

Evaluating the interchangeability of infrared and digital devices with the traditional mercury thermometer in hospitalized pediatric patients: an observational study.

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Research Article

Keywords: Body temperature, children, Bland-Altman analysis, thermometers, mercury thermometers,

Posted Date: September 16th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-78040/v1

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Abstract

A gradual replacement of the mercury thermometers with alternative devices is ongoing around the world as effect of the global strategies to reduce mercury pollution. However, to reduce the risks of misdiagnosis, unnecessary treatments, and omission of care in the pediatric population, more evidence on the reliability and validity of alternative thermometers are needed. The aim of this comparative observational study was to detect any differences in temperature measurements between the gold-standard axillary mercury thermometer (AXL $_{MER}$) and the alternative devices. Temperature values in Celsius (°C) were simultaneously measured in a group of Albanian children aged up to 14 years using both (AXL $_{MER}$) and digital axillary thermometers (AXL $_{DGT}$), as well as forehead and tympanic infra-red thermometers. The AXL $_{DGT}$ device, compared with the AXL $_{MER}$, showed no clinically significant difference in the mean values (-0.04 ± 0.29 °C) and the narrowest 95% Level of Agreement (+0.53 °C to -0.62 °C) in the paired comparisons. For cut-off points of 37.0 °C and 37.5 °C, the AXL $_{DGT}$ showed the highest levels of sensitivity (67.4% and 72.5%) and specificity (95.3% and 99.1%) in detecting fever. This study indicates that the AXL $_{DGT}$ thermometer may prove the better option since it adequately balances accuracy, safety and children's comfort.

Introduction

Body temperature (BT) measurement is an essential component of pediatric health assessment in hospital settings and elsewhere. Normal BT values range from 36.5 °C to 37.5 °C depending on physiological variations, patient characteristics, and sites of measurement 1.2.

Since BT values, when associated to the clinical assessment, contribute to orient diagnoses and therapies for children, unreliable measurements may lead to misdiagnosis, omittance or delay of necessary treatments and prescription of unnecessary therapies or exams^{3–5}. For these reasons, BT measurement should be carried out with valid and reliable devices⁶.

In this regard, intra-corporeal thermometry methods used to obtain 'core' temperature, such as thermistor probes inserted in the pulmonary artery or oesophagus, are considered the gold-standard for BT measurement⁷. However, these methods are invasive and expensive, could expose patients to the risk of complications, and are generally used in critically ill patients^{8,9}.

Historically, the mercury thermometers were accepted as the 'clinical gold-standard devices' for BT measurement in daily clinical practice and, among them, those axillary (AXL_{MER}) have been used routinely everywhere around the world^{7,10,11}.

Some evidence demonstrates the AXL_{MER} thermometer measurements only to be 'proxy' of core BT values since they underestimate the internal BT of about 1.0 °C. However, the lack of accurate alternative devices, comfort for patients, and easiness of use made AXL_{MER} thermometersessential for clinical practice^{2,12}.

However, the risk for environment and public health due to mercury pollution derived from anthropic activities made mercury a global concern and led Governments to adopt strategies aimed to reduce its emissions in the atmosphere, soil, and water¹³. In this regard, a series of initiatives aimed at banning the production, import, and export of mercury products, as well as controlling manufacturing processes in which this substance is used, have been carried out^{13–15}. In accordance with these initiatives, a gradual replacement of mercury thermometers with alternative devices is ongoing in the health systems of countries who are signatories to the Minamata Convention¹³.

Among the alternative devices, galinstan-in-glass, digital, and infrared thermometers are currently available in the market; they are easy to use, cost-effective, non-invasive, and safe¹⁶⁻¹⁸. Nevertheless, only digital axillary (AXL_{DGT}) and infrared tympanic (TYM_{IR}) thermometers are currently recommended in pediatric clinical practice^{1,5,19.20}, since the lack of data confirming the accuracy of other devices to diagnose fever does not allow them to be considered useful tools for BT measurement in pediatric patients^{8,9}. However, the guidelines and recommendations on BT measurement of pediatric patients are based on moderate quality evidence, and most of the available studies aimed to explore the validity and reliability of the alternative devices as 'proxy' measures of core BT, instead of exploring their interchangeability with the historical gold standard (AXL_{MFR})^{10,19,21,22}.

