Prophylactic intraaortic balloon counterpulsation in high-risk cardiac surgery: a survey of opinion and current practice

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ABSTRACT

Introduction: Patients undergoing cardiac surgery increasingly have greater comorbidities and subsequently are at higher risk of adverse postoperative outcomes. Despite some evidence suggests that prophylactic intraaortic balloon counterpulsation reduces mortality in selected high-risk patients, its use remains low. The aim of this study was to investigate reported management strategies of high-risk patients and attitudes towards further research in this area.

Methods: A 22-question survey was developed and distributed electronically to all practicing cardiothoracic fellows through the email list of the Australian and New Zealand Society of Cardiac and Thoracic Surgeons.

Results: The response rate was 28% (n=31). Reported use of prophylactic intraaortic balloon counterpulsation varied depending on the specified preoperative indication. Prophylactic intraaortic balloon counterpulsation was used occasionally or never by the majority of respondents for their patients with characteristics similar to those of previous trials. The most frequent reason given for not using prophylactic intraaortic balloon counterpulsation was lack of data (42.9%), with a willingness to consider participation in an randomised controlled trial of prophylactic intraaortic balloon counterpulsation by a large majority of respondents (79.3%).

Conclusions: The majority of surgeons who responded to this survey do not routinely use prophylactic intraaortic balloon counterpulsation for high-risk patients. Further prospective data is warranted to ascertain whether potential barriers to a randomised control trial of prophylactic intraaortic balloon counterpulsation, such as adequate patient numbers and clear selection criteria, can be overcome.

Keywords: high-risk, intraaortic balloon pump.

INTRODUCTION

Routine cardiac surgery is associated with a low risk of mortality (1). However, patients undergoing cardiac surgery are increasingly older, with greater comorbidities and consequently the proportion and absolute number of patients at high-risk of postoperative adverse outcomes is increasing (2, 3).

As well as increased short-term mortality, high-risk patients also have a significantly increased incidence of perioperative acute myocardial infarction, cardiac failure, acute kidney injury and stroke (4-7). Postoperative major morbidity is associated with increased longer-term mortality, cost and reduced quality of life (8, 9).

The optimal management of high-risk patients remains uncertain and has been
identified as a research priority by several leading organisations (10, 11).

In a recently updated Cochrane systematic review of high-risk patients undergoing coronary artery bypass graft (CABG) surgery, prophylactic intraaortic balloon counterpulsation (IABC) significantly reduced postoperative mortality (odds ratio 0.18, 95% confidence interval 0.08-0.41) (12). Despite this, preoperative IABC use is variable and employed in only a small proportion of high-risk patients in Australia and New Zealand (13) and worldwide (14, 15). Current low and variable use may reflect the strength of the available data upon which individual management decisions are based (16). In addition, there may be difficulties in identifying appropriate high-risk patients preoperatively, contraindications to intraaortic balloon pump (IABP) placement, lack of time, or surgical preference for alternative management strategies. Further prospective research, including a randomised controlled trial (RCT) of prophylactic IABC in selected high-risk patients, would help to clarify the role of this intervention but is contingent on first understanding current management strategies and attitudes towards this program of research amongst key stakeholders.

The aim of this study was to conduct a questionnaire-based survey of cardiothoracic surgeons in order to determine self-reported management strategies of high-risk patients and attitudes towards further research in this area.

METHODS

Survey development. Three survey domains of interest were identified. First, the current strategies for identifying and managing high-risk patients (defined as a peroperative mortality or major morbidity >5%) undergoing cardiac surgery. Second, the attitudes and beliefs towards research priorities in high-risk cardiac surgery and third, the individual and institutional characteristics of respondents.

Survey item were generated around these three domains and continued until redundancy. Items were then ranked and reduced in consultation with experts in the field. The draft survey was pilot tested by several senior cardiothoracic trainees using a one page assessment sheet. The draft survey was assessed for flow, salience, clarity, acceptability, face validity and content validity. The final survey included 22 questions (Appendix 1).

Survey administration. The survey was distributed electronically through the email list of the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) to all practicing Cardiothoracic Surgery Fellows. The email included a cover letter detailing the aims of the survey and a link to allow one-time, anonymous, online completion of the questionnaire using an internet-based commercially-available survey sponsor (www.surveymonkey.com). The survey was sent a total of three times over a period of five weeks.

Statistical analysis. The response rate was determined by comparing the number of current Fellows in the ANZSCTS database with the number of responses. Normally distributed data were presented as means, non-normally distributed data as medians. No inferential statistics was used.

The study was conducted after approval by the Northern Sydney Local Health District Human Research Ethics Committee (reference: 1201-032M, LR).

