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Practice Guidelines for Pulmonary Artery Catheterization

An Updated Report by the American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization

PRACTICE guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. The guidelines provide basic recommendations that are supported by analysis of the current literature and by a synthesis of expert opinion, open-forum commentary, and clinical feasibility data. The recommendations, although derived in part from evidence obtained in other countries, are intended for practitioners in the United States; elements of the recommendations and the principles on which they are based may also apply to practice settings in other countries.

The balloon-flotation pulmonary artery (PA) catheter was introduced in 1970.[1] PA catheter monitoring has expanded rapidly and broadly in clinical practice since the late 1970s. As of 1996, an estimated 2 million catheters were sold annually worldwide,[2] with an estimated 2 billion dollars spent in the United States alone.[3,4]

The appropriate indications for PA catheter monitoring have been debated for many years. The potential benefits of using the device are well known. Its use in measuring important hemodynamic indices (*e.g.*, PA occlusion pressure, cardiac output, mixed venous oxygen saturation) allows more accurate determination of the hemodynamic status of critically ill patients than is possible by clinical assessment alone. The additional information can be important in caring for patients with confusing clinical pictures, in whom errors in fluid management and drug therapy can have important consequences. In surgical patients, PA catheter data often help evaluate hemodynamic changes that may lead to serious perioperative complications. Preoperative PA catheter data are purported to be helpful in determining whether it is safe for high-risk patients to proceed with surgery.

PA catheterization can also have important adverse effects. Catheter insertion can result in arterial injury, pneumothorax, and arrhythmias. The catheter can be associated with potentially fatal PA hemorrhage, thromboembolism, sepsis, and endocardial damage.

The American Society of Anesthesiologists established the Task Force on Pulmonary Artery Catheterization in 1991 to examine the evidence for benefits and risks from PA catheter use in settings encountered by anesthesiologists. By the time the Society's guidelines were adopted in 1992 and published in 1993,[5] several groups had issued statements on the appropriate indications for PA catheterization and on competency requirements for hemodynamic monitoring. These groups included the American College of Physicians/American College of Cardiology/American Heart Association Task Force on Clinical Privileges in Cardiology,[6] a panel established by the Ontario Ministry of Health,[7] and an expert panel of the European Society of Intensive Care Medicine.[8]

In subsequent years, a variety of studies, most notably an investigation by Connors *et al.*,[9] raised doubts about the effectiveness and safety of pulmonary artery catheterization (PAC). This literature, and the controversy it stimulated, gave rise to additional policy statements from the American College of Chest Physicians (Northbrook, Illinois), American Thoracic Society (New York, New York), and the American College of Cardiology (Bethesda, Maryland)[10] and from such convocations as a consensus conference convened by the Society of Critical Care Medicine (DesPlaines, Illinois)[11] (subsequently endorsed by multiple organizations) and a 1998 workshop convened by the Food and Drug Administration (Rockville, Maryland) and the National Institutes of Health (Bethesda, Maryland).[12] Few of these efforts fo-

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Developed by the American Society of Anesthesiologists Task Force on Guidelines for Pulmonary Artery Catheterization: Michael F. Roizen, M.D. (Chair), Department of Anesthesiology, SUNY Upstate, Syracuse, New York, and Department of Anesthesia and Critical Care, University of Chicago, Chicago, Illinois; David L. Berger, M.D. (Private Practice), Piedmont, California; Ronald A. Gabel, M.D., Department of Anesthesiology, University of Rochester, Rochester, New York; John Gerson, M.D. (Private Practice), Syracuse, New York; Jonathan B. Mark, M.D., Department of Anesthesiology, Duke University Medical Center, Durham, North Carolina; Robert I. Parks, Jr., M.D. (Private Practice), Dallas, Texas; David A. Paulus, M.D., Department of Anesthesiology, University of Florida, Gainesville, Florida; John S. Smith, M.D. (Private Practice), Las Vegas, Nevada; and Steven H. Woolf, M.D., M.P.H. (Methodology Consultant), Department of Family Practice, Virginia Commonwealth University, Fairfax, Virginia. Submitted for publication November 20, 2002. Accepted for publication November 20, 2002.

Address reprint requests to the American Society of Anesthesiologists: 520 North Northwest Highway, Park Ridge, Illinois 60068-2573. Individual Practice Guidelines may be obtained at no cost through the Journal Web site, www.anesthesiology.org.

cused their deliberations on the role of PAC in the perioperative setting.

The American Society of Anesthesiologists therefore reconvened the Task Force on Pulmonary Artery Catheterization in 2000 to review its 1993 guideline, consider evidence and policy concerns that have emerged in the interim, and issue an updated guideline. This report summarizes the Task Force's recommendations and rationale.

Methodology

Task Force documents and primary evidence are available at the Wood Library, American Society of Anesthesiologists, Park Ridge, Illinois.

A. Task Force Composition

The members of the Task Force were originally selected by the American Society of Anesthesiologists Committee on Practice Parameters and by the Task Force chair. Members were invited to reprise their roles on the Task Force for the current update. The nine-member Task Force included four university-based anesthesiologists, four community-practice anesthesiologists, and a methodologist. Median experience with PA catheter use among the eight anesthesiologists was 21 yr (range, 18–29 yr). Task force members used an average of nine PA catheters per month, primarily for cardiovascular surgery cases. Current monthly averages were 0–3 for four panel members, 10–12 for three panel members, and 31 for one panel member.

Reliable national data are lacking to assess whether these practice patterns are representative of PAC use among most anesthesiologists, even for those who regularly care for high-risk patients. A survey of 1,000 critical care physicians revealed that 12% inserted no catheters, 60% inserted one to five catheters per month, and 27% inserted six or more catheters per month.[13] An anonymous cross-sectional survey of 214 anesthesiologists in Canada and the United States reported that physicians practicing in sites with transesophageal echocardiography (TEE) availability averaged 17.6 cardiovascular cases per month, whereas those practicing in sites without TEE availability anesthetized 4.6 cardiovascular cases per month.[14] As a proportion of the total cases, fewer PACs were inserted when TEE was available (11.4/17.6, or 65%) as compared to when in it was not available (3.2/4.6, or 70%). In a survey of 170 attendees at the May 2001 meeting of the Society of Cardiovascular Anesthesiologists in Vancouver, British Columbia, Canada, 25% reported that they placed 0–5 PA catheters per month, 22% placed 5–10, 36% placed 10–25, and 17% placed more than 25.

B. Purpose and Focus

The objectives of the Task Force, as in its original effort, were to develop guidelines on the appropriate indications for PA catheter use. The purpose was not to describe how to perform the procedure or to interpret results. The Task Force sought to develop guidelines based on scientific evidence supplemented by expert opinion, and to follow a systematic methodology for reviewing evidence and developing recommendations. The guidelines were intended for situations encountered by anesthesiologists and the perioperative care team. They do not address the use of PA catheters in nonsurgical settings or by other medical specialists.

C. Process

In its original effort, the Task Force developed its recommendations following a systematic review of the clinical benefits and harms of PA catheterization. Benefits and harms were evaluated by reviewing relevant scientific evidence and incorporating expert opinion about effectiveness. The review was guided by an evidence model developed by the Task Force. In addition to clinical effects, the Task Force also considered public policy issues, such as costs and implementation issues and strategies. The current effort began by revisiting its earlier process and determining which aspects of the methodology to revise before proceeding with updating. Among the changes was a refinement of the evidence model (fig. 1).

D. Review of Scientific Evidence

Both the original review of scientific evidence in 1991–1992 and the update in 2000–2002 included a detailed literature search, a critical appraisal of individual studies to assess methodologic quality, and a synthesis of the results.

1. Literature Search. The original computerized and manual literature search was conducted in November 1991 and was updated in May 1992. It sought all relevant English-language articles or abstracts published after 1972. A total of 860 clinical trials, controlled observational studies, uncontrolled case series reports, and individual case reports were considered. The update in 2000–2002 involved three computerized literature searches of the MEDLINE database (conducted in September 2000, March 2001, and May 2002) for articles published between 1992 and 2002. The search sought all English-language articles or abstracts indexed under the Medical Subject Heading "Catheterization, Swan-Ganz." That search strategy retrieved 665 articles, 71 of which met inclusion criteria. A manual search (review of bibliographies, consultation with Task Force members) identified 19 additional articles, for a total of 90 new studies meeting inclusion criteria.

2. Admissible Evidence. Detailed exclusion criteria are described in table 1. The Task Force focused its

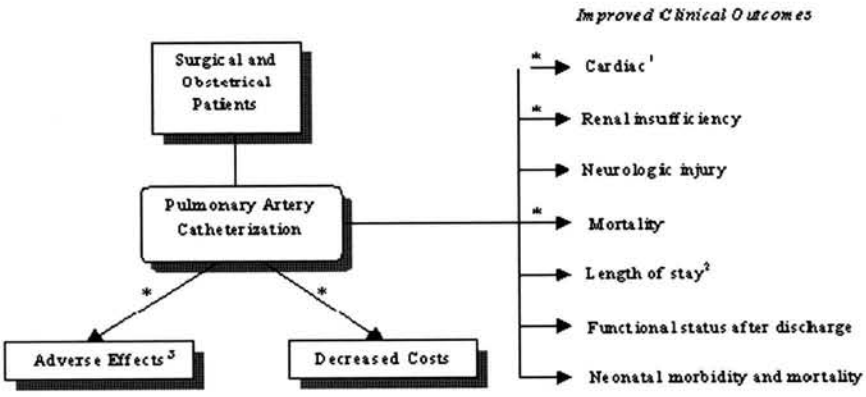

Fig. 1. Evidence model for literature review. The outcomes (benefits, harms, costs) listed in this model represent the potential effects of pulmonary artery catheterization identified by the Task Force before performing its literature review. The literature review was organized around this model to determine whether evidence existed to validate the potential benefits and harms that it had identified. Supporting evidence was found only for those linkages identified by an *asterisk*. Linkages not identified by an asterisk, which represent potential benefits that have not been studied, define important priorities for future research. [1] indicates a decreased incidence of myocardial infarction, arrhythmias, congestive heart failures; [2] indicates length of surgery, duration of stay in postanesthesia care unit and ICU, and total hospital stay; [3] indicates, for example, trauma, infection, dysrhythmias due to catheterization.

review on evidence of effectiveness based on clinical outcomes. PAC use was interpreted as including its diagnostic applications (in measuring PA pressures, cardiac output, mixed venous oxygen saturation, and other indices) and selected therapeutic uses (*e.g.*, pacing, PA venting). Systematic reviews and meta-analyses were included. Editorials, review articles, and letters were not systematically reviewed. The Task Force did not directly examine the accuracy of PA catheter monitoring, value of PA catheter data as predictors of morbidity and mortality, or evidence of the effectiveness of treatment for PA catheter-detectable conditions. The Task Force did not evaluate the effectiveness of alternate hemodynamic monitoring technologies (*e.g.*, TEE), although it recognizes that in settings in which TEE is available and appropriate it may supplant the need for PAC.[15] Issues related to the performance of PA catheterization, such as rates of utilization, practitioner skill, resource constraints imposed by staff and equipment availability, medicolegal concerns, and reimbursement, were not a specific focus of the literature review. A focused review of the "learning curve" literature was performed to examine what is known about the number of procedures physicians must perform to acquire and to maintain cognitive and technical skills.