Therefore, in order to increase the available evidence and, thereby, reduce the risks of misdiagnosis, unnecessary treatments, and omission of care in the pediatric population, research on the reliability, validity, and interchangeability of the alternative devices in clinical practice is ongoing globally^{6,10,18,23–26}. It is in this regard that we undertook this study, which aimed to detect any differences in BT measurements between the old clinical gold standard AXL_{MER} thermometer and those new digital and infrared in a pediatric setting. The study hypothesis was that no clinically significant differences existed between the old mercury thermometer and the new devices, especially in regard to sensitivity and specificity for fever detection.

Methods

Study design, setting, and participants

A comparative observational study was conducted from September 2018 to January 2019 in a fifty-bed pediatric ward of a general hospital in Albania, where about one thousand patients are admitted annually for a broad spectrum of medical health issues ranging from respiratory diseases to infectious diseases such as enteritis. Albania is one of the developing countries of Europe where the use of mercury thermometers was still allowed when the study was conducted.

Using consecutive sampling, all pediatric patients aged up to 14 years and requiring BT measurements were enrolled if the parents gave their informed consent. Hospitalized children in critical conditions or those unable to tolerate multiple BT measurements were excluded. Referring to subjects that had to receive BT measurements twice a day, a sample size of at least 327 children was estimated to provide a 95% power (1- β) and a 5% α error in detecting BT measurement differences, using G* Power 3.1.9.2 software.

Variables

In order to perform a secondary analysis of subgroups potentially affecting differences in BT detection between the compared thermometers, data on demographic and clinical variables, such as age, gender, site of BT measurements, admission diagnosis, and antipyretic drugs administration were also collected. In this study, AXL_{MER} was considered the gold standard while AXL_{DGT} , FHD_{IR} , and TYM_{IR} were the alternative methods.

Instruments and data collection

Following each thermometer manufacturer's instructions, BT measurements were collected, twice a day, at 8:00 in the morning and at 5:00 in the afternoon, from axillary, tympanic, and forehead sites simultaneously.

For axillary temperature detection, GEA Medical Mercury thermometers (Product code 10901902464, GEA®, Indonesia) and Easy Touch Digital thermometers (Product code 00006929000000, Chicco®, Italy) were used, whereas for tympanic and forehead temperature detection Infra-Red Comfort Quick devices (Product code 00000656000000, Chicco®, Italy) and Infra-Red Easy Touch thermometers (Product code 00004757100000, Chicco®, Italy) were respectively used. The manufacturer of the alternative thermometers reported a ± 0.1 °C measurement error for the AXL_{DGT} device (BT range from 35.5 °C to 42.0 °C) and a ± 0.2 °C for both TYM_{IR} and FHD_{IR} thermometers (BT range from 35.0 °C to 42.0 °C).

Both the AXL_{DGT} and AXL_{MER} devices were placed deeply in each child's left or right armpit with the arm being held steady taking one and five minutes to measure BT, respectively. The AXL_{MER} was used after making the mercury level down to the minimum (35.0 °C). Recordings were timed through a chronometer for the AXL_{MER} and the beeper of the AXL_{DGT}.

The tympanic BT was detected by scanning the infrared radiation from the tympanic membrane for one second. For each measurement, the probe of the TYM_{IR} thermometer was replaced and the measurements in the ear in contact with pillows were avoided.

As recommended by the manufacturer, the forehead temperature was measured by scanning the infrared radiation from the temporal artery for about five-eight seconds (maximum 30 seconds). Using the same side for temporal measurements allowed to prevent BT differences due to blood vessels depth.

All measurements were performed on clean and dry skin, waiting at least 30 minutes after meals or baths. Prior to their use, all thermometers were calibrated according to the manufacturer's instructions.

To ensure the accuracy of measurements, five nurses, after having attended a theoretical-practical training about the characteristics and usage of new thermometers and about the research protocol, performed all BT measurements and recorded the data on a BT flowsheet under the supervision of one of the researchers.

Data analysis

Data were summarized using frequencies (n), percentages (%), central tendency indexes (mean, median), and dispersion measures standard deviation (SD), interquartile range (IQR), range.

Differences between measurement results of the mercury thermometers and the alternatives devices were statistically checked using paired sample *t*-tests and visually compared using the Bland-Altman scatterplots 27. Pearson's *r* coefficient was calculated to explore the correlation between the investigated devices. Considering as not desirable the differences between the gold standard's and other measurements, a maximum significant level of 0.05 was considered for the *t*-tests, whereas for the Bland-Altman analysis 95% Limits of Agreement (LoA), defining the range within which most BT differences fell, were computed with the formula '*mean of BT measurement differences* ± 1.96 * SD'^{27,28}; mean values of ± 0.5 °C were considered the maximum acceptable LoA based on the available evidence 8.

