



Complete Summary

GUIDELINE TITLE

Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after arterial switch operation.

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after arterial switch operation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 22. 9 p. [16 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Low cardiac output after arterial switch operation

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Pediatrics
Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide a clinical guideline for the use of inotropic support with phosphodiesterase inhibitors after arterial switch operation

TARGET POPULATION

These guidelines are intended primarily for use in neonates (age ≤ 30 days) who have undergone an arterial switch operation (with or without ventricular septal defect closure).

The guidelines do not address all considerations needed to manage those with the following:

- Significant hypotension
- Significant post-operative left ventricular outflow tract obstruction.

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Continuous monitoring of arterial blood pressure via arterial line
2. Continuous monitoring of left atrial pressure with a transthoracic catheter
3. Monitoring of urine output and for presence of metabolic or lactic acidosis

Treatment

1. Inamrinone
2. Milrinone

MAJOR OUTCOMES CONSIDERED

Acute left ventricular dysfunction in the immediate post-operative period

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The recommendations contained in this guideline were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using a grading scale, and examined current local clinical practices.

During formulation of these guidelines, the team members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues by consensus where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by senior management, Legal Services, the Institutional Review Board, the hospital's Pharmacy and Therapeutics, Clinical Practices, Executive, and other committees and other individuals as appropriate to their intended purposes.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is followed by evidence grades (A-X) identifying the type of supporting evidence. Definitions of the evidence grades are presented at the end of the "Major Recommendations" field.

Clinical Assessments

1. It is recommended that cardiac index be supported to maintain normal to minimally elevated left atrial pressure (5–15 mmHg) with evidence of adequate tissue and organ perfusion as defined by physical exam, urine output >1cc/kg/min, and no ongoing metabolic acidosis or lactic acidemia.

Note 1: Ongoing metabolic acidosis caused by the continued production of lactic acid has been associated with a poor outcome following cardiac surgery in infants and children (Charpie et al., 2000 [C]; Munoz et al., 2000 [C]).

Note 2: Continuous monitoring of arterial blood pressure via an arterial line is recommended (Local Expert Consensus [E]).

Note 3: Continuous monitoring of left atrial pressure with a transthoracic catheter is recommended (Local Expert Consensus [E]).

Treatment Recommendations

2. It is recommended that inamrinone be considered for any patient following arterial switch operation to prevent the occurrence of low cardiac output over the first 24 hours following arterial switch operation.

Note: There is no direct evidence to suggest that routine use of inamrinone following arterial switch operation improves outcome, but this recommendation is based on evidence that cardiac output decreases in the 6 to 18 hours following cardiopulmonary bypass (Wernovsky et al., 1995 [A]) and that inamrinone is effective in improving cardiac output after cardiopulmonary bypass (Hamada et al., 1999 [B]; Kikura et al., 1998 [C]; Laitinen et al., 1999 [B]; Bailey et al., 1997 [C]; Lynn et al., 1993 [C]; Berner et al., 1990 [C]).

3. It is recommended that inamrinone be started for any patient with a left atrial pressure >15 mmHg or with signs or symptoms of low cardiac output. The recommended loading dose of inamrinone is 1 to 3 mg/kg over 30 to 60 minutes, followed by an infusion at 5 to 10 micrograms/kg/min.

Note 1: If inamrinone is loaded on cardiopulmonary bypass, a loading dose of up to 4 mg/kg may be necessary because of the high volume of distribution (Lawless et al., 1989 [C]).

Note 2: If hypotension develops, blood pressure support with other inotropic/vasopressor agents may be necessary (Lynn et al., 1993 [C]).

4. Milrinone may serve as an effective alternative to inamrinone. The usual loading dose of milrinone is 50 micrograms/kg over 30 to 60 minutes, followed by an infusion at 0.375 to 0.75 micrograms/kg/min.

Note: Direct comparison has failed to show any significant hemodynamic differences between inamrinone and milrinone. There are anecdotal reports of less thrombocytopenia with milrinone, so milrinone may be particularly useful for patients in whom phosphodiesterase inhibition is desired, but who are thrombocytopenic (Hamada et al., 1999 [B]; Rathmell et al., 1998 [B]).

