Pa Catheter Controversy Continues, why?: Part II

J Civetta

Citation

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Abstract

Patients who suffered hypotension or pulmonary edema after acute myocardial infarction were reported retrospectively in 1987 in a large metropolitan area ([1]). There was no management protocol. Clinicians, acting independently, chose to use or not to use pulmonary artery catheterization to aid in the management of these patients. No criteria for selection were established either beforehand or retrospectively. Mortality rates in the invasively monitored group were higher (Table 1).

Figure 1

Table 1

COMPLICATION	WITH PA CATHETER	WITHOUT PA CATHETER	DIFFERENCE	P
CHF	45%	25%	+20%	<.001
HYPOTENSION	48%	32%	+16%	<.001
SHOCK	74%	79%	-5%	n.s.
ANY	44%	23%	+21%	<.001

Legend: Adapted from Gore (11); CHF = congestive heart failure; PA = pulmonary artery

The authors noted that, “given the retrospective observational nature of the present study, and its reliance on the use of the medical record as its primary source of data, we could not determine if patients with specified hemodynamic complications of acute MI who received a PA catheter were indeed sicker than patients with these complications who did not have a PA catheter inserted. The decisions to place these catheters were made by scores of physicians, with varying levels of skills in the use of the PA catheter, at 16 different hospitals over a ten-year period. It is very unlikely that there was a uniform or even a consistent pattern of practice with regard to the use of PA catheterization throughout the periods studied.” The authors also stated that, “appropriate reservation must be exercised in the interpretation of data from non-randomized/observational studies”. Some objective data seemed to support the bias towards using PA catheters in the sicker patients (Table 2).

Table 2: Possible Confounding Variables

Large infarct (peak CPK < 5X normal)

Men

Q wave infarct

Length of stay

Legend: Variables noted by Gore (1) associated with more severe myocardial infarction and occurring in a significantly higher percentage of patients who received pulmonary artery catheter.

However, they concluded that these results should be used to promote a randomized prospective study. However, an accompanying editorial,([2]) Death by Pulmonary Artery Catheter, dismissed the authors’ concerns and concluded that perhaps over 100,000 patients had died since 1975 as a result of the “excess mortality” induced by unnecessary pulmonary artery catheterization. Robin recommended an immediate moratorium until the question could be resolved. Because a diagnosis does not uniformly result in agreed upon diagnostic and therapeutic interventions, this apparent “controversy” received an unfortunate amount of attention even in daily newspapers, as can be seen in this headline,([3]). “Diagnostic Tool May be Fatal”.

The authors incorrectly identify a possible source of selection bias in choosing patients who may or may not have been initially more critically ill. The physicians involved

were treating their own patients and, it seems highly reasonable to suppose that there was intentional selection of sicker patients for invasive monitoring. Selection bias implies that an unknown factor was operative; in this series, severity of illness which is not quantitated in the report was immediately assessed by the clinicians but we may assume that it was not an unknown factor. In general, the amount of infarcted myocardium is expressed initially as the degree of "pump failure" and later as an ascending mortality rate. This, in fact, was demonstrated in the study. Thus, another inference is that these patients with the more severe initial clinical manifestations secondary to a larger myocardial infarction were appropriately selected for invasive monitoring. Invasive monitoring may aid in delineation of abnormal hemodynamics and this information may assist clinicians in the selection of interventions. However, a diagnostic tool should not be judged solely upon its ability to reduce mortality rates. Unfortunately, it would seem that patients with too much infarcted myocardium would have been selected for a PA catheter but that a fatal outcome had been determined by the size of the infarct. This study then might be interpreted as validation of clinical judgment; in fact, in a worst case scenario would be that the mortality rate in the non-monitored patients would have been higher than those selected for monitoring for then the sickest patients would not have been identified. Criticism might then justifiably be levied against clinicians who had been unable to assess the severity of initial presentation. The primary problem with both the study and editorial is that the clinical decision-making process was never outlined. This limitation did not prevent interpreting disparate outcomes as a function of the utilization or misutilization of a monitoring tool. The ultimate result may be that undue caution and fear of litigation will deprive patients of useful monitoring, not saving them from increased risk.

Again, if the pulmonary artery catheter is just a tool, it is appropriate to consider the knowledge and experience of the "workmen". A multiple choice examination dealing with the pulmonary artery catheter was given to nearly 500 physicians($_4$). The examination consisted of 31 questions. The mean unscaled score of correct responses was 20.7 (67% correct). The authors reported that the mean score was significantly associated ($p < .01$) with level of training, frequency of insertion, frequency of PAC data and treatment, specialty area, and primary or secondary medical school affiliation by one factor analysis of variance. Indeed the data support the concept of a structured and hierarchical residency training system (Table 3).

