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Control charts and chronic respiratory patients

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SUMMARY

Statistical Process Control has been the focus of many researchers who have tried to expand its applicability to different areas, from industry to health. The main objective of the present work is to use Statistical Process Techniques in the control and follow-up of respiratory patients, since in clinical practice it has been observed that the variation between patients is much larger than the variation shown by a single patient. Therefore we tried to compare, under the same experimental conditions, the most cited control charts for control of the mean of independent data. The charts compared in this study are the Shewhart and EWMA charts and the modified MA. The measure used to compare the performance of the different charts was the Average Run Length. Noteworthy is the performance of the modified MA chart, which is much more robust with respect to false alarms, and also much simpler to implement than the EWMA chart. Lastly, we constructed control charts that might provide insights in medical decision-making.

Key words: Control charts, Average Run Length, False Alarms, Statistical Process Control, Shewhart Chart, Exponential Moving Average chart, Moving Average Chart, Chronic Respiratory Patients

1. Introduction

The development of medicine and improving quality of life in the Western world have led to an increase in general life expectancy. At the same time, however, lifestyle changes have led to an increase on the number of people suffering from chronic diseases. An example is the number of patients with obstructive respiratory chronic diseases. This number has increased in recent years, making such diseases a public health problem with social and economic implications resulting from the diminished working capacity of patients and from the costs associated with medical treatment.

Thus, with the objective of reducing the use of hospital emergency resources to treat acute respiratory conditions, and rationalizing the prescription and consumption of therapeutic products, we aim to monitor each patient, allowing detection of any abnormal changes, and thus avoiding the development of complications and allowing the use of corrective measures and, consequently, improving the patient's quality of life.

However, in clinical practice, it has been observed that the variations amongst individuals can be larger than the variations registered for the same individual. In practice, an observation that is on the range of reference values for a population can represent a relevant clinical change with respect to the usual values of a patient; of course, the reciprocal can also be true.

As stated by several authors (Woodall, 2006), control charts and Statistical Process Control (SPC) can be alternative methods for the analysis and presentation of data in the field of health. Thus, we attempted to apply the techniques of SPC in the monitoring and medical follow-up of respiratory chronic patients.

In order to identify the charts that exhibit the best results, we compare, under the same experimental conditions, the performance of several control charts for the study of the mean of individual independent observations.

The control charts introduced by Shewhart in 1924 are, unquestionably, the graphical method most widely known and used in the monitoring of a production process. However, the lack of power to detect small variations in the process mean have inspired researchers to develop new techniques that offer greater sensitivity for those cases.

Thus, as alternative charts reported in the literature (Montgomery,1991), the EWMA (Exponentially Weighted Moving Average) charts, the CUSUM (CUmulative SUM) charts and, more recently, the Q charts (Quesenberry, 1997) have been implemented; these last, combined with the EWMA, gave rise to the EWMAQ charts.

In general, all studies conclude that CUSUM charts have a similar performance to that of EWMA charts (Montgomery, 1991, Quesenberry, 1995, Lucas, Saccucci, 1990), and so the first of these is not studied in this work.

On the other hand, in this study it is considered that the mean and standard deviation are known. Therefore, the Q charts are similar to the Shewhart, and EWMAQ to EWMA (Quesenberry, 1991, 1997, Montgomery, Castillo, 1994).

Notably, the Moving Average (MA) charts that inspired the development of the EWMA charts have received less attention, because they are considered unstable due to correlation between values (Quesenberry, 1997). However, and in contrast to the conclusions of other authors (Carson, Yeh, 2008), it will be shown that these charts have their own merits.

2. Methodology

Considering the situation where both parameters μ and σ are known, the performance of the Shewhart (and Q), EWMA (and EWMAQ) and MA (with slight modification) charts is compared, for the case of individual observations (n=1). Simulations for individual observations were implemented and results are presented for the cases where the perturbation on the mean occurs at time instants t=1 or t=100.

