Research Article

Effect of extra-corporeal shock wave therapy in Cases of nonunion and delayed union of bones

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Abstract

Introduction: Long bone fractures are common in field of Orthopedics trauma and it requires careful treatment to avoid refractory disabilities. With newer modalities of treatment and better quality implants for fracture fixation, most of the complications have been reduced. Even though this is true, non union and delayed union remains one of the major complication after skeletal trauma or elective surgery and surgical modality of treatment of such chronic nonunion has its own dreaded complications which has produced a need of an effective and simple nonsurgical method of nonunion treatment. **Material and methods:** 35 patients of diagnosed long bone nonunion were included in the study. All patients received shock wave treatment. The intensity of shock wave varied depending on bone fractured and area of fracture gap. The shock waves were applied in two planes and the region of metallic internal fixation such as cortical plates was avoided..Presence of intramedullary rod did not interfere with application of shock wave and was not a contraindication for shock wave therapy. **Results:** It was observed that out of 26 patients with hypertrophic nonunion, 21 patients showed signs of union or clinical improvement after ESWL treatment. Two out of remaining 5 patients showed consolidation after second dose of ESWT whereas remaining three cases of hypertrophic nonunion were treated by surgery. While out of 7 atrophic non union 3 showed union while remaining 4 showed no union on x ray or no clinical improvement at all. Out of these four, three got operated for persistency of nonunion while one patient was not willing for surgery. **Conclusion:** Extracorpeal shock wave therapy is an effective noninvasive method of nonunion treatment with comparable positive results to surgical modality of treatment. Further if stringent selection criteria were used (fracture gap less than 5 mm, patient with hypertrophic nonunion) the success rate would have been higher.
Key Words: nonunion, delayed union, shock wave therapy.

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INTRODUCTION

Treatment of nonunion and delayed union of bones still remains the unsolved mystery in Orthopaedics. Until the last decade surgical treatment was the preferred modality of treatment of this nonunion, which has its own complications with major complication rate upto 8.6% and minor upto 20% as found by Younger and Chapman[1]. So there arose the need of an effective, simple non-surgical method of nonunion treatment.

ESWT has been used successfully in the treatment of UROLITHIASIS over decades. Looking at the success of ESWT in renal stones, the question arose to what effect the absorption of shock wave energy would have on the bony structure. When shock waves encounter an abrupt change in acoustic impendence for e.g. in soft tissue and bone interference, compressive and tensile forces are generated resulting in micro fractures which in turn stimulate neovascularisation, osteoblast formation and bone healing[2,3,4]. This form the basis for use of ESWT for the treatment of nonunion. Numerous investigators approached this by experimenting on animals followed by humans and they found positive results both in animals as well as in humans[2,3,5,6]. The

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present study reviews the effect of ESWT in 35 patients of diagnosed long bone nonunions treated with ESWT.

MATERIAL AND METHODS

This study was carried out over a period of three years. Total 35 patients of diagnosed long bones nonunion were included in the study. Out of 35 patients 6 were female patients and 29 were male. The youngest patient was 15 year old boy and oldest is a 70 year old female. The longest duration of nonunion treated in this study was a patient with 14 months history and shortest duration was a patient with 6 months history since the day of last treatment taken.

Inclusion criteria included any age group patients of either sex diagnosed to have nonunion or delayed union of long bones with fracture gap up to 5mm. Nonunion was diagnosed clinically and confirmed with full length radiograph of involved bones. In cases of doubt oblique radiograph and/or CT scan was obtained to diagnose nonunion. Exclusion criteria included underlying neoplastic disease, coagulopathies, acute infections, fracture in epiphyseal region of bones, pregnant woman, major neurovascular structures in shock wave field, patients with cardiac pacemaker, patients receiving immune suppressive or anticoagulant drugs.

Before procedure patient were evaluated in the form of detailed history of fracture and treatment taken, complete medical history, all routine laboratory investigations including ESR and C reactive protein and investigation to rule out bleeding disorders(bleeding time, clotting time, PT/INR). All females in reproductive age group underwent pregnancy test to rule pregnancy. Clinical evaluation of patients included parameters like pain intensity on visual analogue scale, local tenderness, motion at fracture site and ability of the patient to weight bear or functional use of the limb.

All patients were given precise information about the shock wave therapy and written informed consent was taken before application. All patients were admitted for one day for post anesthesia observation. Because of pain associated with shock wave therapy, patient needs anesthesia for therapy, Out of 35 patients, 25 patients were given general anesthesia , 8 patients were given only sedation while 2 patients were not given any kind of sedation or anesthesia as they tolerated shockwaves well without any medication. All patients received one shock wave treatment. The intensity of shock wave varied depending on bone fractured and area of fracture gap. In general the doses of shock wave for different bones are as shown in table 1.

