# Early Experience with Transmyocardial Laser Revascularization

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## Abstract

Conventional treatment of coronary artery disease consists of either Coronary Artery Bypass Grafting (CABG), medical therapy or percutaneous transluniinal coronary angioplasty (PTCA) or a combination. However, certain group of patients do not even qualify for CABG. Transmyocardial Laser Revascularization (TMR) is a unique new surgical modality specially for that sub group of patient population who have small and diffuse coronary artery disease not suitable for grafting. King Fahad Heart Center initiated its TMR program in February, 1994 and until February, 1996,100 patients under went the TMR procedure. Eighty-one were males and 19 females with a mean average age of 55 years. Seventy-nine patients had 3 vessel disease (VD) and 66 patients had non-graftable small vessels. Ten patients had left ventricular ejection fraction (LVEF) less than 30%. All the patients underwent a strict protocol of follow-up. The pre and post TMR assessment at six months and 12 months follow-up showed an increase in LVEF at six and 12 months as compared to pre TMR level. The exercise time also increased from a base line level at six months and showed further improvement at 12 months which was statistically significant ($p<0.05$) along-with VO2 max. which also showed improvement. Clinically, haemodynamically and symptomatically these patients showed significant improvement and use of anti-anginal drugs (87%) was reduced to minimum. Isotope myocardial perfusion scan on 15 segment viability score showed an improvement from pre TMR level of 33.8 to 45.9 at post TMR 12 months follow up. The surgical mortality in this high risk TMR population was 10%. TMR was found to be a reasonable alternative to medical treatment in patients with angina due to diffuse and or small vessel disease or occluded previous grafts not amenable toCABG (JPMA 48:329,1998).

## Introduction

The treatment of Coronary Artery Disease vanes from medical treatment to PTCA and coronary artery bypass graft surgery (CABG). Surgical revascularization has indeed dynamically changed the survival and improved the quality of life of patients with angina pectoris. Still the patients with small coronary arteries or diffusely diseased vessels do not qualify for CABG. The coronary arterial system of vipers and reptilian hearts is rather diminutive and their myocardial perfusion occurs via direct channels between the left ventricle and coronary arterial tree[1]. In human beings it has also been demonstmted that such created channels can lead to revascularization of the myocardium by producing direct myocardial perfusion[2]. Mirhoseini used laser energy to revasculaiize myocardium by producing direct myocardial channels[3] and such channels have been reported clinically and histopathologically to be patent for over four years[4] and have protected the myocardium against ischernia[5].

## Patients and Methods

King Fahad Heart ?enter has the privilege to be the first center in the Middle East to have started the TMR project in February, 1994 and 100 patients have been opemted uponuntil February, 1996.
Selection Criteria
1. Severe diffuse multi vessel disease.

2. Small vessel disease.
3. Advanced ischemic cardiomyopathy with refmctory angina.
4. Closure of previous grafts with distal vessels not amenable to bypass.
5. Calcified ascending aorta with severe atheromatous disease that can lead to cerebro vascular accident during CABG, with informed consent and preference of the patient for TMR.

Of these 100 patients, 81 were males and 19 females. The age range was between 32 to 82 years with a mean age of 55 years. The coronary artery pathology showed 79 patients having three vessel disease and 10 each two and one vessel disease. Sixty-six patients had non-graftable small vessel disease of which 15 patients had left ventricular ejection fraction less than 30%.

Due to the nature of the procedure, which is in the investigational stage, informed consent wastakenfrom all the patients. Once agreed, the patients underwent the formatted protocol for the TMR procedure (Table I).

Table I. TMR follow-up protocol.

| | Baseline | 3 months | 6 months | 12 months |
|---|---|---|---|---|
| Clinical evaluation | Y | Y | Y | Y |
| Quality of life assessment | Y | Y | Y | Y |
| Karnofsky score | Y | Y | Y | Y |
| Blood profile | Y | Y | Y | Y |
| CXR - ECG | Y | Y | Y | Y |
| Echo/Doppler | Y | Y | Y | Y |
| Pulmonary function tests | Y | N | Y | Y |
| Metabolic stress test $VO_2$ Max | Y | N | Y | Y |
| Myocardial isotope perfusion scan | Y | N | Y | Y |
| Muga scan | Y | N | Y | Y |
| Right and left heart cath | Y | N | N | Y |

Y=Yes
N=No

All the patients underwent routine clinical examination and Karnofsky score assessment (Table II).

