Economic evaluation favours physiotherapy but not corticosteroid injection as a first-line intervention for chronic lateral epicondylalgia: evidence from a randomised clinical trial

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▸ Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/bjsports-2015-094729).

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Accepted 13 May 2015
Published Online First 2 June 2015

ABSTRACT

Aim To determine the cost-effectiveness of corticosteroid injection, physiotherapy and a combination of these interventions, compared to a reference group receiving a blinded placebo injection.

Methods 165 adults with unilateral lateral epicondylalgia of longer than 6 weeks duration from Brisbane, Australia, were randomised for concealed allocation to saline injection (placebo), corticosteroid injection, saline injection plus physiotherapy (eight sessions of elbow manipulation and exercise) or corticosteroid injection plus physiotherapy. Costs to society and health-related quality of life (estimated by EuroQol-5D) over the 1 year follow-up were used to generate incremental cost per quality-adjusted life year (QALY) ratios for each intervention relative to placebo.

Results Intention-to-treat analysis was possible for 154 (93%) of trial participants. Physiotherapy was more costly, but was the only intervention that produced a statistically significant improvement in quality of life relative to placebo (MD, 95% CI 0.035, 0.003 to 0.068). Similar cost/QALY ratios were found for physiotherapy ($A29 343; GBP18 962) and corticosteroid injection ($A31 750; GBP20 518); however, the probability of being more cost-effective than placebo at values above $A50 000 per quality-adjusted life year was 81% for physiotherapy and 53% for corticosteroid injection. Cost/QALY was far greater for a combination of corticosteroid injection and physiotherapy ($A228 000; GBP147 340).

Summary Physiotherapy was a cost-effective treatment for lateral epicondylalgia. Corticosteroid injection was associated with greater variability, and a lower probability of being cost-effective if a willingness to pay threshold of $A50 000 is assumed. A combination of corticosteroid injection and physiotherapy was ineffective and cost-ineffective. Physiotherapy, not corticosteroid injection, should be considered as a first-line intervention for lateral epicondylalgia.

Trial registration number anzctr.org Trial identifier: ACTRN12609000051246.

INTRODUCTION

Lateral epicondylalgia (LE),[1] a common musculoskeletal condition, also known as tennis elbow, typically presents in the fourth to sixth decade of life, and results in considerable individual morbidity and substantial healthcare utilisation and lost time from work. It accounts for an estimated 0.3–1.1 medical consultations per year per 100 subjects of general practice,[2] while work absenteeism is documented for 5% of the affected working adults, with a median duration of 29 days in the past 12 months.[3]

There are no UK or Australian national guidelines or literary consensus for the optimal management of LE. Corticosteroid injection remains in widespread use,[4] despite systematic review evidence showing worse outcomes in the long term compared to a 'wait and see' approach or physiotherapy.[5] Inconsistent long-term clinical benefits of physiotherapy are observed,[6 7] raising debate as to whether the surplus value of physiotherapy is worth the additional resources needed for treatment. On this basis, clinical guidelines were issued by the Dutch College of General Practitioners in 1997 recommending a wait and see policy, including advice and prescription of pain medication if necessary. More recently, guidelines were issued by the Swedish Counsel on Health Technology Assessment, strongly arguing against the use of corticosteroid injection.[8]

The cost-effectiveness of competing therapeutic interventions for LE has been the subject of only two previous studies, both finding no significant differences.[9 10] A limitation of both of these trials was that the utilities that were used to generate cost-effectiveness ratios were derived from quality of life scores estimated at 1 year from baseline, whereas the costs were calculated over the entire 1 year period. This risks measurement error in the cost-effectiveness analysis denominator by assuming that the health state over the preceding 12 months was equal to that observed 1 year from baseline.

We aimed to determine the cost-effectiveness of corticosteroid injection, physiotherapy and their combination by comparison with a reference group receiving placebo injection.

METHODS

Study design

Economic evaluation was conducted alongside a randomised controlled trial, performed in a community setting in Brisbane, Australia. Full details of the trial design, participants, interventions and results of clinical outcomes are reported elsewhere.[11 12] The factorial-design trial was powered to explore the long-term clinical efficacy of (1) corticosteroid versus placebo injection and (2) of adding physiotherapy to an injection. Differences in the analysis and reporting of clinical efficacy and economic evaluation are a reflection of the different research objectives.

To cite: Coombes BK, Connelly L, Bisset L, *et al. Br J Sports Med* 2016;**50**:1400–1405.

