A Dissertation on

COMPARISON OF EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY Vs CONVENTIONAL NORMAL SALINE DRESSING IN DIABETIC FOOT

Submitted to

THE TAMILNADU Dr. M.G.R MEDICAL UNIVERSITY

CHENNAI

in partial fulfillment of the regulations
for the award of the degree of

M.S BRANCH-I

GENERAL SURGERY

GOVT.STANLEY MEDICAL COLLEGE & HOSPITAL

CHENNAI – TAMILNADU

APRIL - 2017

CERTIFICATE

This is to certify that this dissertation entitled "**COMPARISON OF EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY Vs CONVENTIONAL NORMAL SALINE DRESSING IN DIABETIC FOOT"** submitted **by DR.RAJA CHANDRASEKAR.M** to the Tamilnadu Dr. M.G.R medical University is in partial fulfillment of the requirement of the award of M.S DEGREE (BRANCH-I) and is a bonafide research work carried out by him under direct supervision and guidance.

Signature of the Unit Chief **Signature of HOD**

DR.A.K.RAJENDRAN.D.ORTHO.,M.S., **DR.D.NAGARAJAN.M.S.,**

Signature of the dean

DECLARATION

I solemnly declare that the dissertation entitled "**COMPARISON OF EFFICACY OF NEGATIVE PRESSURE WOUND THERAPY Vs CONVENTIONAL NORMAL SALINE DRESSING IN DIABETIC FOOT"** was done by me at the Government Stanley Medical College and Hospital during APRIL - SEPTEMBER 2016 under the guidance and supervision of **Prof. Dr. A.K. RAJENDRAN. D. Ortho., M.S.** The dissertation is submitted to the Tamilnadu Dr.M.G.R Medical University towards the partial fulfillment of requirement for the award of M.S. Degree (Branch-1) in General Surgery.

Place:

Date : **DR.RAJACHANDRASEKAR.M**

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IEC

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Title of the Work : Study on Comparison of efficacy of negative pressure wound therapy Vs conventional normal saline dressing in diabetic foot

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ANNEXURE

INTRODUCTION

1. INTRODUCTION

Negative Pressure Wound Therapy (NPWT) also called VAC [Vacuum Assisted Closure], Topical Negative Pressure Therapy (TNPT) or vacuum sealing is a modern surgical procedure, in which the vacuum assisted drainage is utilized to extract out blood or edema fluid from a wound or an operation site.

The new method of placing a wound to sub- atmospheric pressure for an increased period to induce healing and removal of exudative fluid was first described by Fleischman et al in 1993(1). Morykwas et al(2) in their seminar paper ,based on a series of experiments, reported that there was increase in blood flow at ~125mmHg that was equivalent to 4 times the of the baseline pressure .

Deva Boone et al (3), in their study conducted on a porcine infected wound model, showed that NPWT with either standard NPWT foam or silver NPWT foam caused noticeable improvements in local wound morphology, but this occurred inspite of having a high level of bacterial burden for an extended time," thus the healing that occurred in these wounds cannot be explained by a change in the bacterial load". Chester DL et al(4) recommended close surveillance of bacterial flora of

the wound, during the course of VAC treatment as they observed worsening of anaerobic infection with NPWT, which settled with antibiotics and cessation of NPWT.

This study was undertaken in Stanley Government Medical College and Hospital to compare the effect of NPWT and conventional saline dressing on duration of wound closure and reduction in the bacterial burden of the wound.

AIM OF THE STUDY

2. AIM OF THE STUDY

To compare the efficacy of negative pressure wound therapy (NPWT) and conventional saline dressing in patients with diabetic foot in the following aspects:-

(i) Duration of wound closure.

(ii) Reduction in the bacterial burden of the wound.

REVIEW OF LITERATURE

3. REVIEW OF LITERATURE

Dr.George D.Winter (5) [1927-1981] called as the Father of Moist Wound Dressing ,published his landmark Nature paper in 1962,where he concluded that , wounds that were kept in moist conditions healed well than dry wounds. This paper changed the previous ideas in wound dressing and enlightened the benefits of moist wound dressing.

3.1.CHRONIC WOUND:

Chronic wounds may never heal or do not heal within three months or may take several years to heal. Healing does not take place in a timely manner. Impaired and prolonged healing may be due to increase pressure, prolonged inflammation, poor nutrition, co-existing disease conditions and poor circulation. Lower extremity wounds are the most common types of chronic wounds ,their causal factors may be due to vascular (arterial, venous, mixed), pressure (trophic ulcers, bed sores) and neuropathy (eg: diabetic ulcers).

3.2.WOUND HEALING:

The body's response to tissue injury in a healthy individual is an inbuilt, sequentially arranged physiologic process that results in wound

healing with full re-epithelialization, resolution of drainage, and attainment of function to the affected tissue (6).The sequential phases of wound healing are hemostasis, inflammation, proliferation and tissue remodeling or resolution.

We cannot say that Chronic wounds will follow this cycle of events and can challenge the great talented clinician if the underlying factors that are affecting wound healing are not recognised earlier. Such wounds usually come across a state of pathological inflammation due to a delay in healing process. Most chronic wounds are ulcers associated with neuropathy, vasculopathy.(7)

3.3.FACTORS CAUSING IMPAIRED WOUND HEALING: (8)

LOCAL FACTORS:

- Hypoxia
- Infection
- Foreign Body
- Venous insufficiency.

SYSTEMIC FACTORS:

- Ischemia
- Diseases: Diabetes, jaundice, anemia, uremia, jaundice, hereditary healing disorders.
- Obesity
- Medications: steroids, NSAIDS, chemotherapy
- Alcoholism and smoking
- Immunocompromised conditions-cancer, radiation therapy, AIDS
- Poor nutrition.

3.3.1.HYPOXIA

Fibroblasts are oxygen sensitive. Collagen synthesis cannot take place at PO2<40mmHg.Low PO2 is the most common cause of wound infection. Wound healing is an energy dependent process. Endothelium response to hypoxia is vasodilatation and capillary leak causing fibrin deposition, TNF- α induction and apoptosis and impairing wound healing.(9)

3.3.2.INFECTION

Infection decreases tissue PO2 and prolongs the inflammatory phase of wound healing. There is impaired angiogenesis and epithelization along with increased collagenase activity.

3.3.3.EDEMA

Edema causes increased tissue pressure that compromises tissue perfusion leading to cell death and ulceration.

3.3.4.NUTRITION

Protein deficiency can result in decreased collagen production, angiogenesis and fibroblast proliferation, all affect wound healing. In addition, ingested proteins are metabolized into amino acids and peptides that serve as enzymes, hormones, cytokines, growth factors, and components of antibodies (10) (11)(12)

3.3.5.HYDRATION

A well hydrated wound epithelialize faster than dry wound. Occlusive wound dressings improves epithelial repair and improves proliferation of granulation tissue.

3.3.6.TEMPERATURE

Wound healing is fastened at an environmental temperature of 30^{o} C.Tensile strength is decreased by 20% in a cold wound environment.

3.3.7.RADIATION THERAPY

Ionizing radiation is not focussed solely on the cancerous tissue it was actually to do so . The radiation beam also cause effects on the nearby tissues (such as the epithelium that the radiation passes before reaching the cancerous tissues) by disintegration of the DNA and uncoupling of cell replication ideally essential for repair of tissue injury. Actively dividing cells are targetted and affected the most by the radiation. As a consequence, radiation-induced damage to the epithelium can result in skin breakdown, disturbance of tensile strength, atypical fibroblast formation and impairment of wound healing .

3.3.8.STEROIDS

Steroids stabilizes the lysosomes and arresting the inflammatory response (13).It inhibits both macrophages and neutrophils and interferes with fibrogenesis,angiogenesis and wound contraction.Steroids have a direct inhibitory effect on fibroblasts.(14)

3.3.9.SMOKING

Nicotine acts via sympathetic system causing vasoconstriction, thereby limiting distal perfusion. One cigarette is believed to cause vasoconstriction for more than eighty minutes (15).Smoking alters the proliferation of erythrocytes, fibroblasts and macrophages. High levels of carbon monoxide shifts the oxy-hemoglobin curve to the left causing decreased tissue oxygen.(16)

3.3.10.ALCOHOL

Alcohol intake affects wound healing by causing increased insulin resistance and hyperglycaemia. In addition, protein energy malnutrition is more commonly seen in alcoholics (17). The results include decreased inflammatory and immune responses to tissue injury, decreased fibroblast migration and angiogenesis, and decreased Type I collagen production and weaker scar tissue during remodeling. Thus there is slower healing and increased risk for recurrence with any mechanical force.(18)

3.3.11.OBESITY

An obese person hyperventilates because the descent of diaphragm is restricted because of the increased amount of adipose tissue. Hyperventilation and restricted chest expansion the decreased vital capacity and decreased oxygenation of blood are caused by hyperventilation and restricted chest expansion that affects tissue oxygenation (19). Inadequately oxygenated tissues nearby wound does not heal faster.(20)

Risk factors which increase patient susceptibility to infection

INTRINSIC FACTORS	EXTRINSIC FACTORS
1.Extremes of age: Children < 1 year and elderly >65 yerars	1.Drug therapy- steroids, cytotoxic drugs.
2.Underlying disorders-diabetes, hematological disorders, respiratory disorders	2.Break in the integrity of the skin in burns.
3.Smoking and alcohol	3.Presence of foreign bodies
4.Nutritional status of the patient.	4.Bypassing of defense mechanisms through devices eg.intubations.

3.4.BACTERIAL IMBALANCE IN CHRONIC WOUNDS:

All chronic wounds will contain some bacteria in them, inspite of bacterial presence, the wound healing process is occured. The Interaction of bacteria with host influence on chronic wound healing (21).Replicating microorganisms in a wound is called wound infection which affects wound healing. Because of that, wound infection should be recognized earlier. Factors that affect the bacterial burden of chronic wounds and increase the risk of infection are the growth of bacteria in the wound, their virulence.(22)

Synergy between micro organisms plays a role in wound healing process. Biofilm formation delays wound healing. Micro colonies are formed when bacteria profilerates, that become attached to the wound bed and secrete their glycocalyx or biofilm that shields microorganisms from antimicrobial action. The cluster of individual bacterial types or mixed colonies which may attain several changes express different genes and these factors alter the organism antimicrobial sensitivity.(23)

Persisitent infection is due to the periodic release of motile bacteria from the colonies. Biofilms are bacterial colonies that resist the effects of antimicrobial agents and can delay the wound healing.(24) (25)

Turner (26) (27) described the characteristics of ideal dressing as the dressing which removes excess toxins and exudates, provide high humidity at the wound bed essential for good gaseous exchange, protects against secondary infection, provide thermal insulation, causes no trauma during its removal and it is inert and safe to use.

3.5.TECHNIQUES TO HASTEN WOUND HEALING IN CHRONIC WOUNDS

3.5.1.TOPICAL OXYGEN THERAPY:

Topical oxygen heals open wound by providing pure oxygen to wound surface. This is an FDA approved non invasive and safe alternative for chronic wounds. Oxygen is delivered through portable, disposable for 90 minutes per treatment for four consecutive days per week and three days off treatment. This cycle is repeated until the wound is healed.(28) (29)

3.5.2.ELECTROSTIMULATION: (30)

Electrical current of above 1-50 mA pulsed or direct based on type of wound, applied to wounds accelerates migration of cells to the wound

bed. The changes caused by electrostimulation are 109% increase in collagen and 40% increase in tensile strength of the wound.

