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Document name:

Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients. Protocol

Title of the study:

Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients

NCT number:

Not yet available

Date:

December 15, 2023

STUDY PROTOCOL - TermoCam UCI-1

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Code: TERMOCAMUCI1

Version: 2

Date: December 15, 2023

Title

Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients

Introduction

Body temperature is one of the most frequently studied physiological variables in hospitalized patients. The normal temperature value is around 36.7°C, with significant variability ranging from 35.3 to 37.7°C among different individuals or within the same person throughout the day. The definition of fever is established by a consensus reached by the American College of Critical Care Medicine and the IDSA, placing it at a central temperature of 38.3°C (1), where central temperature refers to the temperature of internal organs. This thermal elevation is typically found in approximately 50% of critical patients (2) and is not only clearly associated with infectious processes but can also be observed in various other conditions such as autoimmune diseases, oncological conditions, bleeding, inflammatory reactions, after surgical procedures, or drug-induced (3).

There are multiple methods for temperature measurement in Intensive Care Units (ICUs), with the most common being peripheral temperature measurement every eight hours using contact thermometers in the axilla(4). In patients with sustained fever or those undergoing therapeutic hypothermia, continuous monitoring of central temperature through rectal, tympanic, vesical, or esophageal methods can be performed (5). However, it is considered a more invasive measure, and its use is limited mainly due to technical difficulties, higher economic costs, and potential serious complications (6, 7).

Thermal monitoring in critical patients is essential. Many critical patients with fever will receive antibiotic treatment, even in the absence of evidence of infection, as early initiation of this treatment in septic patients clearly improves survival (8, 9).

The wide variability of temperature between individuals, circadian changes, different methods of temperature measurement, the influence of medications, and deficiencies in measurement methods make defining fever with a single temperature value impractical (10) Therefore, other patient variables should also be considered before establishing the presence of fever. One of these variables is the thermal curve, or the evolution of temperature throughout the day, which can be sustained or in peaks and may or may not respond to antipyretics, antibiotics, or other temperature control methods. Studying a patient's thermal curve is useful even before reaching definitive fever values (11).

Another issue in fever monitoring, especially with sporadic measurements rather than continuous monitoring, is that febrile peaks may go unnoticed or that the maximum or minimum values that the patient will experience may not be captured.

Therefore, as a first step, the main purpose of this study would be to establish the concordance between axillary temperature measurements (widely used method) taken in patients multiple times a day and temperatures recorded by a thermal imaging camera at the same moments.

Thermal imaging cameras have been widely used during the Covid-19 pandemic for fever screening in healthcare settings and other facilities(12). Their use in hospitalized patients could translate into numerous advantages compared to routine clinical practice. Firstly, it is a non-invasive and contactless measurement, reducing the risk of pathogen transmission, especially in patients colonized by multidrug-resistant microorganisms, and facilitating measurement in patients with compromised skin integrity. Secondly, the automated and continuous acquisition of temperature provides valuable information that has proven useful in patient management

without requiring extra effort from healthcare professionals and may even reduce the nursing and auxiliary workload.

However, the lack of diagnostic test validity studies for most thermal imaging cameras and contradictory results found in published studies (13) have led to their limited use in the hospital environment. Despite this, recent systematic reviews emphasize their great potential pending further studies to validate their utility (14, 15). Therefore, within one of the secondary objectives of this study, we also aim to assess the validity of these cameras as a diagnostic test for fever and hypothermia.

In this regard, the use of thermal imaging cameras integrated into a system capable of automated and real-time peripheral temperature acquisition could potentially lead to a change in the standard practice for temperature monitoring in ICUs. Additionally, this system would provide a wealth of data that could be used to train intelligent systems through machine learning algorithms in the near future, with the goal of predicting events such as the onset of fever, nosocomial infections, or shock.

Hypothesis and Objectives

Hypothesis:

Temperature measurements using thermal imaging cameras in critical patients show good concordance with those taken using contact thermometers in the axilla.

Objectives:

Primary Objective:

To assess the concordance of temperature obtained continuously by a thermal imaging camera with that obtained by an axillary contact thermometer.

