

Diagnostic Ultrasound Imaging for Lateral Epicondylalgia: A Case–Control Study

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ABSTRACT

HEALES, L. J., N. BROADHURST, R. MELLOR, P. W. HODGES, and B. VICENZINO. Diagnostic Ultrasound Imaging for Lateral Epicondylalgia: A Case–Control Study. *Med. Sci. Sports Exerc.*, Vol. 46, No. 11, pp. 2070–2076, 2014. **Introduction:** Lateral epicondylalgia (LE) is clinically diagnosed as pain over the lateral elbow that is provoked by gripping. Usually, LE responds well to conservative intervention; however, those who fail such treatment require further evaluation, including musculoskeletal ultrasound. Previous studies of musculoskeletal ultrasound have methodological flaws, such as lack of assessor blinding and failure to control for participant age, sex, and arm dominance. The purpose of this study was to assess the diagnostic use of blinded ultrasound imaging in people with clinically diagnosed LE compared with that in a control group matched for age, sex, and arm dominance. **Methods:** Participants (30 with LE and 30 controls) underwent clinical examination as the criterion standard test. Unilateral LE was defined as pain over the lateral epicondyle, which was provoked by palpation, resisted wrist and finger extension, and gripping. Controls without symptoms were matched for age, sex, and arm dominance. Ultrasound investigations were performed by two sonographers using a standardized protocol. Grayscale images were assessed for signs of tendon pathology and rated on a four-point ordinal scale. Power Doppler was used to assess neovascularity and rated on a five-point ordinal scale. **Results:** The combination of grayscale and power Doppler imaging revealed an overall sensitivity of 90% and specificity of 47%. The positive and negative likelihood ratios for combined grayscale and power Doppler imaging were 1.69 and 0.21, respectively. **Conclusions:** Although ultrasound imaging helps confirm the absence of LE, when findings are negative for tendinopathic changes, the high prevalence of tendinopathic changes in pain-free controls challenges the specificity of the measure. The validity of ultrasound imaging to confirm tendon pathology in clinically diagnosed LE requires further study with strong methodology. **Key Words:** TENNIS ELBOW, SENSITIVITY, SPECIFICITY, DIAGNOSTIC ACCURACY, MUSCULOSKELETAL ULTRASOUND

Lateral epicondylalgia (LE) commonly presents to primary care clinicians with an annual incidence of 4–7 cases per 1000 patients in general practice (20) and between 1% and 4% prevalence in the general population (39,43). This condition is thought to be an overuse syndrome of the common extensor tendon (33), resulting in pain and functional disability during gripping and manipulation of the hand (6). Those at greater risk of developing LE include tennis players (18) and people who are required to

use a combination of force, repetition, and suboptimal wrist postures in their occupations (19,39,42).

In both research and clinical practice, LE is typically diagnosed using clinical criteria. These include aspects of patient history and provocation tests designed to reproduce pain over the lateral elbow (e.g., palpation, resisted wrist and finger extension, and gripping tasks (23)) without the requirement to include diagnostic imaging (26). Imaging techniques including musculoskeletal ultrasound (MSUS) and magnetic resonance imaging have been suggested for further investigation of patients with suspected LE who require further evaluation in preoperative planning or due to failure in conservative treatment (31,44). MSUS is increasingly used as a selection criterion in clinical trials for lower limb tendinopathies such as Achilles and patellar tendons (9,17,30,45), although this does not seem to have been transferred to standard clinical practice.

Tendon changes observed with grayscale MSUS of the common extensor tendon of people with LE include tendon thickening, changes in tendon fibrillar patterns, focal areas of tendon hypoechogenicity, tendon calcification, and/or

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bone spurs and irregularities (4,27,31). Power Doppler MSUS identifies neovascularization, and this has been suggested as an element of the pathophysiological process of tendinopathy and a potential contributor to the pain experience (24,46). Previous reports using a combination of grayscale and power Doppler MSUS to diagnose LE demonstrate a large variation in the sensitivity and specificity, ranging from 72% to 100% and 36% to 100%, respectively (10,12,26,27,34). Most of these studies have failed to include an age-matched control group, and most have not blinded the sonographer to the patient's presentation. This latter issue may bias the selection of images to send for interpretation. The aim of this study was to determine the diagnostic accuracy of MSUS for confirmation of the clinical diagnosis of LE, with control of potential sources of bias, such as blinding the sonographer to the clinical diagnosis of each participant and inclusion of a control group matched for age, sex, and arm dominance.

