Early Results of Percutaneous Myocardial Revascularization with Three Dimensional Non-fluoroscopic Electromechanical Mapping - A Novel Revascularization Therapy in Patients with End Stage Coronary Artery Disease

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Early Results of Percutaneous Myocardial Revascularization with Three Dimensional Non-fluoroscopic Electromechanical Mapping - A Novel Revascularization Therapy in Patients with End Stage Coronary Artery Disease

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LEE ET AL.: Early Results of Percutaneous Myocardial Revascularization with Three Dimensional Non-fluoroscopic Electromechanical Mapping - A Novel Revascularization Therapy in Patients with End Stage Coronary Artery Disease. Patients with end stage coronary artery disease who are not suitable candidate for conventional revascularization procedures including percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting surgery (CABG) can have disabling angina despite maximal medical treatment. Despite its convincing symptomatic benefit, transmyocardial revascularization has limited role in these patients because of its significant perioperative morbidity and mortality. Percutaneous route of direct laser myocardial revascularization (DMR) has emerged and initial results are encouraging. We describe a novel way to perform DMR - with non-fluoroscopic electromechanical mapping. Between April to July 2000, we have performed DMR in six patients. Five patients had triple vessel disease and one had single vessel disease. Five patients had prior PTCA and two had prior CABG. One patient had DMR to left anterior descending artery territory and the other five had DMR to right coronary artery territory. The mean number of DMR channels was 23.3±2.9. There was no acute complication. On three months follow up, three of four patients had angina class improved from class III to II. One patient had remained in class III angina. The average number of additional nitrate tablets use decreased from 4 to 1.75 per week. Hence, DMR with non-fluoroscopic electromechanical mapping is a safe and feasible revascularization option for patients with end stage coronary artery disease. (J HK Coll Cardiol 2000;8:179-184)

Coronary artery disease, laser, percutaneous myocardial revascularization

摘 要
對於那些不適合常規血運重建手術（經皮腔內血管成形術和冠脈搭橋術）治療終末期冠心病病人，盡管已經進行了最大劑量的藥物治療，但是仍然有致殘性心絞痛發生。盡管已經有令人信服的症狀改善，但是由於較高的圍手術期死亡率和併發症，經心肌血運重建術的地位已經受到限制。目前已經出現經皮直接激光心肌打孔（DMR），且效果令人振奮。我們描述了一種新的實行DMR的方法，非熒光電機標測法。2000年4月至7月間，我們對6個病人實行了此類手術。5例病人是三支血管病變，1例病人單支血管病變。5例病人有PTCA手術史，2例CABG術手術史。一例病人行DMR到LAD區域，1例行DMR到RCA區域，平均DMR通道數是23.3±2.9，沒有急性併發症發生。三個月的隨訪結果顯示，3/4的病人心絞痛分級從111級改善到11級。一例病人仍然為心絞痛11級。平均硝酸酯類藥物用量從4/周降低至1.75周。因此，對於終末期冠心病病人，非熒光機電標測DMR是一個安全可行的血運重建選擇。

關鍵詞：冠心病 激光 經皮心脈血運重建

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PERCUTANEOUS LASER MYOCARDIAL REVASCULARIZATION

Introduction

Coronary artery disease is the second leading cause of death in Hong Kong. Revascularization by either percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass grafting surgery (CABG) constitutes an important part of the management of these patients. However, a significant proportion of patients have either diffuse coronary artery disease, no adequate distal target vessels, chronic total occlusion or blocked grafts, who are not amendable by conventional PTCA or CABG. More importantly, they may have disabling angina despite maximal antianginal medication. It has been estimated that, in the United States alone, there may be 200000 patients per year that belong to this category.1

Transmyocardial revascularization (TMR) designed to produce channels in the ischaemic myocardium by carbon dioxide (CO2) laser has been shown to improve angina class, prolong exercise tolerance and, in some studies, enhance perfusion in these patients with end stage coronary artery disease.2-4 However, TMR requires general anaesthesia and open thoracotomy and is associated with significant perioperative morbidity and mortality. The development of yttrium-aluminium-garnet (YAG) laser allows the delivery of energy via optic fibers and hence the emergence of direct myocardial revascularization (DMR).5

While early results of DMR are encouraging, the present technique is performed under conventional fluoroscopic guidance which may be too crude for precise positioning of the guiding and laser catheters. Potential complications include damage to papillary muscles and the mitral valve apparatus, repeated lasing into the same area, myocardial perforation and subsequent cardiac tamponade and ventricular arrhythmia from catheter manipulation.

In this study, we describe the early results of a non-fluoroscopic system to effect DMR.

