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CLINICAL ISSUES

Performance of non-contact infrared thermometer for detecting febrile children in hospital and ambulatory settings

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Aims. To assess the performance of the non-contact infrared thermometer compared with mercury-in-glass thermometer in children; to assess the diagnostic accuracy of non-contact infrared thermometer for detecting children with fever; to compare the discomfort caused by the two procedures in children aged > one month.

Background. Non-contact infrared thermometer is a quick and non-invasive method to measure body temperature, not requiring sterilisation or disposables. It is a candidate for temperature recording in children.

Design. Prospective multicenter study.

Methods. Body temperature readings were taken from every child consecutively admitted to the Pediatric Emergency Departments or Pediatric Clinics participating in the study. Two bilateral axillary temperature measurements using the mercury-in-glass thermometers and three mid-forehead temperature measurements using the non-contact infrared thermometer were performed.

Results. Two hundred and fifty-one children were enrolled in the study. Mean body temperature obtained by mercury-in-glass thermometer and non-contact infrared thermometer was 37·18 (SD 0·96) °C and 37·30 (SD 0·92) °C, respectively (p = 0·153). Non-contact infrared thermometer clinical repeatability was 0·108 (SD 0·095) °C, similar to that of the mercury-in-glass thermometer (0·11 SD 01 °C; p = 0·517). Bias was 0·0150 (SD 0·09) °C. The proportion of outliers > 1 °C was 4/251 children (1·59%). A significant correlation between temperature values obtained with the two procedures was observed (r^2 = 0·84; p < 0·0001). The limits of agreement, by the Bland and Altman method, were −0·62 (95% CI: −0·47 to −0·67) and 0·76 (95% CI: 0·61–0·91). No significant correlation was evidenced between the difference of the body temperature values recorded by the two methods and age (p = 0·226), or room temperature (p = 0·756). Calculating the receiver operating characteristic curve to determine the best threshold for axillary temperature > 38·0 °C, for a non-contact infrared thermometer temperature = 37·98 °C the sensitivity was 88·7% and the specificity 89·9%. Mean distress score (on a 5-point scale) was significantly lower using the non-contact infrared thermometer than using the mercury-in-glass thermometer (1·92 SD 0·56 and 2·40 SD0·93, respectively; p < 0·0001).

Conclusion. Non-contact infrared thermometer showed a good performance in our study population, has the advantage of measuring body temperature in two seconds and is comfortable for children.

Relevance to clinical practice. Non-contact infrared thermometer may be taken into consideration when assessing body temperature in children aged > one month in hospital or ambulatory.

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Introduction

The mercury-in-glass thermometer has been used as the standard for human temperature measurement for hundreds of years, but it is going to be withdrawn from the market because of the potential for metal toxicity (Chiappini *et al.* 2009). In this study, we aimed at comparing a new non-contact infrared thermometer (NCIT) with an historical standard method (axillary measurement by mercury-in-glass thermometer), in a large population of children aged > one month, in hospital or ambulatory settings (performed by trained personnel).

Background

The ideal method to measure body temperature in children is still under debate (NICE 2007, Chiappini *et al.* 2009). An ideal thermometer should accurately reflect the core body temperature in all age groups, be convenient, easy and comfortable to use, give rapid results, not cause cross-infection among patients, not be influenced by ambient temperature and be safe and cost-effective (El-Radhi & Barry 2006, NICE 2007, Chiappini *et al.* 2009). In practice, every available method has several advantages and disadvantages (Chiappini *et al.* 2009), but no one method completely fulfils all the above-mentioned criteria. In ambulatory and hospital settings, in children aged > four weeks, use of infrared tympanic thermometer is currently recommended by the National Institute for Health and Clinical Excellence (NICE 2007) and the Italian guidelines (Chiappini *et al.* 2009). When used by trained healthcare providers, this method has been found to accurately estimate central body temperature by some authors (El-Radhi & Barry 2006). However, data are discordant. In other well-designed studies, poor accuracy of tympanic thermometer has been reported in children, when compared to axillary temperature (Devrim *et al.* 2007), or rectal temperature recorded by mercury-in-glass thermometer (Jean-Mary *et al.* 2002). Moreover, in a large systematic review, Dodd *et al.* (2006) found poor sensitivity (63·7%; 95% CI: 55·6–71·8) of infrared ear thermometry for fever diagnosis in children. In a previous systematic review including 5935 children, infrared ear thermometry showed poor agreement with rectal measurement (Craig *et al.* 2002). Another disadvantage of this technique is that curvature of the ear canal may make it difficult to reach the tympanic membrane (NICE 2007, Chiappini *et al.* 2009). The presence of hyperaemia or earwax may also interfere with the measurement (NICE 2007, Chiappini *et al.* 2009).

