

ORIGINAL ARTICLE

Clinical accuracy and agreement between tympanic and forehead body temperature measurements for screening of patients with COVID-19

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Abstract

Aim: To investigate the accuracy, reliability and agreement between infrared forehead thermometers versus infrared tympanic thermometers temperature, a cross-sectional study was conducted in April 2020.

Methods: The forehead and tympanic temperatures of 615 subjects were measured simultaneously in three exposed SARS-COV-2 groups at one hospital in Iran, during April 2020. These comparisons were evaluated by Bland–Altman Plot, repeatability, Passing–Bablok regression and Lin's concordance correlation coefficient. The receiver operating characteristic (ROC) analysis was done to describe the discrimination accuracy of a diagnostic test. The study adhered to STROBE checklist for cross-sectional studies.

Results: A Bland–Altman plot indicated that the limits of agreement between the forehead and tympanic temperature were -0.259 to $+0.19^{\circ}\text{C}$. Passing–Bablok regression analysis illustrated that the infrared forehead was not linearly related to tympanic temperatures (reference method), with a slope estimate that was significantly different from 1.00. The infrared forehead thermometer showed poor precision and lower accuracy than the tympanic. The forehead temperature readings had 60.0% sensitivity and 44.4% specificity ($p > .05$) to predict disease.

Conclusion: According to the results of study, there is no evidence that the assessment of temperature by infrared forehead thermometer could discriminate between the two groups (positive and negative).

KEYWORDS

agreement, body temperature, fever, forehead, hospital infection, nursing, SARS-COV-2, screening, thermometer, tympanic

1 | INTRODUCTION

A coronavirus disease 2019 (COVID-19) emerged from Wuhan, China in December 2019. It transmitted easily and spread rapidly to other countries. In order to control the current COVID-19 pandemic in the absence of any effective vaccine, the World Health Organization (WHO) has demanded that health authorities of all countries engage in social distancing, active detection and management of suspected cases (Alwashmi, 2020). Many countries attempt multiple public health measures to screen and control infected people and reduce the outbreak of the disease (Aragón-Vargas, 2020).

Many persons with COVID-19 can be infected and contagious while being asymptomatic. Although the reverse transcription-polymerase chain reaction (RT-PCR) is a reliable test in detecting both symptomatic and asymptomatic COVID-19 (Bwire & Paulo, 2020). Body temperature might not be an adequate screening measure, but checking body temperature is one of the quickest and most cost-efficient screening tools in public health (Wu & Qi, 2020). Indeed, measurement of changes in body temperature to detect fever is one major steps in triaging suspected and positive patients, and it is mandatory for the screening of all travellers entering the countries (Chen et al., 2020) and at the entry to public buildings in many governmental buildings (Wilder-Smith et al., 2020).

Fever is an early symptom that affects up to 89% of patients with COVID-19 (Fong et al., 2020). Given that the WHO recommends screening as one of the COVID-19 signs, evaluation of the temperature is considered a good screening method (de Oliveira Neto et al., 2020). Nevertheless, some of the investigators claimed that only 30.7% (Richardson et al., 2020) to 43.8% (Guan et al., 2020) of patients with COVID-19 presented with fever on admission.

1.1 | Background

Fever is defined as an elevation of temperature $>100^{\circ}\text{F}$ (37.7°C), is considered normal diurnal body temperature, is an adaptive physiological response to perceived immunological threat and a sign of active infection (Amjadi et al., 2021). The central body temperature may range between about 35°C and 39°C , depending on environmental thermal and physiological changes such as fever. Circadian rhythms can vary in body temperature with fluctuations of about 0.5°C to 1.0°C (Aragón-Vargas, 2020). Body temperature measurement depends on weight, gender and age of individuals (Aadal et al., 2016). In hospitals, nurses are responsible for measuring temperature accurately. In COVID-19 conditions, choosing a reliable and accurate thermometer that gives both accurate measurements and does not spread the disease is an important and challenging concern.

The chief objective for taking a body temperature measurement is to obtain an estimate of a patient's core body temperature. Although pulmonary artery catheterisation is the reference standard to measure core body temperature (Aw, 2020), this method is invasive, requires specialised skills and equipment and is not suitable

What does this paper contribute to the wider global clinical community?

- This is a key finding suggesting that the infrared forehead thermometer measurement produced a 'false sense of security' if used as a screening device.
- During COVID-19, it is essential that a reliable and accurate thermometer is used to obtain temperature measurements and that the procedure does not spread the disease.

for screening. Instead, axilla, oral, tympanic, rectal, oesophageal and bladder routes are noninvasive methods to measure temperature (Sener et al., 2012). Rectal and oral thermometers are moderately correlated with core body temperature but require contact with bodily fluids and hence risk contamination and are not suitable for COVID-19 screening (Aw, 2020). The technique that is optimal for fever screening is to measure non-contact temperature with an infrared, contactless device that provides a practical, reasonably safe and quick reading. The tympanic membrane and the hypothalamus share an arterial blood supply originating from the carotid artery; therefore, the tympanic membrane is considered to directly reflect core temperature in adults and even in paediatric patients (Dante et al., 2019; Gasim et al., 2013).

Results in Gasim et al. (2013) study showed that a tympanic thermometer can be used in clinical practice, especially in the emergency setting, and it is easy and quick to use. Infrared skin thermometers can be used to measure temperature rapidly and noninvasively. For instance, infrared tympanic thermometers can provide temperature readings within seconds. Most of them measure temperature over the central forehead area, but temperature over other body surfaces may also be measured (Bharti et al., 2017). The forehead is the ideal part of the body to take a temperature because it is supplied by the temporal artery, which receives high blood flow from the carotid artery (Sener et al., 2012).

Although each method has its own advantages and disadvantages, there are many challenges in choosing the type of thermometer as well as a suitable area of the body for taking the measurement based on the patient's age and medical condition (Rubia-Rubia et al., 2011). Mohd Fadzil et al. (2010) recommended that among noninvasive thermometers, the digital oral thermometer gave the best concordance (limits of agreement 0.48 – 0.59°C) and the digital infrared tympanic ranked second (limits of agreement -0.88 to 0.85°C) (Mohd Fadzil et al., 2010). Another study showed that there is a lack of agreement between body temperature measurements by non-contact forehead, tympanic and axillary modes in the adult emergency department population (Sener et al., 2012). Many studies mentioned that to reduce the risk of spreading COVID-19 infections it is better to use non-contact thermometers. However, the validity, reliability and accuracy of such readings have not been evaluated (Aragón-Vargas, 2020).

Regarding the comparison of the accuracy of tympanic and forehead thermometers, the results of some studies demonstrated that tympanic temperature measurements showed a higher correlation to axillary temperatures compared to forehead temperature measurements that have a high value of bias (Apa et al., 2013; Teller et al., 2014). Chen et al. (2020) concluded that during the COVID-19 outbreak the wrist measurements are more stable than forehead measurements in different type of transportation of patients (Chen et al., 2020). Another study showed that despite the forehead thermometer being commonly used, the temperature measurement may not be valid and it can therefore give a false sense of security during the COVID-19 pandemic (Aragón-Vargas, 2020). The infrared non-contact thermometer readings predict core temperatures and may differ based on atmospheric temperature that can be affected by the surroundings (Onubogu et al., 2021). Also environmental conditions, including combinations of air temperature, radiant temperature, humidity and air velocity, can influence non-contact forehead infrared digital thermometer accuracy (Goggins et al., 2022).

