COMPARISON OF ANGIOSOME BASED INCISION WITH CONVENTIONAL AGGRESSIVE DEBRIDEMENT FOR THE TREATMENT OF DIABETIC FOOT ULCERS.

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ABSTRACT... Objectives: To compare the efficacy of angiosome based incisions versus aggressive debridement for the treatment of diabetic foot ulcer. Study Design: Randomized Controlled Trial. Setting: Surgical Unit 1 Nishtar Medical University/ Hospital Multan. Period: 9 months duration, from 1st January 2017 to 30th September 2017. Material & Methods: Sample Size: Total 210 patients, 105 in each group. Sampling Technique: Non-probability, consecutive sampling. 210 patients of both genders with history of diabetes mellitus having Grade II diabetic foot ulcer below the ankle. Before the procedure, foot ulcers were measured and ulcer dimensions equal or greater than 4 cm² were included in the study. 105 patients were in angiosome based incision group (Group A), while 105 patients were in aggressive debridement group (Group B). Patients were called for follow up after every 5 days. Regular dressings were done to allow more regular wound inspection and cleansing to avoid infection. Results: Age range in this study was from 30 to 60 years with mean age of 45.971± 4.89 years in Group A while 46.457± 6.22 years in Group B. Mean duration of diabetes was 10.171±4.09 years in Group A and 10.561±5.58 years in Group B. Mean duration of foot ulcer was 3.895±2.72 months in Group A and 3.790±2.03 months in Group B. Mean size of foot ulcer was 5.047±1.52 cm² in Group A and 4.895±1.67 cm² in Group B. Mean weight of the patients was 68.238±10.44 kg in Group A and 67.742±9.53 Kg in Group B. Majority of the patients were of 46-60 years range in this study was from 30 to 60 years with mean age of 45.971± 4.89 years in Group A while 46.457± 6.22 years in Group B. Mean duration of diabetes was 10.171±4.09 years in Group A and 10.561±5.58 years in Group B. Mean duration of foot ulcer was 3.895±2.72 months in Group A and 3.790±2.03 months in Group B. Mean size of foot ulcer was 5.047±1.52 cm² in Group A and 4.895±1.67 cm² in Group B. Mean weight of the patients was 68.238±10.44 kg in Group A and 67.742±9.53 Kg in Group B. Majority of the patients were of 46-60 years in Group A (63.8%) and in group B (66.7%). Male gender was dominant in both group (73.3% and 55.25). In group A efficacy was seen in 96 (91.4%) patients as compare to 47 (44.8%) patients in group B, (P=0.000). Conclusion: Angiosome based incision in the treatment of diabetic foot ulcer has shown outstanding outcome with respect to wound healing compared with aggressive debridement.

Key words: Angiosome Based Incision, Aggressive Debridement, Diabetic Foot Ulcer.

INTRODUCTION

Diabetes mellitus (DM) is major health problem in our society. Globally it is increasing over the last 20 years.¹,²,³ Diabetic patients are prone to develop many complications. Diabetic Foot Ulcer (DFU) is the most common complication of diabetes mellitus.⁴,⁵ Diabetic patients has 15% chance to develop DFU during their lifetime.⁶,⁷

“Debridement means removal of the necrotic tissues, foreign bodies and infected materials from the wound”.⁸ Debridement reduces pressure thus facilitates wound drainage and decreasing the bacterial load.⁹ Debridement stimulates growth factors thus improves healing.

The angiosome principle, defined by Ian Taylor in 1987, divides the body into three-dimensional anatomic units of tissue supplied by specific arteries.¹⁰ “An angiosome is an arterial supply to a defined area of tissues”. The word angiosome is derived from Greek word angeon, meaning blood vessel and somatikos means the pertinence to the body.¹¹,¹² Incisions based on Angiosome facilitate wound healing and decrease amputations rates.

Taylor divides the leg in to 3 angiosomes, the angiosomes of anterior tibial, posterior tibial and peroneal arteries.¹² Some tissues receive blood from branches of two angiosomes.
OBJECTIVE
To compare the efficacy of angiosome based incisions versus aggressive debridement in treatment of diabetic foot ulcer patients.

