

Title Page

1. Title of the article.

The Use of Acupuncture for Plantar Heel Pain: a systematic review.

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2968

ABSTRACT

Introduction: Plantar heel pain (PHP) is a common complaint, yet there are no definitive guidelines for its treatment. Acupuncture is increasingly used by podiatrists, and there is a need for evidence to validate this practice.

Method: A systematic review (PROSPERO no. CRD42012001881) of the use of acupuncture for PHP is presented. Five RCTs and 3 comparative studies were included. Quality of the studies was assessed with reference to CONSORT, STRICTA and Quality Index (QI) criteria. Pooling of data, or even close comparison of studies, was not done due to heterogeneity of the studies.

Findings: High quality studies report significant benefits. In one, acupoint PC7 was shown to be significantly more effective than LI4. In another, acupuncture was associated with significant increase in benefit, when combined with standard treatment (including NSAIDs). Other papers were of lower quality but suggest benefits from other acupuncture approaches.

Discussion: There is a need for more uniformity in carrying out and reporting such work and the use of STRICTA and QI is recommended. Future research should recognise the complexity of PHP, of acupuncture and of the relationship between them, to explore the optimum use and integration of this approach.

Conclusion: There is evidence at levels I-II supporting the use of acupuncture for PHP. This is comparable to the evidence available for conventionally used interventions, such as stretching, night splints or dexamethasone. Therefore acupuncture should be considered in recommendations for the management of patients with PHP.

MAIN TEXT

INTRODUCTION

Heel pain is one of the commonest problems dealt with in podiatry and causes substantial morbidity and costs[1-4].

A number of specific pathological conditions can give rise to pain in the heel, ranging from autoimmunity to malignancy; once such conditions are excluded, what remains is primary, plantar heel pain (PHP) which is the focus of this study. The typical syndrome consists of a history of pain on taking the first few steps in the morning, worsening pain with weightbearing, and pain and tenderness to palpation over the medial calcaneal tubercle.[5]

Historically, the diagnostic label 'plantar fasciitis' (PF) has been used and some authors also use the term 'calcaneal spur'. The accuracy of such terms has been contested[6] and they are beginning to be replaced by others, such as 'plantar fasciosis'[7]. However, even this term is inappropriate here, as it embodies the assumption that the plantar fascia is the seat of the problem – which is not compatible with the assumptions made by some of the practitioners whose work we review. The aetiology of PHP is complex, involving the interplay of tissue, biomechanical, psychological and other factors and, as Sackett *et al*[8] point out, the practitioner perspective is an important aspect of the Evidence Based Practice (EBP) triad.

Recognising the heterogeneity in the reporting of this phenomenon, an inclusive search strategy was chosen to identify relevant work; similarly, in discussing findings, this review uses the concept Plantar Heel Pain (PHP) as it is inclusive and makes no assumptions regarding causation.

Conventionally many different interventions are used, yet the evidence for their use is patchy[9-12]. A Cochrane review dated 2010 stated "Although there is limited evidence for the effectiveness of local corticosteroid therapy, the effectiveness of other frequently

employed treatments in altering the clinical course of plantar heel pain has not been established... At the moment there is limited evidence upon which to base clinical practice.”[13]

Compliance is often poor[14] and interventions such as non-steroidal anti-inflammatory drugs (NSAIDs) and steroid injections carry significant risks[15 16].

Recently, increasing numbers of podiatrists are incorporating acupuncture into their practices[17] and initial results seem favourable[18]. One of the current authors (RJC) runs a training programme, validated by the Society of Chiropractors and Podiatrists. Anecdotally, alumni of this programme report good results from incorporating acupuncture into their approaches. Meanwhile the body of published work in this area is increasing. Thus it is now appropriate to conduct a rigorous assessment of the role acupuncture might play in the management of PHP.

An earlier systematic review[19] addressed a related question, considering dry needling and injections of myofascial trigger points (MTPs) associated with plantar heel pain. Recognising (from clinical experience) that many patients suffer from PHP in the absence of MTPs, the current authors chose to review a wider range of studies drawing on all types of acupuncture practice. Thus, the research question was: “what is the evidence regarding the effectiveness of acupuncture for PHP?” Safety of the technique was not considered in this review; this aspect has been studied more appropriately elsewhere[20-23]. This paper presents a systematic review of publications relating to this question, discusses the implications, and makes suggestions for future development.

METHODS

The protocol was registered with PROSPERO (no. CRD42012001881)[24].

A comprehensive literature search was carried out as follows. The databases searched were: PubMed, AMED (EBSCO), British Nursing Index, CINAHL plus (EBSCO), EMBase,

MEDLINE (EBSCO), MEDLINE (Ovid), Oxford Journals, PsychARTICLES, ScienceDirect, SocINDEX (EBSCO), SwetsWise, Taylor & Francis Online, Wiley Online Library.