Table 1. Exclusion Criteria for Literature Search

- Articles in which only the title is in English language; also excludes articles that fail to present English-language abstract on Medline.
- Physiologic research in which PA catheterization is used to understand disease process.
- Studies about pulmonary artery and not PA catheter.
- Studies examining correlation of PA catheter data with other variables.
- Comparison of PA catheterization with other technologies in detecting physiologic parameters, with no description of clinical outcomes.
- Routine care and maintenance (*e.g.*, nursing aspects), technical suggestions on procedure, factors that affect measurements.
- Descriptions of surgical techniques and other procedures (*e.g.*, stress tests, ventilation techniques, drug therapy) in which PA catheter was used if not addressing outcomes of interest. A "package" of interventions that included PA catheterization and was evaluated by outcomes of interest to the Task Force was included.
- Studies examining role of PA catheterization in detecting intermediate physiologic changes (*e.g.*, elevated PA occlusion pressure) that are not linked directly to clinical outcomes.
- Benefits of PA catheterization for rare diseases.
- Use of PA catheter outside of pulmonary artery (*e.g.*, bronchus).
- Therapeutic balloon catheter procedures in congenital heart disease (*e.g.*, atrial septostomy, valvuloplasty).
- Studies reporting the first occurrence of an adverse effect.
- Studies of techniques to prevent adverse effects.
- New and investigational uses of PA catheters.

See also discussion in text regarding categories of evidence that were not reviewed.

PA = pulmonary artery.

3. Evaluation of Individual Studies. The methodologic quality of individual studies was assessed in a systematic manner by considering study design category (*e.g.*, observational *vs.* experimental design) and the quality of the research methods (*e.g.*, statistical power, selection bias, measurement error, confounding variables, internal and external validity). The Task Force recognized the general superiority of randomized controlled trials over observational studies in evaluating the effect of interventions on outcomes.

4. Synthesis of Results. The synthesis was narrative and utilized traditional evidence tables. Evidence of effectiveness was not suitable for formal meta-analysis.

E. Assessment of Expert Opinion of the Task Force

The expert opinion of the Task Force was assessed in its original guideline by informal consensus development. It was later suggested that such opinions should be assessed according to a more formal group consensus process.[16,17] In this update, the Task Force used a confidential voting scheme to assess the appropriateness and necessity of PAC, specifying its views for 27 clinical scenarios. The 27 scenarios considered each potential

Table 2. Definitions for Clinical Scenarios and Ratings Used in Voting Exercise

Terms	Definition
Patient	
Low-risk	ASA 1 or 2, hemodynamic disturbances unlikely to cause organ dysfunction
Moderate-risk	ASA 3, hemodynamic disturbances that occasionally cause organ dysfunction
High-risk	ASA 4 or 5, hemodynamic disturbances with a great chance of causing organ dysfunction or death
Surgery	
Low-risk	Small probability of fluid changes or hemodynamic disturbances, low perioperative morbidity or mortality
Moderate-risk	Moderate chance of fluid changes, hemodynamic disturbances, or infection that could cause morbidity or mortality
High-risk	Large chance of fluid changes or hemodynamic disturbances or other factors with high risk of morbidity and mortality
Practice setting	
Low-risk	Good catheter-use skills and technical support, training and experience of nursing staff in the recovery room and ICU, technical support for ancillary services, and availability of specialists and equipment to manage complications
Moderate-risk	Moderate catheter-use skills and technical support, training and experience of nursing staff in the recovery room and ICU, technical support for ancillary services, and availability of specialists and equipment to manage complications
High-risk	Poor catheter-use skills and technical support, training and experience of nursing staff in the recovery room and ICU, technical support for ancillary services, or availability of specialists and equipment to manage complications
Appropriate	May or may not be necessary, but doing it is not wrong
Necessary	Should be performed

ASA = American Society of Anesthesiologists; ICU = intensive care unit.

combination of patients, surgical procedures, and practice settings in low-, moderate-, and high-risk categories, as defined in table 2.

After considering the findings of the updated systematic review, seven Task Force members (one panel member was absent and one was not an anesthesiologist) completed an anonymous questionnaire at the second Task Force meeting, assigning scores for the appropriateness and necessity of PAC in each of the 27 scenarios. Task Force members were unaware of the votes taken by other Task Force members. A 1–9 scale was used, with 1 representing the most inappropriate (or unnecessary) indications and 9 indicating the most appropriate (or necessary) indications. The definition for *appropriate* set more liberal boundaries ("may or may not be necessary, but doing it is not wrong") than that for *necessary* ("should be performed"). The distinction allowed for circumstances in which catheterization is appropriate but not mandatory ("necessary") and, conversely, unnecessary but not inappropriate. The median (and distribution) of the scores for each of the 27 scenarios was reviewed by the group (without disclosing the votes taken by individual members) and was used as a basis for formulating recommendations. PAC was considered appropriate (or necessary) when median scores were in the range of 7 through 9 and inappropriate (or unnecessary) when in the range of 1 through 3. The definitions of low-, moderate-, and high-risk were not expounded beyond the level of detail provided in table 2 (*e.g.*, giving examples of specific operations that are high-risk) because these judgments depend on local circumstances, but this decision was made with a conscious recognition that the lack of specificity creates some ambiguity in how the categorizations might be interpreted and applied.

F. Assessment of Public Policy Issues

Costs and implementation issues were considered by the Task Force only after the clinical benefits and harms of PA catheterization were studied. The Task Force's recommendations were based on perceived clinical benefits, harms, and cost-effectiveness of PA catheterization. Cost information provided in published clinical research was reviewed, but the Task Force did not seek out cost data from other sources (*e.g.*, payers, manufacturers).

G. Public Forum

The Task Force's first guideline was informed by a widely publicized open forum on the proposed guidelines, which was held in San Francisco in March 1992 at the annual meeting of the International Anesthesia Research Society. A similar vetting of the update occurred at open forums held at the March 2001 meeting of the International Anesthesia Research Society in Fort Lauderdale, Florida, and at the May 2001 meeting of the Society for Cardiovascular Anesthesiologists in Vancouver, British Columbia, Canada.

Attendees at both sessions were invited to complete the same survey that panel members used to vote on the appropriateness and necessity of PA catheterization in 27 clinical scenarios. Seven attendees at the International Anesthesia Research Society meeting completed the surveys before the panel votes were presented. The five attendees at the Society for Cardiovascular Anesthesiologists who completed the survey were given clinical examples to illustrate the risk categories and were asked to answer questions about their clinical background. More than half indicated that they had used PA catheters for longer than 15 yr; 50% used the catheters 5–10 times per month, and 40% used them 11 or more times per month. The proportion that used them more than 30% of

Table 3. Outside Reviewers

Content experts
Thomas J. Iberti, M.D., F.C.C.M., F.C.C.P. (Deceased) Director, Critical Care Associate Professor of Surgery, Medicine, and Anesthesiology Mount Sinai Medical Center New York, New York
Nathan L. Pace, M.C. Professor of Anesthesiology Adjunct Professor of Bioengineering University of Utah Salt Lake City, Utah
Jeffery S. Vender, M.D., F.C.C.M. Chairman, Department of Anesthesiology Director, Critical Services Evanston Northwestern Healthcare Professor and Associate Chairman Northwestern University Medical School Chicago, Illinois
Organizational reviewers
American College of Cardiology American College of Physicians American College of Surgeons
Organizations that received but did not review the document
Agency for Healthcare Research and Quality American College of Obstetricians and Gynecologists American College of Pediatricians

the time was 100% for open-heart chamber cardiac cases, 60% for closed-heart chamber cardiac cases, 73% for off-pump bypass cases, 75% for aortic valve cases, and 100% for peripheral leg vascular cases.

H. Peer Review

The guideline underwent peer review by experts in PA catheterization and by relevant specialty societies and organizations. Reviewers are listed in table 3.

Clinical Effectiveness of Pulmonary Artery Catheterization

Clinical effectiveness was judged by considering the benefits and harms of PA catheterization. Clinical benefits and harms were evaluated by reviewing relevant scientific evidence and expert opinions of effectiveness held by the Task Force and reviewers.

A. Scientific Evidence of Effectiveness

The results and design of individual studies are reviewed next. The results of the controlled studies are summarized in table 4.

1. Benefits

a. Effect on Treatment Decisions. Survey studies in postoperative and intensive care units have demonstrated that PA catheter data provide new information or seem to change therapy in 30–62% of cases.[18–25] The clinical significance of these changes is uncertain. Treatment modifications were judged important in 25% of adults[21] and in 10% of children[26] monitored by PA catheter. Studies have found no association with mortality among patients whose therapy is altered based on PA catheter data.[22–24] In one study, the added information from mixed venous oxygen monitoring changed the therapy in 57% of patients undergoing cardiac surgery, but the changes were not associated with improved outcomes.[27] A subgroup analysis in one cohort study reported that patients with shock unresponsive to standard therapy had significantly lower mortality rates when PAC hemodynamic data led to a change in therapy than when therapy was unmodified.[24]

The quality of this evidence is poor. The conclusions are based largely on self-reported data in questionnaires, which are subject to measurement and recall biases. Most studies were unblinded and, in many cases, judgments about whether treatment was altered based on PA catheter data were made subjectively. Sample sizes were inadequate to conclude that alterations in treatment had no effect on mortality, and clinical outcomes beside mortality were generally not examined.

b. Preoperative Catheterization. Uncontrolled case series reports have shown that preoperative PA catheterization is associated with cancellation or modification of surgical procedures and with altered hemodynamic management, and investigators have concluded that it therefore prevents morbidity and mortality.[28,29] Controlled trials attempting to confirm this hypothesis have yielded mixed results and suffer from design limitations. *Post hoc* data analysis in one trial demonstrated a lower mortality rate in patients who were monitored preoperatively than in patients who were first monitored after surgery, but control for confounding was limited.[4] Another trial suggested that preoperative catheterization reduced intraoperative complications and graft thrombosis in patients undergoing peripheral vascular surgery,[30] but it also was vulnerable to confounding.[31]

Conversely, a trial examining routine catheterization before elective vascular surgery reported no significant differences in mortality or complications, but the sample was small and excluded high-risk patients.[32] An observational study found no difference in outcomes between elderly patients who did not undergo preoperative catheterization and unmatched patients who were admitted to the hospital during the same time period for other reasons.[33] The similar outcomes may have been due to selection biases. In summary, no high-quality evidence exists to infer that routine, or even selective, preoperative catheterization improves outcomes regarding hemodynamic optimization).

c. Perioperative Monitoring. For many years, the principal evidence regarding the benefits of hemodynamic monitoring in the surgical setting was limited to nonrandomized observational studies. For example, a historical control study of 733 patients found that patients with previous myocardial infarction who underwent noncardiac surgery during a period when invasive hemody-

Table 4. Evidence Table: Controlled Studies of PA Catheterization with Clinical Outcomes

