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The Pulmonary Artery Catheter in Anesthesia Practice

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Catheterization of the heart in man with use of a flow-directed balloon-tipped catheter. By J. H. C. Swan, W. Ganz, J. Forrester, H. Marcus, G. Diamond, and D. Chonette. N Engl J Med 1970; 283:447–51. Reprinted with permission.

Pressures in the right side of the heart and pulmonary capillary wedge can be obtained by cardiac catheterization without the aid of fluoroscopy. A No. 5 French double-lumen catheter with a balloon just proximal to the tip is inserted into the right atrium under pressure monitoring. The balloon is then inflated with 0.8 ml of air. The balloon is carried by blood flow through the right side of the heart into the smaller radicles of the pulmonary artery. In this position when the balloon is inflated wedge pressure is obtained. The average time for passage of the catheter from the right atrium to the pulmonary artery was 35 s in the first 100 passages. The frequency of premature beats was minimal, and no other arrhythmias occurred.

MORE than 30 yr ago, my colleagues and I published an article entitled "Catheterization of the Heart in Man with the Use of a Flow-directed Balloon-tipped Catheter" in the *New England Journal of Medicine*,[1] and during the next few years, the pulmonary artery catheter (PAC) became a standard in the management of serious illnesses. It was possible to measure cardiac output and stroke volume and pulmonary artery and pulmonary wedge pressures with an accuracy and precision adequate for clinical use. The PAC was introduced initially to conduct a safe and rapid right heart catheterization (RHC) in patients with acute myocardial infarction. Successful application in these patients, with few complications, resulted in general application and acceptance in several specialties, of which the most important was in anesthesia for complex surgical procedures, a situation in which potential cardiopulmonary complications are increased. The PAC procedure is under the direction and control of qualified anesthesiologists and independent of any third party. Understanding of the physiology of anesthesia and surgical procedures was advanced with the invention of this innovative tool. The PAC was developed through a positive cooperative relationship between me and William Ganz, M.D., Ph.D. (Professor, Cedars of Lebanon Hospital, Los Angeles, California), as physician scientists, and Edwards Laboratories (Los Angeles, California), a division of the American Hospital Supply Corporation, a manufacturer of medical devices.

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Historical Background

I was born in Ireland in 1922 and graduated from St. Thomas' Hospital Medical School, London, United Kingdom, in 1945. I knew the late Derek Wiley (Consultant Anesthesiologist, St. Thomas Hospital) and was a classmate of Harry Churchill-Davidson (Consultant Anesthesiologist, St. Thomas Hospital), gentlemen who were later coauthors of an authoritative text on anesthesiology. I obtained a Ph.D. in human physiology under the direction of the late Henry Barcroft, F.R.S. (Professor, Department of Physiology, Queens University, Belfast, Ireland, 1935–1948), a man whose kindest encouragement and support were essential to my future intellectual growth. In 1951, I started a 2-yr fellowship at the Mayo Clinic in Rochester, Minnesota, and, under the strong influence of Dr. Earl Howard Wood (Professor, Department of Physiology, University of Minnesota, Mayo Clinic, Rochester, Minnesota, 1951–1982, currently retired), developed skills in the new procedures of cardiac catheterization. As director of the Mayo Laboratory at St. Mary's Hospital in Rochester, I developed skills in cardiovascular diagnostic investigation and, in partic-

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Dr. Swan, an innovative cardiologist who had an illustrious career in basic and clinical cardiac physiology, died on February 7, 2005. To the best of our knowledge, this was his last manuscript.

ular, in the management of small infants and critically ill adults. I was impressed with the frequency of atrial and ventricular ectopy during catheter manipulation and with the autopsy evidence of frequent subendocardial hemorrhage due to the stiff catheters then in use. Induced arrhythmias were often of serious import, difficult to manage, and unacceptable in a diagnostic procedure. Movement of sick patients from a hospital bed to a separate, specialized facility was a serious practical disadvantage. In 1965, after 14 yr at Mayo, I accepted the position of Chief of the Division of Cardiology at Cedars-Sinai Medical Center in Los Angeles, California, with the rank of Professor of Medicine at the University of California at Los Angeles, California.

William Ganz was born in Czechoslovakia in 1919. After the defeat of the Nazis, he returned to complete his medical studies at the Charles University in Prague, Czech Republic, obtaining his M.D. degree in 1947. He was appointed Director of Coronary Research at the Cardiovascular Institute in Prague, with the academic degree of Ph.D. Frustrated with the political situation in Czechoslovakia, he and his family immigrated to Los Angeles in 1966. Already an established scientist with a special interest in thermodilution blood flow measurement, he joined my embryonic department of cardiology at Cedars-Sinai Medical Center, with the rank of Professor of Medicine at the University of California, Los Angeles.

