Managing critically ill patients with a pulmonary artery catheter

No monitoring device has polarized opinion as much as the pulmonary artery catheter. This review will describe the history and the reasons for much of the controversy surrounding this device, and then go on to discuss the available evidence.

With the possible exception of electronic fetal monitoring, no monitoring device has polarized opinion as much as the pulmonary artery catheter (PAC) (Robin 1987, 1988; Dalen and Bone, 1996; Pulmonary Artery Catheter Consensus Conference, 1997; Vincent et al, 1998), a device used to monitor the cardiovascular system in both perioperative and severely ill patients.

The first pulmonary artery catheterization in man was carried out by Andre Cournand in 1944 in a laboratory setting using X-ray guidance to position the catheter. Twenty years later, Bradley and Branthwaite undertook the first pulmonary artery catheterization at the bedside using a thermodilution technique to measure cardiac output (Bradley 1964; Branthwaite and Bradley, 1968; Jenkins et al, 1970). The use of the PAC at the bedside was further enhanced by the introduction of the balloon 'flotation' catheter by Swan, Ganz and their colleagues (Swan et al, 1970) which facilitated its placement by allowing the catheter to be 'floated' through the right heart into its correct position. This balloon-tipped catheter became commercially available soon afterwards and as a result the PAC is often referred to as the Swan–Ganz catheter.

Insertion and use

The catheter is usually inserted into the subclavian vein or the internal jugular vein and advanced, by means of a small air-filled balloon at its tip, through the superior vena cava, right heart and into the pulmonary artery. The PAC continues to be advanced until it finally 'wedges' in a branch of the pulmonary artery. The pulmonary vasculature downstream from the occlusion acts as a conduit and transmits the left atrial pressure to the catheter tip. The balloon is then deflated, and only inflated briefly to record the wedge pressure, or more correctly, the pulmonary artery occlusion pressure. If the pulmonary vasculature is normal, this reading corresponds with left atrial filling pressure, which reflects left ventricular filling pressure. With the balloon deflated, pulmonary artery pressures are measured continuously at the tip.

Cardiac output (strictly pulmonary blood flow) can be determined using a thermodilution technique, whereby injectate of a bolus of cold fluid upstream is detected by a thermistor at the tip of the catheter. More recently, a modified PAC provides 'continuous' cardiac output measurement by using heat coils to generate pulses of heat upstream to the thermistor. If blood pressure and heart rate are recorded simultaneously, a comprehensive set of primary and calculated variables can be generated to describe the functioning of the cardiovascular system. These data can then be used to select and modify treatment.

Management of patients in critical care using PACs

The PAC was initially used for diagnostic purposes in cardiac catheterization laboratories but with the introduction of the balloon-tipped catheter, the technique moved into the intensive care unit (ICU) where it was increasingly used to guide therapy. As Dalen and Bone (1996) noted in an editorial, the benefits of the PAC seemed obvious at the time and randomized controlled trials (RCTs) were not performed to evaluate the benefits and safety of the procedure. Thus, pulmonary artery catheterization gradually became accepted as a gold standard method to measure cardiac output. It also gave critical care doctors, cardiologists and anaesthetists their own special tool providing data not generally available to others.

In its heyday during the 1980s and 1990s, the PAC was used extensively in a variety of clinical settings – more than 1.5 million catheters per year worldwide. However, doubts about its safety began to surface with suggestions from small retrospective studies that PAC use could actually be causing harm (Gore et al, 1987; Zion et al, 1990). This led critics to argue for a moratorium on its use until prospective studies were carried out (Robin, 1987, 1988). An attempt was made in Canada

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to conduct an RCT but it had to be abandoned prematurely because of poor recruitment resulting from lack of equipoise among clinicians (Guyatt, 1991).

