COMPARATIVE STUDY ON ROLE OF RETROGRADE VENOUS PERFUSION THERAPY AND SYSTEMIC ANTIBIOTIC THERAPY IN TREATMENT OF DIABETIC ULCER FOOT IN GRH, MADURAI

Dissertation submitted to

THE TAMILNADU DR.M.G.R.

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With fulfillment of the regulations for the Award of the Degree of

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DEPARTMENT OF GENERAL SURGERY,
MADURAI MEDICAL COLLEGE AND GOVERNMENT
RAJAJI HOSPITAL, MADURAI – 625020

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Place : Madurai
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I, **DR.D.GOWTHIN** hereby declare that this dissertation entitled "**A COMPARATIVE STUDY ON ROLE OF RETROGRADE VENOUS PERFUSION THERAPY AND SYSTEMIC ANTIBIOTIC THERAPY IN TREATMENT OF DIABETIC ULCER FOOT IN GRH, MADURAI**" is a bonafide and genuine research work carried out by me in the Department of General Surgery, Madurai Medical College during the period of JANUARY 2018 TO JANUARY 2019. I also declare that this bonafide work or a part of this work was not submitted by me or any others for any award, degree, diploma to any other University, Board either in India or abroad. This is submitted to The Tamilnadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of regulations for the award of M.S. degree (Branch I) General Surgery course.

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CONTENTS

INTRODUCTION

Diabetes mellitus usually affects most of the organ systems in the body and it is well said that “Knowing diabetes, is like knowing the entire human body”. The ancient physician, Aretaeus of Cappadocia (81- 138 AD) first used the term diabetes. The word diabetes is derived from a Greek word meaning a “siphon”. In 1920, Fredrick Banting, Charles Best and John James McLeod first isolated insulin from the pancreas and named it “Isletin”.

The world is at present facing a pandemic of Diabetes Mellitus, especially type 2 or adult onset diabetes. The magnitude of the problem of diabetes is high. By 2030, there will be 366 million diabetics in the world, which is due to longer life expectancy and change in dietary habits. In future, India will have the largest number of diabetics. A majority of these diabetic patients will be around 35 to 45 years of age. About 15% of these patients will present with foot problems.

And 1% of these patients may lose a limb due to foot pathology. However, in Indian patients, neuropathic – infective foot is more common than ischaemic infective foot. The ischaemic infective foot is

more difficult to treat when compared to the treatment of neuropathic ulcers.

Sadly, as of today, a regular foot examination and monitoring is not being done routinely. In fact, the routine practice is – "No complaints- No examination". However, when the patient complains of some symptoms, the pathology is usually advanced and foot is mostly beyond salvage. Early detection and intervention to warning signals in the foot surely can salvage the limb to a greater extent.

DIABETIC FOOT

The diabetic foot is a group of syndromes characterized by neuropathy, ischemia and infection leading to tissue breakdown which results in increased morbidity and possible amputation.

WHO definition:

"The foot of a diabetic patient that has the potential risk of pathologic consequences including infection, ulceration and/or destruction of deep tissues associated with neurologic abnormalities, various degrees of peripheral vascular disease and or metabolic complication of diabetes in the lower limb".

AIM OF THE STUDY

- The study the **effects and advantage** of RETROGRADE VENOUS PERFUSION THERAPY OVER SYSTEMIC ANTIBIOTIC THERAPY IN TREATMENT OF DIABETIC ULCER FOOT IN GRH, MADURAI"

MATERIALS & METHODS

- **Study area :** Govt Rajaji Hospital, Madurai.
- **Source of data :** All patients diagnosed to have diabetic ulcer , who also come under the inclusion criteria.
- **Method of collection of data :** Details of cases, Full history, Clinical Examination, Dimensions of the ulcer
- It is a prospective analytical study.
- Patients with diabetic foot will be included in the study and classified according to Wagner's grade.
- **METHOD**:

The affected area should be assessed and a photograph should be taken, Pus culture and sensitive to be done, based on which antibiotics should be used, then RVP with Drug I.V Antibiotics (eg.Cefotaxim 1 gm, Gentamycin 80 mg), Heparin 2500 unit and 2% lignocaine with adrenaline 0.4 ml in 100 ml of normal saline should be given intravenously to the affected limb daily upto 6 days.

Again photograph should be taken. Another 6 dose should be given after the interval of 1 week and photograph of the affected limb is taken. If requires, another course of same therapy should be given after interval of 6 weeks. Sensitivity to Lignocaine will be assessed. Patient should be made

to lie in supine position. The affected limb should be elevated for 5 minutes to empty the veins and then cuff of sphygmomanometer was applied on thigh. The pressure applied should be about 20 mmHg below to systolic pressure, which affects the venous flow but maintain arterial flow to the distal part. Combination of the drugs was infused retrogradely with appropriate pressure. Wait upto 20 minutes and then cuff should be released.

The Assessment of RVP THERAPY

The outcome is based on Reduction in size of the wound and amount of exudate along with healing time will be noted and with those derived from conventional systemic antibiotic and dressing methods.

REVIEW OF LITERATURE

DIABETIC FOOT-MORBID ANATOMY

A profound knowledge of anatomy is crucial in managing diabetic foot complications, especially infections. If not aggressively and appropriately treated for infections," the patient pays with his foot' and may go home without it".

Peculiarities of the foot

"Foot is a highly complex design of nature- energy efficient and shock proof with resilient biomechanism, adopted to weight bearing and locomotion on uneven surfaces". The foot is a vulnerable target in diabetes. As it is the farther point from the heart and it becomes the commonest site for arterial insuffiency. Being the most dependent part of the body, it is the favourite site for venous insufficiency. It is the maximum weight bearing part having multiple pressure points which are poor prospects for survival of free skin grafts.

The foot is vulnerable to injuries. It is the common site for peripheral neuropathy, and the foot is susceptible to physical and thermal injuries, small muscle atrophy, deformities and trophic changes. The foot is also vulnerable to footwear associated problems like blisters(new shoes),corn or callosities,ingrown toe nail,hallux valgus

and Hammer toe and due to sociocultural practices associated with bare foot walking.

Skin, nails and subcutaneous tissues of the foot

The dorsal skin is thinner (2mm thick), lax and can be pinched, whereas the plantar skin is thick (5mm) and cannot be pinched. The foot has a thick stratum corneum and a thin dermis. The skin has enormous sweat glands on the plantar skin. The dermis is attached to underlying fascia to improve grip and to avoid gliding or sliding. Infections of sole tend to point to the dorsum, as the plantar skin is thick.

The epidermis gets transformed in to the nail matrix which has three ill defined layers dorsal, intermediate and ventral layers. It is firmly adherent to the epithelium of nail bed. The margins of the nail are overhung by skin folds predisposing to cryptonychia. The plantar subcutaneous region has more fibrous tissue. The fluid fat is loculated inside the fibrous septa that provides shock absorption and prevents gliding or sliding of plantar skin.

Skeleton and fascia of the foot

The skeleton of the foot is designed to form arches to adjust uneven surfaces. there are 7 tarsal bones, 5 metatarsals and 14 phalanges. The superficial fascia of the sole is fibrous and dense. fibrous bands bind the skin to deep fascia or plantar aponeurosis. The fibrous bands separates the subcutaneous fat in to small compartments that serves as cushions and reinforce the spring effect of the arch while walking, jumping, running,,etc.

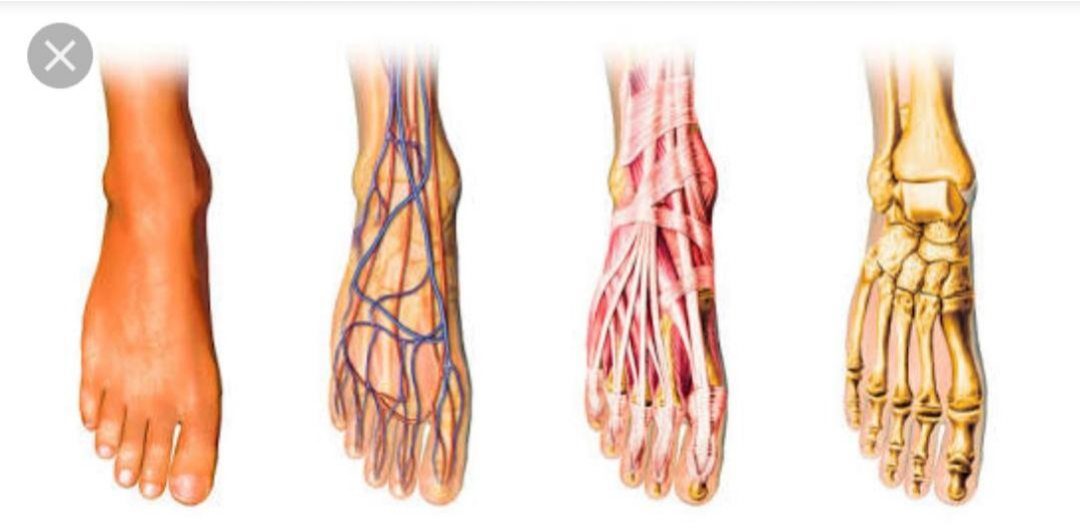


Fig 1: Human foot anatomy

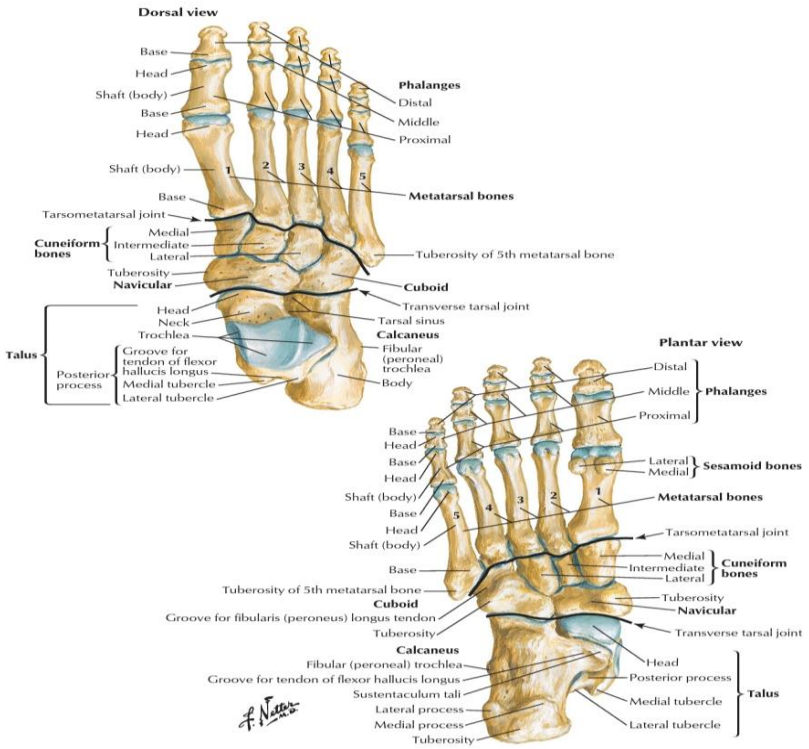


Fig1.1 : Bones of foot

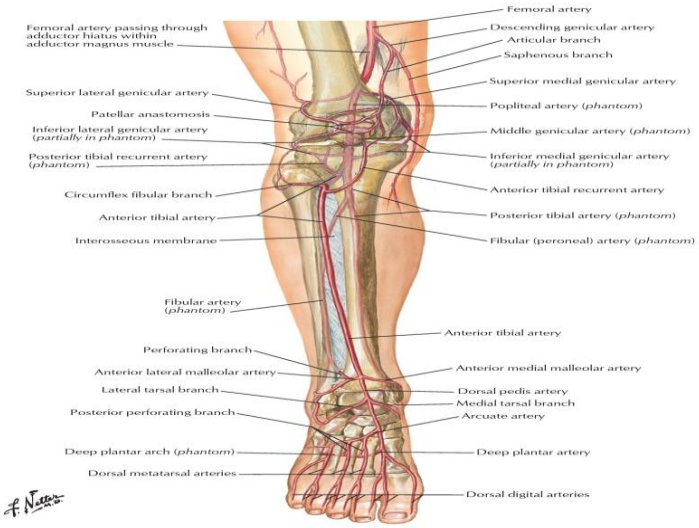


Fig2 : Arteries of knee ,leg and foot

The fascia is thick over weight bearing parts and it contains cutaneous nerves and vessels. Plantar aponeurosis is the thickened central part of the deep fascia. The plantar aponeurosis attaches the skin of the sole, protects deeper structures of foot. This helps in maintaining the longitudinal arches of the foot. It also gives origin to the muscles of the first layer of the sole.

Ligaments of the foot

The ligaments helps in maintaining the arches and stability. Ligaments have a springing effect during the locomotion and also helps in shock absorption. The ligaments of the foot are long plantar ligament ,plantar calcaneocuboid (short plantar)ligament, plantar calcaneonavicular (spring)ligament, deltoidligament (medial), transverse metatarsal ligament, interosseous ligament.

