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Pulsed Electromagnetic Field and Extracorporeal Shock Wave in Treatment of Delayed or Non-United Tibial Fracture, A Comparative Study

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Abstract

Objectives: To compare the effect of pulsed electromagnetic field (PEMF) extracorporeal shock wave therapy (ESWT) on healing of delayed as well as non-united tibial fractures.

Methods: This study was carried out on 60 adult patients suffering from delayed or non-union tibial fractures in spite of previous conservative treatment by (closed reduction and casting), or operative treatment by: ORIF by (IMN, plate and screws or gliding nail), or external fixation. They were divided according to line of treatment into 2 equal groups. The first group received (PEMF) therapy at the site of fracture of 12 Hz, 3 mT for 60 minutes per session, for 3 months, the patient of the second group were treated by focused (ESWT) at the site of fracture 3 sessions of 2500-3000 impulses each given at 0.25-0.84 mJ/mm^2, at interval of 48-72 h between sessions, a maximum of 3 cycles of treatment was given at 3 months intervals. Clinical and radiological assessments were done before, after and then 6 months later as follow up. However functional assessment was done after treatment and 6 months later as follow up.

Results: Our results showed better and earlier improvement of clinical, radiological as well as functional scores in group II more than group I.

Conclusion: The best significant as well as more rapid clinical, radiological and functional improvement in cases of delayed or non-united tibial fractures was obtained with ESWT compared to PEMF therapy.

Keywords: Extracorporeal shock wave therapy; Pulsed electromagnetic wave therapy; Delayed tibial fracture

Introduction

Non or delayed union is one of the most common complications of bone fracture, and union is considered delayed if the fracture fails to demonstrate clinical and radiological progression through the inflammatory, the soft callus and the hard callus stages within the usual range of time. This range varies widely depending on the fracture type and location. Most fractures should achieve union within 3 months, after this time, some stimulus for osteogenesis may be indicated [1].

Non or delayed union can result from a confluence of patient factors such as smoking, diabetes, vascular disease or other comorbidities, or injury factors such as high-energy trauma or significant soft tissue loss [1]. It may then result in further surgery with subsequent prolonged hospitalization, disability, and delays in returning to the work [2]. The associated costs are not insignificant including both personal and societal such as lost wages and productivity as well as direct health care costs. Alternative, less expensive nonsurgical methods of managing such condition could potentially lessen the impact felt from these entities from both a patient and economic perspective [2]. The effect of PEMF therapy on fracture healing was found to be superior to other mentioned physical therapy modalities; the basic difference is its contactless, distance application and proven penetration of PEMF through plaster fixation of the affected bone. It is very important that the presence of metal implants and internal fixators is not a contraindication to the application of PEMF thus enables to support modeling of bone tissue and healing of the fracture by increasing blood supply to the fracture site, increasing calcification, stimulating osteoblasts and inhibition of bone resorption and also it reduces the natural atrophy of immobilized muscular structures even at a time of fixation [3].

Extracorporeal shock wave therapy (ESWT) has been used as a noninvasive treatment modality for non-unions and delayed unions [4], it promotes callous formation as well as a dose-dependent osteogenesis. Furthermore, the callous produced appears to undergo appropriate remodeling to lamellar bone. More recently, the bone treated with shockwave therapy has been shown to be associated with neovascularisation and an increased expression of angiogenic growth factors suggesting that increased vascularity may play a role in osteogenesis [4].

The aim of this work is to compare the effect of PEMF and ESWT on healing of delayed as well as non-united tibial fractures.

Patients and methods: registration number 31082/08/16 research ethical committee faculty of medicine tanta university

This study was carried out on 60 adult patients suffering from delayed or non-union tibial fracture. Nonunion was defined as persistent fracture line with or without pain at the site for more than 6 months post fracture or no progression of healing on radiographs taken 3 months apart; delayed union was generally defined as delayed healing in less than 6 months post fracture .The patients were selected from the clinics of Orthopedic Department of Tanta university . They showed delayed or nonunion inspite of previous conservative treatment by (closed reduction and casting), or operative treatment by: ORIF by (IMN, plate and screws or gliding nail), or external fixation.

Exclusion criteria

1. Patients with contraindication to PEMF or ESWT therapy as: (bleeding wound, active infection [T.B or viral], endocrinal disturbances or malignancy) [5].
2. Patients with any severe generalized disease as DM.
3. Patients on systemic corticosteroid therapy.
4. Patients with bone disease such as Paget's disease, osteomalacia and osteoporosis.
5. A fracture with severely atrophic or marked hypertrophic bone ends [6].