Study	n	Clinical Setting	Study Design	Significant Clinical Outcomes	Comment
Intensive care of surgical patients					
Connors *et al.* (1996)[9]	5,735	Critical illness in intensive care	Prosp-cohort; groups = PAC, no PAC	Higher mortality, longer length of stay	Propensity score for confounding; no data on mechanism for harm; limited inclusion of surgical patients; high-risk group
Tuchschmidt *et al.* (1992)[37]	26/25	Septic shock	RCT; groups = high cardiac index goal, normal CI goal	Lower mortality, length of stay	Randomization method not described; postrandomization exclusions; no blinding or concealment of allocation; violation of intention-to-treat analysis
Boyd *et al.* (1993)[36]	53/54	Surgical patients	RCT; groups = high pre- and postoperative oxygen delivery index, normal index	Lower 28-day mortality, mean complications per patient	No concealment of allocation; anesthesiologist and surgeon blinded, intensive care team and chart reviewers not blinded; study terminated early; intention-to-treat analysis; external validity limited to high-risk groups
Yu *et al.* (1993)[38]	35/32 (5 removed)	ICU patients with PAC, 85% surgical, with sepsis and ARDS	RCT; groups = high oxygen delivery index, normal delivery index	None (by original design); *post hoc* mortality differences in subgroups	5 patients removed postrandomization; no blinding or allocation concealment; no power calculations; control group also reached high oxygen delivery; violation of intention-to-treat analysis
Hayes *et al.* (1994)[40]	50/50	High-risk critical care patients (mostly surgical) who did not reach target values with fluid resuscitation	RCT; groups = high cardiac index and increased oxygen delivery and consumption, usual care	No difference in length of stay, higher in-hospital mortality rate	No concealment of allocation or blinding; well-specified intervention; oxygen consumption not different between groups; many PACs inserted postoperatively, often after complications on ward; trial stopped early because of higher mortality
Gattinoni *et al.* (1995)[41]	252/253/257	High-risk patients admitted to 56 ICUs (high-risk after surgery, one of 5 risk groups)	RCT; groups = normal cardiac index, supranormal cardiac index, normal Svo_2	No difference in mortality, organ dysfunction, length of stay	No allocation concealment or blinding; telephone randomization using permuted block algorithm to stratify by ICU; baseline differences in oxygenation and PA parameters; no power calculations; intention-to-treat analysis
Yu *et al.* (1995)[39]	89	Critically ill patients admitted to surgical ICU, all with PAC	RCT; groups = Do_2 of $\geq$600 ml · min · m^{-2}, Do_2 of 450–550 ml · min · m^{-2}		Allocation procedures unclear; no blinding or allocation concealment; no power calculations; no difference in oxygen delivery; violation of intention-to-treat analysis; *post hoc* data analysis
Valentine *et al.* (1998)[42]	60/60	Low-risk elective abdominal aortic reconstruction	RCT; groups = preoperative PAC with optimization + intraoperative PAC, no PAC	Increased intraoperative complications	Concealed allocation, prerandomization exclusions, no blinding, low-risk group, intention-to-treat analysis only for intraoperative outcomes, high complication rates in both groups limiting external validity

(continues)

Table 4. (continued)

Study	n	Clinical Setting	Study Design	Significant Clinical Outcomes	Comment
Wilson *et al.* (1999)[44]	92/46	High-risk patients undergoing major elective surgery	RCT; groups = preoperative optimization including postoperative ICU (half adrenaline, half dopexamine), usual care	Lower hospital mortality (both intervention groups), lower morbidity and length of stay (dopexamine group)	Concealed allocation, blinding to dopexamine *vs.* adrenaline, large drop-out before randomization, large proportion of control patients (16) did not obtain postoperative intensive care, lack of details on causes of death
Pölönen *et al.* (2000)[46]	196/197	Consecutive elective cardiac surgery patients	RCT; groups = postoperative optimization, standard care	Shorter hospital stay and faster discharge, fewer patients with organ dysfunctions	Concealed allocation, no blinding, intention-to-treat analysis
Preoperative catheterization					
Shoemaker *et al.* (1988)[35]	146	General surgery in high-risk patients	RCT; groups = CVC, PAC-normal, PAC-supranormal	Lower postoperative mortality, mean ICU stay, ventilator use in PAC-supranormal group	Small sample size, poor control for confounding, uncertain case mix
Berlauk *et al.* (1991)[30]	89	Vein graft arterial bypass for limb salvage	RCT; groups = PAC 12 and 3 hr before surgery, no preoperative PAC	Fewer intraoperative hemodynamic disorders and postoperative graft thromboses	Uncertain group assignment methods, discrepancies in data reporting regarding cardiac morbidity
Bender *et al.* (1997)[32]	51/53	Elective infrarenal aortic reconstruction or lower limb revascularization	RCT; groups = routine preoperative PAC, PAC for complications	None	Inadequate power; no blinding or concealment of allocation; case mix differences; excluded very high-risk patients
General perioperative catheterization					
Rao *et al.* (1983)[34]	733/364	Noncardiac surgery in patients with prior myocardial infarction	Obs-historical controls; 1977–1982 cohort *vs.* 1973–76 cohort	Lower perioperative reinfarction and mortality rates in study cohort	Historical controls, nonrandom selection, uncertain case mix, role of hemodynamic monitoring unclear
Polanczyk *et al.* (2001)[96]	215/215	Major noncardiac surgery	Prosp-matched cohort; groups = PAC, no PAC	Higher postoperative CHF in PAC group	Nonrandom selection, matched pairs
Cardiac surgery					
Pearson *et al.* (1989)[66]	226	Elective cardiac surgery	RCT; groups = CVC, PAC, PAC with mixed venous oxygen	None	Small sample size, significant crossover between groups
Tuman *et al.* (1989)[63]	1,094	Elective CABG	Controlled prospective cohort	Mean ICU stay greater in PAC high-risk group than CVC group	Nonrandom selection, uncertain case mix
Stewart *et al.* (1998)[64]	133/61	Patients undergoing CABG meeting criteria for CVC	Retrosp-cohort; groups = CVC, PAC	Increased overall complications, longer intubation time	Retrospective chart review, known differences in case mix
Ramsey *et al.* (2000)[65]	8,064/5,843	Nonemergent CABG at 56 hospitals	Retrosp-cohort; groups = PAC, not PAC	Higher in-hospital mortality, length of stay	Retrospective analysis of administrative data from HBSI EXPLORE database, case mix adjustment by APR-DRG
Aortic reconstruction					
Isaacson *et al.* (1990)[72]	102	Abdominal aortic reconstruction	RCT; groups = CVC, PAC	No difference in morbidity, mortality, ICU, or hospital stay	Possible type II error
Joyce *et al.* (1990)[71]	40	Abdominal aortic aneurysm repair	RCT; groups = CVC, PAC. Comparison group of 11 high-risk patients	ICU stay longer in CVC and high-risk patients (combined) then PA catheter	Small sample size, comparison of CVC and PAC ICU stay not reported

(continues)

Table 4. (continued)

Study	n	Clinical Setting	Study Design	Significant Clinical Outcomes	Comment
Hesdorffer *et al.* (1987)[68]	61/87	Abdominal aortic aneurysm repair	Obs-historical controls; 1983–84 cohort *vs.* 1980–1982 cohort	Lower perioperative hypotensive episodes and mortality in study cohort	Historical controls, nonrandom selection, does not compare PAC use, inconsistent data, uncertain attrition, statistical significance not reported.
Trauma					
Fleming *et al.* (1992)[78]	33/34	Trauma patients with EBL of at least 2,000 ml, mostly surgical	RCT; groups = intra- or postoperative PAC with optimization, PAC as per surgeon	Fewer organ failures/ patient, ventilator days, ICU stay	No blinding or allocation concealment, possible baseline differences in groups, reported number of organ failures (possibly more subject to bias) but not patients with organ failure
Bishop *et al.* (1995)[79]	50/65	Trauma patients with EBL of at least 2,000 ml, pelvic fracture	RCT; groups = postoperative PAC + optimization, PAC as per surgeon	Lower mortality, organ failures/patient, ventilator days, ICU stay	No description of randomization methods, no blinding or allocation concealment, possible baseline differences in size and characteristics of groups
Durham *et al.* (1996)[80]	27/31	Critically ill (mostly trauma) patients with PAC	Groups = optimization, conventional resuscitation	No effect	No blinding or allocation concealment, unclear subject allocation, 26% of intervention group did not meet goals, no power calculations
Schiller *et al.* (1997)[76]	53/33/30	Life-threatening burns	Retrosp-cohort; groups = PAC, irregular PAC (historical), PAC + optimization	Lower mortality and organ failure, especially for group with optimization	Subject allocation nonrandom, historical controls selected arbitrarily by resident, comparability of groups unclear, no adjustment for confounding
Chang *et al.* (2000)[77]	20/39	Critically injured patients with PAC	Prosp/retrosp-cohort; groups = optimized LVP, oxygen transport criteria	Lower organ dysfunction	Historical controls, confounding variables, lack of adjustment for confounding

ARDS = acute respiratory distress syndrome; CABG = coronary artery bypass graft; CHF = congestive heart failure; CI = cardiac index; CVC = central venous catheterization; Do_2 = oxygen diffusion; EBL = estimated blood loss; ICU = intensive care unit; LVP = left ventricular pressure; Obs = observational; PA = pulmonary artery; PAC = pulmonary artery catheterization; Prosp = prospective; RCT = randomized clinical trial; Retrosp = retrospective; Svo_2 = mixed venous oxygen saturation.

namic monitoring was common had lower reinfarction and mortality rates than patients in previous years during which invasive monitoring was less common.[34] It is unclear from this study whether hemodynamic monitoring or other temporal factors were responsible for the improved outcomes and whether the two groups of nonrandomly selected patients were comparable in terms of case mix and severity of illness.

A subsequent randomized controlled trial involving 146 patients found no difference in intraoperative mortality, length of hospital stay, length of intensive care unit (ICU) stay, ventilator use, or postoperative mortality when surgical patients monitored by PA catheter were compared with central venous catheter (CVC)-monitored patients.[35] However, sample size may have been inadequate to reveal a true benefit. Patients monitored by PA catheter who were managed with the goal of achieving supranormal metabolic goals seemed to have significantly lower postoperative mortality, length of ICU stay, and ventilator use.[35] Because of uncertain methodology and inconsistent data reporting, it is unclear whether this group of patients differed in case mix from other patients monitored by PA catheter, but the findings stimulated research efforts to confirm the benefits of goal-directed therapy.

Goal-directed therapy. Most studies of goal-directed therapy have been conducted in the ICU and have included, primarily or exclusively, surgical patients monitored by PAC. One randomized trial involving 107 high-risk surgical patients found that a pre- and postoperative protocol to achieve high oxygen delivery rates was associated with significantly lower 28-day mortality and complication rates.[36] Although a smaller trial with design flaws also reported encouraging results—a higher cardiac index was associated with lower mortality in patients with septic shock[37]—subsequent randomized trials of goal-directed therapy have been less encouraging.

Two trials from the same center reported no reduction in mortality, organ dysfunction, or length of stay, although they failed to achieve a difference in oxygen

delivery between the two groups.[38,39] *Post hoc* data comparisons suggested a significant mortality reduction in patients who achieved high oxygen delivery levels, but this disregarded intention-to-treat analysis. Another trial examined the benefits of increased oxygen delivery in 100 high-risk, critically ill patients who did not reach target values with volume expansion. The authors reported increased in-hospital mortality rates and no significant improvements in surrogate outcomes (days of ventilation, length of stay).[40] The protocol was unsuccessful in significantly improving oxygen consumption, however, and PAC insertion often did not occur until after surgery when complications occurred on the ward. The largest trial involved 762 high-risk patients admitted to 56 ICUs; surgical patients comprised only one of five subgroups. The trial reported no difference in mortality, organ dysfunction, or length of stay when the goals of normal cardiac index, supranormal cardiac index, and normal mixed venous oxygen saturation were compared.[41] A trial in the setting of aortic surgery compared patients receiving PAC with preoperative and intraoperative goal-directed therapy and patients receiving no PAC. The PAC group had significantly more intraoperative (but not postoperative) complications, but complication rates even in the control group exceeded current norms, raising questions about the external validity of the study.[42]

A randomized trial in an urban emergency department of patients admitted with severe sepsis or septic shock compared 130 patients receiving 6 h of early goal-directed therapy with 133 patients receiving standard therapy before admission to the ICU.[43] Twenty-eight day mortality was significantly lower for the early goal-directed therapy group, with a relative risk of 0.58 (95% CI, 0.39–0.87). A special mixed venous oxygen sensing central venous catheter was used in this study; therefore, this article does not fit the evidence model as described above, nor does it describe the effect of PAC guided therapy. However, it confirms a benefit to "goal-directed therapy" for this specific subgroup of patients and suggests that other monitoring techniques to guide goal-directed therapy (including PAC) may also lead to beneficial outcomes.