I had found that the patient mix at Cedars-Sinai differed from that at Mayo and that ischemic heart disease dominated the population. With my "catheter background," it was apparent to me that a safe approach to RHC was essential if this disorder was to be better understood. From my previous experiences, two fundamental issues seemed evident: Conventional catheters caused ectopy, and manipulation through the right heart chambers required stiff or semistiff catheters. A former student of mine from 1950 London, Ronald Bradley, M.D. (Consultant, St. Thomas Hospital), now a well-respected intensivist, had reported successful bedside RHC using fine-gauge silastic tubing. My own experience with this device was unsatisfactory, in that ectopy was still frequent, and failure to reach the pulmonary artery was common and almost universal in heart failure patients. Here, serendipity played its part. In the fall of 1969, I was on the beach in Santa Monica, California, with my young children and noted a sailboat with a large spinnaker making good progress in a calm sea. I wondered whether a sail or parachute at the tip of a flexible catheter would solve the problem. I had been a consultant to Edwards Laboratories for several years and brought this proposal for discussion. David Chonette, new product manager, did not favor the solutions suggested, but proposed a small inflatable balloon that would be relatively easy to fabricate. The balloon worked superbly, and sail and parachute were abandoned as the guidance device. After brief additional experience in the animal laboratory by Ganz, we used the device for human RHC, with and without fluoroscopy, with equally gratifying results. The effectiveness of right heart and pulmonary artery catheterization without fluoroscopy or catheter manipulation was proven within the week, and the near absence of ectopy during passage of the catheter was an important bonus. Ganz's experience in thermodilution led to the later incorporation of a thermistor into the catheter shaft and the development of a reliable method for the measurement of cardiac output at the bedside.

Federal device legislation and institutional review boards did not exist at that time, so, with other colleagues, we proceeded directly to bedside catheterization in the coronary care unit. But the patients were safeguarded by the late, great, cardiology head nurse, Birdie Justice, R.N., who pronounced, "Dr. Swan, my nurses and I will cooperate fully with your studies, which must not interfere with our nursing care. But if I see any patient harmed by these procedures, then I will recommend they be forbidden." And so it was. There were no serious complications associated with catheter use, even in acute myocardial infarction patients. The value of the catheter was established one morning when a cardiac nurse reported in distress that the medical intensive care unit had "stolen" a catheter for a patient with acute pancreatitis. Elated, I counseled her that only things of value are stolen.

Our initial clinical objective was to perform RHC in a group of acute myocardial patients by a defined and rapid procedure not exceeding 30 min to determine the presenting hemodynamics in this disease. Although initially planned as a short procedure performed by physicians with traditional catheterization, our interest with the PAC quickly extended to several protocols, including outcomes and the effects of cardiac drugs, which required extension of the procedure time from several hours to 1–2 days and placement by noncardiologists. This new monitoring function also seemed to be well tolerated, although, logically, the likelihood of complications should have increased. More prolonged monitoring was reserved only for a minority of unstable patients who seemed to have a potential for survival.

As the number of users grew, others reported arterial and cardiac perforation on catheter insertion, pulmonary artery rupture, endocarditis, sepsis, and thrombosis. Our growing experience included infrequent isolated examples, but in small numbers. Matthay and Chatterjee[2] reported the incidence of serious complications as small, highlighting ". . . pneumothorax, 1%, pulmonary artery rupture, .01–.02%. . . . However, the risk of many of these complications has declined in the 1980s, probably because of better physician awareness of how to minimize complications." At that time, I was not aware of

reports of any serious complications from catheterization laboratories or anesthesia suites.

Clinical Trials as to Safety and Efficacy

Many small observational studies did not report excess mortality or morbidity with PAC use. Two large studies by Connors *et al.*[3] in 1996 and by Murdoch *et al.*[4] in 2000 resulted in strikingly differing conclusions. Murdoch's article has not been widely cited in the U.S. literature. Both used a "propensity score" to correct for disease acuity, because PAC use is more frequent in sick and terminal patients. Connors concluded that the PAC was associated with an unacceptable hazard, and a moratorium as to its use was recommended.[5] Murdoch concluded that PAC use *per se* did not result in excess mortality. No clear reason for the contradictions between these very large studies was given, but differences in practice standards, medical supervision, and more rigid criteria for PAC use may play a part. PAC use is less common in units with a full-time director, but the very simplicity of the procedure and its apparent safety allows many minimally trained physicians to use it. Also, the understanding and interpretation of hemodynamic findings in complex clinical situations is frequently poor. Both studies were associated with increased costs, and both failed to identify improved patient outcome with PAC use.

