Corticosteroid injections, physiotherapy, or a wait-and-see policy for lateral epicondylitis: a randomised controlled trial

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Summary

Background Lateral epicondylitis is generally treated with corticosteroid injections or physiotherapy. Dutch clinical guidelines recommend a wait-and-see policy. We compared the efficacy of these approaches.

Methods Patients with lateral epicondylitis of at least 6 weeks' duration were recruited by family doctors. We randomly allocated eligible patients to 6 weeks of treatment with corticosteroid injections, physiotherapy, or a wait-and-see policy. Outcome measures included general improvement, severity of the main complaint, pain, elbow disability, and patient satisfaction. Severity of elbow complaints, grip strength, and pressure pain threshold were assessed by a research physiotherapist who was unaware of treatment allocation. We assessed all outcomes at 3, 6, 12, 26, and 52 weeks. The principal analysis was done on an intention-to-treat basis.

Findings We randomly assigned 185 patients. At 6 weeks, corticosteroid injections were significantly better than all other therapy options for all outcome measures. Success rates were 92% (57) compared with 47% (30) for physiotherapy and 32% (19) for wait-and-see policy. However, recurrence rate in the injection group was high. Long-term differences between injections and physiotherapy were significantly in favour of physiotherapy. Success rates at 52 weeks were 69% (43) for injections, 91% (58) for physiotherapy, and 83% (49) for a wait-and-see policy. Physiotherapy had better results than a wait-and-see policy, but differences were not significant.

Interpretation Patients should be properly informed about the advantages and disadvantages of the treatment options for lateral epicondylitis. The decision to treat with physiotherapy or to adopt a wait-and-see policy might depend on available resources, since the relative gain of physiotherapy is small.

Lancet 2002; **359:** 657–62

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Introduction

Lateral epicondylitis (tennis elbow) is a frequent complaint in primary care, and is judged an overload injury, affecting the common extensor muscles at the lateral humeral epicondyle. The incidence of lateral epicondylitis is estimated at 4–7 per 1000 patients per year in general practice,[1] and between 1% and 3% per year of adults in the general population are affected.[2–5] A typical episode of lateral epicondylitis lasts 6–24 months on average,[6,7] but most patients recover within a year.[8,9]

Systematic reviews of the effectiveness of physiotherapy, corticosteroid injections, and non-steroidal anti-inflammatory drugs for lateral epicondylitis present conflicting results.[10,11] Labelle and colleagues[11] concluded that there is insufficient evidence for any specific treatment. The methodological quality of research is generally poor, and the statistical power of most randomised controlled trials is low.[10–16] Corticosteroid injections seem safe and effective in the short-term treatment of lateral epicondylitis.[10] However, there is insufficient evidence with respect to their long-term effectiveness.

In view of the absence of scientific data for the effectiveness of active interventions, and the benign course of lateral epicondylitis, the clinical guidelines of the Dutch College of General Practitioners recommend a wait-and-see policy, including ergonomic advice and prescription of pain medication if necessary.[10] Our aim was to compare the efficacy of a wait-and-see policy with that of physiotherapy and corticosteroid injections.

Methods

Study participants

We did a randomised trial in a primary-care setting. We considered for inclusion consecutive patients who consulted one of 85 participating family doctors for elbow complaints. Inclusion criteria were: pain at the lateral side of the elbow, increasing with pressure on the lateral epicondyle and with resisted dorsiflexion of the wrist; age 18–70 years; ability to complete questionnaires in Dutch; and informed consent. Exclusion criteria were: treatment of elbow complaints with physiotherapy or injections during the preceding 6 months; bilateral elbow symptoms; duration less than 6 weeks; presence of signs and symptoms suggestive of another cause of elbow pain—eg, cervical radiculopathy; congenital or acquired deformities of the elbow; surgery of the elbow; dislocation, tendon ruptures, or fractures in the area in the preceding 12 months; systemic musculoskeletal or neurological disorders; and contraindications for corticosteroids. We referred all eligible patients to one of five research centres after a 2-week qualification period. A trained research physiotherapist examined patients who had not shown any signs of recovery within this period. The physiotherapist checked all selection criteria and enrolled patients, who gave written informed consent. The medical ethics committee of Vrije Universiteit Medical Centre approved our protocol.