Secondary Objectives:

1. To describe the sociodemographic (age and gender) and clinical characteristics (HTN, DM, DL, reason for ICU admission, SAPS3) of the study population.
2. To study the diagnostic test validity of the thermal imaging camera for fever and hypothermia. Fever is defined as an axillary temperature of ≥ 37.5°C, and hypothermia is defined as an axillary temperature < 34.2°C.
3. To determine the time difference until fever detection between the SF-HANDHELD-80TA05 thermal imaging camera or similar, and temperature measurement through the usual nursing practice following standard protocols in critical patients.
4. To describe the continuous thermal curve patterns taken by the thermal imaging camera in patients with the following pathologies: altered level of consciousness, acute coronary syndrome, cardiac rhythm disturbances, cardiac arrest, heart failure/cardiogenic shock, hypovolemic shock, sepsis/septic shock, shock of other etiology, respiratory failure, renal failure, metabolic disorders, intoxications, trauma, postoperative monitoring and surveillance, non-surgical procedure monitoring and surveillance, and others. Thermal curves will be obtained in at least 20 patients per pathology.

5. To describe the continuous thermal curve patterns taken by the thermal imaging camera in patients with infectious complications in two cases: patients with infection upon admission and patients who develop infection during admission. Thermal curves will be obtained in at least 20 patients in each case.
6. To determine the adequacy of regional thermal measurement by reviewing the complete thermal image obtained by the SF-HANDHELD-80TA05 or similar camera

Materials and Methods

Design:

This is a single-center, observational, descriptive, longitudinal, and prospective study to investigate the concordance between temperatures obtained by the thermal imaging camera and axillary temperatures.

Scope and Study Population:

The study will be conducted on all patients admitted to the ICU rooms at HLA Moncloa University Hospital equipped with an infrared camera for continuous measurement of skin temperature.

Inclusion Criteria:

• Patients admitted to the ICU in a room with a thermal imaging camera

• Aged 18 years and above

• Patients who provide voluntary consent to participate in the study (Annex 2). If the participant is not in full physical or intellectual capacity to provide their signature in the informed consent, the responsible investigator will seek consent from their direct family member or the legally designated person to make decisions on their behalf regarding health matters. This measure is adopted to ensure the participant's rights are respected and the integrity of the consent process is maintained, even in situations where their decision-making capacity may be compromised.

Exclusion Criteria:

Patients from whom information from the thermal imaging camera cannot be obtained due to technical reasons.

Sample Size:

To determine the degree of concordance between the temperature recorded by the thermal camera and axillary temperature, a minimum of 224 pairs of data (224 temperature records by thermal camera vs. 224 axillary temperature records) will be required to estimate an Intraclass

Correlation Coefficient (expected to be 0.8 or higher) with an estimation error of +- 0.05 points, a confidence level of 95%, and anticipating a 10% loss.

Data Collection:

Temperature measurements will be autonomously recorded by the SF-HANDHELD-80TA05 thermal imaging camera, or another with similar characteristics, which provides temperature values every second, thermal images, bed number, date, and time.

The rest of the variables needed for the study will be manually collected by the researchers or through the clinical information system (CIS) "Innovian" and included in a study-dedicated database hosted on the hospital intranet.

Finally, all data will be collected in a pseudonymized manner. For this purpose, two databases will be constructed. One will contain personal data associated with a code (one for each patient), which will be safeguarded by the investigator. The second database will contain the associated clinical data. In the case of images generated by thermal cameras, these will also be pseudonymized, generating images with the aforementioned association code. These coded images will be sent to the Computing Center of the European University of Madrid for the creation of temperature patterns (secondary objectives 4 and 5) and for the adequacy of regional thermal measurement (secondary objective 6).

Standard Practice in Peripheral Temperature Measurement in Our Unit

The standard practice for peripheral temperature measurement in the ICU at HLA Moncloa University Hospital is not formally documented but adheres to recommendations for monitoring temperature in critically ill patients. Peripheral temperature is obtained using a contact thermometer in the axilla every 8 hours or whenever thermal disturbances are suspected by healthcare personnel (both medical and nursing staff).

Axillary temperature measurement through standard practice will be repeated every 8 hours and collected in triplicate to establish an average used for assessing concordance at that point and so forth until reaching the 224 measurements needed to complete the primary objective of the study. If, during the 8-hour collection, there is a difference of more than 15% between the first 3 measurements, a fourth measurement will be taken, and only the average of the three most similar measurements will be used for concordance. If all four measurements are different, a fifth measurement will be taken, and so on until three measurements considered similar are obtained.

Definitions of Thermal Disturbances and Infectious Complications:

• Fever: Defined as a central temperature (rectal, esophageal, vesical, or tympanic) ≥ 38.3°C. Peripheral temperature (cutaneous or axillary) is 0.6 to 1°C lower than central temperature; therefore, for this study, we will consider a peripheral temperature ≥ 37.5°C as a fever.