Finally, to analyze the diagnostic accuracy of the alternative devices in detecting fever, their sensitivity 'true positives' / ('true positives' + 'false negatives') and specificity 'true negatives' / ('true negatives' + 'false positives') were calculated²⁹. For this purpose it needed to fix cut-off to discriminate the fever/no-fever conditions and since normal BT values are related to the site of measurement and no international agreement has been reached on the exact values to define fever^{12,30,31}, this study considered the peripheral BT \geq 37.0 °C and \geq 37.5 °C as cut-off values to include febrile patients.

All data were analyzed using IBM SPSS version 25.0 (IBM Corp., Armonk, New York, USA).

Ethics

This study is a result of an international cooperation between Italian and Albanian academy institutions and was conducted in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board of the Albanian hospital where the research was conducted (letter of approval #1693/2018). Before data collection, a written informed consent was obtained from the children's parents. Nevertheless, no child was forced to participate if there was verbal or non-verbal refusal.

Results

Participants

A total of 356 pediatric patients were enrolled (Table 1). Two hundred and eleven (59.3%) were male and the average age was 3.0 ± 3.0 years (median 2.0; IQR 3.1; range 0-14). The main reasons for hospitalization were respiratory (209, 59.3%) and gastrointestinal diseases (73, 20.6%). Forty patients (11.2%) received antipyretic drug administration before BT measurements.

Differences in BT measurements between the alternative devices and gold standard

As shown in Figure 1, in a paired comparison with the AXL_{MER} device, both AXL_{DGT} and TYM_{IR} showed slightly lower mean BT values, ranging from -0.04 °C to -0.12 °C, respectively (p < 0.001), while mean differences between AXL_{MER} and FHD_{IR} (0.03 °C) were not statistically significant (p = 0.141). A strong correlation was detected between BT measurements performed with AXL_{DGT} and AXL_{MER} thermometers (r = 0.844), while moderate correlations were detected between TYM_{IR} and AXL_{MER} (r = 0.665).

Table 1. Participants' characteristics (n = 356)

		n	%
Gender			
	Male	211	59.3
	Female	145	40.7
Age	(Mean ± SD)	(3.0 ± 3.0)	
Admission diagnosis (grouped by system)*			
	Respiratory	209	59.0
	Gastrointestinal	73	20.6
	Neurologic and sensorial	29	8.2
	Urinary	9	2.5
	Locomotor and articular	3	8.0
	Other	31	8.8
Antipyretic drugs administered before BT measurements			
	Yes	40	11.2
	No	316	88.8

*Missing data n = 3

With reference to daily BT variations, the average data of the measurements taken in the morning and afternoon show that all the alternative thermometers reported values less than that reported by the mercury thermometer (Figure 2), although all the BT variations fell within the maximum measurement error provided by the manufacturer for each device.

The Bland-Altman scatterplots (Figure 3a, 3b, and 3c) show the narrowest 95% LoA (\pm 0.53 °C to \pm 0.62 °C) for the measurement comparison between AXL_{MER} and AXL_{DGT}, and the broadest 95% LoA (\pm 0.81 °C to \pm 1.04 °C) for the comparison between AXL_{MER} and TYM_{IR} values. In all the Bland-Altman scatterplots, the magnitude of differences between the alternative and gold-standard thermometers decreased when the average BT values increased.

Taking \pm 0.5 °C as the maximum clinically acceptable difference, when the three alternative devices were compared to the gold standard, 94.0% of AXL_{DGT} values fell within these cut-offs, followed by FHD_{IR} (83.4%), and then TYM_{IR} (79.3%) (Figure 3d).

In addition, across the entire sample, AXL_{DGT} thermometer showed the highest levels of sensitivity and specificity in detecting fever, regardless of the established cut-offs (Table 2).

