

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

V Costa

December 2012

Suggested Citation

This report should be cited as follows:

Cost V. Intra-aortic balloon pumps for heart failure management: a rapid review. Toronto, ON: Health Quality Ontario; 2012 Dec. 17p. Available from: www.hqontario.ca/evidence/publications-and-ohtac-recommendations/rapid-reviews.

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.

Table of Contents

List of Abbreviations	5
Background	6
Objective of Analysis	6
Clinical Need and Target Population.....	6
Technology/Technique	6
<i>Regulatory Status</i>	6
Evidence-Based Analysis	8
Research Questions.....	8
Research Methods.....	8
<i>Literature Search</i>	8
<i>Inclusion Criteria</i>	8
<i>Exclusion Criteria</i>	8
<i>Outcomes of Interest</i>	8
<i>Statistical Analysis</i>	8
Quality of Evidence	9
Results of Literature Search.....	9
Guidelines	10
Conclusions	11
Acknowledgements	12
Appendices	14
Appendix 1: Literature Search Strategies	14
References	16

List of Abbreviations

IABP	Intra-aortic balloon pump
RCT	Randomized controlled trial

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.

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 1: Health Canada Licensed Indications for IABP

Licence #	Indication
722	Patients whose myocardial oxygen supply and demand are imbalanced
28787	Used to assist the cardiovascular system and in particular, the left ventricular function of the heart, by ventricular unloading and coronary perfusion
63563	Provides temporary support to the left ventricle via the principle of counterpulsation in adult and pediatric patients
64146	Provides temporary support to the left ventricle via the principle of counterpulsation
77561	Supports the heart's left ventricle by increasing coronary perfusion and reducing left ventricular work in adult and pediatric patients

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

Guideline	Statements
Canadian Cardiovascular Society Consensus Conference recommendations on heart failure update 2007: Prevention, management during intercurrent illness or acute decompensation, and use of biomarkers (9)	IABP may be considered in patients with refractory heart failure despite medical therapy (class IIb, level B) ^a

Abbreviation: IABP, intra-aortic balloon pump.

^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

Editorial Staff

Joanna Odrowaz, BSc

Medical Information Officers

Kaitryn Campbell, BA(H), BEd, MLIS

Corinne Holubowich, Bed, MLIS

Kellee Kaulback, BA(H), MIST

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

Name	Title	Organization
Dr. David Alter	Senior Scientist	Institute for Clinical Evaluative Sciences Research Program Director and Associate Staff, The Cardiac and Secondary Prevention Program at the Toronto Rehabilitation Institute-UHN; Associate Professor of Medicine, University of Toronto
Dr. Douglas Lee	Scientist	Institute for Clinical Evaluative Sciences
Dr. Catherine Demers	Associate Professor	Division of Cardiology, Department of Medicine McMaster University
Dr. Susanna Mak	Cardiologist	University of Toronto: Department of Medicine, Division of Cardiology, Mount Sinai Hospital
Dr. Lisa Mielniczuk	Medical Director, Pulmonary Hypertension Clinic	University of Ottawa Heart Institute
Dr. Peter Liu	President, International Society of Cardiomyopathy and Heart Failure of the World Heart Federation / Director, National C-CHANGE Program Scientific Director/VP Research, University of Ottawa Heart Institute / Professor of Medicine,	University of Ottawa Heart Institute
Dr. Robert McKelvie	Professor of Medicine, Cardiologist	McMaster University, Hamilton Health Sciences
Dr. Malcolm Arnold	Professor of Medicine	Western University , London Health Sciences Centre
Dr. Stuart Smith	Chief of Cardiovascular Services And Director , Heart Failure Program	St. Mary's General Hospital
Dr. Atilio Costa Vitali	Assistant Professor of medicine – Division of Clinical Scientist	Sudbury Regional Hospital

Dr. Jennifer Everson	Physician Lead	Hamilton Niagara Haldimand Brant Local Health Integration Network
Dr. Lee Donohue	Family Physician	Ottawa
Linda Belford	Nurse Practitioner, Practice Leader PMCC	University Health Network
Jane MacIver	Nurse Practitioner Heart Failure/Heart Transplant	University Health Network
Sharon Yamashita	Clinical Coordinator, Critical Care	Sunnybrook Health Sciences Centre
Claudia Bucci	Clinical Coordinator, Cardiovascular Diseases	Sunnybrook Health Sciences Centre
Andrea Rawn	Evidence Based Care Program Coordinator	Grey Bruce Health Network
Darlene Wilson	Registered Nurse	Heart Function Clinic, Trillium Health Centre
Kari Kostiw	Clinical Coordinator	Health Sciences North Ramsey Lake Health Centre
Janet Parr	CHF Patient	
Heather Sherrard	Vice President, Clinical Services	University of Ottawa Heart Institute
Sue Wojdylo	Manager, Case Costing	Lakeridge Health
Jane Chen	Manager of Case Costing	University Health Network
Nancy Hunter	LHIN Liaison & Business Development	Cardiac Care Network of Ontario
Ministry Representatives		
Gary Coleridge	Senior Program Consultant	Ministry of Health and Long-Term Care
Louie Luo	Senior Methodologist	Ministry of Health and Long-Term Care

