Accuracy of a Noninvasive Temporal Artery Thermometer for Use in Infants

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Objectives: To assess the accuracy of a new noninvasive temporal artery (TA) thermometer in infants; to compare the accuracy of the TA thermometer with that of a tympanic thermometer, using rectal thermometry as the criterion standard; and to compare the tolerability of the TA thermometer with that of the tympanic and rectal thermometers.

Design: Prospective evaluation of the accuracy of TA and tympanic thermometry, using rectal thermometry as the criterion standard.

Setting: Emergency department of an urban pediatric hospital.

Subjects: Convenience sample of 304 infants younger than 1 year presenting for care.

Main Outcome Measures: Temperatures were measured using TA, tympanic, and rectal thermometers for all infants. Agreement between TA or tympanic and rectal temperatures was assessed. The sensitivity and specificity of TA or tympanic thermometers for detecting rectal fever were determined. Discomfort scores, using a standardized scale, were assessed by trained observers after each temperature measurement was made.

Results: Linear regression analysis of the relation between TA and rectal temperatures yielded a model with a slope of 0.79 (vs a slope of 0.68 for tympanic vs rectal temperature; \( P=.02 \)) and an \( r \) of 0.83 (vs \( r = 0.75 \) for tympanic vs rectal temperature; \( P < .001 \)). Among 109 patients with a rectal temperature of 38°C or higher, the TA thermometer had a sensitivity of 0.66 compared with the tympanic thermometer's sensitivity of 0.49 (\( P < .001 \)). Discomfort scores with TA thermometry were significantly lower than with rectal thermometry (\( P = .007 \)).

Conclusions: The TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry.

Rectal thermometry has generally been considered the standard for measurement of temperature in infants. Published guidelines for the management of febrile infants have based their recommendations on measurement of rectal temperature, and other thermometry methods have generally been evaluated with rectal temperature as the criterion standard.

Although rectal thermometry has evolved as the standard, it has several disadvantages, including discomfort for the patient, emotional upset for the patient and parent, risk for traumatic injury to the rectum, and transmission of stoolborne pathogens. Several alternative methods of thermometry, which eliminate the problems inherent in rectal thermometry, have been shown to have limited value in other regards. Axillary and supralingual thermometers have generally proven too inaccurate for routine clinical use. Tympanic thermometers, although popular with patients and parents and fairly reliable in adults, have not proven adequate for infants and young children. Thus, a continued need exists for a form of thermometry that is as well tolerated as the tympanic technique but gives results that closely agree with rectal temperature.

The purpose of this study was to evaluate the performance of a new noninvasive temporal artery (TA) thermometer for clinical use in infants. Our objectives were (1) to evaluate the accuracy of the TA thermometer, using rectal temperature as the criterion standard; (2) to compare the accuracy of the TA thermometer with that of a tympanic thermom-
PATIENTS AND METHODS

PATIENT SELECTION

We performed a prospective study of a convenience sample of infants presenting to the triage area of an emergency department in a tertiary care pediatric hospital. Children were eligible for inclusion in the study if they were younger than 1 year. Children were excluded if they had any medical condition that contraindicated the use of a rectal, tympanic, or TA thermometer. Children were also excluded if they were too ill to remain at triage for an initial assessment before proceeding to a treatment room.

Patients were enrolled during shifts when trained research assistants were available. During these shifts, the research assistants attempted to enroll all eligible patients. Our study was approved by the Committee on Clinical Investigation of Children's Hospital, Boston, Mass. The committee required that verbal consent be obtained from the parents of study subjects.

THERMOMETRY MEASUREMENTS

On arrival to the triage area of the emergency department, patients and their families were invited to participate in the study. After oral consent was obtained, 4 successive temperature measurements were made, including a rectal temperature, a tympanic temperature, and left- and right-sided TA temperatures. Rectal temperatures were measured using the Diatemp electronic thermometer (Welch Allyn Inc, Skaneateles Falls, NY). Tympanic temperatures were measured using the First Temp Genius tympanic thermometer (Sherwood Medical, St Louis, MO). Both thermometers are used for routine clinical care in our hospital and were maintained by the hospital's medical engineering department. Left- and right-sided TA temperatures were measured using the Exergen TempScan Temporal Artery Thermometer (model LXTA) (Exergen Corp, Watertown, Mass).