In 1996 a landmark article by Connors et al (1996) shook the critical care establishment to its core. This large retrospective study interrogated an existing database of patients from five USA ICUs collected for a study on end-of-life decision making. Using sophisticated statistical techniques they compared outcomes in patients receiving a PAC during their first 24 hours in the ICU with controls matched for severity of illness. The authors reported higher odds of dying before discharge from hospital in the PAC group (odds ratio 1.39, 95% confidence interval 1.15–1.67) (Connors et al, 1996).

Their results fiercely reignited the debate about the utility and safety of the PAC. Proponents argued for its unique ability to allow accurate measurement of cardiac output and other haemodynamic variables, enabling improved diagnosis and management of circulatory instability (Pulmonary Artery Catheter Consensus Conference, 1997; Vincent et al, 1998). Critics, on the other hand, pointed to complications associated with its insertion and use (Coulter and Wiedmann, 1999; Bowdle, 2002), inaccuracies in measurement and poor interpretation of data (Iberti et al, 1990, 1994; Gnaegi et al, 1997). The lay media picked up on the study, with predictably lurid headlines (Winslow, 1996). This led the US Society of Critical Care Medicine (SCCM) (Hoyt, 1996) to challenge the conclusions of this non-randomized study with an immediate and forceful rebuttal.

In December 1996, the SCCM convened a multidisciplinary consensus conference on the PAC and the subsequent consensus statement identified that the level of published evidence to support the use of PACs was both paltry and scientifically lacking. Even so, the authors of the consensus statement came out in support of its continuing use (Pulmonary Artery Catheter Consensus Conference Participants, 1997). In an accompanying editorial, Fink (1997) was struck by 'a sense of cognitive dissonance' as to how these recommendations could be made. Nevertheless, the Connors et al (1996) study proved to be a pivotal turning point as it created the necessary uncertainty within the critical care community to enable RCTs to be conducted.

What's the evidence to support the use of PACs in critical care?

Two meta-analyses of PAC trials have been conducted recently; one is due to be published soon in the Cochrane Library (Harvey et al, 2001) and the other was published in *Journal of the American Medical Association* (Shah et al, 2005). The former was a systematic review of the literature (to end-November 2003) using the Cochrane Collaboration methods (Harvey et al, 2001) to identify RCTs (any language) where patients were allocated to be managed with a PAC (of any type) in one arm, or to be managed without a PAC in another (control) arm. The search was restricted to studies that involved adult patients (aged 16 years and above), where placement of the PAC occurred in an ICU or during a surgical procedure leading to admission to an ICU, and had included measures of mortality and/or length of stay in ICU or hospital. Eleven published studies fulfilled the criteria for inclusion in the review. In addition, two multicentre RCTs which were ongoing at the time of the literature searches have since been published (Binanay et al, 2005; Harvey et al, 2005) and have been included in the current article.

The studies fell broadly into those investigating critically ill patients (n=5), and those studying patients undergoing high-risk major surgery with or without preoperative optimization of haemodynamics (n=8). The latter meta-analysis (Shah et al, 2005) combined both groups together but the authors felt that it was more instructive to view the groups separately.

A summary of the five RCTs conducted on patients in intensive or coronary care (Guyatt, 1991; Rhodes et al, 2002; Richard et al, 2003; Binanay et al, 2005; Harvey et al, 2005) is presented in *Table 1* with the main results presented in *Table 2*. The earliest of these RCTs was discontinued prematurely after only 33 patients had been enrolled as a result of the lack of equipoise and excessive cross-over from the control group (Guyatt, 1991). Ten years on, Rhodes et al (2002) reported the results of a single-centre study which enrolled 201 patients with predominately septic or cardiogenic shock. No statistically significant difference was found in 28-day mortality between patients managed with and without a PAC. This was followed by two larger multicentre trials – one involving patients with sepsis and/or acute respiratory distress syndrome from 26 French ICUs (Richard et al, 2003), the other enrolling a broad range of critical care patients from 65 UK ICUs – the PAC-Man Study (Harvey et al, 2005). Both trials found no statistically significant difference in either 28-day or hospital mortality.

