Short- and Intermediate-Term Clinical Outcomes From Direct Myocardial Laser Revascularization Guided by Biosense Left Ventricular Electromechanical Mapping

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Background—Direct myocardial revascularization (DMR) has been examined as an alternative treatment for patients with chronic refractory myocardial ischemic syndromes who are not candidates for conventional coronary revascularization.

Methods and Results—We used left ventricular electromagnetic guidance in 77 patients with chronic refractory angina (56 men, mean age 61±11 years, ejection fraction 0.48±0.11) to perform percutaneous DMR with an Ho:YAG laser at 2 J/pulse. Procedural success (laser channels placed in prespecified target zones) was achieved in 76 of 77 patients with an average of 26±10 channels (range 11 to 50 channels). The rate of major in-hospital cardiac adverse events was 2.6%, with no deaths or emergency operations, 1 patient with postprocedural pericardiocentesis, and 1 patient with minor embolic stroke. The rate of out-of-hospital adverse cardiac events (up to 6 months) was 2.6%, with 1 patient with myocardial infarction and 1 patient with stroke. Exercise duration after DMR increased from 387±179 to 454±166 seconds at 1 month and to 479±161 seconds at 6 months (P=0.0001). The time to onset of angina increased from 293±167 to 377±176 seconds at 1 month and to 414±169 seconds at 6 months (P=0.0001). Importantly, the time to ST-segment depression (≥1 mm) also increased from 327±178 to 400±172 seconds at 1 month and to 436±175 seconds at 6 months (P=0.001). Angina (Canadian Cardiovascular Society classification) improved from 3.3±0.5 to 2.0±0.2 at 6 months (P<0.001). Nuclear perfusion imaging studies with a dual-isotope technique, however, showed no significant improvements at 1 or 6 months.

Conclusions—Percutaneous DMR guided by left ventricular mapping is feasible and safe and reveals improved angina and prolonged exercise duration for up to a 6-month follow-up. (Circulation. 2000;102:1120-1125.)

Key Words: myocardium ■ lasers ■ ischemia ■ revascularization ■ angina
Methods

Patient Population
Patients were candidates for the safety and feasibility phase of the Biosense DMR procedure if they (1) had symptomatic coronary artery disease with chronic refractory angina defined as Canadian Cardiovascular Society (CCS) class III to IV angina despite best tolerated pharmacological therapy (ie, long- or short-acting nitrates, β-adrenergic–blocking agents, or calcium antagonists at maximal tolerable doses), (2) were poor candidates for percutaneous angioplasty, and (3) were poor candidates for surgical revascularization procedures. These criteria were determined by at least 2 physicians in each of the tertiary referral centers that participated in the study, in addition to a similar definition made by the referral cardiologist. Major exclusion criteria included severe left ventricular (LV) dysfunction (ejection fraction [EF] <0.30), recent (within 1 month) myocardial infarction (MI), recent (<4 months) angiplasty, chronic atrial fibrillation, and major (life-threatening) comorbidity. Informed consent had been obtained for all patients who were potential trial candidates before the procedure. All antiangiogenic medications (long- or short-acting nitrates, β-adrenergic–blocking agents, and calcium antagonists) were continued at their long-term prescribed dosages throughout the course of the study. Medical history, pertinent physical examination, laboratory studies (CBC with platelet count, cardiac enzymes [CK-MB], and blood chemistry) and 12-lead ECG were obtained the day before the DMR procedure. On the day before the DMR procedure, each patient underwent a transthoracic echocardiogram, a standard treadmill exercise test (modified Bruce/Beth-Israel protocol), and radionuclide stress dual-isotope perfusion studies with SPECT techniques. All patients had a positive exercise tolerance test defined as chest pain symptoms and ST-T changes that developed during exercise or the recovery period and evidence of reversibility perfusion defect during the SPECT study.

