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ORIGINAL ARTICLE

Operative Versus Non-Operative Management of Closed, Displaced Intra-Articular Calcaneus Fractures: a Randomized Control Trial

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ABSTRACT

Aim: To determine whether internal fixation & open reduction are superior to non-operative treatment for displaced intra-articular calcaneal fractures.

Study Design: Randomized controlled trial

Place and duration: This study was conducted at Muhammad Medical College and Hospital Mirpurkhas, Pakistan from 2019 and 2020

Methodology: Patients' Kerr-Atkins scores for pain and function at two years following injury were used as the main outcome measure in this study. Complications, hindfoot discomfort and function general health, life 'quality, clinical examination, walking speed, & symmetry of gait were all considered secondary outcomes. A treatment-oriented approach to analysis was used.

Results: Total 151 patients were taken for this study. There were 95 percent follow-ups for the primary outcome (69 for patients who had surgery and 74 for those who had not), and 75 percent of patients fulfilled all secondary goals. There was no statistical difference in the primary outcome or any of the secondary outcomes between the both groups. Patients who had surgery experienced greater problems and needed additional surgeries

Conclusions: Two years following surgery, individuals with a typical displaced intra-articular calcaneus fracture exhibited no clinical or functional improvement, and the risk of comorbidities rose. Open reduction plus internal fixation for these fractures is not suggested based on these results.

Keywords: Displaced intra-articular calcaneus fractures, Operative management, Nonoperative management

INTRODUCTION

Around 2% of all fractures are caused by the calcaneus, often known as the heel bone, and it is the most frequent tarsal bone fracture. (1) Although some calcaneal fractures are mild, the majority are serious, high-energy injuries. These more catastrophic injuries frequently happen because of a fall from a great height, such as from scaffolding or a ladder, or because of a car accident. 17274 In the united states and 2721 individuals in England (2) were hospitalized in hospitals with severe injuries, with most of them spending more than a week in the hospital. In poor nations, the rate is significantly greater. (3, 4)

The complete bone and its joint surfaces are fractured and displaced in these calcaneal fractures, and the subtalar joint, in particular, may be significantly affected. The fracture pieces normally mend together with conservative therapy, Because of its deformity, however, the heel joint is dislocated; this results in a distorted lower leg posture. The subtalar joint is often affected by severe, painful osteoarthritis. Recovery takes a longer time, usually two years. Even yet, the majority of patients suffer from a painful, inflexible, deformed foot that prohibits them from wearing conventional shoes; walking is uncomfortable, and many need the assistance of a cane or walker. (5) Unfortunately, patients who work as laborers or in the outdoors will be unable to return to work due to these unfavorable results. The man who fractures his heel bone is done, so far as his professional career is concerned (6) Patient and family in poor nations are particularly affected by this loss of economic opportunity. Healthcare and social expenditures are high in industrialized nations as a result of lengthy hospital stays, prolonged treatment, postponed or non-returned to work, and long-term benefits for disabled workers. (7)

Elevation, use of ice, early mobilization, and the use of a splint are all examples of conservative, non-operative treatment options. Six orthopedic surgeons have targeted severe calcaneal fractures to speed healing while also reducing pain and deformity. Percutaneous "spike" therapy became popular in the 1950s and was frequently used in the following decades. (8) In the 1960s, excitement for technology decreased because of reports of technical problems. The use of restricted exposure of the subtalar joint and fixation with wires was explored in the 1980s, however, a randomized controlled study found that surgery was not beneficial in this case. (9)

Restoring a subtalar joint to its pre-fracture location was made possible in the 1990s because to improved surgical techniques and a better knowledge of fracture patterns. (10) More and more people in Australia, the United States, Canada, and Europe began using this novel surgical therapy for large calcaneal fractures after finding that it was less dangerous and had better clinical outcomes than prior non-operative studies in these trials (11) now it's being pushed in underdeveloped nations, which is a good thing. (12)

Four independent systematic reviews (13-15) have looked at the controlled evidence on the efficacy of this

procedure, including a recent Cochrane review. The scarcity of data and the low quality of research to date were mentioned in all four assessments. One researcher stated that surgery would lead to a greater functional recovery than conservative therapy, but all of them warned about the potential of post-surgical problems, such as infection and the need for reoperation. All of them came to the same conclusion: the existing information is inadequate to determine the optimum treatment plan for these fractures.

