Assessment of the clinical effectiveness of pulmonary artery catheters in management of patients in intensive care (PAC-Man): a randomised controlled trial

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Summary

Background **Over the past 30 years the pulmonary artery catheter (PAC) has become a widely used haemodynamic monitoring device in the management of critically ill patients, though doubts exist about its safety. Our aim was, therefore, to ascertain whether hospital mortality is reduced in critically ill patients when they are managed with a PAC.**

Methods **We did a randomised controlled trial to which we enrolled 1041 patients from 65 UK intensive care units. We assigned individuals to management with (n=519) or without (n=522) a PAC. The timing of insertion and subsequent clinical management were at the discretion of the treating clinician. Intensive care units decided a priori to have the option of using an alternative cardiac output-monitoring device in control patients.**

Findings **1014 patients were eligible for analysis. We noted no difference in hospital mortality between patients managed with or without a PAC (68% [346 of 506] *vs* 66% [333 of 507], p=0·39; adjusted hazard ratio 1·09, 95% CI 0·94–1·27). We noted complications associated with insertion of a PAC in 46 of 486 individuals in whom the device was placed, none of which was fatal.**

Interpretation **Our findings indicate no clear evidence of benefit or harm by managing critically ill patients with a PAC. Efficacy studies are needed to ascertain whether management protocols involving PAC use can result in improved outcomes in specific groups if these devices are not to become a redundant technology.**

Introduction

No monitoring device has polarised opinion as much as the pulmonary artery catheter (PAC).[1–5] Introduced 30 years ago, it is widely used in critically ill patients, yet there has been no formal assessment of either its clinical effectiveness or cost-effectiveness. Proponents[4,5] argue that its unique ability to allow accurate measurement of cardiac output and other haemodynamic variables enables improved diagnosis and management of circulatory instability. Critics, however, point to complications associated with its insertion and use,[1,2,6,7] inaccuracies in measurement, and difficulties with interpretation of data.[8–10] Furthermore, a lack of positive outcome benefits in the critically ill and some suggestions of increased mortality from retrospective analyses[11,12] indicate potential problems with this device.

In 1996, a large, non-randomised, risk-adjusted study[13] indicated an increased 30-day mortality associated with PAC use within the first 24 h after admission to intensive care. This fresh uncertainty encouraged governments in both Europe and North America to provide funding to enable large, randomised controlled trials of PAC use in intensive care. We designed the PAC-Man study as a pragmatic, randomised controlled trial to address the hypothesis that hospital mortality is reduced in critically ill patients managed with a PAC.

Methods

Patients

Between Oct 15, 2001, and March 29, 2004, we enrolled patients admitted to adult intensive care and identified by the treating clinician as someone who should be managed with a PAC. We invited all adult intensive care units (ICUs) in the UK to participate. Our only exclusion criteria were: age younger than 16 years; elective admission for preoperative optimisation; presence of a PAC on admission to intensive care; previous enrolment to the study; or haemodynamic optimisation before organ donation.

We sought written informed consent before enrolment. However, since most eligible patients were unconscious at this point, we obtained signed agreement to participate from a relative. We then obtained informed consent retrospectively if the patient regained competency. The study protocol was approved by the London Multicentre Research Ethics Committee and every hospital's local research ethics committee.

Procedures

We did an open, randomised controlled trial. As a condition of participation, all consultants within every ICU agreed to include all eligible patients and to abide by randomisation to reduce to a minimum selective enrolment and crossover of patients. Given the increasing use of less invasive cardiac output

monitoring devices, however, ICUs elected a priori to enter one of two strata: those having no option (stratum A) or retaining the option (stratum B) of using alternative monitoring devices in controls.

Randomisation was done via a central 24-h telephone service and minimised by: ICU; age (16–44, 45–64, or >65 years); presumptive clinical syndrome at the time of randomisation (acute respiratory failure, multiorgan dysfunction, decompensated heart failure, or other); and surgical status (non-surgical, elective surgical, or emergency surgical). We assigned patients on a one-to-one allocation to management either with or without a PAC.

Patients allocated to management with a PAC had the catheter placed as soon as possible after randomisation, according to local practice. The PAC remained in place for as long as the treating clinician thought necessary. Patients allocated to the control group were managed without a PAC. In both groups, clinical management after randomisation was at the discretion of the treating clinician. Participating units maintained a screening log of eligible patients not enrolled.

