

## **Bayesian Estimation of Change Point in Phase One Risk Adjusted Control Charts**

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### **Abstract**

Use of risk adjusted control charts for monitoring patients' surgical outcomes is now common. These charts are developed based on considering the patient's pre-operation risks. Change point detection is a crucial problem in statistical process control (SPC). It helps the managers to analyze root causes of out-of-control conditions more effectively. Since the control chart signals do not necessarily indicate the real change point of the process, in this research a Bayesian estimation method is applied to find the time and the size of a change in patients' post-surgery death or survival outcome. The process is monitored in phase I using Risk Adjusted Log-likelihood Ratio Test (RALRT) chart, in which the logistic regression model is applied to take into account pre-operation individual risks. Markov Chain Monte Carlo method is 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. Performance evaluations of the Bayesian estimator in comparison with the maximum likelihood estimator (MLE) are conducted by means of different simulation studies. When the magnitude of the change is small, simulation results indicate superiority of the Bayesian estimator over MLE, especially when a more accurate estimation of the change point is of interest.

**Keywords:** Risk Adjusted Control Charts, Change Point, Bayesian Estimation, Markov Chain Monte Carlo (MCMC).

### **1- Introduction**

Risk adjusted control charts which are designed to identify unusual patterns in patients' after surgery outcomes are used in many clinics and hospitals worldwide. The most frequently-used variables for monitoring purposes are patients' post-surgery binary and survival time outcomes. Since the patients have different pre-operation conditions in terms of age, gender, hyper tension, etc., which are usually called potential risk factors, there is a need to evaluate individuals' risks and adjust patients' outcomes, accordingly.

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Otherwise, the results of monitoring might be misleading. For monitoring patients' Bernoulli process of death or survival, or their survival time after surgery, patients' risk-adjusted outcomes are plotted on an appropriate Risk Adjusted Control Chart (RACC). When the chart signals, it is most likely due to a significant change in the performance of surgical team. There are many articles in this area, investigating both phases I and II of process control. Most of them have focused on phase II. Unkel et al. (2001) reviewed the statistical methods used for identifying infectious diseases outbreak. Tsui et al. (2010) mentioned Risk Adjusted CUSUM and Risk Adjusted EWMA charts as proper methods for patients' health surveillance. Cock et al. (2008) reviewed applications of different risk adjusted control charts in monitoring mortality data in clinics. Woodall (2006) provided interesting studies on the use of control charts in public health applications. As one of the most frequently-used control charts, Risk Adjusted CUSUM chart is proposed for monitoring patients' Bernoulli and survival time data by Collins et al. (2010), Jones and Steiner (2011), Sego et al. (2009), Sibanda and Sibanda (2007), and Steiner et al. (2000). Steiner and Jones (2009) proposed an updating EWMA chart for monitoring patients' survival time data in which the chart is updated according to time index instead of sample index. Gombay et al. (2011) proposed four truncated and risk adjusted sequential tests for monitoring medical performances. Matheny et al. (2011), Matheny et al. (2007) and Spiegelhalter et al. (2003) used Risk Adjusted Sequential Probability Ratio Test (RASPR) chart for performance analysis in the hospitals and clinics. Alemi and Sullivan (2001) presented a tutorial on risk adjusted  $\bar{X}$  chart and studied its applications in evaluation of diabetes control.

As control charts have a delay on identifying the process changes, the change point analysis is used to find the real time and magnitude of the change. Amiri and Allahyari (2012) have provided a recent review on the estimation methods and their properties for change point identification after an out-of-control signal appears on the monitoring control chart. Woodall and Montgomery (2014) have also recently discussed the capabilities of generalized likelihood ratio (GLR) approach as a generalization of the conventional CUSUM chart for change point detection and diagnosis.

In spite of widespread use of change point analysis in industrial process monitoring, it is rather a new area of research in healthcare quality surveillance. According to Woodall and Montgomery (2014) the application of monitoring in healthcare can be grouped in several categories including aggregation of data, healthcare monitoring, public-health surveillance, and syndromic surveillance. They remark that most focus in health-related issues however, is on the category of monitoring in healthcare. Paynabar et al. (2012) used risk adjusted Log-likelihood Ratio Test (RALRT) chart for monitoring patients' outcomes in phase I and provided MLE estimator of the change point. In addition to patients' individual risk factors, they included categorical operational covariates such as surgeon groups in their risk adjustment model. Assareh and Mengersen (2012), (2011a,b) and Assareh et al. (2011a,b,c) dealt with finding Bayesian estimators of the time and the magnitude of the process change in Risk Adjusted CUSUM and EWMA charts in phase II. Despite use of the Bayesian estimation approach in phase II of healthcare process monitoring, there is no use of this approach in phase I. Detecting the change point in phase I however, is quite helpful as it helps one to detect where the process has changed, find the sequence of in-control data and estimate the in-control process parameters. The flexibility and capability of the Bayesian estimation method is beneficial in constructing a more realistic model in phase I. Therefore in this study we use the Bayesian estimation method for change point detection in phase I patients' post-surgery Bernoulli outcomes. To be able to compare the performance of the Bayesian estimators with other estimators, the MLE estimators are also obtained in this study, for the data in phase I. Considering Woodall and Montgomery (2014), this study is beneath the category of healthcare monitoring.

In section 2 preliminaries including the risk adjustment and the process change point models are expressed. In section 3 the process monitoring in phase I is considered. The ML estimations of the time and the size of change are proposed in section 4. In section 5 a Bayesian approach along with the MCMC computational algorithm is proposed to obtain the Bayesian estimators of the time and the size of the change. In section 6 a phase I surgical outcome dataset is used to examine the control chart's capability and to obtain a baseline risk adjustment model. The efficiency of the Bayesian estimators are compared with

the ML estimators of the time and the size on different data sets. Finally, in section 7 concluding remarks and potential areas for future researches are proposed.

