Review

Which general intensive care unit patients can benefit from placement of the pulmonary artery catheter?

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Abstract

From the report by Connors and coworkers in 1996 until now, much effort has been directed at demonstrating the safety and/or effectiveness of strategies based on pulmonary artery catheter (PAC) data. Although studies have failed to demonstrate a clear benefit of PAC use, neither have any corroborated the initial report of PAC-induced mortality. With this in mind, it is important to clarify the indications for PAC, taking into account the development of new technologies to measure cardiac output and stroke volume. The present review focuses on safety and effectiveness data, with a special focus on reasonable indications for PAC use in the intensive care unit. The PAC has evolved since its initial presentation, and it now offers numerous parameters in addition to cardiac output and pressure measurement, such as mixed oxygen saturation and right ventricular ejection fraction. Because many techniques may be used to measure cardiac output, the indications for PAC use have become founded on other parameters that are useful in more specific situations, essentially involving the right circulation.

Introduction

The pulmonary artery catheter (PAC) is a monitoring device that is still largely used in the intensive care unit (ICU). However, the context surrounding use of this invasive monitoring system has evolved over the past decade. The motivation to find noninvasive or mildly invasive surrogate techniques has been partially successful; echocardiography, Doppler and pulse contour techniques have been proposed as alternatives. The famous report from Connors and coworkers [1] created turmoil among intensivists and resulted in clinical trials to test the potential benefit of PAC use. That report used a propensity score as a technique to compare patients with versus those without PAC placement. In a mixed population of medical and surgical ICU patients, Connors and coworkers found that increased mortality, length of stay and costs were associated with use of a PAC. In addition, many have claimed that there are no good data to support the use of the PAC because no study has demonstrated an outcome benefit in patients undergoing a therapeutic strategy based on PAC data.

Before reviewing the data available in order to define the type of patients who may benefit from PAC use, some important issues must be borne in mind. First, the prognosis of severely ill patients cannot be improved by catheter insertion *per se*. Second, performing randomized controlled studies in homogeneous, specific groups of patients is impracticable because of marked overlap between the different syndromes or diseases. For example, acute respiratory distress syndrome (ARDS) is most often related to severe lung infection with sepsis or septic shock.

The issues important for intensivists are embodied by the following three questions. Does PAC insertion carry a significant risk of complications? Can the data provided by the PAC improve outcomes in severely ill patients? Finally, do we have data to improve our definition of the type of patients or diseases for which PAC may improve quality of care and outcomes in the ICU?

Risk for complications

Previous studies reported a series of complications related to PAC insertion, including arrhythmia, vein thrombosis, infection, pulmonary artery (PA) rupture and intracardiac lesions [2]. More recent data did not provide evidence for either a high risk for complications or a link between PAC use and death. The ESCAPE (Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness) study [3] found that approximately 4% of patients undergoing PAC placement had complications, including cardiac arrest and infection, but there were no PAC-related deaths. A recent French study [4] reported no cases of pulmonary embolism, but 2.8% of patients suffered PAC-related infections.

AHF = acute heart failure; ARDS = acute respiratory distress syndrome; ICU = intensive care unit; PA = pulmonary artery; PAC = pulmonary artery catheter; SCCM = Society of Critical Care Medicine.

Sandham and coworkers [5] reported a higher incidence of pulmonary embolism in the PAC group than in the control group.

If it is presumed that any risk associated with PAC placement results from the invasiveness of the technique and not the device *per se*, then the PAC in itself cannot influence prognosis directly. Rather, justification for PAC insertion must be based on better strategies of care in complex patients resulting from its use, in turn yielding better outcomes. No study evaluating PAC-induced changes in management strategy and resulting outcomes has yet been reported. In the absence of such data, it is a challenge to define the proper indications for PAC use. The list of indications in the general ICU were based on expert opinion or nonrandomized trials, and pertain to patients with severe cardiac failure, severe sepsis or septic shock, or acute respiratory failure. Developments in PAC technology allowed additional variables to be evaluated that changed the indications, mainly focusing on global tissue oxygenation or right-sided problems.

