Introduction

Lateral Epicondylalgia (LE), more commonly known as tennis elbow, is a tendinopathy of the wrist extensors at the lateral epicondyle. LE is the most common chronic musculoskeletal pain condition affecting the elbow [1], and has a prevalence of 1-3% [2]. In the UK, the incidence of lateral elbow pain in general practice is 4.23/1000 people a year [3]. The burden of LE can be significant, accounting for up to 219 workdays, with direct costs of US$8099 per person [4,5], the greatest burden being amongst manual workers [1].

The pathoaetielogy of tendinopathy is not fully understood, there being a complex interplay between structure, pain and function [6]. Notable advances have been made relating to both the understanding and treatment of tendinopathies in the last couple of decades. The tendon continuum [7] brought together three of the previously proposed stages of tendon pathology, which has been recently updated [6]. However, despite these advances, LE still remains a challenge to treat.

An audit cycle was initiated, clinical audit being an essential element of professional quality practice and supporting continuous improvement in patient care and service delivery within the Health Service [111,112]. It was perceived that, within the physiotherapy service, outcomes for LE patients were sub-optimal. Which factors contribute to a sub-optimal outcome in LE is an area of much debate. Various theories have been suggested including central pain mechanisms [126,127], self efficacy [122], psychosocial factors [37-39, 48,49], metabolic factors [123-125] and sub-optimal loading [114]. Recent work in patellofemoral pain have focused on sub grouping and targeted intervention and have shown greater improvement short term [115].

Methods

A three phase audit cycle of physiotherapy treatment for LE was conducted in 2012 (Phase 1), 2014 (Phase 2) and 2015 (Phase 3) with each cycle reviewing the previous years' data (figure 1). The location was the musculoskeletal outpatient department across four sites within Salford Royal NHS Foundation Trust, a large teaching hospital NHS Trust in the northwest of England. Within the department clinical diagnosis is commonly based on clinical history combined with positive clinical tests of pain reproduction with resisted wrist extension, resisted middle finger extension and pain on palpation of the common extensor origin at the lateral epicondyle.

Insert Figure 1 here

Phase One. Records of patients attending for initial physiotherapy assessment between 1st January and 31st December 2011, with a diagnosis of LE were audited. Data extracted included the variety and number of treatments, outcome measures used and the outcomes of treatment. Improvement was measured using the VAS and a form of the Global Rating of Change Scale (GRCS), where patients were asked on a scale of 1-10 how much better they were.

Following the audit a literature review of the evidence base for the treatment of LE was undertaken. This highlighted that a number of non-evidence based treatments were being used. Across the Trust a team consensus was subsequently developed so that the primary focus of treatment for all LE patients would be on strengthening exercises [1] and that non-evidence based treatments would be discontinued. It was agreed that the type of strengthening exercises and the specific muscle groups targeted would be determined by the treating physiotherapist. Accompanying this change, a more comprehensive set of outcome measures were implemented for LE patients across the physiotherapy service [8-11].

Phase Two. The second audit took place between 1st May 2013 – 30th April 2014. The data extraction was expanded to include risk factors, chronicity, occupation and patient anthropometrics.

In addition to the data collected in the Phase one audit, process evaluation was also conducted to seek feedback from the physiotherapy team regarding what they felt worked well, what could be improved and to discuss any problems encountered, or any challenges hindering therapist fidelity with the new treatment approach. One of the key themes to emerge from the process evaluation was the variety of approaches to load setting adopted when prescribing exercises. Feedback was then given on the Phase two audit, discussing areas highlighted both from the audit and the process evaluation, including compliance with the use of outcome measures. Based on staff feedback, a training session on pathophysiology of tendinopathy was delivered which included teaching on different ways to explain tendinopathy to patients. At this training session the tendon continuum [7], potential mechanical pathoaetielogical mechanisms contributing to the development of tendinopathy including stretch-shorten cycles [12,13] and compression theories [14-19], and the conflicting approaches of pain provocation [20] or pain avoidance [21] with loading programmes were discussed. A range of recognised loading programmes for tendinopathy were reviewed, including isometric exercises, combined concentric and eccentric exercise, heavy slow resistance (HSR) training, and eccentric exercises. Following the completion of the Phase two audit, an evidence based standardised treatment protocol (Table 1) was implemented for the Phase three audit, based on the current literature available at that time. This commenced with moderate to high load isometric loading in a standardised position (figure 2a and 2b), progressing to a combined slow concentric and eccentric exercise, which was then further progressed by increasing load (Table 1). An area identified during the process evaluation with the physiotherapists was the use of very light weights for eccentric exercise, and it was highlighted that finding suitable weights without cost to the patient was problematic. An adjustable elbow crutch was used to increase the lever arm, once extended to the full length it could be shortened and a small weight of 250g or 500g attached securely to the end of the crutch so that slow progressive lengthening of the crutch could recommence. An illustrated exercise instruction leaflet sheet was devised for the initial isometric phase (Figures 2a & 2b) and issued to patients along with a table to record their exercises and to

