Accuracy and Precision of Continuous Non-Invasive Arterial Pressure Monitoring Compared with Invasive or Non-Invasive Blood Pressure Monitoring

A systematic review and meta-analysis

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### Abstract

**Purpose**

Zero-heat-flux thermometers provide clinicians with the ability to continuously and non-invasively monitor body temperature. These devices are increasingly being used to substitute for more invasive core temperature measurements during surgery and in critical care. The aim of this review was to determine the accuracy and precision of zero-heat-flux temperature measurements from the 3MTM Bair HuggerTM Temperature Monitoring System.

**Methods**

Medline and EMBASE were searched for studies that reported on a measurement of core or peripheral temperature that coincided with a measurement from the zero-heat-flux device. Study selection and quality assessment was performed independently using the Revised Quality Assessment of Diagnostic Accuracy Studies tool (QUADAS-2). The Grading of Recommendations, Assessment, Development and Evaluations (GRADE) approach was used to summarize the strength of the evidence. Pooled estimates of the mean bias and limits of agreement with outer 95% confidence intervals (population limits of agreement) were calculated.

**Results**

The primary meta-analysis of zero-heat-flux versus core temperature consisted of 6 comparisons from 6 individual studies. Data from 178 participants with 47,171 paired measurements were included. The pooled estimate for the mean bias was -0.93°C. Population limits of agreement, which take into consideration the between-study heterogeneity and sampling error, were wide, spanning from -183.34°C to 181.47°C. The GRADE evidence quality rating was downgraded to moderate due to concerns about study limitations. Population limits of agreement for the sensitivity analysis restricted to studies rated as having low risk of bias across all the domains of the QUADAS-2 were similar to the primary analysis.

**Conclusion**

The range of uncertainty in the accuracy of a thermometer should be taken into account when using this device to inform clinical decision-making. Clinicians should therefore consider the potential that a temperature measurement from a 3MTM Bair HuggerTM Temperature Monitoring System could be as much as 1°C higher or lower than core temperature. Use of this device may not be appropriate in situations where a difference in temperature of less than 1°C is important to detect.

Clinical trial number: Not applicable

Keywords: measurement, surgery, anesthesia

## Declarations

Availability of data and material (data transparency): All data used in the meta-analyses is available here.

Code availability: All data used in the meta-analyses is available [here](https://github.com/nkamboj06/cnap-review) and archived here.

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**Glossary of terms:**

GRADE = Grading of Recommendations, Assessment, Development and Evaluations

QUADAS-2 = Revised Quality Assessment of Diagnostic Accuracy Studies tool

LoA = Limits of Agreement

CI = Confidence intervals

SD2 = Variance

τ2 = Tau-squared

## Introduction

## Methods

A systematic review was conducted. The primary comparison for this review was zero-heat-flux temperature measured using the 3MTM Bair HuggerTM Temperature Monitoring System versus temperature measured from a core site, which we defined as temperature measured at either an arterial, esophageal, bladder, rectal, nasopharyngeal or oropharyngeal site.

### Inclusion criteria

Observational studies that reported temperature measurements from a 3MTM Bair HuggerTM Temperature Monitoring System and comparator thermometer were included. Studies involving a case control design were excluded due to potential for overestimation of the intervention performance. Studies were excluded if conducted on non-human subjects or outside of a clinical healthcare setting. No publication date restrictions were applied. Published conference abstracts were included if there was enough information reported to appraise the quality of the study. There were no language restrictions applied during the search.

### Data sources and searches

Published studies were found by searching Medline and EMBASE to January 2020. The Cochrane-recommended search strategy combining terms for the ‘target condition’ and ‘index test’ was used.[1] This search strategy is an efficient approach for systematic reviews of diagnostic test accuracy studies.[2] We also conducted forward citation searching, by using Google Scholar to search the citations of the first article published on the accuracy of the 3MTM Bair HuggerTM Temperature Monitoring System.[3] The search strategies used for each database are available in the appendix. Selection of studies was undertaken independently by two reviewers.

### Data extraction and quality assessment

Information was extracted regarding study characteristics (author, year of publication, country, design, sample size, clinical setting, numbers studied and analyses for each outcome), population characteristics (inclusion and exclusion criteria) and temperature measurement characteristics (placement of sensor, timing and methods of measurements). The outcomes that were extracted included the mean bias (eg, accuracy) and variance (eg, SD, precision) in temperature measurement between the zero-heat-flux and comparator thermometers. We also extracted information about how repeated measurements were handled. In particular we assessed whether studies: (1) analysed each pair of data separately; (2) treated each pair of data as independent; or (3) used either analysis of variance or a random effects model as a way to control for the dependent nature of the repeated measures data.[4]

