Scientific evidence for the PiCCO-Technology
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Clinical Indications

Evidence of the clinical benefit for the PiCCO-Technology by indications

Septic shock


Acute Respiratory Distress Syndrome (ARDS)

Cardiogenic shock

- Schmid B, Fink K, Olschewski M, Richter S, Schwab T, Brunner M, Busch HJ. 
  **Accuracy and precision of transcardiopulmonary thermodilution in patients with cardiogenic shock.** 

- Perny J, Kimmoun A, Perez P, Levy B. 
  **Evaluation of cardiac function index as measured by transpulmonary thermodilution as an indicator of left ventricular ejection fraction in cardiogenic shock.** 

- Friesecke S, Heinrich A, Abel P, Felix SB. 
  **Comparison of pulmonary artery and aortic transpulmonary thermodilution for monitoring of cardiac output in patients with severe heart failure: validation of a novel method.** 

Severe burn injury

- Sanchez-Sanchez M, Garcia-de-Lorenzo A, Herrero E, Lopez T, Galvan B, Asensio MJ, Cachafeiro L, Casado C. 
  **A protocol for resuscitation of severe burn patients guided by transpulmonary thermodilution and lactate levels: A 3-year prospective cohort study.** 

- Bognar Z, Foldi V, Rezman B, Bogar L, Csontos C. 
  **Extravascular lung water index as a sign of developing sepsis in burns.** 
  Burns 2010; 8: 1263-70.

- Csontos C, Foldi V, Fischer T, Bogar L. 
  **Arterial thermodilution in burn patients suggests a more rapid fluid administration during early resuscitation.** 
Clinical Indications

Evidence of the clinical benefit for the PiCCO-Technology by indications

Neuro Surgery (SAH)

- Obata Y, Takeda J, Sato Y, Ishikura H, Matsui T, Isotani E.
  
  A multicenter prospective cohort study of volume management after subarachnoid hemorrhage: circulatory characteristics of pulmonary edema after subarachnoid haemorrhage.

  
  Impact of transpulmonary thermodilution-based cardiac contractility and extravascular lung water measurements on clinical outcome of patients with Takotsubo cardiomyopathy after subarachnoid hemorrhage: a retrospective observational study.

  
  Early intensive versus minimally invasive approach to postoperative hemodynamic management after subarachnoid hemorrhage.

- Mutoh T, Kazumata K, Ishikawa T, Terasaka S.
  
  Performance of bedside transpulmonary thermodilution monitoring for goal-directed hemodynamic management after subarachnoid hemorrhage.

Pancreatitis

- Sun Y, Lu ZH, Zhang XS, Geng XP, Cao LJ, Yin L.
  
  The effects of fluid resuscitation according to PiCCO on the early stage of severe acute pancreatitis.

  
  The impact of early goal-directed fluid management on survival in an experimental model of severe acute pancreatitis.

  
  Volume assessment in patients with necrotizing pancreatitis: A comparison of intrathoracic blood volume index (ITBI), central venous pressure, and hematocrit, and their correlation to cardiac index and extravascular lung water index.
Cardiac Surgery

  *Individually optimized hemodynamic therapy reduces complications and length of stay in the intensive care unit: A prospective, randomized controlled trial.*

- Smetkin AA, Kirov M, Kuzkov VV, Lenkin AI, Eremeev AV, Slastilin VY, Borodin VV, Bjertnaes LJ.
  *Single transpulmonary thermodilution and continuous monitoring of central venous oxygen saturation during off-pump coronary surgery.*

- Goepfert M, Reuter D, Akyol D, Lamm P, Kilger E, Goetz A.
  *Goal directed fluid management reduces vasopressor and catecholamine use in cardiac surgery patients.*

Transplantation

  *Extravascular lung water and pulmonary vascular permeability index measured at the end of surgery are independent predictors of prolonged mechanical ventilation in patients undergoing liver transplantation.*

- Minambres E, Coll E, Duerto J, Suberviola B, Mons R, Cifrian JM, Ballesteros MA.
  *Effect of an intensive lung donor-management protocol on lung transplantation outcomes.*


  *Early donor management increases the retrieval rate of lungs for transplantation.*

