Quality Control in the Chiropractic Clinical Setting Utilizing Thermography Instrumentation as a Model

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ABSTRACT

Objective: To describe a model for quality control in the chiropractic health care setting.

Methods: The study presents one model for monitoring the reliability of reproducing thermal pattern scans using a series of different instruments in different adjusting rooms. The study was comprised of two separate trials (A), and (B). In each trial, one student served as the "subject" while a second student obtained thermographic scans. The subject then moved to the next room, and the second student again obtained a thermographic scan on the same subject. The scan from room 1 was then compared to determine percent agreement with the scan from room 2. This procedure was repeated in room 3, etc. Data was then analyzed and interpreted. Trial B also included a recording of the ambient temperature of each adjusting room immediately prior to the scan, and directly after each scan was taken.

Results: Trial A: Comparisons of scans from instruments 1 through 18 fell within a range of 2 standard deviations (84.3 – 59.1 % similarity) around a mean of 71.7 ± 6.3. The coefficient of variation for Trial A was 8.8% for the left and 6.6% for the right paraspinal thermographic comparisons. Trial B: The same results were observed as with Trial A, with one exception. One instrument fell outside of 2 standard deviations of the mean, 72.4 ± 5.2, by 0.3 % similarity for the right paraspinal thermographic findings. The coefficient of variation for the left paraspinal thermographic comparisons was 8.1% for the left and 7.2% for the right. Pre – Post scan temperature readings taking place for the 16 instruments assessed in Trial B were not significantly different (p 0.24).

Conclusions: Quality control procedures are well documented and employed in many different settings ranging from clinical laboratories to manufacturing enterprises and has direct application to the chiropractic setting.

Key Words: Quality control, chiropractic, chiropractic instrumentation, reliability, clinical validity.

Introduction

Quality Control

Quality control is customary in all settings that involve repeated use of instrumentation or other measures of assessment by numerous personnel. The purpose is to insure that the instrument or measures remain reliable while being used multiple times. Quality control, once established, also serves to monitor inter and intra-examiner reliability as well as signaling when a measure, instrument or examiner needs to be either re-calibrated (i.e., an instrument) or re-assessed for technique (i.e., an examiner). Thus, the data obtained serve as an ongoing indicator of the current state of reliability.1-4

After examiner reliability has been established through previous studies, a quality control protocol can next be placed in operation to test the instruments or other measures under "real" conditions to establish levels of agreement. This is usually done by collecting data from the instruments or other measures, and determining a mean value for the group based on some outcome produced by the instrument or other measure. Next a standard deviation (an indication of the closeness of the numbers contributing to the mean) is determined.

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Control Limits

Limits on a control chart are used as criteria for signaling the need for action, or for judging whether a set of data does or does not indicate a "state of control." This refers to the defined limits or ranges of results expected due to the random error of the method, beyond which some course of action should be taken. Generally, anything outside of 3 standard deviations is considered aberrant in regard to the population being measured. Loss of integrity is generally suspected in regard to instruments or other measures if values begin to appear greater than 2 standard deviations from the mean. Any value beyond 3 standard deviations calls for immediate change.5

Control Graph

A control graph, or chart, is a method for evaluating whether a process is or is not in a state of statistical control.5 The determinations are made through comparison of the values of some statistical measure(s) for an ordered series of samples with control limits (i.e., ± 1-3 standard deviations). In health care settings, the Levey-Jennings Chart is commonly used to plot the result observed for a supposedly stable material, instrument or other measure against a time period (daily or monthly).6

Application to the Chiropractic Setting:

Currently, quality control with regard to instrumentation, comparative supervisor reading of x-rays, and other assessments are areas that should be monitored regularly to assess for consistency, reliability, and examiner competence. This study is presented as a model relative to assessment protocols on a periodic basis to ensure a level of demonstrable "control." The approach applies to any type of assessment performed in the chiropractic setting.

