of the differences, $D_{ij} = A_{ij} - E_{ij}$, is calculated as

$$S_i = \sqrt{\sum_{j=1}^{n_i} \frac{(D_{ij} - D_i)^2}{n_i - 1}},$$

where D_i is the average of the differences for the i-th time period. Then the control limits are set at two or three standard deviations away from the expected values (depending on the degree of precision the researcher wants to achieve—the higher the cost of making an erroneous conclusion, the tighter the limits should be), i.e.,

$$LCL_i = E_i - t_{a/2} \times S_i \text{ and } UCL_i = E_i + t_{a/2} \times S_i.$$

The interpretation of the chart is as usual.

Hart et al. [37] discussed the use of 3-sigma $\bar{X}$ and S control charts for continuous data that are often skewed. The key feature of these charts is their application of risk-adjusted data in addition to actual performance data. The resulting charts should decrease the occurrence of both type I and type II errors as compared to the unadjusted control charts.

Zhang et al. [92] developed a phase I risk-adjusted Shewhart control chart for monitoring surgical performances. The risk-adjusted statistic used is shown to be a likelihood-ratio test statistic. The procedure consists of 3 steps. At the first step, a logistic regression model

$$\log\left(\frac{z}{1-z}\right) = a + bx$$

is fitted using historical data of the form $(x_t, y_t), t = 1, 2, \ldots, N$ from N patients operated by m surgeons to estimate the true probability of death z of a patient who undergoes a cardiac operation. The x_t is the Parsonnet score, i.e., a score based on a patient's characteristics [63] and y_t is the operation outcome of patient t (1 if the patient dies within 30 days or 0 if the patient survives). The surgical outcome is determined by two main factors: the surgeon who performs the operation and the condition of the patient which is summarized by the Parsonnet score. This probability of death is based on the average performance of the m surgeons. At Step 2,

$$\hat{Z} = \frac{e^{\hat{a}+\hat{b}X}}{1 + e^{\hat{a}+\hat{b}X}}$$

is used to calculate the predicted probabilities of death $\hat{z}_t, t = 1, 2, \ldots, N$ and the risk-adjusted outcomes $w_t = y_t - \hat{z}_t, t = 1, 2, \ldots, N$. At the third step, a lower-sided Shewhart chart using the negative w_t's and an upper-sided Shewhart chart using positive w_t's is set up to identify points that are beyond the chart limits. Any of these points will be removed if an assignable cause can be found. The chart limits are then recalculated using the reduced dataset to identify points that are beyond the chart limits. This process is repeated until no more points can be removed.

The lower control limit can then be set at

$$LCL \approx \alpha_{\mathrm{L}}\text{-th sample quantile of } \{w_t | w_t \leq 0, \text{ for } t = 1, 2, \ldots, N\},$$

while the upper control limit can then be set at

$$UCL \approx (1 - \alpha_{\mathrm{U}})\text{-th sample quantile of } \{w_t | w_t > 0, \text{ for } t = 1, 2, \ldots, N\},$$

where $\alpha_{\mathrm{L}} = \max\left\{0.00135, \frac{k_{\mathrm{L}}}{\#\text{ of } w_t<0}\right\}$ and $\alpha_{\mathrm{U}} = \max\left\{0.00135, \frac{k_{\mathrm{U}}}{\#\text{ of } w_t>0}\right\}$. The value 0.00135 comes from the traditional 3-sigma Shewhart control charts. Using the maximum of the two numbers is to ensure that the checking rate is not less than 0.135%. Both control limits can be obtained by using the bootstrap method.

Asadayyoobi and Niaki [6] proposed a general Phase I accelerated failure time (AFT)-based RA control chart for monitoring continuous surgical outcomes based on a likelihood-ratio test derived from a change-point model. Assuming that T_i is the random variable denoting the failure time of the i-th subject, and $x_{i1}, \ldots, x_{ip}$ are the values of covariates for the same subject, the AFT model is

$$\log T_i = \beta_0 + \beta_1 x_{i1} + \beta_2 x_{i2} + \cdots + \beta_p x_{ip} + \sigma \epsilon_i,$$

where ϵ_i is the random disturbance term. Define $\psi^{(sl)}$ as the parameter vector of the risk-adjustment model for observations $s + 1$ to l. Suppose an assignable cause occurs at an unknown time τ, which leads to the change of the parameter vector from the in-control vector $\boldsymbol{\psi}^{(0l)} = \boldsymbol{\beta}_0^{\mathrm{T}} = (\gamma_{01}^{\mathrm{T}}, \gamma_{02}^{\mathrm{T}}, \ldots, \gamma_{0K}^{\mathrm{T}}, \beta_0^{\mathrm{T}})^{\mathrm{T}}$ to the out-of-control vector $\boldsymbol{\psi}^{(\tau l)} = \boldsymbol{\beta}_1^{\mathrm{T}} = (\gamma_{11}^{\mathrm{T}}, \gamma_{12}^{\mathrm{T}}, \ldots, \gamma_{1K}^{\mathrm{T}}, \beta_1^{\mathrm{T}})^{\mathrm{T}}$. If all the data follow an identical distribution, i.e., $\psi^{(0l)} = \psi^{(\tau m)}$ for all $\tau = u, u + 1, \ldots, m - u$, then the process is in-control,

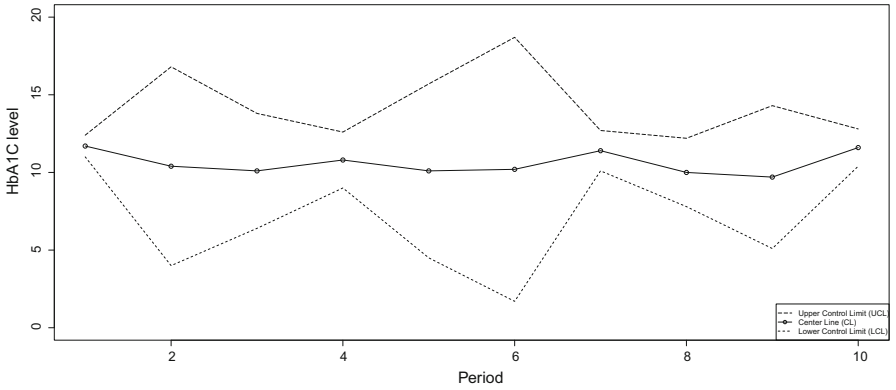

Fig. 2 The RA CC for monitoring the HbA1C level

where u ($u >$ the number of coefficients) is the minimum required sample size to estimate the parameters of the RA model. The value of u is chosen so that at least one outcome with value 0 and one outcome with value 1 exist among the sampled data from 1 to u and also from $m-u+1$ to m. Then, the aim is to evaluate the hypotheses

$$H_0 : \boldsymbol{\psi}^{(0\tau)} = \boldsymbol{\psi}^{(\tau m)} - H_1 : \boldsymbol{\psi}^{(0\tau)} \neq \boldsymbol{\psi}^{(\tau m)}, \tau = u, u+1, \ldots, m-u.$$

$\boldsymbol{\psi}^{(0\tau)}$ or $\boldsymbol{\beta}_0^{\mathrm{T}}$ is the parameter vector of the RA model for observations 1 to τ (before the change) and $\boldsymbol{\psi}^{(\tau m)}$ or $\boldsymbol{\beta}_1^{\mathrm{T}}$ corresponds to the parameter vector after the change. This monitoring procedure is more sensitive in detecting increases in mortality rate than a procedure that only uses binary outcomes.