High risk surgical procedures

  *Evaluation of respiratory status in patients after thoracic esophagectomy using PICCO system.*

- Sato Y, Motoyama S, Maruyama M, Hayashi K, Nakae H, Tajimi K, Ogawa J.
  *Extravascular lung water measured using single transpulmonary thermodilution reflects perioperative pulmonary edema induced by esophagectomy.*
There are two femoral PICCO catheters that can be used in paediatrics (PV2013L07, 3F, 7cm and PV2014L08, 4F, 8cm). The decision in which kind of patient (age, weight) this catheter is used should be made by the treating physician. Recommendations on the body weight can be derived from publications e.g. Cecchetti et al (Min Anest 2013), where a 3F catheter was used with a body weight less than 10kg and 4F catheters for paediatrics with at least 10kg body weight. In other publications (e.g. Lemson et al, Crital Care 2010; Szekely et al, Ped Card 2010; Gil Anton et al, An Ped 2009; Egan et al, Intensive Care Med 2005; Cecchetti et al, Min Anest 2003) the youngest patients were 2 months old with a body weight of 3 kg. A review on PiCCO in paediatrics was published by Proulx et al (Pediatr Crit Care Med 2011).

Clinical Indications

Evidence of the clinical benefit for the PiCCO-Technology by indications

Pediatric - Acute respiratory failure


Pediatric - Severe burn injury


Pediatric - Head trauma

**Pediatric - Cardiac surgery**

  Cardiac index monitoring by femoral arterial thermodilution after cardiac surgery in children.  

- Keller G, Desebbe O, Henaine R, Lehot JJ.  
  Transpulmonary thermodilution in a pediatric patient with an intracardiac left-to-right shunt.  

- Szekely A, Breuer T, Sapi E, Szekely E, Szatmari A, Toth M, Hauser B, Gal J.  
  Transpulmonary thermodilution in neonates undergoing arterial switch surgery.  

- Fakler U, Pauli Ch, Balling G, Lorenz HP, Eicken A, Hennig M, Hess J.  
  Cardiac index monitoring by pulse contour analysis and thermodilution after pediatric cardiac surgery.  

- Cherqaoui I, Raux O, Dehour L, Rochette A, Dadure C, Capdevila X.  
  Transpulmonary thermodilution hemodynamic monitoring for pheochromocytoma surgery in a child with complex congenital heart disease.  
  Paediatr Anaesth 2006; 16(12): 1277-80.

- Egan J, Festa M, Cole A, Nunn GR, Gillis J, Winlaw DS,  
  Clinical assessment of cardiac performance in infants and children following cardiac surgery.  

  Pulse contour analysis for cardiac output monitoring in cardiac surgery for congenital heart disease.  

**Pediatric - Liver transplantation**

  Pulse contour cardiac output system use in pediatric orthotopic liver transplantation: preliminary report of nine patients.  

**Pediatric - Normal range areas in paediatric patients**

The normal ranges are slightly different to those of adult patients. It has been shown that GEDI tends to be lower and ELWI tends to be higher, the younger the patient and lower their weight.

- Nusmeier A, Cecchetti C, Blohm M, Lehman R, van der Hoeven J, Lemson J.  
  Near-normal values of extravascular lung water in children.  

- Lemson J, Merkus P, van der Hoeven JG.  
  Extravascular lung water index and global end-diastolic volume index should be corrected in children.  
Cost Effectiveness

Several publications confirmed improved patient outcome when advanced haemodynamic variables have been used to set up a goal directed treatment algorithm. In the studies mainly a reduction of complication rates have been reported and consequently the treatment costs have been reduced. Even when the installation of advanced haemodynamic monitoring is associated with an investment, the cost reduction by avoiding complications is much higher than the investment.

Validation of the PiCCO parameters

Accuracy of PiCCO thermodilution cardiac output compared to the pulmonary artery catheter.

In terms of accuracy the two methods are comparable. However, the PiCCO thermodilution measurement is less user dependent and gives more stable measurements. When compared to the gold standard (Fick method) the PiCCO thermodilution cardiac output shows an excellent correlation.

Validation of the PiCCO parameters

Accuracy of PiCCO pulse contour cardiac output compared to the pulmonary artery catheter

Several validation studies of the PiCCO pulse contour cardiac output versus pulmonary artery thermodilution have been published, mainly in the early days after market introduction of the PiCCO technology.

