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EDITORIAL

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PA catheterization – quo vadis?

Do we have to change the current practice with this monitoring device?

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The recent report by Connors et al. [1] that attempts to address the effectiveness of pulmonary artery catheterization (PAC) in critically ill patients and, especially, the accompanying editorial [2] have provoked considerable discussion and uncertainty both in the medical community and the public. The data was obtained from the SUPPORT (Study to Understand Prognoses and Preferences of Outcomes and Risks of Treatment), which was not primarily designed to investigate the utility of PAC monitoring but rather the process and improvement of decision-making in critically ill patients. There were 5,732 patients enrolled in five US medical centres of whom 2184 had a PAC placed. The principle findings of the study were that patients receiving PAC within the first 24 h of initial care had a slightly, but significantly, higher 30-day mortality rate (odds ratio 1.24, 95% confidence interval 1.03–1.49) and increased utilization of resources. These findings were apparent after a "propensity" adjustment, which the Connors article describes as correcting for discretionary factors which might influence clinicians in placing PACs. This had the effect of providing 1006 pairs of patients for analysis, who were apparently well matched for severity of illness. The study has several potential flaws and these limitations are acknowledged by the authors, especially the fact that this was an observational study rather than a randomized clinical trial. One conclusion of the authors was that such a randomized prospective trial is necessary. Patients monitored with a PA catheter had significantly higher APACHE III scores and a lower 2-month survival probability as well as a higher rate of therapeutic interventions as measured by the TISS score, even when PAC was not taken into account for calculation of the TISS score. This is not surprising, since invasive monitoring procedures are obviously more often used in more severely ill patients. Peculiarly however, the incidence of acute respiratory failure was significantly lower in the PAC group.

The propensity technique/score used by the authors to define two comparable groups of critically ill patients (one with, and the other without, PAC) [3] may have failed to adequately match the two study groups for severity of disease. Unfortunately, data on the incidence of shock and/or the use of vasopressors and inotropic

support, that could help to answer this question, are not reported in the paper. It is not unlikely that the decision for the physicians of whether or not to catheterize the patients with a PAC, was the severity of cardiovascular instability. Another concern is whether this new propensity score is peculiar to the five medical centres studied or, perhaps, even to US practice. This is a particular concern given that patients in the study group were 4 times more likely to receive a PAC than, for example, in European intensive care generally. Furthermore, the score pertains only to 13 categories of disease, e.g., COPD, CHF (congestive heart failure), and it would be a considerable extrapolation to regard the technique as universally applicable. Certainly a number of the components to the propensity score are not readily recognizable as universal indications (or propensity factors) for PAC, e.g., sex, race, patient education, income or type of health insurance, whereas suprisingly the use of catecholamines was not included in the score. The authors suggested a number of hypotheses that could explain their results including the one that PAC is actually beneficial but that this relationship is missed by not adequately identifying important confounding factors. In the face of these study limitations, it is not possible to draw definitive conclusions, although the results need to be considered seriously.

The accompanying editorial to the paper recommends two possible paths of action. One is to undertake an appropriately designed, multicentre, randomized controlled clinical trial for the use of PAC in critically ill patients by the National Institute of Health, the other a moratorium on the use of flow-directed PA catheters. In the meanwhile both the Society of Critical Care Medicine (SCCM) and the American Thoracic Society have addressed the issue and acknowledged that the study by Connors et al., despite its limitations, raises important questions regarding the utility of PAC which must be addressed, but that it would be imprudent to advocate a moratorium on the use of PAC at present.

