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Cost-Effectiveness of Low-Level Heat Wrap Therapy for Low Back Pain

Adam Lloyd, MA, MPhil,[1] David A. Scott, MA,[1] Ron L. Akehurst, BSc, MFPHM,[2]
Elena Lurie-Luke, Msci, PhD,[3] George Jessen, MPhil, MRPharmS[3]

[1]Fourth Hurdle Consulting Ltd, London, UK; [2]School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; [3]Procter & Gamble Health Sciences Institute, Surrey, UK

ABSTRACT

Objectives: To evaluate the cost-effectiveness and budget impact of a new heat wrap therapy for low back pain compared to paracetamol and ibuprofen from the perspective of the UK National Health Service (NHS).

Methods: We evaluated cost-effectiveness using data from a phase III trial comparing the three therapies in 371 patients aged 18 to 55 years presenting with acute uncomplicated low back pain. The primary effectiveness measure used was successful treatment, defined as both clinically meaningful pain relief and clinically meaningful reduction in disability. We conducted a simple evaluation using NHS prescription costs and a modeled extrapolation including the costs of further treatment and consultations for patients treated unsuccessfully or with adverse events. Uncertainty was addressed using nonparametric bootstrapping and sensitivity analyses.

Results: Successful treatment was reported by 57% of patients treated with heat wrap therapy, 26% treated with paracetamol and 18% treated with ibuprofen ($P < 0.05$ for heat wrap vs. both other groups). NHS prescription cost per patient was estimated to be £1.35 for heat wrap therapy, £0.26 for paracetamol, and £0.28 for ibuprofen and cost per successful treatment was £3.52 for heat wrap therapy compared to paracetamol, and £2.72 compared to ibuprofen. In the modeled extrapolation, NHS cost per patient was £27.77 for heat wrap therapy, £34.20 for paracetamol, and £36.04 for ibuprofen. Sensitivity analyses indicated that the findings were robust to plausible changes in data and assumptions.

Conclusions: Economic evaluation of this study suggests that the NHS cost of introducing heat wrap therapy in place of oral analgesics would be modest and heat wrap therapy might potentially reduce the total cost of managing episodes of lower back pain.

Keywords: budget impact, cost-effectiveness, heat therapy, low back pain, UK drug tariff.

Introduction

Approximately 40% of UK adults report suffering from back pain in the course of 1 year, of which 15% report being in pain throughout the year, the remainder reporting shorter periods [1]. The prevalence of back pain varies by age group, peaking in adults aged 45 to 64 years, with lower frequency reported in both younger and older adults [1]. Although not life-threatening and often self-limiting, low back pain is a substantial cause of morbidity and impairs quality of life. Quality of life assessed by the EuroQoL 5-item quality of life assessment questionnaire (the EQ-5D) in patients with low back pain presenting to the general practitioner (GP) is estimated to be in the range 0.62 to 0.67 on a utility scale of 0 to 1 [2], substantially lower than age-matched population norms [3].

Although individual episodes are brief, the economic impact of back pain, including the consultation with GPs, physiotherapy, radiology, and prescription drug use [4], was estimated to be £1.6 billion in the UK in 1998 [1,4,5]. Cost to the National Health Service (NHS) was estimated to be £1.1 billion and the remainder was funded by private sector insurers or by patients themselves. In the same survey, the annual cost of work loss due to back pain was estimated to be in the range of £5.0 billion to £10.7 billion [4].

In the UK, the Royal College of General Practitioners (RCGP) [6] issues guidelines for the management of acute low back pain. These guidelines recommend that patients presenting to the GP with acute low back pain should be managed initially

Address correspondence to: Adam Lloyd, Fourth Hurdle Consulting Ltd., 2 Fisher Street, Holborn, London WC1R 4QA, UK. E-mail: AdamLloyd@FourthHurdle.com

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with diagnostic triage to exclude nerve root pain and serious spinal pathology. For patients with acute and uncomplicated low back pain, recommended initial therapy is to remain active, combined with symptomatic measures. The most commonly used treatments for symptomatic relief are oral analgesics, e.g., nonsteroidal anti-inflammatory drugs (NSAIDs) [7], although application of ice or heat is also recommended. Referral to physiotherapy is recommended if oral analgesics are ineffective in relieving pain and restoring normal functional status [6].

