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ORIGINAL ARTICLE

Evaluation of commercial, wireless dermal thermometers for surrogate measurements of core temperature

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ABSTRACT

Extensive research has been devoted to developing methods for assessing core body temperature, and to determine which method is most accurate. A number of wireless dermal thermometers for home use are presently available, but their relation to core body temperature and suitability for use in clinical research has hitherto not been assessed. The current study aimed to evaluate such thermometers by comparing them to the results of a rectal thermometer. Four wireless dermal thermometers for home use (FeverSmart, iThermonitor, Quest Temp Sitter, and Thermochron iButton) were applied to 15 patients during 24 h, and rectal temperature was measured at four occasions. Pearson correlation revealed moderate correlation for the Feversmart ($r = 0.75$), iThermonitor ($r = 0.79$), and Thermochron iButton ($r = 0.71$) systems. The Quest Temp Sitter system malfunctioned repeatedly, and the correlation ($r = 0.29$) for this method should therefore be assessed with caution. All dermal thermometers rendered lower average temperatures than Terumo c405 (Feversmart $-0.70 \pm 0.65\,^{\circ}C$; iThermonitor $-0.77 \pm 0.53\,^{\circ}C$, Quest Temp Sitter $-1.18 \pm 0.66\,^{\circ}C$, and Thermochron iButton $-0.87 \pm 0.65\,^{\circ}C$). Sensitivity of the dermal thermometers for detecting core temperatures $\geq 38.0\,^{\circ}C$ was low, ranging from 0.33 to 0.6, but improved to 0.60 to 0.80 after adjusting temperatures by the methods' average deviation from rectal temperature. The results from the dermal thermometers tested here showed an insufficient correlation to core temperature to be used for core temperature monitoring in clinical research and practice. Unfortunately, other options for non-invasive temperature measurements are few. The two thermometers with the least unsatisfactory performance profile in our evaluations were the Feversmart and iThermonitor systems.

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Body temperature elevation; fever; thermometer; methodology

Background

Much research has been devoted to developing methods for body temperature measurements and to determine which method is most reliable and accurate [1,2]. Measurement of body temperature depends upon the accuracy of the thermometer, the measuring site and the skills of the person measuring the temperature. The ambition is generally to measure the core temperature, which is the temperature of the blood that circulates in the large blood vessels in the internal organs and in the brain [2,3]. The gold standard for core temperature assessment is a pulmonary artery catheter, which however is invasive and therefore rarely used [2,4]. Other sites for measuring temperature include the esophagus, rectum, arm pits, mouth, tympanic membrane, and temporal artery. The sites vary in sensitivity and reliability when compared with a pulmonary artery catheter, and esophageal measurements are generally recognized as the most accurate non-invasive index for core temperature. The esophagus has a blood supply similar to the brain's, and is sensitive to rapid changes in the blood temperature. Rectal temperature is about $0.2 - 0.5\,^{\circ}C$ higher that the temperature of the blood leaving the heart and reacts more slowly to temperature changes in the blood, but is better tolerated than esophageal measurements and is less prone to operator errors. Esophageal and rectal measurements are both generally considered valid surrogates for core temperature [4–6].

However, if continuous readings for longer periods of time are in demand, as may be the case in clinical research, neither rectal or esophageal measurements are tolerable to participants in the studies. The possibility that a new, convenient and reliable surrogate measurement may be provided by a new generation of wireless dermal thermometers, which measure body temperature continuously under longer periods of time, was tested in the present study. These new thermometers, developed for home use, are applied to the person's skin with the help of adhesive tape and log the measurements on specific applications on mobile phones or built-in memory chips. However, before using such methods as surrogate measurements of core temperature in clinical research they need proper validation in a clinical context, and hitherto no such evaluations have been performed. iButton in a few studies has been found to be reliable when measuring skin temperature in animals and in sleep/wake

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circadian rhythm evaluation in humans, but has not been tested for correlation against core temperature [7,8]. A review concerning Thermochron iButton by Hasselberg et al. emphasized the need for more research to evaluate the method's usefulness in the clinical setting [9]. Therefore, the aim of the current study was to evaluate this type of wireless dermal thermometers by comparing them to a professional rectal thermometer.

