

VALIDATION OF A NON INVASIVE CORE TEMPERATURE SENSOR FOR NEONATES; ADULT PATIENTS AND FIRE FIGHTERS

Jochim Koch¹, Frank Sattler¹, Oliver Kimberger² Hanns Christian Gunga³

¹ *Research Unit, Drägerwerk AG & Co. KGaA, Luebeck, Germany*

² *Department of Anesthesiology, General Intensive Care and Pain Control, Medical University Vienna, Austria*

³ *Department of Physiology, Charite Berlin, Germany*

Contact person: jochim.koch@draeger.com

INTRODUCTION

It is easy to obtain accurate core temperature measurements from several locations of the human body with relatively invasive methods. Three standard core-temperature measurement sites are the pulmonary artery, nasopharynx and the distal oesophagus. None of these sites is easy to use in neonates and sedated critical patients undergoing regional anaesthesia. Also for fire fighters during their mission these invasive methods are not appropriate. Yet adequate core temperature monitoring is clearly indicated in these focus groups because both groups are prone to hypo- or hyperthermia respectively.

A new non-invasive thermometer (“Double Sensor”) [1] has been developed combining two sensors separated by a known thermal resistance that is capable of continuously monitoring the core temperature of humans. This measuring device was to be validated within the scope of clinical studies of neonates in warming therapy devices [2], of adults perioperatively [3] and a laboratory study of fire fighters under physiological strain on walk mills [4] to show the range of accurate core temperature monitoring and the system's limitations.

METHODS

- a) In a first study the measurements of 80 neonates with the device under test positioned on the abdomen were compared to rectal temperatures [2].
- b) In a second study the measurements of 68 adult patients during surgery [3] the device under test positioned on the forehead was compared to oesophageal temperatures. For reference, we also evaluated the accuracy of a simple forehead skin temperature, adjusted upwards by 2°C.
- c) And in a third study the measurements of 20 subjects under physiological strains in three different ambient conditions the device under test positioned on the vertex was compared to rectal temperatures.

RESULTS

a) The comparison of both measuring methods on neonates less than 2500 g revealed a standard deviation of $SD = 0.15\text{ }^{\circ}\text{C}$ for neonates (Fig. 1). The CCC (Concordance Correlation Coefficient [5]) was 0.90, i.e. the Double Sensor applied on the abdomen correlated very well with the rectal temperature. The mean bias was only $-0.01\text{ }^{\circ}\text{C}$ and could therefore be disregarded. Another important criterion was whether the temperature differences between the two procedures in the Bland-Altman diagram [6] correlated. The correlation resulted in a value of $r=-0.22$, i.e. a slight systematic dependency could be possible. However, there are not sufficient measuring values present at low body temperatures to be able to evaluate this more accurately.

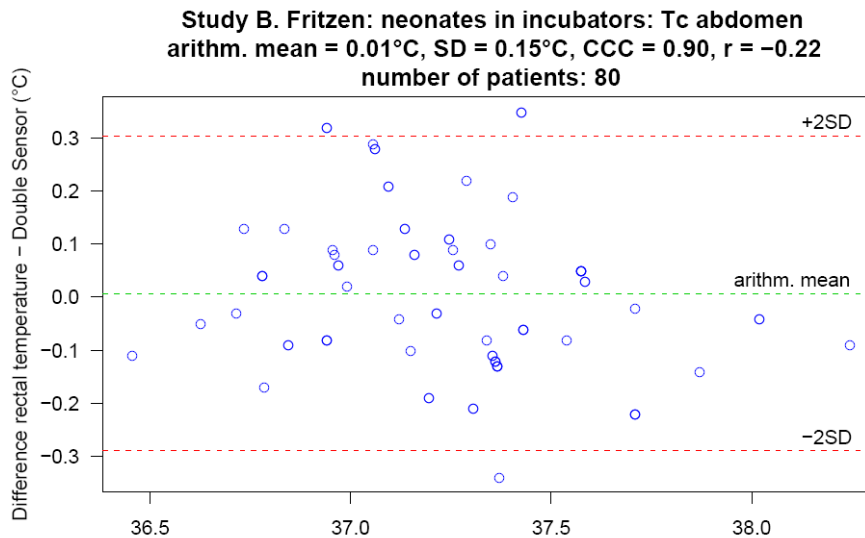


Fig.1: Bland-Altman plot comparing the rectal temperature measurements with the Double Sensor, placed on the abdomen on 80 neonates cared in incubators with a standard deviation of $SD=0.15\text{ }^{\circ}\text{C}$, a mean bias of $0.01\text{ }^{\circ}\text{C}$ and $CCC=0.90$.