There is a lot of ambiguity in the present scenario. This procedure for calcaneal fractures is popular among orthopedic doctors, who advocate it to their patients, others believe that procedures are difficult, expensive, and hazardous (16) and that they provide no demonstrable benefit, and so advocate for non-operative therapy. (16) Over two years following injury, we conducted a major, pragmatic, randomized controlled study in the Health Service to see whether operational treatment is better than non-operative care in patients with typical, closed, displaced intra-articular calcaneal fractures.

METHODOLOGY

We performed an exploratory multicenter research with two arms and parallel groups that was assessor-blinded and randomized with a 1:1 treatment allocation. We adopted an experimental design that was pragmatic. Patients had to be 18 years old, competent to provide informed permission, and have a closed, intra-articular, displaced calcaneal fracture within three weeks to be considered. To rule out those with obvious hindfoot deformities (such as fibula impingement, which we defined as either extremely severe calcaneal valgus or extreme calcaneal varus), other serious leg injuries that would affect the patient's outcome after two years, inability to undergo surgery, peripheral arterial disease, or inability to walk, we examined the hind foots of those who were not eligible for the study. Both fractures were considered if none of the exclusion criteria were met in either one or both of the patients**.**

Between 2017 and 2019, we recruited volunteers from 22 different hospitals throughout the country. These hospitals all served as regional referral centers for calcaneal fractures, and the surgeons who worked in them were all experts in the treatment of these fractures, as was the case with the other hospitals. Over the course of the recruiting period, prospective research was carried out to establish the number of calcaneal fractures that were seen in the emergency department or referred to orthopedic surgeons at each of the study locations. We analyzed emergency department attendance and radiological data to ensure that all eligible individuals were identified.

Each center's doctors looked for potential volunteers, assessed their eligibility, and classified each fracture into one of four groups, according to Sanders categorization: Broken bones with less than 2 mm displacement, two-part or split subtalar joint fractures, three-part or split depression fractures, and four-part or extensively comminuted articular fractures are denoted by the numbers 1 through 4, respectively. Non-displaced fractures are represented by the numbers 1 through 4. (Displacement less than 2 mm). Twenty members of the research team went door to door to talk to eligible patients about the study, which was supported by a DVD presentation. Participating subjects were randomized to either surgery or non-operative therapy using a minimization method that took into consideration criteria such as geographic location, smoking status, diabetes, bilaterality or Sanders classification of the patient's condition. Individuals with bilateral fractures got the same treatment on both sides since the therapy was allocated according to the participant. The usage of a secure telephone randomization service ensured the secrecy of allocations.

Before the randomization process, we obtained baseline data. All participants gave written informed permission before taking part in the study. Permission was taken from the review committee of the institute

All of the subjects were given bed rest, analgesia, foot elevation, and ice as their first therapy. Within three weeks after damage, open reduction and internal fixation were done using an extensible lateral approach, interfragmentary screws, and the insertion of a neutralization plate or plates to the calcaneus lateral wall. (17). A structured physiotherapy rehabilitation program was used to successfully treat this. Within three months after surgery, a postoperative computed tomography was conducted, and the technical result of the operation was judged by the accuracy of reduction by an independent radiologist.

The non-operative therapy started with modest ankle and subtalar joint movement as pain permitted, as well as the use of a detachable splint. After six weeks of non-weight-bearing and mobility, subjects were allowed to begin partial weight-bearing. To assess patient compliance with the prescribed physiotherapy program, a proforma created by the treating physiotherapist as well as questions inpatient assessments at the six-week and six-month mark was employed.

Patient-reported outcome measures such as pain and function after a calcaneal fracture have been developed. Total 100 points reflect the average level of pain and function. Significant pain, limited walking ability, and the use of a walking stick on an almost daily basis is indicated by scores in the 80-100 range. Mild discomfort and modest limitations in walking ability, such as the use of a walking stick on an almost daily basis are indicated by scores in the 60-80 range. Specifically, we looked at the primary outcome two years after the event, when it was expected that at least two-thirds of the patients would have recovered to their full ability. (18) The EuroQol EQ-5D as well as the SF-36 were used to assess participants' general health condition and quality of life. Global hindfoot function was quantified using the American Orthopedic Foot and Ankle Society score. Patient-reported outcomes were collected using postal questionnaires before to randomization, and at 6, 12, and 18 months following randomization. At a 6 follow-up session, as well as six, twelve, eighteen, and twenty-four months following the first procedure, sequelae, further surgery, and come back to work, were all recorded.

