

A cost consequences analysis of local corticosteroid injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care

M. James, E. A. Stokes, E. Thomas¹, K. Dziedzic¹ and E. M. Hay^{1,2}

Objective. Local steroid injections and community-based physiotherapy have been shown to be of similar benefit for treating shoulder pain presenting to primary care. This paper presents a cost consequences analysis of a prospective economic evaluation, conducted alongside a randomized clinical trial (RCT) of corticosteroid injections versus physiotherapy for new episodes of unilateral shoulder pain, to determine the economic implications of injection versus physiotherapy.

Methods. A pragmatic RCT with 207 patients randomized to either physiotherapy ($n = 103$) or local steroid injection ($n = 104$) was conducted. The resource inputs required were identified for each treatment arm in terms of capital, staff and consumables. These were measured for the period up to 6 months post-randomization. Outcome measures included shoulder disability, shoulder pain, global assessment of health change and the EQ5D, all at 6 months. A sensitivity analysis was performed around the general practitioner minor surgical fee.

Results. Analysis is presented on the 199 patients for which the general practice record review (101 physiotherapy, 98 injection) was available. The total mean costs, per patient, were £71.28 for the injection group and £114.60 for the physiotherapy group. The difference in average total cost per patient was £43.32 (95% bootstrap confidence interval: £16.21, £68.03). This is a statistically significant difference in cost. Outcome was similar in both groups across all measures following intervention. Smaller mean differences in cost were observed between the treatment groups in the sensitivity analysis, but the difference remained in favour of injection over physiotherapy.

Conclusions. This study has shown, given similar clinical outcomes across the treatment groups, that corticosteroid injections were the cost-effective option for patients presenting with new episodes of unilateral shoulder pain in primary care.

KEY WORDS: Shoulder pain, Economic evaluation, Primary care, Cost consequences analysis, RCT, Physiotherapy, Corticosteroid injection.

Local steroid injections and community-based physiotherapy have been shown to be of similar benefit for treating new episodes of shoulder pain presenting to primary care, in terms of both shoulder disability and health status measured at 6 months [1]. Patients and general practitioners (GPs) have a choice when deciding on treatment options for shoulder problems that will depend not only on outcome but also on cost and other factors such as patient preference. Currently only 22–50% of GPs offer local steroid injections for shoulder pain [2, 3] whilst physiotherapy is a popular treatment choice with GPs and patients [3].

The detailed study protocol and clinical outcomes are reported elsewhere [1]. Given the similar clinical outcomes for physiotherapy and steroid injections in the treatment of unilateral shoulder pain, the cost of treatment is an important consideration. This work reports the cost consequence analysis of a prospective economic evaluation, conducted alongside a randomized clinical trial of corticosteroid injections versus physiotherapy for unilateral shoulder pain. Cost consequence is the technique of choice given the array of outcomes alongside cost for the two therapies [4, 5]. Currently there is no other work directly comparing the costs of these two treatments in a primary care setting and thus this analysis provides important new information.

Methods

Study participants

The study was a pragmatic, multicentre randomized clinical trial conducted in nine GP practices in North Staffordshire between June 1998 and March 2000. Briefly, patients aged 18 yr and over who consulted their GP with a new episode of unilateral shoulder pain were recruited to the trial. Participants were randomized to receive either a course of community-based physiotherapy ($n = 103$) or local steroid injection administered by a GP ($n = 104$). The study nurse obtained written informed consent for randomization. Both groups were assessed blind by a study nurse at 6 months post-randomization.

Details of the resources, costs and outcomes measured are presented below. A health service perspective was taken in the measurement of costs and benefits. The local research ethics committee of North Staffordshire approved all stages of the study.

Interventions

Physiotherapy consisted of up to eight 20-min sessions over a 6-week period and was provided by experienced musculoskeletal

Centre for Health Planning and Management and ¹Primary Care Sciences Research Centre, Keele University, Keele, Staffordshire ST5 5BG, ²Staffordshire Rheumatology Centre, The Haywood, Stoke-on-Trent ST6 7AG, UK.

