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EDITORIAL

PA catheter-guided therapy does not benefit critically ill patients

In 1970, Swan et al[1] introduced a flow-directed catheter that permitted catheterization of the pulmonary artery (PAC) at the bedside, thus permitting measurement of right heart pressures, "wedge pressure"[2] as a surrogate of left ventricular filling pressure, and cardiac output. When the PA catheter was left in place, it became possible to perform continuous hemodynamic monitoring in critically ill patients.

Soon the standard practice in coronary care units was to use hemodynamic monitoring to select and adjust therapy in patients with acute myocardial infarction (AMI) complicated by heart failure, hypotension, or cardiogenic shock. PAC-guided therapy also became the standard of care for other critically ill patients. A textbook of critical care in 1997 stated, "PAC is responsible for the specialty of critical care".[3] The benefits of PAC in critically ill patients seemed self-evident; randomized clinical trials (RCTs) to determine its risks and benefits were not performed.

In 1987, Gore et al.[4] reported an observational study of 3263 patients hospitalized with AMI from 1975 to 1984, 14% of whom underwent PAC. They could find no evidence that PAC-guided therapy decreased mortality when used in patients with CHF, hypotension, or cardiogenic shock. In fact, the case fatality rate and length of stay were greater in those undergoing PAC. This nonrandomized observational study showed no evidence of any benefit of PAC in patients with AMI.

In 1990, Zion et al.[5] reported an observational study of 5481 patients with AMI. As with the Gore study,[4] Zion et al.[5] found no evidence that PAC benefited patients with AMI. The case fatality rate was higher in those undergoing PAC. An editorial accompanying that report suggested that randomized clinical trials should be performed to determine the benefits and risks of PAC in patients with AMI.[6]

Randomized trials of PAC in AMI have still not been reported; however, in this issue of the journal, Cohen et al.[7] report the results of a large (26 437 patients) observational study of patients treated for acute coronary syndromes in 2 international clinical trials from 1994 to 1997. PAC was performed in 2.8% of the patients. Mortality, adjusted for baseline variables and for subsequent events that may have led to PAC use, was substantially higher in those who received PAC.

These 3 observational studies of more than 35 000 patients with AMI failed to demonstrate any benefit from PAC and in fact they suggested harm, as evidenced by increased case fatality rates in those undergoing PAC.

A critical study of the effectiveness of right heart catheterization (RHC) in the care of critically ill patients was reported by Connors et al. in 1996.[8] This prospective cohort study included 5735 critically ill patients with 1 of 9 specific disease categories. Case-matching and multivariate regression modeling were used to estimate the association of RHC with specific outcomes. Thirty-day mortality, ICU length of stay, and hospital length of stay were greater in those patients undergoing RHC. Subgroup analyses did not reveal any patient group that benefited from RHC. The authors suggested that the increased mortality in those undergoing RHC may have been due to a more aggressive style of therapy in patients undergoing RHC.

An editorial[9] accompanying the Connors article[8] recommended that the National Heart, Lung, and Blood Institute (NHLBI) should initiate RCTs to determine the benefits and risks of PAC in critically ill patients. The editorial recommended that if such RCTs were not initiated, the FDA should issue a moratorium on the use of PAC. The latter suggestion evoked a rapid response! The Society of Critical Care Medicine[10] released a press statement that said, "To not make right heart catheterization available could potentially endanger the lives of thousands of patients facing life-threatening illness or injury." However, the Society of Critical Care Medicine did agree with the need for RCTs. A joint statement from the American College of Chest Physicians and the American Thoracic Society[11] stated that there was no basis for a moratorium on the use of PAC. However, both organizations agreed with the need for RCTs to determine the risks and benefits of PAC.