The search parameters included All Dates (from inception to the end of 2011), All Types of publication, All Languages, and All Fields. The precise wording of the searches varied in different databases, using different thesauri. The general principle was to include 'Acupuncture' OR 'dry needl*' OR 'Trigger Points' OR 'moxibustion' OR 'TENS' OR 'laser therapy' AND 'heel pain' OR 'plantar fasci*' OR 'heel spur' OR 'calcan*'.

The search was extended by following all relevant leads in sources read. Reference lists of papers obtained were scanned for further relevant papers. Journals identified were searched electronically where possible, or by scanning tables of contents. Leads were also obtained from available textbooks, online forums and the internet and personal communications.

Titles and abstracts were scanned to identify papers for inclusion. Papers relating to PHP and related diagnoses were included; those relating to pain secondary to other pathologies[25 26], or to experimental pain in animal subjects[27] were excluded.

Papers were included if they described the use of acupuncture, acupuncture points, TCM or moxibustion. Papers describing the use of MTPs were included if the treatment was (dry) needling, whether or not an acupuncture-related rationale was used. Papers describing the use of laser therapy or transcutaneous electrical nerve stimulation (TENS) were included only if the therapy was applied specifically to acupuncture points, or if an acupuncture-related rationale was used[28].

Randomised Controlled Trials (RCTs) and comparative studies were included. Case series, single case studies and secondary reports were excluded from this review but will be considered in detail elsewhere (Clark & Tighe, in preparation).

Two papers were translated[28 29]. Data were extracted into a spreadsheet, as summarised below in Table 1.

Systematic assessment of the quality of the studies was carried out using CONSORT[30] (for RCTs) and using STRICTA[31] and the Downs & Black Quality Index (QI)[32] for all studies. To enable comparison, the QI scale was modified as recommended by Cotchett[19] (however, only one paper appeared in both studies, so meaningful comparison was impossible). The two authors rated each paper independently; scores were discussed to identify and resolve differences, and so achieve consensus.

Percentage scores were calculated in relation to the number of relevant items, to enable comparison across the scales. Further quality data was extracted, as summarised below in Table 2.

In view of the extreme heterogeneity of the papers (elaborated below), neither data synthesis nor meta-analysis was possible; narrative summarisation was performed.

RESULTS

Papers

The searches identified 342 potentially relevant articles (see Fig. 1), of which 8 met the inclusion criteria: 5 RCTs[28 29 33-35], 2 comparative studies[36 37] and 1 cohort study using “patients as their own controls”[38].

A summary of the papers is provided in Table 1

Table 1: Summary overview of papers

Study	Participant	Acupuncture	Comparison	Outcome measures	Results / Conclusions
Type (N)	characteristics	intervention	intervention(s)		
Setting					
Chen & Zhao, 1985 Comparative case series (900) <i>Hospital setting</i>	Heel pain, mostly non-specific +/- calcaneal spurs. <i>Duration 3 m - 30 y</i> 33.3% male. <i>Aged <30 to >70</i> Prior treatments not stated.	(Gp 3) BL61 Depth 0.3-0.5 cun Retained 5min. 10 sessions, daily, during two weeks plus herbs as in Gp 2	(Gp 1) Steroid + LA local pt, x5-6 in 3wk; (Gp 2) As Gp1 plus individualised herbal decoction b.d. x15	Excellent = complete resolution Good = remarkable improvement Poor = no response	3 groups comparable - no sig diff. Acupuncture group: Excellent 15/50, Good 20/50, Poor 15/50 [allowing for typo] Follow-up 1-8yr (mean 3.5)
Karagounis et al, 2011 DBRCT (38) <i>Laboratory of Functional Anatomy and Sports Medicine setting</i>	Plantar Fasciitis <i>Duration >2wk (mean 16.1d)</i> 100% male. <i>Mean age 37.1</i> No prior treatments received.	(Gp 2) Up to 12 painful and other points chosen from BL31, 54, 58, 60, 62, ST 36, LI4, PC7, SP5, KI7, 8, TE5, LR2, 3, GB 30, 34, 37, 38. "Inserted perpendicularly through plaster and skin	(Gp 1) standard tmt including: ice, extensive stretching program and NSAID drug	PFPS (Plantar fasciitis pain scale – Willis et al)	Both groups improved significantly, Gp2 more so. At wk 8 improvement = Gp1 26%, Gp2 47%; p<0.05 Minor adverse effects noted

into deeper tissue"

Slight rotation and

thrusting to elicit deqi

(dull, numb or heavy)

Retained 20-30 min, with

"periodic manual

stimulation".

16 sessions, 2/wk, during

8 weeks.

Plus standard treatment

as Gp1.

Liu et al, 2010	'Calcaneus spur' (on XR)	(Gp 1) GB39	(Gp 2) "common	PRR (points	Both gps PRR >50%.
[Chinese]	<i>Duration 4-38m</i>	Even method, deqi to	acupuncture" - GB34,	reduction rate)	PRR of over 60% for
RCT (66)	37.9% male.	heel, Retained 20 min.	BL60, BL57, KI3.	based on: walking	64.7% Gp1, 37.5% Gp2
<i>Hospital setting</i>	<i>Age 31-64</i>	Daily, 30 sessions during	Ipsilateral	pain, walking	P<0.05.
	Prior treatments not	3 courses of 10.		function, swelling,	Asserts safe, but without giving
	stated.	Plus pyrogenic herbal		burning sensation,	data.
		dressing & heat		each on 5-pt scale	
		application.			