Study funding was received from the National Health and Medical Research Committee (Grant 511238), and a University of Queensland Research Scholarship awarded to BKC. Ethical approval was gained from University of Queensland Medical Research Ethics Committee. Trial registration anzctr.org (#12609000051246).

Patients

Patients responding to media announcements between August 2008 and May 2010 were assessed for eligibility by telephone interview, followed by physical screening. Individuals were required to be 18 years or older and have experienced unilateral, lateral elbow pain for more than 6 weeks. A minimum pain intensity of 30 mm on a 100 mm visual analogue scale (VAS) was chosen to minimise floor effects and to ensure those with very mild pain were not subjected to unnecessary treatment. A clinical diagnosis of LE was defined as pain provoked by at least two of the following: gripping, palpation, resisted wrist or middle finger extension or stretching of wrist extensor muscles with reduced pain-free grip. Patients were excluded if they had received any injection (preceding 6 months), a course of physiotherapy (preceding 3 months); concomitant neck or arm pain necessitating treatment or limiting usual activities (preceding 6 months); radicular, neurological or systemic symptoms; pregnancy; breastfeeding or contraindication to injection.

Interventions

Following written informed consent, 165 patients were randomly allocated by concealed allocation to one of four groups —saline injection ('placebo'), saline injection plus physiotherapy ('physiotherapy'), corticosteroid injection ('corticosteroid') or corticosteroid injection plus physiotherapy ('combination'). Randomisation was stratified by high or low pain scores, based on a cut-off VAS of 65/100. One of five general practitioners injected either 0.5 mL(0.9%) isotonic saline (placebo) or 10 mg/1 mL of triamcinolone acetonide plus 1 mL(1%) lignocaine (corticosteroid), in a manner that ensured the participant was blinded to the contents of the syringe. A previous dose–response study demonstrated similar results for 10 mg triamcinolone compared to a higher dose (20 mg), but with lower rates of skin atrophy (18% compared to 27%).[13] Patients received standardised advice recommending rest for 10 days, followed by gradual return to activity. They were discouraged from using other treatments, but were advised they could use over-the-counter analgesic or anti-inflammatory medication, forearm braces or heat or cold packs as needed.

Participants allocated to receive physiotherapy underwent eight 30 min sessions of treatment from one of the 11 postgraduate physiotherapists. Treatment was individually prescribed based on a standardised protocol.[12] It included manual therapy techniques at the elbow with gripping, concentric and eccentric wrist extension exercises, motor control retraining and global upper body strengthening. Each participant was asked to complete a daily home exercise programme, which was reviewed by the physiotherapist at the start of each session to monitor compliance and to progress the programme.

Resource utilisation and costing

A societal viewpoint was used as the basis for economic evaluation, and as such included direct healthcare and non-healthcare costs, and indirect costs incurred due to LE, its treatment or any adverse events related to its treatment.[9] Costs for the 1 year study period were derived from the following three sources and are reported in 2013 Australian dollars (1 \$A =0.64623 GDP, January 2013). Utilisation of study treatments was ascertained from medical records. Costs of medical services, including both government subsidies and patient copayments were obtained from the Medicare Australia database for the 1 year follow-up period. Items listed as elbow, forearm or upper limb were included in the analysis. All other resources/costs were collected via standardised telephone interviews[14] administered by a research assistant blinded to health outcomes. At each of four randomly timed interviews, resources/costs incurred during the preceding month were recorded and multiplied by three to generate annual costs. Where actual costs incurred were not available, costs were estimated as listed in table 1.

Quality of life

Health-related quality of life was measured at baseline, 4, 8, 12, 26 and 52 weeks using the paper-based EuroQol-5D (EQ-5D) by an examiner blinded to treatment allocation.[9] Responses were converted to an overall utility score, by applying scoring weights based on the UK population.[15] Quality-adjusted life years (QALYs) were estimated for each individual using area-under-the-curve analysis with linear interpolation between observations.[16]

Statistical analysis

Sample size was based on primary clinical effects of corticosteroid injection and physiotherapy at 1 year.[11 12] Economic analysis was performed by intention-to-treat. As only one participant reported work absence, costs related to this were excluded for the base case analysis. Discounting was not applied, as the study duration was only12 months.