Study protocol

We used a computerised random number generator to draw up an allocation schedule. Block randomisation (permuted blocks of three) was done after prestratification for the duration of complaints (≤13 weeks or >13 weeks) and research centre. The assignment of patients to corticosteroid injections, physiotherapy, or a wait-and-see policy took place after final selection by the research physiotherapist and baseline assessment. An administrative assistant allocated interventions via opaque sealed envelopes marked according to the allocation schedule. The research physiotherapist and the administrative assistant were unaware of the block-size.

Patients allocated to the wait-and-see policy group visited their family doctor once during the intervention period of 6 weeks. Activities that provoked pain, and practical solutions (including ergonomic advice) were discussed with the patient. If necessary, paracetamol (2000–4000 mg daily) or non-steroidal anti-inflammatory drugs (NSAIDs, naproxen 1000 mg daily) were prescribed. The patient was encouraged to await further spontaneous improvement.

Patients assigned to corticosteroid injections were treated by their doctors with local infiltration of 1 mL triamcinoloneacetonide (10 mg/mL) and 1 mL lidocaine 2%. Every tender spot was identified with the needle and injected until the patient was free of pain during resisted dorsiflexion.[17,18] The amount of fluid remaining in the syringe was recorded. Patients were asked to avoid pain-provoking activities, although absolute rest of the arm was not necessary. During the 6-week intervention period, a maximum of three injections was recommended. We gave family doctors training in the injection technique before the trial.

Physiotherapy consisted of nine treatments of pulsed ultrasound, deep friction massage, and an exercise programme over 6 weeks. Pulsed ultrasound (20% duty cycle) was given with an intensity of 2 W/cm^2 for 7·5 minutes per session.[19] Ultrasound equipment was checked and calibrated by the manufacturer (Enraf Nonius BV, Delft, Netherlands) before and once during the trial. After pain reduction, exercise treatment consisted of progressive, slow, repetitive wrist and forearm stretching, muscle conditioning, and occupational exercises, intensified in four steps.[20] All patients received home exercise equipment and an instruction book. We gave all 72 physiotherapists (31 practices) special training for techniques required for the intervention.

Details of the content of each treatment session and of any adverse effects were reported on standardised forms by family doctors and physiotherapists. We discouraged all co-interventions during the 6-week intervention period, but allowed prescription of pain medication if necessary.

We did outcome assessments before randomisation, once during the intervention (3 weeks after randomisation), and at 6, 12, 26, and 52 weeks. General improvement was scored by the patient on a six-point Likert scale ("completely recovered" to "much worse" compared with baseline). For the computation of success rates, patients who rated themselves "completely recovered" or "much improved" were counted as successes.[21] Patients also scored the severity of their main complaint, pain during the day, and inconvenience on an 11-point numerical rating scale (0=no pain to 10=very severe pain).[21] We assessed functional disability with the modified pain-free function questionnaire; a 10-item scale that consists of common situations that might cause elbow pain[22] (range 0–40 points, 40 indicating severe disability). The research physiotherapist scored overall severity of the elbow complaints on an 11-point scale (0=no complaints to 10=very severe complaints) after taking a standardised history and physical examination.

With respect to secondary outcome measures, pain-free grip strength and maximum grip strength were measured by the research physiotherapist with a Jamar hand dynamometer (PGB Active Living, 's-Hertogenbosch, Netherlands). The mean value (kg) of three efforts was calculated, separated by 20 s rest intervals. Grip strength of the affected side was presented as a ratio of the maximum grip strength of the unaffected side.[23,24] We measured pressure pain threshold with an algometer[25,26] (Pain Diagnostics and Thermography, Great Neck, USA). The research physiotherapist gradually applied pressure, with a maximum of 6 kg/cm^2 perpendicular to the common extensor tendon at the elbow, until the patient indicated that the sensation of pressure changed to pain. The mean of three consecutive measurements separated by intervals of 20 s was taken. The pressure-pain threshold was presented as the ratio of the pain-free pressure of the unaffected side. Satisfaction with the received intervention was reported by the patient on an 11-point scale (0=not satisfied at all to 10=very satisfied).