The Connors article resulted in several reports from interested societies. Support for a moratorium on PAC use was not forthcoming. Participants in the Pulmonary Artery Catheterization and Clinical Outcomes workshop stated that the need existed for collaborative education of physicians and nurses in performing, obtaining, and interpreting information from the use of PACs and, further, that this education should be led by professional societies with the purpose of disseminating standard education programs.[6] Topics given high priority for clinical trials were PAC use in persistent/refractory congestive heart failure, respiratory distress syndromes, severe sepsis and septic shock, and coronary artery bypass grafting surgery. The American Society of Anesthesiologists' (ASA) report, "Practical Guidelines for Pulmonary Artery Catheterization,"[7] states, "Clinical effectiveness in preoperative monitoring, postoperative monitoring, cardiac surgery, peripheral vascular surgery, obstetrics, gynecology, pediatric, hemodynamic disorders has been reported. Deaths attributable to PACs are 0.2–1.5% overall." Clinical experience suggests that use of PAC in selected surgical patients can reduce perioperative complications and might reduce the duration of stay. The ASA task force on Pulmonary Artery Catheterization believes they opined that having immediate access to a PAC is valuable. PAC data are more accurate than clinical assessment in evaluation of complicated patients. PAC trained nurses provide an important means of rapid communication of precise information. Experienced PAC users achieve better outcomes and encounter fewer complications because of enhanced skills.

Personal Commentary

The PAC is a diagnostic device only and, as such, has no therapeutic role. I believe increased mortality with PAC use is an association. PAC use is far more common in sicker patients, but complication risk is also increased with poorly trained, unsupervised personnel and long periods of continuous monitoring. Currently, effective treatments do not exist for many critical illnesses, and no benefit can logically be anticipated.

The basic contraindications for the use of the PAC are (1) the absence, in a life-threatening disease, of any rational treatment form that could improve outcome, or (2) a situation very unlikely to result in death or serious disability. PAC use should not be routine but should serve a specific purpose consistent with the clinical situation. Terminal or hospice patients are never candidates for a PAC.

The various recommendations of the professional societies involved are reasonable and, by now, should be implemented. (1) All persons who use PACs should undergo high-quality supervised training to establish confidence; (2) there should be quality improvement programs in place at all sites where PACs are used; (3) competency in the interpretation of catheter data should be based on predefined cognitive requirements; and (4) nurses who provide care to patients should be required to meet minimum training.[7]

I believe that credentialing or other assurance of competence should be considered. A "propensity score" might be developed to determine survival likelihood promptly and whether the PAC should be used. Perioperative PAC use in a surgical setting should be based on "the health state of the patient, the surgical procedure proposed, and the clinical characteristic of the practice setting" and, therefore, is never routine.

Use of the PAC requires adequate continued training of physicians and nurses. Little progress has been made in the understanding and correction of the physiologic, biochemical, and other aspects of many life-threatening states. Clinical trials have been and are recommended to clarify issues of utilization. Although accepted as the basic criterion for evidence-based medicine, alone they provide limited insight into the actual causes of disease, the clinical course, and improved treatment options. Clinical expertise is the combination of a critical knowledge of trial data and related genetic, biochemical, and physiologic factors and extensive clinical experience. In all disciplines, it is this clinical expertise—the combination of differing knowledge sources—that serves to advance understanding of diseases and improves outcomes. Such studies may not seem

attractive to regulators, but improved knowledge may reduce the necessity for a procedure or render it obsolete. So it is with the PAC. In anesthesiology,[8] only a proportion of operative patients may benefit from a PAC—perhaps those with more than one acute myocardial infarction, coexisting heart failure, additional vascular disease, and other unusual complications. However, defining who will best benefit cannot be accomplished by trials alone, because clinical needs vary from patient to patient, from doctor to doctor, and from institution to institution. A decision to use the PAC should be a matter for the expert and experienced clinician, who considers each aspect of an individual patient as a specific problem.

Our original study[1] used a device that is essentially unchanged in purpose and configuration, has been in use for close to four decades, has maintained its acceptance among physician users, has advanced knowledge in several fields, and has improved outcome in certain patients. It provides potentially relevant information to research investigators and to the doctors and nurses involved in patient care. Negative recommendations regarding PAC use during the past decade have not reduced utilization patterns. Indeed, there has been a steady, if modest, increase in its use.

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