Intra-Aortic Balloon Pumps for Heart Failure Management: A Rapid Review

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Suggested Citation

This report should be cited as follows:


Conflict of Interest Statement

All reports prepared by the Division of Evidence Development and Standards at Health Quality Ontario are impartial. There are no competing interests or conflicts of interest to declare.

Rapid Review Methodology

Clinical questions are developed by the Division of Evidence Development and Standards at Health Quality Ontario in consultation with experts, end-users, and/or applicants in the topic area. A systematic literature search is then conducted to identify relevant systematic reviews, health technology assessments, and meta-analyses; if none are located, the search is expanded to include randomized controlled trials (RCTs), and guidelines. Systematic reviews are evaluated using a rating scale developed for this purpose. If the systematic review has evaluated the included primary studies using the GRADE Working Group criteria (http://www.gradeworkinggroup.org/index.htm), the results are reported and the rapid review process is complete. If the systematic review has not evaluated the primary studies using GRADE, the primary studies included in the systematic review are retrieved and a maximum of two outcomes are graded. If no well-conducted systematic reviews are available, RCTs and/or guidelines are evaluated. Because rapid reviews are completed in very short timeframes, other publication types are not included. All rapid reviews are developed and finalized in consultation with experts.

Disclaimer

This rapid review is the work of the Division of Evidence Development and Standards at Health Quality Ontario, and is developed from analysis, interpretation, and comparison of published scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all the available scientific research and is not intended as an exhaustive analysis. Health Quality Ontario assumes no responsibility for omissions or incomplete analysis resulting from its rapid reviews. In addition, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current to the date of the literature search specified in the Research Methods section, as appropriate. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: http://www.hqontario.ca/evidence/publications-and-ohtac-recommendations.
About Health Quality Ontario

Health Quality Ontario is an arms-length agency of the Ontario government. It is a partner and leader in transforming Ontario’s health care system so that it can deliver a better experience of care, better outcomes for Ontarians, and better value for money.

Health Quality Ontario strives to promote health care that is supported by the best available scientific evidence. Health Quality Ontario works with clinical experts, scientific collaborators, and field evaluation partners to develop and publish research that evaluates the effectiveness and cost-effectiveness of health technologies and services in Ontario.

Based on the research conducted by Health Quality Ontario and its partners, the Ontario Health Technology Advisory Committee (OHTAC)—a standing advisory sub-committee of the Health Quality Ontario Board—makes recommendations about the uptake, diffusion, distribution, or removal of health interventions to Ontario’s Ministry of Health and Long-Term Care, clinicians, health system leaders, and policy-makers.

Rapid reviews, as well as evidence-based analyses and their corresponding OHTAC recommendations, and other associated reports are published on the Health Quality Ontario website. Visit http://www.hqontario.ca for more information.

About Health Quality Ontario Publications

To conduct its rapid reviews, Health Quality Ontario, its research partners, or both, reviews the available scientific literature, making every effort to consider all relevant national and international research; collaborates with partners across relevant government branches; consults with clinical and other external experts and developers of new health technologies; and solicits any necessary supplemental information.

In addition, Health Quality Ontario collects and analyzes information about how a health intervention fits within current practice and existing treatment alternatives. Details about the diffusion of the intervention into current health care practices in Ontario can add an important dimension to the review. Information concerning the health benefits, economic and human resources, and ethical, regulatory, social, and legal issues relating to the intervention may be included to assist in making timely and relevant decisions to optimize patient outcomes.

Disclaimer

This rapid review is the work of the Division of Evidence Development and Standards or one of its research partners, and the Ontario Health Technology Advisory Committee of Health Quality Ontario, and is developed from analysis, interpretation, and comparison of scientific research. It also incorporates, when available, Ontario data and information provided by experts. As this is a rapid review, it may not reflect all scientific research available. Additionally, it is possible that other relevant scientific findings may have been reported since completion of the review. This report is current to the date of the literature review specified in the methods section, if available. This rapid review may be superseded by an updated publication on the same topic. Please check the Health Quality Ontario website for a list of all publications: www.hqontario.ca/evidence/publications-and-ohtac-recommendations.
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## List of Abbreviations

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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>IABP</td>
<td>Intra-aortic balloon pump</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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Background

As legislated in Ontario’s *Excellent Care for All Act*, Health Quality Ontario’s mandate includes the provision of objective, evidence-informed advice about health care funding mechanisms, incentives, and opportunities to improve quality and efficiency in the health care system. As part of its Quality-Based Funding (QBF) initiative, Health Quality Ontario works with multidisciplinary expert panels (composed of leading clinicians, scientists, and administrators) to develop evidence-based practice recommendations and define episodes of care for selected disease areas or procedures. Health Quality Ontario’s recommendations are intended to inform the Ministry of Health and Long-Term Care’s Health System Funding Strategy.

For more information on Health Quality Ontario’s Quality-Based Funding initiative, visit [www.hqontario.ca](http://www.hqontario.ca).

Objective of Analysis

The objective of this analysis is to evaluate the use of intra-aortic balloon pumps (IABP) in the management of patients hospitalized with heart failure.