The three research physiotherapists in the study trained thoroughly before the trial. We did a reproducibility study in 50 consecutive patients. Interassessor agreement was good to excellent for gripstrength and assessment of overall severity, and satisfactory for pressure pain threshold (intraclass correlation coeficients 0·72–0·98).[27] We transformed all primary and secondary outcome values to

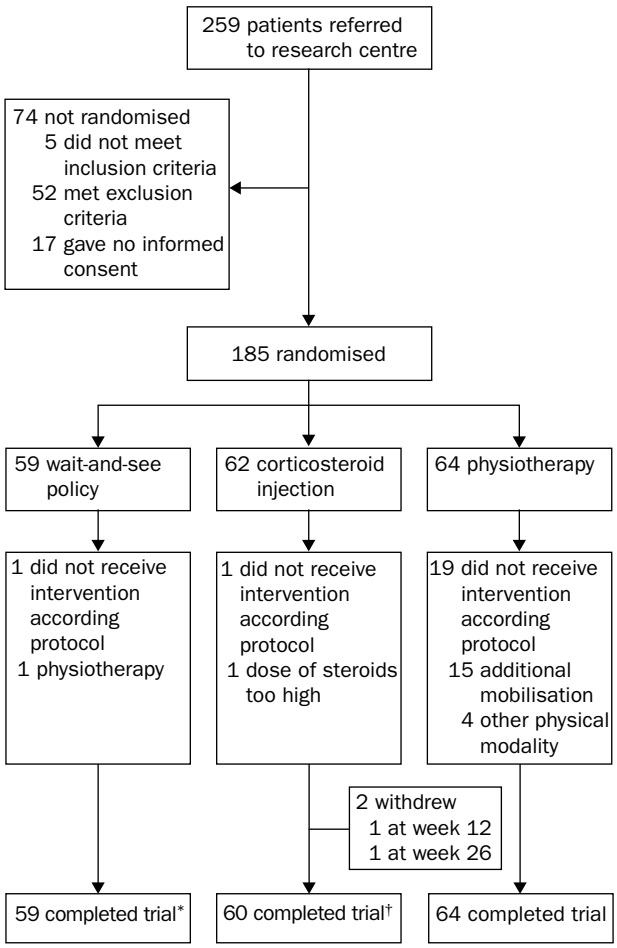

Figure 1: **Trial profile**

*One patient missed assessment at 3 weeks due to holiday; †one patient missed assessment at 12 weeks due to a car accident.

	Wait-and-see policy (n=59)	Corticosteroid injection (n=62)	Physiotherapy (n=64)
Age (median IQR) (years)	46 (42–54)	47 (41–54)	48 (41–52)
Women	31 (53%)	34 (55%)	28 (44%)
Duration of current episode of lateral epicondylitis (median IQR) (weeks)	11 (8–21)	11 (8–16)	11 (8–21)
Acute onset	13 (22%)	16 (26%)	17 (27%)
Dominant elbow affected	46 (78%)	48 (77%)	51 (80%)
Concomitant neck disorders	12 (20%)	18 (29%)	9 (14%)
Previous episodes of lateral elbow pain	18 (31%)	25 (40%)	16 (25%)
Putative cause			
Overuse, usual activities	22 (37%)	16 (26%)	21 (33%)
Overuse, unusual activities	15 (25%)	15 (24%)	15 (23%)
Other (sport injury, unexpected movement)	8 (14%)	11 (18%)	12 (19%)
Unknown	14 (24%)	20 (32%)	16 (25%)
Patient's preference for treatment			
Physiotherapy	26 (44%)	22 (36%)	27 (42%)
Wait-and-see policy	1 (2%)	3 (5%)	4 (6%)
Injections	5 (9%)	6 (10%)	8 (13%)
No preference	31 (52%)	32 (52%)	27 (42%)
Use of analgesics during past week	9 (15%)	10 (16%)	8 (13%)
Primary outcome measures (median IQR)			
Severity of main complaint	70 (50–80)	70 (50–80)	70 (60–80)
Pain during day	60 (30–70)	60 (40–70)	60 (40–70)
Inconvenience of elbow complaints	70 (50–80)	75 (50–90)	70 (50–90)
Severity of elbow complaints	40 (40–50)	40 (30–60)	40 (30–50)
Elbow disability	45 (35–55)	48 (38–61)	48 (38–60)
Secondary outcome measures (median IQR)			
Pain-free grip strength	27 (17–48)	30 (22–50)	27 (18–43)
Maximum grip strength	83 (59–98)	72 (56–93)	84 (51–96)
Pressure-pain threshold	47 (38–65)	50 (40–61)	47 (33–62)