Study End Points
The primary end point of the present study was the absence of in-hospital major adverse cardiac events (MACE) defined as death, MI (Q and non-Q wave defined as CK-MB ratio >8 normal value), LV perforation (with and without cardiac tamponade), systemic embolization (including cerebrovascular events), CABG (for procedure-related complications), and PTCA (for procedure-related complications) and the incidence of MACE up to 6 months defined as a combination of death, recurrent MI (Q and non-Q wave), and ischemia-driven revascularization procedures. The end points for this trial were adjudicated by an outside clinical event committee. Secondary end points included (1) procedural success defined as device success without intra procedural complications (MACE), (2) change in exercise time at 30 and 180 days, (3) change in radionuclide perfusion studies at the treatment sites at 30 and 180 days, (4) improvement in angina and health status according to the Seattle anginal questionnaire (quantitative instruments) and change in CCS angina class compared with baseline at 14, 90, and 180 days, and (5) change in repeat LV electromechanical mapping at 6 months.

Myocardial Perfusion Imaging
At baseline and 1 and 6 months after DMR, all patients underwent SPECT myocardial perfusion imaging with a dual-isotope protocol with 3 mCi 99mTc-Tc-sestamibi and 25 mCi 201TI for rest and 25 mCi 99mTc-sestamibi for adenosine stress imaging according to previously published methodology.2 Sestamibi was administered at 3 minutes of the 6-minute adenosine infusion (140 μg · kg⁻¹ · min⁻¹). Stress imaging was performed beginning 60 minutes after 99mTc-sestamibi injection. These data were submitted to the central core laboratory for blinded uniform processing, interpretation, and comparative analysis. A 20-segment semiquantitative visual analysis was used as well as an automated quantitative analysis. The following score was used: 0, normal; 1, mildly reduced uptake; 2, moderately reduced uptake; 3, severely reduced uptake; and 4, no uptake. The summed scores of rest, rest-redistribution, and stress images were determined at 1- and 6-month follow-up and compared with baseline values.

LV Mapping and DMR
The LV electromechanical mapping system and procedure have been previously described in detail.7,8 Heparin was administered (70 UAE) and supplemented as needed to maintain an ACT of 200 to 250 seconds. After acquisition of the LV map, all patients were advanced to the laser DMR phase of the study. Treatment zones for this study were predefined using both the SPECT imaging and the diagnostic LV mapping data according to the following criteria: (1) voltage amplitudes of >10 mV and local endocardial shortening (LS) of <6%, signifying severe myocardial ischemia at rest,9 (2) voltage amplitudes of 7 to 10 mV with reference regions of >10 mV regardless of LS values,2,8 and (3) laser channels not placed in zones with voltage amplitudes of ≤6 mV that likely represent infarct tissue,2,8 or in areas with myocardial thickness of <2.5 mm as detected by echocardiography (4) in case of voltage amplitudes of >10 mV and LS values of >10%, the definition of target zones for DMR was made exclusively based on the SPECT definition. At the conclusion of LV mapping, an 8F laser catheter was introduced and advanced to the LV. The laser source was a pulsed Ho:YAG laser (Sharplan 2040: Ho:YAG Laser Systems). Laser channels were created using a tip deflecting mapping and Ho:YAG laser catheter integrated with a 300-μm fiber (LaserStar; Biosense-Webster). After a transmission test, the DMR catheter was inserted through the femoral artery sheath, and the DMR procedure was initiated. A single laser pulse (2 J/pulse) was fired as close as possible to perpendicular to the endocardial surface with the catheter tip icon used to verify the location and orientation of the tip in relation to the mapped endocardium. Between 10 and 25 laser pulses were fired within the confines of the treatment zone with ≥5 mm between each laser pulse. The software provides precise visual annotation of the location in 3 dimensions for each laser pulse. Care was taken to avoid the mitral valve apparatus, the LV apex, and regions of myocardium with known previous infarction or thinning (see earlier). The system allowed the laser to fire only if a QRS peak was detected to which the laser was triggered and the stability of the cycle length and catheter location were verified. At the conclusion of the laser DMR procedure, all patients were monitored (ECG, arterial and right heart pressures) in the catheterization laboratory for 15 minutes. At the end of the procedure, patients were transferred to an intermediate care facility with continuous ECG monitoring overnight. Blood samples for CK-MB were serially acquired from all patients every 8 hours for 24 hours after the procedure. CK-MB elevation has been defined as “minor” (1 to 3 times normal), “intermediate” (3 to 8 times normal), and “major” (>8 times normal). In addition, serial 12-lead ECGs were acquired from all patients every 8 hours for 24 hours after the procedure. Transthoracic echocardiograms were obtained within 1 hour of the procedure and the next day before hospital discharge.

