The Pulmonary Artery Catheter (PAC) is used to diagnose various diseases and physiological states, monitor the progress of critically ill patients, and guide the selection and adjustment of medical therapy. The PAC is often considered a cornerstone of critical care and a hallmark of the intensive care unit (ICU). Approximately 1 million PACs are used annually in the United States. However, despite widespread use of these devices, there are conflicting data about their utility. The majority of nonrandomized studies in critically ill patients have suggested that the PAC is associated with increased morbidity and mortality. Conversely, some nonrandomized studies have shown improved quality of life when the PAC was used to direct a specific therapeutic approach.

Since the mid-1980s, randomized clinical trials (RCTs) have been conducted to evaluate the efficacy of the PAC. However, none of these trials have been persuasive individually, because the sample sizes were small. Some nonrandomized studies suggest that PAC use is associated with increased morbidity and mortality.

Objective To estimate the impact of the PAC device in critically ill patients.

Data Sources MEDLINE (1985-2005), the Cochrane Controlled Trials Registry (1988-2005), the National Institutes of Health ClinicalTrials.gov database, and the US Food and Drug Administration Web site for RCTs in which patients were randomly assigned to PAC or no PAC were searched. Results from the ESCAPE trial of patients with severe heart failure were also included. Search terms included pulmonary artery catheter, right heart catheter, catheter, and Swan-Ganz.

Study Selection Eligible studies included patients who were undergoing surgery, in the intensive care unit (ICU), admitted with advanced heart failure, or diagnosed with acute respiratory distress syndrome and/or sepsis; and studies that reported death and the number of days hospitalized or the number of days in the ICU as outcome measures.

Data Extraction Information on eligibility criteria, baseline characteristics, interventions, outcomes, and methodological quality was extracted by 2 reviewers. Disagreements were resolved by consensus.

Data Synthesis In 13 RCTs, 5051 patients were randomized. Hemodynamic goals and treatment strategies varied among trials. A random-effects model was used to estimate the odds ratios (ORs) for death, number of days hospitalized, and use of inotropes and intravenous vasodilators. The combined OR for mortality was 1.04 (95% confidence interval [CI], 0.90-1.20; P=.59). The difference in the mean number of days hospitalized for PAC minus the mean for no PAC was 0.11 (95% CI, −0.51 to 0.74; P=.73). Use of the PAC was associated with a higher use of inotropes (OR, 1.58; 95% CI, 1.19-2.12; P=.002) and intravenous vasodilators (OR, 2.35; 95% CI, 1.75-3.15; P<.001).

Conclusions In critically ill patients, use of the PAC neither increased overall mortality or days in hospital nor conferred benefit. Despite almost 20 years of RCTs, a clear strategy leading to improved survival with the PAC has not been devised. The neutrality of the PAC for clinical outcomes may result from the absence of effective evidence-based treatments to use in combination with PAC information across the spectrum of critically ill patients.
they are limited by small sample sizes in heterogeneous populations. Ivanov et al performed 2 meta-analyses on PAC use through 1996.8,9 One study focused on mortality from 16 RCTs of the PAC8 and the other focused on major morbidity from 12 RCTs; however, neither study restricted the randomization specifically to catheter vs no catheter use. There was no difference found in mortality, but there was a statistically significant difference in major morbidity, which was defined separately for each organ system.8,9

Despite the overwhelmingly negative tenor of the literature, clinicians continue to use the PAC in ICUs based on personal experience and the belief that careful monitoring will improve decision making and clinical outcomes. To provide a broad perspective for the recently completed ESCAPE trial,10 in which patients with advanced heart failure were randomized to the PAC or clinical assessment alone, we performed a meta-analysis of 13 recently published clinical trials testing the safety and efficacy of the PAC.

METHODS

Study Search
We searched MEDLINE (1985-2005), the Cochrane Controlled Trials Registry (1988-2005), the National Institutes of Health ClinicalTrials.gov database, and the US Food and Drug Administration Web site (http://www.fda.gov) for reports of articles pertaining to the PAC. The MEDLINE search results included all articles yielded by other search methods. The search terms used were pulmonary artery catheter, right heart catheter, catheter, and Swan-Ganz.

For the MEDLINE search, we used the term pulmonary artery catheter as a keyword. We then searched the subject headings catheterization, Swan-Ganz, and pulmonary artery catheter. The search was limited to articles that were written in English, included only human beings, and published between 1985 and 2005. These citations were then manually searched to identify articles that were RCTs, systematic reviews, prospective cohort studies, or editorial letters and comments. The references from the citations were also searched to identify additional RCTs.