Orellana Molina et al, 1996 [Spanish]	Heel spur (but diag clinically) <i>Duration not stated</i> 30.8% male. Age <40 to >60 Prior treatments not stated.	(Gp 2) Acupuncture to ahshi, BL40, BL60, KI3, KI6. Rotate at start & at 10min. Retain 20 min. Daily x10, repeat if necessary.	(Gp 1) Point application of infra-red laser (904 nm) to ahshi, BL40, BL60 16J/cm ² to ash, 7J/cm ² to other points. Daily x10, repeat if necessary.	VAS pain scores at sessions 3, 6, 10 combined into 3 categories: Cured = VAS ≤ 2 Improved = VAS 3-5 Not improved = > 5	Gp1: Cure 11/26; Improved 15/26 Gp2: Cure 16/26, Improved 10/26 Also Gp2: Onset of benefit sooner; fewer pts required 2 nd course.
Ouyang & Yu, 1996	'Pain in the sole' (including heel). <i>Duration 1-6m (N=14); >1y (N=29); 3y (N=1); rest not stated.</i> 43.8% male Age 30-78 Prior treatments not stated.	Gp 1: ST7, Ipsilateral. Depth 1.5 cun; Rotation 1 min counter-clockwise; Retain 20-30 min. Daily x5 per course	Gp 2: 'corresponding' palmar pt, Ipsilateral. Depth 0.5 cun; Rotation 1 min counter-clockwise; Retain 20-30 min. Daily x5 per course Gp 3: both ST7 and palmar point	CR = complete relief MR = marked relief PR = partial relief NR = no relief CR+MR+PR = response rate (RR).	RR% = 97.1 (Gp1); 92.6 (Gp2); 100 (Gp3) Concludes combination is more effective, but palmar points often painful, so use latter only if ST7 fails.
Tillu & Gupta, 1998	Plantar fasciitis <i>Duration 12-30m</i> 27.8% male	'Classical acupoints' KI3, BL60, SP6; Ipsilateral; Deqi sought (tingling)	Trigger points (calf and plantar) added if needed for sessions 5-6.	VAS pain score; VAS % change; verbal rating score	Sig reduction from baseline in VAS scores at wk 4 [40.3%] (p<0.0009) and wk 6 [69%]

controls' (18)	Mean age 49.17 (SD	each 5 min;			(p<0.0001). Significant
Orthopaedic	10.66).	Retained 15m.			reduction between w4 and wk6
outpatients clinic	Previously unsuccessful	Weekly x 4			(p<0.047).
setting	conservative treatment (physiotherapy, shoe support, steroid injection)				Concludes classical acupoints effective, enhanced by addition of trigger points in failed cases. Recommends use of MTP from the start.
Vrchota et al, 1991	Plantar fasciitis	Gp 1 - 'true acupuncture':	Gp 2 - 'Sham	Pain score,	Mean pain score >50% less.
DBRCT (40)	Duration not stated	Electroacupuncture to	acupuncture': sham	tenderness score,	Sig diff. True > sham > sports
Pain clinic and	Gender not stated	KI1, KI3, Ahshi;	points on sole, with	decided by doctor	medicine (including antiinflam
research centre	Age not stated	5/80 Hz, to tolerance.	minimal depth and	with patient, each on	drug)
setting	Prior treatments not stated.	Retained 20 min.	subthreshold	4-point scale.	
		Plus calf stretches, footwear advice, insoles.	electrostimulation, Plus calf stretches, footwear advice, insoles;	Pain log, daily until 3wk after last treatment. Activity log (data not used).	Pain log showed more relief in Gp1 than Gp3 at wk 4 (P=0.010) and follow-up (P=0.016). Pain score showed more relief in Gp1 than Gp3 at wk 4 (P=0.014). Tenderness scores changed
			Gp 3 - 'sports medicine therapy', including reduced training, stretches, ice and NSAID.		

Plus footwear advice,
insoles.

little.

