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Appendices

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Introduction and Background

Sciatica is a common and bothersome medication problem (Liu et al., 2019). Sciatica is a type of neuropathic pain, characterised by unilateral radicular pain from the lower back region down the leg following the dermatome or innervated region of the sciatic nerve (Perreault et al., 2021), often accompanied by paraesthesia and muscle weakness. Neuroradiology studies show that sciatica to be caused by lumbosacral nerve root (L4-S1) inflammation or herniated lumbar disc disease with nerve root compression (Valat et al., 2010; Zhang et al., 2021). In Chinese Medicine (TCM), Sciatica being a type of Bi Syndrome described in Ling Shu chapters 41 and 43 (Wang et al., 1997), as ‘flank and leg pain’ along the Gall Bladder or Bladder channels caused by waist strain, sprain, trauma, invasion of wind cold or wind damp or channel obstruction (Qin et al., 2015). Sciatica is a very disabling condition (Poquet & Lin, 2016) with persistent or unresolved pain eventually leading to neurological deficits and functional disability, which has a serious impact on a patient’s quality of life (QoL). Sciatic pain also poses a huge financial burden on the patient through lost productivity (Maslak et al., 2020). In recent years, Sciatica has become a global concern with its high prevalence of about 43% of the population at some point in their lifetime (Konstantinou et al., 2015). A literature search conducted during April 2023 revealed that no Cochrane Reviews have been done on acupuncture and sciatica. This literature review critically appraises four systematic reviews and meta-analyses (SR-MAs) *Table 3* on the effectiveness of acupuncture treatment on Sciatica (Han et al., 2022; Ji et al., 2015; Qin et al., 2015; Zhang et al., 2023) to inform clinical practice and make recommendations for future RCT study designs.

Rationale

Zhang’s Delphi Survey is establishing an expert consensus providing clinical guidance on acupuncture treatment of sciatica (Zhang et al., 2021). Acupuncture intervention is a strong contender in the conventional treatment of sciatica as it is primarily aimed at pain control. Acupuncture’s endogenous opioid mechanisms (EOM) and anti-inflammatory actions are widely acknowledged in pain studies (Lewis et al., 2015; Perreault et al., 2021). It is estimated that 80-90% of patients with new or recent disc herniation will improve without surgery (Gu, 2019) Gu’s study found that 60% of electroacupuncture cases were still

functioning at the 10 year follow up without surgical intervention. A systematic review reported that there were no differences in any clinical outcome between surgery and conservative care at one and two year follow ups (Jacobs et al., 2011). Recent literature has shown that epidural corticosteroid injections have small short-term effects on pain and disability with small effect indicating that the treatment may not be clinically worthwhile. The evidence on drugs is of low quality and unclear (Poquet & Lin, 2016) and there is apprehension surrounding the adverse effects of Conventional Western Medicine (CWM) such as NSAIDs, paracetamol, muscle relaxants, opioid analgesics and corticosteroids concerning the resultant hepatic and gastrointestinal dysfunction (Enthoven et al., 2017). This brings us to the present where there is no international consensus for the management of sciatica (Poquet & Lin, 2016; Zhang et al., 2021). NICE controversially recommended the withdrawal of acupuncture and NSAIDs from its 2016 Guidelines on Low Back Pain and Sciatica, in contrast to the American College of Physicians and the American Pain Society who recommended that clinicians consider acupuncture for patients with chronic or sub-acute lower back pain (Lai, 2016; Lewis et al., 2011).

Methodology

A literature search was conducted for Systematic Reviews and Meta-Analyses (SR-MAs) on acupuncture and sciatica until 2023. The chosen SR-MAs pooled 57 Randomised Control Trials (RCTs) from 1993 to 2021 (*Table 2, Table 4*) from a search through 16 databases: CBM, CiNii, CMCC, CNKI, Cochrane Library, EBSCOhost, Embase, FMRS, KTKP, Medline, PubMed, Science Direct, VIP, Wanfang and Web of Science. All studies completed PRISMA flowcharts showing their literature search strategies with three of the four SR-MA's involving two reviewers in the database search and data extraction stages with independent arbiters. Most excluded grey literature and did not seek expert opinions. The SR-MAs were evaluated using AMSTAR2 (Beverley J. Shea et al., 2017) checklist and guidance from Guyatt's 'Essentials of Evidence-Base Clinical Practice' (Guyatt, 2008) and 'Evidence based practice across the health professions' (Hoffmann et al., 2017). Zhang and Qin registered their protocols in INPLASY and PROSPERO respectively. Zhang, Han and Qin applied PRISMA (it is not clear whether they used PRISMA-A) reporting standards for SR-MAs. Zhang and Qin used the STRICTA checklist to report acupuncture interventions. Only Zhang's SR-MA used Cochrane's GRADE score to rate the certainty of evidence, with his evidence for Total

