Office of Evidence Based Practice (EBP) – Critically Appraised Topic: Cardiopulmonary Bypass (CPB) Temperature

Specific Care Question

In pediatric patients undergoing Cardiopulmonary Bypass (CPB) surgery which temperature site, urinary bladder temperature (UBT) versus rectal temperature (RT), is better for measuring/monitoring and/or regulation core body temperature?

Recommendations from the CPB Thermometers Team

No recommendation can be made for/against the use of urinary bladder temperature versus rectal temperature, based on review of current literature by the department of EBP. The overall certainty in the evidence is very low.

Literature Summary

Background. Monitoring temperature in children undergoing CPB is an important component of care due to the critical steps of cooling before surgery, cooling maintenance during surgery, and rewarming after surgery (Engelman et al., 2015). Numerous strategies for measuring temperature are currently used, including pulmonary artery (PAT), nasopharyngeal, axillary, tympanic, rectal, and bladder (Engelman et al., 2015). This review will compare rectal versus bladder temperatures for measuring core temperature during and after CPB surgery. Pulmonary artery temperature (PAT) and nasopharynx temperature sites were used as the gold, or reference, standard for core temperature (Engelman et al., 2015).

The Society of Thoracic Surgeons, The Society of Cardiovascular Anaesthesiologist, and The American Society of ExtraCorporeal Technology published a guideline with recommendations for core and cerebral temperature management in adults (Engelman et al., 2015). Pulmonary artery temperature and nasopharynx sites were recommended as the best sites for core temperature recording during CPB surgery (Engelman et al., 2015). After CPB, bladder temperature is recommended as a non-invasive approach for monitoring core temperature (Engelman et al., 2015).

Study characteristics. The search for suitable studies was completed on May 1, 2019. Kelly Fehlhafer, MBA, RN, CNOR and Stephanie Bennett, RN reviewed the 79 titles and/or abstracts found in the search and identified one guideline and 11 articles believed to answer the question. The guideline was assessed with the AGREE II[a] instrument to assist the team to determine the appropriateness to adopt as the governing guideline for this CAT. Engelman et al. (2015) was selected with an overall AGREE II score of 64% with the recommendation to be used with modifications (see Table 1). After an in-depth review of the remaining articles, six diagnostic studies (Akata, Yamaura, Kandabashi, Sadamatsu, & Takahashi, 2004; Bone & Feneck, 1988; Earp & Finlayson, 1991; Fallis, Gupton, & Kassum, 1994; Maxton, Justin, & Gillies, 2004; Ramsay, Ralley, Whalley, DelliColli, & Wynands, 1985) answered the question.

Summary by Outcome

Temperature management during CPB surgery. Two diagnostic studies compared UBT and/or RT to PAT during CPB surgery (Akata et al., 2004; Bone & Feneck, 1988).

Bone and Feneck (1988) compared UBT and RT to the nasopharynx site, in adults, during CPB surgery (N = 33). The rate of temperature change of bladder temperature during cooling and rewarming on bypass was significantly (p < .01) slower than the nasopharynx site but was similar to the rate of change for the RT. During rewarming, while still on bypass, the percentage change in temperature from baseline was similar for bladder, nasopharynx, and rectal sites, between 15.5% and 17.5% below baseline values.

Akata et al. (2004) compared UBT to PAT in adults (N = 10) during CPB surgery. After the start of cooling or rewarming, the UBT change lagged behind PAT (p < .05). Pulmonary artery temperature was significantly lower than UBT at all time points after 18 minutes of cooling (p < .05). During stabilized hypothermia, UBT was significantly higher than PAT (p < .05).

The evidence was of very low certainty based on serious imprecision, serious inconsistency, and serious indirectness. The studies are downgraded because it occurred in adults (indirectness), used different reference standards (inconsistency), and included only 43 patients (imprecision).

