■ ANNOTATION

Calcaneal fractures: selection bias is key

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In this paper, we critically appraise the recent publication of the United Kingdom Heel Fracture Trial, which concluded that when patients with an absolute indication for surgery were excluded, there was no advantage of surgical over non-surgical treatment in the management of calcaneal fractures.

We believe that selection bias in that study did not permit the authors to reach a firm conclusion that surgery was not justified for most intra-articular calcaneal fractures.

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Improving the level of evidence in orthopaedics is a constant struggle and often a thorny issue.[1,2] This statement is supported by the fact that the majority of Cochrane reviews on any subject pertaining to our specialty conclude that there is not enough high-level evidence on which to draw any firm conclusions.[3-5] Perhaps it is because there is such a paucity of level 1 studies in the orthopaedic literature that, when a valiant attempt is made at producing one, it is taken at face value by most people, resulting in the irresponsible and tabloidesque headline that appeared on the front of the British Medical Journal (BMJ) recently: "Calcaneal fractures: Surgery provides no benefits".[6]

Calcaneal fractures are often severe injuries which can result in long-term morbidity.[7] The challenge for the orthopaedic surgeon is to decide which fractures in which patients will benefit from operative intervention, bearing in mind that the most severe complications of surgery may make the cure worse than the disease. When searching for evidence to assist in the decision making process, the Cochrane database may be the natural place to start, but the conclusion from the review in 2013[8] was (perhaps unsurprisingly) that "overall, there is insufficient high quality evidence relating to current practice to establish whether surgical or conservative treatment is better for adults with displaced intra-articular calcaneal fracture." As usual, further good quality research was called for and the UK heel fracture trial was eagerly awaited. Griffin et al[9] published the results of this trial in the BMJ in July 2014. It was a pragmatic, multicentre, two-arm, parallel group, assessor-blinded, randomised controlled trial, to investigate if open surgery provides benefit compared with conservative treatment for displaced intra-articular calcaneal fractures. It is an impressive piece of work and the researchers are to be congratulated for addressing many of the criticisms levelled at previous studies on the same topic. To say, however, that "surgery is no longer justified for most intra-articular displaced fractures" (of the calcaneus)[6] based on this study, is just plain wrong.

The major strengths of the study were that there were 22 hospitals and 27 specialist surgeons involved, as opposed to just one 'super specialist' as is the case in many other large studies. The researchers went to considerable effort to prevent having high-risk patients in one group by chance by using a minimisation algorithm in the randomisation process. A power analysis was performed and an adequate sample size was obtained to detect a 10-point difference in the Kerr–Atkins score[10] (a specific pain and function scale for calcaneal fractures from 0 to 100, with 100 being the best possible score), which was the primary outcome measure. A 95% follow up was achieved and intention-to-treat analysis adhered to. After a follow-up period of two years, there was no significant difference in clinical scores, and complications and re-operations were much more common in those who received operative care. This does, on first reading, sound like the end of the debate and that we should be treating all calcaneal fractures (apart from the ones that clearly need surgery and were excluded on that basis from this study (n = 102)) conservatively from now on. There are several reasons why this is not the case.

