Pulmonary artery catheterization: a narrative and systematic critique of randomized controlled trials and recommendations for the future

Ivanov R I, Allen J, Sandham J D, Calvin J E

Authors' objectives
To assess the efficacy of pulmonary artery catheterisation (PAC) for monitoring on patient outcome (e.g. survival).

Searching
MEDLINE was searched from 1970 to 1996 using the headings 'pulmonary artery catheterization', 'Swan-Ganz catheterization', and 'right heart catheterization', restricting the results to 'effectiveness' and 'usefulness'. The authors also consulted other experts about published RCTs.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) comparing management with and without PAC were eligible for inclusion.

Specific interventions included in the review
Studies of PAC were eligible for inclusion.

Participants included in the review
No inclusion criteria relating to the participants were specified. The included studies were of people undergoing surgery or in intensive care for the following: hip fractures; heart surgery; abdominal aortic surgery; mixed medical and surgical conditions; limb-salvage arterial surgery; high-risk trauma; high-risk surgical and high-risk mixed; moderate-risk surgical and moderate-risk mixed; and septic shock.

Outcomes assessed in the review
No inclusion criteria relating to the outcome measures were specified. The risk of death between the treatment groups using PAC-guided strategies and the control groups was assessed.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
Quality scores were assigned on a scale of 1 to 100 using the method of Chalmers et al. (see Other Publications of Related Interest). Two independent reviewers scored the studies for quality, and the scores were averaged.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
The authors performed a statistical meta-analysis and provided a narrative review of the included studies. Sixteen 2x2 tables were set up to assess the risk of death between the treatment groups using PAC-guided strategies and the control groups. The combined relative risk (RR) for the 16 studies was calculated using the Mantel-Haenszel method.

How were differences between studies investigated?
A random-effects model was used to explain the variability between studies. The between-study variability was also calculated using a least-squares method.

Sensitivity analyses of the RR ratio of PAC-guided strategies and the between-study variability were performed, by recomputing the RR ratio and between-study variability after deleting each study one at a time.

**Results of the review**

Sixteen RCTs with 2,052 patients were included.

The overall quality score of the trials was 40.15 (plus or minus 6.32) out of a possible score of 100.

The overall RR of mortality of patients treated with PAC strategies was 0.907 (95% confidence interval, CI: 0.803, 1.025, P=0.117).

Using a no-covariate model, PAC-based strategies had a protective effect with a RR of 0.808 (95% CI: 0.598, 1.091, P=0.148).

The between-study variability was 0.112.

Using only surgical studies, the RR was 0.578 (95% CI: 0.357, 0.937, P=0.03). Using only nonsurgical studies, the RR was 1.043 (95% CI: 0.784, 1.387, P non significant).

**Authors' conclusions**

Existing RCTs on PAC-guided strategies revealed a modest risk reduction (approximately 19%) that did not reach statistical significance. The risk reduction appeared greatest in the surgical series. Significant issues about the quality of these trials exist. Nonetheless, there is no observed trend for harm produced by PAC.

**CRD commentary**

The search was limited to searches of one database (MEDLINE) and contact with experts in the field. It was unclear whether non-English articles were considered. These restrictions, and the lack of searching for unpublished data, mean that relevant studies might have been missed.

The authors made a thorough quality assessment of the included studies and reported the results, but they did not state whether the reviewers were blinded.

The research question was not stated clearly: it was unclear whether this was an assessment of the efficacy of PAC, or whether the aim of the article was really to assess the quality of past literature.

The authors acknowledged that the quality of the included studies was low, there was heterogeneity between the studies, there were no a priori sample size calculations, and there was a lack of blinding in the original studies. The conclusions should therefore be viewed with caution.

One of the authors' conclusions, that there was no observed trend for harm produced by PAC, does not follow since this was not investigated in this review.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors stated that deficiencies of these trials have important implications for the proper design of future trials. Specifically, the authors recommended that future studies should be more rigorously designed in terms of sample size calculations, blinding, randomisation, intention-to-treat allocation, and in the ethical considerations of obtaining patient consents.
Funding
Institutional funds.

Bibliographic details

PubMedID
9259342

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Catheterization, Swan-Ganz /adverse effects; Humans; Meta-Analysis as Topic; Outcome Assessment (Health Care); Randomized Controlled Trials as Topic; Research Design

AccessionNumber
11998003044

Date bibliographic record published
31/07/1999

Date abstract record published
31/07/1999

Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.