This study assesses the quality control of an instrument recording absolute temperature of the paraspinal musculature (thermography). Thermography is a well established protocol,7 and is considered to be an important component of overall patient assessment. The Sherman College Health Center utilizes the Tytron-C3000 [Titronics Research & Development, Oxford, IA]. The Tytron-C3000 is a dual-probe infrared instrument recording temperatures on both sides of the spine. The Tytron instrument and protocol have been described elsewhere.8 Both intra and inter-examiner reliability in the use of the instrument have been established,9 and the scanning procedure has been shown to have high reliability.10 Data from the scans are exported to a notepad file, which is then imported into Thermal Pattern Calculator (TPC) software for analysis revealing the regions of any two scans that are statistically similar (percent agreement).

Methods

Protocol

The current study was approved by the Institutional Review Board (IRB) of Sherman College. The study was comprised of two separate trials (A), and (B), conducted on February 24, 2007 and March 24, 2007. In each trial, one student served as the "subject" while a second student obtained thermographic scans. Each scan was obtained with the Tytron-C3000 dedicated to the adjusting room being used. The subject then moved to the next room, and the second student again obtained a thermographic scan on the same subject.

The scan from room 1 was then compared via the Thermal Pattern Calculator to determine percent agreement with the scan from room 2. This procedure was repeated in room 3. Scans were then compared between rooms 2 and 3. This allowed scans from 18 different Thermographic instruments to be compared between each room and the adjacent room. Data was then analyzed and interpreted by a member of the research department blinded to the study.

Trial B also included a recording of the ambient temperature of each adjusting room immediately prior to the scan being taken and directly after each scan was taken. Trial B involved comparisons of scans from 16 instruments whereas Trial A involved 18 instruments.

The study was designed to assess the findings from the scans under what would be considered "real" conditions. Since there were two unknown variables in this study (environment of the room and different thermographic instruments), the second aspect of the study, Trial B, was conducted to determine if constant temperatures prevailed. This is important as different ambient temperatures could influence the "subjects" temperature, and/or the sensitivity of the instrument, hence possibly altering the thermographic readings.

Results

Trial A

Table 1 and Figures 2 and 3 show that that comparisons of scans from instruments 1 through 18, tested in their designated adjustment rooms, all fell within a range of 2 standard deviations (84.3 – 59.1 % similarity) around a mean of 71.7 ± 6.3 This was observed for both the left and right paraspinal thermographic findings. Moreover, the coefficient of variation for Trial A was 8.8% for the left and 6.6% for the right paraspinal thermographic comparisons.

Trial B

Table 1 and Figures 3 and 4 showed the same results as Trial one, with one exception. Instrument number 7, fell outside of 2 standard deviations of the mean, 72.4 ± 5.2, by 0.3 % similarity for the right paraspinal thermographic findings. All values for the left thermographic scans were consistent with Trial A in that all values were within 2 standard deviations of the mean. The coefficient of variation for the left paraspinal thermographic comparisons was 8.1% for the left and 7.2% for the right.

Pre – Post scan temperature readings taking place for the 16 instruments assessed in Trial B were not significantly different (p = 0.24, Table 2). This indicated that minor temperature fluctuations in the rooms were not contributory to any aberrant reading, such as that seen for instrument number 7. Isolating the temperatures in room 7 also revealed that the variation was only 0.7 degrees F.
Quality control procedures are well documented and employed in many different settings ranging from clinical laboratories to manufacturing enterprises. Quality control has direct application to the chiropractic setting, and should be considered as a continuous method of determining the “control” level of all assessments. Coefficients of variation in this study ranged from 6.6% - 8.8%, demonstrating sound methodology. Procedures can be readily modified to suit the nature of the setting under quality control. A basic understanding of fundamental statistical procedures is the minimum requirement to initiate a continuous quality control program and on-going training for those involved in a control program is recommended.