Diabetic foot ulcer was defined as a wound of dimensions equal or greater than 4 cm² on physical examination below the ankle with Grade II Ulcer.

The efficacy was defined as when ulcer heals on physical examination after 30 days.

MATERIAL AND METHODS

It was a Randomized Controlled Trial, conducted at Surgical Unit 1 Nishtar Medical University/Hospital Multan.

The Duration of Study was 9 months duration, from 1st January 2018 to 30th September 2018.

This is study were Total 210 patients, 105 in each group these were selected by Non-probability, consecutive sampling.

Inclusion Criteria
Age 30-60 years of both Genders having H/o Diabetes with Grade II Diabetic foot ulcer below the ankle and Ulcer dimensions equal or greater than 4 cm² on physical examination.

Exclusion Criteria
Gangrene foot on physical examination, history of getting immunosuppressive therapies, Osteomyelitis and renal disease.

Patients fulfilling the inclusion criteria were admitted in surgical Unit I Nishtar hospital Multan. Study started after permission from ethical committee and research department of Nishtar Medical University/ Hospital Multan. A detailed explanation about the procedure was given to the patient and a written informed consent was obtained explaining the risks and benefits.

Before the procedure, foot ulcers were measured. A double layer of polyethylene sheets was held firmly in place over the wound, and an outline of the wound was traced using a permanent marker. The layer in direct contact with the wound was discarded. The tracing made on the top layer of polyethylene was fixed against a graphic paper and its area was measured.

In Group A, incisions were made according to angiosome model and in group B aggressive debridement was done in routine manner. Debridement was performed on all wounds in the operating theatre under local Anesthesia. Prophylactic antibiotics were given. Debridement entailed the excision of all necrotic and infected tissue until healthy, bleeding tissue was reached. After debridement, the wound was thoroughly cleansed and irrigated by jet lavage, dressing was placed and patients were sent to home. Patients were called for follow up after every 6th day to allow more regular wound inspection and cleansing to avoid infection.

Dressing was left in place for 2 days, and then change of dressing was done by a local doctor. Efficacy of treatment was finally determined after 30 days as per operational definition by measuring the ulcer dimension by similar procedure as done before the start of procedures. Data was noted on especially designed proforma.

Data was analyzed with statistical analysis program (SPSS version20). Frequency and percentage was computed for qualitative variables like gender and efficacy. Mean ±SD was presented for quantitative variables like age, duration of diabetes, duration of foot ulcer, size of ulcer and weight of the patient. Chi-square test was applied to compare efficacy in both groups taken p ≤0.05 as significant. Stratification was done with regard to age, gender, duration of diabetes, duration of foot ulcer, size of ulcer and weight to see the effect of these on efficacy. Post stratification using the chi-square test for both groups, p ≤0.05 was considered statistically significant.

RESULTS
Age range in our study was from 30 to 60 years with mean age of 45.971 ± 4.89 years in Group A while 46.457 ± 6.22 years in Group B. Mean duration of diabetes was 10.171 ± 4.09 years in
Group A and 10.561±5.58 years in Group B. Mean duration of foot ulcer was 3.895±2.72 months in Group A and 3.790±2.03 months in Group B.

Mean size of foot ulcer was 5.047±1.52 cm² in Group A and 4.895±1.67 cm² in Group B. Mean weight was 68.238±10.44 kg in Group A and 67.742±9.53 Kg in Group B as shown in Table-I.

Majority of the patients were of 46-60 years in group A (63.8%) and 66.7% were in group B. Male gender was dominant in both group (73.3% in group A and 55.25% in group B). In group A efficacy was seen in 96 (91.4%) patients as compare to 47 (44.8%) patients in group B, (P=0.000) as shown in Table-II.

