Complete Summary

GUIDELINE TITLE

Heart failure - systolic dysfunction.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Heart failure - systolic dysfunction. Ann Arbor (MI): University of Michigan Health System; 2006 Sep. 18 p. [15 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Heart failure - systolic dysfunction. Ann Arbor (MI): University of Michigan Health System; 1999 Aug. 12 p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- August 16, 2007, Coumadin (Warfarin): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.
- October 6, 2006, Coumadin (warfarin sodium): Revisions to the labeling for Coumadin to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Left ventricular systolic dysfunction
- Heart failure

GUIDELINE CATEGORY

Diagnosis
Evaluation
Treatment

CLINICAL SPECIALTY

Cardiology
Family Practice
Geriatrics
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To improve mortality and morbidity for patients with heart failure (HF)
- To present a framework for treatment of patients with HF

TARGET POPULATION

Adults patients with left ventricular systolic dysfunction

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Patient history and physical exam.
2. Symptom-based classification of symptoms using a scheme based on the American College of Cardiology/American Heart Association (ACC/AHA) system.

3. Diagnostic studies:
    - Monitoring of electrolyte serum concentrations
    - Electrocardiography
    - Assessment of ejection fraction by transthoracic echocardiography, radionuclide ventriculography, or single-photon emission-computed tomography (SPECT)
    - Evaluation of coronary artery disease by stress testing and cardiac catheterization
    - Ambulatory rhythm monitoring
    - Serum levels of b-type natriuretic peptide (BNP) and its N terminal fragment

Treatment

1. Non-pharmacologic:
    - Exercise
    - Dietary changes (sodium restriction)
    - Operative therapy
2. Automatic implantable cardiac defibrillators (ICD)
3. Resynchronization therapy with biventricular (Bi-V) pacemakers
4. Major drugs:
    - Diuretics
    - Angiotensin-converting enzyme (ACE) inhibitors
    - Beta blockers
    - Digoxin
    - Aldosterone antagonists
    - Direct acting vasodilators
    - Angiotensin receptor blockers
5. Minor drugs:
    - Calcium channel blockers if needed for management of hypertension
    - Inotropes (**Note**: Intermittent bolus or continuous home infusion therapy of either dobutamine or milrinone is not recommended for routine management of heart failure.
    - Anti-arrhythmic drugs in conjunction with device therapy
    - Lipid-lowering agents
6. Other treatments:
    - Anti-thrombotics: Aspirin/clopidogrel or warfarin
    - Influenza vaccination
    - Pneumococcal vaccination
    - Narcotics in patients with end-stage heart failure

Note: Nonsteroidal anti-inflammatory drugs (NSAIDs), COX II inhibitors, and Coenzyme Q10 were considered but not recommended.

7. Systems aiding treatment:
    - Disease-based management
    - Surveillance and follow-up
8. Treatment of comorbid conditions when appropriate
9. Advance directive discussions with patient and family

MAJOR OUTCOMES CONSIDERED

- Mortality associated with heart failure
- Symptom relief
- Rate and length of hospitalization
- Drug interactions and side effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature search for this guideline started with the results of the literature search performed in 1998 for an earlier version of this guideline. Then a search was conducted prospectively using the major keywords of: *congestive heart failure, guidelines, controlled trials, published 1/1/98 to 3/31/05, adults, English language* on Medline. Terms used for specific topic searches within the major key words included: BNP and B-type natriuretic peptide; left ventricular ejection fraction measurement: echocardiography, sestamibi, radionuclide ventriculogram; aldosterone antagonists; beta blockers; angiotensin converting enzyme (ACE) inhibitor; angiotensin receptor antagonist/blocker, diuretics; digoxin; lipid lowering drugs; devices: ICE, biventricular pacing, AICD, implantable cardiodefibrillator; vasodilators (e.g., nitrates, hydralazine); calcium channel blockers, anti-coagulants; antiarrhythmics; influenza vaccination; pneumovax immunization; inotropic agents; narcotics; electrolytes; NSAIDS; coenzyme Q10; disease based management; exercise; dietary restrictions; salt substitutes; functional testing, stress testing; catheterization; electrocardiogram; revascularization; telemanagement (diuretics & weight); gender differences; racial differences and pharmacotherapy; comorbid conditions: anemia, diabetes, depression, erectile dysfunction, sleep apnea, dementia, arthritis; complementary and alternative medicine: nutritional supplements, herbal remedies (e.g., hawthorn); any other reference identified by the major keywords and not included in results of specific topic searches. Specific search strategy available upon request.

The search was conducted in components each keyed to a specific causal link in a formal problem structure. The search was supplemented with very recent clinical trials known to expert members of the panel. Negative trials were specifically sought. The search was a single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of evidence reflect the best available literature in support of an intervention or test:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

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

University of Michigan Health System (UMHS) guidelines are reviewed in clinical conferences of physicians in departments to which the content is most relevant and by leadership in those departments. This guideline concerning heart failure was reviewed by members of the following units: Division of Cardiology; Division

of General Medicine; Department of Family Medicine, Division of Geriatric Medicine, and Pharmacy Services.