References

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Discussion

The relevance of quality control has been documented in a variety of ways. While the applications are broad, the ease of construction make the utilization of such monitoring both feasible and necessary. It is obvious that any type of measuring device or method that is faulty will return faulty results. Without quality control there is little likelihood that “out of control” measuring will be detected. In a situation such as a series of chiropractic adjusting rooms, where the same patient may be assessed in any one of the rooms on a given visit, it is essential to have confidence that the same measuring devices are operating within a pre-determined standard. Should this not be done, measurements obtained by “out of control” devices or methods could readily lead to incorrect decisions regarding the status of the patient.

The Trials

The present study utilized two Trials with two different subjects and two different practitioners to simulate “real” conditions. In the first trial, all values were within a 2 standard deviation limit. However, in Trial B, one instrument had begun to wander beyond that limit. The single rule quality control procedure would be followed in this instance. That is, one set of control limits such as a Levey-Jennings chart, modifications of which are seen in Figures 1-4, would be used to determine if adequate control between “runs” exists. Should the instrument in question continue to wander to the 3 standard deviations, it would then be inspected, cleaned, recalibrated, and put back into use to determine if it was functioning within the 2 standard deviation limits of control.

Thus, while Trial A indicated no instruments wandering beyond the 2 standard deviation limit, Trial B, two months later, revealed that one instrument was following the “single rule” application, and would warrant close scrutiny during the next trial period.

Coefficient of Variation (CV)

The CV, defined as the standard deviation divided by the mean, provides a measure of the variation around the mean. The extent of variation that is tolerated is a function of the setting under which measurements are monitored. The acceptable CV can range from 5% - 30%. The lower the CV the less variation is present, and in the instance of repeated instrument recordings, that would be most desirable. In the present study values ranged from 6.6% - 8.8%, well within acceptable limits which are often assigned in healthcare settings to be between 5% and 10%, thus demonstrating sound methodology.

When conducting quality control, it is important to also monitor other variables that could affect the outcome as well. In this instance, ambient room temperature was of such a concern. Thus, Trial B also included monitoring the temperature pre and post scan with the same instruments used in the Trial in their designated adjusting rooms. The results indicated that ambient temperature was indeed stable thus eliminating it as a variable in the present study.

Although the procedures are well documented, it is also important to involve those conducting quality control to supplement their training with continuing education to remain informed of new concepts in the field. In regard to the present study, it is intended to be a first step in establishing on-going statistical monitoring to ensure quality control of all assessments conducted in the chiropractic clinical setting. Further reports will be necessary to comment on the effectiveness of this approach in the teaching setting.

Quality Control Graphs (Charts)

Figures 1-4 represent quality control graphs. It can be visualized where each comparison, and respective instrument, is within or outside of the limit of 2 standard deviations from the mean. Further, the room temperature data could also be transformed into a visual of repetitive temperature measurements over any time period.


Figure 1. Left A%,* Trial A

* A % derived by comparing instruments 1 and 2, 2 and 3, etc.

**Mean of 18 instruments = 71.7 ± 6.3. Vertical bars = 3 s.d (18.9) 
All values are within ± 3 s.d. range of 90.6 - 52.8.

Figure 2. Right A%, * Trial A

* A % derived by comparing scans 1 and 2, 2 and 3, etc.

**Mean of 18 instruments = 73.1 ± 4.8. Vertical bars = 3 s.d. (14.4).
All values are within ± 3 s.d. of 87.5 - 57.7
Figure 3. Left A%, * Trial B

*A % derived by comparing scans 1 and 2, 2 and 3, etc.

**Mean of 16 instruments = 77.1 ± 5.6
Vertical bars = 3 s.d (16.8).
All values are within ± 3 s.d. range of 93.6 - 60.3

Figure 4. Right A%, * Trial B

*A % derived by comparing scans 1 and 2, 2 and 3, etc.

**Mean of Instruments = 72.4 ± 4.9. Vertical bars = 3 s.d (14.7).
All values are within ± 3 s.d. range 87.1 – 57.7.