Survey data suggest that the guidelines are broadly followed. Of patients with low back pain consulting GPs, 61% to 68% receive a prescription, and the most commonly prescribed drugs for back pain are oral analgesics such as ibuprofen, coproxamol, or cocodamol [7–10]. Other therapies reported include topical creams or sprays [8]. Topical heat is an alternative, and effective therapy, relaxing tight muscles and providing pain relief. Unfortunately, common methods of delivering heat, such as hot water bottles and electric heating pads, are inconvenient and may restrict patient mobility: immobility is itself detrimental to recovery from back pain [11].

A new therapeutic heat wrap therapy (ThermaCare® Procter & Gamble Ltd.) has been developed for use for low back pain. It is a single-use device suitable for use in a GP setting that provides at least 8 hours of continuous, consistent low-level heat at 40°C, by means of controlled iron oxidation, is suitable to be worn under clothing, and does not restrict patient mobility. It has been shown to be effective and safe for acute uncomplicated low back pain compared to a placebo in pilot clinical trials and subsequently in a large phase III clinical trial. ThermaCare has achieved regulatory approval for marketing as a Class IIa medical device in the European Union.

The UK NHS is a cash-constrained system in which resources are limited, so the potential benefits of therapy must be seen in the context of the effect on prescription costs and GP workloads. Because low back pain is a very common condition, the potential impact on the NHS of introducing new treatments may be substantial. It is therefore appropriate to assess whether new interventions for low back pain offer sufficient benefit to justify the expenditure of scarce NHS resources.

The objective of this study was to evaluate the cost-effectiveness in the UK of low-level heat wrap therapy in the management of acute uncomplicated low back pain, in comparison with the standard practice of oral analgesics.

Methods

Study Design

We evaluated the likely costs and benefits of ThermaCare from the perspective of the UK NHS. We performed a simple cost-effectiveness evaluation using prescription cost to the NHS and the effectiveness of the therapeutic heat wrap using data from the pivotal study comparing therapeutic heat wrap with paracetamol and ibuprofen [12]. We further constructed a cost-effectiveness model to estimate the potential impact of the therapeutic heat wrap on the overall management of acute uncomplicated low back pain, including the costs of GP consultations and referral to physiotherapy. We finally made an estimate of the likely budget impact of introducing the therapeutic heat wrap product into general prescription use in the NHS.

Simple Cost-Effectiveness Evaluation

Effectiveness data used in this evaluation were taken from the pivotal trial reported by Nadler et al. [12]. A total of 371 adult patients, aged 18 to 55 years, who had presented with acute, uncomplicated, muscular, nontraumatic, nonspecific low back pain of moderate or greater intensity, were included in the study. Patients with severe underlying morbidity or sciatica and other secondary causes of low back pain were excluded. Patients were asked to refrain from taking usual analgesic medication and were randomized to receive 2 days' treatment with either 8 hours of heat wrap therapy ($n = 113$), paracetamol at 2×500 mg four times daily ($n = 113$), or ibuprofen 2×200 mg three times daily ($n = 106$). Two small control groups, oral placebo ($n = 20$) and unheated back wrap ($n = 19$), were included to maintain blinding. In addition, the investigator remained blinded throughout the duration of the study. Patients were followed up on day 4.

The primary end point of the study was day 1 mean pain relief. The patient assessed pain relief on a 6-point numerical rating scale (NRS), hourly for 8 hours on day 1, every 2 hours on day 2, and once on each of days 3 and 4 (Fig. 1). Secondary efficacy end points included disability, lateral trunk flexibility, and muscle stiffness. Disability was assessed at baseline and on days 2 and 4 using the Roland-Morris Disability Questionnaire (RMDQ) rated on a 0 to 24 scale [13].

On each of the four days, mean pain relief was significantly higher with heat wrap therapy than with either comparator ($P < 0.001$). Disability, assessed on day 4, was reduced to a significantly