Incremental costs and incremental QALYs (and 95% CI) were computed using generalised linear modelling (GLM) bias-corrected and accelerated bootstrapping with 2000 replications, with increments calculated as the intervention group value minus the placebo group value. Models were adjusted for baseline Patient Rated Tennis Elbow Evaluation (PRTEE) scores because of prognostic significance.[17] Adjustment for baseline utilities was also performed for estimation of incremental QALYs.[16] The primary outcome was the incremental cost-effectiveness ratio (ICER), calculated by dividing the incremental cost by the incremental QALY. Uncertainty was explored by graphical display of cost-utility planes and acceptability curves.[18] Since cost-effectiveness analysis is a relative technique, we also compared our results to a theoretical ICER threshold of \$A 50 000 per QALY, consistent with previous studies.[19]

Three sensitivity analyses were performed to test the robustness of assumptions. First, we tested the impact of including work absence. Second, we tested by excluding all productivity costs, as inclusion of lost productivity as a cost is considered controversial.[20] Third, we tested the effect of alternative calculation of medical costs, using self-reported costs/resources.

Statistical analysis was performed using STATA V.13.1 for Mac (StataCorp, 2014), and cost-utility planes and acceptability curves were generated using Excel for Mac 14.4.5 (Microsoft, 2011).

RESULTS

The flow of participants leading to economic analysis of 154 (93%) participants is illustrated in figure 1. There were no significant differences at baseline between participants included (n=154) and excluded (n=11) from the analysis. Per protocol resources were available for all participants, while 3.9% of interviews (25/644) were missing, with no differences between treatments or between survey periods. Six people missed a single

Table 1 One-year costs to society and QALYs

Resource	Data source	Placebo	Physiotherapy+Placebo	Corticosteroid	Corticosteroid +Physiotherapy	p Value
Direct healthcare costs (total)		\$101 (5)	\$673 (102)	\$159 (245)	\$636 (143)	<0.001*
Per protocol medical	\$100/visit†	\$100 (0)	\$100 (0)	\$100 (0)	\$100 (0)	NA
Per protocol physiotherapy	\$75/visit†	–	\$569 (97)	–	\$515 (118)	0.031*
Non-protocol medical (MBS)	Real costs‡	\$1 (5)	\$0 (0)	\$20 (49)	\$7 (25)	0.008*
Non-protocol other	Real costs§	\$0 (0)	\$4 (26)	\$39 (215)	\$14 (58)	0.42
Direct non-healthcare costs (total)		\$34 (108)	\$144 (169)	\$78 (204)	\$100 (32)	0.01*
Over the counter medication	Real costs§	\$3 (11)	\$3 (13)	\$19 (38)	\$4 (16)	0.004*
Assistive devices (eg, brace, ultrasound, hotpack)	Real costs§	\$0 (0)	\$11 (33)	\$37 (161)	\$0 (0)	0.168
Paid or unpaid labour	\$36.33/h§, ¶	\$18 (108)	\$23 (122)	\$0 (0)	\$0 (0)	0.481
Per protocol transportation	\$0.63/km§, ††	\$13 (0)	\$106 (15)	\$13 (0)	\$94 (19)	<0.001*
Non-protocol transportation	\$0.63/km§, ††	\$0 (0)	\$0.2 (1.5)	\$9 (34)	\$2 (9)	0.059
Indirect costs (total)		\$38 (0)	\$360 (57)	\$157 (626)	\$333 (75)	0.001*
Time loss due to work absence	Individual rate§, ‡‡	\$0 (0)	\$0 (0)	\$99 (627)	\$0 (0)	0.419
Per protocol leisure time loss	\$36.33/h§, §§	\$38 (0)	\$358 (54)	\$38 (0)	\$327 (66)	<0.001*
Non-protocol leisure time loss	\$36.33/h§, §§	\$0 (0)	\$2 (13)	\$20 (54)	\$6 (25)	0.017*
Societal costs excluding work absence		\$173 (108)	\$1177 (251)	\$295 (372)	\$1069 (244)	<0.001*
Societal costs (total)		\$173 (108)	\$1177 (251)	\$394 (708)	\$1069 (244)	<0.001*
QALYs		0.880 (0.092)	0.920 (0.075)	0.873 (0.078)	0.891 (0.084)	0.069

