Complete Summary

GUIDELINE TITLE

The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization.

BIBLIOGRAPHIC SOURCE(S)

Bridges CR, Horvath KA, Nugent WC, Shahian DM, Haan CK, Shemin RJ, Allen KB, Edwards FH. The Society of Thoracic Surgeons practice guideline series: transmyocardial laser revascularization. Ann Thorac Surg 2004 Apr;77(4):1494-502. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic, severe angina

GUIDELINE CATEGORY

Treatment

CLINICAL SPECIALTY

Cardiology
Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To assist physicians and other health care providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions
- To present a clinical guideline with specific recommendations for the selection of patients for Transmyocardial Laser Revascularization (TMR)

TARGET POPULATION

- Patients whose coronary anatomy precludes complete revascularization by either coronary artery bypass graft (CABG) or percutaneous catheter intervention (PCI)
- Patients in whom complete revascularization may be achieved with CABG but for whom the risk/benefit ratio of CABG is prohibitive

INTERVENTIONS AND PRACTICES CONSIDERED

Transmyocardial laser revascularization (TLR):

- as sole therapy
- as an adjunct to coronary artery bypass graft (CABG)

MAJOR OUTCOMES CONSIDERED

- Symptoms (e.g., angina)
- Function (e.g., exercise capacity)
- Survival
- Mortality
- Morbidity

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
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Reviewed articles were obtained through a search of the MedLine database (1966-present), the National Center for Biotechnology Information (NCBI), PubMed database (using keywords including "TMR," "laser," "revascularization," "transmyocardial," "TMLR," "PMR," and "DMR" as well as subject headings to

which these terms were mapped and logical combinations of these sets). Using the same databases, searches were performed by author for investigators active in the field. Additional references were obtained through direct communication with investigators. Selected manuscripts cited in the references were also reviewed.

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

Level of Evidence

Level A: Data derived from multiple randomized clinical trials

Level B: Data derived from a single randomized trial or from several nonrandomized trials

Level C: Consensus expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

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

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment

II.a.: Weight of evidence/opinion is in favor of usefulness/efficacy

II.b.: Usefulness/efficacy is less well established by evidence or opinion

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful and in some cases may be harmful

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence (A-C) and classification of recommendations (I-III) are defined at the end of the "Major Recommendations" field.

Recommendations for Transmyocardial Laser Revascularization (TMR) as Sole Therapy

Class I

1. Patients with an ejection fraction greater than 30% and Canadian Cardiovascular Class III or IV angina that is refractory to maximal medical therapy. These patients should have reversible ischemia of the left ventricular free wall and coronary artery disease corresponding to the region of myocardial ischemia. In all regions of the myocardium, the coronary disease must not be amenable to coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA), either due to a) severe diffuse disease, b) lack of suitable targets for complete revascularization, c) lack of suitable conduits for complete revascularization. ***(Level of Evidence: A)***

Class IIB

1. Patients who otherwise have Class I indications for TMR but who have either

a. Ejection fraction less than 30 percent with or without insertion of an intraaortic balloon pump. ***(Level of Evidence: C)***
b. Unstable angina/acute ischemia necessitating intravenous antianginal therapy. ***(Level of Evidence: B)***
c. Patients with Class II angina. ***(Level of Evidence: C)***

Class III

1. Patients without angina or with Class I angina. ***(Level of Evidence: C)***
2. Acute evolving myocardial infarction or recent transmural or nontransmural myocardial infarction. ***(Level of Evidence: C)***
3. Cardiogenic shock defined as a systolic blood pressure less than 80 mm/Hg or a cardiac index of less than 1.8L/min/m2. ***(Level of Evidence: C)***
4. Uncontrolled ventricular or supraventricular tachyarrhythmias. ***(Level of Evidence: C)***
5. Decompensated congestive heart failure. ***(Level of Evidence: C)***

<u>Recommendations for TMR as an Adjunct to CABG</u>

Class IIa

1. Patients *with angina* (Class I - IV) in whom CABG is the standard of care who also have at least one accessible and viable ischemic region with demonstrable coronary artery disease which cannot be bypassed, either due to a) severe diffuse disease, b) lack of suitable targets for complete revascularization, or c) lack of suitable conduits for complete revascularization. ***(Level of Evidence: B)***

Class IIb

1. Patients *without angina* in whom CABG is the standard of care who also have at least one accessible and viable ischemic region with demonstrable coronary artery disease which cannot be bypassed, either due to a) severe diffuse disease, b) lack of suitable targets for complete revascularization, or c) lack of suitable conduits for complete revascularization. ***(Level of Evidence: C)***

Class III

Patients in whom CABG is not the standard of care ***(Level of Evidence: C)***

<u>Definitions</u>

Level of Evidence

Level A: Data derived from multiple randomized clinical trials

Level B: Data derived from a single randomized trial or from several nonrandomized trials

Level C: Consensus expert opinion

Classification of Recommendations

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment

II.a.: Weight of evidence/opinion is in favor of usefulness/efficacy

II.b.: Usefulness/efficacy is less well established by evidence or opinion

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful and in some cases may be harmful

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated for each recommendation (see 'Major Recommendations' field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Assist physicians and other health care providers in clinical decision-making regarding selection of patients for Transmyocardial Laser Revascularization (TMR)
- Reduce angina symptoms
- Improve quality of life

POTENTIAL HARMS

Morbidity and mortality

Subgroup Most Likely to Experience Harms

Patients at highest risk for morbidity and mortality following transmyocardial laser revascularization (TMR) include patients with unstable angina, global myocardial ischemia, and diminished left ventricular function.

QUALIFYING STATEMENTS

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These guidelines should not be considered inclusive of all proper methods of care or exclusive of other methods of care reasonably directed at obtaining the same results. Moreover, these guidelines are subject to change over time, without notice. The ultimate judgment regarding the care of a particular patient must be made by the physician in light of the individual circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2003

GUIDELINE DEVELOPER(S)

Society of Thoracic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of Thoracic Surgeons

GUIDELINE COMMITTEE

Workforce on Evidence-Based Medicine

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workforce Members: Charles R. Bridges, MD (*TMR Taskforce Chair*), ScD; Keith A. Horvath, MD; William C. Nugent, M.D; David M. Shahian, MD; Constance K. Haan, MD; Richard J. Shemin, MD; Keith B. Allen, MD; Fred H. Edwards, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Society of Thoracic Surgeons Web site.

Print copies: Available from The Society of Thoracic Surgeons, 633 N. Saint Clair St., Suite 2320, Chicago, IL, USA 60611-3658

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on March 30, 2005. The information was verified by the guideline developer on May 3, 2005.

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