Muscles and tendons of the foot

Foot has four layers which helps in movement and grip. Muscles of foot have a cushioning effect thereby protect nerves and vessels and they maintain the arches. First layer includes abductor

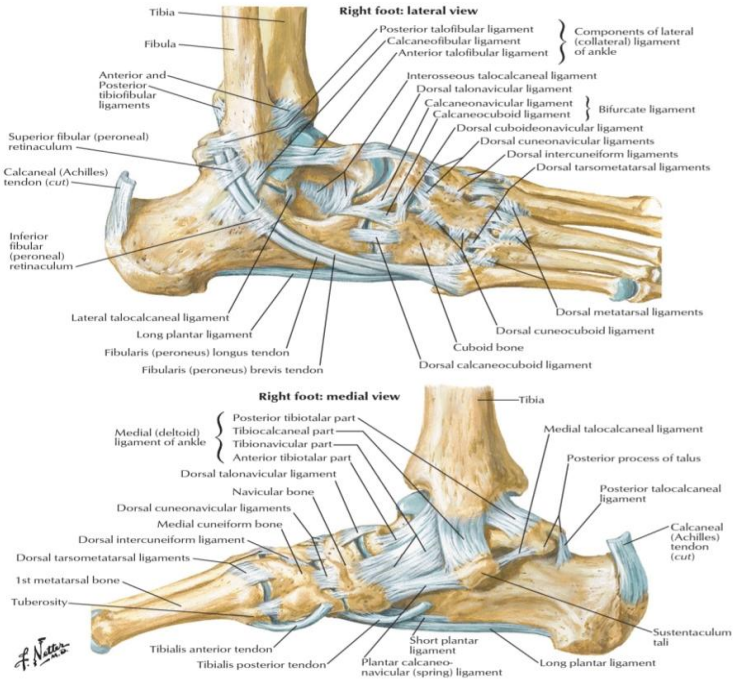


Fig3 : Ligament and tendons of ankle

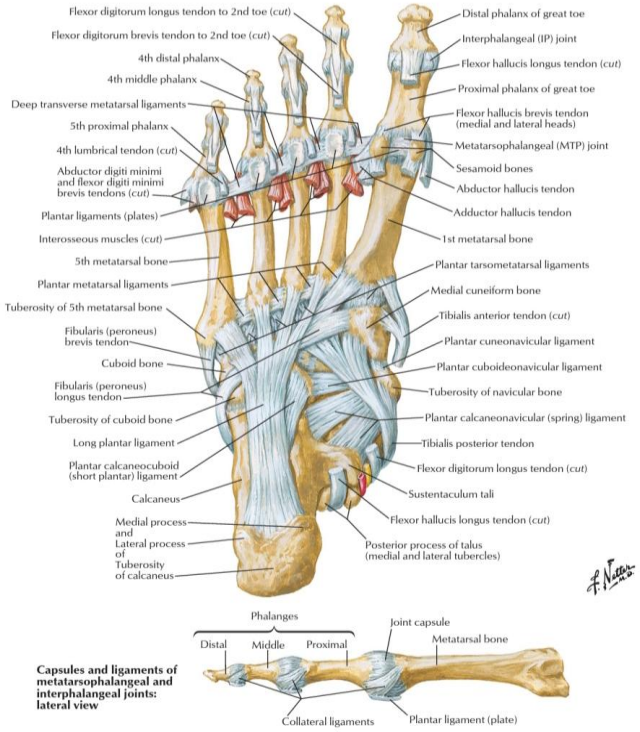


Fig4 : *Ligament and tendons of foot*

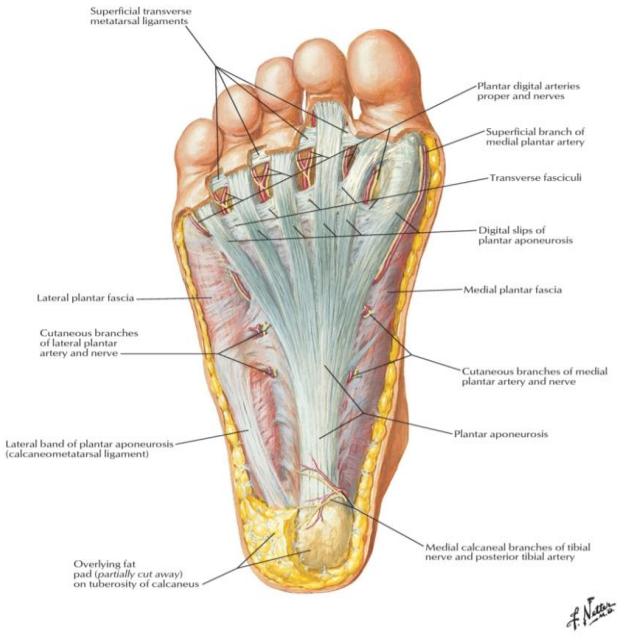


Fig5 : Superficial dissection of sole

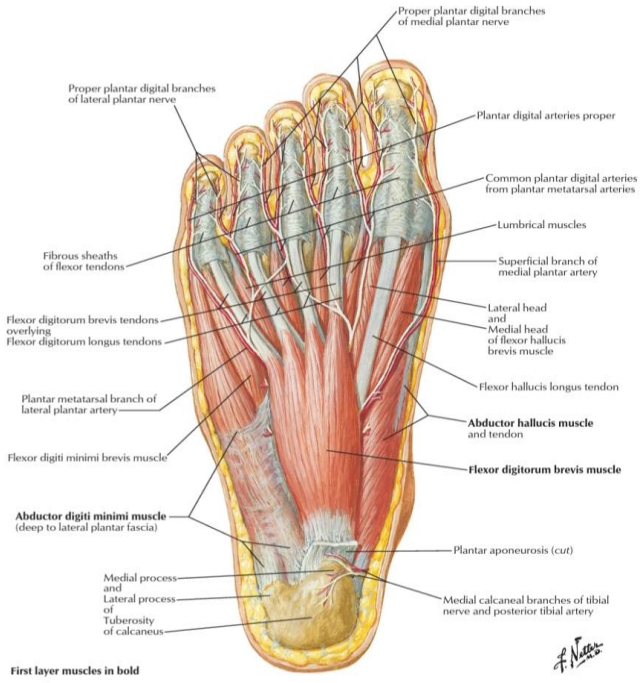


Fig6 : First layer of sole

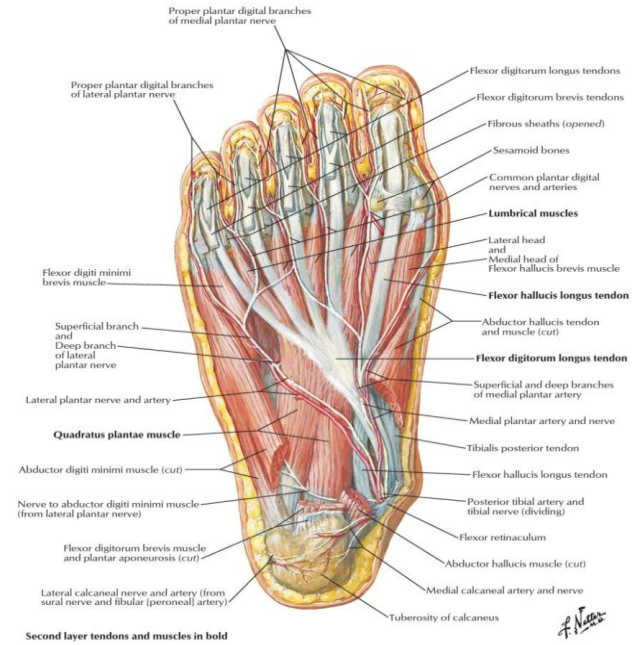


Fig7 : Second layer of sole

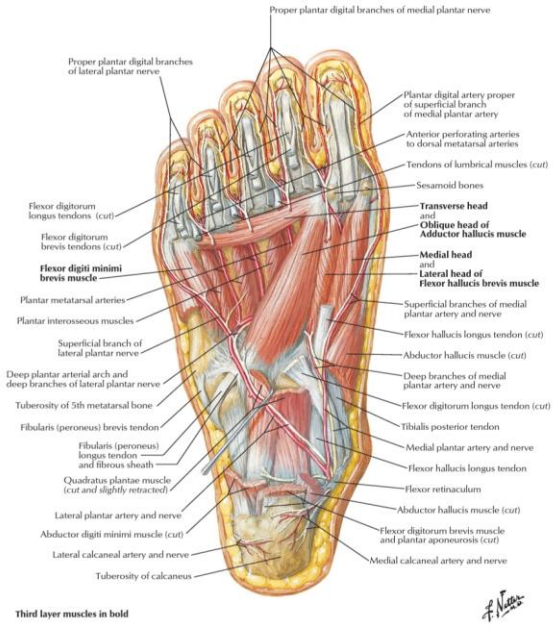


Fig8 : Third layer of sole

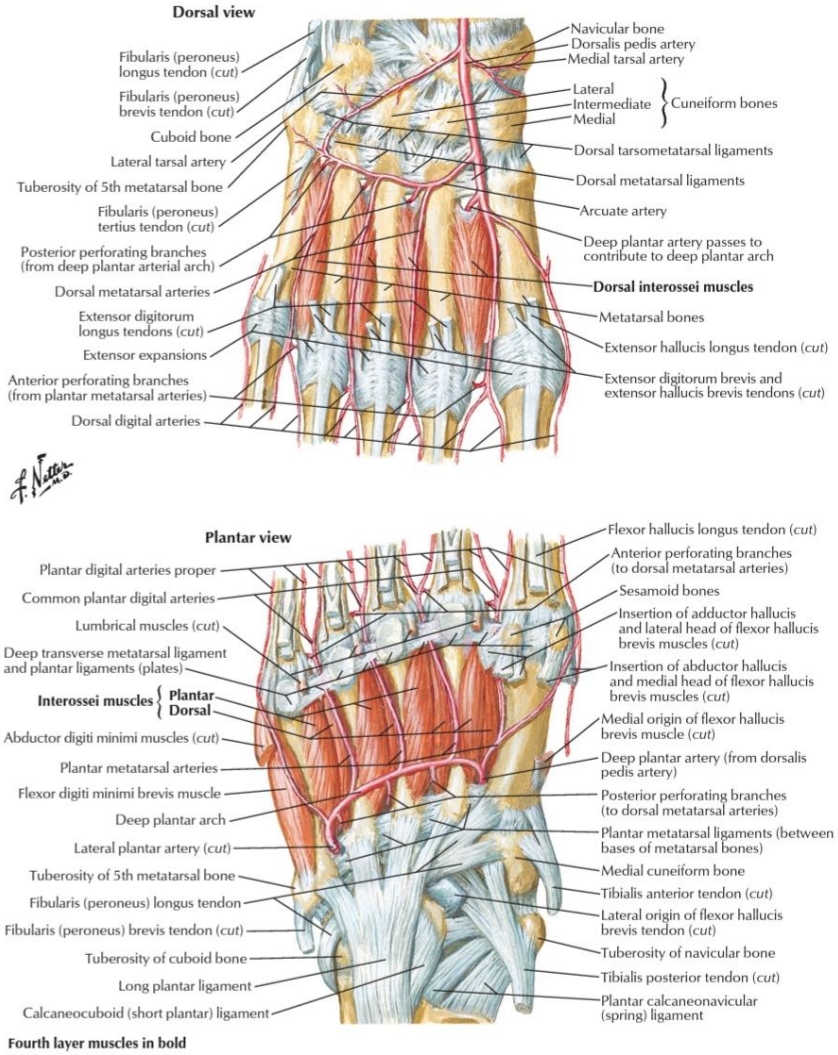


Fig9 :Interosseous muscles and deep arteries of foot

hallucis longus, flexor digitorum brevis, abductor digiti minimi . Second layer consists of flexor accessorium (quadratus plantaris),tendons of flexor hallucis longus,flexor digitorum longus and the lumbricals. Third layer is made by the flexor hallucis brevis,transverse and oblique heads of the adductor hallucis,flexor digiti minimi brevis. The fourth layer includes the interrossei.

Musculo-fascial compartments of the foot

There are four compartments in the foot, formed by vertical septa extending from the plantar aponeurosis. There are 4 compartments namely the medial, central, lateral and interosseus compartments.

The content of the medial compartment are medial plantar nerve, artery, vein and the central(larger)compartment contains lateral plantar nerve,artery and vein.

Nerves of the foot

Saphenous nerve originates from the femoral nerve. Saphenous nerve supplies medial aspect of the foot up to the first metatarsal. **Superficial peroneal (fibular)nerve** is the smaller terminal branch of the common peroneal nerve, which gives cutaneous branches to the dorsum of foot including digital branches to medial side of great

toe,adjacent sides of second,third,fourth and fifth toes. The terminal branch of the common peroneal nerve is **Deep peroneal (fibular)nerve and this** supplies the extensor digitorum brevis and gives cutaneous branch to the adjacent side of great and second toes. **Medial plantar nerve** is the largest terminal branch of the tibial nerve and it supplies abductor hallucis,flexor digitorum brevis,flexor hallucis brevis, first lumbrical muscle, cutaneous branches supply skin of the medial part of the sole, medial three and half toes.

Lateral plantar nerve is the small terminal branch of tibial nerve. The main trunk innervates the flexor digitorum accessorius, abductor digiti minimi and skin of the sole. It divides into superficial and deep branches. S**ural nerve** originates from tibial and common fibular nerves and runs along the course of the short saphenous vein. Sural nerve innervates the lateral side of the foot and fifth toe and all intrinsic muscles of the foot(S2 and S3).

Arterial tree

The dorsalis pedis artery is a continuation of anterior tibial artery and it lies in between tibialis anterior and extensor hallucis longus tendons. It may be absent in about 5% of population. Dorsalis pedis artery gives arcuate artery,supplying the dorsum of foot and toes. The

dorsalis pedis artery enters deep into the first inter-metatarsal space to form the plantar arch, by uniting with the medial and lateral plantar arteries. The posterior tibial artery, which runs behind the medial malleolus and divides into medial and lateral plantar arteries, supplying the sole and toes. The plantar arch is formed by the medial and lateral plantar arteries with the dorsalis paedis artery. The digital arteries arise from the plantar arch (plantar aspect)and arcuate artery(dorsally).

Venous drainage

The dorsal venous arch lies in the dorsum of foot over the proximal parts of the metatarsal bones. Dorsal venous arch receives four dorsal metatarsal veins. These metatarsal veins are formed by the union of two dorsal digital veins. The long saphenous vein is formed by the union of the medial end of dorsal venous arch and the medial marginal vein. The medial marginal vein drains the medial side of the great toe. The short saphenous vein is formed by the union of lateral end of dorsal venous arch and lateral marginal vein. The lateral marginal vein drains the blood from the lateral side of the fifth toe. Perforators com. Both the saphenous veins connects to deep veins through the perforating veins.

Lymphatic drainage :

Superficial lymphatics drains along the course of saphenous veins,short saphenous zone, in to popliteal group and long saphenous zone in to inguinal group. Deep lymphatics drain along the course of the arteries to both popliteal and inguinal groups.

Arches of foot

The arches help to adjust to uneven surfaces.The presence of arches makes the sole concave and that concavity protects the neurovascular structures. There are 4 arches of foot- medial and lateral longitudinal arches and the anterior and posterior transverse arches.

Anatomical principles of surgical incisions

There exsists few anatomic principles that one should keep in mind while making incisions in the foot.

They are

- To avoid neuro-vascular injury,
- To avoid weight-bearing points,
- To make liberal counter incisions,
- To De-roofing should be liberal,
- To excise metatarsal head, during toe amputation for better realignment of toes.

DIABETIC FOOT - PATHOPHYSIOLOGY

Diabetes mellitus is the cause for more than half of all non-traumatic lower limb amputations. The major pathophysiological factors leading to loss of limb are ischemia, neuropathy and wound infection. They operate sequentially and concurrently, enhancing the risk of amputation fifteen times in diabetic subjects when compared with non diabetics. Since the diabetic foot is the consequence of the interaction of various factors, hence, the intervention must be directed toward treating of all the causative factors.