A trial in Britain involving 138 patients undergoing major elective surgery reported positive results, including a significant reduction in mortality, for patients who underwent PAC-guided preoperative optimization as part of a protocol that included return to a high-dependency or intensive care unit following surgery.[44] Because 16 patients in the control group did not receive postoperative intensive care, it is unclear to what extent the observed outcomes were due to the latter and not optimization.[45]

A Finnish trial involving 393 patients undergoing cardiac surgery reported that length of stay was slightly shorter (median of 6 rather than 7 days) and hospital discharge faster for the group randomized to receive goal-oriented therapy postoperatively.[46] Although it was not a primary outcome measure, the proportion of patients with organ dysfunctions on the day of discharge was significantly lower (1% *vs.* 6%) in the intervention group. Other outcomes, including prolonged stays in intensive care and mortality rates, did not differ between groups.

Hemodynamic monitoring. Hemodynamic disturbances, for which PAC is often useful in the perioperative setting, have been the context for studies of PAC involving medical patients who did not necessarily undergo surgery. Some of these studies are reviewed here because the hemodynamic disorders that prompted PA catheter use (*e.g.*, myocardial infarction, sepsis, pulmonary edema) include the principal risk factors for which surgical patients often undergo PA catheterization.

Uncontrolled studies have produced inconsistent findings.[47,48] A study with historical controls reported that mortality in patients with septic shock decreased during a period in which use of PA catheters had increased, but the study design provided weak evidence that PA catheters had a causal role.[49] Studies with control groups have generally found that patients with myocardial infarction and other hemodynamic disorders who are monitored by PA catheters have a higher in-hospital mortality, longer hospital stay, and shorter long-term survival than patients who do not undergo PA catheterization.[50–52] Although these studies have included large samples (300–6,000 patients), their designs were retrospective and failed to control adequately for differences in severity of illness, selection bias, and variation in catheter use. The data therefore do not clarify whether patients who underwent PA catheterization were sicker than unmonitored patients.

The most careful effort to control for this form of confounding was a cohort study of the effects of PAC in 5,735 critically ill medical patients who entered a trial during the initial 24 h of their ICU stay.[9] The investigators developed a "propensity score" to adjust for over 30 demographic, prognostic, and physiologic variables known to be associated with PAC use. In an analysis that paired patients by propensity scores (to eliminate confounding variables other than whether patients received PAC), the investigators observed that patients who received a PAC were 24–27% more likely to die within 1–6 months and had longer admissions and required more intensive care. The hazard rate for PAC use was even higher for the subset of patients receiving postoperative care—their risk of death in association with PAC was increased by 58% (95% CI, 1.17–2.13)—but the latter accounted for only 708 (12%) of the 5,735 patients in the study.

The authors noted the limitations of the study. Although the propensity score held up under several sensitivity analyses, it retained wide confidence intervals

and the authors could not exclude the possibility of a missing covariate. They noted, however, that for PAC to have a true hazard ratio of 0.8 (20% reduction in risk), a missing covariate would have to independently increase the risk of death and likelihood of PAC sixfold to explain the observed increase in mortality. Some contend that subtle clinical variables not addressed in the propensity score, such as physiologic trends over time and response to treatment, do have such an effect.[53] Others critique the magnitude of the estimated influence of a missing covariate.[10] Moreover, the study did not capture data on causes of death or on how patients were managed to know whether observed outcomes were due to the direct effects of PAC, level of skill in insertion or catheter use, therapies directed by the catheter, or other interventions associated with PAC.[54] Finally, the generalizability of the study to conventional perioperative monitoring is limited because surgical and trauma patients were poorly represented, the study cohort was severely ill (30-day mortality of 31–38%), and most patients had noncardiac disease.

i. Cardiac surgery. Uncontrolled observational studies that examined outcomes in cardiac surgery patients who were monitored by PA catheter[55–61] have been limited by the lack of comparison data from unmonitored patients. A small study that included historical controls found that 28 patients who underwent PA catheterization for repair of the left main coronary artery stenosis had lower rates of perioperative myocardial infarction, ventricular fibrillation, and deaths than 20 patients from the previous year who were monitored by CVC.[62] However, the historical design left unanswered questions about whether the results were attributable to temporal factors or differences in case mix.Studies that included internal controls found little benefit. A controlled prospective observational study of 1,094 patients found no difference in measured outcomes (*e.g.*, mortality, cardiac ischemia, postoperative myocardial infarction) among coronary artery bypass graft patients who were monitored by CVC, elective PA catheterization, or emergency PA catheterization.[63] High-risk patients who underwent elective PA catheterization had longer ICU stays and were more likely to receive vasopressor agents.

Other observational studies have suggested an adverse association between PAC and health outcomes. A retrospective study compared outcomes among 194 patients who met predetermined criteria for CVC, a third of whom were monitored by PAC to accommodate physician preference; the PAC-monitored patients had increased complications and duration of mechanical ventilation.[64] These differences and the lack of observed differences in other outcomes may have been attributable to the case mix, because patient assignment to groups was made selectively; for example, PAC-monitored patients were older and more likely to have congestive heart failure. Another study retrospectively reviewed administrative data on 13,907 patients who underwent nonemergent coronary artery bypass surgery at 56 hospitals in the United States. The 8,064 patients who received PAC, even after adjustment for case mix and other covariables, had significantly higher in-hospital mortality rates and length of stay than those who did not receive PAC. The association was strongest for hospitals that inserted fewer PACs per year.[65]

Whether such associations are due to PAC or other confounding variables is difficult to ascertain without conducting a randomized controlled trial. One such trial involving 226 patients found no difference in measured outcomes (deaths, length of ICU stay, use of vasopressors) between coronary artery bypass graft patients monitored by PA catheter and CVC, but this may have been attributable to the small sample size and selection biases. Fully 64% of patients in the control group were removed selectively after randomization if the anesthesiologist thought that they required PA catheterization.[66] In summary, there is conflicting evidence from controlled studies regarding the benefit that cardiac surgery patients receive from PA catheterization.

ii. Peripheral vascular surgery. A randomized controlled trial found that patients undergoing peripheral vascular surgery were less likely to experience intraoperative disorders (tachycardia, hypotension, arrhythmia) if PA catheters were placed preoperatively and if hemodynamic status was optimized.[30] The overall incidence of postoperative complications (renal failure, congestive heart failure, myocardial infarction, graft thrombosis, death) seemed to be lower in the patients monitored by PA catheter. This was due mainly to a higher incidence of postoperative graft thrombosis in the control group, which was attributed to poor cardiac output. Postoperative morbidity and mortality otherwise did not differ between groups. The reported data do not support the authors' conclusion that postoperative morbidity was reduced. The study was limited by discrepancies in data reporting and by uncertain methods for group assignment.

iii. Abdominal aortic reconstruction. Although some case series reports have noted that outcomes in patients monitored by PA catheter were better than adjusted rates for the general population,[67] the absence of control groups limits the value of the data. A study with historical controls found that mortality, perioperative hypotensive episodes, and renal failure were less common in patients who received an aggressive fluid management protocol that included PA catheterization than in previous patients who did not receive the protocol.[68] The study was limited by its historical design, inconsistent data reporting, unexplained attrition, and the fact that PA catheterization was only one component of the protocol. Uncontrolled case series have suggested that low-risk cases can be safely managed without PAC.[69] One prospective study of two hospitals with notably different mortality rates for nonelective aortic repair, despite com-

parable acuity, noted that PAC (and colloid and inotrope) use was much more common in the hospital with higher mortality rates.[70] The only two randomized controlled trials examining the benefits of PAC over CVC in patients undergoing abdominal aortic reconstruction found no difference in outcomes.[71,72]

iv. Neurosurgery. An uncontrolled case series and an observational study with a comparison group have examined the effectiveness of PA catheterization in patients undergoing neurosurgical procedures.[73,74] The studies only addressed the ability of PA catheters to detect air embolism and did not measure clinical outcomes. An uncontrolled observational study of pediatric head trauma patients who underwent monitoring that included PA catheterization reported lower mortality rates than published rates for patients with similar trauma scores.[75] The study lacked internal controls, and PA catheterization was only one of the multiple interventions offered.

v. Trauma. Some studies of limited quality have suggested that hemodynamic monitoring of trauma patients, often including PAC, improves outcomes. For example, a retrospective analysis concluded that patients with life-threatening burns who were monitored by PAC had lower mortality and organ-failure rates than a historical control group in which PAC was used irregularly; patients managed with hyperdynamic endpoints had substantially better outcomes.[76] A small observational study of critically injured patients reported a significantly lower incidence of organ dysfunction, but not of organ failure, in the group monitored by PAC to achieve optimal left ventricular performance.[77] Retrospective biases and failure to adjust for confounding variables limit the generalizability of the findings.

Randomized controlled trials examining goal-directed therapy in trauma patients offer encouraging results but suffer from design limitations. A trial involving 67 primarily surgical trauma patients reported significantly fewer organ failures per patient among those receiving PACs in the operating room or postoperatively as part of a protocol to achieve supranormal values.[78] The number of patients with organ failure was not compared, however, and the study suffered from failure to conceal allocation, nonblinding, and other design flaws. A subsequent trial from the same group reported similar findings, as well as lower mortality rates, but it suffered from additional design limitations.[79] Another trial involving 58 patients with critical illness due primarily due to trauma reported no significant benefit from PAC and goal-directed therapy.[80] It also suffered from numerous design limitations.

d. Obstetric-Gynecologic Procedures. Evidence regarding the effectiveness of PA catheterization in obstetrics and gynecology is lacking. PA catheterization has been recommended for severe preeclampsia,[81] case reports have supported its value,[82] and its use in critical illness seems common,[83] but controlled clinical outcome studies have not been reported. Case reports have also described PA catheter use in uncommon obstetric settings,[84-86] whereas others have documented its lack of necessity in myocardial infarction during pregnancy.[87] Uncontrolled case series have examined mortality and other outcomes in series of obstetric and gynecologic surgical patients that underwent PA catheterization, but they did not include control groups for comparison.[88,89]

e. Pediatric Catheterization. PA catheterization is performed in critically ill newborns, infants, and children,[90] but its effect on clinical outcomes is poorly studied. Uncontrolled case series reports have shown that it is useful in clarifying diagnoses, but these studies have not examined clinical outcomes or included unmonitored controls.[91,92]

f. Meta-analyses. A meta-analysis of 16 randomized controlled trials involving PAC, which examined results from studies published between 1970 and 1996 and which used a random effects model to compensate for study heterogeneity, yielded a relative risk ratio of 0.81 (95% CI, 0.60-1.10) for mortality in patients treated with PAC.[93] Patients from surgical series had a relative risk ratio of 0.58 (95% CI, 0.36-0.94). The same research team later extended the analysis to include morbidity data from 12 of the 16 trials, calculating a relative risk ratio of 0.78 (0.65-0.94) for the incidence of organ failure.[94] Although the estimates were statistically robust under sensitivity analysis, their validity is arguable, given the disparate patient populations and protocols and the numerous design flaws of the studies collated in the analysis. Another meta-analysis of PAC, which examined results from four homogeneous randomized controlled trials published between 1991 and 1998 involving vascular surgery patients yielded an odds ratio of 1.198 for mortality when PAC was used ($P = 0.60$; confidence intervals were not reported).[95] The odds ratio for postoperative complications between PA catheter patients and controls was not significant.

2. Harms. Evidence regarding the adverse effects of PA catheterization comes from studies that examined multiple complications[96-108] and from studies of specific complications. The Task Force considered only potentially life-threatening complications. The reported incidence of complications is summarized in table 5.