Alternatively, NCIT is a promising device. The fact that this is a quick and non-invasive method, not requiring sterilisation or disposables, makes it a candidate for the screening of febrile individuals (such as, for example, international travellers) or for temperature recording in children, particularly in hospital or ambulatory settings (Mounier-Jack *et al.* 2007, Osio & Carnelli 2007, Duran *et al.* 2009). However, available data about accuracy of NCIT s to discriminate febrile patients are conflicting, and few studies include large proportion of febrile children (Ng *et al.* 2005, Osio & Carnelli 2007, Hausfater *et al.* 2008, Bitar *et al.* 2009, Duran *et al.* 2009).

Methods

Objectives

The study objectives were the following:

1 To assess the performance of the NCIT applied to the mid-forehead in comparison with the axillary temperature recorded by the mercury-in-glass thermometer in children;
2 To assess diagnostic accuracy of non-contact infrared thermometry for detecting children with fever (defined as an axillary temperature measured by mercury-in-glass thermometer > 38·0 °C) (Michael Marcy *et al.* 2004);
3 To compare the discomfort caused by the two procedures in children.

Study design

This was a prospective multicenter study involving five centres located in five Italian cities (Florence, Como, Anzio, Gallarate and Bergamo). In particular, one centre was a Pediatric Emergency Department (Florence), three centres were Pediatric Clinics (Como, Anzio, Gallarate) and the last was a Primary Care Center (Bergamo). Body temperature readings were taken from each child by a single experienced physician or nurse in every centre.

Data collection

Data were collected between 1st January–1st August 2009. The study children were consecutively admitted to each

centre, for any reason. Inclusion criteria were (1) age between one month and 18 years, (2) stable clinical conditions (defined as stable vital signs and blood pressure values, heart rate and oxygen saturation), (3) absence of skin infection, rash, recent topical treatment or abundant sweating in measurement areas, (4) absence of underlying chronic conditions.

Two bilateral axillary temperature measurements using the mercury-in-glass thermometers and three mid-forehead temperature measurements using the NCIT were performed. In the absence of a gold standard method for the measurement of the body temperature in children, axillary temperature was chosen as a reference, considering its relative precision reported in previous studies and minimal discomfort for the child, according to the most recent National Institute for Health and Clinical Excellence (2007) and Italian Guidelines (Chiappini *et al.* 2009). For the same reasons, rectal measurement was excluded for its invasiveness and subsequent child's discomfort (National Institute for Health and Clinical Excellence 2007, Chiappini *et al.* 2009). Mercury-in-glass thermometer will be withdrawn from the market by 2009, given the potential for metal toxicity (European Parliament 2007); however it has been the standard reference method for years and proven to be accurate in children (National Institute for Health and Clinical Excellence 2007, Chiappini *et al.* 2009). Thus, it was chosen as reference thermometer in this study. Child's discomfort assessment during the measurements was also performed. In every child, all the measurements were recorded within 12 minutes. The following data were also obtained from the children and entered into a database: age, sex, recent drug assumption and presence of underling conditions. Room temperature was also recorded. Informed consent for the study was obtained from the children's parents/tutors. The study was approved by the Children's Meyer Hospital Ethic Committee.