Diabetic Neuropathy

Peripheral neuropathy with insensitive foot is the leading factor resulting to amputation for the person with uncontrolled, diabetes. Diabetic neuropathy affects the autonomic, motor neurons and sensory neurons of the peripheral nervous system, In diabetic neuropathy each and every type of nerve fibres are affected. Diabetic peripheral neuropathy may be classified into two types, acute sensory neuropathy and chronic sensorimotor neuropathy (most common).

Biochemical dysfunctions resulting in neuropathy includes

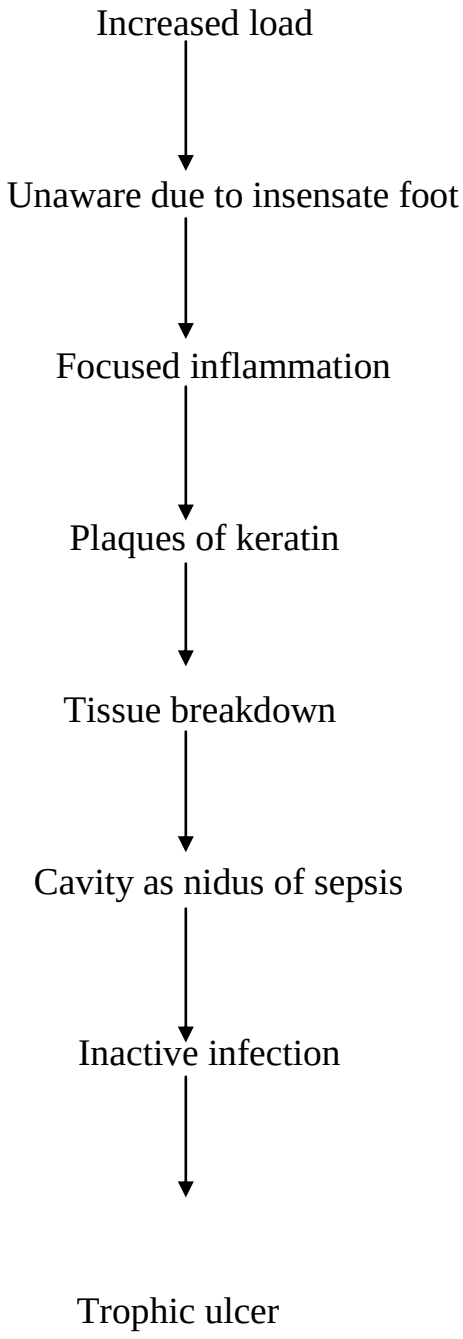
- defective polyol pathway,

- increased advanced glycosylation end products
- neurovascular alterations and
- impaired resistance to oxidative stress.

The common manifestations of sensory neuropathy are parasthesia, reduced pain perception, loss of joint sense, loss of vibration sense, glove and stocking anaesthesia, charcot joint. Motor neuropathy presents as weakness of muscles, paralysis of small muscles of foot leading to deformed toes.

Autonomic neuropathy is associated with the micro circulatory derangement of the tissues of the foot. There will be abnormal sweating and in some,with absence of sweating, dry foot with a lot of cracks in the sole, loss of thermoregulation and calcification of the medium sized arteries can be noted.

Development of neuropathic ulcer



Diabetic macroangiopathy

Major blood vessels are commonly involved in diabetes. The abdominal aorta and its branches are commonly affected. The risk of atherosclerosis is 20 times more among the diabetics than the non diabetics. Calcification of the artery is the common feature of diabetes. Monckeberg sclerosis is defined as calcification of the media of artery and this is the result of neuropathy.

Calcification makes the vessel rigid and this gives a falsely eincreased perfusion pressure. The crucial artery is the popliteal artery and popliteal artery narrowing produces foot gangrene. Diabetes and smoking are the risk factors for peripheral arterial disease. The diabetes is strongly associated with femoral- popliteal and tibial (below the knee) peripheral arterial disease.

Diabetic peripheral arterial disease has predilection for tibial and peroneal vessels but dorsalis pedis artery, the distal posterior tibial artery and the plantar arteries are usually spared. Diabetic patients with atherosclerotic peripheral vascular disease exhibit a decreased ability to establish collateral circulation.

Microvascular changes

Peculiar to diabetes is development of microvascular dysfunction, which starts early in diabetic life. It is commonly seen in the capillaries and arterioles of kidneys, retina and peripheral nerves, but spares no organ. In diabetic patient, RBC ‘s become flat and rigid, the blood becomes more viscous which are the major cause for microvascular impairment. Defect in nitric oxide pathway, abnormal vasoconstrictor prostanoids, intracellular signalling, reduction in sodium –pottasium ATPase activity and advanced glycosylation end products are responsible for microvascular changes.

Vascular diseases:

The most common risk factors for diabetic vascular disease are smoking, hyperlipidemia, insulin resistance with compensatory hyperinsulinemia, severity and duration of diabetes, age and generic factors. Smoking increases the risk of peripheral vascular disease more than hundred times compared to non – diabetic non smokers.However , cessation of smoking is related to retardation in the progression of atherosclerosis.

Hypertension is two times more common in diabetics as compared to non-diabetics; about one third to one half of diabetics also suffers from hypertension. Systolic hypertension has been associated with disease of proximal blood vessels.

Diabetics and endothelial dysfunction

The cause for endothelial cell dysfunction in diabetes is derangement of nitric oxide bioavailability. Nitric oxide inhibits vascular smooth muscle cell migration and proliferation and limits the platelet activation. Diabetes activates the pro-atherogenic activity in vascular smooth muscle cells.

Diabetes,coagulation and rheology

Diabetes can cause hypercoagulable state .It is associated with the enhanced production of tissue factor by endothelial cells and vascular smooth muscle cells as well as elevated plasma concentration of Factor VII.

Hyperglycemia is characterized by decrease in concentration of antithrombin and protein c, defective fibrinolytic function and increased production of plasminogen activator inhibitor. **Platelet** aggregation is increased in diabetes. Platelet in diabetic patients also have enhanced expression of Glycoprotein IIb/IIIa receptors,which are play an important role in thrombosis via their role in platelet adhesion and aggregation.

Infection

Infection refers to the condition characterized by invasion of the tissues with proliferation of microrganisms resulting in tissue damage with or without an associated inflammatory response by the host. Foot sepsis accounts for about 70% of all infections. Adherence of granulocytes and other WBC functions like phagocytosis are affected in diabetes.T cell function is affected and cell mediated immunity is decreased. Hyperkeratosis in foot is mistaken for a corn and removing it using rusted nail or a safety pin is the prime cause for infection. Absent sweating causes cracks and fissures in foot which serves as the entry for microbes. The microbe may be causative ,commensal ,contaminent or coexisting polymicrobial.. Incidence of polymicrobial infection is high. staphylococcus aureus and beta haemolytic streptococci are the most commonly involved pathogen in acute infection. In chronic wounds, Enterococci, Enterobacteriaceae, Obligate anerobes, Psuedomonas, Fungi are also involved.

Biomechanical aspects

Neuropathy and trauma leads to tissue breakdown. The atrophy of the intrinsic muscles of the foot, mainly plantor flexors of the toes affects the flexor/ extension balance at the metatarsophalangeal joints and causes clawing of the toes and prominence of the metatarsal heads.

Alterations of the foot shape leads to increased plantar pressure. The most common cause for wound on insensitive foot is not caused by accidental injury or ischemia but due to continuous pressure.

Often minimal stress that occurs during locomotion on the same part of the insensitive foot may leads to callus formation and ulcer. The presence of callus may increase the problem by acting as a foreign body and by increasing the plantar pressure.

Charcot foot

Charcot foot or neuroarthropathy is defined as a relatively painless, progressive, degenerative arthropathy of single or multiple joints caused by neuropathy. Charcot neuropathy is characterized by presence of bone and joint destruction, fragmentation and remodelling. Diabetes is the commonest cause for charcot foot and most patients suffers from dense neuropathy but good circulation. Walking on an insensitive foot can cause repetitive stress to bone leading to micro fracture and finally bone and joint destruction

Diabetic neuropathy and presence of auto symphathectomy results in peripheral vasodilation(warm foot). A Significant arteriovenous shunting occurs, resulting in abnormal bone cell activity (osteoclastic) and eventual resorption and weakening of bone. This results in foot

deformities. Damage in the metatarsal region is the commonest site of involvement in neuropathic joint and this leads to the two classical deformities.

- Rocker bottom deformity which is characterized by displacement and subluxation of the tarsus downward.
- Medial convexity ,result from displacement of the talonavicular joint or from tarso-metatarsal disocation.

Both are associated with a bony prominence which is very prone to ulceration wherein healing is difficult.

If these deformities are not diagnosed early and treated with properly fitting footwear, ulceration at vulnerable pressure points may develop. It is common to mistake acute charcot foot for cellulitis and osteomyelitis. If the affected foot is elevated ,the erythema of charcot foot will reduce but in case of cellulitis, the erythema will persist.

Plain X ray of the foot will show demineralization, osteolytic changes and periosteal reaction. Marked osseous resorption of bone leading to “pencil pointing “ and “sucked candy” appearance of the metatarsal heads and shafts. In the largest joints of the foot there occurs destruction of bone and formation of new bone.

It is a rule that a “warm swollen foot in a diabetic with neuropathy with no local and systemic signs of infection, charcot foot must be ruled out first”.

Osteomyelitis

Osteomyelitis is suspected if the ulcer does not heal for more than 6 weeks of appropriate and adequate care and off loading ,and if there is swollen foot with ulcer, sausage toe, high WBC count or inflammatory markers. Radiographic evaluation is required if osteomyelitis is suspected. Bone scan findings will be positive within 24 hrs whereas a plain X -ray will take 10 – 14 days to show any abnormality. There will be soft tissue swelling and periosteal elevation in acute osteomyelitis and osteopenia, osteolysis and tapering of bones in chronic osteomyelitis.. When a bone is felt on probing through the ulcer with a sterile metal probe, osteomyelitis is suspected.

DIABETIC FOOT – CLINICAL ASSESSMENT

CLINICAL ASSESSMENT OF NEUROPATHY

1.Filament test: Semmes-Weinstein monofilament is used to detect the reduced sensation of foot.

Semmes –weinstein monofilaments

The monofilaments is a valuable and easy to use tool. The monofilament is a long nylon wire, the tip of which gives a force of 10 grams. The monofilament is pressed against the skin to the point of buckling for atleast one second. The points of testing are plantar aspects of 1^{st},3^{rd} and 5^{th} digits, the plantar aspect of 1^{st} ,3^{rd} and 5^{th} metatarsal heads,plantar mid foot medially and laterally and the plantar aspect of heel (10 sites totally).Neuropathy is said to exists when 4 out of these 10 sites show absence of sensation when the wire is pressed against the skin.

2.**Testing for vibration sense in toes and over the Malleoli**

Biothesiometer

This is also called as vibration perception threshold meter. it has a hand held probe whose tip vibrates at 100HZ.The probe is applied to a part of the foot, usually on the big toe. The probe can be made to vibrate at increasing intensity by turning a dial.The voltage supplied to the

probe can be adjusted from 0 -50 V.The probe is placed against the skin and the voltage is increased until the patient perceives the vibration. Mean of three readings is used to determine the vibration perception threshold for each foot. Normal reading is less than or equal to 25V.

3.**Loss of joint position** is common in diabetic neuropathy.Joint sense of great toe is tested. Severe neuropathy results in muscle wasting in the foot which leads to **collapse of arches** and deformity of toes. These are predisposing factors for ulcer formation. **Absence of sweating** makes the foot dry and this increases the risk of infection and cracks. Prominent long saphenous vein is an index of **autonomic microcirculatory dysfunction.** This is an important clinical sign (J D Ward sign) of microcirculatory arterio venous shunting.

Clinical assessment of vascular disease

It begins with inspection of the foot for hue of toes, nicotine staining of fingers, the thinning of skin is due to loss of subcutaneous tissue and acral ulcers. Palpation of pulses (dorsalispedis,popliteal and femoral) is the important factor of screening for periphery vascular disease. Absence of distal pulse is the sure sign of significant arterial

disease. However the presence of palpable pulse does not exclude vascular disease.

Ankle brachial pressure index (ABI)

It is used to assess the vascular insuffiency. It is obtained by dividing Ankle systolic pressure by Brachial systolic pressure. Normal values are 1+ 0.1. ABI can be deceptive because calcification of vessels in diabetic can result in falsely elevated ABI. All diabetics are advised, annual assessment of ABI.

Indication for ABI monitoring :

1.All those with type 1 diabetes older than 35 years or who have had diabetes for over 20 years at base line.

2.All those older than 40 years at base line with type 2 diabetes.

3.Any diabetic patient who has newly detected weak pulses, femoral bruits or a foot ulcer.

4.Any diabetic with a leg pain of unknown etiology.

If ABI is more than 0.9 repeat every 2 -3 years.If ABI is 0.5 - 0.89 repeat the test within 3 months and treat the associated cardiovascular risk factors. If ABI is less than 0.5 ,refer for vascular work up and intervention. If an incompressible artery with an ankle pressure above 300mmhg or ankle pressure 75mmhg above arm

pressure is found, ABI should be repeated in 3 months. If still present refer for vascular work up.

Infection

Infected ulcers are usually asymptomatic in neuro ishemic foot of diabetics. The categorization of wound infection can be mild, moderate and severe. Mild infections are superficial limited to the skin and subcutaneous tissue with minimal or no purulence or cellulitis.

Moderate infections are deep involving the fascia, musles, tendons, joints and bones. They may present as cellulitis of less than 2 cm diameter, plantar abscess and with systemic symptoms. Severe infections are deep with cellulitis more than 2cm , lymphangitis, gangrene and or necrotizing fasciitis, threatening limb loss and causing systemic toxicity.

INTEGRATED EXAMINATION OF DIABETIC FOOT

In common practice the examination of the foot is divided into following four main parts:

inspection, palpation, neurological examination and vascular assessment.

1.Inspection

The foot is fully inspected including dorsum, sole, back of the heel and inter digital areas with full assessment regarding colour (as an indicator of ischemia),deformity ,swelling,callus,skin breakdown, infection ,necrosis.

2.Palpation

Pulse is palpated and skin temperature is compared between both feet with the dorsum of the examining hand. The measurement of the skin temperature is helpful in the management of the charcot foot where a digital skin thermometer is used.

3.Neurological examination

Peripheral neuropathy is detected either by using the monofilament or biothesiometer or by performing a simple sensory examination.

4.Vascular status

All the peripheral pulses should be examined and compared with the normal limb. Femoral, popliteal, dorsalis pedis and posterior tibial arterial pulses must be examined in lower limb.

