physicians.

Optimization of hemodynamic parameters is very important in critically ill patients, especially those who are in shock. Proper administration of fluids, vasoactive drugs, IABP, ventricular assist devices, etc., cannot be done in these patients without hemodynamic monitoring. Clinical examination can be misleading in critically ill patients. Fein et al demonstrated that the diagnosis of pulmonary edema from clinical criteria alone is often incorrect, and PA catheter placement was needed to make the correct diagnosis and provide appropriate treatment. Startling information was obtained by Eisenbert et al., demonstrating that hemodynamic variables were accurately predicted by physicians 50 percent of the time by clinical examination. PAWP was correctly predicted in only 30 percent of patients; both over- and underestimation of PAWP were done, and overestimation of cardiac output predominated. Treatment was altered by hemodynamic data in more than half of the patients and an entirely new therapeutic modality was instituted in nearly one-third of them.

Noninvasive techniques (ie, portable echocardiography, Doppler study, radio-nucleotide techniques) are cumbersome, expensive, and not easily available. Information may be operator-dependent, hence not very reliable and not available in some institutions.

I would like to draw the attention of the medical community to a historic paper presented by Harvey Cushing in 1903. His paper was entitled, "The Routine Determination of Arterial Tension (BP) In the Operating Room and Clinic". Subsequently, a committee was appointed to determine whether such information was necessary. The report was published in March, 1904 in the second bulletin of the division of surgery at Massachusetts General Hospital. It concluded that: "The adoption of blood pressure operations (noninvasive BP monitoring) in surgical patients does not appear necessary as a routine measure." However, common sense prevailed and monitoring of blood pressure during surgery and in the clinic has remained a cornerstone in the management of patients. This report shows that good intentions do not necessarily translate into good judgment.

Naturally, the question arises; Why has the randomized study not been done? The answer is obvious. Ethically, my colleagues and I do not want to deny the benefits of a PA catheter to a patient in a shock state. Until a safe, reliable, good technique is available and acceptable to the medical community, what should we do? Should we go back to the unreliable, inconsistent clinical examination techniques and change therapy randomly? Many physicians may be reluctant to do so or wait for a prospective randomized trial.

Since Dr. Robin has suggested putting a moratorium on PA catheters, we urge him to initiate and lead a multi-center randomized controlled trial (if he already has not started one) and substantiate that his call for a moratorium was appropriate.

References

6. Uhl RR. Current problems in anesthesia and critical care medicine, 1977; 1:4-9

There are four assumptions in this letter that warrant comment. 1) These physicians know how to recognize those few patients who "should" be catheterized. There is, of course, no valid data base to evaluate this claim. 2) High mortality associated with use of the catheter is related to the inexperience of some catheterizers. Of course, differential skill of physicians is a fact of life influencing the outcome of all technologic approaches in medicine. One leader of the Swan-Ganz movement has attributed the high complication rate to its use by nonsurgeons as contrasted to surgical users. But since these authors presumably do not have rigorous data obtained at their institutions for comparison to other institutions, how do they know they are doing any better or worse than anyone else? 3) Harvey Cushing was rebuked by the Massachusetts General Hospital. In fact, he was not an easy fellow to get along with. 4) A randomized study would not be ethical. As the risk-benefit balance of the catheter is unknown, the ethical basis of continuing to use the catheter is not clear. Should it turn out that many patients have died and are dying needlessly as a result of the use of the catheter, perhaps these patients would be more content to survive nonethically than to die ethically.

The proponents of the use of Swan-Ganz catheters include an overwhelming number of cardiologists, intensivists, anesthesiologists, and trauma and cardiovascular surgeons. This majority view is reflected in the present correspondence. This raises the issue of whether overwhelming majorities in medicine can be wrong. The answer is yes, not infrequently. In fact, this correspondence has much in common with correspondence defending the failure to use anesthesia during surgery in neonates or insisting that lumpectomy is never a useful alternative for treatment of cancer of the breast.

That association does not establish that majority positions are always wrong, but a consensus view is no guarantee that the view endorses a practice which improves patient care.

One problem faced by proponents of use of the catheter is the lack of rigorous data which establishes the efficacy of the catheter. There are also no data which establish the precise rate of complications, including death. But the fact that needless complications and death do occur is undubitable. What is being debated is not whether death and disability occur, but how many deaths occur and whether

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there are compensating patient benefits. Parenthetically, one excess death in the absence of patient benefit should be unacceptable.

