Evaluation of Percutaneous Laser Myocardial Revascularization in Chinese Patients with Refractory Angina Pectoris

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LU ET AL.: ***Evaluation of Percutaneous Laser Myocardial Revascularization in Chinese Patients with Refractory Angina Pectoris.*** *The study aims to evaluate the feasibility and effect of percutaneous laser myocardial revascularization (PMR) in patients with refractory class III-IV angina. Patients were selected by: (1) angina class ≥III; (2) unsuitable to CABG and PTCA; (3) LVEF ≥30%; (4) absence of myocardial infarction in 6 months; (5) maximum diastolic wall thickness of left ventricle (LV) ≥8 mm in echocardiography. Eclipse Holmium laser generator and catheter were used. Eighteen patients (17 male and 1 female) with age of 63.3±7.5 years and a history of angina for 9.6±7.0 years were studied. They were refractory to 5.8±0.7 antianginal drugs. The angina class was IV in 11 patients and III in 9 patients. Maximum diastolic LV wall thickness was 10.2±0.8 mm. LVEF was 41.2±6.2%. Eleven and 9 patients had triple vessel and double vessel diffuse disease, respectively. A mean of 19.7±6.3 endomyocardial channels were made. Procedure time was 78.2±12.5 minutes and radiation time 24.3±7.4 minutes. There were no complications. During the follow-up of 18.7±1.6 months, angina class decreased from 3.8±0.7 to 2.1±0.8 (P<0.05). Ischemia in SPECT was significantly improved. PMR using Eclipse Holmium laser generator and catheter is safe in Chinese patients. This results suggest that patients with refractory class III or IV angina could be controlled by conjunctive use of PMR and regular antiangina drugs. (J HK Coll Cardiol 2000;9:3-8)*

Angina pectoris, Holmium laser, myocardial revascularization

摘要
本研究的目的是評價經皮激光心肌血運重建術(PMR)治療頑固性III-IV級心絞痛的可行性和療效。病例選擇標準為：(1)心絞痛級別≥III級，(2)不適合作CABG和PTCA；(3)LVEF ≥30%；(4)6個月內無心梗病史；(5)超聲心動圖測定左室壁最大舒張期厚度≥8 mm。使用Eclipse鈥激光發生器及其導管系統。18 例病人中男17例，女1例，年齡63.3±7.5，心絞痛史9.6±7.0年。聯用5.8±0.7種抗心絞痛藥物效果不好。心絞痛IV級11例，III級9例。左室壁最大舒張厚度10.2±0.8 mm。LVEF41.2±6.2%。三支病變11例，兩支病變9例，均為彌漫性病變。每例病人打孔19.7±6.3個。操作時間78.2±12.5 min，透視時間24.3±7.4 min。無併發症。隨訪18.7±1.6月，心絞痛級別從3.8±0.7下降到2.1±0.8(P<0.05)。ECT示心肌缺血明顯改善。採用Eclipse 鈥激光發生器及其導管進行PMR操作安全可行。本文結果表明，PMR配合常規藥物治療能很好控制頑固性III-IV級心絞痛。

關鍵詞：心絞痛　鈥激光　心肌血運重建術

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Introduction

The principle of percutaneous laser endomyocardial revascularization (PMR) is to make endomyocardial channels in the ischemic left ventricular walls by translating laser energy via a steerable optic fiber catheter. From these channels, new capillary network is reconstructed by angiogenesis development. The channels are 6 mm in depth and 2 mm in diameter and are apart from each other by 10 mm. Unlike angioplasty (PTCA) or coronary bypass (CABG), PMR is not limited by the characteristic and degree of coronary vessel lesions, and is suitable to all kinds of end-stage ischemic heart disease patients who cannot be revascularized. Therefore, PMR will be a very important supplement to PTCA/STENT and CABG.[1-3] In order to evaluate the feasibility and safety of PMR in the treatment of Chinese patients with ischemic heart disease, we analysed the clinical and follow-up date of 18 patients who received PMR procedures in our center in the recent 2 years.

