Evaluating the Accuracy of Four Temperature Instruments on an Adult Inpatient Oncology Unit

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Accurate determination of temperature in patients with cancer is important because treatment decisions often are based on such information. A reliable temperature reading is critical and may make the difference between sending a patient home from a physician's office or drawing blood cultures, administering antibiotics, and admitting a patient to the hospital. Noninvasive sites to measure temperature are oral, axillary, tympanic, and temporal artery. Use of an electronic probe with a disposable cover is the most common method for oral temperature measurement (Lippincott's nursing procedures, 2008). Oral temperature also can be measured with a disposable device that has heat-sensitive dots on a plastic strip that change colors at different levels of temperature. The devices commonly are used for patients who require isolation.

Two methods for temperature monitoring that often are advocated for use in oncology patients with mucositis are tympanic and temporal artery thermometers. Both devices use an infrared heat scanner, which is placed into the ear canal (tympanic) or lightly pressed against the forehead during movement of the temporal artery area.

Research has supported that electronic oral thermometers have a high level of agreement with core body temperatures when compared with invasive thermometry (Erickson & Meyer, 1994; Giuliano, Scott, Elliot, & Giuliano, 1999; Lawson et al., 2007). Studies of tympanic thermometers support that the devices are unreliable for temperature monitoring, primarily because of poor reliability among users and with repeated measurements by the same user (Erickson & Woo, 1994; Giuliano et al.; Klein et al., 1993; Lawson et al.). Despite their poor performance in clinical studies, tympanic thermometers continue to be used in a variety of clinical practice situations.

Limited research is available on the accuracy of temporal artery thermometers (Callahan, 2003; Frommelt, Ott, & Hays, 2008; Greenes & Fleisher, 2001; Hebbar, Fortenberry, Rogers, Merritt, & Easley, 2005; Lawson et al., 2007; Roy, Powell, & Gerson, 2003; Schuh et al., 2004; Siberry, Diener-West, Schappell, & Karron, 2002), and most of the studies were performed in children (Callahan; Greenes & Fleisher; Hebbar et al.; Roy et al.; Schuh et al.; Siberry et al.) or had inappropriate statistical analyses (Greenes & Fleisher; Roy et al.). Similarly, limited studies have evaluated performance of disposable oral thermometers (Erickson, Meyer, & Woo, 1996; Potter, Schallom, Davis, Sona, & McSweeney, 2003).

Given the paucity of studies of temporal artery and disposable oral thermometers performed to date on adults, additional studies are needed to validate their use in adult inpatient care situations. The purpose of the current study was to compare different methods for noninvasive measurement of temperature in patients with cancer. Temperature devices studied were a disposable oral thermometer frequently used for patients in isolation, a tympanic thermometer, and a temporal artery thermometer.

Materials and Methods

The study was conducted on a 19-bed oncology unit of a 485-bed not-for-profit hospital in the Pacific Northwest region of the United States and was approved by the health system's institutional review board.

Study Design

A method-comparison design was used to evaluate different methods for temperature monitoring (disposable oral, tympanic, and temporal artery), with an electronic oral temperature serving as the clinical reference standard. Each subject served as his or her own control. The primary dependent variable was the difference in temperature indicated by each test temperature device from the electronic oral temperature reference standard. The
order of temperature measurement was assigned randomly by a computer-generated randomization scheme.

Sample Selection

Subjects for the study were a convenience sample of adult patients with cancer on an inpatient unit. Inclusion criteria were patients aged 18–85 years who did not smoke, eat, or drink within 15 minutes prior to data collection. Exclusion criteria were patients in the comfort care or hospice care program and those who had an oral abscess or severe mucositis.

Instruments

The following instruments were used in the study.

