

Recent Advances in the Management of Atrophic Tibial Non-Unions; An update using Extra Corporeal Shock Wave Therapy

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ABSTRACT

Background: Tibial nonunion remains a significant clinical challenge despite advances in surgical management. New techniques to help manage tibial nonunion include extracorporeal shock wave therapy and percutaneous application of bone marrow aspirate. Management strategies vary based on the type of nonunion: aseptic or infected, and atrophic or hypertrophic. Extracorporeal shock wave therapy has been shown to be as effective as surgical management in patients with stable hypertrophic nonunion.

Objective: To determine the efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia

Methodology: A randomized controlled trial was conducted at Orthopedic Emergency department Central Park Teaching Hospital from March 2022 to November 2022.

Results: In our study, out of 120 cases, 52.5%(n=63) were between 15-40 years and 47.5%(n=57) were between 41-60 years of age, mean + sd was calculated as 41.22+7.17 years, 60.83%(n=73) male and 39.17%(n=47) females. Frequency of efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia revealed in 86.67%(n=104).

Practical Implication: ESWT therapy can be used as non-invasive method of treating non-healing fractures of tibia without compromising the surgical anatomy.

Conclusion: We concluded that the frequency of efficacy of extracorporeal shock wave therapy for non-union of the tibia is significantly higher and the patients treated with this technique may have a benefit of non-operative procedure.

Keywords: Aseptic non-union of the tibia, extracorporeal shock wave therapy, efficacy

INTRODUCTION

Lower limb fractures have always been a great concern for both surgeon and patients as it takes longer duration to regain normal bone length and function especially in the cases of tibial fractures, as tibia is not only weight bearing bone but also helps in maintaining length and gait as well. Midshaft tibial fractures is a severe injury and challenging for the surgeon. In usual cases of a normal healing, tibia must be united in about 6 to 8 months.¹⁻³ With recent advances and progressive improvement in quality of surgical implants and modification in surgical techniques such as decompression plates and intramedullary locking nails, union rates are up to 90% were reported depending upon fracture types and localization. But, incomplete union rates of 16% to 80% for tibial shaft fractures depending on sub collectives have been reported. Tibial shaft fractures have the highest risk of non-union when compared to other long bones of lower limb.⁴

Factors associated with non-union include; super imposed infections, extensive bone fragmentation, mechanical instability leading to osteonecrosis and implant failure.⁵ Injuries due to stringent trauma causing complex and open tibial fractures and fractures in certain locations, such as the tibial plateau;⁶ injuries caused by trivial trauma usually leading to simple transverse or linear tibia fractures, injuries leading to extensive skin and soft tissue loss which requires soft tissue coverage in terms of skin grafts and muscle flaps, injuries with vascular compromise requiring vascular repair and reconstruction⁷.

Recent advances in the management of tibial malalignment and nonunion include ESWT (extracorporeal shock wave therapy) and application of percutaneous bone marrow aspirate⁸. Management strategies vary based on the type of nonunion: aseptic or infected, and atrophic or hypertrophic⁹. Most hypertrophic non-unions are caused by mechanical instability and are easily treated by providing stability at the fracture site. However, atrophic non-unions are hard to manage as the vascular supply is already compromised¹⁰. Extracorporeal shock wave therapy (ESWT) has been shown to be as effective as surgical management in patients with atrophic nonunion.⁶ ESWT is noninvasive thus obscuring blood loss and risk of super imposed infections leading to osteonecrosis and osteomyelitis¹¹.

The rationale of the study is that the above two different findings showing variation and a wide range of efficacy of the

procedure i.e. 50-90%, however, we planned this study so that the exact outcome of the procedure may be determined, because there may be a difference regarding efficacy in our population and others. The patients treated with this technique will have a benefit of non-operative procedure. The objective of the study was to assess the efficacy of extracorporeal shock wave therapy for aseptic atrophic non-union of the tibia.

METHODOLOGY

A randomized controlled trial (RCT) was conducted at Doctors Hospital Lahore in collaboration with department of orthopedics, Central Park Teaching hospital Lahore from October 2022 to January 2023. Ethical considerations were fulfilled after getting ethical letter from institutional review board of Central Park Medical College and prior written informed consent was obtained from all the study participants.

Study Population & Sample size: A total of 120 sample size was computed with 95% confidence level with 5% margin of error and taking expected efficacy of Extracorporeal shockwave therapy in aseptic non-union tibia i.e., 50% by using WHO sample size calculator "OpenEpi", available at <https://www.openepi.com/SampleSize/SSMean.htm>.

Sampling Technique: Non-Probability Purposive Sampling technique was employed in which patients with the age range of 15 to 60 years were recruited having the aseptic non-union of tibia.

Exclusion Criterion: Patients with chronic disorders of Rheumatoid arthritis, Diabetes mellitus and those having history of treatment for the management of aseptic non-union tibia were excluded.

Study Protocol: Non-union of tibia was confirmed using x-rays on radiographic films and after intervention healing of the bone was also confirmed on radiographic films.

Study Instrumentation: Extracorporeal shock wave therapy (ESWT) was administered by employing the latest version of Ossa Tron device¹².