During the COVID-19 pandemic, tympanic thermometers and non-contact infrared thermometers are being used for temperature screening and rapid triaging (Chen et al., 2020). Considering body temperature is an important value for clinical decision-making in patients with COVID-19, thus the results from this study may help to mitigate the occurrence of false-negative cases, because they falsely reassure and can result in a potential future infection clusters.

In this study, we sought to examine and compare the accuracy of tympanic and forehead temperature measurements using infrared sensor tympanic thermometer and non-contact infrared thermometer in negative, positive and suspected COVID-19 cases. Moreover, we aimed to identify the optimal cut-point for the diagnosis of fever.

2 | MATERIALS AND METHODS

2.1 | Design

This is cross-sectional study was conducted in April 2020. The guidelines on 'Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)' were chosen to guide this study (File S1).

2.2 | Method

In this study, adult patients who were admitted for COVID-19 infection and presented with or without fever to the emergency room of the hospital affiliated with the Mazandaran University of Medical Sciences. Mazandaran Province is an Iranian province located along the southern coast of the Caspian Sea. In this study, 615 cases (200 negative, 215 positive and 200 suspected cases) were recruited using convenience sampling.

- *Positive cases* are patients who had a confirmed disease that was approved by specialist opinion with laboratory findings and lung computerised tomography (CT).
- *Suspected cases* are patients who were admitted with a positive clinical examination but their laboratory findings were negative and they were waiting for the results of a lung CT.
- *Negative cases* were those who were admitted for a check-up (patients' family) and their laboratory findings and lung CT results were negative.

Inclusion criteria were participants' willingness to take part in the study, no smoking and drinking cold/hot liquid or food within 30 min. In addition, participants were excluding from study if they had the following conditions: acute otitis media, wearing hearing aid or having excessive earwax, and head trauma or any injuries.

Participants' temperatures were measured by a nurse and the data were collected consecutively over three days, (one day for each group) in April 2020. Two thermometer devices were used in this study (i) OELEO™ NCFT-805 Infrared Sensor Thermometer Non-Contact Temperature for forehead temperature (measurement range = 32–42.9°C, accuracy = $\pm 0.3^\circ\text{C}$, made in China) and (ii) Truly Instrument TET350 Infrared Ear & Forehead Thermometer™ for left and right ear temperature (measurement range = 34–42.2°C, accuracy = $\pm 0.2^\circ\text{C}$, made in China). The instructions for using of the thermometers were read and followed precisely by the nurse.

In addition, demographic information (age, gender), Body Mass Index (BMI), room temperature and time of measuring were recorded for each case. After assessing eligibility criteria and obtaining participants' informed consent, a nurse collected the required data. The same procedure for measurement was applied to both the right and left ear of the same patients with at least 15-second interval. Meanwhile, there were a few minutes' between measurements of ear and forehead temperatures.

2.3 | Data analysis

Descriptive statistics for the temperature readings were presented as mean with standard deviations (SD) and frequencies (per cent) for categorical variables. Differences in the temperature readings in patients who were suspected to be positive or patients who were negative were compared using one-way ANOVA (if normality and homogeneity assumptions were satisfied); otherwise, the Kruskal–Wallis test was used. Pairwise comparisons were adjusted using Bonferroni. Since one operator measured the forehead and tympanic temperatures, thus interclass correlation coefficients (ICC) were used to assess intra-rater reliability.

Agreement between the forehead and ear temperatures was assessed using Bland–Altman plot. Then, coefficient of repeatability (CR) was assessed. CR was estimated as 1.96 times the SD of the differences between the two measurements (Bland & Altman, 1986). Given that the proportional changes between

TABLE 1 Bland-Altman plot (Tympanic temperatures consider as a gold standard)

Measurement	n	Mean Difference (SD)	Difference range (error)	Mean difference ±2SD	% Points out of Mean difference ±2 SD	Repeatability (95% CI)
Right ear						
Positive	215	0.827 (0.541)	-0.32 to 2.39	-0.255 to 1.909	5.1	1.236 (1.094,1.421)
Suspected	200	0.553 (0.365)	-0.44 to 2.34	-0.177 to 1.238	5.0	1.18 (0.97, 1.52)
Negative	200	0.716 (0.312)	-0.26 to 1.78	0.033 to 1.401	3.3	1.28 (1.13, 1.49)
Left ear						
Positive	215	0.790 (0.506)	-0.43 to 2.53	-0.222 to 1.802	6.5	1.24 (1.09, 1.42)
Suspected	200	0.552 (0.361)	-0.44 to 2.736	-0.170 to 1.274	5.5	1.18 (0.97, 1.52)
Negative	200	0.700 (0.332)	-0.37 to 1.83	0.036 to 1.364	5.0	1.30 (1.14, 1.51)

