

Operative versus Non operative treatment of displaced intraarticular fracture of calcaneum: a meta-analysis of randomized controlled trials

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Various studies comparing operative and nonoperative intervention for displaced intrarticular calcaneal fractures have reported conflicting findings in the past. The objective of this meta-analysis was to compare the efficacy and safety of open reduction and internal fixation (ORIF) vis-a-vis conservative management.

Relevant randomized controlled trials (RCTs) comparing operative and non-operative intervention for displaced intraarticular calcaneal fractures were assessed and included in this meta-analysis. Data was extracted independently and methodological quality was further assessed.

The inclusion criteria of this meta-analysis were: randomized controlled trials comparing operative with non-operative intervention for displaced intra-articular fractures of calcaneum and reporting atleast one of the main outcomes as failure to resume preinjury work, residual pain and other complications.

Eight randomized controlled trials fulfilled the criteria for this meta-analysis. Pooled results showed that patients managed conservatively failed to resume pre-injury work (RR 0.60, 95% CI = 0.37-0.98, P = 0.04). However operative intervention was associated with more complications (RR 1.74, 95% CI = 1.28 to 2.37, P = 0.0005). There was no statistically significant difference in residual pain (RR 0.73 95% CI = 0.40-1.36, P = 0.33) and reoperation (RR = 0.75, 95% CI = 0.48-1.16, P = 0.20) between the two groups.

Surgery can benefit patients with calcaneal fracture and increases their likelihood to resume preinjury work. However, the complication rates are significantly higher in the operative group. Since the included trials have used different scores to measure patient outcomes, hence little effective data could be pooled for the meta-analysis from these scores or scales.

Keywords: calcaneal fracture; surgery; conservative; foot

INTRODUCTION

Calcaneal fractures account for about 2% of all fractures in the human body. Amongst all the calcaneal fractures, 75% are intra-articular (1,2). Majority of these are associated with severe injury

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caused due to high energy trauma in young adult men. They commonly occur due to falls from height or road traffic accidents (3). With conservative management alone, these fractures heal due to the cancellous nature of this bone, however the calcaneus remain deformed leading to incongruity of the subtalar joint (4). This leads to loss of alignment of leg through ankle to the heel. Walking on the incongruous joint may then subsequently give rise to secondary osteoarthritis of the subatalar joint, which may become a source of chronic pain (5). Operative management of calcaneal fractures is associated with its own set of complications. Moreover, correlation between anatomical restoration and outcome (function, quality of life) has not been proven unambiguously. Problems in wound healing occur in about 16-25% of patients after open reduction and internal fixation (ORIF) of calcaneal fractures, and have been reported to be as high as 43% (6,7). Results obtained from previous randomized controlled trials and systematic reviews are conflicting. Some studies indicate that operative treatment may be better than non-operative management, while others found no significant difference between the two methods (8,9). Almost all of them had methodological flaws, and most authors concluded that large scale, high quality randomized controlled trials were needed to provide significant scientific evidence in the management of calcaneus fractures. Recently, two large scale, multicentric randomized controlled trials have been published on this topic, which have not been taken into account by previous meta-analyses (10,11). This review identifies and evaluates randomized controlled trials (RCTs) comparing operative and non-operative method of treatment for calcaneus fractures.

METHODS

Search strategy and eligibility criteria

We searched PubMed, Embase and Cochrane controlled trial registers for RCTs comparing operative and non-operative intervention for displaced intrarticular calcaneal fractures (last update June 2015). Keywords used for the search were: displaced intrarticular calcaneal fracture,

displaced intrarticular fracture of calcaneus, conservative, operative, non-operative, surgery, non-surgery, randomized controlled trials. The associated references of the retrieved articles were also searched for any possible studies/ trials. Language restriction was not imposed in our search. The inclusion criteria of this meta-analysis were: randomized controlled trials comparing operative with non-operative intervention for displaced intra-articular calcaneal fractures. Studies lacking effective reporting of primary results and those with data inadequate for meta-analysis were excluded.

Data extraction and quality assessment

Two reviewers (SM and AH) participated in the collection of effective data from all eligible studies. Conflict of opinion was resolved by discussion and a third reviewer's opinion was asked for, whenever necessary. Effective data collected from all trials included data available for meta-analysis and information on general characteristics of studies and participants (study setting, study type, number of cases in each group, etc.). The quality of RCTs included into this meta-analysis was assessed by the modified Jedad score (12). It is an eight item scale designed to access randomisation, blinding, withdrawals and dropouts, inclusion and exclusion criteria, adverse effects and statistical analysis (Fig 1).

