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Vascular Image
*Tarek Radwan MSc. FRCS,*
Editorial

Dear Colleagues

As we are closing this year with the 3rd issue, we are very pleased to have a 3-issue volume that I hope to increase this number in near future. For-sure we still reminding ourselves that the mission of the EgJVES is to publish the high quality clinical and basic research studies. This issue contains the abstracts submitted for the abstract competition presented during the 10th annual meeting of EVC.

Tarek Radwan FRCS
Editor in Chief
Current Endovascular Uses of Liquid Ethanol Therapeutic Embolotherapy

Wayne F. Yakes MD, FSIR, FCIRSE

Director, Vascular Malformation Center, Englewood, Colorado, USA

Introduction

Embolotherapy is a burgeoning field developed by subspecialties of Interventional Radiology (IR) and Interventional Neuroradiology (INR) and is being rapidly embraced by Neurosurgeons, Neurologists, Vascular Surgeons and Cardiologists who have “morphed” into performing minimally invasive catheter-directed procedures in recent years. The vast array of embolic agents that can be super-selectively delivered with multiple catheter systems and by direct puncture needles and the like, has blossomed due to the innovative ideas of numerous investigators which has led to the improved quality of care, quicker recuperation times, lowered costs of care, and the better outcomes that our patients deserve. The purpose of this report deals with the uses of absolute ethanol as an embolic agent in use today.

History

Particulate agents, coils and detachable balloons dominated the early years of embolotherapy. Professor Plinio Rossi was the first to develop selective catheter arteriography of brachiocephalic arteries. Professor Rossi, in the late 1960s, had a scientific exhibit at Karolinska University Hospital in Stockholm, Sweden. Prof. Rossi described his pioneering selective catheter technique to Prof. Hans Newton, M.D., whereby previously only direct carotid injections with 18g needles was the technique employed. Selective catheterization along the carotid artery distribution opened the intellectual concept of selective catheter delivery of not only contrast agents, but the intellectual concept of selective catheterization of other arterial anatomies and delivery of contrast and embolic agents.

In the late 1960s this led to Professor Fedor A. Serbinenko, M.D. pioneering catheter systems to navigate the internal carotid artery to the level of the cavernous carotid to deliver his hand-made detachable balloons to treat carotid-cavernous fistulae (CCF), whether secondary to trauma or aneurysm rupture. By the early 1970s a genius, Professor Charles Kerber, M.D., began working with IBCA (isobutyl cyanoacrylate) When he finished his Neuroradiology Fellowship under Professor Hans Newton, M.D. (of Newton & Potts textbook fame) at UCSF, he then became staff Neuroradiologist.
of University of Oregon Health Sciences Center in Portland, Oregon. As an aside, Prof. Charles Kerber, M.D., was the FIRST to perform carotid angioplasty. Prof. Charles Kerber, M.D. was the first to take the next step and develop micro-catheter systems to navigate the cerebral vasculature; this calibrated-leak balloon catheter system and many other important pioneering developments. Because the lumen size of calibrated-leak balloon systems was small (no wire system was yet developed for it), only liquid agents were possible to inject through this catheter system. Professor Kerber then worked with a liquid polymerizing embolic agent (IBCA). Now embolization of brain AVMs was possible. Professor Charles Dotter, M.D. broke into Professor Kerber's desk to use the IBCA to close vasculature of pelvis after trauma while Professor Kerber was on vacation. Because the concepts of selective catheterization of arterial systems was firmly in place, transcatheter delivery of many embolic agents was aggressively pursued by many investigators. Brian Elman, M.D. first developed the transcatheter pre-operative embolizations of renal cell carcinomas with absolute ethanol. Absolute ethanol proved a superior embolic agent to particle and coil renal artery embolization because of the absence of any infarction syndrome post-embolization. Other indications for the use of absolute ethanol soon occurred.

**Cardiopulmonary Collapse Issues**

Before the etiology of post-ethanol injection cardiopulmonary (CP) collapse was elucidated, it was a rare, but dire, complication. The mechanism of the complication is as follows. A bolus of ethanol reaches the pulmonary vascular bed. Pulmonary artery spasm can then occur. If it becomes severe enough, it can lead to pulmonary hypertension and right heart failure. This then causes decreased left heart filling and resultant systemic hypotension. Severe systemic hypotension then causes decreased coronary artery perfusion. If severe enough, this can lead to cardiac arrhythmias such as Electro Mechanical Dissociation and asystole.

Prof. Young Soo Do, M.D. and co-investigators published that, in AVM treatment patient series, if the operator does not exceed 0.14ml ethanol per kilo body weight over a 10 minute period, CP collapse will not occur. I did a prospective in-house study of over 200 consecutive procedures in conjunction with my Anesthesiologists. In the ethanol endovascular treatment of high-flow lesions (AVM, AVF; congenital and acquired) as well as low-flow lesions (venous malformations, lymphatic malformation, mixed lesions) by adhering to doses of 0.10ml/kg ideal body weight every 10 minutes, we determined pulmonary pressures never increased to any significant degree and CP collapse was obviated. Therefore, if one stays within these parameters for any intravascular ethanol procedure, CP collapse will not occur. One caveat is that a patient pulmonary hypertension of whatever etiology, they should have an arterial line
placed and Swan Ganz monitoring of pulmonary pressures during the ethanol procedure. Small ethanol amounts can worsen their pulmonary hypertension and cause CP collapse.

**Mechanism of Action**

Absolute ethanol is a liquid embolic agent that penetrates to the capillary bed levels. Because of this distal penetration to the capillary bed level, tissues are totally devitalized and infarcted collateral flow cannot occur. Therefore, great care and vigilance must be maintained to prevent unwarranted non-target embolization of vascular territories with ethanol. Ethanol when injected into any vascular space (artery, vein, lymphatic) denudes the endothelial cell from the vascular wall and precipitates its protoplasm. The denuded vascular wall is then fractured to the level of the internal elastic lamina. Platelet aggregation then occurs on the fractured and denuded vascular wall. Thus, thrombosis occurs beginning upon the vascular wall with more and more accumulation until it thromboses centrally in the vascular lumen.

In vascular malformations, the endothelial cell is the reason recurrences are so common with embolic agents other than ethanol. The acute thrombosis that occurs with any embolic agent (Polyvinyl alcohol (PVA), coils, glues, etc.) produces an ischemic state that is sensed by the intact endothelial cell lining all vascular surfaces. Reacting to the acute ischemic state caused by the thrombosis, the endothelial cell then seeks to rectify this situation by releasing “Chemotactic Cellular Factor” (CCF), “Angiogenesis Factor” (AF). CCF causes the migration of macrophages that carry off the intravascular debris formed by the previous embolization procedure. After there is significant removal, the endothelial cell then re-enthusializes the “new” lumen. This is termed “recanalization” of the vascular malformation leading the recurrences. “Angiogenesis Factor” secreted by the endothelial cell stimulates new vascularity to the thrombosed ischemic area of the vascular malformation. This is termed “neo-vascular stimulation phenomenon” or “neo-vascular recruitment phenomenon”.

With the use of ethanol as an embolic agent causing the destruction of the endothelial cell, these two phenomena of “recanalization” and “neovascular recruitment” are noticeably absent. Thus, there is a permanence of treatment and cures are now possible.

**Current Indications for the Use of Ethanol as an Embolic Agent**

1. Curative treatment of arteriovenous malformations (AVMs) has been published by many authors. Long-term cures, many years post-treatment, have been documented in these high-flow lesions (Figure 1).

2. Curative treatment of low-flow venous and lymphatic malformations has been published by many authors. Magnetic Resonance (MR) imaging utilizing T-2 weighted sequences with fat suppression and also STIR imaging document...
permanent ablation of these low-flow lesions at long-term follow-up (Figure 2)\textsuperscript{14, 16}

3. Preoperative embolization of renal cell carcinoma was one of the first indications for the use of ethanol as an embolic agent. However, because the nerves that cause the ischemic pain of infarction syndrome are destroyed with ethanol embolization, no infarction syndrome occurs and is tolerated well by patients. If a patient is a poor operative candidate, then primary treatment of, and occlusion with, cellular destruction of large renal cell cancers causing significant hematuria and transfusion requirements is possible by this endovascular technique alone.\textsuperscript{7}

4. Hemorrhaging renal angiomyolipomas can be non-surgically managed by superselective ethanol embolization of the tumor and preservation of the normal functioning renal parenchyma (Figure 3).

5. Vascular tumors and their metastases can be infarcted and treated palliative by superselective ethanol embolization in selected cases. In patients with metastatic renal cell carcinoma to the spine, relief of spinal block has been reported with this non-operative minimally invasive technique. Superselective ethanol embolization of inoperable and recurrent meningioma has been a useful non-operative adjunct to treat these vexing tumors (Figure 4).

6. Varicocele endovascular embolization with coils and ethanol is routinely successful to curatively manage this problem. Care must be taken not to have ethanol flow during embolization into the pampiniform plexus of the testicle. This can cause severe pain and an inflammatory reaction. Simple techniques such as placing a few small fibered coils in the refluxing varix immediately proximal to the Inguinal Canal and then additionally externally to manually compress the Inguinal Canal during the ethanol injecting will prevent this potential complication. Frequently varicoceles have multiple large and small collateral venous pathways that may be extremely challenging to access endovascularly for treatment. However, just as contrast injections flow into and opacify these multiple collateral channels, liquid ethanol can also fill these collateral channels and thrombose them completely, thus preventing recurrences (Figure 5). In those patients who have Varicocele recurrence post-surgery and post-endovascular treatment by other methods, ethanol injections of these collateral channels is also curative.

7. Pelvic Congestion Syndrome (PCS) is a challenging condition to manage clinically. Chronic pelvic pain is the rule. Catheterization of the distal refluxing gonadal vein varices (the female version of Varicocele) is difficult. But just as contrast can penetrate deep into the pelvic venous varices, ethanol does penetrate deeply to thrombose these dilated, refluxing abnormal venous structures. Despite successfully thrombosing these extensive venous channels, the pain syndrome can still persist for months. This suggests that the chronic venous engorgement pressuring against the pelvic nerves causes an inflammation of the nerves that may take a while to abate. One more reason why this venous vascular lesion is so vexing to treat.
8. Benign cystic structures of the liver and elsewhere have many reported successes of their shrinkage by direct puncture aspiration of the cyst fluid and distillation of ethanol. It is important to drain the cyst of all fluid so that when the ethanol is injected to sclerose the wall of the cyst, it will not act as a diluent to decrease the efficacy of ethanol.