3.2 Example

In this subsection, we present the application of a RA $\bar{x}$ control chart for monitoring HemoglobinA1C (HbA1C) level of Type 2 diabetic patients [68]. The HbA1C level were collected from 8 patients for 10 times. To construct the CC, we need the number of cases in each time period, the actual HbA1C level for individual cases, the average HbA1C level for specific time periods, and the expected HbA1C level for individual cases. Following the procedure of Alemi and Sullivan [3], we take the CC of Fig. 2, from which we conclude that after patient-mix adjustment the process is characterized as in-control.

4 Risk-Adjusted Control Charts for Attributes

4.1 Theoretical Aspects

Alemi and Oliver [2] presented a step by step tutorial on the construction of a RA p-chart, in which both the observed and the expected rates are plotted. They demonstrated

the use of the RA version of the chart to data regarding falls in nursing homes. To calculate the expected rate of falls, the formula

$$E_i = \frac{1}{N}\sum_{i=1}^{N_i} E_{ij},$$

where E_{ij} is the expected fall rate of case j in time period i, is used. The expected fall rate can be calculated using the expected probability of falls for each patient.

Hart et al. [36] presented a new class of control charts for monitoring and improving health care performance. These charts combine observed rates with the rates obtained from a risk adjustment process using multivariate logistic regression models. These control charts are either additive or multiplicative models depending on how the observed and risk-adjusted data are combined. Through the comparison of each patient's demographic and clinical history with a large reference population, the risk-adjustment process estimates the a priori probability of occurrence of some event for each patient. Month i will have n_i of these estimates, with their sum being the expected number of occurrences for the month E_i. Because of the averaging methods of risk adjustment, the month-to-month variation of the monthly E_i values tends to be much lower than that of the observed O_i values; the expected monthly counts are not binomially distributed. To avoid any possible confusion between the distributional properties of the observed monthly mortality count and the monthly expected mortality count, the monthly expected mortality rate (not proportion) is referred as $E_i/n_i = r_{E_i}$ (where r_{E_i} is the expected rate). Additive models work with the difference $r_{D_i} = p_{O_i} - r_{E_i}$. Because the difference in rates alone can be misleading because its significance should be assessed in relation to the size of expected rate, a multiplicative model should be considered. The multiplicative method the authors considered was based on the indirect standardization approach. A_i is the "adjusted observed occurrence count" indirectly standardized to the overall expected rate, r_E. The A_i values are the counts that would have occurred if the same standard risks were observed each month and are assumed to be binomially distributed. The risk-adjusted mortality proportion each month is therefore

$$p_{A_i} = \frac{O_i\left(\frac{r_{\bar{E}}}{r_{E_i}}\right)}{n_i}.$$

Because the variation in r_{E_i} is small, as noted previously, the quotients $\frac{r_{\bar{E}}}{r_{E_i}}$ will be close to unity and the variations of the p_{A_i} values will be close to those of p_{O_i}. The authors then compared six control charts—a p chart on observed proportions, a run chart on expected rates, a p chart on risk-adjusted proportions with no standard given (the centerline is calculated from the data), a p chart on risk-adjusted proportions with standard given (the centerline is calculated from the "standard" value), a special "rate difference" chart on risk-adjusted differences with no standard given, and a special "rate difference" chart on risk-adjusted rate differences with standard given. A p chart is a chart that monitors the process fraction non-conforming p, while a run chart plots

Table 3 The steps for a risk-adjusted negative binomial charts

Step	Description
1	Before the monitoring phase starts, take the following preliminary steps
1a	Select a desired $ARL^* = 1/\alpha$ and a degree of change θ during out of control that should be optimally protected against
1b	Apply the rule of thumb $\tilde{r}^{\text{opt}} = [\alpha(2.6\theta + 2) + 0.01(4\theta - 3)]^{-1}$ to obtain r (typically truncate at 5 in practice)
1c	Find λ such that $P(Z_\lambda) \geq r\alpha$, where Z_λ is Poisson, or simply use its approximation $\tilde{\lambda} = \alpha_r(1 + \zeta_r)$ with $\zeta_r = \frac{\alpha_r}{r+1} + 0.5\alpha_r^2 \frac{3r+5}{(r+1)^2(r+2)}$
1d	Wait till m failures have occurred
1e	From this Phase I sample, evaluate the fraction of failures p_j for each of the categories $j = 1, \ldots, k$
2	Now wait till Y_1, the moment at which the r-th failure occurs
3	Obtain the corresponding numbers g_j from category j (i.e., $\sum_{j=1}^{k} g_j = Y_1$)
4	Give a signal if $\sum_{j=1}^{k} g_j \hat{p}_j \leq \lambda$; otherwise go back to Step 2, leading to $Y_2, Y_3, \ldots$
	$*$ ARL = Average Run Length, i.e., the expected number of subgroups until a control chart first signals

the data values versus time [56]. They concluded that only the p chart on risk-adjusted proportions with no standard given can be used to assess whether the risk-adjusted mortality rate is stable over time, while the p chart on risk-adjusted proportions with no standard given can be used to assess whether the risk-adjusted results fail to meet expectations.

Albers [1], in the context of health care monitoring, presented the way that information about category membership can be used to adjust the basic negative binomial charts to the actual risk incurred. The steps to apply the RA control chart are presented in Table 3.

Zeng and Zhou [91] proposed a Bayesian approach for risk-adjusted monitoring of health care outcomes in the case where historical data are not available. The detection of change was formulated as a model-selection problem and solved using a popular Bayesian tool for variable selection, the Bayes factor. The steps to apply the Bayesian approach are presented in Table 4. With this procedure, the changes in a care provider's performance is detected promptly as the information on the performance is updated as each patient outcome becomes available.

