

Mobilisation with movement and exercise, corticosteroid injection, or wait and see for tennis elbow: randomised trial

Leanne Bisset, Elaine Beller, Gwendolen Jull, Peter Brooks, Ross Darnell, Bill Vicenzino

Abstract

Objective To investigate the efficacy of physiotherapy compared with a wait and see approach or corticosteroid injections over 52 weeks in tennis elbow.

Design Single blind randomised controlled trial.

Setting Community setting, Brisbane, Australia.

Participants 198 participants aged 18 to 65 years with a clinical diagnosis of tennis elbow of a minimum six weeks' duration, who had not received any other active treatment by a health practitioner in the previous six months.

Interventions Eight sessions of physiotherapy; corticosteroid injections; or wait and see.

Main outcome measures Global improvement, grip force, and assessor's rating of severity measured at baseline, six weeks, and 52 weeks.

Results Corticosteroid injection showed significantly better effects at six weeks but with high recurrence rates thereafter (47/65 of successes subsequently regressed) and significantly poorer outcomes in the long term compared with physiotherapy. Physiotherapy was superior to wait and see in the short term; no difference was seen at 52 weeks, when most participants in both groups reported a successful outcome. Participants who had physiotherapy sought less additional treatment, such as non-steroidal anti-inflammatory drugs, than did participants who had wait and see or injections.

Conclusion Physiotherapy combining elbow manipulation and exercise has a superior benefit to wait and see in the first six weeks and to corticosteroid injections after six weeks, providing a reasonable alternative to injections in the mid to long term. The significant short term benefits of corticosteroid injection are paradoxically reversed after six weeks, with high recurrence rates, implying that this treatment should be used with caution in the management of tennis elbow.

Introduction

Tennis elbow affects 1-3% of the general population and 15% of workers in at risk industries.¹⁻⁶ Medical practitioners following an evidence based approach will find little high level evidence for treating tennis elbow. Recent studies indicated that corticosteroid injections were more efficacious within three to six weeks than were wait and see (control) or drugs but that by three to 12 months injections were no better than control.⁷⁻⁹ A programme of massage, ultrasound, and exercise was also not different from control.⁷ We recently identified preliminary evidence of beneficial initial effects of elbow manipulation (mobilisation with movement) and exercise.¹⁰⁻¹¹ Moreover, recent systematic reviews

report that poor quality of methods is a problem with much of the published research.¹¹⁻¹²

The aim of this randomised controlled trial was to investigate the short term and long term efficacy of a physiotherapy intervention (elbow manipulation and exercise) compared with corticosteroid injections and wait and see. We hypothesised that physiotherapy would be superior to wait and see in the short term and superior to injections in the long term.

Methods

Participants

We did a pragmatic randomised single blinded controlled trial in a community setting. Volunteers were people from the greater Brisbane region of Australia who responded to advertisements and media releases between March 2002 and April 2004. Volunteers were eligible for participation if they met the inclusion criteria of pain over the lateral elbow that increased on palpation of the lateral epicondyle, gripping, resisted wrist, or second or third finger extension¹³ and age 18-65 years with pain of at least six weeks' duration. Exclusion criteria were any treatment of the elbow pain by a healthcare practitioner within the preceding six months; bilateral elbow symptoms; cervical radiculopathy; any other elbow joint pathology; peripheral nerve involvement; previous surgery to the elbow; or a history of dislocation, fracture of the elbow, or tendon ruptures. Other exclusion criteria were systemic or neurological disorders; shoulder, wrist, and hand pathology; and contraindications to corticosteroids. All participants gave written informed consent.

Protocol

A blinded assessor who was not involved in the treatment allocation made the final selection and recorded baseline characteristics and measures. We randomised participants by telephone via concealed allocation to physiotherapy, corticosteroid injections, or a wait and see group. The randomisation sequence (kept off site and drawn up by a computerised random number generator in permuted blocks of six) and group allocation were kept concealed from all study personnel throughout the entire study, including the data analysis phase, except for the administrative assistant responsible for contacting participants.

Assignment

We reassured participants allocated to the wait and see group that the condition would eventually settle and encouraged them to wait. We also gave them specific instructions on modifying their daily activities to avoid aggravating their pain while still being as active as possible and to use analgesic drugs, heat, cold, or braces as needed.

One of two medical practitioners treated participants assigned to corticosteroid injections with the full amount of a local injection, consisting of a 1 ml quantity of 1% lidocaine with 10 mg of triaminolone acetonide in 1 ml, delivered to painful elbow points. We advised participants to return gradually to normal activities. We allowed a second injection after two weeks if deemed necessary by the medical practitioners.