monitor progress. The audit revealed that the use of outcome measures was inconsistent with high physiotherapist fidelity at initial assessment but low fidelity at discharge. The importance of routine outcome measurement on discharge was reinforced.

Phase Three. The third audit took place between 1st October 2014 – 30th September 2015. Data extraction remained the same as for Phase two.

Global Rating of Change Scale (GRCS)

Two different GRCS were used. In phase one GRCSv1 was used. This ranged from 0-10, the cut point for responders was 8 or higher. This accounted for 20% of the scale. Following the audit of Phase one, it was identified that more robust outcome measures were required. The GRCSv2 was then adopted, GRCCv2 is a balanced 21-point Likert scale with numerical descriptors at each point, complimented by written descriptors of no change at the mid-point '0', whilst the extremes displayed 'completely recovered' (+10) or 'very much worse' (-10) [10]. At the start of each treatment session the following standardised question was asked: 'with respect to your tennis elbow, how would you describe yourself now compared to a) last treatment b) when it first came on?'. The cut point for the responders was +7 and above, which, identical to GRCSv1, accounted for 20% of the scale to the nearest whole number.

INSERT FIGURE 2A, 2B HERE

INSERT TABLE 1 HERE

RESULTS

Insert table 2 here

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Of those patients completing treatment in Phase two, only 10 had initial and discharge PFGS data recorded. Initial PFGS ranged from 0-30.3kg with a mean of 11.0 KG, whilst the discharge PFGS ranged from 2-46kg with a mean of 22kg.

Of the 32 patients completing treatment in Phase three, 27 had initial and discharge PFGS data recorded. Initial PFGS ranged from 0-38kg with a mean of 16.2 kg, whilst the discharge PFGS ranged from 8-62kg with a mean of 27.5 kg.

The PRTEE therapist fidelity at discharge was low, with Phase two having 10 patients with both initial and discharge data; whilst in Phase three only 5 patients had this data.

In Phase two average initial PRTEE score was 48.7 and average discharge score was 24.3, giving an average improvement of 50%. In Phase three average initial PRTEE score was 33.7 and average discharge score was 12.1, with an average improvement of 64%.

Insert Table 5 here

DISCUSSION:

The records of 182 patients were reviewed, with data extracted on the variety and number of treatments, outcome measures used and the outcomes of treatment. The demographics of these patients are presented in Table 2; they are considered typical patients that attend an NHS service with LE. The average age of 50 years was in keeping with other studies [1,2,22]. Shiri et al. [2] demonstrated that prevalence did not differ between men and women, however gender demonstrated an unexplained variation in this audit. Phase one consisted of 51% male patients however both Phases two and three consisted of a lower percentage (36%) of male patients (Table 2). Although sample sizes were smaller in the latter two phases this would not explain this

difference. Chronicity also demonstrated unexplained variation (Table 2), the relatively high chronicity in both phases being typical for LE. LE commonly affects the dominant arm [1,23], our data support this as, where this was recorded, 63% of the patients presented with symptoms on their dominant side. The initial Phase one audit did not document side dominance, occupation, chronicity and specific past medical history relating to risk factors, however, in the latter two phases the audit was expanded to capture this information, which was a limitation for the phase one data.

