Transmyocardial laser revascularization: a qualitative systematic review

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Authors' objectives
To evaluate the safety, efficacy and utility of transmyocardial laser revascularisation (TMLR) in the treatment of ischaemic heart disease.

Searching
A computerised search was conducted of MEDLINE, BIOSIS Previews, EMBASE, Sci Search, and Current Contents between January 1985 and March 1997 using the following keywords: 'transmyocardial revascularization'; 'transmyocardial laser revascularization' (TMLR); 'TMR'; and 'TMLR'. Bibliographies of identified studies were examined. Each week the clinical medicine speciality section of Current Contents on Disk was searched to identify new studies after the initial search. Additional information was sought from medical device manufacturers and government agencies.

Study selection
Study designs of evaluations included in the review
The following types of trials of TMR were included: multicentre without randomisation; non randomised uncontrolled experiments; descriptive studies; case reports; and expert reviews. Duration of clinical trials was reported as 2 months, 12 months and averaging 10 months. Duration of studies reported in abstract ranged from 2 weeks to 1 year.

Specific interventions included in the review
The following transmyocardial revascularisation (TMR) systems were studied: Excimer laser; Holmium; and carbon dioxide laser (including low power continuous wave and high powered pulsed laser). Systems were produced by 5 different manufacturers. TMR was studied both as the sole intervention and in combination with coronary artery bypass graft (both primary and redo). Other interventions reported included medical therapy, redo or primary CABG, and percutaneous transluminal coronary angioplasty including multi vessel (PTCA).

Participants included in the review
Patients studied included those with the following characteristics: severe angina refractory to medical therapy; reversible ischaemia; unstable angina; and those with contraindications to coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty.

Outcomes assessed in the review
The primary outcome was anginal severity indicated by the Canadian Cardiovascular Society (CCS) angina class. Other outcomes included: myocardial function expressed in terms of left ventricular ejection fraction (LVEF) or wall motion score index measured using multigated acquisition radionuclide ventriculography or Doppler echocardiography; myocardial viability and perfusion measured using positron emission tomography (PET), radionuclide scintigraphy (thallium-201), or technetium-99m sestamibi (Tc-99m) or TI-201 or Tc-99m single emission computed tomography (SPECT); mechanisms (histological evidence of patency, angiogenesis, and denervation); and follow-up resource utilization (additional revascularisation procedures, subsequent hospital admissions for unstable angina and need for antianginal medications).

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the authors performed the selection.

Assessment of study quality
Primary studies were graded according to trial design (see Other Publications of Related Interest no.1). The authors do not state how the papers were assessed for validity, or how many of the authors performed the validity assessment.
Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative review.

How were differences between studies investigated?
The authors do not state how differences between the studies were investigated.

Results of the review
Three clinical trials (328 patients) including 1 multicentre trial without randomisation (200 patients); one summary report (116 patients, 12 undergoing TMR and 104 undergoing TMR plus CABG); and 1 prospective trial (12 patients having TMR as adjunct to CABG) were included plus 15 abstracts (14 clinical trials with 704 patients and 1 retrospective database analysis with 786 patients, 301 of whom underwent TMR). The authors state 9 clinical trials were used but this figure appears to include duplicated patient data.

No RCTs were identified. The multicentre trial reported 30 day mortality of 9% (results from 3 centres ranged from 9.5% to 20%); 30 day to 317 day mortality of 9%; 1 year mortality of 18% (results from 3 centres ranged from 20% to 24%). No operative laser-induced arrhythmias were observed. Anginal status decreased by 2 classes in 75% of patients at 3.6, 12 months (P < 0.001). Decreased number of segments with perfusion defects at 6 and 12 months (P< 0.0002). Additional procedures at 1 year in 6.5% of patients. Decreased medication use in 56%, increased use in 19%. 1 summary report of TMR plus CABG reported a 30 day mortality of 3% (3/104); 1 prospective trial reported 0% mortality at 2 months. The multicentre trial reported hospital admissions for unstable angina decreased from an average 2.5 in the year preceding TMLR to 0.5 in the year after TMRL. However, this figure would exclude those dying in the post-operative year. The 15 abstracts reported mortality at 1 year ranging from 0% to 27%. Symptomatic relief of angina improved in most studies. Data on myocardial function were mixed. The retrospective data base analysis compared mortality at 6 and 12 months and reported mortality < 7% in CABG (96 patients with or without PTCA) and PTCA (47 patients) compared with 12% and 14% for TMR (301 patients) and 13% and 15% for a medical therapy group (50 patients).

Cost information
Transmyocardial laser capital costs reported as $200,000 to $500,000.

Authors' conclusions
Early evidence regarding transmyocardial laser revascularization suggests it will be useful for treating patients with end-stage coronary artery disease. Definitive recommendations await critical analysis of the results from ongoing randomised clinical trials, post-marketing surveillance studies and third party payer acceptance.

CRD commentary
The aims of the review were stated but inclusion criteria were not defined. The discussion includes mention of the subjective nature of the outcome of angina with the potential for reporting bias due to lack of blinding and benefits arising from placebo effect or life-style changes.

No details were given of the methods used to select studies or extract data. Fuller details of the primary studies would have been helpful. It is not clear whether abstracts were checked for duplicated data. Validity assessment was limited to grouping by study design. Results were not reported separately for patients undergoing TMR as the sole procedure and those undergoing TMR combined with CABG. Some investigation of comparable results for different centres used in the multicentre trial may have been useful and provided scope for exploration of factors influencing outcomes. Some
results may be influenced by exclusion of data from patients dying post operatively but no comment is made regarding this censoring.

In view of the lack of inclusion criteria defining the population targeted and reporting of results from a range of procedures it is not possible to comment whether TLR is of greater benefit than procedures currently in use. As the authors state definitive recommendations await further evidence.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors reported that RCTs on TMLR have been conducted but that results have not yet been published. They reported that further studies are needed to assess the cost-effectiveness of TMLR.

Bibliographic details

PubMedID
10185991

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Centers for Medicare and Medicaid Services (U.S.); Coronary Disease /surgery; Data Collection; Decision Making, Organizational; Evidence-Based Medicine; Health Care Rationing; Humans; Insurance, Health, Reimbursement; Laser Therapy /adverse effects /economics /methods; Myocardial Revascularization /adverse effects /economics /methods; Surgery Department, Hospital /organization & administration; Technology Assessment, Biomedical; Treatment Outcome; United States; United States Food and Drug Administration

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Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.