Participants in the physiotherapy group received eight treatments of 30 minutes over six weeks, consisting of a previously described programme of elbow manipulation and therapeutic exercise.¹⁰ Participants were taught home exercises and self manipulation,¹⁰ which were checked by the treating therapist at each session and progressed as appropriate. They also received home exercise equipment (resistant exercise band) and an exercise instruction booklet. Six postgraduate qualified physiotherapists administered the treatment; they were trained in the treatment protocol to standardise the intervention.

We gave all participants an information booklet outlining the disease process and providing practical advice on self management and ergonomics on entering the study. We discouraged additional treatments to that assigned (that is, not per protocol) during the intervention period, but we allowed the use of analgesics as needed. Participants reported all not per protocol treatments, such as drugs, in a diary.

Outcome measures

Primary outcome measures throughout the follow-up period were global improvement, pain-free grip force, and assessor's rating of severity. Global improvement was recorded on a six point Likert-type scale ("completely recovered" to "much worse"). We calculated success rates from global improvement; we considered "completely recovered" or "much improved" to be successes.⁷ We also calculated recurrence rates beyond six weeks as the number of cases that went from "successful" to "unsuccessful" on global improvement. Pain-free grip force was measured with a digital grip dynamometer (MIE, Medical Research, UK).¹⁴ We calculated the mean of three efforts with intervening 30 second rest intervals and expressed it as a ratio of affected side to unaffected side.^{7 15 16} The blinded assessor rated severity of the elbow complaints on a continuous visual analogue scale (0 = no severity, 100 = maximum severity).

The secondary outcome measures included severity of pain in the previous seven day period (visual analogue scale: 0 mm = no pain, 100 mm = worst pain imaginable) and elbow disability, measured with the pain free function questionnaire (dichotomous eight item scale).¹⁷ The validity and reliability of the outcome measures have previously been established.^{7 18-22} We assessed outcomes before randomisation (baseline) and then at 3, 6, 12, 26, and 52 weeks after randomisation.

Masking

We asked the blinded assessor to nominate the treatment allocation of each participant after the 52 week measures to evaluate the success of blinding.

Statistical analysis

We did statistical analyses on a blinded, intention to treat basis with SPSS software (v11.0.0). We also did a per protocol analysis. The primary end points for the trial were six weeks (short term) and 52 weeks (long term). We estimated all continuous outcome measures by using baseline values as covariates in linear mixed models with participant defined as a random effect and treatment and time as fixed effects. For the dichotomous measure of success, we used the generalised estimating equations method with "geepack" written for R (v2.3.0, www.R-project.org).²³ We included baseline demographic characteristics in all models as covariates and reported adjusted results if they were found to affect outcomes significantly over time. Given the complex treatment effect profiles over time and a significant time by treatment interaction ($P < 0.01$), we decided to compare treatments at each time point (six and 52 weeks) with significance set at 0.01 (99% confidence intervals) to compensate for the increase in type I error rates resulting from multiple testing. We calculated the relative risk reduction and number needed to treat in order to facilitate development of clinical guidelines for future management. We also expressed continuous data as area under the curve as a means of comparing the overall effectiveness of the treatments over the course of the study.²⁴

We determined a sample size of 60 participants per group on the primary outcome measure of global improvement, on the basis of ability to detect a clinically important difference of 25% in success rate between physiotherapy and the other interventions⁷ and assuming the minimum success rate to be 68% at 52 weeks ($\beta = 0.2$, two tailed $\alpha = 0.05$). To allow for loss to follow-up, we increased the sample size by 10% to 198 (66 per group).

We determined a sample size of 60 participants per group on the primary outcome measure of global improvement, on the basis of ability to detect a clinically important difference of 25% in success rate between physiotherapy and the other interventions⁷ and assuming the minimum success rate to be 68% at 52 weeks ($\beta = 0.2$, two tailed $\alpha = 0.05$). To allow for loss to follow-up, we increased the sample size by 10% to 198 (66 per group).

Results

Participant flow and follow-up

We enrolled all participants between March 2002 and May 2004 and completed all follow-up assessments by June 2005. Figure 1 illustrates the flow of participants through the trial, and table 1 shows baseline characteristics of the study sample by group. The participants were well matched for demographic and clinical characteristics.

Primary end points

Participants' characteristics (such as sex and duration of symptoms) and outcome measures taken at baseline did not significantly influence the dichotomous and continuous measures over time; we therefore present unadjusted data. Significant time by group interactions for all outcome measures occurred in the omnibus analysis.