In addition to the trials above, another study (ESCAPE; Evaluation study of congestive heart failure and pulmonary artery catheterization effectiveness) has been published (Binanay et al, 2005). This trial was restricted to patients with cardiac failure and enrolled 433 patients from 26 experienced heart failure centres in the USA and Canada. The use of the PAC did not affect the primary end point of days alive out of hospital during the first 6 months.

The second group of studies investigated the effectiveness of managing patients undergoing high-risk surgery with a PAC, with subsequent admission to an ICU postoperatively. Of these, three compared haemodynamic monitoring using either a PAC or a central venous pressure (CVP) catheter during the perioperative period (Pearson et al, 1989; Isaacson et al, 1990; Joyce et al, 1990). All were small, single-centre studies conducted in

the USA, and all found that perioperative monitoring with a PAC did not reduce mortality or morbidity.

The remaining five trials investigated preoperative optimization of haemodynamics guided by a PAC, using treatment protocols to achieve physiological goals to maximize cardiac output and oxygen delivery (Shoemaker et al, 1988; Berlauk et al, 1991; Bender et al, 1997; Valentine et al, 1998; Sandham et al, 2003). Patients allocated to the control group received standard preoperative care without the use of a PAC. None found statistically significant differences between PAC and control groups in terms of mortality or hospital length of stay, although the majority were underpowered.

Shoemaker et al (1988) did, however, report a significant outcome benefit in a PAC group randomized to receive a management protocol targeting specified values of cardiac index, oxygen delivery and consumption, but no benefit in the PAC group who were not 'goal-directed'. Only one of the trials above involved more than one centre, with 1994 patients enrolled from 19 Canadian hospitals (Sandham et al, 2003). They found no difference in hospital mortality, however, this study has been subsequently criticized because pre-defined goals for cardiac index and oxygen delivery were not met in many of the patients and volumes of fluid given in the two groups were not reported.

In addition to the Shoemaker et al (1988) study mentioned above, other trials have reported improved outcome for surgical patients undergoing goal-directed therapy guided by a PAC. These were excluded from the systematic review either because some or all of the control patients were managed on a general ward rather than the ICU following surgery, e.g. Wilson et al (1999), or because the control group were allocated to receive a PAC but without therapy to achieve specific haemodynamic goals, e.g. Boyd et al (1993). A meta-analysis of haemodynamic

Table 1. Randomized controlled trials that have evaluated pulmonary artery catheters in the management of general intensive care patients