In summary, complications from PA catheterization can occur with the establishment of central venous access, the catheterization procedure, and catheter residence. Complications of establishing central venous access include malpositioning,[109] unintentional puncture of nearby arteries, (*e.g.*, carotid or subclavian artery),[110,111] bleeding, neuropathy, air embolism, and pneumothorax.[109,112,113] Technologies, such as ultrasound guided venous cannulation, are available and may reduce the risk of catheter misplacement.[114-119]

Dysrhythmias are the primary complication of the

Table 5. Reported Incidence of Adverse Effects

Complication	Reported Incidence (%)	References	Incidence in Most† Studies (%)
Central venous access			
Arterial puncture	0.1–13	97,99,103,104,106,205	≤3.6
Bleeding at cut-down site (children)	5.3	206	
Postoperative neuropathy	0.3–1.1	97,99	
Pneumothorax	0.3–4.5	97,100,104–107,109,113,206	0.3–1.9
Air embolism	0.5	105	
Catheterization			
Minor dysrhythmias*	4.7–68.9	97–106,120,124,205–208	>20
Severe dysrhythmias (ventricular tachycardia or fibrillation)*	0.3–62.7	97,100,102,103,106,120,121,122,124,125,205, 207,208	0.3–3.8
Minor increase in tricuspid regurgitation	17	129	
Right bundle-branch block*	0.1–4.3	98,104,126,128	
Complete heart block (in patients with prior left bundle-branch block)*	0–8.5	104,126–128	
Catheter residence			
Pulmonary artery rupture*	0.03–1.5	102,104,105,140,141,143,209	0.03–0.7
Positive catheter-tip cultures	1.4–34.8	98,102,146–152,154,155,210	≥19
Catheter-related sepsis	0.7–11.4	98,100,107,113,147,150,152,154,155,210,211	0.7–3.0
Thrombophlebitis	6.5	99	
Venous thrombosis	0.5–66.7	98–100,107,130	0.5–3
Pulmonary infarction*	0.1–5.6	97,98,102–104,131,205	0.1–2.6
Mural thrombus*	28–61	132,212	
Valvular/endocardial vegetations or endocarditis*	2.2–100	98,104,105,133–136,146,212,213	2.2–7.1
Deaths (attributed to pulmonary artery catheter)*	0.02–1.5	100,104,105	

* Complications thought to be more common (or exclusively associated) with pulmonary artery catheterization than with central venous catheterization. † More than half of studies reported values in this range.

catheterization procedure. Minor dysrhythmias, such as premature ventricular and atrial contractions, occur often with catheter insertion or withdrawal but usually resolve spontaneously after the catheter is advanced or withdrawn through the right heart chambers.[120–123] Ventricular tachycardia or fibrillation occurs occasionally and can usually be cardioverted with antiarrhythmic agents or electrical defibrillation.[124,125] Catheter advancement can produce a right bundle-branch block, and in patients with a preexisting left bundle-branch block it can precipitate a complete heart block.[126–128] A minor increase in tricuspid regurgitation has been shown to occur 17% of the time after catheter placement.[129] This study did not show that PAC resulted in new severe tricuspid regurgitation.

Complications of catheter residence include venous thrombosis,[130] thrombophlebitis, and pulmonary embolism and infarction.[131] Autopsy studies have revealed evidence of mural thrombi, endocarditis, and valvular injury in patients with indwelling PA catheters.[132–136] Catheter-related venous thrombosis can be reduced with heparin,[137] but the latter carries its own risks.[138] A serious complication of PA catheters is PA rupture, which occurs in an estimated 0.03–0.2% of cases.[139–143] Mortality from this complication has been estimated to be 41–70%,[142–144] a rate that can be influenced by a variety of factors (*e.g.*, age, pulmonary hypertension, coagulopathy, heparinization).

Sepsis is a potential complication of PA catheter residence, but its exact incidence is uncertain. Positive cultures of indwelling PA catheter tips are common[145–151] and are often due to incidental contamination from skin flora, but in the context of septic patients it is frequently unclear whether positive cultures reflect colonization from another source or the primary nidus of infection. Incidence rates for culture-positive catheters, positive blood cultures, and catheter-related sepsis, therefore, vary considerably in the literature. In general, the incidence of infection increases with the duration of placement[152,153]; the risk seems to increase significantly when catheters are in place for more than 72–96 h.[145,146,152–154] Although the complication therefore has largely postoperative rather than intraoperative origins, poor technique at the time of insertion can introduce contamination. Skin flora are a common source of infection.[154–156] Evidence regarding long-term infectious complications is limited. For example, invasive hemodynamic monitoring during placement of prosthetic aortic grafts does not seem to be associated with graft infection after 4 yr.[157]

The rate of iatrogenic deaths from PA catheterization is uncertain. Patients who are monitored by PA catheter have high mortality rates, but in few cases is it possible

to attribute their deaths specifically to PA catheterization and not the underlying illness.

B. Expert Opinion of Effectiveness

Currently available evidence from published research provides incomplete information about the effectiveness of PA catheter monitoring and the incidence of complications. Gaps in the evidence occur at several levels. First, surgical procedures that have been examined in studies of PA catheterization (*e.g.*, cardiac surgery, abdominal aortic reconstruction, neurosurgery) represent only a subset of clinical settings for which PA catheters are used. Second, available studies generally suffer from poor design and lack the statistical power to demonstrate benefit. In its 1993 review, the Task Force called for randomized controlled trials to offer more compelling evidence about the effectiveness of PAC. Although a number of such trials have since been published, they have not settled the issue, in part because of inadequate documentation and design flaws; Ivanov *et al.* calculated a mean Chalmers quality score of 40 (on a scale of 1–100) for trials examining PAC.[93] Third, studies without randomized designs generally do not control for differences in case mix and practitioner skill and, therefore, may not be generalizable to typical practice conditions. In one analysis, severity of illness was 7% greater for cardiac surgery patients receiving a PAC.[65] Failure to account for the conditions with which PAC is associated often limits study validity.

Because of deficiencies in the evidence, it is difficult to draw meaningful conclusions about the effectiveness and safety of PA catheterization based on currently available data. In general, the evidence suggests that the routine use of PA catheters in low-risk patients does not reduce mortality, length of stay, or other surrogate markers for severity of illness. In some settings, the risks from the procedure may outweigh its benefits. The evidence does not exclude the possibility that PA catheterization improves outcomes in select clinical circumstances. *Post hoc* data analyses in the above literature, although an inadequate evidence base for drawing firm conclusions, suggest that patient subgroups do benefit from interventions that include or require PA catheter monitoring.

There is a great need for additional research to provide this information. In the meantime, important insights about the benefits and harms of PA catheterization can be obtained from clinical experience. The Task Force acknowledges the limitations of expert opinion, which include subjectivity, recall bias, nonuniformity of measures, and confounding. With these caveats in mind, the following observations about the benefits and harms of PA catheterization are offered:

Clinical experience suggests that PA catheter monitoring of selected surgical patients can reduce the incidence of perioperative complications, primarily by providing immediate access to critical hemodynamic data. The expert opinion of the Task Force is that access to these data for selected indications and settings, coupled with accurate interpretation and appropriate treatment tailored to hemodynamic status, can reduce perioperative mortality and morbidity through reduced cardiac complications (*e.g.*, myocardial ischemia, congestive heart failure, arrhythmias), renal insufficiency, brain injury, and pulmonary complications. The Task Force also believes that, in selected cases and settings, PA catheter use may reduce length of stay in the hospital and ICU, enhance postoperative functional status, and reduce the need for transfused blood products through optimization of fluid therapy. The Task Force believes the use of PA catheters in selected obstetric patients may reduce maternal and neonatal morbidity and mortality.

Although these benefits may not be realized in every surgical patient who is catheterized, the Task Force believes that having immediate access to PA catheter data allows important preemptive measures for that subset of patients who encounter hemodynamic disturbances that require immediate and precise decisions about fluid management and drug treatment. The exact proportion of patients for whom this applies and the magnitude of benefit from PA catheterization are uncertain. However, the Task Force believes that reliance on clinical assessment or alternative devices (*e.g.*, CVC monitoring) is inadequate and that TEE, which can provide similar and important additional information, may be unavailable or impractical. The delay associated with PA catheter placement after complications have developed may endanger certain patients and may increase the risk of complications from insertion. Emergency catheterization under hastily prepared conditions may increase the risk of vascular injury and catheter-related sepsis. Prospective studies have found that the relative risk for catheter-related sepsis is 2.1 when PA catheters are inserted in the operating room using a less stringent sterile technique.[154]

Numerous studies have shown that PA catheter data are more accurate than clinical assessment in evaluating the hemodynamic status of complicated patients.[18,19,23–25] For postoperative patients, who have less immediate access to physicians after leaving the operating room, PA catheter data and trained nurses may provide an important means of rapidly communicating precise information about hemodynamic status to physicians not at the bedside. This enables immediate execution of treatment decisions that are tailored to the patient's physiologic state.

The Task Force believes that these benefits have not been demonstrated in currently available research because of deficiencies in study design and performance. It is suggested that a properly designed randomized controlled trial with adequate sample size, well-trained physicians and nurses, well-defined interventions, and meaningful outcome measures would reveal the benefits observed in practice. To do this, trials must be carefully

designed to distinguish between the incremental benefits offered by PAC and those attributable to other treatment interventions with which PAC is associated (*e.g.*, intensive care). It is recognized that the performance of such a study might be difficult because of logistical and ethical considerations, but calls for such research have intensified in recent years.[10,12]

The generalizability of research findings to practice conditions is often limited. For example, the Task Force believes that outcomes for experienced clinicians may differ significantly from published rates, because catheterizations in clinical studies were often performed under conditions in which interventions were not adequately standardized or implemented according to protocol, or in early years, when outmoded techniques and materials were used. The Task Force believes that experience and understanding are major determinants of PA catheter effectiveness. Experienced PA catheter users can achieve better outcomes and encounter fewer complications because of their enhanced skill in the interpretation of PA catheter data, in the prompt design of rational treatment strategies, and in the use of safe techniques of catheter insertion and management. Characteristics of the practice setting, such as the skill of nurses and their attentiveness to PA catheter tracings, also influence significantly the outcome of PA catheter use.

There is compelling evidence that PA catheterization can result in serious and potentially fatal complications. Catheterization is, therefore, inappropriate as a routine practice in surgical patients and should be limited to cases in which the anticipated benefits of catheterization outweigh the potential risks. The actual complication rate is uncertain, in part because of variability in the designs and results of studies of complications and in part because only a subset of reported complications is attributable uniquely to PA catheters. Serious complications also occur with the principal alternatives to PA catheterization, such as CVC (*e.g.*, unintentional arteriotomy, pneumothorax, line sepsis) or less frequently with transesophageal echocardiographic monitoring (*e.g.*, esophageal injury, vocal cord paralysis, dysrhythmias). Published rates for certain complications are based on old studies that may not reflect recent advances. For example, venous thrombosis has been reduced by the use of prophylactic heparin and heparin-bonded catheters.[137]

The opinion of the Task Force, based on clinical experience, is that serious complications due specifically to PA catheterization (PA rupture, serious ventricular dysrhythmias, endocardial lesions) occur in 0.1–0.5% of PAC-monitored surgical patients. Physicians dealing with other patient populations have made different estimates. In one survey, American cardiologists and other internists, when asked to estimate the probability of severe morbidity or death from PAC, gave higher estimates (2–5% and 0.5–1.0%, respectively) that seemed to differ by specialty.[158] A study by the same group, comparing American and British physician perspectives on PAC, yielded estimates of 5% and 1%, respectively.[159]

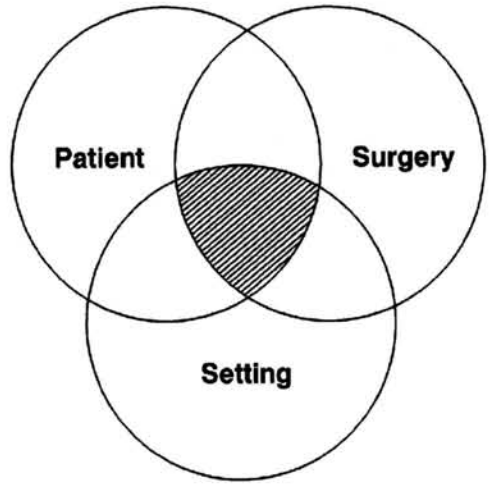

Fig. 2. Factors affecting the risk of complications from hemodynamic changes.