Table 3: Correct Responses

(Primary Medical School Affiliate Hospitals)
Total items on test 31.
Skilled, effective clinicians 28.8
Attending physicians 23.3
Fellow or PGY-4 23.1
PGY 2-3 20.8
PGY 1 16.4

Legend: Results extracted from 31 item questionnaire. There is a clear relationship between level of training and experience and the number of correct responses. Adapted from Iberti et al (4).

A small set of selected, experienced and skilled clinicians achieved very high scores (27-31 correct). However, PGY 1 average was 16.4 with a consistent increase with the level of training and experience. What should be clear is, therefore, that lower level residents need supervision, not just for insertion but also for interpreting and applying the information that is obtained. It is also gratifying to see that fellows in critical care training approach the level of attending scores. Therefore, exposure and education in the use of pulmonary artery catheters occurs in a satisfactory fashion. What is also clear, but perhaps should go without saying, is that junior residents should not be permitted to either insert or use the data obtained independently, any more than PGY1 surgical residents should be allowed to perform aortic aneurysm resections independently. Thus, this study documents that the training process "works" and that a significant degree of supervision and evaluation is necessary in critical care as well as in other medical disciplines. The establishment of critical care training programs and special certification in critical care by various member boards of the American Board of Medical Specialties seem to be appropriate steps in achieving these ends. But far more can – and should – be done.

Robin (2) then sets criteria for judging medical tests (though he uses them specifically for evaluating pulmonary artery catheters): "The use of the catheter is a form of medical test. By its use alone, no one ever cured pulmonary edema or any other pathophysiologic disturbance. Its effectiveness can only be judged in terms of improved patient outcome. The only benefit (to patients) that would be acceptable would be firm evidence that its use improved decision-making and that as a result of improved decision-making, patient outcome were improved. This means that the only justification for the use of a test depends on demonstrating a better outcome for

patients. No such data have been provided for the use of pulmonary flow catheters." It is interesting to note that no current test used for hemodynamic monitoring satisfies his criteria. There are no data to support the use of arterial or central venous pressure monitoring, cardiac output, arterial and mixed venous oximetry and even inspection, palpation, percussion and auscultation.

The incorporation of new technology is not merely limited to the ICU. Feinstein ([5]) has discussed this elegantly: "Nor has any era of man been spared the occupational disruption of new technology. . . . Whenever introduced, a new technological advance has been initially rejected and feared: rejected, because of the belief it could not work as well as existing devices; fear, because of the suspicion that it might." A constant source of wry amusement in any era is to read the deprecations of the initial reception given to technology developed in a previous era. For example, Laennec's introduction of the stethoscope was not greeted as a universal symbol of the clinician that it has now become. Said the London Times in 1834, "that it will ever come into general use notwithstanding its value ... [is] extremely doubtful; because its beneficial application requires much time and gives a good bit of trouble both to the patient and the practitioner, because its hue and character are foreign and opposed to all of our habits and associations...There is something even ludicrous in the picture of a great physician proudly listening through a long tube applied to the patient's thorax ([6]).

And then for another 10 years not much happened in the way of controversy. I know that I raised more questions about the appropriateness of pulmonary artery catheterization in individual patients at the bedside and at morning rounds. I suspect that many clinicians, having learned both normal and abnormal physiology using pulmonary artery catheterizations for a number of years, elected to be more selective, really, not just placing catheters in every patient who was the least bit unstable. But then again in 1997 the controversy resurfaced. Interestingly, the data set was again not collected for the purpose of evaluating pulmonary artery catheterization. There had been a series of descriptive studies and a couple of randomized studies performed between 1970 and 1997, but few had even addressed the issue of catheterization vs. no catheterization; the majority of studies used catheters as a tool to define whether, for instance, supranormal oxygen delivery was "better than" normal oxygen delivery in different patient populations. The new study was taken from the SUPPORT database, a study designed to evaluate interventions to improve the alleviation of suffering and communication at the end-of-life. As it was a study based in the ICU and contained thousands of patients, it was not surprising that many of these patients had pulmonary artery catheters placed. Again, a retrospective analysis of the data ([7]) showed that patients with right heart catheterization had an increased 30 day mortality, that the in-hospital cost was increased and that the ICU stay was longer in those patients who had right heart catheterization. So once again, pulmonary artery catheterization conferred no benefit and in fact was associated with increased mortality and resource utilization. And once again ([8]) an accompanying editorial had a catchy title, "Is it time to pull the pulmonary artery catheter?". In this editorial, two options were recommended. First, a multicenter randomized controlled trial should be performed or if this was not undertaken, that the FDA should issue a moratorium on the use of PA catheters. Not surprisingly, the same kind of heat (not light) was generated. But after a few headlines and even a spot on CNN, the public's attention died away but the Society of Critical Care Medicine sponsored a Pulmonary Artery Catheter Consensus Conference. The consensus statement ([9]) was published in Critical Care Medicine in June 1997, and manuscripts responding to each question were consolidated in an issue of New Horizons ([10]). The Consensus Conference took the form of a series of questions with the evidence evaluated and presented by individuals assigned by the conference committee. The questions were then answered and graded.