9. Absolute ethanol infiltration in nerve plexus, e.g., Celiac Plexus Block, can permanently ablate nerve structures bathed in it. Many authors have reported the success of this technique.

**Summary**

Absolute ethanol as an intravascular embolic agent must be respected. Inadvertent non-target ethanol embolization must be completely obviated or devitalization of tissues with resultant necrosis will invariably occur. Unopacified ethanol as an embolic agent can be challenging to use successfully when one is only used to visualizing embolic agents fluoroscopically. Adhering to an ethanol injection protocol of not exceeding 0.10ml/kg ideal body weight every 10 minutes will obviate the need for Swan Ganz monitoring of pulmonary artery pressure and arterial line monitoring of systemic arterial pressures unless the patient suffers from chronic pulmonary artery hypertension. Absolute ethanol has many indications for the treatment of the previously listed pathologic conditions. Investigators will invariably develop more

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**Fig 1a.** 42 year old female with large left buttock AVM. AP Pelvis arteriogram. Note enlarged Superior Gluteal artery supplying the Lt buttock AVM.

**Fig 1b.** AP Lt Superior Gluteal arteriogram with arterial phase & venous drainage phase Note venous drainage into Lt Internal Iliac vein.
Fig 1c. Direct puncture DSA into inferior aspect of AVM nidus of the Lt buttock AVM. Direct puncture ethanol embolization was performed to treat the AVM because super-selective catheterization was not possible and a proximal embolization in the Superior Gluteal artery could lead to Sciatic nerve injury.

Fig 1d. Direct puncture DSA post-embolization with 31 ml of ethanol. Note the thrombosis and contrast stasis in the AVM nidus.

Fig 1e. Pelvis DSA post-embolization documenting AVM thrombosis. No AV shunting present.

Fig 1f. Pelvis DSA at 3 year arteriographic follow-up documenting persistent cure of the Lt buttock AVM.
**Fig 2a.** T-1 weighted MR of Lt forearm venous malformation (VM) infiltrating completely the Pronator Quadratus muscle. Note increased signal in VM compared to muscle.

**Fig 2b.** T-2 weighted MR with fat-suppression Lt forearm VM. Note the bright signal of the VM and its presence and extent is better demonstrated.

**Fig 2c.** T-2 weighted MR with fat-suppression Lt forearm at 6 month follow-up. Note absence of increased signal post-ethanol ablation of the VM by direct injections. The VM is totally ablated and no remaining blood spaces (no bright signal) are present as the ethanol treatment causes the VM lesion to scar down into soft tissue.
Fig 3a. 22 year old male with a hemorrhagingLt renal angiomyolipoma. Selective Lt renalDSA demonstrating renal branches drapingaround the lesion.

Fig 3b. Selective microcatheter DSA in upperpole renal branches to lesion post-ethanolembolization.

Fig 3c. Selective microcatheter DSArenal lower pole branches post-ethanolembolization.

Fig 3d. Lt Renal DSA post-ethanolembolization of the angiomyolipoma.The hematuria ceased sparing surgicalnephrectomy. No infarction syndromeoccurred.
Fig 4a. 80 year old male with large left middle cranial fossa hypervascular meningioma. Surgical removal was obviated due to age and multiple co-morbidities. Superselective arterial catheterization with ethanol embolization was then performed as a primary form of therapy. Progressive speech problems and right body motor weakness were the presenting symptoms. Lt Internal Maxillary DSA shows the hypervascular tumor supplied from the Lt Deep Temporal artery and Lt Middle Meningeal artery.

Fig 4b. Lt External Carotid DSA post-ethanol tumor devascularization of the arterial supply noted. Care must be taken when embolizing the Middle Meningeal artery for the microcatheter to be well beyond the Foramen Spinosum to prevent a 7th Cranial nerve injury.

Fig 5a. Lt Renal vein DSA demonstrating reflux down the incompetent Lt Gonadal vein in a 7 year old boy suffering from a Lt testicular varicocele.

Fig 5b. Selective Lt Gonadal vein DSA demonstrating reversal of vein flow and reflux into the Lt Tesicular vein plexus in the Lt scrotum.
Fig 5c. Selective Lt Gonadal vein DSA with manual compression at the Lt Inguinal Canal blocking contrast flow into the Lt Testicular vein plexus. This compression maneuver during ethanol injection of the vein prevents ethanol irritation in the Lt Pampiniform Vein Plexus.

Fig 5d. Lt Gonadal vein DSA post-ethanol & coil embolization of the distal Lt Gonadal vein.

Fig 5e. Lt Gonadal vein DSA demonstrating collateral vein channels that can cause lesion recurrence if only coils without the addition of ethanol were used.

Fig 5f. Lt Renal vein DSA demonstrating varicocele occlusion after distal Lt Gonadal vein occlusion with coils and ethanol, mid-Lt Gonadal vein ethanol embolization to thrombose the retroperitoneal vein collaterals, and the proximal Lt Gonadal vein occlusion with coils & ethanol, thus curing the Lt testicular varicocele.
References

8. Yakes WF, Pevsner P Reed M, Donohue HJ, Ghaed N. Serial Embolizations of an Extremity Arteriovenous Malformation with Alcohol via Direct Puncture. AJR 1986; 146:1038-1040.
A scientific paper is the link between scientists over time and place. Otherwise, we will be working in isolated islands. Scientific paper is essential for the development and progress of modern science. It is also; part of our continuous medical education. It is used either for sharing our own research project (one that agrees with others, raises questions or suggests new ideas) or for reviewing the literature. Writing a scientific paper is no less than the hard work of scientific work itself. A good example is to, “Write with precision, clarity and economy. Every sentence should convey the exact truth as simply as possible.”. A badly written paper is not only a waste of time but also a waste of hard work that might not see the light.

The main target audience of a scientific paper are the Referees (to accept) and the Readers (to cite and reference to). Therefore, a scientific paper needs to persuade them that the research is important, valid and relevant. It should highlight the motivation for the work and its outcome. A scientific paper is structured in a special format; Title, Abstract, Introduction, Material and Methods, Results, Discussion, Conclusion, Acknowledgment and literature Cited. This is a uniform way to effectively communicate with the scientific society. In the body of the paper (material and methods, results and discussion), every paragraph should have a topic sentence to be explained in to get the message across easily to the readers and help them in selective reading.

This is a concise description of how to write a scientific paper

Title, Author’s Names, authors’ Names and Institutional affiliation:
The title should be concise and unambiguous describing the content of the paper. As a rule, it should contain the key words to the presented work, as it will form the basis for on-line searches. It should be centred and followed by the authors and their institutions affiliation.

Abstract
An abstract is a summary of the whole paper. Readers should be able to understand the principal points of the work by reading it. Therefore, an abstract should briefly address four elements. The Aim of the study (Question posed),
Material and Methods used (experimental design), Results obtained (major findings and trends) and conclusions made in a succinct way. It should be between 200-300 words and use the past tense.

**Introduction**

An effective introduction must provide the reader with four components: context, need, task, and object of the paper. The introduction explains the motivation of the work by describing the background and nature of the problem (context and need). It also states the aim of the study, question posed, and the hypothesis, tentative answer to the question, (task and objective).

**Material and Methods**

This section describes the exact work/experiment done. It should provide sufficient details for other scientists to reproduce the work (in novel work) or just citing the reference (in previous work). It describes how data were summarised and analysed by stating the statistical methods, tests and software used. Some journals prefer this information to be placed in an appendix at the end to avoid boring the reader. Use the past tense throughout this section.

**Results**

This section presents and summarises the key results and general data trends of the work without explanations in the form of texts and illustrations (Tables and Figures). The text should include all supporting and non supporting data to hypothesis. Parentheses are used to present the result of statistical tests. Both text and Tables/Figures should stand-alone and/or be complementary. Tables and figures should be sequentially numbered and with titles to describe them. Tables and Figures may be also separately presented at the end after citation. The Key factor of the results is statistical significance of any presented/obtained numbers. Use the past tense again.

**Discussion**

Discussion analyses and interprets the results and relates them together and with other known studies. In this section you explain how the results answer the question and/or prove or reject the hypothesis. State possible answers for unexpected observations and results. You may discuss non-statistical significant trends if interesting but avoid conclusion bias. Some journals put the Results and Discussion together in a single section to make it more interesting for the reader.

**Conclusion**

It is the principal outcome of the work, in view of interpretation of the results and relating these to the motive declared in the introduction. Include a perspective, if any present, this is an idea of a further research project in relation to the topic addressed in paper. This is the take home message for the reader with a summary of the main points.
Acknowledgment

In this section the author appreciate any help or advice given throughout. Disclosure of any funding or conflict of interest should also be mentioned.

Literature Cited

This is the final section of the paper, where it is mandatory to site published papers mentioned in the manuscript in a chronological order.

References are listed by author

Each Journal has its own style to use.

Citing References in the Text

Wherever a researcher's work is mentioned in the paper, this should be cited by the authors name and date of publication.

Appendices: (Optional)

Appendix contains non-essential information not mentioned in the body of the paper but might help in better understanding. Each appendix is labelled in Roman as Appendix I, Appendix II, etc. Figures and Tables, statistical and/or mathematical methods for data analysis extra photographs are examples included in an Appendix.

General Rules: (Do and Do not)

Abbreviations

Whenever possible use standard abbreviations e.g.: (mg, ml. sec, etc) instead of complete words. Any other abbreviations should be defined first then used.

Empty phrase

Use simple phrases to describe your point and avoid long ones that are not contributory. Always make it short.

Flow

Make your reader tour smoothly through a journey into the paper starting from the background cruising through the rationale and ending to the conclusion.

Parentheses

Do not use double parentheses. Place them apart at the beginning and end of the sentence.

Past, Present and Future

The Introduction is written in either past or present tense. Material and Methods as well as Results are written in the past tense. Only Results from previous work are facts and can be written in the present tense. Although Conclusions are written in the present tense, the future tense is reserved for researches to come (perspective).

Specify

Be specific when using the pronoun “it” or “they” in describing a previous point.
Unless it is clear what the pronoun refers to, emphasise the point again to avoid confusing the reader.

**Spelling**

Do spell check your paper and carefully read the manuscript before submission to check for cohesiveness.