During the first 24 h in ICU, clinicians or nurses, or both, in the local units collected raw clinical data for the acute physiology and chronic health evaluation (APACHE II) severity scoring system.[14] At the time of randomisation, we recorded the primary reason for wanting to manage the patient with a PAC, their current organ support, and raw clinical data for the sequential organ failure assessment (SOFA) score.[15] We also recorded complications related to insertion of the PAC, changes in management of patients within the first 2 h as a direct result of PAC-derived data, duration of management with the initial PAC, and overall management with a PAC. We obtained daily information about post-randomisation use of other monitoring technologies and type of organ support (as per the augmented care period dataset,[16] see webappendix). Finally, we noted outcome (alive or dead) and length of stay in the original ICU and in an acute hospital ward.

Our primary outcome measure was hospital mortality, defined as death from any cause before final discharge from an acute hospital ward. We also recorded death while in intensive care and 28-day mortality rates for comparability with other studies. Secondary outcome measures were length of stay in the original ICU, total length of stay in an acute hospital ward, and organ days of support in the original ICU after randomisation. We calculated organ days of support as the sum of the days of individual organ support. For example, 1 calendar day where three individual organs were supported was equivalent to 3 calendar days where one individual organ was supported.

Statistical analysis

Based on data collected in 1999 by the Scottish Intensive Care Society Audit Group (SICSAG; personal communication), which indicated a hospital mortality of 50% in patients managed with a PAC, we calculated that 5673 patients would be needed to give 90% power to detect a 5% change in hospital mortality (10% relative change), based on a 5% level of significance, and to allow for non-compliance rates of 4% in the PAC group, 8% in the control group, and for a 5% loss to follow-up. During the early stages of recruitment in 2002, low enrolment and anecdotal evidence suggested that management with PACs was being restricted to more severely ill patients. This fact prompted us to inspect the control group data (n=147 patients), which indicated a hospital mortality of 69% (95% CI 61–77). As such, the steering group felt that a greater absolute reduction in hospital mortality was needed to be clinically important. We therefore revised the sample size to 1281 patients to provide 90% power to detect a 10% change in hospital mortality (14·5% relative change), based on a 5% level of significance and to allow for similar non-compliance rates and 100% follow-up. This change was approved by the data monitoring and ethics committee, and by national and local research ethics committees.

All the main analyses were by intention to treat and followed an a-priori identified statistical analysis plan. We compared numbers of deaths in each group with Fisher's exact test. We compared survival times with Kaplan-Meier curves and tested them with a log-rank test, for all patients and by stratum. For the purpose of survival analyses, we assumed that patients discharged