- Oral electronic thermometer (reference standard): Vital Signs Monitor 300 (Welch Allen Inc.). Manufacturer’s specifications indicate a range of 80°F–110°F, with calibration accuracy (or drift) of ± 0.2°F.
- Oral disposable thermometer: 3MTM Tempa-DOTs™ (Model #5122, 3M Health Care). Manufacturer’s specifications indicate a range of 96°F–104.8°F, with calibration accuracy of ± 0.2°F.
- Tympanic thermometer: First Temp 3000A (Sherwood Medical). Manufacturer’s specifications indicate a range of 77°F–110°F, with calibration accuracy of ± 0.2°F.
- Temporal artery thermometer: Exergen Model #TAT 5000 (Exergen). Manufacturer’s specifications indicate a range of 61°F–110°F, with calibration accuracy of ± 0.2°F.

Study Procedure

Prior to data collection, all nondisposable temperature devices were tested by the biomedical engineers at the institution to ensure compliance with manufacturers’ guidelines. For nondisposable devices, temperatures for the study were taken with a single device dedicated to data collection only and not used in routine patient care. For disposable oral temperature devices, care was taken to use devices from the same manufacturer’s lot number. All investigators were trained in the proper use of each of the temperature devices, using the manufacturers’ recommended procedures. Only investigators (a total of six individuals) collected temperatures for the study.

After providing informed consent, subjects had sequential temperature measurements with four noninvasive temperature devices (electronic oral, disposable oral, tympanic, and temporal artery thermometers) during a regularly scheduled time for temperature measurement. The order of device use was determined by computer randomization, with electronic oral temperature always measured after the completion of the test temperature device measurement. Each temperature measurement was recorded prior to measurements with the other devices.

Data Analysis

Data were summarized with descriptive statistics. Analysis of variance for repeated measures was used to determine the difference among temperatures obtained with each of the three test temperature devices and the reference standard temperature device (electronic oral). Bonferroni’s multiple comparison test was used to determine specific group differences. Differences and limits of agreement among the test temperature devices and the reference standard device were calculated with the Bland-Altman method (Bland & Altman, 1986, 1995; Chatburn, 1996; Flemons & Littner, 2003; Hanneman, 2008; Szafarski & Slaughter, 1996). Multiple regression analysis was used to determine whether body temperature explained variances among the test temperature devices and the oral temperature reference standard. The level of significance for all statistical analyses was p < 0.05.

Results

A total of 60 subjects were studied (35 men and 25 women). Patient characteristics are presented in Table 1. Ages of the subjects ranged from 23–79 years, with an average age of 56.2 years (SD = 12.9 years). Temperatures ranged from 97.3°F–103.0°F, with an average of 99.0°F (SD = 1.1°F) (see Table 2). Fifteen of the 60 patients studied had temperatures above normal (higher than 99.8°F).

Differences and limits of agreement among the test temperatures (disposable oral, tympanic, temporal artery) and reference standard (electronic oral) temperatures were 0.39°F (SD = 1.01°F) (bias ± precision) for the tympanic device, 0.00°F (SD = 0.92°F) for the disposable oral device, and 0.68°F (SD = 0.99°F) for the temporal artery device (see Figure 1 and Table 2). Bias is the average difference between a test and reference standard.

The percentage of subjects who had a 1.0°F difference or more between the electronic oral thermometer and the test thermometer were 38% (n = 23), 30% (n = 18), and 43% (n = 26) for the tympanic, disposable oral, and temporal artery devices, respectively. The percentage of subjects who had 2°F difference or more between the electronic oral thermom-