Values represent mean (SD) per participant for each group. Costs are in \$A. Differences between groups were examined using Analysis of Variance, with significant (<0.05) differences marked by an asterisk.
†Rate paid to practitioners taking part in the study.
‡Costs determined by Medicare Benefits Schedule (MBS) items listed as either elbow, forearm or upper limb.
§Resources/costs derived from interview, multiplied by three to give annual estimates.
¶Shadow price based on average weekly earnings for an adult (\$1453 per 40 h/week) from the Australian Bureau of Statistics (2012).
††Mean travel distances for medical (19.9 km) and physiotherapy appointments (18.9 km) were multiplied by \$0.63/km, based on private vehicle reimbursement rate by the Australian Taxation Office (2011), plus any other out-of-pocket transport costs.
‡‡Total days of work absence were multiplied by the respondent-specific hourly rate.
§§Mean (appointment plus travel) times per session for medical (62.4 min) and physiotherapy (69.5 min).
MBS, Medicare Benefits Schedule; NA, not applicable; QALYs, quality-adjusted life years.

interview and estimates were replaced using the mean of their three completed interviews. Five people did not complete any of the interviews and were excluded from the analysis. Medical Benefit Schedule data was missing or ineligible for 5% participants, because of international residence (n=5), non-consent (n=1) or invalid paperwork (n=3). Quality of life estimates were missing for 2.4% individuals, because of death (n=2) or loss to follow-up (n=2) and were excluded from analysis. Demographic and injury characteristics did not differ between groups at baseline (table 2).

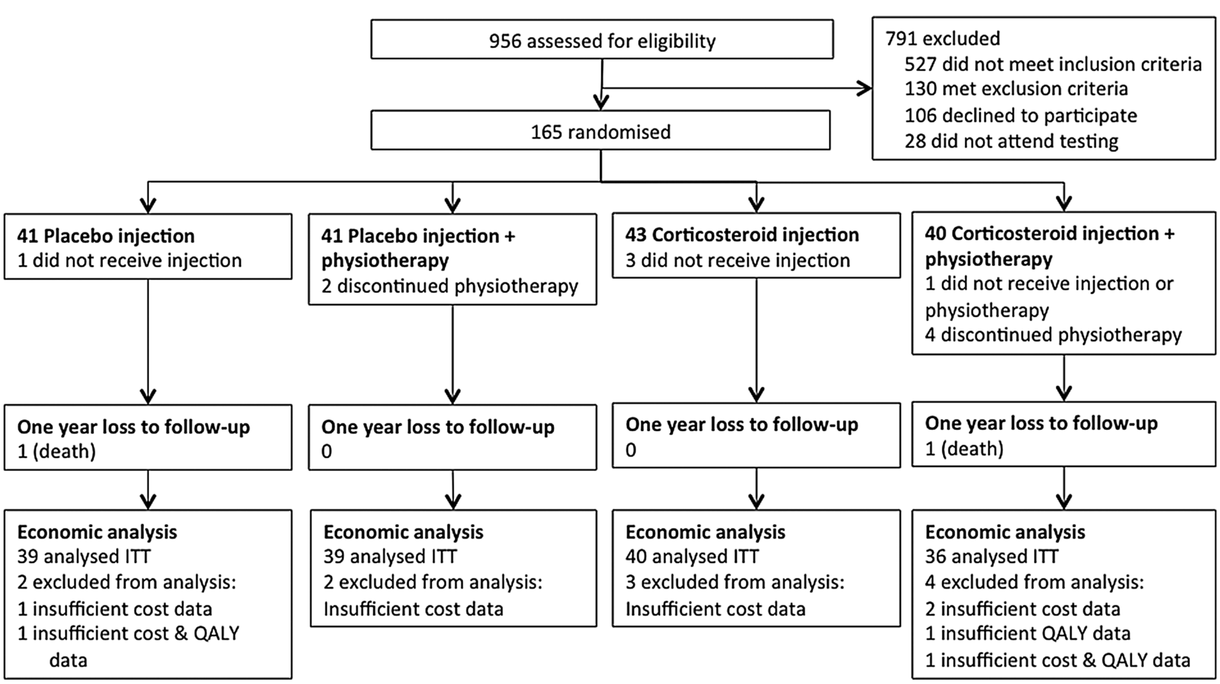

Figure 1 Flow of participants from randomisation to economic analysis of 154 (93%) participants by intention to treat (ITT). QALY, quality-adjusted life years.