Submitted 6 July 2005; accepted 12 July 2005.

Correspondence to: M. James, Centre for Health Planning and Management, Keele University, Keele, Staffordshire ST5 5BG, UK.
E-mail: m.james@keele.ac.uk

TABLE 1. Resource components and their cost sources

Resource component	Cost (£) ^a	Cost source
GP visit—home	13.67	Netten <i>et al.</i> [6]
GP visit—surgery	48.52	Netten <i>et al.</i> [6]
Physiotherapy visit	12.62	Netten <i>et al.</i> [6]
Injection	2.65	British National Formulary [7]
GP fee for injection	9.87	NHS GMS Contract 1999 [9]
Orthopaedic out-patient visit—first	98.62	NHS Executive reference costs [8]
Orthopaedic out-patient visit—follow-up	62.46	NHS Executive reference costs [8]
Rheumatology out-patient visit—first	133.69	NHS Executive reference costs [8]
Rheumatology out-patient visit—follow-up	79.99	NHS Executive reference costs [8]
Manipulation under anaesthetic	381.34	NHS Executive reference costs [8]
X-ray	30.68	University Hospital of North Staffordshire Imaging Directorate

^aAll costs were inflated to 2002/2003 prices.

community physiotherapists. The corticosteroid injection group received an injection from their GP of methylprednisolone mixed with lidocaine (lignocaine) into the sub-acromial space. If symptoms persisted, participants could return within 4 weeks to receive a second injection. This was a pragmatic study, and after the 6-week assessment GPs were at liberty to prescribe other treatments if clinically indicated.

Resources

The resource inputs required were identified for each treatment arm in terms of capital, staff and consumables. The focus was on use of primary and secondary care resources measured from entry to the study until 6 months post-randomization. The analysis took place on an intention to treat basis for the participants with available GP records. All courses of physiotherapy and injections received in the 6-month period following entry to the study were included in the analysis. Resource use was recorded on a per item basis for each of the variables at the time of intervention. Each component was identified in terms of their natural units. A natural unit is the resource or event itself, for example the physiotherapy session, rather than the cost attached to the physiotherapy session.

Trial treatments. The trial treatment resource use for the physiotherapy group was obtained from specially designed audit sheets. These identified the number of sessions and the staff involved. Trial physiotherapy took place in a community setting. The average time for each session was attributed based on a standard (20 min) or double (40 min) physiotherapy session being recorded. The trial treatment resource use for the injection group was obtained from a retrospective GP record review of all available data. The data were searched for records of the trial injections in the 6-week treatment period following the known date of randomization to the trial. Attendance at a GP practice for injection was assumed to be a minor surgery attendance. If the injection took place at the hospital, a standard out-patient visit was assumed.

Co-interventions. An extended review of all available GP records was used to determine co-interventions received for shoulder pain during the 6-month post-randomization period. Hence additional elements such as manipulation under anaesthetic, out-patient referrals for orthopaedic or rheumatology appointments, X-rays or additional visits to the GP associated with shoulder pain were recorded.

Cost

Monetary costs were attached to each of the natural units. The resources were valued using a combination of local and national data. Table 1 shows the resource components and their sources.

All costs were presented in 2002/2003 prices and inflated where appropriate. Capital cost was apportioned as a percentage of all salaries and time, and taken from standard national figures [6]. Physiotherapy costs were assigned on a sessional basis. The cost of the injection at a GP surgery was assumed to be the cost of a normal GP session, plus an additional minor surgical fee for administering the injection, plus the cost of the injected drug [7]. The cost of the injection in hospital is that of a standard rheumatology out-patient visit [8] plus the cost of the drug. A base case analysis was presented on the pre-2004 position regarding the payment of minor surgical fees to GPs [9]. This was based on a total surgical fee of £147.99 per quarter for minor surgical sessions payable per principal. It assumed that the principal would undertake the maximum three sessions with five procedures performed at each session, hence 15 procedures and a fee of £9.87 per injection.