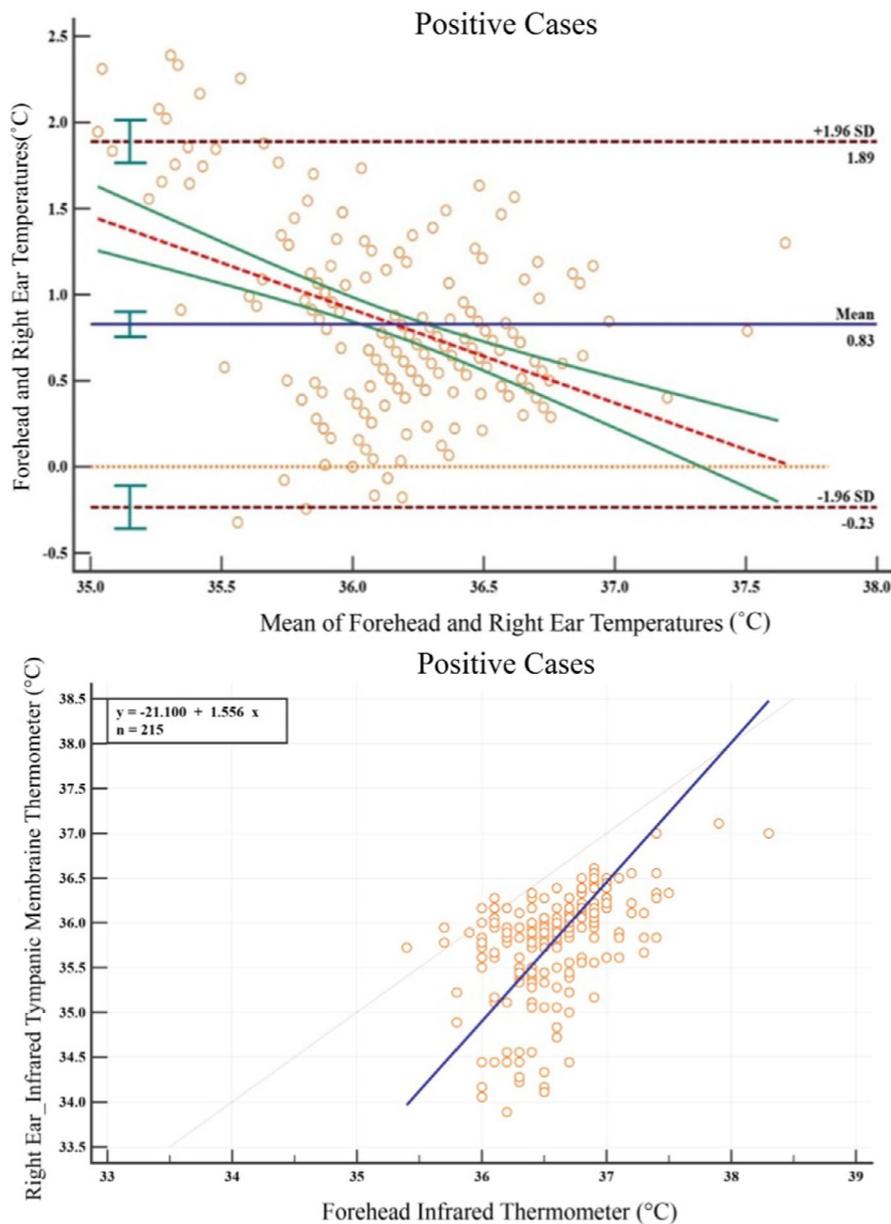


FIGURE 1 Bland-Altman plots and Passing-Bablok regression lines of temperature of forehead infrared thermometer and right infrared tympanic membrane thermometer in positive cases (n = 215)

the two techniques are very sensitive to non a normality distribution, linear relationships and especially outliers, the agreement between the forehead and ear temperatures was assessed

using graphical method such as Passing and Bablok regression. Because Passing and Bablok regression is not sensitive to outliers and assumes that measurement errors in both procedures have

the same distributions, not necessarily normal, constant ratio of variance, arbitrary sampling distribution and imprecision in both procedures (Bilic-Zulle, 2011) are accommodated. Also there must be a high correlation between scores to be appropriate to compare by Passing–Bablok regression (Passing & Bablok, 1983). Passing–Bablok regression analysis was estimated to determine the systematic and proportional differences (Passing & Bablok, 1984) between forehead and ear (right and left) temperatures by forehead infrared thermometer and infrared tympanic membrane thermometer. The Passing–Bablok regression equation is less sensitive to outliers, the intercept A and the slope B are measures of the systematic differences and are measures of proportional differences between the two methods, respectively. These hypotheses are accepted if the confidence interval for A and B contains the value 0 and 1, respectively. While the cumulative sum linearity test (CUSUM) was used to evaluate whether residuals are randomly scattered above and below the regression line and do not exhibit any distinct trend. The CUSUM test $p \leq .05$ indicates a significant difference from linearity and two analytical methods (forehead infrared thermometer versus infrared tympanic membrane thermometer) should be further investigated (Bilic-Zulle, 2011). Passing and Bablok suggested that a preliminary Kendall's Tau test (T) be conducted to evaluate the positive high correlation assumption (Passing & Bablok, 1983) that $T \geq \pm 0.7$ was considered as a strong value (Akoglu, 2018).

Also concordance correlation coefficient (CCC) (Lawrence & Lin, 1989) was applied to determine reproducibility as an absolute agreement. It also assesses the degree to which pairs of measurements fell on the 45° line through the origin. This measure included an estimation of precision ('r', which measures how far each measurement deviates from the best-fit line) and accuracy (bias correction factor 'Cb', which measures how far the best-fit line deviates from the 45° line through the origin). CCC values >0.99 , 0.95 to 0.99, 0.90 to 0.95 and <0.90 are considered to be almost perfect, substantial agreement, moderate and poor, respectively (McBride, 2005).

Receiver operating characteristics (ROC) analysis was performed to determine the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the temperature readings on positive or suspected cases compared to negative cases. All analyses were performed using IBM SPSS Statistics for Windows, version 26 (IBM Corp., Armonk, N.Y., USA) and MedCalc for Windows, version 20.015 (MedCalc Software; Ostend, Belgium) with statistical significance set at two-sided 5%.

2.4 | Ethical considerations

The protocol of this study was approved by the Mazandaran University of Medical Sciences Research Ethics Committee (IR.MAZUMS.REC.1399.7317). All participants gave verbal informed consent to this study.

3 | RESULTS

The mean age of participants was 47.05 (SD = ± 16.9) years, and the gender distribution was almost equal. All of the COVID-19 positive and suspected cases were having their temperature checked before fever-reducing medicine (they received a fever-reducing drug one to three hours after admission to the hospital). The mean and standard error of the room temperature at the time of measurement of the temperatures of positive, suspected and negative cases were $25.01 \pm 0.19^\circ\text{C}$, $21.53 \pm 1.8^\circ\text{C}$ and $25 \pm 0^\circ\text{C}$, respectively.

Table 1 shows that the error of the forehead measurements is as high as 2° (Centigrade) above the ear measurements, with most of the differences having more than 5% outside the ± 2 SD range. This signifies a moderately weak agreement. Furthermore, Figures 1 and 2 showed that for patients' measurements, there is a bias for forehead having higher readings in the lower temperature range. For negative cases, forehead bias was lower at lower temperatures but the bias was higher as well at higher temperatures. For suspected subjects, there is no dominant bias (see Figures 3 and 4). The RC_5 ranged between 1.188 and 1.302 degree for three groups of forehead vs. tympanic for the right and left ear.

The results of Kendall's Tau showed a positive and strong correlation between temperatures of forehead and tympanic membrane infrared thermometer. According to Table 2, the results of the Passing and Bablok regression analyses showed that compression between temperatures of forehead infrared thermometer and right and left infrared tympanic membrane thermometer were different in the three groups. Thus, there were systematic and proportional differences between the two methods. Namely, both methods had significant differences and forehead infrared thermometer could not be used instead of the infrared tympanic membrane thermometer. The regression plot confirms these observations (see Figures 5 and 6).

With regard to CCCs, there were poor agreements between temperature of forehead infrared thermometer and right and left infrared tympanic membrane thermometer in the three groups (Table 2).

The area under the ROC curves (AUCs) of the three measurements for prediction of patients and suspected cases are low (<0.7). The NPVs are below 40% with a high false-negative rate of 60%. The PPVs range was between 64% and 89%. These three variables, namely the forehead temperature, left ear temperature and right ear temperature, were non-significant predictor of disease status. Further evaluated through ROC curve analysis was necessary to determine if a cut-point value could be obtained for the prediction of disease status. Forehead temperature, left and right ear temperature did not confer any cut-point value of diagnostic significance, because the AUC for these variables did not reach the level of statistical significance ($p > .05$). According to the ROC curve analysis, the optimal cut-point value to predict disease status was 36.5 for the forehead temperature (see Figure 7). With this cut-point value, the forehead temperature had 60.0% sensitivity and 44.4% specificity to predict disease status (AUC: 0.52; 95% CI: 0.46–0.57; $p = .55$).