Data are number of patients (%) unless otherwise indicated.

Table 1: **Baseline characteristics**

100-point scales to enable a straightforward interpretation and comparison across outcome measures.

Finally, the use of analgesics and all consultations with family doctors, physiotherapists, specialists, and other health-care providers were reported every week in a diary kept by the patient. The diaries were collected and checked by the administrative assistant during each subsequent visit to the research centre. The research physiotherapist was unaware of the allocated intervention. Before every assessment, patients were asked by the administrative assistant not to reveal any information about their treatment. Immediately after every assessment, the research physiotherapist was asked to guess the allocated treatment, and state any reasons for their assumption.

Statistical analysis

We calculated changes in scores over time for every patient by subtracting the results at baseline from those at follow-up. Although absolute scores for most outcome measures were skewed, changes from baseline generally showed a normal distribution. We computed the differences (95% CI) in improvement between the groups. The principal analysis was done on an intention-to-treat basis. Furthermore, we did an alternative analysis, excluding all patients who had not been treated according to protocol. We analysed differences in improvement between the groups for continuous outcomes by means of one-way analysis of variance with SPSS (version 8.0). We studied the potential effect of differences between groups on prognostic indicators at baseline by means of MANOVA for continuous outcomes, and logistic regression for success rates. We used MANOVA for repeated measures to prevent multiple testing and to ascertain differences between the intervention with respect to the course of elbow complaints. We judged p values less than 0·05 as significant.

We based sample-size on the ability to detect a clinically important difference of 25% in success rate between groups

	Wait-and-see policy (n=59)	Corticosteroid injection (n=62)	Physiotherapy (n=64)
No additional treatment	45 (76%)	23 (37%)	12 (19%)
Physiotherapy	4 (7%)	13 (21%)	42 (66%)*
Corticosteroid injection	3 (5%)	21 (34%)	4 (6%)
Elbow support	2 (3%)	6 (10%)	3 (5%)
Pain medication	12 (20%)	17 (27%)	6 (9%)
Ergonomic advice by family doctor	4 (7%)	9 (15%)	2 (3%)
Surgery of elbow	1 (2%)	2 (3%)	0
Cast	0	1 (2%)	0
Complementary medicine	0	2 (3%)	1 (2%)

Data are number of patients (%). *Additional physiotherapy was given for <6 weeks in 38 of 42 patients.

Table 2: **Additional treatments during follow-up (6–52 weeks)**

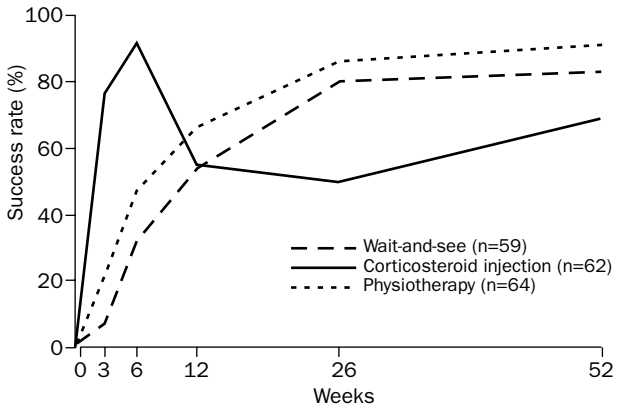

Figure 2: **Success rates of three treatment regimens**

at 6 weeks after randomisation. Assuming a success rate of 40% in the least successful group, the target sample size was estimated at 60 patients per group (two-tailed α=0·05, β=0·20).