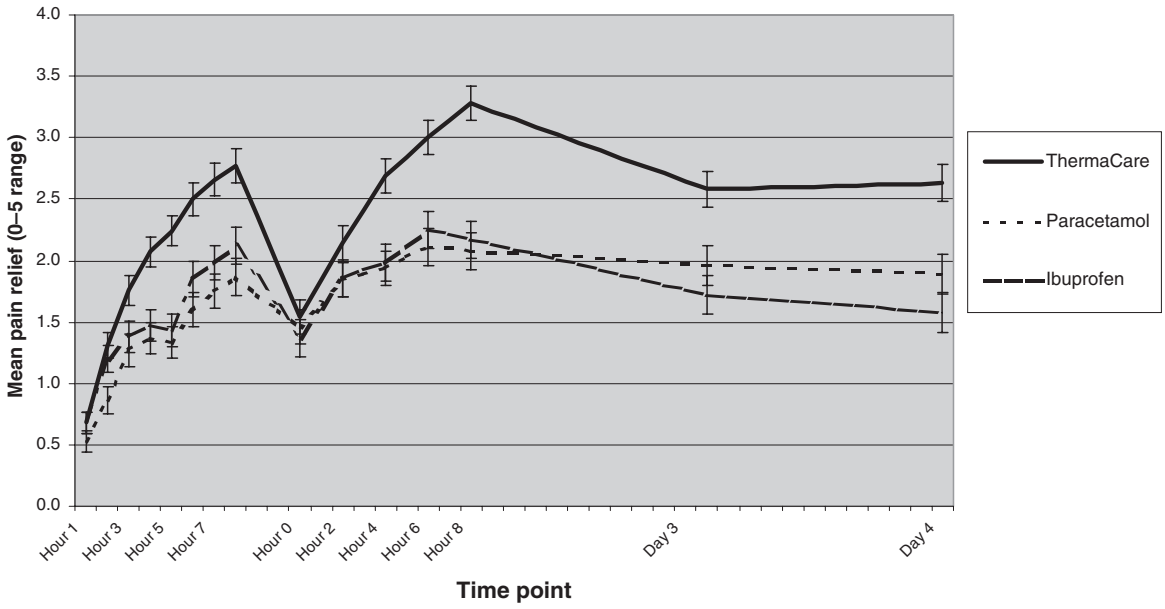

Figure 1 Mean pain relief scores at different time points. Error bars show ± one standard error.

greater extent with heat wrap therapy compared to either of the other two treatments ($P < 0.01$). A number of other secondary effectiveness parameters showed significant improvement.

Noncompliance with the study protocol was reported in six patients (one randomized to the heat wrap, two to paracetamol, and three to ibuprofen). All patients for whom effectiveness measures were recorded at baseline and for whom at least one other observation was available were, however, included in this evaluation. Full details of the methodology and conduct of the trial are presented elsewhere [12].

No adverse events reported in the study were serious although systemic adverse events were reported in 10.4% of the ibuprofen group, 6.2% of the heat wrap group, and 4.4% of the paracetamol group (statistical differences not noted). For costing purposes we included only events considered by the investigators to be probably or possibly related to treatment. These events occurred in 4.7% of the patients treated with ibuprofen, 1.8% of the heat wrap therapy group, and 2.7% of the paracetamol-treated group.

The primary efficacy end point for the economic evaluation was the percentage of "successfully treated patients." Successful treatment was defined as both clinically meaningful pain relief and clinically meaningful reduction in disability, because the main goals of pain management are to reduce pain and to reduce the level of disability in daily life [14].

We were not able to locate a published assessment of clinically meaningful improvements for a 6-point NRS for pain relief. Nevertheless, a 2-point improvement has been found to be clinically relevant both in a 5-point pain relief NRS and in an 11-point NRS for pain intensity [15,16]. Clinically meaningful pain relief was therefore defined as a 2-point improvement in the 6-point NRS. Clinically meaningful reduction in disability was defined as a 2-point improvement or better on the 24-point RMDQ, following the definition suggested by the questionnaire's designers [17]. Patients were considered to be successfully treated if they experienced clinically meaningful pain relief on at least three of the four days observed in the study and also reported a clinically meaningful reduction in disability from baseline at day 4. Patient-level data were reanalyzed to calculate the proportion of patients successfully treated in each of the active treatment groups.

The simple cost-effectiveness evaluation included the cost of each prescription, calculated as the basic NHS price of the treatment, plus the dispensing charge, corrected for patient contribution [18]. NHS prices for ibuprofen and paracetamol were taken from published sources [19]. At the time of writing, the therapeutic heat wrap is not yet available in the UK, and the price used is the manufacturer's estimate.