The Task Force believes that the risk of PAC is both appropriate and necessary in selected surgical patients undergoing procedures associated with complications from hemodynamic changes (*e.g.*, cardiac surgery, aortic reconstruction) or entering surgery with preexisting risk factors for hemodynamic disturbances (*e.g.*, advanced cardiopulmonary disease). The level of hemodynamic risk should be assessed as a function of three interrelated variables: the health status of the patient, level of risk associated with the specific surgical procedure, and characteristics of the practice setting (*e.g.*, physician skills, technical support related to PAC). Consideration of the interrelationships between these three variables (fig. 2) aids in the accurate assessment of hemodynamic risk.

Public Policy Issues

Although the recommendations in this report are based primarily on clinical benefits and harms, the following resource and implementation issues were considered by the Task Force in structuring its recommendations:

A. Costs

The costs of PA catheterization include the costs of equipment (*e.g.*, PA catheters, pressure transducers, electronic monitoring devices, solutions) and personnel (*e.g.*, physician costs for insertion and interpretation, nurses, technicians). There is limited information from published literature about the actual costs of PA catheterization. Published estimates of charges for the procedure range widely, from $300 to $1,649.[66,160,161] Yet another study estimated the PAC cost to be $667 on the first day of catheterization and $541 for each additional day.[162] An analysis of 13,907 patients who underwent

nonemergent coronary artery graft surgery in 1997 found that even after regression analysis for case mix and other covariables, total hospital costs were significantly higher for PAC-monitored patients than for patients not receiving PAC, a difference of $1,402.[65]

In the previously mentioned analysis of 5,735 critically ill patients during the first 24 h of admission to an ICU, PAC use was associated with significantly higher total hospital costs ($7,900; SE, $3,900) even after multivariate adjustment for confounding variables.[9] A logarithmic formula was used to adjust costs for the portion of the hospital stay spent in the ICU. The authors speculated that a large part of the cost related to the association between PAC use and other expensive technologies, and to increased nursing care. In their study, patients with PAC spent 2 days longer in the ICU, and the average intensity of care was four to seven points higher on the Therapeutic Intervention Scoring System,[163] but the generalizability of such findings to perioperative settings is limited.

Perhaps a more pertinent issue is the incremental cost of PAC compared with alternatives. A study of 194 patients who underwent coronary artery bypass surgery found that the difference in total hospital charges (1996 dollars) for patients monitored by PAC or CVC ($31,300 and $28,900, respectively) lacked statistical significance, which for demonstration would require a sample size of 778.[64]

More important than whether PAC increases hospital costs is its cost-effectiveness, which considers the health benefits of the procedure to determine whether resources are being spent wisely. There have been few published cost-benefit or cost-effectiveness analyses of PA catheter monitoring, and none regarding its use in the perioperative setting. An analysis of PAC use in patients with chronic obstructive pulmonary disease estimated that its incremental cost-effectiveness was $77,407 per quality-adjusted life year saved (if changes based on the information improve survival by 5%).[162] A procedure's cost-effectiveness cannot be properly ascertained without establishing its clinical effectiveness, a more fundamental uncertainty with PAC,[164] and until the latter is resolved estimations of cost-effectiveness can be based only on speculative assumptions.

B. Implementation Issues

In addition to clinical benefits, harms, and costs, the Task Force also considered patient and provider concerns that could influence implementation of the guideline:

1. Patient Concerns. Disadvantaged patients who meet criteria for PA catheterization may lack access to hospitals with facilities and qualified personnel to perform the procedure. This is especially true for patients in minority or disadvantaged populations, who have experienced documented disparities in care, and for those with inadequate insurance coverage.[165] Although in most cases the urgency of conditions requiring PA catheterization does not lend itself to discussions beyond the basic requirements for informed consent, patients undergoing procedures for which the use of PAC is elective may benefit from the opportunity to review the indications for using the device and to decide, based on personal preferences, whether to proceed.

Preoperative catheterization, which as noted earlier lacks compelling evidence of benefit, may also be less desirable to patients. Insertion of the PA catheter in the operating room may be more comfortable, less anxiety-provoking, and induce less physiologic stress than preoperative insertion.[166]

2. Provider Competency and Training. The appropriateness of PA catheterization and the determination of whether benefits exceed risks hinge on the competence of physicians and nurses in catheter use. This competence encompasses both technical and cognitive skills, which are first acquired in residency or postresidency training. Maintenance of skills following training often requires regular catheter use, but there is disturbing evidence that skill levels are inadequate. A 1990 study by Iberti *et al.*, in which a 31-item examination on PA catheters was completed by 496 North American physicians, found that only 67% of the answers were correct.[167] The instrument yielded similar results in Europe.[168] A 1996 survey of more than 1,000 critical care physicians found that, although 83% of questions were answered correctly, a third of the respondents could not correctly identify PA occlusion pressure on a clear tracing and could not identify the major components of oxygen transport.[13]

Similar problems have been identified among critical care nurses. Exposure to the subject in nursing school is limited,[169] and surveys of practicing nurses demonstrate knowledge deficits. A 31-item examination of critical care nurses in California found that only 57% of the responses were correct.[170] Only 39% of respondents correctly identified a PA wedge measurement value from a waveform recording. Most of the nurses (95%) had more than 1 yr of experience in critical care, and 99% used the PAC more than once per month. Scores were better for nurses with CCRN certification, attendance at a PA catheter class, more years of critical care experience, and frequent PA catheter use.

Because PA catheterization by persons who have not maintained these skills is potentially harmful to patients and could threaten the acceptability of the procedure, it is important for the profession to periodically assess technical and cognitive performance. Recognition of the need to strengthen quality control and competency has grown in recent years.[133,171] The best measure of competence is clinical outcome, but long periods of observation and careful data analysis may be necessary to obtain meaningful information. Surrogate measures such as the frequency of catheter use or the results of profi-

ciency examinations may be the best alternative, but they are imperfect measures of competence.

d. Reimbursement. Reimbursement policies play a role in the ability of providers to offer PAC. In addition to other factors, the evidence that PAC is only appropriate for certain indications and should therefore not be used as a matter of routine in the perioperative setting makes it inappropriate to assume that PAC is part of the surgical procedure or for payers to bundle it in reimbursement.[172]

e. Utilization Review and Medicolegal Liability. Because of limitations in scientific evidence about the limits of appropriateness for PA catheterization, guidelines based on expert opinion should not be used as standards of care or to define cases of unnecessary catheterization.

Guidelines

The evidence reviewed to date clearly does not support the routine use of PA catheters when there is a low risk of hemodynamic complications. In its 1993 report, the Task Force indicated that such risk is a function of three interdependent variables: the patient, procedure, and practice setting (fig. 2). When these conditions culminate in a high-risk situation is both subjective and variable and is influenced by interpretations of the scientific evidence, individual circumstances of the case, and local conditions.

To provide further guidance on when these conditions arise, the Task Force turned to expert opinion because current data are inadequate to establish firm evidence-based criteria. The Task Force's expert opinion, assessed using the voting process and the criteria for appropriateness and necessity described in Methodology, represents its best judgment on when PA catheterization is appropriate or necessary. The votes on which the recommendations are based are tabulated in tables 6 and 7, and the definitions for terms used in the ballot are in table 2. In certain cases, the alternative to PA catheterization should be CVC, TEE, or other less invasive monitoring methods (*e.g.*, esophageal Doppler, pulse wave analysis, bioimpedance, carbon dioxide Fick, lithium dilution), rather than no hemodynamic monitoring. The degree of appropriateness of PA catheterization may differ in circumstances when these alternatives are available.

Recommendations

The votes by the Task Force (tables 6 and 7) demonstrated that the appropriateness of routine PA catheterization depends on the combination of risks associated with the (a) *patient*, (b) *surgery*, and (c) *practice setting* (the latter referring to the risks from PA catheterization introduced by practice conditions and staff circumstances). The votes are depicted graphically in figure 3. With some exceptions, *routine catheterization is generally inappropriate for low- or moderate-risk patients*. The three variables are defined in greater detail below.

Patient. Patients at increased risk for hemodynamic disturbances are those with clinical evidence of significant cardiovascular disease, pulmonary dysfunction, hypoxia, renal insufficiency, or other conditions associated with hemodynamic instability (*e.g.*, advanced age, endocrine disorders, sepsis, trauma, burns). Patients at *low risk* include those with American Society of Anesthesiologists (ASA) physical status[173] of 1 or 2 or those with hemodynamic disturbances unlikely to cause organ dysfunction. Those at *moderate risk* are in category ASA 3 or have hemodynamic disturbances that occasionally cause organ dysfunction. Those at *high risk* are in category ASA 4 or 5 and have hemodynamic disturbances with a great chance of causing organ dysfunction or death. The assessment of risk should be based on a thorough analysis of the medical history and physical examination findings, rather than on exclusive consideration of specific laboratory results or other quantitative criteria.

Procedure. Surgical procedures associated with an increased risk of complications from hemodynamic changes, including damage to the heart, vascular tree, kidneys, liver, lungs, or brain, may increase the chance of benefiting from PA catheterization. This report does not provide a list of indicated procedures and disease states for catheterization because the Task Force believes that catheterization decisions should be based on the hemodynamic risk characteristics of the individual case rather than on the type of procedure. The Task Force defines *low-risk* procedures as those carrying a small probability of fluid changes or hemodynamic disturbances and having low perioperative morbidity or mortality. *Moderate-risk* procedures have a moderate chance of fluid changes, hemodynamic disturbances, or infection that could cause morbidity or mortality. *High-risk* procedures have a predictably large chance of fluid changes or hemodynamic disturbances or other factors with high risk of morbidity and mortality.

Patients undergoing procedures that usually lack hemodynamic complications may need PA catheterization if circumstances pose a special risk. The clinician should therefore assess hemodynamic risks based on the case at hand and not on generic criteria.

Practice Setting. The setting for the procedure may increase the risk of complications from hemodynamic changes. Factors that should be considered in assessing perioperative risk include catheter use skills and technical support. Factors affecting postoperative risk include the level of training and experience of nursing staff in the recovery room and ICU, technical support for ancillary services, and the availability of specialists and equipment to manage potential complications detected by the PA catheter.

Table 6. Task Force Votes on Appropriateness of Pulmonary Artery Catheterization

Clinical Scenario	Appropriateness Score 1	2	3	4	5	6	7	8	9	Median Vote
Low-risk practice setting										
Low-risk patient	×*									1
Low-risk surgery	××									
	××									
	××									
Low-risk patient	×	×		×	×					1
Moderate-risk surgery	×									
	×									
	×									
Low-risk patient			×	×	×	×			×	5
High-risk surgery					×	×				
Moderate-risk patient	×		×	×						1
Low-risk surgery	×			×						
	×									
	×									
Moderate-risk patient					×	×	×			6
Moderate-risk surgery					×		×			
					×		×			
Moderate-risk patient							×	×	×	8
High-risk surgery							×	×		
							×	×		
High-risk patient	×		×		×				×	5
Low-risk surgery					×					
					×					
					×					
High-risk patient							×	×	×	8
Moderate-risk surgery							×	×	×	
									×	
High-risk patient									×	9
High-risk surgery									××	
									××	
									××	
Moderate-risk practice setting										
Low-risk patient	×									1
Low-risk surgery	××									
	××									
	××									
Low-risk patient	××	×	×							1
Moderate-risk surgery	××		×							
Low-risk patient	×	×	×	×	×					3
High-risk surgery		×		×						
Moderate-risk patient	××		×							1
Low-risk surgery	××		××							
Moderate-risk patient	×		×		×	×				3
Moderate-risk surgery			××			×				
Moderate-risk patient				×	×	×	×			6
High-risk surgery					×	×	×			
High-risk patient	×	×	×	×				×		3
Low-risk surgery	×			×						
High-risk patient					×	×	×	×		7
Moderate-risk surgery						×	×	×		
High-risk patient					×		×	××	×	8
High-risk surgery								××		

(continues)

Table 6. (continued)

Clinical Scenario	Appropriateness Score 1	2	3	4	5	6	7	8	9	Median Vote
High-risk practice setting										
Low-risk patient	×									1
Low-risk surgery	××									
	××									
	××									
Low-risk patient	××	×								1
Moderate-risk surgery	××									
	××									
Low-risk patient	××	×	×							1
High-risk surgery	××	×								
Moderate-risk patient	××	×		×						1
Low-risk surgery	××	×								
Moderate-risk patient	××	×			×					1
Moderate-risk surgery	××									
Moderate-risk patient	×	×	×			×				2
High-risk surgery	××					×				
High-risk patient	×	×	×				×			2
Low-risk surgery	××	×								
High-risk patient	×	×	×		×	×	×			3
Moderate-risk surgery	×									
High-risk patient	×		×	×	×	×	×			4
High-risk surgery	×									

* Each × represents an individual respondent to the questionnaire.

