Re: The role of ultrasonography in the diagnosis and management of idiopathic plantar fasciitis

Sir, We read with interest the article by Kane et al. [1] on the role of ultrasonography in the diagnosis and management of idiopathic plantar fasciitis. There are several flaws in the study design which limit the conclusions drawn.

First, although rheumatologists commonly use steroid injection to treat plantar fasciitis, there is no evidence for its effectiveness bar a single randomized controlled trial indicating its usefulness up to 4 weeks only [2, 3]. An important objective of an equivalence trial, beyond establishing equivalence of both treatment arms, should be to establish definitively that the experimental regimen being tested is efficacious. In the absence of convincing evidence for the effectiveness of steroid injection in the treatment of plantar fasciitis and without a placebo group in this study, the conclusion that either injection method is effective in the management of plantar fasciitis is not supported by the negative observations between the two groups at a mean of 12 weeks after injection.

Secondly, in comparing ultrasound- and palpation-guided injection in idiopathic plantar fasciitis, Kane et al. expressed the result as the mean and standard error of the mean with the accompanying 95% confidence interval (CI) for improvement after injection. We calculated the 95% CI for each group, as shown in our Table 1, and there are obvious differences from the data of Kane et al. in the visual analogue scale (VAS) score at baseline [4, 5]. We would ask Kane et al. to kindly clarify this matter.

Thirdly, and critically, disclosure of the method of power calculation, sample size determination and pre-determination of non-inferiority margin is lacking in the Methods section. With the small sample size, the reported response rate cannot reflect the true response reliably, as illustrated by the wide CI both in our Table 1 and in Table 2 of Kane et al. (8.9–402 in Table 2a, 5.1–411.2 in Table 2b and 4–120 in Table 2c). To declare equivalence between treatments, one needs an adequate sample size with special attention to the upper boundaries of the difference in 95% CI [6]. Failure to detect statistical difference does not imply equivalence [7].

Fourthly, what Kane et al. tested in their Table 2a–c was ‘association’, not ‘correlation’, as correlation cannot be tested with two category variables in their 2 × 2 contingency table.

Kane et al. stated that the reduction in the mean plantar fascia thickness was 1.05 mm after steroid injection. In the absence of details of intra- or inter-observer variance, there is uncertainty whether this represents a true difference between the two values. Similarly, as there was no comparison with a non-injected control group, we do not know whether this reduction reflects the natural progression of the disease or a true response to steroids. In this respect, the appreciable improvement also seen in the VAS and heel tenderness index (HTI) scores of the non-injected group on follow-up is noteworthy.

Finally, Kane et al. compared the symptomatic heels with the asymptomatic heels using as a marker for plantar fasciitis a universal discriminator of plantar thickness ≥4.5 mm or when there was a difference of >1 mm in plantar fascia thickness between the symptomatic and asymptomatic heels. The application of these criteria does not seem to hold true for patients 6, 11, 16 and 19 in their study group, as shown in their Table 1. Using the contralateral heel as a normal control is not to be recommended when evaluating plantar fasciitis. Previous studies have shown increased thickness of the plantar fascia in the asymptomatic heel of patients with unilateral symptoms of plantar fasciitis [8, 9]. This may reflect the bilateral nature of plantar fasciitis or a response to increased weight-bearing on this heel due to pain in the contralateral heel [10]. Comparison of the symptomatic heels with normative data derived from a control group of asymptomatic patients may be more precise [8, 9].

S. M. WONG, J. F. GRIFFITH1, A. TANG2, A. C. F. HUI

Department of Medicine and 1Department of Diagnostic Radiology and Organ Imaging and 2Centre for Clinical Trials and Epidemiological Research, Prince of Wales Hospital, The Chinese University of Hong Kong, Hong Kong

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Correspondence to: S. M. Wong, Department of Medicine, Prince of Wales Hospital, 30–32 Nga Shing Street, Shatin, New Territories, Hong Kong.

References


Table 1. Comparison of ultrasound- and palpation-guided injection in idiopathic plantar fasciitis (95% CI)

<table>
<thead>
<tr>
<th></th>
<th>Ultrasound-guided injection (n = 14)</th>
<th>Palpation-guided injection (n = 10)</th>
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<tbody>
<tr>
<td>VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>46.03–74.97</td>
<td>46.13–73.27</td>
</tr>
<tr>
<td>Follow-up</td>
<td>7.51–34.29</td>
<td>3.50–32.90</td>
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<tr>
<td>Improvement</td>
<td>19.72–59.48</td>
<td>23.40–59.60</td>
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<tr>
<td>Heel tenderness index</td>
<td></td>
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<tr>
<td>Baseline</td>
<td>1.21–2.07</td>
<td>1.42–2.78</td>
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<tr>
<td>Follow-up</td>
<td>0.18–0.62</td>
<td>0.35–1.25</td>
</tr>
<tr>
<td>Improvement</td>
<td>0.92–1.78</td>
<td>0.40–2.21</td>
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</tbody>
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