Thermometry measurements

Axillary temperatures were measured using mercury-in-glass thermometer (Thermovedo®, Pic, Artsana, Italy). The temperature was read five minutes after replacement on the child's axilla. Two bilateral axillary measurements were performed in every child. Three temperature measurements using the NCIT in the mid-forehead were performed, following the manufacturer's instructions (Thermofocus®, model 0800; Tecnimed, Varese, Italy). Temperature measurement with this latter procedure takes about two seconds and was executed according to the *American Society for Testing and Materials* (ASTM 2009) E 1965–1968 standard specifications for infrared thermometers for intermittent determination of patient temperature. This device includes a luminous pointer, which indicates the correct distance from the mid-forehead to execute the procedure (Fig. 1). All the measurements were performed at a stable indoor temperature, and the infrared thermometer was stabilised at the room temperature. Both mercury-in-glass and infrared thermometer calibrations were checked before and after the study beginning.

Discomfort assessment

The discomfort was assessed by trained physicians or nurses using a 5-point scale, as previously described (Shane *et al.* 1994, Greenes & Fleisher 2001). The discomfort was first assessed using the non-contact skin thermometer (during the three mid-forehead measurements) and, subsequently, using the mercury-in-glass thermometer (mean score of the two- to five-minute axillary measurements).

Statistical analysis

Power calculation was performed to determine sample size. At least 198 children were needed to achieve a study power of 80%, with α error = 0·05, estimating a potential difference between the two methods = 0·2 °C and SD 1·0 °C.

To assess the variability of repeated measures (reproducibility) of the NCIT, children had triplicate measures of body temperature. Clinical repeatability was calculated, as a measure of the reproducibility of three repeated temperature measurements, defined as the SD of the differences between

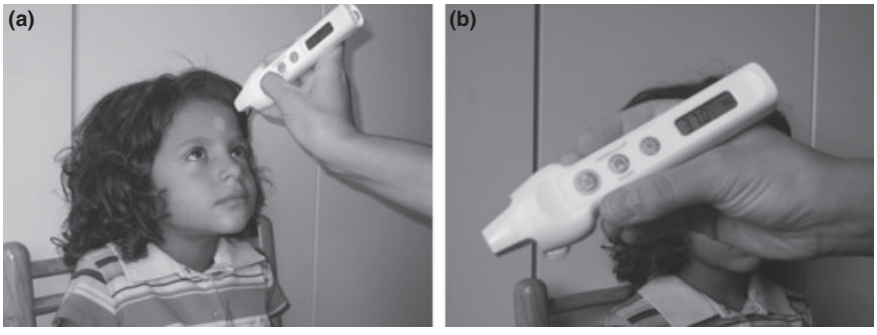

Figure 1 Measurement of body temperature using a non-contact infrared thermometer. (a) The device is placed in front of the child's mid-forehead. The luminous pointer indicates the correct distance to perform the measurement. (b) The temperature measured is shown on the display. Used with permission.

the three sets of measurements (i.e.: T_2-T_1, T_3-T_2 and T_1-T_3) in all children undergoing the test (Chamberlain *et al.* 1995).

Age was expressed as median and interquartile range (IQR). Normal distribution of variables was tested by one-sample Kolmogorov–Smirnov test. Room temperature, body temperature and distress score were normally distributed. Thus, these results were presented as mean, standard deviations (SD) and 95% confidence intervals (95% CI). Comparisons of two means were performed by using the paired Student *t* test.

To compare body temperatures obtained in each child using the two methods, the mean value of the two bilateral axillary measurements with the mercury-in-glass thermometer and the mean value of the three mid-forehead measurements with the NCIT were calculated.

