SYNOPSIS

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Title of Research Project: **Comparison of wound healing for diabetic carbuncle treated with incision & drainage technique using cruciate incision versus saucerization technique both followed by vacuum assisted closure**		
Synopsis Submitted For: ☐ **MD / MS / MDS** ☐ **Ph. D** ☐ **M. Phil** ☐ **Research Grant**	**Discipline:**	
Name Of The Applicant:		**D.O.B:**
Nationality:	**NIC #:**	
Address:		
Phone #:	**Email:**	
Qualifications (list all; with date of graduation):		
Qualification	**Year**	**Institution**
Practical Experience (list all; with dates of employment):		

Name of Parent Institution (if on Deputation):		
Name of Academic Supervisor / Principal Investigator:	**Signature:**	**Date:**
Name of Co Supervisor / Co-Principal Investigator	**Signature:**	**Date:**
Name of Chairman/ Head of Department	**Signature:**	**Date:**
Name of Principal/ Dean	**Signature:**	**Date:**
Convener, Institutional Review Board	**Signature:**	**Date:**
Chairman (Advanced Studies & Research Board) ☐ **Approved** ☐ **Not Approved** **Vice Chancellor, KEMU**	**Signature:**	**Date:**

TITLE:

Comparison of wound healing for diabetic carbuncle treated with incision & drainage technique using cruciate incision versus saucerization technique both followed by vacuum assisted closure

INTRODUCTION:

A carbuncle is an infective gangrene of skin and subcutaneous tissue, characterized by cluster of boils caused by bacterial infection, most commonly with Staphylococcus aureus. Carbuncle appears as tender painful lesion with cluster of severe boils filled with purulent Discharge. It mostly occurs at the nape of the neck, the back, shoulder or thighs[1]. Carbuncle is usually associated with immunocompromised patients specially in diabetics[2,10]. Treatment of carbuncle varies from conservative management to a radical surgery. It includes use of broad spectrum antibiotics, deroofing, incision & drainage and saucerization [1,3,4].

Saucerization involves radical excision of all dead necrotic center and surrounding cellulitis. In saucerization healthy bleeding margins are achieved, whole septic focus is removed and patient may not need post-operatively antibiotics. This technique leaves the patient with significant intraoperative blood loss and large wound which may need blood transfusion and graft or flap coverage of the wound respectively [4,5].

Incision & drainage is less radical procedure which gives a drainage pathway to underlying pus and broad spectrum antibiotics are given to control the remaining cellulitis and septic focus. This technique is associated with early healing and smaller scar. Patient's postoperative stay in hospital is usually prolonged after incision & drainage till adequate control of sepsis [3,4].

Wounds and their management are fundamental to the practice of surgery. Vacuum assisted Closure provides a new paradigm for wound dressings. Vacuum-assisted wound closure (VAC) is a wound management technique that exposes wound bed to negative pressure by way of a Closed system.. The application of VAC therapy to a wound provides a moist wound-healing environment leading to enhanced granulation tissue formation and improved wound healing which is the standard of care for wound healing [6,8,9].

The standard procedure of saucerization for diabetic carbuncle is associated with extensive Blood loss at the time of surgery due to wide excision. Blood loss often requires blood Transfusion. Additionally, the wound created needs to be filled by granulation tissue by Secondary intention/vacuum therapy which is translated into huge expenditure in terms of Dressings and financial loss due to days off work as well as larger scar mark. Whereas incision & drainage followed by vacuum assisted closure is and generally associated with decrease Blood, tissue loss and smaller scar mark. The study had been designed to compare the two procedures, saucerization versus Incision and drainage of a diabetic carbuncle followed be VAC with respect to wound healing.

OBJECTIVES:

To compare wound healing for diabetic carbuncle treated with incision & drainage technique using cruciate incision versus saucerization technique both followed by vacuum assisted closure in terms of blood loss , granulation tissue , duration required of wound healing and Post operative transfusion.

OPERATIONAL DEFINITIONS:

Blood Loss:

Blood loss will be assessed by counting number of supersaturated gauze sponges measuring 30x30cm used during surgery. 1 supersaturated sponge will be equal to 130ml of blood [7].

Wound Healing:

Wound healing will be assessed by using photographic wound assessment tool (PWAT). Score of PWAT ranges from 0-32, score less than 12 will represent wound is healing.

Duration of Wound Healing:

Duration of wound healing will be measured by calculating days between day of first surgery to the day when epithelial tissue appears on the wound.