The 60 patients with non or delayed union fracture tibia included in this study were divided randomized according to line of treatment into 2 groups (30 patients in each group) matched in their age, sex and level of injury.

The first group

The patients of this group received PEMF at the site of fracture of 12 Hz, 3 mT for 60 minutes per session, by inductive coupling. The patients received 3 sessions per week for 3 months. The apparatus used was magnetic-bio-stimulation-mbs system (Biotron up standard) included generator in portable case with large ring solenoid coil.

The second group

The patients of this group were treated by focused ESWT at the site of fracture using high energy shock wave generator. The shock wave was applied in 3 sessions of 2500-3000 impulses each given at 0.25-0.84 mJ/mm^2, at interval of 48-72 h between sessions. A maximum of 3 cycles of treatment was given at 3 months intervals, if needed.

All patients were subjected to the following assessment.

Clinical assessment

History taking complete orthopedic examination of tibial fracture (degree of pain (VAS) [7], degree of tenderness [8] and mobility of fracture [9]).

Radiological assessment

Antero-posterior and lateral radiographs were taken. The radiographs were assessed and scored according to Hammer et al. [10] Assessment was done before, after treatment and then 6 months later as follow up.

Functional assessment

All the patients were assessed for their functional outcome by the lower extremity functional scale [11] and the knee society clinical rating system [12].

Functional assessment was done after treatment and 6 months later

Statistical analysis

The collected data was organized, tabulated and statistically analysed using SPSS soft were statistical computer package version 13 for quantitative data, and the range, mean and standard deviation were calculated. The difference between two means was statistically analysed using the students (t) test. Mann-Whitney test was performed to test mean values when the observations were not found to follow the normal distribution .For qualitative data the number and percent distribution was calculated. Chi square was used as a test of significance and when found inappropriate. Fisher exact test was used. Significance was adopted at $p<0.05$ for interpretation of results of tests of significance [13].

Results

60 patients were included and finished follow up of our study, they were 52 males and 8 females, their ages ranged between 19-52 years old and their mean age was (32.4 ± 6.5) years in group I, (35.7 ± 8.3) years in group II. There was insignificant difference between the two groups as regard age and sex .There were 34 patients with right tibial shaft fracture, and 26 patients with fracture on left side, as regard the site of fracture, there were 14 patients had a fracture in upper third, 24 in middle third and 22 in the lower third of tibial shaft.

In our study, there was a highly significant improvement of degree of pain by VAS, degree of tenderness, mobility of fracture and radiological scoring of bone healing after treatment and at the end of follow up when compared with before treatment, and at the end of follow up when compared with after treatment in both groups. However, group II showed better improvement after treatment and the end of follow up compared with group I with a highly significant difference between the two groups, The percentage of complete radiological union was 93.33% in group II , 73.3% in group I at the end of follow up, (Tables 1 and 2) and (Figures 1 and 2).

		Pain (VAS)	P-value	Tenderness	P-value
		Mean ± SD		Mean ± SD	
Before treatment	Group I	4.010 ± 0.543	0.164	2.655 ± 0.434	0.792
	Group II	4.243 ± 0.725		2.620 ± 0.587	
After treatment	Group I	2.400 ± 0.598	<0.001*	1.820 ± 0.598	<0.001*
	Group II	1.015 ± 0.487		0.878 ± 0.342	

Follow up	Group I	0.578 ± 0.545	<0.001*	0.197 ± 0.455	<0.001*

Table 1: Comparison of pain (VAS) before, after treatment and at follows up between the studied groups.

		Mobility of fracture	P-value	Radiological scoring	P-value
		Mean ± SD		Mean ± SD	
Before treatment	Group I	9.540 ± 2.965	0.327	4.576 ± 0.534	0.927
	Group II	8.845 ± 2.456		4.564 ± 0.476	
After treatment	Group I	4.780 ± 2.651	0.0002*	2.623 ± 0.854	<0.001*
	Group II	1.988 ± 0.978		1.653 ± 0.711	
Follow up	Group I	0.634 ± 0.655	<0.001*	1.855 ± 0.398	<0.001*

Table 2: Comparison of fracture mobility and radiological scoring before, after treatment and at follow up between the studied groups.