### Table 1. Sample Demographics

<table>
<thead>
<tr>
<th>CHARACTERISTIC</th>
<th>n</th>
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<tbody>
<tr>
<td><strong>Admission diagnosis</strong></td>
<td></td>
</tr>
<tr>
<td>Interleukin-2 biochemotherapy</td>
<td>18</td>
</tr>
<tr>
<td>Acute myelogenous leukemia</td>
<td>6</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>3</td>
</tr>
<tr>
<td>Malignant melanoma</td>
<td>3</td>
</tr>
<tr>
<td>Intractable nausea and vomiting</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>27</td>
</tr>
<tr>
<td><strong>Age (years)</strong></td>
<td></td>
</tr>
<tr>
<td>( \bar{X} = 56.2 )</td>
<td>–</td>
</tr>
<tr>
<td>SD = 12.9</td>
<td>–</td>
</tr>
<tr>
<td>Range = 23–79</td>
<td>–</td>
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<tr>
<td><strong>Order of testing of temperature devices</strong></td>
<td></td>
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<tr>
<td>Group 1: tympanic, temporal artery, disposable oral, electronic oral</td>
<td>17</td>
</tr>
<tr>
<td>Group 2: temporal artery, disposable oral, tympanic, electronic oral</td>
<td>24</td>
</tr>
<tr>
<td>Group 3: disposable oral, tympanic, temporal artery, electronic oral</td>
<td>19</td>
</tr>
<tr>
<td>( N = 60 )</td>
<td></td>
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</tbody>
</table>
eter and the test thermometer were 7\% (n = 4), 3\% (n = 2), and 8\% (n = 5) for the tympanic, disposable oral, and temporal artery devices, respectively.

Significant differences were found among the temperature devices ($F_{1, 171} = 12.51$, p < 0.0001) but not for the order of temperature device testing ($F_{1, 171} = 0.535$, p = 0.59). Multiple comparison testing found a significant difference between the tympanic and temporal artery temperature devices and the reference temperature device (p = 0.003 and p < 0.0001, respectively). No significant difference was found between the disposable oral and reference temperature devices (p > 0.05). Multiple regression analysis did not find that the level of body temperature explained the differences between the test and reference thermometers (tympanic $F_{1, 59} = 0.24$, p = 0.88; disposable oral $F_{1, 59} = 0.10$, p = 0.76). Post hoc power analysis for repeated-measures analysis of variance found power of the study to be 0.87 (Foul & Erdfleder, n.d.), indicating that the sample size was adequate.

### Discussion

The current study evaluated the level of agreement among several different types of noninvasive thermometers used for patients with cancer and found that only one of the devices studied, a disposable oral thermometer, did not have significant differences from electronic oral thermometer temperatures. The tympanic and temporal artery thermometers produced statistically significant differences than the electronic oral thermometer. Large discrepancies in temperatures (2ºF or more) were found among the electronic oral and temporal artery (8\%) and tympanic (7\%) thermometers.

### Accuracy of Tympanic Thermometers

The vast majority of studies on the accuracy of tympanic thermometry which used appropriate statistical analyses have found significant statistical and clinical differences between tympanic thermometers and reference standard comparisons (Erickson & Meyer, 1994; Erickson & Woo, 1994; Giuliano et al., 1999; Klein et al., 1993; Lawson et al., 2007). The current study also found significant differences from electronic oral temperatures, as well as quantified the number of temperature differences that were at least 2ºF different than the reference standard (8\% of the temperatures). The results highlight that continued use of tympanic thermometry in acute-care patients, especially neutropenic patients, is inappropriate if temperature accuracy is important.

### Accuracy of Temporal Artery Thermometers

Limited clinical studies are available on the accuracy of temporal artery thermometers (Callahan, 2003; Frommelt et al., 2008; Greenes & Fleisher, 2001; Hebbar et al., 2005; Lawson et al., 2007; Roy et al., 2003; Schuh et al., 2004; Siberry et al., 2002), with the majority of the studies conducted in children (Callahan; Greenes & Fleisher; Hebbar et al.; Roy et al.; Schuh et al.; Siberry et al.) or afebrile patients (Callahan; Frommelt et al.; Greenes & Fleisher; Roy et al.). Generalization of the findings of some of the studies is not possible because of methodologic problems associated with each study, including inadequate statistical analyses (Greenes & Fleisher; Roy et al.) and inadequate reporting of study methods (Callahan). Of the remaining studies (Frommelt et al.; Hebbar et al.; Lawson et al.; Schuh et al.; Siberry et al.), all but two (Frommelt et al.; Lawson et al.) were conducted in infants or small children and had findings similar to the current study of significant differences between the temporal artery device and the reference standard.