Table 2. Diagnostic accuracy of alternative devices to detect fever compared to Gold Standard (Measurements = 711)

Indexes	AXL_DGT	FHD_IR	TYM_IR
(BT ≥ 37.0 °C)			
Sensitivity	67.4	50.4	47.4
Specificity	95.3	91.7	94.8
(BT ≥ 37.5 °C)			
Sensitivity	72.5	64.7	51.0
Specificity	99.1	96.8	98.3

Discussion

This study aimed at detecting any differences in BT measurements between the old gold-standard AXL_{MER} thermometer and the new digital and infrared thermometers in a hospital pediatric setting in Albania where mercury thermometers were still allowed despite the Minamata Convention due to a transition phase related to the in-country resources and capacities¹³. This study could not be currently conducted since on 26 May 2020, the Government of Albania deposited its instrument of ratification, becoming the 120th Party to the Minamata Convention. For this reason, the window of opportunity exploited in this study has been closed and the mercury thermometer cannot longer be used in Albania resulting in beneficial effects for the environment, children, and community.

Following the ban on mercury, in the last 10 years numerous environment-friendly devices have been introduced into clinical settings in many countries around the world to replace mercury thermometers, and a great amount of research has been conducted to explore their validity and reliability ¹⁶⁻¹⁸. Some recent meta-analyses carried out to compare peripheral electronic devices (e.g. AXL_{DGT}, FHD_{IR}, and TYM_{IR}) with central devices (e.g. bladder, esophageal, and rectal) indicated that the peripheral devices showed poor accuracy when used to estimate core BT and inadequate sensitivity when used for fever detection in adults and children^{8,9,22}. However, using a different research methodology, other authors, comparing the peripheral electronic devices, achieved contradictory evidence³²⁻³⁵. For example, some studies found that FHD_{IR} thermometers could serve as a good alternative to AXL_{DGT} due to their user-friendliness and speed of use³⁶, while others, reporting great mean differences between the investigated devices, did not consider the FHD_{IR} device as accurate as the AXL_{DGT} thermometer^{24,34,35}.

The research approaches in the above-mentioned studies had two distinct goals: comparing peripheral devices with central ones and exploring the level of agreement among the alternative thermometers. Surprisingly, available evidence has not completely dissolved concerns about the validity and reliability of the new thermometers and have not fully allayed nurses' doubts emerging from clinical contexts. In fact, when nurses need to make their clinical decisions on the basis of BT values detected with the alternative peripheral devices, they need to know if these new thermometers (e.g. AXL_{DGT} , FHD_{IR} , and TYM_{IR}) are as reliable at least as the old mercury device they used for a long time. To tackle this issue and contribute to the global debate, we conducted this perspective pragmatic research.

In the light of our results, the research hypothesis of no clinically significant differences between the old gold-standard mercury thermometer and the new devices should be partially rejected.

In fact, although moderate to strong significant direct correlations were found between BT values detected by all the alternative devices and those by the AXL_{MER} (r = from 0.623 for TYM_{IR} to 0.844 for AXL_{DGT}), also significant mean differences were found for the paired BT comparisons between each of AXL_{DGT} and TYM_{IR} and the mercury thermometer (-0.04 °C and -0.12 °C, respectively). However, in this case statistically significant differences cannot correspond to a strong clinical significance since it is unlikely that a maximum difference of -0.12 °C can affect some clinical judgements, such as drugs administration or caring interventions. Nevertheless, considering the poor clinical significance of these differences, it would be hazardous to state that the new alternative devices are all equally reliable tools for BT measurement in children.

In fact, beyond the statistical significance, in the visual analysis of difference between measurements (Bland-Altman scatterplots) it is noticeable that the AXL_{DGT} values are the closest to the gold standard's since 95% of their differences fell within the narrowest range (95% LoA = -0.62 °C to +0.53 °C). In addition, the AXL_{DGT} showed the highest percentage (94.0%) of BT differences within the clinical acceptable value of 0.5 °C⁸. For these reasons, AXL_{DGT} thermometer should be considered most similar to the old gold-standard mercury thermometer and, in accordance with current guidelines, may be preferable for measuring BT in children^{3-5, 20}.

 FHD_{IR} and TYM_{IR} devices showed poor agreement with AXL_{MER} thermometer, exhibiting broader 95% LoAs (-0.92 °C to 0.87 °C and -1.04 °C to 0.81 °C, respectively) and more differences higher than 0.5 °C compared to AXL_{DGT} thermometer. In the light of this findings, it would not be cautious to indicate FHD_{IR} and TYM_{IR} as the first choices for BT measurements in children. However, in pediatric clinical settings where FHD_{IR} and TYM_{IR} are used 32,36 , we suggest that BT values be validated through clinical observation and AXL_{DGT} thermometer be used in case of discrepancy.

