International Journal of Biomedical And Advance Research

ISSN: 2229-3809 (Online)
Journal DOI:10.7439/ijbar
CODEN:IJBABN

Research Article

Does the nutritional status changes the healing outcome of simple diaphysel tibial fractures in adults: A prospective cohort study

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Abstract

Objectives: The main objective of the study was to correlate the healing outcome of the simple diaphyseal fractures with the nutritional status of the patients.

Method: In this longitudinal cohort study, total sixty five adult patients (eighteen to forty-five years) with simple, fresh traumatic diaphyseal fractures of both bones of leg managed conservatively; were analysed. The assessment of nutritional status of enrolled patients was done by estimating serum albumin and serum ferritin at the start of treatment. The clinico-radiological follow-up was done to analyze the fracture healing outcomes. As per clinico-radiological outcomes, these patients were divided into two groups: Group-A: clinico-radiological bone healing with RUST score ≥ 7 at or by the end of 06th months (normal healing) and Group-B: clinico-radiological bone healing with RUST score < 7 by the end of 06th months (impaired healing). These healing outcomes were correlated with nutritional status of the patients.

Results: Difference between the demographic variables of both groups was statistically insignificant. Fifty four patients belonged to Group A and eleven patients to Group B. Serum albumin and serum ferritin shows non-significant relative risk. However, the serum albumin showed a significant correlation (< 0.001) with the bony healing progression of diaphysial tibia.

Conclusions: Impaired nutritional status of the patients having non-significant relative risk with impaired fracture outcomes, but serum albumin showed positive correlation with the bony healing progression of diaphysial tibial fractures.

Keywords: Serum albumin, Nutrition, Outcomes of tibial fracture, Impaired healing, Nutritional status

1. Introduction

The subcutaneous position of the tibia results in a greater incidence of fractures and less soft-tissue coverage produce a higher incidence of impaired healing[1-5]. Only the rate of tibial nonunions is estimated to constitute 2-10% of all tibial fractures[6-7]. Fracture impairment leads to prolonged disability, associated with substantial pain and put extra burden on the patient [8-9]. Fractures impairment may be caused by several factors such as extensive soft tissue damage, the presence of a gap at the fracture site, poor mechanical stability, open fractures, administration of pharmacological agents, such as NSAIDs and smoking, etc[10-11]. The potential role of nutritional health in the fracture healing outcomes among individuals also known[12-15]. But till now, they are not in use as a prognostic marker, in parallel to clinic-radiological diagnosis.

Serum albumin level[16] of ≥3.5 g/dl and serum ferritin[17] of range between 30-400 ng/mL (male) and 13-150 ng/mL (female) is widely accepted as normal. Some authors have used albumin levels alone as a laboratory indicator for malnutrition in orthopaedic patients[16-18]. Many studies had been correlated protein depletion with increased mortality and morbidity, wound infection, surgical failure, sepsis as well as impaired fracture union and wound healing[19, 12-15]. Koval *et al*. in a study also demonstrated that albumin level of < 3.5 g/dl was predictive of delay of fracture to heal, increased length of hospital stay as well as their mortality rate[20].

Based on above, we planned our study to correlate the fracture healing outcomes with nutritional status of the patients, by taking serum albumin and serum ferritin as a nutritional status indicator.

2. Material and Methods

In this longitudinal cohort study, total 78 adult patients in the age group between 18 to 45 years with simple, fresh (< 7 days) traumatic diaphyseal fractures (42-A1,A2 &A3, as per as AO muller classification) of both bones of leg managed conservatively were included. The exclusion criterion were as follows: age less than 18 yrs and more than 45 yrs, osteoporotic fractures, polytrauma, pathological fractures, compound or infected fractures, chronic alcoholic or tobacco smokers, immune-compromised patients, patients with intact fibula, uncontrolled diabetes, patients with bile duct obstruction and chronic inflammatory bowel disease, patients on prolonged drugs like anabolic steroids, thiazides, diuretics, hormonal therapy, NSAIDs, calcium, fluorides and immunosuppressive drugs, and those not willing for inclusion in study.

After obtaining ethical clearance (Ref. Code: 57 E.C.M. IIA/P4) from institutional ethical review committee, total 78 patients were included in this study from 2011 to 2013. After the informed consent, demographic data of all enrolled patients was collected. The peripheral blood (2ml) was collected into plain vials under standard aseptic technique at the time of management for the estimation of nutritional status of enrolled patients by measuring their serum albumin (ELITech Clinical System) and serum ferritin (Roche Analyser) levels. These biochemical examinations were performed in duplicates as per as their manual protocol. Our reference value of serum albumin are ≥3.5 g/dl and serum ferritin are between 30-400 ng/mL (male) and 13-150 ng/mL (female) respectively, accepted as normal All were managed conservatively (reduction setting and above knee plaster were applied under regional / general anesthesia). All were discharged after 24 – 48 hours with a standard advice written on discharge card.