## 2- Preliminaries of the problem

### 2-1- Risk adjustment for binary outcomes

Consider Bernoulli process of patients' survival or death, which is measured with outcome  $y_i, i = 1, 2, \dots, m$ , where  $y_i = 1$  indicates that  $i$  th patient dies and  $y_i = 0$  indicates she/he survives, beyond a 30 days period after surgery. The  $m$  denotes sample size. The  $i$  th patient's mortality rate,  $p_i$ , is a function of patient's risks factors as follow:

$$p_i = f(\beta, u_i), \quad (1)$$

Where  $u_i = (x_{i1}, \dots, x_{ir})$ , is a vector of patients' risk factors,  $\beta = (\beta_0, \beta_1, \dots, \beta_r)$  denotes the coefficient vector and  $f$  denotes an appropriate link function. Also  $r$  denotes the number of risk factors. As the outcome is a binary variable the *logit* function can be used as a reasonable risk adjustment model as follow:

$$\text{logit}(p_i) = \beta \begin{pmatrix} 1 \\ u_i^T \end{pmatrix} = \beta_0 + \sum_{j=1}^r \beta_j x_{ij}, \quad (2)$$

Where  $\text{logit}(p_i) = \log(p_i / (1 - p_i))$ . Hence:

$$p_i = \frac{\exp\left(\beta_0 + \sum_{j=1}^r \beta_j x_{ij}\right)}{\left(1 + \exp\left(\beta_0 + \sum_{j=1}^r \beta_j x_{ij}\right)\right)}. \quad (3)$$

Let  $x_i$  denotes the Parsonnet score which is a composite risk factor. Parsonnet score was also mentioned in the previous related works such as Sego et al.(2007) and Assarehet al.(2011b). The larger the Parsonnet score  $x_i$ , the higher is the death risk of the  $i$  th patient. By considering this composite risk factor  $x_i$ , the risk factors and coefficient vectors are summarized as  $u_i = (1, x_i)$  and  $\beta = (\beta_0, \beta_1)$ . So  $p_i$  may be obtained as follows:

$$p_i = \frac{\exp(\beta_0 + \beta_1 x_i)}{1 + \exp(\beta_0 + \beta_1 x_i)} \quad (4)$$

To obtain the coefficients  $\beta_0$  and  $\beta_1$ , the method of maximum likelihood estimation of logistic regression model proposed by Myers et al. (2002) is applied with the data in section 6.

### 2-2- The process change point model

To monitor the Bernoulli process of patients' after surgery death or survival, when the patients possess different pre-operation risks, it is allowed for the in-control process rate to change among patients. Then the observations are checked against the expected rate of death obtained by the risk adjustment model. According to Assarehet al.(2012), "in this setting, a Bernoulli process is in the in-control state when

observations can be statistically expressed by the underlying risk models, taking into account their individual covariates". For modeling a change in the process, consider  $y_i, i = 1, 2, \dots, m$  as independent phase I Bernoulli-distributed observations. These observations come from patients' process of death or survival in an interval of 30 days after surgery. The process is initially in-control and each observation  $y_i$  follows a Bernoulli distribution with the failure rate  $p_{0i}$ . At an unknown time  $\tau$ , an assignable cause results in a change in the patients' failure rate from the in-control  $p_{0i}$  to an out-of-control rate,  $p_{1i}$ , so that

$$\text{logit}(p_{1i}) = \text{logit}(p_{0i}) + \delta, \quad i \geq \tau. \quad (5)$$

Where  $\delta > 0$  represents an increase in patients' mortality rate. Therefore,

$$p_{1i} = \frac{\exp(\delta)p_{0i} / (1 - p_{0i})}{1 + \exp(\delta)p_{0i} / (1 - p_{0i})}. \quad (6)$$

The change point model is proposed as:

$$y_i \infty \begin{cases} \text{Bernoulli}(p_{0i}) & i = 1, 2, \dots, \tau - 1 \\ \text{Bernoulli}(p_{1i}) & i = \tau, \dots, m. \end{cases} \quad (7)$$

### 3- Phase I process monitoring

By considering equation (7), the phase I control chart is equivalent to testing the following hypothesis:

$$\begin{cases} H_0 : p_{1i} = p_{0i} & i = 1, 2, \dots, m \\ H_1 : p_{1i} \neq p_{0i} & i = \tau, \tau + 1, \dots, m. \end{cases} \quad (8)$$

To monitor the process in phase I, RALRT chart which is constructed based on the observations' likelihood function and the change point model is applied. By considering hypothesis (8), under  $H_0$ , according to Paynabar et al. (2012) the corresponding log-likelihood function is written as

$$\begin{aligned} L_0 &= \log \left( \prod_{i=1}^m P(y_i | p_{0i}) \right) = \sum_{i=1}^m \left\{ y_i \log(p_{0i}) + (1 - y_i) \log(1 - p_{0i}) \right\} \\ &= \sum_{i=1}^m \left\{ y_i \text{logit}(p_{0i}) + \log(1 - p_{0i}) \right\}. \end{aligned} \quad (9)$$

Under alternative hypothesis the log-likelihood function is written as

$$\begin{aligned} L_1(\tau) &= \log \left( \prod_{i=1}^{\tau-1} P(y_i | p_{0i}) \right) + \log \left( \prod_{i=\tau}^m P(y_i | p_{1i}) \right) \\ &= \sum_{i=1}^{\tau-1} \left\{ y_i \text{logit}(p_{0i}) + \log(1 - p_{0i}) \right\} + \sum_{i=\tau}^m \left\{ y_i \text{logit}(p_{1i}) + \log(1 - p_{1i}) \right\}, \\ &\quad \tau = l, l + 1, \dots, m - l. \end{aligned} \quad (10)$$