RESULTS

The survey was emailed to all 111 Cardiothoracic Fellows between February and April 2012. Thirty one surveys were com-
Table 1 - Method(s) used preoperatively to identify patients at high-risk of adverse outcomes.

| Method                        | Response count (%) |
|-------------------------------|-------------------|
| Ejection fraction < 30%       | 23 (76.7)         |
| EuroSCORE                     | 20 (66.7)         |
| Redo surgery                  | 15 (50.0)         |
| Significant left main stenosis| 12 (40.0)         |
| Anticipated prolonged bypass  | 9 (30.0)          |
| Creatinine                    | 9 (30.0)          |
| Unstable angina               | 8 (26.7)          |
| Troponin                      | 6 (20.0)          |
| AuSCORE                       | 4 (13.3)          |
| BNP or NT pro-BNP             | 2 (6.7)           |
| No Specific Method            | 2 (6.7)           |
| Parsonnet                     | 1 (3.3)           |

Table 2 - The reported frequency of prophylactic intraaortic balloon counterpulsation and prophylactic levosimendan for patients with various preoperative risk factors.

| Intraaortic Ballon Counterpulsation | Never n (%) | Occasionally n (%) | Sometimes n (%) | Usually n (%) | Always n (%) |
|-------------------------------------|-------------|--------------------|-----------------|--------------|-------------|
| Left main disease > 70%             | 11 (36.7)   | 13 (43.3)          | 6 (20.0)        | 0            | 0           |
| Redo sternotomy                     | 25 (83.3)   | 4 (13.3)           | 1 (3.3)         | 0            | 0           |
| Left ventricular ejection fraction < 30% | 6 (20.0)   | 17 (56.7)          | 5 (16.7)        | 2 (6.7)      | 0           |
| Unstable angina in the 24 hours prior to surgery | 6 (20.0) | 15 (50.0) | 7 (23.3) | 2 (6.7) | 0 |
| Two or more of the above risk factors | 4 (13.8) | 9 (31.0) | 9 (31.0) | 6 (20.7) | 1 (3.4) |

| Levosimendan                        |             |                   |                 |              |             |
|-------------------------------------|-------------|-------------------|-----------------|--------------|-------------|
| Left main disease > 70%             | 28 (93.3)   | 2 (6.7)           | 0               | 0            | 0           |
| Redo sternotomy                     | 28 (93.3)   | 1 (3.3)           | 1 (3.3)         | 0            | 0           |
| Left ventricular ejection fraction < 30% | 15 (50.0)   | 11 (36.7)         | 2 (6.7)         | 2 (6.7)      | 0           |
| Unstable angina in the 24 hours prior to surgery | 29 (100) | 0 | 0 | 0 | 0 |
| Two or more of the above risk factors | 19 (63.3) | 9 (30.0) | 2 (6.7) | 0 | 0 |
prophylactic IABP was low ejection fraction (86.7%), followed by unstable angina in the 24 hours prior to surgery (56.7%) and significant left main disease (40.0%) (Table 3).

When prophylactic IABC is placed, this was reported to occur primarily before arriving in the operating theatre (53.3%) compared with pre-induction (3.3%), post-induction (26.7%) pre or post-induction (13.3%) or never placed (3.3%). In considering contraindications to IABC, moderate aortic incompetence, severe peripheral vascular disease and severely calcified aorta were considered absolute contraindications by 92.6%, 89.9% and 37.0% of respondents respectively. No respondents considered mild aortic incompetence, mild peripheral vascular disease or therapeutic anticoagulation absolute contraindications. Finally, the degree of agreement that prophylactic IABC may improve outcome in selected patients undergoing high-risk cardiac surgery was 3.4% strongly agreed, 69.0% agreed, 20.7% neutral, 6.9% disagreed, 0% strongly disagreed.

Table 3 - Characteristics identifying patients that may benefit from prophylactic intraaortic balloon counterpulsation.

| Characteristic                              | Response count (%) |
|--------------------------------------------|--------------------|
| Low ejection fraction                      | 26 (86.7)          |
| Unstable angina in the 24 hours prior to surgery | 17 (56.7)          |
| Significant left main disease              | 12 (40.0)          |
| High EuroSCORE or equivalent               | 10 (33.3)          |
| High BNP or NT pro-BNP                    | 5 (16.7)           |
| Expected prolonged bypass                  | 1 (3.3)            |
| Chronic renal impairment                   | 0                  |
| Redo sternotomy                            | 0                  |

BNP = Brain natriuretic peptide, NT pro-BNP = N-terminal brain natriuretic peptide.

