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Review Article

The evolution and current use of invasive hemodynamic monitoring for predicting volume responsiveness during resuscitation, perioperative, and critical care☆,☆☆,★

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Abstract Traditional hemodynamic monitors such as pulmonary artery and central venous catheters provide continuous data and secure intravenous access, but their diagnostic efficacy has been criticized. Dynamic arterial waveform monitoring is promising, but studies suggest it is reliable only within narrow ventilation and rhythm parameters. Newer algorithm-based hemodynamic monitors have emerged; they, too, are limited in their accuracy and applicability. Intravascular monitors are used to predict fluid responsiveness and need for alternative therapies, such as vasomotor or inotropic support. Recent efficacy data, along with other important clinical findings, are reviewed with regard to invasive monitors. We caution against over-generalizing from existing studies, and provide guidance for clinicians wishing to target monitoring techniques for appropriate patients.

1. Part 1. The pulmonary artery catheter

The December 13, 1973 issue of the *New England Journal of Medicine* led off with an article by Crexells et al that included H.J.C. Swan [1]. They used a then-novel balloon-tipped pulmonary artery catheter (PAC) to show that post-myocardial infarction cardiac performance increased with volume administration until the pulmonary artery occlusion pressure (PAOP) reached 15 mmHg. Beyond that, additional fluid decreased cardiac performance, caused pulmonary edema, and increased work of breathing. The

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group also found that right ventricular (RV) performance plateaued when right atrial (RA) pressure reached 8 mmHg. Acting on this information, the Crexells et al group infused volume to patients with low filling pressures and administered diuretics to those who were congested [1]. The possibility that clinicians would use a bedside catheter to derive individual patients' Starling curves and act on these repeated real-time estimates proved to be very attractive to intensivists, cardiologists, anesthesiologists, and surgeons. The PAC would come to be called the Swan-Ganz catheter, and the Swan-Ganz catheter would come to define a large part of the management of critically ill patients [2].

The publication that first weakened the PAC's hold was a 1996 retrospective case-controlled JAMA study of 5,735 mixed critically ill patients that associated the catheter with increased mortality, hospital length of stay, and costs [2,3]. The accompanying editorial called for National Institute of Health (NIH) sponsorship of a prospective randomized controlled trial (RCT), and failing that, a Food and Drug Administration (FDA) moratorium on use of the PAC outside the catheterization lab [4]. This led to a series of RCTs, which failed to find mortality benefit in critically ill patients with congestive heart failure (CHF) [5], high-risk surgery [6], acute respiratory distress syndrome (ARDS) [7], and other common critical illnesses [8].

These studies have had a great influence on current opinion [9] and, more important, they have translated into less PAC use in both medical and surgical settings [10]. Critics of the trials have responded that the goals and methodology, considered by individual study or as a group, are flawed and have generated a greater-than-justified repudiation of the device. First, they note that the PAC is a monitor, not a therapy, and as such does not independently cause benefit or harm [11,12]. Pulmonary artery catheter-related outcomes are mediated by clinicians' ability to competently interpret and act on a stream of hemodynamic data, and several skill assessment studies have found that many who use the PAC make errors [11-14]. In addition, few if any monitoring devices that we routinely employ are justified if held to the morbidity and mortality reduction standard of the PAC studies. Pulse oximetry is a key component of sweeping changes in care that correlated historically with a massive reduction in anesthesia-related mortality [15], but pulse oximetry for perioperative monitoring itself has not been proven to reduce perioperative mortality [16].

Another critique is that these studies are flawed by the inclusion of too many relatively stable or physiologically straightforward patients [11,12], who would have been unlikely to benefit from the device [11,12,17]. In contrast, physiologically complex patients with comorbidities commonly seen in critical care settings were excluded from key studies, as were many patients judged by individual clinicians to be too sick or complex to be randomized. In the landmark *New England Journal of Medicine* high-risk surgery study [6], 87% of patients were classified as ASA physical status 3, patients for whom expected operative mortality is too low to permit an adequately powered trial [18]. The ESCAPE CHF trial excluded patients receiving more than 3.0 μg/kg/min of dopamine or dobutamine, or any milrinone at enrollment, and non-randomized PAC patients were sicker than randomized ones [5]. The FACTT (Fluids and Catheters Treatment) trial, which used complex methodology to evaluate both PAC use and conservative versus liberal fluid strategies in ARDS, had very restrictive exclusion criteria [7]. The trial enrolled patients with bilateral pulmonary edema "…without evidence of left atrial hypertension…." Exclusion criteria included "...severe chronic respiratory disease....", pregnancy, patients with "…burns > 40% body surface area…", patients "...requiring renal replacement therapy....", and patients with "...severe chronic liver disease (Child-Pugh score of 10-15)...." [19] Also excluded were patients whose physicians refused randomization and those patients who already had a PAC by the mean study enrollment times of 41 and 43 hours after ICU admission. Of the 11,512 patients screened, only 1,001 were enrolled [7].

The PAC-Man (*Pulmonary Artery Catheters in Patient Management)* trial, performed between 2001 and 2004 in the United Kingdom, provides the strongest evidence to date that then-current physician preference-driven PAC use conferred neither benefit nor harm to a broadly defined ICU population. Clinicians selected patients they thought might derive benefit from PAC monitoring, and contacted a 24-hour hotline for randomization. The only exclusion criteria were age < 16 years, elective admission for preoperative optimization, optimization for organ donation, and preenrollment PAC use. Of the 1,263 eligible patients, 1,053 were randomized. The device had no effects on mortality, ICU or hospital stay, or any important endpoint. To evaluate PAC use as it would occur in a mix of practice settings, the trial enrolled patients from any adult ICU in the UK that wished to participate [8].

Just as intention-to-treat methodology strengthens therapeutic studies by accounting for patient interaction with the study agent (ie, compliance), PAC-Man accounted for provider-driven device selection, data interpretation, and therapeutic decision making typical of everyday clinical practice. Pulmonary artery catheter measurements are subject to significant operator error [13,14] and physiologic variation [20] that complicate interpretation and response. These problems undoubtedly feed back into trial outcomes, but one would also expect them to occur in practice. Ease of use, need for familiarity, and individual clinician competence should be considered in device selection because studies suggest that these variables affect outcome [11-14].

Less familiar studies have questioned the technical reliability of PAC-derived data. For example, clinical [21] and experimental [22] studies of patients with filling pressures near those highlighted by Crexells et al's group [1], have shown that single measurements of PAOP predicted volume responsiveness less precisely than other