Methods

Design, subjects, and setting

A prospective method study was planned to evaluate all commercially available home use wireless dermal thermometers for continuous temperature monitoring by comparing them to a rectal thermometer.

The subjects were hospitalized patients in the neurological and infection wards at the University Hospital Örebro, Sweden, from December 2016 to September 2017. The inclusion criteria for the first eight included patients were only that the patient signed the informed consent. For the last seven patients, an additional inclusion criteria (morning temperature $\geq$38.0 °C) was added to obtain registrations over a larger temperature spectrum. To minimize the risk of disturbances by our measurements subjects were excluded if they or their room neighbor had ongoing telemetric ECG monitoring, medication by electronic syringe pump or required medical ventilation. Forty-two patients were offered participation in the study, and 15 were finally included.

Instruments

An Internet search revealed seven different wireless dermal thermometers that could potentially have been included in the study. Three of these could not be purchased (TempTraq, CadiSense wireless thermometer and RespiHeart), resulting in a final inclusion of four thermometers (FeverSmart, iThermonitor, Quest Temp Sitter, and Thermochron iButton).

FeverSmart (model WT701, iMobile Healthcare LLC, Philadelphia, PA) and iThermonitor (model WT701, Railing Medical Company, Beijing, China) are battery-operated reusable electronical devices consisting of a thermistor and a Bluetooth unit. The sensor is placed under the arm, in the region of the armpit, with the help of adhesive tape. The sensor registers axillary temperature continuously and transmits the information to a mobile device equipped with a specific application. The sampling rate is once every 4 s. The registered temperature is real time temperature with a timestamp. The thermometers have a measurement range of 25 – 45 °C and, according to the manufacturers, an accuracy of ±0.05 °C (35 – 38.5 °C) and ±0.1 (<35 °C and >38.5 °C), respectively. A memory unit in each thermometer stores the measurements in the event the connection to the mobile unit is lost. The information can be accessed in the form of a graph and can be exported to a computer for future evaluation in a jpeg file.

Quest Temp Sitter (model QPT01744, Quest products Inc., Pleasant Prairie, WI) is a reusable, electronic wireless dermal thermometer that can measure the body temperature continuously. The sensor has a probe that senses the temperature, the data are transmitted by Bluetooth to a mobile device equipped with a special application. The thermometer has a measuring range of 25 – 45 °C and, according to the manufacturers, an accuracy of ±0.05 (35 – 38.5 °C) and ±0.1 °C (<34.99 °C and >38.51 °C), respectively. The sample rate is once every 3 s. The measurements can be accessed in the application in a graph.

Thermochron iButton (model DS1921H-F5, Maxim Integrated, San Jose, CA) is a wireless dermal thermometer that consist of a thermistor and a memory unit, and can monitor body temperature continuously. The sample rate is user defined with a maximum of 1 per minute. The memory unit can record a maximum of 2048 samples. The temperature measurements are transmitted to a computer by a 1-wire unit and can be exported in a csv file for further analysis. The thermometer has an operating range between 15 and 46 °C with an accuracy of ±1.0 °C.

Standard protocol on the neurology and infection wards is temperature measurement by the rectal method twice a day, but this was for the current study increased to four times during the 24 h the dermal thermometers were in place. Because we assumed that the staff was well acquainted with the method and the literature confirms its validity, we chose the rectal method as golden standard for temperature measurement. Terumo c405 is a conventional device for measuring rectal temperature and it is the standard device used on the neurologic wards. The thermometer has a measurement range between 32.0 and 42.0 °C and an accuracy of ±0.1 °C with a measurement time of 5 min. The device is an electronic thermometer with a probe and the model is specifically designed for the oral or rectal measuring method.

Data collection procedure

Subjects were informed both verbally and in text about the study, and were included if they signed an informed written consent. Demographics (age and sex) and clinical data (diagnosis and antipyretic medication) were extracted from the patients' medical records.