Stratification of efficacy with regard to age, gender, duration of diabetes, duration of foot ulcer, size of foot ulcer and weight are shown in Table-III, IV, V, VI, VII and VIII respectively.

| Demographics | Mean ± SD Group A n=105 | Mean ± SD Group B n=105 |
|---------------|-------------------------|-------------------------|
| 1 Age(years)  | 45.971±4.89             | 46.457±6.22             |
| 2 Duration of Diabetes (years) | 10.171±4.09 | 10.561±5.58 |
| 3 Duration of Foot Ulcer (months) | 3.895±2.72 | 3.790±2.03 |
| 4 Size of Foot Ulcer (cm²) | 5.047±1.52 | 4.895±1.67 |
| 5 Weight (Kg) | 68.238±10.44 | 67.742±9.53 |

Table-I. Mean ± SD of patients according to age, duration of diabetes, duration of foot ulcer, size of foot ulcer and weight in both groups. n=210

| Efficacy | n=105 | n=105 | P-Value |
|----------|-------|-------|---------|
| Yes      | 96 (91.4%) | 47 (44.8%) | 0.000 |
| No       | 9 (8.6%)   | 58 (55.2%)  |       |

Table-II. Comparison of efficacy in both groups n=210

| For Age Group 30-45 Years | Efficacy | P-Value |
|---------------------------|----------|---------|
| Group                     | Yes      | No      |         |
| A                         | 33(86.8%)| 5(13.2%)| 0.000   |
| B                         | 17(48.6%)| 18(51.4%)|        |

| For Age Group 46-60 Years | Efficacy | P-Value |
|---------------------------|----------|---------|
| Group                     | Yes      | No      |         |
| A                         | 63(94%)  | 4(6%)   | 0.000   |
| B                         | 30(42.9%)| 40(57.1%)|        |

Table-III. Stratification of efficacy with respect to age in Group A and Group B

| For Male | Efficacy | P-Value |
|----------|----------|---------|
| Group    | Yes      | No      |         |
| A        | 69(89.6%)| 8(10.4%)| 0.000   |
| B        | 23(39.7%)| 35(60.3%)|        |

| For Female | Efficacy | P-Value |
|------------|----------|---------|
| Group      | Yes      | No      |         |
| A          | 27(96.4%)| 1(3.6%) | 0.000   |
| B          | 24(51.1%)| 23(48.9%)|        |

Table-IV. Stratification of efficacy with respect to gender in Group A and Group B

| Duration ≤ 10 Years | Efficacy | P-Value |
|---------------------|----------|---------|
| Group               | Yes      | No      |         |
| A                   | 62(89.9%)| 7(10.1%)| 0.000   |
| B                   | 23(35.9%)| 41(64.1%)|        |

| Duration > 10 Years | Efficacy | P-Value |
|---------------------|----------|---------|
| Group               | Yes      | No      |         |
| A                   | 34(94.4%)| 2(5.6%) | 0.000   |
| B                   | 24(58.5%)| 17(41.5%)|        |

Table-V. Stratification of efficacy with respect to duration of diabetes in Group A and Group B

| Duration 1-5 Months | Efficacy | P-Value |
|---------------------|----------|---------|
| Group               | Yes      | No      |         |
| A                   | 86(91.5%)| 8(8.5%) | 0.000   |
| B                   | 39(42.4%)| 53(57.6%)|        |

| Duration > 5 Months | Efficacy | P-Value |
|---------------------|----------|---------|
| Group               | Yes      | No      |         |
| A                   | 10(90.9%)| 1(9.1%) | 0.097   |
| B                   | 8(61.5%) | 5(38.5%)|        |

Table-VI. Stratification of efficacy with respect to duration of foot ulcer in Group A and Group B
Table VII. Stratification of efficacy with respect to size of foot ulcer in Group A and Group B

| Group | Yes   | No    | P-Value |
|-------|-------|-------|---------|
| A     | 73(89%) | 9(11%) | 0.339   |
| B     | 33(39.3%) | 51(60.7%) |         |

Size > 6 cm²

| Group | Yes   | No    | P-Value |
|-------|-------|-------|---------|
| A     | 23(100%) | 0(0%) | 0.002   |
| B     | 14(66.7%) | 7(33.3%) |         |