Material and Methods

Patient Selection

Patient selection has been described in previous publications.[1-5] The 18 cases were selected by the criteria of: (1) angina pectoris of class III-IV (Canadian Heart Association Class),[6] (2) refractory to more than 4 antianginal drugs, (3) left ventricular ejection fraction (LVEF) on echocardiography ≥30%, (4) absence of acute myocardial infarction in the recent 6 months, (5) multi coronary vessel diffuse lesions in paroxysmal and distal parts on coronary angiography, (6) cardiac ischemia confirmed by treadmill test and/or single positron emmission computerised tomography (SPECT), (7) the thickness of target left ventricular wall in maximum diastolic period on echo ≥8 mm, and (8) without catheter interventional complications.

Equipment

MLAS-1 Holmium: YAG laser generator (Eclipse Corp., San Francisco, CA, USA) was used. The machine has the parameters of: (1) wavelength 2100 nm, continuous adjustable energy from 1 to 6W, (2) pulse width 200 µ, 2J per pulse and 1-3 pulse delivered per burst, (3) automatic active energy calibration system, (4) synchronization with ECG R wave and adjustable delay triggered window, (5) Holmium: YAG laser, (6) usable for both PMR and transmyocardial laser revascularization. The laser catheter (PMRL-1, Eclipse Corp., Figure 1) was 110 cm long, comprised of a 9F XL2 guiding catheter (100 cm) and a 5F L1 laser catheter (the inner laser fiber, 500 cm). At the tip of the laser catheter, there is a mirror with a dimension of 1.75 mm and 4 limiting petals mounted on it.

Procedure

A 9.5F artery sheath was introduced into right femoral artery by Seldinger technique. Ten thousand units of heparin was given via the sheath. The LV was entered with a 6F pigtail catheter, through which a 9F long sheath was reel rolled into LV. A LV angiogram was performed with biplane DSA during quiet breathing. The maximum diastolic LV imaging was fixed and major LV landmarks were marked on the video screens. Then the pigtail was withdrawn, and the laser catheter advanced. The laser generator was controlled at following parameters: 2 pulses per burst, 2J per pulse, synchronization window lasted 30 ms and located before the first third of T wave ascending limb. Delivered energy was calibrated before washing the catheter system.

The following steps was adapted to make endomyocardial channels in targeted ischemic LV walls. Coronary and LV angiograms and echo results were reviewed to confirm the targeted LV wall. The LV wall was divided into anterior, lateral, inferior, septal and blunt apical. The 9F sheath was then directed to the targeted wall. By the continuous flushing of pressurised normal saline, the laser catheter and its outer sheath

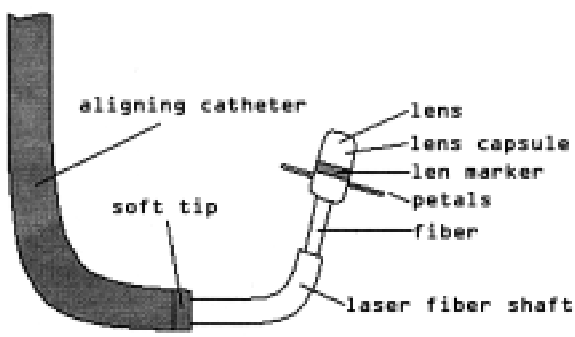

Figure 1. *PMRL-1 laser catheter system (Eclipse Corp.), including a XL2 guiding catheter and a L1 fiber catheter.*

were introduced into the LV chamber. The radiopaque mark at the tip of the laser catheter enabled the operator to visualize the catheter at the tip of the 9F sheath. The laser catheter was then advanced until its tip was in contact with the endomyocardium perpendicularly (Figure 2); and a laser application was made. The created channel was marked on the biplane video screens to ensure the channels were evenly distributed and to avoid two channels were made at the same point (Figure 3). The laser catheter was then withdrawn and the process repeated, until all targeted LV walls were revascularized. During above procedure, ECG, arterial pressure and the fluoroscopic heart movement were monitored.