Mapping and Laser System

The NOGA system (Biosense, Johnson and Johnson) consists of an electrophysiological mapping catheter with miniature magnetic field sensor at the tip, a reference catheter with similar sensors at the tip, a location pad which generates an ultralow magnetic field and a workstation which processes the information obtained from the mapping catheter. The electrophysiological counterpart (Biosense system) has been described in our laboratory. The mapping catheter (Noga Star, Biosense, Cordis) is introduced through an 8F femoral sheath and placed in the left ventricle as the usual mapping catheter used in electrophysiology study. The mapping catheter is then manipulated so as to make a stable contact with the left ventricular endocardial surface. The mapping catheter will then pick up the electromagnetic signal and then its position relative to the reference catheter will be determined. By moving the mapping catheter tip to multiple left ventricular endocardial sites, the workstation uses a triangular algorithm to reconstruct the left ventricular anatomy. A three dimensional mechanical map is constructed to represent the local shortening function, with various colour-coded for different degrees of motion. At the same time, unipolar and bipolar endocardial potentials are recorded by the electrode tip of the mapping catheter. These will then be converted into a three dimensional electrical map by displaying the voltage potentials on a graded colour scale (Figure 1).

The ability of this new system to determine the location and orientation of the catheter, to record local electrogram from its tip and to reconstruct the three dimensional geometry of the chamber with the electrophysiological information colour-coded and superimposed on the anatomy have been validated by both in vitro and in vivo studies.7 By using the discrepancy between the unipolar voltage and linear shortening, it has been suggested that this system could differentiate between normal, ischaemic and hibernating myocardium.8-10 The target region is the ischaemic myocardium which has normal voltage potential but with impaired contraction (Figure 2).

An electromechanical mapping catheter containing the location sensor and tip electrodes is specifically designed to integrate with a laser fiber to perform the left ventricular-mapped direct percutaneous myocardial revascularization. With the real time guidance of the catheter location, accurate creation of multiple laser channels into the target zone of ischaemic myocardium is possible. Each DMR channel is created with a single 2-Joules pulse. Meanwhile, the exact location of laser channels will be indicated on the map and, hence, avoiding repeated lasing into the same site.
Figure 1. Unipolar (left) and local shortening (right) maps of a patient with ischaemia. The colour code is indicated on the right upper corner of each map. Notice the normal voltage potential and local shortening (blue to purple) over the left ventricle and the physiological low voltage and local shortening (red) over the mitral annulus area.

Figure 2. Unipolar (left) and local shortening (right) maps (right anterior oblique view) in a patient with ischaemia over right coronary artery territory. Notice the presence of electromechanical dissociation (red arrow) - i.e. normal unipolar voltage (blue) with associated impaired local shortening (red).
This article describes our early results of this novel revascularization method in patients with end-stage coronary artery disease.

**Patients and Methods**

Consecutive patients with end-stage coronary artery disease satisfying the following inclusion criteria were recruited.

1. Canadian Cardiologic Society (CCS) Angina Scale class III or IV while receiving at least two antianginal medications at the maximum tolerated doses.
2. All patients have severe coronary artery disease which were not amendable to either PTCA or CABG due to diffuse disease, complete occlusion, lack of graftable vessels or any combination thereof.
3. Normal or only moderately impaired left ventricular performance (ejection fraction >35%).
4. Stress induced myocardial perfusion defects on thallium-201 scintigraphy.
5. Wall thickness in the DMR target region >8 mm as determined by echocardiography. The "target region" were defined as the region of stress induced myocardial perfusion defects on thallium-201 scintigraphy which is not amendable to CABG or PTCA.

Patients were excluded from DMR if they had the following exclusion criteria:

1. Unprotected left main coronary artery disease >50%.
2. Unstable angina pectoris or a change in antianginal medication within the last three weeks.
3. Myocardial infarction within the last three months.
4. Left ventricular thrombus.
5. Severe peripheral vascular disease that precluded femoral artery access.
6. Aortic stenosis that prohibited catheter access to the left ventricle.
7. Renal insufficiency with serum creatinine levels >220 µmol/l.

All eligible patients underwent left ventriculography performed in two orthogonal views using biplane imaging. Left ventricle electromechanical mapping using the NOGA system were performed, with at least 80 point recordings to profile the left ventricle, and more sampling points at the target region. Then, the laser catheter were used to create channels in the target ischaemic region. Care was taken to space channels at approximately equal distances of at least 1cm from each other, and a total of up to 25 applications per myocardial region. Echocardiograms were performed immediately and at 6-hour after the procedure in order to exclude perforation of the left ventricular wall and ensuing pericardial tamponade. All patients were observed for 24 hours in the coronary care unit and serial electrocardiograms and cardiac enzyme levels were obtained. Clinical assessment including quality of life questionnaire, echocardiography for regional and global left ventricular function and treadmill exercise were performed before, and at 3 after the procedure.