3.5.3.MIST THERAPY/APWT: (31)

The MIST therapy system is an evidenced based recent advancement in wound healing and new cell growth. In MIST therapy system a low frequency ultrasound generated MIST is used to accelerate wound healing through wound cleaning and debridement by the removal of slough, fibrin, tissue exudates and microorganisms. Acoustic pressure is used in MIST therapy to promote new cell growth and remove bacteria and so called as APWT(Acoustic Pressure Wound Therapy).The proliferation of cells will be at a faster rate when the cell walls of the cells are put under stress.

APWT is useful in removing biofilm which slows down the healing process in wounds. MIST therapy is painless, non contact, nonthermal procedure. It is included in one of the six products and one among the three devices approved by FDA.

The major drawback is high cost.

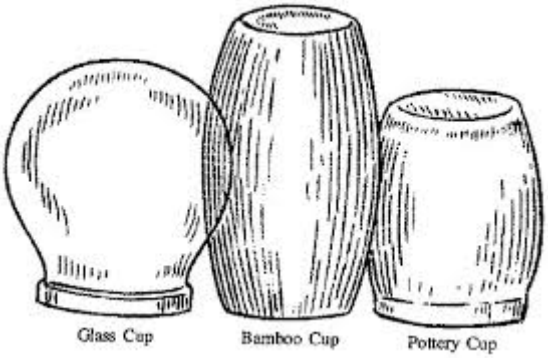
3.6.NPWT

NPWT otherwise known as VAC (Vacuum Assisted Closure), SPD (Sub Atmospheric Presssure), SSS (Sealed Surface Suction),TNP(Topical Negative Pressure) and VST(Vacuum Sealing Technique) is a alternative wound dressing system in which porous material is placed in the wound bed and enclosed with polyurethane films to create an air tight seal to which a vacuum machine is connected via tubes which creates intermittent or continuous negative pressure inside wounds. (32)

3.6.1.HISTORY OF NPWT

3.6.1a.CUPPING THERAPY

NPWT is a modern form of ancient Chinese alternative medicine-CUPPING THERAPY. A local suction is applied on the skin to increase blood flow in order to promote healing (33).Suction is created using heat(fire),electrical pumps. The Chinese practice of cupping dates back 1000 B.C.In 400 B.C Hippocrates used cupping for structural problems and internal disease, this method didn't attain popularity as it created temporary bruise, painful marks over the skin and it causes added risk of burns (34).The American Cancer Society has stated that scientific evidence does not support cupping for cancer or any other disease.



Materials used in Cupping Therapy

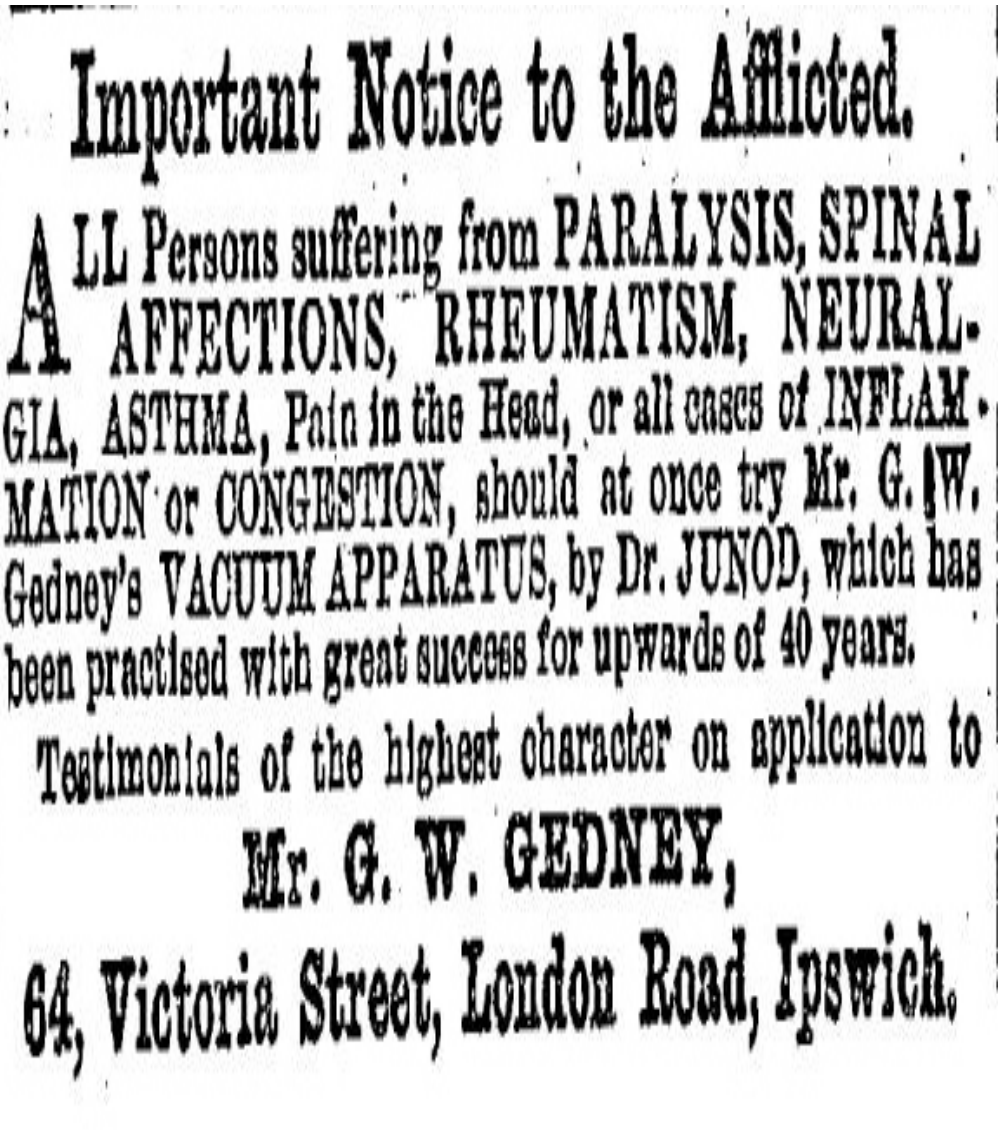
3.6.1b.JUNODS BOOT

"Junods Boot was developed by Victor Theodore Junod in 1830 and also called as haemospasic apparatus or exhausting apparatus."It was an alternative to blood letting and created supposed beneficial effects without blood loss. In The Journal of Health a description about Junods boot was stated as –a tin boot, into which the leg of the patient is inserted, and from which the atmospheric air is withdrawn by means of a small air pump, the top of the boot being kept in air-tight apposition to the leg, by means of a broad belt of vulcanized India rubber."

"The idea was like dry cupping on a larger scale – the blood would be sucked into the limb (the device could be also be used on the arm), therefore withdrawing it from general circulation, weakening the pulse and possibly even causing the patient to faint. This, Junod believed, would reduce fever and palliate any inflammatory conditions. The effects, while not gruesome, don't sound very pleasant: No pain, but only a slight uneasiness, is experienced in the limb enclosed in the boot, which is found, on being withdrawn, to be much increased in size, and the blood does not entirely return into the circulation, and the leg resumes its original size, at first for twenty-four hours. (Journal of Health)."

"The invention was popular in French hospitals and when it was displayed at the Great Exhibition, its potential to replace blood-letting resulted in it being tried out in British hospitals too, with mixed results. Army surgeon A. MacLean M.D. (quoted in The Medical Times, July-Dec 1853) was somewhat underwhelmed: have to report that this apparatus has been tried in a variety of cases in this hospital, with the view of testing its power as a therapeutic agent; and have to state that the beneficial results have been very partial, and in many instances no effect of a favourable character was obtained."

Dr Junod's Exhausting Apparatus



Important Notice to the Afflicted.

ALL Persons suffering from PARALYSIS, SPINAL AFFECTIONS, RHEUMATISM, NEURALGIA, ASTHMA, Pain in the Head, or all cases of INFLAMMATION or CONGESTION, should at once try Mr. G. W. Gedney's VACUUM APPARATUS, by Dr. JUNOD, which has been practised with great success for upwards of 40 years.

Testimonials of the highest character on application to

Mr. G. W. GEDNEY,

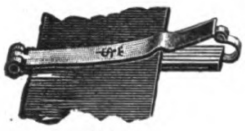
64, Victoria Street, London Road, Ipswich.

3.6.1C BIER'S HYPEREMIC TREATMENT: (35)

Bier's Hyperemic treatment was a brief and comprehensive manual of hyperemic treatment based on concepts described by Professor August Bier of Germany in 1890's.By applying suction apparatus the skin plus underlying tissues are sucked into the mouth of the glass creating increased blood supply not only into the surface but also into the deeper layers. Likewise NPWT came into exisistence since 1940s.The first device for NPWT was cleared by FDA in USA for marketing in 1997.

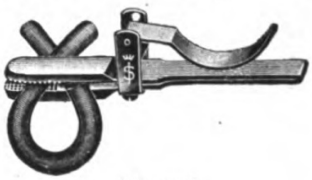
Dr. A. Bier's Vacuum Apparatus.

A.—Congestion Bandages and Clamps.



No. 103

Bandage and Clamp.
Price of Clamp,
$1.00.



No. 106

Tubing and Clamp.
Price of Clamp,
$2.50.

No. 107-108

Elastic Bandage for otitis.
No. 107—Elastic webbing **$0.40**
No. 108—Pure gum . **1.00**

Pure Gum Bandage..... 2½ in. wide, 9 ft. long.. **1.00**
3 in. wide, 9 ft. long.. **1.20**

B.—Suction Cups, with firmly attached bulb.

No. 110

For the gums.

Code: each.
Abba 2 sizes..**$0.60**

No. 110½

For stye

Code: each.
Abdi 2 sizes...**$0.60**

No. 111

For furuncle in the face.

Code: each.
Abgu 2 sizes..**$0.60**

No. 112

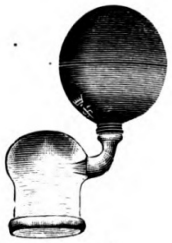
For furuncle on the lips.

Code:
Acfi Price.....**$0.65**

No. 113

For furuncle.

Code:
Adbe 1 inch.**$0.80**
Adci 1¼ inch. **0.95**
Addo 1½ inch. **1.15**



No. 113½

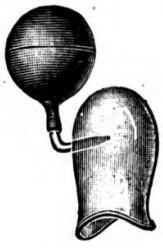
For furuncle.

Code:
Adfa 1 inch.**$0.95**
Adhu 1¼ inch. **1.15**
Afbi 1½ inch. **1.35**

No. 114

For high furuncle.

Code:
Afgo ¾ inch.**$0.95**
Afku 1¼ inch. **1.15**
Afda 1½ inch. **1.35**



No. 114½

For high furuncle.