b) Overall more than 1287 measurement pairs were obtained (every 5 min) in the clinical study. Limits of agreement of $\pm 0.5\text{ }^{\circ}\text{C}$ were defined a priori as clinically acceptable. The limits of agreement between core temperature and simulated temperature were $-0.51\text{ }^{\circ}\text{C}$ to $0.66\text{ }^{\circ}\text{C}$ (Fig. 2) for all patients. The CCC (Concordance Correlation Coefficient [5]) was 0.90, i.e. the Double Sensor applied on the forehead correlates very well with the esophageal temperature. The mean bias was only $-0.08\text{ }^{\circ}\text{C}$ and can therefore be disregarded. The correlation in the Bland-Altman diagram results in a value of $r=-0.18$; bias of measurements did not appear to change systematically with the mean core temperature.

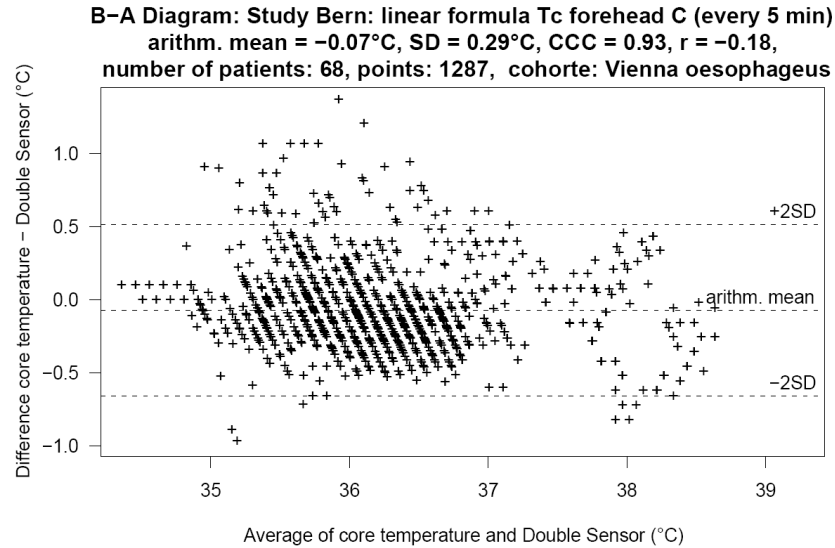


Fig. 2: Bland-Altman plot comparing the oesophageal temperature measurements with the Double Sensor, placed on the forehead of 68 patients perioperatively and in critical care units with a standard deviation of $\text{SD}=0.29^{\circ}\text{C}$, a mean bias of 0.08°C and a $\text{CCC}=0.90$.

Forehead skin temperature was also recorded from the skin temperature probe of the Double Sensor. As in previous studies [9, 10] a 2°C offset was added to approximate core temperature to account for skin temperature being less than core temperature. We included the analysis of the forehead temperature + 2°C in the present study primarily to show, that the Double Sensor thermometer markedly outperforms a simple forehead thermometer with a fixed correction like e.g. a liquid crystal thermometer.

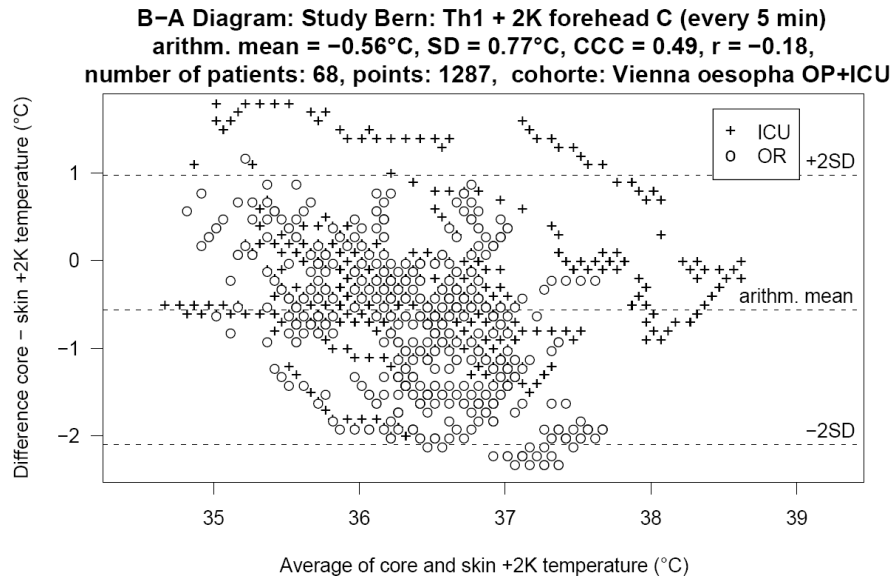


Fig. 3: Bland-Altman plot comparing the forehead and double-sensor temperature measurements ($n = 1287$). The x-axis is the average of the two measurements. The y-axis is the bias that is the difference of the two measurements (oesophageal – Double-Sensor).

