

Original article

The clinical and functional outcomes of ultrasound-guided vs landmark-guided injections for adults with shoulder pathology—a systematic review and meta-analysis

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Abstract

Objective. To compare the clinical and functional outcomes of US-guided (USG) vs landmark-guided (LMG) injection for the treatment of adults with shoulder pathology.

Method. MEDLINE, AMED and Embase in addition to unpublished literature databases were searched from 1950 to August 2011. Studies were included if they were randomized or non-randomized controlled trials comparing USG vs LSG injections for the treatment of adults with shoulder pathology. Two reviewers independently performed data extraction and appraisal of the studies. Meta-analyses were performed where possible and when inappropriate a narrative review of the data was presented.

Results. Six papers including 307 patients were reviewed; 142 received LMG injections and 165 received USG injections. There was a statistically significant difference in favour of USG for pain at 6 weeks (standardized mean difference 1.03; 95% CI 0.12, 1.93; $P=0.03$). There was no statistically significant difference between the injection methods with respect to shoulder function (standardized mean difference 0.33; 95% CI -0.59 , 1.25; $P=0.48$). There was a significant difference between interventions for shoulder abduction at 6 weeks in favour of the USG method (mean difference 2.81; 95% CI 0.67, 4.95; $P=0.01$). No other movements showed a statistically significant difference.

Conclusion. There is a statistically significant difference in pain and abduction between LMG and USG steroid injections for adults with shoulder pathology. However, these differences are small and may not represent clinically useful differences. The current evidence base is limited by a number of important methodological weaknesses, which should be considered when interpreting these findings. The cost-effectiveness of the intervention should be considered in the design of future studies.

Key words: shoulder, ultrasound, intra-articular injection, systematic review, meta-analysis, steroids.

Introduction

CS injections (CSIs) directed to both intra- and peri-articular structures have been used for many years to relieve the symptoms of various shoulder conditions [1].

These injections are performed regularly by general practitioners, orthopaedic surgeons, physiotherapists and radiologists.

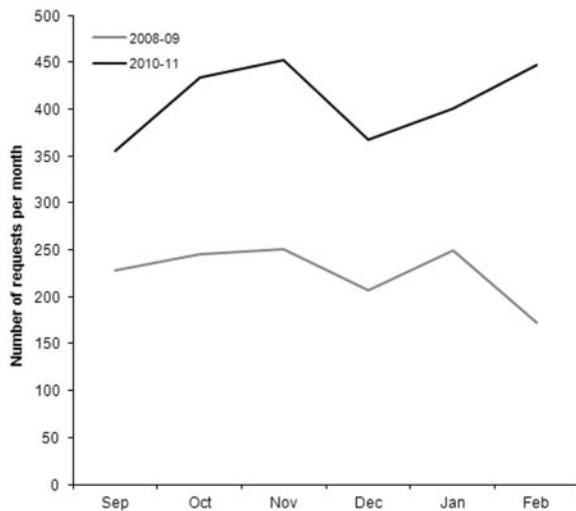
The physiological effects of local CSs are numerous [2]. Through their binding to cytoplasmic glucocorticoid receptors, CSs regulate the transcription of numerous pro- and anti-inflammatory proteins [3]. As a result of these properties, local injections of glucocorticoids have been advocated in the management of adhesive capsulitis, subacromial bursitis, subacromial impingement syndrome and supraspinatus tendonitis [4].

Despite widespread application in the clinical setting, the evidence supporting local CSI is equivocal [5–7]. As early as 1963, Quin and colleagues [5] reported that CSs

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Fig. 1 Graph demonstrating the rise in demand for musculoskeletal US at the Norfolk and Norwich University Hospital between 2008–9 and 2010–11.



and exercise therapy did not improve range of movement (ROM) or pain when compared with exercises alone. This limited efficacy is also reflected in more recent publications that have concluded that there is little reproducible evidence for the use of CSI in the management of shoulder pathology [6]. However, a recent systematic review on this topic acknowledged the poor methodological quality of studies previously reported that potentially account for these findings [7].