Role of the funding source

The sponsors of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between September, 1997, and October, 1998, 259 patients with lateral epicondylitis were referred to a research centre. 185 patients met all selection criteria and were randomly assigned. Figure 1 shows the trial profile. Three patients enrolled should not have been, since they had loss of strength due to stroke (injection group), had previously had a wrist fracture (physiotherapy group), or had had a partial paresis of the ulnaris nerve (wait-and-see group). Of the two patients who withdrew from the study, one had fully recovered and the other was not satisfied with treatment.

Table 1 shows the baseline characteristics of patients. Despite randomisation, there were slight differences between the intervention groups with respect to concomitant neck disorders, previous episodes of lateral elbow pain, maximum grip strength, and presumed

	Wait-and-see policy (n=59)	Corticosteroid injection (n=62)	Physiotherapy (n=64)	Mean differences in improvement (95% CI)			p*
				Injection *vs* wait-and-see	Physiotherapy *vs* wait-and-see	Injection *vs* physiotherapy	
Primary outcome measures							
Main complaint							
3 weeks	6 (14)	43 (28)	11 (18)	37 (29 to 44)	4 (–3 to 12)	32 (25 to 40)	..
6 weeks	21 (32)	46 (30)	26 (28)	24 (14 to 35)	4 (–6 to 15)	20 (10 to 31)	..
12 weeks	33 (30)	37 (30)	43 (31)	4 (–7 to 15)	10 (–1 to 21)	–6 (–17 to 5)	..
26 weeks	47 (30)	36 (34)	53 (31)	–11 (–22 to 1)	6 (–5 to 17)	–17 (–28 to –6)	..
52 weeks	53 (28)	44 (32)	59 (25)	–9 (–19 to 2)	7 (–4 to 17)	–15 (–25 to –5)	<0·0001
Pain during the day							
3 weeks	6 (16)	36 (23)	6 (17)	30 (23 to 36)	–0·1 (–7 to 7)	30 (23 to 37)	..
6 weeks	15 (23)	47 (20)	21 (23)	32 (24 to 40)	6 (–2 to 14)	26 (18 to 34)	..
12 weeks	25 (26)	33 (27)	34 (25)	8 (–1 to 18)	9 (–0·2 to 18)	–0·3 (–10 to 9)	..
26 weeks	34 (26)	27 (26)	41 (27)	–7 (–17 to 2)	7 (–3 to 16)	–14 (–23 to 5)	..
52 weeks	39 (26)	35 (26)	46 (28)	–4 (–13 to 6)	7 (–2 to 17)	–11 (–20 to –2)	<0·0001
Inconvenience							
3 weeks	12 (17)	44 (29)	13 (20)	33 (25 to 41)	1 (–7 to 9)	31 (23 to 39)	..
6 weeks	22 (26)	60 (26)	31 (24)	37 (28 to 46)	8 (–1 to 18)	29 (20 to 38)	..
12 weeks	35 (30)	44 (33)	47 (28)	8 (–3 to 19)	12 (0·6 to 22)	–3 (–14 to 8)	..
26 weeks	47 (31)	38 (36)	56 (28)	–9 (–20 to 2)	9 (–3 to 20)	–18 (–29 to –6)	..
52 weeks	52 (31)	49 (30)	62 (32)	–4 (–15 to 8)	10 (–1 to 21)	–14 (–25 to –3)	<0·0001
Severity of elbow complaints							
