USING CONTROL CHART METHOD TO MONITOR OCCUPATIONAL ASTHMA

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ABSTRACT

The purpose of this research was to investigate whether the Shewhart control chart method can be used as an effective method to detect and monitor occupational asthma. Peak expiratory flow (PEF), a lung function marker, from 45 workers was used for this study. Control charts of PEF measurements at work and away from work were constructed. Multiple rules were developed and investigated. Reviewing the results, the best rule showed a sensitivity of 85.71%, specificity of 87.50%, and an error rate of 13.33% in detecting occupational asthma. Excluding the dubious cases, the test produced a sensitivity of 95.24%, a specificity of 95.83% and an error rate of 4.44%. Also, control chart method was used to detect lung function deterioration at work. The Average and Range control chart provided a method to monitor the acute and chronic conditions of asthma and characterize the PEF variability. The magnitude of variation was estimated using Variability Index. The results of this investigation were as good as and in some cases better than published clinical guidelines. This research showed that the control chart method is an effective, simple and inexpensive tool for early intervention in workers suspected for occupational asthma.

INTRODUCTION

Background

Asthma is the most common occupational respiratory disorder in the industrialized world. Although the incidence of occupational asthma is unknown, the proportion of cases of asthma attributable to the workplace is estimated at 15% to 20% in Japan and the United States. In British Columbia, Canada, and the United Kingdom, surveillance programs indicate that occupational asthma accounts for 26% and 52% of occupational lung disease, respectively (Cartier, 1994; Chan-Yeung & Malo, 1995; Venables & Chan-Yeung, 1997). In a review of published citations from 1966 through May 1999, Blanc and Toren (1999) extrapolated estimates from the incidence rates of occupational asthma and concluded that occupational factors were associated with about 1 in 10 cases of adult asthma including new onset disease and reactivation of preexisting asthma. The cost of occupational asthma has risen steadily over the last twenty years. Leigh et al. (2002) studied the cost and mortality rate of occupational asthma. They estimated 805 deaths due to occupational asthma each year in the U.S. alone. The total cost of occupational asthma was estimated at $1.6 billion.

Quality Control Charts

Walter Shewhart introduced control chart methods in his classic text Economic Control of Quality of Manufactured Products in 1931. Since their introduction, the control charts have been proven to be an effective way to improve industrial processes. Shewhart’s greatest contribution was to characterize the process variation into two categories; variation due to chance causes and variation due to assignable causes. The eminent statistician, W. Edwards Deming, applied control charts in understanding variation and a basis for management decision making (Deming, 1986; 1994).

Diagnosing Occupational Asthma

When a worker is suspected of suffering from asthma, the first and the most important feature of diagnosis is to establish work-relatedness of asthma (Burge, 2000; Cartier, 1994; Malo et al. 1993). The Specific Inhalation Challenge (SIC) test is widely accepted as the gold standard in the diagnosis of occupational asthma (Cartier, 1994; Cartier and Malo, 1999; Burge, 2000). However, the test is limited to specialized centers and requires expensive equipment, trained staff and medical supervision. Since specific inhalation tests and exposure tests are not readily available to many clinicians, many researchers have suggested serial measurement of peak expiratory flow (PEF) at work and away from work as an objective measure and an appropriate first step in establishing a causal relationship or confirming a relationship between asthma and work exposure (Burge, 2000; Cartier, 1994; Chan-Yeung, 1990; Malo et al., 1993). The peak expiratory flow (PEF), a lung function marker, is the maximum of airflow that can be achieved during a sudden forced expiration from a position of full inspiration.

The aim of this paper is to investigate the effectiveness of Shewhart control charts as a robust method to monitor and analyze peak expiratory flow (PEF) variability in occupational asthma. Although
Shewhart quality control charts have been widely used in industry, their application in clinical environments has been limited. No application of quality control charts to occupational asthma was found in the literature.

**METHODOLOGY**

Subjects were recruited from workers referred to four Canadian centers suffering from suspected occupational asthma. Physicians specializing in occupational respiratory health at the hospital outpatient clinics initially examined the subjects. Fifty subjects were selected for this study. Of the 48 subjects who completed the study, 3 were excluded due to incomplete or unusable data.

In addition to sputum induction test, methacholine challenge test and specific inhalation challenge test (gold standard), daily peak expiratory flow measurements were performed for periods at work and away from work. The PEF measurements and the gold standard test results for each subject were provided for the purpose of this research.

