

Endovascular Balloon Angioplasty in Management of Infragenicular Critical Lower Limb Ischemia

Thesis

Submitted for partial fulfillment of M.D degree in vascular surgery

By

Mohamed Mahmoud Mohamed Zaki Ali

M.B.BCh., M.Sc of general surgery, MRCS

Supervised by

Prof. Dr. Tarek Ahmed Abdelazim

Professor of general and vascular surgery
Faculty of medicine-Ain Shams University

Prof. Dr. Wagih Fawzy Abdelmalek

Professor of general and vascular surgery
Faculty of medicine-Ain Shams University

Dr. Sherif Mohamed Essam Eldin

Assistant professor of general and vascular surgery
Faculty of medicine-Ain Shams University

Dr. Atef Abdelhameed Desoki

Lecturer of general and vascular surgery
Faculty of medicine-Ain Shams University

Faculty of Medicine - Ain Shams University
2014

Acknowledgement

I would like to thank Allah, the most merciful and giving for all his blessings. I would like to convey my deepest gratitude and respect for my professors and tutors for their continuous mentoring and guidance, namely Professor Dr. Tarek Abdelazim, Professor Dr. Wagih Fawzy, Professor Dr. Sherif Essam, Dr Atef Abdelhamid and Professor Dr. Sherif Sultan. I would also like to attribute my success and progress to my wife; I couldn't have done it without her support and sacrifices. I would inevitably thank my parents for their lifetime counseling and encouragement; none of my achievements would have been attained if it weren't for them. They have been and will always be my paradigm and the figure I will relentlessly aspire to mimic. And finally, I would like to dedicate this work to my children, and hope that I would always make them proud and that one day it would be a motive for them to excel.

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قَالَ كُنْ فَيَكُونُ

صَدَقَ اللَّهُ الْعَظِيمُ

Table of Contents

Title	Page
<i>Introduction</i>	1
<i>Anatomy of the Infra-Genicular arterial System</i>	4
<i>Pathophysiology of Critical Limb Ischemia</i>	33
<i>Diagnosis of Critical Limb Ischemia</i>	59
<i>Management of Critical Limb Ischemia</i>	95
<i>Patients and Methods</i>	134
<i>Results</i>	146
<i>Discussion</i>	181
<i>Conclusion</i>	194
<i>References</i>	197
<i>Arabic Summary</i>	211

List of Abbreviations

ACCF	<i>American College of Cardiology Foundation</i>
AHA	<i>American Heart Association</i>
AMS	<i>Application of Absorbable Metal Stents</i>
BASIL	<i>Bypass versus Angioplasty in Severe Ischemia of the Leg</i>
BMS	<i>Bare Metal Stents</i>
CAD	<i>Coronary Artery Disease</i>
CFA	<i>Common Femoral artery</i>
CLI	<i>Critical Limb Ischemia</i>
CSS	<i>Churg-Strauss syndrome</i>
CTA	<i>CT Angiography</i>
DEB	<i>Drug eluting balloons</i>
DES	<i>Rug Eluting Stents</i>
DSA	<i>Digital Subtraction Angiography</i>
GCA	<i>Giant cell arteritis</i>
HS	<i>High significance</i>
IC	<i>Intermittent Claudication</i>
IPC	<i>Intermittent Pneumatic Compression</i>
KD	<i>Kawasaki Disease</i>
LS	<i>Low significance</i>
MRA	<i>Magnetic Resonance Angiography</i>
NS	<i>Non Significant</i>
PAD	<i>Peripheral Arterial Disease</i>
PAN	<i>Polyarteritis Nodosa</i>
PTA	<i>Percutaneous Trans-luminal angioplasty</i>
PTA	<i>Percutaneous Transluminal Angioplasty</i>
RCT	<i>Randomized Controlled Trial</i>
RP	<i>Raynaud's Phenomenon</i>
SD	<i>Standard Deviation</i>
SFA	<i>Superficial Femoral Artery</i>
TA	<i>Takayasu Arteritis</i>