MATERIALS AND METHODS

Participants. Participants between 18 and 70 yr of age with unilateral LE symptoms were recruited via media advertising between January and July 2013. Inclusion criteria were the presence of pain over the lateral humeral epicondyle for greater than 6 wk that was provoked by palpation over the lateral epicondyle, resisted wrist and middle finger extension, and gripping activities. Participants were excluded if they had a neurological or systemic disease, limitations with passive movement of the forearm, an indication of cervical radiculopathy or peripheral nerve involvement through neurodynamic tests, bilateral elbow symptoms, previous physiotherapy treatment or cortisone steroid injections, and neck or arm pain (other than LE), which had prevented participation in work or recreational activities or required consultation of a health care practitioner in the past 6 months.

Thirty healthy controls matched for age, sex, and arm dominance were recruited simultaneously via media advertising. Inclusion criteria included no history or current signs and symptoms of lateral elbow pain, full pain-free range of motion, no pain with gripping or resisted wrist extension, and no neck or arm pain, which had prevented participation in work or recreational activities or required consultation of a health care practitioner in the past 6 months. The institutional medical research ethics committee approved the study, and a written informed consent was obtained from each participant before participation.

Criterion standard examination. The criterion standard was diagnosis made by clinical identification of LE (3) based on assessment by a registered physiotherapist. Both arms of each participant were assessed using the previously mentioned inclusion/exclusion criteria. Each elbow was classified as either affected or unaffected. Clinical identification of LE was used as the criterion standard because it is currently the gold standard for diagnosis of LE, is relatively

simple and easy to administer (6), and is the accepted method for diagnosis in most published high-quality randomized clinical trials (1,8,40) and observational studies (2,13,35). After completion of the clinical examination (criterion standard test), participants were given a referral for the MSUS assessment.

Description of LE group. To describe the LE group, we took the clinical measures of patient-rated tennis elbow evaluation (PRTEE) questionnaire, grip strength dynamometry, and visual analog scales (VAS) for pain intensity. The validated PRTEE, which is specific to LE, includes 15 questions measuring pain severity and functional disability, with an overall score from 0 to 100 (higher scores imply worse pain and disability) (38). A 10-cm VAS was used (0 = "no pain" and 10 = "worst pain imaginable") to assess current resting pain intensity and worst pain intensity over the preceding week. Pain-free grip force of the affected side of LE participants and the matched arm of controls was measured with an electronic grip dynamometer (MIE Medical Research Ltd., Leeds, United Kingdom). During grip strength measurement, the participant was supine, with the elbow extended beside their body and the forearm pronated so that the palm was facing down (29).

Ultrasound imaging and interpretation. MSUS examinations were performed at CitiScan Radiology in Brisbane, Queensland, Australia. Participants were examined bilaterally by one of two qualified musculoskeletal sonographers, each with over 9 yr of experience. Sonographers were blinded to the results of all clinical examinations (criterion standard test) and group allocation. Ultrasound examination was performed using a Philips LU22 ultrasound with a high-frequency linear area transducer (frequency range, 5–17 MHz). The common extensor tendon was examined using a standardized protocol of still images involving longitudinal and transverse views.

The standardized protocol involved assessment of grayscale images followed by power Doppler on the right elbow and then the left. Participants were seated, with their arm supported on an examination table having 70° of elbow flexion and a neutral wrist (thumb pointing up). The grayscale imaging was used to assess tendon thickening, hypoechoic areas, fibrillar disruption, and calcification using a previously established scoring system (36). The sonographer assigned an ordinal value to each grayscale feature using a four-point abnormality scale with the following definitions: 0 = normal, 1 = only just apparent, 2 = visible in less than half the tendon, and 3 = visible in more than half the tendon. This system allows for an individual score of the four grayscale features and an aggregate abnormality rating by summing the scores, together giving a possible maximum score of 12 points.