Electromechanical Mapping Data
Repeat electromechanical mapping was performed before and at 6 months after laser DMR in most patients. LV maps were projected into 16-segment models, and unipolar voltage amplitudes (UpVs) and LS data were submitted to a central core laboratory for interpretation and matched analysis.7,9 Segments (n=864) were distinguished by the number of annotated laser channels per mapped segment (none, 1 to 5, 6 to 10, >10 channels per segment) to examine the presence of a regional treatment effect.

Follow-Up (Postdischarge)
Patient follow-up included evaluations at 2 weeks (QOL assessment), 1 month (exercise test, echocardiography, and dual-isotope SPECT), 3 months (QOL assessment), and 6 months (exercise test, dual-isotope SPECT, and repeated electromechanical mapping). All follow-up end point assessments were performed at the specific times indicated unless the patient required hospitalization. All follow-up assessments (exercise test, echocardiography, SPECT, LV mapping, and QOL assessment) were performed at independent core laboratories, and data were transferred to a coordinating center (Cardiovascular Data Analysis Center, Boston, Mass).
TABLE 1. Patient Characteristics and Medications

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y (range)</td>
<td>61±11 (36–82)</td>
</tr>
<tr>
<td>Male sex, n (%)</td>
<td>56 (73)</td>
</tr>
<tr>
<td>Angina class III, n (%)</td>
<td>49 (64)</td>
</tr>
<tr>
<td>Angina class IV, n (%)</td>
<td>38 (36)</td>
</tr>
<tr>
<td>Previous CABG, n (%)</td>
<td>67 (87)</td>
</tr>
<tr>
<td>Previous PTCA, n (%)</td>
<td>47 (62)</td>
</tr>
<tr>
<td>Previous MI, n (%)</td>
<td>44 (72)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>35 (45)</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>63 (83)</td>
</tr>
<tr>
<td>Ejection fraction (range)</td>
<td>0.48±0.11 (0.28–0.79)</td>
</tr>
<tr>
<td>Antianginal medication, n (%)</td>
<td></td>
</tr>
<tr>
<td>Aspirin</td>
<td>77 (100)</td>
</tr>
<tr>
<td>Nitrates</td>
<td>65 (84)</td>
</tr>
<tr>
<td>β-Blockers</td>
<td>63 (82)</td>
</tr>
<tr>
<td>Calcium antagonists</td>
<td>66 (86)</td>
</tr>
<tr>
<td>ACE inhibitors</td>
<td>43 (56)</td>
</tr>
</tbody>
</table>

Statistical Analysis

All data are presented as mean±1 SD. Nominal data (pre-DMR versus post-DMR) were compared by paired t test analysis. Fractional values were compared by χ² analysis. Changes in electromechanical mapping data were calculated and compared by trend analysis. P value of <0.05 was considered statistically significant.

Results

Patients

Seventy-seven patients who fulfilled protocol inclusion criteria were enrolled from the 3 institutions and were entered into the study. Clinical demographics are presented in the Table. The majority of patients underwent CABG or PTCA in the distant past. The average EF was 0.48±0.12. The use of antianginal medications is outlined in the Table. With only a few exceptions, all study medications were kept constant throughout the course of the study. The mean heart rate at rest was 64.6±10.8 bpm (range 45 to 89 bpm), with 78% of patients having a resting heart rate of <70 bpm. The mean systolic and diastolic blood pressures were 130.7±23.2 and 75.3±9.3 2 mm Hg, respectively.