DIABETIC FOOT – INVESTIGATIONS

LABORATORY TESTING

1.Blood sugar monitoring is the important in managing any diabetic problem. A fasting and postprandial plasma glucose monitoring is crucial in all diabetic foot patients. HBA1c monitoring is commonly practised nowadays.

2.Bacterial culture

Superficial swabs are not useful. Necrotic tissue should be removed before taking a swab. Culture of swabs taken from the deeper part of the wounds will be effective in identifying the pathogens.

IMAGING STUDIES

Plain Radiographs are used to identify osteomyelitis, osteolysis, fractures, dislocations, etc. In a CT scan, the resolution of bone with osseous fragmentation and subluxation are well visualised. MRI aids in diagnosis of osteomyelitis, deep abscess, septic joint and tendon rupture. Three phase Technetium scans are used for early detection of osteomyelitis, fractures, charcot artheopathy . Indium III leucocyte scans and Tc 99 labelled white cell scan – is used to differentiate osteomyelitis and neuropathic arthropathy. Duplex ultrasound and Arteriography are used in diagnosis of arterial stenosis.

Gait analysis and Thermography

A walking cycle refers to the time between the heel making contact with the ground and the same heel again coming in to contact with the ground. In diabetes thickening of skin of sole due to abnormal weight bearing and infection under thick skin leads to altered gait. Neuropathy leading to claw toes and bent toes can lead to ulcers. Hence gait analysis in diabetics is crucial for early detection of neuropathy.

Moderate repetitive stress with repetitive shearing force results in the typical neuropathic ulcer. Frictional forces below the calcaneum is longitudinal whereas in the forefoot it is both longitudinal and transverse. In both normal and insensitive feet, walking briskly is accompanied by progressive hyperaemia over points of maximum stress. Thermography aids to outline the temperature contrast of progressive inflammation from such a process. In patients with insensitive foot thermographic pattern demonstrates hyperaemia at sites of old scar, there by inferring that these patients have been stressing those particular areas more than optimally, due to absence of pain and as the result of motor neuropathy. Similarly, in – shoe foot prints help to identify the points of continuous and maximum stress on the feet which likely could be alleviated by proper footwear.

Harris mat

The feet can be assessed for high pressure points by means of devices which can quantify the pressure under the foot during walking or standing. A relatively inexpensive method to demonstrate the presence of pressure points is the harris foot mat, which is an ink pad with graded depths of grid lines. The patient walks across the pad and the pressure points can be evaluated by the intensity of the ink. This can be fed in to a computer and a color coded analysis of pressure points can be made which is called as podio scan.

Plantar pressure measurement

Both the hind foot and fore foot pressures are increased in diabetics. Restriction of movement of subtalar joint results in high plantar pressures. The areas of high pressure eventually lead to tissue breakdown and ulceration. The Computerized assessment of foot pressures is important in assessing the changing pattern of pressure transmission in the feet. Plantar peak pressure more than 70N/cm2 is considered elevated.

Transcutaneous oximetry

It is measured at the dorsum of foot with the subject in supine position. A transcutaneous oxygen tension more than 55mmHg is normal and less than 40mmHg leads to non healing of wounds and less than 30mmHg predict limb loss.

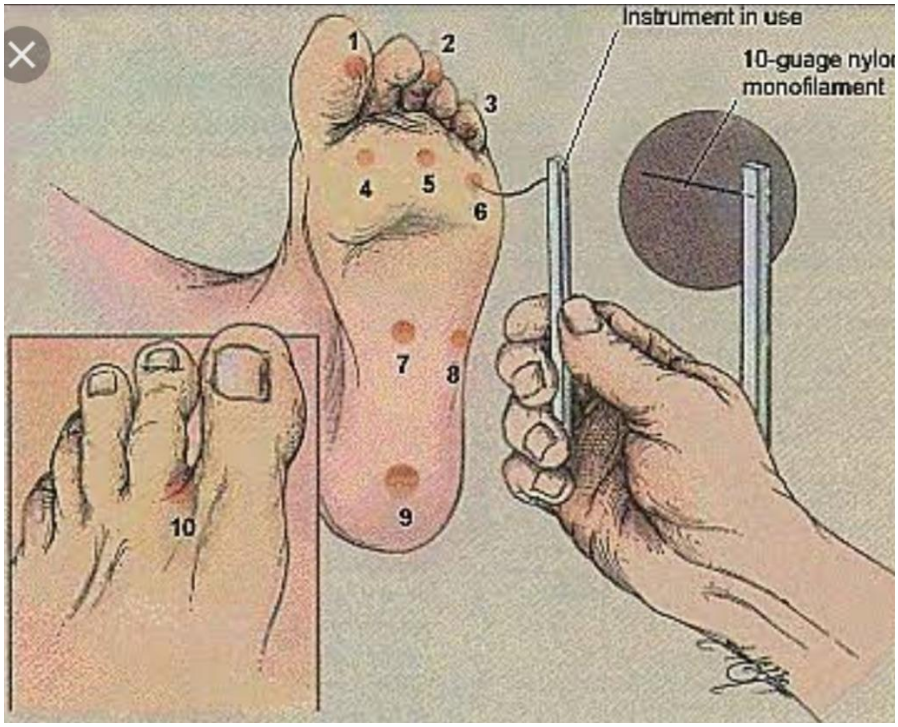


Fig10 : Harris foot mat

Fig 11: Foot imprint box

CLASSIFICATION OF DIABETIC FOOT ULCERS

Wagner classification system

Grade	Lesion
0	No open lesions ; may have deformity or cellulitis
1	Superficial ulcer
2	Deep ulcer to tendon or joint capsule
3	Deep ulcer with abscess, osteomyelitis, or joint sepsis
4	Local gangrene – forefoot or heel
5	Gangrene of entire foot

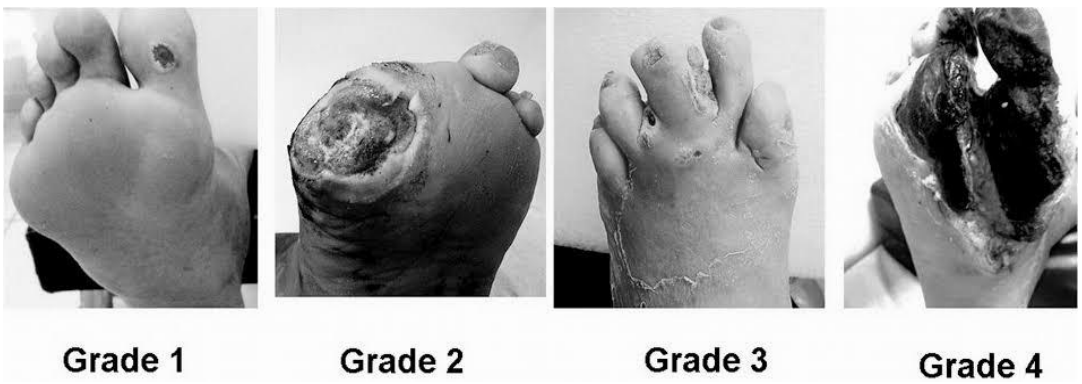


Fig12 : Wegner's ulcer grading

University of texas classification system

Stage	Grade			
	0	1	2	3
A	Pre or post ulcerative lesions completely epithelized	Superficial wound not involving tendon,capsule,or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
B	Infected	Infected	Infected	Infected
C	Ischemic	Ischemic	Ischemic	Ischemic
D	Infected and ischemic	Infected and ischemic	Infected and ischemic	Infected and ischemic

MANAGEMENT OF DIABETIC FOOT

The foot ulcers in diabetics are usually maltreated ulcers. Factors leading to wound healing deficiencies in diabetes are;

- decreased growth factor production,
- angiogenic response,
- macrophage function,
- collagen accumulation,
- epidermal barrier function,
- quantity of granulation tissue,
- keratinocyte and fibroblast migration and proliferation,
- poor expression of matrix metalloproteinases and their inhibitors

a) WAGNER grade 0 foot:

This includes patients with apparently normal foot, with varying degrees of neuropathy or joint deformities. They would not have any ulcer or infection but are “at risk”. Neuropathy must be looked for during each annual assessment. The ideal way to prevent neuropathy or delay it, is to keep blood sugar under control. Assessment of vascular status is must. Absent foot pulses even in the absence of claudication or rest pain represents signicant vascular disease and such patients are ideal candidates for vascular reconstruction or

angioplasty. A diabetic may not manifest with claudication symptoms if he had neuropathy. These high risk patients may have increased pressure over some points on the sole. They need appropriate footwear with extra depth shoes with cushioned insoles. The Charcot's feet need custom shoes. Regular trimming of callus is advised. These patients need foot care advice.

(b)**WAGNER grade 1 foot :**

These are patients presenting with either cellulitis or a superficial ulcer. Ulcers are result of either repetitive low pressure or sustained high pressure (>6kg/cm) at that point on the sole during walking. Relief of pressure is the mainstay of treatment of ulcer. A variety of methods are available to "off load" the ulcer. These comprises of complete bed rest, use of total contact casts, walkers, braces etc. In case of grade 0 feet, appropriate management of vascular disease is needed. Infection needs antibiotics and debridement. Education, foot care and regular careful follow up are the prime factors in management of grade 1 foot.

(c)WAGNER grade 2 and 3 foot :

This includes patients with deep ulcer with or without complications like abscesses and osteomyelitis. These patients require aggressive surgical debridement. Osteomyelitis must be appropriately

treated with debridement/excision of infected bone. After the healing of ulcer, the patient requires long term foot care, to advise appropriate foot wear and also education regarding foot care, in order to prevent recurrence.

(d)**WAGNER grade 4 and 5 foot :**

These are patients with either focal or extensive gangrene. They are treated with minor or major amputation respectively. It is usually associated with vascular occlusive disease. These patients hence need appropriate surgical amputation along with vascular reconstructions. Aftercare involves special footwear for both ipsilateral and contralateral foot as these patients tend to over use the other foot and develop ulcers of the opposite foot. In major amputees, prosthetic devices need to be fitted in order to mobilize the patient. Mortality rate is nearly 50% after a major amputation in diabetics.

Principles of medical management:

1. Pus from ulcers to be sent for pus culture and sensitivity.
2. Careful monitoring of blood sugar levels.
3. Appropriate antidiabetic medications – either insulin preparations or oral hypoglycemic drugs.

4. Broad spectrum antibiotics coverage to be started at the onset and change over to other antibiotics depending on culture and sensitivity report.

Principles of surgical management:

1. Early identification and prompt intervention.

2. Blood glucose optimization.

3. Complete rest of ulcerated area.

4. Careful and thorough debridement and drainage of all involved areas.

5. Appropriate antibiotic therapy.

6. Regular wound care and dressings.

7. Vascular reconstruction as and when needed.

8. Careful follow up - podiatric appliances and modified footwear.

9. Experienced consultation as necessary

VARIOUS TREATMENT MODALITIES

1.**Protective dressing**

Modern moist dressings with foams, calcium alginates, hydrogels, hydrocolloids, and adhesive membranes

2.**Topical antiseptics**

Superoxide solutions are used as topical antiseptics which are active against many organisms

3.**Drainage of pus**

Vaccum assisted drainage at a continuous negative pressure of 125 mmHg, to the wound will promote healing of the ulcer.

4.**Debridement**

Aggressive ongoing surgical debridement changes a chronic non healing ulcer in to an acute healing wound.

Adequate debridement of necrotic tissue like eschar and slough is needed before adequate assessment and staging can be accomplished. There are various methods of wound debridement, including sharp surgical, mechanical, enzymatic and autolytic. It is followed by flushing away debris with low pressure irrigation to wide excision.

Sharp surgical debridement

The most selective and effective method of debridement is by sharp surgical debridement. Debridement of the hyperkeratotic rim and ulcer base to bleeding is the ideal method of debridement for the patient with an ulcer.

Autolytic debridement

Autolytic debridement with moist interactive dressings like hydrogel,alginates,transparent films,hydrocolloids are selective and liquefies the slough and eschar and promotes granulation tissue formation.

Mechanical debridement

Mechanical debridement may be done with wet to dry gauze dressings, irrigation, pulsatile lavage or whirl pool

Enzymatic debridement

Historical enzymes (collagenase , papain, urea) can be used as debriding agents for eschar and slough. Though they have a selective action, they are slow, costly and labour intensive.

5. Antibiotic

The use of double or triple antibiotics therapy are advised. The antibiotics should have broader spectrum covering against gram positive, gram negative and anaerobic organisms.

MANAGEMENT OF INDOLENT NON HEALING ULCERS

A. Collagen sheets and powders

B. Silver dressing

C. Growth factors

Growth factors are obtained from platelets, bioengineered tissues or by recombinant techniques.

NEGATIVE PRESSURE WOUND THERAPY & HYDRODEBRIDEMENT

NPWT is an ideal technique for managing an open wound by submitting the wound to either intermittent or continuous subatmospheric pressure. Negative pressure is maintained by transferring away the gas molecules that are present within the wound by using a suction pump.

There are two types of NPWT in practice now:

1) Foam based technique

2) Chariker Jeter Technique

FOAM BASED TECHNIQUE:

Here, a foam is cut in the shape of the ulcer is placed over the wound and sealed in place using an adhesive film drape and a TRAC (Therapeutic Regulated Accurate Care) system. Plastic tube connects the dressing to the console that creates the suction effect.

CHARIKER JETER TECHNIQUE:

It is a recently developed system, where flexible drains and moist gauze are used. The moist gauze is placed over the wound after insertion

of a silicone drain and sealed with an adhesive film drape creating an airtight seal. The silicone drain is attached with the suction console.

MECHANISM OF ACTION:

- Enhanced blood flow to wound bed.
- Enhanced neovascularization with profuse granulation tissue.
- Enhanced activity of fibroblasts.
- Rapid epithelial cell migration.
- Reduction of bacterial toxins.
- Reduction of harmful wound fluid and toxic products.
- Reduction in microvascular occlusion and inelasticity.
- Reduced periwound induration.
- Reduction in number of dressing changes → decreased damage to delicate new tissue.
- Increased healing by primary intention by mechanical approximation.
- Stimulates epitheliasization and synthesis of growth factors.
- continuous stimulation of cytoskeleton → increased mitosis.
- Increased viscoelastic flow due to stretching of tissues.
- Reduced shear forces due to uniform wound bed immobilization.
- reduced seroma of grafts and flaps.
- Splinting effect (sternal, abdominal wound)

Contrindications to NPWT:

- Open wound with exposed vital organs
- unhealthy wounds,
- osteomyelitic changes,
- Coagulopathic disorder.
- Necrotic tissue with eschar.
- Suspicious of malignancy in the wound.
- Allergy to the component used in the procedure.