Table 2 shows the outcome data, and table 3 shows the absolute event rates, relative risk reductions, and numbers needed to treat. We found significant differences for all primary outcome measures at six weeks that favoured injection over wait and see; 51/65 (78%) participants reported success with injections compared with 16/60 (27%) with wait and see (relative risk reduction 0.7, 99% confidence interval 0.4 to 0.9), representing a number needed to treat of 2. Injection was also superior to physiotherapy on all outcome measures except global improvement (0.4, -0.2 to 0.9); 41/63 (65%) participants reported success at six weeks with physiotherapy (fig 2, table 3). At 52 weeks' follow-up, the injection group participants were significantly worse on all outcomes compared with the physiotherapy group (0.3, 0.1 to 0.5; number needed to treat = 4) and on two out of three measures compared with wait and see (0.3, 0.04 to 0.4; 4).

Physiotherapy performed significantly better than wait and see at six weeks for all outcome measures (for example, success: 0.6, 0.2 to 0.9; number needed to treat = 3) (fig 2). However, by 52 weeks no difference existed on any primary outcome measure, as most participants had either much improved or completely recovered (wait and see 56/62; physiotherapy 59/63) (table 3, fig 2).

Overall benefit and clinical implications

Area under the curve analysis revealed a significant advantage in favour of physiotherapy over injection for all primary outcome

Table 1 Baseline characteristics for the wait and see, corticosteroid, and physiotherapy groups and the total study population. Values are numbers (percentages) unless stated otherwise

Characteristics	Wait and see (n=67)	Steroid injection (n=65)	Physiotherapy (n=66)	Total (n=198)
Mean (SD) age (years)	47.3 (8.1)	47.8 (8.2)	47.9 (7.2)	47.6 (7.8)
Women	24 (36)	25 (38)	21 (32)	70 (35)
Median (interquartile range) duration (weeks)	26 (10-42)	26 (12-42)	16 (11-35)	22 (12-42)
Dominant elbow affected	42 (63)	49 (75)	42 (64)	133 (67)
Previous episodes of lateral elbow pain	22 (33)	19 (29)	14 (21)	55 (28)
Alleged cause:				
Overuse, usual activities	4 (6)	2 (3)	2 (3)	8 (4)
Overuse, unusual activities	8 (12)	12 (18)	18 (27)	38 (19)
Other (such as sport, unexpected movement)	16 (24)	11 (17)	12 (18)	39 (20)
Unknown	39 (58)	40 (62)	34 (52)	113 (57)
Employment:				
Unemployed	10 (15)	12 (18)	9 (14)	31 (16)
Non-manual work	30 (45)	32 (50)	36 (66)	98 (50)
Manual work	27 (40)	21 (32)	21 (32)	69 (35)
Mean (SD) pain-free grip force ratio*	48.0 (21.5)	38.4 (17.1)	42.4 (20.8)	42.9 (20.0)
Mean (SD) assessor rating of severity (/100)	51.9 (19.5)	58.0 (17.3)	51.6 (19.3)	53.8 (18.8)
Mean (SD) pain severity in previous week (/100)	61.3 (22.6)	53.5 (23.0)	57.5 (25.0)	57.5 (23.7)
Mean (SD) pain free function questionnaire (/100)	76.7 (21.3)	80.8 (16.1)	75.4 (18.9)	77.6 (18.9)

*Affected side/unaffected side×100.

measures, over wait and see for pain-free grip (mean difference=534, 99% confidence interval 3 to 1065) and

assessor severity (447, 137 to 758), as well as for wait and see over injection for global improvement (-8.3, -15.0 to -1.5) and assessor severity (-337, -642 to -32) (table 2, fig 2).

Per protocol analysis

Removal of participants who failed to adhere to the trial protocol only minimally changed the results of the intention to treat analysis (fig 2¶).

Recurrences

The corticosteroid injection group had most reported recurrences; 47/65 (72%) participants deteriorated after three or six weeks. Recurrences after injection were significantly greater than recurrences after physiotherapy (5/66, 8%; relative risk reduction 0.9, 0.6 to 1.1) or wait and see (6/67, 9%; 0.9, 0.6 to 1.1), which were not significantly different from each other (relative risk reduction 0.2, -1.4 to 1.7).

Not per protocol treatment

Wait and see participants (34/62, 55%) sought significantly more not per protocol treatment than physiotherapy participants (13/63, 21%; relative risk reduction 0.6, 0.2 to 1.0), but no more than corticosteroid injection participants (32/65, 49%; 0.1, -0.3 to 0.5) (table 4). Injection participants sought significantly more not per protocol treatment than physiotherapy participants (relative risk reduction 0.6, 0.1 to 1.0).