Procedural Details

In all cases, full electromechanical maps were obtained without complications. The overall number of mapping points was 78±21 (range 40 to 134), and the LV mapping time before DMR was 26±9 minutes (range 13 to 50 minutes). After electromechanical map acquisition and online interpretation, all patients were advanced to the DMR treatment phase of the study. Each patient received an average of 26±10 (range 11 to 50) laser pulses in an average of 1.6±0.5 treatment zones (defined as either anterior, lateral, or infero-posterior). Device success was achieved in 76 of 77 patients. In 1 patient, a sufficiently stable endomyocardial position could not be established to permit safe laser firing due to small ventricular cavity size, marked hypercontractility, and persistent multiple ventricular premature beats; the procedure was aborted and recorded as a technical failure. The average DMR procedure time was 29±13 minutes (range 9 to 78 minutes), and the overall procedure time (mapping and laser) was 55±12 minutes (range 26 to 129 minutes). Treatment zones were anterior (n=31), lateral (n=32), inferior (n=25), and posterolateral (n=24). Two representative cases of percutaneous DMR with use of the Biosense electromechanical navigational system in the anterior and inferior walls are shown in Figures 1A and 1B, respectively.

In-Hospital Clinical Events

Procedural success, defined as device success without the occurrence of MACE through hospital discharge, occurred in 76 of 77 patients (98.7%). The 1 procedural failure was described. There were 2 in-hospital complications; 1 patient had postprocedural stroke manifested by left-sided diplopia and ptosis with diagnosis of third cranial nerve palsy. The second complication involved a patient who underwent angioplasty to treat a total occlusion of the left posterior descending branch of the left circumflex artery immediately before the DMR procedure. After a series of guidewires were used without success to cross the lesion, the patient was immediately enrolled into the DMR study. A routine postprocedural echocardiogram revealed a large (200 to 300 mL) pericardial effusion that was drained with a subxiphoid catheter to prevent hemodynamic consequences. This procedure was performed without difficulty, with the return of normal hemodynamic and echocardiographic findings. The patient was observed overnight in the coronary care unit and had no further complications. It is unclear whether the perforation occurred as a result of the angioplasty attempt with stiff guidewires or of the DMR procedure.

There were no deaths, Q-wave or non-Q-wave MIs, or emergency angioplasty or surgical procedures. Importantly, no patient experienced clinical heart failure after DMR. Three patients (4.2%) sustained significant CK-MB enzyme elevations (>3 and <8 CK-MB ratio). Eighteen patients (22.2%) sustained CK-MB elev-
tion of >1 but <3 times normal values. No permanent ECG changes have been noted in any patient. Postprocedural echocardiography revealed no LV dysfunction or valve damage (see later). There have been no significant vascular complications (transfusion or surgical repair) in any patient. Generally, patients were discharged the next day, and none could identify specific negative effects or symptoms associated with the DMR procedure.

Follow-Up Clinical Events
There were no deaths or Q-wave MIs from the time of DMR to the 6-month follow-up. There were 4 post-DMR revascularization procedures (angioplasty in 2 patients, bypass surgery and surgical TMR in 1 patient, and bypass surgery alone in an additional patient) due to progressive coronary disease and continued or worsening symptoms. One patient sustained a non-Q-wave MI between hospital discharge and 1 month, and an additional patient sustained a stroke. One patient was diagnosed as having colon cancer and underwent abdominal surgery.

Echocardiographic Data
Transthoracic echocardiography was performed within 24 hours before DMR, within 24 hours after the procedure, and again at 1 month. There was no change in the average measured LVEF after DMR or during follow-up (0.48±0.12 postprocedure and 0.46±0.11 at 1 month versus 0.48±0.11 at baseline, P=NS for both comparisons). Interestingly, the degree of mitral regurgitation (assessed on a scale of 0 to +4) did not change acutely after DMR (1.9±1.2 postprocedure versus 2.0±1.1 at baseline, P=NS), but at 1 month, an overall decrease was noticed in the degree of mitral regurgitation compared with before DMR (1.7±1.0 versus 2.0±1.1, P=0.038). Diastolic function as detected by mitral inflow E/A ratio showed a significant improvement at 1 month (1.35±0.61) compared with E/A wave ratio value before DMR (1.23±0.50, P=0.014).