**Third vs. First Person**

Although scientific writing accepts the use of first person sparingly –especially if denotes exclusive work– always use the third person throughout the paper. In short, to write a scientific paper simply ask yourself these questions and answer them. Abstract, what did I do in brief? Introduction, what is the problem? Material and Methods, How did I solve the problem?

Results, what did I find? Discussion, what does it mean? Conclusion, what is the Outcome? Acknowledgment, who helped me? Literature Cited, Whose work did I refer to? Appendices (optional), What Extra Information we have?

Writing a scientific paper is an art that needs to be mastered by almost every scientist. Scientific paper “manuscript” is the legacy, triumph and the jewel in the crown of the scientific work.

**Literature**


2. [http://www.nature.com/scitable/ebooks/english-communication-for-scientists](http://www.nature.com/scitable/ebooks/english-communication-for-scientists).

3. [www.sci.sdsu.edu/~smaloy/MicrobialGenetics/topics/scientific-writing.pdf](http://www.sci.sdsu.edu/~smaloy/MicrobialGenetics/topics/scientific-writing.pdf).

The Optimum Duration Required for Treatment of First Time Proximal Lower Limb Deep Vein Thrombosis

Hatem Abd Elazim, MD,(1) M. Ayman Fakhry, MD(2), Mostafa Ibrahim(3), and Asem Fayed MD(4)

1) Prof. Vascular Surgery Menofeya University. 2) Prof. Vascular Surgery Mil. Academy. 3) Vascular Surgeon Sharq Elmadina Hospital. 4) Lecturer of Surgery Menofeya University

Abstract

Objective: A study to define the optimal duration required for treatment of first time proximal lower limb deep vein thrombosis.

Background: Deep vein thrombosis (DVT) refers to the formation of one or more blood clots in one of the body’s deep veins, most commonly in the lower limbs (proximal lower limb veins as iliac, femoral or popliteal veins and distal lower limb veins as calf veins). The optimal duration of treatment of first time proximal DVT is still controversial. The aim of this study is to define the optimal duration required for treatment of first time proximal lower limb deep vein thrombosis.

Materials and Methods: In the period from March 2012 till March 2014, fifty patients presenting acute proximal DVT to the Vascular Surgery Unit at Menofeya University Hospital, Sharq Elmadina Hospital, clinically diagnosed and confirmed by Duplex Ultrasonography. Fifteen patients were given an intravenous bolus of 100 u/Kg of U.F.H followed by 20 u/Kg/Bw /hour UFH, the dose being monitored by APTT (1.5-2 times, for 10 days). Thirty five patients were given LMWH for 10 days. Warfarin was started on day 7 (5 mg/d) for both groups till day 10 (overlap with heparin. The warfarin dosage was adjusted to obtain therapeutic ratio of INR (2-3.5). The warfarin was continued for 3 months.

Results: There was statistical significant difference between circumference of both lower limbs of the patients at ankle, mid-calf and mid-thigh at first presentation and at end of follow up (P< 0.05). In our study, the fate of the thrombosis at the end of three months period is studied through Duplex scan. Progression of thrombosis was found in 2 patients (4%), no change in the cases was found in 7 patients (14%), partial clearance was found in 17 patients (34%), substantial clearance was found in 13 patients (26%) and complete lysis was found in 11 patients (22%).

Conclusion: Three months therapy is an efficient and a safe method for treatment of first time proximal lower limb DVT thus no need for extending the duration of therapy.

Key words: Deep vein thrombosis, optimal duration.
Introduction

Deep vein thrombosis (DVT) refers to the formation of one or more blood clots in one of the body’s deep veins, most commonly in the lower limbs (proximal lower limb veins as iliac, femoral or popliteal veins and distal lower limb veins as calf veins). The duration of anticoagulant treatment following deep vein thrombosis (DVT) and pulmonary embolism (PE) remains controversial. The duration of anticoagulation should be dictated by the balance between two risks: the risk of recurrent VTE with and without treatment, and the risk of treatment-induced hemorrhage.

Materials and Methods

The study was carried on fifty patients presenting as acute proximal DVT to the Vascular Surgery Unit at Menofeya University Hospital and Sharq Elmadina Hospital. All patients were submitted to:

- Voluntary, written informed consent obtained from them.
- Careful history taking.
- Clinical examination.
- Duplex Ultrasonography (D/U) of the venous system of lower limb and repeated at the end of the 3 months period of treatment.

Investigation:

Complete blood picture.
Fasting blood sugar.
Kidney functions tests.
PT, PTT, INR.
D-dimer.

Fifteen patients were given an intravenous bolus of 100 u/Kg of U.F.H followed by 20 u/Kg/Bw/hour UFH, the dose being monitored by APTT (1.5-2 times, for 10 days).

- Thirty five patients were given LMWH for 10 days.
- Warfarin was started on day 7 (5 mg/d) till day 10 (overlap with heparin), INR was ordered on day 11. The warfarin dosage was adjusted to obtain therapeutic ratio of INR (2-3.5) and continued for 3 months.

Each patient was assigned (according to D/U picture) to one of the following scores:

Score(1): recurrent of extension of the thrombosis.
Score(2): unchanged thrombosis.
Score(3): Partial recanalization (>10% up to 50%).
Score(4): Substantial clearance (50% up to 90%).
Score(5): Complete clearance (> 90%).

Statistical Analysis

Data into the computer was done followed by tabulation and analysis. Analysis was done using SPSS-17 (Statistical package for Social Sciences version 20). Two types of statistics were done

1-Descriptive: : e.g. Percentage (%), mean and standard deviation SD

2-Analytical:-

A) Student (Unpaired-sample) “t” test. It is used to collectively indicate the presence of any significant difference between two groups for a not normally distributed quantitative variable.
B) Chi-square (X2): For comparison between distributions of patients according to different items of study.

Results

In our study, regarding the gender; males were 23 (46%), and females were 27 (54%). Age ranged from 42-65 with mean value 56.4 ± 10.23 Table(1). The risk factors; recent trauma, surgery and immobilization were 6 each (12% each factor), cancer was 7 (14%) and unprovoked DVT was found in 25(50%). Table(2) Calf vein thrombosis was found in 5 patients (10%), popliteal vein thrombosis was found in 22 patients (44%), femora-popliteal vein thrombosis was found in 13 patients (26%) and ilio-femoral thrombosis was found in 10 patients (20%). Table (3) Two types of heparin were used. U.F.H was given to 15 patients (30%) and L.M.W.H was given to 35 patients (70%). The difference in circumference between the two legs of the patients at ankle, mid-calf & mid-thigh (cm) at first presentation and at end of follow up was studied. At first presentation, ankle circumference was 2.01±1.06, mid-calf circumference was 2.77±1.59 and mid-thigh circumference was 1.85±0.98. While at end of follow up, ankle circumference was 1.03±1.10, mid-calf circumference was 1.23±0.98 and mid-thigh circumference was 1.22±0.97. There was statistical significant difference between the two legs of the patients at ankle, mid-calf and mid-thigh at first presentation and at end of follow up (P<0.05). Table (4) In our study, the fate of the thrombosis at the end of three months period is studied through Duplex scan. Progression of thrombosis was found in 2 patients (4%), no change in the cases was found in 7 patients (14%), partial clearance was found in 17 patients (34%), substantial clearance was found in 13 patients (26%) and complete lysis was found in 11 patients (22%). Table (5)

Table 1. Demography

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<th>Gender</th>
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Table 2. Risk Factors

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<td>Surgery</td>
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<tr>
<td>Cancer</td>
<td>7</td>
<td>14.0</td>
</tr>
<tr>
<td>Unprovoked</td>
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Table 3. Location of Vein Thrombosis

<table>
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<th>%</th>
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<tbody>
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</tr>
<tr>
<td>Popliteal V</td>
<td>22</td>
<td>44.0</td>
</tr>
<tr>
<td>Femora-popliteal</td>
<td>13</td>
<td>26.0</td>
</tr>
<tr>
<td>Ilio-femoral</td>
<td>10</td>
<td>20.0</td>
</tr>
</tbody>
</table>

Table 4. The difference in circumference between the two legs of the patients at ankle, mid-calf & mid-thigh (cm) at first presentation and at end of follow up

<table>
<thead>
<tr>
<th></th>
<th>At first presentation</th>
<th>At end of follow up</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ankle</td>
<td>2.01±1.06</td>
<td>1.03±1.10</td>
<td>0.021*</td>
</tr>
<tr>
<td>Mid-calf</td>
<td>2.77±1.59</td>
<td>1.23±0.98</td>
<td>0.042*</td>
</tr>
<tr>
<td>Mid-thigh</td>
<td>1.85±0.98</td>
<td>1.22±0.97</td>
<td>0.036*</td>
</tr>
</tbody>
</table>

Table 5. Duplex scan-picture at the end of 3 months – period.

<table>
<thead>
<tr>
<th>Fate of thrombosis</th>
<th>No.</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Progression of thrombosis</td>
<td>2</td>
<td>4.0</td>
</tr>
<tr>
<td>No change</td>
<td>7</td>
<td>14.0</td>
</tr>
<tr>
<td>Partial clearance</td>
<td>17</td>
<td>34.0</td>
</tr>
<tr>
<td>Substantial clearance</td>
<td>13</td>
<td>26.0</td>
</tr>
<tr>
<td>Complete lysis</td>
<td>11</td>
<td>22.0</td>
</tr>
</tbody>
</table>

Discussion

The aim of our study is to study the optimal duration of treatment of first time proximal deep vein thrombosis. Regarding the gender, we found 23 male patients (46%) and 27 female patients (54%) with male/female ratio of 1:1.2. This was in agreement with Shannon M. Bates et al., 2004 who studied the duration of anticoagulation therapy of proximal DVT and its association with risk factors. On studying risk factors, we found 25 patients (50%) with a definite (provoked) cause (trauma, surgery, immobilization, malignancy.... etc); while the rest (25 patients, 50%) were considered as unprovoked. This was in agreement with Laurent Pinede et al., 2001 (4) who found 55.4% of his patients lie in the provoked group. All patients in our study had a clinical diagnosis of DVT with high Wells probability score that was confirmed by positive D-dimer test and proved by Duplex examination on admission. The importance of Duplex examination of VTE was also agreed by Phillip Wells et al., 2000 who worked on axial vein thrombosis and put a strategic plan for its management.