Success of blinding

At 52 weeks, the blinded assessor correctly guessed the allocated treatment in 101/198 (51%) cases, on the basis of the course of elbow complaints and four participants who inadvertently revealed their group allocation. The assessor guessed correctly for 39/67 (58%) participants in the wait and see group, 27/65

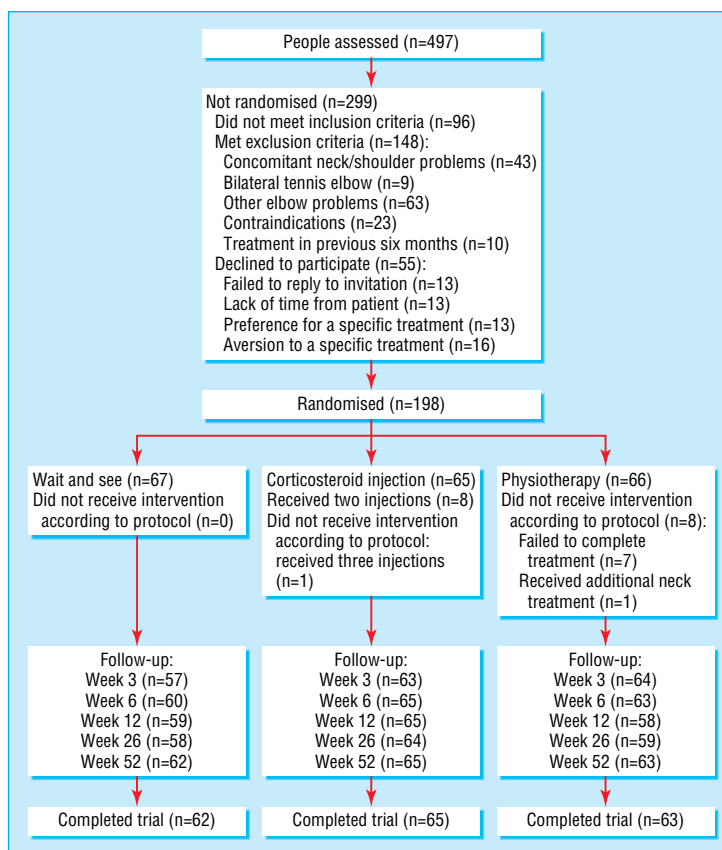


Fig 1 Flow of participants through each stage

Research

Table 2 Mean (SD) scores and area under the curve (AUC) for continuous outcome measures and mean difference (99% confidence intervals) between groups at 3, 6, 12, 26, and 52 weeks