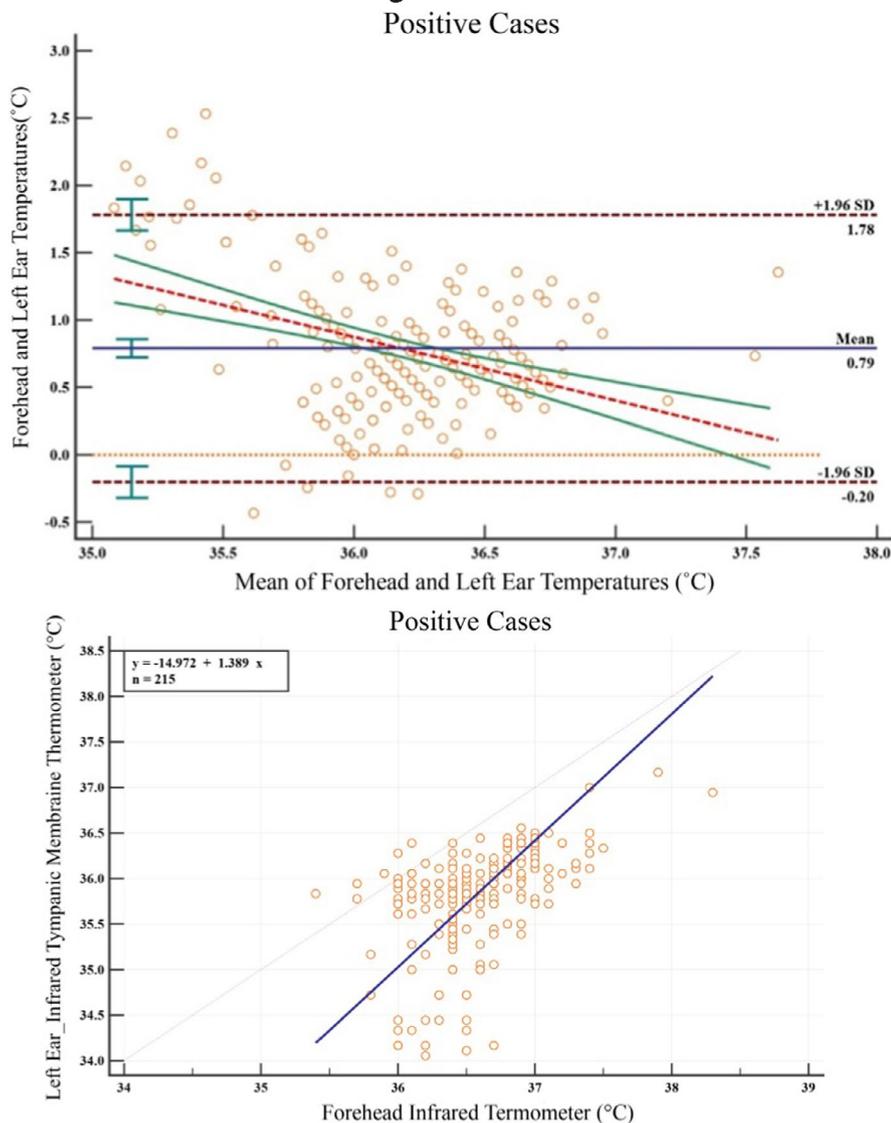


FIGURE 2 Bland-Altman plots and Passing-Bablok regression lines of temperature of forehead infrared thermometer and left infrared tympanic membrane thermometer in positive cases ($n = 215$)

The optimal cut-point value to predict disease status was 35.9 for the left and right ear temperature. With this cut-point value, the left ear temperature had 61.0% sensitivity and 48.0% specificity to predict disease status (AUC: 0.55; 95% CI: 0.49, 0.60; $p = .10$), and the right ear temperature had 63.0% sensitivity and 42.0% specificity to predict disease status (AUC: 0.53; 95% CI: 0.47, 0.58; $p = .29$) (see Figure 7 and Table 3).

For discriminant validity, differences were observed between the positive and suspected cases for the forehead and left ear measurements (Table 4).

4 | DISCUSSION

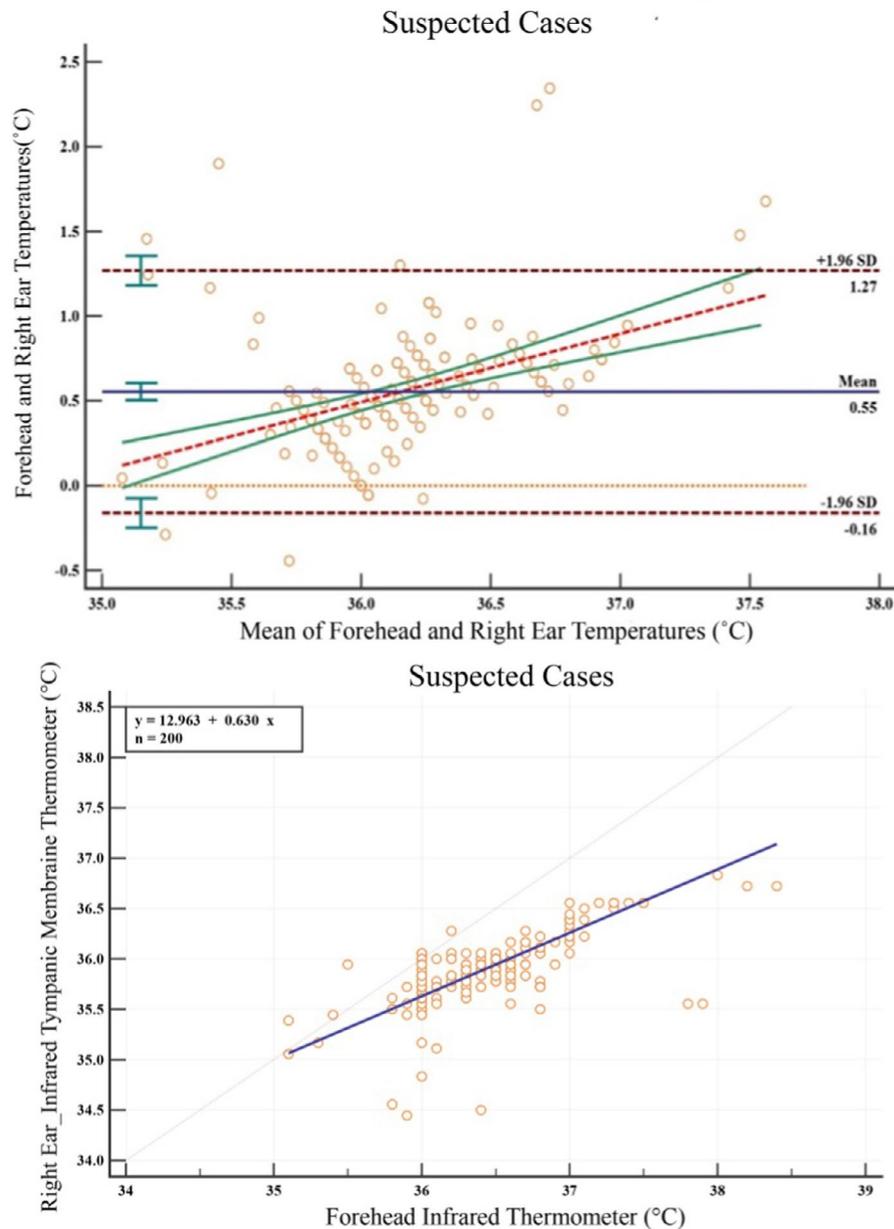
The SARS-CoV-2 virus which is the etiological agent for the COVID-19 pandemic is transmitted through aerosol droplets expelled from the mouth and nose when talking, coughing and sneezing (Liu et al., 2020; World Health Organisation Commentaries, 2021). The initial symptoms of the infection are rather general and indistinguishable from common diseases such as common cough, cold, influenza and