The clinico-radiological examinations of these patients were done at 6th, 10th, 16th, 20th, 24th, weeks. Clinical examination of the fracture site was done for the assessment of –skin condition, abnormal mobility (if required), bony tenderness and transmitted movements. Radiological assessment was done using RUST score[21] by taking standard plain radiographs of full length of leg (AP and Lateral views). The radiographic scoring was done by an orthopaedic surgeon and by a radiologist separately and blindly. The average of the two scores was given to each radiograph. No specific treatment of impaired nutritional status was done except diet correction if required.

Based on the above clinico-radiological evaluation, we divided these patients into 2 groups – Group-A: clinic-radiological bone healing with RUST score ≥ 7 by the end of 06th months (normal healing) and Group-B: clinic-radiological bone healing with RUST score < 7 by the end of 06th months (impaired healing).The clinical bone union was defined as the stage in the healing process when the fracture site was painless (no tenderness), motionless (no abnormal mobility) with presence of transmitted movements. Radiographic bone healing was defined when bony callus was evident on at least 3 cortices in standard AP and Lateral views and with RUST score was greater or equal to seven[21].

2.1 Statistical analysis

The data were entered in Microsoft Excel and were checked for any inconsistency before analysis. Statistical analysis was performed using SPSS software for Windows program (15.0 version). The continuous variables were evaluated with mean (±SD) or range value when required. For comparison of the means between patient groups, relative risk with its 95% confidence interval and Pearson correlation coefficient was used. A p value less than 0.05 or 0.001 were regarded as significant.

3. Results

Total 78 patients were enrolled in present longitudinal study. Thirteen patients were lost in follow up, so we analysed only 65 patients. According to the clinic-radiological outcomes, these fractures were divided into two groups: Group A (n = 54), with normal bony union and Group B (n = 11), with impaired bony union. **Table-1** describes the baseline characteristics of all 65 patients. The difference between these baseline characteristics between two groups was statistically insignificant.

Table-1: Baseline characteristics of the patients

Characteristics of the patients	n=65
Age in years	31.03±9.20
Male gender, no. (%)	58 (89.2)
Mode of injury, no. (%)	
Fall from height	18 (27.7)
Road traffic accident	42 (64.6)
Simple fall	5 (7.7)
Site of injury, no. (%)	
Left	32 (49.2)
Right	33 (50.8)
Hemoglobin	10.28±1.35
S. albumin	3.60±0.25
S. ferritin	98.30±40.26
RUST score	4.00±0.00
AO type, no. (%)	
42-A1	22 (33.8)
42-A2	23 (35.4)
42-A3	20 (30.8)

The baseline serum sampling was done at 2.07 day (range 1-3). The mean level of serum albumin, ferritin and haemoglobin were 3.60±0.25, 98.30±40.26 and 10.28±1.35 respectively. The healing (RUST score) was higher among the patients of age less than 30 years (n= 34) compared with patient of age 30 years or more (n= 31) (RR=1.04, 95%=0.83-1.30, p=0.69), which was statistically insignificant. The healing was 1.18 times higher among males patients than females (RR=1.18, 95%CI=0.73-1.91, p=0.38), which was statistically insignificant. In present study the mode of injury did affect the healing status found to be statically insignificant (p>0.05). The healing was 20% and 11% lower respectively, among the patients whose serum albumin (RR=0.80, 95%CI=0.60-1.07, p=0.08) and serum ferritin (RR=0.89, 95%CI=0.50-1.59, p=0.19) were low at the baseline. However, these were also statistically not significant **(see Table-2)**.

Table-2: Comparison of parameters according to healing status

Parameters	No. of patients	Group-A		Group-B		RR (95%CI), p-value
		No. (%)	%	No. (%)	%	
Serum Albumin						
<3.5 (Abnormal)	21	15(71.4)	71.4	6	28.6	0.80 (0.60-1.07), 0.08
≥3.5 (Normal)	44	39(88.6)	88.6	5	11.4	
Serum Ferritin[1]						
Abnormal	4	3(75.0)	75.0	1	25.0	0.89 (0.50-1.59), 0.19
Normal	61	51(83.6)	83.6	10	16.4	

RR-Relative risk, CI-Confidence interval, [1]Normal: male: 30-400 ng/mL, female: 13-150 ng/mL, abnormal: otherwise