Table 2 Baseline characteristics

Characteristic	Placebo	Physiotherapy+placebo	Corticosteroid	Corticosteroid+physiotherapy	p Value
Analysed, n	39	39	40	36	
Age, years	49.8 (7.5)	48.9 (7.7)	49.7 (9.0)	50.7 (8.6)	0.813
Female, n (%)	15 (38)	14 (36)	15 (38)	14 (39)	0.993
Duration (median (IQR), weeks)	16 (8,32)	16 (8, 26)	16 (10, 28)	13 (10, 26)	0.217
Worst pain (VAS: 0–100)	62.0 (19.7)	63.0 (18.3)	61.6 (19.4)	59.3 (15.8)	0.844
Resting pain (VAS: 0–100)	13.9 (16.1)	7.9 (9.2)	11.9 (16.1)	9.7 (10.3)	0.225
Pain and disability (PRTEE: 0–100)	42.2 (14.5)	36.4 (13.1)	41.1 (13.8)	38.2 (12.9)	0.224
Quality of life (EQ-5D: 0–1)	0.737 (0.122)	0.744 (0.125)	0.692 (0.175)	0.755 (0.036)	0.139
Annual income ($A)	77 390 (51 843)	65 031 (46 171)	57 439 (37 453)	65 135 (39 549)	0.253
Nil income, n (%)	4 (10)	4 (10)	2 (5)	1 (3)	0.448

Data represents mean (SD) or count (%), unless otherwise stated. Differences between groups were analysed using Analysis of Variance or Pearson χ^2 statistic.
PRTEE, Patient-rated tennis elbow evaluation; EQ-5D, Euroqol questionnaire.

Costs

Mean costs per individual (excluding work absence) for each group were: $173 for placebo, $295 for corticosteroid, $1177 for physiotherapy plus placebo and $1069 for corticosteroid plus physiotherapy (table 1). Incremental costs showed that all interventions were significantly more costly than placebo (table 3; p<0.035). Baseline pain and disability (PRTEE score) was a significant independent predictor of societal costs, with greater costs incurred by individuals with higher pain and disability at baseline (β 4.0, 95% CI 0.3 to 7.6; p=0.034). No participants required surgery or prescribed medication.

The major contributors to direct healthcare costs, productivity costs and travel expenses were physiotherapy driven. Participants assigned to physiotherapy plus placebo completed an average of 7.6 sessions (range 1–9), while significantly (p=0.031) fewer sessions were completed by those assigned to corticosteroid plus physiotherapy (mean 6.9, range 2–9). Non-protocol medical costs (derived from Medicare database) and over-the-counter medication costs also differed between groups, with higher costs incurred by participants assigned to corticosteroid injection. Costs of other appointments, not listed by the Medicare, such as shockwave therapy, physiotherapy, chiropractic and massage, were also highest in participants assigned to corticosteroid although differences did not reach significance.

Quality of life

Utilities estimated over the 1 year follow-up for the four interventions ranged from 0.873 to 0.920 (table 1). Incremental QALYs (table 3) showed significantly greater benefit for physiotherapy plus placebo (p=0.032), but not for corticosteroid (p=0.746) or corticosteroid plus physiotherapy (p=0.743) when compared to placebo. Baseline EQ-5D was a significant independent predictor of 1 year QALY (β 0.25, 95% CI 0.13 to 0.37; p<0.001).

Cost-effectiveness

Incremental cost/QALY ratios were $29 343 for physiotherapy plus placebo, $31 750 for corticosteroid and $228 000 for

Table 3 Incremental costs and incremental QALY for physiotherapy, corticosteroid injection and their combination, compared to a reference group receiving placebo injection

	Physiotherapy+placebo	Corticosteroid	Corticosteroid+physiotherapy
Incremental QALY (95% CI); p value	0.035 (0.003 to 0.068)*	0.004 (−0.030 to 0.039)	0.004 (−0.032 to 0.041)
Base case—societal costs excluding work absence			
Incremental cost (95% CI)	$1027 (941 to 1113)*	$127 (9 to 245)*	$912 (822 to 1002)*
Cost per QALY (ICER)	$29 343	$31 750	$228 000
Probability ICER <$50 000†	81%	53%	24%
Sensitivity 1—societal costs inclusive of work absence			
Incremental cost (95% CI)	$1027 (941 to 1113)*	$226 (5 to 447)*	$912 (822 to 1002)*
Cost per QALY (ICER)	$29 343	$56 500	$228 000
Probability ICER <$50 000†	81%	48%	24%
Sensitivity 2—direct healthcare and non-healthcare costs, that is, productivity costs excluded			
Incremental cost (95% CI); p value	$702 ($627 to 776)*	$106 (2 to 209)*	$615 (545 to 684)*
Cost per QALY (ICER)	$20 057	$26 500	$153 750
Probability ICER <$50 000 †	90%	53%	34%
Sensitivity 3—medical costs derived from interview			
Incremental cost (95% CI); p Value	$1028 (940 to 1116)*	$182 (6 to 359)*	$905 (817 to 994)*
Cost per QALY (ICER)	$29 371	$45 500	$226 250
Probability ICER <$50 000 †	81%	50%	24%