TAO	<i>Thrombangitis Obliterans</i>
TASC	<i>Trans Atlantic Inter-Society Consensus</i>
TBI	<i>Toe/Brachial Pressure Index</i>
TIA	<i>Transient Ischemic Attacks</i>
V.A.C	<i>Vacuum assisted wound closure</i>
WG	<i>Wegener granulomatosis</i>

List of Figures

Figure	Title	Page
Figure 1	<i>Branches and Relations of the Popliteal Artery, posterior aspect of the knee</i>	7
Figure 2	<i>Anastomosis Around the Knee</i>	10
Figure 3	<i>Anterior Tibial Artery Course and relations, anterolateral Part of the Leg</i>	13
Figure 4	<i>Anterior Tibial Artery Course and Relations, Transverse section in the Leg 4 cm below the knee joint</i>	16
Figure 5	<i>Course and Relations Of Dorsalis Pedis Artery</i>	18
Figure 6	<i>Branches of Dorsalis Pedis Artery</i>	20
Figure 7	<i>Posterior Tibial Artery Course and Relations in the Leg</i>	22
Figure 8	<i>Posterior Tibial Artery Course and Relations in the ankle</i>	23
Figure 9	<i>Peroneal Artery, Posterolateral aspect of the leg</i>	28
Figure 10	<i>Plantar Arch as seen from the sole of the foot</i>	32
Figure 11	<i>Prevalence of peripheral arterial disease by age and gender in adults 40 years and older, United States, 1999–2000 (n = 2174)</i>	36
Figure 12	<i>TASC classification of femoral popliteal lesions</i>	40
Figure 13	<i>Risk Factors for CLI with Odds ratio</i>	46
Figure 14	<i>Approximate odds ratios for risk factors for symptomatic peripheral arterial disease</i>	47
Figure	<i>Ischemic Ulcer of the toes</i>	63

15		
Figure 16	<i>Ischemic Gangrene of the hallux</i>	67
Figure 17	<i>Correlation of ABPI and Toe pressures with ulcer healing</i>	73
Figure 18	<i>Duplex categories of peripheral artery stenosis based on velocity spectral waveform interpretation. EDV, end-diastolic velocity; PSV, peak systolic velocity.</i>	80
Figure 19	<i>Angiography images vs. duplex images of the right leg in the same patient</i>	81
Figure 20	<i>Pathogenesis of Contrast Induced Nephrotoxicity</i>	91
Figure 21	<i>Flow chart displaying management of Critical Limb Ischemia due to infra-genicular disease as adopted by our study</i>	97
Figure 22	<i>Artassist Device</i>	114
Figure 23	<i>Angioplasty Concept</i>	120
Figure 24	<i>Stenosis of the proximal anterior tibial artery in a patient with digital gangrene successfully revascularised by PTA</i>	121
Figure 25	<i>Pseudoaneurysm thrombin injection. Duplex ultrasound of a femoral pseudoaneurysm</i>	123
Figure 26	<i>Foot and ankle arterial angiosome represented as a topographic map divided into five territories, provided by three main arteries and their branches as shown in the right foot and the left foot</i>	132
Figure	<i>Cool Excimer Laser Emission Device ,</i>	141

27	<i>Spectranetics, Colorado Springs</i>	
Figure 28	<i>V.A.C. negative suction therapy applied over an infected toe amputation stump using black foam</i>	142
Figure29	<i>KCI V.A.C (Kinetic Concepts, Inc., San Antonio, Texas, United States)</i>	143
Figure 30	<i>RENESYS GO V.A.C. (Smith & Nephew, Inc. St. Petersburg, Florida, United States)</i>	143
Figure 31	<i>Gender difference in patients in conventional PTA group</i>	150
Figure 32	<i>Graphic representation of preoperative co-morbidities and risk factors in Conventional PTA group</i>	150
Figure 33	<i>Gender difference in patients in Laser group</i>	152
Figure 34	<i>Graphic representation of preoperative co-morbidities and risk factors in Laser group</i>	152
Figure 35	<i>Graphic representation of lab data among Conventional PTA group</i>	154
Figure 36	<i>Graphic representation of lab data among Laser group</i>	155
Figure 37	<i>Rutherford Category preoperatively in Conventional PTA group</i>	156
Figure 38	<i>Preoperative Rutherford Category in Laser group</i>	158
Figure 39	<i>Piechart showing number of stenting cases in Conventional PTA</i>	159
Figure 40	<i>Piechart showing number of stenting cases in Laser</i>	160
Figure 41	<i>Postoperative Rutherford Category in Conventional PTA group</i>	162
Figure	<i>Postoperative Rutherford Category in</i>	164

