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

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References:
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Abstract Summary:
Numerous devices are available to measure body temperature. An innovative, thin, disposable, flexible, battery-powered temperature skin patch that continuously measures and transmits skin temperature to a smart device was found feasible to use with no risks identified related to wearing the device or transmitting the temperature readings.

Learning Activity:

LEARNING OBJECTIVES	EXPANDED CONTENT OUTLINE
State the intended purpose of the skin thermometer patch	a. Background b. Study purpose
Describe the results of a seminal study of the skin patch thermometer.	a. Methods b. Results c. Future research d. Implications and Conclusion

Abstract Text:

Background

Determination of body temperature is an important vital sign providing a quick indication of a person's general physical condition. Numerous devices applied to varying body sites are available for measuring body temperature (Sund-Levander & Grodzinsky, 2013). An innovative, thin, disposable, flexible, battery-powered temperature skin patch (TSP) device that provides continuous skin temperature measurements is now available.

Study aims:

The primary aim of this study was to conduct preliminary testing of the device on adult volunteer subjects to determine the feasibility and accuracy of the TSP. Secondary aims were to: 1. compare body temperature measurements when obtained using a thermometer skin patch (TSP) vs a standard body temperature measurements (e.g. oral, temporal artery) and 2. evaluate the wireless transmission of continual TSP temperature measurements.

Methods

Design and sample

This descriptive study used a quantitative, comparative design with convenience sampling of volunteer adult participants. Participants were recruited in morning (~6:30-8:00am) and night (~6:30–8:00 pm) via announcements through hospital communications to staff. A total of 31 adult participants comprised of nurses, unit secretaries and respiratory therapists participated in the study. One participant who reported applying a thick, moisturizing body lotion prior to volunteering was removed from the study within the first hour of placement due to the patch not adhering resulting in a final sample of 30 participants for analysis.

Procedures

Participants provided consent and were given verbal instructions in addition to the TSP user manual. Participants downloaded the TSP application to their personal smart phone (android or iOS operating system) and were encouraged to keep their smartphones with them or nearby. Prior to the study being conducted, testing of the TSP device was performed to verify that it did not interfere with the operation of other medical equipment in use.

A TSP was placed below the axilla on the lateral aspect of the upper thorax under the arm with continuous skin temperature measurements beginning upon placement of the TSP. The majority of subjects (n=23, 79.3%) placed the TSP under the left axilla, five subjects (17.2%) placed it under the right axilla and one subject reported that the device had been placed under both the right and left axilla during the course of the study. Participants wore the TSP for 12-24 hours. At the time of TSP placement and prior to removal, temperature readings of were measured via oral, temporal artery and/or axillary method(s) including documentation of the temperature reading, time temperature obtained, and thermometry device used to obtain temperature. The participants e-mailed the TSP readings to the investigator following removal of the device and completed a form that provided feedback to their experience with the TSP device and data recordings.

Findings

There were 30 subjects who each had temperature measured by devices at multiple time points. Data was examined via repeated measures analysis as well as by summary measures. Comparison of TSP to oral and axillary temperature measurements at start, 4 hours, 8 hours and removal found no significant difference over time between the TSP and oral measurements (*p-value* = 0.25) or axillary measurements (*p-value* = 0.33). Repeated Measures Factorial ANOVA indicated no significant effect of time or method (*p-value*= 0.36 & 0.99 respectively).

The unbalanced design with missing data limited the value of repeated measures analysis. Given this plus the fact that there were no within subject differences or interactions noted, further analysis for assessment of agreement focuses on summary measures only.

A Bland-Aultman (needle) plot was created to assess the agreement betweenMean Traq Temp and Mean Oral Temp. Width of the 95% Confidence Interval (-1.26, 1.26) indicates poor agreement, while asymmetry around the 'zero difference' line indicates potential bias towards a higher oral reading. Shukla's method was employed to assess equality of precision between the two methods. A correlation coefficient was calculated for the sum (Mean Traq Temp + Mean Oral Temp) and difference (Mean Traq Temp - Mean Oral Temp). Results indicate that oral and temp traq methods are not equally precise (*rho* = 0.6, *p-value*< 0.001). Similar methodology was used for Mean Traq Temp and Mean Axi Temp. Width of the 95% Confidence Interval (-0.8, 0.8) indicates modest agreement, while asymmetry around the 'zero difference' line indicates potential bias towards a higher traq reading. Shukla's method was utilized and a correlation coefficient was calculated for the sum (Mean Traq Temp + Mean Axi Temp) and difference (Mean Traq Temp - Mean Axi Temp). Results indicate that oral and temp traq methods are equally precise (*rho* = -0.33, *p-value*= 0.07). For Mean Oral Temp and Mean Axi Temp the width of the 95% Confidence Interval (-1.1, 1.1) indicates magnitude of lack of agreement, while asymmetry around the 'zero difference' line indicates potential bias towards a higher axillary reading. From Shukla's method a correlation coefficient was calculated for the sum (Mean Oral Temp + Mean Axi Temp) and difference (Mean Axi Temp - Mean Oral Temp). Results indicate that oral and axillary methods are not equally precise (*rho* = -0.4, *p-value*= 0.03), although evidence is weak.

Continual temperature measurements transmission resulted TSP device temperature recordings every two minutes. User feedback responses to the experience description regarding read range indicated 12 participants offered a positive rating, 5 participants reported a negative experience and 14 did not respond to the question. The negative comments included connection issues with the device not syncing and displaying an out of range message. The positive comments described no issues with connectivity when phone was in the participants' pockets.

Twenty seven participants found it easy to apply the patch, three did not respond and one participant found it difficult to apply independently. Sixteen participants found the device comfortable to wear, ten found the device uncomfortable to wear and five participants did not respond. Five participants had adherence issues with the TSP device that did not prohibit them from completing the study. The majority of participants found the TSP mobile application user friendly.

Discussion and Conclusions

The study found the TSP feasible for use in the adult population and no risk was identified related to wearing the device or transmitting the temperature readings. Testing of the device on adult volunteer subjects was completed with no adverse events and with no significant difference over time between the TSP, oral or axillary measurements at start, 4 hours, 8 hours and at removal of the device. Agreement between oral and TSP findings indicate use of TSP is a viable alternative. This study was conducted in an adult population per IRB request and the results are being submitted for review prior to studying the device in a pediatric patient population. Results of this testing will be used to help determine the risk of the device in a future study in pediatric patients.