most other infectious diseases. However, the incubation period for SARS-CoV-2 is longer than for the influenza virus, and a much higher proportion of SARS-CoV-2 patients' progress to a severe and critical stage of illness, with a large number succumbing to the disease (Centers for Disease Control & Prevention, 2021; Ejima et al., 2021).

Viral nucleic acid detection via real-time RT-PCR is the standard method for diagnosis of COVID-19. Although only a small percentage of RT-PCR positive individuals show clinical symptoms that need hospitalisation and clinical intervention. According to the COVID-19-associated hospitalisation surveillance network (COVID-NET), hospitalisation rates were 4.6 per 100,000 populations among patients identified as COVID-19 positive through COVID-NET during a 4-week period of 1-28 March 2020, (CDC Morbidity & Mortality Weekly Report, 2020). Nonetheless, during the pandemic, the healthcare facilities in many countries are struggling to cope with the high number of COVID-19 patients, and thus a system for triage of patients is of paramount importance to ensure prompt treatment.

In our study, we had chosen the tympanic temperature as the reference standard for comparison, as recommended by health authorities across the world for best nursing practice [The National

FIGURE 3 Bland–Altman plots and Passing–Bablok regression lines of temperature of forehead infrared thermometer and right infrared tympanic membrane thermometer in suspected cases ($n = 200$)



Health Service Pediatric Guidelines for Temperature Measurement (NHS Greater Glasgow & Clyde, 2020)]. This procedural guideline for nurses is intended for highly dependent or critically ill infant or children who require body temperature monitoring, and according to our interpretation is applicable to the current COVID-19 pandemic situation. This notion was also supported by a recent systematic review and meta-analysis conducted by Shi et al. (2020) that concluded that tympanic thermometry has a high diagnostic accuracy and is a good alternative for screening of the temperature in paediatric patients. The blood supply of the tympanic membrane from the common carotid artery is shared with the hypothalamus. It has long been suggested that the tympanic membrane temperature closely represents the hypothalamic temperature and thus the core temperature and is therefore a strong indicator for fever (Brinnel & Cabanac, 1989; Childs et al., 1999). Brinnel and Cabanac (1989) suggested that the lower anterior quarter of the tympanic membrane has a higher temperature on the surface of the tympanic membrane

and a temperature measurement from a point in this region is least sensitive to head cooling. A recent study revisited this hypothesis and demonstrated that a point in front of the malleus bone registered high steady-state temperature and showed stability by indicating the core body temperature (Yeoh et al., 2017). The advantages of tympanic thermometer readings are as follows: it is noninvasive, gives rapid results and is relatively easy to use as well as compatible with the paediatric population (Mogensen et al., 2018). Other advantages of tympanic or aural thermometry are that the procedure itself is more hygienic, less invasive and safer than measuring rectal and oral temperature. In the context of the COVID-19 pandemic, this is a point of precaution as the virus RNA is shedding in oral fluids as well as in the rectal cavity, suggesting a possible faecal-oral route of transmission (Xu et al., 2020). Hence, oral thermometry in adults and rectal thermometry in children may present a risk of infection and is discouraged. Instead, non-contact infrared sensor type thermometers should be used.

Suspected Cases

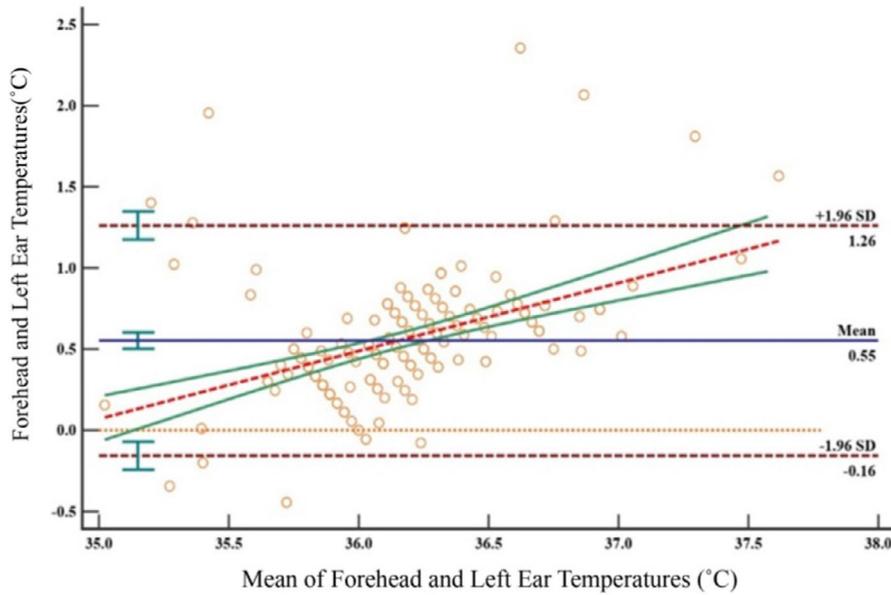


FIGURE 4 Bland-Altman plots and Passing-Bablok regression lines of temperature of forehead infrared thermometer and left infrared tympanic membrane thermometer in suspected cases (n = 200)