Linear regression analysis, calculating the '*r*' value, was performed to assess the correlation between temperature values measured with the two methods. Bias (mean of differences) and numbers of outliers (defined as a difference > 1 °C) were also recorded (Bland & Altman 1986). The Bland and Altman (1986) method was used to compare two sets of measurements, and the limit of agreement was defined as ± 2 SDs of the differences, as previously described (Smitz *et al.* 2009).

Receiver operating characteristic (ROC) curve analysis was conducted to determine the best threshold in determining the presence of fever (defined as axillary temperature ≥38·0 °C). The area under the ROC curve (AUC) with 95% CI was also calculated. Additionally, using Cohen's '*k*', the diagnostic performance of the NCIT to detect fever (defined as axillary temperature >38·0 °C) was evaluated by calculating sensitivity, specificity, the predictive positive value, the predictive negative value and the concordance among the two methods.

Linear regression analysis was performed to evaluate the correlation between body temperature difference using the two methods and age or room temperature. A *p*-value <0·05 was considered statistically significant. The statistical analyses were performed using the SPSS software package (SPSS 11·5; Chicago, IL, USA) and Medcalc® 9·2 (MedCalc Software bvba, Mariakerke, Belgium).

Results

Two hundred and fifty-one children were enrolled in the study. Characteristics of the study children are shown in Table 1. The mean room temperature was 24·15 (SD 1·81) °C.

Table 1 Characteristics of the 251 study children

Age (years, median) (interquartile range)	4·5 (3·0–8·6)
Males (No.) (%)	127 (50·59)
Children with axillary body temperature (No.) (%)	
<37·0 °C	129 (51·39)
37·0–37·9 °C	69 (27·50)
>38·0–38·5 °C	18 (7·17)
>38·5 °C	35 (13·94)

Clinical repeatability and other reproducibility measures of non-contact infrared thermometers

Clinical repeatability of the NCIT was 0·108 (SD 0·095) °C, similar to the mercury-in-glass thermometer clinical repeatability (0·114 (SD 0103) °C; $p = 0·517$). Bias was 0·015 (SD 0·089) °C and the percentage of outliers >1 °C was 1·59% (four children). The correlation between measurements obtained with the two procedures is reported in Fig. 2, showing the Bland and Altman diagram.

Mean body temperature obtained by mercury-in-glass and NCIT was 37·18 °C (SD 0·96) °C and 37·30 (SD 0·92) °C, respectively ($p = 0·153$). At linear regression analysis, a significant correlation between temperature values obtained with the two procedures was observed ($r^2 = 0·837$; $p < 0·0001$). No significant correlation was evidenced between the difference between the body temperature values recorded with the two methods and age ($p = 0·226$), or room temperature ($p = 0·756$).

Diagnostic performance of non-contact infrared thermometer measurement in predicting fever (axillary temperature >38 °C by mercury-in-glass thermometer)

Calculating the Cohen's *k*, a significant agreement between the two procedures was observed for body temperatures >38·0 °C (Table 2). Diagnostic performance of NCIT measurement in predicting axillary temperature >38·0 °C by mercury-in-glass thermometer was calculated: sensitivity was

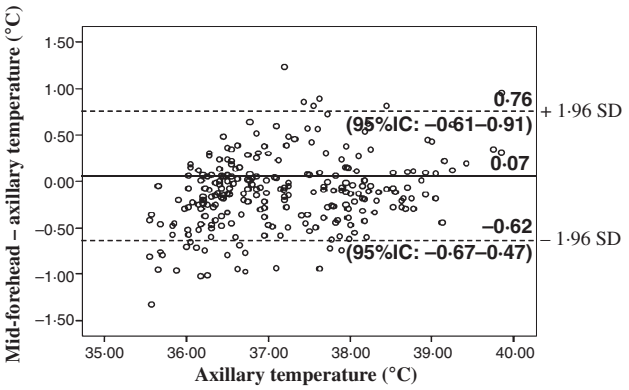

Figure 2 Bland and Altman diagram comparing mid-forehead temperature recorded by non-contact infrared thermometer and axillary temperature recorded by mercury-in-glass thermometer in 251 children.