In equations (9) and (10) the process failure rates,  $p_{0i}$ , and  $p_{1i}$  are unknown and need to be estimated. For estimating the failure rates under  $H_0$ ,  $p_{0i}$ , ( $i = 1, 2, \dots, m$ ), all patients' risk data are considered as a homogeneous dataset. Hence, the MLE method proposed by Myers et al.(2002) may be used to estimate the coefficient vector of the risk adjustment model. The  $\hat{\beta}_{(1,m)}^T = (\hat{\beta}_{0,(1,m)}, \hat{\beta}_{1,(1,m)})$  denotes the ML estimator of the risk adjustment model parameters. The ML estimator of the failure rates  $p_{0i}$  for  $i = 1, 2, \dots, m$  under  $H_0$  are denoted by  $\hat{p}_{0i(1,m)}$ , which can be obtained by substituting  $\hat{\beta}_{(1,m)}^T$  in equation (4). Under  $H_1$  the observations are divided at a potential change point. When a change occurs at the unknown time  $\tau$ , the data before and after the change point are not homogeneous. In this situation the risk adjustment model coefficients are estimated separately before and after the process change. Consider  $\hat{\beta}_{(1,\tau-1)}^T = (\hat{\beta}_{0,(1,\tau-1)}, \hat{\beta}_{1,(1,\tau-1)})$  and  $\hat{\beta}_{(\tau,m)}^T = (\hat{\beta}_{0,(\tau,m)}, \hat{\beta}_{1,(\tau,m)})$  as the ML estimators of the risk adjustment model parameters corresponding to observations 1 to  $\tau-1$  and  $\tau$  to  $m$ , respectively, under  $H_1$ . The coefficients can be obtained using the iterative method proposed by Myers et al.(2002). Hence, the ML estimators of  $p_{0i}$  for  $i = 1, 2, \dots, \tau-1$  and  $p_{1i}$  for  $i = \tau, \tau+1, \dots, m$  under the  $H_1$ , are  $\hat{p}'_{0i(1,\tau-1)}$  and  $\hat{p}_{1i(\tau,m)}$  respectively. These estimators are obtained by substituting  $\hat{\beta}_{(1,\tau-1)}^T$  and  $\hat{\beta}_{(\tau,m)}^T$  in equation (4). As Hogg and Craig(2004) proposed, in the LRT method, the chart's statistic is the ratio of the data likelihood function under hypotheses  $H_1$  and  $H_0$ . Since in this paper the data log-likelihood function is used, the ratio of the likelihood functions is changed to their logarithm subtraction. Therefore, considering the log-likelihood functions in equations (9) and (10), RALRT chart's statistic could be obtained as the following equation:

$$\Lambda(\tau) = L_1(\tau) - L_0, \quad \tau = l, l+1, \dots, m-l. \quad (11)$$

It is assumed that  $\tau = l, l+1, \dots, m-l$ , where  $l$  is the minimum sample size required to estimate the coefficients of the risk adjustment model.

#### 4- ML estimation of the change point parameters

$\Lambda(\tau)$  s are plotted against time index  $\tau$  and as long as  $\Lambda(\tau)$  s are under a pre-specified upper control limit, UCL, the process is considered in control, otherwise it is in out-of-control status. In this situation, the ML estimator of the change point is the time when the likelihood function receives its maximum value. Therefore, according to Paynabar et al.(2012):

$$\hat{\tau}_{mle} = arg \left\{ \max_{\tau=l, l+1, \dots, m-l} (\Lambda(\tau)) \right\}. \quad (12)$$

Substituting the patients' modified mortality rates  $p_{i1}$  for  $i = \tau, \tau+1, \dots, m$  from equation (6) and replacing  $\tau$  by its corresponding value,  $\hat{\tau}_{mle}$ , from equation (12), into equation (10), the log-likelihood function changes to:

$$L_1(\tau, \delta) = \sum_{i=1}^{\hat{\tau}_{mle}-1} \left\{ y_i \logit(p_{0i}) + \log(1-p_{0i}) \right\} + \sum_{i=\hat{\tau}_{mle}}^m \left\{ y_i \left( \delta + \log\left(\frac{p_{0i}}{1-p_{0i}}\right) \right) - \log\left(1 + \frac{\exp(\delta)p_{0i}}{1-p_{0i}}\right) \right\}. \quad (13)$$

The ML estimator of  $\delta$  is the value that maximizes equation (13). The partial derivative of equation (13) with respect to  $\delta$  is

$$\frac{\partial L_1(\tau, \delta)}{\partial \delta} = \sum_{i=\hat{\tau}_{mle}}^m \left\{ y_i - \frac{\exp(\delta)p_{0i}}{1-p_{0i} + \exp(\delta)p_{0i}} \right\}. \quad (14)$$

Since setting this differential equation equal to zero results in no closed form solution for  $\delta$ , the Newton-Raphson's numerical method is applied to solve the equation for  $\delta$ . "This method is based on the derivative of a given equation with respect to its unknown parameters that uses the following linear approximation equation" (Perry et al, 2006):

$$f(x + \Delta x) \approx f(x) + \frac{d}{dx} f(x) \Delta x, \quad (15)$$

where  $\Delta x = x_k - x_{k-1}$ . When  $f(x + \Delta x)$  is set to zero and the equation is rearranged then

$$x_k = x_{k-1} - \frac{f(x_{k-1})}{f'(x_{k-1})}, \quad (16)$$

where  $x_k$  is the value of  $x$  at the  $k$ th iteration of the algorithm. Using an initial value and an termination threshold, this method will converge to the optimum value of  $f(x)$ . Using this method to solve equation (14) for  $\delta$  results in:

$$\delta_k = \delta_{k-1} - \frac{\sum_{i=\hat{\tau}}^m \left\{ y_i - \frac{p_{0i} \exp(\delta_{k-1})}{1-p_{0i} + p_{0i} \exp(\delta_{k-1})} \right\}}{\sum_{i=\hat{\tau}}^m \left\{ -\frac{P_{0i}(1-P_{0i}) + P_{0i}^2 \exp(\delta_{k-1})(1-\exp(\delta_{k-1}))}{(1-P_{0i} + P_{0i} \exp(\delta_{k-1}))^2} \right\}}. \quad (17)$$

The algorithm ends when the  $|\delta_k - \delta_{k-1}|$  is smaller than a pre specified partial positive constant  $\varepsilon$ . In this paper the initial value  $\delta_0$  and the ending measure  $\varepsilon$  are set to 0 and  $10^{-4}$ , respectively. The algorithm converges to  $\hat{\delta}_{mle}$ , the MLE estimator of the shift size after finite iterations.

## 5- Bayesian estimation

### 5-1- Priors

“Statistical inferences for a quantity of interest in a Bayesian framework are described as the modification of the uncertainty about their value in the light of evidence, and Bayes’ theorem precisely specifies how this modification should be made as below” Assareh et al.(2011b):

$$\text{posterior} \propto \text{likelihood} \times \text{prior}. \quad (18)$$

The word “Prior” indicates the knowledge about the quantity of interest in terms of a probability distribution before any observation is made. The word “Likelihood” notifies the underlying likelihood function of the observations, and the word “Posterior” is the state of knowledge about the quantity after the data is observed. This is also a probability distribution.