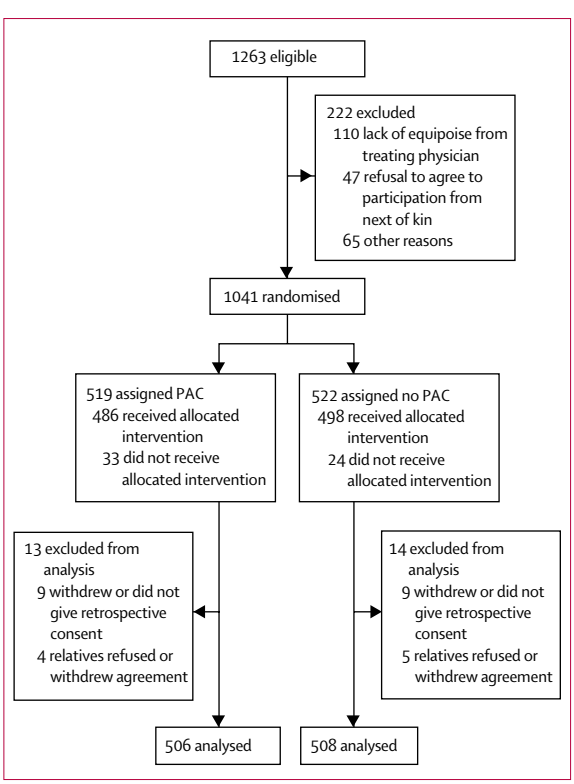

Figure 1: **Trial profile**

See Lancet Online for webappendix

	Treatment group	
	PAC (n=506)	Control (n=508)
Randomisation stratum		
A (no option of alternative cardiac output monitoring device)	105 (21%)	107 (21%)
B (option of alternative cardiac output monitoring device)	401 (79%)	401 (79%)
Age (years) (mean, SD)	64·7 (14·3)	65·3 (13·1)
Surgical status		
Medical	332 (66%)	340 (67%)
Elective surgery	32 (6%)	32 (6%)
Emergency surgery	142 (28%)	136 (27%)
Major presumptive clinical syndrome		
Acute respiratory failure	68 (13%)	66 (13%)
Multiorgan dysfunction	328 (65%)	337 (66%)
Decompensated heart failure	55 (11%)	56 (11%)
Other	55 (11%)	49 (10%)
Sex		
Female	219 (43%)	204 (40%)
Male	287 (57%)	304 (60%)
First 24-h APACHE II acute physiology score (mean, SD)*	17·3 (6·3)	18·0 (6·4)
First 24-h APACHE II total score (mean, SD)*	22·1 (6·6)	22·7 (6·5)
APACHE II risk of death (median, IQR)†	0·37 (0·23–0·57)	0·39 (0·23–0·55)
Likely infection on ICU admission‡	300 (59%)	273 (54%)
Time (h) to randomisation post ICU admission (median, IQR)§	16·2 (5·8–42·0)	15·3 (4·3–34·8)
SOFA score at time of randomisation (mean, SD)	8·6 (2·7)	8·6 (2·7)
Main reason for wanting to manage patient with a PAC		
To guide inotropic or vasoactive drug treatment in a patient not yet receiving these drugs	41 (8%)	39 (8%)
To guide inotropic or vasoactive drug treatment in a patient already receiving these drugs	371 (73%)	358 (71%)
To guide fluid, diuretic, or haemofiltration treatment	50 (10%)	50 (10%)
To guide treatment of oliguria	10 (2%)	21 (4%)
To guide treatment of a metabolic acidosis	19 (4%)	21 (4%)
To diagnose or guide treatment of cause for failure to wean from mechanical ventilation	3 (1%)	3 (1%)
Other diagnostic reasons	11 (2%)	13 (3%)

Data are number (%) unless otherwise stated. *Excludes 23 patients in control group and 23 in PAC group who stayed <8 h. †Excludes 44 patients in control group and 47 in PAC group who stayed <8 h or who had incomplete data. ‡Likely infection=strongly suggestive by evidence, or laboratory confirmed infection. §Excludes 13 patients for whom date or time of randomisation or admission were missing.

Table 1: **Baseline characteristics**

from hospital alive survived until the end of the follow-up period (3 months after recruitment ended). Data from patients still in an acute hospital ward at this point were censored. We calculated the hazard ratio for management with a PAC compared with no PAC from a Cox proportional hazards model, both with and without adjustment for prognostic factors (age, sex, surgical status, major presumptive clinical syndrome at time of randomisation, SOFA score at time of randomisation, and APACHE II score during the first 24 h in ICU).

We also assessed hospital mortality in a-priori identified subgroups based on: option or not to use alternative cardiac output monitoring technologies in the control group; APACHE II predicted risk of hospital death; presumptive clinical syndrome; and historical frequency of PAC use in the participating ICU derived from the 1998 audit commission survey.[17] We compared the subgroups by testing the interaction with treatment effect in the adjusted Cox proportional hazards model. For APACHE II predicted risk of hospital death, we entered predicted log odds of death as a linear term in the Cox model.

We compared the secondary outcome measures, length of stay in ICU and hospital, and organ days of support with the Wilcoxon rank-sum test and with a bootstrap *t* test of 1000 resamples.[18]

An independent data monitoring and ethics committee did two interim safety analyses but did not make any recommendations to halt the trial.

The protocol for this study was peer-reviewed and accepted by *The Lancet*; a summary of the protocol was published on the journal's website, and the journal then made a commitment to peer-review the primary clinical manuscript.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

65 ICUs (from 13 university, eight university-affiliated, and 44 non-university hospitals) participated. 42 ICUs decided to join stratum B (option to use alternative cardiac output monitoring technologies in control group). A further five ICUs swapped to stratum B during recruitment; we considered patients randomly assigned after this point as stratum B patients.

