Complete Summary

GUIDELINE TITLE

Evidence-based care guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot.

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2006 Mar. 10 p. [17 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for inotropic support with phosphodiesterase inhibitors after repair of tetralogy of Fallot. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 Jan 25. 9 p. [16 references]

The guideline was reviewed for currency in August 2006, using updated literature searches, and was determined to be current.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Diastolic dysfunction after tetralogy of Fallot repair

GUIDELINE CATEGORY

Evaluation
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Pediatrics
Pharmacology
Surgery
Thoracic Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve cardiac output following tetralogy of Fallot repair
- To decrease length of stay required in cardiac intensive care unit (CICU)

TARGET POPULATION

These guidelines are intended for use in infants and children who have undergone complete repair of tetralogy of Fallot (TOF).

Note: The guidelines do not address all considerations needed to manage those with significant hypotension.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Physical exam
2. Monitoring of urine output
3. Blood work for metabolic acidosis or lactic acidemia
4. Continuous monitoring of arterial blood pressure via an arterial line
5. Continuous monitoring of right and left atrial pressure with a transthoracic or internal jugular/subclavian vein catheters
6. Renal panel
7. Monitoring of arterial blood gas and lactate

Treatment with Phosphodiesterase Inhibitors

1. Milrinone

MAJOR OUTCOMES CONSIDERED

- Cardiac output
- Oxygen levels
- Adverse effects of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

To select evidence for critical appraisal by the group for the update of this guideline, the Medline, EmBase, and the Cochrane databases were searched. Evidence from 2000 and before was verified for inclusion in the guidelines. Evidence from 2001 through 2005 were reviewed to generate an unrefined, "combined evidence" database using a search strategy focused on answering clinical questions relevant to inotropic support with phosphodiesterase inhibitors following tetralogy of Fallot (TOF) repair and employing a combination of Boolean searching on human-indexed thesaurus terms (Medical Subject Heading [MeSH] headings using an OVID Medline interface) and "natural language" searching on searching on human-indexed thesaurus terms (MeSH headings using an OVID Medline interface) and "natural language" searching on words in the title, abstract, and indexing terms. The citations were reduced by eliminating duplicates, review articles, non-English articles, and adult articles. The resulting abstracts were reviewed by a methodologist to eliminate low quality and irrelevant citations. During the course of the guideline development, additional clinical questions were generated and subjected to the search process, and some relevant review articles were identified. July, 2000 was the last date for which literature was reviewed for the previous version of this guideline. The details of that review strategy are not documented. However, all previous citations were reviewed for appropriateness to this revision.

A search using the above criteria was conducted for dates of January, 2006 through July, 2006. No relevant articles were found that would require changes to the January, 2006 version of the recommendations.

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 document were formulated by an interdisciplinary working group which performed systematic and critical literature reviews, using a grading scale, and examined local clinical practices.

Recommendations have been formulated by a consensus process directed by best evidence, patient and family preference, and clinical expertise. During formulation of these guidelines, the committee 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

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines have been reviewed and approved by clinical experts not involved in the development process, senior management, Risk Management & Corporate Compliance, other appropriate hospital 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 right atrial pressure or central venous pressure (CVP) (5 to 15 mm Hg) with evidence of adequate tissue and organ perfusion as defined by physical exam, urine output >1 cc/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 right and left atrial pressures with transthoracic or internal jugular/subclavian vein catheters is recommended.

Laboratory Studies

2. It is recommended that in order to monitor for metabolic acidosis and lactic acidemia, a renal panel be obtained on arrival to the cardiac intensive care unit (CICU) and every morning (AM) until transfer from the CICU, and arterial blood gas (ABG) and lactate be obtained every 4 hours for first 24 hours, then every AM until transfer.

   Note: 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]).

Treatment Recommendations

Medications

3. It is recommended that milrinone be considered for any patient following tetralogy of Fallot (TOF) repair to prevent the occurrence of low cardiac output due to restrictive right ventricular physiology after TOF repair.