The TA thermometer is a handheld device that is operated by placing its probe on the patient's forehead and then sweeping it laterally until the hairline of the temporal scalp is reached. The device continually measures surface temperature as it moves along its path and assumes the highest temperature recorded to be the TA temperature. Using a simultaneous measure of ambient temperature from a separate thermistor, the device calculates the patient's core temperature and instantaneously reports this calculated temperature.

All temperatures were measured by trained research assistants. These assistants were trained by the nursing staff of our emergency department to use the rectal and tympanic thermometers, and they were certified by the nursing department so that their measurements could be used in the clinical care of patients. Representatives from Exergen trained the assistants in the use of the TA thermometer. During a pilot phase, the assistants had several days of practice sessions, in which their thermometry technique and results were reviewed by the authors and representatives from Exergen, before data collection began.

Research assistants were instructed to make each measurement only once. Only when there were obvious mechanical failures (eg, the patients pulled their heads away during the process) were the research assistants allowed to repeat measurements with any of the thermometers. Research assistants were told not to consider the measured temperature reading in determining whether a measurement needed to be repeated. Conditions that appeared to the research assistants to make a measurement unreliable were reviewed by the authors and representatives from Exergen, before data collection began.

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During the 3-month study period, 304 patients were enrolled, of whom 109 (36%) had rectal fever and 49 (16%) had high rectal fever. Rectal temperature was 37.9°C±1.0°C (mean±SD), with a range of 33.7°C to 40.7°C. Temporal artery temperature was 37.6°C±0.9°C, with a range of 35.9°C to 40.7°C. Tympanic temperature was 37.1°C±0.9°C, with a range of 35.0°C to 39.9°C.

AGREEMENT BETWEEN LEFT- AND RIGHT-SIDED TA TEMPERATURES

For the purpose of this subanalysis, 44 patients were excluded because the research assistants noted that either the left- or right-sided TA temperature measurements were potentially unreliable. Among the remaining 260 patients, the mean±SD left-right difference was 0°C±0.39°C, with a range of −1.3°C to 1.0°C. The r between left- and right-sided TA temperatures was 0.91. A paired sample t test found no significant difference between left- and right-sided TA temperatures (P = .59).

AGREEMENT BETWEEN TA OR TYMpanic AND RECTAL TEMPERATURES

For all remaining analyses, all 304 patients were included. Linear regression analysis of the relation between TA temperature and rectal temperature (Figure 1) yielded a model with a slope of 0.79 and an r of 0.83. Linear regression analysis of the relation between tympanic temperature and rectal temperature (Figure 2) yielded a model with a slope of 0.68 and an r of 0.75. Both slopes were significantly different from 1 (P < .001), indicating that neither tympanic nor TA temperature was equivalent to rectal temperature.

The slopes generated for the 2 curves differed significantly from one another (P = .02), indicating that TA temperature was significantly closer to equivalence with rectal temperature than was tympanic temperature. Comparison of the correlation coefficients from the 2 models using the Fischer z transform showed significantly closer correlation between TA and rectal temperature than between tympanic and rectal temperature (P = .006).
DISCOMFORT ASSESSMENTS

To assess the experience of children with thermometry, a semiquantitative discomfort scale was used. The scale, adapted from the work by Shane et al., is shown in Table 1. Research assistants were asked to assess behavior of the patients and to assign a discomfort score immediately after measuring the rectal, tympanic, and left-sided TA temperatures.

To ensure that the behavioral responses recorded after the use of a given thermometer would not be influenced substantially by the preceding measurements, the order of routes was varied from patient to patient. The right-sided TA temperature was always the fourth measurement made. The order of the other 3 measurements was dictated by a preprinted data collection form. The data collection form for each patient was taken blindly from the top of a shuffled stack of data forms after the patient consented to enrollment.

DATA ANALYSIS

Reproducibility of TA temperature was assessed by performing a paired sample $t$ test and calculating a correlation coefficient for the relation between left- and right-sided TA temperatures. For the purpose of this analysis, cases in which 1 of the 2 TA measurements was noted to be unreliable were excluded.