3 weeks	8 (13)	27 (20)	6 (17)	19 (12 to 25)	–2 (–8 to 4)	21 (15 to 27)	..
6 weeks	13 (16)	33 (17)	13 (21)	20 (13 to 26)	–0·1 (–6 to 6)	20 (14 to 26)	..
12 weeks	20 (19)	16 (28)	24 (22)	–4 (–12 to 5)	5 (–4 to 13)	–8 (–17 to 0·2)	..
26 weeks	27 (23)	22 (22)	32 (18)	–5 (–12 to 3)	5 (–3 to 13)	–10 (–17 to –2)	..
52 weeks	33 (19)	26 (22)	36 (20)	–7 (–14 to 1)	4 (–3 to 11)	–11 (–18 to –3)	<0·0001
Elbow disability							
3 weeks	4 (12)	29 (21)	6 (17)	25 (18 to 31)	2 (–4 to 8)	22 (16 to 29)	..
6 weeks	11 (18)	38 (19)	16 (20)	27 (20 to 33)	5 (–2 to 12)	21 (15 to 28)	..
12 weeks	22 (20)	24 (22)	29 (21)	2 (–6 to 10)	7 (–1 to 14)	–5 (–12 to 3)	..
26 weeks	33 (21)	22 (24)	36 (20)	–11 (–19 to –3)	2 (–5 to 10)	–14 (–21 to –6)	..
52 weeks	35 (21)	27 (23)	40 (22)	–8 (–16 to 1)	5 (–3 to 13)	–13 (–20 to –5)	<0·0001
Pain–free grip strength							
3 weeks	4 (18)	38 (27)	8 (19)	34 (26 to 42)	4 (–4 to 12)	30 (23 to 38)	..
6 weeks	14 (21)	45 (26)	18 (24)	31 (22 to 39)	4 (–5 to 12)	27 (18 to 35)	..
12 weeks	30 (30)	24 (25)	35 (33)	–6 (–17 to 5)	5 (–5 to 16)	–11(–21 to –0·3)	..
26 weeks	42 (28)	31 (31)	48 (29)	–11(–22 to –0·4)	6 (–5 to 16)	–17 (–28 to –6)	..
52 weeks	51 (24)	37 (40)	61 (26)	–14 (–25 to –3)	10 (–1 to 21)	–24 (–35 to –13)	<0·001
Secondary outcome measures							
Maximum grip strength							
3 weeks	–0·3 (12)	21 (23)	–1 (20)	21 (14 to 28)	–1 (–7 to 6)	22 (15 to 29)	..
6 weeks	3 (18)	24 (26)	9 (23)	21 (13 to 29)	5 (–3 to 13)	15 (7 to 23)	..
12 weeks	10 (24)	14 (27)	17 (26)	4 (–5 to 14)	7 (–2 to 16)	–3 (–12 to 7)	..
26 weeks	18 (25)	17 (28)	23 (25)	–1 (–11 to 8)	4 (–5 to 14)	–6 (–15 to 4)	..
52 weeks	22 (24)	22 (36)	27 (29)	0 (–11 to 11)	5 (–6 to 16)	–5 (–15 to 6)	<0·0001
Pressure pain threshold							
3 weeks	3 (20)	24 (23)	4 (22)	21 (13 to 29)	1 (–7 to 9)	20 (12 to 28)	..
6 weeks	7 (25)	35 (41)	16 (24)	28 (16 to 39)	9 (–2 to 20)	19 (8 to 30)	..
12 weeks	18 (31)	16 (27)	19 (25)	–1 (–11 to 9)	2 (–8 to 12)	–3 (–13 to 7)	..
26 weeks	27 (26)	16 (29)	35 (27)	–11 (–21 to –1)	8 (–2 to 18)	–19 (–29 to –10)	..
52 weeks	40 (36)	27 (33)	38 (30)	–13 (–25 to –1)	–2 (–14 to 10)	–11 (–23 to 0·3)	<0·0001
Patient satisfaction							
6 weeks	67 (25)	90 (16)	82 (14)	23 (15 to 31)	15 (7 to 23)	8 (0·2 to 16)	..
12 weeks	74 (20)	81 (23)	83 (16)	6 (–1 to 14)	9 (2 to 16)	–2 (–9 to 5)	..
26 weeks	76 (24)	78 (23)	84 (20)	2 (–6 to 10)	8 (0·2 to 16)	–6 (–14 to 2)	..
52 weeks	78 (25)	77 (23)	86 (18)	–1 (–9 to 7)	8 (–1 to 16)	–9 (–16 to –1)	..

Data are mean (SD) unless otherwise indicated. *Differences in trend over time between intervention groups.