Validation of Panel Votes in Open Forum. To assess whether panel votes differed distinctly from the views that might be held by others with expertise in PA catheterization, the same questionnaire used by the panel was administered to 12 anesthesiologists attending an open forum about the guideline at the 2001 meetings of the International Anesthesia Research Society and the Society for Cardiovascular Anesthesiologists. The results suggested significant concordance in views.

In judging *appropriateness*, the median scores of the attendees were often identical and within the same range as the panel's vote in 22 out of 27 scenarios. When their results were pooled with the panel votes, conclusions about the appropriateness of routine PA catheterization shifted for only three scenarios. Specifically, they shifted for low-risk patients undergoing high-risk surgery in a moderate-risk setting, moderate-risk patients undergoing moderate-risk surgery in a moderate-risk setting, and high-risk patients undergoing moderate-risk surgery in a high-risk setting. In these cases the panel had voted that routine PA catheterization was inappropriate, but the combined votes that included open-forum attendees placed these circumstances in the "possibly appropriate" range (median score of 4-6) but the median score did not exceed 4.

In judging *necessity*, the votes taken by the attendees fell within the same range as the panel's median scores for 17 out of 27 scenarios. When these were pooled with the panel votes, conclusions about necessity shifted definitively for only four scenarios. In two scenarios for which the panel considered routine PA catheterization unnecessary (median score, 1-3)—moderate-risk patients undergoing high-risk surgery in a moderate-risk setting and high-risk patients undergoing high-risk surgery in a high-risk setting—the median combined vote was 5, suggesting that necessity was uncertain (range, 4-6). In two circumstances for which the panel considered necessity uncertain—high-risk patients undergoing either moderate-risk surgery in a low-risk setting or high-risk surgery in a moderate-risk setting—the median combined vote was 7 and 8, respectively, suggesting that PA catheterization was necessary (range, 7-9).

Preoperative Catheterization. There is insufficient evidence to support preoperative PA catheter monitoring (*e.g.*, the evening before surgery) in patients who are hemodynamically stable. The risk of catheter-related sepsis and other complications increases with the duration of catheter residence. It is recognized that preoperative PA catheterization is often under the control of other medical specialists, such as cardiologists, pulmonologists, and surgeons.

Competency. Because of the risk of complications from PA catheterization, the procedure should not be performed by clinicians who lack competence in safe insertion or in the accurate interpretation of results. Competence in catheter placement is related to experience and is a function of the quality of the initial training and regular performance of the procedure after training.

All persons who use PA catheters should undergo high-quality, supervised training to establish compe-

Table 7. Task Force Votes on Necessity of Pulmonary Artery Catheterization

Clinical Scenario	Necessity Score 1	2	3	4	5	6	7	8	9	Median Vote
Low-risk practice setting										
Low-risk patient	×*									1
Low-risk surgery	××									
	××									
	××									
Low-risk patient	××	×								1
Moderate-risk surgery	××									
	××									
Low-risk patient	×	×			×					2
High-risk surgery	×	×			×					
		×								
Moderate-risk patient	×		×			×				1
Low-risk surgery	××									
	××									
Moderate-risk patient	×	×		×		×				2
Moderate-risk surgery	×	×				×				
Moderate-risk patient	×		×	×	×			×		5
High-risk surgery					×			×		
High-risk patient	×				×		×			1
Low-risk surgery	××									
	××									
High-risk patient	×		×		×		×	×		5
Moderate-risk surgery					×		×			
High-risk patient	×				×			×	×	8
High-risk surgery								×	××	
Moderate-risk practice setting										
Low-risk patient	×									1
Low-risk surgery	××									
	××									
	××									
Low-risk patient	××	×								1
Moderate-risk surgery	××									
	××									
Low-risk patient	×	×		×						2
High-risk surgery	××	×		×						
Moderate-risk patient	×	×		×						1
Low-risk surgery	××									
	××									
Moderate-risk patient	××		×		×					1
Moderate-risk surgery	××				×					
Moderate-risk patient	×		×				×			3
High-risk surgery	×		××				×			
High-risk patient	×			×		×				1
Low-risk surgery	××									
	××									
High-risk patient	×		×	×			×	×		4
Moderate-risk surgery				××						
High-risk patient	×				×	×		×		6
High-risk surgery					×	×		×		
High-risk practice setting										
Low-risk patient	×									1
Low-risk surgery	××									
	××									
	××									

(continues)

Table 7. (continued)

Clinical Scenario	Necessity Score 1	2	3	4	5	6	7	8	9	Median Vote
Low-risk patient	×									1
Moderate-risk surgery	××									
	××									
	××									
Low-risk patient	××	×								1
High-risk surgery	××									
	××									
Moderate-risk patient	×		×							1
Low-risk surgery	××		×							
	××									
Moderate-risk patient	××	×		×						1
Moderate-risk surgery	××			×						
Moderate-risk patient	×	×				×				1
High-risk surgery	×					×				
High-risk patient	×		×		×					1
Low-risk surgery	××									
	××									
High-risk patient	××	×				×				1
Moderate-risk surgery	××					×				
High-risk patient	××	×				×	×			1
High-risk surgery	××									

* Eash × represents an individual respondent to the questionnaire.

tency. Across specialties, however, there is little agreement about the minimum number of procedures that must be performed to acquire cognitive and technical skills. The American College of Physicians, American College of Cardiology, and American Heart Association hold that at least 25 procedures must be performed to acquire technical and cognitive skills in hemodynamic monitoring (defined as pressure measurement in the PA, central venous system, and arterial system and the measurement of cardiac output). In a national survey of critical care physicians, 73% believed that 20–50 supervised PA catheterizations were required to establish competency.[13]

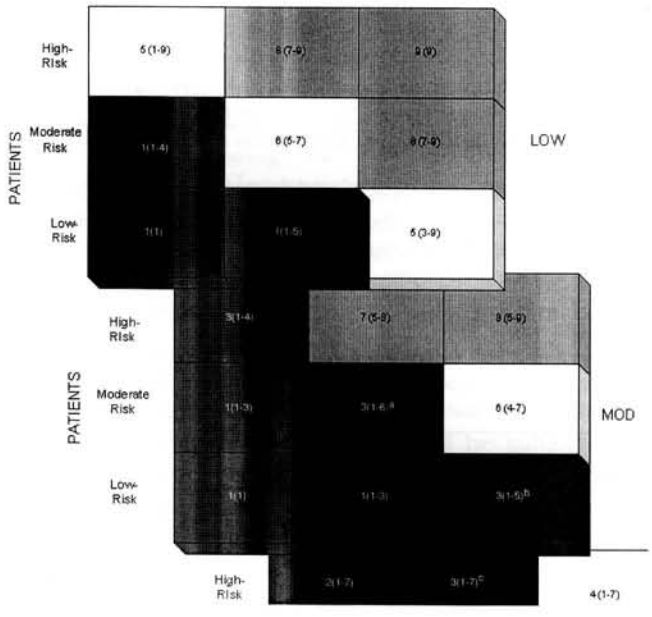

Fig. 3. Appropriateness of routine pulmonary artery catheterization secondary to practice setting. MOD = moderate.

However, learning curve research, conducted primarily in gastroenterology, has found that different and variable levels of experience are required to establish competency, depending on the type of procedure: 25–30 procedures for flexible sigmoidoscopy,[175] 30 for laparoscopic hernia repair[176] and pediatric caudal epidural blocks,[177] 40 for endoscopic sphincterectomy,[178] 130 for upper endoscopies,[179] 100–200 for colonoscopy,[179–182] and 40–200 for endoscopic retrograde cholangiopancreatography.[183–185] Citing such evidence, a 1998 report by the American Society for Gastrointestinal Endoscopy (Oak Brook, Illinois) acknowledged that its previous criteria on the minimum number of procedures required to attain competency (which ranged from 5 to 100, depending on the procedure) "are not adequate for most trainees."[186]

Moreover, even groups that require a minimum number of procedures acknowledge that more or less than a nominal training requirement may be needed, depending on case severity and other individual training circumstances. The use of simulators and software-based decision aids[187] may improve knowledge and reduce experiential requirements in actual cases. In recognition of these variables, although the aforementioned minimum requirements for establishing competency in PA catheterization can help in decision-making about train-

ing requirements, it is important that other factors be considered.

A quality improvement program must be in place at all sites where PA catheters are used. Ideally, maintenance of knowledge and skills should be evaluated based on clinical outcomes. It is widely held that such skills cannot be maintained without performing some minimum number of procedures per year. For example, in a survey of 1,095 critical care physicians, 69% of the respondents believed that physicians must perform 10–25 PA catheterizations per year to maintain competence.[13] Similarly, four out of six attendees at the open forum convened by this panel at the Society for Cardiovascular Anesthesiologists indicated that 10–25 PA catheter insertions per year were necessary to maintain competence. Swan has suggested that 50 procedures must be performed annually.[188]

Allowances for smaller case loads have been made by other groups. The American College of Physicians, American College of Cardiology, and American Heart Association state that "physicians with extensive experience who work in hospitals where these procedures are done infrequently may be able to maintain competence with a minimum number of continuing procedures, perhaps as few as 12 per year. The same groups, however, recommend that 100 echocardiograms must be performed annually to maintain competence.[189,190] Requirements for credentialing at individual hospitals vary widely. One survey found that the required number of procedures per year required for cardiologists to be recredentialed in angioplasty and coronary angiography were 10–150 and 12–300, respectively.[191]

The wide variation in requirements reflects, in part, the absence of good data to inform such policies.[191] Although studies have demonstrated correlations between anesthesiologists' self-reported comfort level in giving anesthetics and the number of procedures they perform each year,[192] there is no scientific proof for the belief that procedural competence, once established in initial training, decays significantly over time if the procedure is performed infrequently.[193] Studies at an institutional level consistently demonstrate an inverse relationship between complication and volume rates×a pattern confirmed in the administration of anesthesia[193]×but factors other than the procedural competence of physicians (*e.g.*, hospital characteristics, population profiles, referral preferences) may account for such observations.[194]

Competence in the interpretation of catheter data should be based on cognitive and technical requirements, such as those outlined by the American College of Physicians/American College of Cardiology/American Heart Association Task Force on Clinical Privileges in Cardiology (table 8).