The constants used in the EWMA chart, as used in the simulations, were $\left(\lambda, k\right) = \left(0.25, 2.9\right)$, since for an ARL_{in} equal to 370, Crowder (1989) and Lucas and Saccucci (1990) verified that this pair was the best to detect a shift of 1.5σ on the mean.

The measure used to compare the performance of the different charts was the ARL (Average Run Length). ARL corresponds to the mean value of collected samples until an out-of-control situation is signaled on the chart, i.e., a value is out of the control limits. The performance of the different charts will also be elucidated by the percentage of cases where the charts signal a false alarm. This measure is particularly important since excessive false alarms not only oblige the process to be stopped with unnecessary costs (Eljach *et al*., 2006), but might also question the utility of SPC and, thus, its use.

Brief introduction to control charts

Shewhart charts for variables are a simple and easy method of monitoring a series of data under study. First introduced by Shewhart, in the early 20th century, they consist in a graphical representation of the evolution, along time (*t*), of the individual values of a given variable representing a given quality characteristic. It is assumed that the variable under study is normally distributed, i.e., $X_i \sim N\left(\mu,\sigma^2\right)$.

In the graphic, a central line is drawn (CL) which represents the known (or estimated) value of the mean of the observations, around which the values should vary randomly when the process is stabilized.

Additionally, an upper control limit (UCL) and lower control limit (LCL) lines, which are obtained from $\mu \pm 3\sigma$, are represented on the graph. If these limits are surpassed by any observed value, the situation is automatically signaled as out of control, so that corrective actions can be taken.

Starting from analogous principles to the Shewhart charts, in the EWMA charts, introduced in 1959 by Roberts (Lucas, Saccucci, 1990), the represented value in time *t* is however calculated using the equation

$$Z_t = \lambda X_t + \left(1-\lambda\right) Z_{t-1} \qquad t = 1,2,3,... \tag{1}$$

where X_t represents the individual observations along time *t*, λ is a constant belonging to the interval [0;1] and the initial value Z_0 is equal to the known value of the mean μ. The reference limits are now calculated through the equations:

$$\begin{cases} UCL = \mu + k\sigma\sqrt{\left(\dfrac{\lambda}{2-\lambda}\right)\left(1-(1-\lambda)^{2t}\right)} \\ CL = \mu \\ LCL = \mu - k\sigma\sqrt{\left(\dfrac{\lambda}{2-\lambda}\right)\left(1-(1-\lambda)^{2t}\right)} \end{cases} \tag{2}$$

Similarly to the EWMA chart, the MA chart combines the information of two or more observations, in such a way as to increase the performance of the chart. Thus, the following modification is proposed, calculating the statistic,

$$\begin{cases} M_t = X_t & \text{se} \quad t < r \\ M_t = \dfrac{\sum_{i=t-r+1}^{t} X_i}{r} & \text{se} \quad t \geq r \end{cases} \tag{3}$$

and representing it on a graph whose central line (CL) is the mean of the observations and the control limits (UCL and LCL) are at a distance from CL equal to k=3 times the standard deviation of M_t .

The proposal corresponds to the values of the Shewhart chart for the first r -1 observations, which allows rapid detection of large perturbations for zero-state, i.e., when the perturbation on the mean occurs at t=1. The remaining observations correspond to those generated by the traditional MA chart. Results are presented for values r = 3, 5, 7, 9, 11 and 30. The process is out of control if a point is outside the control limits.

3. Results – Estimated values for ARL and False Alarms

The estimated values for ARL for the different charts were obtained by simulation, using a Visual Basic programming environment, for each experimental condition. In each experiment, samples of size n=1 (individual observations) were generated by a Normal distribution with mean $\mu + \delta\sigma$ and standard deviation σ - $X_i \sim N\left(\mu + \delta\sigma, \sigma^2\right)$. When no out-of-control observation was detected, the process was stopped at the end of 2000 iterations and a new experiment was initialized.

The perturbation $\delta\sigma$ (δ = 0.0, 0.25, 0.5, 1.0, 1.5, 2.0 and 3.0) on the mean of the variables was studied at two distinct instants: in the first case, from the instant t=1 and, in the second, with the perturbation at t=100. Tables 1 and 2 show the ARL values for t=1 and t=100, respectively.