Clinical Need and Target Population

Heart failure, a complex condition characterized by impairment of the heart function, may lead to low cardiac output and pulmonary or systemic congestion. (1) The condition is more common in older patients, (1) and therefore its incidence has been increasing with the aging of the population, leading to an increase in the number of hospitalizations for the condition. (2) Acute heart failure presents with a poor prognosis: the risk of death or rehospitalization is estimated to be between 30% and 60% within 60 days of hospital admission. (2)

Technology/Technique

IABP has been used in clinical practice since 1968. (3;4) It consists of a circulatory-assist device that supposedly increases cardiac output by decreasing systolic arterial pressure and increasing diastolic arterial pressure, thus reducing myocardial oxygen demand and myocardial ischemia. (4)

Regulatory Status

Different IABPs are available and are licensed by Health Canada as class IV devices. (5) Licensed indications obtained by contacting Health Canada are listed in table 1 (personal communication, September 28, 2012).
<table>
<thead>
<tr>
<th>Licence #</th>
<th>Indication</th>
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<tr>
<td>722</td>
<td>Patients whose myocardial oxygen supply and demand are imbalanced</td>
</tr>
<tr>
<td>28787</td>
<td>Used to assist the cardiovascular system and in particular, the left ventricular function of the heart, by ventricular unloading and coronary perfusion</td>
</tr>
<tr>
<td>63563</td>
<td>Provides temporary support to the left ventricle via the principle of counterpulsation in adult and pediatric patients</td>
</tr>
<tr>
<td>64146</td>
<td>Provides temporary support to the left ventricle via the principle of counterpulsation</td>
</tr>
<tr>
<td>77561</td>
<td>Supports the heart’s left ventricle by increasing coronary perfusion and reducing left ventricular work in adult and pediatric patients</td>
</tr>
</tbody>
</table>
Evidence-Based Analysis

Research Questions
What is the effectiveness of intra-aortic balloon pumps (IABPs) in the management of patients hospitalized with acute heart failure?

Research Methods

Literature Search

Search Strategy
A literature search was performed on October 4, 2012, using OVID MEDLINE, OVID MEDLINE In-Process and Other Non-Indexed Citations, OVID EMBASE, the Wiley Cochrane Library, and the Centre for Reviews and Dissemination database, for studies published until the search date, October 4, 2012. Abstracts were reviewed by a single reviewer and, for those studies meeting the eligibility criteria, full-text articles were obtained. Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment. Reference lists were also examined for any additional relevant studies not identified through the search.

Details about the systematic literature search strategy are presented in Appendix 1.

Inclusion Criteria

- English language full-reports
- systematic reviews, meta-analyses, health technology assessment reports, randomized controlled trials (RCTs), and guidelines
- evaluating the use of IABP in patients hospitalized with heart failure

Exclusion Criteria

- Studies evaluating IABP in patients presenting with heart failure and any of the following conditions were excluded: acute myocardial infarction, heart transplant, pre-heart transplant, cardio-renal syndrome, dialysis, patients using left ventricular assist devices, acute valvular insufficiency, and patients with other active chronic medical condition that requires acute stabilization such as chronic obstructive pulmonary disease, stroke, and active bleeding.
- Studies evaluating IABP in patients with conditions other than heart failure.

Outcomes of Interest

- Mortality
- IABP-related complications

Statistical Analysis
The results of the eligible studies are presented as shown in the publications. The guideline recommendations on the use of IABP in patients with heart failure are shown in tabular format.
Quality of Evidence

The Assessment of Multiple Systematic Reviews (AMSTAR) measurement tool was used to assess the methodological quality of systematic reviews. (6)

The quality of the body of evidence for each outcome was examined according to the GRADE Working Group criteria. (7) The overall quality is determined to be very low, low, moderate, or high using a step-wise, structural methodology.

Study design was the first consideration; the starting assumption was that RCTs are high quality, whereas observational studies are low quality. Five additional factors—risk of bias, inconsistency, indirectness, imprecision and publication bias—were then taken into account. Limitations or serious limitations in these areas resulted in downgrading the quality of evidence. Finally, 3 factors are considered which may raise the quality of evidence: large magnitude of effect, dose response gradient, and accounting for all residual confounding. For more detailed information, please refer to the latest series of GRADE articles. (8)

As stated by the GRADE Working Group, (7) the final quality score can be interpreted using the following definitions:

- **High**: Very confident that the true effect lies close to that of the estimate of the effect
- **Moderate**: Moderately confident in the effect estimate—the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
- **Low**: Confidence in the effect estimate is limited—the true effect may be substantially different from the estimate of the effect
- **Very Low**: Very little confidence in the effect estimate—the true effect is likely to be substantially different from the estimate of effect

Results of Literature Search

The database search yielded 399 citations (with duplicates removed). Articles were excluded based on information in the title and abstract. The full texts of potentially relevant articles were obtained for further assessment.