Paynabar et al. [65] presented a general Phase I risk-adjusted control chart for monitoring binary surgical outcomes based on a likelihood-ratio test derived from a change-point model. Different from the existing methods, this paper further shows that the binary surgical outcomes depend on not only the patient conditions described by the Parsonnet scores but also on other categorical operational covariates, such

Table 4 The steps for the Bayesian approach of Zeng and Zhou [91]

Step	Description
Step 1	Specify priors for the change point K and the parameter of the logistic regression model $\boldsymbol{\beta}$
	The prior of K follows a discrete uniform$(1, 2, \ldots, m-1, m)$ distribution
	When prior information, related historical data or domain expert knowledge, is available, a conditional means prior of $\boldsymbol{\beta}$ will be specified following the CMP procedure proposed by Bedrick et al. [25]. When there is no prior information, a truncated flat prior will be specified by common sense
Step 2	Conduct change detection: as each new data point (x_m, y_m), $m \geq 2$, is obtained, BF_m is calculated through the procedure presented in Section 3.3 and compared with a preset threshold η. If $BF_m > \eta$, M_1 will be selected, indicating that a change, either a performance improvement or deterioration, has occurred, and then the change point will be estimated. Otherwise, M_0 will be selected, meaning that there has been no change till now

as different surgeons. The inclusion of the categorical surgeon covariate in the risk-adjustment model effectively models the heterogeneity of the surgical outcome data and the risk-adjusted chart provides better detection power.

Mohammadian et al. [55] proposed a RA geometric control chart for monitoring the number of patients survived at least 30 days after a surgery. In this chart, the patient's risk is modeled using a logistic regression. The new scheme is proposed to be used in Phase I where a likelihood-ratio test derived from a change-point model is employed. Compared to the chart with a binary random variable, the RA geometric control chart is more effective as far as power is concerned.

Recently, Bersimis et al. [16] presented a new method for the monitoring doctors' performance and the assessment of their competence using more than one performance outcome variable. Although their method does not take patients' heterogeneity into account, they outlined its risk-adjusted version, fitting a logistic regression model in the Phase I analysis.

4.2 Example

In this subsection, we present the application of a RA control chart for monitoring falls in nursing homes. Following the steps of Alemi and Oliver [2] (i.e., calculation of observed rates, of expected rates, of expected deviation, and of control limits), we take the CC of Fig. 3, from which we conclude that after taking into account the fall risk factors (e.g., ability to ambulate, presence of chronic medical conditions, number of medications, mental status, history of falls), the process is characterized as in-control as none of the expected fall rates are outside the control limits.

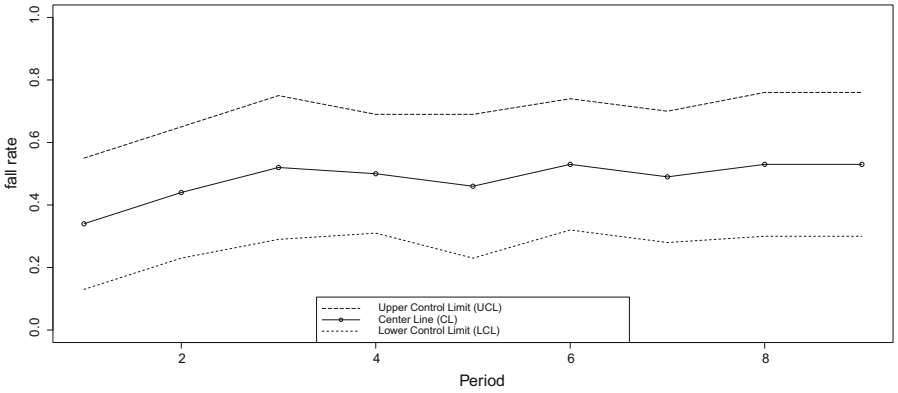

Fig. 3 The RA CC for monitoring the fall rate

5 Time-Weighted Risk-Adjusted Control Charts

5.1 Theoretical Aspects

Time-weighted control charts use information from both current and past observations. The main time-weighted control charts are the cumulative sum (CUSUM) control chart and the Exponentially Weighted Moving Average (EWMA) control chart.

Lovegrove et al. [50] modified the CUSUM chart to weight death and survival by each patient's risk status and to provide a display of surgical performance over time. This chart was called variable life-adjusted (VLAD) chart and shows the difference between expected and actual cumulative mortality. This chart is just a descriptive technique and can be applied to any area of clinical practice. Lovegrove et al. [51] described an alternative approach which takes account of an individual cardiac surgeon's case mix by explicitly incorporating the inherent risk faced by patients due to a combination of factors relating to their age and the degree of disease they have.

Poloniecki et al. [66] proposed cumulative plots for the expected mortality counts minus the observed counts ($E-O$ chart, i.e., a VLAD-type chart) that could be applied, for example, to physicians or hospitals, while Steiner et al. [79] described a new CUSUM procedure that adjusts for each patient's pre-operative risk of surgical failure through the use of likelihood-based scoring method. The authors proposed two possible log-likelihood-ratio scores, i.e.,

$$W_t = \begin{cases} \log\left[\frac{(1-p_t+R_0 p_t)R_\mathrm{A}}{(1-p_t+R_\mathrm{A} p_t)R_0}\right], & \text{if } y_t = 1 \\ \log\left[\frac{1-p_t+R_0 p_t}{1-p_t+R_\mathrm{A} p_t}\right], & \text{if } y_t = 0, \end{cases}$$

where p_t is the estimated risk, R_0 and R_A are the odds ratios under the null and the alternative hypotheses, respectively.

Grigg et al. [33] discussed the use of charts derived from the sequential probability ratio test (SPRT): the CUSUM chart, RSPRT (resetting SPRT), and FIR

(fast initial response) CUSUM. They described the theoretical development of the methods and explored some considerations including the approximation of average run lengths (ARLs), the importance of detecting improvements in a process, as well as detecting deterioration and estimation of the process parameter following a signal.

Sismanidis et al. [73] explored the properties of the cumulative RA mortality (CRAM) chart, including the number of deaths before a doubling of the death rate is detected. Grigg and Farewell [32] proposed the RA version of the Sets method [18] for monitoring adverse medical outcomes and presented the graphical representation of it, called the Grass plot. For the risk-adjusted Sets method, the authors imposed three restrictions: (i) the weights added to the size of a set at each observation need to be equivalent for successes and failures, (ii) the weight for average risk patients equals to one, and (iii) a weight is added on each observation such that, if subsequent observations were all of the same risk type, it fixes the expectation of the in-control size of set to be equal to that if all subsequent observations were of average risk type and weight one was added at each stage.

Sherlaw-Johnson [71] proposed to apply the control limits from CUSUM charts onto the VLAD, enhancing in this way the role of VLAD as an effective monitoring tool.