42	<i>Laser group</i>	
Figure 43	<i>Graphic presentation of Immediate and Sustained Hemodynamic Improvement among Conventional group</i>	166
Figure 44	<i>Graphic presentation of Immediate and Sustained Hemodynamic Improvement among Laser group</i>	167
Figure 45	<i>Graphic representation of the age difference in both groups</i>	169
Figure 46	<i>Graphic representation of the incidence of hyperfibrinogenemia as a risk factor in both groups</i>	170
Figure 47	<i>Graphic representation of the degree of stenosis and number of total occlusions in patients of both groups</i>	172
Figure 48	<i>Graphic representation of minor amputation rates in the 2 groups</i>	174
Figure 49	<i>Graphic representation of procedure related adverse effects in the 2 groups</i>	176
Figure 50	<i>Graphic representation of long term follow up criteria differences between the 2 groups</i>	177
Figure 51	<i>Infected forefoot with gangrenous big toe</i>	178
Figure 52	<i>Emergency Trans-metatarsal amputation for drainage</i>	179
Figure 53	<i>A- CT angiogram and B -3D reconstruction of the tibial vessels</i>	179
Figure 54	<i>V.A.C. therapy applied to the wound</i>	180
Figure 55	<i>Wound progress after revascularization and with V.A.C. therapy</i>	180
Figure 56	<i>Kaplan-Meier table for Comparison between the two study groups as regard</i>	186

	<i>mean time for binary re-stenosis</i>	
Figure 57	<i>Kaplan-Meier table for Comparison between the two study groups as regard mean time for amputation</i>	187
Figure 58	<i>Graphic representation for the correlation between the need for stenting in total occlusion and in stenosis in conventional PTA group</i>	190
Figure 59	<i>Graphic representation for the correlation between the need for stenting in total occlusion and in stenosis in Laser group</i>	192
Figure 60	<i>Graphic representation for the relation between the presence of a distal runoff and the occurrence of binary restenosis in the whole study population</i>	203

List of Tables

Table	Title	Page
Table 1	<i>Classification Schemes for Peripheral Arterial Disease</i>	38
Table 2	<i>TASC II Guidelines for Femoro-popliteal lesions</i>	39
Table 3	<i>Differential Diagnosis of Ischemic Ulcer</i>	63
Table 4	<i>Diabetic Foot Risk Classifications</i>	64
Table 5	<i>Meggitt-Wagner Classification of Diabetic Foot Ulcers</i>	65
Table 6	<i>University of Texas Wound Classification System</i>	66
Table 7	<i>Clinical Diagnosis of CLI</i>	69
Table 8	<i>Pulse Force Grading</i>	71
Table 9	<i>Potential role of the toe-brachial index (TBI) and absolute toe pressures</i>	74
Table 10	<i>Typical Segmental Systolic Arterial Pressures (mm Hg)</i>	75
Table 11	<i>Sites of disagreement observed on comparing duplex imaging to catheter angiography</i>	79
Table 12	<i>Comparison between DSA, MRA and CTA</i>	82
Table 13	<i>Comparison between DSA, MRA and CTA</i>	94
Table 14	<i>Description of personal and medical data (risk factors) among Conventional group</i>	149
Table 15	<i>Description of personal and medical data (risk factors) among Laser group</i>	151
Table 16	<i>Description of lab data among Conventional PTA group</i>	153
Table 17	<i>Description of lab data among Laser group</i>	154