Table II. Karnofsky performance score.

| | |
|---|---|
| 100 | Normal, no complains, no evidence of disease. |
| 90 | Minor symptoms; able to carry out normal activity |
| 80 | Some symptoms; normal activity with some effort |
| 70 | Care for self; unable to carry out normal activity |
| 60 | Care for most needs; unable to carry out normal activity |
| 50 | Requires considerable assistance and frequent care |
| 40 | Disabled; requires special care and assistance. |
| 30 | Severely disabled; hospitalized, death not imminent |
| 20 | Very sick; active supportive treatment needed |
| 10 | Moribund; fatal process rapidly increasing |

Then they were sent for MUGA scan and Stress Isotope NuclearMyocardial Scan, metabolic stress test to assess their exercise capacity and VO2 max was also performed. Echocardiography was routinely done for all patients to see the left ventricular (LV) function and LV dimensions. All these tests were repeated at six months and twelve months to assess the patient's performance in the post TMR period. Access to the heart was through left anterior thoracotomy in 76 patients while 24 patients underwent median stemotomy, as these patients had either low LVEF or unstable angina, so that cardio-pulmoriaiy bypass support could be instituted if needed. Transoesophageal echocardiography was used intraoperatively to document laser penetration as well as intra operative improvement or deterioration of left ventricular contractility. Number of channels drilled in patients usually were around 27-30 channels. In 100 patients, 2484 channels were drilled with an average of 24.8 channels per patient and the average laser energy used to produce transmurdI penetration was 45 Joules.

**Results and Follow-up**

Post TMR, all patients were followed up at three six and twelve months. At three months only clinical assessment was made while at six and twelve months full clinical and haemodynainic assessment was made and compared to that of preTMRstatus. Thefollow-upwas done intwo groups. Group A with LVEF >35% and Group B with LVEF <35%. At six months follow-up of patients qualifying for full protocol in group A, showed an increase in LVEF from the pre at six months and it increased to 55.2% ±8.6% at twelve months which was statistically ($p<0.05$) significant. While group B patients had pre TMR LVEF of 24.3%±3.8%, which increased to 3 1.3%±6.2%atsix months and 36. l%f6.9%attwelve months and was statistically significant ($p<0.05$) (Table III and IV).

Table III. Follow-up "Group A"

| | Pre TMR | 6 months | 12 months |
|---|---|---|---|
| LVEF% | 49.6±10.1 | 51.7±9.1 | 55.2±8.6 ($p<0.05$) |
| Exercise time (min) | 5.2±3.4 | 7.4±4.3 | 7.9±4.5 |
| Work load (METS) | 5.4±2.6 | 5.7±2.5 | 7.1±3.3 |
| $VO_2$ Max ml/kg/min | 9.5±3.7 | 10.0±3.9 | 12.3±4.7 |
| Karnofsky score KS% | 50 | 80 | 90 |

Table IV. Follow up "Group B"

| | Pre TMR | 6 months | 12 months |
|---|---|---|---|
| LVEF% | 24.3±3.8 | 31.3±6.2 | 36.1±6.9 ($p<0.05$) |
| Exercise time (min) | 3.96±2.29 | 8.45±5.8 | 10.2±5.8 |
| Work load (METS) | 8.1±2.5 | 9.7±3.0 | 10.1±4.6 |
| Karnofsky score KS% | 55 | 67 | 77 |

There was impressive improvement in the exercise perfomance in both groups - Group A patients shewed an increase in exercise time from 5.2 mm. ±3.4 min to 7.4 min±4.3 min at six months and 7.9 min ± 4.5 min at twelve months with an increase in work load units (METS) from 5.4 (METS) ±2.6 to 5.7 (METS)±2.5 at six months and 7.1±3.3 at twelve months while Group B patients showed an average increase from 3.96±2.29 to 8.45 min±5.8 at six months to 10.2 min ±5.8 at twelve months with an increase in work load from 8.1 (METS) 2.5 at baseline to 9.7 (METS)± 3.0 at six months and 10.1 (METS)±4.6 at twelve months (Table III and IV).

An increase of O2/ml/Kg consumption(VO2 max) from 9.5±3.7 to 10±3.9 was observed at six months and it even increased to 12.3±4.7 at twelve months in group A patients while this could not be performed in group B patients due to technical limitations.

