Accuracy and Precision Test of TempTraq® compared to Pulmonary Artery Catheter for Monitoring Temperature in Adults in Intensive Care Unit

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Introduction

Temperature monitoring is an important assessment tool for healthcare providers. Over the years a number of changes have been made to improve our ability to accurately and precisely measure and monitor a patient's temperature (Sund-Levander, & Grodzinsky, 2013). However, most of these new technologies have limitations and many provide readings that are too variable under different conditions and thus cannot be relied upon to provide a true measure of a patient's temperature. Inaccurate temperature monitoring can result in delayed treatment or administration of treatment not actually needed. To be useful a thermometer must demonstrate precision and accuracy.

Background

The gold standard against which all thermometer devices are compared in the core temperature as measured by the pulmonary artery (PA) catheter (Farnell et al. 2005). Although body temperature measured using a PA catheter is the most accurate measure to date, it is an invasive procedure and the risks of inserting and maintaining a PA catheter may not be justified (Pinsky, & Vincent, 2005). Chemical thermometers are a non-invasive method for obtaining a temperature orally, rectally, inguinal, or axillary. Chemical thermometers are affected by many variables and each route has different limitations. Previous studies identify accuracy and precision issues with chemical thermometers. Electronic thermometers (if calibrated often) are a bit more accurate; but they also have limitations. Some electronic thermometers are non-invasive (, oral, tympanic & temporal), but others require invasive methods to insert the thermistor (esophageal, rectal, or urinary bladder). None of these methods have been found to be as accurate or reliable for patients as the PA catheter temperature measurement (Farnell et al. 2005; Lawson, et al. 2007).

One alternative to the use of invasive temperature monitoring that may be more accurate and reliable that either chemical or electronic thermometers is the TempTraq® thermometer. This thermometer developed by Blue Spark Technologies (Westlake, Ohio) is applied to the skin as a patch. The TempTraq® thermometer is a thin, single-use, battery-powered skin patch that monitors and records skin temperature. Previous studies have demonstrated that it is reliable and accurate for monitoring temperature in children and in healthy adults. However, it has not been tested in ill adult patients.

Methods

Purpose

The purpose of this feasibility study is to assess the accuracy and precision of the Temp-Traq thermometer for monitoring body temperature in adult patients under three conditions (hypothermia, normothermia, and hyperthermia).

Specific Aims

1. To assess the accuracy of the Temp-Traq thermometer as compared to a gold standard (Core temp measured by Pulmonary Artery Catheter)
2. To assess the precision of the Temp-Traq thermometer over repeated measures
3. To determine if accuracy &/or precision is consistent in three conditions (hypothermia, normothermia, or hyperthermia)

Design

A repeated measures within-group comparative design will be used for this study.

Sample/Setting

To address the specific aims of this study we will identify patients (N = 40) who have a pulmonary artery (PA) catheter in place (patients in intensive care units). Letters of support are attached from the unit managers where the study will take place (see attached).

Inclusion Criteria

Adult patient (male or female) in intensive care unit who will have a PA catheter in place for at least the next 8 hours; and who have no visible skin condition to the axillary region upon inspection by the research nurse are eligible for this study

Exclusion Criteria

1. Patients younger than 21
2. Patients who will not have a PA catheter in place for the next 8 hours
3. Patients who have a visible skin condition to the axillary region upon inspection by

the research nurse

4. Patients who will be going for procedures or for some reason will not be available for the 6 hours of the study

Procedure

Once a patient is identified, the researcher will record basic demographic data (see data collection form attached) and the axillary area will be assessed for visible signs of any skin conditions. If there are no visible signs of a skin condition the researcher will apply the Temp-Traq thermometer to the right or left axilla of the subject and record the location of the placement. The researcher will record both the PA and Temp-Traq recordings of subject's temperature (taken at the same time) on the data collection form (see attachment) at four data points; baseline (5 minutes post application of Temp-Traq) and every two hours (+/- 15 minutes) after baseline X 3 (See Protocol attachment). Previous testing of the TempTraq® on children and healthy adults has not resulted in any adverse skin reactions. However, as this is a new thermometer format and there is not a significant body of literature on potential skin reactions, we will assess skin before and after application. Thus, at the end of the last reading the Temp-Traq thermometer will be removed and the skin will be assessed for erythema. If erythema is present the patient's nurse and physician will be notified by the researcher.