Figure 1 shows the trial profile. We randomly assigned 1041 patients. Of the 522 patients allocated to the control group, 24 (5%) were managed with a PAC. In all but one instance (due to staff error), loss of equipoise was the reason. Of the 519 patients allocated to the PAC group, 34 (7%) were not managed with a PAC. Of these, insertion was unsuccessful in 14 (3%), the clinical condition either deteriorated or improved such that a PAC was considered inappropriate in 14 (3%), and there were safety concerns (coagulopathy) in a further six (1%). Table 1 shows the baseline characteristics, which were similar between groups. For the PAC group the median time from randomisation to PAC insertion was 1·7 h (IQR 1·1–2·7).

We followed up all patients until discharge from an acute hospital ward, except for one patient who was still in hospital 3 months after the end of recruitment and whose data were censored at that point. Hospital mortality was similar in the two groups (66% control, 68% PAC; table 2), as was in-hospital survival to 90 days (figure 2). In the a-priori identified subgroups, we noted no differences in treatment effect on hospital mortality (table 2). Length of stay in ICU, hospital, and organ-days of support for survivors and non-survivors were similar in both groups (table 2).

One or more direct complications were reported in 46 of 486 (10%) patients in whom PAC insertion was attempted. The most frequent complications reported

were haematomata at the insertion site (n=17, 4%), arterial punctures (n=16, 3%), and arrhythmias needing treatment within 1 h of insertion (n=16, 3%—one of which was a cardiac arrest). Other complications included pneumothoraces (n=2), haemothorax (n=1), and retrieval of lost insertion guidewires from the femoral vein and inferior vena cava (n=2).

One or more changes in clinical management within 2 h of insertion as a direct result of PAC-derived data were reported in 389 (80%) patients in the PAC group. The most frequently reported changes were: infusion of 200 mL or more of fluid above maintenance levels in 1 h (n=205, 42%); changes in dose of a vasoactive drug of greater than 25% (n=211, 43%); and introduction of vasoactive drug(s) (n=156, 32%).

The first PAC remained in place for a median of 2 (IQR 1–3) days; the total number of days that a PAC was indwelling in individual patients was 3 (2–4) days.

	Treatment group*		Hazard ratio (95% CI) (adjusted unless stated)	p
	PAC	Control		
Mortality				
Ultimate hospital mortality	346/506 (68%)	333/507 (66%)		0·39†
Unadjusted hazard ratio			1·07 (0·92–1·24)	0·40‡
Adjusted hazard ratio			1·09 (0·94–1·27)	0·25§
ICU mortality	304/506 (60%)	291/508 (57%)		0·37†
28-day mortality	314/506 (62%)	305/508 (60%)		0·52†
ICU length of stay (days)				
Survivors (median, IQR)	12·1 (6·2–22·3)	11·0 (5·7–21·0)		0·26¶
Non-survivors (median, IQR)	2·6 (0·7–8·4)	2·5 (0·8–7·2)		0·71¶
Hospital length of stay (days)				
Survivors (median, IQR)	34 (23–61)	40 (21–70)		0·43¶
Non-survivors (median, IQR)	3 (1–11)	3 (1–11)		0·90¶
Organ-days of support in ICU				
Survivors (median, IQR)	19 (12–33)	19 (10–32)		0·32¶
Non-survivors (median, IQR)	9 (4–20)	8 (4–21)		0·74¶
Subgroup analyses, ultimate hospital mortality by				
Alternative cardiac output monitoring				0·48‖
Stratum A	75/105 (71%)	71/107 (66%)	1·21 (0·87–1·68)	
Stratum B	271/401 (68%)	262/400 (66%)	1·06 (0·90–1·26)	
APACHE II risk of death**				0·92‖
0–0·281	101/169 (60%)	89/158 (56%)	1·14 (0·85–1·52)	
0·282–0·499	108/156 (69%)	107/158 (68%)	1·08 (0·83–1·42)	
0·500–1	124/154 (81%)	123/167 (74%)	1·09 (0·85–1·40)	
Major presumptive clinical syndrome				0·69‖
Acute respiratory failure	48/68 (72%)	38/66 (58%)	1·39 (0·91–2·13)	
Multiorgan dysfunction	224/328 (68%)	231/336 (69%)	1·04 (0·87–1·26)	
Decompensated heart failure	39/55 (71%)	35/56 (63%)	1·07 (0·68–1·69)	
Other	35/55 (64%)	29/49 (59%)	1·13 (0·69–1·85)	
PACs per admission††				0·97‖
<0·05	79/99 (80%)	71/100 (71%)	1·19 (0·85–1·65)	
0·05–0·11	60/96 (63%)	62/100 (62%)	1·11 (0·77–1·61)	
0·11–0·15	70/106 (66%)	71/102 (70%)	1·14 (0·81–1·60)	
≥0·15	63/88 (72%)	56/90 (62%)	1·25 (0·86–1·81)	