Peak expiratory flows were collected using Mini Wright flow meters. The subjects were trained in using the meter. The subjects were asked to record PEF four times daily, approximately at similar times, three maneuvers on each occasion and record the best of the three values, for a period of two weeks at work and two weeks away from work. Subjects were allowed to begin recording PEF during a period either while they were at work or away from work first, depending on which was most convenient. In case of medication use, the subjects were asked to record their PEF before and after medication.

**RESULTS**

**Rules to establish work-relatedness of asthma**

The first step in diagnosing occupational asthma is to establish work-relatedness; therefore, PEF control chart was used to determine if a worker’s asthma was related to workplace. Figure 1 shows a PEF control chart of a worker while at work.

Since the lower control limit (LCL) is the boundary of extreme low values, an index was developed using each worker’s control chart LCL and personal best (PB) value and presented as a percent, that is, \( \frac{LCL_{PB}}{LCL_{PB}} \times 100 \). The following rules were used to establish work-relatedness:

**Rule1:** Comparison of at Work Daily Minimum PEF Lower Control Limit (LCL\(_W\)) to the Individual’s Personal Best
**Rule2:** Comparison of at Work Daily Maximum PEF Lower Control Limit (LCL\(_W\)) to the Individual’s Personal Best

Each index was compared to 60%, 70% and 80% of the personal best value and the results were compared to the gold standard as shown in Table 1. In Table 1, worker 1 is identified as experiencing occupational asthma at 60%, 70% and 80% of his personal best value when compared to the gold standard. To determine the effectiveness of the method, sensitivity and specificity were estimated. Sensitivity is the ability of the test to correctly identify individuals with asthma, while specificity is the ability of the test to correctly identify nonasthmatics.
Table 1: Comparison of LCL to Personal Best Values

<table>
<thead>
<tr>
<th>Worker</th>
<th>Personal Best PEF</th>
<th>(LCL / PB) x100%</th>
<th>60% PB Result</th>
<th>70% PB Result</th>
<th>80% PB Result</th>
<th>Gold Standard Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>490</td>
<td>10</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
<td>Positive</td>
</tr>
<tr>
<td>2</td>
<td>410</td>
<td>61</td>
<td>Negative</td>
<td>Positive</td>
<td>Positive</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Selecting the Best Rule

Several rules were presented that were candidates for use in testing for occupational asthma. The aim was to select the rule which results in the highest level of sensitivity and specificity, i.e. the lowest error rate. Discarding any rule with a sensitivity < 80%, only Rule 1, using daily minimum PEF measurements, meets this requirement. Therefore, LCL< 60% PB gives the best results, with a sensitivity of 85.71%, specificity of 87.50% and a 13% error rate. After removing dubious cases, the results can produce a sensitivity that might be as high as 95.24%, a specificity that might be as high as 95.83%, and an error rate that might be as low as 4.44% if the gold standard test was wrong for these dubious cases. The comparisons between Rule 1 and the gold standard are summarized in Table 2.

Table 2. Comparison of Results for Rule 1 and the Gold Standard

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Gold Standard</th>
<th>Total</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>LCL&lt;60% PB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>18</td>
<td>3</td>
<td>21</td>
<td>85.71%</td>
<td>87.50%</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>21</td>
<td>24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>21</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCL&lt;70% PB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>18</td>
<td>11</td>
<td>29</td>
<td>85.71%</td>
<td>54.17%</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>13</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
<td>24</td>
<td>45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCL&lt;80% PB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>19</td>
<td>21</td>
<td>40</td>
<td>90.48%</td>
<td>12.50%</td>
</tr>
<tr>
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<td>Total</td>
<td>21</td>
<td>24</td>
<td>45</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Control Chart and Lung Function Deterioration

One of the objectives of this paper is to show the effectiveness of Shewhart quality control charts to anticipate and detect lung function deterioration for early intervention. When subjects suspected of occupational asthma are asked to record their PEF measurements at work and away from work, the aim is to determine whether there has been a significant downward shift in lung function during the work period. A control chart of PEF measurements of baseline data (away from work) is constructed to establish the baseline control limits. The baseline control limits are then extended and imposed on the work measurements. If the work exposure factors have no significant impact on the subject, the work PEF values are expected to remain within the control limits with no special causes of variation present. However, if the work exposures perturb the process and the PEF values at work manifest special causes of variation, then one can assume a significant change has occurred. Since all other factors are assumed constant, this significant change can only be attributed to the work exposure factors.