In the UK NHS, nonexempt patients make a flat rate payment (the "prescription charge") of £6.20

Table 1 Unit costs and sources

Item	Unit cost	Source
GP consultation	£16.00	[21]
Prescription charge (per item)	£6.20	[18]
Cost per physiotherapy, average episode of 5.2 hours patient contact	£185.00	[21]
Dispensing/prescription preparation cost	£0.95	[18]
Heat wrap, six pack	£13.99	Manufacturer
Heat wrap, cost per treatment course (two wraps)	£4.66	Calculated
Ibuprofen 84 × 200 mg pack	£1.69	[19]
Ibuprofen, cost per treatment course (2 days, 400 mg tid)	£0.24	Calculated
Paracetamol 20 × 500 mg pack	£0.15	[19]
Paracetamol, cost per treatment course (2 days, 1000 mg qid)	£0.12	Calculated

Abbreviations: Qid, four times daily; tid, three times daily.

per item dispensed [20]. For all three treatments, the cost to the patient of buying the item over-the-counter (OTC) would be less than £6.20. We have assumed that nonexempt patients will purchase these items OTC rather than paying the prescription charge, resulting in zero cost to the NHS. This is a conservative assumption: if nonexempt patients pay the prescription charge, the NHS would make a net profit.

Many UK patients are, however, exempt from prescription charges and make no payment for NHS prescriptions. We assumed that exempt patients would have their prescriptions dispensed through the NHS. We estimated that 24% of prescriptions for this population would be written for exempt patients, calculated as the percentage of prescriptions exempt from charges in the UK population aged 18 to 55 years. The estimate of the percentage of people exempt from prescription charges was varied in the sensitivity analysis.

All costs were estimated from the NHS perspective using standard published sources (see Table 1) [21].

We calculated cost-effectiveness ratios by dividing the mean NHS prescription cost per patient by the proportion of patients successfully treated to calculate the NHS prescription cost per successfully treated patient. Incremental cost-effectiveness ratios (ICERs) were calculated as the difference in mean NHS prescription cost per patient between therapies divided by the difference in the proportion of patients successfully treated.

Sensitivity tests performed included varying the definition of treatment success and varying the proportion of patients exempt from prescription charges. Confidence intervals around the percentage of successfully treated patients, alternative definitions of successful treatment, and between-group differences in these values were calculated using nonparametric bootstrapping [22]. We also defined a "worst case" scenario, in which the national rate of free prescriptions of 85% was used [18].

Cost-Effectiveness Model

A decision tree (Fig. 2) was constructed to describe the management of an episode of low back pain,

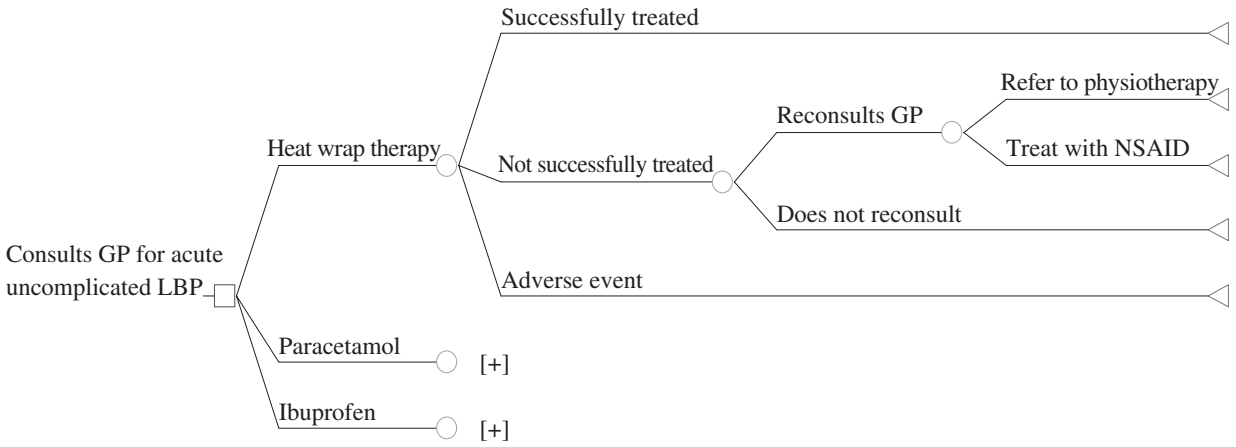

Figure 2 Decision tree for treatment of low back pain (LBP). NSAID, nonsteroidal anti-inflammatory drug.

including therapies recommended by the guidelines of the RCGP [6].