Duplex examination revealed that all patients had axial DVT, 44% of them had popliteal vein thrombosis (highest percentage), 26 % had femoral vein thrombosis, 20 % of patients had venous thrombosis that extended to the iliac
vein, and only 10% of them had isolated calf deep vein thrombosis. This was in agreement with Prandoni P et al., 2004⁶ who studied the importance of ultrasound compression method for the diagnosis of lower limb DVT. All patients were treated by initial phase with heparin (UFH in group A and LMWH in group B) that was continued for 7 days, and combined with warfarin till reaching the therapeutic level of INR2-3, and continued for three months. This was in agreement with Clive Kearon et al., 2003⁷ who worked on proximal DVT of lower extremities and proved the efficacy of three months period of warfarin treatment using venography.

In our study, the all over improvement after three months therapy of proximal DVT was found in 41 patients (82%). Complete resolution and lysis of proximal DVT was achieved in eleven patients (22%). Substantial clearance was achieved in 13 patients (26%) while partial clearance was achieved in 17 patients (34%). This result was similar to those attained by Kearon C et al., 2004⁸ who compared one to three months treatment for VTE of the lower extremity. Our results are in agreement with those of Henri Boutitie F et al., 2011⁹ who treated the first episode of proximal DVT for duration of three months. They found that duration of three months therapy is sufficient for treatment.

Also Henri Boutitie F et al., 2011⁹ found that not only the incidence of recurrence does not decrease even with extending the duration of therapy more than three months, but also the risk of bleeding increases with this extension of therapy duration. Also in a study by Dr M.F.Sudlow et al., 1992¹⁰, A multicentre comparison of 4 weeks’ and 3 months’ anticoagulation in patients admitted to hospital with acute DVT, PE, or both. A multicentre comparison of 4 weeks’ and 3 months’ anticoagulation in patients admitted to hospital with acute DVT, PE, or both. If venous thromboembolism arises after surgery, 4 weeks of anticoagulation should be adequate. In other settings, patients with new DVT, PE, or both, who do not have a persisting underlying cause or risk factor should receive anticoagulants for 3 months.

In a study by Levine MN et al., 1995¹¹, Patients with venographically confirmed acute proximal DVT who had received four weeks of warfarin after initial heparin and whose four week impedance plethysmogram (IPG) was normal were allocated to either continue warfarin (targeted INR 2.0 to 3.0) for a further eight weeks or receive placebo. Patients with an abnormal four week IPG received warfarin for a further eight weeks. During the eight weeks following randomization, nine (8.6%) of the 105 placebo patients developed recurrent VTE compared to one (0.9%) of the 109 warfarin patients. Over the entire 11 months of follow-up, 12 placebo patients developed recurrence compared to seven warfarin patients, \( P = 0.3 \). Nineteen of the 192 patients with an abnormal four week IPG experienced recurrence during the nine months after discontinuing warfarin. In the 301 patients who received three months of warfarin in
the randomized trial or in the cohort study, all 26 recurrent events were in the 212 patients with continuing risk factors.

**Conclusion**

Three months therapy is an efficient and a safe method for treatment of first attack of proximal lower limb DVT.

**References**

Safety and Efficacy of Negative Pressure Wound Therapy in Comparison with Advanced Moist Wound Therapy in the Treatment of Diabetic Foot Ulcers

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Vascular Surgery and Rheumatology & Rehabilitation Departments, Zagazig University, Zagazig.

Abstract

Objective: This study is designed to prove that negative pressure wound therapy (NPWT) leads to more frequent and earlier complete healing of diabetic foot wounds as compared to conventional advanced moist wound therapy (AMWT). Furthermore, show the effect of both modalities on long-run patient compliance after offloading.

Methods: This randomized controlled study included 111 patients treated and followed up for diabetic foot ulcers between 2011 and 2014. The patients were randomized into 2 groups, the group I (57 patients) subjected to NPWT (43 males and 14 females, age ranged from 24 to 62 years), the group II (54 patients) subjected to AMWT (40 males and 14 female, age ranged from 24 to 62 years). All foot ulcers were assessed and debrided as needed within 2 days of randomization. Patients were examined at regular visits for ulcer closure and/or adequate granulation tissue formation.

Results: 64.9% of patients subjected to NPWT achieved complete wound healing during active therapy time (16 weeks) which is more than the patients subjected to AMWT (44.4%). The duration for complete wound healing is lower for patients in NPWT group than for patients in AMWT group. Although all patients were subjected to offloading modalities until complete wound healing, the incidence of amputations and recurrence were significantly less in patients treated with NPWT.

Conclusion: NPWT is as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers. The advantage of this study is that all patients were treated at home without long hospital stay.

Keywords: Diabetic foot ulcer, negative pressure wound therapy, advanced moist wound therapy, offloading.
Introduction

The diabetic foot wound is a common and frequent secondary syndrome that can lead to amputation. Due to arterial abnormalities and diabetic neuropathy, as well as a tendency to delay wound healing, infection or gangrene of the foot may develop. Acute and chronic wounds with healing impairment are a common problem of health care. Complications associated with non-healing wounds range from inconvenient to life threatening and can be more common and serious than those related to the underlying disease. The occurrence of impaired wound healing represents a multi-disciplinary treatment and cost-intensive clinical problem whether it is caused by infectious or non infectious reasons.

Various diabetic foot ulcers treatment have been reported in the literature, including advanced moist wound therapy, bioengineered tissue or skin substitutes, growth factors, electric stimulation and negative pressure wound therapy. Treatment success depends on ulcer chronicity, patient compliance, appropriate off loading of the appendage, and the mechanisms of action of the therapy. Negative pressure wound therapy (NPWT) was developed at the Wake Forest University (Winston-Salem, North Carolina) in early 1990s. NPWT is an adjuvant treatment obtained by applying sub-atmospheric pressure between 50-175 mmHg on the wound, in a controlled manner. The vacuum-assisted closure (VAC) system is a wound closure device use for this purpose; it applies localized and controlled negative pressure on the wound. The suction effect, generated by a portable, adjustable pump, is applied on the wound cleaned by a sponge made of polyurethane or polyvinyl alcohol. These sponges are closed with an adhesive drape to obtain a sealed environment. Between the drape and the device, an electrical pump is connected to a canister which collects the wound exudates, using a flexible pipe. The polyurethane sponge has pore sizes ranging from 400-600 µm. The polyvinyl alcohol sponges has pore sizes ranging from 200-300 µm.

NPWT exerts mechanical forces on the wound bed and has positive effects on both the contraction of the wound and the proliferation of granulation tissue. It also contributes to the healing, process as it reduces excess interstitial fluid and keep the wound moist in a sealed environment. Moreover, it has been demonstrated in experimental studies that the NPWT technique promotes granulation tissue formation and stimulates local blood circulation, in addition to this, it significantly reduces bacteria count in tissues.

Reduction of pressure or offloading is another essential aspect of diabetic wound care. Foot pressures, shock, and shear can be reduced with appropriately fitted shoes, insoles, and socks. Total contact casts (TCCs) and removal casts are effective in significantly reducing pressure but may cause additional problems when inappropriately applied. TCCs are used for offloading the plantar aspect of the
foot. Published studies suggest TCCs heal greater than 72 percent of all patients treated with them. Contraindications include acute infection ischemia, deep ulcers, and draining wounds. Additional contraindications include ataxic patients and those who are noncompliant, blind, morbidly obese, or have severe peripheral arterial disease. Removable cast walkers may be preferable to TCCs, as they do not have the same inherent disadvantages. Pressure reduction has been shown to be similar to TCCs with certain types of these devices. This randomized controlled study is designed to prove that NPWT leads to more frequent and earlier complete healing of diabetic foot wounds as compared to conventional advanced moist wound therapy. Furthermore, it aims to show that NPWT is also safe and effective when provided in an ambulatory care setting.

Patients And Methods

This study was conducted at Vascular Surgery Unit, Zagazig University at the period from 2011 to 2014. The study included 111 patient randomized into 2 groups. Group I subjected to NPWT and included 57 patients, Group II subjected to advanced moist wound therapy and included 54 patients. The patient population inclusion criteria were diabetic adults ≥ 18 y., with stage 2-4 (as defined by Wagner’s classification) but without lower limb ischemia and has calcaneal, dorsal or plantar foot ulcer ≥ 4 cm² in area after debridement. Adequate blood circulation was assessed by ankle brachial index values; which must ≥ 0.8. Chronic diabetic foot wounds after adequate wound pretreatment (debridement and/or wound cleansing) as well as amputation wounds resulting from a planned amputation below the upper ankle joint may be considered for inclusion. Patients with recognized active Charcot disease or ulcers resulting from electrical, chemical, or radiation burns and those with collagen vascular disease, or ulcer malignancy were excluded from the study. Exclusion criteria also included ulcer treatment with normothermic or hyperbaric oxygen therapy, concomitant medications such as corticosteroids, immunosuppressive medications or chemotherapy, recombinant or autologous growth factor products, skin and dermal substitutes within 30 days of the study start and pregnant and nursing mothers. Before randomization, patients were screened for neuropathy, adequate perfusion, and blood sugar control. All foot ulcers were assessed and debrided (by the same vascular surgeon) as needed within 2 days of randomization.

Randomized wound therapy must be started within 6 hours after the last wound preparation which can either be a wound cleansing, debridement or an amputation. Patients were examined weekly for the first 4 weeks then every other week until week 16 (112 days) or ulcer closure by any means. At each study visit, ulcers were assessed for area via wound tracing, ulcer closure, and/or adequate granulation tissue formation. The study therapy was started at hospital and continued in ambulatory care in all patients. The maximum study
treatment time is set as 16 weeks after randomization and initiation of therapy. The NPWT system used in this study was vacuum-assisted closure therapy, Smith & Nephew Renasys machine. The system consists of three components: a negative pressure generating unit with a disposable canister, a pad with evacuation tube, a reticulated open cell sterile polyurethane or a dense open-pore polyvinyl alcohol foam dressing cut to fit the wound. The system unit is programmed to deliver controlled negative pressure ranging from 50-200 mmHg, and treatment was continued until ulcer closure or sufficient granulation tissue formation for healing by primary of secondary intention by day 112. NPWT dressing changes were performed every 72 hours, the progress of the wounds is shown in Figure 1.

Advanced moist wound therapy (AMWT) dressings were used according to Wound, Ostomy and Continence Nurses Society guidelines and institutional treatment protocols, consistent with standards of care for treating diabetic foot ulcers. We have used hydrogel dressings, calcium alginate and antimicrobial dressings in all patients of group II, according to the availability of the dressing. All patients randomized treated by offloading devices during active therapy time and continue until complete wound healing. A physical medicine doctor chose between different types of offloading devices, many factors were considered when selecting offloading modality, including: compliance, risk of adverse effects, psycho-social factors, restrictions on activities of daily living, work needs and features of the wound. Patients who achieved ulcer closure, were followed up for 6 months, for complications such as secondary amputation, recurrence, osteomyelitis, infection and cellulitis.

