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REFERENCES

12 Reeves TJ. Advances in cardiology and escalating costs to the physician. Circulation 1985; 71:637-41
22 Parnell WW. The post MI role of hemodynamic monitoring. Hosp Pract 1982; 17:169-75

Death by Pulmonary Artery Flow-Directed Catheter (editorial)

Time for a Moratorium?

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A study by Gore et al in this issue of Chest (see page 721) raises some critically important issues involving the safety of large numbers of patients.

The impact of the use of the pulmonary artery flow-directed catheter on patient outcome following acute (usually complicated) myocardial infarction was analyzed retrospectively in 3,263 patients. No benefit in terms of mortality, length of hospital stay (longer in those with the catheter), or long-term prognosis could be demonstrated. These findings, although not anticipated by the overwhelming majority of catheter users, are scarcely surprising. The probable lack of benefit was anticipated in 1980 and has been emphasized since 1982.2-4 A lack of benefit in the use of pulmonary flow catheters in the ICU is also implicit in the data of Knaus et al.5

The present study by Gore et al, however, surprisingly shows a very large excess mortality in patients in

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whom the catheter was used, as compared to those without the catheter. The possibility of substantial net harm from the use of the catheter has only been raised theoretically in the past.5,6

The data were as follows. Following an acute MI, the hospital mortality for patients with congestive failure, with a catheter, was 45 percent compared to 25 percent without a pulmonary artery (PA) catheter; excess mortality = 20 percent (p<0.001). For patients with hypotension, the mortality was 48 percent with a catheter vs 32 percent for those without; excess mortality = 16 percent (p<0.001). Only in patients with cardiogenic shock was no significant excess mortality demonstrable between patients with and without a catheter. However, the number of these patients was small—only 25 percent survived hospitalization, and it is possible that many of these patients died too quickly of their underlying disease for catheter-associated risks to catch up with them.

A significant increase in mortality was demonstrable even when the data were corrected by multivariate analysis for the size of infarcts and other indices of severity of infarct. The increased mortality associated with the use of the catheter was so high that no explanation for its occurrence was advanced by Gore et al. Thus, in a large group of patients with acute myocardial infarction, the use of the catheter was associated with a marked increase in case fatality rate. The (probably unexpected) sharp increase in mortality associated with use of the PA catheter suggested to these workers the desirability of a prospective randomized, controlled trial.

While strongly agreeing with this suggestion, the purpose of this commentary is to go considerably beyond that suggestion. Why go beyond? If the data are representative of what takes place in American hospitals, then thousands of patients have died and are currently dying because of complications associated with the use of the pulmonary artery catheter in acute myocardial infarction.

Just how many excessive numbers of patients are dying or have died? Extrapolating from the data in the paper to all patients in the US gives rise to figures like 10,000 to 15,000 deaths per year in 1984, and a total of perhaps 100,000 deaths since 1975. The assumptions required for such calculations are always open to question, but even if the calculations represent a five-fold overestimate, the use of the catheter must be considered a major problem of public safety. Excess death rates in this context, of course, really means avoidable or unnecessary deaths. The data suggest that perhaps 8 percent of patients with acute myocardial infarction die because of the use of the catheter.

An immediate question is whether the study un- equitocally establishes the fact there is a major problem (and, if so, its quantitative magnitude). As empha-
sized by the authors themselves, the answer is: no. Retrospective, uncontrolled, clinical analyses are not capable of providing highly accurate conclusions.7,8 Multivariate analysis might well have overlooked the fact that the catheter was used in a more gravely ill segment of the population than those without the catheter. A precise evaluation of the data in the paper would require an appropriate prospective clinical trial, but the possibility (?probability) that such a risk exists does indicate that safeguarding patient welfare requires rapid, effective action even before an appropriate clinical trial can be implemented, its results digested, and its conclusions translated into practice (see below).

The major criticism that will be used to contest the validity of the study will focus on its retrospective observational nature. That criticism is valid, although it may largely come from sources which have not needed a prospective clinical trial to justify mass use of the catheter.

Despite the tentative nature of the conclusions of the study, the stakes in terms of patient welfare are too high to be ignored.

Another issue is whether the known hazards of the catheter can account for the increased mortality from its use. Overt hazards of the catheter include a series of mishaps including death (0-4 percent), and a number of functional and structural complications spanning a broad range of disasters as reported by Gore et al.5 What is generally not recognized is that there is a series of hidden causes of death in patients with pulmonary artery catheters which leads to a sharp underestimation of the incidence of serious harm or death.