	Mean (SD) for each intervention			Mean (99% CI) differences in improvement between groups*		
	Wait and see	Injection	Physiotherapy	Injection–wait and see	Physiotherapy–wait and see	Injection–physiotherapy
Primary outcome measures						
Pain-free grip ratio (affected side/unaffected side×100):						
3 weeks	46.2 (22.1)	83.2 (21.3)	54.5 (24.4)	42.0 (32.6 to 51.3)	10.8 (1.6 to 20.0)	31.2 (22.2 to 40.2)
6 weeks	51.8 (23.0)	83.6 (22.9)	70.2 (25.4)	36.4 (26.5 to 46.3)	20.1 (10.3 to 30.0)	16.3 (6.6 to 26.0)
12 weeks	72.1 (23.0)	63.7 (28.1)	80.8 (22.6)	-5.4 (-16.7 to 6.0)	9.4 (-2.1 to 20.9)	-14.8 (-26.1 to -3.5)
26 weeks	86.5 (20.2)	64.1 (30.8)	96.3 (29.9)	-19.6 (-33.0 to -6.2)	10.5 (-3.0 to 24.0)	-30.1 (-43.1 to -17.2)
52 weeks	96.5 (18.5)	84.6 (21.9)	100.9 (30.9)	-12.1 (-23.6 to 0.3)	4.3 (-7.5 to 16.2)	-16.4 (-27.9 to -4.8)
AUC	1743 (960)	1744 (883)	2278 (1269)	0.9 (-518 to 520)	534 (3 to 1065)	533 (30 to 1037)
Assessor severity rating (/100):						
3 weeks	52.9 (17.9)	18.9 (17.8)	42.2 (19.2)	35.9 (28.3 to 43.4)	9.8 (2.3 to 17.3)	26.1 (18.7 to 33.4)
6 weeks	44.1 (16.7)	16.0 (17.3)	28.1 (19.9)	29.9 (22.2 to 37.7)	15.0 (7.3 to 22.8)	15.0 (7.2 to 22.6)
12 weeks	27.4 (16.5)	32.9 (24.9)	17.8 (16.8)	-4.4 (-13.8 to 4.9)	9.2 (-0.4 to 18.7)	-13.6 (-23.0 to -4.2)
26 weeks	17.0 (14.3)	35.2 (24.6)	8.3 (11.7)	-17.5 (-26.2 to -8.9)	8.2 (-0.7 to 17.1)	-25.7 (-34.4 to -17.1)
52 weeks	10.3 (13.2)	19.0 (19.7)	5.1 (9.6)	-8.3 (-15.2 to -1.3)	5.1 (-1.9 to 15.2)	-13.3 (-20.4 to -6.3)
AUC	1179 (500)	1516 (751)	732 (544)	-337 (-642 to -32)	447 (137 to 758)	-784 (-1082 to -487)
Global improvement (success): AUC						
	36.4 (12.4)	28.2 (15.7)	41.6 (12.8)	-8.3 (-15.0 to -1.5)	5.2 (-1.7 to 12.1)	-13.5 (-20.1 to -6.8)
Secondary outcome measures						
Pain severity (/100):						
3 weeks	61.3 (25.3)	18.9 (23.2)	46.8 (26.7)	40.3 (28.8 to 51.7)	13.5 (2.1 to 24.8)	26.8 (15.7 to 37.8)
6 weeks	51.0 (26.5)	16.4 (21.7)	33.8 (28.2)	31.3 (20.5 to 42.2)	15.6 (4.7 to 26.4)	15.8 (5.1 to 26.4)
12 weeks	30.4 (29.4)	33.9 (30.6)	18.5 (21.3)	-5.2 (-17.8 to 7.5)	11.2 (-1.8 to 24.1)	-16.4 (-29.0 to -3.7)
26 weeks	19.8 (24.0)	30.0 (26.8)	14.0 (22.1)	-11.4 (-23.0 to 0.1)	5.1 (-6.6 to 16.8)	-16.5 (-27.9 to -5.1)
52 weeks	13.9 (22.6)	20.8 (27.7)	6.6 (14.6)	-7.7 (-18.0 to 2.7)	6.9 (-3.6 to 17.3)	-14.5 (-24.8 to -4.2)
Pain free function questionnaire (/100):						
3 weeks	71.3 (25.2)	31.2 (29.6)	63.9 (21.0)	41.9 (30.4 to 53.5)	6.7 (-4.8 to 18.2)	35.2 (24.0 to 46.5)
6 weeks	63.8 (25.4)	31.9 (30.6)	46.8 (29.7)	33.3 (20.5 to 46.0)	15.6 (2.8 to 28.4)	17.7 (5.0 to 30.3)
12 weeks	53.6 (31.2)	52.7 (35.5)	34.9 (27.5)	2.5 (-11.9 to 16.8)	17.2 (2.4 to 31.9)	-14.7 (-29.2 to -0.2)
26 weeks	32.8 (30.2)	53.3 (29.1)	26.5 (28.1)	-19.5 (-33.1 to -5.8)	5.3 (-8.6 to 19.3)	-24.8 (-38.4 to -11.2)
52 weeks	24.6 (29.6)	37.1 (31.7)	12.9 (29.9)	-11.5 (-24.5 to 1.5)	11.0 (-2.1 to 24.0)	-22.5 (-35.4 to -9.5)

*Positive score favours reference group (that is, first group listed in comparison).

(42%) in the injection group, and 35/66 (53%) in the physiotherapy group. As this proportion was greater than expected by chance, we did a post hoc subgroup analysis to assess the impact of the loss of blinding on outcome measures. We detected no significant difference in outcomes between the participants whose treatment allocation the assessor guessed correctly and those for whom the assessor remained blinded.

Side effects

A total of 20 participants experienced an adverse event from treatments (13 injection; 7 physiotherapy). Most of these were mild, and pain after treatment was the most commonly reported side effect (12 injection; 7 physiotherapy). Only one participant in each group reported pain lasting seven days or longer. Two participants reported loss of skin pigment, and one also had

atrophy of subcutaneous tissue after receiving the corticosteroid injection.

Discussion

In answer to our research question, we found evidence to support the use of corticosteroid injections or physiotherapy over wait and see in the short term; in the long term, however, corticosteroid injection was inferior to both wait and see and physiotherapy, which were very similar in effect. Notably, this is the first long term study to show an overall beneficial effect of a physiotherapy intervention, as supported by area under the curve analyses and fewer additional treatments sought by participants receiving physiotherapy compared with either wait and see or corticosteroid injections.