A technological assessment of PAC with the parameters described by Guyatt et al. [4] including the diagnostic capability and range of uses of the PAC, the diagnostic accuracy, the impact on health care providers, the therapeutic impact and patient outcome, has been reported [5]. The catheter measures right atrial and ventricular filling pressures, pulmonary artery and pulmonary artery wedge pressures and cardiac output, and enables one to sample mixed venous blood and make several important calculations. The pulmonary artery wedge pressure, the thermodilution cardiac output and the mixed venous oxygen saturation derived from the PA catheter have been shown to be accurate [6–8]. The information provided by the PA catheter cannot be obtained by clinical judgment alone, or by basic haemodynamic monitoring [9–11]. In fact, physicians change their therapeutic plan due to the additional information obtained from the PA catheter [9]. There is, therefore, particular diagnostic benefit in selected clinical situations and in a variety of monitoring scenarios where serial measurement of clinical responsiveness may facilitate therapeutic benefit. However, despite the many studies on the utility of PAC in a variety of settings, there are as yet no definitive answers in relation to increased patient survival. Results have ranged from reduced morbidity and mortality to no effect or even harm [10–19]. The additional information on the physiology and pathophysiology of critically ill patients has promoted the worldwide use of PAC, since its initial description in 1970 [18]. The rationale for the use of PAC is that this additional information helps us to treat our patients better, and that this outweighs the potential risk of its application.

The death rate attributed to PAC varies in the various studies between 0.02 and 1.5 % [19]. Early complications directly attributed to PA catheter insertion seem not to be causative for the increased mortality rate in the Connors study, since the adjusted risk of death associated with PAC on day 3, was 1.12 (95 % confidence interval 0.91–1.36). This was much higher than could be expected from the incidence of such complications in all former studies that have addressed this question [19–22]. Unfortunately, the authors do not report on the causes of death in the early period. The risk of death increased with hospitalization; although infectious complications due to PAC are known to increase with time, no data are reported regarding the time the catheters were in place. Finally, the fact that the Connors study demonstrates a difference in survival between the two groups only after approximately 8 days clearly supports the contention that the increased mortality was not secondary to the catheter itself.

For these reasons it is difficult to attribute the higher mortality rate in the PAC group to catheter-related complications. Without any doubt, the potential risk of PAC outweighs the potential benefits the less ill the patients are who are catheterized. The high numbers of patients in the Connors study who had a PAC inserted (38 % within the first 24 h on the ICU) does not rule out the possibility of overzealous use. In contrast, the data from ICUs in European countries reveal an average of only 12.8 % of patients with PAC [23]. The risk/benefit ratio also depends on both the quality and quantity of the data that are obtained by this monitoring technique – inserting the catheter and obtaining data only once a day or not at all is very unlikely to provide benefit to the patient. Serious concerns have been raised in respect to practices in some ICUs in the US where the numbers of catheters may negatively correlate with the amount of data that is obtained and consequently used for better patient management [24]. Furthermore, almost 50 % of the respondents to a questionnaire on the insertion, use and interpretation of PAC sent to physi-

cians (most being physicians in training) in 13 hospitals in the US and Canada were unable to obtain and interpret the data available with the PAC properly [25]. Similar findings were noted for French, Swiss and Belgian intensive care physicians [26]. On the other hand, it has been demonstrated that patient outcome from septic shock [27] and congestive heart failure, sepsis or myocardial infarction [28] can be improved when an ICU is run by physicians with special training in intensive care medicine. The intensivists used PACs significantly more often than physicians without special training in this speciality. Furthermore, changing the organization of a medical intensive care unit from an "open" to a "closed" format significantly improved the clinical outcome without an overall increase in resource utilization, despite the fact that the incidence of PA catheter utilization almost doubled [29]. Similarly better survival rates were reported for high risk patients, not through the use of PAC per se, but when this more sophisticated monitoring was used to achieve predefined goals for "optimal" haemodynamics [30, 31].