Furthermore, AXL_{DGT} thermometer also showed better performance in screening for fever than FHD_{IR} and TYM_{IR} devices, even if in this study, as in some other studies, all the investigated devices showed moderate to low sensitivity and high specificity in detecting fever^{8,9,22}. In fact, even if to a lesser extent than the other alternative devices, also the AXL_{DGT} thermometer resulted in a higher proportion of false-negative than false-positive readings, and this could be explained by the tendency to underestimate the gold-standard measurements

adopted in this study. In practice, also using the AXL_{DGT} thermometer, in a minimal proportion of children found to be non-febrile, fever could not be ruled out with certainty. In this regard, it is always advisable, in accordance with current guidelines, a conservative approach to protect children from missed care, by repeating BT measurements or using rectal thermometers to confirm fever, especially when clinical signs and symptoms contrast with detected BT values^{5,20}.

Practice implication

The results of this study suggest that AXL_{DGT} thermometer may be the best choice for BT measurement in pediatric settings, considering especially that this device adequately balances accuracy, safety, and children's comfort. Even if there are practical reasons suggesting the use of TYMIR and FHDIR thermometers in pediatric clinical practice, such as their ease of use, speed of measurements and improved hygiene, the results of this study show that these devices cannot be considered interchangeable with the gold standard adopted in this study, and AXLDGT should be preferred, especially if there are clinical doubts. However, considering the performance of AXLDGT in the screening of fever, clinical decisions should not be based exclusively on BT values, but, in accordance with current guidelines, it is always advisable assessing children for the presence or absence of signs and symptoms potentially associable with fever⁵. Assessing the skin colour and turgor, respiratory function, cardio-circulatory condition, the child's activity, and the presence of headache, shiver, and nausea provide excellent criteria to confirm or doubt a BT value^{5,20}. This last recommendation should be strongly considered for clinical practice especially during epidemic events, such as the current Coronavirus disease 2019 (COVID-19) pandemic. In this regard, one of the special accommodations made in clinical practice and other contexts is the use of the infrared thermometers. For its 'no contact' process aimed at limiting the virus spread, the FHDIR device has become the most widely accepted thermometer in this pandemic. However, considering that in this study fever (≥ 37.5 °C), in about one-third of febrile children could not be detected with the FHD_{IR} device, temperature screening alone should be avoided in every context since it may not be very effective, as also supported by previous evidence⁹. Those signs and symptoms commonly present in children with Coronavirus disease 2019, such as fatigue, dry cough, and other respiratory symptoms, should be considered along with BT values 37,38.

Limitations of the study

The strengths of this study included the adequate sample size of pediatric patients, the measurement of BT in a real clinical setting, the use of axillary mercury thermometers as the gold standard, and the use of appropriate statistical methods for data analysis. However, the results of this study should be accepted bearing in mind the monocentric approach of the study and the differences between core and peripheral BTs.

In conclusion, the results of this study confirmed the AXL_{DGT} device as the best alternative to the AXL_{MER} thermometer in detecting children's BT both in cases of fever or not.-

However, according to current guidelines, when clinical signs and symptoms contrast with detected BT values, it is recommended repeating BT measurements or using rectal thermometers.

Declarations

Acknowledgements

We thank children and their parents for participation. We also thank Dr. Brikena Gjata, Dr. Esmeralda Qevani, Dr. Klementina Xhaferri, and Dr. Erinda Vreto for their assistance in data collection process and Nurses Head Dr. Hedije Bylyku and Dr. Emanuela Ferra for their assistance with patient enrolment.

Authors' contributions

DA: participated in the conception and design of the work, performed the data analysis and drafted the manuscript **GE:** participated in the conception of the work, participated in the acquisition of data and drafted the manuscript. **MV, CV, CC:** participated in the conception of the work and drafted the manuscript **PC:** participated in the conception and design of the work, and critically revised the manuscript. **LL:** participated in the conception and design of the work, performed the data analysis, and critically revised the manuscript. All authors read and approved the final manuscript

Competing interests

The authors declare that they have no competing interests.

Data availability

Data and materials are available from the corresponding author on reasonable request.

Ethics declarations

This study is a result of an international cooperation between Italian and Albanian academy institutions and was conducted in accordance with the Declaration of Helsinki. The study was approved by the Institutional Review Board of the Albanian hospital where the research was conducted (letter of approval #1693/2018). Before data collection, a written informed consent was obtained from the children's parents. Neverthless, no child was forced to participate if there was verbal or non-verbal refusal from the child.