Indications for use of the pulmonary artery catheter

Since its introduction, the PAC has been used to characterize circulatory failure by measuring cardiac output, right and left filling pressures, and more recently mixed venous oxygen saturation (a global index of tissue oxygenation); and to evaluate the effects of haemodynamic therapeutic strategies. Studies conducted in specific patient populations, such as those who have undergone cardiac surgery or organ transplantation, are excluded from the present review.

Following the report by Connors and coworkers [1], many investigators began to evaluate whether long-term use of the PAC may affect morbidity or mortality in critically ill patients. In a retrospective study conducted in more than 10,000 patients included in a critical care database maintained by the Society of Critical Care Medicine (SCCM) [6], independent factors linked to PAC use were the setting of a surgical ICU and (for patients of white race) having a private medical insurance contract. Importantly, the presence in the ICU of a full-time critical care physician was associated with reduced PAC use [7].

In 2000, a meta-analysis of the effectiveness of the PAC was conducted [8]. The authors searched the Medline database, from 1970 to 1996, for reports including the following terms in the title: 'pulmonary artery catheterization' and 'Swan-Ganz catheterization'. The results were restricted to those on 'effectiveness' and 'usefulness'. A total of 1610 patients included in 12 trials were analyzed. The results showed that there was lower mortality in the PAC group, with a relative risk ratio of 0.8 (corresponding to $P < 0.02$). Although such meta-analyses have certain limitations, this observation at least confirmed the safety of PAC use in ICU patients and suggested potential benefit.

In a prospective, descriptive cohort study, Mimoz and coworkers [9] demonstrated a change in therapy after insertion of a PAC in patients with circulatory shock who did not respond to standard therapy. This therapeutic modification was statistically associated with better morbidity, and this was independent of the other outcomes evaluated.

Recently, a European observational study on PAC use and outcomes in the ICU was reported [10]. Compared with controlled trials, observational studies have certain advantages in that they avoid selection bias and problems relating to physician compliance, among others. The study carefully considered and corrected for all possible confounding variables. The authors adjusted for confounding variables between the PAC and non-PAC populations using multivariate regression analysis and propensity score case matching. Although ICU and hospital mortality rates were higher in patients undergoing PAC placement, its use was not an independent risk factor for 60-day mortality (multivariate analysis). In 453 propensity-matched pairs of ICU patients with or without PAC placement, ICU and hospital mortality rates were similar. Survival to 60 days was similar between the two matched groups, allowing the authors to conclude that PAC use was not associated with increased mortality in this heterogeneous population.

Five randomized trials (including two reported in 2005) examined the effectiveness of PAC use in critically ill populations [3,4,11-13]. None of these trials demonstrated an impact of PAC use on the outcome variables assessed. We summarize the results of these trials below, focusing on patient populations who may benefit from PAC use where possible. Patients enrolled in these trials suffered from cardiovascular disease, severe sepsis or septic shock, and ARDS or acute lung injury (ALI).

Rhodes and coworkers [12] randomized 201 critically ill patients to a PAC group ($n = 95$) or a control group ($n = 106$). Survival to 28 days, intensive care and hospital lengths of stay, and organ dysfunction were compared on an intent-to-treat basis. There was no significant difference in mortality between the PAC group and the control group, allowing the authors to conclude that PAC use is not associated with increased mortality. Richard and colleagues [4] conducted a multicentre, randomized controlled study of 676 patients (335 underwent PAC placement and 341 did not) who fulfilled criteria for shock or ARDS, or both. Using mortality at 28 days as the primary end-point, they found no significant differences in mortality between the two groups. They concluded that clinical management involving early use of a PAC did not significantly affect mortality or morbidity.

In the recent PAC-Man (Pulmonary Artery Catheters in Patient Management) study [13], Harvey and coworkers randomized 1041 patients from 65 UK ICUs to management with ($n = 519$) or without ($n = 522$) a PAC. Again their results

indicated no difference in hospital mortality between critically ill patients managed with or without a PAC. Although complications associated with PAC insertion were noted in 9%, none of these were fatal. The authors concluded that there was no clear evidence of benefit or harm resulting from management of critically ill patients with a PAC. They highlighted the need for efficacy studies based on management protocols involving PAC use in specific groups of patients, in order to identify whose who could benefit from management using a PAC.