Patients enter the model at the time of first consultation for acute uncomplicated low back pain. We compare three possible treatment choices: heat wrap therapy, paracetamol, and ibuprofen. After each treatment, the patient may be successfully treated, not successfully treated, or experience an adverse event:

1. Patients successfully treated exit the model.
2. Patients who experience adverse events return for one additional GP visit to manage the event.
3. Patients not successfully treated may reconsult their GP, or may choose not to do so, and those who reconsult may receive treatment with an NSAID (assumed to be the least cost option, paracetamol), or may be referred to physiotherapy.

The proportion of patients successfully treated and free of adverse events was taken from the simple cost-effectiveness model above. The proportion of unsuccessfully treated individuals who return for an additional GP consultation was estimated as 50%. This figure causes the model to estimate overall reconsultation of 40% after initial consultation for low back pain, which matches UK survey data [8]. The likelihood of physiotherapy referral for patients who return after unsuccessful initial therapy was estimated as 18%. This figure causes the model to estimate the number of people receiving physiotherapy annually for low back pain to be around 330,000, the lower end of estimates of the annual number of NHS-financed referrals to physiotherapy for low back pain [1,23]. The cost of referral used is that of one typical "episode" of physiotherapy, consisting of a mean of 5.2 hours of care [21].

Costs included in the modeled extrapolation from the trial included the cost of the initial GP consultation for low back pain, costs of repeat consultations, and cost of physiotherapy referrals. These costs were used to calculate the total NHS cost of managing an episode of acute uncomplicated low back pain. Cost-effectiveness ratios were calculated in the same manner as for the simple cost-effectiveness analysis, and the outcome measure used was total NHS cost per successfully treated patient.

Sensitivity analyses used for the simple evaluation were repeated for the modeled extrapolation. Additional sensitivity tests explored the effect of the following changes to the inputs of the model: varying the rate of reconsultation after adverse events, removing physiotherapy referral—a "worst case" analysis, removing all costs other than the initial prescription, and with the percentage of exempt prescriptions set at 85%.

Budget Impact Assessment

We estimated the number of patients aged 18 to 55 years receiving a prescription for an NSAID in primary. The UK population of 18- to 55-year-olds is 33.1 million [24], in whom the prevalence of low back pain is 40% [1]. Each year 39% of low back pain sufferers consult their GP [1], leading to an estimate of 5.2 million total GP consultations for low back pain (calculated as 33.1 million × 40% × 39%). Acute uncomplicated low back pain is estimated to account for 66% of GP consultations for low back pain [25] and 68% of GP consultations for low back pain result in a prescription [7]. The number of prescriptions for acute uncomplicated low back pain issued annually was estimated to be 2.3 million (calculated as 5.2 million × 66% × 68%).

We estimated the budget impact of introducing the therapeutic heat wrap by combining the estimated prevalence of acute uncomplicated low back pain with the estimated total NHS cost of treatment per patient. Additional data inputs were made to estimate the budget impact: current prescriptions for acute low back pain were estimated to be split equally between paracetamol and ibuprofen; heat wrap therapy was estimated to be prescribed for 20% of patients, divided equally between those who would have received paracetamol or ibuprofen. The same sensitivity analyses were conducted as in the modeled evaluation.

Results

Simple Cost-Effectiveness Evaluation

Of the 371 patients in the intent-to-treat population, we excluded 39 patients from this analysis (10.5%) in the small control groups and 9 patients (2.4%) for whom no data were available for either pain relief or disability. Effectiveness data were evaluable for 323 patients, 112 in the heat wrap group, 108 in the paracetamol group, and 103 in the ibuprofen group.

Using the base case definition of treatment success, the percentage of patients successfully treated was 57% (95% confidence interval by bootstrapping: 47–66%) with therapeutic heat wrap, 26% (20–37%) with paracetamol, and 18% (9–24%) with ibuprofen (both ibuprofen and paracetamol $P < 0.05$ compared with the therapeutic heat wrap). The between-group differences in the proportion of

patients successfully treated were robust to different definitions of success—in each scenario heat wrap therapy showed a statistically significant higher rate of success than either of the other treatments (Table 2).

Costs and cost-effectiveness results are presented in Table 3. Including the dispensing fee and allowing for patients exempt from prescription charges, the NHS prescription cost per patient would be £1.35 for heat wrap therapy, £0.26 for paracetamol, and £0.28 for ibuprofen. The additional cost of treatment with heat wrap therapy is £1.09 per treated patient compared to paracetamol and £1.06 compared to ibuprofen.