Temperature management after CPB surgery. Four diagnostic studies compared UBT and/or RT to PAT temperatures after CPB surgery (Earp & Finlayson, 1991; Fallis et al., 1994; Maxton et al., 2004; Ramsay et al., 1985).

Maxton et al. (2004) compared UBT and RT to PAT in children (*N* = 19) post-CPB surgery. The mean difference (*MD*) of UBT from PAT was -0.30, 95% CI [-0.92, 0.32]. The *MD* of rectal temperature from PAT was -0.69º C, 95% CI [-1.27, -1.00]. There was a significant time lag between PA and RT during the measurement period ($p = 0.015$).

Ramsay et al. (1985) compared UBT and RT to PAT in adults (*N* = 29) post-CPB surgery. The UBT and rectal temperature showed significant differences throughout rewarming when compared to PAT ($p < .05$). Forty minutes after CPB, there was no significant difference between the temperature at any site ($p > 0.05$). The authors reported RT as a less reliable predictor of total body rewarming, but no data was provided to support this conclusion.

Earp and Finlayson (1991) compared UBT to PAT in adults (*N* = 29) post CPB surgery. Urinary bladder temperature was 0.1ºC to 0.2ºC higher than PAT with a *correlation coefficient* of .94 to .99. There was a significant difference in UB temperature of > 0.1º C one-hour post-surgery ($p < .05$). Both temperatures, UBT and PAT, increased steadily throughout the 6-hour post-surgery with normothermia occurring at the end of 6 hours.

Fallis et al. (1994) compared RT to PAT in adults (N = 33) post-CPB surgery. Rectal temperature versus PAT difference increased from 0.08ºC one hour after surgery to 0.34ºC eight hours after surgery. The temperature difference was significantly different at 8 hours after surgery ($p < .05$).

The evidence was of very low certainty based on serious indirectness and serious imprecision. The studies are downgraded because only one study included children (indirectness) and the overall number of participants was 110 (imprecision).

Identification of Studies

Search Strategy and Results (see Figure 1)

("bladder temperature" OR "urinary temperature" OR ((bladder[tiab] OR "Urinary Bladder"[MeSH Terms]) AND ("core temperature" OR "temperature measurement" OR "Body Temperature"[Mesh] OR "Body Temperature Regulation"[Mesh] OR "Monitoring, Physiologic"[MeSH))) AND ("Cardiopulmonary Bypass"[Mesh] OR "Cardiopulmonary Bypass"[tiab])

("Cardiopulmonary Bypass"[Mesh]) AND (("Body Temperature"[Mesh] OR temperature[tiab]) AND (Pulmonary artery OR nasopharyngeal OR oxygenator OR "Spectrophotometry, Infrared"[Mesh] OR "Monitoring, Intraoperative/standards"[Mesh] OR "Intraoperative Care/standards"[Mesh] OR measurement OR monitor OR monitoring OR instrumentation OR central OR peripheral)) AND (child OR children OR pediatr* OR paediatr*) Filters: From 2014/01/01 to 2019/12/31

("Cardiopulmonary Bypass"[Mesh] OR "Cardiopulmonary Bypass"[tiab]) AND ("Body Temperature"[Mesh] OR "temperature management") AND (child OR children OR paediatr* OR pediatr*) Filters: From 2014/01/01 to 2018/12/31
Records identified through database searching *n* = 79

Studies Included in this Review

Citation	Study Type
Akata et al. (2004)	Diagnostic
Bone and Feneck (1988)	Diagnostic
Earp and Finlayson (1991)	Diagnostic
Fallis et al. (1994)	Diagnostic
Maxton et al. (2004)	Diagnostic

Ramsay et al. (1985)	Diagnostic

Studies Not Included in this Review with Exclusion Rationale

Citation	Reason for exclusion
Harasawa et a. (1997)	No bladder or rectal temperatures
Takaki et al. (1993)	Non-English article
Camboni et al. (2008)	Compared to cerebral temperature
Khan et al. (2006)	Bladder temperature used as the reference standard
Suleman et al. (2002)	Only included patients with a fever

Methods Used for Appraisal and Synthesis

[a]The Appraisal of Guidelines Research and Evaluation II (AGREE II) is an international instrument used to assess the quality and reporting of clinical practice guidelines for this analysis (Brouwers et al. 2010).