Two reviewers independently assessed the risk of bias for the included studies using the revised Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2).[5] Reviewers rated the risk of bias for patient selection, conduct of the zero-heat-flux measurements, conduct of the comparator thermometer measurements, and timing and flow (eg, timing of zero-heat-flux and established core temperature measurements, dropouts) as ‘high’, ‘low’ or ‘unclear’ risk of bias. We worked to minimize the risk of publication bias by conducting a comprehensive search of multiple databases as well as an international clinical trial registry.[6] Statistical approaches for detection of reporting bias were not conducted due to lack of validated methods.[7] Simulations have revealed that tests for detecting funnel plot asymmetry will result in publication bias being incorrectly identified too often.[8]

In order to rate the quality of evidence, we applied the Grading Quality of Evidence and Strength of Recommendation methodology.[9] Evidence was downgraded in accordance with study limitations, inconsistency and imprecision. There were no circumstances in which evidence was downgraded for indirectness as this systematic review only included relevant studies. Although the possibility of publication bias was not excluded, this bias was not formally assessed as it was not considered sufficient enough to reason downgrading the quality of evidence.

### Data synthesis and analysis

The objective for the meta-analysis was to estimate the population limits of agreement between temperature measurements from the 3MTM Bair HuggerTM Temperature Monitoring System and established comparator thermometers. A framework for meta-analysis of Bland-Altman method comparison studies based on limits of agreement approach was used.[10] This method was selected because it parallels the approach used in primary Bland-Altman studies, whereby an estimate is generated for the pooled limits of agreement in the population (not just in the samples studied). The ‘population limits of agreement’ is more broad than the limits of agreement commonly reported in the meta-analyses of Bland-Altman studies.[10] Pooled limits of agreement were calculated using , where is the average bias across studies, is the average within-study variation in differences and is the variation in bias across studies.

Estimations of and were made using a weighted least-squares model (similar to a random-effects approach), with the associated standard errors estimated using robust variance estimation. Robust variance estimation was used alternatively to model-based standard errors as some studies included in the systematic review used repeated-measures designs without accommodating for the correlation between measurements.[11–13] We used the method-of-moments estimator from DerSimonian & Laird [14] for the parameter.

Measures of uncertainty were included in our meta-analyses by calculating the outer 95% confidence intervals for pooled limits of agreement. We also accounted for repeated measurements if they were not properly adjusted for in individual studies. This was achieved by using weights proportional to the number of participants, not the total number of measurements. The R statistical program was used to conduct all analyses.[15] All data and R code used in the meta-analyses is available [here](https://github.com/nkamboj06/cnap-review) and archived here.

Prior to conducting the meta-analyses, the results from each study were converted into a standard format, with bias meaning comparator thermometer temperature measurement minus the 3MTM Bair HuggerTM Temperature Monitoring System measurement in degrees Celsius (°C). In several studies, results were reported for multiple groups of participants, therefore in the meta-analysis each of these groups was treated as a separate ‘comparison’.[16–19] Other studies reported multiple sets of results, whereby analyses were conducted between zero-heat-flux and various comparator devices used on the same participant. These instances were also treated as a separate ‘comparison’ if the comparator devices were a part of separate meta-analysis groups.[19–22] One study used both nasopharyngeal and oropharyngeal temperature as comparators.[20] Both combined and separate estimates were reported. We used the combined estimate in our primary analysis and the estimate for just the nasopharyngeal temperatures in a subgroup analysis. One study reported intraoperative, postoperative and overall results for the same participants[3]. Only the paired measurements from the overall results were included in the main and low risk bias analyses, leaving paired measurements exclusively from the intraoperative and postoperative timepoints to be included in respective meta-analyses subgroups. The conventionally cited clinically acceptable agreement between zero-heat-flux and comparator devices is 0.5°C.[3] It was deemed that outer confidence bounds for 95% limits of agreement between zero-heat-flux and core temperature measurements (termed as ‘population limits of agreement’) outside of these bounds would be clinically unacceptable.

A sensitivity analysis for the primary comparison (zero-heat-flux versus temperature measurement at core site) was performed based on risk of bias, whereby ‘unclear risk of bias’ was treated as ‘high risk’ and ‘high risk of bias’ studies were excluded from analyses. We also conducted a sensitivity analysis for the primary comparison (zero-heat-flux versus temperature measurement at core site) excluding studies that received funding from industry. Probe insertion distance for temperature measurements from the nasopharynx and oropharynx may impact accuracy.[23] For this reason, we also conducted a separate analysis excuding these comparators and an analysis of the studies that compared temperature measurements from the 3MTM Bair HuggerTM Temperature Monitoring System with nasopharyngeal temperature. As clinicians would be interested in the accuracy of zero-heat-flux relative within the clinical setting in which they use it, we conducted subgroup analyses for the primary comparison according to clinical setting of the study (either intraoperative or intensive care unit).