Accuracy of the lung water measurement (EVLW/ELWI) by PiCCO

Evidence shows that measuring lung water with the PiCCO for quantification of pulmonary oedema is accurate and correlated strongly with the ‘gold standard’ gravimetric method.


Clinical & Medical Questions

Influence on PiCCO measurements by special clinical situations or therapies

Aortic aneurysm

In patients with known aortic aneurysm, if a femoral arterial catheter is used, GEDI will be overestimated due to the volume of the aneurysm. In these cases, a brachial or axillary catheter is recommended.


Valvulopathies, cardiac valve insufficiencies

Valve insufficiency may cause regurgitation of the thermodilution injectate and prolong the transit time of the indicator, or interfere with the thermodilution curve. However, where a thermodilution curve is possible, the calculation of the cardiac output is correct.

In mitral valve insufficiency the accuracy of the PiCCO cardiac output measurement has been confirmed.


Aortic Stenosis

In aortic stenosis arterial thermodilution accurately reflects Cardiac Output. The arterial pressure curve may have reduced systolic and elevated diastolic pressures. However the area under the arterial curve still reflects Stroke Volume. Recalibration of the pulse contour (with thermodilution) substantially improves reliability in severe aortic stenosis.


Hypothermia

There is no influence on the thermodilution measurements as long as the patient’s temperature is stable. Cooled injectate should be used.


Vasoconstrictor and/or inotrope therapy

All parameters are correctly calculated. Where there are significant changes in the catecholamine requirements or volume therapy, recalibration of the pulse contour analysis is recommended.

Clinical & Medical Questions

Influence on PiCCO measurements by special clinical situations or therapies

Intra-aortic Balloon Pump (IABP)

The thermodilution measurement with the PiCCO is not influenced by the IABP, but the Pulse Contour Analysis is unable to provide valid continuous cardiac output.


Extracorporeal membrane oxygenation (ECMO), extracorporeal lung assist (ECLA)

When a patient is on ECMO there is no way for the thermodilution injectate to get from the point of injection to the point of detection as the ECMO machine lies in its path. It is not known if the pulse contour analysis is accurate or not.

Ventricular assist device (VAD)

With a VAD the PiCCO thermodilution measurement has been shown to work.


Continuous renal replacement therapy (CRRT), haemofiltration, dialysis

PiCCO works when patients are on CRRT, with the following recommendations from the literature: thermodilution measurements should be avoided directly after the CRRT is switched on or off due to potential unstable blood temperatures and the CRRT catheter outflow and inflow should not lie in the PiCCO indicator passage track.

Research shows that the EVLW can be used to show the positive effect of proning the patient. It has also been shown that the calibrated PiCCO is more accurate than non-calibrated systems.


Kinetic therapy (e.g. prone positioning)

Research shows that the EVLW can be used to show the positive effect of proning the patient. It has also been shown that the calibrated PiCCO is more accurate than non-calibrated systems.


Effect of lung resection on ELWI

Lung resection procedures (lobectomy, bilobectomy, pneumectomy) theoretically reduce the Pulmonary Blood Volume (PBV) and may lead to inaccurate calculation (underestimation) of the Extravascular Lung Water (EVLW). To evaluate this theoretical assumption a double indicator dilution technique is required to determine PBV before and after lung resection. Clinical studies using this approach show that:

- The amount of extracted lung tissue and pulmonary blood volume do not correlate
- Clear correction factors for PBV calculation cannot be determined
- An initial effect on PBV is widely physiologically compensated latest two days post-operatively

Thus, it is not recommended to correct the measured values for PBV and EVLW with fixed calculation factors. Clinical evidence is not available and such corrections may lead to unexpected and unpredictable errors in the calculation of EVLW in patients after lung resection.

Clinical & Medical Questions

Influence on PiCCO measurements by special clinical situations or therapies

Effect of pleural effusion on ELWI

Pleural fluid does not affect the EVLWI measurement. The capillary surface of the lung parenchyma that is in contact with the pleural fluid is very small in comparison to the pulmonary capillary network. Temperature loss to the pleural fluid is negligible.