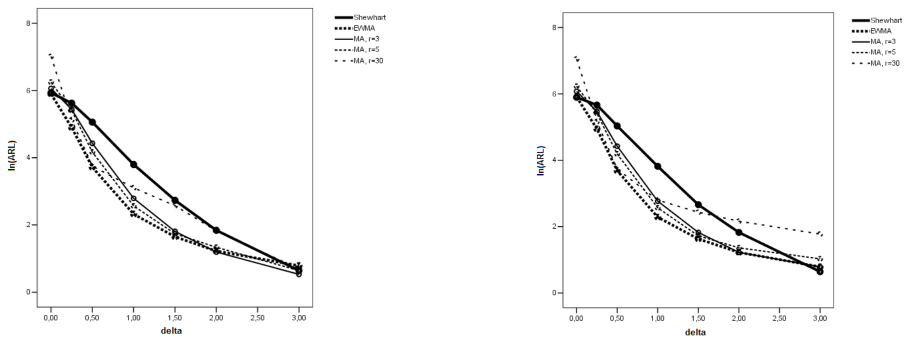
Table 1. ARL for t=1.

|δ|	Shewhart or Q	EWMA or EWMAQ	MA (modified)					
			r = 3	r = 5	r = 7	r = 9	r = 11	r = 30
0.00	376.3	364.4	428.6	516.7	526.2	657.1	723.3	1112
0.25	277.3	134.2	230.2	222.9	217.2	200.5	201.1	168.4
0.50	157.3	41.2	83.9	64.6	56.6	50.4	49.3	42.6
1.00	44.6	10.2	16.3	13.0	11.7	11.8	12.3	22.3
1.50	15.4	5.2	6.1	5.7	6.2	7.2	8.1	13.1
2.00	6.3	3.4	3.3	3.8	4.4	4.9	5.4	6.2
3.00	1.9	2.2	1.7	1.9	2.0	2.0	2.0	2.0

Table 2. ARL for t=100.

|δ|	Shewhart or Q	EWMA or EWMAQ	MA (modified)					
			r = 3	r = 5	r = 7	r = 9	r = 11	r = 30
0.00	364.3	367.9	435.2	507.9	600.4	659.3	732.6	1153.5
0.25	288.2	140.5	237.4	224.1	220.7	209.5	202.7	175.1
0.50	153.5	39.9	83.4	65.9	56.4	53.7	48.9	41.8
1.00	45.4	9.8	15.9	13.0	11.7	11.6	11.4	16.4
1.50	14.3	5.1	6.2	5.6	6.0	6.5	7.2	11.4
2.00	6.2	3.4	3.4	3.9	4.5	4.9	5.4	8.7
3.00	1.9	2.2	2.2	2.8	3.2	3.5	3.8	5.9

In Figure 1 some of the curves obtained for ARL, on the different experiments, are presented. In Table 3 we present the percentage of false alarms in 2000 experiments, when the perturbation on the mean occurs at time instant t=100, i.e, the number of times that an out-of-control situation is signaled before the perturbation in the mean has occurred at time t=100.



a) ARL, at instant t=1. b) ARL, at instant t=100

Figure 1. ARL curves for the Shewhart, EWMA and MA charts.

Table 3. False alarms for t=100.

|δ|	Shewhart or Q	EWMA or EWMAQ	MA (modified)					
			r = 3	r = 5	r = 7	r = 9	r = 11	r = 30
0.00	23.0	23.6	21.5	17.1	15.9	13.7	11.9	12.0
0.25	23.1	23.2	21.4	17.9	14.6	13.4	13.2	11.4
0.50	25.1	23.9	21.0	16.1	15.6	14.7	12.9	12.6
1.00	23.5	24.1	20.9	16.9	14.8	13.3	13.7	11.4
1.50	24.1	23.1	22.3	17.1	15.1	14.0	13.6	10.8
2.00	22.8	24.4	20.9	16.9	15.4	13.0	13.7	11.8
3.00	23.4	23.1	20.2	19.5	14.8	13.9	12.0	11.3
Mean	23.6	23.6	21.2	17.4	15.2	13.7	13.0	11.6

In Figure 2 we can visualize, simultaneously, the obtained values of ARL for the different charts with the percentage of false alarms that each chart presents.