NHS prescription cost per successfully treated patient was £2.37 in the heat wrap group, £1.00 in the paracetamol group, and £1.55 in the ibuprofen group. ICERs were £3.52 for the comparison between the therapeutic heat wrap and paracetamol, and £2.72 for the comparison between the therapeutic heat wrap and ibuprofen.

In the "worst case" sensitivity analysis (85% of prescriptions exempt), the additional cost of heat wrap therapy was £3.86 versus paracetamol and £3.76 versus ibuprofen, and the incremental costs per successful treatment with heat wrap therapy was £12.46 versus paracetamol and £9.64 versus ibuprofen. Other sensitivity tests included varying the definition of success used, varying the cost of physiotherapy within published limits, testing confidence limits around the percentage of patients successfully treated, and including costs for all and for none of the adverse events in the clinical study. The results of these tests all indicated that the heat wrap was less costly and more effective than either paracetamol or ibuprofen.

Cost-Effectiveness Model

Including the costs of GP visits, reconsultation, and physiotherapy, the per patient cost of managing an episode of acute uncomplicated low back pain with heat wrap therapy was £27.77, with paracetamol £34.20, and with ibuprofen £36.04 (see Table 4). A further analysis using the lowest recommended dosages of ibuprofen (600 mg/day) and paracetamol (2 g/day) and assuming similar efficacy and a 50% reduction in adverse events maintained the dominance in favor of heat wrap therapy.

Therapeutic heat wrap was more expensive than NSAIDs in two tests. When only the drug/device cost and initial GP consultation were included, the incremental cost-effectiveness of heat wrap was estimated to be £3.06 per successfully treated patient compared to paracetamol, and £1.51 per success-

Table 2 Proportion of patients successfully treated

	Definition of success		Proportion successfully treated: Mean (95% CI)				
Scenario	RMDQ change from baseline	Pain relief on 6-point NRS	Heat wrap (HW) (n = 112)	Paracetamol (P) (n = 108)	Ibuprofen (I) (n = 103)	Increment (HW-P)	Increment (HW-I)
Base case	≥2-point improvement at day 4	≥2 points on ≥3 of 4 days	0.57 (0.47–0.66)	0.26 (0.20–0.37)	0.18 (0.09–0.24)	0.30 (0.15–0.40)	0.38 (0.28–0.51)
Sensitivity 1 (95% CI)	≥2-point improvement at day 4	≥2 points on **all 4 days**	0.32 (0.40–0.59)	0.10 (0.18–0.35)	0.06 (0.08–0.22)	0.22 (0.10–0.36)	0.26 (0.23–0.46)
Sensitivity 2 (95% CI)	≥3-point improvement at day 4	≥2 points on ≥3 of 4 days	0.50 (0.25–0.42)	0.23 (0.08–0.22)	0.16 (0.05–0.18)	0.26 (0.08–0.30)	0.33 (0.12–0.33)
Sensitivity 3 (95% CI)	≥2-point improvement at day 4	**≥3 points** on ≥3 of 4 days	0.33 (0.20–0.37)	0.15 (0.07–0.20)	0.12 (0.05–0.18)	0.18 (0.04–0.25)	0.21 (0.06–0.27)
Sensitivity 4 (95% CI)	**≥2-point improvement** less **≥2-point deterioration**	Any	0.73 (0.63–0.82)	0.43 (0.33–0.58)	0.43 (0.26–0.52)	0.30 (0.12–0.42)	0.30 (0.18–0.49)
Sensitivity 5 (95% CI)	≥2-point improvement at **day 2**	≥2 points on ≥3 of 4 days	0.48 (0.39–0.58)	0.26 (0.20–0.38)	0.18 (0.10–0.24)	0.22 (0.06–0.32)	0.30 (0.20–0.44)

Changes from base case in **bold**.
Abbreviations: CI, confidence intervals calculated by nonparametric bootstrapping; NRS, numerical rating scale; RMDQ, Roland-Morris Disability Questionnaire.