Follow Up

The following parameters were assessed during follow-up: (1) Angina class, (2) standard 12 lead ECG,

(A) (B)

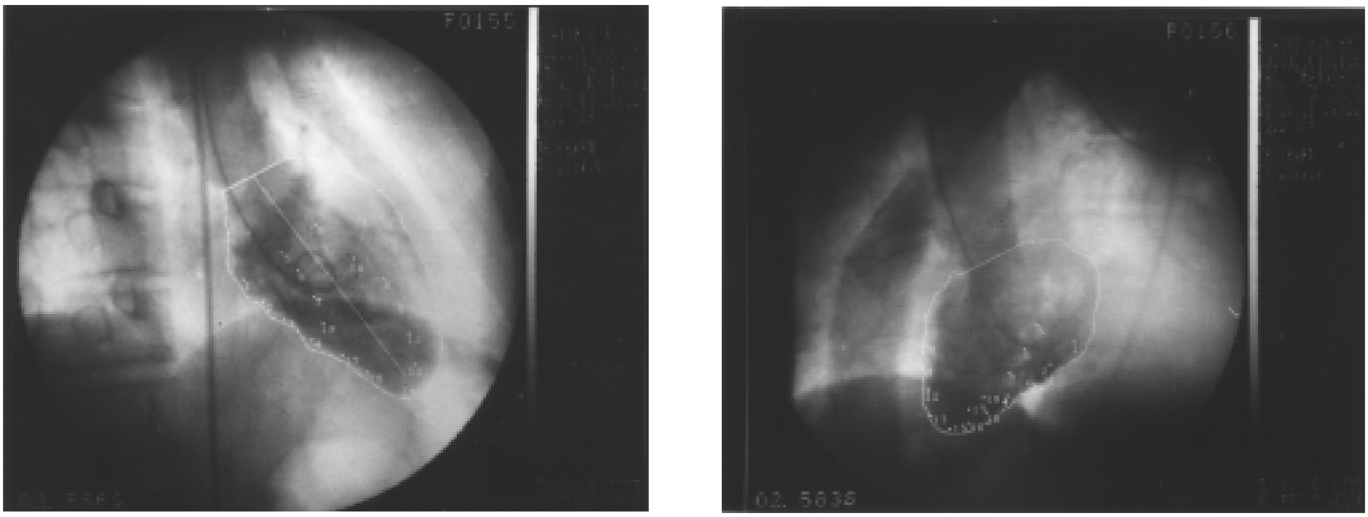

Figure 2. *Laser channels were marked on the right anterior oblique 30°(A) and left anterior oblique 45° (B) fluoroscopic screens of left ventricular angiogram.*

(A) (B)