In this section the Bayesian estimators of change point parameters,  $\tau$  and  $\delta$  are proposed. The first step is to determine the appropriate prior distributions for  $\tau$  and  $\delta$ . Assareh et al.(2011a,b) suggested the use of uniform and truncated normal distributions as the prior distributions for the time and the size of the change point, respectively. However, since  $\delta$  is assumed to be a positive quantity, it is possible to use other positive distributions such as gamma.

Here the uniform distribution  $u(l, m-l)$  is applied as a prior for the change time  $\tau$  because it is assumed that a change can occur at any time in the interval  $(l, m-1)$ . For the change magnitude however, the gamma distributions  $G(a, b)$  is considered. The values of  $a$  and  $b$  are chosen in such a way that reflect the prior knowledge about the change magnitude. Here a realistic and practical assumption is considered. It is assumed that when a change occurs in the process due to surgical team performance, it cannot be a fundamental change that radically increases the mortality rates. The reason for this assumption is that the surgical team is professional however, and has gained some experiences still. Therefore the values for  $a$  and  $b$  are set to 2 and 0.5 that result in a prior density function that is denser in the interval  $[0, 2]$  having a mean equal to 1. Consequently, the probability for a large  $\delta$  is small. The effect of different change sizes in the in-control rate  $p_0$ , according to the equation (6), is displayed on Figure 1.

Considering the priors:

$$\begin{aligned} \pi_1(\tau) &= \frac{1}{(m-l)-(l)} = \frac{1}{m-2l}, \\ \pi_2(\delta) &= \frac{\delta^{a-1} \exp(-\delta/b)}{\Gamma(a)b^a}, \end{aligned} \quad (19)$$

The likelihood function is

$$\begin{aligned} L &= \prod_{i=1}^{\tau-1} P(y_i | p_{0i}) \times \prod_{i=\tau}^m P(y_i | p_{1i}) \\ &= \prod_{i=1}^{\tau-1} p_{0i}^{y_i} (1-p_{0i})^{1-y_i} \prod_{i=\tau}^m p_{1i}^{y_i} (1-p_{1i})^{1-y_i}. \end{aligned} \quad (20)$$

By replacing  $p_{1i}$  for  $i = \tau, \tau+1, \dots, m$  from equation (6) the likelihood function can be represented as:

$$L = \prod_{i=1}^{\tau-1} p_{0i}^{y_i} (1-p_{0i})^{1-y_i} \prod_{i=\tau}^m \frac{[\exp(\delta)p_{0i} / (1-p_{0i})]^{y_i}}{1 + \exp(\delta)p_{0i} / (1-p_{0i})}. \quad (21)$$

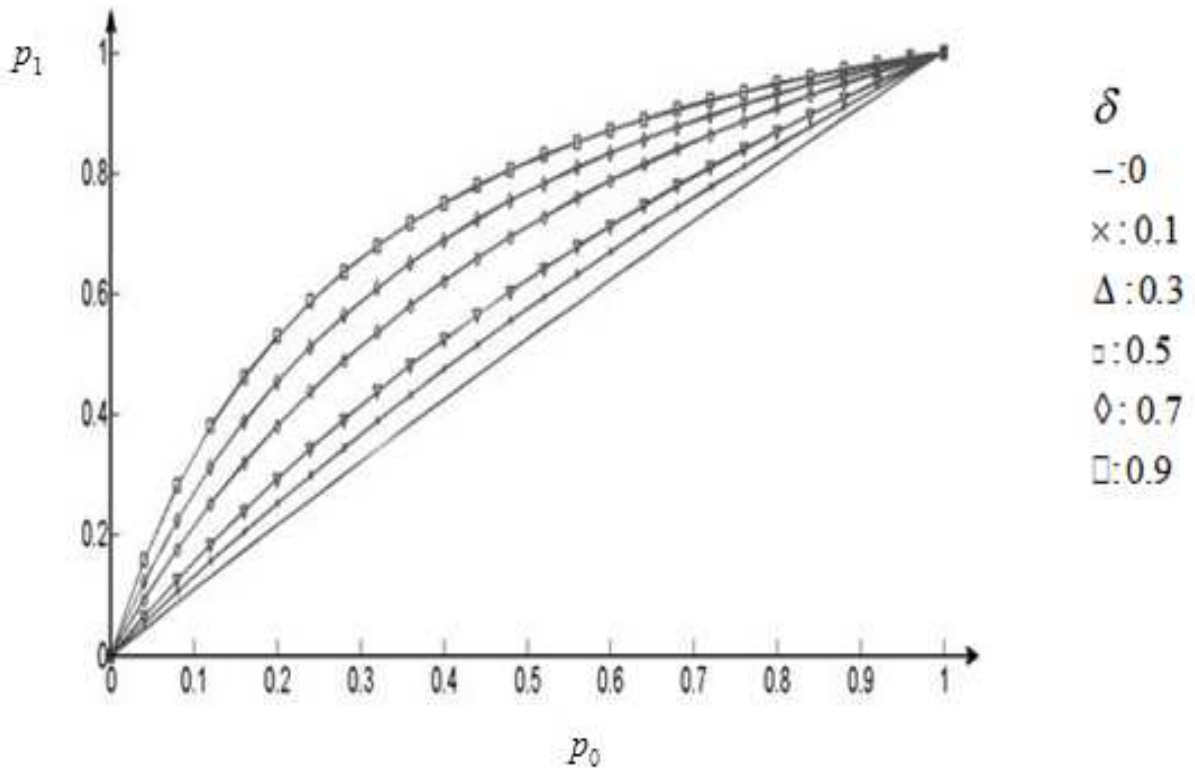
Considering the equation (18), the joint posterior distribution may be expressed as

$$\pi(\tau, \delta | y) \propto L \times \pi_1(\tau) \times \pi_2(\delta). \quad (22)$$

By simplification and omitting the irrelevant parameters the joint posterior distribution would be

$$\pi(\tau, \delta | y) \propto \prod_{i=1}^{\tau-1} (p_{0i}^{y_i} (1-p_{0i})^{1-y_i}) \prod_{i=\tau}^m \left( \frac{[\exp(\delta)p_{0i} / (1-p_{0i})]^{y_i}}{1 + \exp(\delta)p_{0i} / (1-p_{0i})} \right) \delta^{\alpha-1} \exp(-\delta/b). \quad (23)$$

As the joint posterior distribution has no specific form, it is difficult to obtain the posterior distribution for each parameter. Therefore, in the next section the Markov Chain Monte Carlo(MCMC ) simulation method is employed to obtain posterior distribution for the unknown time and the size of the change,  $\tau$  and  $\delta$ .