Zhang et al, 2009	Plantar fasciitis	(Gp 1) PC7, contralateral	(Gp 2) LI4, contralateral	Morning pain VAS	Significantly greater
DBRCT (53)	(diagnosed as 'pain	to pain.	to pain. Depth 10mm.	(MP), also	improvement in Gp1 than Gp2
<i>School of Chinese</i>	localized to the medial	Depth 10mm.	Deqi elicited each 5min;	Activity pain VAS	at 4 data points (MP at 1m,
<i>Medicine setting</i>	tubercle of the calcaneum')	Deqi elicited each 5min;	Retained 30 min.	(AP)	P=0.044, AP at 6m, P=0.048,
	<i>Duration > 3m (3-216 m)</i>	Retained 30 min.	Daily x10	Overall pain VAS	OP at 1m, P=0.049, PP at 1m,
	26.4% male.	Daily x10		(OP)	P=0.007). Significant decrease
	<i>Age >18 (mean 48.5)</i>			Pressure algometry	in MP (from baseline) was
	Various prior treatments			(PP)	seen in Gp1 at 1, 3 and 6m f-u
				At each daily	(P<0.001). Gp1 also showed
				session and follow-	significant decreases in AP
				up at 1, 3 & 6	and OP (P<0.05). In Gp2
				months	improvement in MP did not
					reach significance, but AP and
					OP were both significantly
					improved by 6m (P<0.05).

A negative correlation was found between the prior duration of complaint and the effect of treatment.

One patient withdrew due to needling pain at L14.

and quality assessment is summarised in Table 2

Table 2: Quality assessment of papers

Date	Place	Authors	STRICTA %	QI %	CONSORT %	Funding	Vested interest	Committed	Peer review	Ethical governance	Notes re pub bias	Randomisation	Blinding	Journal title bias
2009	China	Zhang et al	94.1	72.2	75.0	Declared - partial academic	Clinical research	No	No	Yes	Ethical approval	Computer generated	Patients and Assessor. Credibility rated	No
2011	Greece	Karagounis et al	78.1	85.2	44.6	None declared	Clinical research	No	No	Informed consent ?clinical	Ethics ü Unable to determine	Computer generated	Patients and Assessor	No
2010	China	Liu et al	64.7	55.6	41.4	None declared	Clinical research	No	No	No	Unreported	Yes, method not stated	Patients	Yes
1996	China	Ouyang & Yu	61.8	20.4		None declared	Clinical research	No	No	No	Report 'satisfactory' results	?no	No	Yes
1998	UK	Tillu & Gupta	55.9	55.6		None declared	Clinical research	No	No	Not evident	? Research governance	No	No	Yes
1985	China	Chen & Zhao	55.9	11.1		None known	Clinical research	No	No	No	Unable to determine	No	No	Yes
1996	Cuba	Orellana	52.9	61.1	41.7	None	Clinical	No	No	No	States no	Yes,	No	No

		Molina et al				declared	research				conflict	method not stated		
1991	US	Vrchota et al	46.9	51.9	40.3	None declared	Clinical research	No	No	Not evident	? Research governance	Yes, method not stated	Implied, patients and assessor	Yes

Quality

The combined use of STRICTA, QI and CONSORT gave a multifaceted appreciation of the overall quality of the papers. There was a general agreement between the rankings by the three instruments and there was a clear indication of the contrast between the two highest quality papers, as discussed below.

Table 2 also illustrates the wider quality issues of clinical and research ethics governance. Consideration of: funding arrangements, vested interests of commissioning context, peer review, ethical processes and publication bias reveals weak methodology in all but the best of the papers. The relationship between clinical practice and research was often blurred (indicating potential for Hawthorne effect and social desirability bias) and there was a lack of transparency and detail regarding ethical governance.

Following Montané *et al*[39] “The quality of RCTs was classified in three categories according to CONSORT score: excellent ($\geq 20/22$ items [90%]), good (between 13 and 19 [59-86%]), and poor (≤ 12 [55%])”. The mean score was 15.2 which compares favourably (eg) with surgical trials reported by Thoma *et al*[40].

Excellent RCT

Zhang *et al*[35] assess the specific efficacy of acupoint PC7 (compared to LI4) for PF of over 3 months duration. They conclude that PC7 gives a significantly greater benefit, at 1m and 6m follow-up. This trial scores well on internal validity, less so on external validity.

One might criticise the choice of LI4 as a comparator, in that it is widely used to treat pain, including heel pain (e.g.[41]). Conversely, this makes it ideal as a ‘control’ treatment; if LI4’s reputation is undeserved and it is, in fact, an inert intervention, then it serves as a demonstrably credible placebo; conversely, if it is an effective point, then PC7 has been shown to be even more so.

Good RCTs

In contrast, **Karagounis et al**[33] assess the value of adding acupuncture treatment to a standard clinical approach, for men with acute PF. While the 'standard' group showed improvement (pain score reduced 26%), the acupuncture group improved almost twice as much (47%, $P < 0.05$). While this paper was rigorous in many ways, the detail provided for the acupuncture given is inadequate.

Orellana Molina et al[28] studied pain related to heel spurs, comparing the effectiveness of laser treatment at acupoints with needling a similar group of points. While both groups showed benefit, the laser group reported improvement sooner and to a greater degree. Significance is claimed for this result but (even after professional translation) the method used is unclear.