Effective Rate (TER) and Adverse Events (AE) rated as ‘moderate quality’; evidence for reoccurrence rated ‘low quality’, and pain threshold and pain intensity rated ‘very low quality’ (Zhang et al., 2023). Heterogeneity was measured using Cochane’s Q and I^2 statistics with high heterogeneity reflecting the diversity of acupuncture techniques especially Manual Acupuncture (MA) and point selection (Zhang et al., 2023). Sensitivity analysis was conducted by excluding RCTs individually, shown in Zhang’s Baujat plots (Zhang et al., 2023). Regrettably, all four of the SR-MA’s PICO statements have serious internal and external validity shortfalls.

Patient Population

There were no baseline participant demographics or characteristics described in any of the SR-MAs and furthermore, none of the studies reported on how the study or comparator populations were recruited. Unhelpfully, the participants are not stratified by demographics (e.g. age groups) or by potential confounders such as obesity. A number of risk factors are thought to be associated with the first-time incidence of sciatica and influence the development of sciatica including obesity, occupational factors (e.g. jobs requiring prolonged standing and bending, heavy manual labour, heavy lifting (Fairag et al., 2022)) and age (Cook et al., 2014; Fairag et al., 2022; Stafford et al., 2007). Presently, there is no agreed diagnostic criteria for sciatica. Han’s inclusion criteria was ‘patients diagnosed with sciatica’ (Han et al., 2022). Ji had the more defined inclusion criteria of patients diagnosed with sciatica or presenting with any or all of the following symptoms: radiating pain in the sciatic nerve distribution area; tenderness at the nerve stem; positive Lasegue’s sign; Kernigs sign, or Bonnet’s sign (Ji et al., 2015). Most studies excluded participants with back pain without sciatica, and sciatica patients diagnosed with serious infections or tumours. The patient populations have not been categorised by CWM diagnostics (e.g. acute, chronicity, nerve root, nerve trunk etc or TCM diagnostics (e.g. channel disorder, Cold, Damp, Blood stagnation). In the absence of this data, insightful population sub-analyses cannot be done. The sample size and number of included of RCTs is very small, and there was no reporting that power calculation was used to determine sample size required for effect.

Intervention

Acupuncture is a complex intervention. How do researchers test for the elicited sensation of ‘De Qi’? Practice styles vary, (e.g. Han’s included RCTs did not explicitly report ‘deviations from intended interventions’ (Han et al., 2022)) and the skill and expertise of the practitioner may influence the outcome of treatment (Smith et al., 2017). The intervention for the SR-MAs involved types of acupuncture including: manual acupuncture (MA); electronic or electroacupuncture (EA); warm acupuncture (WA), and acupuncture with moxibustion etc. Zhang’s inclusions defined acupuncture therapy including MA, WA, and acupuncture plus moxibustion regardless of acupoints, needle types and materials (Zhang et al., 2023). Han’s inclusion was ONLY acupuncture treatment, however, added ear and classical acupuncture as interventions (Han et al., 2022). Qin’s inclusion criteria included abdominal acupuncture, invasive acupuncture, elongated needle acupuncture and auricular acupuncture. Ji’s inclusion criteria included laser acupuncture (Ji et al., 2015). Point selection generally followed the local and distal points on the Gall Bladder and Bladder meridians e.g. GB30, GB31, GB34, BL23, BL40 (Ji et al., 2015). The STRICTA checklist (MacPherson et al., 2010) has improved reporting of acupuncture interventions with, however, important items remaining “NR” not reported, such as practitioners experience. This missing data diminishes the reliability of the intervention with the treatments repeatability uncertain.