Code:
Agca 1¼ inch.**$1.35**
Agge 1½ inch. **1.50**

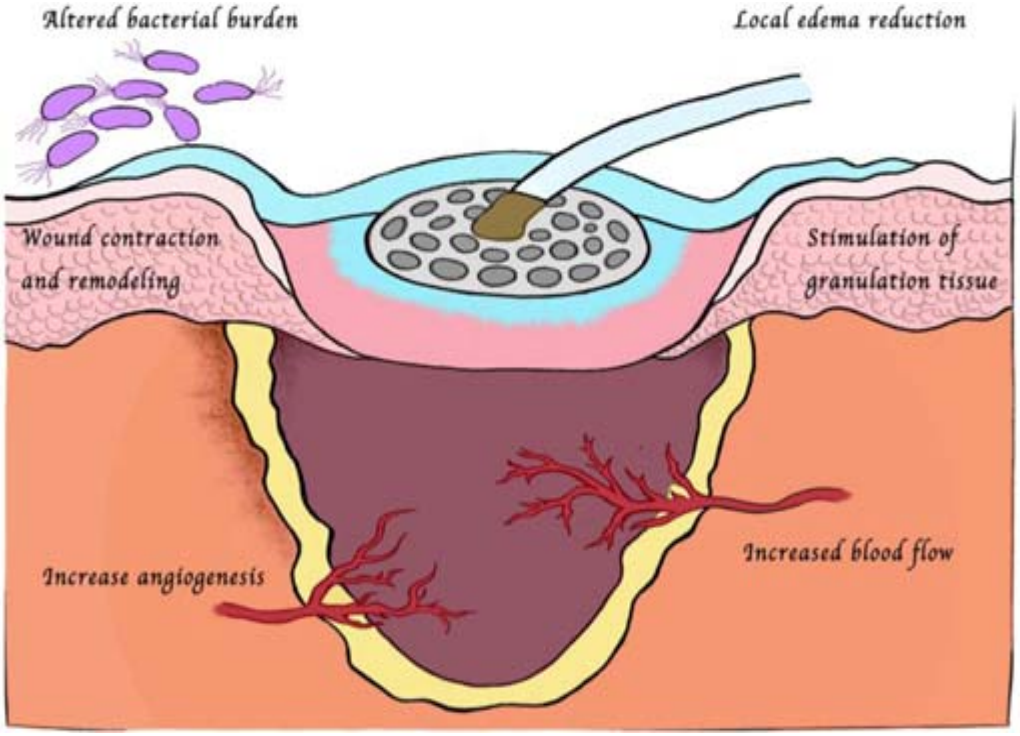
3.7.NPWT (36) (37)

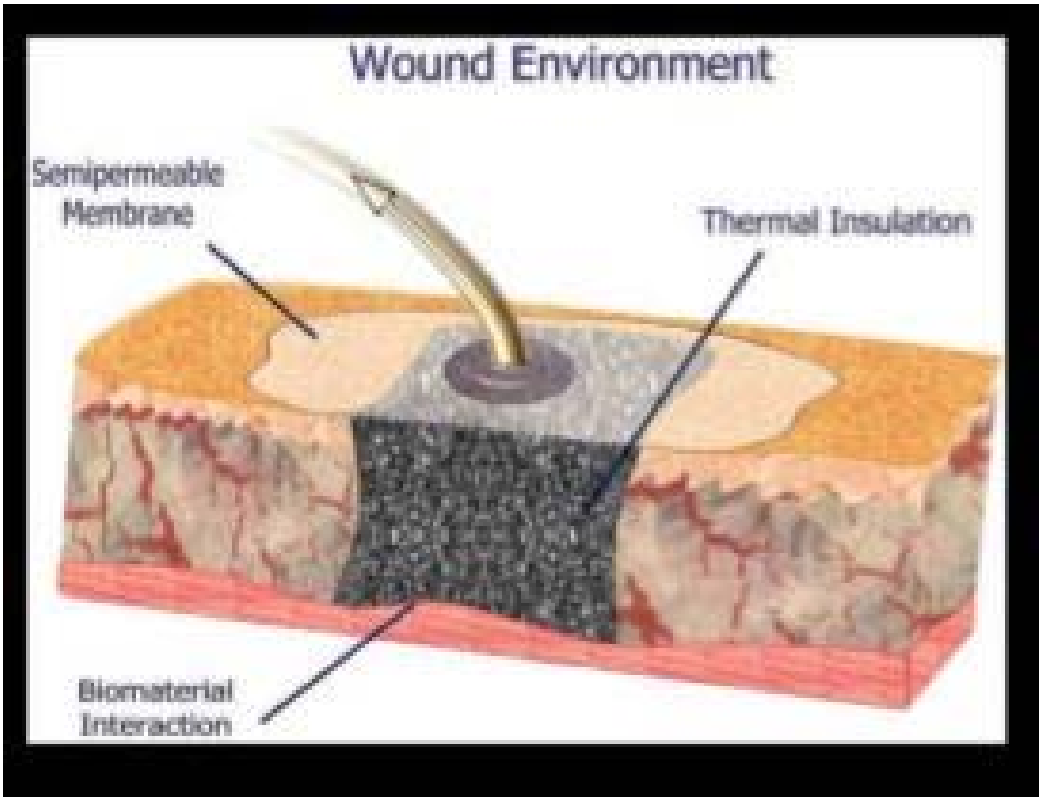
NPWT by exposing the wound to sub atmospheric pressure it promotes angiogenesis and granulation and thereby accelerates wound healing. Healing process is achieved via primary effects such as macrodeformation (wound contraction) and microdeformation at foam wound surface (mechanotransduction),removing surrounding interstitial fluid and removal of debris. Secondary effects includes changes in wound biochemistry, blood flow, SIRS (Systemic Inflammatory Response Syndrome) and reduction in bacterial burden which still controversial.

In NPWT the anti bacterial effects based on two effects: (38)

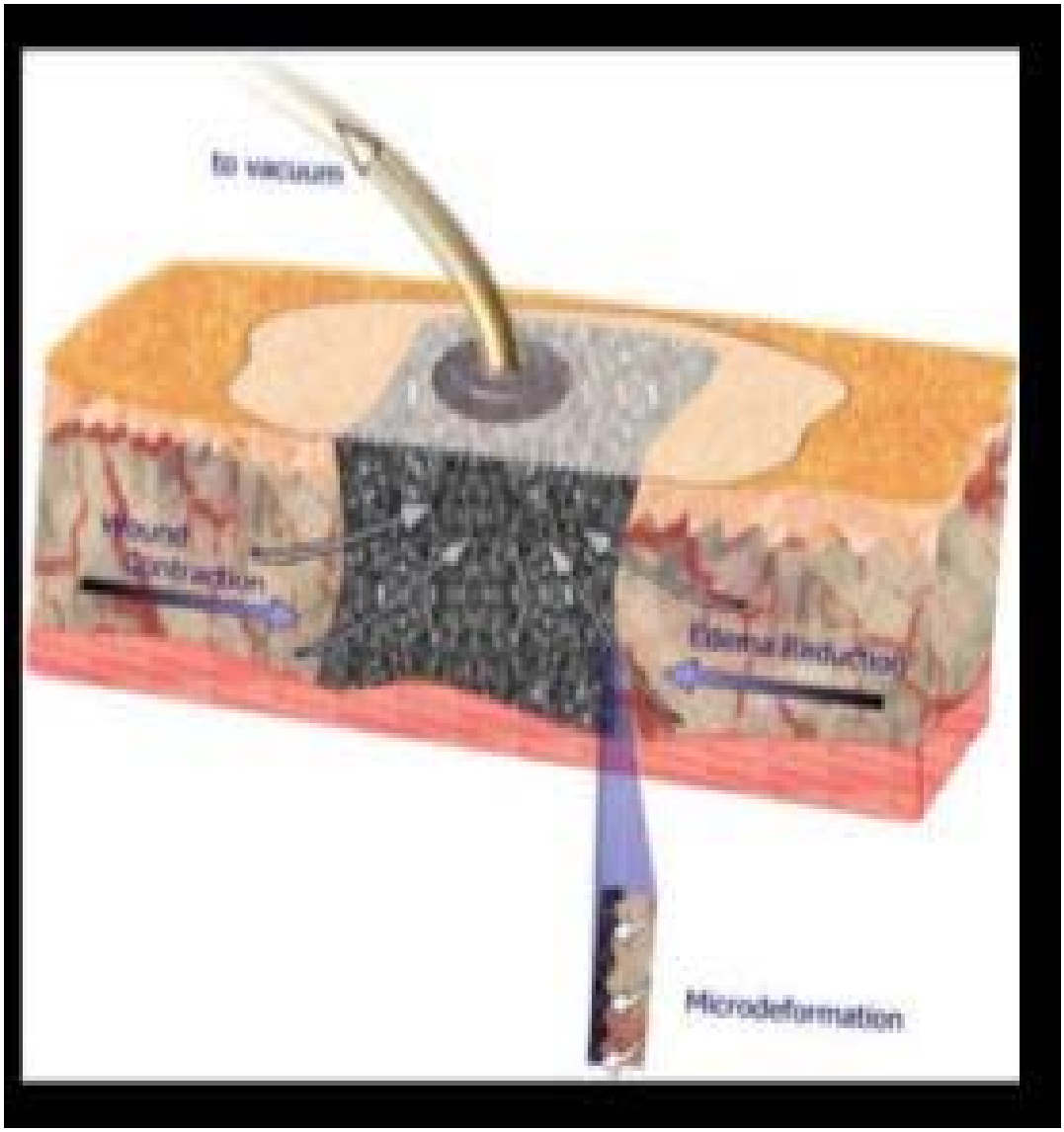
(i) Local immune function is strengthened by removing edema, cell debris. Edema decreases local oxygen tension and increase the diffusion distance among keratinocytes and impairing the immunological response to biological contaminants and infection.

(ii) Reducing the bacterial burden which is based on increasing perfusion to wound site. Therefore the delivery of oxygen and leukocytes in the wound bed is needed in improving local immune function.