Primary and secondary endpoints

Time until complete (100% epithelialization) wound closure and the number of wound closures in each treatment group achieved in the maximum study treatment time of 16 weeks (112 days) are the primary endpoints. If the wound was not healed before the end of the maximum treatment time of 16 weeks, a study visit to assess the wound status and for evaluation of the secondary endpoints is performed. Secondary clinical endpoints are the time until complete wound closure within the study time of 6 months, the number of wound closures per treatment group achieved within 6 months (either by primary or secondary intention closure).

Megitt-Wagner ulcer classification

<table>
<thead>
<tr>
<th>Grade</th>
<th>Wound characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Pre ulceration lesions, healed ulcers, bony deformity</td>
</tr>
<tr>
<td>1</td>
<td>Superficial ulcer without subcutaneous tissue involvement</td>
</tr>
<tr>
<td>2</td>
<td>Penetration through subcutaneous tissue (expose bon, tendon, ligment, or joint capsule)</td>
</tr>
<tr>
<td>3</td>
<td>Osteitis, abscess or osteomyelitis</td>
</tr>
<tr>
<td>4</td>
<td>Gangerene of digit</td>
</tr>
<tr>
<td>5</td>
<td>Gangerene of foot</td>
</tr>
</tbody>
</table>
Figure 1. Cases treated with NPWT

Patient No.1

After debridement 6 weeks 14 weeks

Patient No.2

After debridement 8 weeks 12 weeks

Patient No.3

After debridement 10 weeks 16 weeks
Results

This randomized controlled study was conducted at the period from February 2011 to February 2014; included 111 patients randomized into 2 groups subjected to NPWT (Group I) and AMWT (Group III). Group I included 57 patients; 43 (75.4%) males and 14 (24.6%) females, their ages ranged from 24-62 years. 82.5% of them were type I diabetes mellitus, ABI (ankle brachial index) was normal in all patients and 86% of them had peripheral neuropathy (lost perceptive sensation).

Group II included 54 patients; 40 (74.1%) males and 14 (25.9%) females, their ages ranged from 24-62 years. 79.6% of them were type I diabetes mellitus ABI was normal in all patients, and 83.3% of them has peripheral neuropathy (lost perceptive sensation).

Both groups showed no significance in relation to wound criteria, the ulcer duration before start treatment was (5.85±3.74) in NPWT and (6.14±3.47) in AMWT, the baseline wound surface area was (15.88±3.87) in NPWT and (15.77±4.09) in AMWT. There was no significant difference in demographic data of both groups as shown in Table (1).

Table 1. Demographic data.

<table>
<thead>
<tr>
<th></th>
<th>NPWT (N=57)</th>
<th>AMWT (N = 54)</th>
<th>Test</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X±SD</td>
<td>43.14±9.44</td>
<td>42.77±10.84</td>
<td>0.018**</td>
<td>0.11</td>
</tr>
<tr>
<td>Range (years)</td>
<td>24-62</td>
<td>24-62</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43 (75.4%)</td>
<td>40 (74.1%)</td>
<td>0.03*</td>
<td>0.86</td>
</tr>
<tr>
<td>Female</td>
<td>14 (24.6%)</td>
<td>14 (25.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type of DM</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>47 (82.5%)</td>
<td>43 (79.6%)</td>
<td>0.14*</td>
<td>0.70</td>
</tr>
<tr>
<td>II</td>
<td>10 (17.5%)</td>
<td>11 (20.4%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>ABI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1.0</td>
<td>30 (52.6%)</td>
<td>27 (50.0%)</td>
<td>0.16*</td>
<td>0.92</td>
</tr>
<tr>
<td>≥1.0</td>
<td>27 (47.4%)</td>
<td>27 (50.0%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Neuropathy</strong></td>
<td></td>
<td></td>
<td>0.15*</td>
<td>0.70</td>
</tr>
<tr>
<td></td>
<td>49 (86%)</td>
<td>45 (83.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Ulcer duration</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X±SD</td>
<td>5.85±3.74</td>
<td>6.14±3.47</td>
<td>0.42**</td>
<td>0.67</td>
</tr>
<tr>
<td>Range (weeks)</td>
<td>2-24</td>
<td>2-16</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Baseline wound</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>surface area (cm²)</td>
<td>15.88±3.87</td>
<td>15.77±4.09</td>
<td>0.15**</td>
<td>0.88</td>
</tr>
<tr>
<td></td>
<td>10-23 cm²</td>
<td>15-24.5 cm²</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*: X²*: t-testABI: ankle brachial index  DM: diabetes mellitus
The treatment of all patients started at hospital and continued at home with regular visits by trained nurse for dressings and settings at the VAC system. 95% of all patients received offloading modality; they were 54 patients (94.7%) in NPWT group and 52 patients (96.3%) in AMWT group. Total contact casts (TCCs) were used by only 30% of patients for the majority of diabetic foot ulcer treatment, whereas 65% of the patients reported use of removable cast walkers. A total of 15% of patients reported application of other modalities such as therapeutic shoes, crutches and wheelchairs. Complete ulcer closure was defined as skin closure (100% re-epithelialization) without drainage or dressing requirement. Within the active therapy period (16 weeks) the NPWT group proportion was significantly (P=0.03) greater for complete ulcer closure than that for the AMWT group (37 of 57 (64.9%) vs. 24 of 54 (44.4%), respectively).

After sufficient wound bed preparation 17.5% (10 out of 57) NPWT-treated ulcers were surgically closed by split thickness skin grafts, flaps, sutures or heal by 2ry intention. For AMWT-treated ulcers 55.5% (30 out of 54) ulcers were surgically closed by split thickness skin grafts, flaps, sutures and 2ry intention. These results were highly significant for the high efficacy of NPWT for wound healing (P=0.003) as shown in table (2). The duration of therapy for NPWT was 12.9±2.36 weeks versus 14.9±1.24 weeks for AMWT; and these results were statistically significant (P=0.007). The results showed high efficacy of NPWT in comparison to AMWT, as there was significant results in relation to primary endpoint and success rate (P=0.007 and P = 0.03, respectively), but was not significant in regard to the secondary endpoint (P= 0.71) as shown in Table (2). Table (3) reports treatment-related rates for secondary amputation, recurrence, osteomyelitis, cellulitis and infection during the 6 months of follow up. Although all patients were subjected to offloading modalities, there was significant difference between two groups as regard all complication observed. There is significant decrease in the number of amputations (6 of 57, 10.5%), in NPWT group in comparison to AMWT group (14 of 54, 25.9%). There is also significant decrease in the recurrence rate in NPWT (1 of 57, 18%) compared with AMWT (7 of 54, 13%). So, the rate of complications is much less with NPWT and the safety is more.

Table 2. Efficacy of treatment methods.

<table>
<thead>
<tr>
<th></th>
<th>NPWT (N=57)</th>
<th>AMWT (N = 54)</th>
<th>Test</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary endpoint</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>X±SD Range</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flap</td>
<td>12.9±2.36</td>
<td>14.91±1.24</td>
<td>2.79**</td>
<td>0.007</td>
</tr>
<tr>
<td>8-16 weeks</td>
<td>12-16 week</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary endpoint</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flap</td>
<td>4 (20%)</td>
<td>4 (7.4%)</td>
<td>6.88*</td>
<td>0.71</td>
</tr>
<tr>
<td>Graft</td>
<td>8 (40%)</td>
<td>10 (18.5%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2ry intention</td>
<td>8 (40%)</td>
<td>16 (29.6%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>20 (35.1%)</td>
<td>30 (55.5%)</td>
<td>28.6*</td>
<td>0.003</td>
</tr>
<tr>
<td>Success Rate</td>
<td>37 (64.9%)</td>
<td>24 (44.4%)</td>
<td>4.69*</td>
<td>0.03</td>
</tr>
</tbody>
</table>

*: X2**: t-test

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### Table 3. Complications during follow-up:

<table>
<thead>
<tr>
<th></th>
<th>NPWT (N=57)</th>
<th>AMWT (N = 54)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amputation</td>
<td>6 (10.5%)</td>
<td>14 (25.9%)</td>
<td>0.03**</td>
</tr>
<tr>
<td>Recurrence</td>
<td>1 (1.8%)</td>
<td>7 (13%)</td>
<td>0.02*</td>
</tr>
<tr>
<td>Osteomyelitis</td>
<td>0</td>
<td>4 (7.4%)</td>
<td>0.05*</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>3 (5.3%)</td>
<td>2 (3.7%)</td>
<td>1.0*</td>
</tr>
<tr>
<td>Infection</td>
<td>2 (3.5%)</td>
<td>2 (3.7%)</td>
<td>1.0*</td>
</tr>
</tbody>
</table>

*: Fisher exact  **: X^2

### Discussion

Chronic diabetic foot ulcers represent a significant challenge to treating physicians. Treatment involves multiple modalities including debridement, assessment and treatment of infection, revascularization if indicated, and sufficient off-loading of the foot. A key component of the healing process is debridement because it enables removal of devitalized and necrotic tissue. Debridement is critically important to the initiation of healing. NPWT and other wound healing technologies work in conjunction with debridement as the foundation upon which the wound healing process can begin.

In 2005, Armstrong and Lavery reported that NPWT may be an alternative therapy to achieve an improved granulating wound bed in diabetic foot wounds to prepare the wound bed for other closure techniques. This study also showed the good granulation tissue induced by NPWT resulted in higher number of ulcers healed completely during the active therapy time either by primary or secondary intentions. In this study, 64.4% of patients subjected to NPWT achieved complete wound healing during active therapy period (16 weeks), which is more than the patients subjected to AMWT (44.4%). These results parallels the findings by Argenta and Morykwas in 1997, who reported that the success of NPWT in chronic wounds is associated with removal of excess interstitial fluid, an increase in vascularity and associated decrease of bacterial colonization, and stimulation of granulation tissue formation. In separate studies, Saxena et al. and Green et al. have further elucidated the role of open pore foam dressing in the creation of micro-mechanical deformations of the wound surface. These micromechanical deformations are caused when negative pressure draws tissue into the foam pores. Also, Peter et al. reported high efficacy of NPWT group for complete wound healing than that for AMWT group (73 of 169 (43.2%) vs. 48 of 166 (28.9%), respectively.