Eligibility and Data Abstraction
We reviewed references identified by the search method specified above. Additional references were identified by manually searching the bibliographies of these articles. These citations were included in our meta-analysis. We included trials if the randomization scheme included groups that assigned patients to treatment guided by the PAC or treatment without the PAC. We only included trials if they reported death and number of days hospitalized or the number of days in the ICU as outcome measures. Studies were excluded if the randomization scheme did not specify groups as PAC or no PAC, if patients were not randomized to a conventional PAC, if investigators combined randomized and nonrandomized groups when reporting outcomes, or if there were no outcome data on death or hospitalizations.

Eligibility assessment and data abstraction were performed independently in an unblinded standardized manner by 2 reviewers (M.R.S. and V.H.). Abstracted data included eligibility criteria, baseline characteristics, interventions, outcomes, and methodological quality. The outcome of interest was the number of deaths from any cause and the number of days hospitalized. Trial methodological quality was assessed by abstracting reported use of intention-to-treat analysis and reported allocation generation and allocation concealment. Disagreements between reviewers were resolved by consensus.

Data Analysis
Random-effects models were used for the meta-analysis of both mortality and days hospitalized. Mortality was summarized by odds ratio (OR) with 95% confidence intervals (CIs). Days hospitalized were summarized as the difference in mean number of days. The measures were combined using an empirical Bayes random-effects estimator,11 which also provides an estimate of heterogeneity. The calculations were performed by using FAST*PRO software version 1.80.12 P < .05 was considered statistically significant.

Some of the studies had zero deaths in a particular group, which is problematic for conventional meta-analysis methods. Meta-regression analysis is an alternative method of estimating the pooled OR. Based on the assumption used in standard meta-analysis, we assumed that the OR for mortality remained constant across studies, except for some additional random variation. The model was fitted using a logistic-normal model as implemented in EGRET for Windows.13 These results were used as a check on the empirical Bayes estimator.

RESULTS

Search Results
We identified 2305 articles with the subject headings catheterization, Swan-Ganz, or pulmonary artery catheter (FIGURE 1). We limited our analysis to articles that were written in English, included only human beings, and were published between 1985 and 2005, which yielded 1715 articles. We manually searched these citations and identified 11 RCTs evaluating the PAC that met the prespecified criteria. In addition, we included 2 recently published trials. The first trial, Evaluation of the Clinical Care and Cost Effectiveness of Pulmonary Artery Flotation Catheters in Intensive Care (PAC-Man), was conducted in England and completed in March 2004.14 The second trial, the ESCAPE trial,10 was presented at the American Heart Association meeting on November 9, 2004.

Qualitative Findings
In total, 5051 patients were randomized into the 13 trials included in our meta-analysis.10,14-25 Eight studies focused on patients undergoing major general, abdominal, vascular, or orthopedic surgery.15-18,20,22,24 These trials included 2667 (52.8%) of 5051 patients
in the meta-analysis. Three studies evaluated patients admitted to the ICU who were diagnosed with sepsis or acute respiratory distress syndrome. These trials included 910 patients (18.0%) of the meta-analysis study population. Only 1 study, ESCAPE, focused primarily on patients with advanced heart failure.

**Baseline Characteristics**

**Treatment Protocols.** Specific hemodynamic targets were outlined in 7 studies, targeted a specific pulmonary capillary wedge pressure as 1 of the therapeutic goals, 6 studies used the cardiac index, 3 studies aimed at oxygen delivery, and 4 studies focused on systemic vascular resistance.

Five studies did not require investigators to use specific hemodynamic targets. The protocols of these studies called for clinicians to use their own judgment in assessing therapeutic goals and designing treatment strategies.

In contrast, 2 studies clearly outlined hemodynamic targets but did not specify which therapies should be selected to achieve these goals. The protocol of the ESCAPE trial encouraged the use of vasodilators and diuretics and discouraged inotropes but did not mandate use of these drugs.

The 5 most specific protocols focused on the surgical population. These trials outlined treatment strategies to achieve specific hemodynamic goals. A summary of fluids and therapies used in the 13 trials is shown in [TABLE 2](#).

**Quantitative Findings.** Overall, there was a significantly higher rate of use of vasodilator agents in patients randomly assigned to PAC (OR, 2.35; 95% CI, 1.75-3.15; P < .001). In addition, use of inotropes was also significantly higher in patients randomly assigned to PAC (OR, 1.58; 95% CI, 1.19-2.12; P = .002).

The meta-analysis of death in the 13 RCTs demonstrated that the PAC did not significantly increase mortality. More importantly, the use of the PAC also did not improve survival (OR, 1.04; 95% CI, 0.90-1.20; P = .59) (FIGURE 2).