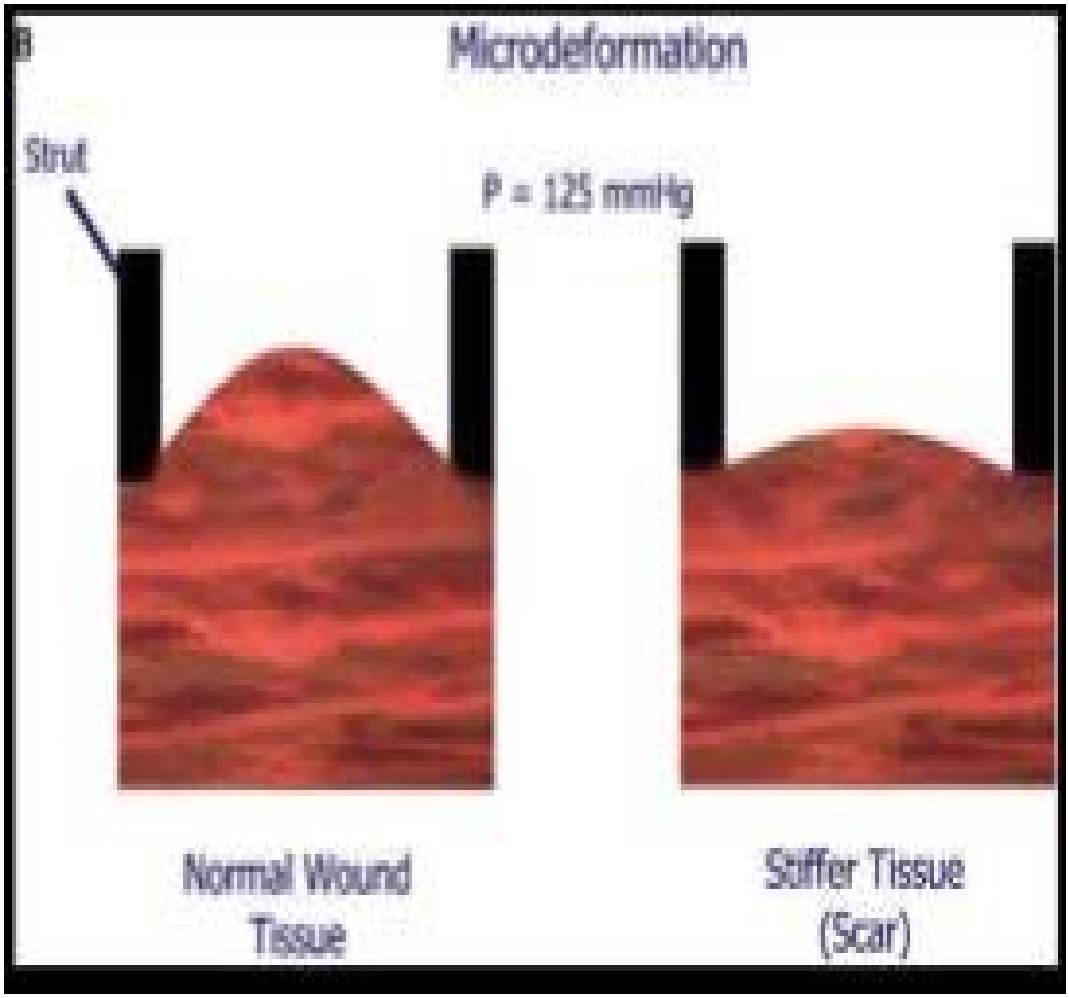




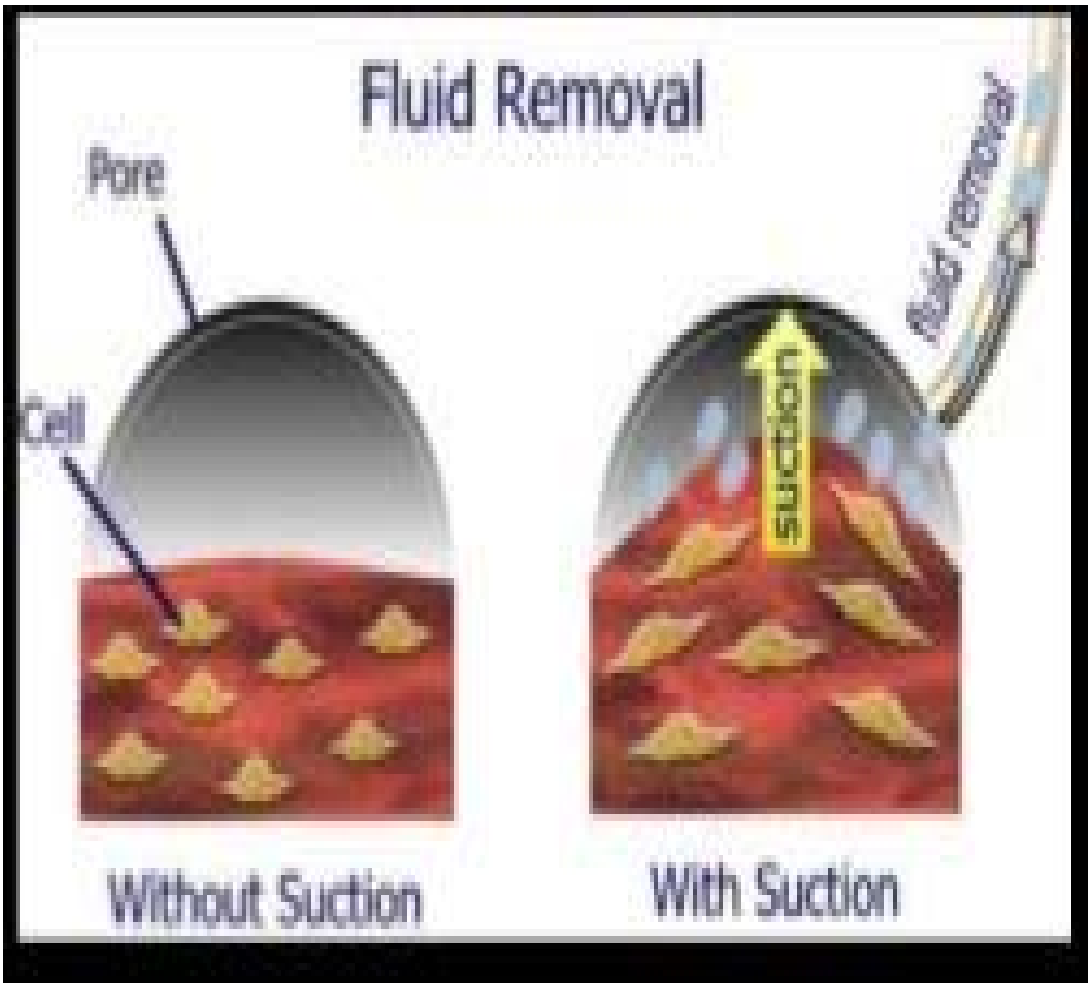
Mechanism of Suction Therapy



Mechanism of Suction Therapy



Mechanism of Suction Therapy



Mechanism of Suction Therapy

Fraccalvieri M (39) used both gauze and foam based NPWT to prepare wounds for closure and observed that less pliable skin grafts were noted in foam treated patients than those on the gauze treated patients and suggested that a thicker layer of scar tissue beneath skin grafts was observed in foam based therapy than gauze based therapy.

Medela AG et al (40) studied the effect of NPWT on wound closure and granulation tissue formation in a porcine wound model. Marked wound area and wound edge reduction was seen in NPWT group. When gauze, black foam, silver foam etc where coupled with VAC varying degrees of collagen and new small vessel formation, proliferation of cells with inflammatory cells being sparsely spread throughout the wound bed was seen.

Armstrong et al. (41) studied transmetatarsal amputation wounds in 162 patients by comparing NPWT with modern moist wound treatment. The foot had to have sufficient blood circulation as determined by transcutaneous oxymetry ($tcpO_2 \geq 30$ mmHg) or toe pressure measurement (≥30 mmHg). More patients reached a 100% re-epithelialisation. with or without secondary surgical intervention, in the NPWT group than in the control group (43 [56%] vs. 33 [39%], p=0.04). In the patients who reached complete closure, the rate of wound healing was faster in the NPWT group (56 vs. 77 days, p=0.005). In the NPWT group, 2 (3%) of the patients needed further surgical revision or amputation, whereas this number was 9 (11%) in the control group (p=0.06). Above ankle level amputations were done in 5 (6%) of the control group patients, whereas none of the treatment group patients were subjected to a high amputation (p=0.06).

In a 24-patient study by Etöz *et al.*, on diabetic foot ulcers, the formation of granulation tissue was fastened and significant wound shrinkage observed in NPWT patients. In a cross-over trial of 10 patients, Eginton *et al.*compared NPWT with moist wound treatment.[11] The ulcer size shrinkage was very much appreciable in NPWT patients than saline dressings.

In another 10-patient study by McCallon et al (42*).*,no difference noted between the patients with NPWT or moist bandages with a 6 week follow-up period.

In two separate 44-patient studies reported in one publication, by Stannard et al. (43), the influence of NPWT on the amount of wound exudate after surgery was evaluated. After incision of traumatic haematomas (part A), exudation of the wound ceased earlier in the NPWT group than in the pressure dressing group (1.6 [0–5] vs. 3.1 [0–11] days, p=0.03). Wound infection or breakdown rates did not differ in this study.

In the study concerning operated complex fractures in the lower extremities (part B), faster reduction in wound exudate was noted in the NPWT than with the patients treated by means of traditional dressing (1.8 [0–6] vs. 4.8 [0–28] days,p=0.02). On the other hand, the numbers in

need of repeat surgery (1 [8%] vs. 5 [16%], *ns*) or those with wound infections (0 vs. 1, *ns*) did not show any significant differences between the treatment and control groups.

Llanos et al (44)" randomized 60 patients with acute traumatic injuries and skin loss, which needed skin grafting. The randomisation was performed after the split thickness skin grafting and the dressing of the wound. At four days the wounds were photographed and the final analysis from the photographs was made by a blinded observer. The main outcome measure, loss of the skin graft in cm^2, was significantly smaller in the treatment group (0.0 [0.0–11.8] vs. 4.5 [0–52.9] cm^2, p=0.001). Need for a second coverage procedure was less common in the treatment group (5 [16.7%] vs. 12 [40.0%] patients, p=0.045). Also the time in days from the procedure to discharge from the unit was shorter when the suction was connected (8 [7–13] vs. 12 [7–23] days, p<0.001)".

Fleischmann and colleagues used NPWT in combination with antiseptic solutions in 27 orthopedic wounds and wounds healed faster and skin grafting done in 7 days of treatment.

Morykwas et al study on NPWT gave the current recommendation of -125mmHg negative pressure. The ranges he included was from 0 to -400mmHg with -25mmHg increments. The maximal flow was four times the baseline with -125mmHg and with increasing pressure the blood flow started to decrease. Borgquist et al concluded that blood flow is similar at both -80mmHg and -125mmHg and inadvertent high pressure of >400mmHg may lead to limb ischemia and gangrene.

NPWT has been successfully used in many types of both acute (trauma, fracture, tissue loss and dehiscence) and chronic (pressure, diabetic, venous stasis) wounds.

3.7.1. INDICATIONS

MAIN INDICATIONS	OFF LABEL INDICATIONS
Acute and Chronic wounds	Maxillofacial reconstructions
Diabetic foot ulcers	Soft tissue infections
Venous stasis ulcers	Transport of blast injuries
Burn wounds	Empyemas
Open abdomens	Bronchopleural fistulas
Sternal wound infections	Hidradenitis suppurativa
Pressure ulcers	Fournier’s gangrene
Composite tissue flaps	Maxillofacial reconstructions
High risk incisions	Acute soft tissue loss
Split thickness skin grafts	
Orthopedic/hand trauma	

3.7.2.CONTRAINDICATIONS & CAUTIONS

• Wounds involving untreated osteomyelitis	• Wounds with visible fistula
• Wounds with necrotic slough	• Clotting disorder
• Wounds involving open joint capsules	• Compromised micro-vascular blood flow to wound
• Skin malignancy	• Wounds with exposed bone or tendon
• Wounds exposing blood vessels or organs or with an unexplored fistula	

3.7.3.ADVANTAGES:

NPWT has proven to be useful in

1. Frequency of dressing change is decreased.
2. The duration between debridement and definitive closure is reduced.
3. Cost effective since it reduces hospital stay.

3.7.4.DISADVANTAGES:

1. Cannot replace surgical debridement which is best for removal of nonviable necrotic tissue.
2. Poor ambulation.
3. Maintaining air-tight seal in irregular surface is difficult.

3.7.5.COMPLICATIONS:

- Abrasions
- Overgrowth of granulation tissue into the foam
- Hemorrhage
- Tube blockage

- Kinking of tubes
- Late infection
- Pain sensation on suctioning
- Pressure effect of tubing to body
- Fistula formation for dehiscence abdominal wound
- Serious complications –bleeding that occurred in six patients. six deaths & 77 injuries reported over 2007-2009 with bleeding (FDA,2009) (45)

3.7.6.IMPROVED WOUND HEALING UNDER MOIST CONDITIONS:

Improved wound healing under moist conditions described by George winter. it has the following advantages such as:

ADVANTAGES	MECHANISM
Increased angiogenesis	Angiogenesis requires moist environment; low oxygen tension favours angiogenesis.(46)
Decreased dehydration and cell death	Cells need moist environment for growth
Increased autolytic debridement	Moist environment increases cellular life and enzymes needed

	for protein digestion are carried to the wound bed allowing for painless debridement(47)
Enhanced re-epithelisation	Migration of epidermal cells is favoured in moist environment(48)
Pain alleviation	Moist wound bed shields nerve endings that decreases pain
Bacterial barrier and decreased infection rates	Occlusive dressings protects from microorganisms entering into the wound and reduces infection rates.(49)(50)

3.7.7.NPWT USE IN COMMUNITY:

NPWT Use in community is a means of treating patients with chronic and complex wounds at home. NPWT facilitates early discharge. Patients with NPWT initiated in hospital should receive the same treatment even at their home. So creation of Community NPWT is needed.

