Transmyocardial revascularization utilizing a holmium:YAG Laser

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Abstract

Objective: To evaluate the efficacy of transmyocardial revascularization performed on patients with refractory class IV or unstable angina with a holmium:yttrium-aluminum-garnet laser.

Methods: Transmyocardial revascularization with a holmium:yttrium-aluminum-garnet laser was performed in 42 patients with refractory angina who were not candidates for percutaneous transluminal coronary angioplasty or coronary artery bypass grafting. Patients had either Canadian Heart Association class IV angina (n = 23) or unstable angina (n = 19) and were unable to be weaned from intravenous nitroglycerin. Preoperative thallium studies identified the extent and location of reversible ischemia. Operative exposure was via a limited left anterior thoracotomy. An average of 45–11 laser channels were created with a mean operative time of 106–38 min.

Results: Perioperative mortality was 12% (5/42) with no late deaths. Complications included ventricular 7.1% (3/42) and atrial 4.7% (2/42) arrhythmias, reoperation for chest-wall hemorrhage 2% (1/42), and respiratory failure requiring reintubation 2% (1/42). Intra-aortic balloon pump placement was required in 12% (5/42). The mean postoperative length of stay was 5.5–4.9 (1–25) days. Mean follow-up on 100% of patients is 5.4–3.0 (1–12) months. At 3 (n = 33) and 6 (n = 21) months follow-up the mean angina class was 1.5 ± 0.1 (P, 0.002) and 1.1 ± 0.1 (P < 0.001), respectively.

Conclusions: Transmyocardial revascularization utilizing a holmium:yttrium-aluminum-garnet laser resulted in a significant reduction in angina class and was beneficial in patients with refractory angina untreatable by conventional methods. © 1998 Elsevier Science B.V. All rights reserved

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1. Introduction

Medically refractory angina which is not amenable to percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass grafting (CABG) continues to frustrate clinicians. Indirect methods of myocardial revascularization such as Beck’s omentopexy, [1] Vineberg’s thoracic artery implantation, [2] and Sen’s mechanical myocardial acupuncture [3,4] had limited success and are of historical interest only. Mirohseini and associates [5–9] proposed transmyocardial revascularization (TMR) as a means of providing oxygenated left ventricular blood to ischemic myocardium through laser generated transmural channels. While there is a growing body of literature supporting the use of TMR performed with a carbon dioxide (CO2) laser, this report provides preliminary clinical results regarding the efficacy of TMR performed with a holmium:yttrium-aluminum-garnet (Ho:YAG) laser in patients with refractory angina that were untreatable by conventional methods.

2. Materials and methods

2.1. Patient selection and demographics

Between June, 1996, and January, 1997, 42 patients with refractory angina not amenable to PTCA or CABG were treated with TMR utilizing a Ho:YAG laser at St. Vincent Hospital and Health Care Center, Indianapolis, IN, and The University of Louisville Hospital, Louisville, KY. Study protocols were approved by the Institutional Review Board at each institution as well as the United States Food and Drug Administration. Inclusion criteria included: (i) patients with stable class IV angina (n = 23) or patients...
with unstable angina (n = 19) who were unable to be weaned from intravenous antianginals (Canadian Cardiovascular Society definition), (ii) coronary artery disease not amenable to PTCA or CABG, (iii) evidence of ischemic myocardium (defined as >10% reperfusion) as determined by a myocardial perfusion study and (iv) ejection fraction greater than 25%. Exclusion criteria included: intolerance to anesthesia, uncompensated heart failure, severe arrhythmias, chronic anticoagulation for mechanical heart valves or chronic atrial fibrillation (due to increased risk of postoperative bleeding) and hemorrhagic propensity. Patient demographics are outlined in Table 1. Preoperatively, operative bleeding) and hemorrhagic propensity. Patient demographics are outlined in Table 1. Preoperatively, 93% (39/42) of patients were in Canadian Angina class IV and 7% (3/42) were in class III.

### 2.2. Operative technique

Anesthesia includes short-acting inhalation agents supplemented with low-dose narcotics and propofol. A single lumen endotracheal tube is routinely used, ventilation with a decreased tidal volume and an increased respiratory rate provides excellent visualization of the heart even in patients with emphysema. External defibrillator pads are utilized on the chest. Laser calibrations are set to deliver 6–8 W of power per laser pulse at a rate of five pulses/s from a flexible 1-mm optical fiber. Application of the energy is controlled with a foot switch and is not gated to the cardiac cycle; 3–8 pulses are typically required to traverse the myocardium. Channels are placed every square centimeter throughout the distal two-thirds of the left ventricle avoiding areas which are obviously scarred. Three to five channels are placed followed by 2–3 min of digital pressure to obtain hemostasis and allow the myocardium to recover. This process is repeated until 30–50 laser channels have been placed. A mean of 45 ± 11 channels were created with a mean operative time of 106 ± 38 min. Intraoperative arrhythmias are unusual if channels are placed slowly; epicardial ligation of a laser channel for persistent bleeding has not been required.