Definitions:

Evidence Based Grading Scale:

- A: Randomized controlled trial: large sample
- B: Randomized controlled trial: small sample
- C: Prospective trial or large case series
- D: Retrospective analysis
- E: Expert opinion or consensus
- F: Basic laboratory research
- S: Review article
- M: Meta-analysis
- Q: Decision analysis
- L: Legal requirement
- O: Other evidence
- X: No evidence

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and classified for each recommendation (see "Major Recommendations") using the following scheme:

Evidence Based Grading Scale:

- A: Randomized controlled trial: large sample
- B: Randomized controlled trial: small sample
- C: Prospective trial or large case series
- D: Retrospective analysis
- E: Expert opinion or consensus
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- S: Review article
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BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Clinically, phosphodiesterase inhibitors improve myocardial contractility, diastolic relaxation, and cause a decrease in afterload through vasodilation. These agents therefore improve cardiac index and lower left ventricular filling pressure after cardiopulmonary bypass, even in comparison to other inotropes or vasodilators.
- Phosphodiesterase inhibition is also of benefit in treating low cardiac output due to pulmonary hypertension, a complication known to occur after arterial switch operation. Because of these beneficial effects on afterload, myocardial function, and pulmonary vascular resistance, phosphodiesterase inhibition is a potentially useful treatment for neonates in low cardiac output after an arterial switch operation. Furthermore, it may be useful for prevention of a low cardiac output state in the patient who appears to be doing well, but this has not been extensively studied.

POTENTIAL HARMS

Hypotension may develop when using inamrinone, which may necessitate blood pressure support with other inotropic/vasopressor agents

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These recommendations are based on the most current scientific information.
- In developing this guideline, the working group recognizes the paucity of large-scale studies with direct bearing on this particular focus population. The specific recommendations in this guideline are drawn from directly applicable

- studies where possible, but are largely extrapolated from smaller studies, and from studies more indirectly related to the present issues.
- These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The implementation process for each Cincinnati Children's Hospital Medical Center (CCHMC) guideline is a phase in a larger process of Guideline Development. This process is utilized for every guideline but is not addressed in the content of every guideline.

At the start of each guideline, a projected implementation date is determined. Reservations for education are then made (Grand Rounds, Patient Services Inservices). When the guideline is complete and enters into the Approval Process, education planning begins. Changes created by the guideline are outlined as well as anticipated outcomes. The implementation date is confirmed. Education is provided. The guideline is implemented and pilot information collection started. The Guideline Coordinator makes daily rounds and eligible children are followed to document the use of the guideline. The implementation phase aids in finding areas for improvement or question. When issues identified are improved, the guideline progresses to the monitoring phase.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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switch operation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 22. 9 p. [16 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan 22

GUIDELINE DEVELOPER(S)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

Clinical Effectiveness Team for Arterial Switch Operation (ASO)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of the Cardiac Clinical Pathway Development Team 2000

Children's Hospital Medical Center Physicians: Peter Manning, MD (Cardiac Surgery); Steve Schwartz, MD (Cardiac Intensive Care); Robert Spicer, MD (Cardiology); Dawn Sweeney, MD (Anesthesia); James Cnota, MD (Cardiology/Fellow)

Patient Services: Karen Uzark, PhD, CPNP (Cardiology); Susan Ryckman, MS, CPNP (Cardiac Services); Betsy Adler, MS, PNP (Cardiac Surgery); Lisa Koons, MSN (Cardiac ICU); Vicki McDonald, RN (Cardiac ICU); Tracey Martini, RN (Cardiac ICU); Kendall Rider, RN (C5 South); Tamara Hutson, PharmD (Clinical Pharmacy); Jenni Raake, RRT (Respiratory Care); Kathy Dressman, RN (Manager, C5 South)

Other Services: Wendy Engstrom Gerhardt, RN (Clinical Effectiveness)

Ad Hoc Advisors: Melissa Berner, ESQ (Legal Services); Uma Kotagal, MBBS, MSc (Director, Clinical Effectiveness); Dorine Seaquist, RN, MS (VP, Patient Services)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Cincinnati Children's Hospital Medical Center Web site](#).

For information regarding the full-text guideline, print copies, or evidence based practice support services contact the Children's Hospital Medical Center Health Policy and Clinical Effectiveness Department at HPCEInfo@chmcc.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 11, 2004.

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