3.7.8.REVIEW OF EARLIER STUDIES ON NPWT

Allen gabiel et al conducted a pilot study on 5 patients, using NPWT with a silver foam dressing demonstrated a reduction in mean

time to wound closure, infection clearance and hospital discharge without the use of antibiotics.

Steenvorde p et al at rijnland hospital, Netherlands reported a case of a72 year old man who have undergone meshplasty for an incisional hernia and subsequently developed a wound infection. Wound debridement was done leaving mesh exposed. This Patient was also receiving broad spectrum antibiotic for pneumonia was treated in isolation, his wounds cultured, MRSA was identified. Then the wound was treated with NPWT, set pressure was125mmhg, the black urethane sponge changed twice weekly. After one month of treatment with NPWT, the wound closure was attained.

Chester DL et al conducted a pilot study on 4 patients receiving VAC therapy advised close surveillance of bacterial flora since anerobic infection with NPWT, which got settled with antibiotics and NPWT is stopped.

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MATERIALS AND METHODS

Picture Showing Vacuum Suction Dressing

Picture Showing Vacuum Suction Dressing

4. MATERIALS AND METHODS

This study done on diabetic patients with foot ulcers, randomized into two groups ,the study group who received NPWT and the control group who received conventional saline dressings for their wounds during the study period of April 2016 to September 2016.

STUDY DESIGN: PROSPECTIVE STUDY

DATE OF APPROVAL BY ETHICALCOMMITTEE:14/06/2016

PLACE OF STUDY: DEPARTMENT OF GENERAL SURGERY, GOVERNMENT STANLEY GENERAL HOSPITAL,CHENNAI.

SELECTION OF CASES:

From cases attending our institute with diabetic foot ulcers was randomly selected and divided into study and the control group. These patients were made to understand and sign the consent form.

SAMPLE SIZE:

A total of 40 patients of Diabetic foot ulcer who were admitted in surgery included in the study.

Study group (A): 20 Received negative pressure dressing therapy. Dressing change every 3rd day.

Control group (B): 20 Received daily dressing changes with saline-moistened gauze.

4.1. INCLUSION CRITERIA:

•Age group 20-75 years.

•Ulcer area ranging between 5cm^2 and 10cm^2

•Diagnosis of diabetes mellitus made by American Diabetes

Association Criteria

4.2. EXCLUSION CRITERIA:

- Age < 20 years or > 75 years.
- Any obvious septicemia
- Osteomyelitis.
- Wounds resulting from venous insufficiency/arterial disorders.
- Malignant disease in a wound.
- Patients being treated with corticosteroids, immunosuppressive drugs or chemotherapy.

- Any other serious pre-existing cardiovascular, pulmonary and immunological disease.

4.3. METHODOLOGY

Patients were made to understand in their local language and informed consent was obtained before randomizing into the two groups

Both the groups underwent sharp surgical debridement initially and during subsequent dressing change to remove necrotic tissue and slough

4.3. STUDY GROUP

After debridement, foam-based dressing applied over the wounds of The study group Covered with an adhesive drape to create an airtight seal. evacuation tube embedded in the foam connected to a vacuum pressure within a range of 80–125 mmHg on a continuous basis for 72 hours after which dressing changed with similar procedure.

4.4. CONTROL GROUP

Patients in this group received once daily saline dressing.

After every 3 days, wound cultures were sent in both groups, which taken from bottom of the ulcer to the bacterial burden.

Standard antibiotics were given to all patients, which consisted of broad-spectrum antibiotics initially and later changed based on culture & sensitivity.

Blood glucose levels were monitored strictly during treatment and controlled by appropriate doses of insulin.

Ulcers were treated until the wound closed spontaneously, surgically or until completion of the 8-week period, whichever was earlier.

Treatment outcome and patient satisfaction was assessed in terms of time taken for wound closure.

Treatment success was defined as wound closure within a period of 8 weeks and failure, as inability of wound closure within 8 weeks.

ASSESSMENT OF PARAMETERS

1. DURATION FOR WOUND CLOSURE

2. PUS C&S REPORT

OBSERVATION AND RESULTS

5. OBSERVATIONS

40 consecutive consenting patients admitted with diabetic foot ulcers in the Department of General Surgery in Stanley Medical College in the period of April 2016 to September 2016 and who are conforming into the inclusion criteria, data was collected using a profoma and where included the study.

5.1. BACKGROUND CHARACTERISTICS:

5.1.1PATIENT PROFILE:

Men (32/40,80%) outnumbered women (8/40,20%) with a male to female ratio of 4:1 in the entire study population. The gender distribution (M:F) was 16:4 in both conventional and study groups. The mean (mean ± SD) age of patients in conventional group was 54.40±13.63 yrs (ranging from 40-68 yrs with a median of 54 yrs.) and in NPWT group was 51± 10.052 yrs (ranging from 41-61 yrs with a median median of 51yrs).The mean age and gender were comparable in both the study groups.(TABLE 1)

5.2.PARAMETERS STUDIED:

5.2.1. DURATION OF WOUND CLOSURE: (TABLE 2)

WOUND CLOSURE IN NPWT GROUP

- In the NPWT group the duration of wound closure was found to be hastened when compared to **conventional group.**

- In our study **11 out of 20 patients** wound closure was attained within a period of **two weeks** by **SSG.**

- **7 out of 9 remaining patients** attained wound closure at the end of **third week** of NPWT.

- The remaining 2 patients attained in the fourth week.

- Ulcer shrinkage was significantly noted in NPWT group compared to conventional group.

PRE TREATMENT

FIRST WEEK OF NPWT

15 TH DAY -NPWT

3 RD WEEK -NPWT

5.2.2. WOUND CLOSURE IN CONVENTIONAL GROUP

- In the conventional group the duration of wound closure was found to be prolonged when compared to **NPWT.**

- In our study **8 out of 20 patients** wound closure was attained within a period of 4 weeks.

- **5 out of 12 remaining patients** attained wound closure at the end of **6 weeks.4 out of 20 attained wound closure by 8 weeks..**

- **3 out of 20 attained wound closure by more than 8 weeks..**

5.3.PUS C&S

- Pseudomonas aeruginosa was the most common organism isolated..

- In NPWT , Clearance of anaerobic organisms was excellent ..

- NPWT was able to clear the uncommon wound contaminants such as proteus mirabilis, klebsiella pneumonia, providencia rettgeri and beta haemolytic streptococci.

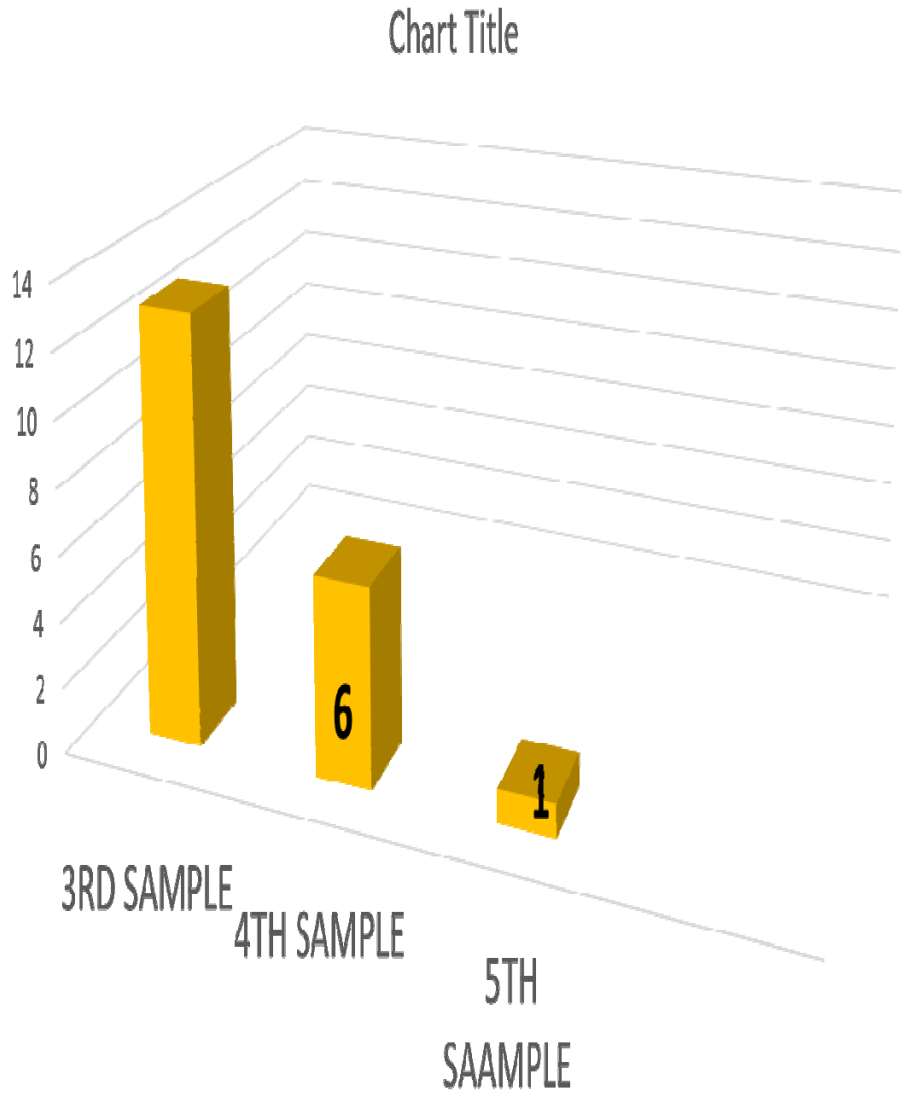
AEROBIC GROWTH

	PRE-TREATMENT	
AEROBES	**CONVENTIONAL**	**NPWT**
PSEUDOMONAS	**7**	**11**
STAPH.AUREUS	**6**	**6**
MRSA	**3**	**3**
COAGULASE NEGATIVE STAPH	**1**	**4**
ACINETOBACTER	**7**	**1**
OTHERS	**3**	**4**