NPWT must be used with extreme caution if there is active bleeding, if the patient is taking anti-coagulants and if the dressing is in near the blood vessels.

If there is any exposed vessel or vital organ, petroleum impregnated gauze can be interposed between vital structure and sponge.

HYDRODEBRIDEMENT:

Hydrodebridement refers to the use of a high pressure waterjet placed parallel to the surface of the wound capable of tangentially excising soft tissues at variable strengths. It works on the basis of Venturi effect, a special case of Bernoulli's principle, which says that a

fluid flowing through a tube that contains a constriction should increase the velocity in order to decrease the pressure and maintain the conservation of energy. This procedure simplifies the method of debridement by selectively removing slough and debris and thus reduces the bacterial growth in the contaminated wounds.

RETROGRADE VENOUS PERFUSION THERAPY

First, Ferreira introduced retrograde venous perfusion technique in 1989 for diabetic foot ulcer. This concept based on Bier,s principle of retrograde transvenous perfusion of the capillary circulation into the circulation to achieve higher concentration of the substances in the target tissues.

Mechanism of action:

Retrograde venous perfusion induces dilatation of venous capillaries, post capillary venules and lymphatics whereas arterioles remains unaffected. Loosening of contacts between endothelial cells and pericytes with focal formation of small gaps in the vessels rises the filtration and diffusion of drugs in the interstitial tissue leading to high concentration of the administered drugs into the tissue.

Technique of retrograde venous perfusion:

The affected area should be assessed and a photograph should be taken, Pus culture and sensitive to be done, based on which antibiotics should be used, then RVP with Drug I.V Antibiotics (eg.Cefotaxim 1 gm, Gentamycin 80 mg), Heparin 2500 unit and 2% lignocaine with adrenaline 0.4 ml in 100 ml of normal saline should be given intravenously to the affected limb daily upto 6 days. Again photograph should be taken.

Another 6 dose should be given after the interval of 1 week and photograph of the affected limb is taken. If requires, another course of same therapy should be given after interval of 6 weeks.

Sensitivity to Lignocaine will be assessed. Patient should be made to lie in supine position. The affected limb should be elevated for 5 minutes to empty the veins and then cuff of sphygmomanometer was applied on thigh. The pressure applied should be about 20 mmHg below to systolic pressure, which affects the venous flow but maintain arterial flow to the distal part. Combination of the drugs was infused retrogradely with appropriate pressure. Wait upto 20 minutes and then cuff should be released.

Drugs used:

- Heparin – prevents intravascular thrombosis due to venous stasis.

- Sodium bicarbonate –prevents local acidosis and helps in painless injection
- Lignocaine- reduction of vascular tone and increases perfusion
- Specific antibiotics- based on culture and sensitivity.

Advantages :

According to El Sarky Mel s et al study , the retrograde venous perfusion does not cause cellular damage to blood and lymphatic vessels.

In Siedel, Jochmann etall, Brunner M Goring study, the drug concentration in retrograde venous perfusion is 2.5-7 times than that of systemic venous infusion and 3 times than that of inta-arterial route.

In Buhler singer S, Hiller D et al study, retrograde venous perfusion proven that the retrograde venous perfusion improves the cutaneous microcirculation in diabetic patients, by shifting blood flow to superficial nutritive capillaries.

In Langer K, Partsch et al study the retrograde venous perfusion perfusion reduces the time of therapy, which is associated with

decreased compliance, cumulative increase in cost, loss of working hours and compromised quality of life.

Disadvantage:

The common problem in retrograde venous perfusion therapy is cannulation of vein in ischaemic limbs, rashes during the course of treatment, mild pain in the limb during the infusion of drugs and inflation of the cuff, which subsides onces the cuff is released.

MATERIALS AND METHODS OF MY STUDY

AIM & OBJECTIVE

To study the comparative study on the role of retrograde venous perfusion therapy and systemic antibiotic therapy in the treatment of diabetic ulcer foot in GRH, Madurai.

INCLUSION CRITERIA

- Patients more than 25 years of age groups in both sexes presenting with diabetic ulcer.
- Patients consented for inclusion in the study according to designated proforma
- Wagner's classification- ulcer of Grade 0,1,2

EXCLUSION CRITERIA

- Patients less than 25 years of age.
- Osteomyelitis.
- Patient not consented for inclusion in the study
- Arterial and venous doppler study with abnormal study
- Patient not consented for inclusion in the study.

STUDY AREA

Govt Rajaji Hospital, Madurai.

STUDY PERIOD

January 2018 to January 2019

- **Source of data :** All patients diagnosed to have diabetic ulcer , who also come under the inclusion criteria.
- **Method of collection of data :** Details of cases, Full history, Clinical Examination, Dimensions of the ulcer

First of all the affected area will be assessed and a photograph will be taken , Pus culture and sensitive to be rule out , based on which antibiotics to be used then RVP with Drug I.V. Antibiotics(eg.Cefotaxim 1 gm, Gentamycin 80 mg), Heparin 2500 unit and 2% lignocaine with adrenaline 0.4 ml in 100 ml of normal saline will be given intravenously to the affected limb daily upto six days. Again photograph will be taken. Another 6 dosage will be given after the interval of 1 week and photograph of the affected limb to be taken. If needed, another course of same therapy will be given after interval of 6 weeks. Sensitivity to Lignocaine will be checked. Patient will be made to lie in supine position. The affected limb will be elevated for 5

minutes to empty the veins then cuff of sphygmomanometer was applied on thigh. The pressure applied by it was about 20 mmHg below to systolic pressure, which hamper venous flow but maintain arterial flow to the distal part. Combination of the drugs was infused retrogradely with pressure. We need to wait upto 20 minutes and then cuff will be released.

The Assessment of RVP THERAPY

The outcome is based on Reduction in size of the wound and amount of exudate along with healing time will be noted and with those derived from conventional methods.

OBSERVATIONS AND RESULTS

The 100 patients admitted for the study were divided into two equal and comparable groups. Patients subjected to retrograde venous perfusion therapy were classified under study and those who underwent systemic antibiotic therapy with dressing were classified as control.

Table 1: Sex wise distribution of patients.

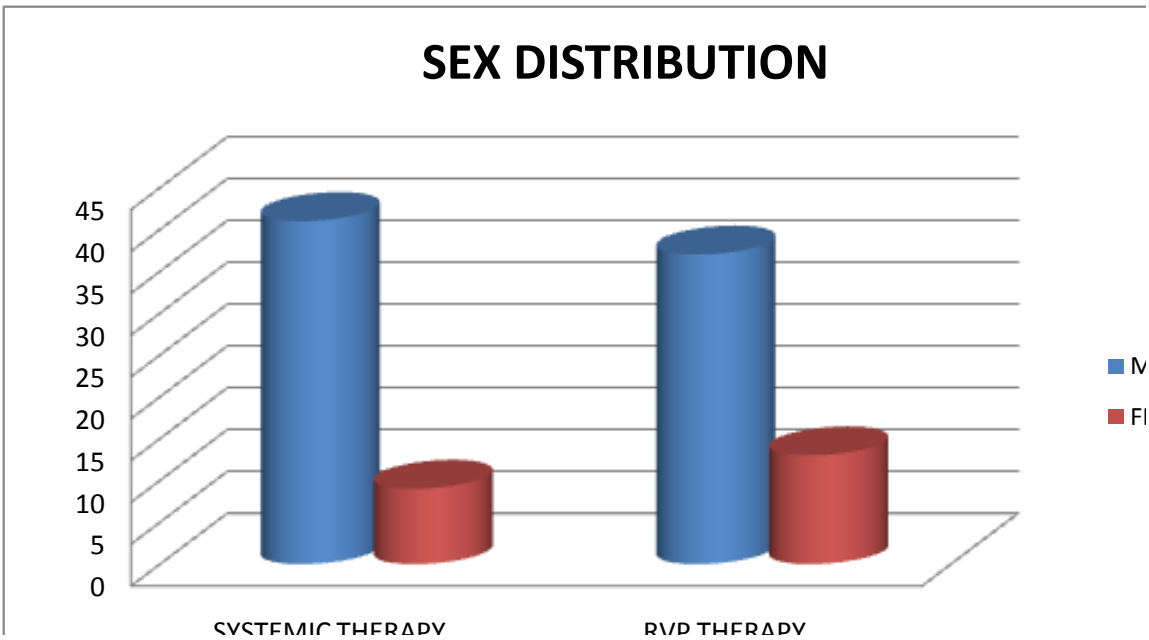
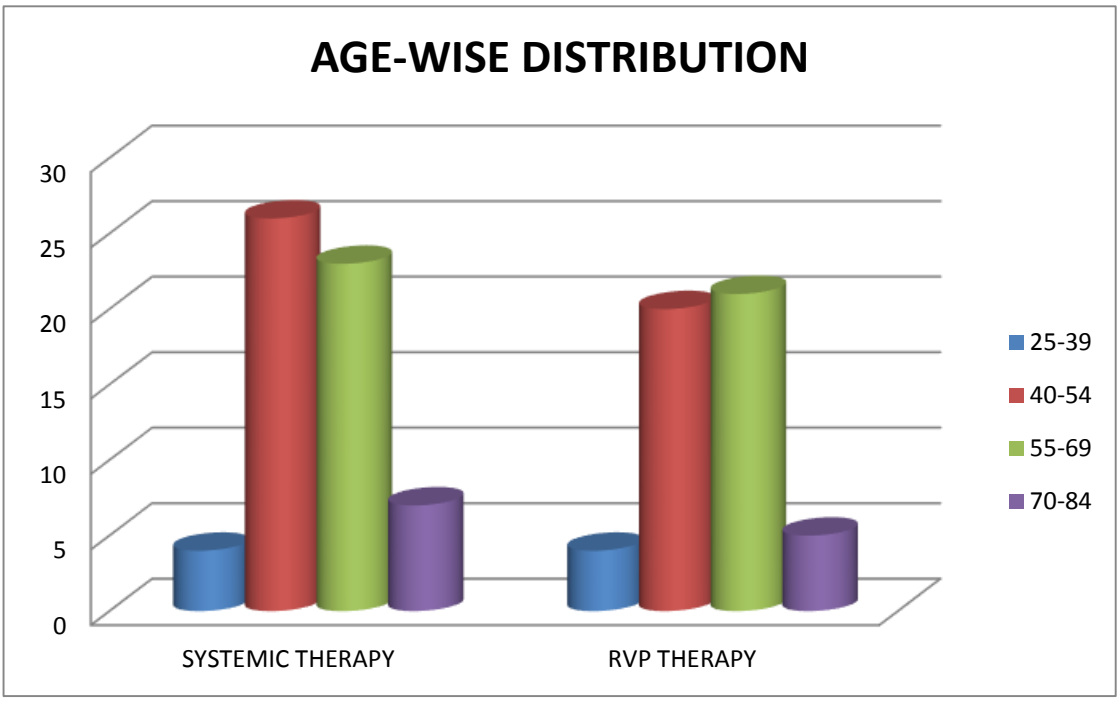


Table 2: Age-wise distribution



AGE (YRS)	25-39	40-54	55-69	70-84
SYSTEMIC ANTIBIOTIC THERAPY	4	26	23	7
RVP THERAPY	4	20	21	5

AGE	N	MEAN	MEDIAN	STD.DEVIATION	t VALVE	p VALVE
SYSTEMIC ANTIBIOTIC THERAPY	50	55.8	55	10.83645		
RVP THERAPY	50	54.54	55	11.00317	0.576916	0.56533

significance level	p valve	AGE
0.01	0.56533	not significant
0.05	0.56533	not significant
0.1	0.56533	not significant

Mean age of systemic antibiotic therapy group is 55.8

Mean age of RVP therapy group is 54.54

P value is 0.56533 . not significant

Table 3 :Wagner's grading distribution

WAGER'S	GRADE 1	GRADE 2
SYSTEMIC ANTIBIOTIC THERAPY	33	17
RVP THERAPY	18	42

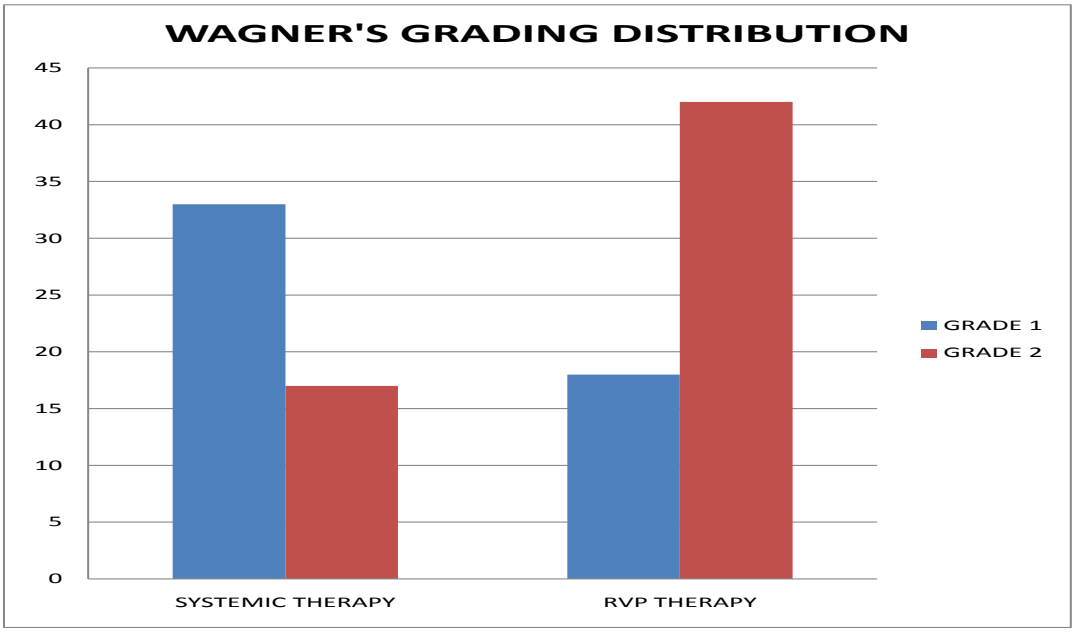
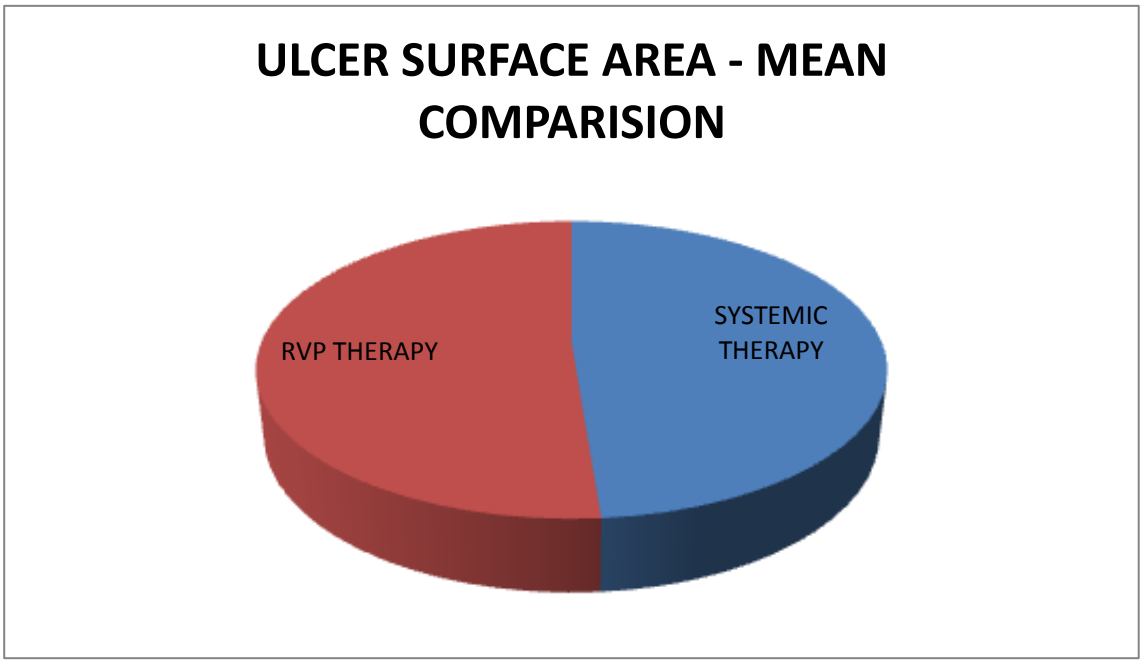