Outcomes

The primary outcome measure in the trial was shoulder disability at 6 months measured using a shoulder disability questionnaire previously validated for use in primary care [10]. Secondary outcome measures recorded were the EQ5D [11], participant's global assessment of change, pain severity and impairment of function and severity of 'main complaint' [12].

Each measure of outcome used was designed to capture a different dimension of health-related quality of life. The shoulder disability score is a questionnaire with the range of 0 to 23; where 23 indicates severe disability. The EQ5D is a multidimensional measure of health outcome producing an index with 1 being perfect health, 0 dead or unconscious, and the worst health state valued at -0.59. The global assessment of change compares from baseline measurement on a five-point scale of 'complete recovery' to 'much worse'. Pain severity and impairment of function were measured on a 10-point numerical rating scale. A 10-cm visual analogue scale was used to measure the severity of the 'main complaint'.

Statistical analysis

Data were entered into Microsoft Excel and analysis undertaken using the Statistical Package for Social Sciences (SPSS Version 11.5). Average total costs were calculated for patients in each treatment group. Given that cost data are often positively skewed, the non-parametric bootstrap was used to obtain confidence intervals for the mean differences in cost [13]. Bootstrapping is a resampling procedure: 1000 independent samples were generated for each treatment group by sampling with replacement from the study data, with each bootstrap sample being the same size as the original sample. The mean of each of these samples was calculated, and the bias-corrected bootstrap method used to

TABLE 2. Average resource use per patient by treatment group

	Physiotherapy (n = 101)	Injection (n = 98)
Trial physiotherapy sessions	6.35	0.00
Non-trial physiotherapy sessions	0.20	1.00
Trial injections	0.00	0.97
Non-trial injections	0.34	0.14
Other GP visits	0.53	0.86
Manipulation under anaesthetic	0.00	0.01
X-rays	0.09	0.02
Rheumatology/orthopaedic/pain management OP visits	0.03	0.01
Rheumatology/orthopaedic OP visits with injection	0.04	0.02
Manipulation under anaesthetic with injection	0.01	0.02

OP, out-patient.

TABLE 3. Mean costs per patient by treatment group (in £)

	Physiotherapy (n = 101)	Injection (n = 98)
Trial physiotherapy	80.09	0.00
Non-trial physiotherapy	2.50	12.62
Trial injection	0.00	25.88
Non-trial injection	9.16	4.10
Other GP visits	7.31	11.72
Manipulation under anaesthetic	0.00	3.89
X-ray	2.73	0.63
Rheumatology/orthopaedic/pain management OP visits	4.30	2.18
Rheumatology/orthopaedic OP visits with injection	4.71	2.42
Manipulation under anaesthetic with injection	3.80	7.84
Total cost	114.60	71.28

OP, out-patient.

calculate 95% confidence intervals for the mean differences in cost [14]. Bootstrapping was performed using Stata statistical software.

Sensitivity analysis

The role of a sensitivity analysis is to test whether changes in key variables will change the results obtained from the base case analysis. In the base case analysis, assumptions had been made regarding GP caseload and the minor surgical fee assigned, and it was felt appropriate to test the effect of these assumptions. The sensitivity analysis was performed around both these variables. Two scenarios were chosen for analysis. Firstly, a GP performing only the minimum number of surgical procedures listed in the pre-2004 contract [7] that is five per quarter equivalent to £29.60 per injection, hence low volume. Secondly, using the new fee of £40 per injection per minor surgical procedure payable to GPs, in the 2004 contract [15].

Results

Two hundred and thirty-seven subjects were registered for the trial, of whom 207 were randomized—103 to receive physiotherapy and 104 to injection. The mean age was 57 and 58 yrs in the physiotherapy and injection groups, respectively. Forty-nine per cent of the physiotherapy group were female as were 58% of the injection group. The review of GP notes was completed at 6 months for 101 (98%) in the physiotherapy group and 98 (94%) in the

TABLE 4. Intervention and non-intervention costs (in £)

	Physiotherapy (n = 101)	Injection (n = 98)
Intervention costs, mean (range)	80.09 (0, 202)	25.88 (0, 61)
Follow-up costs, mean (range)	34.51 (0, 410)	45.40 (0, 917)
Total cost, mean (range)	114.60 (0, 423)	71.28 (0, 943)

Range to nearest £.

injection group. Eight sets of GP notes were not reviewed for the following reasons: four patients had moved, two refused, one was deceased and one set was missing. The analysis presented is therefore on 199 subjects.

