

Commentary

The pulmonary artery catheter: the tool versus treatments based on the tool

Jukka Takala

Clinic of Intensive Care Medicine, University Hospital Bern, CH-3010 Bern, Switzerland

Corresponding author: Jukka Takala, jukka.takala@insel.ch

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Abstract

The pulmonary artery catheter (PAC) is a powerful tool that has been used extensively in the assessment and monitoring of cardiovascular physiology. Gross misinterpretation of data gathered by the PAC is common, and its routine use without any specific interventions has not been shown to influence outcome. However, there currently is no evidence from randomized, controlled trials that any diagnostic or monitoring tool used in intensive care patients improves outcome. Studies evaluating the use of the PAC have included numerous potential confounding factors, and should be interpreted with caution. The information obtained with the PAC should be used to find better treatment strategies, and these strategies, instead of the tool itself, should be tested in clinical trials.

The pulmonary artery catheter is a diagnostic and monitoring tool. The ongoing debate over the use of pulmonary artery catheters is focused on their impact on outcome. The value of any diagnostic tool in improving outcome depends, first, on its ability to correctly diagnose the disorders it is meant to diagnose, second, on the relevance of such disorders to the outcome of interest, and third, on the availability of treatment to correct the diagnosed disorders. The value of clinical monitoring tools goes somewhat further. The rationale for using clinical monitoring tools can be based as well on prevention of disorders that, if allowed to develop, can have relevant effects on outcome.

Do we have evidence from randomized controlled trials that any diagnostic tool, *per se*, currently used in intensive care patients improves outcome? Here the answer is clearly no. Such diagnostic tools include echocardiography, CT scan, magnetic resonance imaging, angiography, ultrasound and Doppler measurements for any purposes, measurement of intracranial pressure, and gastroscopy, just to name a few. Does this mean that all such diagnostic tools that have not been proven to improve outcome in randomized controlled trials should be abandoned? Here the answer is also clearly no.

Do we have evidence from randomized controlled trials that any monitoring tool, *per se*, currently used in intensive care patients improves outcome? Here the answer is also clearly no. Such monitoring tools include pulse oximetry, measurement of arterial blood pressure and other intravascular pressures; monitoring of electrocardiogram (ECG), electroencephalogram (EEG), and concentrations of inspiratory, expiratory, and end-tidal gases; intracranial pressure monitoring, monitoring of cardiac output by any method, and monitoring of intracardiac and intrathoracic blood volumes or extravascular lung water by any method, just to name a few. Does this mean that all such diagnostic tools that have not been proven to improve outcome in randomized controlled trials should be abandoned? Here the answer is just as clearly no.

What is the background of the controversy surrounding the use of the pulmonary artery catheter, a very powerful tool for assessment and monitoring of cardiovascular physiology? First, there is little doubt that the use of the pulmonary artery catheter in revenue-driven health care systems has been extensive, in part due to the financial incentives involved. Hence, it is very likely that this tool has been widely used in patients who have had either no physiological problems that need to be solved, or a low risk of developing such problems. Second, there is no doubt that the measurement of complex physiological interactions is, by definition, complex, and requires careful performance and sufficient knowledge of the underlying physiology in order to correctly interpret the results. Third, gross misinterpretation of the available measurements has been common, and therapeutic strategies based on such interpretations widely advocated.

In comparison with any other diagnostic and monitoring strategy currently used in the intensive care unit, the pulmonary artery catheter has undergone an unusually detailed evaluation – albeit only after its widespread application. Several single- or multicentre trials [1-5], some of them

randomized and controlled [1,2], have demonstrated that the routine use of the pulmonary artery catheter without any specified therapeutic interventions does not influence the outcome – that is, is neither dangerous nor beneficial. With respect to a lack of benefit in routine use, this puts the pulmonary artery catheter in the same position as the other monitoring technologies – with the major difference being that it has been assessed in the randomized controlled setting. In terms of not producing harm, the data available for the pulmonary artery catheter are superior to those available for other diagnostic and monitoring technologies – practically no other technology has comparable safety data obtained in randomized controlled trials.

The ability of the pulmonary artery catheter to measure intravascular pressures, blood flow, mixed venous saturation and, more recently, intracardiac volumes and right ventricular ejection fraction with reasonable accuracy, providing that the measurements have been correctly made, is rarely an issue. The interpretation of these measurements (diagnostic interpretation) and application of correct interventions to treat the disorders (therapeutic or preventive strategy) are difficult and subject to controversy. Despite this, several single-centre, randomized, controlled trials have successfully applied therapeutic strategies based on information obtained from the pulmonary artery catheter, and have used these strategies to improve outcome(s) in surgical patients [6-9]. All the successful studies have applied strictly controlled therapeutic strategies to affect physiological variables in a pre-emptive fashion, that is, either to treat the disorders early or to prevent their onset. It is reasonable to assume that the success in these trials is based on the success in designing appropriate protocols and selecting the correct groups of patients at risk, and not on the presence of a diagnostic or monitoring technology *per se*.