Power Doppler imaging was used to identify intratendon neovascularity. The specifications for power Doppler were a pulse repetition frequency of 500 Hz, wall filter of 40 Hz and preset color gain of 80%. Sonographers applied the transducer with light pressure to minimize potential for blood vessel constriction. Because it has been suggested that more "levels" of abnormality can be assessed with power

Doppler imaging (36), the sonographer rated neovascularization on a five-point ordinal scale with the following definitions: 0 = no signal, 1 = single small signal, 2 = several signals visible in less than 33% of the tendon, 3 = multiple signals in 33%–66% of the tendon, and 4 = multiple signals in more than 67% of the tendon. To evaluate intertester reliability, both sonographers scored nine participants independently, following the standardized protocol.

Statistical analysis. Although both clinical examination and MSUS were completed bilaterally for all participants, only the affected elbows of those in the LE group ($n = 30$) and the matched elbows of the controls ($n = 30$) were included in the analysis. This analysis was selected because of recent evidence from a systematic review, with meta-analysis demonstrating motor system changes in the uninjured side of people with LE (21), and it was considered that this may bias the results. A series of 2×2 contingency tables were assembled to cross-tabulate the results of the criterion standard

test (affected or unaffected) and diagnostic ultrasound (positive or negative). Separate contingency tables were constructed for each category of tendon change interpreted from the grayscale image (thickening, hypoechoic area, fibrillar disruption, and calcification), neovascularization score, total grayscale score ≥ 1 , and sum of the total grayscale score and neovascularization score. Contingency tables were then analyzed to calculate point estimates of accuracy (sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios) and the respective 95% confidence intervals using the MedCalc statistical software (MedCalc Software, Ostend, West Flanders, Belgium).

Intertester reliability of the MSUS examination was assessed using SPSS V21 software (SPSS Inc., Chicago, IL). κ statistics were used to report the intertester reliability between the two sonographers. Interpretation of intertester reliability was interpreted as poor (<0.00), slight (0.00–0.2), fair (0.21–0.4), moderate (0.41–0.6), substantial (0.61–0.8),