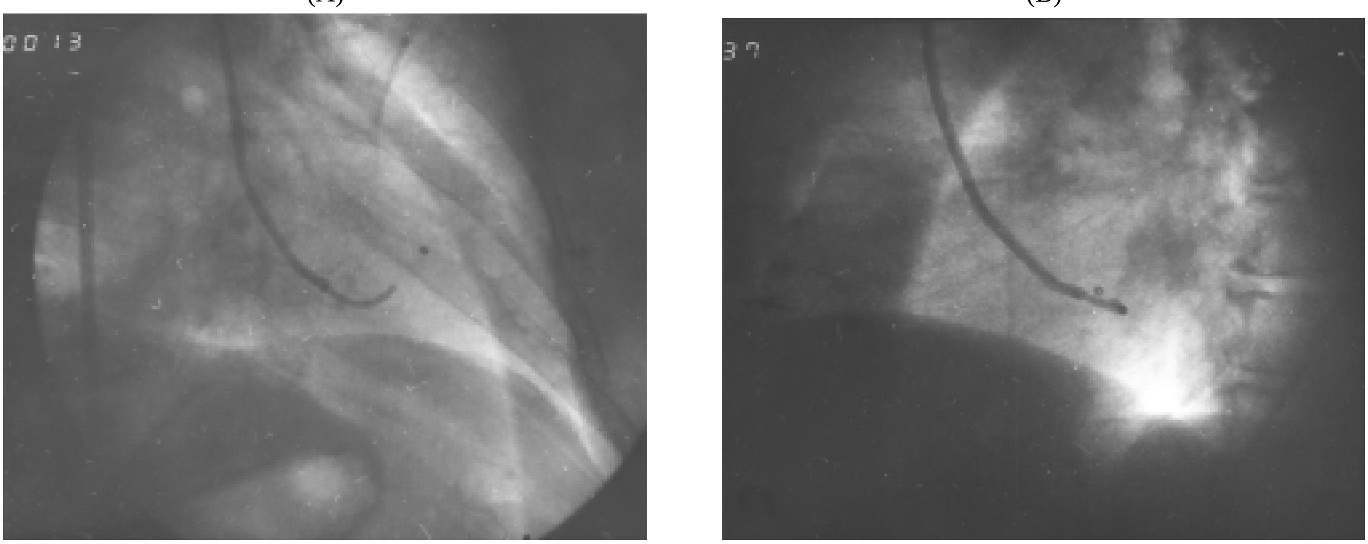

Figure 3. *When perpendicularly pointed to the ventricular endocardium, the tip mark of the laser catheter could be visualized as a filled rectangle on right anterior oblique 30º (A) and an open circle on left anterior oblique 45º (B), respectively.*

(3) treadmill test, (4) echocardiography, (5) SPECT, (6) cardiac enzymes, (7) LV late potential, and (8) Holter monitoring.

Statistic Analysis

Categoric data were expressed in percent and value data in mean ± standard division (M±SD). Student t test or χ^2 test was used to analyse the data and a $P<0.05$ was considered to be statistically significant.

Results

Patient Data

Eighteen patients (17 male and 1 female) with age of 65.4±8.2 (51-78) years were studied. Their angina history was 9.6±7.0 (1-42) years. Their angina class was 3.8±0.7 (class IV in 11 cases and III in 7 cases). They were refractory to the combination of 4.8±1.7 (3-7) types of antianginal agents. On SPECT, the ischemic LV walls were demonstrated in anterior, lateral and inferior walls (9 patients), anterior, lateral and septal walls (5 patients), and anterior, lateral and blunt apical walls (4 patients). All had normal cardiac enzyme, liver and kidney function and negative LV late potential. On echocardiography, all patients showed normal cardiac chamber size without aneurysm and thrombus. The maximum diastolic LV wall thickness was 10.2± 0.8 (9-14) mm with regional motion amplitude of 7.4± 0.7 (5-9) mm. On coronary angiogram, fourteen patients (78.6%) showed triple vessel disease and 4 patients (21.4%) had double vessel disease. The LVEF was 43.5±3.7 (42-58)%.

PMR Procedure Data (Table 1)

A mean of 19.7±6.3 (9-30) laser channels were made on 3±0.9 (2-4) LV walls. A mean of 70.3±11.5 (38-106) laser pulses and 137.9±20.4 (74-210) J were delivered.

Complications

During laser delivery, all patients did not experience abnormal sensation. There were no complications of cardiac perforation, aortic or mitral valve damage. Ventricular premature contraction was provoked in 14 (77.8%) patients and nonsustained ventricular tachycardia was induced in 9 (50.0%) by intracardiac laser catheter manipulation. Total procedure time was 78.2±12.5 (48-126) minutes and X-ray radiation time was 24.3±746 (12-36) minutes.

Early Observation after PMR Procedure

All patients showed normal cardiac enzyme at 6, 12 and 24 hours after PMR procedure. Seven patients had ST segment resolution in ECG.