Table 3: **Improvement in primary and secondary outcome measures**

	Wait-and-see policy (n=59)	Corticosteroid injection (n=62)	Physiotherapy (n=64)
Number of patients reporting adverse effects	10 (17%)	36 (58%)	41 (64%)
Increased pain ⩽1 day	1 (2%)	6 (10%)	9 (14%)
Increased pain >1 day	1 (2%)	10 (16%)	11 (17%)
Radiating pain to forearm or upper arm	7 (12%)	17 (27%)	27 (42%)
Facial flush	0	2 (3%)	0
Skin irritation	0	3 (5%)	3 (5%)
Red swollen elbow	0	2 (3%)	3 (5%)
Change of skin colour	0	7 (11%)	3 (5%)
Other minor or temporary adverse reactions	1 (2%)	8 (13%)	17 (27%)

Data are number of patients (%).

Table 4: **Adverse reactions during 6-week intervention period**

precipitating cause. Differences in these prognostic variables had little effect on outcome of analyses. We therefore present the unadjusted analysis.

In the group treated with a wait-and-see policy, 20 patients (34%) took pain medication during the intervention period (seven paracetamol and 15 NSAIDs). 17 patients (27%) in the injection group received two injections, nine (15%) received three injections. The median amount of liquid injected increased from 0·9 mL (IQR 0·5–1·4) for the first dose to 1·5 mL (1·0–1·5) for the third. Ten patients (16%) took pain medication (six paracetamol and five NSAIDs). Physiotherapy consisted of eight sessions of about 30 min in most patients. Ten patients (16%) took pain medication (seven paracetamol and seven NSAIDs). NSAIDs were generally prescribed by the family doctor.

Only 14 (24%) patients in the wait-and-see group received additional treatment for elbow complaints during the 1-year follow-up, compared with 39 (63%) in the injection group and 52 (81%) in the physiotherapy group (table 2). Many patients allocated to physiotherapy continued their treatment after the intervention period, but this lasted for less than 6 weeks in most cases.

Figure 2 shows the success rates at all assessments. At 6 weeks, success was reported by 57 (92%) patients in the injection group, 30 (47%) in the physiotherapy group, and 19 (32%) in the wait-and-see group. However, the beneficial effects of corticosteroid injections were only seen at short-term follow-up. At 52 weeks, success rates were 69% (43) for injections, 91% (58) for physiotherapy, and 83% (49) for the wait-and-see policy.

At 6 weeks, significant differences in favour of corticosteroid injections were seen for all primary and secondary outcomes. By contrast, at 26 and 52 weeks, significant differences for nearly all outcome measures were noted in favour of physiotherapy compared with injections (table 3). Physiotherapy also showed better results compared with the wait-and-see policy, but these differences were small (between 5% and 10%), and not significant. The long-term outcome of the wait-and-see policy was also better than injections, but most differences were small (<12%) and not significant for most outcome measures.

MANOVA for repeated measures showed that the course of symptoms was very different across intervention groups for all outcome measures ($p<0·0001$). The course of the severity of pain, elbow disability, severity of symptoms, grip strength, and pressure pain threshold concur with the results reported for success rate.

We did an alternative analysis in which we excluded 21 patients who were not treated according to protocol (figure 1) and three patients who were incorrectly enrolled. The results of the alternative analysis were much the same as those of the intention-to-treat analysis. The success rates at 6 weeks were 92% (55) for injections, 48% (21) for physiotherapy, and 33% (19) for the wait-and-see policy.

Although 87 (47%) patients reported adverse reactions, most were mild (table 4). Increased pain after treatment, and radiating pain were reported more frequently for physiotherapy and injections than for the wait-and-see policy. The frequency of other presumed adverse effects, such as facial flushes or skin irritations, was low, and similar for injections and physiotherapy. For six patients allocated to physiotherapy, the intensity of therapy was adjusted because of adverse reactions.

At 6 weeks, the research physiotherapists correctly guessed the allocated treatment in 94 of 181 patients. Correct guesses were made for 29 patients (50%) in the injection group, 24 (38%) in the physiotherapy group, and 41 (72%) in the wait-and-see group. A slip of the tongue by the patient disclosed allocation in 17 instances. In 41 of 181 instances, the guess was based on the course of symptoms during the intervention period, and was correct for 26 patients. In 115 patients, the physiotherapists just took a guess, which turned out to be correct in 45 instances.