**Figure 1.** Effect of change magnitude  $\delta$  on an in-control failure rate  $p_0$



## 5-2- Markov Chain Monte Carlo (MCMC) Simulation

MCMC approach includes methods to sample from univariate and multivariate distributions in which the samples constitute a Markov chain. Gibbs sampling and Metropolis-Hasting (M-H) methods are quite popular in the context of MCMC approach. Sometimes it is impossible to directly sample from the conditional posterior distribution of the parameters. In these cases using MCMC methods to obtain the posterior distributions is very helpful. Although the Gibbs sampling is an ineffective technique to generate samples from the conditional distributions of two or more variables, it fails to work with highly complicated multivariable distributions as it requires decomposition of the joint posterior distribution into full conditional distributions. In this paper, the M-H algorithm is applied to obtain the posterior distributions of the change point parameters. The key advantage of M-H algorithm is its efficiency to work with multivariate distributions. For more details on MCMC methods readers are referred to Fienberg et al. (2007) and Colosimo and Castillo (2007).

## 5-3- M-H algorithm for estimating change point parameters

Considering the joint posterior distribution of  $\tau$  and  $\delta$  in equation (23), the conditional distribution for each parameter can be obtained as follows:

$$\pi(\tau | y, \delta) \propto \prod_{i=1}^{\tau-1} \left( p_{0i}^{y_i} (1-p_{0i})^{1-y_i} \right) \prod_{i=\tau}^m \left( \frac{[p_{0i} / (1-p_{0i})]^{y_i}}{1 + \exp(\delta) p_{0i} / (1-p_{0i})} \right) \exp((m-\tau)\delta), \quad (24)$$

$$\pi(\delta | y, \tau) \propto \prod_{i=\tau}^m \left( 1 + \exp(\delta) p_{0i} / (1-p_{0i}) \right)^{-1} \delta^{\alpha-1} \exp((m-\tau-1/b)\delta). \quad (25)$$

Although these conditional distributions have unknown forms, the graphical assessment of them shows that they may be approximated by the Normal and the Weibull distributions, respectively. To execute the M-H algorithm, the first step is to choose a proposal density function for each parameter. Here the normal distribution  $N(\tau^{(k-1)}, \lambda)$  and the Weibull distribution  $Wbl(v_1 \delta^{(k-1)}, v_2)$  are chosen as the proposal distributions of  $\tau$  and  $\delta$ , respectively.  $\tau^{(k-1)}$  and  $\delta^{(k-1)}$  are the values of  $\tau$  and  $\delta$  in  $(k-1)$ st iteration of the algorithm and  $\lambda = 1$ ,  $v_1 = 1.5$ , and  $v_2 = 2.5$  are set to the stated parameters. As the values of the likelihood function and the conditional distributions are too small, their logarithms are used instead of the algorithm. The algorithm for obtaining marginal posterior distributions is as follows:

*Algorithm for obtaining posterior distributions of  $\tau$  and  $\delta$*

1. Start with initial value  $\tau^{(0)}$  and  $\delta^{(0)}$ .
2. Set  $k = 1$ ,
3. Use M-H algorithm, generate  $\tau^{(k)}$  from posterior  $\pi(\tau^{(k-1)} | y, \delta^{(k-1)})$  with proposed normal distribution  $N(\tau^{(k-1)}, \lambda)$ .
4. Use M-H algorithm, generate  $\delta^{(k)}$  from posterior  $\pi(\delta^{(k-1)} | y, \tau^{(k)})$  with proposed Weibull distribution  $Wbl(v_1 \delta^{(k-1)}, v_2)$ .
5. Set  $k = k + 1$ .
6. Repeat steps 3-5,  $N$  times.

The algorithm converges in finite steps. Good starting values will accelerate convergence.  $N$  is set to 10000 and the first 25% of the samples are considered as burn-in values and removed as they come from unstable posterior distributions of  $\tau$  and  $\delta$ . So the last 75% samples are used to obtain the Bayesian

estimators. Having the posterior distributions, the mean and the median of each distribution,  $\bar{\tau}, \tilde{\tau}$  and  $\bar{\delta}, \tilde{\delta}$ , are used as Bayesian estimators for the time and the size of the process change.