Several of the pediatric studies included febrile subjects (Hebbar et al., 2005; Schuh et al., 2004; Siberry et al., 2002). One study reported that 32\% of febrile subjects had a 1.4ºC or higher difference between the temporal artery and rectal temperatures, with 5\% of the febrile subjects having more than 2.6º C differences (Schuh et al.). To the authors’ knowledge, the current study is the first to include febrile subjects in the evaluation of the temporal artery thermometer in adults. Regression analysis, though, failed to find that the level of body temperature explained differences between the electronic oral and temporal artery thermometers. Because the number of febrile patients in the current study was limited (n = 15) and only a few subjects (n = 3) had temperatures of 101.0ºF or higher, the lack of significance could be because of the small sample size for febrile subjects or because no differences existed.

None of the well-designed clinical studies to date that evaluated the temporal artery thermometer has recommended the clinical use of the device in children (Hebbar et al., 2005; Schuh et al., 2004; Siberry et al., 2002). The current study’s findings of significant differences between the temporal artery and reference temperature supports the results and conclusions of the two studies of adults published to date (Frommelt et al., 2008; Lawson et al., 2007), extending the pediatric recommendation to adults. Additional studies are needed to confirm the findings in additional popula-

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**Table 2. Temperature Values Bias Precision Root-Mean-Square of the Differences (RMSD), Scores, and Percentage of Temperature Differences From the Clinical Reference Standard**

<table>
<thead>
<tr>
<th>DEVICE</th>
<th>RANGE</th>
<th>$\bar{X} \pm SD$</th>
<th>BIAS $^a$</th>
<th>PRECISION $^b$</th>
<th>RMSD</th>
<th>DIFFERENCE OF 2ºF OR MORE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral electronic (reference standard)</td>
<td>97.3–103.0</td>
<td>99.0 ± 1.1</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Tympanic</td>
<td>96.0–104.4</td>
<td>99.4 ± 1.5</td>
<td>0.39</td>
<td>1.01</td>
<td>1.08</td>
<td>7</td>
</tr>
<tr>
<td>Disposable oral</td>
<td>96.0–104.6</td>
<td>99.0 ± 1.5</td>
<td>0.00</td>
<td>0.92</td>
<td>0.92</td>
<td>3</td>
</tr>
<tr>
<td>Temporal artery</td>
<td>96.7–104.9</td>
<td>99.7 ± 1.4</td>
<td>0.68</td>
<td>0.99</td>
<td>1.19</td>
<td>8</td>
</tr>
</tbody>
</table>

N = 60

$^a$ Difference scores (test temperature device—reference standard)

$^b$ SD of the bias
tions, particularly acute-care patients with abnormal body temperatures. To date, no published clinical studies have evaluated device performance during hypothermia in children or adults. The reasons the temporal artery device is not as accurate in febrile as afebrile pediatric patients are not clear. The differences may be related to changes in forehead skin vasculature associated with fevers, such as vasodilation or diaphoresis. In hypothermic body temperatures, changes in skin vasculature, such as vasoconstriction, also may lead to greater inaccuracy of the device. Prior to use of temporal artery thermometers in pediatric and adult patients with hypothermia (e.g., postanesthesia, cardiac surgery, medically induced hypothermia after cardiac arrest, environmental exposure), or in adult patients with hyperthermia, additional studies are needed to determine device performance in such conditions.

Accuracy of Disposable Thermometers

Despite the frequency of use of disposable thermometers in hospitals for patients on isolation precautions, studies of disposable thermometers with appropriate statistical analysis of the data and methodologic rigor are few in number (Erickson et al., 1996; Potter et al., 2005). The brand and manufacturer of the disposable oral temperature devices tested in the current study were similar to those studies. The current findings are similar to the differences (bias) and limits of agreement (+2 SD) between the disposable oral and the reference standard (electronic oral) temperatures found in those studies.