The dermal thermometers were, all at the same time, applied to the skin under the arms in the armpit region, following the manufacturers' instructions. The skin surface was cleaned with soap and water, dried and wiped with Chlorhexidine solution 5 mg/mL. The armpit was shaved to maximize the contact between the skin and the adhesive tape. The patients did not get any instructions regarding how to keep their arms, whether to use blankets or bed sheets etc. Every subject got assigned a code and got a profile in the specific applications. After the sensors were synchronized with the applications the registrations were started. Each subject temporarily got a mobile phone (Samsung Galaxy A3.6, Samsung Electronics, Suwon, South

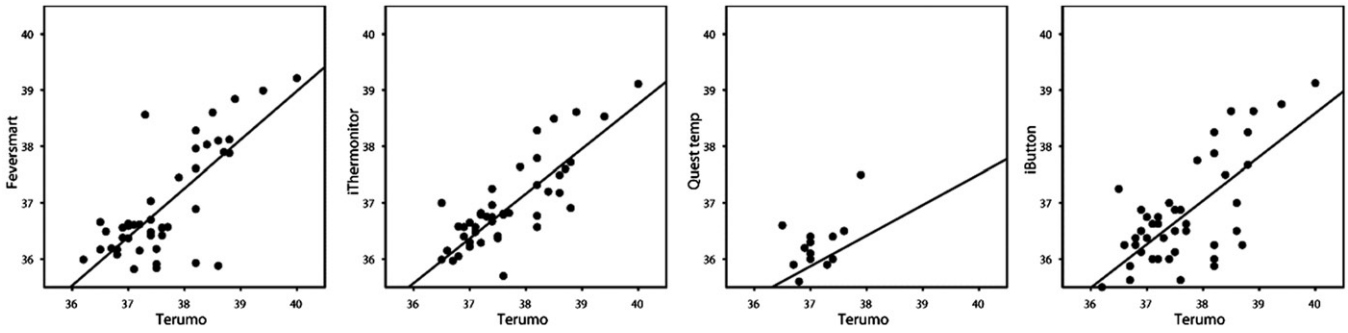

Figure 1. Comparison between the four dermal thermometers (Feversmart, iThermonitor, Quest Temp Sitter, and iButton) and the rectal thermometer Terumo c405. Temperatures measured with each thermometer are plotted against the temperatures simultaneously measured with the rectal thermometer. Number of measurements plotted in each graph differs because of missing data at specific occasions.

Korea) because the sensors needed continuous contact with a mobile device to register the measurements. For safety reasons, the mobile phones were locked with a code and adjusted to "flight mode." Bluetooth has a functioning range of 10 m, which was why we asked the subjects to have the mobile devices with them continuously under the data collection and to keep to their rooms if possible. The length of temperature registration for each subject was 24 h. The thermometers were cleaned with an isopropanol-based surface disinfectant both prior application and after removal. The registrations were saved as csv files or graphs in jpeg. The rectal temperature was measured by a nurse and registered on a specific measurement protocol at 12, 16, 20, and 7 h. The specific time (hour and minute) of each measurement was noted in the protocol.

At the end of data collection each of the first eight included subjects was asked to complete a questionnaire evaluating the tolerability of the dermal thermometers. The questionnaire had a scale from 0 to 10 evaluating how uncomfortable the thermometers were patched to the skin, with 0 meaning not uncomfortable at all and 10 most uncomfortable, and room for free text comments regarding the experience of having the dermal thermometers on their skin for a long period of time.

Statistical analysis

Temperature registrations from each of the dermal thermometers were compared with concurrent temperature registrations from the rectal thermometer by Pearson's correlation analysis and linear regression analysis. Average deviation from rectal temperature was calculated for each of the dermal thermometers.

Further, in an effort to investigate whether the dermal thermometers were more suited to follow temperature trends in specific individuals rather than measuring absolute temperatures, each individual's dermal and rectal temperature recordings were normalized, and correlations calculated anew. The normalization was done by computing the average temperature for each individual and each registration method, and subsequently subtracting this average from each temperature recording. This resulted in a positive or negative number, either indicating that the specific measurement was above or below the patient's average for the specific measurement method. After normalizations, correlations between the dermal thermometers and Terumo c405 were calculated anew.

Further, the sensitivity and the specificity of the dermal thermometers to detect rectal temperature elevations $\geq$37.6 °C and $\geq$38.0 °C, respectively, were calculated. The same calculations were also performed after adjusting each dermal temperature registration with the average temperature deviation (from rectal temperature) for the method.