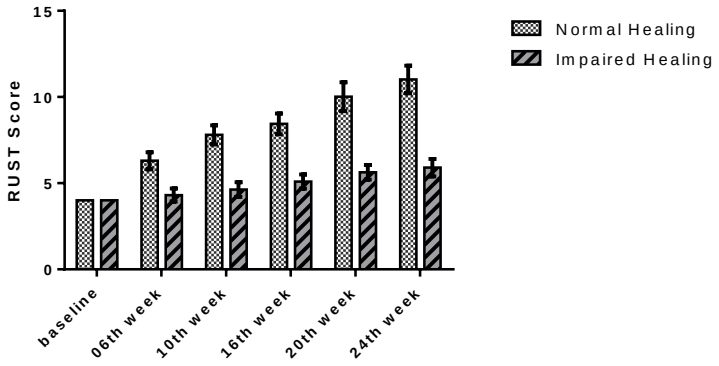
Group-A had the mean RUST score of 11.03 (range 8-12) at the end of 06th months and Group-B had the mean RUST score of 5.91 (range 5-6.5) at the end of 06th months, shows statistically significant difference **(see Fig.1)**. The mean healing time of group-A patients was 12.40±2.05 weeks having RUST score ≥ 7. The correlation between RUST score and serum albumin level was found to be significant whereas there was insignificant correlation between RUST score and serum ferritin levels at all the follow-ups **(see Table-3)**.

Table-3: Correlation coefficient between serum albumin, ferritin and fracture healing progression measured by RUST score.

Follow-up period (RUST score)	r, p-value	
	Serum Albumin	Serum Ferritin
06 week	0.39, 0.001*	0.10, 0.39
10 week	0.40, 0.001*	0.18, 0.13
16 week	0.40, 0.001*	0.16, 0.19
20 week	0.43, 0.0001*	0.23, 0.05
24 week	0.43, 0.0001*	0.22, 0.07

*Significant

Fig-1: Healing progression at different follow up measured by RUST Score.



4. Discussion

Diaphyseal tibial fractures are common and may leads to substantial burden on patients and the healthcare system. The problem of fracture healing impairment further more common in tibial fractures and challenging for the treating surgeons that worsen the burden of tibia diaphyseal fractures many fold.[8-9] Many of the factors are responsible for fracture impairment,[10-11] including nutritional status of the patient.[12-15] Based on above findings, we planned the study to correlate the tibial fracture healing outcomes with nutritional status by taking serum albumin and serum ferritin as a nutritional status indicator of the patients and hypothesised that the fracture healing outcomes of tibial fractures was significantly associated with these nutritional status parameters of the treating patients.

According to Davis *et al*.[22] healing is a continuous process to achieve a bony union. Thus, healing should be measurable. But unfortunately, no clinically validated method to measure healing over time is available to date. Currently, clinical and radiological methods are most commonly used to assess the healing of fractures. Hammer *et al*.[23], further described that the probability of correct radiological evaluation of fractures union of the tibia has been shown to be only about 50%. Therefore, radiographic assessment is not a very good method to asses fracture healing, essentially when their clinical outcomes are confusing, a fact borne out by a study on the radiological evaluation of the stage of union in fractures of the tibia[24]. Thus, the patient will have to suffer for a larger period of time.

Many studies had correlated the nutritional status of patients with hip fracture with fracture healing outcomes.[25-29] It was shown that impaired nutritional status of these patients was correlated with impaired fracture healing. For the same, the current study is an effort to overcome the issue of early prediction of the outcomes of diaphyseal tibial fractures healing by using a simple laboratory test. So that the proper management or intervention may give to the patients with in time, to relieve the socioeconomic burden of the suffering patients.

As per our knowledge, Dwyer *et al*.[15] was the first to studied the association of nutritional status on healing of tibial fractures in humans. In that study, 34 patients with open tibial fracture were followed for 40 weeks. Similar to our result, they also found statistically insignificant association of fracture healing outcomes with nutritional status of the patients. But on other hand, Day *et al*.[13], Einhorn *et al*.[14] & Guarniero *et al*.[30] found the significant association of nutritional status with tibial fracture healing in rats and concluded that nutrition significantly directs the fracture healing in tibia.

In the present study, we found statistically insignificant association of nutritional status of treating patients with tibial fracture outcomes. Although out of total group-A patients (n= 54), 28.6% of fractures showed impaired healing and rest 71.4% patients had normal healing. However, out of 88.6% patients with normal nutritional status, 11.4% showed impaired fracture healing.

So in respect to our obtained result, we observed that malnutrition of these patients was not always predicted to result into impaired bone healing, but serum albumin shows positive correlation with the bony healing progression and outcome of diaphysial tibia. The weakness of the current study is that, a relatively small number of patients were enrolled.

5. Conclusion

The subcutaneous position of the tibia results in a greater incidence of fractures and less soft-tissue coverage produce a higher incidence of impaired healing. In day to day practice, clinical and radiological methods are most commonly used to assess the healing have only 50% accuracy. Moreover, clinicians are unable to identify delayed and non-unions early (only after 10 weeks of starting the treatment one can suspect few cases), hereby increasing the suffering time of the patients. As the potential role of nutritional health in the fracture healing progression among individuals also revels in many studies. We observed that nutritional status of patients with simple diaphyseal tibial fractures shows insignificant relative risk in relation to fracture healing outcomes, but serum albumin shows positive correlation with the bony healing progression of these fractures.

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