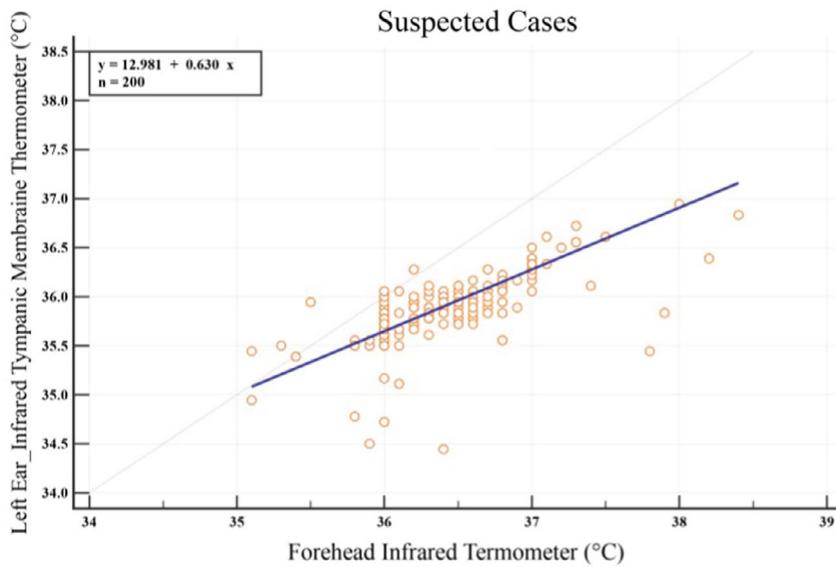
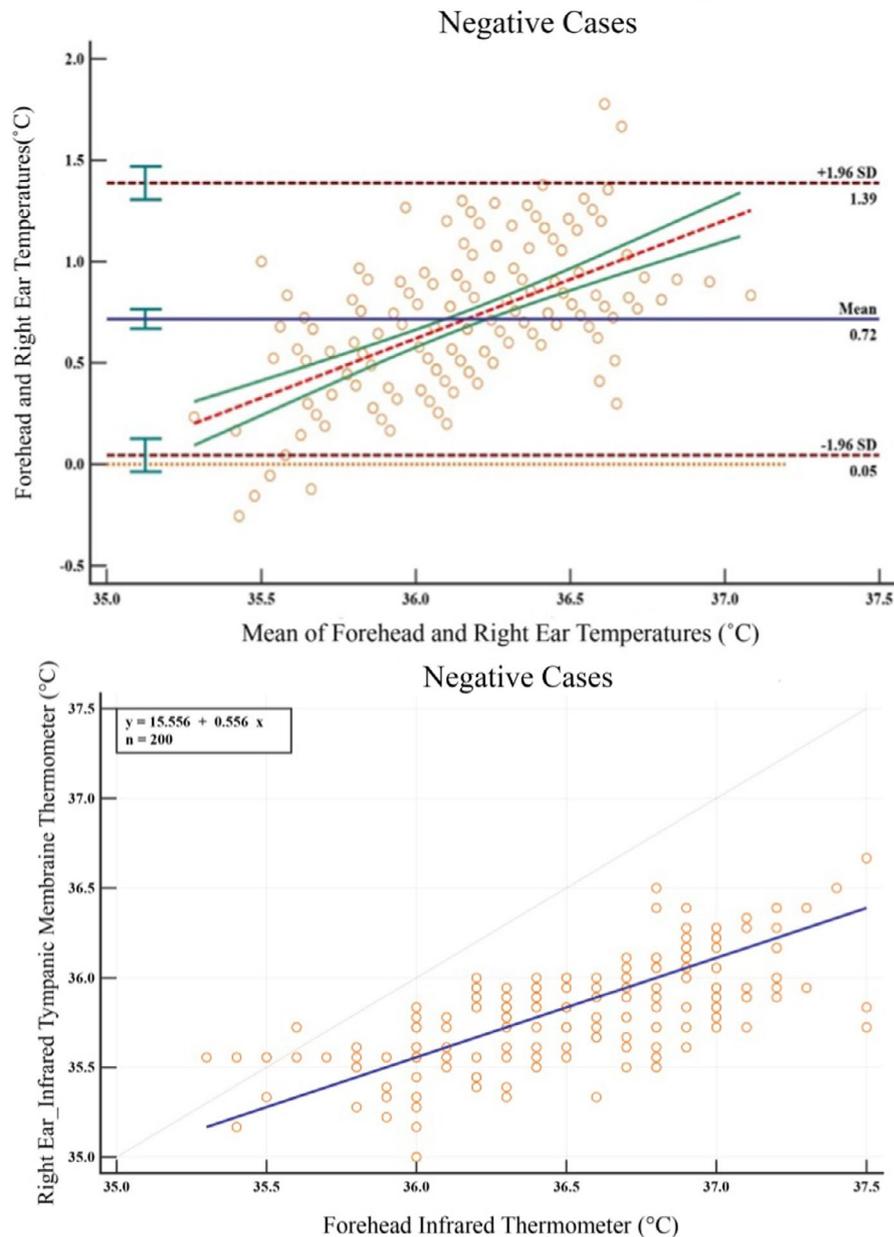


TABLE 2 Passing-Bablok regression and concordance correlation coefficient analysis of evaluated body temperature between forehead and tympanic temperature

Forehead versus Tympanic		Statistical Procedures								
		Passing-Bablok regression					Concordance correlation			
Ear	Status	Intercept A	95% CI ¹	Slope B	95% CI	CUSUM test ²	CCC ³	95% CI ¹	r ^{c4}	Cb ⁵
Right	Positive	-21.10	-33.31, -9.90	1.55	1.25, 1.88	p < .00	0.20	0.14, 0.25	0.49	0.40
	Suspected	12.96	10.61, 15.66	0.62	0.55, 0.69	p = .05	0.35	0.29, 0.42	0.68	0.52
	Negative	15.55	13.54, 18.09	0.55	0.48, 0.61	p = .08	0.21	0.17, 0.26	0.67	0.31
Left	Positive	-14.97	-25.16, -4.77	1.38	1.11, 1.66	p < .00	0.20	0.14, 0.25	0.49	0.40
	Suspected	12.98	10.61, 15.66	0.62	0.55, 0.69	p = .05	0.35	0.29, 0.42	0.69	0.51
	Negative	15.55	15.55, 18.10	0.55	0.48, 0.55	p = .05	0.22	0.17, 0.27	0.70	0.31

Note: (1) 95% Confidence interval, (2) Cumulative sum linearity test, (3) Concordance correlation coefficient, (4) Pearson correlation coefficient (precision), (5) Bias correction factor Cb (accuracy).

FIGURE 5 Bland–Altman plots and Passing–Bablok regression lines of temperature of forehead infrared thermometer and right infrared tympanic membrane thermometer in negative cases ($n = 200$)



In our study, we found a positive correlation between forehead temperature and tympanic temperature, the error of the forehead measurements was 2 degrees higher than ear measurements; $>5\%$ beyond ($SD \pm 2$). range). The discordance between the forehead thermometer measurements compared to the tympanic measurement signifies that it is not suitable for use in the clinical setting for screening healthy, suspected and positive COVID-19 patients for fever. Forehead temperatures had the lowest sensitivity, and moderate specificity, left ear temperatures had moderate sensitivity and the highest specificity. Whereas right ear measurement had the highest sensitivity and lowest specificity for predicting disease status.

Indeed, when analysing the difference between the three groups (positive, suspected and negative cases), the high false-negative rate (60%) for prediction of positive and suspected cases from our study confirms the finding that forehead thermometry is not an ideal method for body temperature measurement.