Discussion

Our results suggest that corticosteroid injections are the best treatment option in the short-term for patients with lateral epicondylitis. The differences compared with physiotherapy and a wait-and-see policy were large, clinically relevant, and consistent for all outcome measures. However, these beneficial effects only persisted for a short time. At long-term follow-up, our findings suggest that physiotherapy becomes the best option, followed by a wait-and-see policy.

The poor results of corticosteroid injections after 12 weeks might seem surprising. However, results of two other trials[28,29] also indicated poor long-term outcomes for corticosteroid injections compared with alternative conservative treatments for epicondylitis, although the differences were not as large or consistent as those seen in our trial. We believe that the poor long-term outcome of corticosteroids is associated with a high frequency of additional treatment after 6 weeks. The high number of relapses and recurrences (23, 37%) could be explained in a couple of ways. First, corticosteroid injections might be harmful to the tendon, although reported adverse reactions were generally mild. Second, patients might not have followed the advice given by their family doctor, and might have overtaxed their elbow after receiving an injection.

Our trial was done in a primary-care setting. Selection bias was prevented by use of a strictly organised selection and randomisation procedure. Furthermore, drop-out rate was kept to a minimum (<2%, 2). However, in a pragmatic trial, comparing different types of interventions, implementation of a blinded and unbiased assessment of outcome is difficult. The research physiotherapists were aware of the treatment being received by patients in some instances, and the frequency of disclosure was not wholly consistent across interventions. However, the clues for guessing the assigned treatment were often the results of examination (course of symptoms), which could indicate that the assessment of outcome measures itself (as part of the examination) was not greatly affected.[30] Furthermore, before randomisation, patients were asked about their preferences with respect to treatment, because this could have affected their assessment of treatment efficacy. A large number of patients indicated a preference for physiotherapy, but these preferences showed little effect on outcome.

The pragmatic design of our study enhances the possibilities for generalisation of its findings to everyday

care. However, not all eligible patients with epicondylitis were referred to a research centre and enrolled in the trial. When asked about the reasons for not referring patients, family doctors indicated that exclusion criteria were important, but that busy office hours or forgetfulness were the main reasons for missed cases. We therefore feel that the external validity of our findings was not substantially threatened by inadequate patient referral. Furthermore, although consistent with Dutch national guidelines for epicondylitis, the maximum number of injections (three) in our trial might be somewhat higher than usual in primary care. Finally, we excluded patients with a symptom duration less than 6 weeks, since we felt that corticosteroid injections or physiotherapy might not be indicated in these individuals.

In view of our results, we have no reason to believe that awaiting spontaneous recovery will not be adequate treatment for patients with a short duration of symptoms at presentation. Patients should be properly informed about the advantages and disadvantages of the treatment options for lateral epicondylitis. If individuals prefer quick relief of symptoms, a corticosteroid injection might be suitable, but the long-term outcome can be poor. A wait-and-see policy, with adequate advice and pain medication if needed, will often suffice. The highest probability of recovery after 6 months, however, was associated with physiotherapy, but differences compared with the wait-and-see policy were small. Whether or not the surplus value of physiotherapy is worth the additional resources needed for treatment is debatable.

Contributors

N Smidt planned and coordinated data collection, analysed data, and wrote the report. W J J Assendelft designed the trial. W J J Assendelft and D A W M van der Windt supervised the planning, coordination, and collection of data. W L J M Devillé provided statistical advice and assisted with analysis and interpretation of data. I B C Korthals-de Bos participated in data collection. L M Bouter contributed to design of the trial, discussed ideas, and chaired the supervisory committee.

Conflict of interest statement

None declared.

Acknowledgments

We thank Marianne Koridon, Michel van Aarst, Anneke Mourits, and Samyra Keus for their work during data collection; all participating general practitioners and physiotherapists; and Jan Mens, Gerard Koel, Piet Schoonheim, and Jan Verhaar for their advice in the planning phase of the trial. The work was funded by Health Insurance Council (Fund for Investigative Medicine) and the Netherlands Organisation for Scientific Research.

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