Phase one revealed a wide variety of treatments were being used (n=33), patients received between 1-17 treatments and with an average of 5.1 treatments (Tables 3 and 4). The outcome measures used were limited in number (n=2) and lacked robustness; using the results from the GRCS for those completing treatment (n=47), 64% (n=30) of patients responded to treatment (figure 3). As was hoped the Phase two audit demonstrated a marked reduction in the variety of interventions employed with greater emphasis on muscle strengthening (Table 4) and a reduction in the average number of treatments to 3.11 (table 3) whilst maintaining similar outcomes; 63% (n=17) of patients responded to treatment (figure 3). Phase three demonstrated complete cessation of non-evidence based treatments. Therapist fidelity was high with the exercise component of the standardised treatment protocol with 98% of patients receiving isometric loading (Table 4). The average number of treatments reduced to 2.95 and outcomes were improved by 8% with 72% (n=23) of patients responding to treatment. It is interesting to note that for some unexplained reason, phase two demonstrated lower average initial PFGS than phase three, particularly considering similarities in chronicity (table 2).

The aim of this project was to improve outcomes for LE patients and it was felt that to achieve this, a core treatment intervention that was standardised and evidence based needed to be implemented, so that all patients received the same quality of treatment irrespective of whether they saw a newly qualified physiotherapist or an experienced physiotherapist, and irrespective of which clinic within the Trust they attended. This is not to say that one size fits all, neither is it to say that everyone

needs the same treatment, however it is a method by which to ensure that there is good practice at the core of all treatments across the department so that, once initiated, these treatments can be individualised to meet the needs of individual patients [24]. As part of this audit process the evidence base for treatments commonly being delivered in Phase one was reviewed. Many, with the exception of muscle strengthening, were found to have a weak evidence base. For example a Cochrane review by Green et al. [25] demonstrated no benefit lasting more than 24 hours following acupuncture. Systematic reviews by Bisset et al. [26] and Bisset, Coombes and Vicenzino [22] found Ultrasound to be no more effective than placebo for pain relief or self-perceived global improvement in the short term. More recently Loew et al. [27] in their Cochrane review on LE found there to be insufficient evidence to determine the effects of Deep Transverse Frictional Massage (DTFM) on LE and there was no evidence of clinically important benefit. Despite conflicting evidence for exercise in LE, a review by Bisset & Vicenzino [1] concluded that there was evidence from several RCTs of sound methodological quality that exercise may be more effective at both reducing pain and function compared to other treatment modalities, however there may be no difference in effect between different types of exercise.

In Phase one 69% of patients received strengthening exercises which were predominantly eccentric exercises in isolation (90%). Concentric/eccentric exercises were only given to 5 patients and isometric exercises were not prescribed. The specific exercise prescription was often poorly documented, with no reference to being pain-free or painful, how long each contraction should last (speed of contraction), and frequently either a light weight was used (<1kg) or no weight was documented. However it was clearly perceived that eccentric exercise was the 'best' form of strengthening exercise. In Phase two the situation had improved considerably with 98% of patients receiving some form of strengthening exercise (table 4). Of these 54 patients 76% were given eccentric exercises (n=41) with 15 of these patients being given eccentric exercises in isolation. Isometric exercises were used in 15% of those receiving strengthening whilst 12 patients received concentric/eccentric exercises. An increase in the prescription of supinator strengthening was also

observed. Supination exercises have been observed in previous studies [28,29]. Supinator has attachments to the annular ligament, lateral epicondyle and lateral ligament so is intimately related to lateral elbow structures. Erak, Day and Wand [30] demonstrated a biomechanical basis for the involvement of the superficial head of supinator in the aetiology of lateral epicondylitis, whilst Stroyan and Wilk [31] suggested that supinator has a role in the stability of the radio-humeral and superior radio-ulnar joints particularly with tasks in pronation, such as gripping and lifting. More recently Ranger et al. [32] suggested that the radial head may act as a cam in pronation, mitigating the load on the origin of extensor carpi radialis brevis (ECRB), all of which certainly require consideration clinically. In Phase three all 56 patients received strengthening exercises, 55 of which were commenced on the standardised isometric loading programme. In phase three, 100% of patients that completed treatment received isometric loading (n=32). Of those responding to treatment (n=24) 67% of patients (n=16) received isometric exercise in isolation and were sufficiently improved not to require further treatment progression, whilst only 7 patients responding to treatment were progressed onto slow concentric/eccentric exercises. Interestingly greater gains were seen in phase three, which consisted mainly of isometric strengthening (figure 4). Whether this was attributable to the isometric strengthening regime, the improved load setting, the hypoalgesic effect of isometric exercises seen [33] and the resultant improved compliance, or a combination of reasons is impossible to differentiate.