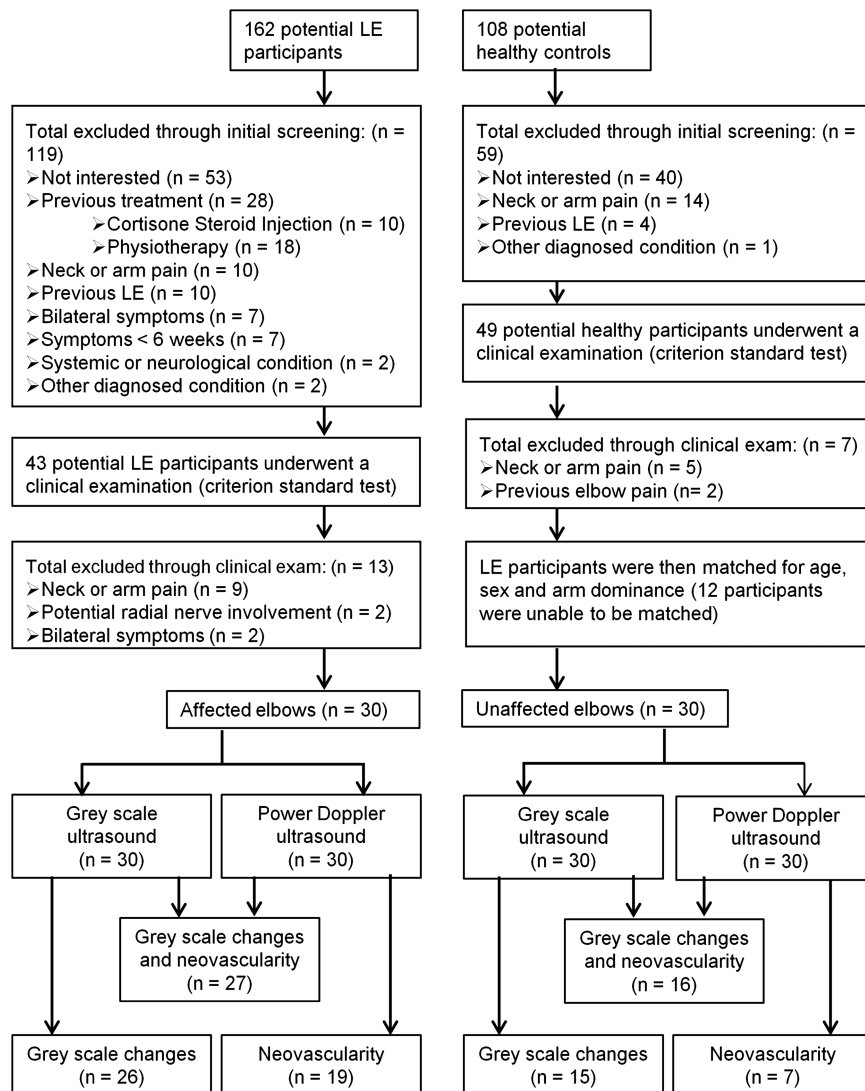


FIGURE 1—Participant flow chart.

TABLE 1. Participant characteristics and demographics (mean (SD) or *n* (%)).

	LE (<i>n</i> = 30)	Control (<i>n</i> = 30)
Sex: male, <i>n</i> (%)	16 (53)	16 (53)
Age range (yr)	49.6 (31–65)	50.6 (34–68)
BMI (kg·m ⁻²)	27.2 (5.17)	25.9 (3.84)
Pain-free grip strength (N)	106.0 (59.3)*	308.3 (87.4)
Right arm dominant	29	29
Dominant arm affected, <i>n</i> (%)	23 (77)	N/a
Range of duration of symptoms (wk)	19.9 (8–52)	N/a
PRTEE out of 100	36.2 (14.2)	N/a
Pain severity out of 10	6.6 (2.2)	N/a

*Indicates significance ($P < 0.001$).

BMI, body mass index; N/a, not applicable.

or almost perfect (0.81–1.0) on the basis of established criteria (25). Participants' characteristics were assessed between LE and controls using Student's *t*-tests.

RESULTS

Participants. The recruitment and inclusion of participants within the study are detailed in Figure 1. Participant characteristics and demographics are presented in Table 1. As expected, the LE group demonstrated significantly less grip force during their pain-free grip compared with the force during the controls' maximum grip ($P < 0.001$).

Intertester reliability. Intertester reliability demonstrated moderate-to-almost perfect agreement for the scoring of grayscale (total and individual features) and neovascularity using diagnostic ultrasound (Table 2). Agreement was lowest for calcification ($\kappa = 0.44$) and total grayscale score ($\kappa = 0.49$) but was still rated moderate. Neovascularity demonstrated highest agreement ($\kappa = 0.86$) and was rated as almost perfect.

Diagnostic accuracy. There were no adverse effects with respect to the clinical examination or diagnostic ultrasound. The criterion standard test and ultrasound examination were conducted 1 wk apart on average for all participants (7.5 d; range, 0–29). Table 3 displays the raw data from contingency tables and the estimates of diagnostic use and their 95% confidence intervals.

Blinded diagnostic ultrasound identified 90% of the LE participants and 53% of the controls as having tendinopathic changes. Total grayscale score ≥ 1 and grayscale in combination with power Doppler ≥ 1 demonstrated a high sensitivity (87%–90%) and low specificity (47%–50%). Both total grayscale score and grayscale in combination with power Doppler demonstrated a high negative predictive value (79%–82%). These indices of accuracy were reflected with moderate negative likelihood ratios for total grayscale score ≥ 1 (0.27) and grayscale in combination with power Doppler (0.21).

With the exception of specificity rates for fibrillar disruption and calcification, which were 100% and 83%, respectively, the estimates for diagnostic accuracy of separate grayscale measures (thickening, hypoechoic area, fibrillar disruption, and calcification) were poor. Fibrillar disruption demonstrated a 100% positive predictive value and an extremely substantial positive likelihood ratio (infinity). Grayscale changes

demonstrated a higher specificity (60%–100%) and lower sensitivity (7%–70%) for individual categories; however, when combined, they resulted in the opposite effect (total grayscale score ≥ 1 ; sensitivity, 87%; specificity, 50%). Neovascularization demonstrated moderate measures of diagnostic use (63%–77%).