Our study agrees with a previous study that showed that tympanic temperature measurements had the highest, while forehead method had the lowest accuracy. Whereby the authors had compared the accuracy and precision of four common peripheral temperature measurements including tympanic, forehead, axillary and oral methods (Asadian et al., 2016). The subjects of the Asadian study were patients in the ICU. Our findings had also concurred with two other studies by Ganio et al. (2009) and Rubia-Rubia et al. (2011) who found low sensitivity, specificity and lack of agreement of forehead temperature with the standard method (Ganio et al., 2009; Rubia-Rubia et al., 2011). Nonetheless, the limitation in the previous study was the controlled ambient temperature that was similar for all patients, whereas this was not the case for our study. In the present study, we had measured the ambient temperature conditions for the three groups of subjects, whereby the ambient temperatures for positive and negative cases were similar at $25 (\pm 0.19)^\circ\text{C}$, compared

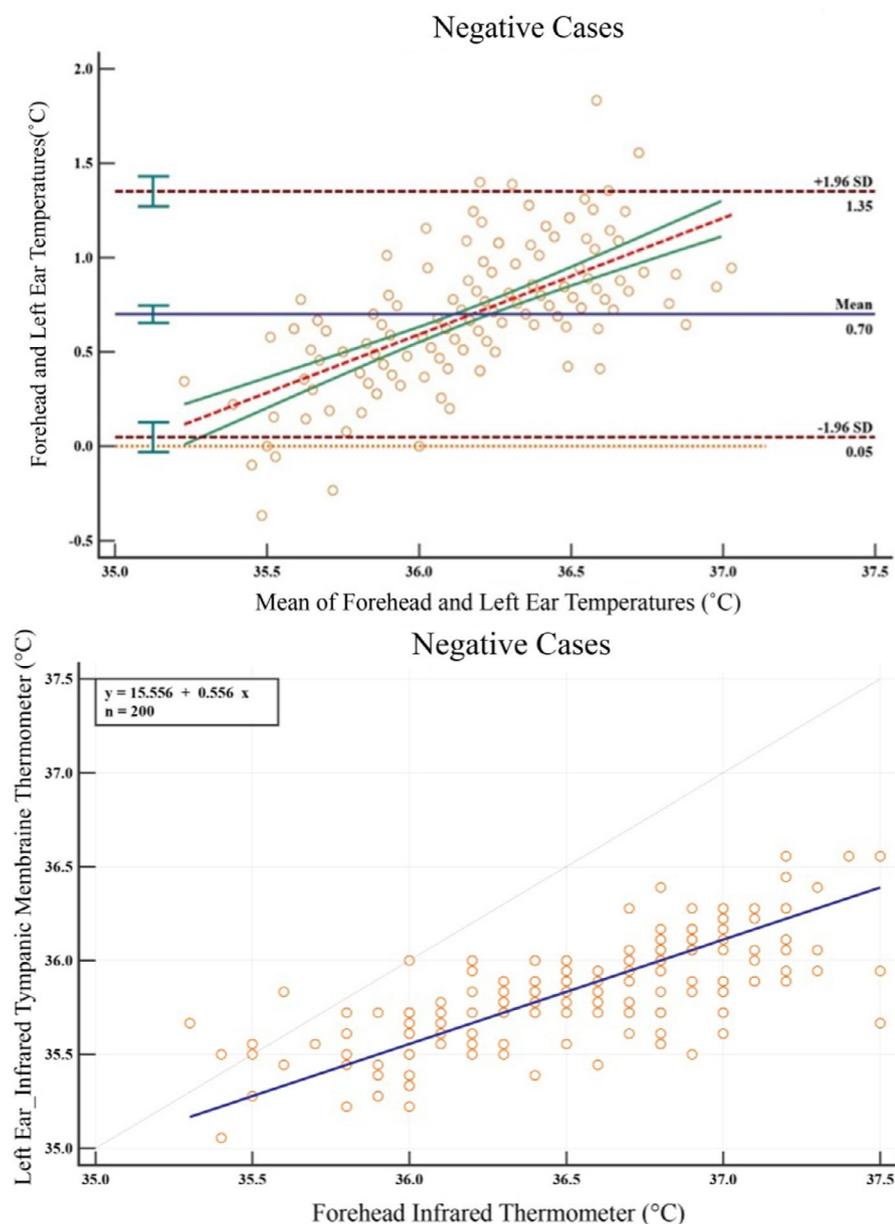


FIGURE 6 Bland-Altman plots and Passing-Bablok regression lines of temperature of forehead infrared thermometer and left infrared tympanic membrane thermometer in negative cases ($n = 200$)

to the much lower ambient temperature for suspected cases at $21.53 (\pm 1.8)^\circ\text{C}$. We surmise that the forehead method is unreliable as the ambient temperature can affect the accuracy of body temperature measurements, especially if the individuals have been exposed to the cold outdoor temperature for extended periods, and this could mask the actual presence of an elevated core temperature or fever.

Several comparative studies between the use of tympanic temperature measurement against oral, rectal and axillary sites of measurement had been performed by others (Dzarr et al., 2009; Jahanpour et al., 2008; Khosravi et al., 2006; Lawson et al., 2007; León et al., 2005). Almost all the research results in these studies, with the exception of Lawson et al. (2007), have confirmed the accuracy, precision and sensitivity of the tympanic thermometry. The authors of these studies have recommended the right and left tympanic measurement as the most optimal method for measuring body temperature in patients. This is because the tympanic measurement

is said to have good correlation and agreement with the standard method, it is accessible and easy to use, besides prevention of transmission of infection.

Conversely, some studies suggested that there was lack of agreement between different thermometer types. A study on 161 nursing students found that non-touch infrared forehead thermometers had significantly different temperature readings compared to digital oral and digital axillary thermometers; but they were similar to the readings of infrared tympanic thermometers (Sweeting et al., 2021). A report based on de-identified electronic health records of 154 hospitals from the ICU Collaborative Research Database v2.0 may have provided a possible explanation (Harding et al., 2021). This report demonstrated that temperature measurement for all body sites had very low agreement with reference temperatures. Moreover, for temperatures retaken at the same site, every site showed low reproducibility. The authors