Has any benefit from PAC use been demonstrated in severe heart failure? Congestive heart failure is among the most common, persistent and deadly cardiovascular diseases. PAC use in this condition varies markedly between centres, suggesting a lack of consensus on the safety and utility of this device in congestive heart failure [14]. The recent ESCAPE study [3] was conducted to test whether PAC use is safe and can improve the clinical outcome in patients with severe symptomatic and recurrent heart failure. In the ESCAPE study, a randomized controlled trial including 433 patients, therapy was guided either by clinical assessment and a PAC or by clinical assessment alone. The target in both groups was resolution of clinical congestion, with additional PAC targets of a pulmonary capillary wedge pressure of 15 mmHg and a right atrial pressure of 8 mmHg. The primary end-point was days alive out of the hospital over the first 6 months, with secondary end-points of exercise, quality of life, and biochemical and echocardiographic changes. The use of the PAC did not significantly affect the primary end-point. However, the authors did observe a trend toward greater improvement in exercise capacity and quality of life in the PAC group. In conclusion, addition of a PAC did not affect mortality or hospitalization.

Practical guidelines for use of the pulmonary artery catheter

None of the present studies found any positive impact of PAC use on outcome variables. However, prospective, randomized studies in which the PAC was used as part of a management algorithm have shown improved outcomes in high-risk surgical patients [15,16], although it should be noted that these studies did not provide an explicit protocol for care based on PAC-generated data. Assessment of a monitoring technology in a vacuum is unlikely to demonstrate benefit. Efficacy (PAC linked to explicit treatment protocols dictated by the study) cannot therefore be assessed at present.

What, then, is the evidence regarding the broader issue of PAC use in the ICU? The data collected to date do not support routine use of the PAC in any patient group, justifying withdrawal of the PAC from routine use. The only trial as yet to evaluate a strategy guided by PAC use in patients with ARDS was recently completed (results are yet to be published) [17]. The trial compared a 'fluid conservative' approach with a 'fluid liberal' strategy. If a positive result attributable to PAC is demonstrated, then a specific 'niche' for the technology may remain in critical care. If the results demonstrate no benefit, then PAC use will become limited to rescue therapy in a small number of select patients. Among these, complex cases associated more with right than with left ventricular failure within the context of ARDS secondary to severe sepsis or septic shock may benefit from guidance of therapy with PAC-derived data.

The previous consensus conference on PAC use must then be revisited in light of the most recently published trials and meta-analyses. In critical care and/or perioperative settings, two major reports must be considered: the consensus conference from the SCCM [6] and the guidelines from the American Society of Anesthesiologists [2]. The recent publication of guidelines for diagnosis and treatment of cardiac failure provides an opportunity to define better the position of PAC use in this setting as well [18].

Indications for pulmonary artery catheter use in cardiac failure

Myocardial infarction complicated by cardiogenic shock or progressive hypotension is a class I indication for PAC use in the formulated American College of Cardiology/American Heart Association guidelines [19]. This recommendation is also included in the PAC consensus conference convened by the SCCM in 1997 [6]. It is based on expert opinion, and there is no conclusive proof that PAC use improves outcomes in this patient population [6]. The SCCM consensus conference also indicated that PAC use was appropriate in patients with congestive heart failure refractory to empirical therapy.

The European Society of Cardiology guidelines [18] published in 2005 insist that invasive monitoring of patients with acute heart failure (AHF) should be initiated as soon as possible after they arrive at the emergency unit, concurrent with ongoing diagnostic measures to determine the primary aetiology. Those guidelines based on expert opinion also indicate that although PAC insertion for diagnosis in AHF is usually unnecessary, it could be used to distinguish between a cardiogenic and a noncardiogenic mechanism in complex patients with concurrent cardiac and pulmonary disease. The use of PAC is a class IIb recommendation (level C evidence) in haemodynamically unstable patients who are not responding in a predictable manner to traditional treatment, and in patients with a combination of congestion and hypo-perfusion. In these cases, the PAC is inserted to ensure optimal fluid loading of the ventricles and to guide vasoactive therapies and inotropic agents.