The EWMA chart exhibits, as expected, a good performance for the different values of the perturbation on the mean. However, it should be noted that unlike the EWMA chart, the MA chart only uses a small subset of all the observations. It can be observed that, for different combinations of the perturbation on the mean and of the value of r, the MA chart also displays good performance, particularly with respect to the number of false alarms.

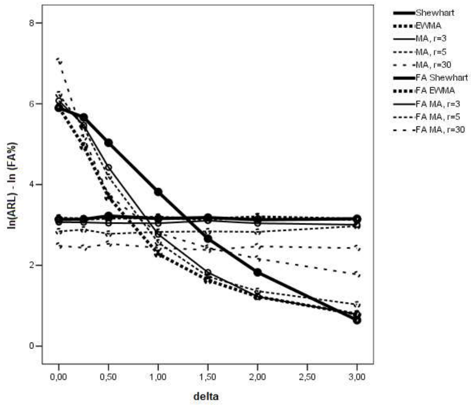


Figure 2. ARL and Percentage of False Alarms (*t*=100)

Moreover, in the MA chart it is possible to verify that the lower is the value of r, the more quickly large perturbations on the mean are detected, while, conversely, small perturbations on the mean are best detected with large values of r.

Thus the reported results (please refer to the previous tables and figures) show that there is no single chart that presents the best performance for all values of the perturbation on the mean.

Therefore, depending on the value of the perturbation that one wishes to detect more rapidly, the MA chart may provide results that are superior to the other charts, as shown in Table 4.

Table 4. ARL with different control limits for the MA chart (*t*=100).

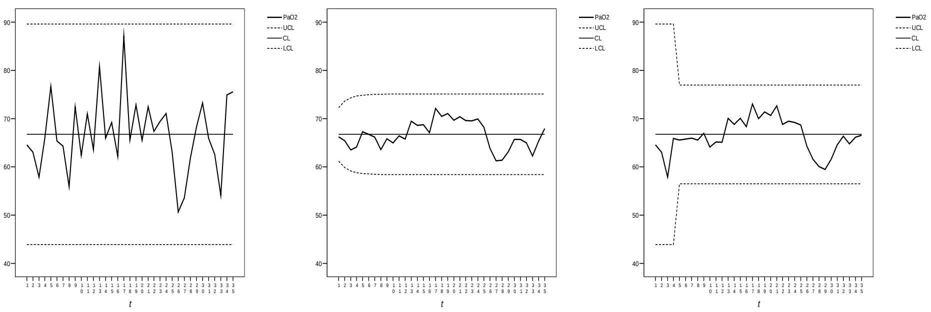
$\|\delta\|$	Shewhart or Q	EWMA or EWMAQ	MA (modified) $r = 5$, $k = 2.9$	MA (modified) $r = 11$, $k = 2.7$
0.00	364.3	367.9	376.7	349.3
0.25	288.2	140.5	166.8	111.3
0.50	153.5	39.9	51.9	31.6
1.00	45.4	9.8	11.8	9.6
1.50	14.3	5.1	5.3	6.4
2.00	6.2	3.4	3.8	4.8
3.00	1.9	2.2	2.6	3.4

4. Results – Application of the studied control charts to two respiratory patients

Chronic respiratory diseases can cause Respiratory Insufficiency (RI), which is defined as an incapacity of the respiratory system to maintain gaseous exchanges at adequate levels. This incapacity results in a deficient peripheral transport of oxygen (O_2) and/or deficient elimination of carbon dioxide (CO_2). Setting exact limits for the levels of the oxygen and carbon monoxide arterial partial pressures (**PaO_2** and **$PaCO_2$**, respectively) constitutes the main difficulty in RI diagnostics. Excess weight can also be a factor affecting the well-being of chronic respiratory patients, due to possible obstructing of air flow, and, for this reason, doctors monitor patients' Body Mass Index (**BMI**).