Figure 2

Table 4: Grading of responses to questions and levels of evidence

Grading of Responses to Questions	
A	Supported by a least two level I investigations
B	Supported by only one level I investigation
C	Supported by level II investigations only
D	Supported by a least one level III investigation
E	Supported by level IV or level V evidence
Levels of Evidence	
Level I	Larger, randomized trials with clear-cut results; low risk of false-positive (a) error false negate (b) error
Level II	Small, randomized trials with uncertain results; moderate to high risk of false-positive (a) and/or false negative (b) error
Level III	Nonrandomized, contemporaneous controls
Level IV	Nonrandomized, historical controls and expert opinion
Level V	Case series, uncontrolled studies, expert opinion

Adapted from Sackett ([11]).

Could this properly be called a Consensus Conference? Of 22 clinical questions usually phrased to determine if pulmonary artery catheters reduced morbidity, mortality or improved outcome, in 8 cases the answer was “yes” and the supportive evidence in 7 of these cases was expert opinion; 1 was supported by a nonrandomized, contemporary control study. 3 other questions were answered “no”, 2 supported by expert opinion and 1 by a small randomized trial with uncertain results. For the final 11 questions, the answer was “uncertain.” 3 of these 11 were supported by the highest level of evidence, randomized controlled trials. To reiterate, PA catheters were felt to be beneficial in 8 of 22 clinical situations, but were only supported by low-level evidence. The largest number of questions had an uncertain answer and most of the uncertainty was only bolstered by low-level evidence. In August of 1997, the FDA and NIH convened a Pulmonary Artery Clinical Outcomes Conference. After 2 days of deliberation, it was clear that clinical studies would be extremely difficult to do but were supported by many participants. Unfortunately, ARDS and sepsis were two areas selected for clinical studies. No protocols have been developed. From my own perspective, sepsis and multiple organ system failure patients have many different antecedents, clinical courses that last for weeks to even months, and tremendous variations in therapy within a single unit. If I was to estimate, only perhaps 3-5% of the patient’s outcome would be effected by pulmonary artery catheterization. For instance in most discussions of sepsis, the first principle is to control the source. Next, the experts advocate appropriate antibiotic treatment; many patients have respiratory failure thus introducing a myriad of variables concerning the treatment options for ventilator and PEEP therapy. Then there are controversies concerning enteral or parenteral nutrition and so forth and so on. The group did recommend education and there was a flurry of activity for about 4 months but now this sounds like 1970 all over again: perhaps a new generation of young intensivists can try to educate practitioners in the proper utilization of the data obtained from pulmonary artery catheterization. What seems to be missing is an understanding of the role of the diagnostic tool. First, we must recognize that a monitoring tool allows one to collect information that is not available otherwise. At the time the pulmonary artery catheters were introduced, there were no other ways of estimating left atrial pressure or cardiac output. Today, there are noninvasive methods of assessing cardiovascular performance and cardiovascular performance (or at least the parameters produced by pulmonary artery catheterization) may not be as important in patient management as it was two decades ago. After all, pulse and blood pressure became relegated to positions of less importance when invasive monitoring arrived. Perhaps Doppler signals showing the change in stroke volume with response to treatment and gastric tonometry will replace pulmonary artery catheters in the future. In any case whenever a particular monitoring device is used, the clinician must be assured that the information is correct. It has been disturbing that more than 50% of ICU nurses could not correctly identify a wedge pressure tracing – and physicians probably would do even worse if they allowed themselves to be tested! Having grown up with the earliest generation of two lumen catheters and bedside monitors, I think I know many of the pitfalls because we had to do so much of the troubleshooting on our own. Today, with everything automated, I wonder if anyone ever questions the validity of the numbers that are produced. Maybe it’s similar to the evolution of the automobile. In the early days, one could pick the hood and tinker with all sorts of things. Today, if the car will not start, it has to be towed to the dealer so they could hook it up to a computer and figure out what is wrong. At least that was the way it was with my Corvette with its 16 onboard computer systems. Instead of an instruction manual, you were provided with a road-side assistance telephone number. Assuming that the clinician knows enough to verify the numbers (and that is a gratuitous assumption), the numbers must reveal an