Study	Selection criteria	Outcomes	Eligible (*n*)	Randomized (*n*)	Crossovers/ withdrawals (*n*)	Included in analysis (*n*)
Guyatt (1991)	**Inclusion:** Assisted ventilation; hypotension with CVP >10cm H_2O; oliguria with CVP >10cm H_2O; oliguria with hypoxaemia; hypoxaemia and CVP <10cm H_2O; physician believed patient might benefit from a PAC **Exclusion:** PAC ethically contraindicated; PAC an ethical imperative; PAC placed preoperatively for intraoperative monitoring; organ transplant surgery; receiving high frequency jet ventilation; consent from a close relative not obtained	Mortality (not defined) ICU length of stay	148	PAC: 16 Control: 17	PAC: 0/0 Control: 8/0	PAC: 16 Control: 17
Rhodes et al (2001)	**Inclusion:** Circulatory shock-heart rate >100 beats/min, systolic BP <100 mmHg, unresponsive to 500 ml fluid challenge; oliguria-urine output <0.5 ml/kg/hr despite 500 ml fluid challenge; requirement for vasoactive infusion; need for mechanical ventilation **Exclusion:** Less than 18 years of age; admitted to ICU for preoperative optimization	Primary: 28-day mortality Secondary: Included ICU and hospital length of stay	202	PAC: 96 Control: 106	PAC: 0/0 Control: 0/1	PAC: 96 Control: 105
Richard et al (2004)	**Inclusion:** patients that met criteria for shock (less than 12 hours), acute respiratory distress syndrome (more than 24 hours), or both (criteria reported in paper) **Exclusion:** Less than 18 years old; haemorrhagic shock; myocardial infarction complicated by cardiogenic shock requiring re-vascularization; thrombocytopenia; participated in other trials within last 30 days; moribund; clinician refused to agree with use of full life support	Primary: 28-day mortality Secondary: Included ICU and hospital length of stay	Not reported	PAC: 338 Control: 343	PAC: 8/3 Control: 15/2	PAC: 335 Control: 341
Harvey et al (2005) (PAC-Man)	**Inclusion:** Patients deemed to require management with PAC by the treating clinician **Exclusion:** Less than 16 years old; admitted to ICU with a PAC already in situ; admitted to ICU for preoperative optimization; previously enrolled into the trial; undergoing haemodynamic optimization before organ donation	Primary: Hospital mortality Secondary: Included ICU and hospital length of stay	1,263	PAC: 519 Control: 522	PAC: 33/13 No PAC: 24/14	PAC: 506 Control: 508
Binanay et al (2005) (ESCAPE)	**Inclusion:** Sufficently ill with advanced heart failure to make use of a PAC reasonable but sufficiently stable to make crossover to PAC for urgent management unlikely; severity before admission met by following criteria: 1) hospitalization for heart failure within the past year; 2) urgent visit to the emergency department; or 3) treatment during the preceding month with >160 mg of furosemide daily (or equivalent). Randomization required at least 3 months of symptoms despite angiotensin-converting enzyme inhibitors and diuretics; left ventricular ejection fraction ≤ 30%, systolic BP ≤ 125 mmHg; at least one sign and one symptom of congestion **Exclusion:** Creatinine >309 µmol/litre; before use of dobutamine or dopamine >3 µg/kg/min, before use ofmilrinone during current hospitalization	Primary: Days alive outside hospital during the first 6 months Secondary: Included length of stay for initial hospitalization	Not reported	PAC: 215 Control: 218	PAC: 17/4 Control: 21/2 Note: 5 PAC and 9 control patients lost to follow up of primary end point	PAC: 206 Control: 207

BP = blood pressure; CVP = central venous pressure; ESCAPE = Evaluation Study of Congestive heart failure and Pulmonary artery catheterization Effectiveness; ICU = intensive care unit; PAC = pulmonary artery catheter

Table 2. Main results of RCTs that have evaluated PACs in the management of general intensive care patients

Study	Group	Mortality	Measure of effect (if given) *P*	ICU length of stay (days) Survivors	*P*	Non-survivors	*P*	Hospital length of stay (days) Survivors	*P*	Non-survivors	*P*
Guyatt (1991)		Not defined		Mean							
	PAC	10/16 (63%)	*P*=0.58	10.3	0.58	Not reported		Not reported		Not reported	
	Control	9/17 (53%)		8.1		Not reported		Not reported		Not reported	
Rhodes et al (2001)		28-day		Median (IQR)		Median (IQR)		Median (IQR)		Median (IQR)	
	PAC	46/96 (47.9%)	*P*=>0.99	10 (2, 14)	0.27			29 (15, 54)	0.81		
	Control	50/105 (47.6%)		6 (2, 13)		Not reported		25(15, 53)			
Richard et al (2004)		28-day	RR (95% CI)	All, mean (SD)						All, mean (SD)	
	PAC	199/335 (59.4%)	0.97 (0.96–1.10)	11.6 (10.1)			0.72			14.0 (11.6)	0.67
	Control	208/341 (61.0%)	*P*=0.67	11.9 (10.0)						14.4 (11.3)	
Harvey et al (2005) (PAC-Man)		Hospital	HR (95% CI)	Median (IQR)		Median (IQR)		Median (IQR)		Median (IQR)	
	PAC	346/506 (68.4%)	1.09 (0.94–1.27)	12.1 (6.2–22.3)	0.26	2.6 (0.7–8.4)	0.71	34 (23–61)	0.43	3 (1–11)	0.90
	Control	333/507 (65.7%)	*P*=0.26	11.0 (5.7–21.0)		2.5 (0.8–7.2)		40 (21–70)		3 (1–11)	
Binanay et al (2005) (ESCAPE)		180-day	OR (95% CI)					Mean			
	PAC	43/209 (20.5%)	1.26 (0.78–2.03)					8.7		Not reported	
	Control	38/212 (17.9%)	*P*=0.35					8.3		Not reported	