Vrchota et al[34] studied the efficacy of 'True Acupuncture' compared to 'Sham Acupuncture' and to 'Sports Medicine Therapy' for PF in a Sports Medicine Clinic. True acupuncture included the use of ahshi, local trigger points and classical acupoints, to which electroacupuncture was applied at the level of tolerance. Sham consisted of shallow needling at two unrelated points on the sole, with minimal electroacupuncture (below threshold of perception). The other control group received advice to reduce training, apply ice, stretching exercises and NSAID medication. Pain reduction was significantly greater in the True Acupuncture group than the Sports Medicine group after 4 treatments and 3 weeks later. The results in the sham group were intermediate between the other two groups, but differences did not reach significance. This paper did not give details of demographic characteristics, duration of complaint, prior treatments or blinding.

Poor RCT

Liu et al[29] studied the effectiveness of needling a single point (GB39) in conjunction with local heat application via a herbal dressing, in comparison to 'common acupuncture'

needling 4 other points, for patients with chronic pain related to heel spurs. Using a combined 'Points Reduction Rating' they found significantly greater improvement in the 'GB39 plus heat' group ("marked improvement" in 64.7% compared to 37.5%; $P < 0.05$).

Comparative studies

Chen & Zhao[36] retrospectively report an extensive series of patients with heel pain. They compare the results of 50 receiving acupuncture to BL61 (plus an individualised herbal decoction), with 102 receiving steroid injection into tender point (plus herbal decoction), and with 748 receiving steroid alone (5-6 injections during 3 weeks). They state that there was no significant difference between the 'effective rate', which averaged 73.5% in the three groups. Close inspection of their data does suggest that the 'excellent' rate in the acupuncture group was lower than the other two groups, however the numbers in the table do not add up to the totals given, so it is impossible to draw a conclusion from this.

Ouyang & Yu[37] studied patients with pain in the sole (including an unstated number in the heel), comparing the use of ST7 with a 'corresponding point' on the palm, or both of these combined. (Corresponding point is assumed to mean a location on the palm analogous to the pain location on the foot but this is not made explicit.) They conclude that the combination is more effective, however the differences are small and unlikely to be of statistical significance. This paper reports outcomes as clinical judgements of relief obtained (complete, marked, partial, none) and, unlike comparable papers, combine the first 3 into a global Response Rate. When the complete/marked sum was compared (by the current authors) ST7 emerged as more effective than the Palmar point (76.5 cf 59.3%). Furthermore, needling the palm was found to be too painful for some patients, so the recommendation was to use ST7 as first choice and reserve palmar needling for unresponsive cases.

Tillu & Gupta[38] studied a series of 18 consecutive patients with PF of over a year duration. All had failed to benefit from prior conservative treatments, including steroid injection in 12 cases. Patients received acupuncture to 'classical points' (KI3, BL60, SP6), weekly for 4 weeks which resulted in significant improvement of mean VAS (Visual Analog Scale) pain scores ($P < 0.0009$). Two patients needed no further treatment; the remaining 16 were then given the same treatment twice more, with the addition of needling 'trigger points in the gastro-soleus and plantar fascia'. This resulted in a significant further improvement ($P < 0.047$). This was a non-blinded study; the authors argue that each patient served as their own 'control' in view of the long duration of complaint, with failure of prior treatments.

Heterogeneity

Meaningful comparison of these studies is difficult in view of the many ways in which they vary. The indication for treatment is variously stated as heel pain (although one paper is less precise), plantar fasciitis (but the definitions differ) or heel spur (with or without XR confirmation). Although all studies involve acupuncture, none of them use the same approach. The outcome measures vary from precise, prospective use of a relevant pain scale to retrospective clinical judgements.

Prior duration of the complaint, where stated, varied between 2 days and 30 years. This is perhaps of particular significance in that one paper[35] noted an inverse correlation between duration and benefit obtained.

The gender ratio also varied. In most papers it was between 26.4 and 43.8% male, which is comparable to the distribution of heel pain in the general population. However one study[33] included only male patients, which may be a significant confounding factor; recent papers highlight effects of patient or practitioner gender on perceptions of pain and acupuncture[42-44].

DISCUSSION

Limitations of this paper

Bias

As a practising acupuncturist, the present author (RJC) might be biased in favour of a positive outcome. Any such bias should be apparent, if not neutralised, by the transparency and systematic nature of this review.

Publication bias

Positive outcomes

Five of the papers reviewed were published in acupuncture journals, with unknown peer-review standards, so it seems likely that there is a bias in favour of positive findings, particularly as they date back as far as 1985. However the two higher quality papers were published in peer-reviewed non-acupuncture journals, so we place more confidence in them. It is impossible to know if there were similar studies with negative outcomes that remain unpublished.

Positivist methodology

By including RCTs and comparative studies, and excluding case studies, we have imposed a bias towards formulaic (rather than individualised) approaches. Evidence that this fails to reflect the reality of practice will be elaborated in a separate paper. Sackett notes the importance of this: “*Evidence based medicine ... requires a bottom up approach that integrates the best external evidence with individual clinical expertise and patients' choice*”[8].