In addition, the meta-analysis of the number of days hospitalized showed that the PAC did not have a significant impact on this end point (mean for PAC − mean for no PAC, 0.11 days; 95% CI, −0.51 to 0.74; P = .73) (FIGURE 3).

**COMMENT**

Our meta-analysis of 13 RCTs evaluating the safety and efficacy of the PAC demonstrates that use of the catheter neither improves outcomes in critically ill patients nor increases mortality or days in hospital. This provides a broader confirmation of the recent results of the ESCAPE trial, which showed that the routine use of the PAC in patients with advanced heart failure did not reduce or increase death or days in hospital.

**PAC: A Diagnostic Tool**

Previous clinical trials have evaluated the PAC as an intervention, although it is only a diagnostic tool, similar to a chest radiograph or an echocardiogram. To expect a diagnostic device to increase survival may be unrealistic unless there is a therapeutic intervention associated with it that improves outcomes. Our meta-analysis emphasizes the lack of consensus about the goals of therapy in critically ill populations, the paucity of standard guidelines on how to use the PAC, and the dearth of therapies that have met modern criteria for evidence, which provide clinical benefit in acutely ill populations.

**Use of the PAC in Different Populations**

The PAC may be used differently in the spectrum of critical illnesses. Because the role of the PAC in different disease states varies, the catheter may benefit some patients and harm others. The specific role the device plays in treating patients may be a factor in determining its ultimate impact on clinical outcomes. For example, in the ICU and surgical populations, the focus of the PAC is on diagnosis of volume and perfusion status and the selection and titration of drugs. In contrast, in the heart failure population, the PAC is used not only to diagnose volume and perfusion status and titrate therapy, but also to refine drug combinations and select equivalent oral doses of intravenous medications. Because the use of the PAC may vary by disease state, combining the results of different trials may not give an accurate estimate of the impact of the device in specific patient populations. However, none of the individual trials included in our meta-analysis showed a significantly positive effect of the PAC on outcomes, so heterogeneity of response as an explanation for the neutral results would have to be within each trial. We are unable to address this issue because we do not have the individual patient data.

**Therapies Associated With the PAC**

Another potential reason that the results of our meta-analysis were neutral may be that use of the PAC increased the accuracy of diagnosis, potentially leading to increased survival, but that

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**Figure 1. MEDLINE Articles Evaluated for Inclusion in the Meta-analysis**

| 1715 Potentially Relevant Articles Identified |
| 1690 Articles Excluded |
| 1683 Reviews, Commentaries, Case-Control Studies |
| 5 Major Nonrandomized Studies Since 1986 |
| 2 Meta-analyses |

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**Figure 2. Baseline Characteristics**

| 14 Trials Excluded |
| 12 Patients Were Not Randomized to PAC vs No PAC |
| 1 Patients Were Not Randomized to Conventional PAC |
| 1 Nonrandomized and Randomized Data Were Combined |

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**Figure 3. Quantitative Findings**

*Results from the ESCAPE trial and the recently published PAC-Man trial were also included.*
### Table 1. Overview of Major Randomized Clinical Trials Evaluating the Safety and Efficacy of the PAC