Our results showed that the duration for complete wound healing is lower for patients in NPWT group than for patients in AMWT group. Apelquist et al. reported that VAC therapy was more efficient, safer and a lower-cost method than moist wound dressing in patients with complex diabetic foot. On the other hand, Baakenburg et al. did not detect a significant difference
between the success of VAC therapy and normal dressing therapy in acute and chronic wounds. However, they found that VAC had important advantages for patients with diabetes and cardiovascular diseases and suggested that this may be the result of increased neo-angiogenesis.18

Peter et al. reported that the incidence of secondary amputations was significantly less for NPWT (4.1%) than for AMWT (10.2%)16, these results are better than our results, which showed significant decrease in the number of amputations in NPWT (10.5%) in comparison to AMWT (25.9%). This may be due to the smaller number of patients in our study in comparison to their study. Our study showed significant decrease in the recurrence rate in NPWT (1.8%) compared with AMWT (13%). We included the patients with Wagner grades 2-4 in this study, that is why our results were superior to the results reported by Ali Engin et al.19, who include grade 5 in their studies and reported that 37% of patient treated with VAC therapy were amputated (25% local amputations and 12% major amputations) and our results are parallel the results of Nather et al.20

Conclusions

In summary, this study of 111 patients with diabetic foot ulcers showed that NPWT is as safe as and more efficacious than AMWT for the treatment of diabetic foot ulcers. Combining an effective, easy-to-use offloading device that ensures patient compliance with advanced wound healing modalities may form a formidable team in healing ulcers and potentially averting lower-limb amputations.

References

8. Evans D and Land L: Topical negative


Conservative Management of Patients with Critical Limb Ischemia not to be Forgotten

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Abstract

Introduction: Critical Limb Ischemia (CLI) is associated with both a significantly reduced life expectancy and an elevated risk of major amputation. CLI is universally accepted as an absolute indication for invasive therapy. In selected cases, however, non-operative therapy may be the reasonable option.

The aim: Of this study is to show our experience and to report the results of conservative management of selected patients with critical limb ischemia (CLI.)

Patients and Methods: This was a prospective non-randomized cohort study conducted on 40 patients who refused, or were not candidates for surgical revascularization. Thorough clinical and radiological examination of the patients was carried out. A treatment plan was established including exercise, control of risk factors, antiplatelet therapy, lipid-lowering agents and foot care. Patients were followed up until they reached one of the end points of the study which were improvement in pain (intermittent), healing (completely covered with healthy granulations), and/or healed wounds (within three months), major amputation or death.

Results: We included 28 men (70%) and 12 women (30%) with a mean age of (62.3±13.3) years. During the follow-up period (mean 8.25±2.9 months) 4 patients died (10%), 25 patients (62.5%) showed good clinical outcome (four of them showed disappearing pulse), eight patients (20%) fair (two of them were considered lost to follow up) and only three (7.5%) of these 40 patients required surgical intervention. The relation between the 6-minute walking test and the outcome was statistically significant (p = 0.018).

Conclusion: Carefully designed conservative therapy can be considered a reasonable option for well selected patients with critical limb ischemia.

Key words: “critical limb ischemia,” “non-operative” and “Peripheral arterial disease”
Introduction

Peripheral arterial disease (PAD) is a chronic athero-thromboticocclusive disorder of the peripheral circulation that may be asymptomatic or can present with intermittent claudication (IC) and/or critical limb ischemia (CLI). CLI can be defined as arterial blood flow that is inadequate to accommodate the metabolic needs of resting tissues in the limbs. CLI is associated with both a significantly reduced life expectancy and an elevated risk of major amputation of the involved extremity if improvement in distal arterial flow is not established. These patients would be classified in the more severe ends of the Fontaine classification (stage III-IV) or the Rutherford classification (grades 4-6) (Table I).

Table 1. Classification Schemes of Peripheral Arterial Disease

<table>
<thead>
<tr>
<th>Classification Stage</th>
<th>Clinical description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fontaine I</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>IIa Mild</td>
<td>Claudication</td>
</tr>
<tr>
<td>IIb Moderate-to-severe</td>
<td>Claudication</td>
</tr>
<tr>
<td>III</td>
<td>Rest pain</td>
</tr>
<tr>
<td>IV</td>
<td>Ulceration or gangrene</td>
</tr>
<tr>
<td>Rutherford 0</td>
<td>Asymptomatic</td>
</tr>
<tr>
<td>1</td>
<td>Mild claudication</td>
</tr>
<tr>
<td>2</td>
<td>Moderate claudication</td>
</tr>
<tr>
<td>3</td>
<td>Severe claudication</td>
</tr>
<tr>
<td>4</td>
<td>Rest pain</td>
</tr>
<tr>
<td>5</td>
<td>Minor tissue loss</td>
</tr>
<tr>
<td>6</td>
<td>Severe tissue loss or gangrene</td>
</tr>
</tbody>
</table>

The modern evidence-based approach to treatment of PAD emphasizes on the importance of non-operative management for claudicant patients. Although CLI is universally accepted as an absolute indication for invasive therapy, non-operative therapy has been proved to be the most appropriate choice in selected cases.

Patients and methods

This was a prospective non-randomized cohort study conducted on 40 patients in Mansoura University Hospital which is a tertiary referral center, from May 2013 to May 2014. Patients selected for this study were those with CLI (Fontaine III & IV), who refused, or were not candidates for surgical revascularization due to lack of target vessels. Those with progressing CLI, severe co-morbidities and/or non-ambulatory status were not included in this study. Thorough clinical and radiological examination was carried out for all patients.
Routine ankle \ brachial index (ABI) was done. Objective evaluation was performed using computed tomographic angiography (CTA) or magnetic resonance angiography (MRA) and/or color duplex studies. All patients signed a written consent after detailed discussion with the patient about all risks and benefits. A treatment plan was established including exercise, control of risk factors, antiplatelet therapy (Cilostazol 50 - 100 mg twice daily, Naftidrofuryl, 600 mg daily, and aspirin 75 -300 mg daily) (6,7 and 8), lipid-lowering agents and foot care. A monitored 6-minute walk test was used as a valid method of exercise. Walking exercise was considered positive when the patient walk for 6 minutes in a 30 meters hall. The test was aborted upon reaching maximum paintolerance by the patient. Patients were followed up until they reached one of the end points of the study which were improvement in pain (intermittent), healing (completely covered with healthy granulations), and/or healed wounds (within three months), major amputation or death.

The outcome was assessed on clinical basis and classified into good outcome when the patient achieved improvement in his symptoms, and fair outcome when the patient did not have any change of these symptoms. Bad outcome was reported in case of deterioration.

Statistical analysis

Data was analyzed using SPSS (Statistical Package for Social Sciences), version 20. Qualitative data was presented as number and percent. Quantitative data was presented as mean ± standard deviation (SD) for parametric data distribution, and median and range for non-parametric data distribution. Kaplan-Meier method was used for survival analysis, Cox-regression analysis used for comparison between survival between patients with single and multilevel vascular affection. Pearson Chi-square test was used to assess the significant difference in associated change of results of 6 minute walk test and survival.

Results

This study included 28 men (70 %) and 12 women (30 %) with a mean age of (62.3±13.3) years. These patients demonstrated the usual risk factors for peripheral arterial disease. Hypercholesterolemia was present in 28 patients (70 %), but reasonably controlled by statin medications. Hypertension was present in 26 (65%), but pharmacologically controlled in all (Table 2). Atherosclerosis was the commonest cause as it affected 28 (70 %) of patients. Twelve patients (30 %) presented with neglected viable acute limb ischemia which progressed to CLI (Table 3). Physical examination, Doppler examination, and imaging studies in combination confirmed the presence of unilateral arterial occlusive disease in 31 patients (77.5 %) and bilateral disease in 9 (22.5 %), (Nine limbs were chronically ischemic but not critical) (Table 3). These patients were classified according to Fontaine classification as stage III (26 patients 75 %) and stage IV (14 patients...
Fig 1. Right CLI in patient with chronic venous insufficiency.

Fig 2. Trans-metatarsal amputation with good vascularity of the edges.

Fig 3. CTA showing bilateral infra-popliteal disease more severe on the right side, (CTO of the right peroneal and tibial arteries).

Fig 4. A and B Three months postoperative with healed stump.

25%), with a mean duration of complaint of (3 ±1.8) months. None of the patients showed palpable pulse during first visit assessment (Table 4). The arterial pressures (median 42.5 mm Hg, Range 0:75) And ABI (median 0.3, Range 0:0.6) were assessed by Doppler examination at the time of the initial visit. CTA (32) or MRA (8) documented complete total vessel(s) occlusion (CTO) in 33 (82.5 %), diffuse atherosclerosis and stenosis in 7 (17.5%) and bilateral findings in 9 (22.5%) patients (Table 4). During the follow-up period (mean 8.25 ±2.9 months) there were 4 deaths (10%), (Fig.5), twenty five patients (62.5%) showed good clinical outcome with positive 6-minute walktest, (four of them “2vasculitis and 2 atherosclerotic “showed disappearing pulse). Eight (20%) had fair outcome, (2 of them were lost to follow up after 3 and 4 months). Three patients (7.5%) of these 40 patients progressed and required surgical intervention (3 major amputations). Only two patients (fair outcome) showed headache as adverse reaction to Cilostazol and improved on halving the dose. (Figs.6,7) The relation between the 6-minute walking test and
the outcome was statistically significant ($p = 0.018$), especially in patients with infra-popliteal disease. (Figs. 8, 10)

Improvement of the ankle-brachial index was reported, but the difference was statistically insignificant ($p = 0.86$). (Fig. 9)

**Table 2.** Risk Factors for Peripheral Arterial Occlusive Disease in a 40-Patient Cohort

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Number &amp; percent (N=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypercholesterolemia</td>
<td>28 (70%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>26 (65%)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>23 (57.5%)</td>
</tr>
<tr>
<td>Insulin-requiring diabetes</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>Current tobacco use</td>
<td>17 (42.5%)</td>
</tr>
<tr>
<td>Remote history tobacco use</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>24 (60%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>6 (15%)</td>
</tr>
</tbody>
</table>

**Table 3.** Aetiology for Peripheral Arterial Occlusive Disease in a 40-Patient Cohort

<table>
<thead>
<tr>
<th>Cause</th>
<th>Number &amp; percent (N=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atherosclerosis</td>
<td>28 (70%)</td>
</tr>
<tr>
<td>Thrombo-embolism(4 embolic&amp; 2 polycythemia)</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Thromboangiitis obliterans</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Vasculities</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>

**Table 4.** Physical examination and imaging studies for Peripheral Arterial Occlusive Disease in a 40-Patient Cohort

<table>
<thead>
<tr>
<th>Finding</th>
<th>Number &amp; percent (N=40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rest pain(Fontaine III ) as only presentation</td>
<td>26 (65%)</td>
</tr>
<tr>
<td>Ulcer (Fontaine IV)</td>
<td>6 (15%)</td>
</tr>
<tr>
<td>Gangrenous toe or toes (Fontaine IV)</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>Aorto-iliac</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>Superficial femoral artery (SFA)</td>
<td>23 (57.5%)</td>
</tr>
<tr>
<td>Popliteal artery</td>
<td>5 (12.5%)</td>
</tr>
<tr>
<td>Infra-popliteal artery</td>
<td>29 (72.5%)</td>
</tr>
</tbody>
</table>
Fig. 5. Kaplan-meier Survival curve for Mortality (The overall cumulative survival after 12 months is 90%).