At this point it is worth noting the different ranking of the best two papers produced by the QI and CONSORT tools. Zhang et al[35] is a rigorous and well-reported DBRCT, high on internal validity, and so performs well in CONSORT. However the interventions compared

bear little relation to common practice, and the effect size is small. In contrast, Karagounis et al[33] demonstrated a worthwhile level of effect, using a treatment approach which is much closer to real-world practice, and it scored well on external validity. In view of this, and its applicability to non-RCT studies, the QI is recommended.

Heterogeneity

The problem of diagnostic labelling for heel pain was discussed above. Both 'heel spur' and 'plantar fasciitis' were used in the papers reviewed, with variable awareness shown of their shortcomings. The assumptions underlying such labels are now seen to be incorrect, yet it is likely that they influence the design of treatments. For example, if the focus is on 'inflammation', then acupoints thought to influence inflammation may be chosen; meanwhile a potentially more useful approach (e.g. treating MTPs) may be overlooked. In an earlier systematic review Cotchett *et al*[19] focused exclusively on MTPs. While this has the merit of simplicity, it may not reflect a reality which is complex. This review has shown that MTPs may give additional benefit when added to classical acupuncture[38] but also that acupuncture unrelated to MTPs confers significant benefits[35]. Clinical experience (RJC) shows that some patients have MTPs related to their heel pain and others do not; there is a need to explore the possibility that these are two diagnostically distinct groups, requiring different treatment approaches.

One paper suggested that the benefit of treatment was inversely proportional to prior duration of the complaint, which suggests that it would be prudent to control for duration in future studies.

Various outcome measures were used in these studies. All assessed subjective pain, some assessed function and one assessed tenderness objectively. Several used VAS and one used PFPS (Plantar fasciitis pain scale)[45].

Perhaps the greatest difference between these papers is the treatment approach used – none are alike. This should remind us that acupuncture is not a unitary intervention,

indeed it is very complex[46]. Future research should avoid the simplistic question ‘Is acupuncture efficacious for heel pain?’ and instead focus on exploring the optimum use of acupuncture for heel pain. The field is not yet ripe for RCT studies. We are currently at the ‘Development’ stage as defined by the MRC[47] – this paper is ‘Identifying the evidence base’ and the next two phases (2 Identifying/developing theory and 3 Modelling process and outcomes) will be addressed in a separate paper (Clark & Tighe, in preparation).

Conclusions

In view of the heterogeneity of these papers, it is not possible to give a simple conclusion, in the form: *X is shown (or not) to be efficacious for Y*. A number of different approaches were identified, which indicate potential uses of acupuncture for treating heel pain, as summarised in Table 3:

Table 3: Summary of findings

<ul style="list-style-type: none"> • An excellent RCT has shown:
<ul style="list-style-type: none"> ○ PC7 is significantly more effective than LI4 for medial heel pain
<ul style="list-style-type: none"> • Good RCTs suggest that:
<ul style="list-style-type: none"> ○ a part-individualised approach using up to 12 classical points gave significantly increased benefit, when added to standard treatment (including NSAIDs)
<ul style="list-style-type: none"> ○ Electroacupuncture to local points (classical, ahshi and MTPs) gives significantly more benefit than Sports Medicine Treatment (including NSAIDs)
<ul style="list-style-type: none"> ○ Infrared laser stimulation of BL40 + BL60 + Ahshi seems more effective than needling BL40 + BL60 + KI3 + KI6
<ul style="list-style-type: none"> • A poor RCT suggests that:

<ul style="list-style-type: none"> ○ GB39 plus local heated herbal dressing gives significantly more benefit than GB34 + BL57 + BL60 + KI3
<ul style="list-style-type: none"> • Comparative studies suggest that:
<ul style="list-style-type: none"> ○ Needling BL61 + individualised herbal decoction, is as effective as multiple steroid injections into Ahshi point (with or without the herbs)
<ul style="list-style-type: none"> ○ Needling ST7 is as effective as (and more comfortable than) palmar points
<ul style="list-style-type: none"> ○ In patients unhelped by prior treatments (including steroid injection) for 12 months, significant benefit was obtained by needling KI3 + BL60 + SP6, and this was enhanced by the addition of MTPs

Thus there is evidence at level I and II supporting the use of acupuncture for heel pain, leading to a recommendation at Grade B[48]. This is comparable to the evidence available for conventionally used interventions, such as stretching, night splints or dexamethasone[10]. Therefore acupuncture should be included in recommendations for the treatment of PHP. Its optimum deployment will be discussed in a separate paper (Clark & Tighe, in preparation).

CONTRIBUTORS

RJC carried out the searches, screened the papers, assessed quality, drafted and finalised the paper.

MT collaborated in the design of the literature search strategy, provided independent assessment of bias and quality, discussed the findings, contributed to writing of the paper and agreed its final draft.

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DECLARATION OF INTEREST

RJC offers training courses on the use of acupuncture for podiatrists and other health professionals.