Notably, the largest trial evaluating the use of the pulmonary artery catheter with therapeutic guidelines in surgical patients showed no benefit (and no harm) [10]. What is the difference between this landmark multicentre study and the increasing number of smaller, single-centre trials showing controversial results? First, the multicentre study by Sandham and colleagues [10] included patients with a considerably lower mortality than all the successful studies in high-risk patients. It is conceivable that any beneficial effect of physiology-oriented protocol-driven treatments on mortality will be evident in patients at a higher risk of mortality – regularly around twice as high in the positive studies compared to the study of Sandham and colleagues. Second, the Sandham trial used guidelines instead of a treatment protocol, and the adherence to these guidelines is scarcely reported. Third, the treatment goals in the Sandham trial may not have been well selected – indeed, they are very similar to those used in a study in young trauma patients, where goal-directed treatment attempting to increase the oxygen delivery beyond the patients' ability to respond resulted in increased mortality

[11]. This underscores that, to improve outcome, a diagnostic or monitoring tool must be coupled with a treatment that improves outcome.

At the current stage, routine clinical use of the pulmonary artery catheter has been shown to be safe (comparable to central venous catheters), as long as physiologically reasonable therapeutic goals are used. The pulmonary artery catheter should be used with the same scrutiny as any other diagnostic and monitoring tool used to diagnose disorders and adjust therapy in critically ill patients – patients without an actual hemodynamic problem or without a high risk of developing one should not receive a pulmonary artery catheter. The pre-emptive use in high-risk surgery requires definition of patients at high risk, and a treatment strategy proven to work. The information obtained should also be used to find better treatment strategies, and these strategies, instead of the tool itself, should be tested in clinical trials – an approach that so far has been almost unique to the pulmonary artery catheter.

Recently, the ARDS (Acute Respiratory Distress Syndrome) Clinical Trials Network published a study in which two treatment strategies were tested simultaneously with two different monitoring approaches in patients with established acute lung injury [12]. One thousand patients were randomized to have their hemodynamic management guided by monitoring using either the pulmonary artery catheter or the central venous catheter. Both groups had explicit treatment protocols to guide the hemodynamic support and were simultaneously randomized to two different strictly defined fluid management regimens (restrictive and liberal fluid administration) [13]. Extensive training was implemented to make sure that pressure recordings were made correctly. The rates of death at 60 days before discharge home (primary outcome variable), as well as the number of ventilator-free days and days not spent in intensive care, and various other secondary outcome variables were similar between the two groups with different monitoring strategies. The rates of catheter-related (either central venous or pulmonary artery catheter) adverse events were low and similar per catheter inserted, but since the pulmonary artery catheter group had more catheters, they also had significantly more adverse events total, most of which were arrhythmias. Notably, arrhythmias were not prospectively recorded by insertion of central venous lines. Independent of the monitoring strategy, the restrictive fluid management strategy increased the number of ventilator-free days and days not spent in intensive care in these patients.

This study has a very clear message: the use of the pulmonary artery catheter, as defined in the protocol, did not offer any benefit compared to the central venous catheter-guided protocol. While a major strength of the study was the use of strict protocols, this is at the same time a limitation. As in the case of successful studies, the conclusions of

unsuccessful studies are limited to the protocol, and the way the monitoring tool guides treatment within the protocol. In this respect, the study of the ARDS Network deserves some scrutiny and comments.

In patients with pulmonary artery catheters, cardiac index and pulmonary artery occlusion pressure were the data used in addition to blood pressure and urinary output. Clinical assessment of circulation was explicitly not used for decision making. In the central venous catheter-guided treatment, clinical assessment of circulation was explicitly included with the central venous pressure, blood pressure and urine output to guide the treatment. Although prompt reversal of hypotension, oliguria, and ineffective circulation was a foreseen overriding goal, neither blood lactate levels nor mixed or central venous oxygen saturation were measured. The treatment of circulatory shock was not protocolized. The main uses of the pulmonary artery catheter in the study to evaluate whether cardiac index was higher than 4.5 l/min/m² in order to avoid fluid administration for normotensive patients with normal urinary output but low filling pressures; and to measure pulmonary artery occlusion pressure to define when to stop giving furosemide or start giving fluids in normotensive patients with normal urinary output. It is also of interest that 29% of all patients with pulmonary artery catheters had a pulmonary artery occlusion pressure higher than 18 mmHg at protocol start. In order to recruit 1,001 patients, the study screened over 11,000 patients, more than 2,100 of whom were excluded because they already had a pulmonary artery catheter in place. These are among the issues that should be considered when applying the results of this important trial in clinical practice. Perhaps the most important message from this study is that too much fluid in established acute lung injury is harmful and that the iatrogenic effects of hemodynamic support can be reduced by protocols using clinical judgement and central venous pressure – measurement of cardiac output and pulmonary artery occlusion pressures offers no additional benefit in this context.

The search for alternative and complementary strategies of hemodynamic monitoring has brought exciting new technologies to clinicians. Before repeating many of the pitfalls that have characterized the debate on the value of the pulmonary artery catheter, the search for effective therapeutic interventions should be emphasized. The need for any diagnostic or monitoring tool depends fundamentally on what information is needed to perform such interventions – all of the existing and future technologies have a potential value in this context.

Competing interests

The Clinic of Intensive Care Medicine, University Hospital Bern, has existing research and/or consultation agreements with the following companies involved in clinical monitoring: Edwards Lifesciences, General Electric, Pulsion Medical

Systems AG. The author has received lecture fees from Edwards Lifesciences.

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