[b]Rayyan is a web-based software used for the initial screening of titles and / or abstracts for this analysis (Ouzzani, Hammady, Fedorowicz & Elmagarmid, 2017).

[c]Review Manager (Higgins & Green, 2011) is a Cochrane Collaborative computer program used to assess the study characteristics as well as the risk of bias and create the forest plots found in this analysis.

[d]The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram depicts the process in which literature is searched, screened, and eligibility criteria is applied (Moher, Liberati, Tetzlaff, & Altman, 2009).

[e]The Quality Assessment of Diagnostic Accuracy Studies-2 (QUADAS-2) (Whiting et al., 2011) is was used to assess the sources of bias and variation in the diagnostic studies found in this analysis.

[a]Brouwers, M.C. et al. for the AGREE Next Steps Consortium. (2010) AGREE II: Advancing guideline development, reporting and evaluation in healthcare. *Canadian Medical Association Journal, 182*, E839-842. Retrieved from https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf

[b]Ouzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan-a web and mobile app for systematic reviews. *Systematic Reviews, 5*(1), 210. doi:10.1186/s13643-016-0384-4

[c]Higgins, J. P. T., & Green, S. e. (2011). *Cochrane Handbook for Systematic Reviews of Interventions [updated March 2011]* (Version 5.1.0 ed.): The Cochrane Collaboration, 2011.

[d]Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 **For more information, visit www.prisma-statement.org.**

[e]Whiting, P. F., Rutjes, A. W., Westwood, M. E., Mallett, S., Deeks, J. J., Reitsma, J. B., ... & Bossuyt, P. M. (2011). QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. *Annals of internal medicine*, *155*(8), 529-536.

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Acronyms Used in this Document

Acronym	Explanation
CI	Confidence Interval
CPB	Cardiopulmonary bypass
EBP	Evidence Based Practice
ICC	Intraclass correlation
MD	Mean difference
PAT	Pulmonary artery temperature
RT	Rectal temperature
UBT	Urinary bladder temperature