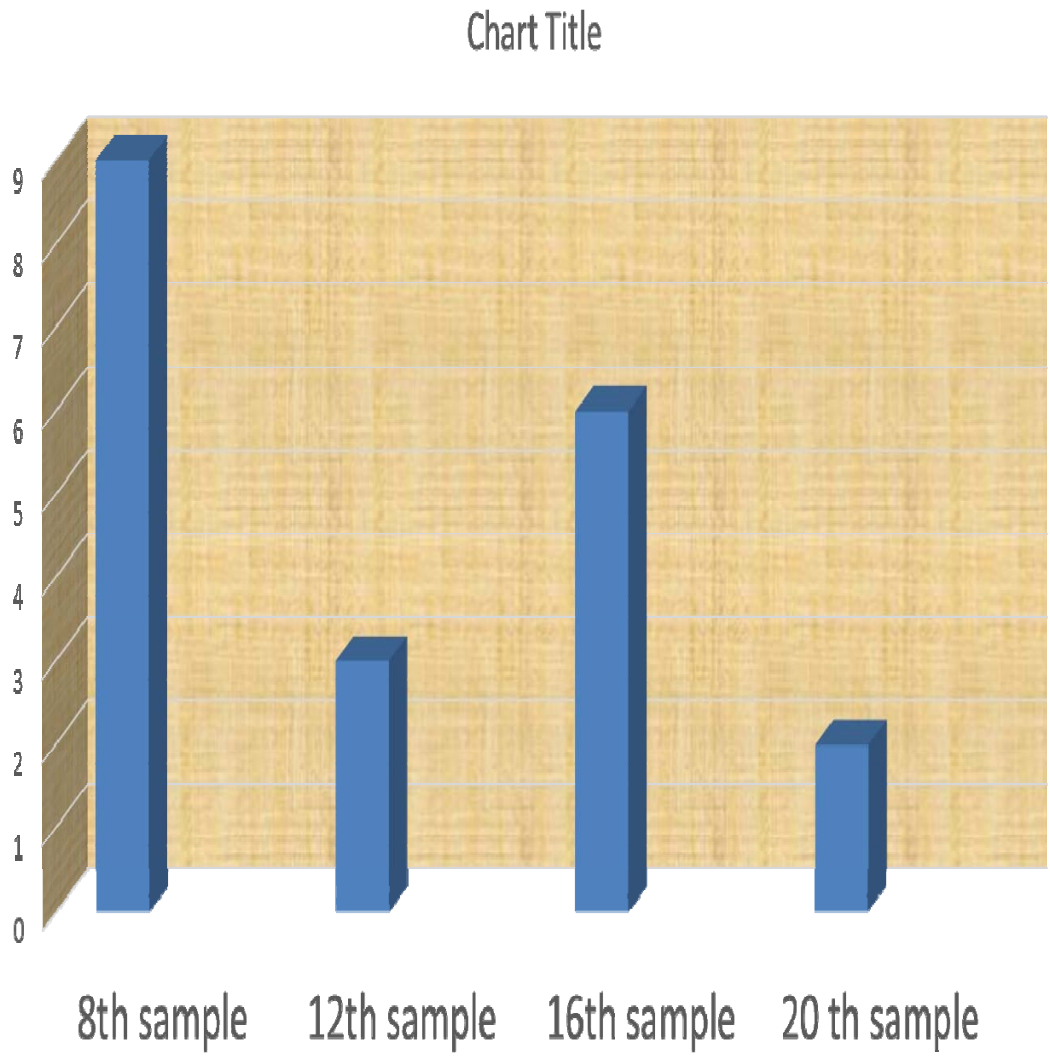
ANEROBIC GROWTH:

	PRE TREATMENT	
	CONVENTIONAL	**NPWT**
ABSENT	**19**	**17**
PRESENT	**1**	**3**

PUS C&S SHOWING NO GROWTH IN NPWT GROUP



PUS C&S SHOWING NO GROWTH IN CONVENTIONAL GROUP



DISCUSSION

6. DISCUSSION

This study was done in forty consecutive patients with diabetic foot where NPWT can be applied and those patients were admitted in Department of General Surgery as inpatients after randomly selected into two groups of twenty Patients each. The sample size was fixed to be twenty in each group with a power of study of 90% using open-epi software 2.3 for sample size calculation. Allocation concealment was done using serially numbered opaque sealed envelopes. Randomization and sealed envelopes were prepared by a person, independent of the investigators or anyone involved inpatient care and statistician. After decoding, Group A(study group) received NPWT and Group B (conventional group) received conventional normal saline dressings.

After debridement NPWT was applied using controlled application of sub-atmospheric pressure to the diabetic wounds, using foam based dressings with a nasogastric tube in between, and the whole dressings is sealed using a sterile transparent plastic sheet and it is connected to the vacuum suction device.

Comparison of effect of NPWT over conventional saline based dressings in reducing the bacteriological burden of wound in terms of pus culture negativity and in duration of wound closure.

In our study all the wounds were include in both the groups were infected prior to the start of treatment. In the conventional group the duration of wound closure was found to be prolonged when compared to NPWT.

In our conventional group 8 out of 20 patients wound closure was attained ≤ 4weeks,5 out of 20 attained wound closure at ≤ 6weeks,4 out of 20 by ≤ 8 weeks and 3 out of 20 by > 8 weeks.

In our study group (NPWT) 11 out of 20 patients wound closure ≤ 2 weeks, 7 out of 20 by ≤3 weeks and 2 out of 20 attained wound closure by 4^{th} week.

Bacteriological clearance was studied by using pus culture negativity. Pus cultures were taken under strict aseptic precautions on every 3^{rd} day and sent to Microbiology Department of Stanley Medical College.

In conventional group pus culture negativity was attained by 9 patients by 8^{th} sample,3 patients by 12^{th} sample,6 patients by 16^{th} sample and 2 patients by 20^{th} sample. In our study group pus culture negativity was attained by 13 patients by3rd sample,6 patients by 4^{th} sample and 1 patient by 5^{th} sample.

Complete clearance of both aerobic and anaerobic flora was attained within a shorter period of time as compared to conventional group. Pseudomonas aeruginosa was the most common organism isolated from the wounds in both study and conventional group.7 patients in conventional group and 11 patients in NPWT had growth of Pseudomonas aeruginosa in pus culture.

The next common organism isolated from pus culture was Staphylococcus aureus in both the groups. Other organisms which were MRSA (Methicillin Resistant Staphylococcus Aureus), Coagulase negative Staphylococcus Aureus, Acinetobacter, proteus vulgaris, beta hemolytic streptococci, klebsiella species, bacteriods, peptostrepococci. In this study, no increase in the anerobic growth was observed after NPWT. Anerobes were noted in only 1 out of 20 wounds, while 17 wounds continued to be free of anerobic infection after NPWT. Surprising in 3 wounds, which had anerobes before starting NPWT, it disappeared after first cycle of NPWT.

We observed that NPWT decreased the duration of hospital stay and the time taken for definitive treatment like skin grafting both causing an overall decrease in efficient man hour lost due to delayed wound healing and prolonged hospital stay. In our study, mainly all the wounds were closed by skin grafting.

SUMMARY

7.SUMMARY

This study was conducted in forty patients who came with diabetic foot ulcers where NPWT and conventional normal saline dressing was applied. After randomizing patients into two groups of twenty patients each, group A received NPWT and the group B received conventional normal saline dressings. The study outcome was studied was assessed in terms of reduction in duration of wound closure, reduction of bacteriological burden of diabetic wounds. Age, gender distribution, types of wounds, pus culture negativity, duration of wound closure were all comparable between the two groups.

13 wounds became pus culture negative for organisms in 3rd culture sample in NPWT group, but in conventional group, only 9 patients attained pus culture negativity in 8th sample. And this showed the power of NPWT in reducing the bacteriological burden of diabetic wounds.

11 out of 20 patients, wound closure was attained within or equal to 2 weeks in NPWT group.8 out of 20 patients, wound closure was attained within or equal to 4 weeks. And this showed the power of NPWT in reducing the duration of wound closure mainly by skin grafting.

Complete clearance of aerobic flora and anerobic flora was observed much earlier in patients who received NPWT.

TABLES AND FIGURES

TABLES AND FIGURES

Crosstabs

Gender * Groups

Crosstab

			Groups		Total
			Study group	Control group	
Gender	Male	Count	16	16	32
		% within Groups	80.0%	80.0%	80.0%
	Female	Count	4	4	8
		% within Groups	20.0%	20.0%	20.0%
Total		Count	20	20	40
		% within Groups	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.000[a]	1	1.000		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.000	1	1.000		
Fisher's Exact Test				1.000	.653
Linear-by-Linear Association	.000	1	1.000		
N of Valid Cases	40				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 4.00.

b. Computed only for a 2x2 table

Pus C & S in both groups

Crosstab

			Groups		Total
			Study group	Control group	
Pus c & s	3	Count	13	0	13
		% within Groups	65.0%	0.0%	32.5%
	4	Count	6	0	6
		% within Groups	30.0%	0.0%	15.0%
	5	Count	1	0	1
		% within Groups	5.0%	0.0%	2.5%
	8	Count	0	9	9
		% within Groups	0.0%	45.0%	22.5%
	12	Count	0	4	4
		% within Groups	0.0%	20.0%	10.0%
	16	Count	0	6	6
		% within Groups	0.0%	30.0%	15.0%
	20	Count	0	1	1
		% within Groups	0.0%	5.0%	2.5%
Total		Count	20	20	40
		% within Groups	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	40.000[a]	6	.000
Likelihood Ratio	55.452	6	.000
Linear-by-Linear Association	32.383	1	.000
N of Valid Cases	40		

a. 12 cells (85.7%) have expected count less than 5. The minimum expected count is .50.

Wound Closure in both groups

Crosstab

			Groups		Total
			Study group	Control group	
Wound closure	2 Weeks	Count	11	0	11
		% within Groups	55.0%	0.0%	27.5%
	3 Weeks	Count	8	0	8
		% within Groups	40.0%	0.0%	20.0%
	4 Weeks	Count	1	7	8
		% within Groups	5.0%	35.0%	20.0%
	6 Weeks	Count	0	5	5
		% within Groups	0.0%	25.0%	12.5%
	8 Weeks	Count	0	5	5
		% within Groups	0.0%	25.0%	12.5%
	> 2 Months	Count	0	3	3
		% within Groups	0.0%	15.0%	7.5%
Total		Count	20	20	40
		% within Groups	100.0%	100.0%	100.0%

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	36.500[a]	5	.000
Likelihood Ratio	49.423	5	.000
Linear-by-Linear Association	27.576	1	.000
N of Valid Cases	40		

a. 10 cells (83.3%) have expected count less than 5. The minimum expected count is 1.50.

T-Test

Group Statistics

	Groups	N	Mean	Std. Deviation	Std. Error Mean
Age	Study group	20	51.00	10.052	2.248
	Control group	20	54.40	13.632	3.048

Independent Samples Test

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Age	Equal variances assumed	.572	.454	-.896	38	.375	-3.400	3.797	-11.087	4.287
	Equal variances not assumed			-.896	34.848	.375	-3.400	3.797	-11.089	4.289