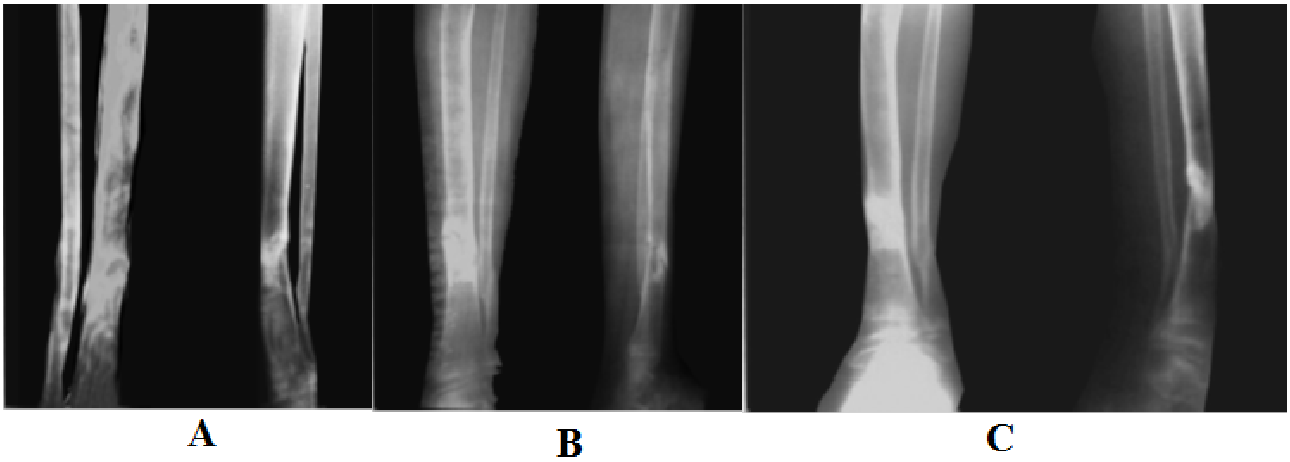

Figure 1: Radiography of fractured tibial shaft in a patient of group II. (A) Before treatment showing delayed union. (B) After treatment with ESWT showing incomplete radiological union. (C) At follow up showing complete radiological union.

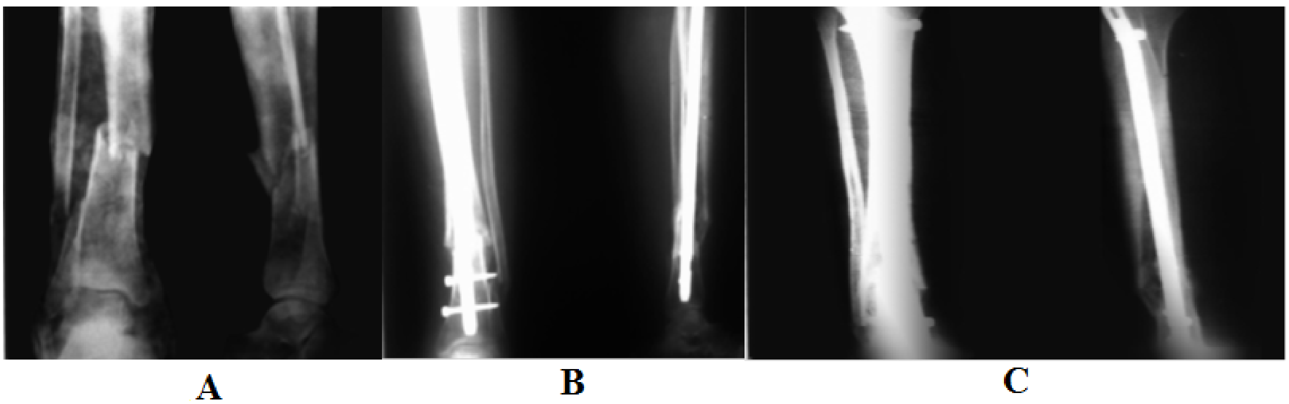

Figure 2: Radiography of fractured tibial shaft in a patient of group I. (A) Before treatment showing delayed union. (B) After treatment with PEMF showing incomplete radiological union. (C) At follow up showing complete radiological union.

Regarding functional assessment by Lower extremity functional scale and Knee society clinical rating system, there was a highly significant improvement in group II with the best results when compared with group I after treatment as well as at the end of follow up, (Table 3).