Table 3 Costs and effectiveness of treatment—simple model

Treatment group	Heat wrap (HW) (n = 112)	Paracetamol (P) (n = 108)	Ibuprofen (I) (n = 103)	Increment (HW-P)	Increment (HW-I)
Mean values					
Proportion successfully treated	0.57	0.26	0.18	0.31	0.39
Cost of prescription (item plus dispensing charge)	£5.61	£1.07	£1.19	£4.54	£4.42
Base case					
Twenty-four percent of patients exempt from prescription charge					
NHS prescription cost per patient (after correcting for patient payment)	£1.35	£0.26	£0.28	£1.09	£1.06
NHS prescription cost per successfully treated patient	£2.37	£1.00	£1.56		
Incremental cost-effectiveness ratio (ICER)				£3.52*	£2.72*
Sensitivity test					
Eighty-five percent of patients exempt from prescription charge					
NHS prescription cost per patient (after correcting for patient payment)	4.77	0.91	1.01	£3.86	£3.76
NHS prescription cost per successfully treated patient	£8.37	£3.50	£5.62		
ICER				£12.46*	£9.64*

*Calculated as difference in cost divided by difference in effect.

fully treated patient compared to ibuprofen. In our "worst case" scenario (85% free prescriptions and ignoring all costs apart from the drug/device and initial GP contact), the incremental cost-effectiveness of heat wrap was estimated to be £12.00 per successfully treated patient compared to paracetamol, and £8.43 per successfully treated patient compared to ibuprofen.

Budget Impact Assessment

In the base case scenario, using costs and effectiveness from the modeled extrapolation, heat wrap therapy would result in a cost saving to the NHS of £3.4 million per year (Table 5). This saving includes the cost savings implications of the occurrence of 85,000 fewer GP consultations and 14,000 fewer physiotherapy referrals.

Using the same set of sensitivity analyses as the modeled extrapolation, the savings to the NHS ranged from £0.9 million to £3.8 million. In the conservative scenario, where only the drug/device cost and initial GP consultation were included, the increase in NHS expenditure resulting from the introduction of the therapeutic heat wrap was £0.3 million per year. In the "worst case" scenario the additional NHS costs were estimated to be £2.4 million per year.

Discussion

Clinical data were taken from a large randomized clinical trial for uncomplicated acute low back pain comparing therapeutic heat wrap with ibuprofen and paracetamol. The objective of this trial was to compare the efficacy of continuous low-level heat wrap therapy with that of ibuprofen and paracetamol in subjects with acute nonspecific low back pain. Evaluations of economic

Table 4 Cost-effectiveness model for three therapies for low back pain: cohort of 1000 patients

	Heat wrap (HW)	Paracetamol (P)	Ibuprofen (I)	Increment (HW-P)	Increment (HW-I)
Treatment outcomes					
Successfully treated patients	570	260	180	310	390
Adverse events	18	27	47	–9	–29
Patient reconsultation	224	383	434	–159	–210
Treatment events					
GP consultations	1,224	1,383	1,434	–159	–210
Courses of physiotherapy	37	64	69	–27	–32
Prescriptions for initial drug/device	1,000	1,000	1,000	0	0
Prescriptions for second line NSAID	169	293	318	–124	–149
Treatment costs					
GP consultations	£19,582	£22,132	£22,937	–£2,551	–£3,356
Courses of physiotherapy	£6,797	£11,762	£12,740	–£4,965	–£5,943
Prescriptions for initial drug/device	£1,346	£256	£285	£1,090	£1,061
Prescriptions for second line NSAID	£43	£75	£81	–£32	–£38
Total cost	£27,768	£34,225	£36,044	–£6,457	–£8,276
Per patient cost	£27.77	£34.22	£36.04	–£6.46	–£8.28
Cost per person successfully treated	£48.72	£131.63	£200.24	Dominant	Dominant

Abbreviation: NSAID, nonsteroidal anti-inflammatory drug.

Table 5 Estimated budget impact of introducing heat wrap therapy in England and Wales

	% of patients	Number of patients	Successfully treated patients	Adverse events	GP reconsultations	Physiotherapy referrals	Cost
Per patient data (results of cost-effectiveness model)							
Heat wrap therapy			0.57	0.02	0.22	0.037	£27.77
Paracetamol			0.26	0.03	0.38	0.064	£34.22
Ibuprofen			0.18	0.05	0.43	0.069	£36.04
Budget impact in England and Wales							
If no heat wrap therapy available							
No. receiving heat wrap therapy	0	0	0	0	0	0	£0
No. receiving paracetamol	50	1,157,907	301,056	30,741	443,796	73,615	£39.6 million
No. receiving Ibuprofen	50	1,157,907	208,423	54,618	502,051	79,742	£41.7 million
Total		2,315,813	509,479	85,359	945,847	153,358	£81.4 million
If heat wrap therapy available							
No. receiving heat wrap therapy	20	463,163	264,003	8,198	103,679	17,017	£12.9 million
No. receiving paracetamol	40	926,325	240,845	24,593	355,037	58,892	£31.7 million
No. receiving Ibuprofen	40	926,325	166,739	43,695	401,641	63,794	£33.4 million
Total		2,315,813	671,586	76,485	860,356	139,703	£78.0 million
Impact of heat wrap therapy			162,107	–8,874	–85,491	–13,655	–£3.4 million