Exercise Test Data
Significant prolongation in exercise duration was noted throughout the study among treated patients. Exercise duration after DMR increased from 387±179 to 454±166 seconds at 1 month and 479±161 seconds at 6 months (P<0.001 and P=0.0001 versus baseline, respectively) (Figure 2). By paired analysis, there was a 49±111- and 78±107-second exercise prolongation at 1 month (65 patients) and 6 months (56 patients) after the DMR procedure (P<0.001 for both comparisons versus baseline). The time to angina symptom onset during exercise after DMR increased from 293±167 to 377±176 seconds at 1 month and 414±169 seconds at 6 months (P=0.0001 for versus baseline). Importantly, the time to ST-segment depression (≥1 mm) during exercise was also increased from 327±178 to 400±172 seconds at 1 month and
and 3 months (3M) and 6 months (6M) after percutaneous DMR (P<0.0001 for 3- and 6-month time points versus baseline).

Angina Assessment
Angina class (CCS) improved from 3.3±0.5 to 2.3±1.1, 2.1±1.1, and 2.0±1.1 at 2 weeks and 3 and 6 months, respectively (P<0.001 for each comparison versus baseline, Figure 3). Of the patients, 75% and 79% experienced sustained symptomatic improvement of ≥1 CCS class at 3 and 6 months, respectively, whereas 33% and 43% of the patients experienced sustained symptomatic improvement of ≥2 CCS classes at 3 and 6 months, respectively. Angina stability score showed a sustained improvement from a value of 35.8±26.2 at baseline to 70.0±25.4, 66.7±28.5, and 71.8±28.8 at 2 weeks and 3 and 6 months, respectively (P<0.0001).

Nuclear Imaging
The visual summed stress scores data failed to show a difference between baseline and the 30-day study (20.0±11.5 versus 19.1±10.7, P=NS) or the 6-month SPECT study (19.2 versus 18.8, P=NS) for 65 patients. Similar findings were noted for the summed rest and rest 4-hour redistribution scores. A blinded visual side-by-side comparison of the perfusion data also failed to reveal a treatment effect. Quantitative analysis confirmed the lack of a demonstrated effect on myocardial perfusion by radioisotope imaging technique. When regional perfusion data were correlated to the laser-treated regions, no effect on perfusion was noted with DMR treatment. Thus, overall nuclear perfusion studies with a dual-isotope technique did not show significant improvements in rest, stress, or redistribution imaging scores at 1- and 6-month follow-up after DMR.

Electromechanical Mapping
Segments (n=864) were distinguished by the number of annotated laser channels per mapped segment (none, 1 to 5, 6 to 10, >10 channels per segment; n=477, 267, 87, and 33 segments, respectively). On average, 25±12% of the endocardial surface area was treated with a mean channel density of 1.0±0.4 channel/cm² within the treatment zone. The overall and regional unipolar voltage showed slight but significant (P<0.05) reduction (by ≈1 mV) in voltage amplitudes observed at 6 months compared with baseline without an apparent effect of DMR or the number of laser channels placed on this finding (Figure 4). By contrast, LS improved from baseline to 6 months in DMR-treated segments but not in segments without treatment. Moreover, the increase in LS was related to the channel density (8.7%, 25.5%, and 40.8% increase in LS by 6 months in zones with 1 to 5, 6 to 10, and >10 channels per segment, respectively, versus 2% change in nontreated segments; Figure 4, P<0.001).

Discussion
In the present study, we examined the use of a novel electromagnetic field–based LV navigational system integrated with an Ho:YAG laser catheter specifically designed for the DMR procedure. The results of this study shows for the first time that Biosense-guided DMR (1) is technically feasible in the vast majority of patients with an acceptable safety profile, (2) provides enhanced diagnostic and localization information that facilitates precise placement of laser channels, (3) results in few complications, and (4) may provide sustained clinical benefit, including improved angina and prolonged exercise duration, that extends up to 6-month follow-up. Although nuclear perfusion studies failed to show significant improvements in perfusion assessments, repeat LV mapping documented significant improvements in mechanical activity in laser-treated areas that seemed to correlate well with the number of laser channels per segment.