A cost consequences analysis was performed to take into account the broad range of outcomes and costs. Average resource use per patient for both arms of the trial is shown in Table 2. The related costs are shown in Table 3. It can be seen from these findings that the treatment of choice in terms of the economic argument is treatment of shoulder pain by injection. To achieve a similar outcome in each arm, the cost is £114.60 if treated by physiotherapy and £71.28 by injection. The difference in average total cost per patient was £43.32 and the 95% bootstrap confidence interval was (£14.36, £66.38) indicating a statistically significant difference in cost in favour of the injection group over the physiotherapy group.

Costs are split into the active treatment period and the follow-up period, that is those attributable to the treatment alone and those to subsequent care. These are presented in Table 4. Although follow-up costs were greater for injection than for physiotherapy, they do not outweigh the intervention costs for trial physiotherapy.

Table 5 shows the results at 6 months across all the different outcome measures, previously presented in Hay *et al.* [1]. It can be seen from Table 5 that for each outcome, the results are broadly similar across the two groups with no significant difference between the treatment groups in the primary or secondary outcome measures.

Sensitivity analysis

The base case analysis was presented on the pre-2004 situation using a fee of £9.87 per injection per principal GP. Sensitivity analyses were performed on the two scenarios presented in the methods. Table 6 shows the results of these analyses. It can be seen that the gap between injection costs and physiotherapy costs narrows in each scenario. In terms of costs in scenario one—low volume—the cost difference remains significant. In option two—new fee—the cost difference is not significant.

Discussion

This cost consequences analysis of a randomized clinical trial comparing local steroid injection and physiotherapy for treating new episodes of unilateral shoulder pain has shown a statistically significant difference in treatment costs in favour of injections. Given the similar outcomes seen in the two treatment groups, and the significant difference in costs, the reporting and discussion of costing results will therefore be of primary importance in the treatment choice of physiotherapy versus injection in shoulder pain for a health-care decision-maker. This study has shown that corticosteroid injections are the cost-effective option for patients presenting with new episodes of unilateral shoulder pain in this randomized clinical trial. Given a fixed budget and limited resources, more patients could be treated by a GP using injection therapy than physiotherapy (up to eight sessions). In real terms, the opportunity cost of two physiotherapy courses is just over

TABLE 5. Outcome measurement

		Physiotherapy	Injection
Disability score, mean (s.d.)	Baseline (<i>n</i> = 207)	10.85 (4.4)	10.96 (4.7)
	6 months (<i>n</i> = 196)	4.85 (4.9)	6.40 (6.2)
EQ5D, mean	Baseline (<i>n</i> = 201)	0.54	0.56
	6 months (<i>n</i> = 180)	0.75	0.72
Participants global assessment of change (%)	6 months (<i>n</i> = 193)		
	Complete recovery	23 (24)	17 (18)
	Some improvement	59 (61)	63 (65)
	No change	7 (7)	6 (6)
	Worse	7 (7)	10 (10)
Shoulder pain in day, median (IQR ^a)	Baseline (<i>n</i> = 205)	5 (4–7)	5 (4–6)
	6 months (<i>n</i> = 193)	1 (0–3)	2 (0–3)
Shoulder pain at night, median (IQR ^a)	Baseline (<i>n</i> = 204)	5 (3–7)	5 (3–7)
	6 months (<i>n</i> = 193)	1 (0–3)	1 (0–4)
Function, median (IQR ^a)	Baseline (<i>n</i> = 202)	4 (2–6)	3.5 (2–5)
	6 months (<i>n</i> = 193)	1 (0–3)	2 (0–4)
Main complaint, median (IQR ^a)	Baseline (<i>n</i> = 207)	52 (38–77)	54 (43–74)
	6 months (<i>n</i> = 196)	11 (2–36)	24 (8–53)

^aIQR, interquartile range.