Table 3 Absolute event rates of successes, as measured by those participants who rated themselves as either much improved or completely recovered on the six point Likert scale of global improvement; relative risk reductions (RRR) and numbers needed to treat (NNT) for between group comparisons

Time (weeks)	No (%) successes			Mean (99%CI) differences in success between groups*					
	Wait and see	Injection	Physiotherapy	Injection–wait and see		Physiotherapy–wait and see		Injection–physiotherapy	
				RRR (99% CI)	NNT	RRR (99%CI)	NNT	RRR (99%CI)	NNT
3	9/57 (16)	47/63 (75)	15/64 (23)	0.7 (0.4 to 0.9)*	2	0.1 (-0.1 to 0.3)	13	0.7 (0.4 to 0.9)*	2
6	16/60 (27)	51/65 (78)	41/63 (65)	0.7 (0.4 to 0.9)*	2	0.5 (0.2 to 0.8)‡	3	0.4 (-0.2 to 0.9)	7
12	35/59 (59)	29/65 (45)	45/58 (76)	0.3 (-0.1 to 0.6)	7	0.2 (-0.05 to 0.5)	5	0.4 (0.1 to 0.7)‡	3
26	48/58 (83)	29/64 (45)	51/59 (86)	0.5 (0.2 to 0.7)†	3	0.04 (-0.2 to 0.3)	27	0.5 (0.2 to 0.7)‡	2
52	56/62 (90)	44/65 (68)	59/63 (94)	0.3 (0.04 to 0.4)†	4	0.04 (-0.1 to 0.2)	30	0.3 (0.1 to 0.5)‡	4

*Between group differences in favour of corticosteroid injection.

†Between group differences in favour of wait and see.

‡Between group differences in favour of physiotherapy.

Table 4 Additional not per protocol treatments

Additional treatment*	Wait and see (n=62)	Corticosteroid injection (n=65)	Physiotherapy (n=63)
None	28	33	50
GP/specialist	2	4	1
Physiotherapy	3	3	1
Corticosteroid injection	1	1	0
Elbow support/brace	11	10	2
Analgesic or NSAID	22	20	9
Acupuncture	2	1	2
Complementary medicine	13	12	3

GP=general practitioner; NSAID=non-steroidal anti-inflammatory drug.
*Some participants had more than one type of additional treatment.

Corticosteroid injection was initially superior to both wait and see and physiotherapy, but this effect was lost after six weeks, with a concomitantly high recurrence rate in the corticosteroid group (47/65), which did not occur with wait and see or physiotherapy. The high recurrence rate with corticosteroid may be due to the rapid improvement in pain, which may lead to increased activity levels and overtaxing of the affected elbow. However, we gave all participants ergonomic and self care advice, which included graduated resumption of usual activities. Importantly, injection performed worst of all the interventions at 52 weeks and on area under the curve analysis. Furthermore, the poor outcome in the long term relative to wait and see suggests a delay in recovery after this treatment.

At 52 weeks, wait and see was superior to corticosteroid injection on global improvement, and physiotherapy was superior to injection for all outcome measures. Notably, the progress of the wait and see group seen in this study was not a function only of the natural history of the condition but also of the general advice that was given to all groups, as well as possibly the use of additional not per protocol treatments, which was

highest in this group. None the less, the positive long term results seen here support the notion proposed by Smidt et al that given appropriate advice, tennis elbow is a self limiting condition at 52 weeks in most cases.⁷ In providing advice to patients, medical practitioners need only advise four patients to wait and see or have physiotherapy in order to have one more successful outcome at 52 weeks than if they had given a corticosteroid injection instead.

A potential confounding factor in this study was the discrepancy in the number of treatment sessions between protocols; the physiotherapy participants needed eight treatment sessions compared with one or two sessions for the other protocols. This discrepancy may have been responsible for the relatively superior clinical efficacy of physiotherapy over wait and see in the short term. This discrepancy is difficult to overcome in a pragmatic trial such as this. None the less, the physical intervention studied by Smidt et al consisted of nine treatments and showed no significant benefit over wait and see.⁷ Our study supports the notion that the specific intervention may in part be responsible for clinical efficacy—that is, beyond any non-specific clinical interaction effects. However, we did not test for a non-specific placebo effect for physiotherapy or corticosteroid injection, and further investigation of this is needed. Another potential confounder was that both the wait and see and corticosteroid injection groups used more than twice the amount of analgesics or non-steroidal anti-inflammatory drugs that the physiotherapy group used; this warrants further investigation because of the risk of adverse side effects associated with these drugs.