In current clinical practice, radiologists have adopted a US-guided (USG) approach to administering CSI. This procedure allows the direct visualization of anatomical structures of the shoulder [8]. One large teaching hospital (Norfolk and Norwich University Hospital) currently has seen a doubling in demand over 2 years, with an average daily increase in referrals from 8 in 2008–09 to 17 in 2010–11. The majority (61%) of these referrals are made directly from primary care (Fig. 1).

Previous authors have hypothesized that a USG approach can increase accuracy, thus maximizing the benefit of CSI [9]. Other clinicians however use a landmark-guided (LMG) approach. This is based on the palpation of anatomical landmarks such as the acromion, to guide the location of their injections [4]. Advocates of this method suggest that the technique is effective while costing less than a USG injection. While both methods are designed to deliver glucocorticoids locally, little consensus remains as to the most effective approach. This is important because the use of CSI for shoulder symptoms is common, in our experience referrals to radiology departments for image-guided injections are increasing and the potential financial implications of providing first-line USG CSI for shoulder disease are substantial.

Two recent systematic reviews into this area have found small advantages to a USG approach. Soh *et al.* [10] included two studies in their review and found greater

improvement with USG on both visual analogue scales (VASs) [mean difference (MD) 2.23 (95% CI 1.27, 3.18)] and shoulder function [standardized MD (SMD) 1.09 (95% CI 0.61, 1.57)]. However, the unpublished literature was not searched and a limited number of studies were found. Gilliland *et al.* [11] also found a USG approach improved outcomes, but did not focus on the shoulder joint alone, and no meta-analysis was performed.

The USG approach for CSI requires specific US skills and training and is usually undertaken in radiology departments in a hospital setting [12]. There is a resultant increase in cost when compared with an LMG approach, especially if this is undertaken in the community. In our health care economy, these costs are £274 vs £43.54, respectively.

At a time of significant cost constraint in health care, and a combined political and patient-driven imperative to provide services closer to patients' homes wherever possible [13], it is vital that techniques such as LMG CSI in the shoulder are thoroughly evaluated. The aim of this study was to perform a meta-analysis of the available literature comparing USG and LMG CSI injections for shoulder pathology.

Materials and methods

Search strategy

A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) compliant literature search strategy was performed on 1 August 2011 by two reviewers (W.S., L.P.). The electronic databases AMED (1985–August 2011), Embase (1974–August 2011) and Medline (1948–August 2011) were searched using the Ovid platform. Once all relevant full-text papers had been gathered, the reference lists of each eligible paper were scrutinized by two reviewers (W.S., L.P.) for any omitted studies.

A search of unpublished literature and trial registers was performed. This included OpenGrey, the WHO International Clinical Trials Registry Platform, Current Controlled Trials, National Technical Information Service, UKCRN Portfolio Database and the UK National Research Register Archive and National Institute for Health Research Portfolio. Finally, all corresponding authors of the identified papers were contacted to ensure that any publications not previously highlighted through the search strategies were included.

Eligibility criteria

All randomized and non-randomized controlled trials comparing LMG with USG CSI to the shoulder were included in the review. All paediatric, animal and cadaver studies were excluded. Articles published in any language were included and studies were not excluded based on poor methodological quality.

Study selection

Two authors (W.S., L.P.) independently reviewed all titles and abstracts generated from the search strategy. Following this initial screening process, the full text of

eligible articles was then reviewed independently by each author against the predefined eligibility criteria.

Data extraction

Following selection of all relevant articles, two authors (W.S., L.P.) extracted all data into a pre-constructed data table. Information gathered included patient diagnosis, number of participants, age range, sex distribution, specific details on the interventions (e.g. type of steroid used and dosage) and time of follow-up post-intervention. Data were from the outcome measures pain scores (VAS, ROM, as well as functional outcome measurements using instruments such as the Oxford Shoulder Score (OSS) [14], the Shoulder Function Assessment (SFA) questionnaire [15] and the Constant score [16]).