TABLE 6. Sensitivity analysis for GP injection fee (in £)

Scenario	Cost component	Physiotherapy (<i>n</i> = 101)	Injection (<i>n</i> = 98)	Cost difference (95% bootstrap CI)
Base case	Trial injection	0.00	25.88	
	High volume	9.16	4.10	
	Total costs	114.60	71.28	43.32 (14.36, 66.38)
Scenario 1	Trial injection	0.00	45.01	
	Low volume	15.80	6.92	
	Total costs	121.24	93.22	28.02 (−0.54, 53.30)
Scenario 2	Trial injection	0.00	55.09	
	2004 contract	19.30	8.40	
	Total costs	124.74	104.79	19.95 (−10.56, 45.33)

three injections, that is with the same funds either two physiotherapy courses could be funded or three courses of injection.

The study used direct identification and presentation of the resources used in each intervention. Presentation of the findings in this manner enables local decision-makers to apply the results of the study to their own setting and impute local cost figures as deemed appropriate.

A major contributor to the resources required for an intervention is staffing. Costs attributable to staff, quantified by the hourly wage rate and the amount of staff time consumed or attributable to each intervention, were large cost drivers in this study. In the interventions reported here, although GPs earn a higher hourly wage rate than physiotherapists, it is the actual amount of staff time that is the key cost driver. In this study, physiotherapy was highly intensive of staff time in terms of the length of sessions and the frequency of attendance. Patients had, on average, six 20-min sessions, i.e. in excess of 2 h of care. While a GP's time is more expensive, the time involved in patient contact is shorter as injections were usually given in a single, short GP appointment. Although there are additional drug costs for injections, these factors did not outweigh the much greater time input given by the physiotherapist and hence the costs of treatment were greater for physiotherapy.

We found that the injection group had slightly more GP post-intervention visits than the physiotherapy group. However, the greater frequency of contact with more costly GP time did not outweigh the initial physiotherapy contact, and hence financially did not outweigh the benefits of injection over physiotherapy in this trial.

In this study, primary and secondary care resource use and costs have been included for 6-months post-randomization. If a wider viewpoint were considered that also included patient costs, it is likely that there would be an even greater difference in costs between the groups. For injections, patients usually attended their GP practice once for a short appointment; while patients receiving physiotherapy made repeated visits for 20-min sessions hence incurring greater travel costs. Physiotherapy is time-consuming for patients in terms of time off work or away from usual activities, hence the treatment itself imposes a greater impact on society.

The economic findings do not take into account other factors which may affect choice of treatment, including patient preferences. We have previously shown that patient preference was associated with outcome and that future treatment preference was affected by previous clinical outcome [16]. Patients may prefer to receive a course of physiotherapy rather than an injection. It is possible that as the physiotherapy group had more professional contact time they were more able to express any worries and concerns throughout their treatment and hence felt less need to visit their GP once treatment had ended. This may explain the lower rate of GP visits in the follow-up period in the physiotherapy group.

This study is the first to address an economic evaluation of physiotherapy and injections for shoulder pain in a primary care setting. The presented results are supported by those of a secondary-care-based study which showed similarities in clinical outcomes between treatment groups, but substantial differences in costs, in line with the present findings [17]. Caution, however, should be attached to directly comparing these results with those

reported in that paper as vital information such as the duration of time allocated to administer the injection and the number of sessions of physiotherapy received was not reported in the earlier study.

It can be seen from the sensitivity analysis that the more expensive the GP minor surgical fee the less the cost advantage for injection. However, even when the GP fee becomes the new minor surgical fee of £40, injection is still the more cost-effective option. Who administers corticosteroid injection is something that merits further discussion. Injection therapy has been within the remit of physiotherapists since 1995 [18] and its addition to the key core skills in the physiotherapist role may reduce the cost associated with injections when compared with those incurred when injections are administered by GPs.