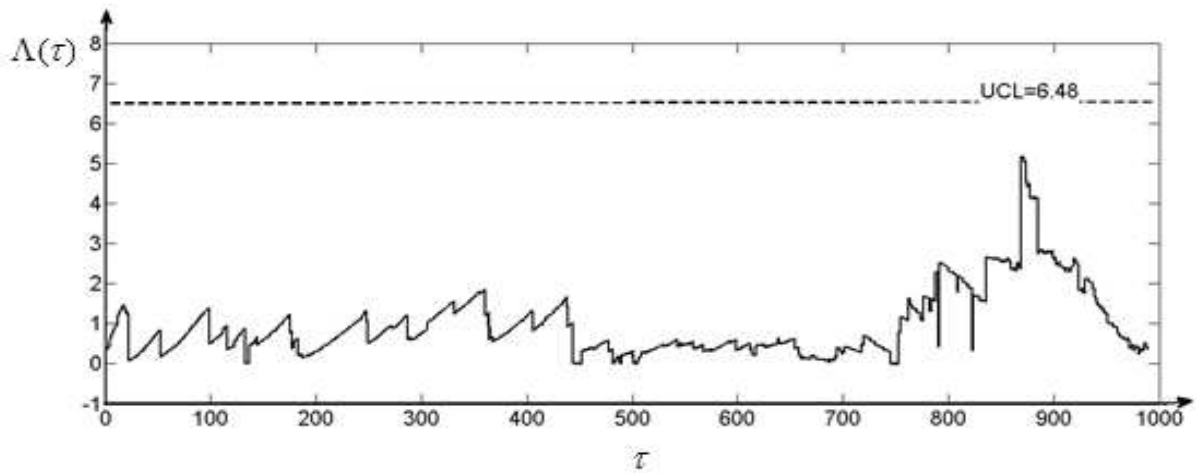
## 6- Discussion

### 6-1- An application in phase I cardiac surgery data

A data set containing the patients' cardiac surgery data which was considered by different authors including Sego et al. (2009) and Paynabar et al. (2012) is examined here. The Patients' potential risk data are represented by their Parsonnet scores. Sego et al. (2009) stated that the Parsonnet scores are closely approximated by an exponential distribution with mean 8.9. Paynabar et al. (2012) considered the first two years data (including data for  $m = 1000$  patients) as the phase I data for estimating the risk adjustment model parameters and obtained  $[\hat{\beta}_0, \hat{\beta}_1] = [-3.373, 0.073]$ . Therefore,

$$\text{logit}(\hat{p}_i) = -3.473 + 0.073x_i \Rightarrow \hat{p}_i = \frac{\exp(-3.473 + 0.073x_i)}{1 + \exp(-3.473 + 0.073x_i)}. \quad (26)$$

In this study the data for phase I are generated by means of simulation using the risk adjustment model in equation (26). The upper control limit of the RALRT chart of Paynabar et al. (2012) is also applied here. They obtained the simulated UCL's for different sample sizes ( $m$ ), different numbers of the risk adjustment model coefficients ( $\beta$ ) and two different values of the type I error probability,  $\alpha$ , as 0.05 and 0.01. The number of patients and the number of the risk adjustment model coefficients in this simulation study are  $m = 1000$  and 2, respectively. For  $\alpha = 0.01$ , the UCL is considered to be 6.48. The value for  $l$ , the minimum sample size, is set to 5 in the numerical examples. Also on the basis of some trial and error, the values of  $a$  and  $b$ , the parameters for the prior distribution of  $\delta$  are set to 2 and 0.5, respectively. The Parsonnet scores  $x_i$ , for  $i = 1, 2, \dots, 1000$ , are generated from an exponential distribution with mean equal to 8.9 as the patients' risk scores. Substituting for  $x_i$ ,  $i = 1, 2, \dots, 1000$  in equation (26), the mortality probabilities,  $p_i$ ,  $i = 1, 2, \dots, m$  are obtained for the  $m = 1000$  patients. Then, Bernoulli outcomes  $y_i$ ,  $i = 1, 2, \dots, m$  are independently generated from the Bernoulli distributions with the failure rates,  $p_i$ , for  $i = 1, 2, \dots, 1000$  as the patients' after surgery death or survival outcome. Finally, these data are considered as the phase I dataset and the RALRT control chart is used to evaluate them. The chart is displayed in Figure 2. Investigation of Figure 2 reveals that all the values are under the UCL. So the process is in its control state. Therefore, the risk adjustment model in equation (26) may be applied as a base risk-adjustment model to monitor observations during phase II.



**Figure2.** The RALRT chart for the phase one data

## 6-2- Performance Evaluation of Bayesian Estimators

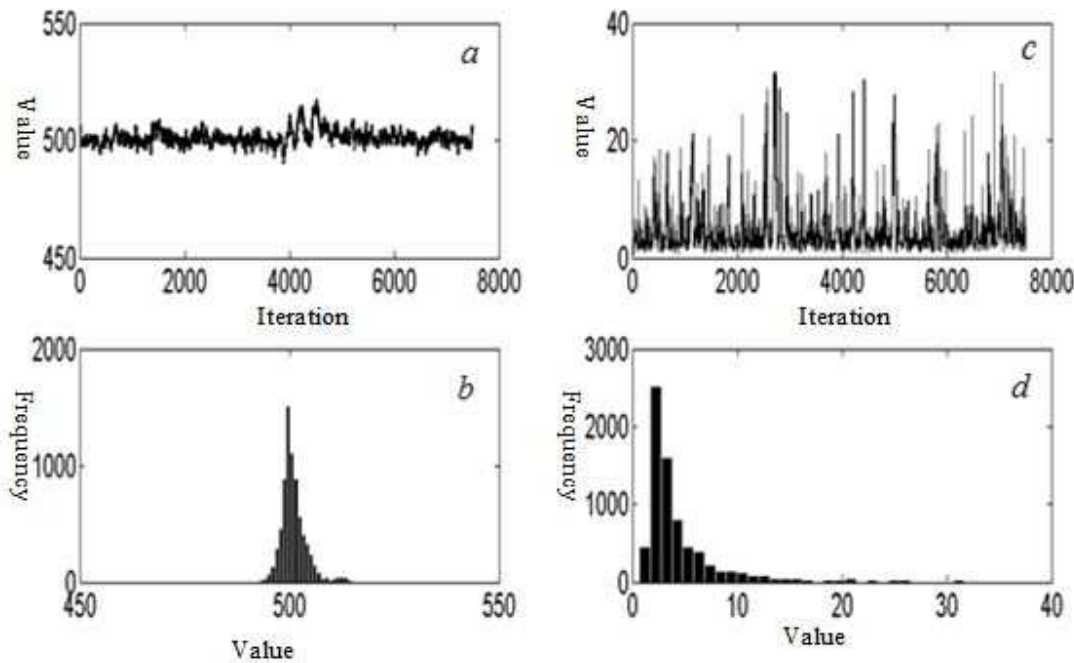
In this section simulated data are generated to examine the Bayesian estimators' performance in detecting the time and the size of the process change. The risk-adjustment model given in equation (26) is used to generate data. Following steps are executed to simulate data and then to obtain the estimates.