Guidelines are approved by the Executive Committee of Clinical Affairs (ECCA).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on dosing and cost of drugs as well as information on other interventions considered.

The levels of evidence (A-D) are defined at the end of the Major Recommendations.

Diagnosis

- Ejection fraction (EF) evaluated to determine the etiology as systolic dysfunction rather than diastolic dysfunction or valvular heart disease *[A*]*.
- Serum b-type natriuretic peptide (BNP) to help determine if dyspnea is due to heart failure (HF) *[C*]*.

Pharmacologic Treatment (See Table 1 in the original guideline document)

- For patients with systolic dysfunction (ejection fraction [EF] <40%) who have no contraindications:
    - Angiotensin-converting enzyme (ACE) inhibitors for all patients *[A*]*.
    - Beta blockers for all patients except those who are hemodynamically unstable, or those who have rest dyspnea with signs of congestion *[A*]*.
    - Aldosterone antagonist (low dose) for patients with rest dyspnea or with a history of rest dyspnea or for symptomatic patients who have suffered a recent myocardial infarction *[A*]*.
    - Isordil-hydralazine combination for symptomatic HF patients who are African-American *[A*]*.
    - Angiotensin receptor blockers (ARBs) as a substitute for patients intolerant of ACE inhibitors *[A*]*.
    - Digoxin only for patients who remain symptomatic despite diuretics, ACE inhibitors, and beta blockers or for those in atrial fibrillation *[A*]*.
    - Diuretics for symptomatic patients to maintain appropriate fluid balance *[C*]*.

Device Therapy

- Implantable defibrillators considered for prophylaxis against sudden cardiac death in patients with EF $\leq$ 35% *[A*]*.
- Bi-ventricular pacemakers considered for patients requiring defibrillators who have symptomatic HF and QRS durations $\geq$ 120 msec *[A*]*.

Other

- HF patients on multiple medications are at a risk of potential drug interactions and side effects. For example, the risk of hyperkalemia is increased in patients with renal insufficiency treated with an aldosterone antagonist and an ACE inhibitor.

***Definitions**:

Levels of evidence:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

Algorithms are provided in the guideline document for:

- Identifying systolic heart failure
- Device referral

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see Major Recommendations).

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data; if RCTs were not available, observational studies were admitted to consideration. If no such data were available for a given link in the problem formulation, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Patients with heart failure secondary to systolic dysfunction gain symptomatic and/or survival benefit from at least five classes of medications in combination with dietary sodium restriction. Identification of a patient's symptomatic class can aid in the addition of step-wise therapy and help to reduce unnecessary poly-pharmacy.

POTENTIAL HARMS

Please refer to Table 3 ," 'Clinical Pearls' in the Pharmacologic Treatment of Heart Failure," the "Rationale for Recommendations" section, and Appendices A, B, and C in the original guideline document for risks and complications of using

pharmacologic agents, information on common drug interactions, potential and documented interactions of herbs with warfarin, and interactions of complimentary alternative medication (CAM) and congestive heart failure (CHF).

CONTRAINDICATIONS

CONTRAINDICATIONS

Please refer to Table 3, " 'Clinical Pearls' in the Pharmacologic Treatment of Heart Failure" in the original guideline document for contraindications to angiotensin-converting enzyme (ACE) inhibitors/angiotensin receptor blockers (ARBs), beta blockers, and isordil-hydralazine.

QUALIFYING STATEMENTS

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These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgement regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Staff Training/Competency Material

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
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Heart failure - systolic dysfunction. Ann Arbor (MI): University of Michigan Health System; 2006 Sep. 18 p. [15 references]

ADAPTATION

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

DATE RELEASED

1999 Aug (revised 2006 Sep)

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

Internal funding for University of Michigan Health System (UMHS) guidelines is provided by the Office of Clinical Affairs. No external funds are used.

GUIDELINE COMMITTEE

Heart Failure Guideline Team

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Team Leader: William Chavey, MD, Family Medicine

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Consultant: Todd M Koelling, MD, Cardiology

Guidelines Oversight Team: Connie J Standiford, MD; William E Chavey, MD; R Van Harrison, PhD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not

intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

Team Members; Company; Relationship:

Barry Bleske, PharmD; Abbott, Consultant; Astra Zeneca, Consultant and Research support; Scios, Consultant

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GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following is available:

- Understanding heart failure: answers to common questions. University of Michigan Health System; 2006 Feb. Various p. Available from the University of Michigan Health System 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

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NGC STATUS

This summary was completed by ECRI on August 21, 2000. The information was verified by the guideline developer on November 22, 2000. This summary was updated by ECRI on January 8, 2007. The updated information was verified by the guideline developer on January 19, 2007. This summary was updated by ECRI Institute on September 7, 2007 following the revised U.S. Food and Drug Administration (FDA) advisory on Coumadin (warfarin).

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