To the Editor:

Dr. Robin's editorial1 on our report of community-wide assessment of pulmonary artery catheters in patients with acute myocardial infarction2 is well written and thoughtful, but distinctly wrongheaded. The University of Massachusetts study emphasized careful matching of those with and without PA catheters, but it was entirely retrospective. Moreover, "X" factors operate for patient selection for critical decisions like surgery or, indeed, intravascular instrumentation that cannot be scientifically accounted for, particularly in retrospective analyses. For example, it has been shown repeatedly that retrospective analyses—even with matching of patients—in clinical trials of drug and surgical therapies either 1) obtain results that are directionally different from those of prospective, randomized, controlled trials; or 2) even with results qualitatively the same, show significant quantitative differences—virtually always in favor of the trial therapy.3 Therefore, numeric extrapolations from our results cannot be warranted—even with the caveats appropriately added by Dr. Robin.

Another curious aspect of Dr. Robin's editorial is that his reference 1 is my 1980 analysis of the undetermined risk/benefit ratio in patients with heart disease who are monitored by any kind of invasive instrumentation.4 This was, indeed, the impetus for the University of Massachusetts investigation—which was designed only as a preliminary look and a basis for an ultimate controlled trial. My publication in 1980 proposed just such a trial with one example of how it might be done. Dr. Robin now calls for a prospective controlled trial of pulmonary artery catheterization and, curiously, does not reference my original suggestion5 (this is equally true of his earlier publications on the subject). If he truly understands the more-than-theoretic flaws of the retrospective approach, Dr. Robin should have been more conservative in his proposals to proceed from our retrospective data.

Another aspect, widely overlooked (including in recent press reports of Dr. Robin's editorial and our study1) is that overt complications of PA catheters are not the central issue here. My 1980 paper was an analysis of our and others' investigations of noninvasive vs invasive instrumentations which indicated that deleterious and (arguably) helpful effects are associated with the mere presence of intravascular instrumentation, irrespective of any clear cut complications.6

Finally, although many of us believe in the apparent necessity of pressure and flow monitoring to fine-tune some potentially dangerous treatments, we still do not know the risk/benefit ratio in the absence of a prospective trial. The University of Massachusetts retrospective trial adds to that as a general principle, but without permitting specific extrapolations. One can only repeatedly emphasize the flaws in any retrospective studies including the report of Knaus (Dr. Robin's reference 5). That Gore et al retrospectively matched patients only accounts for a part of the equation. Retrospective (like prospective) matching only accounts for the known variables. As in any appropriately-designed study, randomization—with chance alone dictating who gets the intervention—attempts to account for the unknown variables ("X" factors)—and they may be many indeed.

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References


Dr. Spodick is a clinical epidemiologist, a distinguished editor of a journal (American Journal of Noninvasive Cardiology) and is one of the authors of the Gore article. It is not for these reasons alone that I hope readers will pay close attention to his communication. An analysis of his communication provides some scientific and, more critically, some clinical insights into some important issues I will take the liberty of addressing him personally.

Having been involved in a retrospective study, you have decided that your methods were good enough to rule out beneficial effects of the pulmonary artery catheter in acute MI but not good enough to indicate the possibility of extensive harm. I know of no theoretical or pragmatic justification for such a distortion of the science of epidemiology. The twin dilemmas you face are that, if retrospective studies are globally invalid then your paper is not valid, and if so, why was it submitted for publication? (Parenthetically, I am delighted that the paper was submitted. Its impact may be lifesaving for large numbers of patients.)

By some legerdemain, a “100% increase” in mortality has been converted into a “lack of benefit”! I would submit that even if multivariate analysis had not been performed by the Worcester group and even if subgroup comparisons had not been performed (pulmonary edema, hypotension and shock), the mere existence of such a phenominal difference in patient outcome would require rapid investigation and possible remedial action.

I reject the rationalization that "X factors" or their equivalent, the tooth fairy theory, invalidates the requirement for some action on the use of the catheter in real life. In fact, in the specific case of the Swan-Ganz catheter, the X factor theory (no mechanism was uncovered by your group for such a large number of excess deaths) simply does not hold water. As indicated, there are a host of complications of the catheter which can cause death in patients with acute MI which are not usually sought for or detected. For example, it has been documented that about 50% of patients dying with the catheter in place develop myocardial bruising, contusions or...