Biswas and Kalbfleisch [17] outlined a RA-CUSUM procedure based on the Cox model for a failure time outcome. This work seems to be the first to use survival analysis models for monitoring [27]. The Cox regression model based on the measured covariates Z_i is

$$\alpha(x_i) = \lambda_0 \exp\{Z_i^{\mathrm{T}}\beta\},$$

where $\alpha(x_i)$ is a national average failure rate for an individual with covariate Z_i. The authors presented both the continuous and the discrete version of the method.

Sego et al. [70] proposed a RA survival time CUSUM chart, called RAST CUSUM for monitoring a continuous, time-to-event variable that may be right censored. Risk adjustment is accomplished using accelerated failure time regression models to account for the heterogeneity among patients. The predicted density and survival functions from the accelerated failure time model are then used to construct a likelihood ratio for the scores in the chart. This chart detects more efficient a sudden increase in the odds of mortality than the Steiner et al. [79]'s chart.

Gandy et al. [27] investigated how time-to-event models may be used for monitoring purposes. They considered monitoring using CUSUMs based on the partial likelihood ratio between an out-of-control state and an in-control state. They also considered both proportional and non-proportional alternatives, as well as a head start. Against proportional alternatives, they presented an analytic method of computing the expected number of observed events before stopping or the probability of stopping before a given observed number of events.

Steiner and Jones [78] proposed an updating EWMA (uEWMA) control chart to monitor risk-adjusted survival times. The uEWMA is defined as

$$E_t = \gamma s_{it} + \gamma(1-\gamma)s_{i-1,t} + \gamma(1-\gamma)^2 s_{i-2,t} + \gamma(1-\gamma)^3 s_{i-3,t} + \ldots$$

where s_{it} is the score for patient i (i denotes the order of surgery) at time t. At time t, for patient i, the available information are $(x_{it}, \delta_{it}, \boldsymbol{u}_i)$, where x_{it} is the minimum of the current time since time zero, the time to death and the follow-up time (or time at occurrence of a competing risk) each minus the time of surgery, δ_{it} is an index function (it equals to 1 if patient i dies by time t and to 0 otherwise), and $\boldsymbol{u}_i$ is a vector of covariates. The values of the covariates are determined only at the time of surgery (they are not updated as time goes on). If t is the current time, a_i is the time of surgery, c_i is the time of a competing risk (or follow-up time), and d_i is the time of a death, then $x_{it} = min\{t, c_i, d_i)\} - a_i$. For patient i there are three possibilities for (x_{it}, δ_{it}). These are (i) *death*, i.e., $(x_{it}, 1)$, where $x_{it} = d_i - a_i$ is the time between surgery and death, (ii) *success*, i.e., $(x_{it}, 0)$, where $x_{it} = c_i - a_i$ is the time between surgery and the follow-up time (or some competing risk), and *at risk*, i.e., $(x_{it}, 0)$, where $x_{it} = t - a_i$ is the time between surgery and the current time. The patient scores, s_{it}, are based on $(x_{it}, \delta_{it}, u_i)$; hence, as x_{it} and possibly δ_{it} change for case (iii) as time passes, so will (some of) the scores. A patient in case (iii) can become case (i) or (ii) or remain in case (iii) with a larger x_{it}. Note that once a patient is in case (i) or (ii) x_{it} and δ_{it} (and thus the patient score) stay the same. The patient scores also depend on the selected survival time distribution.

Gombay et al. [29] proposed four sequential curtailed and risk-adjusted charts by using score statistics. They performed Monte Carlo simulations to explore the merits of each of these methods in terms of ARLs as well as in terms of type I probabilities. They also compared the proposed methods to the RA-CUSUM chart. They illustrated the methodologies by using data on monitoring performance of seven surgeons from a cardiac surgery center in the UK. The proposed charts have different early stopping (signaling a change) and error probability characteristics.

Assareh et al. [9] modeled change-point detection for a clinical process with dichotomous outcomes (i.e., death and survival) through Bayesian hierarchical models. Then, they investigated the performance of the new estimators in conjunction with the risk-adjusted CUSUM and EWMA control charts monitoring mortality rates. This is also the topic of a chapter written by the same authors [10].

Assareh et al. [8] considered estimation of the time when a linear trend disturbance has occurred in an in-control clinical dichotomous process in the presence of variable patient mix. To model the process and change point, they formulated a linear trend in the odds ratio of a Bernoulli process using hierarchical models in a Bayesian framework. The performance of the Bayesian estimator is investigated through simulations and the result shows that precise estimates can be obtained when they are used in conjunction with the risk-adjusted CUSUM and EWMA control charts for different magnitude and direction of change scenarios.

Jones and Steiner [42] studied the effect of estimation error on risk-adjusted binary CUSUM performance using actual and simulated data on patients undergoing coronary artery bypass surgery and assessed for mortality up to 30 days post-surgery. The effect of estimation error was indicated by the variability of the "true" average run lengths (ARLs) obtained using repeated sampling of the observed data under various realistic scenarios.

Assareh and Mengersen [7] presented change-point Bayesian estimation methods for the case of survival times. They first applied hierarchical models to formulate

the change point and then captured the effect of risk factors prior to the surgery using a Weibull accelerated failure time regression model and used Markov Chain Monte Carlo to obtain posterior distributions of the change point parameters including location and magnitude of changes and also corresponding probabilistic intervals and inferences. The result shows that precise estimates can be obtained when they are used in conjunction with the risk-adjusted survival time CUSUM control charts for different magnitude scenarios.

Assareh et al. [11] developed change-point estimation methods through Bayesian hierarchical models for a clinical dichotomous process in the presence of case mix. The performance of the Bayesian estimator was investigated through simulations and the result showed that precise estimates can be obtained when they are used in conjunction with the risk-adjusted CUSUM and EWMA control charts.

Richards et al. [67] proposed Poisson regression instead of the logistic regression model used with Bernoulli data for the risk-adjusted monitoring of non-homogeneous Poisson processes.

Tang et al. [81] developed the risk-adjusted CUSUM chart based on more than two outcomes (e.g., death, return to operating room, postoperative stroke, mediastinitis, postoperative atrial fibrillation, and full recovery) with the aim to better monitor surgical performance. The chart is obtained by plotting

$$C_n = \max(0, C_{n-1} + W_n),$$

where

$$W_n = \log \frac{f_A(S_n, Y_n)}{f_0(S_n, Y_n)}.$$

The statistic W_n is risk-adjusted by taking S_n, i.e., the patient's risk score (a real number measuring the mortality risk of a patient undergoing a cardiac surgery), into account. f_0 and f_A are the joint density of (S, Y) under the null and the alternative hypothesis, respectively. Y represents the outcome of a cardiac surgery, usually assessed after 30 days. To estimate the probabilities of surgical outcomes, they used a proportional odds logistic regression model.