Critical appraisal

All papers were critically appraised independently by two authors (W.S., L.P.). Methodological appraisal was conducted using the Physiotherapy Evidence Database critical appraisal tool (PEDro). This has previously been shown to be a validated tool for evaluation of the methodological rigour of trials [17, 18]. Any disagreements between the two reviewers were adjudicated by a third reviewer (T.O.S.) to gain a consensus through discussion.

Outcome measures

The primary outcome measure was pain represented using a VAS score at 6 weeks post-intervention. Secondary outcome measures included the OSS, the SFA questionnaire and the Constant score, shoulder ROM including flexion, abduction, internal and external rotation, and night pain at 1 and 6 weeks post-intervention.

Statistical analysis

Statistical analysis was conducted by three reviewers (W.S., L.P., T.O.S.) using Review Manager 5.0 for Windows (Nordic Cochrane Centre, Copenhagen, Cochrane Collaboration, 2008). The evidence-base's methodological heterogeneity was assessed in relation to the population, interventions and outcome measurements presented. If substantial homogeneity was demonstrated, a meta-analysis was conducted. For the purposes of assessing statistical heterogeneity χ^2 and I^2 statistics were used. If χ^2 was greater than $P=0.10$ and the I^2 was $>20\%$, this was interpreted as higher levels of statistical heterogeneity requiring a random effects model to be adopted. When χ^2 and I^2 values were less than these values, a fixed effects model was adopted.

Each outcome measurement was assessed for its MD between the groups. When different measurement methods were reported for a specific outcome domain, an SMD was adopted to account for this potential variability. The level of statistical significance was established as $P<0.05$. Ninety-five per cent CIs were presented for each outcome. When it was considered inappropriate to perform a meta-analysis, a narrative review of the data was presented for the outcome measurements.

Results

Search strategy results

A total of 304 studies were identified as potentially eligible. Of these, four satisfied the predefined inclusion/exclusion criteria. A further three papers were identified from the reference list search. Of these, two were included in the final analysis and one was discounted after reviewing the full text, as it was written in Korean [19] and it was not possible to translate the transcript. The results of the search strategy are presented as Fig. 2.

Methodological appraisal

There was considerable variation in the methodological quality of the six included papers (Table 1). Only two papers specified how their subjects were randomized at allocation [18, 19]. Only one of these stated that their allocation had been concealed [18]. There was no attempt to blind either participant or clinician to the intervention, potentially introducing ascertainment or selection biases. Blinding of the assessors was performed in three papers to limit assessor bias [20–22]. All participants appeared to receive the intervention to which they were allocated, although not all the studies provided complete information on all participants at follow-up [23, 24]. Two studies did not present the findings of between-group analyses [21, 23], but all provided some examples of point and variability measures.