In 1997 the NHLBI and the FDA convened a special workshop on PAC and its clinical outcomes. They recommended that RCTs be performed to determine the safety and effectiveness of PAC in patients with severe/refractory CHF, patients undergoing low-risk coronary artery bypass grafting (CABG), patients with acute respiratory distress syndrome (ARDS), and severe sepsis/septic shock.[12]

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Table 1 Studies of the benefits and risks of PAC

Study, date	Type of study	Patients	Benefits	Risks
Acute coronary syndrome				
Gore, 1987[4]	Observ	3623	None	Increased mortality
Zion, 1990[5]	Observ	5481	None	Increased mortality
Cohen, 2004[7]	Observ	26 437	None	Increased mortality
Critically ill ICU patients				
Connors, 1996[8]	Observ	5735	None	Increased mortality
Rhodes, 2002[15]	RCT	201	None	None
Patients undergoing major noncardiac surgery				
Polanczyk, 2001[13]	Observ	4059	None	Increased cardiac complications
Sandham, 2003[16]	RCT	1994	None	Increased PE
Refractory congestive heart failure				
Shah, 2004[19]	RCT	433	None	None
ARDS/shock				
Richard, 2003[17]	RCT	676	None	None

Observ = observational trial; RCT = randomized clinical trial; PE = pulmonary embolism.

While many of the recommended RCTs were underway, Polanczyk et al.[13] reported an observational study of 4059 patients undergoing high risk noncardiac surgery. When the 5.4% of patients who underwent PAC were matched with comparable patients who did not receive PAC, they could not find evidence of the benefit of PAC. The incidence of postoperative cardiac complications was higher in those who underwent PAC, suggesting potential harm. An editorial accompanying the Polanczyk article again stressed the need for RCTs of PAC, especially in patients with ARDS and refractory CHF.[14]

In addition to the multiple observational studies of the risks and benefits of PAC,[4,5,7,8,13] we now have available the results of 4 RCTs[15-17,19] on the use of PAC in critically ill patients, as shown in Table 1.

Rhodes et al.[15] reported the results of 201 critically ill ICU patients who were randomized to PAC or no PAC. The mortality was the same in both groups; there was no evidence of benefit or harm.

In a much larger RCT, Sandham et al.[16] randomized 1994 high-risk surgical patients age 60 or older who required postoperative intensive care. The in-hospital mortality and the 6-month survival rate were the same for patients who did and did not receive a PAC. The incidence of postoperative pulmonary embolism was higher in those who received PAC.

The benefits and risks of PAC in patients with acute respiratory distress syndrome, with or without shock, was reported by Richard et al.[17] Six hundred and seventy-six patients in 36 ICUs in France were randomized to PAC or no PAC. There was no difference in mortality or morbidity. An NHLBI RCT of PAC in patients with ARDS, the Fluid and Catheter Treatment Trial (FACTT) is still underway.[18]

The most recent RCT of the use of PAC, the NHLBI-sponsored Evaluation Study of Congestive Heart Failure and Pulmonary Artery Catheterization Effectiveness (ESCAPE) trial, was reported by Shah et al.[19] A total of 433 patients with decompensated heart failure were randomized to receive or not receive PAC. There was no evidence that PAC was of benefit. The 30-day and 6-month mortality were the same, and there was no difference in complications, adverse events, or clinical outcomes.

None of these 4 long-awaited RCTs[15-17,19] found evidence that PAC benefits critically ill patients.

What have we learned since PAC was introduced 35 years ago[1] and since its efficacy and safety were first questioned nearly 20 years ago?[4] We have found no evidence that PAC benefits patients with acute coronary syndromes,[4,5,7] patients with refractory CHF,[19] patients undergoing major noncardiac surgery,[13,16] those with ARDS,[17] or critically ill ICU patients.[8,15]

Many studies have found a higher mortality in those undergoing PAC.[4,5,7,8,13] Because the PAC procedure itself has few major complications, any increased mortality must be attributed to the risks of the therapy that is PAC guided. It has been suggested that PAC-guided therapy is more aggressive, leading to a more frequent use of inotropic agents that may increase mortality.[7,8,14]

To me, the bottom line is this. PAC-guided therapy is an invasive, expensive procedure that has not been shown to benefit critically ill patients and may lead to therapy that can increase mortality. How do we justify its continued use?

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