Table 4: Ulcer surface area

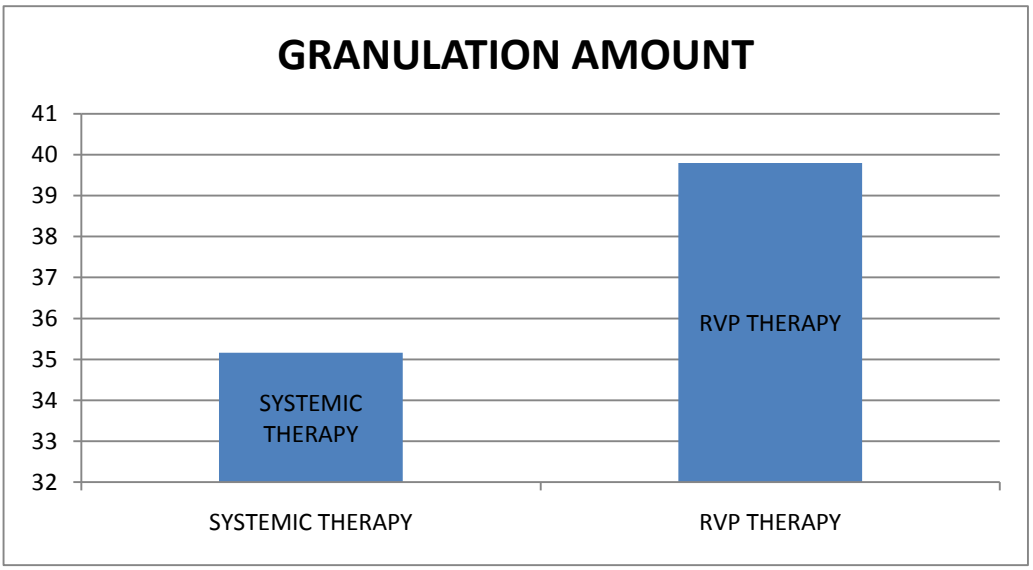


ULCER SURFACE AREA	N	MEAN	MEDIAN	STD.DEVIATION	t VALVE	p VALVE
SYSTEMIC ANTIBIOTIC THERAPY	50	38.5489	39	5.4668		
RVP THERAPY	50	40.5102	40.2	3.1418	2.1993	0.30208

significance level	p valve	ulcer surface area
0.01	0.30208	not significant
0.05	0.30208	Significant
0.1	0.30208	Significant

The mean ulcer surface area in control group is 38.54 cm^2 ± 5.466 SD and in the study group is 40.51 cm^2 ± 3.141 SD. The ulcer surface area is measured twice using butter paper.

TABLE 5: Amount of granulation tissue formation as percentage of ulcer surface area



AMOUNT OF GRANULATION	N	MEAN	MEDIAN	STD.DEVIATION	t VALVE	p VALVE
SYSTEMIC ANTIBIOTIC THERAPY	50	35.162	37.1	7.348		
RVP THERAPY	50	39.7978	39.8	2.894	4.1506	0.000071

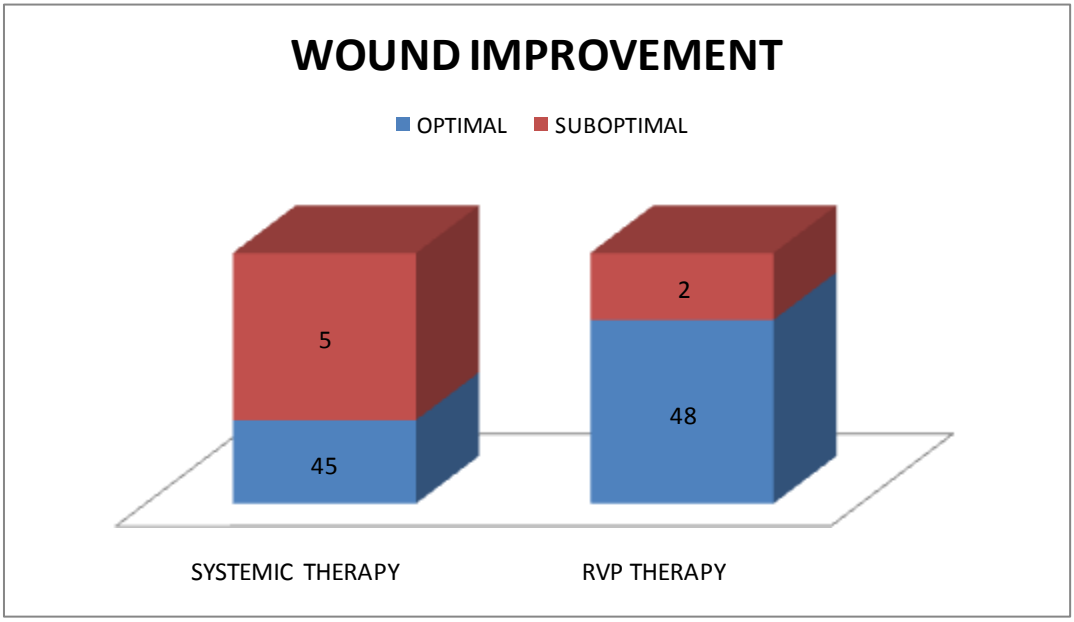
significance level	p valve	Granulation amount
0.01	**0.000071**	**Significant**
0.05	**0.000071**	**Significant**
0.1	**0.000071**	**Significant**

The mean amount of granulation tissue formation in

Systemic antibiotic therapy group is 35.162 cm2 $\pm$ 7.348 (SD) of total ulcer surface area and in RVP therapy is 39.7878 $\pm$ 2.894 (SD) of total ulcer surface area.

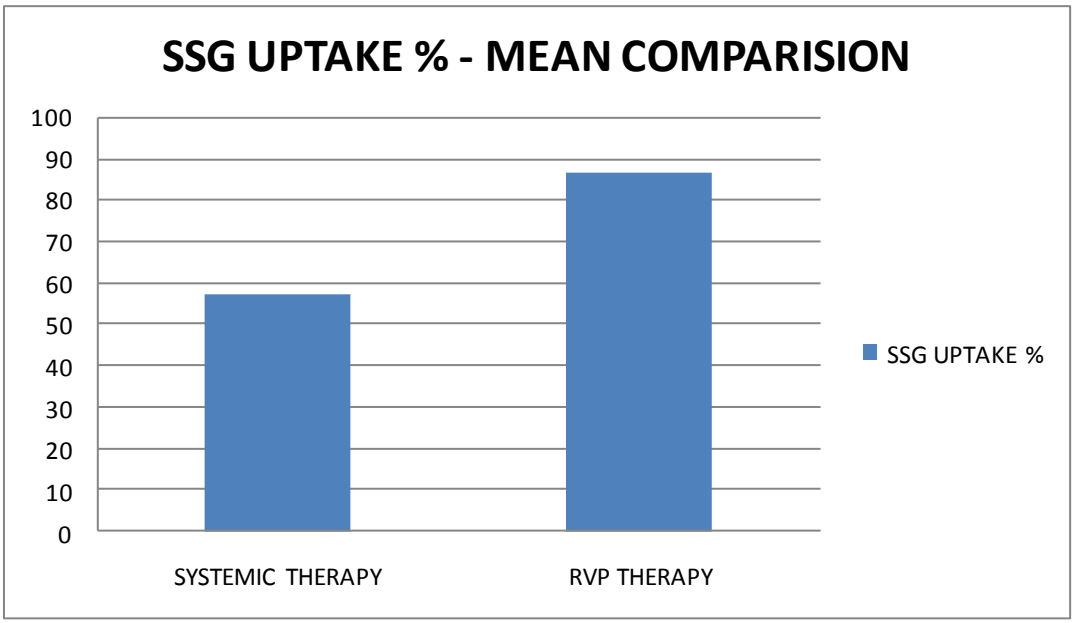
Table 6 : Wound improvement

WOUND IMPROVEMENT	OPTIMAL	SUBOPTIMAL
SYSTEMIC ANTIBIOTIC THERAPY	45	5
RVP THERAPY	48	2



The wound improvement in systemic antibiotic therapy only 90% whereas in RVP therapy it is about 96%

TABLE 7: SSG % uptake in granulated area

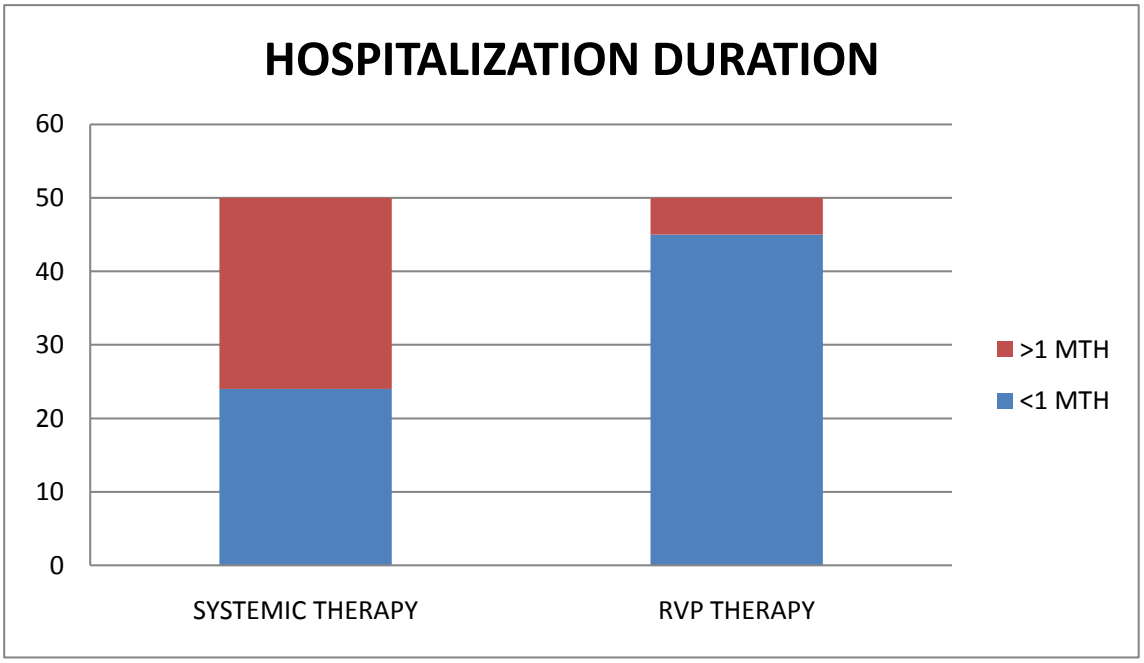


SSG% UPTAKE	N	MEAN	MEDIAN	STD.DEVIATION	t VALVE	p VALVE
SYSTEMIC ANTIBIOTIC THERAPY	45	57.4	56	21.6379		
RVP THERAPY	48	86.437	88	8.2922	8.429	0.00001

significance level	p valve	Ssg uptake %
0.01	**0.00001**	**Significant**
0.05	**0.00001**	**Significant**
0.1	**0.00001**	**Significant**

Assessment of graft uptake was done at the end of POD 5 as percentage of ulcer surface area. The mean graft uptake in the study group is 86.43% $\pm$ 8.29 (SD) and in the control group is 57.4% $\pm$ 21.63 (SD).

TABLE 8: Hospitalized duration :



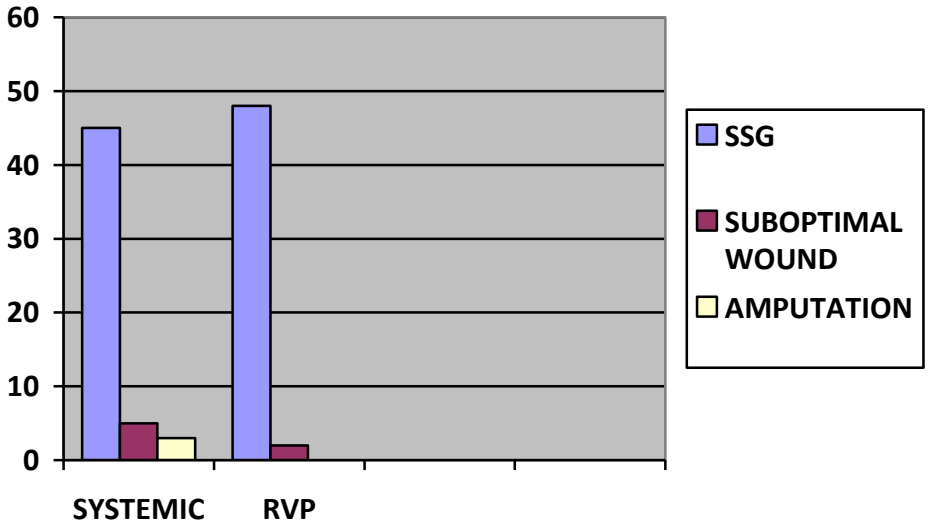
HOSPITALIZATION	N	MEAN	MEDIAN	STD.DEVIATION	t VALVE	p VALVE
SYSTEMIC ANTIBIOTIC THERAPY	50	31.8	30	4.6335		
RVP THERAPY	50	27.565	28	2.682	5.5931	<0.00001

significance level	p valve	Hospitalization
0.01	**<0.00001**	**Significant**
0.05	**<0.00001**	**Significant**
0.1	**<0.00001**	**Significant**

The quality of life of the patient in both the groups was assessed by the assessment of total hospital stay as number of days of admission in the hospital. The mean hospital stay in the control group was 31.8 +4.63 (SD) days and that in the study group was 27.56 + 2.68 (SD) days. P value is <0.00001 which is significant.