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 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

30	(control* adj2 clinical trial*).ti,ab.	38289
31	exp Practice Guideline/ use emez	278008
32	exp Professional Standard/ use emez	268276
33	exp Standard of Care/ use mesz	581
34	exp Guideline/ use mesz	23104
35	exp Guidelines as Topic/ use mesz	102275
36	(guideline* or guidance or consensus statement* or standard or standards).ti.	218943
37	(controlled clinical trial or meta analysis or randomized controlled trial).pt.	456069
38	or/10-37	2969553
39	3 and 9 and 38	500
40	limit 39 to english language	464
41	remove duplicates from 40	415

Cochrane Library

Line #	Terms	Results
#1	MeSH descriptor: [Heart Failure] explode all trees	4860
#2	((cardia? or heart) next (decompensation or failure or incompetence or insufficiency)) or cardiac stand still or ((coronary or myocardial) next (failure or insufficiency)):ti,ab,kw (Word variations have been searched)	9323
#3	Enter terms for search #1 or #2	9328
#4	MeSH descriptor: [Intra-Aortic Balloon Pumping] this term only	115
#5	MeSH descriptor: [Counterpulsation] this term only	48
#6	intra-aortic balloon pump* or intraaortic balloon pump* or intra-aorta balloon pump* or intraaorta balloon pump* or counterpulsation or IABP:ti,ab,kw or counterpulsation or counter pulsation or counterpressure or counter pressure or diastolic augmentation:ti (Word variations have been searched)	297
#7	Enter terms for search #4 or #5 or #6	297
#8	Enter terms for search #3 and #7	35

CRD

Line	Search	Hits
1	MeSH DESCRIPTOR Heart Failure EXPLODE ALL TREES	510
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	307
3	#1 OR #2	542
4	MeSH DESCRIPTOR Intra-Aortic Balloon Pumping EXPLODE ALL TREES	5
5	MeSH DESCRIPTOR Counterpulsation EXPLODE ALL TREES	18
6	(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	20
7	#4 OR #5 OR #6	23
8	#3 AND #7	6

References

- (1) Arnold JM, Liu P, Demers C, Dorian P, Giannetti N, Haddad H, et al. Canadian Cardiovascular Society consensus conference recommendations on heart failure 2006: diagnosis and management. *Can J Cardiol*. 2006 Jan;22(1):23-45.
- (2) Nieminen MS, Bohm M, Cowie MR, Drexler H, Filippatos GS, Jondeau G, et al. Executive summary of the guidelines on the diagnosis and treatment of acute heart failure: the Task Force on Acute Heart Failure of the European Society of Cardiology. *Eur Heart J*. 2005 Feb;26(4):384-416.
- (3) Unverzagt S, Machemer MT, Solms A, Thiele H, Burkhoff D, Seyfarth M, et al. Intra-aortic balloon pump counterpulsation (IABP) for myocardial infarction complicated by cardiogenic shock. *Cochrane Database of Systematic Reviews*. 2011 Jul 6; (7): CD007398. DOI: 10.1002/14651858.CD007398.pub2.
- (4) Bahekar A, Singh M, Singh S, Bhuriya R, Ahmad K, Khosla S, et al. Cardiovascular outcomes using intra-aortic balloon pump in high-risk acute myocardial infarction with or without cardiogenic shock: a meta-analysis. *J Cardiovasc Pharmacol Ther*. 2012;17(1):44-56.
- (5) Health Canada Drugs and Health Products. Medical Devices Active Licences [Internet]. Ottawa (ON): Health Canada; [updated 2012; cited 2012 Oct 1]. Available from: <http://webprod5.hc-sc.gc.ca/mdll-limh/index-eng.jsp>
- (6) Shea BJ, Grimshaw JM, Wells GA, Boers M, Andersson N, Hamel C, et al. Development of AMSTAR: a measurement tool to assess the methodological quality of systematic reviews. *BMC Med Res Methodol*. 2007;7:10.
- (7) Atkins D, Best D, Briss PA, Eccles M, Falck-Ytter Y, Flottorp S, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004 Jun 19;328(7454):1490.
- (8) Guyatt GH, Oxman AD, Schunemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the *Journal of Clinical Epidemiology*. *J Clin Epidemiol*. 2011 Apr;64(4):380-2.
- (9) Arnold JM, Howlett JG, Dorian P, Ducharme A, Giannetti N, Haddad H, et al. Canadian Cardiovascular Society Consensus Conference recommendations on heart failure update 2007: prevention, management during intercurrent illness or acute decompensation, and use of biomarkers. *Can J Cardiol*. 2007;23(1):21-45.

Health Quality Ontario
130 Bloor Street West, 10th Floor
Toronto, Ontario
M5S 1N5
Tel: 416-323-6868
Toll Free: 1-866-623-6868
Fax: 416-323-9261
Email: EvidenceInfo@hqontario.ca
www.hqontario.ca

© Queen's Printer for Ontario, 2012