To evaluate the accuracy of TA and tympanic thermometry, rectal temperature was considered the criterion standard. Both TA temperature and tympanic temperature were assessed for their ability to predict rectal temperature. In doing this analysis, left-sided TA temperature was used as the representative TA temperature. In cases in which the left-sided TA temperature was noted to be unreliable, right-sided temperatures were used.

Linear regression analysis was performed and correlation coefficients were calculated for the relation between TA and rectal temperature and for the relation between tympanic and rectal temperature. In addition, $t$ tests were performed to compare the slopes of each of the 2 lines generated by the linear regression models to a value of 1 to determine whether TA or tympanic temperature readings were equivalent to rectal temperatures. The slopes of the 2 lines generated were compared with one another using a $t$ test as well. Correlation coefficients were compared using the Fischer $z$ transform technique.

Patients with a rectal temperature of $38^\circ C$ or higher were considered to have rectal fever, and those with a rectal temperature of $39^\circ C$ or higher were considered to have high rectal fever. The sensitivity and specificity of tympanic and TA thermometers for detecting temperatures of $38^\circ C$ or higher in cases of rectal fever were calculated. The sensitivities of tympanic and TA thermometers for detecting temperatures of $38^\circ C$ or higher in cases of high rectal fever were calculated separately. Sensitivities and specificities of the 2 thermometry methods were compared with one another using the McNemar test. When comparisons showed no significant differences between the 2 thermometry methods, post hoc power calculations were performed.

Discomfort scores for each of the 3 methods were compared with one another using the Wilcoxon signed rank test. Because multiple (3) comparisons were done in assessing discomfort scores, a Bonferroni correction was used, with $P \leq .017$ considered significant for this analysis.

Statistical analysis was performed using the Statistical Program for the Social Sciences, version 6.0 for Windows (SPSS Inc, Chicago, Ill), and the Stata statistical package for Windows (Stata Inc, College Station, Tex).

SENSITIVITY AND SPECIFICITY

The sensitivities of the TA and tympanic thermometers for detecting fever in patients with rectal fever (temperature $\geq 38^\circ C$ or high rectal fever (temperature $\geq 39^\circ C$) are shown in Table 2. Using the McNemar test, we found the TA thermometer to be significantly more sensitive than the tympanic thermometer for detecting rectal fever ($P < .001$) and high rectal fever ($P = .004$).

The specificities of the TA and tympanic thermometers in patients with no rectal fever are shown in Table 2. Using the McNemar test, we found no significant difference between the specificity of the tympanic and TA thermometers ($P = .07$). A post hoc power calculation indicated that our study had a power of 0.35 for detecting a statistically significant difference between 2 thermometry methods with the measured specificities.

DISCOMFORT SCORES

The median discomfort score for the rectal thermometer was 3, with a range of 1 to 5. For both the tympanic and TA thermometers, the median discomfort score was 2, with a range of 1 to 5. The tympanic thermometer was associated with significantly lower discomfort scores than the rectal thermometer ($P < .001$). The TA thermometer was also associated with significantly lower discomfort scores than the rectal thermometer ($P = .007$).

We have found the TA thermometer to be significantly more accurate than the tympanic thermometer for predicting rectal temperature in infants. The TA thermometer is significantly more sensitive than the tympanic thermometer for the detection of rectal fever in infants. In addition, the TA thermometer is better tolerated by patients than the rectal thermometer.

Previous investigations have also suggested that tympanic thermometry is a poor predictor of rectal temperature in infants. Brennan et al found that tympanic thermometry had a sensitivity of only 0.76 for detecting rectal fever in children 6 months to 6 years of age. Hooker reported that tympanic thermometers had a sensitivity of 0.67 for detecting rectal fever in patients younger than 6 years. Muma et al reported that tympanic thermometers had a sensitivity of 0.55 for detecting fever in 87 children younger than 3 years.

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Our data suggest that TA thermometry is a better choice than tympanic thermometry for use in infants. However, TA thermometry does not reliably predict rectal temperature in all clinical situations. Thirty-five percent of all cases of rectal fever and 6% of cases of high-grade rectal fever were missed by the TA thermometer.