The time course for wait and see and corticosteroid injections seems to be similar across different countries, health systems, and population recruitment strategies.^{7,8} This suggests

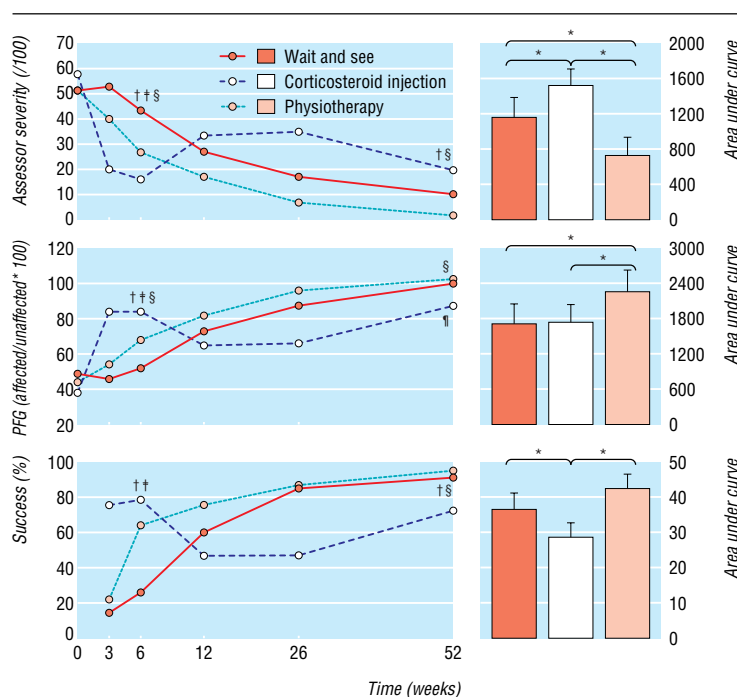


Fig 2 Primary outcome measures: mean assessor's rating of severity (visual analogue scale), mean pain-free grip (PFG—affected/unaffected, expressed as a percentage), and percentage success. Significant differences between study arms at six and 12 weeks: †corticosteroid injection v wait and see; ‡physiotherapy v wait and see; §corticosteroid injection v physiotherapy. ¶Significant difference between corticosteroid and wait and see on per protocol analysis. Bar graphs represent mean (99% confidence interval) area under curve (trapezium method²⁴) analysis of assessor severity, PFG, and global improvement. *Significant differences between groups (P<0.01)

that the results of our study may be generalisable across different patient populations with tennis elbow.

Conclusions

The high recurrence rates, general delay in recovery, and poor overall performance with corticosteroid injections should be taken under consideration by both patients and their doctors in the management of tennis elbow. An approach combining elbow manipulation and exercise has a superior benefit to wait and see in the first six weeks and to steroid injections in the long term and may be recommended over corticosteroid injections. However, patients with tennis elbow can be reassured that most cases will improve in the long term when given information and ergonomic advice about their condition.

Contributors: LB was responsible for the recruitment and screening of participants, did baseline and follow-up outcome assessments, analysed data, and prepared the manuscript. EB assisted in the trial design and reviewed the manuscript. GJ and PB assisted in the NHMRC grant application and trial design and reviewed the manuscript. RD advised on the statistical design of the trial and in the data analysis and interpretation. BV, as chief investigator on the NHMRC grant, supervised the running of the project, cross checked the participants entering the trial, and supervised data analysis and preparation of the manuscript. BV is the guarantor.

Funding: University of Queensland and the National Health and Medical Research Council, Primary Health Care Project Grant, Australia #252710.

Competing interests: None declared.

Ethical approval: Institutional research ethics committee.

- 1 Allander E. Prevalence, incidence and remission rates of some common rheumatic diseases or syndromes. *Scand J Rheumatol* 1974;3:145-53.
- 2 Bot S, van der Wall J, Terwee C, van der Windt D, Bouter L. Course and prognosis of elbow complaints: a cohort study in general practice. *Ann Rheum Dis* 2005;64:1331-6.