Blood Transfusion:

Blood transfusion will be done for those patients having postoperative Hemoglobin levels less than 8mg/dl.

HYPOTHESIS:

There is a difference in wound healing for diabetic carbuncle treated with incision & drainage technique using cruciate incision versus saucerization technique both followed by vacuum assisted closure.

MATERIALS AND METHOD:

STUDY DESIGN:

Randomized controlled trial.

STUDY SETTING:

This study will be conducted at surgical floor in Mayo Hospital Lahore.

STUDY DURATION:

6 months from the approval of synopsis.

SAMPLE SIZE:

Sample size of 124 patients (62 patients in each group) is estimated by using 10% absolute precision and 95% confidence level with expected percentage of wound healing In saucerization as 89% [3] and in incision and drainage as 6.6% [3].

$$N = \frac{Z1-a/2\{p1(1-p1)+p2(1-p2)\}}{d2}$$

Z1-α = confidence level 95% = 1.96

P1 = population proportion 1= 2.34%

P2 = population proportion 2 = 25% d

= absolute precision 10%

SAMPLING TECHNIQUE:

Non probability convenient sampling

SAMPLE SELECTION:

Inclusion Criteria:

All patients of either gender having age 25-70 years with ASA class 2-3 presenting to emergency department with carbuncle requiring surgical drainage.

Exclusion Criteria:

1. Failure to tolerate VAC
2. Patient with co-morbidities like: CKD, CLD, CVA
3. Patients not giving consent
4. Close to the anal opening
5. Wound near the joint

DATA COLLECTION PROCEDURE:

All the patients with diagnosis of carbuncle who fulfill the inclusion criteria will be admitted through emergency and outdoor department. Risk to benefit ratio will be explained to patients. After taking informed consent patients will be divided in two groups through lottery method. Group A will represent Incision and drainage group, while group B will represent saucerization group. Intraoperative blood loss will be estimated. Every patient will be admitted in ward and amoxicillin and Broad spectrum antibiotics will be given to patients. VAC dressing will be applied to every patient on 1st post op day, postoperatively patient's Hemoglobin will be assessed for blood transfusion. Patients will be discharged once granulation tissue starts appearing on the wound . Patients will be called back for follow-up after every 14 days and will be assessed for wound healing using PWAT Score.

STUDY TECHNIQUE:

A 1.25cm thick foam film will be specially designed and sterilized. The system will be attached on the wound and a nelton catheter will be attached on the dressing. The whole area will be sealed using plastic fill sheet and sealed using tincture benzoic acid.

The wounds will be declared healthy when they will be filled with healthy granulation tissue and had epithelial growth on their edges. The wound will be assessed by photographic wound assessment tool (PWAT). Photographic images included in the analysis were recorded by mobile Samsung galaxy S-9+ camera. Photographs will take in a variety of clinical settings in which lighting conditions will optimize to reduce glare and shadows and increase image contrast. Mobile will equip to adjust automatically to varying light to permit close-up images of the wound (3 to 6 feet away). Before photography, a 15-cm ruler with clear millimeter divisions will be placed next to the wound as well as a patient identification number and the date of the assessment. Care will be taken to ensure that the camera will angle perpendicular to the wound bed; however, the distance between the camera and the wound will vary in order to capture the entire wound, the ruler, patient identification number, date, and a sample of the surrounding skin. Photographs will take after having receive the patient's written permission with the understanding that the patient's identity would be concealed at all times.

PWAT SCORING INSTRUCTIONS:

Assess the wound photograph and rate each PWAT domain according to the response that best describes observed wound findings. When more than one characteristic is evident, rate according to the majority or predominate feature that is visible in the photograph. Sub-scores are added together to obtain the total score. Total scores range from 0 to 32 where a decreasing total score indicates wound healing.