Date Developed/Updated

August 2019

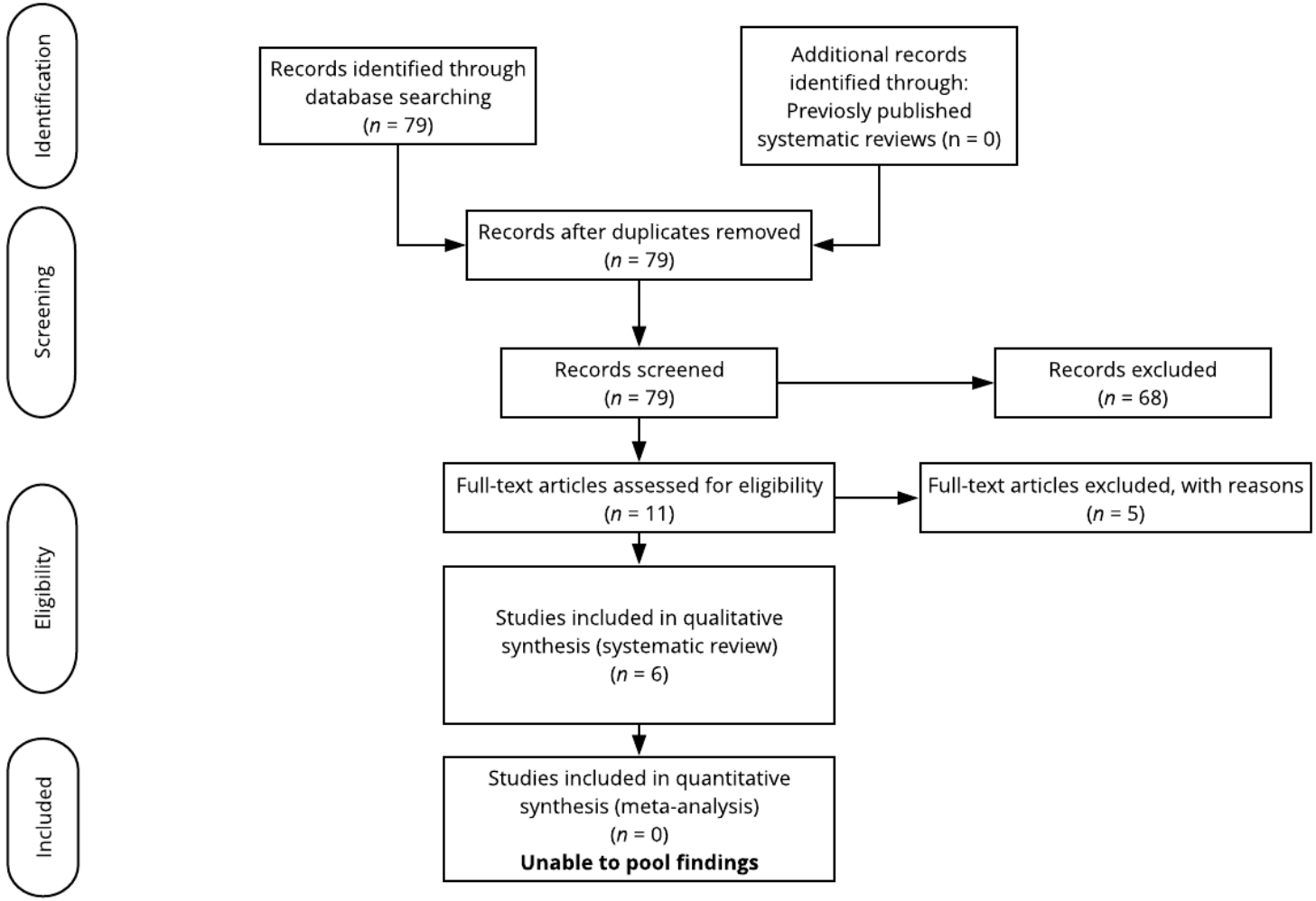

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA)[e]

Domain	Percent Agreement
Scope and purpose	75%
Stakeholder involvement	35%
Rigor of development	56%
Clarity and presentation	89%
Applicability	38%
Editorial independence	6%
Overall guideline assessment	64%
Team's recommendation for guideline use	Yes

Table 1. AGREE II[a] Summary for the Engelman et al. (2015)
Note: Three EBP Scholars completed the AGREE II on this guideline.