Table VIII. Stratification of efficacy with respect to weight in Group A and Group B

For Weight ≤ 70 Kg

| Group | Yes   | No    | P-Value |
|-------|-------|-------|---------|
| A     | 62(96.9%) | 2(3.1%) | 0.000   |
| B     | 35(50.7%) | 34(49.3%) |         |

For Weight > 70 Kg

| Group | Yes   | No    | P-Value |
|-------|-------|-------|---------|
| A     | 34(82.9%) | 7(17.1%) | 0.000   |
| B     | 12(33.3%) | 24(66.7%) |         |

Figure 1. Anterior tibial artery angiosome territory (Dark Grey)
Figure 2. The posterior tibial artery angiosome (Grey)
Figure 3. The peroneal artery angiosome (White)
Figure 4. Angiosome of the foot and ankle.
Figure 5. Achilles tendon. A medial to lateral S-shaped incision.
Figure 6. Lateral calcaneus.
Figure 7. Medial calcaneus.
Figure 8. Medial arch.
Figure 9. Plantar heel and midfoot. Curved or Z shaped incision.
Figure 10. Dorsal and plantar fore foot.
Figure 11. First metatarsophalangeal joint.
DISCUSSION
It is important to know the vascular anatomy while placing incisions for diabetic foot ulcers. Incisions should not be placed over the arteries. Angiosomes based incisions and good debridement can enhance the wound healing.

4 important factors should be considered when placing an incision for DFU.

First, the incision must provide adequate exposure. Second, there must be adequate blood supply on either side of the incision for good healing. Third, the incision should spare the nerves. Fourth, the incision should not be placed perpendicular to a joint.

Statistical analysis of our study shows that age wise both groups shows significant difference in efficacy of angiosome based incision group A (p= 0.000) as compared to group B. This shows that age has no limitation but it the incision which makes the difference. Efficacy of wound healing was better in group A then group B according to same age group.

Our study results shows that gender wise both groups shows significant difference in efficacy of angiosome based incision group A (p= 0.000) as compared to group B. This shows that gender has no limitation but it the incision which makes the difference. Gender wise efficacy of wound healing was better in group A then group B. Statistically duration of diabetes either less than 10 years or more than 10 years has no effect on wound healing. It is angiosome based incision (Group A) which makes the difference (P= 0.000) then group B. It means efficacy of wound healing is batter in group A then in group B.

Duration of diabetic foot ulcer dose effect on the wound healing. If duration of foot ulcer is less than 5 months, wound healing is batter in patients in which incisions were based on angiosome model (group A) as compared aggressive debridement (group B). But if the duration of diabetic foot ulcer is more than 5 months, statistically there is no difference in the wound healing in both the groups (Table-VI). Stratification of efficacy with respect to size of diabetic foot ulcer shows that if ulcer size is 4-6 cm² there is no significant difference in wound ulcer healing in both the groups. But there is significant difference (P=0.002) if ulcer size is more than 6 cm² in both the groups. This shows that there is better wound healing in angiosome based incision as compared to aggressive debridement when diabetic foot ulcer is more than 6cm². This is the basic reason for the better wound healing when incisions were given according to angiosome model as shown in Table-VII.

Statistically weight of the patient has no effect on wound healing either weight is less than 70 Kg or more than 70 Kg. It is angiosome based incision (Group A) which makes the difference (P= 0.000) then group B. It means efficacy of wound healing is batter in group A then in group B as shown in Table-VIII.

Diabetic Foot Ulcer treatment is multi-disciplinary approach, including serial debridement, diabetic control, treatment of sepsis and risk factors must also be employed when treating patients with DM.

CONCLUSION
Angiosome based incisions in the treatment of diabetic foot ulcer have shown outstanding outcomes with respect to wound healing compared with aggressive debridement.

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| 3     | Shafiq Ullah                | Collect the data.                                                |                     |
| 4     | Shahid Mansoor Nizami       | Analysis of data.                                                |                     |
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