One of the limitations to use of disposable thermometers is the potential for errors to occur during reading of measurements. The dots representing the different temperature levels on the disposable device are closely aligned and do not have numeric markings for each temperature dot, making interpretation of exact temperatures difficult. A recent study of clinicians’ ability to correctly interpret temperatures indicated by the dots found that fewer than 50% of the staff could identify the correct temperatures on the Tempa-DOTs device, despite having used the thermometer clinically for more than three years (Creagh-Brown, James, & Jackson, 2005). Data collectors in the current study made no anecdotal reports of that problem; however, other studies have identified reports of user difficulties, despite careful training of the investigators (Frommelt et al., 2008).

Based on the reports of errors or difficulties visualizing correct temperatures with the Tempa-DOTs device, carefully educating staff about the potential problem and validating that staff can correctly identify correct temperature readings would be prudent.

Study Limitations

Although some aspects of the current study’s design attempted to replicate conditions common in actual clinical practice (e.g., having more than one person perform data collection), the researchers did limit the number of researchers to six people, all of whom were highly trained prior to data collection on the proper use of the temperature devices. The researchers also used only one temperature device for each type of device being tested, which is not similar to actual practices of having multiple devices on a unit available for temperature monitoring. In addition, the study devices were restricted to study data collection and were not used in normal therapeutic care conditions. Although those methods improved study control and decreased errors associated with medical device use, they do not reflect conditions of usual device use and, thus, may underestimate device performance in actual clinical conditions. Another limitation of the current study was the limited number of subjects with febrile conditions (only five subjects had temperatures higher than 100.3°F).

Future studies on the temporal artery and disposable oral thermometers should include subjects with alterations in body temperatures (i.e., hypothermia and hyperthermia). Additionally, studies should be conducted using methods that mimic the realities of how temperatures normally are obtained in acute-care patient situations, such as inclusion of large numbers of individuals collecting data and unlicensed personnel. Having information on device performance under pristine, well-controlled circumstances is important, but also important is having studies that provide information on device performance under conditions common in actual patient-care situations.

Clinical Implications

The temperatures obtained with oral disposable thermometers were fairly similar to those obtained with electronic oral thermometers; thus, disposable oral thermometers are a reasonable substitute when use of electronic oral thermometers is not feasible (e.g., patients in isolation). Tympanic and temporal artery thermometers have significant statistical and clinical differences from electronic oral thermometers and should not be used when accurate temperature determination is desired. Seven and eight percent of temperatures obtained with the devices
were at least 2°F different from electronic oral temperatures. Because no studies of adults have been published on device accuracy in situations of hypothermic or hyperthermic body temperature, the devices should not be used in such circumstances until additional studies are conducted to determine device performance in those clinical situations.

The findings of inaccuracy with the temporal artery and tympanic thermometers leave few options for the noninvasive measurement of temperatures in patients with cancer. At this time, the only reliable, noninvasive thermometers for acute-care use are electronic oral thermometers and disposable thermometers. Many patients with cancer have mucositis and discomfort during oral thermometry, so having a different site for temperature monitoring that is accurate and avoids patient discomfort or complications would be ideal. Although limited research has been conducted on devices placed on the skin and left in place for temperature monitoring (Lees et al., 1978; Martyn, Urbano, Hayes, von Windeguth, & Sherrin, 1988), that may be a potential alternative method for temperature monitoring. Additional studies are needed to validate their accuracy in adult patients with normal and abnormal temperature states.

Conclusions

This study found that temperatures measured with temporal artery and tympanic thermometers had statistically and clinically significant differences from temperatures taken with an electronic oral thermometer in patients with cancer. Nonsignificant differences were found between the disposable oral thermometer and the electronic oral thermometer. Based on the results, the performance of temporal artery and tympanic thermometers is not adequate for use in acute-care patient situations that require accurate temperatures for patient-care management.

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