DISCUSSION

The aim of this study was to evaluate the diagnostic use of blinded MSUS in a group of individuals who had been clinically diagnosed with LE compared with that in controls matched for age, sex, and arm dominance. Overall, our data demonstrate that grayscale MSUS in combination with power Doppler MSUS has the highest sensitivity (90%), whereas the finding of fibrillar disruption has the highest specificity (100%) for diagnosis of LE. When no abnormalities were observed using grayscale and power Doppler MSUS, the probability of having the disorder drops to 0.28% from a prevalence of 1.3% in the general population (39). When considered alone, grayscale MSUS demonstrates a high sensitivity (87%) but a low specificity (50%), which suggests that the technique performs well to confirm the clinical presentation but is inadequate to rule out the condition. Power Doppler MSUS seems to have moderate diagnostic use (63%–77%); however, a negative result for power Doppler MSUS can help exclude the likelihood of LE (posttest probability of 0.63% from 1.3% prevalence in the general population). Although most individual grayscale features demonstrate poor-to-moderate results for diagnostic use (7%–83%), disruption of the fibrils within the common extensor tendon reflects a 100% probability of having LE.

Previous studies have reported findings for power Doppler and grayscale MSUS separately (10,26,27) and in combination (12,34). Our results for the accuracy of power Doppler MSUS to detect neovascularization (Table 3) are aligned with previous reports for sensitivity (57%–81%) but are noticeably lower than previously reported values for specificity (98%–100%) (12,34). However, estimates of specificity from the two previous studies may have been inflated by the failure to blind the sonographer, which may cause bias in selecting images and interpretation. The accuracy of grayscale MSUS to detect abnormalities in the current study (sensitivity, 87%; specificity, 50%) is comparable with previously reported sensitivities (72%–100%) and specificities (36%–100%) (10,12,26,27,34). When compared with the one other study in which the sonographer was blinded (10), our study demonstrated a similar sensitivity

TABLE 2. Intertester reliability between sonographers (*n* = 9).

	κ	ICC
Tendon thickening	0.68	0.92 (0.67–0.98)
Hypoechoic area	0.80	0.81 (0.39–0.95)
Fibrillar disruption	0.58	0.73 (0.37–0.96)
Calcification	0.44	0.64 (0.01–0.91)
Total grayscale score ≥ 1	0.49	0.94 (0.75–0.99)
Neovascularity	0.86	0.98 (0.93–1.00)

95% confidence intervals are presented in parentheses.

ICC, intraclass correlation coefficient.

TABLE 3. Reported findings from ultrasound examination with and without power Doppler compared with those from clinical examination.

No. of Affected and Unaffected Elbows (from Contingency Tables)	Diagnostic Use Expressed as Percentages (95% Confidence Intervals)									
	TP	FN	TN	FP	Sensitivity	Specificity	PPV	NPV	Positive LR	Negative LR
Tendon thickening	21	9	20	10	70 (52–83)	67 (49–81)	68 (49–83)	69 (49–84)	2.10 (1.20–3.67)	0.45 (0.25–0.82)
Hypochoic area	16	14	18	12	53 (36–70)	60 (42–75)	47 (30–65)	46 (27–66)	1.33 (0.77–2.31)	0.78 (0.48–1.26)
Fibrillar disruption	13	17	30	0	43 (27–61)	100 (89–100)	100 (72–100)	64 (48–77)	Infinity	0.57 (0.41–0.78)
Calcification	2	28	25	5	7 (2–21)	83 (66–93)	29 (5–70)	47 (34–61)	0.40 (0.08–1.90)	1.12 (0.93–1.35)
Total grayscale score ≥ 1	26	4	15	15	87 (70–95)	50 (33–67)	63 (47–77)	79 (54–93)	1.73 (1.18–2.55)	0.27 (0.10–0.71)
Neovascularity	19	11	23	7	63 (45–78)	77 (59–88)	73 (52–88)	68 (49–82)	2.71 (1.34–5.49)	0.48 (0.29–0.80)
Grayscale and/or neovascularity	27	3	14	16	90 (74–97)	47 (30–64)	63 (47–77)	82 (56–95)	1.69 (1.18–2.41)	0.21 (0.07–0.67)

FN, false negative; FP, false positive; LR, likelihood ratio; NPV, negative predictive value; TN, true negative; TP, true positive; PPV, positive predictive value.