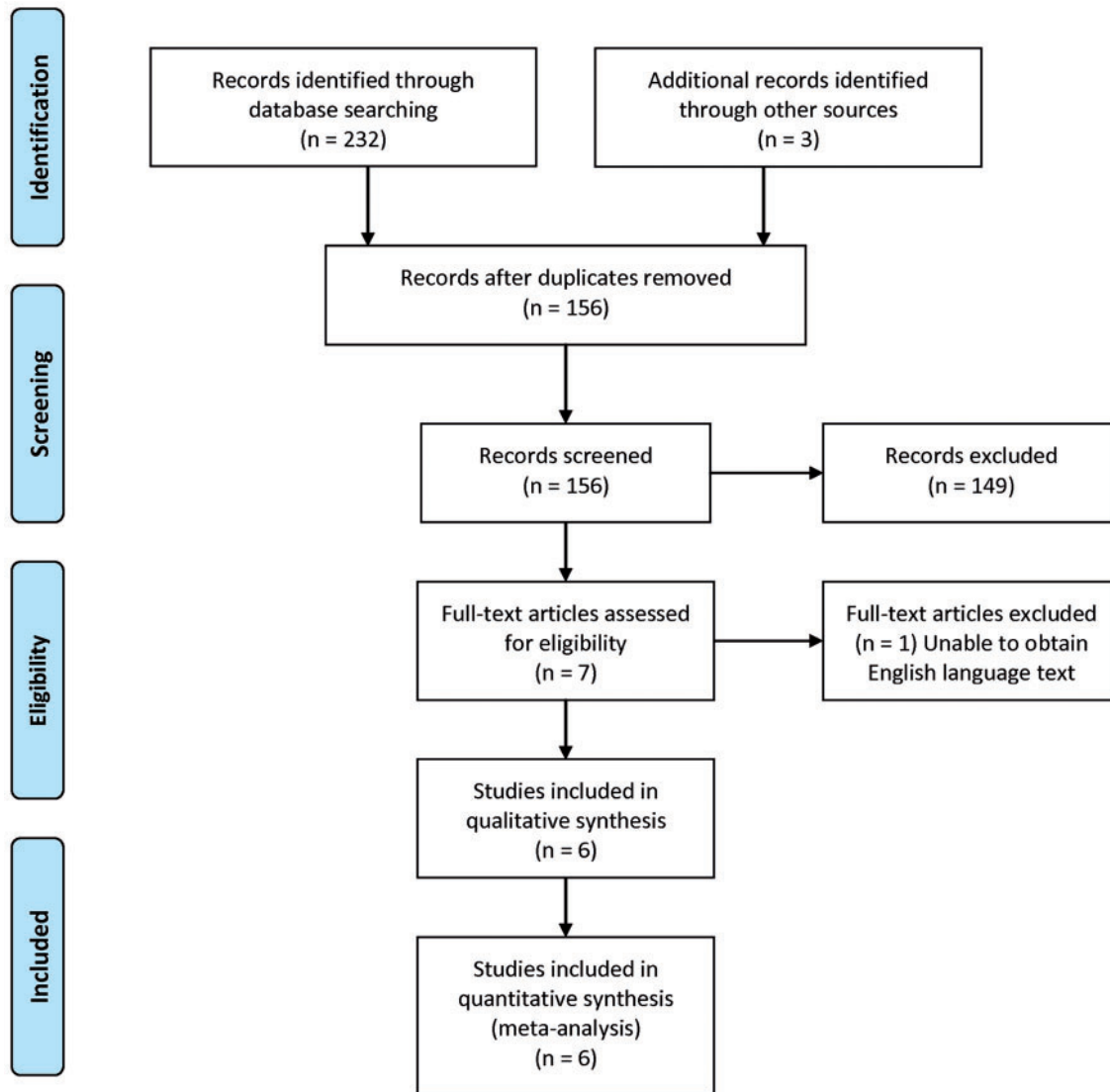
Population characteristics

Three hundred and seven patients were included from the five studies. Of these, 142 received LMG injections and 165 USG injections. The review cohort included 135 men and 172 women. All suffered from shoulder pain that came from a variety of underlying pathologies (Table 2). The follow-up periods ranged from 1 to 6 weeks. One-week follow-up data were available from two studies [22, 23], and 6-week follow-up data were available from five [20–22, 24, 25].

Three studies used triamcinolone, of which two study cohorts were injected with 20 mg [20, 22] and one with 40 mg [25]. One study [21] used 2 ml betamethasone; the remaining studies used betamethasone 1 ml [23] and depo-medrone 80 mg [24]. Four of the six studies included a local anaesthetic agent in their CSIs [22–25]. One study did not state what frequency of US transducer head was used in the USG intervention [24]. For the remaining five studies, transducer probes used ranged from 4–10 MHz [23] to 6–18 MHz [25].