Fig 6. Survival of the cases in relation to complications by Kaplan – meier survival analysis (The overall cumulative survival after 12 months is 62.5%)
Fig 7. Kaplan-meier Survival curve for Major amputations (The overall cumulative survival after 12 months is 92.5%)

Fig 8. Cox-Regression survival curves for difference in survival between single and multilevel angiographic affection (The overall cumulative survival after 12 months in single level & multiple level vascular affection is 87.5% & 12.8% respectively, with P value < 0.001)
Fig 9. Improved ankle-Brachial index but statistically insignificant. (p = 0.86)

Fig 10. 3D graph showing the results of 6 min. walk test in relation to outcome. Using Pearson Chi-square test, it was statistically significant. (p < 0.001)
Discussion

Although CLI represent the end stage of PAD, the progression of the disease is usually variable and unpredictable, furthermore, not all CLI are truly critical. Also, CLI does not always progress through the various stages of the Fontaine or the Rutherford classification systems. The care of many patients with CLI is not always a straightforward plan. It has to be customized and tailored for each and every individual patient according to his or her clinical and radiological findings, and according to the accompanying co-morbidities as well. Regardless of the modality of treatment, risk factors and comorbidities for PAD should be identified and controlled. Medical treatment including antiplatelet, antihypertensive and Statin therapy has been shown to improve survival in patients with CLI and should be always considered for these patients.

The aim of this study is to establish a modality of treatment for selected CLI patients that can relieve their symptoms, reduce the progression of their disease, and to shift these CLI patients to a less severe category. This was planned to be achieved through risk-factor modification, aggressive pharmacotherapy and continuous monitoring with the 6-minute walk test. When symptoms did not resolve or got worse, operative therapy was adopted. Marston et al. conservatively treated ischemic ulcers and achieved complete ulcer healing in 52% of patients within 1 year. The mortality rate was independent of the treatment efforts including either medical, percutaneous, or open surgical therapies. These data support our findings in this study. Also, our rationale for pursuing non-operative management is based on studies showing that patients managed without surgery do not inevitably progress to limb loss.

Walking exercise was used as both a method of assessment and a therapeutic tool, it significantly improved pain-free maximum walking distances and was less anxiety provoking, than treadmill walking. Also, we relied on this tool as an indicator of improved outcome, which has been proved by previous studies.

The outcome was assessed clinically by improvement in pain (intermittent), walking tolerance, healing of the ulcers and amputation stump healing. Not surprisingly, patients with good outcome exhibited angiography findings of single arterial localized infra-popliteal disease with good collaterals, however; those with bad outcome showed multi-level affection with poor collaterals. In the current study the results of conservative management are closely tied to the severity of patient presentation and associated co-morbidities. The best results are achieved when there was absent or minimal tissue damage, infra-popliteal disease and reasonable systemic condition. This study suggests that the mortality and major amputation rates during the follow-up period for CLI patients are significantly lower than those reported in previous similar studies. The reasons for this relatively lower rate of complications, can only be
speculated upon in this relatively small series. We did not offer major amputation unless there was inadequate control of severe symptoms.

Our amputees were diabetics and were among those who develop gangrene regardless of absolute ankle pressures which are, frequently limited by incompressible, calcified leg arteries. This confirms that diabetes is an independent risk factor for amputation and complications in CLI as outlined by the study done by Virkkunen and his group. These amputees in our study never reached independent ambulatory status. This disagrees with Nehler et al (25 )who demonstrated that at 1 year after amputation, 65% and 29 % of below and above knee amputees respectively were ambulatory.

This could be attributed to the fact that his study was not limited to only CLI patients. Intermittent pneumatic compression therapy26,27, gene and cell-based therapies 28,29 are emerging forms of non-operative therapy for CLI. Todate, none of these modalities are used in our center. Although the patient population in our study was heterogeneous(atherosclerosis, embolism, vasculitis and throm boangitisobliterans), their similar clinical presentation allowed for valuable conclusions.

We believe that non-operative therapy for CLI and close follow up of these patients is a viable option of management in selected patients. In addition; it is cost-savings with a large financial impact on society.

Hence, much work in terms of randomized prospective studies needs to be done to validate this.

**Conclusion**

Carefully designed conservative therapy can be considered to be a reasonable option for well selected patients with critical limb ischemia, and can change patient ischemia category to a less severe one.

**References**

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Conservative Management of Patients with Critical Limb Ischemia


Pseudo-Aneurysm of the Superficial Femoral Artery Caused by a Martial Arts Injury

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Abstract

Introduction: We present a 37 years old male an amateur kick-boxer who developed a distal superficial femoral artery pseudo-aneurysm in the left thigh. This was successfully treated with exploration and interposition grafting.

Keywords: pseudoaneurysm, superficial femoral artery, martial arts injury

Introduction

Kick-boxing is a martial art (fighting style and technique) in which the use of punching, kicking, and, under some rules, kneeling, and elbowing are permitted. In a longitudinal study over 16 year, injuries to the lower limbs accounted for 23.3%; 19.4% were facial injuries within tracranial injury making up 17.2%. Over 64% of the injuries categorized were superficial bruising or lacerations. Blunt trauma to the leg rarely causes arterial injury without orthopedic involvement. We present the case of 37 year old man who sustained arterial injury from a direct blunt trauma to the leg.

Case report

A 37 years old male presented with swelling and pain on the antero-medial aspect of his left thigh for three weeks. The patient could not recall a recent history of trauma but further questioning revealed him to be an amateur kick-boxer actively involved in this sport. The patient had no other medical conditions and took no regular medication. On examination he was found to have a 15 x 9cm pulsatile swelling on the antero-medial aspect of the left thigh. Distal pulses in the left leg were intact with normal sensation and movement of the lower limb.

The left knee flexion was limited but articulation was normal and no fractures were detected. Full blood count and C-reactive protein were within normal limits. CT angiogram showed left distal superficial femoral artery pseudo-aneurysm with extensive surrounding hematoma. A medial approach was used...
to expose the left superficial femoral artery. The superficial femoral artery from the mid-thigh proximally to the proximal popliteal artery distally were dissected free, vessels controlled (Figure 1a) and haematoma evacuated. The sac was opened, a 3cm linear tear in the distal SFA was found. This was repaired using a short segment of 6mm PTFE interposition graft due to the long saphenous vein being less than 3mm in caliber (Figure 1b). The post-operative recovery was satisfactory with reduction in swelling, normal knee movements and palpable distal pulses. He was discharged on the 2nd post-op day.

**Figure 1**
1a: operative exploration showing pseudoaneurysm of the superficial femoral artery (arrow)  
1b: superficial femoral artery continuity established with interposition of a PTFE graft

**Discussion**

Distal superficial femoral artery pseudoaneurysm formation is an uncommon pathology with bony or iatrogenic injury implicated in the majority of cases. Contact sport is an extremely rare cause of this condition with only one other case described in the literature where wrestling was the sport in question. The low rate of injury from blunt trauma is due in part to the depth of the artery as it lies deep to the sartorius muscle before it enters the popliteal fossa keeping it out of harm’s way. Lower limb arterial trauma carries a high amputation rate with penetrating stab injuries being the least likely to lead to amputation. The major factor that determines the outcome after arterial injury with lower limb trauma is the severity of the soft-tissue injury with progressive necrosis of tissue and superadded infection being a common cause of late amputation. Occult injuries from iatrogenic, blunt or penetrating trauma may go unobserved whilst the patient remains well with no ischemia and normal pulses on presentation. Presentation may have to rely on a change
in appearance of the limb, sensation of a pulsatile swelling, neurological or venous compressive symptoms.\(^5\) In acute or delayed presentation, investigations should be carried out promptly to delineate the anatomy of the injury and to aid in the planning of operative intervention if required. Intervention falls into three categories:

- **Conservative measures** such as the use of compression of the pseudoaneurysm with or without the use of thrombin injection to obliterate the aneurysm sac.
- **Open surgical repair** will vary from placing a single stitch to close a needle puncture (usually iatrogenic) to bypass surgery with autologous vein or a synthetic substitute (in the case above).
- **Endovascular interventions** are certainly a good option dependent on the site of injury, the level of contamination and the patient’s age.

Open bypass surgery was the preferred option in this patient as he is a young man who leads an active life; the area to be repaired is a point of repetitive flexion at the adductor hiatus which is likely to receive trauma again if he returns to his pre-injury sporting life. Finally the defect in the artery was unlikely to respond to compression and thrombin injection.\(^6\) An added advantage of open surgery was that it allowed removal of the large haematoma which had developed. Venous patching for the defect was considered but delayed presentation meant that there were possible concerns over the health of the vessel edges and it was felt best if this was not undertaken. Long saphenous vein was less then 2.3 mm in diameter and it was not suitable for use as a conduit.

Blunt trauma to the superficial femoral artery is a rare cause of pseudoaneurysm formation. With or without bony injury an accurate and expeditious diagnosis will lead to successful treatment.

### References

Abstracts Submitted for Trainees Competition Presented During the 10th EVC Meeting September 2014

Prospective Study of 51 Patients with Immediate or Early Malfunction of Long-Term Hemodialysis Catheters

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²Department of Radiology, Tanta University, Tanta
³Department of vascular surgery, Ain Shams University, Cairo

Abstract

Introduction: Long-term dialysis catheters provide an important access for hemodialysis for patients with end-stage renal disease. They are however associated with a significant incidence of early malfunction. The present study aims at identifying the various causes of long term dialysis catheter early malfunction as well as the accuracy of the currently used diagnostic modalities for assessment of such causes.