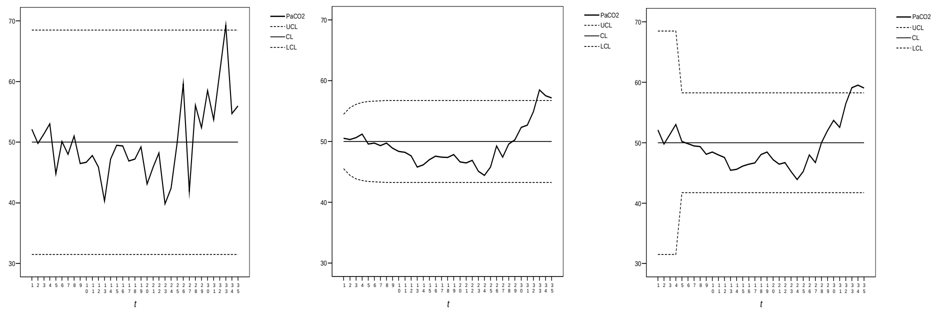
In this study, we first investigated the existence of autocorrelation in the data, which has not been verified. This may result from the long time intervals between consultations, which did not take place in a precise periodic fashion.

After testing each variable for normality, and bearing in mind the previous considerations, we applied the Shewhart, EWMA and modified MA (with r = 5) charts to control of the variables under study (PaO_2, $PaCO_2$ and BMI) in two chronic respiratory patients, as shown below.



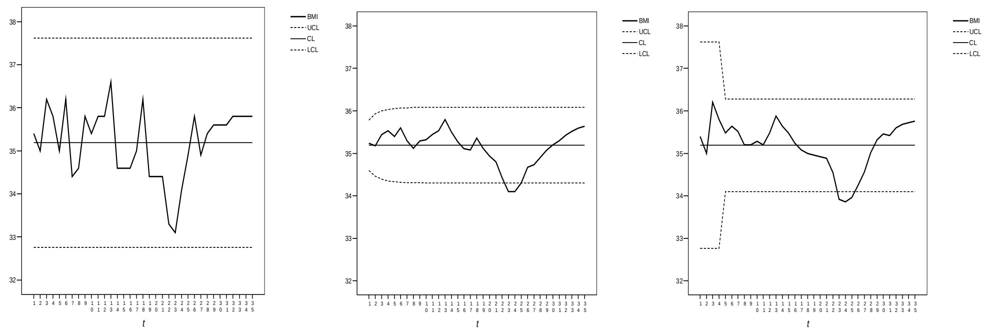
a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 3. Control charts for PaO_2 of Patient A



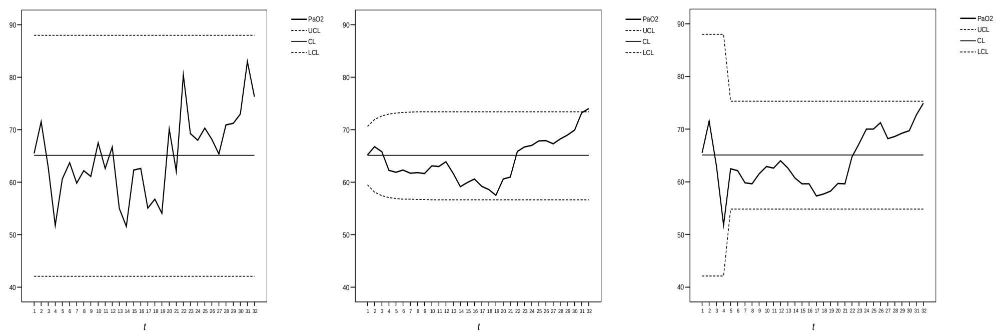
a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 4. Control charts for $PaCO_2$ of Patient A