The score for each article can range from 0 (lowest quality) to 8 (highest quality). The critical appraisal was conducted by one reviewer and verified by the other. RCTs with scores no less than three points were defined as high quality RCTs, while RCTs with scores less than three points were defined as lesser quality RCTs. We did not undertake a subgroup analysis for different fracture types because very few of the included studies described the subgroup data by fracture types.

Statistical analysis

In each study the pooled relative risk (RR) with a 95% confidence interval (CI) was calculated for dichotomous outcomes, and mean difference (MD) with a 95% confidence interval (CI) was

Item Assessed	Score
Was the study described as randomized?	3 4 3
Yes	+1
No	0
Was the method of randomization appropriate?	
Yes	+1
No	-1
Not described	0
Was the study described as blinded?	
Yes	+1
No	0
Was the method of blinding appropriate?	
Yes	+1
No	-1
Not described	0
Was there a description of withdrawals and dropouts?	
Yes	+1
No	0
Was there a clear description of the inclusion/exclusion criteria?	
Yes	+1
No	0
Was the method used to assess adverse effects described?	
Yes	+1
No	0
Was the method of statistical analysis described?	
Yes	+1
No	0

 ${\it Fig. 1.}-{
m Modified}$ Jadad score used for quality assessment of studies.

calculated for continuous outcomes. Heterogeneity was assessed by use of I2. An I2 >50% was the cut off for homogeneity of the data. When there was

no statistical evidence of heterogeneity, a fixed effect model was adopted: otherwise, a random effect model was chosen. Besides, to validate the credibility of outcomes in this metanalysis, a sensitivity analysis was performed by sequential omission of individual studies. Publication bias was investigated by funnel plot and an asymmetric plot suggested possible publication bias.

Statistical analysis were performed with the software program RevMan (Version 5.1, Copenhagen: The Nordic Cochrane Centre, the Cochrane Collaboration). All *P*-values were two-sided and a *P*-value of less than 0.05 was deemed statistically significant.

We intended to assess publication bias by visually observing asymmetry of the funnel plot for each outcome. As a rule of thumb, one should only perform tests for funnel plot asymmetry when there are atleast 10 studies included in the meta-analysis. We were therefore underpowered to assess publication bias.

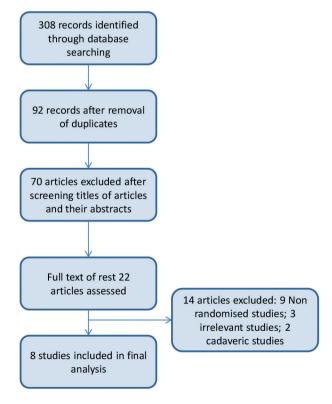


Fig. 2. — Flow chart diagram summarizing the process by which the 8 included studies were identified.

Outcome for meta-analysis

Primary outcomes were: failure to resume preinjury work and residual pain. Secondary outcomes were: problem in wearing shoes, AOFAS score, complications, reoperation and SF-36.

RESULTS

A total of 308 records were identified of which 286 were excluded, leaving 22 potentially relevant studies (Fig 2). We then excluded 9 non randomized studies, 3 irrelevant studies and 2 cadaveric studies. Finally 8 randomized controlled trials were included in this meta-analysis (6,9,10,13,14,15,16). Table I summarizes the main characteristics of the included studies. The quality of randomized controlled trials was assessed using the Modified Jedad scoring system.

Methodological quality assessment

Total trial scores indicated that the quality of most trials was good to excellent. Only two studies scored less than 3. Two studies were high quality studies with scores of 6 and 7.

Meta-analysis

Failure to resume pre-injury work

Three RCTs compared the number of patients who failed to resume pre-injury work. Results showed that operatively managed patients were able to return to pre-injury work (RR 0.60, 95% CI = 0.37-0.98, P = 0.04) (Fig 3).

Residual pain

Three studies measured residual pain in their patients. Although residual pain seems to be less in operative group, but this difference did not reach any statistical significance (RR 0.73, 95% CI = 0.40-1.36, P = 0.33) (Fig 4).

AOFAS

Three trials reported AOFAS scores. There was not much heterogeneity among these trials (I2 = 36%, P = 0.21), and the fixed effect model was used to pool the result. Meta-analysis showed no significant difference between the two groups (RR 1.16, 95% CI = -3.51 to 5.84, P = 0.63) (Fig 5).