## Results

### Study selection and description

Sixteen studies were included (Figure 1). Two studies reported only in abstract form were not included and assigned as ‘studies awaiting classification’ because there was insufficient information provided.[24, 25]

## Discussion

This systematic review showed that a temperature measurement from a 3MTM Bair HuggerTM Temperature Monitoring System device could be as much as about 1°C higher or lower than core temperature. These results may have important implications for practice. It was reassuring that results of our sensitivity analysis restricted to studies assessed to be at low risk of bias using the QUADAS-2 tool were similar. As such, it is vital for healthcare professionals considering using this device to first determine if differences in temperature smaller than this magnitude would be important for the given clinical situation. If so, then it may not be appropriate to substitute the 3MTM Bair HuggerTM Temperature Monitoring System in place of a core thermometer.

Our estimates of the accuracy of measurements from the 3MTM Bair HuggerTM Temperature Monitoring System are similar to results from a previous meta-analysis that compared other peripheral thermometers, such as sublingual and temporal artery devices, with core temperature measurements.[26] However, this previous meta-analysis used a statistical approach that did not incorporate the magnitude of heterogeneity in results between studies or sampling error. As such, it is possible that the zero-heat-flux thermometer may still be more precise than other peripheral thermometers.

The accuracy of 3MTM Bair HuggerTM Temperature Monitoring System has been evaluated in various intraoperative contexts as well as in the intensive care unit setting. Our subgroup analyses did not indicate that the accuracy of this temperature monitoring device was any more effective in a particular setting and revealed insights to direct future research. There were fewer participants included in the subgroup of studies conducted in the Intensive Care Unit compared to those conducted during surgery. As a result, population limits of agreement for the Intensive Care Unit subgroup were broad. Additional studies are required to increase confidence in the accuracy of 3MTM Bair HuggerTM Temperature Monitoring System device in this setting, where continuous temperature monitoring is often required. Also of note, only two studies included in our systematic review included pediatric patients. Additional studies to evaluate the accuracy of this device in children may be warranted to increase confidence.

It should be noted that we did not include studies that used the Temple Touch Pro because it is not strictly a zero-heat-flux device. This is a new thermometer that is similar to the zero-heat-flux device in that it is placed cutaneously, but the underlying technology is different.[27] Likewise, studies that evaluated the Dräger Tcore device were not included because this review focused specifically on the 3MTM Bair HuggerTM Temperature Monitoring System.

Many studies in this review analysed a large number of measurements of temperature with relatively small sample sizes. Importantly, the approach we used for our meta-analysis takes this into account. By using robust variance estimation, weights for pooling estimates in the meta-analysis become proportional to the number of patients, not the total number of measurements.[10]

### Limitations

We did not extract data on adverse events due to temperature monitoring with the 3MTM Bair HuggerTM Temperature Monitoring System. The possibility of publication bias cannot be ruled out, although the evidence suggests this may not be as serious of a problem for studies that are not randomized controlled trials.[7] Our focus for the meta-analysis was on calculating population limits of agreement, which incorporate the variation in bias between studies into the estimates. For this reason, we did not use meta-regression or tests for interaction between subgroups as a way to investigate sources of heterogeneity. It is important to note that this review did not assess the clinical utility of temperature monitoring using the zero-heat-flux device. The evidence from this review should be considered in the context of other information about the reliability and ease of use of this device. For example, the 3MTM Bair HuggerTM Temperature Monitoring System permits use of the same temperature monitoring device to be used throughout the whole perioperative care pathway. As such, replacing indirect estimates of core temperature, such as infrared tympanic and temporal devices, may be an advantage of the 3MTM Bair HuggerTM Temperature Monitoring System. Indirect estimates of core temperature are not recommended for use in surgical patients, yet are commonly used because of convenience.[28]

Finally, our initial protocol was focused on the accuracy of zero-heat-flux temperature measurements in general, not the 3MTM Bair HuggerTM Temperature Monitoring System specifically. A decision was made after data extraction and analysis was conducted to revise our inclustion criteria and include only studies that reported on the accuracy of the 3MTM Bair HuggerTM Temperature Monitoring System for this particular report. This decision was made because of the potential that differences in the technology integrated into zero-heat-flux devices produced by different manufacturers (i.e. 3MTM Bair HuggerTM Temperature Monitoring System and the Dräger Tcore) will influence estimates about the accuracy of zero-heat-flux devices overall. Although revising the inclusion criteria must be considered a limitation, this decision permitted a more targeted evaluation of the 3MTM Bair HuggerTM Temperature Monitoring System and easier interpretation of results.