CI=95% confidence interval; ESCAPE=Evaluation Study of Congestive heart failure and Pulmonary artery catheterisation Effectiveness; HR=hazard ratio; ICU=intensive care unit; IQR=inter-quartile range; OR=odds ratio; PAC=pulmonary artery catheter; RCT=randomized controlled trial; RR=relative risk

optimization in high-risk patients by Kern and Shoemaker (2002) divided studies into those reporting control group mortalities of either greater than 20% or less than 15%, and then subdivided them into those where PAC-directed 'optimization' occurred before or after the onset of organ failure. No survival benefit was seen with goal-directed therapy in the eight low mortality studies cited. However, in the 13 studies with high-control mortality rates, they reported an overall 23% reduction in mortality ($P<0.05$) where PAC-directed optimization occurred before the onset of organ failure ($n=6$ studies), but no difference when optimization was attempted after organ failure was established ($n=7$ studies).

Where now for the PAC?

All RCTs conducted to date refute the findings by Connors et al (1996) that management with a PAC worsens outcome in critically ill patients. The lack of overall benefit of PAC use in general intensive care patients could be variously explained by statistical chance, by inappropriate use, by technical errors in measuring and displaying haemodynamic variables, by misinterpretation of PAC-derived data, or by correct interpretation of data but formulation of ineffective treatment plans. Indeed, it is conceivable that the current paradigm by which haemodynamic data derived from a PAC are applied may be incorrect, or that there is no additional advantage to be gained from a more detailed knowledge of haemodynamics, however applied. The results of the Kern and Shoemaker (2002) meta-analysis suggested outcome benefit when the PAC was used to direct protocolized haemodynamic interventions in high-risk surgical patients, but not when commenced in critically ill patients with established multiple organ failure and a high predicted risk of death. Studies suggest that multiorgan failure is associated with bioenergetic failure secondary to mitochondrial inhibition (Brealey et al, 2002), thus a belated attempt to improve the macrocirculation may prove ineffective (Gattinoni et al, 1995) or even harmful (Hayes et al, 1994).

None of the trials described above examined quality of use. Previous studies have highlighted high levels of ignorance in terms of correct waveform recognition and data interpretation among both ICU doctors (Iberti et al, 1990; Gnaegi et al, 1997) and nurses (Iberti et al, 1994). The PAC-Man Study (Harvey et al, 2005) found no outcome difference comparing units with high and low historical frequency of use, although this is likely to be a poor surrogate for quality of use. Several studies have also reported increased rates of complications associated with PAC use, including arterial puncture, haemothorax, arrhythmias and conduction disturbances, and pulmonary embolus (Richard et al, 2003; Sandham et al, 2003; Harvey et al, 2005).

In recent years, the supremacy of the PAC has been challenged by the advent of less invasive technologies to monitor cardiac output. The increasing availability of sophisticated and less-invasive diagnostic technologies, such as transoesophageal Doppler ultrasonography and lithium dilution, may lead to these devices gradually replacing the PAC in clinical use, particularly as their ease of insertion may result in earlier use. However, whether they can produce a survival advantage in the critically ill remains to be determined. The option to use such alternative devices in control group patients was permitted in the PAC-Man Study, given the marked increase in their use within the NHS in recent years (Neill et al, 2004). Forty-eight of the 65 (73.8%) par-

ticipating ICUs chose to have this option, thus preventing a meaningful comparison of management with a PAC against no cardiac output monitoring. There was no evidence of interaction between the treatment effect and the use or not of an alternative cardiac output monitoring device, however, the statistical power of such tests is low. There still remains a need for formal evaluation of these less invasive monitoring devices in the critically ill.