No Significant Change

Figure 2 shows the baseline control chart for the daily minimum PEF values of a subject who has been tested negative for occupational asthma by the gold standard. The PEF baseline control chart is in statistical control, and there are no special causes of variation present. The baseline control chart limits are then imposed on the daily minimum PEF values during work for the same subject. As the chart shows, the 14 daily minimum PEF values at work indicate no special cause of variation and the daily values behave randomly within the control limits. That is, the work exposure has caused no significant shifts in the baseline PEF process behavior, either adversely or favorably.
**Adverse Change – Deterioration of Lung Function**

Figure 3 shows the baseline control chart limits of another subject imposed on the PEF measurements at work. This subject is identified as positive for occupational asthma by the gold standard. As Figure 3 shows, the daily minimum PEF process indicates a significant shift downward, with 20 out of 22 work days falling below the lower control limit. Thus, work exposure is highly likely to account for the reduction in PEF lung function.

In the example shown in Figure 3, the subject’s PEF at work provides early signals giving immediate notice for action and intervention. Either the offending exposure factor(s) or the subject may be removed from the work environment without delay, thus avoiding extended exposure. In this case, intervention can occur on Day 1 or 2. Once the subject is removed from the work environment, further clinical tests can be carried out to identify the sources of the special cause.

**Control Chart and PEF Variability**

The reference to variation in asthma care is generally suggests two types: diurnal or within-day variation and day-to-day variation. These types of variation represent different aspects of the disease; i.e., acute and chronic respectively [Timonen et al, 1997]. When using Shewhart control charts, these types of variation can be characterized as within subgroup and between subgroup variation. Therefore the Average and Range control chart is the most suitable to monitor both types of variability in an effective way. Table 3 shows the PEF data for a worker while away from work. The PEF measurement away from work is considered as the baseline. The subject recorded the PEF values four times a day for a period of 14 days. The control chart of the data in Table 3 is shown in Figure 4.
Table 3. Daily PEF Data

<table>
<thead>
<tr>
<th>Time</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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<th>11</th>
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<th>14</th>
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<td>7:00-8:00</td>
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<td>420</td>
<td>380</td>
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<td>400</td>
<td>430</td>
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<tr>
<td>11:00-13:00</td>
<td>430</td>
<td>430</td>
<td>450</td>
<td>410</td>
<td>400</td>
<td>440</td>
<td>490</td>
<td>450</td>
<td>420</td>
<td>470</td>
<td>410</td>
<td>440</td>
<td>440</td>
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<tr>
<td>16:00-17:00</td>
<td>420</td>
<td>425</td>
<td>440</td>
<td>420</td>
<td>410</td>
<td>440</td>
<td>440</td>
<td>455</td>
<td>440</td>
<td>460</td>
<td>455</td>
<td>440</td>
<td>460</td>
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<td>21:00-22:00</td>
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<td>430</td>
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<td>460</td>
<td>410</td>
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<td>430</td>
<td>460</td>
<td>410</td>
<td>440</td>
<td>440</td>
<td>425</td>
</tr>
</tbody>
</table>

| Daily Average | 421.3 | 426.3 | 425  | 417.5 | 405  | 427.5 | 442.5 | 432.5 | 422.5 | 440  | 431.3 | 437.5 | 435  | 441.3 |
| Daily Range   | 35    | 10    | 70   | 80    | 10    | 30    | 90    | 40    | 30    | 50    | 45    | 30    | 40    | 50    |

Figure 4. Averages and range chart for the PEF data in Table 1

Figure 5 shows the average and moving range chart of PEF measurements for the same subject during the work period. The measurements were taken approximately about the same daily time periods for 14 days. For the work period, the upper chart shows an average of 269.6 L/min. This is significantly lower than the average during the period away from work (428.9 L/min) indicating deterioration of the chronic condition. The area bracketed between the lower and upper control limits is 180.3 L/min (359.8 - 179.5). The range chart indicates an average diurnal variation of 123.8 L/min and an upper limit of 282.4 L/min. The range chart also shows a significant increase in diurnal variation indicating deterioration of the acute state of the asthma at work. This worker has been identified as having occupational asthma using specific inhalation challenge test (gold standard).

Figure 5. Averages and range chart for the PEF measurements during work period

The example presented here shows the effectiveness of quality control chart in monitoring of the occupational asthma. The average and range chart can monitor the daily PEF averages (the chronic
manifestation of asthma) and the range chart can monitor the diurnal variation (the acute manifestation of asthma).

