Innovation is Hot: Use of a Skin Patch Device to Obtain Temperature Measurements

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Background

Determination of body temperature is an important vital sign providing a quick indication of a person's general physical condition (McCann & Higgins, 2012). Numerous devices applied to varying body sites are available for measuring body temperature (Carr et al., 2011; Sund-Levander & Grodzinsky, 2013). An innovative temperature skin patch (TSP) device that provides continuous skin temperature measurements is now available (TempTRaq®) Continuous Temperature Monitoring. The TempTRaq is thin, disposable, flexible and battery-powered allowing wireless transmission to a personal device (e.g. smart phone, etc.).

This study was conducted in an adult population per IRB request and the results were submitted for review prior to studying the device in a pediatric patient population. Results of this testing were used to determine the risk of the device in a future study of pediatric patients.

Study Purpose and Aims

Purpose: To conduct preliminary testing of the device on adult volunteer participants to determine the accuracy and feasibility of the TempTRaq.

Aims 1. Compare body temperature measurements when obtained using a TempTRaq vs. a standard temperature measurement (i.e. oral, axillary)

2. Evaluate the feasibility of wireless continual TempTRaq temperature measurements

Methods

Design and Sample

• Descriptive, quantitative, comparative
• Convenience sampling of adult volunteer participants employed at study institution (n=31)
• Participants recruited prior to a training session (n=31)
• Data collection over 6 week period

Procedures

• TempTRaq device tested to verify no interference with operation of other medical equipment
• Participants completed written consent
• Provided participants written instructions
• Participants downloaded TempTRaq application to personal devices (Android or iOS operating systems)
• Encouraged to keep devices on person or nearby (within 20 feet)
• Device applied by participant
• Temperature measurements recorded prior to application of TempTRaq
• Oral and axillary measurements
• TempTRaq placed below armpit on lateral aspect of upper thorax under arm
• Continuous skin temperature measurements initiated upon application
• Procedure included measurements between 12-24 hours
• Temperature measurements recorded prior to removal of TempTRaq
• Oral and axillary methods
• Data collected
• Location of device placement
• Standard temperature measurements, time obtained and method
• Prior to application
• Prior to removal
• TempTRaq temperature measurements and time obtained
• Participants emailed TempTRaq readings to the investigator at removal
• Standard temperature measurements recorded every two minutes
• Descriptive user experience feedback regarding the TempTRaq device and data recordings

Analytical Plan

• Descriptive analysis and calculation of summary measures for TempTRaq data
• Repeated Measures Factorial (RMP-ANOVA) utilizing summary measures
• Agreement analysis utilizing a Bland-Altman plot
• Shukla’s Method for determination of precision equality between devices
• Analysis of agreement focus on summary measures

Results

Sample

• 31 participants met criteria for inclusion
• n=31

• 25 participants completed TempTRaq application

Device

The TempTRaq continually measures temperature, records every two minutes

Achieve Agreement & Precision

Table 1. Bland-Altman plot and Shukla’s Method Results

<table>
<thead>
<tr>
<th>Measurements</th>
<th>n</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>T</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TempTRaq vs. Oral</td>
<td>25</td>
<td>-0.36</td>
<td>-0.99</td>
<td>0.4</td>
<td>0.99</td>
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<tr>
<td>TempTRaq vs. Axillary</td>
<td>25</td>
<td>-0.53</td>
<td>-1.04</td>
<td>0.5</td>
<td>0.1</td>
</tr>
</tbody>
</table>

Conclusions

• TempTRaq continual measurements recorded every two minutes
• TempTRaq temperature measurements and time obtained
• Participants emailed TempTRaq readings to the investigator at removal
• Standard temperature measurements recorded every two minutes
• Descriptive user experience feedback regarding the TempTRaq device and data recordings

References