<table>
<thead>
<tr>
<th>Source, y</th>
<th>No. of Patients</th>
<th>PAC vs No PAC</th>
<th>Population</th>
<th>Design</th>
<th>Hemodynamic Targets</th>
<th>Treatment Strategy</th>
<th>End Points</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harvey et al, 2000</td>
<td>1041</td>
<td>519/522</td>
<td>Adult ICU patients</td>
<td>Group 1: PAC</td>
<td>No</td>
<td>No</td>
<td>Days in ICU</td>
<td>Death: PAC: 346 of 506 (68%); No PAC: 33 of 507 (66%)</td>
</tr>
<tr>
<td>Schultz et al, 1995</td>
<td>70</td>
<td>35/35</td>
<td>Hip fracture; orthopedic surgery</td>
<td>PAC vs no PAC</td>
<td>No</td>
<td>No</td>
<td>Death</td>
<td>1 vs 10</td>
</tr>
<tr>
<td>Shoemaker et al, 1988</td>
<td>88</td>
<td>30/30/28</td>
<td>High-risk general surgery patients</td>
<td>Group 1: no PAC</td>
<td>No</td>
<td>No</td>
<td>Death</td>
<td>Days hospitalized</td>
</tr>
<tr>
<td>Isaacson et al, 1990</td>
<td>102</td>
<td>49/53</td>
<td>Abdominal aortic reconstructive surgery</td>
<td>No</td>
<td>No</td>
<td>Complications</td>
<td>Days in ICU</td>
<td>Death: PAC 17 vs 16; APACHE score 2.7 vs 2.1; P = .13</td>
</tr>
<tr>
<td>Berlau et al, 1991</td>
<td>89</td>
<td>45/23/21</td>
<td>Limb salvage arterial surgery</td>
<td>Group 1: PAC 12 h pre-operation vs Group 2: PAC 3 h pre-operation vs Group 3: no PAC</td>
<td>Yes</td>
<td>Yes</td>
<td>Days hospitalized</td>
<td>Death: group 1: 19.4 (11.6); group 2: mean (SD), 18.0 (12.0); group 3: mean (SD), 15.4 (7.5); Death: group 1: 1; group 2: 0; group 3: 1</td>
</tr>
<tr>
<td>Guyatt, 1991</td>
<td>33</td>
<td>16/17</td>
<td>ICU patients</td>
<td>PAC vs usual care</td>
<td>No</td>
<td>No</td>
<td>Days hospitalized</td>
<td>APACHE score 10.3 vs 8.1; Death: PAC 14.4 vs 11.1; 10 vs 9</td>
</tr>
<tr>
<td>Bender et al, 1997</td>
<td>104</td>
<td>51/53</td>
<td>Elective vascular surgery</td>
<td>No</td>
<td>No</td>
<td>Days in ICU</td>
<td>Death: PAC 2.7 vs 2.6; Days hospitalized 12.5 vs 12; 1 vs 1</td>
<td></td>
</tr>
<tr>
<td>Valentine et al, 1998</td>
<td>120</td>
<td>60/60</td>
<td>Aortic surgery</td>
<td>Yes</td>
<td>Yes</td>
<td>Days in ICU</td>
<td>Death: PAC 8 vs 7; Days hospitalized 13 vs 13; 3 vs 1</td>
<td></td>
</tr>
<tr>
<td>Bonazzol et al, 2002</td>
<td>100</td>
<td>50/50</td>
<td>Aortic reconstructive surgery</td>
<td>Yes</td>
<td>Yes</td>
<td>Acute coronary syndrome, heart failure, arrhythmias</td>
<td>PAC 2 vs 4</td>
<td></td>
</tr>
<tr>
<td>Rhodes et al, 2002</td>
<td>201</td>
<td>96/105</td>
<td>ICU patients</td>
<td>PAC vs no PAC</td>
<td>No</td>
<td>No</td>
<td>Renal failure</td>
<td>Days hospitalized 22 vs 12; 13 vs 14; P = .81; 46 vs 50; P &gt; .99</td>
</tr>
<tr>
<td>Sandham et al, 2003</td>
<td>1994</td>
<td>997/997</td>
<td>High-risk major surgery patients</td>
<td>Yes</td>
<td>Yes</td>
<td>Days hospitalized</td>
<td>In-hospital death: PAC 10 vs 10; P = .41; In-hospital morbidity: PAC 78 vs 77; P = .93; 163 vs 155; 504 vs 523; 8 vs 0; P = .004</td>
<td></td>
</tr>
<tr>
<td>Richard et al, 2003</td>
<td>676</td>
<td>335/341</td>
<td>ICU patients with ARDS, sepsis, or both</td>
<td>No</td>
<td>No</td>
<td>28-d death</td>
<td>PAC 199 vs 206; RR, 0.97; 95% CI, 0.86-1.1; P = .67</td>
<td></td>
</tr>
<tr>
<td>ESCAPE, 2005</td>
<td>433</td>
<td>215/218</td>
<td>NYHA class IV heart failure patients</td>
<td>PAC vs no PAC</td>
<td>No</td>
<td>No</td>
<td>Days dead or hospitalized over 180 d</td>
<td>HR, 1.00; 95% CI, 0.83-1.21</td>
</tr>
</tbody>
</table>

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; ARDS, acute respiratory distress syndrome; BP, blood pressure; CI, confidence interval; HR, hazard ratio; ICU, intensive care unit; NYHA, New York Heart Association; PAC, pulmonary artery catheter; PCWP, pulmonary capillary wedge pressure; RR, relative risk; SVR, systemic vascular resistance.
Four studies included in our analysis of therapies that worsened outcomes. Hemodynamic data also triggered the use of drugs that ultimately worsened outcomes. It may be that inotropic agents and vasodilators were used more frequently in patients who received the PAC because objective hemodynamic goals were present. There are few data, and no RCT data, that show either class of drugs improves outcomes in acutely ill patients. In fact, the use of inotropic agents and some vasodilators have been associated with increased morbidity and mortality in the advanced heart failure population. In addition, there is little evidence from RCTs to support the use of fluid loading, blood transfusions, or intravenous vasodilators to achieve hemodynamic goals. Although use of the PAC may have allowed physicians to diagnose clinical and hemodynamic status more accurately, it may have also triggered the use of drugs that ultimately worsened outcomes.