The laser energy, which is absorbed by the blood in the ventricle, produces an acoustic image analogous to steam that is readily visible by transesophageal echocardiography (TEE). Initially, TEE was utilized to confirm penetration of the laser into the left ventricle. After several cases, however, tactile and auditory training enable the surgeon to confirm transmyocardial penetration without TEE.

The chest incision is closed per routine with a single posterior chest tube. Patients are routinely extubated in the operating room and transferred to the standard open heart recovery unit. Postoperative pain management is accomplished for the first 24 h with a patient-controlled analgesia pump and ketorolac (Toradol, Roche, Nutley, NJ) and then by oral narcotics. Patients are maintained in the cardiac recovery unit overnight with transfer to a telemetry unit the morning after surgery. Patients with unstable angina, however, often require several additional days in the intensive care unit as they are weaned from their intravenous antianginals. Unstable patients who were on heparin preoperatively are started on low-dose intravenous heparin (1000 units/h) beginning 6 h after surgery if there is no evidence of bleeding and receive their first dose of coumadin on the night of surgery. Cardiac suppressants (β-blockers, calcium-channel blockers) are avoided during the first 48 h but nitrates and angiotensin-converting enzyme inhibitors are resumed the evening of surgery.

### 2.4. Patient follow-up

Mean follow-up in 100% of patients is 5.4 ± 3.0 (range 1–12) months. Postoperatively, all patients are maintained on their same preoperative medication regimen for a duration of 3 months at which time antianginal medications are weaned as tolerated. Following TMR, angina classification is determined at 3, 6 and 12 months with repeat myocardial perfusion studies at 3 and 12 months.

### 2.5. Statistical methods

All statistical analyses and descriptive statistics were determined using JMP® Statistical Discovery Software.
3. Results

Perioperative mortality was 12% (5/42) with no late deaths. The cause of death for each patient is listed in Table 2. Three of the postoperative deaths occurred in patients with unstable angina and two deaths occurred in patients with stable class IV angina. Perioperative complications are listed in Table 3. The mean postoperative length of stay was 5.5 ± 4.9 (range 1–25) days. Following TMR, angina class decreased significantly at 3 and 6 months compared to the preoperative baseline and this is depicted in Fig. 1A–C. Mean angina classification at 3 (n = 33) and 6 (n = 21) months was 1.5 ± 0.1 (P < 0.001) and 1.1 ± 0.1 (P < 0.002), respectively. In addition, at 3 and 6 months follow-up, 87.8% (29/33) and 85.7% (18/21) of patients had a decrease of two or more angina classes, respectively (Fig. 2). The Kaplan–Meier survival estimate at 1 year is 88%. Detailed comparisons between pre- and post-operative myocardial perfusion studies which are blindly interpreted at a central core laboratory are not available in adequate numbers for meaningful statistical analysis.

4. Discussion

Successful myocardial revascularization relies on improved delivery of oxygenated blood to ischemic myocardium. While the mainstays of conventional revascularization are CABG and PTCA, transmyocardial revascularization may prove beneficial in patients with refractory angina who for anatomic and physiologic reasons are not candidates for conventional therapies.

Mirohseini and associates [5] first advanced laser TMR based on Sen’s earlier concept of mechanical myocardial acupuncture. They proposed the use of a CO2 laser to create transmural channels to perfuse ischemic myocardium. It was theorized that oxygenated left ventricular blood accessed the capillary system through the laser channels via sinusoids; a physiologic system analogous to that of the reptilian heart. This theory was compelling considering Wearn’s [10] 1933 description of a rich myocardial sinusoidal network present in the human heart.

Recent clinical studies utilizing a high powered CO2 laser have demonstrated that TMR reduces angina along with
Transmyocardial revascularization utilizing a Ho:YAG laser study (unpublished) and studies utilizing CO₂ TMR may represent a placebo operative mortality. Preoperative ejection fraction or acuity of procedure and postoperative PET scan evaluation. Our institution is currently evaluating the effects of Ho:YAG TMR on perfusion, metabolism, and sympathetic innervation of ischemic myocardium using pre and postoperative PET scan evaluation.

Operative mortality observed in this study is similar to that previously reported for patients with stable class IV angina [12,13] and much less than that previously reported for unstable angina patients receiving TMR by CO₂ laser [15]. No statistical correlation was observed between age, preoperative ejection fraction or acuity of procedure and operative mortality.

It has been suggested that the subjective angina class improvement provided by TMR may represent a placebo effect. Angina class data from 36 patients in the phase I Ho:YAG TMR study (unpublished) and studies utilizing CO₂ TMR, however, have demonstrated a persistent reduction in angina for up to 2 years after the procedure [12,23].

Two prospective multicenter randomized TMR trails utilizing a Ho:YAG laser are currently underway. One compares TMR as the sole therapy with maximal medical management in patients with refractory angina while the other compares TMR combined with CABG versus CABG alone in patients who cannot be completely revascularized. Future applications may also include the treatment of diffuse coronary artery disease in cardiac transplant patients. While these early clinical results with Ho:YAG TMR are encouraging, longer follow-up and perfusion study analyses are needed. Transmyocardial revascularization utilizing the Ho:YAG laser results in a significant reduction in angina classification and is beneficial in patients with refractory angina untreatable by conventional revascularization techniques.

References