Table 2 Concordance between the two methods in detecting febrile children (body temperature > 38·0 °C). k = 0·717; p < 0·0001

	Mercury-in-glass thermometer (No.) (%)		
	BT > 38 °C	BT ≤ 38 °C	Total
Non-contact infrared thermometer (No.) (%)			
BT > 38 °C	47 (88·7)	20 (10·0)	67
BT ≤ 38 °C	6 (11·2)	179 (89·9)	185
Total	53 (100)	199 (100)	

BT, body temperature.

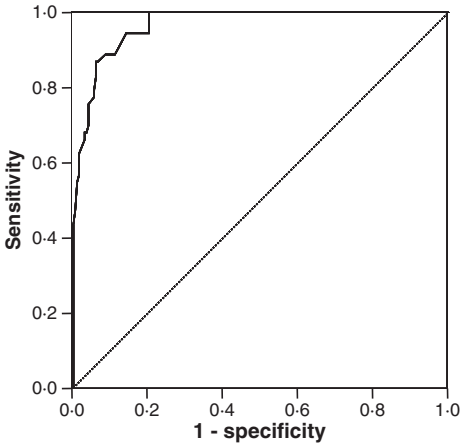

Figure 3 Receiver operative characteristic (ROC) curve for predicting febrile children (axillary temperature > 38·0 °C). Area under the ROC curve = 0·968 ± 0·010; 95% IC 0·949–0·986; p < 0·0001 vs. the identity line (diagonal line).

0·89 (95% CI: 0·80–0·97), specificity 0·90 (95% CI: 0·86–0·94), positive predictive value 0·70 (95% CI: 0·59–0·81) and negative predictive values 0·97 (95% CI: 0·94–0·99). Calculating the ROC curve to determine the best threshold for axillary temperature >38·0 °C, for a mid-forehead temperature of 37·98 °C the sensitivity of the NCIT was 88·7% and the specificity 89·9%.

Mean distress score was significantly lower using the NCIT than using the mercury-in-glass thermometer (1·92 SD 0·56 and 2·40 SD 0·93, respectively; p < 0·0001, Fig. 3). Finally, the variability according to the different people performing the measurement was studied by the nonparametric test Kruskal–Wallis and found no statistical difference (p = 0·07 for the non-contact infrared thermometer measurements; p = 0·45 for the mercury-in-glass thermometer measurements).

Discussion

Our multicentre study evaluated the performance of a new NCIT in 251 children, including a substantial proportion of febrile children. Results demonstrated good clinical repeatability of the measurements in the same patients. Moreover, bias with respect to axillary measurement by mercury-in-glass thermometer was excellent and similar or higher to previous published results using the same thermometer (Osio & Carnelli 2007). Considering other NCIT, Hausfater *et al.* (2008), in a study on adults, calculated a fourfold higher bias. Even in other studies using tympanic infrared thermometers, the reported biases generally higher than ours (Bland & Altman 1986, Rotello *et al.* 1996, Imamura *et al.* 1998, Smitz *et al.* 2000, 2009, Jean-Mary *et al.* 2002). In our study, the difference between the measurements with the two procedures was not correlated to the children's age or the room's temperature, differently from what observed by other authors using other similar thermometers (Ng *et al.* 2005, Hausfater *et al.* 2008). Calculating the ROC curve, the NCIT was demonstrated to predict febrile children (axillary temperature >38·0 °C) accurately, sensitivity being 88·7% and specificity 89·9%. Moreover, this procedure was associated with a significant lower discomfort score comparing to the axillary mercury-in-glass measurement, which took at least five minutes and was less tolerated by the children.