TABLE 1: GENDER DISTRIBUTION IN NPWT AND CONVENTIONAL GROUPS

FIGURE 1: GENDER DISTRIBUTION

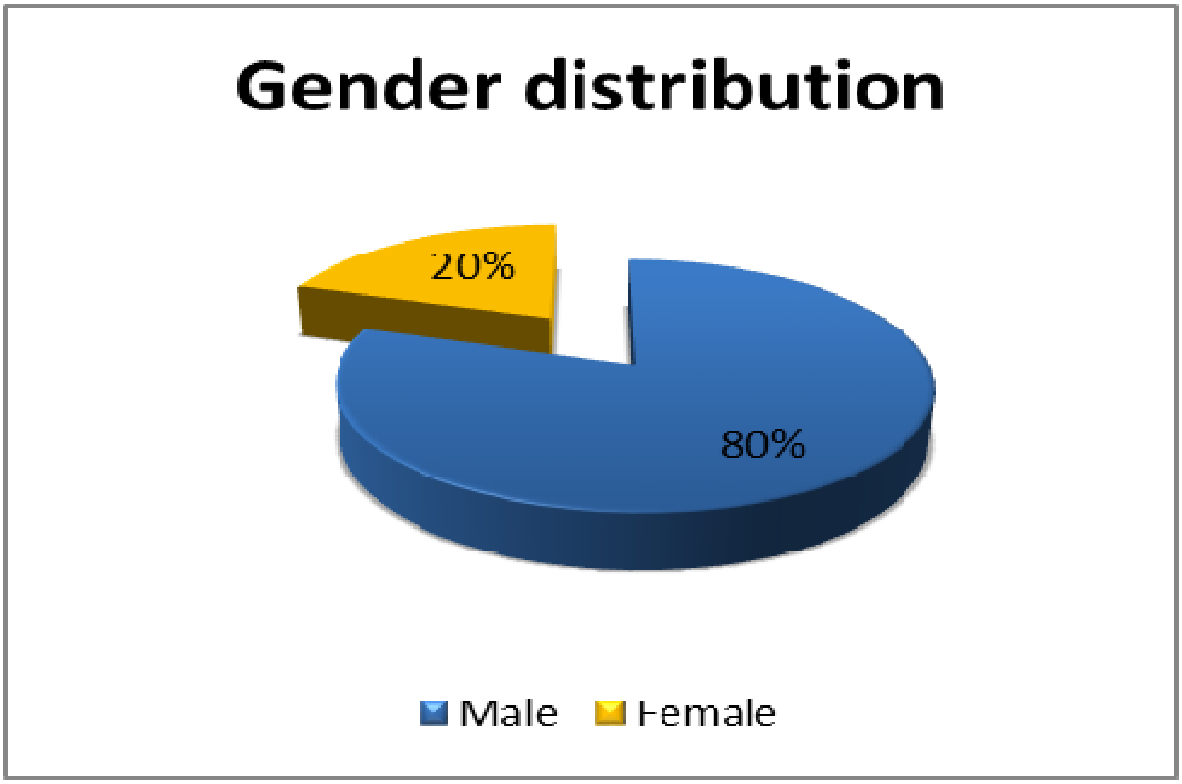


FIGURE 2: GENDER DISTRIBUTION IN STUDY GROUP AND CONVENTIONAL GROUP

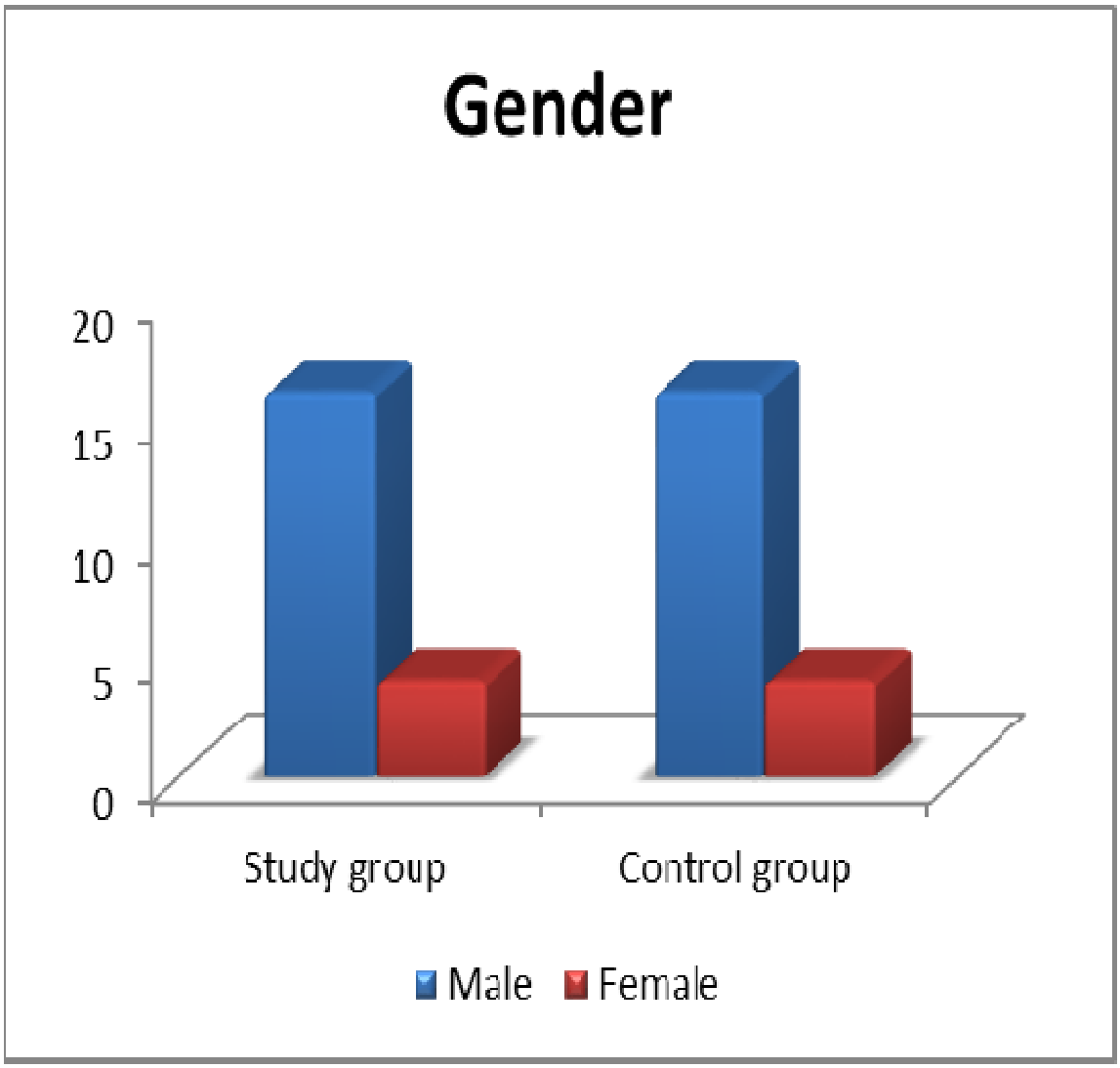


FIGURE 3: AGE DISTRIBUTION IN STUDY AND CONVENTIONAL GROUPS

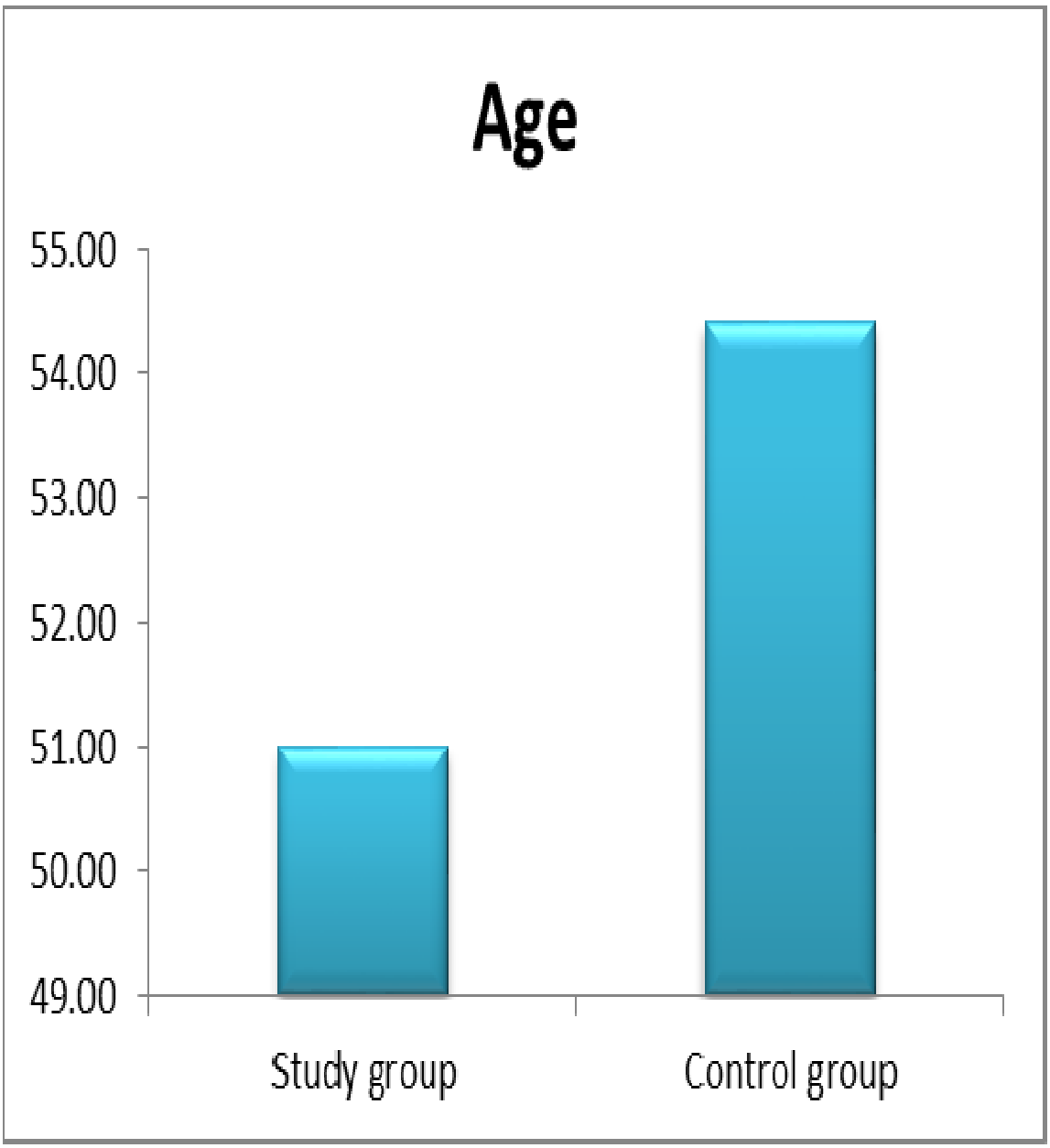


TABLE 2: COMPARISON OF DURATION OF WOUND CLOSURE IN NPWT AND CONVENTIONAL GROUP

			Groups		
			NPWT GROUP	CONVENTIONAL GROUP	Total
Wound closure	2 Weeks	Count	11	0	11
		% within Groups	55.0%	0.0%	27.5%
	3 Weeks	Count	8	0	8
		% within Groups	40.0%	0.0%	20.0%
	4 Weeks	Count	1	7	8
		% within Groups	5.0%	35.0%	20.0%
	6 Weeks	Count	0	5	5
		% within Groups	0.0%	25.0%	12.5%
	8 Weeks	Count	0	5	5
		% within Groups	0.0%	25.0%	12.5%
	> 2 Months	Count	0	3	3
		% within Groups	0.0%	15.0%	7.5%
Total		Count	20	20	40
		% within Groups	100.0%	100.0%	100.0%