Bias

All the studies used the Cochrane Handbook for Systematic Reviews tools for assessing Risk of Bias. Most studies did not report the process of randomisation and allocation concealment to either acupuncture or comparison groups. None of the studies were double blinded, giving rise to performance biases. Asymmetrical funnel plots revealed the potential for reporting biases in pain intensity illustrated in Han’s SR-MA for TER and Zhang’s SR-MA in TER and Pain Intensity (Han et al., 2022; Zhang et al., 2023). Although biases in the RCTs were judged to be of high risk (e.g. Zhang’s 90% high risk of performance bias due to non-blinding of participants and personnel) or unclear risk (e.g. serious systematic errors of measurement bias, selection bias, allocation bias, detection bias) these were still included in the meta-analyses, against AMSTAR2 guidance (Beverley J Shea et al., 2017) to rule them out. Zhang’s low GRADE scores are serious red flag when considering the results.

Comparison

Zhang's comparators were medicine treatment including CWM or Chinese patent medicine and sham acupuncture. Han included only analgesics as the comparator intervention including: paracetamol (acetaminophen); NSAIDs; opioid analgesics, and corticosteroid (analgesic adjuvants). Qin's comparators were no treatment, sham acupuncture/placebo and Western Medicine. Ji's comparators were: CWM including oral drugs (e.g. Prednisone, Ibuprofen, Nimesulide); external drugs (e.g. Diclofenac Diethylamine gel), and injection (e.g. anisodamine).

The acupuncture and comparison groups are matched in number by gender, although it would have been useful to further stratify both groups in terms of age groups, diagnostic and risk factors such as obesity (e.g., BMI). The CWM comparative treatments did not state dosages or regimen. The consideration of Bradfield Hill's criteria of a dose response relationship would strengthen any measurements of associations (Bain, 2020). Qin and Zhang's inclusion of sham acupuncture as a comparator is problematic been implicated in the NICE decision to withdraw acupuncture as a recommended treatment (Lai, 2016).

Outcomes

Effectiveness is an unreliable measurement outcome. The 'effectiveness of acupuncture' was the main outcome of all the RCTs measured by the Total Effective Rate (TER) where $TER = (N1+N2+N3)/N$. N1 is number of participants 'cured' when pain is reduced from 30% to 69% or all symptoms and physical signs basically disappeared with no relapse in 6 months or sciatic neuralgia resolved and limb function recovered; N2 is the number of participants 'markedly improved' when pain is reduced from 70% to 94% or decreased sciatic neuralgia and largely normal function; N3 is cure reduced to above 95%, and N is the sample size. Each SR-MA described their TER differently giving rise to grave systematic errors of measurement bias, further compromised with the measure of 'cure' having unstable intra-rater and inter-rater reliability. The TER and recurrence rate as dichotomous variables were measured using Risk Ratio (RR) with 95% Confidence Interval (CI) p value < 0.05 . Most of the pooled RCTs used the validated 10cm VAS scale. Pain intensity and pain threshold as continual variables were measured using Standard Mean Difference (SMD) with 95% CI p

value < 0.05. Qin's RCTs included a variety of validated tools such as: 6 Point Behavioural Rating Scale (BRS-6); MOS SF-36, and physical examinations such as the Lasegue's Sign (Straight Leg Raising Test) (Qin et al., 2015), however due to sample size, could not be entered into the meta-analysis. Han identified relapse a secondary outcome, reporting relapse rates as crude case number/sample size. The safety of acupuncture compared to CWM was another secondary outcome, merely reported as a crude case numbers of adverse events. Relapse rates and adverse events need to be statistically analysed. Sciatica is a recurring condition and the adverse effects of CWM treatments for sciatica are under-explored for patients who cannot tolerate pain medications or risk invasive spinal surgery (Lai, 2016).

Statistical Significance

All of the SR-MAs reported the effectiveness of acupuncture as TER Risk Ratios (RR) around the 1.20-1.28 range, CI 95% and $p < 0.0001$ showing some (not strong) association in favour of acupuncture (RR not >2 (Bain, 2020)). The Mean Difference in VAS scores for pain reduction compared to medicine treatment ranged from -1.78, CI 95% (-2.44 to -0.86) $p < 0.0001$, again showing some association (if range includes zero, there is no association (Bain, 2020)). However, given the low GRADE scores, the high risks of bias, serious systematic measurement errors and insufficient statistical power in the included RCTs, one cannot rule out the possibilities of Type 1 Error. Zhang's and Qin's Forest Plots favoured acupuncture compared to control (Qin et al., 2015; Zhang et al., 2023). Although the SR-MA results were heading in the acupuncture preferential direction, the authors reporting their results as 'significant' may be an example of publication bias. Only Zhang provided a sub-group analysis on a dose response relationship which gave an unfavourable negative result, concurring with Liu's pilot study on the dose effect of acupuncture in treatment sciatic, where chronicity was identified as confounding factor (Liu et al., 2019; Zhang et al., 2023)