This study has shown that corticosteroid injections are a cost-effective option for patients presenting with new episodes of unilateral shoulder pain. The cost difference between the two treatment arms was statistically significant in the base case analysis. The introduction of a GP minor surgical fee per injection reduces the strength of these findings and statistical significance is lost. The results in terms of cost and effects are still in favour of injection over physiotherapy. With a limited budget it is therefore possible to treat more patients with injections than with a course of community-based physiotherapy.

<i>Rheumatology</i>	Key messages
	<ul style="list-style-type: none"> • Treatment of shoulder pain with a corticosteroid injection was more cost effective than physiotherapy treatment. • The cost of care by injection was significantly less expensive than physiotherapy care.

Acknowledgements

We thank the GPs, the staff, the physiotherapists and the participants involved in the trial. The trial was funded by a project grant from the Arthritis Research Campaign (UK). K.D. is funded by the Arthritis Research Campaign (UK).

The authors declare no conflicts of interest.

References

1. Hay EM, Thomas E, Paterson SM, Dziedzic K, Croft PR. A pragmatic randomised controlled trial of local corticosteroid

injection and physiotherapy for the treatment of new episodes of unilateral shoulder pain in primary care. *Ann Rheum Dis* 2003;62:394–9.

2. Croft P. Soft tissue rheumatism. In: Silman AJ, Hochberg MC, eds. *Epidemiology of the rheumatic diseases*. Oxford: Oxford Medical Publications, 1993:375–421.

3. van der Windt DAWM, Koes BW, de Jong BA, Bouter LM. Shoulder disorders in general practice: incidence, patient characteristics and management. *Ann Rheum Dis* 1995;54:959–64.

4. Briggs AH, O'Brien BJ. The death of cost minimization. *Health Econ* 2001;10:179–84.

5. Jacklin PB, Roberts JA, Wallace P *et al*. Virtual outreach: economic evaluation of joint teleconsultations for patients referred by their general practitioner for a specialist opinion. *Br Med J* 2003;327:84–91.

6. Netten A, Rees T, Harrison G. *Unit costs of health and social care 2001*. Canterbury: PSSRU, University of Kent, 2001.

7. *British National Formulary 43*. London: British Medical Association and Royal Pharmaceutical Society of Great Britain, 2001.

8. NHS Executive. *National Schedule of Reference Costs, 2000*. <http://www.doh.gov.uk/nhsexec/refcosts.htm> (accessed 7 October 2001).

9. NHS Executive. *General Medical Practitioner (GMP) remuneration 1999–2000 revised fees and allowances payable to GMPs in England and Wales*. Health Service Circular 1999/085. Leeds: NHS Executive, 1999.

10. Croft P, Pope D, Zonca M, O'Neill T, Silman A. Measurement of shoulder related disability: results of a validation study. *Ann Rheum Dis* 1994;53:525–8.

11. EQ-5D: an overview. *EuroQol Group Newsletter including survey of usage*. Netherlands: EuroQol Group Business Management, 1999.

12. Beurskens AJ, de Vet HC, Koke AJ *et al*. Efficacy of traction for non-specific low back pain: a randomised clinical trial. *Lancet* 1995;346:1596–600.

13. Thompson S, Barber J. How should cost data in pragmatic randomised trials be analysed? *Br Med J* 2000;320:1197–2000.

14. Briggs AH, Wonderling DE, Mooney CZ. Pulling cost-effectiveness analysis up by its bootstraps: non-parametric approach to confidence interval estimation. *Health Econ* 1997;6:327–40.

15. NHS Confederation. *Investing in general practice: the new general medical services contract*. London: NHS Confederation, 2003.

16. Thomas E, Croft PR, Paterson SM, Dziedzic K, Hay EM. What influences participants' treatment preference and can it influence outcome? Results from a primary care-based randomised trial for shoulder pain. *Br J Gen Pract* 2004;54:93–6.

17. Dacre JE, Beeney N, Scott DL. Injections and physiotherapy for the painful stiff shoulder. *Ann Rheum Dis* 1989;48:322–5.

18. Mullion C. Profession still divided on injection therapy. <http://www.csp.org.uk/libraryandinformation/publications/frontline/archive.cfm?id=128> (accessed 5 October 2004).