The standardised loading programme that developed as a result of this audit placed increased emphasis on patient specific load setting, ensuring that load was as high as tolerable. Pain during exercise was allowed. Historically there are conflicting views regarding whether tendinopathy exercises should be painful or pain-free. Curwin & Standish [21] advocated pain-free strengthening, whilst Alfredson et al. [20] required exercise to be painful, so if no pain was felt, the load was increased until pain was felt. Both painful [34,35] and pain-free [29,36] exercise regimes, however, have demonstrated favourable results for LE. Avoiding pain could potentially contribute to re-enforcing erroneous beliefs regarding exercise [37,38], whilst increasing the chance of the load being

insufficient [20]. Furthermore, exercising into discomfort in a graduated manner has been shown to assist in normalising any over-prediction of pain [39, 126] and by altering pain memories [119], with a painful loaded exercise programme potentially having a therapeutic impact on the central nervous system [120]. A recent systematic review on exercise in chronic musculoskeletal pain [121] found painful exercise to have a small but significant benefit over painfree exercise. Clinicians were specifically educated re the current understanding of tendinopathy, and had a better understanding of the theory behind progressive loading. This was likely to improve patient education and understanding, whilst giving the clinicians more confidence and indirectly improving patient confidence in the physiotherapist, which could be a factor in improving patient compliance with the loading programme [40].

Stretching, manual therapy, epiclasps, soft tissue techniques and 'other' treatments all significantly reduced by phase three whilst outcomes improved. Techniques such as mobilisation with movement (MWM's) combined with exercise were superior to wait and see at 6 weeks and a reasonable alternative to corticosteroid injections in the mid- to long-term [28]. Whether the addition of MWM's into the standardised programme could improve outcomes further remains to be seen. Historically, static stretching has been commonly used in the treatment of LE. The basis of stretching in tendinopathy is questionable, with conflicting evidence regarding the effect of static stretching on tendon stiffness in various tendons, with some studies concluding that tendon stiffness remains unchanged [41-43] whilst other studies demonstrated a decrease in tendon stiffness [44,45]. Anatomically, stretching for LE would certainly increase the risk of tendon compression, which is a proposed risk factor for tendinopathy [15]. This data demonstrates that outcomes can improve despite stretching being all but omitted from treatment, casting further doubt on its place in the treatment of LE. Similar observations were made regarding the use of soft tissue techniques such as DTFM and massage, in keeping with the findings of Loew et al. [27].

225 Education was highlighted as a core component, to address patient expectations and encourage
226 empowerment. However, it was only documented in 45% of patients. Although this was an
227 improvement on phase one (27%) and similar to phase two (44%), it was much lower than expected
228 considering the therapist fidelity with the loading programme. Possible explanations would be that
229 it was poorly documented due to it being written in the standardised protocol and perceived by the
230 clinician of not being necessary to document thus being under-reported, or that it is an area
231 requiring further improvement. Certainly this audit data would not capture the quality of the
232 information being given, which, based on the delivery of the evidenced based training package prior
233 to Phase three, should have improved from phase two. Patients were given an exercise chart to take
234 home so that they could record their daily exercise, which could highlight improvements more easily
235 and objectively thus being motivational. Having an illustrated exercise sheet could also contribute to
236 improving patient recall of the correct technique [46]. Issuing the elbow crutch as a means of
237 lengthening the lever arm meant the patient had all the necessary equipment to progress to the
238 level required, without incurring cost or inconvenience trying to find an object suitable.