All analyses were performed in SPSS (IBM Corp., Version 23.0. Armonk, NY). Data are presented as mean ± standard deviation (SD) if not stated otherwise.

Ethical consideration

The study was conducted according to the local institution's ethical requirements and was approved by the Regional Board for Ethical Vetting, Uppsala (ethical approval number 2016/321).

Results

The mean age of the 15 participants was 68.7 ± 17.1 years, and 7/15 (47%) were female. The Quest Temp Sitter thermometer malfunctioned repeatedly, and the results regarding this thermometer should be assessed with caution due to the small number of analyzed measurements.

The iThermonitor thermometer had the strongest correlation to the rectal thermometer Terumo c405 ($r = 0.79$; $r2 = 0.62$; $p = .000$), compared with Feversmart ($r = 0.75$; $r2 = 0.56$; $p = .000$), Thermochron iButton ($r = 0.71$; $r2 = 0.50$; $p = .000$), and Quest Temp Sitter ($r = 0.29$; $r2 = 0.084$; $p = .121$; Figure 1 and Table 1).

All dermal thermometers rendered lower average temperatures than Terumo c405 (Feversmart −0.70 ± 0.65 °C; iThermonitor −0.77 ± 0.53 °C, Quest Temp Sitter −1.18 ± 0.66 °C, and Thermochron iButton −0.87 ± 0.65 °C), which was reflected in the low coefficients in the regression formulas (Table 1). Due to the tendency of rendering lower measurements, the sensitivity was low for detecting temperature elevations $\geq$37.6 °C and $\geq$38.0 °C, ranging from 0.43 to 0.6 and 0.33 to 0.6, respectively. This tendency also made the specificity generally high, ranging from 0.96 to

Table 1. Comparisons between the dermal thermometers and Terumo c405.

	Total number of measurements	Average deviation from Terumo c405 mean ± SD [°C]	Correlation value r (r^2)	After normalization: Correlation value r (r^2)	Regression Formula (T=Terumo c405 measurement)	Sensitivity and specificity for temperature ≥37.6 °C	Sensitivity and specificity for temperature ≥38.0 °C	After correction for average deviation: Sensitivity and specificity for temperature ≥37.6 °C	After correction for average deviation: Sensitivity and specificity for temperature ≥38.0 °C
FeverSmart	44	−0.70 ± 0.65	0.75 (0.56)	0.65 (0.42)	0.86*T + 4.46	0.60; 0.96	0.60; 0.97	0.70; 0.92	0.80; 0.93
iThermonitor	45	−0.77 ± 0.53	0.79 (0.62)	0.25 (0.064)	0.80*T + 6.94	0.45; 1.00	0.33; 1.00	0.90; 0.72	0.80; 0.93
Quest Temp Sitter	18	−1.18 ± 0.66	0.29 (0.084)	0.029 (0.00085)	0.55*T + 15.7	*NA	*NA	*NA	*NA
iButton	51	−0.87 ± 0.65	0.71 (0.50)	0.44 (0.19)	0.78*T + 7.58	0.43; 1.00	0.40; 1.00	0.62; 0.77	0.60; 0.94

*Sensitivity and specificity could not be calculated for Quest Temp Sitter, and the corresponding cells are therefore marked NA (not applicable).

1.00 and 0.97 to 1.00 for temperatures ≥37.6 °C and ≥38.0 °C, respectively. In an effort to correct for the systematic underestimation, all dermal temperature recordings were increased by a number equal to the methods' average underestimation (Feversmart 0.70 °C; iThermonitor 0.77 °C, Quest Temp Sitter 1.18 °C, and Thermochron iButton0.87 °C), and sensitivity and specificity were calculated anew. This improved the sensitivity (range 0.62–0.90 for ≥37.6 °C and range 0.60–0.80 for ≥38.0 °C) and slightly lowered the specificity (range 0.72–0.92 for ≥37.6 °C and range 0.93–0.94 for ≥38.0 °C; Table 1).