benefits were not included in the study and therefore no pharmacoeconomic parameters were measured. To perform this analysis, original data from the clinical trial were reanalyzed to generate a measure of successful treatment by combining patient-level data on pain relief and reduction in disability. Although this definition of success was not prospectively defined, the definitions of clinically meaningful improvement are supported in the literature [15–17] and sensitivity analyses showed the data to be robust to the definition of treatment success used.

The study comprised 2 days' treatment followed by an additional 2 days of follow-up. The primary analysis reported here was based on data collected on day 4. This time point was selected to make maximum use of the data collected in the study, and to evaluate whether differences between therapies were transitory or would persist after therapy was withdrawn. We found that the difference between heat wrap therapy and both ibuprofen and paracetamol was maintained after the end of therapy. Sensitivity analysis assessed the impact of assessing only up to day 2, and found results consistent with the main evaluation.

A Cochrane review by Tulder et al. [26] reports relative risk of pain reduction with NSAIDs at 1 week compared to placebo, based on six trials using a variety of proxies to indicate improvement. Rates of successful treatment for the ibuprofen and paracetamol arms of this study are based on a definition of success that was more aggressive than that reported in the Cochrane review (improvement within 2 or 4 days), and success rates are therefore lower.

The model was sensitive to the percentage of patients exempt from prescription charges: increasing this percentage from our base case 24% to 85% materially altered the results. The prevalence of low back pain peaks in working age adults [1] who are generally required to pay prescription charges, and the study on which our evaluation was based was limited to adults aged 18 to 55 years. For these reasons we assumed that the working age population will use the therapeutic heat wrap predominantly. The sensitivity analysis using 85% as the rate of free prescriptions was included as a "worst case" scenario, and is felt to be unrealistically pessimistic. Even in the "worst case" analyses, the incremental cost of heat wrap appears to be modest and the cost-effectiveness ratios are low.

We generated a simple decision-analytic model to explore the potential benefits if improved treatment of low back pain results in fewer patients returning for further treatment. The results indicate, using a wide range of assumptions, that improved treatment would offer material resource savings to the NHS. The link between more successful treatment and reduced rates of reconsultation is, however, not yet supported by direct evidence. The model has also not attempted to take account of likelihood of low back pain recurrence nor its potential budget impact.

In addition to cost-effectiveness ratios, the potential impact on the NHS budget is an important factor influencing the rate of uptake of new interventions in the UK. The NHS is a tax-funded health care system operating within a fixed budget, so a new intervention that results in material new spending will require resources to be reallocated

from elsewhere in the organization. Our analysis suggests that the impact of therapeutic heat wrap on total NHS spending would be modest, and if the modeled reductions in reconsultation rate take place, use of the therapeutic heat wrap may result in resource gains for the NHS.

The results indicate, using a wide range of assumptions, that heat wrap therapy offers material resource savings to the NHS. Although encouraging, these findings are tentative however. This analysis is based on results from one small randomized controlled trial designed for regulatory purposes [27]. Furthermore, the link between successful treatment and reduced rates of reconsultation is not yet supported by direct evidence. Further research, demonstrating reduced rates of reconsultation after therapeutic heat wrap therapy, could further strengthen the cost-effectiveness case for its use.

This study included costs from the perspective of the NHS alone. Back pain is a major reason for lost workdays in the UK, and thus imposes substantial costs on employers and on sufferers that are not reflected in NHS costs [1]. Nevertheless, productivity costs were not collected in the study. The impact of the heat wrap therapy in the workplace has been investigated in an exploratory workplace study among manual workers with acute low back pain [28]. The results of this study showed that the use of the heat wrap therapy led to improved productivity.

Conclusions

In this study, continuous heat wrap therapy resulted in a larger percentage of patients being successfully treated compared to paracetamol and ibuprofen. Economic evaluation suggests that the NHS cost of introducing heat wrap therapy in place of oral treatments would be modest. If the increased effectiveness of heat wrap therapy leads to a reduction in GP or physiotherapy consultations, then heat wrap therapy is likely to lead to a net saving of resources for the UK NHS.

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