Patients and methods: 51 patients (24 males 27 females, mean age 64.6 years) with early long term dialysis catheter malfunction were included in the study. All patients were evaluated by duplex ultrasonography and magnetic resonance venography (MRV) and results of the two diagnostic modalities were compared.

Results: Both duplex scan and MRV demonstrated central venous thrombosis in 4 patients (7.8%). Central venous attenuation or stenosis secondary to previous catheter insertion was identified in 13 cases (25.5%) by MRV but was only detected in 3 cases (5.9%) by duplex ultrasonography (p > 0.001).

Conclusions: Causes of catheter malfunction in the present study included malposition, intra or peri-catheter thrombosis, and central vein attenuation or stenosis. While duplex scan and MRV were equally accurate in detection of central venous thrombosis, MRV was much more sensitive in detection of central vein attenuation or stenosis.

We recommend the wider use of MRV for investigating patients with early malfunction of such dialysis catheters as well as for preoperative evaluation of patients with previous catheter insertion.

Key words: Dialysis catheters – MR venography – Vascular access.
Revascularization of a specific Angiosome for Limb Salvage: Does the Target Artery Matter?


Vascular Surgery Unit; Kasr El-aini Hospitals, Cairo University*. El Minia University hospitals, General Surgery Department** and Radiology Department*** and Vascular Surgery Unit; Sohag University Hospitals, Sohag University****.

Introduction: Revascularization in patients with critical limb ischemia (CLI) is ultimately aimed at preventing limb loss, including major amputation (MA), improving patient quality of life and prolonging survival. The need to achieve an acceptable limb salvage rate in a surgical high-risk target population has led many to favor endovascular revascularization as the first-line therapy. An EVT strategy based on the angiosome concept is especially important and could provide the theoretic basis for avoiding MA in CLI patients.

Aim: to compare clinical outcomes between limbs with (Direct Revascularization) and without (Indirect Revascularization) achievement of feeding artery flow by endovascular therapy (EVT) based on the angiosome concept in critical limb ischemia (CLI) patients with isolated below-the-knee (BTK) lesions.

Patients and Methods: We conducted a case series of 55 limbs from 50 consecutive CLI patients with life-threatening nonhealing ulceration or gangrene, or both (Rutherford 5 or 6), due to isolated BTK lesions. These patients presented to Al-Minia University Hospitals and Al-Dokki Insurance Hospital from September 2012 to January 2014. Those patients underwent successful BTK angioplasty with single vessel outflow by the end of EVT, and then we divided the enrolled patients into the direct group 28 patients (31 limbs) in whom feeding artery flow to the site of ulceration/gangrene was successfully achieved by EVT and the indirect group, 22 patients (24 limbs) in whom feeding artery flow to the site of ulceration/gangrene were not successfully achieved by EVT. If the wounds expanded over more than one territory, all supplying arteries were treated if available and the limb was consequently defined as being in the direct group. These patients were followed up at one month intervals for one year. AFS, freedom from major adverse limb event (MALE), defined as MA or any reintervention, and MA compared between the groups. These outcomes suggested as objective performance goals for evaluating catheter-based therapies in CLI by the international Society of Vascular Surgery.

Results: As regard, patients characteristics (Demography and co-morbidities) no statistical differences between the two groups. Also, lower limb and lesion characteristics, there’s no, statistical difference noted between groups. During follow-up (mean, 9±8 months), AFS percentage was 75% in the
direct group (19 patients) vs 67% in the indirect group (11 patients). Freedom from MALE percentage was 65% in the direct group (18 patients) vs 55% in the indirect group (10 patients). Freedom from MA percentage was 86% in the direct group (23 patients) vs 75% in the indirect group (15 patients).

**Conclusions:** Application of angiosome concept during revascularization of patients presented with isolated BTK lesions is crucial and has been shown to be clinically useful in limb salvage for CLI patients.

**Duplex versus Fluoroscopy Assisted Infra-Genicular Angioplasty**

S. Elimam (M Sc), A. Allam (M.D), S. Aly (FRCS), M. Taha (M.D), Al-Zahraa hospital, AFMG.

**Abstract**

**Objective:** To compare between duplex assisted and fluoroscopy assisted infra-genicular angioplasty and detection their capabilities of saving limbs depending on what suits vascular surgeons.

**Patients and Methods:** The present study was conducted on 20 patients 6 females (30%) and 14 males (70%), with mean age of 59.2, with risk factors of smoking, D.M, hypertension and renal insufficiency in 65%, 80%, 85% and 25% respectively, had critical arterial occlusive disease (CAOD) affecting the infra-genicular arteries with palpable femoral pulse in the vascular surgery unit of Al-Zahraa University Hospital from 2011 to 2014. After consent patients were subjected to history taking, clinical examination, basic and specific investigations like duplex ultrasound (DUS) and CTA then according to our MIDLS classification we chose the significant and total occlusion lesions to be intervened either with duplex or fluoroscopy assisted depending on presence of renal insufficiency or long standing diabetes mellitus. We followed them on 1 day, 1, 3, 6, 12 months post intervention with DUS.

**Results:** Our technical success was achieved in 18 patients with 90% for both methods. Technical complications were occurred in three patients in the form of groin hematoma 5%, 5% distal thrombosis and 5% vessel perforation. We found a statistically significant difference to be better toward duplex guided PTA in wound healing, where there was an improvement of healing of wounds of 9 patients from 10 in duplex guided PTA while 4 patients from 10 in fluoroscopy guided PTA with P-value 0.019. Also there was a statistically significant difference with p value 0.025 in limb salvage to be better in duplex guided PTA with 100% while it was 60% in fluoroscopy guided PTA. As regard rest pain disappearance, there was no statistically significant difference between both techniques with p value 0.121. The pre intervention mean of ABPI for the studied patients was 0.3611 which was highly significantly improved one month.
post intervention to be 0.6833 with p value less than 0.001. Analysis by life table and Kaplan meier survival curve was used to calculate the survival after 12 months which was 28%.

**Conclusion:** Duplex guided angioplasty is particularly advantageous for patients with medical conditions (such as diabetes mellitus or pre-existing chronic renal insufficiency) that predispose them to an increased risk of developing contrast-induced renal failure, and for the surgeon and the assistant staff as the lead aprons worn only protect the abdomen and chest while the back still uncovered and unprotected, even the thyroid region is uncovered and the same risk could happen to the eyes as special glasses should be worn. Duplex-guided balloon angioplasty seems to be feasible, safe, effective technique, a bed–side procedure and cost effective as well.
Vascular Image

Type II Endoleaks

Tarek Radwan MSc. FRCS, Chief of Vascular Surgery, IMC, Cairo

(Figure 1)

(Figure 2a)  (Figure 2b)

(Figure 3a)  (Figure 3b)
Case Report

A 70 year old man presented with a 6.8 cm infrarenal abdominal aortic aneurysm (AAA) had undergone an endovascular aneurysm repair (EVAR). Completion angiography (Figure 1) showed a successful EVAR procedure using an Excluder device (JOTEC,E-vita ABDOMINAL XT Stent Graft System). Postoperatively the patient developed left loin pain but was hemodynamic stable. This led to early Surveillance CT angiogram after 3 weeks (Figure 2a&b). It demonstrated a type II endoleak from lumbar arteries. As there was no sac enlargement, conservative management was decided. A 3-month follow up CT angiogram (Figure 3a&b) showed complete resolution of the type II endoleak with no aneurysmal sac change.

Discussion

An endoleak is defined as persistent blood flow in the aneurysm sac extrinsic to the endograft and is the most common complication after EVAR. It has been reported to occur in 10% to 30% of patients at any time during follow-up. Type II endoleak results from collateral retrograde flow from the aortic branches, usually from the lumbar arteries, inferior mesenteric artery, or middle sacral artery. Type II endoleaks are generally considered to have a benign prognosis. A recent publication revealed a high incidence of secondary interventions (20%), continued aneurysm sac growth (37.9%), and a need for graft explantation (8.4%) in patients with type II endoleaks. The EUROSTAR trial revealed that patients with type II endoleaks require more secondary interventions and have higher rates of open conversion but no increased risk of rupture. Apart from the risks of each reintervention and graft explant, there is also a small but persistent risk of aneurysm rupture (0.5%–2.4%) in the setting of type II endoleak with aneurysm sac growth. The Society for Vascular Surgery published guidelines addressing post-EVAR surveillance. The recommended radiologic surveillance is triple-phase CTA at 30 days and 12 months after EVAR. If an endoleak or aneurysm sac growth is identified on the 30-day CTA, a 6-month post-EVAR CTA is recommended. If both 30-day and 12-month post-EVAR CTA scans reveal no endoleak, device abnormality, or aneurysm sac enlargement, surveillance with annual color duplex ultrasound is an accepted alternative to CTA scans when the duplex scan is performed by a skilled technician in an accredited noninvasive vascular laboratory.

Although the risk of endoleak declines as the number of negative postoperative scans increases, new endoleaks may be identified many years after EVAR. Identification of a new type II endoleak warrants an initial CTA, a 6-month interval CTA, and subsequent follow-up with duplex imaging if there is an absence of continued aneurysm sac growth, especially for patients whose aneurysm sac measures < 6.5 cm in diameter. A variety of strategies have been proposed and implemented.
to treat type II endoleaks. Treatment with transfemoral embolization,\textsuperscript{10} translumbar direct sac embolization,\textsuperscript{11} transfemoral transsealing embolization, open and laparoscopic ligation\textsuperscript{12} of the lumbar and mesenteric arteries, aneurysm sac placation,\textsuperscript{13} and open conversion\textsuperscript{2,14} are offered for patients with type II endoleaks who have aneurysm sac growth of \textgreater{} 5 mm or persistent endoleaks (\textgreater{} 6 months).

Future innovations in next-generation endograft design should focus on eliminating the occurrence of type II endoleaks in the first place. Endothelial denudation of the aortic wall with Radiofrequency Ablation\textsuperscript{15} and Endovascular Aneurysm Sealing (EVAS) (the Nellix device (Endologix, Inc., Irvine, CA))\textsuperscript{16} have shown promising early results, and long-term follow-up in this regard should be pursued.

References

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