Table 9: Amputation %

	SYSTEMIC ANTIBIOTIC THERAPY	RVP THERAPY
SSG	45	48
SUBOPTIMAL WOUND	5	2
AMPUTATION	3	-



The percentage of amputataion in RVP therapy is zero when compared with that of systemic antibiotic therapy with 6%

The main postoperative parameters noted in both the groups:

- Wound size
- Contracture
- Pain
- Infection

All these parameters were less in the study group when compared with the control group.

ANALYSIS OF DATA

Both the groups had comparable age and sex distribution as depicted in the graphs above.

The mean amount of granulation tissue formation in study group is 39.797 cm^2 of total ulcer surface area and in control group is 35.162cm^2.the results were analyzed by unpaired student t test which showed highly significant difference in the rate of granulation tissue formation ($p<0.00007$). The mean graft uptake in the study group is 86.437% and in the control group is 57.4%. The results were analyzed by unpaired student t-test which showed highly significant difference in graft uptake (p of 0.0001). The total number of days of hospital stay was also compared. The mean number of days of hospital stay in the control group was 31.8 and that in the study group was 27.5 days. The results were analyzed by unpaired student t-test which showed highly significant difference in the number of days of hospital stay ($p< 0.0001$).

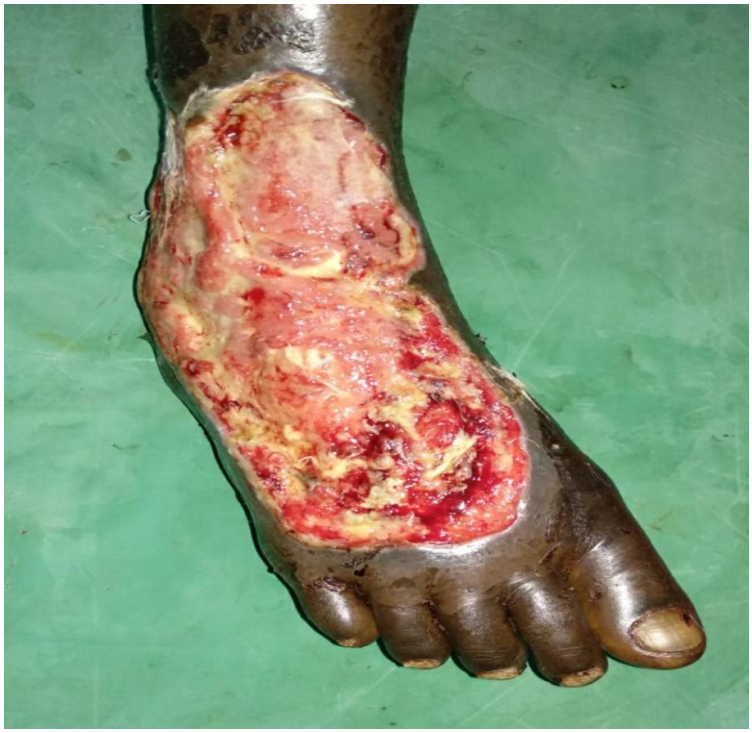


Fig 13 : Diabetic ulcer

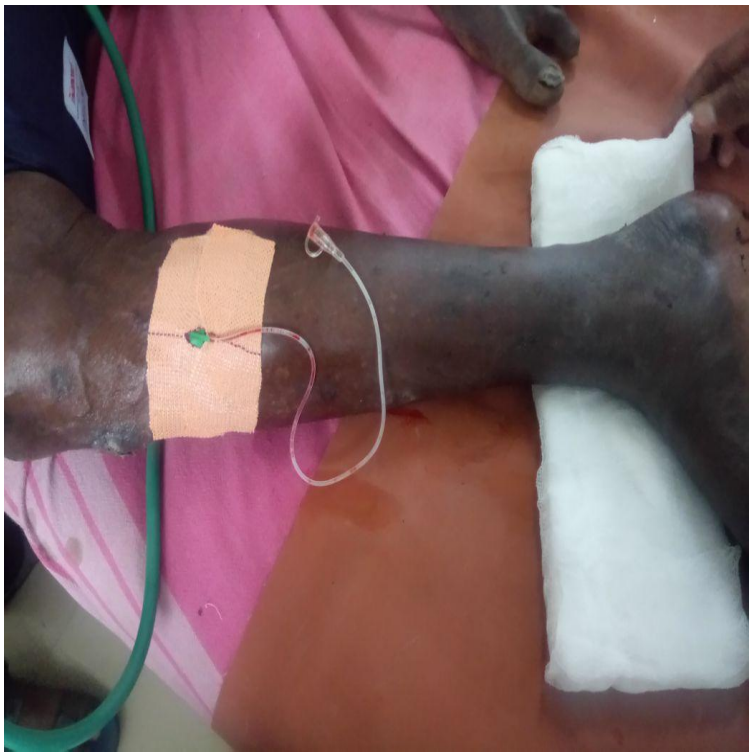


Fig 14: Cannulated vein

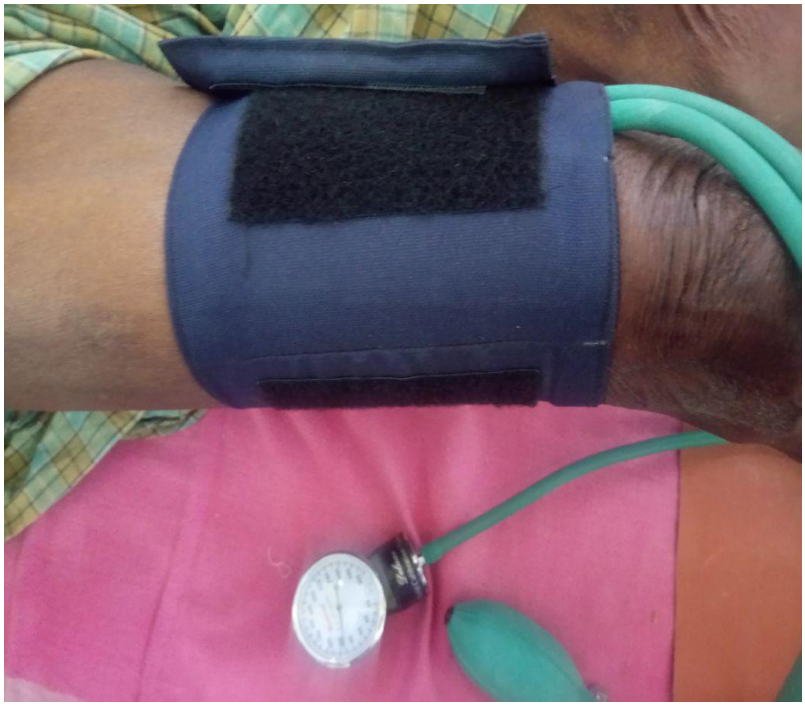


Fig 15 : Pressure maintenance with sphygmomanometer

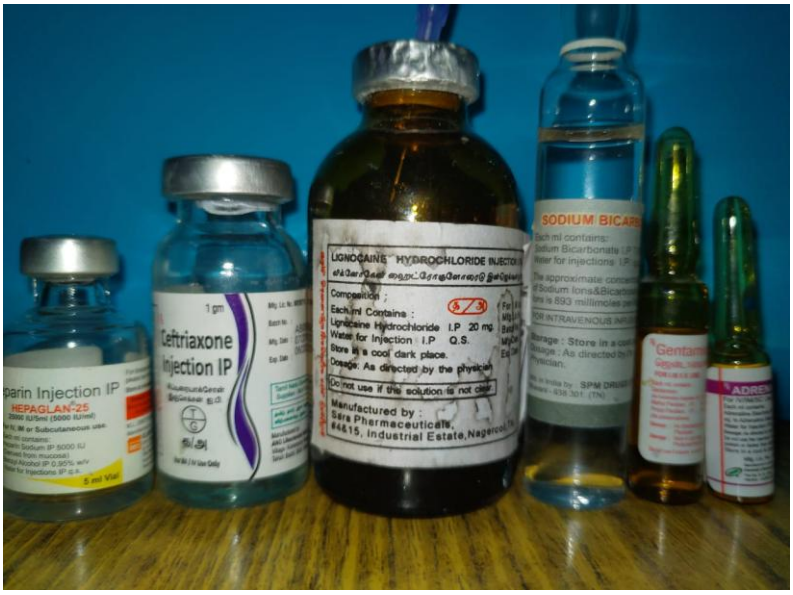


Fig16 : Composition of RVP therapy solution

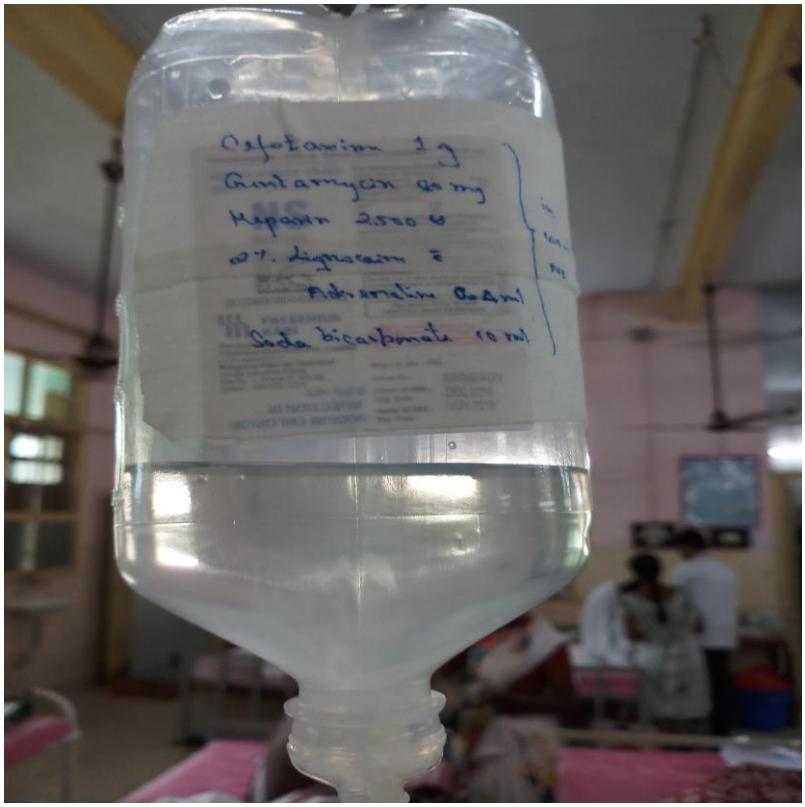


Fig17 : RVP therapy solution

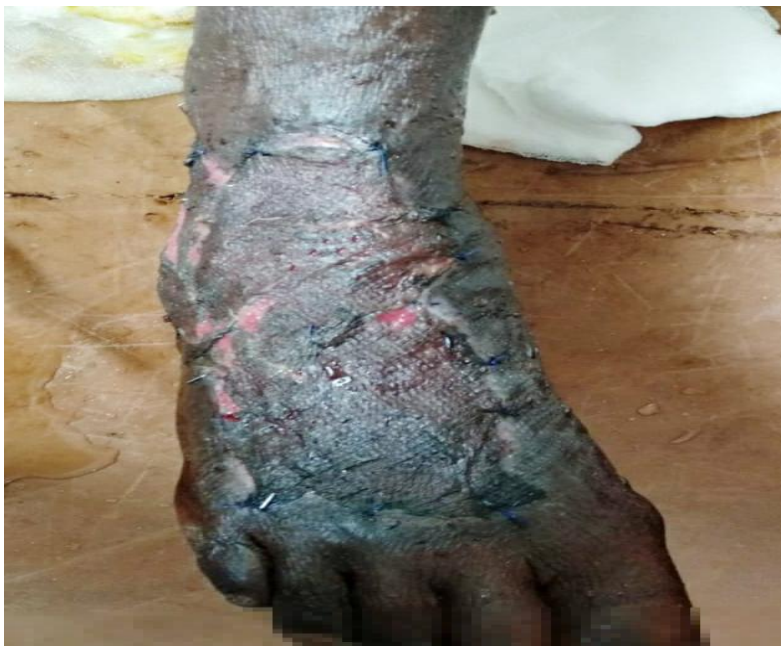


Fig18 : SSG uptake (1st look)

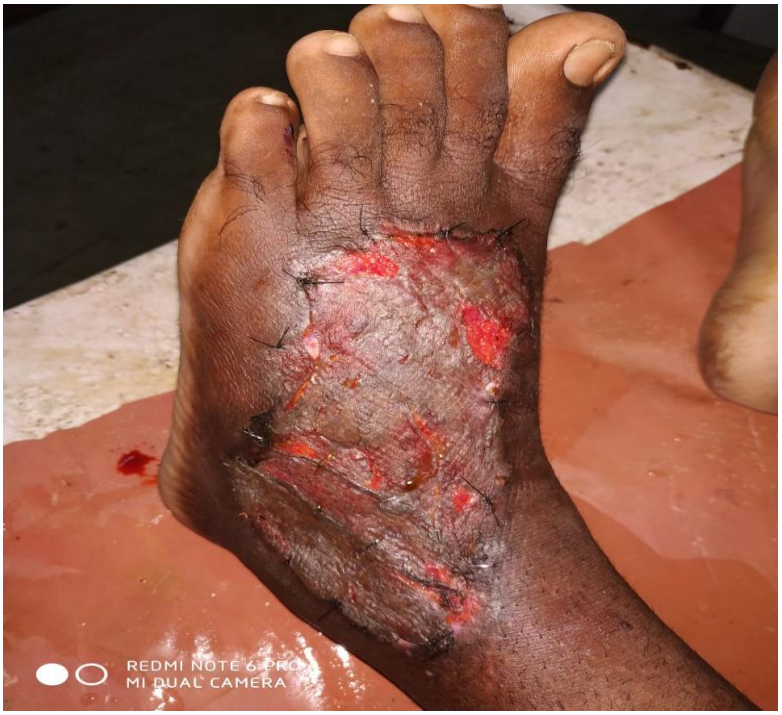


Fig19 : SSG uptake (2nd look)