We hypothesized that the difference between a given dermal thermometer and the rectal thermometer would be relatively stable within the same patient, and in other words that the dermal thermometers were more suited to follow temperature trends within specific individuals rather than measuring absolute temperatures. To investigate this, each individual's dermal and rectal temperature recordings were normalized, and correlations calculated anew. The normalization was done by computing the average temperature for each individual and each registration method, and subsequently subtracting this average from each temperature recording. This resulted in a positive or negative number, either indicating that the specific measurement was above or below the patient's average for the specific measurement method. In contrary to our expectations, correlations between the dermal thermometers and Terumo c405 were even lower after this normalization, ranging from 0.029 to 0.65 (Table 1).

Questionnaires

Five of the first eight subjects completed the evaluating questionnaire. On the discomfort evaluation scale (from 0 to 10; 0 meaning not uncomfortable and 10 most uncomfortable), two subjects ranked the thermometers as 0, two ranked them as 2, and one ranked them as 3. All subjects felt that the thermometers were more or less comfortable, but some commented that the adhesive tapes were weak.

Protocol violations

One of the subjects had to discontinue the data collection because of need for telemetric ECG monitoring and another patient discontinued data collection because of the need for a radiologic examination. In these cases, one measurement was performed with each thermometer. Loss of connection between the dermal thermometers and the mobile devices led to instances of missed temperature measurements. The Quest Temp Sitter system malfunctioned most frequently in this manner. The total number of temperature measurements for analysis varied for each thermometer, with a total of 44 available temperature measurements for FeverSmart, 45 for iThermonitor, 18 for Quest Temp Sitter, and 51 for Thermochron iButton.

Discussion

This is the first study concurrently evaluating several commercial wireless dermal thermometers for continuous use by comparing them with a conventional rectal thermometer. The correlation between three of the evaluated thermometers and the rectal thermometer was moderate, with Pearson correlation r-values above 0.7, while the fourth thermometer – Quest Temp Sitter – malfunctioned too often to enable a proper evaluation in the current study. The average difference compared to the rectal temperature was, as expected considering that the thermometers measured skin temperature, negative and of significant magnitude, ranging from 0.70 to 1.18 °C for the different devices. Such difference is not necessarily a problem if the correlation is high, since cut-off values can be changed to increase the detection of fever. This was tested in the sensitivity analyses where the average bias was added to the dermal thermometer registrations. However, since the correlation was relatively low for all thermometers, the sensitivity/specificity profile could only be optimized to a limited degree by changing the cut-offs. The most favorable sensitivity/specificity profile for temperature ≥38.0 °C in the current study was found by adding the average bias of 0.70 to the Feversmart and 0.77 to the iThermonitor registrations (in both cases sensitivity was 0.80 and specificity 0.93).

At the outset, we supposed that the difference between a given dermal thermometer and the rectal thermometer would be relatively stable within the same patient, and in other words that the dermal thermometers could be more suited to monitor temperature trends within specific individuals rather than measuring absolute temperatures. It was, however, clear from the normalized correlation analyses that the dermal thermometers were only marginally superior in

following individual trends than in assessing absolute temperatures. In case of superiority, the correlations analysis following the normalization procedure had rendered much higher *r*-values.

Before concluding whether any of the thermometers are suitable for gauging core temperature in clinical research, some practical aspects need to be accounted for. First of all, the fact that the dermal thermometer systems were not safe to use along with other medical equipment, including ECG-surveillance and radiologic examinations (even though Thermochron iButtonwas not explicitly stated to be disturbed by radiologic examinations), is a major drawback. The devices were both sensitive for disturbances and risked interfering with other equipment. Despite measures to minimize disturbances, several measurements were lost, and the most sensitive device in this regard was the Quest Temp Sitter. Second, the thermometers need close contact to the skin to be able to measure body temperature properly. Even though the measurement area was cleaned and shaved, some of the adhesive tapes loosened, leading to poor contact and affecting the temperature readings. The Quest Temp Sitter thermometer was the most sensitive regarding this. An interesting observation was that bedridden and obese patients tended to have better more reliable dermal thermometer readings, possibly because of decreased risk that the thermometer would fall off or be displaced. Third, it merits emphasis that the success of the readings to a high degree depended on subject compliance. For example, to optimize measurement conditions the arm needed to be close to the body, which is much to ask from a patient. Fourth, the software for logging the temperatures differed regarding suitability for research use. Most notably, the application for the Quest Temp Sitter was not user friendly, and lacked the needed decimal information on the temperature readings.