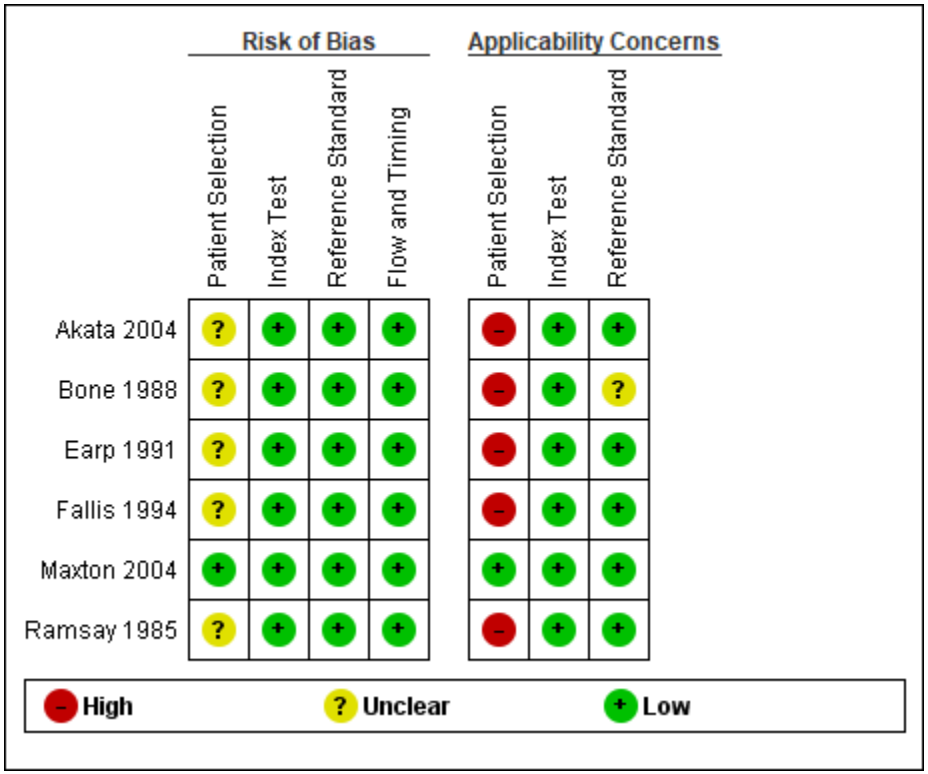

Figure 2. Risk of Bias Summary

Characteristics of studies

Akata 2004

Patient Sampling	Not clearly stated how patients sample enrolled
Patient characteristics and setting	Adult patients who underwent profound hypothermic CPB for aortic arch reconstruction (*N* = 10), Patients served as their own control
Index tests	Urinary Bladder Temperature (UBT) Thermistor-tipped urinary bladder catheter (Respiratory Support Products, Irvine, CA, USA)
Reference standard	Pulmonary Arterial Temperature (PAT), Thermistor at the tip of the thermodilution catheter placed in the right pulmonary artery (Swan-Ganz CCOmbo CCO/SVO2/VIP; Edwards Lifesciences LLC, Irvine, CA, USA
Flow and timing	• Continuously displayed and electronically sampled and stored at 1-min intervals • Manually recorded at several 3 to 5-minute intervals prior and during surgery
Results	• Prior to cooling, PAT and UBT were not significantly different ($p > 0.05$) • PAT began changing immediately after the start of cooling and rewarming • UBT lagged behind PAT ($p < .05$) • PAT was significantly lower than UBT at all time points after 18min of cooling ($p < .05$) • During stabilized hypothermia, UBT was significantly higher than PAT ($p < .05$)

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	Unclear
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Unclear risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	High concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	No
If a threshold was used, was it pre-specified?	No
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Yes

Were the reference standard results interpreted without knowledge of the results of the index tests?	No
Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the target condition as defined by the reference standard does not match the question?	Low concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias?	Low risk

Bone 1988

Patient Sampling	• Not clearly stated how patients sample enrolled
Patient characteristics and setting	Adult patients who underwent cardiac surgery with CPB (*N* = 35) • Group 1 (*n* = 15): Actively cooled to a target temperature of 28ºC • Group 2 (*n* = 18): No active cooling
Index tests	• UBT: thermistor-tipped catheter (Vitalmetrics, Urine Monitoring System, Model 220); • Rectal Temperature: mercury-in-glass thermometer
Reference standard(s)	Nasopharyngeal Temperature
Flow and timing	Temperature measurements from each site were recorded throughout the operation at intervals of 5 minutes.