Three studies only included those people who had experienced pain for >1 month [20, 23, 25]. Three studies stated that their cohorts had all previously reported an unsatisfactory response to NSAID therapy before entering into the trial [20, 21, 25]. Three studies excluded people who had previously undergone surgical intervention on the affected shoulder [20, 24, 25]. Two of these studies also excluded those who had experienced previous trauma, previous local CSI or physiotherapy on the same shoulder [20, 25].

Fig. 2 PRISMA flow chart.



Clinical outcomes

Pain

Three studies assessed pain using a pain score at 6 weeks [20, 24, 25]. The pooled analysis indicated a statistically significant difference between USG and LMG injections at this follow-up period in favour of USG (SMD 1.03; 95% CI 0.12, 1.93; $P = 0.03$) (Fig. 3).

VAS pain at 6 weeks post-intervention was also assessed by Lee *et al.* [22]. However, this study only provided absolute scores, making it inappropriate for inclusion in the meta-analysis. These authors reported no statistically significant difference between the two groups at 6 weeks ($P > 0.01$). They did, however, describe a significant improvement in VAS in the USG group after the first ($P = 0.001$) and second week ($P < 0.001$).

Zufferey *et al.* [21] analysed the effect of injection technique on pain specifically assessed during the daytime rather than pain in general. This was reported as not being statistically significantly between the intervention groups (vocal numerical rating scale: LMG = 4; USG = 3.2; P -value not reported). Zufferey *et al.* [21] and Lee *et al.* [22] assessed the effect of shoulder pain at night. When pooled, a statistically significant difference between the USG and LMG injection methods was reported (SMD 0.4; 95% CI 0.02, 0.79; $P = 0.04$).

Shoulder function

Shoulder function was assessed by two studies [2, 20]. There was no statistically significant difference between USG and LMG injections for shoulder function when assessed with the OSS and SFA questionnaires (SMD 0.33; 95% CI $-0.59, 1.25$; $P = 0.48$).

TABLE 1 Results of PEDro analysis for each of the included papers with criteria

PEDro Scale	Papers					
	Chen <i>et al.</i> [23]	Lee <i>et al.</i> [22]	Naredo <i>et al.</i> [20]	Ucuncu <i>et al.</i> [25]	Panditaratne <i>et al.</i> [24]	Zufferey <i>et al.</i> [21]
Eligibility criteria were specified	Yes	Yes	Yes	Yes	Yes	Yes
Subjects were randomly allocated to groups (in a cross-over study, subjects were randomly allocated an order in which treatments were received)	No	No	Yes	No	No	Yes
Allocation was concealed	No	No	Yes	No	No	No
The groups were similar at baseline regarding the most important prognostic indicators	No	Yes	Yes	Yes	Yes	Yes
There was blinding of all subjects	No	No	No	No	No	No
There was blinding of all therapists who administered the therapy	No	No	No	No	No	No
There was blinding of all assessors who measured at least one key outcome	No	Yes	Yes	No	No	Yes
Measures of at least one key outcome were obtained from >85% of the subjects initially allocated to groups	No	Yes	Yes	Yes	No	Yes
All subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome were analysed by intention to treat	Yes	Yes	Yes	Yes	Yes	Yes
The results of between-group statistical comparisons are reported for at least one key outcome	No	Yes	Yes	Yes	Yes	No
The study provides both point measures and measures of variability for at least one key outcome	Yes	Yes	Yes	Yes	Yes	Yes

The Constant score results were not included in this analysis of shoulder function. This was justified since this instrument assesses shoulder function, ROM and power rather than function alone. The Constant score results at 6 weeks were presented by Ucuncu *et al.* [25]. They reported that USG injections produced statistically significantly better improvement in this outcome compared with the LMG group [LMG 12.2 (8.5); USG 32.2 (19.6); $P < 0.05$].

Zufferey *et al.* [21] presented the findings of a modified Constant score. This outcome discounted measures of shoulder strength, and therefore was not comparable to the data of Ucuncu *et al.* [25] to perform a meta-analysis. While Zufferey *et al.* [21] reported an improvement for both treatment groups, there was no statistically significant difference between the USG and LMG injection groups ($P > 0.05$). Specific numerical data were not provided.