**PEF Variability Index**

A method is presented here to determine the magnitude of the increase in PEF variability when a significant change in the PEF due to work exposure has occurred. Figure 4 shows the control chart of the baseline measurements and Figure 5 shows the control chart of measurements during the work period for a worker identified as having occupational asthma. The area bracketed between the upper and lower control limits of daily PEF values represents the magnitude of the variation present in the lung function process. For the subject above the magnitude of the daily average PEF variation (chronic condition) of the baseline is 64.1 L/min (461.0-396.9). Similarly, the magnitude of the variation for the control chart of PEF measurements during the work period is 180.3 L/min (359.8-179.5) indicating a significant increase in variability for the period at work. Comparing the magnitudes of variability for these two periods, an index of variability for daily averages can be devised using the following relationship:

\[
\text{Variability Index (VI)} = \frac{\text{Magnitude of Variation at Work}}{\text{Magnitude of Variation of Baseline}} = \frac{UCL_{\text{Work}} - LCL_{\text{Work}}}{UCL_{\text{Baseline}} - LCL_{\text{Baseline}}}
\]

For the subject above the index is calculated as:

\[
VI = \frac{359.8 \text{ L/min} - 179.5 \text{ L/min}}{461.0 \text{ L/min} - 396.9 \text{ L/min}} = 2
\]

The area bracketed between the upper and lower control limits represents 6 sigma control limits; the Variability Index can further be simplified as:

\[
VI = \frac{\bar{X}_{\text{Work}} - \bar{X}_{\text{Baseline}}}{\sigma_{\text{Baseline}}} = \frac{R_{\text{Work}}}{R_{\text{Baseline}}} \times 2
\]

The difference is due to rounding effect. The variability index can be expressed as a percentage. Therefore, for this subject the average daily PEF variability at work has increased by 180%.

The Variability Index is a simple and effective method for estimating the magnitude of variation due to exposure to work environment. The increase in Variability Index is thus a comprehensive indication of lung function instability and can assist in the early detection of lung function deterioration and immediate intervention. However, more research is needed to determine the magnitude at which occupational asthma is confirmed.

**DISCUSSION**

One of the objectives of this research was to use statistical methods to help diagnose the work-relatedness of asthma. Several rules applying Shewhart’s methods to PEF measurements were suggested. The aim was to select the rule which results in the highest level of sensitivity and specificity, i.e. the lowest error rate. Rules that failed to produce a sensitivity of at least 80% were eliminated. Rule 1, based on a lower control limit of the work control chart of less than 60% of the subject’s personal best value (LCL_{W} < 60% PB), produced the highest sensitivity (85.71%), specificity (87.50%), and the lowest overall error rate (13.33%). After excluding dubious cases, there was an increase in sensitivity (95.24%) and specificity (95.83%), and a decrease in error rate to 4.44%.

In order to show the deterioration of lung function at work, the three sigma limits of the baseline control chart can be imposed on the PEF measurements at work. If the work environment has no adverse effect, then the work PEF values must behave randomly within the control limits; that is, no special causes present. However, in the case of substantial deterioration of lung function; PEF measurements at work will appear as special causes of variation.

The variability index presented in this paper is an effective method to detect any increase in the PEF variability due to work exposures. The variability index is estimated by the ratio of average diurnal variation at work and the average diurnal variation of the baseline where the baseline is the PEF measurements recorded away from the work environment.

As a screening method, workers can be asked to monitor their PEF to detect any deterioration of lung function at work compared to the period away from work. The method presented here, comparing the subject’s LCL_{W} to the personal best, will provide sufficient evidence for further investigation.
The choice of 60%, 70%, and 80% criteria was based on published literature. The National Heart, Lung, and Blood Institute recommends these percentages for diagnosis and classification of asthma as either mild, moderate, or severe, and Boggs et al. (1998, 1999) have incorporated these recommendations in the use of control charts.

The interesting feature of this study is the generality of the sampled population. The subjects represent different industries and geographical locations. Therefore, the optimal estimates of sensitivity, specificity and error rates produced in this research can be valid for a variety of work environments.

The methods presented here are very simple to calculate requiring simple arithmetic operations. Although not necessary, there are a number of software packages available to produce the charts with minimal effort. However, the interpretation and insight that control charts provide is paramount.

A limitation of this research is the moderately small sample size employed. The final sample size of 45 subjects is considered small to moderate. Although the estimates of sensitivity and specificity presented here are as good as or better than the literature, given the small sample size, sensitivity and specificity would need to be confirmed by a larger study.

Finally, statistical process control software can be used to provide instant graphing of the control chart and feedback. However, devices that can both record lung function and provide graph control charts instantly are not yet available.

Reference will be provided upon request.

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