Photographic Wound Assessment Tool
PWAT – Revised

Item	Assessment			Score
1. Size	0 = wound is closed (skin intact) or nearly closed (<0.3cm^2) 1 = 0.5 – 2.0 cm^2 2 = 2.0 - 10.0 cm^2 3 = 10.0 – 20.0 cm^2 4 > 20.0 cm^2			
2. Depth	0. wound is healed (skin intact) or nearly closed (<0.3cm^2) 1. full thickness 2. unable to judge because majority of wound base is covered by yellow/black eschar 3. full thickness involving underlying tissue layers 4. tendon, joint capsule, bone, visible/ present in wound base			
3. Necrotic Tissue Type	0 = None visible or wound is closed (skin intact) or nearly closed (<0. 3cm^2) 1 = majority of necrotic tissue is thin White/grey or yellow slough 2 = majority of necrotic tissue is thick, adherent white yellow slough or fibrin 3 – majority of necrotic tissue is white/grey devitalized tissue or eschar 4 = majority of necrotic tissue is hard grey to black eschar			
4. Total Amount of Necrotic Tissue	0 = None visible in open wound or wound is closed (skin intact) or nearly closed(0.3cm^2) 1 = < 25% of wound bed covered 2 = 25% to 50% of wound covered 3 = > 50% and < 75% of wound covered 4 = 75% to 100% of wound covered			
5. Granulation Tissue type	0 = Wound is closed (skin intact) or nearly closed (<0.3cm^2) 1 = majority (>50%) of granulation tissue is healthy looking (even bright red appearance) 2 = majority of granulation tissue is unhealthy (eg. pale, dull, dusky, hypergranulation) 3 = majority of granulation tissue is damaged, friable, degrading 4 = there is no granulation tissue present in the base of the open wound (all necrotic)			
6. Total Amount of Granulation Tissue	0 = Wound is closed (skin intact) or nearly closed (<0.3cm^2) 1 =75% to 100% of open wound is covered with granulation tissue 2 = >50% and <75% of open wound is covered with granulation tissue 3 = 25% to 50% of wound bed is covered with granulation tissue 4 = <25% of wound bed is covered with granulation tissue			
7. Edges (directly touching and within 0.5cm of wound edge)	0 = Wound is closed (skin intact) or nearly closed (<0.3cm^2) or edges are indistinct, diffuse, not clearly visible because of re-epithelialization 1 = majority (>50%) of edges are attached with an advancing border of epithelium 2 = majority of edges are attached even with wound base (not advancing) 3 = majority of edges are unattached and/or undermined 4 = majority of edges are rolled, thickened or fibrotic (do not include callus formation)			
8. Periulcer Skin Viability (consider skin visible in photo or within 10 cm of wound edge)	Number of factors affected 0 = None 1 = One only 2 = Two or Three 3 = Four or Five 4 = six or more	- callus - dermatitis - maceration - desiccation or cracking - bright red, erythemic	- edema - excoriation - skin tearing/irritation r/t wound dressing or tape - hypo/hyper pigmentation - other: _____	
TOTAL SCORE				

DATA ANALYSIS PRODECURE:

The data will be analyzed by SPSS v26.0. Mean and standard deviation will be used for Quantitative data and frequency and ratios will be used for qualitative data. Quantitative variables (Blood loss, Duration of wound healing and PWAT score) will be assessed using t test. Qualitative variable (blood transfusion) will be assessed using chi square test. P value less than 0.05 will be considered significant.

OUTCOME & UTILIZATION:

If any of the technique proves better than the other then it will help the surgeons in training to follow that technique for better patient outcome in terms of early healing, no Transfusion and limited blood loss.

SCHEDULE/PHASING:

Month					
	1st month	2nd and 3rd month	4th month	5th month	6th month
Review literature	✓				
Data collection		✓			
Data analysis			✓		
Thesis writing				✓	
Thesis submission					✓

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2. Venkatesan R, Baskaran R, Asirvatham AR, Mahadevan S. 'Carbuncle in diabetes': a problem even today!. Case Reports.2017: doi: 10.1136/bcr-2017-220628.
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5. Kim YH, Kim H, Cheon JH, Kang DH. Epinephrine Infiltration and the Incidence of Bleeding Complications after Surgical Debridement of Pressure Ulcers with Negative Pressure Wound Therapy. J Wound Manag Res. 2019 ;15(2):85-90.
6. Agarwal P, Kukrele R, Sharma D. Vacuum assisted closure (VAC)/negative pressure wound therapy (NPWT) for difficult wounds: A review. J.Ortho.trauma. 2019;10(5):845-8.
7. Algadiem EA, Aleisa AA, Alsubaie HI, Buhlaiqah NR, Algadeeb JB, Alsneini HA. Blood loss estimation using gauze visual analogue. Trauma monthly. 2016 ;21(2):197-9.
8. Mallikarjunaswamy MB. Functional outcome of vacuum assisted closure (VAC) dressing therapy for the management of traumatic wounds and non-healing wounds. JCRD. 2024;15(02):195-8.
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CRF PROFORMA

COMPARISON OF WOUND HEALING FOR DIABETIC CARBUNCLE TREATED WITH INCISION & DRAINAGE TECHNIQUE USING CRUCIATE INCISION VERSUS SAUCERIZATION TECHNIQUE BOTH FOLLOWED BY VACUUM ASSISTED CLOSURE