- 1- One thousand Parsonnet scores  $x_i, i = 1, 2, \dots, 1000$  are generated from an exponential distribution with mean equal to 8.9. Then by substituting them into equation (26), the values for patients' initial risk,  $p_{0i}, i = 1, 2, \dots, 1000$  are obtained.
- 2- Using equation (6), a shift equal to  $\delta$  at time  $\tau$  is considered and the values for  $p_{1i}, i = \tau, \tau + 1, \dots, m$  are obtained. Then, the patients' Bernoulli outcomes  $y_i, i = 1, 2, \dots, 1000$  are produced independently from the patients' specific Bernoulli distributions using the rates equal to  $p_{0i}, i = 1, 2, \dots, \tau - 1$  for patients 1 to  $\tau - 1$ , and the rates equal to  $p_{1i}, i = \tau, \tau + 1, \dots, m$  for patients  $\tau$  to  $m$ . The simulated Bernoulli data and the corresponding risk factors are regarded as phase I data and the RALRT chart with the UCL= 6.48 is applied to monitor the mortality rate.
- 3- When the chart signals, the MCMC simulation is performed and the values for Bayesian estimates of the time and the size of the change are obtained.

The MCMC output and the posterior distribution of  $\tau$  and  $\delta$  when the real change point and change size are 500 and 3 respectively, are shown in Figure 3. Table 1 shows Bayesian estimates and the standard deviation for the posterior distributions of  $\tau$  and  $\delta$  for the values of  $\tau$  and  $\delta$  equal to (400, 500), and (0.5, 0.75, 1, 1.3, 1.8, 2.5, 3.5, 5), respectively. Comparing the Bayesian estimates of the change time for  $\tau = 500$  indicate that for  $\delta$  smaller than 1.3 the posterior mean  $\bar{\tau}$  provides more accurate estimates of  $\tau$  than the posterior median  $\tilde{\tau}$  and for  $\delta$  greater than 1.3 the  $\tilde{\tau}$  is a better estimator of  $\tau$ . When  $\tau = 500$ , the values obtained for  $\bar{\tau}$  and  $\tilde{\tau}$ , are more accurate than those obtained for  $\tau = 400$ . For the change size, when  $\tau = 500$ , the posterior median  $\tilde{\delta}$  is more appropriate than the posterior mean  $\bar{\delta}$  for

$\delta = 0.5$ . However, when  $\delta > 0.5$ ,  $\bar{\delta}$  estimates the change size more precisely than  $\tilde{\delta}$ . When  $\tau = 400$  for all  $\delta$ 's,  $\bar{\delta}$  outperforms  $\tilde{\delta}$ .

As in the Bayesian framework the posterior distribution for each parameter is accessible, the credible intervals may be obtained. "A credible interval is a posterior probability based interval which involves those values of the highest probability in the posterior density of the parameter of interest" (Assaeh et al. 2012). Similar to Assareh et al. (2011b), the 50% and the 80% of the estimated time and the size of the process change are considered and are shown in Table 2 for  $\tau = (400, 500)$  and  $\delta = (0.5, 1)$ . Comparison of the 50% and the 80% credible intervals of the estimated time of the change for  $\tau = 500$  and  $\delta = 1$  reveals that the posterior distribution of the change time is more skewed to the left with respect to the increase in the probability. In other words an increase in the probability changes the left boundary from 472.4215 to 428.5558 in comparison to the right boundary which increases from 502.8745 to 507.7336. This interpretation may be extended to the other situations of change point and change size.



**Figure 3.** MCMC output and posterior distributions of  $\tau$  and  $\delta$  for  $\tau = 500$  and  $\delta = 3$ .

$a, c$  : MCMC output of  $\tau$  and  $\delta$   $b, d$  : posterior distributions of  $\tau$  and  $\delta$

**Table 1.** Bayesian estimation of change point parameters

	$\delta$	$\bar{\tau}$	$\tilde{\tau}$	$\sigma_{\tau}$	$\bar{\delta}$	$\tilde{\delta}$	$\sigma_{\delta}$
$\tau=400$	0.5	449.0327	445.3523	16.6124	0.4807	0.3140	0.5805
	0.75	373.0501	372.1084	20.0594	0.6812	0.3851	0.9963
	1	402.9857	401.6425	14.5885	0.8947	0.4867	1.4655
	1.3	379.9630	397.5790	56.9088	0.9232	0.4827	2.1746
	1.8	457.6051	463.4686	19.8774	1.4840	0.8820	2.3021
	2.5	438.3425	432.2708	21.6584	2.0457	1.0021	3.4653
	3.5	400.3640	400.3846	4.0162	2.1492	1.2915	3.1445
	5	403.2885	401.5714	5.5021	3.5932	2.3068	3.5887
$\tau=500$	0.5	499.5874	488.3129	65.3585	1.0397	0.5298	2.4672
	0.75	464.7723	456.6244	28.3526	0.7985	0.4797	1.1345
	1	497.3043	504.4645	24.8200	1.1119	0.5934	1.9937
	1.3	596.0793	612.8743	42.7222	1.3779	0.7271	2.5103
	1.8	505.0720	504.1157	12.0491	1.2335	0.7954	1.6378
	2.5	507.4838	503.8850	12.5339	2.1677	1.0722	3.6833
	3.5	503.2702	502.6877	4.6322	2.8829	1.6020	4.0507
	5	502.1380	501.4702	4.4279	4.7730	2.8691	5.1253

**Table2.** Credible Intervals for Change point parameters

$\tau$	$\delta$	Parameter	%50	%80
400	0.5	$\tau$	[361.2815 452.3534]	[346.7161 475.3345]
		$\delta$	[0.2979 0.8764]	[0.2061 1.8691]
	1	$\tau$	[312.7669 400.4298]	[281.4053 419.2256]
		$\delta$	[0.1907 0.5841]	[0.1156 1.1197]
500	0.5	$\tau$	[467.4823 504.2285]	[454.9908 511.9533]
		$\delta$	[0.3033 0.8755]	[0.1977 1.6794]
	1	$\tau$	[472.4215 502.8745]	[428.5558 507.7336]
		$\delta$	[0.3852 1.0493]	[0.2736 2.0942]