*Data are deaths/patients (%) unless stated otherwise. Data censored for one patient in control group still in hospital. †p value from Fisher's exact test. ‡p value from unadjusted Cox proportional hazards model. §p value from Cox proportional hazards model adjusted for age, sex, surgical status, major presumptive clinical syndrome, APACHE II score at admission, and SOFA score at randomisation. ¶p value from Wilcoxon rank-sum test for difference in distribution. ‖p value for test of interaction between treatment and subgroup in adjusted Cox proportional hazards model. **Excludes 44 patients in control group and 47 in PAC group who stayed <8 h or who had incomplete data. ††Based on 782 admissions from 48 units (in the PAC-Man study) in England and Wales with historic data on PAC use from the audit commission survey.

Table 2: **Outcomes**

Discussion

Our results indicate no difference in hospital mortality between critically ill patients managed with or without a PAC. Similarly, length of stay in either intensive care or hospital, or organ-days of support did not differ between groups.

The pragmatic design of our study reflected the lack of consensus on a specific management protocol. Though some argue strongly for a structured approach, the lack of supportive data meant that no common strategy could be agreed with respect to timing or indications for catheter insertion, selection and manipulation of specific drugs, fluids and support devices, and haemodynamic endpoints. Furthermore, the study outcome would have reflected the choice of strategy used if we had adopted a structured approach rather than the use of the catheter per se, which was the primary question demanded by the funding body, particularly in view of its potential to harm.[13,19] We thus assessed usual management with a PAC, and, as a result, imitated practice and assessed the clinical effectiveness of the device in ICUs within the UK National Health Service (NHS). The external validity of the study was enhanced by the open invitation to participate, the large number of hospitals (over a fifth of UK ICUs) that took part, and the representative proportion of university and community hospitals included. The limited number of exclusion criteria also enabled enrolment of most patients deemed to need management with a PAC. High compliance and complete follow-up of patients enhanced the internal validity of our results.

Retaining the option to use alternative, less invasive, cardiac output monitoring technologies in some ICUs (stratum B) also reflected usual or current care within the NHS, since adoption of these technologies has greatly increased over the past 5 years.[20] This fact is mirrored by the small number of units opting for stratum A. Although there was no evidence of interaction between the treatment effect and the stratum, the statistical power of such tests is low. Indeed, our trial was never sufficiently powered to compare management with a PAC against no cardiac output monitoring. There remains a need for formal assessment of these less invasive monitoring devices in the critically ill.

The PAC-Man study had an 82% power to detect a 10% change in hospital mortality with a PAC. Our results are similar to those of two smaller, pragmatic (non-protocolised) studies[21,22] in patients in ICU: a multicentre, French study[21] of 676 patients with sepsis or acute respiratory distress syndrome, or both, and a single-centre UK study[22] of 201 patients with predominantly septic or cardiogenic shock. These studies reported 28-day mortality rates of 59·4% versus 61·0%, and 47·9% versus 47·6%, respectively, in patients managed with or without a PAC. All three studies refute the suggestion by Connors and colleagues[13] that catheter use is related to a significant increase in mortality.