Over two years, participants completed score questionnaires, with no knowledge of therapy allocation. The width of the heel was measured from medial to lateral at the widest part of the heel distal to the malleoli using a caliper. While sitting, the participant's hindfoot range of motion was measured using a goniometer. (19) An acceleration and deceleration track of six meters in length

was used in five trials to assess walking speed. An in-shoe pedobarographic device was used to evaluate the subject's gait. The average of the two feet' steps was determined after each one was tallied. We calculated the length of contact, peak pressures for the mid-foot, first metatarsal head, and fifth metatarsal head, and the force-time integral for both the injured and non-injured feet.

We performed an intention-to-treat analysis to examine variations in the Kerr-Atkins score two years after injury in each therapy group. We calculated treatment effects using the difference in means (standard deviations) for the main and secondary outcomes (with 95 percent confidence intervals. (20) The return to work outcome was simulated using a logistic regression model based on the assumption of approximation normalcy for all other outcomes. A P value of less than 0.01 percent was found important for all outcome measures in order to allow for repeated testing of the main outcome. To study the mediating effects of the medicine on the outcome measure, we employed a formal contact test to analyses the influence of Sanders categorization on the regression model. (21) (22)

RESULTS

The participating centers were sent patients with calcaneal fractures. Total 502 of them suffered severe fractures that met the criteria. After a review of all centers, only three additional patients with displaced intra-articular fractures were discovered to be suitable for the research. Out of 502 eligible patients, a median of 5 agreed to participate per site ie total 151 patients were included in the study. They were randomly allocated to either the surgical (n=73) or non-operative (n=78) groups. The participants' average age was 46.5 years (range 18-80), with 24 (16%) of them being female. Sex, age, BMI, smoking, diabetes prevalence, or baseline scores did not differ significantly across treatment groups (As shown in table 1). Each group had a 95% follow-up rate for the primary outcome after two years (As shown in table 2). At all times, 75% of the patients had access to all secondary outcome indicators. Complications and reoperations in both groups are mentioned in table 3.

Table 1: Characteristics of the trial participants at the outset. (n=151)

Characteristics	Operative (n=73)	Non- operative (n=78)
Males	64	63
Mean Age (Years)	44.8	48.2
Mean BMI (Kg/m^2)	25.4	25.3
Smokers (%)	37	44
Diabetes (%)	1	3
Kerr-Atkins (%)	99	99
Classification of sanders	(%)	(%)
2	35	35
3	27	30
4	9	11
SF-36 PCS	51	53
SF-36 MCS	55	56
EQ-5D	0.9	0.9

% = Percentage

Table 2: Two-year follow-up, mean and standard deviations of outcomes were calculated, as well as predicted treatment effects after adjustment. Unless otherwise noted, all values are means (standard deviations).

Outcomes							
Primary outcome	Number	Values	Number	Values	Raw	Adjusted	P values
All participants	69	69.8	74	65.7	4.1	0.0 (7.1 to 7.0)	0.993
Subgroups:							
Sanders 2	33	74.3	34	70.3	4.0	1.0 (–8.9 to 10.9)	0.842
Sanders 3 or 4	34	66.1	38	63.0	3.3	3.1 (–7.6 to 13.8)	0.571
Males	60	71.9	59	67.7	4.2	1.4 (–5.7 to 8.5)	0.706
Females	9	55.7	15	57.5	–1.8	0.2 (–20.6 to 21.0)	0.987
Secondary outcomes							
Patient recorded outcomes							
SF-36 PCS†	54	43.7	62	37.0	6.7	3.3 (–0.9 to 7.6)	0.131
SF-36 MCS†	54	53.4	62	53.6	-0.2	–2.5 (–6.7 to 1.6)	0.235
EQ-5D	59	0.72	62	0.66	0.07	0.03 (–0.06 to 0.11)	0.568
AOFAS	54	79.2	60	76.8	2.5	0.1 (–6.5 to 6.7)	0.976
Return to work	45	84.4	36	88.9	0.68	0.64(0.12 to 3.32)	0.599
Clinical measurements							
Dorsiflexion	49	–35.3	54	–28.1	-7.2	–17.0 (–54.7 to 20.8)	0.381
Plantarflexion (%)	49	–25.3	55	-27.7	2.4	–5.9 (–22.9 to 11.0)	0.493
Inversion (%)	48	–66.4	54	–56.3	–10.1	–18.2 (–39.0 to 2.6)	0.090
Eversion	48	–71.7	54	–56.4	–15.3	–13.2 (–37.4 to 10.9)	0.287
Width of heel	48	67.9	54	68.0	-0.1	–0.9 (–3.9 to 2.2)	0.571
Walking speed	54	1.19	58	1.05	0.15	0.05 (–0.02 to 0.17)	0.137
Gait symmetry indices							
Contact duration	45	–0.9 (7.4)	50	1.1 (8.2)	–2.0	–3.1 (–6.3 to 0.2)	0.072
Midfoot	45	24.7	51	27.3	–2.6	–6.7 (–39.9 to 26.5)	0.693
First metatarsal	45	–31.9	51	–9.9	–22.0	–21.8 (–50.7 to 7.1)	0.144
Fifth metatarsal	45	11.2	51	3.0	8.2	4.7 (–22.3 to 31.7)	0.735
Force time integral	45	–9.2	51	–9.3	0.1	–0.8 (–11.9 to 10.4)	0.895

