Complete Summary

GUIDELINE TITLE

Practice guidelines for pulmonary artery catheterization: an updated report by the American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization.

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization. Practice guidelines for pulmonary artery catheterization: an updated report by the American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization. Anesthesiology 2003 Oct;99(4):988-1014. [213 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Hemodynamic disturbances in surgical patients

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Evaluation
Management

CLINICAL SPECIALTY

Anesthesiology
Cardiology
Critical Care
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide guidelines on the appropriate indications for pulmonary artery (PA) catheter use in the surgical setting

TARGET POPULATION

Adult and child surgical patients at increased risk for hemodynamic disturbances

INTERVENTIONS AND PRACTICES CONSIDERED

Pulmonary artery (PA) catheterization in the surgical setting

MAJOR OUTCOMES CONSIDERED

- Benefits of pulmonary artery (PA) catheterization, including decreased incidence of myocardial infarction, arrhythmias, congestive heart failure
- Adverse effects of PA catheterization
- Costs of PA catheterization

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

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.

Admissible Evidence

Detailed exclusion criteria are described in table 1 of the original guideline document. The Task Force focused its review on evidence of effectiveness based on clinical outcomes. Pulmonary artery catheterization (PAC) use was interpreted as including its diagnostic applications (in measuring pulmonary artery [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., transesophageal echocardiography [TEE]), although it recognizes that in settings in which TEE is available and appropriate it may supplant the need for PAC. 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.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

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.

Synthesis of Results

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

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.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Task Force used a confidential voting scheme to assess the appropriateness and necessity of pulmonary artery catheterization (PAC), specifying its views for 27 clinical scenarios. The 27 scenarios considered each potential combination of patients, surgical procedures, and practice settings in low-, moderate-, and high-risk categories, as defined in table 2 of the original guideline document. 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.

A vetting of the guideline 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 pulmonary artery (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 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.

The evidence reviewed to date clearly does not support the routine use of pulmonary artery (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 (see figure 2 in the original guideline document). 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 of the original guideline document, and the definitions for terms used in the ballot are in table 2 of the original guideline document. In certain cases, the alternative to PA catheterization should be central venous catheter (CVC), transesophageal echocardiography (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.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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).

The costs of pulmonary artery (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. Yet another study estimated the pulmonary artery catheterization (PAC) cost to be $667 on the first day of catheterization and $541 for each additional day. 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.

In the previously mentioned analysis of 5,735 critically ill patients during the first 24 h of admission to an intensive care unit (ICU), PAC use was associated with significantly higher total hospital costs ($7,900; SE, $3,900) even after multivariate adjustment for confounding variables. 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, 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 central venous catheter (CVC) ($31,300 and $28,900, respectively) lacked statistical significance, which for demonstration would require a sample size of 778.

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%). A procedure's cost-effectiveness cannot be properly ascertained without establishing its clinical effectiveness, a more fundamental uncertainty with PAC, and until the latter is resolved estimations of cost-effectiveness can be based only on speculative assumptions.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline underwent peer review by experts in pulmonary artery (PA) catheterization and by relevant specialty societies and organizations. Reviewers are listed in table 3 of the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations

The votes by the Task Force (see tables 6 and 7 of the original guideline document) demonstrated that the appropriateness of routine pulmonary artery (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 of the original guideline document. 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 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 intensive care unit (ICU), technical support for ancillary services, and the availability of specialists and equipment to manage potential complications detected by the PA catheter.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on expert opinion, informed by scientific evidence. Clinical trials, controlled observational studies, uncontrolled case series reports, and individual case reports were considered.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate pulmonary artery catheterization resulting in improved patient outcomes and reduced costs

POTENTIAL HARMS

Pulmonary artery (PA) 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. Refer to the original guideline document for a full discussion of harms associated with PA catheterization.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

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

Patient Concerns

Disadvantaged patients who meet criteria for pulmonary artery (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. 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 pulmonary artery catheterization (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.

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 study 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. The instrument yielded similar results in

Europe. 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.

Similar problems have been identified among critical care nurses. Exposure to the subject in nursing school is limited, 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. 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 pulmonary artery catheterization (PAC) more than once per month. Scores were better for nurses with Certification in Critical Care Nursing (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. 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 proficiency examinations may be the best alternative, but they are imperfect measures of competence.

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.

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.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization. Practice guidelines for pulmonary artery catheterization: an updated report by the American Society of Anesthesiologists Task Force on Pulmonary Artery Catheterization. Anesthesiology 2003 Oct;99(4):988-1014. [213 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Oct

GUIDELINE DEVELOPER(S)

American Society of Anesthesiologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Anesthesiologists

GUIDELINE COMMITTEE

Task Force on Pulmonary Artery Catheterization

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society for Anesthesiologists Web site.

Print copies: Available from the American Society for Anesthesiologists, 520 North Northwest Highway, Park Ridge, IL 60068-2573.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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