It is recommended that, in cardiogenic shock and prolonged severe low output syndrome, the mixed venous oxygen saturation from the PA be measured and maintained above 65% in patients with AHF [6].

Experts have stated that direct measurement of haemo-dynamics can be helpful in patients for whom the physical

examination with symptoms is unrevealing or discordant. It may be particularly useful for determining the contribution of heart failure to a complex clinical picture, such as sepsis, acute renal failure, or acute coronary syndrome, in the setting of chronic heart failure. Another common setting in which PAC insertion may be helpful is in the evaluation of dyspnoea and elevated right heart pressures in patients with concomitant pulmonary and cardiac disease.

Concerning right heart failure, catheterization of the PA is more invasive than echocardiography, but it is useful in evaluating right ventricular function and in confirming the presence of right ventricular failure in patients in the ICU [20].

Indications for severe sepsis or septic shock

Based largely on expert opinion, the consensus conference of 1997 [6] concluded that PAC use may be appropriate in patients with septic shock who are unresponsive to early resuscitative measures. Maintenance of normal haemodynamics in this group appeared to be the most appropriate goal. Research is needed to determine the proper role of the PAC in patients with sepsis or sepsis shock.

In 2004, the American College of Critical Care Medicine reported an update to their recommendations on practice parameters for haemodynamic support of sepsis in adult patients [21]. The authors of the report highlighted the principles that clinicians using haemodynamic therapies should define specific goals and end-points, titrate therapies to achieve these end-points, and evaluate the results of their interventions on an ongoing basis by monitoring a combination of variables that reflect global and regional perfusion and, if possible, the microcirculation. The assessment of cardiac filling pressures may require a central venous catheter or a PAC. With a level D recommendation, invasive haemodynamic monitoring should be considered in those patients who do not respond to initial resuscitative efforts; this monitoring should be combined with fluid infusion titrated to a goal-directed level of filling pressure associated with the greatest increase in cardiac output and stroke volume. For most patients, this will correspond to a PA occlusion pressure in the 12-15 mmHg range.

It is likely that the question of whether the PAC offers potential benefit for patients with septic shock will only be answered by a randomized, prospective trial in which both education on proper measurements and consensus treatment protocols are used.

In a case-control study, nested within a prospective cohort study, Yu and coworkers [22] examined the relationship between PAC use and patient outcomes, including mortality rates and resource utilization, in patients with severe sepsis in eight academic medical centres. They stratified a random sample of 1010 adult admissions with severe sepsis. Among patients with severe sepsis, they found that PAC placement was not associated with a change in mortality rate or resource utilization, although there was a small nonsignificant trend toward lower resource utilization in the PAC group. However, PAC use was associated with an increased risk for renal failure within 28 days after sepsis onset but not with increased risks for other complications, including ARDS, shock, disseminated intravascular coagulation, liver failure, or central nervous dysfunction.

Indications in acute lung injury/acute respiratory distress syndrome

The 1997 consensus conference convened by the SCCM [6] indicated that the optimal role of the PAC as a diagnostic and monitoring device in different types of respiratory failure has not been clearly defined. Research is needed to determine the role of the PAC in very carefully defined groups of patients with respiratory failure. The trial reported by Richard and coworkers [4] failed to find any benefit for PAC use in the subgroup of patients with ARDS.