Table 4 - Reasons high-risk patients do not currently receive prophylactic intraaortic balloon counterpulsation.

| Reason                                         | Response count (%) |
|------------------------------------------------|--------------------|
| Lack of data to support its use                | 12 (42.9)          |
| Not indicated                                  | 10 (35.7)          |
| Lack of clear selection criteria              | 6 (21.4)           |
| Other *                                        | 4 (14.3)           |
| Lack of preoperative identification           | 2 (7.1)            |
| All high-risk patients already receive prophylactic IABC | 2 (7.1)            |
| Lack of time                                   | 0                  |

*Other responses were:
1. IABC not indicated for all types of high-risk patients.
2. Use levosimendan.
3. There is significant potential morbidity with IABC.
4. Lack of appropriate preoperative beds to look after IABC.

Finally, the degree of agreement that prophylactic IABC may improve outcome in selected patients undergoing high-risk cardiac surgery was 3.4% strongly agreed, 69.0% agreed, 20.7% neutral, 6.9% disagreed, 0% strongly disagreed.

Attitude towards further research. The most frequently cited reason for high-risk patients currently not receiving prophylactic IABC was lack of data to support its use (Table 4). When asked to rate the degree of agreement to enrolling selected patients undergoing high-risk cardiac surgery to a randomised controlled trial of prophylactic IABC, 3.4% strongly agreed, 48.3% agreed, 17.2% were neutral, 17.2% disagreed and 13.8% strongly disagreed. Agreement that an intervention showing benefit would alter management depended on the outcome measure chosen (Table 5). The greatest barriers to a randomised controlled trial of prophylactic IABC versus usual care were: too few suitable patients (37.9%), no major barriers (31.0%), a strong view that IABC is already indicated in such settings (24.1%), equally efficacious alternatives...
DISCUSSION

This survey of Australian and New Zealand cardiothoracic surgery Fellows found that high-risk patients were identified by surgeons at a rate that is consistent with the national and international literature, and that in spite of being identified as high-risk, prophylactic IABC is not being instituted for these high-risk patients largely because of a perceived lack of data supporting the efficacy of this intervention. A clear majority of the surgeons who responded to this survey would support a randomized trial to provide further evidence regarding the efficacy of prophylactic IABC in this population.

There have been 6 RCTs (17-22) and a Cochrane meta-analysis (12), all suggesting a large reduction in mortality when IABC is commenced prior to surgery in high-risk patients, however the use of this therapy is very limited. Less than 10% of patients who might benefit from this intervention in ANZ currently receive prophylactic IABC. This survey found that the most common barriers to implementation of prophylactic IABC are the lack of clear selection criteria and the lack of sufficient data to support the intervention. Although not explored in the survey, these beliefs are likely due, at least in part, to the small number of total participants enrolled in RCTs of prophylactic IABC (n=255), high baseline mortality in the control group and single centre origin of 5 out of 6 of the studies (12).

Reported methods to identify high-risk patients and their subsequent management varied considerably amongst respondents. Substantial practice variation in the management of high-risk patients has previously been reported, although not in the Australian and New Zealand context (23). Whilst individual patient factors and differences in case mix and institution may
be partially accountable and were not investigated in this study, such wide practice variation is likely to occur in the setting of a lack of solid evidence to guide practice. In a recent retrospective study of Australian and New Zealand patients undergoing CABG, 4 simple preoperative characteristics used in previous RCTs of IABC, identified a group of patients at significantly increased risk of severe adverse postoperative outcomes including acute kidney injury, myocardial infarction and death (13). The results of this survey suggest that alteration in these outcomes would change management of high-risk patients. Further prospective studies are warranted to ascertain the true serious adverse event rate and potential magnitude of benefit associated with IABC in selected high-risk patients.

There are several limitations to this study that require consideration. First, although the response rate was similar to other studies surveying surgical opinion (24, 25), the response rate was relatively low (28%) and therefore potentially subject to response bias. It should be noted though that the survey population was the entire population of cardiothoracic surgeons in Australia and New Zealand, rather than a sample of them. The willingness to participate in further research depends more on the absolute number of favorable responses rather than the proportion. Second, as with all surveys, the results may be limited by differences between reported behavior and actual clinical practice. We conducted a confidential survey without individual or unit identifiers to limit this effect. In addition, given the magnitude and consistency of responses, the favorable response in conducting research in the use of prophylactic IABC is likely to be a true reflection of the desire of the respondents to advance evidence-based practice and improve patient outcomes.

CONCLUSION

Reported use of prophylactic IABC by practicing Australian and New Zealand cardiothoracic Fellows was low and varied by indication and respondent. The most frequently cited reason for not using prophylactic IABC in a high-risk patient undergoing cardiac surgery was lack of clear data to support its use. Encouragingly, a majority of respondents reported being interested in taking part in a RCT of prophylactic IABC. Further prospective data is required in order to ascertain whether additional barriers to an RCT, such as inadequate patient numbers and lack of clear selection criteria, can be overcome.

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