FIGURE 4: DURATION OF WOUND CLOSURE IN STUDY AND CONVENTIONAL GROUP

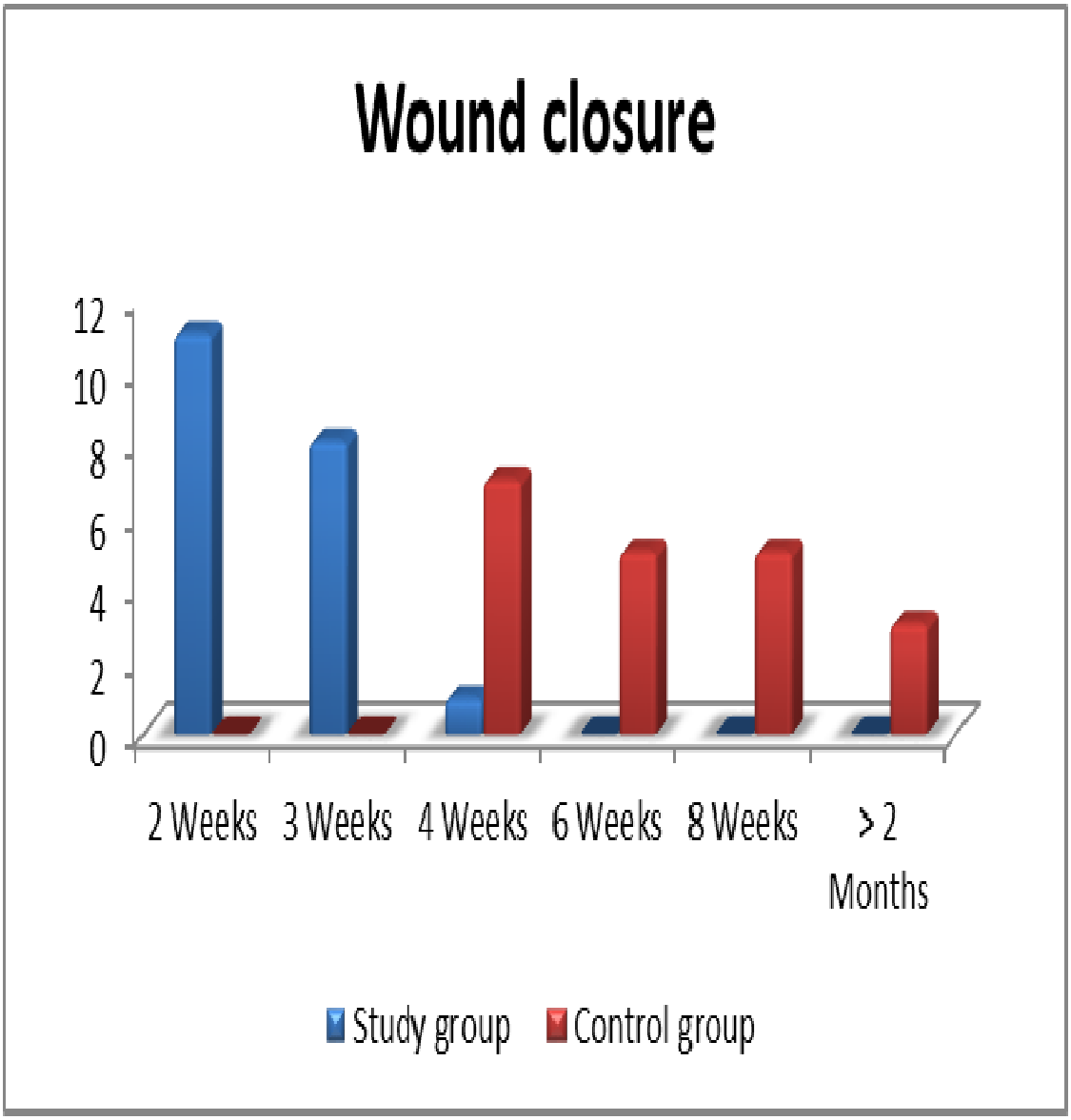
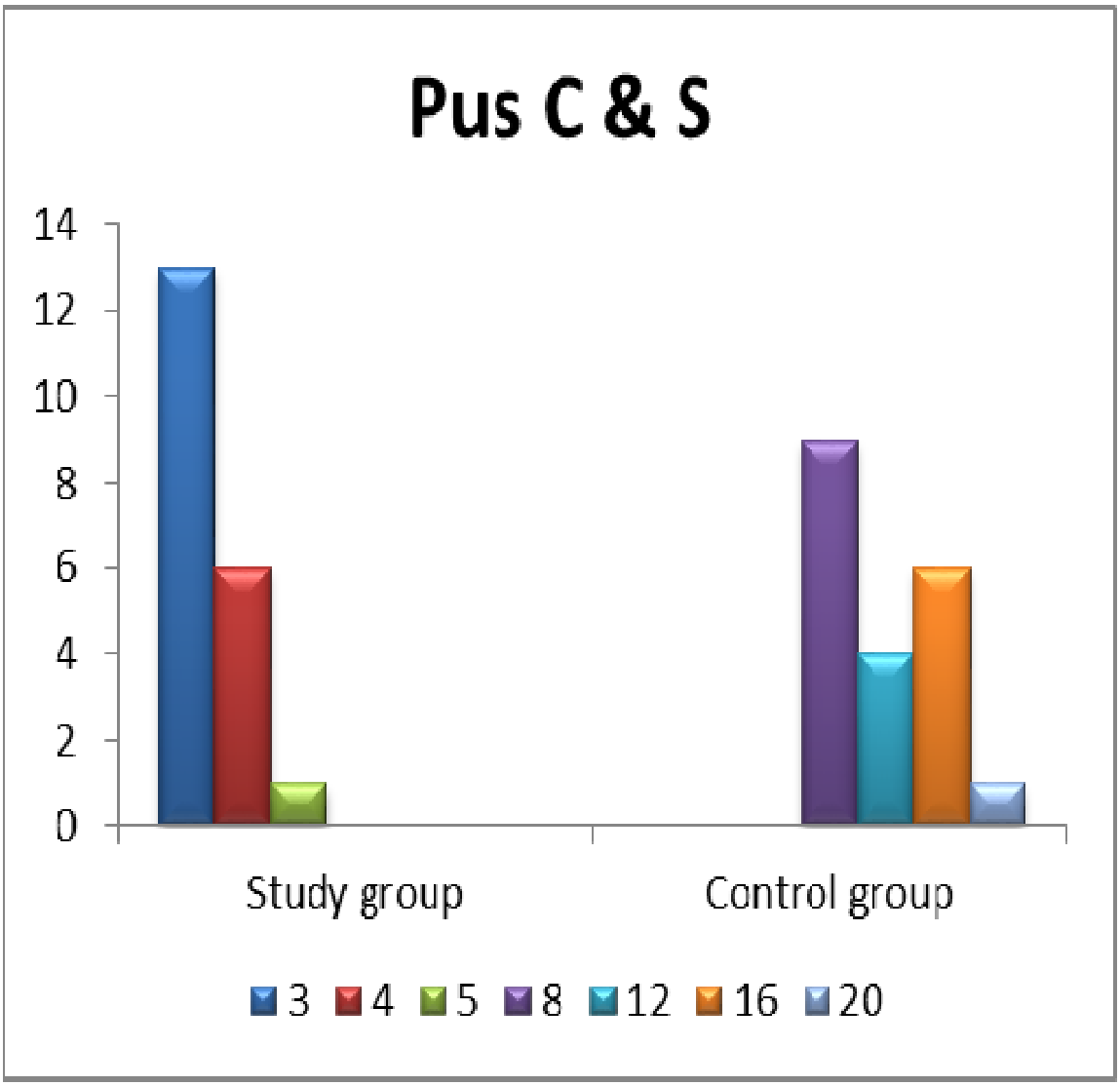


FIGURE 5: PUS C& S NEGATIVITY IN STUDY AND CONVENTIONAL GROUP



CONCLUSION

9. CONCLUSION

NPWT was effective in reduction in reduction of bacterial flora of diabetic wounds as the wound showed pus culture & sensitivity negative for growth.

NPWT was effective in clearing aerobes and anerobic bacteria well. Very effective in clearing pseudomonas which was the most common organism isolated from the wound.

NPWT although it created an anerobic atmosphere around the wound, did not induce proliferation of anerobes.

NPWT caused an increase in proliferation of granulation tissue which was essential for wound closure especially by skin grafting.

Hence we found that NPWT Was effective in reducing the bacterial burden of the wound and caused proliferation of granulation tissue needed for wound closure and decreased the duration of wound closure and hospital stay.

ANNEXURE -I

I.MASTERCHART

Name	Age	IP NO	Sex	study	pus c&s	wound closure
Paripooranam	48	1637169	2	1	1	1
Dharmalingam	58	1637294	1	1	1	1
Sampathkumar	56	1629232	1	2	5	5
Palani	42	1632174	1	1	1	2
Vasudevan	64	1619947	1	2	5	4
Shanthi	53	1601629	2	1	2	2
Satish kumar38		1624444	1	2	4	4
Raghupathy	60	1615313	1	2	5	5
Pannerselvam	56	1608995	1	1	2	2
Narayanan	60	1615269	1	2	6	6
Maruthamuthu	66	1594394	1	1	2	1
Syed abu	65	1604606	1	2	4	4
Thameem	24	1600011	1	1	2	2

Sudalaimuthu	16	1603604	1	2	4	3
Kannan	48	1619947	1	1	1	1
Murugesan	80	1645412	1	2	5	4
Selvakumar	58	1643872	1	1	3	3
Parthasarathy	60	1655811	1	2	6	5
Kannan	43	1652143	1	1	1	1
Murugesan	54	1645696	1	2	6	5
Kanagavendhan	57	1653905	1	1	1	2
Krishnan	64	1646481	1	2	7	6
Abdulrahim	48	1640519	1	1	1	2
Jayaraj	70	1629319	1	2	4	3
Radha	44	1643775	2	2	6	6
Ganesan	52	1618851	1	1	1	1
Masthan	60	1616888	1	1	1	2
Kannan	52	1593514	2	2	6	5
Pichaimuthu	60	1604602	2	1	2	1
Dhuruvan	52	1652386	1	2	6	4

Jagadeesan	52	1652359	1	1	1	1
Panchatsaram	62	1655714	2	2	4	3
Nagaraj	46	1613432	1	1	2	2
Balasubramani	53	1643215	1	2	4	3
Shenbagam	65	1626544	1	1	2	2
Ramaswamy	52	1637654	1	2	4	3
Poongavanam	63	1622985	2	1	1	1
Durairaj	49	1615324	1	2	4	3
Megalai	58	1618736	1	1	1	1
Annapoorni	62	1613956	2	2	4	3

Sex:	**group:**	**pus c&s negativity:**	**wound closure:**
1-male	1-study	1-3rd sample	1-<2 weeks
2-female	2-control	2-4th sample	2-<3weeks
		3-5th sample	3-<4 weeks
		4-8th sample	4-<6 weeks
		5-12th sample	5-<8 weeks
		6-16th sample	6->2months
		7-20th sample	

ANNEXURE II

BIBLIOGRAPHY

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ANNEXURE III

PROFORMA

NAME :

AGE :

IP.NO. :

DOA :

CHIEF C/O :

CO-MORBIDITIES:

POST DEBRIDEMENT ULCER SIZE:

TYPE OF DRESSING:

PUS C&S:

DURATION OF WOUND CLOSURE:

TYPE OF CLOSURE:

INFORMED CONSENT

Name: Age/ Sex:

IP:

I herewith declare that I have been explained in a language fully understood by me regarding the purpose of this study, methodology, proposed intervention, plausible side effects, if any and sequelae.

I have been given an opportunity to discuss my doubts and I have received the appropriate explanation.

I understand that my participation in this study is completely voluntary and that I am free to withdraw from this study at anytime without any prior notice &/ or without having my medical or legal rights affected.

I permit the author and the research team full access to all my records at any point, even if I have withdrawn from the study. However my identity will not be revealed to any third party or publication.

I herewith permit the author and the research team to use the results and conclusions arising from this study for any academic purpose, including but not limited to dissertation/ thesis or publication or presentation in any level.

Therefore, in my full conscience, I give consent to be included in the study and to undergo any investigation or any intervention therein

Patient’s Sign Investigator’s sign

PATIENT INFORMATION MODULE

You are being invited to be a subject in this study.

Before you participate in this study, I am giving you the following details about this trial, which includes the aims, methodology, intervention, possible side effects, if any and outcomes:

All consenting patients who are admitted with diabetic foot ulcer will be included in this study. A detailed clinical history will be taken following a standardized proforma. A detailed clinical examination will be made and relevant basic investigations will be done at the time of admission. Efficacy of negative pressure wound therapy will be evaluated. The results arising from this study will be analyzed and used for academic purposes. You will be given clear instructions at every step and you are free to ask/ clarify any doubts. Your identity will remain confidential. You are free to withdraw from this trial at any point of time, without any prior notice &/ or without any medical or legal implications.

I request you to volunteer for this study.

Thanking You,

Investigator's Sign Patient's Sign

(Dr.RAJACHANDRASEKAR M) (Name:)