CIs were calculated using generalised linear modelling with bias corrected bootstrapping (2000 replicates), adjusted for baseline scores of pain and disability, using the Patient rated tennis elbow evaluation. Incremental QALY was adjusted for baseline EQ-5D utilities. Significant (p<0.05) differences compared to placebo are marked with an asterisk. ICER: Incremental cost-effectiveness ratio calculated as incremental cost divided by incremental quality-adjusted life year.
†Probability that the intervention is more cost-effective than placebo at an ICER threshold of $A50 000.
ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life years.

corticosteroid plus physiotherapy (table 3). Cost-utility planes and acceptability curves are illustrated in figures 2A–C and 3 respectively. For physiotherapy plus placebo, increased costs and increased benefits were seen (figure 2A). For both corticosteroid and corticosteroid plus physiotherapy groups, bootstrapped cost-utility pairs straddled the northern quadrants, indicating increased costs but considerable uncertainty regarding the health benefits. For corticosteroid injection, a small minority (1%) of cost-utility pairs were located in the southeast quadrant, indicating cost saving and increased effectiveness compared to placebo (figure 2B). At a threshold of \$50 000/QALY, the probability of being more cost-effective than placebo, was 81% for physiotherapy plus placebo, 53% for corticosteroid and 24% for corticosteroid plus physiotherapy (figure 3). Thus, at this threshold, physiotherapy was more likely to be cost-effective than the alternatives.

Sensitivity analysis

Inclusion of costs associated with work absence increased the incremental cost/QALY to \$56 500 for corticosteroid, while the probability of being cost-effective at the \$50 000 threshold fell to 48%. When all productivity costs were excluded, cost/QALY fell for all groups to \$20 057 for physiotherapy plus placebo, \$26 500 for corticosteroid and \$153 750 for the combination intervention. Probabilities rose to 90% and 34% for physiotherapy plus placebo and corticosteroid injection plus physiotherapy, respectively, while this was unchanged (53%) for the corticosteroid group. Alternative analysis of medical costs showed similar cost/QALY estimates for physiotherapy plus placebo (\$29 371) and corticosteroid plus physiotherapy (\$226 250), with no change in their probabilistic estimates. However, self-reported data produced greater cost/QALY (\$45 500) and lower probability (50%) for corticosteroid.

DISCUSSION

Rigorous research relating to cost-effectiveness of treatments in sports medicine is a nascent field.[21] The cost-effectiveness of a single corticosteroid injection, 8 weeks of physiotherapy and a combination of the two interventions were each compared with a reference group receiving a blinded, placebo injection. Physiotherapy had greater initial costs due to eight treatment sessions, but was the only intervention that resulted in significantly greater quality of life. Corticosteroid injection demonstrated considerable variability in quality of life benefits over 1 year and higher non-protocol costs. Corticosteroid plus physiotherapy produced both high costs and considerable variability in outcomes.

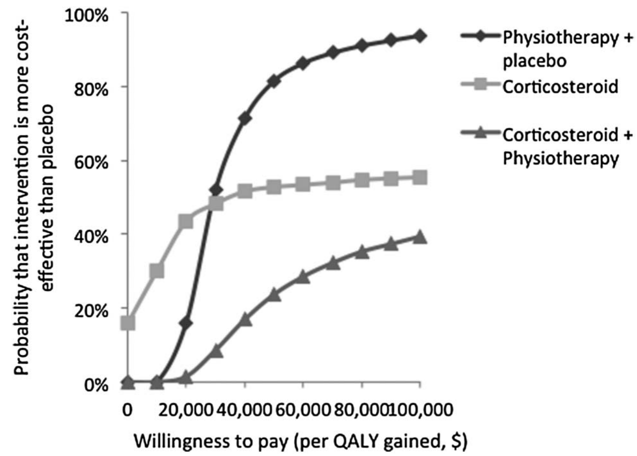

Figure 3 Incremental cost-effectiveness acceptability curves for corticosteroid, physiotherapy or their combination, compared to the reference placebo group. For the base-case analysis presented here, costs to society, excluding work absence were used. Costs are reported in 2013 Australian dollars (\$1A=0.64623GDP, January 2013). QALYs, quality-adjusted life years.