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REFERENCES

1. Riddle DL, Schappert SM. Volume of ambulatory care visits and patterns of care for patients diagnosed with plantar fasciitis: a national study of medical doctors. *Foot Ankle Int.* 2004;**25**:303-10.
2. Riddle DL, Pulisic M, Sparrow K. Impact of demographic and impairment-related variables on disability associated with plantar fasciitis. *Foot Ankle Int.* 2004;**25**:311-17.
3. Tong KB, Furia J. Economic burden of plantar fasciitis treatment in the United States. *Am J Orthop* 2010;**39**:227-31.
4. Scher D, Belmont PJ, Bear R, et al. The Incidence of Plantar Fasciitis in the United States Military. *J Bone Joint Surg Am* 2009;**91**:2867-72. doi:10.2106/JBJS.I.00257.
5. Scher D, Belmont PJ, Owens B. The epidemiology of plantar fasciitis. *Lower Extremity Review* 2010 <http://www.lowerextremityreview.com/article/the-epidemiology-of-plantar-fasciitis>. Accessed 22/2/2012.
6. Bartold SJ. The plantar fascia as a source of pain—biomechanics, presentation and treatment *J Bodyw Mov Ther* 2004;**8**:214-26.
7. Sorensen MD, Hyer CF, Philbin TM. Percutaneous Bipolar Radiofrequency Microdebridement for Recalcitrant Proximal Plantar Fasciosis. *J Foot Ankle Surg* 2011;**50**:165-70.
8. Sackett DL, Rosenberg WM, Gray JAM, et al. Evidence based medicine: what it is and what it isn't - It's about integrating individual clinical expertise and the best external evidence. *BMJ* 1996;**312**:71-2.
9. Landorf KB, Menz H. Plantar heel pain and fasciitis. *Clin Evid* 2008; <http://ukpmc.ac.uk/abstract/MED/19450330>. Accessed 22/2/2012.

10. McPoil TG, Cornwall MW, Wukich DK, et al. Heel Pain-Plantar Fasciitis: clinical practical guidelines. *J Orthop Sports Phys Ther* 2008;**38**:A1-A18.
doi:10.2519/jospt.2008.0302.
11. Donley BG, Moore T, Sferra J, et al. The efficacy of oral nonsteroidal anti-inflammatory medication (NSAID) in the treatment of plantar fasciitis: a randomized, prospective, placebo-controlled study. *Foot Ankle Int.* 2007;**28**:20-3.
12. Thomas JL, Christensen JC, Kravitz SR, et al. The Diagnosis and Treatment of Heel Pain: A Clinical Practice Guideline—Revision 2010. *J Foot Ankle Surg* 2010;**49**:S1-S19. doi:10.1053/j.jfas.2010.01.001.
13. Crawford F, Thomson CE. Interventions for treating plantar heel pain. *Cochrane Database Syst Rev.* 2010:CD000416.
14. Walter JHJ. Heel Pain Treatments Stretch Patients' Tolerance. *BioMechanics* 2001;
<http://www.coachr.org/heelpain.htm>. Accessed 22/2/2012.
15. NSAIDs and adverse effects. *Bandolier* 2007;
<http://www.medicine.ox.ac.uk/bandolier/booth/painpag/nsae/nsae.html>. Accessed 9/2/2012.
16. Tatli YZ, Kapasi S. The real risks of steroid injection for plantar fasciitis, with a review of conservative therapies. *Curr Rev Musculoskelet Med* 2009;**2**:3-9.
17. A Guide to Podiatry. 2008; <http://www.feetforlife.org/search/?q=A+Guide+to+Podiatry>.
Accessed 22/2/2012.
18. Anwar R. An Evaluation Of Acupuncture Treatment In A Podiatry Clinic. 2003;
<http://www.docstoc.com/docs/44204721/An-Evaluation-Of-Acupuncture-Treatment-In-A-Podiatry-Clinic>. Accessed 8/2/2012.
19. Cotchett MP, Landorf KB, Munteanu SE. Effectiveness of dry needling and injections of myofascial trigger points associated with plantar heel pain: a systematic review. *J Foot Ankle Res* 2010;**3**:18.

20. Rampes H, James R. Complications of acupuncture. *Acupunct Med* 1995;**13**:26-33.
doi:10.1136/aim.13.1.26.
21. White A. A cumulative review of the range and incidence of significant adverse events associated with acupuncture. *Acupunct Med* 2004;**22**:122-33.
doi:10.1136/aim.22.3.122.
22. Witt CM, Pach D, Reinhold T, et al. Treatment of the adverse effects from acupuncture and their economic impact: A prospective study in 73,406 patients with low back or neck pain. *Eur J Pain* 2010;**15**:193-97.
23. Zhao L, Zhang F, Li Y, et al. Adverse events associated with acupuncture: three multicentre randomized controlled trials of 1968 cases in China. *Trials* 2011;**12**:87-95. doi:10.1186/1745-6215-12-87.
24. Clark RJ, Tighe M. The use of acupuncture for heel pain: a systematic review
PROSPERO 2012; CRD42012001881
http://www.crd.york.ac.uk/prospero/display_record.asp?ID=CRD42012001881.
Accessed 16/1/2012.
25. Smith SR. Acupuncture in the treatment of tarsal tunnel syndrome. *Journal of Chinese Medicine* 2009;**89**:19-25.
26. Woodrow SL, Brereton-Smith G, Handfield-Jones S. Painful piezogenic pedal papules: response to local electro-acupuncture. *Br J Dermatol* 1997;**136**:628-30.
27. Mao-Ying QL, Cui KM, Liu Q, et al. Stage-dependent analgesia of electro-acupuncture in a mouse model of cutaneous cancer pain. *Eur J Pain* 2006;**10**:689-94.
28. Orellana Molina A, Hernández Díaz A, Larrea Cox PJ, et al. [Láser infrarrojo frente a acupuntura en el tratamiento del espolón calcáneo]. *Revista de la Sociedad Espana del Dolor* 2010;**17**:69-77.