External Validity and Generalisability

Can the findings the SR-MAs be translated to my clinical practice? The first limitation is that without participant characteristics of diagnoses and risk factors the RCT populations cannot be matched to my Sciatica patients. My sciatica patients tend to have occupational factors, are likely to be older than 60 years, inactive and obese. Some have confirmed disc herniation,

although curiously, some present to my clinic post-surgery, post corticosteroid injection or post physiotherapy treatments. They are also likely to be prescribed multiple daily pain medications. The stratification of these characteristics for subgroup analyses would be useful. Guyatt asks were patient important outcomes considered? (Guyatt, 2008) The SR-MA's research questions did not ruminate on range of motion, disability or quality of life outcomes. The biomechanisms of acupuncture in modulating neuropathic pain is widely supported in the literature e.g. Perreault's paper discusses explanations of the adenosine and endogenous opioid mechanisms of therapeutic needling (Perreault et al., 2021). Zhang's sub-group analyses on the effectiveness of types of acupuncture was useful with warm and electroacupuncture having better results than MA (Zhang et al., 2023). The reported point selections confirm conventional selections for sciatica treatment e.g., points along the Gall Bladder and Bladder meridians (Legge & Vance, 2011). Commonly, the experimental daily treatment regimens of the RCTs do not relate to the pragmatics of private practice where patients have fewer treatments where affordability is an issue.

Conclusion

Although, acupuncture SR-MAs are limited by the inherent methodological limitations of the included RCTs, astonishingly, in sciatica research this is not uncommon (Valat et al., 2010). Poquet's PEDro synthesis of Management of Sciatica (not including acupuncture) found only 4% of studies had strong internal and external validity rating (Poquet & Lin, 2016). Despite Vroomen's systematic review reporting that no evidence exists for NSAIDs being superior to placebo (Vroomen et al., 2000), the Dutch College of General Practice still suggest NSAIDs for sciatic pain control (Koes et al., 2007). Chronic sciatic pain is debilitating, with consequences for quality of life and disability. Research outcomes measuring validated quality of life measures such as SF-36 and ODI or Lesegue's sign may be more clinically meaningful than the short term 'effectiveness of pain reduction'. The use of validated measures such as SF-36, ODI and Straight Leg Test in acupuncture RCTs should be encouraged. NICE requires more higher quality acupuncture RCTs. The NICMAN scale is an initiative to improve the quality of acupuncture administered in clinical trials e.g., reporting acupuncture treatment rationale sourced to expert opinion, literature review or textbooks (Smith et al., 2017). The improved use of STRICTA and the NICMAN scale will advance the integrity of acupuncture RCT designs. The acupuncture rationale, randomisation and

allocation processes and double-blind methods need to be described explicitly. Future sample sizes need to be based on statistical power calculation, RCTs need to collect baseline participant characteristics for sub-group analysis and conscientious reporting of the qualification of the acupuncturist is critical to the quality of the intervention. The safety of acupuncture is an under-rated strength in long term treatment. Research into patient's safety concerns over the long-term use of current CWM sciatica treatments has not been done. Follow-up on data, at one, two or ten year intervals may be worthwhile (Gu, 2019).

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Appendices

Table 1: Abbreviations

Acronym	Definition
AE	Adverse Event
AMSTAR2	A MeaSurement Tool to Assess systematic Reviews
BRS-6	6 Point Behavioural Rating Scale
CBM	Chinese Biomedical Literature Database
CI	Confidence Interval
CiNii	National Institute of Informatics Scholarly and Academic Information Navigator
CM	Chinese Medicine
CMCC	Canadian Memorial Chiropractic clinical databases
CNKI	Chinese National Knowledge Infrastructure)
CWM	Conventional Western Medicine
EA	Electronic or Electroacupuncture
EOM	Endogenous Opioid Mechanism
FMRS	Foreign Medical Literature Retrial Service
GRADE	Gradepro.org software for grading systematic reviews
INPLASY	International Platform of Registered Systematic Review and Meta-analysis Protocols
KTKP	Korean Traditional Knowledge Portal
MA	Manual Acupuncture
MD	Mean Difference
MOS SF-36	Medical Outcomes Study 36 item short form health survey
NICE	National Institute for Health and Care Excellence