abnormality that is amenable to treatment. Many years ago, when I was a guest examiner for the American Board of Surgery, I would describe a critical care case and the examinees would knowingly say, well now I would put in a PA catheter. I would say, what do you want to know and they would respond, what is the wedge pressure? I used to always say 14 and they didn't know what other information to ask for next or what to do. But in our scenario, if there is an abnormality, one must select an appropriate form of therapy. This is not as easy as it sounds. Reflect over the many case presentations you have heard: "The patient required," says the presenter. Immediately translate this into "I chose to do the following." For instance, for years our patients "required" epinephrine until we became interested in gastric tonometry and realized that splanchnic vasoconstriction could be expected after epinephrine administration and we then started choosing different agents. Too many patients today "require" pressure-controlled ventilation achieved with neuromuscular blocking agents for the treatment of ARDS - but that's a whole different harangue!

Even if the physiologic abnormality is responsive to the treatment chosen, this response must be examined from a certain number of perspectives: Immediate, i. e., the blood pressure or cardiac output was low and now it is back to normal. For the most part this is how we evaluate the effect of our therapeutic choices. But if PA catheters are "required" to improve outcome, we must decide if the increase in cardiac output that is produced is sufficient to change the patient's outcome from certain death to survival. In fact an aggressive intensivist can restore "normal" hemodynamics in almost every patient; however many of these patients will ultimately die: Was the intervention a failure? Or was the monitoring tool a failure? Not only has restitution of normal hemodynamics been insufficient to "guarantee" survival but after a decade in which we were told that supranormal hemodynamics had improved outcomes, the latest studies have shown that there is an increased mortality associated with supranormal oxygen delivery. And studies of gastric tonometry have shown that hemodynamics can be normalized or even supranormalized and yet pHi remains abnormal and correlates with increased mortality and organ system failure. So, perhaps we should go back to the delight of the early seventies. Pulmonary artery catheters give us information which we can use at the bedside to correct immediate problems. Problems that cannot be defined sufficiently by clinical examination or other forms of monitoring can still be helped by pulmonary artery catheterization. However, there may be other modalities of monitoring that are of equal or even more utility. Further, once abnormalities are identified, a correct form of therapy must be utilized and, of the greatest importance, is that improvement in physiologic parameters chosen must be sufficient to alter the outcome. In other words, correcting a cardiac output may or may not be advantageous. The patient may have already past the point of no return and no change in the cardiac output value can alter this fatal outcome. There are many ways to achieve the desired value but each clinician believes that his or her choice is the "only correct one" and this too is an error, because some methods that "work" initially also set the stage for late organ system failure (like alpha adrenergic agonists for treating hypotension in the face of adequate perfusion - no treatment really necessary). Finally, the PA catheter controversy misplaces the emphasis from identifying a proper clinical decision making process to a single diagnostic tool. The controversy over what diagnostic and therapeutic interventions should be chosen should not be limited to the PA catheter alone. Perhaps the reason that that the controversy continues is that it is easier to continue the controversy than it is to understand physiology, choose monitoring tools appropriately and learn correct forms of therapy. As the SCCM Consensus statement amply demonstrates, we have much to accomplish in all of these areas. Unfortunately, the latest word continues emphasis on the same bases and same biases. For instance some well known European intensivists do not consider the pulmonary artery catheter misused ([12]) and again another point-of-view from Canada ([13]) suggests that this stance is but opinion and data are needed. The studies can be performed, must be performed and technology cannot be assessed solely from the basis of the rationale of physiologic measurement without hard data about potential benefits, costs and harms.

Well, I must thank the PA catheter: it has helped me at the bedside; I have had an enjoyable time exploring its uses (and misuses); finally, it has given me an opportunity to think about clinical decision making. The controversy will continue but about the wrong issues and the proposed studies will not answer the questions. The "PA catheter revolution" started a need to acquire new knowledge; nearly three decades later, the same knowledge is still needed at the bedside to utilize this tool - or any that follow. Would that the scrutiny and standards applied to PA catheters were expected of all that we do!

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Author Information

Joseph M. Civetta, M.D.
Professor and Chairman, Department of Surgery, University of Connecticut Health Center