239

240 In Phase one outcome was measured using two simple generic tools the VAS and a form of the
241 GRCSv1, where patients were asked on a scale of 1-10 about their improvement. In phases 2 and 3,
242 Pain Free Grip Strength (PFGS), Patient-Rated Tennis Elbow Evaluation (PRTEE), Tampa Scale for
243 Kiniesiophobia-11 (TSK-11) and an improved GRCSv2 were added. It is interesting to note that the
244 majority of patients had baseline evaluations recorded on these measures at initial assessment but
245 there were relatively few discharge measures recorded. There are two possible explanations for
246 this: firstly that a number of patients discharged themselves by telephone or secondly that the
247 physiotherapists found the burden of completing these instruments too great. The limited data we
248 have available on these measures suggests that both PFGS and PRTEE in Phases 2 and 3 recorded pre

and post intervention improvements that easily exceeded the Minimum Clinically Important Change (MCIC) of 1.4kg for PFGS and a reduction in score of 10 points on the PRTEE [47].

Therapist fidelity collecting PRTEE discharge data was low. Bisset & Vicenzino [1] suggested a prognostic continuum where poor prognosis was suggested if a patient presents with poor prognostic factors including an initial PRTEE score >54 then a more chronic pain approach should be considered. In Phase two non-responders 70% scored 54 or greater, whilst in the responders 44% scored 54 or more. In Phase three, of the nine non-responders 71% scored >54, Of the responders 41% scored >54. Identification of patients more likely to respond to physiotherapy treatments is an excellent aim; however our data did not fully support their proposed model. Further work on this topic would be of great clinical value.

No discernible differences were observed in the initial scores of the TSK-11 between responders (range 12-33, median 20) and non-responders (range 12-29, median 27), neither were differences observed when broken down into somatic focus (TSK-SF) and activity avoidance (TSK-AA). TSK-11 scores of those that completed treatment and those that did not complete treatment also displayed similar characteristics. These findings are in contrast to those of Das De et al. [48], however they are consistent with the findings of a recent systematic review by Mallows et al. [24]. Although the TSK-11 failed to provide any meaningful information, psychological factors still should be explored. In a recent study on shoulder pain, the formal assessment of psychological factors such as patient expectation and pain self-efficacy, using standardised measures, were recommended [49].

PFGS has been shown to be more sensitive than maximum grip strength for measuring change over time [8]. Phase two only had complete data for 10 patients, showing an average improvement of 8.67 kg (figure 4), whilst in Phase three there were 27 patients with complete data, showing an average improvement of 11.27 kg (figure 4). This improvement could be explained by a number of reasons: The use of isometric and slow concentric/eccentric exercise; the improved patient specific load setting using high load; improved education of both therapists and patients, empowering

patients and improving compliance [40]; the use of the elbow crutch as a strengthening tool; the use of an exercise chart.

Hypoalgesic effects have been shown in healthy adults with the use of acute exercise, whilst in adults with chronic pain both a hypoalgesic and hyperalgesic effects have been seen [33]. PFGS was found to increase even after a few short (10 second) sustained isometric contractions, supporting the findings of Naugle et al. [33]. Demonstrating this improvement in PFGS to patients at initial assessment may be of benefit to highlight improvements in strength, even if no change to pain level is observed, to re-inforce the functional benefits of exercise that patients otherwise might not be aware of due to their focus on pain. This may also have the potential to improve patient compliance with treatment [40].

Conclusion:

The standardised tendon loading programme in Phase three demonstrated superior outcomes compared to both previous phases. High load Isometric exercises should be considered when making clinical decisions about exercise prescription, as should ensuring sufficient load setting for each individual. Exercising into pain can be effective. Strengthening should be a core part of the treatment of LE, whilst other treatments such as stretching and soft tissue techniques are of doubtful significance/effectiveness.

This three phase audit has documented a service evaluation and improvement project and has demonstrated that standardising treatment has helped to improve baseline quality for the treatment of LE. It is important to note that one size doesn't fit all therefore this standardisation should be used in conjunction with evidence based clinical reasoning.

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