**Results**

Between April to July 2000, we have performed DMR in 6 patients. The baseline characteristics of this cohort were shown in Table 1. Five patients had triple vessel disease while one patient had chronic total occlusion of the left anterior descending artery with unsuccessful PTCA. Five patients (84%) had history of prior PTCA and two (33%) had prior CABG. Those

<table>
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<tr>
<th>Table 1. Baseline patient characteristics</th>
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<tr>
<td>Variables</td>
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<tr>
<td>Sex (Male : Female)</td>
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<td>Age</td>
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<tr>
<td>Angina Class (CCS)III</td>
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<tr>
<td>Hypertension</td>
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<td>Diabetes</td>
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<td>SVG disease</td>
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<td>Prior PTCA</td>
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<td>Prior CABG</td>
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CABG: coronary artery bypass grafting; CCS: Canadian Cardiovascular Society; PTCA: percutaneous transluminal coronary angioplasty; SVG: saphenous vein graft
two patients with prior CABG had degenerated vein graft disease which deemed not revascularizable by PTCA, and the patient declined a repeated CABG.

One patient had DMR to left anterior descending artery territory while the remaining 5 patients had DMR to right coronary artery territory (Figure 3). The mean number of DMR channels created was 23.3±2.9. Procedure time ranged from 95 to 160 minutes, with a mean of 124±26 minutes. Mean fluoroscopy time was 16±10 minutes. There was no acute complication including perforation of ventricle, cardiac tamponade, sustained ventricular arrhythmia and myocardial ischaemia. All patients were discharged on the next day following the procedure.

Four patients had three months follow up. Three patients (75%) had improvement of their angina class from class III to II while 1 patient had no significant improvement (still in CCS class III). The average number of additional oral nitrate taken decreased from 4 per week to 1.75 per week.

**Discussion**

Most patients with coronary artery disease have their angina symptoms well controlled with a combination of antianginal medications and revascularization procedure, either by PTCA or CABG. However, patients with end stage coronary artery disease may have disabling angina symptom despite maximal medical treatment. More importantly, they are not candidates for conventional revascularization because of diffuse disease, small distal vessels, chronic total occlusion without graftable distal vessels and history of multiple bypass surgeries. The need for an alternate revascularization is clear.

TMR is proven to improve angina class, increase exercise tolerance and improve quality of life in patients with end stage coronary artery disease. However, there is so far no convincing improvement in myocardial perfusion as documented by nuclear scintigraphy. In a randomized study, Schofield et al reported a nonsignificant trend of increased mortality in TMR treated group.

The underlying mechanism of TMR is still unknown. Long term patency of the laser channels, as was initially suggested, was refuted. Sympathetic denervation was also suggested to be contributory. More recently, promoted angiogenesis in the scar tissue is believed to be the chief mechanism in improving the myocardial perfusion and hence clinical response.

The limitation of TMR is the relatively high perioperative mortality, in the range of 5-9%. The requirement of general anaesthesia and thoracotomy also hinder its widespread use. It is criticized that the different studies reporting the clinical results of TMR lacked rigorous solid outcome endpoints to enable objective assessment of the clinical effect of this treatment modality. Meanwhile, possible placebo effect on the treatment group can not be neglected. Moreover, the disparity between clinical improvement and objective assessment of myocardium perfusion by nuclear scan cannot be explained. Last but not the least, the underlying mechanism for the subjective clinical improvement still remains unknown.

The initial results of DMR are encouraging. Similar to TMR, it is able to improve angina class, increase exercise time and reduce additional nitrate use. More importantly, it is associated with much lower perioperative morbidity and mortality. The NOGA system can produce three-dimensional real time left ventricular electromechanical map. This may help to identify the target ischaemic region as opposed to the normal or infarcted regions. This may facilitate the target of the laser catheter to the appropriate region. It

Figure 3. Posteroanterior view of a unipolar map in a patient who had PMR to the inferior wall. Each brown dots denote a laser channel.
may also help to avoid creating laser channels in mitral
annulus area. Repeated lasing in the same channels can
also be prevented.

Patients with disabling angina (CCS class ≥3),
small, diffusely diseased and nongraftable distal vessels,
chronic total occlusion or blocked grafts are suitable
candidates for DMR. DMR is able to reduce angina
symptom and improve exercise tolerance. As shown by
our cohort, DMR performed with LV electromechanical
mapping is a feasible alternative. It is associated with
high procedural success and low complication rate.
More importantly, it reduces radiation exposure to
medical staff as compared with DMR performed with
conventional fluoroscopy.

Conclusion

DMR with non-fluoroscopic electromechanical
mapping is a safe and feasible therapy for patients with
end-stage coronary artery disease. Moreover, this
revascularization therapy is associated with
symptomatic improvement in these patients who have
disabling angina.

Acknowledgement

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