Sr. no.: _____ Reg. No.: _____

Name: _____

Address: _____

Groups: • Incision and drainage •Saucerization Technique

Age: _____ (years)

Gender: •Male. •Female

Blood loss : _____

Transfusion : • No • Yes

Wound healing score:

Follow up	
At 2 week	
At 4 week	
At 6 week	
At 8 week	
At 10 week	

Sanctity of data - Affidavit

I,Mr/Ms_____S/o_____
__ Student
of_____
working in _____
Under Supervisorship of _____

Hereby undertake to abide by the following rules

1. **That the data collected during my attachment at King Edward Medical University (to be call KEMU here after) for which authorization is being granted by the Institutional Review Board (to be called IRB here after) of KEMU for which I have submitted my synopsis**
   titled_____
   _____ shall be used exclusively for the purpose of "not for profit" research and will not use for any other purpose what so ever. Any financial gain or patent originating from this research shall be equally shared with KEMU.
2. **The data collected shall be strictly limited to the parameters defined in my synopsis titled _____**
   _____
3. **That the identity of patients (cases) shall not be revealed.**
4. **That prior approval for research project (synopsis) has been obtained from the Institutional Review Board/ Ethical Committee of my parent institution.**
5. **That appropriate recognition and acknowledgement shall be given to KEMU in the publication of the paper/papers or any other medium of communication what so ever, if it utilizes the data/ graphs/tables/pictures collected from the aforementioned research, furthermore, in any subsequent publication or any other medium of communication what so ever, if it utilizes the above mentioned data/graphs/tables/pictures with proper acknowledgement (as mentioned below) and with prior intimation and authorization of IRB of KEMU.**
6. **The aforementioned acknowledgement/recognition shall be mutually decided between the principal investigator (myself) and the in charge of the unit concerned at KEMU, under intimation to the IRB of KEMU.**

I have read all the clauses of the above written agreement and hereby agree to be legally bound to this agreement in letter and spirit. I also understand that if I am in breach of this contract; I shall lose the right to the data/publication/graphs/tables collected/published (stored in any form physical/electronic) thereof. In addition, KEMU will reserve the right to initiate proceedings against me at any/all for a deemed appropriate. Research Supervisor (as shown below) shall stand witness and guarantor of this agreement and would be equally liable in case of breech of agreement.

Signature (Principal Investigator) **Signature of Supervisor NIC No.**_____ **NIC No.**_____

Proforma for Evaluation of Research Synopsis

Board of Studies

NOTE: (It should be filled in by All Members of BOS individually)

Title:_____
_____
_____
_____

A. Must fulfill all of the following.

Sr.No.	Essential Criterion	No	Yes
1.	According to prescribed format		
2.	Principal Investigator and Co investigator mentioned		
3.	Consent form given		
4.	Proforma for data collection given		
5.	Follow up proforma given		
6.	Non-compliance with previous research protocol		
7.	Repitition of Study		

B. Kindly evaluate this research proposal and grade the research proposal against each item. Must get at least 1 in all sections to qualify. Please check the appropriate box.

Sr. No.	Criterion	Grading					
1.	Novelty of research idea	0	1	2	3	4	5
2.	Potential for capacity building (Skills)	0	1	2	3	4	5
3.	Multidisciplinary	0	1	2	3	4	5
4.	Contribution of research topic towards public benefit	0	1	2	3	4	5
5.	Contribution of research topic towards medical knowledge	0	1	2	3	4	5

Total Score	**25**	**Score Obtain**	

Name:_____ Signature: _____

List of Required Documents For Approval of Institutional Review Board

- **Informed Consent Form in English and Urdu**

- **Subject Recruitment Procedure**
  (e.g OPD, Indoor, Advetisement)

- **Investigator's Brochure and Available Safety Information for Patient**
  (Please devise patient information in urdu detailing the complications, if any, and benefits of the device/ devices and comparison with conventional technique)

- **Investigator's Curriculum Vitae detailing qualification**

- **Sanctity of Data form - Affidavit duly filled in and signed**

- **Detailed Visit Forms**
  (Please make Seperate Proformas for every visit. Keeping in Mind Inclusion and Exclusion Criteria)
- **Minutes of Board Of Studies / Approval of BOS**
- **Proforma for Evaluation of Research Synopsis filled in individually by members of the Board of Study**
- **Soft Copy of Synopsis alongwith soft copy of articles of all references submit in Research Center on CD.**