FIGURE 7 ROC curve

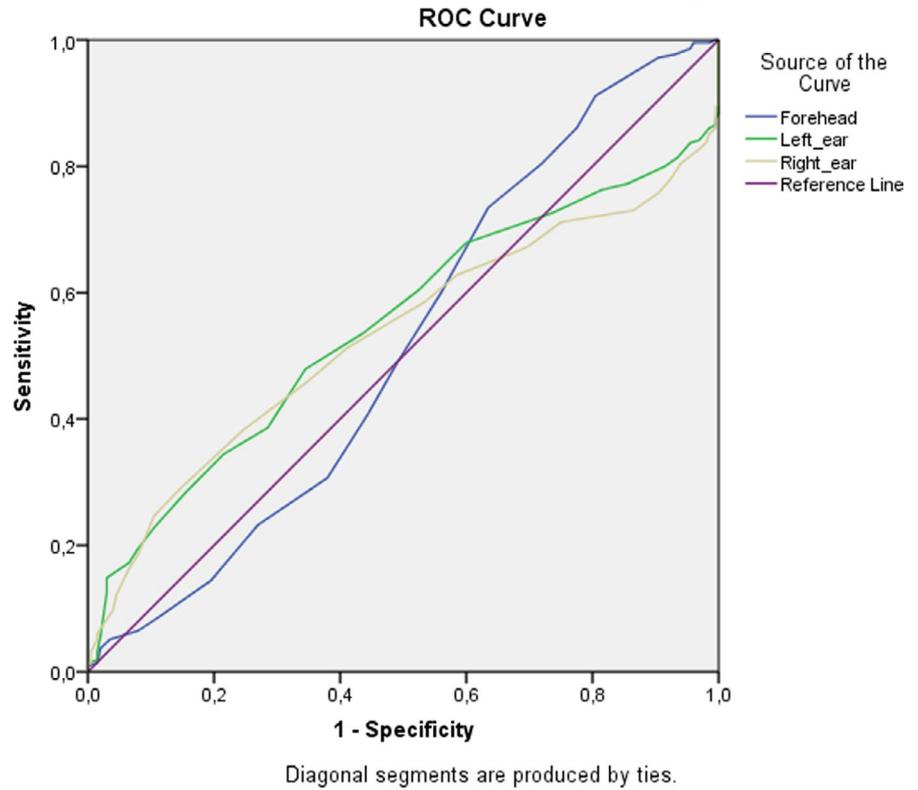


TABLE 3 ROC analysis: prediction for patients and suspected

	Sensitivity (%)	Specificity (%)	PPV	NPV	AUC
Forehead temperature (Cut off = 36.5)	60.0	44.4	51.1	49.0	0.517
Right ear temperature (Cut off = 35.9)	52.0	60.0	53.9	46.0	0.546
Left ear temperature (Cut off = 35.9)	61.0	48.0	46.7	44.0	0.530

TABLE 4 Discriminant validity of the three temperatures across patients, suspected and negatives

	Mean (SD)	Range	p-value	Pairwise comparison ^a
Forehead			.005	
Positive	36.57 (0.40)	35.4–38.3		Positive vs. Suspected <i>p</i> = .004
Suspected	36.43 (0.50)	35.1–38.4		
Negatives	36.52 (0.46)	35.3–37.5		
Right Ear			.072	
Positive	35.78 (0.57)	34.06–37.17		Positive vs. Suspected <i>p</i> = .007
Suspected	35.88 (0.35)	34.33–36.94		
Negatives	35.82 (0.27)	35.06–36.56		
Left ear			.010	
Positive	35.74 (0.60)	33.89–37.11		Positive vs. Suspected <i>p</i> = .007
Suspected	35.88 (0.36)	34.44–36.83		
Negatives	35.81 (0.28)	35.00–36.67		

^aBonferroni correction.

surmised that the quickly (within minutes) retaken temperatures by the clinicians, and patients movement as well as other errors may have led to a lack of reproducibility in the thermometer readings,

forming an overlooked bias that must be taken into consideration when evaluating the accuracy and precision of thermometer readings (Harding et al., 2021).

A large-scale systematic review and meta-analysis of tympanic temperature measurements involving 12 diagnostic studies that pooled 4639 paediatric patients had found that a new generation of tympanic thermometry has high diagnostic accuracy and can be a good alternative for fever screening in children (Shi et al., 2020). According to the practical guidelines recommended by the Global Heat Health Information Network, measurement of tympanic temperature, although arguably not accurate especially during the hot heat season, still has some value (Daanen et al., 2021). This is because when a threshold of 37.5°C is used for fever detection, <5% with fever $\geq 38.0^\circ\text{C}$ will remain undetected (Mogensen et al., 2018). However, one-fifth of the subjects needs a follow-up rectal temperature measurement to rule out fever (Mogensen et al., 2018). Therefore, during the COVID pandemic, it is recommended that the fever screening protocol with the use of tympanic thermometry is followed by rectal temperature measurement as a next step to exclude a large number of false-positive subjects (Daanen et al., 2021).

Similarly, another study by Zhang et al. (2021) has recommended the use of infrared thermal imaging cameras at the main entrances of hospitals and public places to identify a large number of people for preliminary temperature measurements. While tympanic thermometers can be used in second-line screening in clinic rooms, airplanes, long-distance buses, hotels and classrooms to check the temperature. The authors also recommended the use of sterilised thermometers for axillary or rectal temperature as the next step in fever clinics, isolation wards, inpatient wards and for re-evaluation of cases of suspected fever (Zhang et al., 2021).

4.1 | Limitations

One limitation of the present study is the use of the tympanic temperature as a reference standard method. A review of the literature revealed that different authors had utilised different body site measurement as the reference standard. Until now, there is no universally agreed standard method. Although pulmonary artery temperature correlates best with the core body temperature, it is not feasible and practical to perform this procedure in routine screening to triage COVID-19 cases as the procedure is highly invasive and is used only in clinical settings for monitoring critically ill patients. In our study, we had only one operator (a nurse) who measured the participants' temperature, in order to avoid inter-user variability and bias. A second limitation was that the patients were given fever-reducing medications prior to temperature measurement. Depending on the duration between the administration of the medications and the time the temperature measurement, this could have affected the interpretation of actual status of fever.

In addition, the results of CUSUM test ($p < .05$) in positive cases were shown that there was a significant difference from linearity and therefore more of COVID-19 patients with better continuous

distribution should be considered. Although advantages of the CCC are the ability to classify agreement based on CCC obtained and to be able to estimate a confidence interval (CI). A disadvantage of the CCC is its dependence on the variability between cases (Quinn et al., 2009).

5 | CONCLUSION

The results from our study demonstrated that the forehead thermometer readings have low agreement with the tympanic measurements that were used as the reference methods. The limits of agreement were wider for the forehead thermometer. A bias was found with the forehead having higher readings in the lower temperature ranges. Forehead bias was low at lower temperatures but the bias was also higher in positive COVID-19 patients and healthy individuals, respectively. In addition, temperature measurements through infrared thermometers were not anticipated to confer any cut-point value of diagnostic significance. For future work, we recommend that this research be repeated using a mercury thermometer as a gold standard versus forehead and or tympanic thermometer in adults.

6 | RELEVANCE TO CLINICAL PRACTICE

This study did was unable to produce any evidence that assessment of temperature by infrared forehead thermometer can discriminate between positive and negative COVID-19-infected patients. This finding showed that this type of temperature measurement produced a 'false sense of security' as a screening method.

ETHICS STATEMENT

The protocol of this study was approved by the Mazandaran University of Medical Sciences Research Ethics Committee (IR.MAZUMS.REC.1399.7317).

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CONFLICT OF INTEREST

The authors report no conflicts of interest in this work.

AUTHOR CONTRIBUTION

Performance of data gathering: **BT**; Planning and supervision the work: **HSH** and **PR**; Performance of the analysis: **HSH**, **CHY**, **OG** and **SPSH**; Manuscript draft: **PR**, **PCH** and **ESF**; Discussion of the results and comment on the final manuscript: All authors.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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