Aminnayeri and Sogandi [5] proposed a self-starting scheme based on a parametric bootstrap method and dynamic probability control limits for the RA Bernoulli CUSUM control charts. This method is appropriate whenever the nominal value of the process parameter is unknown. Furthermore, it remedies the case where a fixed control limit for the RA Bernoulli chart gives rise to a variable in-control average run length performance for patient populations with dissimilar risk score distributions in monitoring clinical and surgical performance.

Ghasemi et al. [28] applied a Bayesian estimation method to find the time and the size of a change in patients' post-surgery death or survival outcome. It should be noted that the Bayesian estimator is better than the maximum likelihood estimator when the magnitude of the change is small. The process is monitored in Phase I using risk-adjusted log-likelihood-ratio test chart, in which the logistic regression model is applied to take into account pre-operation individual risks. Markov Chain Monte

Carlo method was applied to obtain the posterior distribution of the change-point model including time and size of the change in the Bayesian framework and also to obtain the corresponding credible intervals.

Zhang et al. [95] investigated the effect of estimation error on the performance of risk-adjusted survival time CUSUM scheme in continuous time with the cardiac surgery data. The impact was studied with the use of the median run lengths (medRLs) and the standard deviation of medRLs for different sample sizes, specified in-control median run length, adverse event rate, and patient variability. To account for patient heterogeneity, they used an accelerated failure time (AFT) regression model to estimate the survival time distribution for each patient. The statistic of the risk-adjusted survival time CUSUM chart is

$$S(t) = R(t) - \min_{s \le t} R(S),$$

where $R(t)$ is log-likelihood-ratio test statistic for in-control versus out-of-control. Simulation results showed that the performance of the risk-adjusted survival time CUSUM chart is greatly influenced and this should be taken into account by practitioners when they design the control chart.

Oliveira et al. [62] extended the risk-adjusted survival time cumulative sum (RAST CUSUM) control chart to monitor a time-to-event outcome, possibly right censored, by considering a regression model in which the covariates affect the cure fraction. The CUSUM scores are obtained for Weibull and log-logistic promotion time model to monitor a scale parameter for non-immune individuals. This chart is known as the RACUF CUSUM (risk-adjusted with cure fraction CUSUM). The RACUF CUSUM is better than the RAST CUSUM when monitoring data with cure rate, while it is equivalent to monitoring data without a cure rate.

Keefe et al. [43] proposed a spatially RA Bernoulli CUSUM chart for concurrent observations to monitor foreclosure rates. This is a modification of the RA Bernoulli CUSUM chart developed by Steiner et al. [79], in the sense that

$$\begin{aligned} W_t &= \log\left[\frac{\prod_{i=1}^{n_t} p_{1ti}^{y_{ti}}(1-p_{1ti})^{1-y_{ti}}}{\prod_{i=1}^{n_t} p_{0ti}^{y_{ti}}(1-p_{0ti})^{1-y_{ti}}}\right] \\ &= \sum_{i=1}^{n_t}\left[y_{ti}\log\left(\frac{p_{1ti}}{p_{0ti}}\right) + (1-y_{ti})\log\left(\frac{1-p_{1ti}}{1-p_{0ti}}\right)\right], \end{aligned}$$

where n_t is the number of observations at time t, y_{ti} equals 1 for an event and 0 otherwise for the i-th observation at time t ($i = 1, 2, \ldots, n_t$), and p_{0ti} and p_{1ti} are the predicted probabilities under R_0 and R_1 for the i-th observation at time t, respectively, using

$$p_{0ti} = \frac{R_0 p_{ti}}{1 - p_{ti} R_0 p_{ti}} \quad \text{and} \quad p_{1ti} = \frac{R_1 p_{ti}}{1 - p_{ti} R_1 p_{ti}}.$$

The spatially method detects out-of-control behavior of a process earlier than the RA Bernoulli CUSUM.

Sparks [76] developed an adaptive EWMA control chart that can be used as either a p chart for monitoring significant departures from in-control non-homogenous probabilities of failure or success or a risk-adjusted control chart for success or failure of an event. The adaptive EWMA p chart uses the Adaptive Upper EWMA (AUE) and Adaptive Lower EWMA (ALE) statistics

$$AUE_t = \max\left(\frac{p_t}{hu(\alpha, p_t, ATS_0)}, \frac{\alpha y_t}{hu(\alpha, p_t, ATS_0)} + (1-\alpha)AUE_{t-1}\right),$$

and

$$ALE_t = \min\left(\frac{p_t}{hl(\alpha, p_t, ATS_0)}, \frac{\alpha y_t}{hl(\alpha, p_t, ATS_0)} + (1-\alpha)ALE_{t-1}\right),$$

where p_t is the non-homogeneous in-control p value, while $hu(\alpha, p_t, ATS_0)$ and $hl(\alpha, p_t, ATS_0)$ are positive values that are selected to give an in-control average time to a false signal (ATS) of ATS_0, for flagging shifts on the high and low side, respectively. The two-sided adaptive EWMA p control chart flags a change in likelihood when either $AUE_t > 1$ or $ALE_t < 1$, where these threshold values are modified using simulations but are close to 1. If the future shift is known approximately, then we can select the exponential weights to detect this shift sooner than other EWMA plans.

Zhang and Woodall [93] examined the effect of estimation error on the in-control performance of the risk-adjusted Bernoulli CUSUM chart with dynamic probability control limits (DPCLs) while the same authors applied the DPCLs developed for the upper risk-adjusted Bernoulli CUSUM charts to the lower and two-sided charts and examine their in-control performance [94]. The in-control performance of the lower risk-adjusted Bernoulli CUSUM charts with DPCLs can be controlled for different patient populations, because DPCLs are determined for each specific sequence of patients. Moreover, upper and lower risk-adjusted Bernoulli CUSUM charts with DPCLs can be run side by side simultaneously to obtain desired in-control performance for the two-sided chart for any particular sequence of patients.

Because there is a significant effect of varying risk distributions on the in-control performance of the RA-CUSUM chart based on multiresponses when constant control limits are applied, Zhang et al. [96] applied dynamic probability control limits to it. The RA-CUSUM chart for multiresponses with dynamic probability control limits is more practical and should be applied to effectively monitor surgical performance by healthcare practitioners.

Yue et al. [89] proposed a new risk-adjusted exponentially weighted moving average VLAD, called RAEV. The RAEV chart is designed to detect shifts in the odds ratios of patients' surgical risk, and the quantity plotted is

$$Z_n = \lambda(Y_n - p_n) + (1-\lambda)Z_{n-1}, \quad 0 < \lambda \leq 1,$$

where Y_n is the outcome of the n-th patient (this equals to 1 if the patient dies and to 0 otherwise), p_n is the corresponding risk of the n-th patient, and λ is a smoothing

parameter. The Shewhart control chart is a special case of RAEV chart for $\lambda = 1$. When λ is almost equal to 1, the weight of historical data is small, while the weight is large for other values of λ. The upper control limit is defined to allow the detection of deteriorating performance. Similarly, the lower control limit is defined to allow the detection of improving performance. Summarizing, the RAEV chart does not need an alternative hypothesis, and moreover it has better performance when small shifts and small smoothing parameter values are used.