- 3 Walker-Bone K, Palmer K, Reading I, Coggon D, Cooper C. Prevalence and impact of musculoskeletal disorders of the upper limb in the general population. *Arthritis Rheum* 2004;45:1642-51.
- 4 Chiang HC, Ko YC, Chen SS, Yu HS, Wu TN, Chang PY. Prevalence of shoulder and upper limb disorders among workers in the fish-processing industry. *Scand J Work Environ Health* 1993;19:126-31.
- 5 Kurppa K, Viikari Juntura E, Kuosma E, Huuskonen M, Kivi P. Incidence of tenosynovitis or peritendinitis and epicondylitis in a meat-processing factory. *Scand J Work Environ Health* 1991;17:32-7.
- 6 Ranney D, Wells R, Moore A. Upper limb musculoskeletal disorders in highly repetitive industries: precise anatomical physical findings. *Ergonomics* 1995;38:1408-23.
- 7 Smidt N, Van der Windt D, Assendelft W, Deville W, Korhals de Bos I, Bouter L. Corticosteroid injections, physiotherapy, or a wait-and-see policy for lateral epicondylitis: a randomised controlled trial. *Lancet* 2002;359:657-62.
- 8 Hay EM, Paterson SM, Lewis M, Hosie G, Croft P. Pragmatic randomised controlled trial of local corticosteroid injection and naproxen for treatment of lateral epicondylitis of elbow in primary care. *BMJ* 1999;319:964-8.
- 9 Smidt N, Lewis M, Hay E, van der Windt D, Bouter L, Croft P. A comparison of two primary care trials on tennis elbow: issues of external validity. *Ann Rheum Dis* 2005;64:1406-9.
- 10 Vicenzino B. Lateral epicondylalgia: a musculoskeletal physiotherapy perspective. *Man Ther* 2003;8:66-79.
- 11 Bisset L, Paungmali A, Vicenzino B, Beller E. A systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylalgia. *Br J Sports Med* 2005;39:411-22.
- 12 Smidt N, Assendelft WJ, Arola H, Malmivaara A, Greens S, Buchbinder R, et al. Effectiveness of physiotherapy for lateral epicondylitis: a systematic review. *Ann Med* 2003;35:51-62.
- 13 Haker E. Lateral epicondylalgia: diagnosis, treatment and evaluation. *Crit Rev Physical Rehabil Med* 1993;5:129-54.
- 14 Thurtell O, Tyler A, Cawley M. Grip strength as a measure of response to treatment for lateral epicondylitis [letter]. *Br J Rheumatol* 1984;23:154-5.
- 15 Benjamin S, Williams D, Kalbfleisch J, Gorman P, Panus P. Normalized forces and active range of motion in unilateral radial epicondylalgia (tennis elbow). *J Orthop Sports Phys Ther* 1999;29:668-76.
- 16 Drechsler W, Knarr J, Snyder Mackler L. A comparison of two treatment regimens for lateral epicondylitis: a randomized trial of clinical interventions. *J Sport Rehabil* 1997;6:226-34.
- 17 Stratford P, Levy DR, Gaudie S, Levy K, Miferferi D. Extensor carpi radialis tendonitis: a validation of selected outcome measures. *Physiother Can* 1987;39:250-5.
- 18 Carlsson A. Assessment of chronic pain. I. Aspects of the reliability and validity of the visual analog scale. *Pain* 1983;16:87-101.
- 19 Scott J, Huskisson E. Graphic representation of pain. *Pain* 1976;2:175-84.
- 20 Stratford PW, Levy DR. Assessing valid change over time in patients with lateral epicondylitis at the elbow. *Clin J Sport Med* 1994;4:88-91.
- 21 Stratford PW, Norman GR, McIntosh JM. Generalizability of grip strength measurements in patients with tennis elbow. *Phys Ther* 1989;69:276-81.
- 22 Smidt N, van der Windt DA, Assendelft WJ, Mourits AJ, Deville WL, de Winter AF, et al. Interobserver reproducibility of the assessment of severity of complaints, grip strength, and pressure pain threshold in patients with lateral epicondylitis. *Arch Phys Med Rehabil* 2002;83:1145-50.
- 23 Yan J. Geepack: yet another package for generalized estimating equations. *R-News* 2002;2(3):12-14 (available from <http://CRAN.R-project.org/doc/Rnews/>).
- 24 Matthews J, Altman D, Campbell M, Royston P. Analysis of serial measurements in medical research. *BMJ* 1990;300:230-5.

(Accepted 24 August 2006)

doi 10.1136/bmj.38961.584653.AE

School of Health and Rehabilitation Sciences, University of Queensland, St Lucia, QLD, Australia 4072

Leanne Bisset *PhD candidate*

Queensland Clinical Trials Centre, School of Population Health, University of Queensland

Elaine Beller *director of biostatistics*

School of Health and Rehabilitation Sciences, University of Queensland

Gwendolen Jull *professor*

Ross Darnell *statistician*

Bill Vicenzino *associate professor*

Faculty of Health Sciences, University of Queensland

Peter Brooks *executive dean*

Correspondence to: B Vicenzino bvicenzino@uq.edu.au

What is already known on this topic

Corticosteroid injection is superior to wait and see or drugs for tennis elbow over the first six weeks after randomisation

Physiotherapy consisting of ultrasound, massage, and exercise is no better than a wait and see policy

Adopting a wait and see policy is as effective as any other treatment at 52 weeks after randomisation

What this study adds

Recurrence rates were higher and recovery delayed in the mid to long term after corticosteroid injection compared with physiotherapy or wait and see

Physiotherapy (mobilisation with movement and exercise) was superior to injection after six weeks and to wait and see at six weeks but not 52 weeks

Patients who received physiotherapy sought significantly less other treatment