- Deeren D, Dits H, Daelemans R, Malbrain ML.
  Effect of pleural fluid on the measurement of extravascular lung water by single transpulmonary thermodilution.

Effect of Pulmonary Embolism on ELWI

With pulmonary embolisms, because there is an obstruction in the pulmonary vasculature, EVLW is underestimated.

  Lung perfusion affects preload assessment and lung water calculation with the transpulmonary double indicator method.

Magnetic resonance imaging (MRI)

The effect of MRI on the PICCO-Catheter has been investigated in model experiments and has also been published as correspondence in congress newsletters and as letters. These investigations don’t show any negative effects on the functionality of the PICCO-Catheter during MRI. However, there are currently no systematic tests for all available MRI systems under the various measurement conditions. Therefore PULSION cannot confirm the compatibility of the PICCO-Catheter with MRI systems and must recommend the removal of the PICCO-Catheter before MRI. It is the treating physician’s full responsibility if the decision is made to leave the PICCO-Catheter in the patient during the MRI.

- Greco F, Vendrell JF, Deras P, Boullaran A, Perrigault PF.
  [The Pulsio-catheter and magnetic resonance imaging.]
  Ann Fr Anesth Reanim 2011; 30(9): 697.

- Kampen J, Liess C, Casadio C, Tonner PH, Reuter M, Scholz J.
  Safety of the Pulsio-catheter for haemodynamic monitoring during magnetic resonance imaging.

- Kampen J, Liess K, Casadio C, Tonner PH, Scholz J.
  [Thermal lesions caused by a PICCO catheter left in place in the MRT? – Fibre optical measurements of temperature in a No-flow-model.]
  Intensivmedizin und Notfallmedizin 2002; 39: 113

Passive leg raising (PLR)

The PICCO has been used in several investigations to show if a patient is volume responsive using passive leg raising.

  Effects of passive leg raising and volume expansion on mean systemic pressure and venous return in shock in humans.

- Jabot J, Teboul JL, Richard C, Monnet X.
  Passive leg raising for predicting fluid responsiveness: importance of the postural change.
Clinical significance of PiCCO parameters

Global End-Diastolic Volume Index (GEDI) as an indicator of cardiac preload

Strictly defined, cardiac preload is the myocardial fibre stretch at the end of ventricular diastole. A parameter that accurately reflects preload in clinical practice is not yet available. However, studies have demonstrated that GEDI (or ITBI) is a reproducible and sensitive parameter and a good approximation of preload.


Contractility parameters Cardiac Function Index (CFI) and Global Ejection Fraction (GEF)

These parameters have been compared to the left ventricular ejection fraction from Echocardiography, for e.g. and have been found to closely correlate.

Fluid responsiveness by Stroke Volume Variation (SVV) and Pulse Pressure Variation (PPV)

To fulfil the criteria for SVV and PVV to be accurate, the patient must be on positive pressure ventilation with a tidal volume > 8ml/kg (no spontaneous breathing or assisted breaths) and in sinus rhythm with no artifacts. This is the case for every monitor that provides these parameters.


Weaning from the ventilator


Accuracy of chest x-ray for measuring pulmonary oedema

Research confirms that even today, it is not possible to quantify the extent of pulmonary oedema with a chest x-ray. The reason is the complexity to interpret a chest x-ray, a density measurement which is influenced by all compartments in the chest, like bones, muscles, vessels, blood, air, skin layers, tissue oedema, pleural effusion and, amongst the others, also by the extravascular lung water.

Technique and Technology Questions

Risk of the PiCCO femoral catheter compared to other arterial catheters

Evidence shows there is no additional risk when using any of the PiCCO arterial catheters compared to standard arterial lines.

- Scheer BV, Perel A, Pfeiffer UJ. Clinical review: Complications and risk factors of peripheral arterial catheters used for haemodynamic monitoring in anaesthesia and intensive care medicine. Critical Care 2002; 6(3): 198-204

Recommended application duration of the PiCCO catheter and monitoring kit

Related to the registration (CE approval) PULSION disposables can stay in place for a maximum of 28 days. From a hygienic point of view this is not recommended for clinical practice. Based on a publication by the Commission for Hospital Hygiene and Infection Prevention of the Robert-Koch Institute, Germany (Bundesgesundheitsbl – Gesundheitsforsch – Gesundheitsschutz 2002) the following recommendations are given:

- Exchange interval for PiCCO catheters: every 10 days (exception: long radial artery catheter PV2014L50: max. 3 days)
- Exchange interval for PiCCO monitoring kits: every 4 days

The exchange interval can be shorter in case of detection of complications associated with the application of this disposable articles, e.g. bleeding, haematoma, signs of infection, perfusion impairment, misplacement of the catheter or if local regulations or standard operating procedures overrule this recommendation.