• Hypothermia: Defined as a central temperature < 35°C or peripheral temperature < 34.2°C.

• Infectious Complications: Will include both patients admitted to the ICU due to an infection (pre-admission infection) and patients who develop an infection during their stay in the ICU (infection during admission). Identification and diagnosis of either type of infection will be

carried out by the attending physician following established clinical practice recommendations and guidelines in each specific case. The task of the researchers will be limited to reviewing the patient's medical history and collecting data.

Temporal Differences in Fever Detection:

The time of fever detection will be identified for each measurement method (standard practice vs. thermal imaging camera), and the temporal difference in minutes between them will be determined.

Creation of Temperature Patterns:

Continuous temperature data (every second) offered by thermal cameras will be represented by 24-hour thermal curves and classified automatically based on patterns and patient characteristics using unsupervised machine learning algorithms such as clustering. For this purpose, the data will be physically and securely sent to the Computing Center of the European University of Madrid.

Adequacy of Regional Thermal Measurement:

Thermal cameras SF-HANDHELD-80TA05 or similar perform a scan across the entire thermal image to extract the point of maximum temperature found. It is deemed necessary for the study to visually check the thermal images obtained to verify the adequacy of temperature measurement—ensuring that the temperature is being obtained from the patient and not from any other high-temperature element, such as healthcare personnel or electronic devices (mobile phones, respirators, pumps, etc.). A direct visual check of a sample of thermal images will be performed by the researchers, and all thermal images will be physically and securely sent to the Computing Center of the European University of Madrid for automatic classification using convolutional image recognition algorithms (machine learning) to identify whether the temperature is obtained from the patient or any other element.

Interventions and Procedures:

1. All patients admitted to the ICU in a room with a thermal imaging camera will be considered potential candidates for inclusion in the study and will be verbally informed and provided with patient information sheets about the study, requesting their signature on the informed consent form for participation.
2. If they agree to participate, compliance with inclusion and exclusion criteria will be confirmed.
3. Patients will receive treatments according to the center's usual clinical practice and the criteria of their attending physician based on the patient's characteristics in each specific case.
4. The thermal imaging camera will automatically record temperature readings every second and capture a thermal image. The information will be recorded in real-time on

the server dedicated to the study, located physically within the ICU and connected only to the hospital intranet. This ensures that the information collected for the study has the same level of security as other information related to hospitalized patients. Additionally, all records made on the server will be pseudonymized from personal information. Identifying a person through the thermal image is not possible without additional information; thus, for all intents and purposes, it is considered anonymized information.

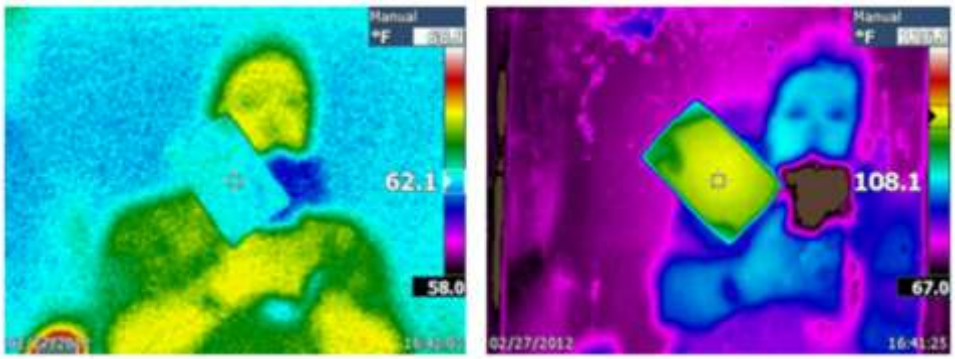

Figure 1. Example of Thermal Image

5. Temperature data for each patient included in the study can be accessed through a tablet connected only to the hospital intranet and will remain within the ICU.
6. At the time of discharge or patient exitus, the principal investigator will review the patient's medical history to create a pseudonymized database that records study variables and patient temperature data.
7. Once data collection is complete over the 11-month study period, the principal investigator will physically send pseudonymized temperature data and thermal images to the Computing Center of the European University of Madrid, which is committed to maintaining data confidentiality and destroying any possible copies of the material once study objectives are fulfilled.
8. After completing the study, pseudonymized patient data will remain recorded for 5 years on the server physically located within the ICU. This is in case data consultation is necessary for clinical reasons or regarding the publication of study data.