Table 3: Complications and reoperation rates by treatment groups

Reoperations and complications	Operative (n)	Non-operative (n)
Dressing and antibiotics	6	0
Debridement of wound	2	0
Removal of plates	2	0
At 6 months		
Treatment of surgical site of infection		
Dressing and antibiotics	3	0
Removal of plates	1	0
Removal of prominent metalwork	1	0
Nerve injury	0	1
Dressing and antibiotics	3	0
At 12 month		
None	0	0
At 24 months		
Elimination of prominent metalwork	2	0
Subtalar fusion for chronic pain	0	3
Reported by patients	n (%)	n (%)
Neuro-vascular injury	0 (0)	1 (1)
Surgical site of infection	14 (19)	0 (0)
Re-operations	8 (11)	3 (4)
Complication or reoperation	17 (23)	3 (4)

n=Number

%=Percentage

Because of the eight patients who switched treatment allocation groups, all of the above intention-to-treat analyses were rerun. Patients who had surgery had a mean Kerr-Atkins score that was 1.08 points lower than those who did not (with a 95 percent confidence interval of 8.10 to 5.95 points) than those who did not.

DISCUSSION

Compared to non-operative therapy, surgical treatment of typical, closed, displaced calcaneal fractures does not enhance outcomes and increases the risk of significant consequences. At two years, there was no difference in patient-reported outcomes between those who underwent open reduction and internal fixation and those who did not. Secondary outcome measures, such as subjective and objective, showed no treatment impact at any point in time, corroborating our primary finding. Patients' health, quality of life, and capacity to return to work did not improve despite our expectations for these outcomes. Neither the damaged hind foot's range of motion nor the heel width (a widely stated cause for surgery, to simplify shoe fitting) differed significantly between treatment groups. Two years after the accident, there was no change in walking speed or any of the five separate gait parameters.

A 19 percent infection incidence and an 11% need for additional surgery to remove infected or uncomfortable screws and plates were seen in the operatively-treated group. Non-operative treatment may prevent these significant and costly problems.

It took roughly 18 months for participants in this trial to reach the point when they no longer showed any progress, no matter what therapy they received. After two years, the majority of those who had been injured were still suffering. There was no significant difference between the groups in terms of the percentage of people who had returned to work.

Early open reduction and internal fixation of the subtalar joint may lead to better outcomes in later fusion surgery, such as the advancement of arthritis or the need for further surgery. Three fusions were conducted in the non-surgical group, whereas none was performed in the operative group, supporting this hypothesis. It is too early to make any conclusions, and we hope to present comparisons after five years of follow-up

CONCLUSION

An open reduction & internal fixation of an intra-articular fracture was no more effective than treatment with non-operative methods two years following the surgery. The operatively treated group had significantly more complications and reoperations than the control group, as well. For closed displaced intra-articular calcaneal fractures that have not undergone substantial displacement, this surgery is not needed. A less intrusive but no less effective therapeutic alternative is non-operative therapy for patients.

We feel that our research offers unambiguous data to guide management for a clinical condition that has been plagued by ambiguity for half a century. Before they are wide, employed, future improvements in surgical procedures to treat these fractures should be evaluated in more randomized controlled studies.

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