Table 18	<i>Description of preoperative lesion characteristics among Conventional PTA group</i>	155
Table 19	<i>Description of preoperative lesion characteristics among Laser group</i>	157
Table 20	<i>Description of operative procedures done among Conventional PTA group</i>	158
Table 21	<i>Description of operative procedures done among Laser group</i>	159
Table 22	<i>Description of immediate postoperative lesion characteristics and outcome among Conventional PTA group</i>	161
Table 23	<i>Description of immediate postoperative lesion characteristics and outcome among Laser group</i>	163
Table 24	<i>Description of time to BS, TLR, major amputation, and MACE among Conventional group</i>	165
Table 25	<i>Description of Immediate and Sustained Hemodynamic Improvement among Conventional group</i>	165
Table 26	<i>Description of time to BS, TLR, major amputation, and MACE among laser group</i>	166
Table 27	<i>Description of Immediate and Sustained Hemodynamic Improvement among laser group</i>	167
Table 28	<i>Comparison between two study groups (conventional and laser) as regard personal and medical data (risk factors)</i>	168
Table 29	<i>Comparison between two study groups as regard Preoperative investigations</i>	169
Table 30	<i>Comparison between two study groups as regard preoperative lesion characteristics</i>	171

Table 31	<i>Comparison between two study groups as regard operative procedures done</i>	172
Table 32	<i>Comparison between two study groups as regard postoperative lesion characteristics</i>	173
Table 33	<i>Comparison between two study groups as regard Immediate and Sustained Hemodynamic Improvement</i>	175
Table 34	<i>Comparison between two study groups as regard time to BS, TLR, TER, major amputation, MACE and RIP</i>	177
Table 35	<i>Time to Binary Re-stenosis in bothe study groups</i>	185
Table 36	<i>Time to major amputation in both study groups</i>	186
Table 37	<i>Comparison between degree of stenosis and technical success among conventional PTA group</i>	188
Table 38	<i>Comparison between degree of stenosis and technical success among laser group</i>	189
Table 39	<i>Comparison between presence of total occlusion and the need for stenting among conventional PTA group</i>	189
Table 40	<i>Comparison between presence of total occlusion and the need for stenting among laser group</i>	190
Table 41	<i>Comparison between presence of a runoff and each of technical success and binary stenosis among conventional group</i>	192
Table 42	<i>Comparison between presence of a runoff and each of technical success and binary stenosis among Laser group</i>	193

Introduction

Critical limb ischemia is associated with high rates of limb loss and mortality. Within 6 months of presentation with CLI, $\geq 25\%$ of patients will require major amputation. An estimated 250,000 major amputations are performed annually in the United States and Europe, resulting in a significant socioeconomic burden and severe reduction in quality of life indicators. Published rates of mortality for CLI approach 25% at 1 year and $>50\%$ at 5 years, exceeding rates observed in any other form of occlusive arterial disease (*Gagan et al., 2013*).

Interventional therapy for tibial arteries is a key part of the vascular specialist armamentarium. Tibial artery interventional therapy has been proven to lead to limb salvage with low morbidity and mortality in patients with critical limb ischemia and should be used as a first line treatment mode in the majority of patients, especially in those with significant medical co morbidities (*Sean, 2009*).

Among revascularization methods for critical lower limb ischemia (CLI), surgical bypass has been regarded as the gold standard, with better anatomical and clinical durability. However, patients with CLI are often aged and not optimal candidates for surgical bypass due to medical co-morbidities with increasing perioperative mortality rates and a poor autogeneous conduit. As an alternative method of revascularization, infrapopliteal angioplasty is preferred by patients with visible stumps, good runoff of distal outflow vessels or high surgical risk. However, it had been regarded as an inferior treatment option compared to surgical bypass due to bulky catheters, lack of low caliber wires and general lack of