ROM

Two studies presented sufficient data for meta-analysis (Fig. 4) to assess abduction ROM 6 weeks post-intervention [22, 25]. This indicated a statistically significant difference between the groups, with greater improvement reported in the USG group (MD 2.81; 95% CI 0.67, 4.95; $P = 0.01$). However, since this difference

was only by two degrees, this indicated little clinical significance [26]. There was no statistically significant difference for the other assessments of ROM ($P > 0.05$).

Lee *et al.*'s [22] study was the only paper that presented data on external and internal rotation ROM. This was assessed at 1-week intervals for the first 6 weeks post-intervention, and flexion and abduction at weekly intervals from week 2–5 post-intervention. They reported that while there were significant differences in some of the movements assessed, i.e. flexion at week 1 and 3, abduction at week 2 and internal rotation at week 4, these were not consistent throughout the follow-up period ($P < 0.05$). Finally, Zufferey *et al.* [21] assessed ROM in their cohort but provided insufficient data for meta-analysis. They reported no statistically significant difference for any of the movements assessed (internal and external rotation and abduction) between the USG and LMG interventions at their 6-week follow-up (P -value not reported).

Discussion

The purpose of this study was to assess whether there is a difference in the clinical and functional outcomes of USG vs LMG injections in adults with shoulder pathology based on the current evidence base. The results indicated a

TABLE 2 Study characteristics

Study	Diagnosis	Population	US	Blind	Interventions	Outcome measure	Follow-up period, weeks
Chen <i>et al.</i> [23]	Subacromial bursitis	n = 40 Age, mean (range), years: 53 (20–66) Gender (M:F) = 2:1	20	20	1 ml betamethasone and 1 ml of 1% lidocaine	ROM (shoulder abduction)	1
Lee <i>et al.</i> [22]	Adhesive capsulitis	n = 40 Age, mean, years: 54.1 (7.74) (blind); 53.1 (7.3) (US) Gender (M:F) = 10:10 (blind); 9:11 (US)	21	22	0.5 ml of 20 mg triamcinolone with 1.5 ml of 2% lidocaine and 4 ml normal saline followed by five weekly injections of 2.5 ml sodium hyaluronate (25 mg)	VAS, ROM (flexion, abduction, external and internal rotation), general shoulder function	1–6
Naredo <i>et al.</i> [20]	Peri-articular disorders (impingement syndrome, rotator cuff lesions, subacromial/subdeltoid bursitis, biceps tendon abnormalities)	n = 41 Age, mean (range), years: 52.4 (24–76) Gender (M:F) = 14:27	21	20	20 mg triamcinolone	VAS, SFA	6
Ucuncu <i>et al.</i> [25]	Shoulder pain—acromioclavicular degeneration, rotator cuff lesion, fluid accumulation in the biceps tendon, partial rupture in the biceps tendon, bursitis (subacromial, subdeltoid)	n = 60 Age, mean (s.d.), years: 52.1 (11.6) (US); 52.9 (9.7) (blind) Gender (M:F) = 16:44	30	30	1 ml of 40 mg triamcinolone, 1 ml of 1% lidocaine	ROM (flexion, abduction), VAS, Constant score	6
Panditaratne <i>et al.</i> [24]	Subacromial bursitis	n = 58 Age, mean (range), years: 58 (25–80) Gender (M:F) = 22:36	41	17	80 mg depo-medrone, 3–10 ml bupivacaine or lidocaine	Pain score, OSS	6
Zufferey <i>et al.</i> [21]	Shoulder pain	n = 65 Age, mean, years: 54 (10) (blind); 53 (1) (US) Gender (M:F) = 18:15 (blind); 19:13 (US)	32	33	2 ml betamethasone	Pain on vocal numerical scale, ROM (abduction, external rotation, internal rotation), modified Constant score	2 and 6

Fig. 3 RevMan data, pain scores at 6 weeks.