## Conclusion

Substantial differences between temperature measurements from core and the 3MTM Bair HuggerTM Temperature Monitoring System were identified in this meta-analysis. Clinicians should consider the range of uncertainty in the accuracy of the zero-heat-flux thermometer when using this device to inform their decision-making. As such, there may be circumstances where use of this device would not be appropriate because a difference in temperature of 1°C is important to detect for the given clinical situation.

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# Figure legend

Fig. 1 PRISMA Flow Diagram

Fig. 2 Risk of bias assessments for included studies

Fig. 3 Comparisons between core and zero-heat-flux thermometers within and across studies

# Appendix

## Medline search strategy

## EMBASE search strategy

## Table 1: Study Characteristics

| Study | | | Participants | | | | Blood pressure measurements | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  | Age (years) |  |  | CNAP device | Comparator |  |  | Participants |  | Measurements |
| 2018 | Berkelmans |  |  | 74 (9) | Atrial fibrillation | ICU, medium care unit or coronary care unit | nexfin | invasive | radial | 31 |  | 4650 |  |
|  | 64 (17) | Sinus Rhythm | 10 |  | 1500 |  |
| Greiwe |  |  | 71 [59, 76) |  | cardiological or cardio-surgical intensive care unit | tline | invasive | radial | 31 |  | 27900 |  |
| 2016 | Bindra |  |  | 62.2 [28 to 87] |  | ICU | finometerpro | invasive | radial | 19 |  | 51 |  |
| Lakhal |  |  | 64 (13) |  | surgical ICU | cnap | invasive | femoralradial | 182 |  | 546 |  |
| noninvasive | brachialopposite |
| noninvasive | brachial |
| 2015 | Ilies |  |  | 68.8 (9.4) |  | cardiovascular ICU | cnapsystem | invasive | radial | 104 |  | 11222 |  |
| Langwieser |  |  | 69 [60, 77) |  | cardiac intensive care unit | tline | invasive | radial | 30 |  | 7304 |  |
| Smolle |  |  | 66 [56, 72) |  | Medical ICU | cnap | invasive | radial | 40 |  | 7200 |  |
| Wagner |  |  | 60 [52, 71) |  | ICU | cnap | invasive | femoral | 55 |  | 4891 |  |
| 2014 | Ameloot |  |  | 57.6 (19.4) |  | medical-­surgical-­burns ICU | nexfin | invasive | femoral | 45 |  | 225 |  |
| invasive | radial | 17 |  | 85 |  |
| noninvasive | brachial | 45 |  | 225 |  |
| Hofhuizen |  |  | 67 [50 to 81] |  | Intensive care unit | nexfin | invasive | radial | 20 |  | 54 |  |
| femoral |
| Martina |  |  | 50 (11) |  | ICU | nexfin | invasive | radial | 29 |  | 8700 |  |
| femoral |
| Meidert |  |  | 67 [54 to 77] |  | ICU | tline | invasive | radial | 24 |  | 2993 |  |
| nexfin | femoral |
| 2013 | Hohn |  |  | 63 [18 to 82] |  | ICU | nexfin | invasive | radialfemoral | 25 |  | 117 |  |
| Meidert |  |  | 60 [55, 65) |  | ICU | tline | invasive | femoral | 23 |  | 2879 |  |
| Saugel |  |  | 63 [51, 74) |  | Medical ICU | tline | invasive | femoral | 34 |  | 4502 |  |
| 2012 | Fischer |  |  | 68 [22 to 85] |  | Post-operative cardiac surgery ICU patients | nexfin | invasive | radial | 44 |  | 220 |  |
| Saugel |  |  | 68 [61.5, 73.5) |  | medical ICU | tline | invasive | femoral | 28 |  | 76826 |  |
| 1994 | Novak |  |  | [20 to 78] |  | ICU | finapres | invasive | radial | 20 |  | 100323 |  |
| 1993 | Searle |  |  | 60.8 (11.7) |  | Cardiac ICU | ncat | invasive | radial | 10 |  | 300 |  |

### Table 2: Results of meta-analyses

|  |  |  |  |  |  |  |  |  |  | Population LoA | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Studies | Comparisons | Participants | Measurements | Mean biasa | SD2ab | τ2ac | Lower 95% LoAad | Upper 95% LoAad | Outer CI for lower 95% LoAade | Outer CI for upper 95% LoAade |
| Nexfin | 6 | 6 | 178 | 47,171 | -0.93 | 161.05 | 35.04 | -28.94 | 27.07 | -183.34 | 181.47 |
| aUnits are °C | | | | | | | | | | | |
| bVariance | | | | | | | | | | | |
| cMeasure of heterogeneity | | | | | | | | | | | |
| dLoA = Limits of Agreement | | | | | | | | | | | |
| eCI = Confidence Intervals | | | | | | | | | | | |