Previous studies in children were conducted evaluating the performance of NCITs, reaching contrasting results (El-Radhi & Barry 2006, Osio & Carnelli 2007, De Curtis *et al.* 2008, Bitar *et al.* 2009, Duran *et al.* 2009). In a recent review on the use of these thermometers for screening of international travellers, the positive predictive value of these devices was found to be poor (Bitar *et al.* 2009). Some characteristics of the thermometer that we used in our study may explain the better performance in detecting febrile children with respect to other studies using different NCITs (Chan *et al.* 2004, Chiu *et al.* 2005, Ng *et al.* 2005, Hausfater *et al.* 2008). For example, most devices tested in previous studies were not currently manufactured for a fever screening purpose (Wong & Wong 2006), thus findings should be interpreted with caution. Moreover, a critical issue when using the NCIT is to stabilise the device at the room temperature. When this procedure is not correctly executed, results may be not accurate, as reported by Hausfater *et al.* (2008). Differently, stabilising the thermometer at the room temperature, no correlation between indoor temperature and difference among temperature measured with the two procedure was found in our study. Also, it should be noticed that the distance between the thermometer and the skin is crucial to obtain a correct measurement. The thermometer used in this study contains a luminous pointer to avoid this kind of error, while the majority of NCITs used in previous studies do not include a similar indicator (Bitar *et al.* 2009).

The body areas targeted by NCITs vary among studies and, besides the forehead, the eye corner or the external auricular meatus was targeted by the devices, but this procedure, to our knowledge, has not yet been validated (Chan *et al.* 2004, Liu *et al.* 2004, Chiu *et al.* 2005, Ng *et al.* 2005, Hausfater *et al.* 2008). Additionally, in most previous studies temperature measured by NCIT was compared to reference values measured by tympanic thermometers (Chan *et al.* 2004, Liu *et al.* 2004, Chiu *et al.* 2005, Ng *et al.* 2005, Hausfater *et al.* 2008). However, accuracy of tympanic thermometers in estimating the actual core temperature has not yet been fully established. The difference in findings in this study may, at least partly, be related to the use of the traditional axillary temperature by mercury-in-glass thermometer as a reference value. This issue is one limitation of our study. Direct measurement of body temperature would definitively allow the estimation of the accuracy of NCIT, but obviously this was not feasible in our setting. Finally, in other studies, the majority of the patients were afebrile, not allowing to accurately evaluate the performance of the thermometer in predicting fever (Bitar *et al.* 2009).

Our data suggest that NCIT may be a good alternative to tympanic infrared devices in children. Although some authors found tympanic thermometers to be accurate (El-Radhi & Barry 2006, National Institute for Health and Clinical Excellence 2007, Chiappini *et al.* 2009), others observed low sensitivity in detecting fever in children (Dodd *et al.* 2006). Errors can occur if the probe is not correctly positioned or in the event of tympanic inflammation or earwax (El-Radhi & Barry 2006, National Institute for Health and Clinical Excellence 2007, Chiappini *et al.* 2009). The NCIT has the advantage of measuring body temperature in two seconds and is comfortable for children. Sterilisation or disposable devices are not required, suggesting its potential use in children in ambulatory or hospital settings, by healthcare providers. Further studies are needed to investigate the performance of NCITs in newborn children and for home-use.

Conclusion

According to our results, the NCIT showed a good performance in our study population, has the advantage of measuring body temperature in two seconds and is comfortable for children.

Relevance to clinical practice

Non-contact infrared thermometer may be taken into consideration when assessing body temperature in children aged > one month in hospital or ambulatory.

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Contributions

Study design: EC, SS, MdM, FB; data collection and analysis: EC, SS, FM, RL, LM, AL, CEO, MP, SL, RP, LG and manuscript preparation: EC, SS, RL, MdM, LG, FB.

Conflict of interests

The study was sponsored by Tecnimed Inc., Italy, providing a grant to the Department of Pediatrics, Florence University. The sponsor did not have any role in study design, the collection, analysis, and interpretation of data, the writing of the report, and the decision to submit the paper for publication.

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