Hussein et al. [40] explored the performance of risk-adjusted CUSUM charts when the assumptions of independence and model correctness are not met. They found out that if autocorrelations are present in the binary series being monitored and such autocorrelations are ignored, the average run lengths of the charts can deviate greatly from their design values. However, the impact of model misspecification on the run lengths is not severe.

Khosravi et al. [44], extending the work of Paynabar et al. [65], presented a general Phase I risk-adjusted control chart for monitoring more than two ordinal surgical outcomes. The adjustment is done through the proportional odds logistic regression models, which is a generalization of the logistic model that accommodates an ordered categorical response. Instead of modeling the probability of a response to be in a particular category, the proportional odds logistic regression model is based on the cumulative probability that the response does not exceed a selected category. Simulation results showed that this chart has high detection probability.

Liu et al. [49] proposed an EWMA control chart for monitoring simultaneously both the location and scale parameters in a surgical outcome model. The test statistic, which is a weighted score function, is derived from the likelihood function and the EWMA procedure for detecting the heterogeneity of data within the same sample. This chart is more efficient than the risk-adjusted CUSUM chart, in detecting the heterogeneity of surgical outcomes.

Tighkhorshid et al. [84] proposed a self-starting RA AFT-based control chart for monitoring the survival time of patients. More specifically, the authors monitor patients' survival times through an EWMA control chart, which is based on the residual values of the AFT regression model. On the control chart, the value

$$Z_i = \min\{\lambda \times ZN_i + (1 - \lambda) \times Z_{i-1}, 0\},$$

is depicted. ZN_i is the inverse normal distribution value of the cumulative probability distribution of the standardized residual value for patient i, while λ is the smoothing parameter. Simulation results revealed that if we consider the therapist groups and simultaneously increase the number of in-control observations, the ability of the control chart to detect shifts in the process increases.

Recently, Grigg [30] proposed a Bayesian RA control chart for monitoring survival outcomes—the STRAND Chart (Survival Time, Risk-Adjusted, N-Division Chart). The STRAND Chart is divided into N strands, each strand relating to a benchmark patient's survival information at t_i days following treatment, $i = 1, 2, \ldots, N$. The chart gives a signal when the credible interval about any strand excludes a target value, for example, the estimated failure rate from the pilot data.

Finally, Knoth et al. [46] showed that a misspecified model can affect directly the in-control false alarm rate and indirectly the out-of-control ARL performances. The effect is more severe when the patient mix includes more high-risk patients. To identify a better model for the estimation of the probability of death of a patient from an operation, the authors proposed the Box-Cox transformation.

At this point we would like to present an attempt of generalization of the Steiner et al. [79]'s method for monitoring multi-attribute processes. More specifically, Shojaei and Niaki [72] extended the RA-CUSUM scheme to monitor multi-attribute medical processes for entities having different levels of risk, using a vector of weights for each patient ($\boldsymbol{w}_t$) instead of one weight. The elements of $\boldsymbol{w}_t$ are

$$w_{t,i} = \begin{cases} \log\left[K\frac{(1-p_{t,i}+p_{t,i}R_{0i})}{(1-p_{t,i}+p_{t,i}R_{\mathrm{A}i})}\right], & y_t = 0 \\ \log\left[K\frac{(1-p_{t,i}+p_{t,i}R_{0i})R_{\mathrm{A}i}}{(1-p_{t,i}+p_{t,i}R_{\mathrm{A}i})R_{0i}}\right], & y_t = 1 \end{cases}$$

for $i = 1, 2, \ldots, n$ and $t = 1, 2, \ldots, k$. In the new chart, called *RA-MCUSUM*, the quantity

$$\boldsymbol{y}_t = \left\{\boldsymbol{s}_t' \boldsymbol{\Sigma}^{-1} \boldsymbol{s}_t\right\}^{1/2},$$

is depicted, where

$$\boldsymbol{s}_t = \boldsymbol{s}_{t-1} + \boldsymbol{w}_t$$

and $\boldsymbol{\Sigma}$ is the covariance matrix of the random vector $\boldsymbol{w}_t$. The initial vector $\boldsymbol{s}_0$ is a vector with all elements equal to 0. If $\boldsymbol{y}_t$ is greater than a threshold h, then the medical process is declared to be out of control. The authors used simulation to estimate $\boldsymbol{\Sigma}$ and h. The constant parameter K appearing in $w_{t,i}$ is needed to prevent from negative weights. This is the first attempt to present a multivariate RA control chart.

5.2 Example

In this subsection, we present the application of a VLAD control chart for monitoring a cardiac surgeon's performance. This example has been described by Steiner et al. [79]. To construct the chart we estimated the risk model coefficients, for each pair of Parsonnet score and operation outcome, and then we computed the difference between expected and observed outcomes. The risk model was estimated using the first two years (Phase I), while the next five years (Phase II) was used for monitoring the surgeon's performance. The resulting VLAD is presented in Fig. 4. It is evident that although the surgeon's performance was rising, at the beginning, from a point on (after about 250 patients) it began to deteriorate. This means for that for some reason (or reasons) the surgeon's performance has been getting worse. It reached a lower level, and then, after corrective actions, it began to rise again.

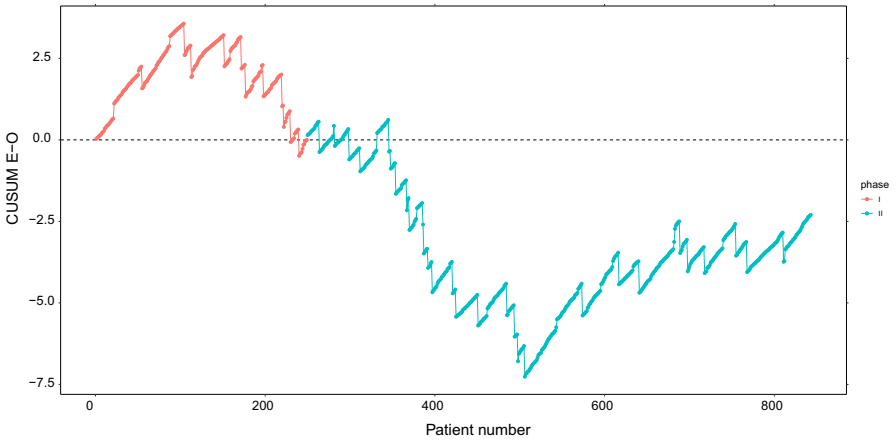

Fig. 4 The RA CC for monitoring a surgeon's performance

6 Applications of Risk-Adjusted Control Charts

Several authors have applied RA control charts to monitor health processes especially after 2000. Table 5 presents the applications of RA control charts presented in the literature.