Acronym	Definition
NR	Not Reported
NSAIDs	Non-steroidal anti-inflammatory drugs
ODI	Oswestry Disability Index
PEDro	Physiotherapy Evidence Database scale to assess clinical trials
PICO	Patient/population Intervention Comparator Outcome Statement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International prospective register of systematic reviews
RCTs	Randomised Control Trials
RR	Risk Ratio
SMD	Standard Mean Difference
SR-MAs	Systematic Review and Meta Analyses
STRICTA	Standards for Reporting Interventions in Controlled Trials of Acupuncture
TER	Total Effective Rate = (N1 + N2 + N3) / N
TCM	Traditional Chinese Medicine
VAS	10cm Visual Analogue Scale
VIP	VIP database for Chinese Technical Periodicals
WA	Warm or Warming Acupuncture

Table 2: Key Search Terms

SRMAs key search terms for RCTs
Cochrane Review systematic review, meta-analys* sciatica plus acupuncture
Sciatic* neuralgia sciatic pain sciatic neuropathy sciatic nerve diseases Ischialneuralgia Discogenic neuralgia bilateral sciatica disc herniation induced sciatica
Acupuncture Electroacupuncture Needle Needling Acupuncture and Moxibustion Warm Acupuncture Needle warming therapy Needling methods Fire-Needle Therapy Acupuncture Therapy Acupuncture Electronic Elongated Needle Three-edged needle Pyronex
Excluded: study protocols, animal studies, SR-MAs before 2015, low back pain without sciatica

Table 3: Number of RCTs and participants

Lead Author	Year	No of RCTs	No of Participants
Zhang	2023	30	2662
Han	2022	28	2707
Qin	2015	11	962
Ji	2015	12	1842

Table 4: Included RCTs

#	RCT	Year	Zhang	Han	Qin	Ji
1	Li et al	2021	Z			
2	Wang	2021		H		
3	Gu	2020	Z	H		
4	Huo	2020	Z	H		
5	Ning	2020		H		
6	Wang	2020	Z	H		
7	Huang et al	2019	Z			
8	Li et al	2019	Z	H		
9	Zheng	2019	Z	H		
10	Jiang	2018	Z			
11	Li	2018	Z	H		
12	Hu	2017	Z	H		
13	Liu	2017	Z	H		
14	Shen	2017		H		

#	RCT	Year	Zhang	Han	Qin	Ji
15	Wang	2017	Z	H		
16	Yu	2017	Z			
17	Zou	2017	Z	H		
18	Ai	2016	Z	H		
19	Li and Kang	2016	Z			
20	Liu	2016		H		
21	Wang	2016	Z			
22	Wei	2016	Z			
23	Ai	2015		H		
24	Huang et al	2015	Z			
25	Liu	2015	Z	H		
26	Maihe	2015		H		
27	Nie	2015	Z	H		
28	Tang	2015		H		
29	Ye et al	2015	Z			J
30	Zhou	2015		H		
31	Huang	2014				J
32	Meng	2014			Q	
33	Shang et al	2014	Z	H		
34	Wang	2014		H		J
35	Qiu	2013		H		J
36	Ren	2013			Q	
37	Jiang	2012	Z			
38	Liu	2012	Z			J
39	Zeng	2012		H	Q	
40	Zeng and Liao	2012	Z			
41	Zhai	2012	Z	H		J
42	Zhang	2012	Z			J
43	Li and Meng	2011	Z			
44	Zhu et al	2011		H		J
45	Chen	2010			Q	J
46	Hu et al	2010			Q	
47	Zhou	2010		H		
48	Chen et al	2009		H	Q	
49	Du et al	2009			Q	
50	Dong et al	2008				J
51	Wang	2008			Q	
52	Zhang et al	2008			Q	
53	Chen et al	2007				J
54	Chen et al	2005	Z			
55	Wang and La	2004			Q	
56	Zhao	2004			Q	
57	Zhan and Liang	1993				J