Some of these hidden causes of death or disability are physical in nature. If a patient dies relatively late in the course of myocardial infarction of a ventricular arrhythmia, it is usually assumed that the cause was the myocardial infarction and not the catheter. However, it is likely that ventricular arrhythmias can arise from long-term placement of the catheter in a hyperirritable ventricle. Some of the major causes of death only can be uncovered by universal postmortem examination. For example, the 53 percent incidence of endocardial lesions resulting from catheter use and the 7 percent incidence of bacterial endocarditis found in one series would be largely unrecognized in a hospital setting. In only one patient was the diagnosis of infective endocarditis suspected clinically.* Death from endocardial lesions or from bacterial endocarditis during the evaluation of a MI would usually not be attributed to the presence of the catheter.

There is another set of hidden complications arising from the use of the catheter, death by misinterpreta-
tion. It is not generally recognized that changes in pulmonary capillary pressure following fluid administra-
tion cannot be clearly interpreted. The appropriate
variables that govern the change in pressure can be derived from the Starling relationship and require an accurate estimate of end-diastolic volume and myocardial compliance.

In practical terms, this means that finding a relatively low wedge pressure and only a small increase in pressure after a trial infusion of fluids does not mean that the patient requires additional fluid. In patients with large end-diastolic volumes and/or decreased myocardial compliance, giving additional fluid can lead to pulmonary edema. And if, in this circumstance, the patient dies of pulmonary edema, the death is attributed to heart failure caused by the myocardial infarction and not to excess fluid administration. Pulmonary edema is so common in myocardial infarction in the absence of a pulmonary artery catheter that its development would not be attributed to a spurious interpretation of hemodynamics. There is little question that numerous patients have been harmed by this form of incorrect interpretation. Conversely, with a stiff left ventricle, following fluid administration, the conclusion might be that the patient did not need additional fluids, whereas in reality fluids were required for optimal management. Technical problems associated with the use of the catheter can lead to dubious interpretations and death.

Given both the overt and the hidden risks of pulmonary artery catheters, it is reasonable to assume that the excess mortality observed with the use of catheters in acute myocardial infarction is a real phenomenon and not an artifact of patient selection. Whether these hidden risks accounted entirely or partially for the observed increase in case mortality rate is not the point. The increased mortality was real enough.

A priori, other disorders for which the catheter is used may be associated with lower rates of excess mortality than is true of myocardial infarction. A guessestimate of 1 percent mortality in patients with ARDS fits scattered reports. In patients undergoing cardiovascular surgery, perhaps the excess mortality is less than 1 percent. In pediatric patients and obstetric patients, it is anyone's guess as to the excess mortality rate. Of course, in the clear-cut absence of demonstrated benefit, the only acceptable rate of excess complications and death would be zero.

Some discussion of the putative benefits of the use of pulmonary artery catheters is warranted. 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. In fact, the only two studies that have looked non-anecdotally at the issue of benefit have concluded that no net benefit is associated with use of the catheter.

Knaus et al investigated patient outcome in 19 different ICUs in this country. Benefit was analyzed in terms of mortality, and patient welfare was analyzed by the APACHE index. Despite wide variations in catheter use between the various ICUs, there was no difference in outcome. In fact, the unit with the lowest rate of utilization showed the best patient outcome. These data indicate that (a) the rate of utilization was a function of physician practice style rather than medical science, and (b) that sharp reductions in the rate of utilization were not accompanied by poorer outcome; that is, no patient benefit could be demonstrated from the use of the catheters.

The present report by Gore et al likewise demonstrates no improvement in mortality, length of hospitalization and long-term prognosis of patients with acute myocardial infarction.

We must therefore conclude that, at present, despite clinical impressions and opinions to the contrary, the benefits of the use of the catheter are dubious. Even if there are subgroups of patients for which improved outcome could be demonstrated, such subgroups have not been established. We now have a subgroup of patients, those with acute myocardial infarction, whose outcome seems to be dramatically changed in an unfavorable direction.

A few words about some new medical-legal implications of using pulmonary artery catheters. Not uncommonly, the argument is made that their use is dictated by legal pressures. Physicians practice so-called "defensive" medicine for fear of being sued for abetting from the use of the catheter.

A recent decision of the appellate court of California has declared "that on the question of hemodynamic monitoring there is no ascertainable practice within the industry." What the evidence does show is that hemodynamic monitoring was and is a disputed question of medical science." When coupled with the results of the present study, the use of the catheter, if associated with harm or death, could conceivably be considered malpractice. If so, then not using the catheter, at least in patients with acute myocardial infarction, might turn out to be truly defensive medicine.