Individuals with limited experience (*e.g.*, house staff, nurse anesthetists) should not insert PA catheters or make clinical decisions based on the data without qualified supervision. Nurses who provide care to patients who are monitored by PA catheters should be required to meet minimum training requirements and continuing education for catheter maintenance and for the interpretation and communication of PA catheter data. The nursing literature describes a number of programs to evaluate

Table 8. Cognitive and Technical Skills for Hemodynamic Monitoring

Cognitive skills[174]

1. Knowledge of indications with emphasis on the subtleties involved. Data obtained should be needed to make management decisions and improve patient outcome. Obtaining high-quality hemodynamic data, even though abnormal and sometimes contrary to clinical judgment, does not of itself constitute an adequate indication.
2. Knowledge of the anatomy of neck, central venous system, peripheral arterial tree, heart, and lungs.
3. Knowledge of and ability to recognize pulse waveforms for the wide array of hemodynamic conditions for which the procedures are indicated.
4. Knowledge of and ability to perform the hemodynamic calculations that are possible and necessary (*e.g.*, cardiac output, peripheral and pulmonary vascular resistance, and derived measurement such as stroke volume, ventricular stroke work).
5. Understanding the importance of and ability to recognize artifacts, clinical circumstances under which data may be misleading and/or difficult to obtain (*e.g.*, situations when pulmonary capillary wedge pressure does not appropriately reflect left ventricular end-diastolic pressure or effect of pulmonary ventilation/ventilators on measurements).
6. Knowledge of fluid and electrolyte balance and their roles in altered hemodynamics.
7. Knowledge of the pharmacologic effects of the drugs that alter preload, afterload, and inotropic state.
8. Knowledge of the complications of hemodynamic monitoring and appreciation of the approaches and techniques necessary to minimize their occurrence, recognize their presence, and treat them promptly.
9. Knowledge of the interaction of multiple pathophysiologic states and diseases that are present in many critically ill patients undergoing hemodynamic monitoring.
10. Knowledge of the importance of and approach to assessing blood gases, pulmonary ventilation, and metabolic derangements.
11. Ability to communicate and document the results of the examination to the patient, to the medical record, and to other physicians.

Technical skills

1. Ability to perform surgical sterile technique.
2. Ability to perform venous access from two (or multiple) sites with the percutaneous technique. Ability to do cut-downs is also desirable.
3. Ability to perform arterial access (primarily radial artery puncture), although ability to do arterial cut-down is desirable.
4. Ability to operate all instrumentation involved in hemodynamic monitoring, including catheters, introducers, strain gauges, and recorders, and to perform calibration, balancing, and zeroing techniques.
5. Knowledge and ability to correct ("troubleshoot") common artifacts and technical problems with recording instrumentation and catheter/tubings.

and maintain PA catheter skills among critical care nurses.[195,196]

Research Agenda. Additional research is needed to demonstrate the effectiveness of PA catheterization. Deficiencies in current evidence suggest that future studies should emphasize certain design features to provide more meaningful evidence. Future studies should use relevant clinical outcome measures to judge effectiveness, including measures of morbidity (*e.g.*, cardiac, pulmonary, renal, and neurologic disease; patient functional status after discharge) and mortality (*e.g.*, in-hospital fatality rates, 5-yr survival, quality-adjusted life years).

Future studies should include adequate sample sizes to demonstrate statistically significant effects. Investigators should perform power calculations before initiating studies to confirm the adequacy of the sample size. Researchers should collect adequate information about severity of illness and comorbid variables to help separate the influence of these factors from the effects of PA catheterization on observed clinical outcomes. Studies must be clear about the endpoints of treatment, specifying the hemodynamic indices that clinicians use to make decisions based on PA catheter data. Published reports from studies should provide complete information about methodology and complete data reporting to minimize confusion about statistical calculations.

Many authors have emphasized the need for well-designed randomized controlled trials to test the effectiveness of PA catheterization.[197,198] The Task Force continues to support the need for such research, as it did in 1993, but lessons learned from trials published in recent years suggest that formidable design challenges must be overcome if the findings from such trials are to gain acceptance and influence policy. There are fundamental logistical and ethical problems with randomizing the allocation of PA catheters in critically ill patients. Of particular concern is the potential contamination of control groups. This crossover effect has occurred frequently in past research when patients assigned to receive no monitoring or CVC monitoring were subsequently reassigned by their physicians to undergo PA catheterization because of clinical deterioration or because the physicians were uncomfortable with the group assignment. In a Canadian randomized trial, 52 of 148 potentially eligible patients were excluded because the attending physician believed that right heart catheterization was "ethically mandated," leaving only 33 patients available for randomization.[199]

Ethicists argue that patients should be subjected to randomization only under conditions of *clinical equipoise*,[200] in which the profession has genuine uncertainty regarding the relative merits of each therapeutic arm in the trial,[201] rather than under conditions of a prevailing belief of benefit, ineffectiveness, or harm. To meet this ethical standard and to minimize crossover, the Task Force therefore recommends that future randomized controlled trials should be undertaken in settings where the profession has split opinions about the appropriateness of PA catheterization.

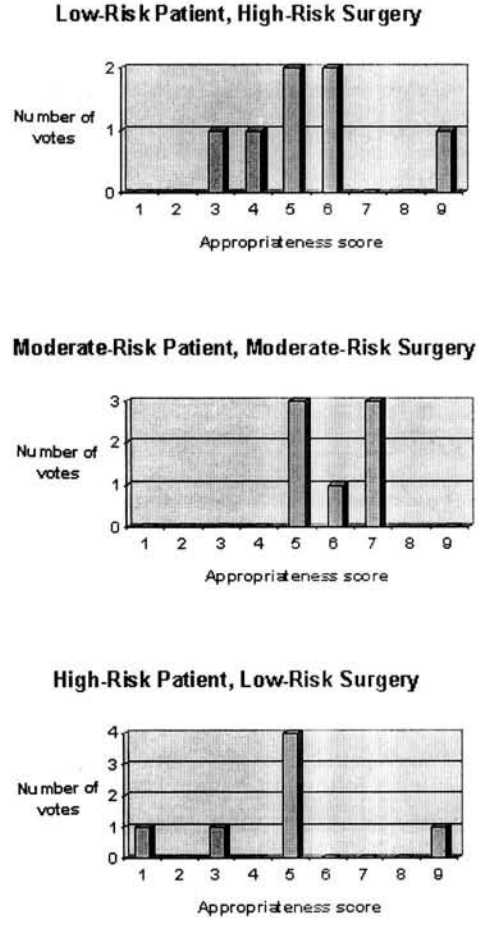

Fig. 4. Heterogeneous voting patterns for three clinical scenarios (assumes risks from practice setting [*e.g.*, catheter-use skills, physician availability] are low).

To determine what these conditions are, the Task Force examined the spectrum of clinical scenarios considered in its voting exercise and identified those conditions that elicited the greatest heterogeneity in views, producing a median vote of 4–6. This occurred in five scenarios: Assuming that risks from the practice setting (*e.g.*, catheter-use skills) are low, views about appropriateness differed substantially for (1) low-risk patients undergoing high-risk surgery, (2) moderate-risk patients undergoing moderate-risk surgery, and (3) high-risk patients undergoing low-risk surgery (fig. 4). The Task Force also expressed heterogeneous votes when (4) the practice setting imposes moderate risk (when moderate-risk patients undergo high-risk surgery in moderate-risk settings), and when (5) high-risk patients undergo high-risk surgery in high-risk settings (fig. 5). The equipoise observed for these five clinical settings offer potential parameters for conducting an ethically justifiable randomized trial of PA catheterization.

Such a trial should probably be restricted to a specific

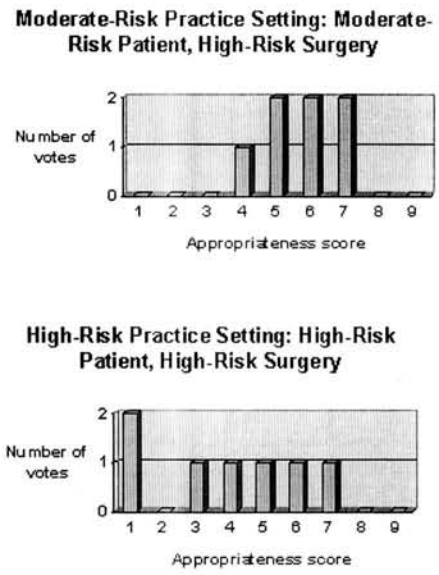

Fig. 5. Heterogeneous votes when practice settings impose added risks.

type of surgery (*e.g.*, coronary artery bypass graft). Physicians participating in such studies should adhere closely to the protocol and should not violate the design by reassigning patients following randomization. Studies that use low-risk patients may require large sample sizes to demonstrate statistically significant results, depending on power calculations; therefore, multicenter involvement may be necessary. The study should be performed in a setting attuned to the management of postoperative hemodynamic status, and the control groups should be monitored by CVC or other appropriate alternate methods (*e.g.*, TEE).

Although a number of randomized trials involving PA catheterization have been published in recent years, deficiencies in their design and conduct have limited their internal and external validity. For example, few trials have included concealment of allocation, the most important source of bias in trial design.[202] Blinding, although infeasible for patients or clinicians at the bedside, is possible and would reduce bias among those who measure outcomes, but this has rarely been attempted in PAC trials. Violation of intention-to-treat analysis and overindulgent *post hoc* data analysis have been commonplace.

Moreover, the questions that trials in the past decade have sought to answer have lacked relevance to perioperative care. Most trials have focused on patients in ICUs and have yielded data of only tangential relevance to conditions in the operating room. A 1997 consensus conference[12] was successful in convincing the National Institutes of Health to fund multicenter trials of PA catheterization, but the trials that were ultimately launched focus on adult respiratory distress syndrome[203] and congestive heart failure.[204–213] The results of these trials will have limited bearing on perioperative care, in which 55% of PA catheters are used in the United States.[12]

A further limitation of past trials has been ambiguity about the intervention. Treatment groups have often received interventions related to, but distinct from, PAC (*e.g.*, admission to ICU), making it difficult to draw firm conclusions about the role PA catheterization plays in observed benefits or harms. For future trials to overcome this limitation, patients must be assigned to groups in a way that disentangles the incremental influence of component interventions. To know whether the treatments initiated by PAC use are themselves responsible for observed benefits and harms, those treatments must be described explicitly, replacing opaque descriptions of types of treatments with detailed explication of treatment targets (*e.g.*, physiologic endpoints) and how well they were achieved.

The optimal randomized controlled trial will provide evidence from only one class of patients and one type of surgery. To provide more comprehensive data about the effects of PA catheterization, the Task Force recommends the performance of a large-scale multicenter observational study that (1) includes adequate numbers of patients for each indication; (2) collects adequate data to generate a comprehensive database regarding past medical history, comorbidity, severity of illness, hospital course, and immediate and long-term clinical outcomes; and (3) provides details about catheter insertion techniques, practitioner skills, and data interpretation. For example, rather than stating that PA catheter monitoring was performed for 48 h, the investigators should document the type of device, the specific hemodynamic variables that were measured, and the manner in which PA catheter data were used to make treatment decisions.

Ultimately, the state of knowledge will need to move beyond expert opinion to provide objective evidence about the benefits and harms of PA catheterization.

Addendum

After acceptance of these guidelines by the ASA House of Delegates, an important article concerning the use of pulmonary artery catheters in surgical patients was published (Sandham JD, Hull RD, Brant RF, Knox L, Pineo, GF, Doig CJ, Laporta DP, Viner S, Passerini L, Devitt H, Kirby A, Jacka M: A randomized, controlled trial of the use of pulmonary-artery catheters in high-risk surgical patients. N Engl J Med 2003; 348:5–14). The article was accompanied by an editorial (Parsons PE: Progress in research on pulmonary-artery catheters. N Engl J Med 2003; 348:66–8). Because the article was published after the guidelines were written and approved, the authors feel it is inappropriate to comment on this work other than to express the opinion that its findings are important and are consistent with the guidelines.

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