**Quality of Hemodynamic Data**

Quality of hemodynamic data is also a critical factor in determining the impact of the device on clinical outcomes. Eleven studies in our analysis did not include a protocol for interpretation of hemodynamic wave-
forms. Thus, there may have been inaccuracies in the hemodynamic data, which had an impact on morbidity and mortality. In addition, only the ESCAPE trial required study nurses to undergo formal training in hemodynamic waveform interpretation. Without standard protocols for the PAC, there may have been errors in gathering hemodynamic data, which may have ultimately affected clinical outcomes.

**Hemodynamic Targets: The Wrong Surrogates?**

Although many of the studies included in our meta-analysis outlined specific hemodynamic goals, there are few definitive data to support the use of any hemodynamic target. The decision to optimize filling pressures in the ESCAPE trial was based mostly on the positive results of single-center, nonrandomized studies using these targets. In contrast, there are few data, even from nonrandomized studies, to support maximizing cardiac index and oxygen delivery. It may be that the observed neutral effect of the PAC was because investigators were targeting drugs, fluid, and blood replacement to the wrong end points.

**Ongoing Randomized Studies**

We identified 1 additional unpublished trial evaluating the safety and efficacy of the PAC. The Fluids and Catheter Treatment Trial focused on 1000 patients with acute respiratory distress syndrome. Patients were randomized in a 2 × 2 factorial design to a liberal vs conservative fluid treatment strategy and to therapy guided by a PAC or central venous catheter. The primary end point was death at 60 days. The investigators outlined specific hemodynamic goals and treatment strategies for the use of inotropes, vasopressors, fluids, and diuretics. The trial was started in 2001 but was suspended by the Office for Human Protections From Research for questions about the ethics of the protocol. After extended review by external consultants, the trial was restarted in 2002 with no major revisions to the protocol.

**Future Studies**

The overview by Ivanov et al suggests that nonfatal end points may be improved by disease-specific targeting of therapy and the ESCAPE trial suggested the possibility of quality of life improvement. Future trials should look at alternate clinical end points, particularly symptom status. Furthermore, given the absence of harm for major clinical end points, renewed emphasis should be placed on the development of novel therapies that might be effective when coupled with the diagnostic information obtained from the PAC.

**Conclusions**

During the past 60 years, the PAC has evolved from a simple diagnostic tool to a device that is used for monitoring and determining goal-directed therapy. Our meta-analysis shows that despite the widespread acceptance of the PAC, use of this device across a variety of clinical circumstances in critically ill patients does not improve survival or decrease the number of days hospitalized. The patients included were those in whom physicians had clinical equipoise about the use of the PAC. That is, clinicians were uncertain about the use of the PAC before they randomized patients.

Although our results suggest that the PAC should not be a standard of care, all of the trials excluded patients in whom clinicians thought a PAC was required for treatment. Thus, it is possible that patients who are outside the boundaries of these trials, such as those who are evaluated for heart and lung transplantation, derive benefit from the PAC. However, these results suggest that the PAC should not be used for the routine treatment of patients in the ICU, patients with decompensated heart failure, or patients undergoing surgery until or unless effective therapies can be found that improve outcomes when coupled with this diagnostic tool.

### Author Contributions

Dr Shah had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. **Study concept and design:** Shah, Hasselblad, Stevenson, Binay, O’Connor, Sopko, Calif. **Acquisition of data:** Shah, Hasselblad, Stevenson, Binay, O’Connor, Calif. **Analysis and interpretation of data:** Shah, Hasselblad, Stevenson, O’Connor. **Drafting of the manuscript:** Shah, Hasselblad, Stevenson, O’Connor. **Critical revision of the manuscript for important intellectual content:** Shah, Hasselblad, Stevenson, Binay, O’Connor, Sopko, Calif. **Obtained funding:** Shah, Stevenson, O’Connor, Calif. **Administrative, technical, or material support:** Shah, Binay, Calif. **Statistical analysis:** Hasselblad. **Obtained funding:** Shah, Stevenson, O’Connor, Sopko. **Financial Disclosures:** None reported. **Funding/Support:** This meta-analysis was funded by the Duke Clinical Research Institute. **Role of the Sponsor:** With the exception of the ESCAPE trial, the Duke Clinical Research Institute did not participate in the design and conduct of the study, in the