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One of the criticisms of the Buckley paper[11] was that the method of randomisation used may have introduced selection bias and Griffin et al[9] claim to have eliminated this in their study. Unfortunately, selection bias is the biggest problem with their paper. During the study period, 2006 patients presented with calcaneal fractures, of which 502 were deemed eligible for recruitment into the trial. Many of these were excluded quite reasonably, for example those with undisplaced fractures, but as mentioned above, also excluded were patients that clearly needed surgery, such as those with open or severely displaced fractures. A much more important point to note when assessing the merits or otherwise of this study, however, was the fact that only 30% of eligible patients consented to be included in the trial, with the majority of those who declined doing so because they had a preference for either operative or non-operative treatment. To say that this does not introduce selection bias is to credit the potential participants with no cognitive ability whatsoever. Of course, the actual process of randomisation of the patients who consented to be involved in the study was carried out by research associates, but the initial consultation was, as it ought to have been, carried out by the surgeon. The patients were diagnosed with a calcaneal fracture and then consulted by one of several experts in managing these injuries. After a discussion of the possible treatment options (which of course includes more than just the two available in this study; open reduction and internal fixation using an extended lateral approach or conservative treatment) and their potential complications, the patients were then asked if they would consent to be randomised. There should be no doubt that these experienced surgeons did their level best to appear unbiased in their discussions, however, is it possible to appear unbiased when discussing an extended lateral approach with a 79-year-old diabetic smoker, or non-operative treatment for a displaced Sanders 2 tongue-type fracture that can very easily be anatomically reduced and fixed percutaneously[12] in a fit and well 18 year old? (These two examples represent the extremes of patients that would fit the inclusion criteria for the study). Unsurprisingly after these discussions, 351 out of 502 patients (70%) did not consent to be randomised with 290 (83%) of these, which represents 58% of the whole cohort, expressly doing so because they had a preference for one treatment over the other – this represents a huge selection bias. The point is further illustrated by the fact that the average surgeon only contributed 2.7 fractures over a two- to three-year period. This very small number of cases per surgeon is, undoubtedly, largely because only 151 out of 2006 fractures (7.5%) that presented during the study period were included in the end.

The authors acknowledge that percutaneous and minimally invasive techniques may be safer and more effective, but state that their results should be tested in randomised controlled trials before they are adopted. While this may be true, it was not something that they studied and, therefore, should not have been one of their conclusions. This also highlights the issue alluded to earlier; that it is too simple to say that these fractures can only be treated by an extended lateral approach or conservative treatment, just as it is too simple to have the inclusion criteria as being a greater than 2 mm depression of the joint surface. It would be very informative to know how many were joint depression-type fractures and how many were tongue-type injuries. By forcing surgeons to perform an extended lateral approach for a tongue-type fracture that should be fixed percutaneously,[13] the complication rate from surgery is going to rise. Of course, we do not yet have level 1 evidence to prove this, but, the infection rate for surgery in this study was 19%. This is higher than most other series,[11,14] and is certainly far higher than with minimally-invasive techniques, some series of which report no infections at all.[12,13,15,16]

Lastly, the issue of drawing global conclusions from a study that has only two years follow-up must be addressed. The authors do concede that longer-term follow-up may reveal differences between the groups with respect to late complications, such as the progression of arthritis, however, their conclusion remains that there is no justification to continue with this type of surgery. Indeed, there is evidence that it takes two years for the symptoms from these fractures to stabilse and that they may even continue to improve for up to six years.[17] In their study patients, even with only two years follow-up, three subtalar fusions have been performed already in the non-operative group compared with none in the operative group. This aspect alone means that it is a little arrogant to conclude that "there is no justification to continue with this surgery" especially considering that the more severe injuries were selected out (so that they could have surgery) before randomisation. As pointed out in the excellent response to the paper by Parker and Winson,[18] there are longer-term studies that report a relative risk reduction in radiographic subtalar arthritis of 41% with surgery[19] and a statistically significant correlation between the best results and surgery at ten years follow-up.[20] Let us also not forget that there is evidence that patients do better, with fewer complications, from subtalar arthrodesis for post-traumatic arthritis after an initial open reduction and internal fixation of a calcaneal fracture than they do with subtalar arthrodesis for arthritis following malunion of a non-operatively treated fracture.[21]

The correct conclusion that should be drawn from this paper is that after excluding fractures that definitely need to be fixed, in the 30% of remaining patients who do not care whether you operate on them or not, and where you can only offer an extended lateral approach or nothing, the benefits of surgery do not outweigh the risks at two years follow-up.

The standard of care for calcaneal fracture management is a fellowship-trained foot and ankle or trauma surgeon selecting the best treatment, with the involvement of the patient, based on appropriate imaging, taking into account the exact fracture pattern and risk/benefit equation for each individual, and then carrying out that treatment expertly,[22]

be it conservative, minimally-invasive, or open operative intervention. This recent paper does not change that.

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