Rationale for DMR
DMR is a generic term that is meant to embrace all forms of treatment that involve intramyocardial approaches to improve anginal symptoms, not those that occur via the epicardial coronary tree. Extensive surgical experiences with transmural intraoperative laser DMR have indicated significant reduction in angina severity, improved exercise tolerance, and improved QOL but no evidence of improved myocardial perfusion in patients who sustain refractory coronary ischemic syndromes.1–3 The likely mechanism of DMR action has not been fully elucidated and may result from local microvascular angiogenic response, local nerve damage that causes an anesthetic effect, or both.10,11 The goal of catheter-based DMR is to create nontransmural endomyocardial channels that are smaller than but comparable in tissue effect to the surgical DMR without the need for surgery or general anesthesia. In addition, it enables access to areas not approachable with surgical DMR (eg, the ventricular septum and the posterior wall) and provides opportunities for multi-
ple treatment sessions with a lesser invasive approach. Furthermore, in theory, the catheter-based alternative to surgery may be associated with lower procedural morbidity and mortality rates. At the present, percutaneous DMR experiences appear promising, with preliminary results from catheter-based DMR clinical trials that report clinical efficacy and safety comparable to those of the surgical procedure.12

LV Mapping to Guide DMR
There are several unique features of the electromagnetic field–based system that may be advantageous to optimize the safety and efficacy of DMR procedures. The navigation and mapping rely solely on low-energy electromagnetic fields generated for real-time 3-dimensional reconstruction of the LV endocardial surface with only minimal or no need for fluoroscopy or contrast administration. Due to the ability to collect the endocardial voltage amplitudes, the status of myocardial viability (presence of normal or reduced voltage amplitudes) can be determined.13 This enables the identification of potential ischemic target zones that may benefit from laser DMR treatment. The mechanical map (end-systolic and end-diastolic volumes, EF, and LS) provides global and regional contractility data. This property can eventually be used for accurate anatomic identification of the “area at risk,” to be used to direct treatment to the proper ischemic site and to avoid the treatment of nonviable infarct issue.7–9

We attempted to address the following issues regarding LV-guided DMR: (1) safety and feasibility of LV mapping and subsequent “guided” DMR in patients with coronary artery disease and (2) assessment of the efficacy of laser DMR through independent core laboratory evaluation of symptomatic improvement, exercise test changes, and perfusion assessment after DMR. The results of the study clearly demonstrate both feasibility and safety; the procedure was successfully completed in all except 1 patient. The frequency of major complications in this study was low (2.6%); only 1 patient had myocardial perforation, and an additional patient had a small cerebrovascular embolic event. Echocardiography before and after the laser DMR procedure was further confirmatory through the exclusion of LV function deterioration, new aortic or mitral valve abnormalities, or pericardial effusion except for the 1 patient we described. The practical use of the Biosense system to generate electromechanical maps was also confirmed in the present study. Data obtained from the ventricular maps were useful in the identification of target ischemic regions for laser DMR procedure and agreed with antecedent interpretation of diagnostic radionuclide scans. Moreover, with voltage amplitudes and mechanical activity data, the avoidance of laser channel placement could be achieved in (1) the mitral valve area (eg, low-voltage amplitudes in the posterior ventricular area) and (2) areas that sustained prior myocardial infection (eg, low-voltage amplitudes and reduced mechanical activity).13

Study Limitations
The potential advantage of electromechanical mapping as a platform modality for DMR must be established and compared in the future with other systems that use either x-ray fluoroscopy or echocardiography for guidance. Despite the observed promising efficacy end points, the present study was not designed to establish the efficacy of the laser DMR procedure. A large-scale blinded randomized clinical trial is under way to establish the definitive therapeutic value of laser DMR. Although the potential mechanisms that may be responsible for a beneficial clinical effect are being elucidated in experimental animal models, our data provide little insight into the potential mechanistic effects of laser DMR in patients with myocardial ischemia. Although far from conclusive, the improved time to ST-segment changes during exercise and the improved LS in the treated zones are suggestive of a positive physiological effect, as opposed to a simple placebo effect. Finally, there remain many unknowns about DMR, which should lead to further clinical investigation; examples include the importance of channel size (depth and diameter) and channel spacing as the need for precise endocardial localization with online guidance systems, the ideal treatment “substrate” (ie, ischemic, border zone, or normal myocardium that supplies collaterals), and the durability of clinical outcomes. Further randomized controlled clinical trials are needed to address these important issues.

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References
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