		Lower extremity functional scale	P -value	Knee society clinical rating system	P-value
		Mean ± SD		Mean ± SD	
After treatment	Group I	29.345 ± 5.187	<0.001*	95.060 ± 18.746	<0.001*
	Group II	46.020 ± 4.453		121.765 ± 22.386	
Follow up	Group I	68.867 ± 3.469	<0.001*	177.547 ± 10.498	<0.001*
	Group II	76.450 ± 2.765	<0.001*	185.855 ± 11.865	

Table 3: Comparison of Lower extremity functional scale and Knee society clinical rating system after treatment and at follow up between the studied groups.

Discussion

Tibial fractures are the most common fractures of long bones [14]. Such fractures occur approximately twice a year per 1000 population in Sweden, and the rate is similar in the United States [15].

Non unions or delayed unions may then result in further surgery with subsequent prolonged or repeat hospitalization, so enhancement of bone healing by non-invasive, costless and advanced physical modalities is necessary [16]. Physical forces applied in bone create electrical potential signaling cellular changes that enhance healing; these forces can be mechanical, electrical or sonic. [17].

In this study, fracture healing was assessed clinically by degree of pain, the tenderness and fracture mobilitry. Regarding degree of pain measured by (VAS) and degree of tenderness assessed by 4-point scale [7,8], our study showed a significant improvement after treatment and at the end of follow up period compared with before treatment, and at the end of follow up compared with after treatment in the two studied groups but the results of group II were better with significant difference when compared with group I, (Table 1).

PEMF affect pain perception in many different ways as mentioned by Jeong M et al. [18]. The positive effect of PEMF on pain reduction could be explained by decreasing the membrane potential to hyperpolarized state (-90 mv), that blocks pain signals transmission. Also the analgesic action of PEMF may be due to the idea of acupuncture. It is theorized that these painful sites might divert the electrical signals that carry information of pain away from the brain. It is thought that magnetic field might activate electric current that also interferes with the signals and essentially blocks the pain. The magnetic field also increases perfusion and local blood flow that carries away toxins and washes the accumulated metabolites that cause chemical irritation acting on pain nerve endings, while bringing in white blood cells which help in reduction of inflammation and pressure over the nerve due to local exudates [19]

Garland et al. [20], Ito and Shirai [21] and Sharrad et al. [22], agreed with our results as regard significant improvement of pain and tenderness in patients with delayed fracture union after PEMF therapy.

The mobility of fracture was assessed by measuring the movement with a goniometer in the mediolateral and anteroposterior planes [9]. Our results showed that there was a highly significant improvement of mobility of fracture after treatment and at the end of follow up, with better results in group II (Table 2).

This result is in agreement with Sharrad et al. [22] who conducted a study on 45 adult patients with tibial shaft fractures with delayed union for more than 16 weeks but less than 32 weeks in a double blind trial, 20 patient received PEMF for 12 weeks and 25 patients were control. All the patients were immobilized by casting. The clinical assessment of the patient at the start of the study revealed that 95% of the patient of the active group showed movement at the fracture site in both antroposterior and mediolateral planes, after 12 weeks treatment of PEMF, 60% of the patient showed no mobility at both planes demonstrating significant improvement of fracture mobility but with insignificant difference between active and control groups.

Extracorporeal shock wave therapy has been used as a non-invasive treatment modality for non or delayed unions and has increasingly been used in fracture management and specifically, in its role as a non-operative treatment strategy for non-unions or delayed unions [4]. Indeed, shockwaves generate direct mechanical and subsequent cavitation forces with some micro fracturing occurring potentially. This is inherently painful, and may require the use of general or regional anesthesia. However, with a shockwave generation of <2,000 impulses, anesthesia may not be necessary [23].

Marina V et al. [24] in their study examine the effect of focused (ESWT) on the treatment of non-unions. As part of a prospective study, they included 143 patients with nonunited fracture. Complete healing was observed in (55.9%) at an average time of 7.6 months, partial healing occurred in (28.7%) and no healing was observed in (15.4%). Patients with trophic nonunions had a better success rate than patients with atrophic non unions. Also, Elster, et al. [25] treat one hundred ninety-two patients with ESWT coupled with post treatment immobilization, external fixation, or ESWT alone, at the time of last follow up, (80.2%) patients have demonstrated complete fracture healing. Mean time from first shock wave therapy to complete healing of the tibia nonunion was 4.8 ± 4.0 months.