Table 1. Channel distribution, pulse and energy data of 18 patients receiving PMR

LV wall	n	laser channel	laser pulse	laser energy
single wall				
anterior	18	11.7±5.1 (7-14)	47.5±9.8 (36-62)	93.6±23.5 (68-118)
lateral	14	10.4±2.5 (7-11)	37.0±7.5 (27-42)	69.5±11.9 (26-74)
inferior	7	7.8±3.2 (5-9)	31.2±3.5 (23-34)	41.6±7.4 (32-49)
septal	6	8.1±1.8 (6-10)	30.1±4.5 (22-36)	64.1±9.4 (32-76)
two walls				
A and L	18	18.5±3.5 (7-26)	66.7±9.1 (36-87)	119.3±16.3 (70-206)
A and I	7	14.4±4.6 (6-18)	49.6±9.1 (27-94)	109.7±13.2 (68-182)
A and S	6	13.8±2.6 (5-21)	53.2±11.2 (37-86)	110.2±16.3 (67-176)
three walls				
A, L and I	7	17.7±3.4 (7-26)	68.3±8.3 (34-96)	138.7±14.6 (72-204)
A, L and S	6	16.2±3.4 (9-21)	66.2±7.4 (36-101)	129.3±16.5 (69-197)
Total	14	17.6±4.3 (9-26)	68.3±9.5 (36-104)	136.4±17.2 (72-208)

Note: A: anterior wall, I: inferior wall, L: lateral wall, LV: left ventricle, S: septal wall

Follow-up Results (Table 2)

The angina class of all patients was improved significantly in the follow-up period of 8.7±1.6 (3.5-11.5) months. The mean reduction in angina class was 1.7±0.4 (1.5-3.5).

Discussion

In this study, we have reported the favorable experience of PMR in 18 patients with angina who were refractory to conventional therapy. To ensure safety of the procedure, the following items should be noted during PMR operation: (1) Measuring the actual delivered laser energy to avoid possible abnormal connection between the catheter fiber and the generator. The latter can cause the delivered laser energy abnormally high or low. High energy will lead to cardiac perforation or damage the cardiac structure, whereas low energy will decrease the PMR effect. (2) The maximum number of laser channel for any ischemic LV wall was limited by the potential complications such as cardiac perforation, at present the channels for one LV wall is limited under 12, nearly approaching the density of one channel per cm^2. (3) To prevent cardiac perforation, the stiff sheath should be manipulated smoothly and without any resistance in the LV chamber. Pushing forward and pulling back the sheath as well as the fiber catheter always under the direction of continuous fluoroscopy, and biplane X-ray screens were used to locate and mark the channels. Continuously monitoring electrocardiogram, arterial pressure and cardiac movement amplitude were useful. (4) During PMR, arrhythmias could be provoked by the mechanical stimulation of catheter manipulation and the delivery of laser energy. The former could be decreased by the use of softer or lower profile laser catheters, individualizing the catheter type and size, adjusting the catheter contact with the endomyocardium according to the cardiac movement and ensuring a stable catheter tip in the LV chamber. Arrhythmia induced during laser delivery could be prevented simply by synchronizing the laser energy delivery to the safe period of the cardiac electric interval.

Conclusion

It is feasible and safe to conduct PMR by Eclipse Holmium laser generator and catheter in Chinese patients. PMR allows patient with refractory class III or IV angina despite conventional treatment to be controlled.

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Table 2 Follow-up results of 18 patients receiving PMR

	Before PMR		After PMR		
	n	Result	n	Result	P value
angina class	18	3.8±0.7	18	2.1±0.8	<0.05
exercise tolerance (sec)	7	317.4±56.4	5	489±76.2	<0.05
antiangina drug (no.)	18	4.8±0.7	14	2.7±0.8	<0.05
ischemic wall on ECT (no.)	18	3.2±0.7	8	2.7±0.6	<0.05
VPC on Holter (no./24h)	4	82.3±34.9	2	75.8±60.8	>0.05
ischemia on ECG (%)	15	83.3	6	33.3	<0.05
late potential (%)	18	—	8	—	>0.05

VPC: ventricular premature contraction

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