Variables

Primary:

- Axillary Temperature
- Temperature from Thermal Imaging Camera

Secondary:

- Age
- Gender
- Reason for Admission:
    - Altered Level of Consciousness and Other Neurological Disorders
    - Acute Coronary Syndrome
    - Cardiac Arrhythmias
    - Cardiorespiratory Arrest
    - Heart Failure/Cardiogenic Shock

    - Hypovolemic Shock
    - Sepsis/Septic Shock
    - Shock of Other Etiology
    - Respiratory Failure
    - Renal Failure and Metabolic Disorders
    - Intoxications
    - Head Trauma
    - Other Traumas without Head Injury
    - Postoperative Monitoring and Surveillance
    - Monitoring and Surveillance of Non-Surgical Procedures
    - Other Unspecified Medical or Surgical Conditions
- Hypertension (Yes/No)
- Diabetes Mellitus (Yes/No)
- Dyslipidemia (Yes/No)
- SAPS3 at Admission
- Thermal Image
- Fever (Yes/No)
- Hypothermia (Yes/No)
- Infectious Complications (Pre-existing or During Admission) Date and Time
- Time to Fever Development

Statistical Analysis Plan

The degree of agreement between temperature measurements recorded with the thermal camera and measurements taken with the axillary contact thermometer will be assessed, as these are quantitative variables, through the intraclass correlation coefficient. Qualitative variables will be summarized based on absolute and relative frequency (n and %), while normally distributed quantitative variables will be described using mean ± standard deviation (SD), or if not normally distributed, using median and interquartile range. Normality will be determined using the Kolmogorov-Smirnov test.

The validity of the thermal camera as a diagnostic test for fever and hypothermia will be calculated based on sensitivity and specificity, as well as Positive Predictive Value (PPV) and Negative Predictive Value (NPV). Considering fever is defined as ≥ 37.5ºC in axillary temperature, and hypothermia as <34.2ºC in axillary temperature.

Limitations

This is a single-center study; other units may have different protocols for monitoring, managing, and treating fever, or admit patients with different baseline characteristics than those in this sample, so the conclusions of this study may not be applicable to other services.

Ethical and Legal Aspects

This study will be conducted in accordance with current legislation. All participating researchers will adhere to strict confidentiality in accessing, collecting, and processing data in

the databases, and commit to strict compliance with relevant laws: Law 41/2002, of November 14, which regulates patient autonomy and rights and obligations regarding clinical information and documentation, Organic Law 3/2018, on the protection of personal data and the guarantee of digital rights, and Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of individuals concerning the processing of personal data and on the free movement of such data, repealing Directive 95/46/EC (General Data Protection Regulation).

All information obtained will be pseudonymized before leaving the hospital network, ensuring the identification of any individual through this information is not possible. The transfer of information to the Computing Center of the European University of Madrid will be done physically on a hard drive guarded by the researchers and deposited at the hospital facilities after the study's completion. Researchers at the Computing Center of the European University of Madrid also commit to the strictest confidentiality in accessing, collecting, and processing data, even though they will always be pseudonymized, and commit to strict compliance with current legislation: Law 41/2002.

Cronograma

	November 2023	November 2023	December - January 2024	May 2024	October 2024	November 2024
Protocol Study Drafting						
HLA Moncloa Hospital Permissions						
Presentation to CEIm (Ethics Committee)						
CEIm (Ethics Committee) validation						
Purchase and Installation of Equipment in ICU						
Patient Recruitment						
Interim Report						
Statistical Analysis						
Final Report"						
Article Writing and Commencement of Outreach						

Economic Report

Budget	
Concept	**Grant Awarded ***
Equipment	3200€
Consumable Material	200€
Publication Expenses	600€
Total	4000€

*** Grant Awarded corresponds to the RESEARCH GROUPS JOINT GRANTS CALL 2023. ASISA FOUNDATION-UNIVERSIDAD EUROPEA DE MADRID CHAIR**

Budget Justification

At the beginning of the project, €1,200 will be used to purchase 3 high-quality thermal cameras, valued at approximately €400 each. Additionally, a budget of €800 will be allocated for the purchase of a PC (€600) and consumable materials (€200) for interconnection and automation of image downloads.

After 6 months, another €1,200 will be used to complete the purchase of an additional 3 thermal cameras, along with a Tablet (€200) for data representation. Furthermore, €600 will be allocated for publication expenses, which may include article translation, publication fees, or dissemination of results at national and international conferences."

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