Potential economic impact if implemented as policy

The resultant incremental cost/QALY ratios ranged from \$A 20 057 to 29 371 (GDP 12 961–18 980) for physiotherapy and from AUD 26 500 to 56 500 (GBP 17 125–36 512) for corticosteroid injection. Placed in perspective, these willingness to pay per QALY values would be unlikely to be rejected by the Australian Pharmaceutical Benefits Advisory Committee (PBAC)[22] or UK National Institute of Health and Care Excellence (NICE)[23] and would be considered *highly* cost-effective by the WHO (<1×GPD per capita).[24] (Australia's GDP per capita in 2013 was AUD 75 348). In contrast, cost/QALY ratios for corticosteroid injection plus physiotherapy ranged from \$A 153 750 to 228 000 (GDP 99 358–147 340), and would be considered *not* cost-effective, based on WHO (>3×GDP per capita),[24] PBAC[22] or NICE[23] guidelines.

Probabilistic sensitivity analyses suggest that physiotherapy is highly likely (81–90%) to be considered a cost-effective intervention for LE when a threshold of \$A 50 000 or greater is applied. In comparison, we found much greater uncertainty (48–65% probability) as to whether corticosteroid injection provides better value for money than placebo.

The results of this study have important implications for health economic policy. Conclusions are in agreement with a large body

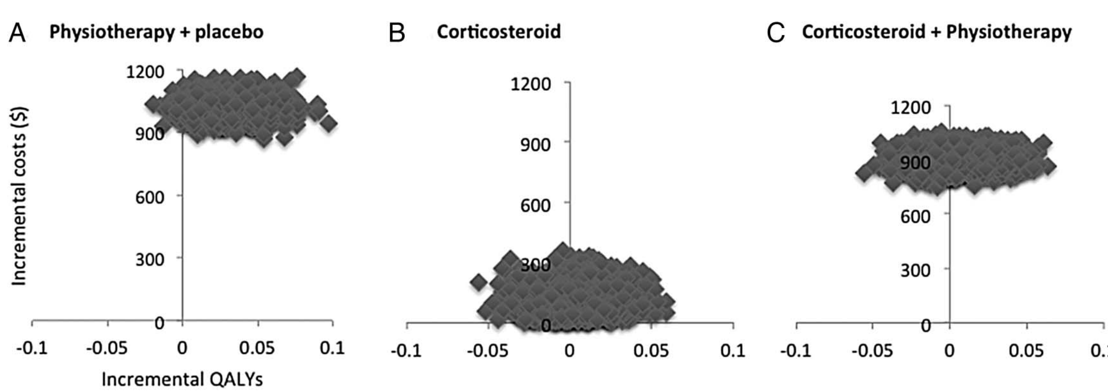

Figure 2 Cost-utility planes for corticosteroid injection, physiotherapy or their combination, compared to the reference placebo group. Data represents 2000 bootstrapped cost and effect pairs. For the base-case analysis presented here, costs to society (\$A), excluding work absence were used. QALYs, quality-adjusted life years.

of clinical evidence[5–7] that states corticosteroid injection should not be recommended as a first-line intervention for LE. Given that 48% of surveyed UK specialists continue to use corticosteroid injection as a first-line intervention for LE, and half stated they had not changed their practice in light of recent evidence, it appears penetrance of the latest evidence remains poor.[4 25]

Economic analysis alongside another randomised controlled trial conducted in the Netherlands estimated the societal cost/QALY for a 6-week physiotherapy programme consisting of ultrasound, massage and exercise to be €34 000 compared to a 'wait and see' approach.[9] Analysis of uncertainty showed 55% of cost-utility pairs were located in the northeast quadrant, indicating physiotherapy produced greater costs and QALYs, while 12% were located in the southeast quadrant indicating cost saving and improved QALY. Corticosteroid injection was less costly, but also less effective than wait and see, with a resulting cost/QALY of approximately €7000. There are likely several potential sources of heterogeneity when comparing the cost-effectiveness of interventions between these trials. Differences in physiotherapy protocols and the reference group studied, as well as differences in recruitment and healthcare settings, may influence findings. The Dutch trial recruited patients who had visited a general medical practitioner for their elbow condition, while our trial recruited participants from the general community. We found much lower self-reported work absence than other published reports,[3 9 10] which may be in part due to our study eligibility requirements where participants were excluded if they had received treatments for their elbow within the preceding 6 months. Methodological differences between the two trials should also be considered. Korthals de Bos *et al*[9] compared costs incurred over 1 year with quality of life estimated at 1 year from baseline and hence, may not have captured the early benefits of treatments.