The major drawback of the dermal thermometers as surrogate measures of core temperature is their low correlation to rectal temperature. This combined with their potential incompatibility with medical equipment makes them suboptimal for clinical research, and potentially hazardous for use in clinical practice. The fact that the thermometers were convenient had a good tolerability and provided continuous (or at least very frequent) measurements do not represent sufficient advantages to merit their use in clinical research. However, there are few other attractive options for non-invasive, continuous measurements of temperature. If dermal thermometers are used, their shortcomings should be kept in mind. Amongst the thermometers we tested, the Feversmart and iThermonitor systems performed best due to relatively high sensitivity and robustness. It should be emphasized that the current study evaluated the dermal thermometers for their ability to gauge *core* temperature, and it could be argued that it from the outset was obvious that skin temperature would differ from core temperature. The results would reasonably have been different if the dermal thermometers had been compared to a gold standard dermal temperature measurement, but this was not the purpose of the paper. Our reason for comparing the dermal thermometers to core temperature was that core temperature generally is the clinically most interesting variable, as is reflected in the multitude of studies investigating the correlation between skin, ear and oral temperature and core temperature in similar fashion as in the current study [10–12].

Even though this type of dermal thermometers has been used in research, surprisingly no previous study has tested their correlation to core temperature. However, extensive studies have evaluated the validity of temperature measurements in the axilla, the location chosen in the current study. Most of the research shows, in concordance with the current results, that axillary methods have a low agreement with rectal methods [11]. It has also been shown that axillary temperature on average is 0.5 °C lower than the rectal temperature, a difference that was even higher in the current study [10]. Further, it has been reported, and is confirmed in the current study, that the difference between dermal and rectal temperature is not consistent, but influenced by the time of day and other factors [10–12]. These inconsistencies in the average difference and the difficulty to adjust axillary temperature to rectal temperature has led to the conclusion that axillary methods are not an acceptable substitution for the rectal method, which is supported by the current results [13].

Study limitations

We have identified the following limitations of the current study. The subjects were left without supervision and therefore the conditions for each temperature measurement varied depending on patient compliance. For example, patient clothing and usage of blankets were not standardized, since patients had to be able to choose what they thought was most comfortable during the 24 h under which the measurements took place. A more strict supervision could have improved performance, but may have hampered generalizability to less controlled conditions. Further, we aimed to include only 60 registrations from 15 subjects, and a larger material may have slightly affected the results. Another shortcoming is that we in the analysis treated the measurements as independent observations, which they in a strict sense are not since each patient contributed with up to four measurements. Also, our evaluation of the dermal thermometers in the current study were focused on the exact timepoints on which rectal temperatures were concurrently measured, which does not take the potential benefits of continuous measurements into account. Further, we did not take into account that temperatures theoretically may differ between dominant and non-dominant arm. However, we are not aware of any publication showing that such a difference exists. After initiating the study, we understood that at least the hardware in the iThermonitor and Feversmart systems were essentially identical (and even had the same model number). However, since the results from the two differed slightly, and we are unsure whether the companies have done relevant alterations in the software, we let the two analyses remain separately presented. The main strength of the study is that it was performed in real patients in a

clinical setting, making the results highly relevant regarding the clinical research situation. Moreover, the fact that all thermometers were concurrently tested in the same patients, all in the axillary region, vouches for good comparability between the method evaluations.

Conclusions

The dermal thermometers tested here are probably not reliable and accurate enough for most types of clinical research. Other options for non-invasive temperature measurements are, however, few. The two thermometers with the least unsatisfactory performance profile in our evaluations were the Feversmart and iThermonitor systems.

Ethical approval

The Regional Ethical Board in Uppsala granted the ethical application including its complementary application (ethical approval number 2016/321).

Disclosure statement

No potential conflict of interest was reported by the authors.
Jakob O. Ström has received consultant fee for participation in an Advisory Board for Bayer AB in 2016.

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