Results	**Cooling on bypass:**
	• **Group 1**
	  ○ Rate of decrease in temperature was least for the rectal site.
	  ○ There was not a significant difference between bladder temperature and rectal temperature ($p > 0.5$).
	  ○ The greatest variations in temperature were at 15 minutes.
	  ▪ Bladder temperature showed an 8.5% change from baseline.
	• **Group 2**
	  ○ Nasopharyngeal site demonstrated the greatest percentage changes in temperature.
	  ○ There were significant differences between bladder temperature and nasopharyngeal but not rectum.
	Rewarming on bypass:
	• **Group 1**
	  ○ The percentage change in temperature from baseline was similar at the start of rewarming for bladder, nasopharyngeal, and rectal sites, between 15.5% and 17.5% below baseline values.
	  ▪ Actual temperatures
	  2. Bladder 30.0 º C.
	  3. Nasopharyngeal 29.1
	  4. Rectal 30.0^0 C
	  ○ Nasopharyngeal demonstrated an increase of 5% from their baseline values at 20 minutes after the start of rewarming.
	  ○ The bladder and rectal temperatures increased more slowly
	  ○ There was a significant difference ($p < .01$) in the temperature of the bladder site compared to all other sites during rewarming.
	• **Group 2**
	• Bladder temperature showed the highest percentage change from baseline at the start of rewarming.
	• The temperature of the arterial inflow blood increased from 33.3º C to 38.2º C at 15 minutes.
	• Nasopharyngeal showed increases above their baseline temperature at ten minutes.
	• There were significant differences ($p < .01$) in the change in bladder temperature compared with nasopharyngeal and PAT but not rectum during this period.
	
	Post-bypass:
	• **Group 1**
	  ○ Nasopharyngeal temperatures remained above their baseline values.
	  ○ Bladder and rectal temperature remained below their baseline values.

	○ Significant difference ($p < .01$) were found between bladder temperature and nasopharyngeal sites during this period of unassisted circulation. • **Group 2** ○ All values, except rectal, were above baseline at the time of coming of bypass ○ All temperatures returned to their baseline values.

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	Unclear
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Unclear risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	High concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	No
If a threshold was used, was it pre-specified?	Yes
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Unclear
Were the reference standard results interpreted without knowledge of the results of the index tests?	No
Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the target condition as defined by the reference standard does not match the question?	Unclear concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Unclear
Could the patient flow have introduced bias?	Low risk

Earp 1991

Patient Sampling	Subjects were recruited from a population admitted to a major southeastern medical center
Patient characteristics and setting	Adult patients who underwent first-time coronary artery bypass graft surgery (*N* = 14), Patients served as their own control
Index tests	UBT (Bardex Biocath temperature sensing Foley catheter and BARD Urotrack Plus Monitor, model; Bard Urological, Covington, GA.)
Reference standard	PAT (Edwards Paceport pulmonary artery catheter and Cardiac Output Computer, Edwards Laboratories, Santa Ana, Ca)
Flow and timing	Post CPB surgery during rewarming, Data collected every 15minutes
Results	UBT were 0.1ºC to 0.2ºC higher than PAT with a correlation coefficient of 0.94 to 0.99.

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	Unclear
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Unclear risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	High concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	No
If a threshold was used, was it pre-specified?	No
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	No
Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the target condition as defined by the reference standard does not match the question?	Low concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias?	Low risk

Fallis 1994

Patient Sampling	Convenience Sample, University-affiliated tertiary care center in Western Canada
Patient characteristics and setting	Adults who underwent open-heart surgery. Patients served as their own control
Index tests	Rectal Temperature, IVAC 2080A electronic thermometer (IVAC Corporation, San Diego, CA)
Reference standard	PAT, Swan-Ganz Thermodilution catheter thermistor (Baxter Healthcare Corporation, Irvine, CA)
Flow and timing	• After 30-minute stabilization period, rectal and PAT were taken on five occasions for each subject • Twice the evening before surgery at a one-half hour interval • Three times after intubation at one, four, and eight hours after surgery.
Results	Post-surgery • Rectal versus PA temperature difference increased from 0.08ºC one hour after surgery to 0.34ºC eight hours after surgery • The temperature difference was significantly different at 8hours after surgery ($p < .05$)