Strengths and limitations

The strengths of our trial are its methodological rigour, comprehensive estimation of costs and low missing data (<5%). To minimise recall bias, as well as burden on participants and researchers, we randomly sampled participants four times over 1 year, asking them to recall resources/costs over the previous month.[26] Several sources were used to determine costs as there is no gold standard measurement.[26] Sensitivity analysis was used to examine the agreement between self-reported and administrative (Medicare) data. A limitation of data from the Medicare Benefits Schedule is that general practitioner and specialist services for LE cannot be distinguished from those for other conditions. Radiology services could be distinguished by their item codes, allowing only those listed as upper limb or forearm to be included in cost estimations. This may have led to conservative estimation of the utilisation of LE-related medical services. Sensitivity analysis using medical costs derived from interview resulted in a higher cost/QALY estimate for corticosteroid injection, but did not change those for physiotherapy or corticosteroid plus physiotherapy. We also evaluated the impact of productivity losses, by excluding the opportunity cost of lost leisure time. While cost/QALY estimates improved for all interventions, study conclusions were robust to the different perspective.

Several caveats should be noted that might affect the generalisability of study findings. In this trial, incremental costs and benefits for each intervention were each compared with a reference group that received a blinded injection of a negligible volume of normal saline, as well as standardised advice and analgesic medication. Although a placebo injection is not consistent with either usual care or a 'wait and see' policy, the pattern of recovery of primary clinical outcomes appears very similar.[6 7] Second, due to the nature of the physiotherapy intervention, it was not possible to blind the physiotherapists and patients, which may have introduced a bias although both were blinded to the injection received. Third, costs could probably be reduced and cost-effectiveness potentially improved by reducing the number of physiotherapy sessions. Our protocol recommended eight sessions of physiotherapy, while others have used six.[6] Reducing the number of sessions reduces direct healthcare and non-healthcare costs, as well as opportunity costs from lost leisure time. Further research is needed to ascertain whether similar benefits can be achieved with fewer treatment sessions. Last, societal costs were found to be independently associated with baseline pain and disability, a known prognostic risk factor.[17 27] Future research should consider whether allocation to a wait and see policy or physiotherapy treatment based on risk of chronicity may allow for more cost-effective resource use. Such an approach for primary care management of low-back pain was found to be highly cost-effective when compared to current best practice.[28]

What is already known

- Corticosteroid injection leads to short-term clinical benefits but poorer long-term outcomes than wait and see or physiotherapy.
- There is little evidence for the cost-effectiveness of interventions for patients with lateral epicondylalgia.

What this study adds

- Physiotherapy is highly likely to be considered a cost-effective treatment for lateral epicondylalgia.
- The cost-effectiveness of corticosteroid injection is more uncertain, while the combination of corticosteroid injection and physiotherapy is neither clinically nor cost-effective.

How might this study impact on clinical practice

Clinical and economic evidence both advise against use of corticosteroid injection as a first-line intervention for lateral epicondylalgia.

Acknowledgements The authors would like to thank the participants in the study and the treating practitioners.

Contributors BKC and BV monitored data collection for the whole trial. BC and LC wrote the statistical analysis plan, cleaned and analysed the data. All authors designed data collection tools, drafted and revised the manuscript. BKC and LB had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Funding This study was supported by the Australian National Health and Medical Research Council grant 511238 awarded to BV, LC and LB. A University of Queensland Research Scholarship was received by BKC.

Competing interests None declared.

Patient consent Obtained.

Ethics approval University of Queensland Medical Research Ethics Committee.

Provenance and peer review Not commissioned; externally peer reviewed.

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Economic evaluation favours physiotherapy but not corticosteroid injection as a first-line intervention for chronic lateral epicondylalgia: evidence from a randomised clinical trial

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Br J Sports Med 2016 50: 1400-1405 originally published online June 2, 2015
doi: 10.1136/bjsports-2015-094729