Doses of Shock Waves

Bone	Intensity	No. of impulses
Femur	5	7000
Tibia	5	6000
Humerus	4	4000
Radius/ ulna	4	3000
Metacarpal and metatarsals	3	2000

The shock waves were applied in two planes and the region of metallic internal fixation such as cortical plates was avoided. Presence of intramedullary rod did not interfere with application of shock wave and was not a contraindication for therapy. Once the fracture had been localized in position and depth, surgical lubricant gel was applied to area of skin in direct contact with the balloon of lithotripter. Fracture were focused with help of C-arm, and impulse intensity and rate adjusted with help of control guide. Half of impulses applied in one direction and other half in different direction. Vitals signs were monitored throughout the procedure. The focus of shock waves was checked intermittently during procedure with help of c-arm. In non union like lateral malleolus it is extremely difficult to focus the non union site on c-arm for shock waves due to overlap of tibia on medial side and presence of internal fixation device (one third semi tubular plate) on lateral side so in such cases shock waves can be given only in one plane that is antero-posterior.

Post procedure, patients were advised to follow same protocol of walking as before procedure provided the fracture was stable. If the fracture was not stable, the limb was immobilized in plaster cast or splint. Follow up assessments were done at one, two, three, six, nine and twelve months. Intensity of pain was assessed at each visit with visual analog scale from 0-10 with 0 referring to no pain and 10 for severe pain. Local tenderness and motion at fracture site, percentage of weight bearing on the affected site were also evaluated at each visit. Radiographs were taken to assess alignment, callus formation, fracture gap and the presence of bony union across the fracture site. Tomography was done for patients in whom adequate information could not be obtained in plain radiographs. Patients were offered an additional session of shock wave treatment if no signs of healing was seen up to three months after the initial treatment.

RESULTS

In the present study total 35 patients were enrolled. Out of them 6 were female patients and 29 were male. The youngest patient was 15 year old boy and oldest is a 70 year old female. Out of 35 diagnosed cases of nonunion treated with shock wave therapy, 1 patient was lost to follow up while one patient chose operative treatment 5 weeks after shock wave therapy. Hence observations and results were analyzed only for remaining 33 patients only.

Table 1: Distribution according to various character of fracture

Variable		No. of patients	Percentage
Bone fractured	Humerus	06	18.18
	Ulna	01	3.03
	Femur	11	33.33
	Tibia	10	30.30
	Fibula	02	6.06
	Subtrochantric	02	6.06
	Metatarsal	01	3.03
Primary Treatment received	Operative	30	90.91
	Conservative	03	9.09
Type of nonunion	atrophic	07	21.21
	hypertrophic	26	78.79

Out of 33 patients, majority of the patients were suffering from femur fracture (33.33%) followed by tibia fracture (30.30%). Among the 33 patients 30 patients were treated operatively with suitable internal or external implants for fracture primarily. Out of remaining 3 one was a 30 year old male patient with metatarsal fractures managed conservatively on below knee cast and remaining two were humerus and ulna fracture patient who were managed conservatively on cast.

No patient had active infection at the time of shock wave treatment but two patients had deep seated infection away from the fracture site at distal locking site of interlock nailing. Out of 26 patients with lower limb nonunion, no patient was able to walk with full weight bearing or walk without help of crutches. Remaining 7 patients with upper limb non union were not able to do any work with the involved limb. Two patients were operated more than twice for nonunion in our study. On visual analogue scale pain intensity at initial evaluation ranged from7 to 9 in most of the patients. Out of 33 patients 7 had an atrophic type of nonunion while remaining 26 had hypertrophic nonunion. Minimum time interval after which union visible on x ray was 5 weeks while maximum interval was 10 months up till now.

Table 2: Distribution according to the outcome

Type of non-union	Outcome	
	Improvement	No Improvement
Atrophic	03 (42.86%)	04 (57.14%)
Hypertrophic	23 (88.46%)	03 (11.54%)
Total	**26 (78.79%)**	**07 (21.21%)**