If and when an appropriate clinical trial is conducted, the results of which show net harm, then another interesting legal situation will arise. In issues of this type, the question usually arises: when should

*The use of the word "industry" to describe medicine may be more appropriate than the justices perceived.

CHEST / 92 / 4 / OCTOBER, 1987 729
the accused party or industry have recognized the potential for harm? Legally, this question is known as the "date of tolling." With the publication of Gore et al in this issue of Chest, the bell may already have begun to toll.

WHAT SHOULD BE DONE?

The least desirable alternative would be to do nothing. If, indeed, large numbers of patients are being harmed, then we are dealing with an emergency. What probably will occur is that the controversy concerning the use of the catheter will intensify. This is not an acceptable alternative because if catheter supporters are wrong, this alternative will only serve to perpetuate the use of catheters and harm masses of patients. If critics of the catheter are wrong, then the use of a test which, at most, could provide indirect patient benefit, would have been inhibited.

An appropriate prospective, controlled, randomized clinical trial is an obvious long-term alternative. Without question, it should be done. The shortcoming is that the conduct of such a trial requires a substantial period of time. Worst case reasoning would suggest that many patients could die needlessly during this period.

Another alternative is possible. If there were suggestive evidence that a given drug was responsible for causing several thousand deaths per year, the drug manufacturers would notify all physicians by mail that the agent was potentially hazardous. If the evidence was sufficiently strong, the drug would be withdrawn from the market. There would be no requirement that the proof of the association between the drug and patient harm be indubitable. For example, methylprednisolone was removed by the manufacturers as a potential treatment for septic shock in 1981. It was not until 1986 that overwhelming evidence by a suitable clinical trial showed excess mortality in patients with septic shock and elevated creatinine values or secondary infection. 4

A temporary moratorium on the use of the catheter, at least in patients with acute myocardial infarction, would appear to be a reasonable proposal. If this were followed by the rapid organization of an appropriate multi-institutional clinical trial, then the best interests of our patients would be served. If the trial showed more benefit than risk, then general use of the catheter could be resumed. If not, then the use of the catheter could be abandoned permanently.

The leadership to consider a moratorium and to organize a subsequent clinical trial might be provided by a single professional organization or by some combination of the American College of Chest Physicians, the American Thoracic Society, the American Heart Association, the American Medical Association, and the Critical Care Society.

These organizations could rapidly assemble a blue ribbon panel whose charge would be to review current data and recommend one of three alternatives: no moratorium, a partial moratorium, or a complete moratorium.

Specifically excluded from membership on the panel would be individuals who are leaders in the use of the catheter and individuals who have opposed its extensive care. Members of both groups might serve as technical experts but would have no vote in the final decision. The panel would differ from the conventional consensus conference in specifically excluding those with any partisan interest in a given area.

The panel might include individuals skilled in analysis of data as it applies to patient outcome (epidemiologists), skilled clinicians from fields other than those involving the use of the catheter, and perhaps several public and governmental representatives.

The characteristics of the panel would thus be impartiality, specificity of objectives, general expertise and rapid response time.

Is this likely to happen? Almost certainly not. Medicine is notoriously slow to correct its systematic errors. The mass use of the pulmonary artery catheter is a form of iatroepidemic, a systematic error introduced into medicine which causes harm or death to masses of patients. 4 Iatroepidemics are notoriously difficult to contain.

While waiting for medicine to change, individual physicians can participate in their own personal moratorium, or at the very least, physicians could try to be much more selective in their use of the pulmonary artery catheter.

If it ultimately turns out that our worst fears have been realized, and masses of patients have been harmed or died as a result of a systematic error (the mass use of a catheter without establishing either its safety or efficacy), there is time enough to mourn for them. The most urgent task is to try to prevent additional harm and death. A general moratorium, or even personal moratoria by large numbers of individual physicians, would help.

In any event, Dr. Gore and his colleagues are to be congratulated for performing a study which might lead to an impressive decline in mortality in patients with acute myocardial infarction. It should, at the very least, lead to some rethinking about the issues.

REFERENCES

3 Robin ED. The cult of the Swan-Ganz catheter: Overuse and

730

Death by Pulmonary Artery Catheter (Eugene D. Robin)

4 Robin ED. Iatroepidemics: A probe to examine systematic preventable errors in (chest) medicine. Am Rev Respir Dis 1987; 135:1152-56


8 Robin ED. Saltem plus boni quam mali efficere conare: At least try to do more good than harm. Pharos 1987; 50:40-44


10 Court of Appeals of the State of California, In and For the Third Appellate District-3 Civil C000268, 1987

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