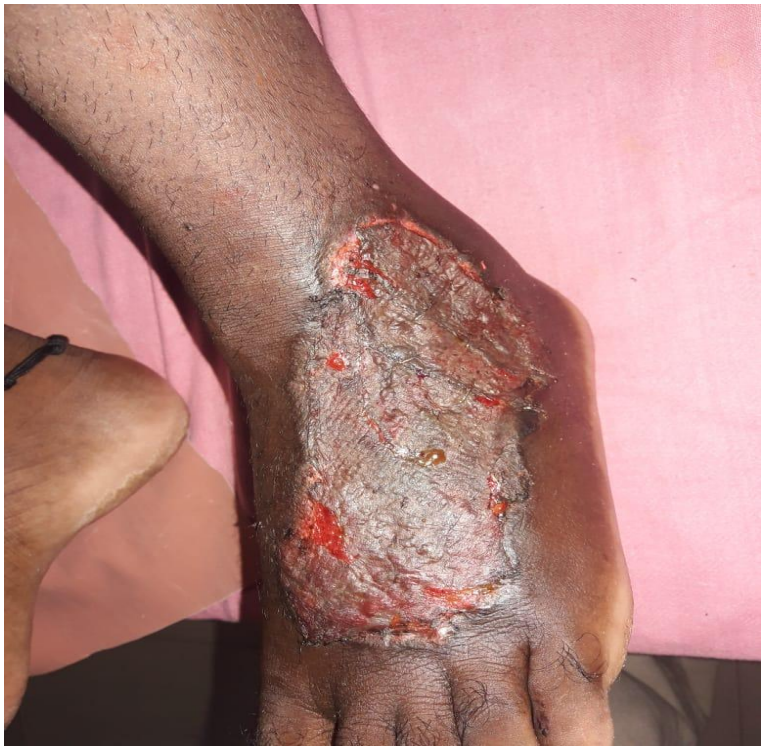


Fig20 : SSS uptake (3rd look)

CONCLUSION

Thus retrograde venous therapy has significant advantages than that of systemic antibiotic therapy.

- RVP therapy significantly reduces the size of ulcer.
- RVP therapy improves the amount of granulation tissue formation.
- RVP therapy improves SSG uptake also.
- RVP therapy reduces the duration of stay at the hospital.
- RVP therapy brings down the rate of amputation.

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PROFOMA

Name:

Age:

Sex:

IP No:

Date of admission:

Date of discharge:

Duration:

DM: Y/N

Alcoholic: Y/N

Co- morbid medical conditions:

History of present ulcer:

Examination of ulcer:

Site:

Size:

Shape:

Margin:

Floor:

Base:

Vascular status:

Skin:

Pulse:

Investigations:

Hb: TC: DC: Blood Group:

FBS/PPBS:

Blood urea/ Sr creatinine:

ECG:

Doppler profile:

Xray:

Viral markers:

Treatment:

Antibiotics (if any):

Insulin dosage:

Any OHA:

Treatment before RVP:

RVP:

No of application:

S No.	DATE OF APPLICATION	DATE OF REMOVAL

After RVP:

Granulation tissue: Y/N

Exudate:

Plan after RVP:

CONSENT FORM

ஆராய்ச்சிதகவல்அறிக்கை

மதுரைஅரசு இராசாசி மருத்துவமனையில் வரும் நோயாளிக்குள் ஒருஆராய்ச்சி இங்கு நடைபெற்றுவருகிறது. நீங்களும் இந்த ஆராய்ச்சியில்பங்கேற்கவிரும்பிகிறோம்

.

உங்களை சில சிறப்புபரிசோதனைக்கு உட்படுத்தி அதன்தகவல்களை ஆராய்வோம்.அதனால் தங்களது நோயின் ஆய்வரிகையோ அல்லது சிகிச்சையோ பாதிப்பு ஏற்படாது என்பதை தெரிவித்து கொள்கிறேன் .

முடிவுகளைவெளியிடும்போதுஅல்லதுஆராய்ச்சியின்போதோதங்களதுபெயரோஅல்லதுஅடையாளங்களோவெளியிடமாட்டோம்என்பதை தெரிவித்து கொள்கிறோம் .

இந்தஆராய்ச்சியில் பங்கேற்பதுதங்களுடையவிருப்பத்தின்பேரில்தான்நடக்கும் . மேலும்நீங்கள்எந்நேரமும்இந்தஆராய்ச்சியில்இருந்துபின்வாங்கலாம்என்பதையும் தெரிவித்துகொள்கிறோம்.

இந்தசிறப்புபரிசோதனைமுடிவுகளைஆராய்ச்சியின்போது அல்லதுஆராய்ச்சியின்முடிவின்போதுதங்களுக்குஅறிவிப்போம்என்பதையும்தெரிவித்துகொள்கிறோம்.

ஆராய்ச்சியாளரின் கையொப்பம் பங்கேற்பாளர் கையொப்பம்

MASTER CHART

S No	NAME	AGE	SEX	WAGNER'S classification	NO OF DAYS OF HOSPITAL STAY	TYPE OF TREATMENT	ULCER AREA	GRANULATION AREA	WOUND IMPROVEMENT	SSG UPTAKE	AMPUTATION
1	VELUCHAMY	38	M	2	33	S	30.9	22.3		51	
2	SELVAM	52	M	1	37	S	44.3	44.2		50	
3	SELVARAJ	65	M	2	35	S	38.4	37.6		81	
4	MAHESHWARI	65	F	2	41	S	44.1	12.8	SUBOPTIMAL		yes
5	HARIHARAN	62	M	2	43	S	37.1	35.9		75	
6	ARUMUGAM	58	M	2	30	S	39.6	37.1		56	
7	MUTHUPECHI	52	F	1	31	S	38.7	37.1		76	
8	PUSHPA	55	F	1	29	S	42.1	41.5		72	
9	MUNISWARI	70	F	1	32	S	43.8	41.9		71	
10	SURESH	50	M	1	34	S	28.7	25.7		27	
11	FATHIMA	55	F	2	38	S	30.3	18.5	SUBOPTIMAL		
12	VANITHA	40	F	1	29	S	37.4	39.5		34	
13	JOSEPH	48	M	1	40	S	38.6	34.3		35	
14	KASIRAM	42	M	1	32	S	43.7	43.2		39	
15	RAM	62	M	2	35	S	39.7	37.6		40	
16	DHARMAR	60	M	2	30	S	42.6	40.1		42	
17	ISAMMA	73	F	1	32	S	36.7	35.2		29	
18	SAROJA	55	F	1	30	S	51.1	45.4		54	
19	MUTHUPECHI	32	F	2	38	S	32.6	25.1	SUBOPTIMAL		
20	SEKHAR	72	M	1	32	S	26.3	24.1		95	
21	NARAYANAN	76	M	1	25	S	29.1	27.6		97	
22	IMRAN	72	M	1	28	S	42.4	39.1		82	
23	USMAN MOHD	58	M	1	42	S	45.5	40.7		79	
24	JOHN	54	M	2	30	S	36.1	35.4		81	
25	KUMAR	46	M	2	28	S	39.4	37.5		89	
26	VINCENT	54	M	1	26	S	32.3	30.1		20	
27	MUNIYAMMA	71	M	1	25	S	37.1	35.9		75	
28	KUMARASAMY	34	M	1	28	S	36.7	34.7		67	
29	MALAISAMY	58	M	1	26	S	40.1	39.1		56	
30	SUBRAMANI	60	M	1	42	S	43.5	41.8		57	
31	KALYANASUNDARAM	58	M	1	30	S	38.1	36.4		59	
32	AKBAR PASHA	49	M	1	28	S	41.6	41.1		69	
33	HUSSAIN	54	M	1	29	S	33.7	30.3		82	
34	MARIMUTHU	31	M	1	28	S	39.3	30	SUBOPTIMAL		yes
35	KHAJA MOHIDEEN	58	M	1	35	S	25.3	23.6		90	

36	SUDHAN	62	M	2	30	S	29.4	20.1	SUBOPTIMAL		yes
37	SOMASUNDARAM	68	M	2	30	S	38.6	37		39	
38	KRISHNAN	54	M	2	32	S	40.9	39.2		42	
39	VEERAPPAN	55	M	1	30	S	44.6	42.7		39	
40	MANIKANDAN	45	M	1	26	S	41.9	40.2		48	
41	JANAKIRAM	60	M	1	28	S	42.7	41.2		42	
42	MATHEW	74	M	1	32	S	32.2	29.6		43	
43	GANESAN	48	M	1	28	S	36.4	33.2		32	
44	PERIYASAMY	47	M	1	28	S	35.4	32.9		21	
45	BABU	48	M	1	35	S	40.3	37.6		45	
46	JEYAMANI	52	M	2	32	S	42.7	39.1		30	
47	MOHD SHEIK	50	M	2	38	S	37.7	37.1		39	
48	RAJENDIRAN	58	M	2	30	S	43.6	40.7		70	
49	CHELLAPANDIAN	62	M	1	28	S	44.5	43.8		78	
50	MANIMARAN	68	M	1	32	S	42	41.3		85	
51	PALRAJ	52	M	2	30	RVP	41.6	40.2		94	
52	HARIHARAN	38	M	2	23	RVP	43.1	42.6		92	
53	VIKRAM	50	M	2	27	RVP	43.2	42.6		81	
54	KAMALA	60	F	1	26	RVP	40.2	39.8		80	
55	ANDICHI	58	F	2	23	RVP	37.2	36.9		89	
56	MANGALAPANDIAN	65	M	1	21	RVP	45.6	43.7		88	
57	KALASIAMMAL	62	F	2	32	RVP	35.4	35.1		85	
58	JEGANATHAN	55	M	1	30	RVP	35.2	36.6		89	
59	RAMAYEE	52	F	2	28	RVP	38.5	38		81	
60	VIGNESHWARI	52	F	2	23	RVP	41.7	40.6		81	
61	CHELLAPANDIAN	62	M	1	25	RVP	42.8	42.1		40	
62	SHEIK MOHD	64	M	2	30	RVP	44.6	44.7		90	
63	PRAKASHRAJ	38	M	2	28	RVP	42.S	41.8		86	
64	NAGESH KUMAR	57	M	2	30	RVP	43.7	47.1		83	
65	SHAHUL KHAN	52	M	2	28	RVP	36.8	36.1		79	
67	JOSEPH	60	M	1	26	RVP	39.4	38.6		97	
68	CHOKKALINGAM	52	M	1	25	RVP	40.1	39.S		96	
69	ABDUL SALEEM	36	M	2	23	RVP	49.1	41.2	SUBOPTIMAL		
70	MUNIYASAMY	69	M	2	26	RVP	39.4	37.6		100	
71	SENTHIL	40	M	2	27	RVP	41.1	39.6		95	
72	VAIRAVAN	32	M	2	25	RVP	43	41.9		94	
73	IRULAYEE	40	F	1	27	RVP	42.7	41.9		93	
74	YASHODAKUMARI	42	F	1	28	RVP	43.1	42.8		92	
75	MUNIYASAMY	62	M	2	26	RVP	42.5	41.1		91	
76	SETHURAMAN	75	M	2	30	RVP	40.6	39.3		87	
77	MUTHUPANDI	60	M	1	26	RVP	36.7	35.4		89	
78	VASUKI	72	F	2	32	RVP	38.4	37.2		88	
79	MOHD ALI	79	M	1	25	RVP	37.4	36.S		85	
80	MARIMUTHU	42	M	2	28	RVP	42.7	41.8		84	

81	PALRAJ	70	M	2	32	RVP	38.1	38		88	
82	RAMARAJAN	68	M	1	25	RVP	40.5	39.6		82	
83	ANBARASAN	79	M	2	28	RVP	36.7	36.1		83	
84	NARAYANANI	45	F	2	26	RVP	39.7	39.2		88	
85	HASARABEGUM	45	M	2	28	RVP	40.1	39.9		89	
86	KANNAN	62	M	2	26	RVP	42.6	41.9		88	
87	SULAIMAN	55	M	2	28	RVP	43.6	42.7		87	
88	RAJI	47	F	1	28	RVP	43.2	42.2		85	
89	SUSAIRAJ	57	M	1	30	RVP	36.5	36.1		84	
90	KISHORE	42	M	2	28	RVP	37.4	36.6		88	
91	DHANUSHA	50	F	2	28	RVP	44.6	43.3		87	
92	AROKIYAMARY	55	F	2	30	RVP	46.7	44.1	SUBOPTIMAL		
93	IBRAHIM	48	M	1	32	RVP	42.3	42.1		83	
94	MARUTHUPANDI	58	M	2	28	RVP	37.1	36.4		88	
95	JEGANNATH	52	M	2	32	RVP	39.4	38.8		87	
96	KARUPANAN	56	M	1	28	RVP	40.6	39.9		84	
97	CHANDRASEKHAR	58	M	1	30	RVP	35.2	34.6		81	
98	MADHINABEGUM	52	F	1	23	RVP	39.7	38.1		83	
99	KAMALANATHAN	55	M	2	28	RVP	37.4	36.8		88	
100	ARJUNAN	53	M	2	30	RVP	39.7	39.S		88	

ABBREVATIONS USED

NPWT : negative pressure wound therapy.

HD : hydrodebridement.

RVP : retrograde venous perfusion

GRAN AREA: area of granulation tissue.

SSG : Split Skin Graft uptake

S : Systemic antibiotic

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ETHICS COMMITTEE CERTIFICATE

Name of the Candidate	:	Dr.D.Gowthin
Course	:	PG in MS., General Surgery
Period of Study	:	2017-2020
College	:	MADURAI MEDICAL COLLEGE
Research Topic	:	Comparative study on role of retrograde venous perfusion therapy and systemic antibiotic therapy in treatment of diabetic ulcer foot in GRH, Madurai
Ethical Committee as on	:	23.01.2018

The Ethics Committee, Madurai Medical College has decided to inform that your Research proposal is accepted.

Member Secretary Chairman Dean / Convenor

Prof Dr V Nagaraajan
M.D., MNAMS, D.M., Dsc.,(Neuro), Dsc (Hon)
CHAIRMAN
IEC - Madurai Medical College
Madurai

DEAN
Madurai Medical College
Madurai-20

10 APR 2018

URKUND

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Submitted:	17/10/2019 08:45:00
Submitted By:	gowthin@gmail.com
Significance:	3 %

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