Gustafson [35] compared the performance of 5 unadjusted and 11 risk-adjusted control charts for infection control. The control charts were applied to data between 1996 and 1998 from 51 hospitals. The analysis flagged 128 suspicious points, and participating infection control professionals investigated and categorized each flag as a "real problem" or "background variation". This gold standard was used to compare the performance of the control charts.

The first attempt for continuous monitoring of local changes in risk-adjusted mortality performance in intensive care units was made by Cook et al. [22]. The authors applied an RA p chart and a two-sided RA-CUSUM chart to monitor intensive care unit outcomes. They concluded that RA outcome monitoring can be used as a method of quality management.

Spiegelhalter et al. [77] investigated the use of the RA sequential probability ratio test in monitoring the cumulative occurrence of adverse outcomes after cardiac surgery. Their retrospective analysis of three longitudinal datasets showed that the RA sequential probability ratio test can be applied in various contexts and is useful for detection of specific instances of past divergent performance.

Cockings et al. [21] discussed process monitoring in intensive care with the use of cumulative expected minus observed mortality ($E - O$) and RA p charts. The use of these charts allows the rapid detection of changes in RA outcome of intensive care patients.

Hart et al. [38] used Shewhart $\bar{X}$ and s charts with RA variables data to compare length-of-stay data from several healthcare organizations. The comparisons were made both before and after risk adjustment, in order to assess the impact of risk adjustment.

Table 5 Applications of RA control charts

Method	Reference	Application
RA p chart, RA-CUSUM	Cook et al. [22]	Monitoring intensive care unit outcomes
RA sequential probability ratio test	Spiegelhalter et al. [77]	Monitoring adverse outcomes
$E - O$ chart, RA p chart	Cockings et al. [21]	Monitoring intensive care unit outcomes
Shewhart $\bar{X}$ and s charts	Hart et al. [38]	Comparison of several healthcare organizations
RA-CUSUM	Novick et al. [61]	Analysis of surgery outcomes
RA p chart	Marshall and Mohammed [52]	Monitoring mortality rates
RA sequential probability ratio test	Matheny et al. [54]	Monitoring mortality rates
RA sequential control charts	Baghurst et al. [12]	Monitoring pediatric intensive care performance
CUSUM, CRAM, VLAD and cumulative excess mortality charts	Coory et al. [24]	Monitoring the quality of hospital care
RA model	Sousa et al. [75]	Monitoring adverse cardiac and cerebrovascular events
RA-CUSUM	Chen et al. [19]	Monitoring out-of-hospital cardiac arrest patient mortality
RA control charts	Morris et al. [58]	Monitoring postoperative mortality
RA XmR chart	Fry et al. [26]	Measuring the quality in surgical care
RA-CUSUM	Chiu et al. [20]	Monitoring the medical information in shoulder surgery study
RA-EWMA	Moran et al. [57]	Monitoring mortality
Simple control charts	Norton et al. [60]	Monitoring risk-adjusted quality indicators
Shewhart-type control charts	Maruthappu et al. [53]	Monitoring surgical procedures
RA-CUSUM	Kim et al. [45]	Analysis of the learning curve for single-incision laparoscopic anterior resection for sigmoid colon cancer
RA $\bar{X}$ control chart	Sasikumar and Devi [68]	Monitoring HemoglobinA1C level of Type 2 diabetic patients
VLAD control chart	Patella et al. [64]	Prediction of morbidity
RA-CUSUM	Tomassini et al. [85]	Evaluation of single-surgeon learning curve
RA-CUSUM	Schrem et al. [69]	Monitoring clinical practice

Novick et al. [61] compared RA and non-RA-CUSUM charts by analyzing coronary artery bypass surgery outcomes. They concluded that RA-CUSUM provides incremental advantages over non-RA methods by not signaling a decrement in performance when pre-operative patient risk is high.

Marshall and Mohammed [52] investigated agreement between the identification of special cause variation in risk-adjusted and observed hospital-specific mortality rates after coronary artery bypass grafting in New York hospitals. The p-chart was used to identify special cause variation.

Matheny et al. [54] evaluated RA sequential probability ratio test control charts for the detection of significant discrepancies between institution or individual interventional cardiologist postprocedural mortality rates and national or local event rate expectations. Eight thousand nine hundred forty-two percutaneous coronary interventional procedures were performed by 27 operators between 2002 and 2006. This method was able to determine that the institution was not performing outside risk-adjusted expectations.

Baghurst et al. [12] applied RA sequential control charts (the VLAD chart, the CRAM chart, and the RA-CUSUM) using the Paediatric Index of Mortality version 2 for monitoring pediatric intensive care performance in Australia and New Zealand. They concluded that major advantage of such control charts is that they allow unit performance to be monitored continuously over time, rather than intermittently, with the aim of rapidly detecting a change in performance as soon as possible after it occurs.

Coory et al. [24] used several RA and expected-minus-observed plots (CUSUM, CRAM, VLAD, and cumulative excess mortality charts) to monitor quality of hospital care with administrative data. Such control charts allow early detection of runs of good or bad outcomes that can help hospitals identify areas for more in-depth self-monitoring and learning.

Sousa et al. [75] developed a RA model for major adverse cardiac and cerebrovascular events following percutaneous coronary intervention, using data from the Portuguese National Registry of Interventional Cardiology, and highlighted its use for the evaluation of the quality of care in interventional cardiology. This model allows the identification and evaluation of patient risk factors that are associated with poor outcomes or adverse events.

Chen et al. [19] presented the application of RA-CUSUM-type charts for monitoring out-of-hospital cardiac arrest (OHCA) patient mortality. First, they used a logistic regression analysis to create a RA model. Then, a RA-CUSUM chart, a RA resetting sequential probability ratio test chart, and a CRAM with prediction limits chart were used to detect excess deaths of the OHCA patients rescued by the emergency medical service system.

The retrospective cross-sectional population-based study of data extracted from the National Cancer Data Repository of Morris et al. [58] used RA control charts to assess the variation in RA 30-day postoperative mortality for patients with colorectal cancer between hospital trusts within the English NHS. The use of RA control charts revealed that one trust had consistently significantly better outcomes and three had significantly worse outcomes than the population mean.

As a method to measure quality in surgical care, Fry et al. [26] proposed the use of control charts. More specifically, they created an average moving range (XmR) control chart for risk-adjusted postoperative length of stay (RApoLOS) for patients discharged alive after elective colectomy. At the same year, Lawson et al. [48] investigated whether p-charts using surgical site infection (SSI) rates predict changes in outlier status for risk-adjusted SSI rates.