29. Liu MY, Nie RR, Chi ZH, et al. [Observation on therapeutic effect of acupuncture at Xuanzhong (GB 39) combined with Chinese herbs pyrogenic dressing therapy for treatment of calcaneus spur]. *Zhongguo Zhen Jiu* 2010;**30**:189-91.
30. CONSORT: transparent reporting of trials. 2011; www.consort-statement.org. Accessed 14/7/11.
31. MacPherson H, Altman DG, Hammerschlag R, et al. STRICTA 2010: STAndards for Reporting Interventions in Clinical Trials of Acupuncture. 2010; <http://www.stricta.info/>. Accessed 22/2/2012.
32. Downs S, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non- randomised studies of health care interventions. *J Epidemiol Community Health* 1998;**52**:377-84.
33. Karagounis P, Tsironi M, Prionas G, et al. Treatment of Plantar Fasciitis in Recreational Athletes. *Foot Ankle Spec* 2011;**4**:226-34. doi:10.1177/1938640011407320.
34. Vrchota K, Belgrade M, Johnson R, et al. True acupuncture vs. sham acupuncture and conventional sports medicine therapy for plantar fasciitis pain: a controlled, double-blind study *International Journal of Clinical Acupuncture* 1991;**2**:247-53.
35. Zhang SP, Yip TP, Li QS. Acupuncture Treatment for Plantar Fasciitis: A Randomized Controlled Trial with Six Months Follow-up. *Evid Based Complement Alternat Med* 2009;**23**:23.
36. Chen BX, Zhao YL. Treatment of painful heel with combined method of traditional Chinese medicine and western medicine. Clinical analysis of 900 cases. *Chin Med J (Engl)* 1985;**98**:471-74.
37. Ouyang Q, Yu G. Acupuncture at upper limb points for pain of the sole: a report of 73 cases. *International Journal of Clinical Acupuncture* 1996;**7**:499-501.
38. Tillu A, Gupta S. Effect of Acupuncture Treatment on Heel Pain due to Plantar Fasciitis. *Acupunct Med* 1998;**16** 66-68.

39. Montane E, Vallano A, Vidal X, et al. Reporting randomised clinical trials of analgesics after traumatic or orthopaedic surgery is inadequate: a systematic review. *BMC Clin Pharmacol* 2010;**10**:2.
40. Thoma A, Chew RT, Sprague S, et al. Application of the CONSORT statement to randomized controlled trials comparing endoscopic and open carpal tunnel release. *Can J Plast Surg* 2006;**14**:205-10.
41. Price MJ. Getting to the point! A case history. *British Journal of Podiatry* 2002;**5**:50-2.
42. Choi PYL, Tweed A. The holistic approach in acupuncture treatment: Implications for clinical trials. *J Psychosom Res* 1996;**41**:349-56. doi:10.1016/s0022-3999(96)00163-8.
43. Yin CS, Park J, Lee J-Y, et al. Acupuncture perception (deqi) varies over different points and by gender with two distinct distribution patterns of dullness and pain. *Journal of Sensory Studies* 2009;**24**:635-47. doi:10.1111/j.1745-459X.2009.00229.x.
44. Lund I, Lundeberg T. Is it all about sex? Acupuncture for the treatment of pain from a biological and gender perspective. *Acupunct Med* 2008;**26**:33-45. doi:10.1136/aim.26.1.33.
45. Willis B, Lopez A, Perez A, et al. Pain Scale for Plantar Fasciitis. *Foot & Ankle Online Journal* 2009; <http://faoj.org/2009/05/01/pain-scale-for-plantar-fasciitis/>. Accessed 22/2/2012.
46. Paterson C, Britten N. Acupuncture as a complex intervention: a holistic model. *J Altern Complement Med*. 2004;**10**:791-801.
47. MRC. Complex interventions guidance. 2008; <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC004871>. Accessed 8/2/2012.
48. CEBM. Levels of Evidence (March 2009). 2011; <http://www.cebm.net/index.aspx?o=1025>. Accessed 17/1/2012.

Legend

Fig. 1: Flow chart for selection of papers

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