



Complete Summary

GUIDELINE TITLE

Evidence based clinical practice guideline for prevention of thromboembolism after cavopulmonary anastomosis (bidirectional Glenn and Fontan operations).

BIBLIOGRAPHIC SOURCE(S)

Cincinnati Children's Hospital Medical Center. Evidence based clinical practice guideline for prevention of thromboembolism after cavopulmonary anastomosis (bidirectional Glenn and Fontan operations). Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2001 May 29. 10 p. [20 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Thromboembolism after cavopulmonary anastomosis

GUIDELINE CATEGORY

- Evaluation
- Prevention
- Risk Assessment
- Treatment

CLINICAL SPECIALTY

- Cardiology
- Critical Care
- Pediatrics
- Surgery

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians
Respiratory Care Practitioners

GUIDELINE OBJECTIVE(S)

To provide a guideline for the effective prevention of thromboembolism after cavopulmonary anastomosis

TARGET POPULATION

These guidelines are intended for use in infants and children who have undergone the bidirectional Glenn or modified Fontan operation.

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

- coagulopathy
- salicylate allergy

INTERVENTIONS AND PRACTICES CONSIDERED

Assessment

1. Preoperative history and physical exam, including family history or physical findings suggestive of coagulopathy
2. Laboratory evaluation, including preoperative complete blood count (CBC) with platelets and coagulation studies if abnormalities suggested

Prevention/Treatment

1. Antithrombotic aspirin therapy
2. Warfarin therapy in high-risk patients
3. Alternative antithrombotic therapy when aspirin therapy is temporarily contraindicated

MAJOR OUTCOMES CONSIDERED

Risk of intravascular and/or intracardiac thrombus formation and thromboembolic complications

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

Internal Peer Review

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.

Assessment

1. Preoperative history and physical exam
 - Patient or family history of coagulopathy, salicylate allergy, or viral exposures
 - Physical findings suggestive of coagulopathy (e.g., petechiae, purpura)
2. Laboratory assessment
 - Preoperative complete blood count (CBC) with platelets
 - Coagulation studies if history or physical suggests abnormalities and prior to initiation of warfarin

Note: Available evidence does not support routine screening for coagulopathies.

Treatment Recommendations

1. It is recommended that patients begin antithrombotic aspirin therapy upon resuming oral intake following the bidirectional Glenn or Fontan operation.

Note: Both aspirin and warfarin reduce the risk of thromboembolism. Although the choice of pharmacologic regimen remains controversial, the risk of hemorrhagic complications in children, compounded by the difficulties of monitoring and maintaining appropriate anticoagulation on warfarin, favors the use of aspirin for antithrombotic therapy. The two appear equivalent in the prevention of myocardial infarction and stroke in the setting of atherosclerosis (Anand & Yusuf, 1999 [M]); however, in pediatric and adult

populations, the risk of hemorrhagic complications is higher with warfarin therapy (Anand & Yusuf, 1999 [M]; Bradley et al., 1985)

2. It is recommended that warfarin therapy be considered in patients at higher risk due to the following factors:
 - Previous thromboembolic complications
 - Poor ventricular function
 - Extracardiac Fontan connections (Shirai et al., 1998[D])
 - Pulmonary stump
3. It is recommended that alternative antithrombotic therapy be considered during periods when aspirin therapy is temporarily contraindicated.

Note: Examples of aspirin contraindications may include exposure to influenza or varicella, receipt of varicella vaccine, and elective surgical or dental procedures associated with bleeding. Risks of discontinuation of aspirin versus the risk of Reye's syndrome or bleeding associated with dental or surgical procedures must be considered by the clinician and family on an individual basis.

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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- Q: Decision analysis
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- X: No evidence

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Decreased risk of intravascular and/or intracardiac thrombus formation and thromboembolic complications

POTENTIAL HARMS

- Risk of hemorrhagic complications is higher with warfarin therapy than with aspirin therapy
- There is a risk of Reye's syndrome with aspirin therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

Potential temporary contraindications for aspirin therapy in the following patients:

- Exposure to influenza or varicella or receipt of varicella vaccine
- Elective surgical or dental procedures associated with bleeding

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Unfortunately, although the problem of thromboembolism has been recognized, clinicians have not systematically evaluated the use of antithrombotic therapy. A controversy exists with respect to the most appropriate choice of pharmacologic regimen. To date, no prospective, randomized controlled trials have addressed this question. Monotherapy with either aspirin or warfarin is most commonly implemented. In developing this guideline, the working group recognized the paucity of large-scale studies with direct bearing on this particular pediatric 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
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2001 May 29

GUIDELINE DEVELOPER(S)

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

SOURCE(S) OF FUNDING

Cincinnati Children's Hospital Medical Center

GUIDELINE COMMITTEE

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COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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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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