Future research

The negative results of the pragmatic randomized studies performed to date in critically ill patients underline the fact that simple insertion of a PAC without a clearly defined management plan is unlikely to produce an outcome benefit. Indeed, critics point to the fact that management of patients randomized to receive PAC was always at the discretion of the treating clinician. Although PACs have been used to manage critically ill patients for more than 30 years, to this day there remains no consensus on specific patient management protocols, such as timing or indications for catheter insertion, selection and manipulation of specific drugs, fluids and support devices, and haemodynamic endpoints. As a result, none of the trials used standardized treatment protocols as part of the intervention.

Future research should thus focus on establishing whether monitoring cardiac output and other haemodynamic variables, using any of the available devices, improves outcomes for critically ill patients within a package of care. There is a pressing need to determine optimal management protocols for circulatory management, including targeted end-points for blood pressure, oxygen delivery, fluid and inotrope therapy, and to see whether these apply equally in the high-risk surgical patient, the patient presenting with sepsis or other critical illness, and those in established organ failure.

The PAC should be assessed in specific patient groups using well-defined treatment protocols. This process has already started with the ESCAPE trial (Binanay et al, 2005) which focused on patients with severe cardiac failure. In addition, the Fluid And Catheter Treatment Trial (FACTT), recently completed in the USA by the ARDSNet group but not yet published, used a 2x2 factorial study design to separate the effects of the PAC itself (PAC *vs* central venous catheter) and the treatment protocol (liberal *vs* conservative fluid management strategy) in patients with acute lung injury and/or septic shock.

Although new cardiac output monitoring devices are becoming increasingly popular, not all clinicians are convinced; many point to the lack of evidence, while others still regard pulmonary artery catheterization as a gold standard method. As with PACs, studies of these new devices in well-defined patient groups with clear treatment plans are urgently needed to prevent the same situation that has occurred with the PAC, namely widespread use and acceptance in the absence of effectiveness data. Multiple single-centre perioperative studies using alternative cardiac output monitoring devices have shown outcome benefit when the devices were used to optimize fluid administration or target elevated levels of oxygen delivery either during or immediately after cardiac surgery (Mythen and Webb, 1995; Polonen et al, 2000; McKendry et al, 2004), orthopaedic surgery (Sinclair et al, 1997; Venn et al, 2002) or other high-risk surgery (Gan et al, 2002; Pearse et al, 2005; Wakeling et al, 2005). Similar multicentre studies need to be conducted in the critical care environment.

Conclusions

The Connors et al (1996) study coupled with the advent of less invasive monitoring has hastened the declining use of PAC in critical care. The results of recent clinical trials will no doubt accelerate this trend further. However, before the PAC does become a redundant technology, there is an urgent need to evaluate the utility of cardiac output monitoring, using any of the available devices, for guiding therapy using well-defined management protocols. **BJHM**

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KEY POINTS

- The pulmonary artery catheter is a device used to monitor the cardiovascular system in perioperative and critically ill patients.
- The device was introduced into critical care about 30 years ago without any evaluation as to its clinical effectiveness for managing critically ill patients.
- Randomized controlled trials conducted recently have demonstrated that the use of pulmonary artery catheters neither improves nor worsens outcome in critically ill patients.
- The introduction of alternative, less invasive cardiac output monitoring devices have, in part, led to decreased use of pulmonary artery catheters in recent years.
- There is an urgent need for clinical trials to establish the utility of monitoring cardiac output in critically ill patients, using a pulmonary artery catherter or any of the alternatives, for guiding therapy using well-defined treatment protocols.

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