(95%) but did not support the findings of specificity (98%). The large number of healthy participants with MSUS changes consistent with LE seems to explain the low specificity identified in the present study.

Sixteen (53%) of the 30 elbows considered to be unaffected by LE were identified to have abnormalities on the basis of grayscale and/or power Doppler MSUS assessment despite the absence of symptoms during the clinical examination. This finding is consistent with current literature, which suggests a high incidence of tendinopathic changes in asymptomatic individuals (5,14,22,41). Recent studies imply that tendinopathic abnormalities in healthy controls are a feature of increasing age, especially for the dominant arm (22,41). Because LE predominately affects the dominant arm (20), 77% of the elbows investigated in the control group were from the dominant arm, and this may contribute to the high prevalence of abnormalities. It would be interesting to follow individuals with these changes longitudinally to determine whether asymptomatic tendinopathy develops into symptomatic tendinopathy. Twenty-seven (90%) of the 30 elbows that were symptomatic for LE had abnormalities detected by grayscale and/or power Doppler MSUS. Only three affected elbows were free from any identified changes. Inspection of the demographic data and results of the criterion standard examination for these three participants against the mean of the LE group revealed no obvious reason for difference in presentation. Similar observations have been made for other tendinopathies. A study of clinically diagnosed symptomatic Achilles and patellar tendinopathy using MSUS found no identifiable tendon changes in two-thirds of participants (15).

MSUS depends on the skill of the operator (4,11,27), and potential sources of variability include both the collection and interpretation of the images. Intertester reliability in previous studies has ranged from extremely poor to perfect agreement, depending on the anatomical feature or MSUS characteristic that is measured (11,36). For example, one study demonstrated perfect agreement ($\kappa = 1.0$) for identification of bony irregularities of the lateral epicondyle but no agreement ($\kappa = 0$) for the margins of the common extensor tendon (11). The same study found moderate agreement for calcification ($\kappa = 0.53$) (in line with the findings of our study ($\kappa = 0.44$)) but only moderate agreement for neovascularity ($\kappa = 0.60$), which is substantially lower than our findings ($\kappa = 0.86$). The low score in intertester reliability for calcification may be explained by differences in interpretation of

how this is defined. Our study demonstrated higher agreement for fibrillar disruption ($\kappa = 0.58$) and tendon thickening ($\kappa = 0.68$) but lower agreement in total grayscale score ($\kappa = 0.49$) than that in a recent study, from which our scoring sheet was customized (36).

In drawing inferences from these data, the reader should be cognizant of the characteristics of the LE group being studied. The PRTEE score (36.2 ± 14.2), pain-free grip force (106.0 ± 59.3 N), and worst pain in the previous week (VAS, 6.6 ± 2.2) are consistent with participants recruited for clinical studies (1,7,8,40). The disproportionately high specificity for fibrillar disruption might be linked to the pathophysiological mechanisms associated with tendinosis, including the increase in tenocyte numbers and disruption of the collagen fibers (16,32,37).

A limitation of the present study was the time between the clinical examination (criterion standard test) and the MSUS assessment. Eighteen (30%) participants were able to attend the MSUS assessment within 48 h of the clinical examination, 22 (37%) attended within 1 wk, 12 (20%) attended within 2 wk, 3 (5%) attended within 3 wk, and five (8%) took more than 3 wk to attend. It is important to consider the findings of this study in light of the case-control study design, which compared participants who definitely had LE against participants who did not. This study design has been suggested to estimate diagnostic accuracy up to 4 times higher than that of other study designs (28). An alternative study design is a consecutive cohort, which measures the accuracy of MSUS in a homogenous group of participants presenting with a similar clinical presentation, which would be likely to yield lower values than those reported here.

In conclusion, the present study shows that blinded grayscale MSUS alone or in combination with power Doppler imaging is accurate for confirmation of the clinical diagnosis of LE but with varying levels of sensitivity and specificity based on the individual parameters included. The high sensitivity implies that individuals who present with lateral elbow pain but no observable tendon changes on MSUS examination should be investigated for an alternative cause of pain. Research is required to determine the longitudinal outcome of asymptomatic tendinopathy.

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