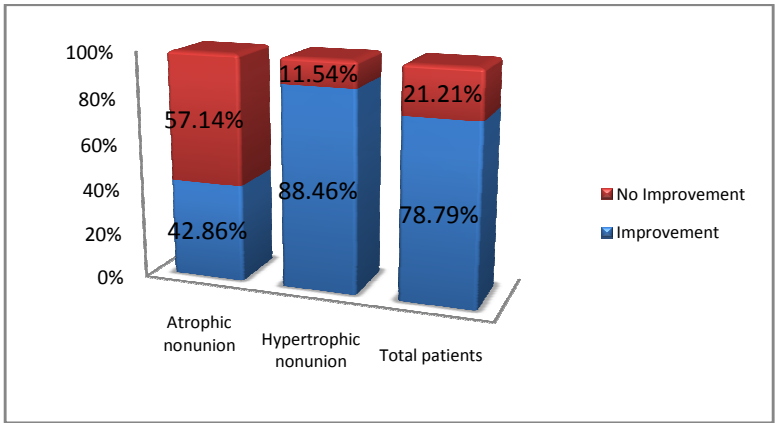

Figure 1: Distribution according to the outcome

It was observed that out of 26 patients with hypertrophic nonunion, 21 patients showed signs of union or clinical improvement after ESWL treatment. Two out of remaining 5 patients showed consolidation after second dose of ESWT whereas remaining three cases of hypertrophic nonunion were treated by surgery. Out of the total 7 atrophic non union cases, 3 showed union while remaining 4 showed no union on x ray or no clinical improvement at all. Out of these four, three got operated for persistency of nonunion while one patient was not willing for surgery.

Figure 1a **Figure 1b** **Figure 2a** **Figure 2b**

Legend

Figure 1a: One year post operative case of right sided femur non union

Figure 1b: Same patient three months post ESWT treatment

Figure 2a: Nine months post operative case of non united fracture humerus

Figure 2b: Same patient six months post ESWT treatment

DISCUSSION

Open reduction with internal fixation using a suitable implant with or without bone grafting or external fixation are choices in the treatment of patients with long bone fractures with chronic nonunion. Cattaneo *et al*[7] reported 86% successful union of humeral fracture treated with the illizarov external fixator . Wu and Shih [8] reported 88%sucess rate in achieving bony union in 84 patients with non united femoral fractures treated with intramedullary nail. In chronic, non united tibial fractures bone transplantation has lead to a union rate of 85-93%[9,10]. Surgical treatment of chronic non unions can however lead to serious complications. Warren and Brooker[11] reported an infection rate of 13% in 47 patients undergoing surgical treatment of chronic non union. Yonger and Chapmann reported 8.6% incidence of major complications including deep infection, persistent wound drainage, hematoma formation, sensory loss, unsightly scar. Minor complications included 20.6%incidences of superficial infection or wound problems[1]. In addition proportion of patients requires additional operative procedure. Further bone graft donor site morbidity is another major problem of surgical treatment of nonunion resulting in 5.8% major complications like herniation of abdominal content through bone graft site, vascular injuries etc and 10% of minor complications like minor hematoma formation, superficial infections[12]. That's why an alternative minimally invasive technique for treatment of such poorly healing fracture seems desirable.

Review of literature revealed contrasting reports on the value of shock wave treatment for chronic nonunion. Clinical studies of shock waves for treating chronic nonunion have confirm a success rate of 75-91%. Valchanou and Michaailov reported bony union in 70 of 82 patients with chronic nonunion of fracture at various locations. Rompe[13] reported 56% success rate in another clinical study whereas Vogel[14] reported a 60.4% union rate in 48 patients with nonunion treated with 3000 shock waves and Schaden reported 75.8% success rate in long bones nonunion.[5] These author concluded that such treatment was less likely to succeed with atrophic nonunion and underlying bone abnormalities like osteogenesis imperfecta.

In the present study we also got over all 78.79% success rate. The success rate in hypertrophic nonunion in our study was 88.46% as compared to 42.86% in cases of atrophic nonunion, but this clearly does not mean that ESWT was ineffective in atrophic nonunion as sample size of atrophic nonunion in our study was very small. Assessment parameter including pain, weight bearing, callus formation and decreased in fracture gap showed significant improvement over period of time after shock wave therapy. These results were comparable with that of other studies which also showed success rate ranging from75% to 90%. The main advantage of this treatment modality is that it has no complications and if they occur they are minor in the form of petechie or hematoma formation which resolves spontaneously on its own[5,15]. In our study also we got only one patient with petechie formation which resolved without any treatment. The

hematomas occurred mainly when high shock wave energies and impulse numbers were used. Also bubble-free coupling with ultrasound gel is necessary for reducing the provocation of petechie and hematomas, particularly because these bubbles absorb a large amount of the applied shock wave energy.

ESWT has comparable positive results with operative treatment of nonunion but in contrast to major complications of operative treatment ESWT has negligible local reactions (swelling, hematomas, petechial hemorrhages), and no complications[15]. In particular, the treatment resulted in no provocation of infection or nerve or vascular lesions. The treatment was noninvasive, and personnel and technical requirements were not problematic and require minimal hospital stay (day-care procedure).

CONCLUSION

From the above observation we reach to the conclusion that extracorpeal shock wave therapy is an effective noninvasive method of nonunion treatment with comparable positive results to surgical modality of treatment. Further if stringent selection criteria were used(fracture gap less than 5 mm, patient with hypertrophic nonunion) the success rate would have been higher.

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