Chiu et al. [20] applied a RA-CUSUM control chart to monitor the medical information in shoulder surgery study. The risk adjustment was done through the logistic and the Cox models. A simulation analysis showed that the Cox model can quickly find the patient's abnormal conditions.

Moran et al. [57] used the RA-EWMA control chart to study mortality using the Australian and New Zealand Intensive Care Society adult patient database. Risk adjustment was undertaken through a random coefficient logistic regression model, which generated the expected mortality series.

Norton et al. [60] used simple control charts to plot risk-adjusted quality indicators, i.e., the prevalence of residents with a stage 2–4 pressure ulcer, the prevalence of residents with pain, and the prevalence of residents receiving an antipsychotic with no diagnosis of psychosis. The control charts were used as a method to improve quality performance management in nursing homes.

Maruthappu et al. [53] extended the risk-adjusted approach in the sense that they proposed that control charts for monitoring surgical procedures should not only be adjusted for patient risk but also for surgeon experience. The comparison of patient-risk-adjusted and fully adjusted (i.e., both patient risk and surgeon experience) control charts showed that adjustment for surgeon's experience, along with patient risk, is a method of accurate monitoring individual operative efficiency.

Kim et al. [45] applied moving average, CUSUM and RA-CUSUM methods to analyze the learning curve (i.e., the process where surgeons develop their skills) for single-incision laparoscopic anterior resection (SILAR) for sigmoid colon cancer. For risk-adjusted CUSUM, surgical failure was defined as conversion to open surgery or conventional laparoscopic surgery, morbidity within 30 days after surgery, < 12 harvested lymph nodes, or local recurrence. The logistic regression model was used to calculate the RA-CUSUM.

Sasikumar and Devi [68] applied the RA $\bar{x}$ control chart for monitoring HemoglobinA1C (HbA1C) level of Type 2 diabetic patients and compared its performance with that of the unadjusted $\bar{x}$ control chart. They concluded that their method is suitable for contexts where there is a variable mix of patients over time.

Patella et al. [64] implemented real-time internal monitoring using a risk-adjusted model specific for video-assisted thoracoscopic surgery (VATS) lobectomy. To develop the risk-adjusted model to predict morbidity, they exploited logistic regression and bootstrap resampling analyses. Then, the VLAD control chart was used.

Tomassini et al. [85] evaluated the single-surgeon learning curve (i.e., improvement in surgical performance over time) in laparoscopic liver surgery over an 11-year period through RA-CUSUM.

Finally, Schrem et al. [69] investigated the use of retrospective two one-sided CUSUM charts in combination with multivariable regression analysis in liver transplantation for transplant center benchmarking. They concluded that the use of these charts would allow targeted improvements of transplant program management as timely as possible.

7 Discussion and Directions for Further Research

The utility of RA control charts in medicine is highlighted in the statement of Groves et al. [34] that as SPC methods continue to evolve, use of key techniques such as RA control charts should be integrated into the healthcare professionals' education. Benneyan and Borgman [13] noted that incorporating RA methods into control charts can contribute to the better monitoring and assessment of health processes. The RA charts achieve higher sensitivity and specificity in comparison with typical control charts [36]. However, attention should be paid to the model used as the simple binary logistic regression model or similar models are not valid [46].

In this paper, we systematically reviewed the advances regarding the RA control charts presented in the literature. To this end, we followed a three groups categorization: control charts for continuous variables, control charts for attributes (i.e., non-continuous variables), and time-weighted control charts. A section was devoted to present applications of RA control charts in medical processes. Most of the papers refer to Phase II analysis (i.e., online monitoring of a process), while only the papers of Albers [1], Paynabar et al. [65], Zhang et al. [92], Asadayyoobi and Niaki [6], Mohammadian et al. [55], Ghasemi et al. [28], and Khosravi et al. [44] make clear reference to Phase I analysis (i.e., assessment of process stability).

The main application field of RA control charts is monitoring the quality of surgical processes and hospital care. Monitoring mortality and intensive care outcomes and performance, analysis of surgeons' learning curve, infection control, comparison length-of-stay, monitoring doctors' experience, and monitoring biochemical indexes are other popular applications.

RA control charts is a fertile ground for research. For example, although several authors have dealt with multivariate CUSUM charts and multivariate EWMA charts, little or no work has been done to multivariate RA time-weighted risk-adjusted control charts. Thus, a topic for further research would be the multivariate extensions of the time-weighted risk-adjusted charts. The central idea is to monitor simultaneously more than one survival times. For example, one may be interested in monitoring both the time of wound healing and the time the patient feels pain after a serious open heart surgery.

Until to now, RA control charts have been used to monitor the quality performance of medical processes, taking into account only the heterogeneity (i.e., the different characteristics) of patients. However, other factors such as the heterogeneity of physicians (e.g., age, experience, studies), and/or health organizations (e.g size, location), may affect the outcome, and thus should been taken into account.

Risk adjustment is not only restricted to control charts. It can be used in any case where the probability of having a disease is a function of numerous risk factors (e.g., demographic, social). For example, Taseli and Benneyan [82] presented the risk-adjusted version of partial scan statistics in order to catch the situation that subjects inside the region under study have different probability of having, for example, a disease.

In conclusion, risk adjustment is a flexible, interesting, and useful tool for monitoring and, in general, studying medical processes.

Appendix

Table 6 lists all the acronyms appearing in the manuscript.

Table 6 Definition of acronyms appearing on the text

Acronym	# Definition
SPC	Statistical process control
RA	Risk-adjustment or risk-adjusted
CC	Control chart
LCL	Lower control limit
UCL	Upper control limit
AFT	Accelerated failure time
ARL	Average run length
CUSUM	Cumulative sum
EWMA	Exponentially weighted moving average
VLAD	Variable life adjusted
SPRT	Sequential probability ratio test
RSPRT	Resetting SPRT
FIR	Fast initial response
CRAM	Cumulative risk-adjusted mortality
RAST CUSUM	Risk-adjusted survival time cumulative sum
uEWMA	Updating exponentially weighted moving average
RACUF	Risk-adjusted with cure fraction
ATS	Average time to a false signal
DPCL	Dynamic probability control limits
AUE	Adaptive upper EWMA
ALE	Adaptive upper EWMA
RAEV	Risk-adjusted exponentially weighted moving average variable life adjusted
MCUSUM	Multivariate cumulative sum
OHCA	Out-of-hospital cardiac arrest
SILAR	Single-incision laparoscopic anterior
HbA1c	HemoglobinA1c
VATS	Video-assisted thoracoscopic surgery

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