Analysis of the role of the PAC in intensive care medicine is confounded by organisational factors which vary widely even between developed countries. Although PACs are used more frequently in a less critically ill patient population in the US, this occurs where full-time directors and round-the-clock experienced physicians are available in only 6% of the ICUs [32]. Most ICUs are in private hospitals which are not affliated to medical schools [32]. It seems probable that PAC practice is yet another illustration of the contrast between US and non-US critical care practice, which has already been widely documented (33, 34). We know, for example, that critical care in the US is relatively fragmented into speciality units, consumes a relatively high number of acute hospital beds (5–10%) and a relatively high proportion (1%) of the country's gross domestic product. Perhaps the relatively high use of PACs is merely a symptom of an infrastructure and culture not pertaining outside the US and a strong indicator of a need to treat these results, and the particular propensity technique on which they are based, with considerable caution in the broader context. In addition, a survey of the American College of Physicians demonstrated that 88% of residency program directors recommended 10 PAC insertions as adequate to obtain proficiency in the use of the PAC and five insertions per year to maintain it [35]. The task force of the American College of Physicians, American College of Cardiology and American Heart Association recommended 25 PAC insertions for initial credentialing with 12 insertions per year for maintenance [36]. Dr. Swan has stated that these (latter) numbers are inadequate [37]. Interestingly, a recent prospective evaluation of the acquisition of trainee procedural competence with endoscopic retrograde cholangiopancreatography (ERCP) demonstrated that mastery required experience of 180–200 procedures – a number 4 times higher than prestudy estimates [38]. It appears that quality training requires experience of technically and cognitively difficult, supervised cases and may necessitate more extensive experience. Perhaps we can hope that the longer period of specific critical care training ($1^1/_2$–3 years, which is required increasingly, particularly in Europe and Australasia) will facilitate, among others, appropriate PAC expertize.

Although there have been many calls for clinical trials of PAC in critically ill patients, physicians have not enrolled patients into the few clinical trials performed because of ethical issues [39]. Procedures to define the patient population which could undergo clinical trials and to give clear indications and contra-indications for PAC have recently been made [40, 41]. Using an expert panel to evaluate clinical scenarios, clinical equipoise could be determined. Clinical equipoise occurs when competent physicians are content to have their patients receive any of the treatment groups in a randomized trial because, based on available data, none has been proven preferable. If more than 70% of the experts believe that specific patient populations should, or should not, have PACs inserted, then these would constitute indications and contra-indications for PAC. On the other hand, if less than 70% of the experts believe PACs are indicated for a specific indication then clinical equipoise would be present and clinical trials could proceed in these groups of patients [41].

Until adequate prospective trials can give us definitive answers on the utility of the PAC for various indications, we should consider the following: There are patients, clinical circumstances and diseases where advanced haemodynamic monitoring like PAC, transoesophageal echocardiography (TOE) or transpulmonary double indicator dilution techniques provide information that is not available with the use of basic haemodynamic monitoring where these procedures provide improved guidance to therapy. Until proven otherwise these could include:

- Severe septic shock with the need for a high level of vasopressor support
- Severe respiratory failure
- Severe cardiac failure
- Major surgery in patients with severe recent myocardial infarction and limited cardiac function
- The management of pre-renal azotemia in patients unresponsive to clinically guided measures, such as initial volume loading.

It must be acknowledged that even if the data from the Connors study can be confirmed in future studies, that would not prove that the PAC is useless or harmful in high risk perioperative patients, who currently account for a considerable number of applications.

To improve potentially the risk/benefit ratio of PAC use we should promote better training and limit the use of PAC to well-trained and experienced physicians. The existing guidelines by the European Society of Intensive Care Medicine (ESICM) and that of other societies should be modified in order to better indicate when the catheter is highly recommended and where it is unlikely to be useful [42, 43]. Data collection and implementation of this information in clinical decision-making should be optimized. In this respect the use of catheters for continuous monitoring of mixed venous oxygen saturation and/or cardiac output may be superior to the use of conventional PACs. However, this hypothesis also remains to be proven in adequate clinical trials. In the Connors study no statement is made concerning the type of PA catheter used, but the study period, dating from 1989 to 1994, makes it unlikely that continuous measurement was available. In addition, the medical and scientific community must make a greater effort to define better the utility of alternative methods to PA catheterization that provide the same or even better information on the cardiovascular system than the PA catheter, such as TOE [44] or the double indicator dilution technique [45]. The tools that are provided by evidence-based medicine can also be helpful in the field of evaluating the benefit of the various established and newer monitoring devices [46]. Expert panels under the auspices of our national, European and international societies have to be established not only to improve the existing guidelines, but also to define the indications, contra-indications and clinical equipoise for the performance of clinical trials that can answer the open questions. The ESICM supports all activities for the organization of an appropriate clinical trial, as we have to be aware that our current practice of extended haemodynamic monitoring is based on the belief in the effectiveness of physiological fine-tuning than on objective evidence that this or any other invasive diagnostic technology leads to improved patient outcome [46].

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