   Note: There is no direct evidence to suggest that routine use of milrinone following TOF repair improves outcome, but this recommendation is based on evidence that restrictive right ventricular physiology is associated with increased morbidity after TOF repair and that phosphodiesterase inhibitors

(PDEI) improve left ventricular diastolic function (Hoffman et al., 2003 [A]; Hoffman et al., 2002 [A]; Norgard et al., 1996 [C]; Chang et al., 1995 [C]; Cullen, Shore, & Redington, 1995 [C]; Berner et al., 1990 [C]; Werner, Herbertson, & Walley, 1995 [F]; Pagel, Hettrick, & Warltier, 1993 [F]).

4. It is recommended that milrinone be started for any patient with a right atrial pressure >15 mm Hg or with signs or symptoms of low cardiac output. The recommended loading dose of milrinone is 50 mcg/kg over 30 to 60 minutes followed by an infusion at 0.375 to 0.75 mcg/kg/min.

   Note 1: 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 or following surgery (Hamada et al., 1999 [B]; Rathmell et al., 1998 [B]).

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

Definitions:

Cincinnati Children's Hospital and Medical Center Grading Scale

M: Meta-analysis
A: Randomized controlled trial: large sample
B: Randomized controlled trial: small sample
C: Prospective trial or large case series
D: Retrospective analysis
O: Other evidence
S: Review article
E: Expert opinion or consensus
F: Basic laboratory research
L: Legal requirement
Q: Decision analysis
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:

Cincinnati Children's Hospital and Medical Center Grading Scale

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improvement in right ventricular diastolic function
- Improved cardiac output
- Decreased length of stay required in cardiac intensive care unit

POTENTIAL HARMS

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

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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

Appropriate companion documents have been developed to assist in the effective dissemination and implementation of the guideline. Experience with the implementation of earlier publications of this guideline has provided information which has been incorporated into this revision. Hemodynamic stability and length of stay in the cardiac intensive care unit (CICU) are outcome measures that are monitored and reviewed quarterly.

IMPLEMENTATION TOOLS

Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2001 Jan 25 (revised 2006 Mar; reviewed 2006 Aug)

GUIDELINE DEVELOPER(S)

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

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

Members of the Cardiac Clinical Pathway Development Team 2006

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

CHMC Physicians: Peter Manning , MD, Cardiac Surgery; Catherine Dent, MD, Cardiac Intensive Care; William Border, MD, Cardiology; James Spaeth, MD, Anesthesia; Michael Alice Moga, MD, Cardiology/Fellow

Patient Services: Karen Uzark, PhD, CPNP, Cardiology; Susan Ryckman, MS, CPNP, Cardiac Services; Betsy Adler, MS, PNP, Cardiac Services; Christa Barlow, CNP, Cardiac Surgery; Karen Jones, MS, PNP, Cardiac Surgery; Melissa Magness, RN, Cardiac ICU; Tammy Lingsch, RN, A6 Central; Cynthia Wedekind, Pharm D, Clinical Pharmacy) Jenni Raake, RRT, Respiratory Care

Division of Health Policy & Clinical Effectiveness Support: Eloise Clark, MPH: Danette Stanko, MA, MPH, Epidemiologist; Kate Rich, Lead Decision Support Analyst; Carol Frese, RN, Medical Reviewer; Eduardo Mendez, RN, MPH, Dir. Evidence-Based Care

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the Cincinnati Children's Hospital Medical Center.

Print copies: 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

The following are available:

- Cardiac anomalies/congenital heart defects: tetralogy of Fallot (TOF). Cincinnati Children's Hospital Medical Center, 2004. Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site.
- Going home after heart surgery. Home care. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2004 Dec. 1 p. Available in English and Spanish from the Cincinnati Children's Hospital Medical Center Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on August 24, 2004. The information was verified by the guideline developer on October 12, 2004. This NGC summary was updated by ECRI on September 8, 2006. The updated information was verified by the guideline developer on October 10, 2006.

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