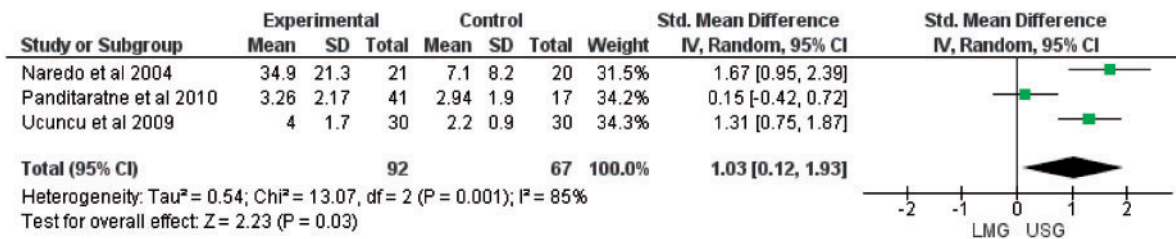
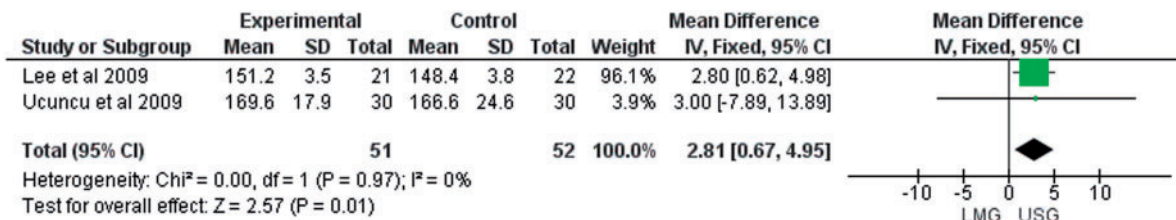


Fig. 4 RevMan data, ROM abduction at 6 weeks.



statistically significant difference in favour of USG injections for pain outcomes at 6 weeks ($P=0.03$). The results also indicated that while there was a statistically significant difference in abduction ROM at 6 weeks post-intervention ($P < 0.01$), the magnitude of this difference was only 2 degrees, which was considered not to be a clinically meaningful difference [26]. For all other outcome measures, there was no strong evidence of a statistically significant difference between USG and LMG injection methods. Accordingly, the current literature would indicate that there is a small benefit to using the USG approach in the short term. None of the included studies included a long-term follow-up. There is therefore insufficient evidence on which to base clinical services in this regard.

The results of the PEDro score indicated that the methodological quality of the included studies was highly variable. Only two studies were truly randomized controlled trials [20, 21]. None of the other studies attempted to randomize or to conceal allocation of their injection methods to assessors, participants or clinicians. A further issue was the differing levels of experience between those administering the injections. This could be considered a confounding variable, both between papers and within the intervention arms, as this was poorly controlled in two studies [22, 24] and information on the administrator was not provided in a further three papers. The longest follow-up within the papers was 6 weeks. While this provides some short-term indication of results, it does not allow any judgements to be made on the difference of efficacy in the longer term. Participant blinding was also poorly controlled within the literature. While it was accepted by the authors that this was difficult to achieve,

it should certainly be considered during the design of future studies. Another recurrent methodological limitation was the lack of justification for the sample size using power calculations. The sample sizes ranged from 40 to 65 people. Accordingly, by not basing the sample size on a power calculation, the potential for committing a type II statistical error was high [27]. To improve the evidence-base, these factors should be taken into consideration during the design of future, well-controlled randomized trials.

Recent systematic reviews examining the use of CSs in shoulder pathologies have indicated that there is little evidence for their efficacy [7]. Green *et al.* [28] examined CSI for subacromial tendonitis and concluded that subacromial steroid injections had no effect on pain, but did improve shoulder abduction compared with placebo. This study also indicated that CSI had no more positive effects than NSAIDs for both ROM and pain. This finding is also mirrored in the pooled analysis of Buchbinder *et al.* [7], which reported no benefit of subacromial CSI over NSAIDs based on three trials in rotator cuff disease. As well as these, Ekeberg *et al.* [29] found that USG subacromial steroid injections were no more effective than systemic administration of steroids when treating rotator cuff disease.