### 6-3- Comparison of the Bayesian estimators with the MLE estimators

Studying the performance of the proposed Bayesian estimators, 100 datasets are generated using the steps 1 and 2 in section 6-2. The Bayesian estimators and the maximum likelihood estimators of the change point parameters are obtained for each set of data. Then the mean and the standard deviation of the estimators are computed. Table 3 shows the resulted mean and standard deviation for each estimator. Concerning this table, the Bayesian estimators  $\bar{\tau}$  and  $\bar{\tau}$  outperform the MLE estimator  $\hat{\tau}_{mle}$  for both small and large shifts. In addition, the standard deviation of  $\bar{\tau}$  is much smaller than  $\hat{\tau}_{mle}$ . As an example, for  $\tau = 500$  and  $\delta = 0.7781$ , we have  $\bar{\tau} = 503.1559$ ,  $\bar{\tau} = 502.711$  and  $\bar{\tau}_{mle} = 492.0625$ . The corresponding standard deviations are  $SD(\bar{\tau}) = 58.7352$ ,  $SD(\bar{\tau}) = 62.4293$  and  $SD(\hat{\tau}_{mle}) = 127.4563$ . Comparison of  $\bar{\tau}$  and  $\bar{\tau}$  shows that they perform almost the same. On the other hand, regarding the change size estimators, for  $\delta \leq 1$ , in two cases the Bayesian estimator  $\hat{\delta}$  and in four cases the MLE estimator  $\hat{\delta}_{mle}$  are the most accurate ones. However, for  $\delta \geq 1$  in two cases  $\hat{\delta}$  and in two other cases  $\hat{\delta}_{mle}$  produce more precise estimates of the change size.

The credible intervals are also given to evaluate the performances of the estimators. The credible intervals of the estimators which are computed for  $\tau = 500$  and a range of  $\delta$  values are provided in Table 4. The

results show that for the change time estimators, in comparison to  $\hat{\tau}_{mle}$ , in many simulation runs the  $\bar{\tau}$  and  $\hat{\tau}$  are within the specified intervals around  $\tau$ . For instance, the probability of  $\bar{\tau}$  and  $\hat{\tau}$  being within  $\pm 10$  of  $\tau = 500$  when  $\delta = 0.5$ , is 0.2143 and 0.1429, respectively. While for  $\hat{\tau}_{mle}$  the probability is equal to 0 in this case. For  $\delta < 1$  the change size estimator  $\bar{\delta}$  surpasses the estimators  $\bar{\delta}$  and  $\hat{\delta}_{mle}$ . While for  $\delta \geq 1$  there is no superior estimator.

**Table 3.** Comparison of Bayesian and MLE estimators for  $\tau = 500$  and a range of  $\delta$

<b>0.2041</b>	456.9022	458.8763	511.1110	72.2927	73.0659	328.4438	0.6584	0.3664
<b>0.4771</b>	479.8635	481.6228	505.7910	76.7997	80.1885	253.1331	0.8628	0.4467
<b>0.5</b>	495.2615	492.8620	595.5000	47.6041	49.0743	267.7504	1.1130	0.6237
<b>0.6021</b>	509.7522	507.0434	520.3617	61.9235	65.8224	186.1663	0.8958	0.4952
<b>0.7781</b>	503.1559	502.7110	492.0625	58.7352	62.4293	127.4563	0.9296	0.5105
<b>1</b>	530.8575	531.9220	526.6393	44.9611	50.5956	118.0719	1.338523	0.7334
<b>2</b>	552.1965	552.9419	495.2490	32.7508	35.5530	10.1684	1.8038	0.9857
<b>3</b>	525.0353	524.6791	494.6101	25.8160	28.3498	7.9302	2.4668	1.3921
<b>5</b>	503.5180	502.6352	489.2500	3.4221	3.4769	30.8739	5.3356	3.3032
<b>7.5</b>	501.4740	500.8396	494.8401	0.8976	0.8926	1.6558	10.0104	7.0350
<b>10</b>	501.1294	500.5755	551.3294	0.4268	0.3792	15.3051	13.1989	10.0820

**Table4:** Estimated precision performance over  $\tau = 500$  and a given range of  $\delta$ . (continue)

5	$\bar{\tau}$	0.3800	0.7800	0.9400	$\bar{\delta}$	0.100	0.3200	0.6200
	$\tilde{\tau}$	0.5400	0.8400	0.9600	$\tilde{\delta}$	0	0	0.0100
	$\hat{\tau}_{MLE}$	0.0200	0.7600	0.9300	$\hat{\delta}_{MLE}$	0.1200	0.9700	0.9700
7.5	$\bar{\tau}$	0.8600	1	1	$\bar{\delta}$	0	0	0
	$\tilde{\tau}$	0.9300	0.9900	1	$\tilde{\delta}$	0.0800	0.1400	0.3000
	$\hat{\tau}_{MLE}$	0.0100	0.7100	1	$\hat{\delta}_{MLE}$	0.0200	0.0200	0.9300
10	$\bar{\tau}$	0.9900	1	1	$\bar{\delta}$	0	0	0
	$\tilde{\tau}$	1	1	1	$\tilde{\delta}$	0.0800	0.1400	0.3100
	$\hat{\tau}_{MLE}$	0.0300	0.6700	1	$\hat{\delta}_{MLE}$	0	0	0

## 7- Conclusion

In this study the Bayesian estimators of the change point parameters (including time and size of the change) are proposed for phase I analysis of the patients' post-surgery death or survival risk-adjusted outcomes. In the Bayesian estimation, for each  $\tau$  and  $\delta$  two Bayesian estimators including the mean and the median of the corresponding posterior distribution are proposed. Having the whole posterior distribution of the parameters in the Bayesian framework is a remarkable advantage that enabled us to construct credible intervals for unknown  $\tau$  and  $\delta$ . Results show that in comparison to MLE, Bayesian estimation method effectively detects the true change point parameters. In the simulation study, the Bayesian method significantly outperformed MLE when the change time is estimated.

In this approach the prior distributions of the change point parameters (time and size) have been considered to be independent. In practice, however, there are situations in which this assumption may not be valid. As an example, over the night working hours, due to the physicians' fatigue when a change occurs it may be more severe than the same change during the daytime. In such cases it is more reasonable to consider dependency between the parameters and, as a result, use a joint prior distribution to describe their behaviors.

In this paper, it was assumed that after a change occurs, the process remains in the new state as long as no out-of-control signal appears on the control chart. While, in practice as the surgeon's or physician's proficiency increases the process improves. Considering this assumption may lead to a more realistic model. Hence, another potential area for future research may be considering the incorporation of physicians' learning process into the model.



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