Table I. — Important characteristics of involved studies

Study,year	Country	Cases(O/NO)	Sex(M/F)	Mean age (O/NO) yr	Follow up time (O/NO) yr	Important conclusion	Jadad Score
O'Farrell et al 1993 (13)	Ireland	12//12	20//4	33.0/38.0	1.3/1.2	Surgery improved functional results	2
Parmar et al 1993 (15)	England	25/31	48/8	48.3/48.8	2.1/1.8	No significant difference in functional outcome.	2
Thordarson and Krieger 1996 (9)	USA	15//11	21//5	35.0/36.0	1.4/1.2	Improved walking ability after surgery	5.5
Buckley et al 2002(6)	Canada	206/218	381/43	41.0/39.0	3.0/3.0	No difference in functional outcome	6.5
Ibrahim et al 2007 (14)	UK	15//11	21//5	61.0/58.0	15.2//14.8	No difference	4
Nouraei and Moosa 2011 (16)	Iran	31/30	NM	46.0/52.0	3.0/3.0	Surgically treated patient more likely to resume pre-injury work	4
Griffin 2014 (11)	England	73/78	127/24	44.8/48.2	2//2	No difference, complication higher after surgery	6
Agren 2013 (10)	England	42/40	59/23	49/48	10//10	Operative management not superior in short term but beneficial in long term	7

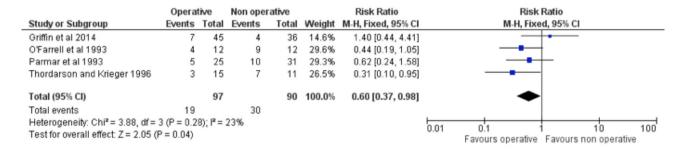


Fig. 3. — Forest plot for failure to resume work.

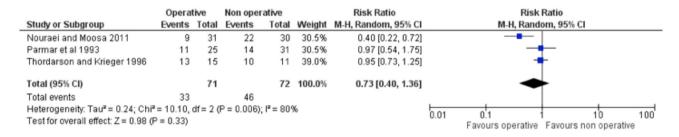


Fig. 4. — Forest plot for residual pain.

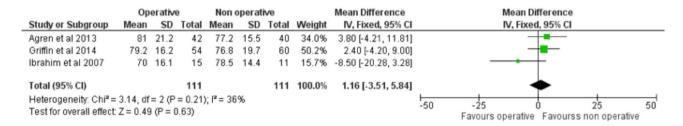


Fig. 5. — Forest plot for AOFAS score.

Problem in wearing shoes

With regards to the problem of wearing shoes after treatment, outcome according to four RCTs showed that surgically treated patients had fewer problems in wearing shoes than the non-surgically treated patients (RR 0.42, 95% CI = 0.26-0.68, P = 0.0004) (Fig 6).

SF 36

Two studies reported on SF-36 (physical and mental). The SF-36, physical was significantly higher in the operative group when compared to non-operative group. (MD 6.75, 95% CI = 3.52-9.97, P<0.0001) (Fig 7). There was no statistically

significant difference in the SF-36, mental (MD 0.69, 95% CI = -3.77 -2.38, P = 0.66) (Fig 8).

Reoperation

Three studies evaluated reoperation in their patients. There was a higher incidence of reoperation in non-operatively managed patients. However, this difference was not statistically significant. (RR = 0.75, 95% CI = 0.48-1.16, P = 0.20) (Fig 9).

Complications

A total of 83 of 319 operatively managed patients were compared with 51 of 338 non operatively managed patients had complications. The significant

difference indicated higher complication rate in the surgical group (RR 1.74, 95% CI = 1.28 to 2.37, P=0.0005) (Fig 10).

DISCUSSION

Our meta-analysis showed that operative intervention of typical closed displaced intrarticular calcaneal fractures improves the functional outcome when compared to conservative management but leads to increase in complications.

Surgically managed patients are more likely to resume their pre-injury work. Buckley et al in their study noted that patients with light to moderate work may lead to better recovery with surgery. However patients with heavy workload are unlikely

to recover well regardless of the treatment type. Leung et al observed that patients managed by surgery had a significantly shorter absence from work (P<0.05) (17). Buckley et al and others reported better functional results and less pain when Bohler angle was restored and anatomic reduction were achieved. On the other hand Ibrahim et al found no association between radiographically measured restoration of the angle and clinical outcome (14).

Operatively managed patients had fewer problems while wearing shoes. This may be due to the fact that surgery results in the restoration of pre-injury calcaneal width. Patients who underwent surgery were likely to have less pain as compared to those who underwent conservative management, although the difference did not reach statistical significance

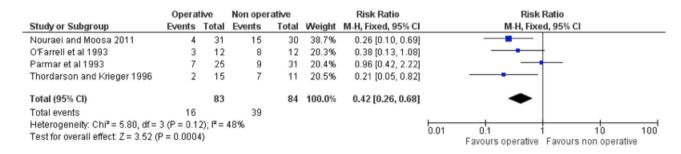


Fig. 6. — Forest plot for problem in wearing shoes.