In this study, radiographic assessment of patients for fracture union was performed guided by anteroposterior and lateral radiographs that were assessed and scored according to Hammer et al. [10] into 5 grades according to callus formation and fracture line. Our results showed that there was a highly significant improvement of radiological scoring of bone healing after treatment and at the end of follow up compared with before treatment, and at the end of follow up compared with after treatment in the two groups. The best improvement of radiological score of bone healing (achievement of complete radiological union) was significantly obtained in group II when compared with group I (Table 2 and Figures 1 and 2).

Darendeliler et al. [26] reported that PEMF stimulation has been shown to have an effect on bone repair via a number of different mechanisms: Firstly, PEMF has been shown to stimulate calcification of the fibrocartilage in the space between the bony fragments. Second, the increased blood supply that arises due to PEMFs effect on ionic calcium channels has been implicated as a source of improved bone healing. It is caused by better blood circulation in the irradiated area and by irritation of cytoplasmatic membranes. This activates the metabolic chain, the key point of which is the change of the cAMP/cGMP (cyclic adenosine monophosphate and guanosin monophosphate) ratio. Thirdly, PEMF has been suggested as having an inhibitory effect on the resorptive phase on wound repair, leading to the early formation of osteoid tissue and callus with significant acceleration of creation of ligamentous tissue. A fourth mechanism is its influence on increasing the bone formation by osteoblasts. The degree to which PEMF stimulation is effective is dependent on several factors, including anatomic location associated surgery, patient age, disability time, date of treatment initiation, adherence to treatment protocol and infection [26].

Matsumoto, et al. [27] in his study to investigate the effect of PEMF with different parameters found that PEMF promote bone formation around dental implants inserted into the femur of rabbits. Also,in Cavani et al. [28] had demonstrated a positive therapeutic effect of PEMF in accelerating hydroxyapatite osteointegration in trabecular bone. Also have compared the effect of PEMF and surgery in treatment of ununited fractures in a prospective study .The result of PEMF stimulation was 100% compared to 89.0% obtained in the other group [28].

Indeed, shock wave therapy promotes callous formation as well as a dose-dependent osteogenesis. Furthermore, the callous produced appears to undergo appropriate remodelling to lamellar bone. Moreover, the bone treated with shockwave therapy has been shown to be associated with neovascularisation and an increased expression of angiogenic growth factors suggesting that increased vascularity may play a role in osteogenesis [29]. Mechanistically, the shockwave is first generated in water and from there it is transferred through a medium to the skin and tissues as a sonic pulse. This creates expansion and compression within the bone. In order to be the most beneficial, the pulses must be concentrated on the point of treatment, in this case the non-union or fracture site. The two basic effects of the shockwave on tissue are direct and indirect. That is, shockwaves generate mechanical tensile forces within the bone that in turn results in cavitation forces. These effects have been seen to cause hematoma formation, cell death, and subsequent new bone formation [29].

Regarding lower extremity functional scale LEFS and Knee society clinical rating system, there was a highly significant improvement at the end of follow up period compared with after treatment in the two studied groups. The best significant improvement was in in group II when compared to group I (Table 3) .In agreement with Geert et al. [30] in his study on patients with non-union of tibia assessed functionally by LEFS, that was a significant improvement with a mean value of LEFS of 59 in upper third, and 53 in lower third of tibia after surgical treatment as a sequence of pain improvement with a positive correlation between pain and LEFS.

The previous results supported the functional improvement in group I. Generally speaking, our results showed superior results in group II more than group I, these superior results are attributed to early and better improvement as regard radiological scores and complete radiological union as well as significant improvement of pain and tenderness scores but the drawbacks of ESWT are the need for anesthesia and the removal of immobilization cast is a must for its application [30].

Conclusions

The best significant as well as more rapid clinical, radiological and functional improvement in cases of delayed or non-united tibial shaft fractures was obtained with ESWT compared to PEMF therapy. PEMF also, was safe, inexpensive and effective modality, even in the presence of immobilization cast, for complete radiological union for patients of tibial shaft fractures with delayed or non-union.

Recommendations

We recommend addition of ESWT as a new therapeutic modality in patients with tibial shaft fractures, especially with delayed or non-union whatever their treatment was conservative or surgical, as this modality is easy, safe, simple, comfortable and inexpensive and it leads to better significant improvement in clinical, radiological and functional outcomes and decrease the time required to achieve complete union, thus improving the final outcome and decrease the burden on the individual and society.

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