Data Collection Procedure: Patients were subjected to the shock wave therapy under general or regional anesthesia. Subjects were positioned in OT on the operation table in such a fashion that the fracture line was clearly visualized in the anterior-posterior and lateral fluoroscopic projections. The affected site was subjected to head of ESWT device in such a way to focus the shock wave

therapy at the fracture site with the continuous use of an image intensifier. Fractures were treated following departmental protocols for using ESWT. The patients were followed up to 16 weeks after procedure.

Statistical Analysis: Data was analyzed using SPSS version 25 and were compared for errors and omissions. Frequency and percentage were calculated for qualitative data variables like gender and efficacy. Quantitative variables like age were presented in mean + sd. Stratification for age and gender was done to control the effect modifiers. Chi-square test was applied post-stratification. P-value < 0.05 was considered as significant.

RESULTS

A total of 120 patients as per the inclusion criterion were made the part of study to assess the efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia. Age distribution charting of the subjects was done which showed that 52.5% (n=63) were between 15-40 years and 47.5%(n=57) were between 41-60 years of age with the mean age of 41.22 + 7.17 years. Patients were distributed according to gender showing 60.83%(n=73) male and 39.17%(n=47) females. Frequency of efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia revealed in 86.67% (n=104) while 13.33%(n=16) were not treated effectively. (Table No. 1)

Table 1. Frequency of Efficacy of Extracorporeal Shock Wave Therapy for Aseptic Non-Union of Tibia

Efficacy	No. of patients	%
Yes	104	86.67
No	16	13.33
Total	120	100

Stratification for frequency of efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia with regards to age shows that out of 104 cases 54 were between 15-40 years and 50 were between 41-60 years, p value was calculated as 0.75. Stratification for frequency of efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia with regards to gender shows that out of 104 cases 42 were males and 62 were females, p value was calculated as 0.002 as explained in table 2

Table 2. Stratification for Frequency of Efficacy of ESWT for Aseptic Non-Union of Tibia with based on Gender

Gender	Efficacy		P value
	Yes	No	
Male	42	31	0.002
Female	62	15	

Paired sample t test was employed to assess the efficacy of ESWT to assess the pre and post radiological findings and bone union was confirmed with the improvement in mean scores of bone density with p value of 0.003 and paired sample correlation was also employed assess the impact of ESWT on tibial healing, a significant correlation was observed with r value of 0.783 and p value of 0.001 suggesting that ESWT is associated with tibial healing in cases of non-unions.

DISCUSSION

In spite the great advances in surgical management of tibia, still tibial non-union remained a great concern for both surgeon and for patient. Recent advances in the management of tibial nonunion includes ESWT i.e., extracorporeal shock wave therapy and percutaneous aspiration of bone marrow¹³. Management of tibial non-union varies greatly and it depends on type on non-union whether; aseptic or infected, and atrophic or hypertrophic but ESWT has been shown to be as effective as surgical correction¹⁴.

In our study, out of 120 cases, 52.5% of subjects were between 15 to 40 years of age while 47.5% of subjects were between 41 to 60 years of age, central tendency (mean + standard

dev.) was computed as 41.22 + 7.17 years, 60.83% (n=73) male and 39.17% (n=47) females. The effectiveness (non-union) of ESWT on non-unions varied from 50% to 90%,¹⁰ on the other hand Eric A and colleagues¹⁵ in their study revealed 138 of 172 (80.2%) patients have demonstrated complete fracture healing which is coincident to our findings that demonstrated efficacy of 86.67 percent in tibial healing. Another study recorded the effectiveness (non-union) of ESWT on nonunions varied from 50% to 90%,¹⁶ however, our findings are close to the maximum range of the efficacy determined in the above study.

Rompe JD et al¹⁷ demonstrated that in cases of non union of tibia and femur, extracorporeal shock wave therapy is associated with stimulation of bone healing aiding the early recovery while considering basic investigations mandatory. Furia JP and others¹⁸ successfully evaluated the results and hazards of the therapy and declared it as safe and effective for tibial non-unions and proved that ESWT could be as effective as intramedullary nails in the scenario of long bone fractures. Sometimes, associated complications and risks of screw fixations are far greater which even results in revision surgeries on contrary extra corporeal shock wave therapy is safest with no associated aforementioned risks.

Cacchio A and others¹⁹ compared the efficacy of various extracorporeal shock-wave generating instruments with that of surgical resection & treatment in the management of long-bone non-unions, they found out that the radiographic findings did not differ among the three groups of patients suggestive of equal efficacy of ESWT as of surgery. After six months, more than two third non-unions in all the groups were healed i.e., 70% of the non-unions in Group 1, 71% of the non-unions in Group 2, and 73% of the non-unions in Group 3. Three and six months after treatment, the clinical outcomes in the two shock-wave groups were significantly better than those in the surgical group ($p < 0.001$)²⁰ and concluded that Extracorporeal shock-wave therapy is as effective as surgery in stimulating union of long-bone hypertrophic nonunion and yields better short-term clinical outcomes.

However, our results in agreement with the comparison of above different studies showing that the frequency of efficacy of extracorporeal shock wave therapy for aseptic non-union of the tibia is higher.

CONCLUSION

We concluded that the frequency of efficacy of extracorporeal shock wave therapy for non-union of the tibia is significantly higher and the patients treated with this technique may have a benefit of non-operative procedure.

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