Bias: -0.56°C ; limits of agreement ranging from -2.1 to $+0.98^{\circ}\text{C}$.

Bland-Altman analysis of the forehead-skin derived core temperature (i.e. measured value +2°C; fig. 3) resulted in a bias of -0.56°C, limits of agreement ranging from -2.1 to +0.98°C, which significantly exceeded bias of the double-sensor thermometer ($p < 0.01$, F test).

c) The comparison of both measuring methods on subjects under physiological strain on a walk mill under different ambient conditions reveals in a standard deviation of $SD=0.37$ °C. The sensor was applied on the vertex. The subjects wore helmet and protective clothing for fire fighters. The CCC rose with rising ambient temperatures (all working periods: 10 °C: 0.41; 25 °C: 0.78 and 40 °C: 0.76)

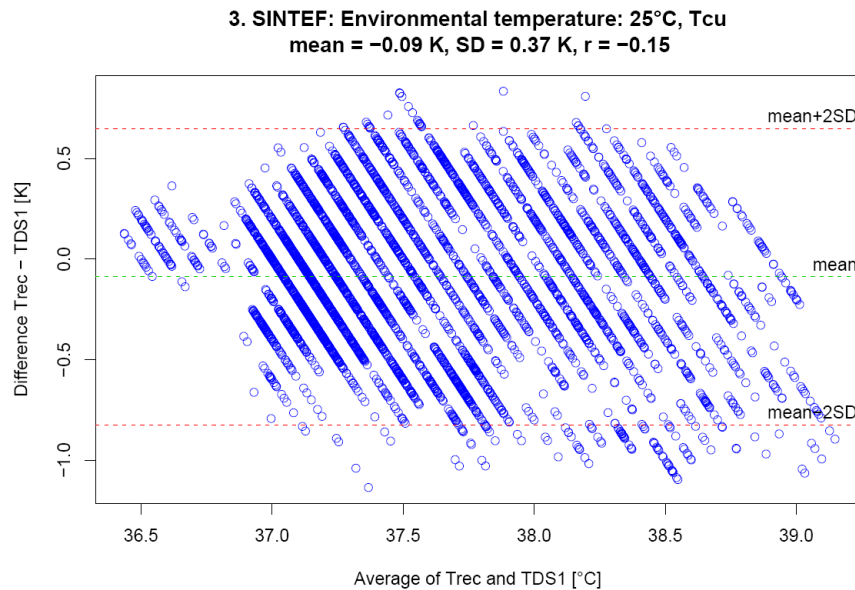


Fig. 3: Bland Altman plot comparing the rectal temperature measurements with the Double Sensor, placed on the vertex on 20 probands placed within the helmet on the vertex under physiological strain at an ambient temperature of 25 °C with a standard deviation of $SD=0.37$ °C, a mean bias of -0.09 °C and a $CCC=0.78$

CONCLUSIONS

It has been demonstrated in clinical studies with adults [7], [8] that the temperatures between two central body organs can be measured with an accuracy of $SD=0.36$ °C to $SD= 0.42$ °C. Greater accuracy cannot really be expected for a non-invasive measuring procedure.

a) The Double Sensor was capable of measuring the near-to-core temperature of neonates in incubators, continuously, sufficiently accurate, and in a non-invasive manner. It provides an interesting and practical alternative to invasive rectal measurement or other common measuring procedures. Non-invasive measurement with the Double Sensor is thus a very good alternative to invasive rectal temperature measurement. In neonates the non-invasive Double Sensor was sufficiently accurate to replace a rectal thermometer in routine clinical practice.

b) The Double Sensor proved sufficiently accurate to replace a distal esophageal thermometer for routine clinical use in perioperative and critical care patients. This non-invasive sensor, which is easy to use, can facilitate temperature measurements in sedated patients or patients having regional anesthesia. Furthermore, the Double Sensor was significantly more accurate than adjusted forehead skin-surface temperatures.

c) In particular for strenuous physical activity during heat exposure, the Double Sensor appears to be a reasonably reliable method to assess heat strain and can well applied in occupations in which individuals are exposed to thermally challenging environments. This new sensor system cannot completely replace rectal or radio pill core temperature recordings. As outlined above, both techniques have their limitations. For people who have to wear helmets routinely as part of their work equipment (fire fighters, military, sportsmen), the Double Sensor seems to be a reasonable method to monitor reliably in real-time core temperatures.

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