While these findings would seem to question the use of CSI as an intervention, Arroll and Goodyear-Smith [30] reported a significant improvement in shoulder pain compared with placebo (MD 1.43; 95% CI 0.95, 2.16), concluding that CSI is probably more effective than NSAID medication.

The rationale for the adoption of USG for steroid injections of the shoulder is that improving the accuracy of the

injections could enhance clinical outcomes. The evidence-base for this assertion is, however, inconclusive. Rutten *et al.* [9] found that in 20 consecutive cases of impingement syndrome, the subacromial subdeltoid bursa was correctly identified by both LMG and USG. Kang *et al.* [31] indicated that there was no correlation between accuracy of injection and improvement in shoulder function in their cohort of 60 cases with impingement syndrome. However, Eustace *et al.* [32] showed that the accuracy of CSI into the shoulder significantly improved the clinical outcomes of stiffness, loss of function, flexion and abduction in their cohort of 37 people with various shoulder pathologies ($P < 0.05$).

There remains little research comparing these interventions in other joints. Cunningham *et al.* [33] reported that for injections for inflammatory arthritis of the shoulder, elbow, wrist, knee or ankle, there was no significant difference in any major outcome between USG and LMG injections despite the accuracy of the USG injections being better ($P = 0.01$).

Although we assessed many different clinical outcomes, it was not possible to assess any one across all the studies, with several only being compared between two. As previously mentioned, the small sample sizes and lack of justification of this may mean that statistical differences were not detected due to the presence of type II statistical error [27]. Sensitivity analysis looking at specific shoulder pathology could not be achieved due to the variable nature of the literature available. Furthermore, across the evidence base there was also poor demographic data provided. We were not able to assess whether adjuvant physiotherapy or NSAID use were important variables between the groups.

The results of this article suggest that the evidence to support routine USG CSI for shoulder pain is limited. A principal limitation of the data is that the indication for CSI is noticeably heterogeneous. We investigated the evidence for a difference between USG and LMG CSI for all causes; there is simply not the available evidence to investigate these interventions for any given clinical condition. We would argue that the available evidence would not currently support the commissioning of routine USG CSI from primary care. There is, however, a separate benefit to USG CSI not considered here. USG injections, when local anaesthetic is included, may be useful for increasing the confidence in the diagnosis of subacromial bursitis of impingement by temporarily removing symptoms. However, it might be argued that this should be reserved for those patients have failed LMG injections and who are being considered for surgical intervention. The use of both methods of steroid injection is common throughout the NHS. Sibbit *et al.* [34] found the USG approach not only improved clinical outcomes ($P < 0.02$), but was also more cost-effective for inflammatory arthritis.

Using USG methods is more expensive than an LMG approach, but if a significant clinical advantage is identified then this may become economically viable. Commissioning a USG approach to all primary CSI in the shoulder would place a heavy burden on radiological

services, with large increases in the number of injections over and above the already substantial increase in cases being performed each year.

Conclusion

USG CSI results in statistically significantly improved short-term outcomes for both pain and abduction at 6 weeks when compared with LMG subacromial injections for all causes of shoulder pain. Although the difference is significant, the magnitude of the difference is small and the clinical usefulness of this improvement is questionable. The repeated methodological limitations in the current literature would support a randomized controlled trial designed to answer this question definitively for specific shoulder conditions. This should also address the issue of guidance method so the most cost-effective approach can be used and due consideration given to the possibility of delivering this service in the community rather than in a hospital setting.

Rheumatology key messages

- USG steroid injection may provide improved short-term outcomes over an LMG approach for various shoulder pathologies.
- A comprehensive randomized controlled trial is required to determine the best method of steroid injection for shoulder pathology.

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