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	No
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Unclear risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	High concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	No
If a threshold was used, was it pre-specified?	No
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Yes

Were the reference standard results interpreted without knowledge of the results of the index tests?	No
Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the target condition as defined by the reference standard does not match the question?	Low concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias?	Low risk

Maxton 2004

Patient Sampling	Convenience sample from a larger pediatric intensive care unit in a tertiary hospital in Australia
Patient characteristics and setting	Children who underwent CPB with systemic hypothermia to less than 30ºC (*N* = 19)
Index tests	• UBT, thermistor probe (Mallinckrodt) • Rectal, YSI 400 (YSI Incorporated, Yellow Springs, OH, USA)
Reference standard	PA, 3.5f Baxter Edslab double-lumen thermodilution catheter (Baxter HealthCare Corporation Irvine, CA)
Flow and timing	Every 30 minutes post-surgery
Results	• UBT showed the best estimate of PAT • UBT correlation compared to PAT: 0.82 Intraclass correlation (ICC) • MD of UBT from PAT: -0.30, 95% CI [-0.92, 0.32] • Rectal temperature from PAT: 0.60 IC • Mean difference of rectal temperature from PAT: - 0.69ºC, 95% CI [-1.27, -1.00] • The significant lag between PA and rectal temperature of between 0 and 150-minutes after the 6-hour measurement period (*p* = .015)

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	No
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	Low concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	No
If a threshold was used, was it pre-specified?	No
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	No

Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the target condition as defined by the reference standard does not match the question?	Low concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Unclear
Were all patients included in the analysis?	Unclear
Could the patient flow have introduced bias?	Low risk

Ramsay 1985

Patient Sampling	Not clearly stated how patients sample enrolled
Patient characteristics and setting	Adults patients who underwent uncomplicated valve replacement or aortocoronary bypass surgery (*N* = 29)
Index tests	UBT and rectal temperatures used a Mon-a-Therm "Cath Temp" Foley catheter) and displayed on the temperature monitor.
Reference standard	PAT was recorded using the catheter thermistor (Model 9520A, Edwards Laboratories, Santa Aria, CA).
Flow and timing	Temperatures at each site were recorded at the start of rewarming, every 10 minutes during rewarming, at the termination of CPB, then at 10 minutes intervals for 1 hour after CPB, and thereafter at 30 min intervals for a further 3 hours.
Results	• The UBT and rectal temperature showed significant differences throughout rewarming when compared to PAT ($p <$ .05). • Forty minutes after CPB and thereafter, there was no significant difference between the temperature at any site. • Rectal temperature was less reliable as a predictor of total body rewarming.

Patient Selection

Risk of Bias	
Was a consecutive or random sample of patients enrolled?	Yes
Was a case-control design avoided?	Yes
Did the study avoid inappropriate exclusions?	Unclear
Could the selection of patients have introduced bias?	Unclear risk
Concerns regarding applicability	
Are there concerns that the included patients and setting do not match the review question?	High concern

Index Test

Risk of Bias	
Were the index test results interpreted without knowledge of the results of the reference standard?	Yes
If a threshold was used, was it pre-specified?	No
Could the conduct or interpretation of the index test have introduced bias?	Low risk
Concerns regarding applicability	
Are there concerns that the index test, its conduct, or interpretation differ from the review question?	Low concern

Reference Standard

Risk of Bias	
Is the reference standards likely to correctly classify the target condition?	Yes
Were the reference standard results interpreted without knowledge of the results of the index tests?	No
Could the reference standard, its conduct, or its interpretation have introduced bias?	Low risk
Concerns regarding applicability	

Are there concerns that the target condition as defined by the reference standard does not match the question?	Low concern

Flow and Timing

Risk of Bias	
Was there an appropriate interval between index test and reference standard?	Yes
Did all patients receive the same reference standard?	Yes
Were all patients included in the analysis?	Yes
Could the patient flow have introduced bias?	Low risk

References

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