No studies on the use of IABP in patients hospitalized with heart failure met the pre-specified inclusion criteria.
Guidelines

The recommendations regarding the use of intra-aortic balloon pumps (IABPs) in patients with heart failure from Canadian Cardiovascular Society’s guidelines on heart failure are summarized in Table 2. (9)

Table 2: Recommendations on the Use of IABP in Patients With Heart Failure Based on Canadian Heart Failure Guidelines

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Statements</th>
</tr>
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<tbody>
<tr>
<td>Canadian Cardiovascular Society Consensus Conference recommendations on heart failure update 2007: Prevention, management during intercurrent illness or acute decompensation, and use of biomarkers (9)</td>
<td>IABP may be considered in patients with refractory heart failure despite medical therapy (class IIb, level B)\textsuperscript{a}</td>
</tr>
</tbody>
</table>

Abbreviation: IABP, intra-aortic balloon pump.

\textsuperscript{a} Class IIb: usefulness or efficacy is less well established by evidence or opinion; level B: data derived from a single randomized trial or nonrandomized studies. (9)
Conclusions

No high quality evidence on the use of IABPs in hospitalized patients with heart failure was identified through the systematic literature search. Therefore no conclusions could be made on its use in hospitalized patients with heart failure.
## Acknowledgements

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### Expert Panel for Health Quality Ontario: 'Episode of Care' for Congestive Heart Failure

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<th>Organization</th>
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<td>Affiliation</td>
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</tr>
</tbody>
</table>

**Ministry Representatives**

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<thead>
<tr>
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<th>Title</th>
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<tbody>
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<td></td>
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</tbody>
</table>
Appendices

Appendix 1: Literature Search Strategies

Search date: October 4, 2012
Databases searched: OVID MEDLINE, MEDLINE In-Process and Other Non-Indexed Citations, EMBASE; Cochrane Library; CRD

Q: Intra-aortic balloon pump for Heart Failure management
Limits: English
Filters: health technology assessments, systematic reviews, meta-analyses, randomized controlled trials and guidelines

Database: Ovid MEDLINE(R) <1946 to September Week 4 2012>, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <October 3, 2012>, Embase <1980 to 2012 Week 39>

Search Strategy:

# Searches Results
1 exp Heart Failure/ 325741
2 (((cardia? or heart) adj (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) adj (failure or insufficiency))).ti,ab. 257076
3 or/1-2 415403
4 Intra-Aortic Balloon Pumping/ use mesz 3088
5 Counterpulsation/ 2103
6 Aorta Balloon/ use emez 6116
7 (intra-aortic balloon pump* or intraaortic balloon pump* or intra-aorta balloon pump* or intraaorta balloon pump* or counterpulsation or IABP).ti,ab. 11011
8 (counterpulsation or counter pulsation or counterpressure or counter pressure or diastolic augmentation).ti. 2549
9 or/4-8 15306
10 Meta Analysis.pt. 36882
11 Meta Analysis/ use emez 66108
12 Systematic Review/ use emez 53391
13 exp Technology Assessment, Biomedical/ use mesz 8864
14 Biomedical Technology Assessment/ use emez 11385
15 (meta analy* or metaanaly* or pooled analysis or (systematic* adj2 review*)) or or published studies or published literature or medline or embase or data synthesis or data extraction or cochrane).ti,ab. 291497
16 ((health technolog* or biomedical technolog*) adj2 assess*).ti,ab. 3656
17 exp Random Allocation/ use mesz 76053
18 exp Double-Blind Method/ use mesz 117569
19 exp Control Groups/ use mesz 1375
20 exp Placebos/ use mesz 31433
21 Randomized Controlled Trial/ use emez 329946
22 exp Randomization/ use emez 59555
23 exp Random Sample/ use emez 4210
24 Double Blind Procedure/ use emez 111113
25 exp Triple Blind Procedure/ use emez 35
26 exp Control Group/ use emez 38017
27 exp Placebo/ use emez 205663
28 (random* or RCT).ti,ab. 1380327
29 (placebo* or sham*).ti,ab. 447606

### CRD

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<td>MeSH DESCRIPTOR Heart Failure EXPLODE ALL TREES</td>
<td>510</td>
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<tr>
<td>2</td>
<td>(((cardia? OR heart) ADJ (decompensation OR failure OR incompetence OR insufficiency)) OR cardiac stand still OR ((coronary OR myocardial) ADJ (failure OR insufficiency))):TI</td>
<td>307</td>
</tr>
<tr>
<td>3</td>
<td>#1 OR #2</td>
<td>542</td>
</tr>
<tr>
<td>4</td>
<td>MeSH DESCRIPTOR Intra-Aortic Balloon Pumping EXPLODE ALL TREES</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>MeSH DESCRIPTOR Counterpulsation EXPLODE ALL TREES</td>
<td>18</td>
</tr>
<tr>
<td>6</td>
<td>(intra-aortic balloon pump* OR intraaortic balloon pump* OR intra-aorta balloon pump* OR intraaorta balloon pump* OR counterpulsation OR IABP):TI OR (counterpulsation OR counter pulsation OR counterpressure OR counter pressure OR diastolic augmentation):TI</td>
<td>20</td>
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References