Protection of Human Subjects

Since non-invasive temperature monitoring poses no risk to patients and is part of usual care and since we will not collect or record any protected health information (PHI), written informed consent will not be sought. Patients will be identified by their study ID number only. The data will be collected by a registered nurse data collector familiar with the intensive care setting and data will be stored in a locked file cabinet in the researchers locked office. Temperature data for the Temp-Traq is collected through the Temp-Traq Application (AP) which will be placed on a Cleveland Clinic Approved and encrypted i-pad. Once the study is completed and all data has been transferred to the study database, the Temp-Traq application and all of its data will be deleted from the i-pad.

Analysis

We will use the TOST (Two One Sided t-tests) method for equivalence testing. This method requires a defined range of mean differences between two test methods, an estimate of the precision of the measurement of the two systems, and an estimate of the size of the possible difference in the means of the two methods under consideration. The TOST null hypothesis is a joint null hypothesis that the mean measurement differences between the two methods is greater than a critical lower bound and less than a critical upper bound. If the null is rejected then we can conclude that the absolute difference of the means for the two groups falls within the specified range. It was determined that to be considered equivalent with respect to accuracy the mean

measurements of the two methods should be within ± 0.2 degrees of each other. Precision tests for Temp-Traq thermometer using accepted ASTM test methods for various combinations of temperature and humidity provided a range of measurement variation between .0000435 and .019928 with a mean of 0.000254500. If we assume both test methods exhibit the same levels of precision then the variance of the differences between their two means will reduce to two times the values listed previously. This will result in estimates of the standard deviations of the mean differences of .0093, .032, and .063 respectively.

The two methods for body temperature that will be examined are core temperature measurements with a PA catheter and temperature measurements using the Temp-Traq. Paired temperature measurements for both methods will be taken simultaneously every 2 hours for a 6 hour period. This will provide 4 repeated temperature measures per patient. The simultaneous measurements within a given patient should exhibit a high degree of correlation. If .7 is chosen as the lower bound for the correlation between the paired readings (higher correlations would result in an estimate of fewer patient samples thus the choice of .7 is conservative) and if the average standard deviation of the mean of the differences is used as an estimate of the expected variability, then it would be possible to declare measurement equivalence for a difference of ±.19 with a sample size of 40 patients. This assumes the ASTM measurements of instrument variation are representative of the within patient variance. Given the vagaries of patient-to-patient this may be too optimistic an estimate. Table 1 (attached) is a summary of patient sample sizes for standard deviations equal to the average standard deviation and for 5 and 10 fold increases in this value.

A sample size of 40 patients will provide 80% or greater power for testing for equivalence between methods where the mean difference is .1 or less for up to a ten-fold increase in the estimates of the variability of the differences based on the ASTM precision measures and for a mean difference of .15 for up to a five-fold increase in these same measures. If the sample size is 40 then the power for the test of equivalence, where the difference is .15 and the standard deviation is a ten-fold increase, is 35%. Agreement testing: The Bland-Altman test will be used to test the agreement of the two methods. This test will permit a check for significance of bias between the two measures (the average difference between the two measures) as well as a check for significant trending over the range of the measurements. If the bias is significant then the results of the two differ by an overall offset in their measurements. If the trending (slope of the regression line) is significant then the difference between the two measurements changes as their magnitude changes which means the two methods are not in agreement.

The only measurements of instrument precision are those provided by the ASTM assessment. It is reasonable to assume the within patient measurement variation will be greater than the measurements from the controlled testing. A sample size of 40 patients is, from a statistical standpoint, a reasonable number and, as indicated in Table 1, this sample size provides acceptable power for a mean difference of .1 for a ten-fold increase in the estimate of minimum test variability. This sample size will also provide enough data for the Bland-Altman test for agreement.

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