	Operative			Non operative		Mean Difference		Mean Difference					
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI		IV, Fix	ed, 95% CI		
Agren et al 2013	47.6	9.8	42	40.8	11.9	40	46.4%	6.80 [2.07, 11.53]			-		
Griffin et al 2014	43.7	11.1	54	37	13.1	62	53.6%	6.70 [2.30, 11.10]			-		
Total (95% CI)			96			102	100.0%	6.75 [3.52, 9.97]			•		
Heterogeneity: Chi ² = 0.00, df = 1 (P = 0.98); $F = 0\%$ Test for overall effect: Z = 4.10 (P < 0.0001)							-50	-25 Favours operati	0 /e Favourss	25 non operative	50		

Fig. 7. — Forest plot for SF-36 (Physical).

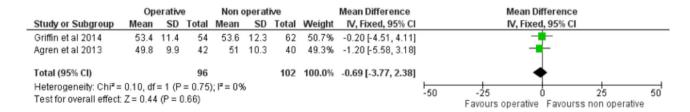


Fig. 8. — Forest plot for SF-36(Mental).



Fig. 9. — Forest plot for reoperation.

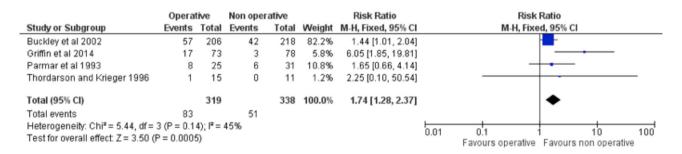


Fig. 10. — Forest plot for complication.

in the present. O'Farell et al reported that surgically treated patients had a significantly longer mean pain free walking distance (4km versus 1 km, P<0.05) (13). They also compared the mean range of subtalar movement and found a significantly larger range of joint motion in the surgical group (P<0.05).

Different types of score were used in various studies. Due to this non-uniformity in comparison methods, little effective data could be pooled for meta-analysis from these scores or scales, as there was no consistent assessment system or presentation of the results in terms of mean and standard deviation. Three studies used AOFAS score and they found no statistically significant difference in operative and non-operative group (10,11,14). The two large multicentric randomized controlled trials from England used SF-36 for comparison. Although SF-36 (physical) score was significantly more in surgically treated patient but no statistically significant difference was found with SF-36 (mental) (19).

Although operative intervention showed good outcomes, but they also had a significantly higher incidence of complications. Complication rates

were much higher with surgery with most frequent complication being infection. The complication rate has been reported to be as high as 54%. 20 Co-morbidities such as peripheral vascular disease, diabetes mellitus, significant positive history of smoking, fracture blisters, delayed presentation and severe associated injuries may not make operative treatment feasible (21).

The newer surgical technique of percutaneous screw insertion as described by Tomesen et al (22) showed excellent results in DIACF (Displaced Intra Articular Calcaneal Fracture) treatment (23). Schepers et al demonstrated that percutaneous distractional reduction and fixation to be a safe technique with overall good results and an acceptable complication rate (24). Dewall et al compared open reduction and internal fixation with use of a lateral extensile approach with percutaneous reduction and found compatible results for the two surgical approaches, with significantly fewer wound related complications in the percutaneous group (25). Woon et al showed that the percutaneous approach could avoid soft tissue complications associated with open reduction (26) According to Rammelt et al, percutaneous fixation was a reasonable alternative for moderately displaced Type II fractures and provided adequate control over anatomical joint reduction with either subtalar arthroscopy or high-resolution (3-D) fluoroscopy (27).

Cochrane review states that even in situations where there is some evidence of benefit of operative treatment compared with non-operative treatment, it remains unclear whether the possible advantages of surgery are worth its risks. Many different types of scores have been used for comparison between the two groups across various studies, such as American orthopaedic Foot and Ankle society (AOFAS), Short form -16 (SF-16), Visual analogue scale(VAS) etc.

Reoperation rate was higher in patients managed non operatively, although this difference was not statistically significant. The most frequent revision surgery required was subtalar arthrodesis. Radnay et al studied the outcome of patients with a displaced intrarticular calcaneal fractures that eventually required subtalar arthrodesis and concluded that patients who had initially been treated surgically had superior results compared with those who were initially managed conservatively. They reasoned that after primary surgery, the anatomy of the calcaneus is somewhat restored which renders the technique for subsequent surgery less demanding.

The limitation of this review is the lack of compatible assessment systems or outcome measures, which may lead to loss of abundant data for meta-analysis and may have effect on the reliability of the conclusions. Other limitations are small sample size and variable period of follow up.

CONCLUSION

Surgery can benefit calcaneal fracture patients with greater likelihood of resumption of preinjury work. However the complication rates are significantly higher in the operative group. Since the included trials use different scores to measure outcomes, hence little effective data could be pooled for meta-analysis from these scores or scales. We hope that subsequent studies use a standardized outcome score which makes comparisons between various studies more meaningful.

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