One limitation of our study is that we do not have a true measure of core body temperature to use as a criterion standard. In the literature, esophageal or pulmonary artery (PA) temperatures are generally considered to be true measures of core body temperature. Several published investigations have evaluated the accuracy of rectal thermometry as an indicator of core body temperature compared with these invasive methods. Some early studies of the physiology of human body temperature suggested a lag between instantaneous changes in core body temperature and more delayed changes in rectal temperature. It is possible, therefore, that in cases with large discrepancies between TA and rectal measurements, the TA thermometer may be correctly reflecting a rapid change in core body temperature, whereas the rectal temperature is lagging behind. For instance, if antipyretics had been given several minutes before the temperatures were measured, the TA temperature might accurately reflect a lowered core body temperature, while the rectal temperature still reflects the preceding fever. Future studies evaluating the changes in TA and rectal temperatures in response to changes in core body temperature would be of interest.

Although we must acknowledge this theoretical limitation, the bulk of the published literature suggests that rectal thermometry is the best available noninvasive indicator of core body temperature. In a study of 16 adults admitted to an intensive care unit (ICU), Stavem et al reported better agreement between rectal and PA temperatures than between tympanic and PA temperatures. Similarly, Schmitz et al reported that rectal temperatures were a better predictor of PA temperatures than were oral, tympanic, or axillary temperatures in 13 adult patients in an ICU. In a study of 20 patients in a pediatric ICU, Romano et al found that rectal thermometry had less bias and variability than tympanic or axillary thermometers in predicting PA temperature. In a study of 9 adult patients in an ICU, Milewski et al found a better correlation between rectal and PA temperature than between tympanic and PA temperature. Only Rotello et al, in a study of 20 adult patients in an ICU, found a closer agreement between tympanic temperature and PA temperature than between rectal and PA temperatures. Even in this study, however, there was less variability in the difference between rectal and PA temperatures than in the difference between tympanic and PA temperatures.

Table 1. Infant Discomfort Scale

<table>
<thead>
<tr>
<th>Score</th>
<th>Description of Behavior</th>
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<tbody>
<tr>
<td>1</td>
<td>Drowsy/asleep Eyes closed, may respond to stimulation, accepts intervention passively</td>
</tr>
<tr>
<td>2</td>
<td>Relaxed Sitting or lying with eyes open, accepts intervention readily</td>
</tr>
<tr>
<td>3</td>
<td>Anxious Verbally or nonverbally seeks support but accepts intervention reluctantly</td>
</tr>
<tr>
<td>4</td>
<td>Upset Tearful, may be clinging to parent, considerable effort required to achieve compliance with intervention</td>
</tr>
<tr>
<td>5</td>
<td>Agitated General loud or high-pitched crying, requires significant physical restraint, strongly refuses intervention</td>
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</tbody>
</table>

*Adapted from Shane et al.*

Figure 1. Scatterplot of rectal vs temporal artery (TA) temperatures.

Figure 2. Scatterplot of rectal vs tympanic temperatures.
Table 2. Sensitivity and Specificity of Temporal Artery and Tympanic Thermometers*

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
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<tbody>
<tr>
<td><strong>Device</strong></td>
<td></td>
<td></td>
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<tr>
<td>Temporal artery</td>
<td>0.66 (0.56-0.75)</td>
<td>0.94 (0.82-0.99)</td>
</tr>
<tr>
<td>Tympanic</td>
<td>0.49 (0.39-0.58)</td>
<td>0.76 (0.60-0.86)</td>
</tr>
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</table>

*CI indicates confidence interval.

Another limitation of our study is that we included only infants in our sample. Given that the tympanic thermometer has been shown to be especially unreliable in young infants, we caution the reader against extrapolating our findings to older children or adults. Future studies comparing the TA thermometer to the tympanic thermometer in older children or adults would be of interest.

We conclude that the TA thermometer has limited sensitivity for detecting cases of rectal fever in infants. However, the TA thermometer is more accurate than the tympanic thermometer in infants, and it is better tolerated by infants than rectal thermometry. Rectal thermometry should still be considered the preferred method for temperature measurement in infants. For clinicians who choose not to use rectal thermometry for infants, the TA thermometer appears to be a better alternative than the tympanic thermometer.

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REFERENCES


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