To Evaluate the Relationship of Nutritional Status with Outcomes of Simple Diaphysel Tibial Fractures

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Abstract—Total sixty five adult patients (eighteen to forty-five years) with simple, fresh traumatic diaphyseal fractures of both bone leg managed conservatively; were analysed. The assessment of nutritional status of enrolled patients was done. As per clinico-radiological outcomes, these patients were divided into two groups: Group-A: clinico-radiological bone healing with RUST score \geq 7 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.

The difference between the demographic variables of both groups was insignificant. There were fifty four in Group A and eleven in Group B. Serum albumin and serum ferritin shows non-significant relative risk, having value of p=0.08 and p=0.19 respectively. However, the serum albumin showed a significant correlation (< 0.001) with the bony healing progression of diaphysial tibia.

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

I. 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].

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

II. MATERIAL AND METHODS

A. Study Protocol

In this longitudinal cohort study, total 78 adult patients in the age group between 18 to 45 years with simple, fresh (< 7days) 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 were collected. 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 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 examinations were performed in duplicates as per as their manual protocol. The clinico-radiological examination of these patients was done in 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 the full length of the 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.

Based on the above clinico-radiological evaluation, we divided these patients into 2 groups – Group-A: clinic-radiological bone healing with RUST score \geq 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. The 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 \geq 7 [21].

B. 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 (\pm 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.

III. RESULTS

Total 78 patients were enrolled in our 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 the impaired bony union. Table-I describes the baseline characteristics of all 65 patients.

The mean day of serum sampling was 2.07 (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

BASELINE CHARACTERISTICS OF T Characteristics of the patients Age in years Male gender, no. (%)	n=65
Age in years	
6	00.00.000
Male gender, no. (%)	32.03±9.20
	58 (89.2)
Mode of injury, no. (%)	
Fall from height	20 (30.8)
Road traffic accident	40 (61.5)
Simple fall	5 (7.7)
Site of injury, no. (%)	
Left	32 (49.2)
Right	33 (50.8)
Hemoglobin	10.58±1.35
S. Albumin	3.40±0.25
S. Ferritin	99.30±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)

less than 30 years (n=34) compared with equal or more than 30 years (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 male patients than females (RR=1. 18, 95%CI=0.73-1.91, p=0.38), which was statistically insignificant. In the 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 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 abnormally low at the baseline. However, these were also statistically not significant (see Table-II).

TABLE II Comparison Of Different Parameters According To Healing Status						
	No. of	Normal		Impaired		RR (95%CI),
Parameters	pts	No.	%	No	%	p-value
Age in years						
<30	33	28	84.8	5	15.2	1.04 (0.83-
≥30	32	26	81.2	6	18.8	1.30), 0.69
Sex						
Male	58	49	84.5	9	15.5	1.18 (0.73-
Female	7	5	71.4	2	28.6	1.91), 0.38
Mode of injury						
Fall from height	18	17	94.4	1	5.6	
Road traffic accident	42	32	76.2	10	23.8	p=0.12
Simple fall	5	5	100.0	0	0.0	
Site						
Left	32	28	87.5	4	12.5	1.11 (0.89-
Right	33	26	78.8	7	21.2	1.38), 0.34
ALB						
<3.5(Abnormal)	21	15	71.4	6	28.6	0.80 (0.60-
\geq 3.5 (Normal)	44	39	88.6	5	11.4	1.07), 0.08
FERR ¹						
Abnormal	4	3	75.0	1	25.0	0.89 (0.50-
Normal	61	51	83.6	10	16.4	1.59), 0.19

RR-Relative risk, CI-Confidence interval ¹Normal: male: 30-400, female: 13-150, 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 a statistically significant difference. The mean healing time of group-A patients were 9.40 \pm 2.05 weeks having RUST score \geq 7.

The correlation between RUST score and serum albumin level was found to be significant, whereas there was an insignificant correlation between RUST score and serum ferritin levels at all the follow-ups (see Table-III).

TABLE III CORRELATION COEFFICIENT BETWEEN SERUM ALBUMIN, FERRITIN AND FRACTURE HEALING PROGRESSION MEASURED BY RUST SCORE.

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

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IV. DISCUSSION

Diaphyseal tibial fractures are common and may lead 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 hypothesized that the fracture healing outcomes of tibial fractures was significantly associated with the nutritional status 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 early 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 fracture 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 has been already revealed that the nutritional status of patients with hip fracture, was an important determinant of their clinical outcomes, including impaired fracture healing [25-29]. 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 within time, to relieve the socioeconomic burden of the suffering patients. The weakness of the current study is that, a relatively small number of patients were enrolled.

As per our knowledge, Dwyer et al. [15] was the first to study the association of nutritional status on healing of tibial fractures in humans. In this study, 34 patients with open tibial fracture were followed for 40 weeks. As like as our study result, they also found statistically insignificant association of fracture healing outcomes with the nutritional status of the patients. But on the other hand, Day et al. [13] found the significant association of nutritional status with tibial fracture healing in rats and concluded that nutrition significantly directs the fracture healing in the tibia. The same result has been found by Guarniero et al. [30] while assessing the effects of nutrition on fracture healing in a controlled animal model. Einhorn et al.14 also found the significant association of nutritional status with fracture healing of long bones in rats.

In the present study, we found statistically insignificant association of nutritional status of treating patients with tibial fracture outcomes. Although 28.6% of fractures showed impaired and 71.4% fracture patients had normal healing of tibial fracture in malnourished patients (serum albumin < 3.5 g/dl). However, 11.4% of fractures showed impaired and 88.6% fracture patients had normal healing of tibial fracture in nourished patients (serum albumin \geq 3.5 g/dl).

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.

V.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 As the potential role of nutritional health in the patients. fracture healing progression among individuals also revels in many studies. In our study, as the nutritional status of treating patients shows non-significant relative risk in relation to fracture healing outcomes, but serum albumin shows positive correlation with the bony healing progression of diaphysial tihia

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