In group A patients the Kamofsky score (Table IV)

Table IV. Follow up "Group B"

| | Pre TMR | 6 months | 12 months |
|---|---|---|---|
| LVEF% | 24.3±3.8 | 31.3±6.2 | 36.1±6.9 ($p<0.05$) |
| Exercise time (min) | 3.96±2.29 | 8.45±5.8 | 10.2±5.8 |
| Work load (METS) | 8.1±2.5 | 9.7±3.0 | 10.1±4.6 |
| Karnofsky score KS% | 55 | 67 | 77 |

for assessing the quality of life, increased from an average of the 50% pre TtvliR levels to 80% at six months and 90% at twelve months post TMR. While group B patients showed an average increase in Karnofsky score from pre TMR level of 55% to 67% at six months and 77% at twelve months post TMR.

Eighty percent of Group A patients were free of angina at twelve months and 15% were taking nitrates only. Five percent of the patients were taking either Beta Blockers or Calcium antagonists alongwith nitrates at twelve months. In Group B, the patients showed an improvement in Canadian Classification Scale (CCS) (Table V)

Table V. Canadian classification scale.

| | |
|---|---|
| Class I | Angina with strenous, rapid or prolonged exertion. |
| Class II | Slight limitation of ordinary activity such as walking or climbing stairs rapidly, walking or standing after meals in cold and in wind or under emotional stress. |
| Class III | Marked limitation of ordinary physical activity. Walking 1 to 2 blocks on the level and climbing more than one flight of stairs under normal condition. |
| Class IV | Inability to carry out any physical activity without discomfort. Angina may be present at rest. |

of angina from class 3.25 atapreTMRlevelto 2.25 atsix months and 1.62 at twelve months. There was an obvious trend of reduction in anti anginal drug consumption in both groups gradually and reaching to minimum at twelve months.

Myocardial Isotope Perfusion Scan

Stress and rest isotope myocardial perfusion scan was interpreted on the basis of 15 segment score, where a total score of 60 signifies normal myocardial perfusion. In our study 20 patients completed pre TMR and twelve months post TMR follow-up Isotope myocardial perfusion scan. At the pre TMR level the mean average score was 33.8 while at twelve months there was a general tendency of improvement

towards the total score individually and the mean average score at twelve months follow up was 45.9, signifying an improvement of 72%.

Morbidity and mortality

Only 4 patients presented with serous pleural effusion while wound infection was documented in 2 obese, diabetic female patients. Four patients developed low cardiac output 8-24 hours after the TMR procedure which necessitated artificial ventilation and intra aórtic balloon pumping. Two patients had electrocardiographic documented perioperative myocardial infarction and in both cases recovery was uneventful. None of the serious systemic complications occurred which may be seen with cardiopulmonary bypass specially intra or post operative bleeding, hepatorenal or respiratory dysfunction. The old age was no contraindication to TMR procedure and 22 elderly patients (>70 years) stood the procedure vety well. Ten deaths were encountered in this TMR population. Nine of these patients had small diffused disease and were refused other forms of re-vascularization. Two patients had LEVF less than 35% and 3 patients were transferred to operating room directly from CCU where they were admitted for refractory unstable angina with unstable haemodynainics which were not responding to full medical treatment.

## Discussion

Surgical myocardial revascularization is the ultimate form of treatment to patients with angina pectoris not 331 responding to medical treatment or PTCA. But many patients are denied CABG as their coronary anatomy does not allow them to undergo CABG due to diffuse nature of the disease or small coronary arteries. TMR using $CO_2$ laser has added a new dimension to the concept of surgical revascularization[6] with documented patency of the drilled channel. Six and twelve months follow-up on patients undergoing TMR, has shown subjective and objective evidence of improvement not only in clinical status but also in the quality of life. It has shown its efficacy and efficiency in those patients as well with low LEVF who present a high risk group for CABG. It is a simple procedure which is performed on beating heart without use of extra corporeal circulation and is less traumatic and less expensive than other fonus of surgical revascularization. Following TMR the patients are discharged as early as 6 days and resume routine work at an average of 18 days.

Transmyocardial laser revascularization was found to be a reasonable alternative to medical treatment of anginal pectoris inpatients with diffuse and orsmall vessel disease and occluded previous grafts not amenable to conventional surgicairevascularization procedures such as CABO. TMR is largely effective in not only relieving angina but it reduces isehemia and improves leftventricularfunction. However, itis not an alternative procedure to CABG and the operative mortality remains considerably higher than in CABO. To establish the effectiveness of TMR for the treatment of angina an relieving of ischemia and prove its superiority over medical treatment, we would recommend further prospective large randomized trials between medical treatment and TMR. This will help to establish the significance of the procedure as well broaden its indications.

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