PiCCO measurements from a standard short radial artery catheter is not possible

In critically ill patients the arterial pressure waveform at the radial site is affected by vascular tone (vasoconstriction and dilation) and compliance making arterial blood pressure measurements inaccurate. Also, due to the distance involved, it is not possible to record a downstream temperature required for the thermodilution measurement.

- Orme RMLE, Pigott DW, Mihm FG. Measurement of cardiac output by transpulmonary arterial thermodilution using a long radial artery catheter. A comparison with intermittent pulmonary artery thermodilution. Anaesthesia 2004; 59: 590-594
Technique and Technology Questions

How many thermodilution measurements are recommended?

It is recommend that three consecutive measurements, with less than 15% (+/-) variation compared to the mean value are performed within a 10 minute time frame.


Importance of an accurate value for the central venous pressure (CVP)

The central venous pressure (CVP) value is only required for the calculation of the afterload parameter, systemic vascular resistance (SVR/SVRI). In the calculation formula [SVR = (MAP-CVP) / CO * 80] the CVP value does not have a significant influence and the default CVP value of 5mmHg enables a sufficiently accurate SVR calculation. Only in case of extremely high or low values the CVP should be adjusted manually. Usually CVP is not measured continuously when PiCCO is applied, but in case of the availability of a continuous CVP measurement this can be connected to the PiCCO and the continuous values are used for the SVR calculation.

Considerations in case of thermodilution injection into the femoral vein and the PiCCO catheter placed in the femoral artery

If both the central venous catheter and PiCCO arterial catheters are placed on the same side (e.g. right femoral groin) the injectate may be detected immediately through the vessel wall (cross talk phenomena) resulting in measurement errors. This is more common in paediatric patients.


Cross talk can be avoided if the PICCO arterial catheter is either placed in the opposite femoral artery or in the brachial / axillary artery. If placed femorally, thermodilution measurement is possible, however, the PIccO preload value, Global End-diastolic Volume (GEDI) will be slightly higher than the actual volume. From PICCO2 software version V3.1 onwards the PIccO asks for confirmation of where both the central venous and arterial catheters are placed to ensure accurate calculation of GEDI.

Thermodilution injection via a peripherally inserted central catheter (PICC line)

In order to get an adequate thermodilution curve for accurate parameter calculation, the injectate bolus must be injected in under 7 seconds, and remain cool enough for the PiCCO catheter to detect a difference between the patient's blood and the bolus. Depending on the PICC used, it may be that these conditions cannot be fulfilled.

Thermodilution injection with a room temperature instead of a cold injectate

Evidence shows that the use of room temperature injectate may not be as accurate. Therefore, particularly in patients with raised lung water, the use of cold injectate is recommended.

- Huber W, Kraski T, Haller B, Mair S, Saugel B, Beitz A, Schmid RM, Malbrain ML. 
  Room-temperature vs. iced saline indicator injection for transpulmonary thermodilution. 

Frequency of thermodilution injections to recalibrate continuous cardiac output

In general the PiCCO should be calibrated every 8 hours by thermodilution; however individual patient needs vary greatly. In case of haemodynamic instability, the pulse contour will deviate from the thermodilution cardiac output. In such cases frequent recalibration (via thermodilution) is recommended.

  Predictors of the accuracy of pulse-contour cardiac index and suggestion of a calibration-index: a prospective evaluation and validation study. 
  BMC Anesthesiol 2015; 15: 45

- Hamzaoui O, Monnet X, Richard C, Osman D, Chemla D, Teboul JL. 
  Effects of changes in vascular tone on the agreement between pulse contour and transpulmonary thermodilution cardiac output measurements within an up to 6-hour calibration-free period. 