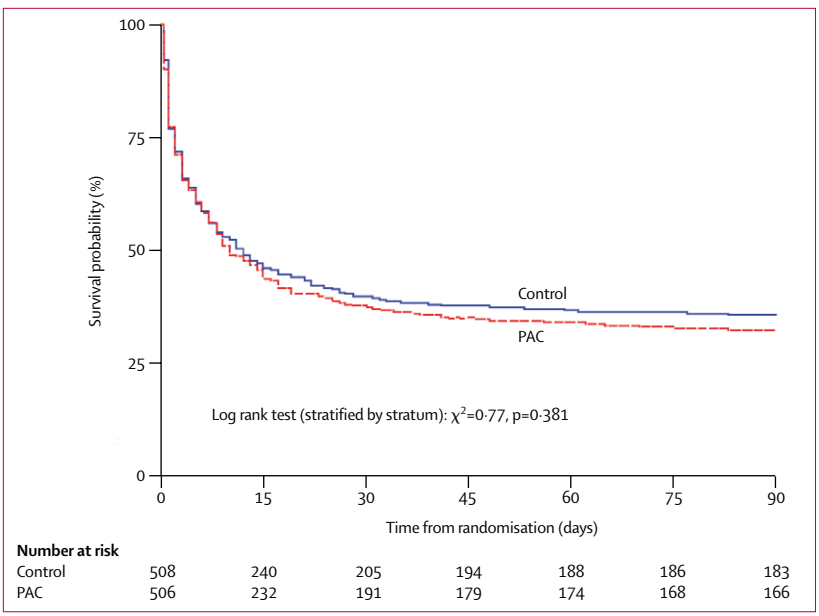

Figure 2: **Kaplan-Meier survival curves for in-hospital mortality by treatment group**
Patients discharged alive from hospital before 90 days assumed to still be alive at 90 days. There were 12 deaths later than 90 days (five PAC, seven control).

The generalisability of our findings to other countries remains to be identified. The high APACHE II severity scores indicate that PAC use is predominantly considered for the gravely ill. The main indication for inclusion in our study (>80% of patients) was to guide vasoactive drug treatment, suggesting a similar patient cohort to that enrolled in the French multicentre study.[21] However, their use of PAC in other groups of patients, such as heart failure, was not stated.

The absence of overall benefit in these intensive care studies could be variously explained by statistical chance or by misinterpretation of PAC-derived data, formulation of ineffective treatment plans, or no additional advantage being gained from a more detailed knowledge of haemodynamics. Questionnaires in the USA[8,9] and Europe[10] have highlighted high degrees of ignorance in terms of correct waveform recognition and data interpretation among both ICU doctors and nurses. PAC insertion is often left to junior doctors and its declining use might only serve to increase the risk of misapplication and complications. We did not assess quality of use, though we noted no outcome difference between units with high and low historical frequency of use. No deaths were directly attributed to PAC insertion in our study, though 10% of patients did have insertion-related complications. We did not study late-onset complications, such as infection.

The high mortality seen in our study population indicates that seriously ill patients were being identified. Reserving use of PACs primarily for these patients with poor outlook could reduce its effectiveness in improving outcome. The results of a meta-analysis[23] support this notion, by showing outcome benefit from the PAC when used to direct protocolised haemodynamic interventions in high-risk surgical patients, but not when commenced in critically ill intensive care patients with established multiple organ failure and a high predicted risk of death. This finding suggests that a different treatment paradigm other than manipulation of macrocirculatory variables might need to be considered in such patients.[24]

In addition to the clinical analysis, we have also assessed the cost-effectiveness of PAC use in managing critically ill patients in ICU, from a decision analysis perspective. This analysis, based on data obtained during the trial, which reported no significant difference in outcomes or resource use, indicated that withdrawal of PACs from routine use in intensive-care units in the UK NHS is likely to produce a health gain, at a price that is considered acceptable by current decision-making bodies. The cost per quality adjusted life year (QALY) gained from withdrawing PAC is UK£2980 (US$5672), which compares favourably with many routinely provided therapies—eg, statins for the management of coronary heart disease.[25] This finding shows the difference in the implications of the PAC-Man study when the data are analysed to inform decision making rather than to test a hypothesis. This decision has been well rehearsed in the published work.[26,27] Indeed, the National Institute of Clinical Excellence for England and Wales promotes the decision-analysis approach.[28] Details of our full economic evaluation are reported elsewhere.[29]

To conclude, results of large randomised studies,[21,22] assessing the effectiveness of PAC in intensive care, have shown no overall advantage. Furthermore, sophisticated and less invasive diagnostic and monitoring technologies are becoming increasingly available, though also still need to be formally assessed. Although benefit might accrue from skilled use of PAC, its declining popularity and thus decreased familiarity among medical and nursing staff mandates regular training to maintain the required skills. Efficacy studies are needed to ascertain optimum management protocols and to identify the groups of patients who could gain from management with a PAC, which could otherwise become a redundant technology.[30]

Contributors
K Rowan and M Singer conceived and designed the study, and S Harvey and D A Harrison did the analysis. All authors participated in data interpretation and writing of the paper.

Participating intensive care units
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Conflict of interest statement

M Singer does consultancy work for, and receives research funds from, Deltex Medical, manufacturers of the CardioQ oesophageal doppler device. All other authors declare that they have no conflict of interest.

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