In their retrospective study, Connors and colleagues [1] found an increased relative risk for death in the 1789 patients who had ARDS. The authors provided the following explanations for the observed lack of benefit. First, direct catheter-related complications during PAC use, such as catheter-related sepsis, might have outweighed any potential benefit of PAC placement. Second, PAC data might have been improperly obtained, leading to spurious haemodynamic profiles and resulting treatment. Finally, even if PAC data had been carefully obtained, the data may have been inaccurate and imprecise (for example, intravascular pressure values do not represent the transmural values, the only one able to inform on heart filling; tricuspid regurgitation may give inaccurate cardiac output measurements; mixed SvO_2 might be artificially high in the presence of left to right shunt. These conditions may change the accuracy even though the technique for measurement is good). Another explanation for these results was given by Richard and coworkers [4], who hypothesized that the study by Connors and colleagues might have overestimated the mortality in the PAC group because of limitations associated with retrospective matching of patients. Connors and colleagues chose to use a propensity score, but this score did not take into account the intensity of treatment used to sustain haemodynamics. This approach could have masked a greater severity of illness in the patients undergoing PAC placement. In any case, all of these possibilities will have to be evaluated in a prospective, randomized controlled trial.

Interestingly, a study addressed predictors of mortality in acute respiratory failure [23]. The authors examined a retrospective cohort study of consecutive ARDS patients admitted to two medical ICUs of tertiary care hospitals in whom two different approaches to haemodynamic monitoring were used: PAC on demand and no use of PAC. The study evaluated risk factors for death and the influence of PAC,

with adjustment to haemodynamic support as a confounding factor, in 98 patients in whom the delay between onset of ARDS, use of vasopressors and PAC placement did not exceed 48 hours. The authors identified only two independent predictors of death: an extrapulmonary cause of ARDS and need for maximal haemodynamic support with epinephrine/norepinephrine to control circulatory failure. The results did not permit detection of either a benefit or an adverse effect of invasive monitoring through the PAC. In 2003, Richard and coworkers [4] found no difference in morbidity and mortality at both 14 and 28 days.

Conclusion

PA catheterization is mostly used to define the mechanism of circulatory failure and to optimize patient management. This remains based on expert opinion, and no data exist from trials using mortality or other 'hard' outcome measures.

Since its introduction in 1970 [24], the PAC has changed the approach to haemodynamic management of patients. In recent years, PAC use has become a subject of controversy. Critics have highlighted difficulties with PAC insertion, use and data interpretation, and complications associated with the device. With respect to PAC-related serious effects, such as death, the rate is probably under 0.1% [1,25].

Pinsky and Vincent, in a recent perspective [26], pointed out that the problem not only pertains to PAC use or non-use or to interpretation of PAC data; rather, they noted that no monitoring device will improve outcomes unless it is coupled with a specific treatment plan that is known to improve outcome.

Indeed, how physicians respond to haemodynamic data is a major issue when evaluating PAC use in management of ICU patients. Jain and coworkers [27] conducted a cross-sectional survey of board-certified intensivists to address this issue. A survey questionnaire containing three medical intensive care clinical vignettes was mailed to critical care physicians. Each vignette contained PAC data and a half of the surveys contained echocardiographic information. Every respondent was asked to select one of six interventions for each vignette. The authors received 126 responses and they identified significant heterogeneity in selecting interventions based on PAC data among intensivists; the presence of echocardiographic results changed the intervention selected but did not reduced the heterogeneity.

In this context, in 2000 the US National Heart, Lung and Blood Institute and US Food and Drug Administration [14] published a workshop report. This report concluded that there is a need for collaborative education of physicians and nurses in performing, obtaining and interpreting information derived from PAC use. It also recommended that PAC use in the following areas should be given high priority for clinical trials: persistent/refractory congestive heart failure, ARDS, severe sepsis and septic shock, and low-risk coronary artery bypass graft surgery.

There remains a need for prospective randomized trials studying the effectiveness of the PAC, including a strict treatment protocol standardizing therapeutic choices according to PAC derived variables.

A prospective, randomized, multicentre trial of 'fluid conservative' versus 'fluid liberal' management of ALI and ARDS was recently completed, and the protocol is available on the internet [17]. This trial will provide real information on the efficacy of the PAC in ICU patients, because strategies will be evaluated comparing use of PAC variables versus clinical evaluation plus other haemodynamic tools.

Competing interests

DP is a consultant to Edwards Lifesciences. EG declares that he has no competing interests.

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