Funding

The authors disclosed receipt of the following institutional financial support: RIA Funds (Research and Innovation Action) - Department of Life, Health, and Environmental Sciences - University of L'Aquila - 2018.

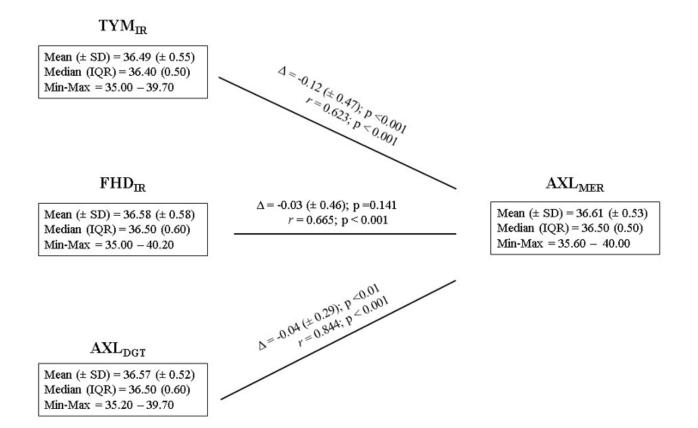
Department of Life, Health, and Environmental Sciences had no part in the design of the study, collection, analysis, and interpretation of data and in writing the manuscript.

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Figures



Paired comparisons between the Gold Standard thermometer and the alternative ones (Measurements = 711)

Figure 1

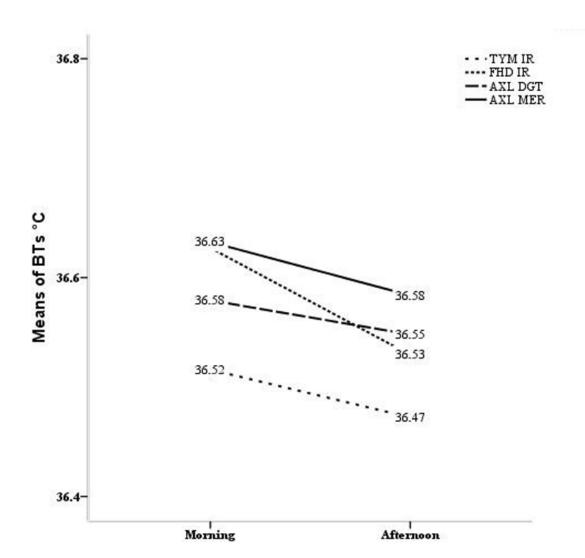


Figure 2

Body temperature values and time of the day

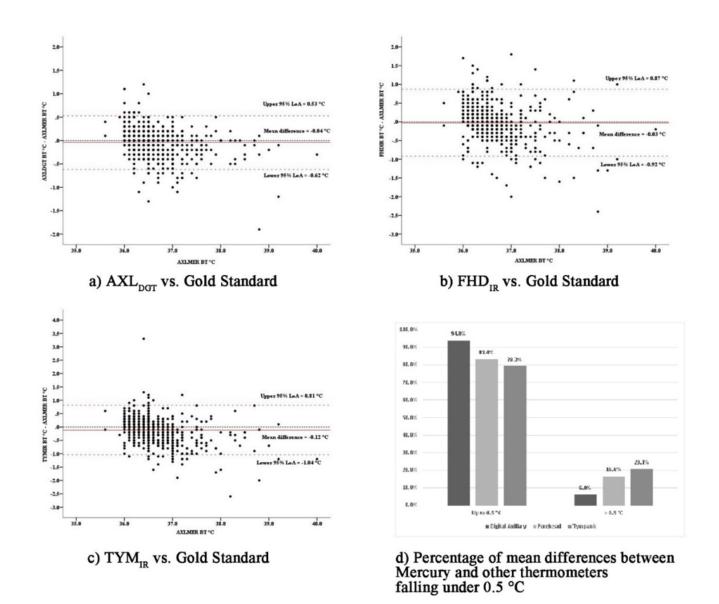


Figure 3

Paired comparisons between the Gold Standard mercury thermometer and the other devices. Legend. a) AXLDGT vs. Gold Standard; b) FHDIR vs. Gold Standard; c) TYMIR vs Gold Standard; d) Percentage of mean differences between Mercury and other thermometers falling under 0.5 °C