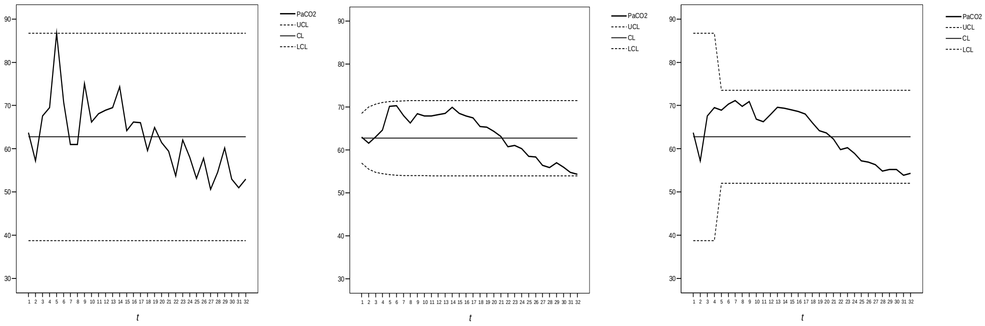
a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 5. Control charts for BMI of Patient A



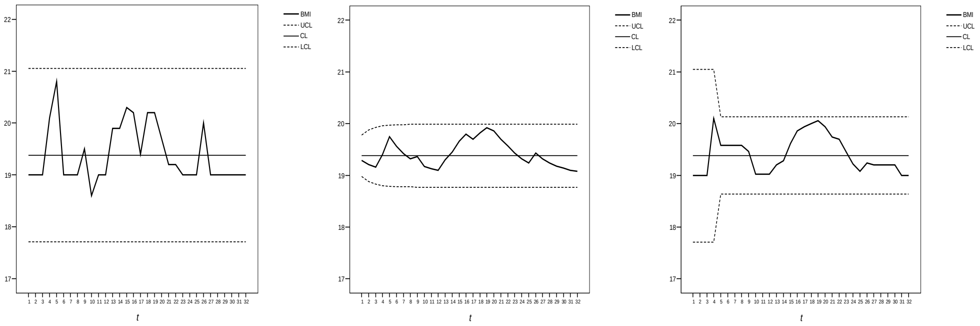
a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 6. Control charts for PaO_2 of Patient B



a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 7. Control charts for $PaCO_2$ of Patient B



a) Shewhart chart b) EWMA chart c) MA chart, with r=5

Figure 8. Control charts for BMI of Patient B

As can be seen, for both patients, the EWMA and MA (with r = 5) charts present similar results, having simultaneously detected out-of-control situations not identified by the Shewhart chart.

5. Conclusions

The results obtained, similar to those found in other works, as for example in Montgomery (1991), Quesenberry (1997), Lucas and Saccucci (1990) e Eljach et al. (2006), show a good performance by the EWMA chart in the detection of small perturbations of the mean, with the Shewhart chart having the best performance for large perturbations of the mean.

From the results of this work, attention can be drawn to the performance of the MA modified chart (usually given no importance in the specialized literature), which exhibits very close values to those of the EWMA chart. It should be mentioned that it is simpler to implement than the EWMA chart, less prone to autocorrelation and much more robust with respect to false alarms. Depending on the values of r, this chart presents values of ARL_{in} superior to the remaining control charts under study and exhibits lower or similar values for ARL_{out}. Therefore, the choice of r depends on the value of the perturbation which one wishes to detect more rapidly, and in the context of small series, as is the case with some medical data, the MA chart presents advantages due to its ease of use and robust results.

This work highlights the fact that control charts can make a great contribution to medical decision-making, since these graphs, as exemplified in the two patients reported, signaled an improvement in the clinical state of patient B, whereas for patient A they showed a tendency for deterioration of the clinical state.

However, it should be stated that regardless of the superior performance of the EWMA and MA charts in the detection of small perturbations, medical doctors find the Shewhart chart easier to read and interpret.

In future work, we will concentrate on the use of multivariate charts in the control of patients and, consequently, on the improvement or worsening of the clinical status of patients.

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