Cost-effectiveness of Spa treatment for fibromyalgia: general health improvement is not for free

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Objectives. To estimate the cost-effectiveness of an adjuvant treatment course of spa treatment compared with usual care only in patients with fibromyalgia syndrome (FM).

Methods. 134 patients with FM, selected from a rheumatology outpatient department and from members of the Dutch FM patient association were randomly assigned to a 2½ week spa treatment course in Tunisia or to usual care only. Results are expressed as quality-adjusted life years (QALYs) for a 6-month as well as a 12-month time horizon. Utilities were derived from the Short Form 6D (SF-6D) scores and the visual analogue scale (VAS) rating general health. Costs were reported from societal perspective. Mean incremental cost per patient and the incremental cost utility ratio (ICER) were calculated; 95% confidence intervals (CIs) were estimated using double-sided bootstrapping.

Results. The data of 128 (55 spa and 73 controls) of the 134 patients (96%) could be used for analysis. Improvement in general health was found in the spa group until 6 months of follow-up by both the SF-6D (AUC 0.32 vs 0.30, \(P<0.05\)) and the VAS (AUC 0.23 vs 0.19, \(P<0.01\)). After 1yr no significant between-group differences were found. Mean incremental cost of spa treatment was €1311 per patient (95% CI 369–2439), equalling the cost of the intervention (thalassotherapy including airfare and lodging), or €885 per patient based on a more realistic cost estimate.

Conclusions. The temporary improvement in quality of life due to an adjuvant treatment course of spa therapy for patients with FM is associated with limited incremental costs per patient.

KEY WORDS: Fibromyalgia, Thalassotherapy, Exercise, Quality of life, Cost-Effectiveness.

Introduction

Fibromyalgia (FM) is a syndrome characterized by chronic widespread musculoskeletal pain and increased tenderness to palpation [1]. Although the exact cause of FM is unknown, it is suggested that a combination of biological, psychological and social factors leads to pain amplification and central sensitization to peripheral stimuli [2]. Pain and other important features like sleep disturbance and fatigue all contribute to increasing disability and reduced quality of life [3]. Furthermore, FM is associated with increased health care consumption, significant productivity loss and considerable economic costs [4–6].

Until now, treatment results in FM are mostly unsatisfactory. Several forms and combinations of physical exercise and patient education have been shown to have positive effects, but effect sizes are often moderate, drop-out rates considerable and long-term effects unknown [6, 7].

In this century, health care policy will increasingly be based on cost–benefit ratios of new interventions. However, cost-effectiveness of treatment programmes for FM has not been subject to study up till now [7]. In a previous publication, we concluded that a group programme of thalassotherapy, exercise and patient education (spa treatment) resulted in temporary improvement of FM symptoms and health-related quality of life [8]. This article addresses the health economic aspects of spa treatment compared with usual care in patients with FM. The cost–utility analysis was performed alongside the pre-randomized controlled trial.

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Methods

Design

The pre-randomized controlled clinical trial (RCT) has been described previously [8]. Outcome assessments were done at baseline and after 1, 3, 6 and 12 months. Costs were measured prospectively via monthly questionnaires filled out by the patients. In order to test group differences for costs at baseline, retrospective data about health care consumption and employment status over the past 6 months were collected as well. The study was approved by the Medical Ethical Committee of Medisch Spectrum Twente Hospital, Enschede, The Netherlands. All participants gave written informed consent.

Patients

Patients with primary FM were included if they met the following criteria: a diagnosis of primary FM made by a rheumatologist, according to the ACR 1990 classification criteria [1]; age between 18 and 65 years; willingness to undergo an in-patient treatment of some weeks. Exclusion criteria were: secondary FM; comorbidity interfering with spa treatment; other serious comorbidity; dependency on a wheelchair or help from other people; current involvement in a legal procedure concerning disability or employment; recent spa treatment for musculoskeletal disorders; difficulty understanding Dutch.

Intervention

The Spa treatment (SPA) was given on the Island of Jerba, Tunisia. Three groups of up to 20 patients travelled to Jerba by air and stayed in a luxurious tourist hotel on a full-board basis for 2½ weeks, sharing rooms with a fellow patient. The treatment programme consisted of five elements: thalassotherapy, group exercise, patient education, recreational activities and relaxation.

Thalassotherapy was provided in a thalasso centre by qualified Tunisian staff. It consisted of seven 3 h sessions. Thalassotherapy was provided in a thalasso centre by qualified Tunisian staff. It consisted of seven 3 h sessions. The supervised group exercise (max. five patients per group) included seven 1 h sessions with various forms of low-intensity aerobic exercise. The patient education programme consisted of seven sessions in groups of up to 10 patients, directed by the
Spa treatment for fibromyalgia

Utility measurement

Utilities refer to preferences individuals or society may have for any particular health state [9] and value the health of the patient from 0 (as bad as death) to 1 (perfect health). For the present study, utilities were assessed in two different ways, using the RAND-36 and a visual analogue scale (VAS) for general health.

The RAND-36 [a validated Dutch version of the Short Form (SF)-36 health survey] measures general health status [10]. From the RAND-36, the SF-6D utility index was calculated [11]. The SF-6D reflects the general public’s valuation of health states derived from the SF-36. General health was also measured with a 100 mm VAS. The VAS score ranges from 0 to 100: worst imaginable to best imaginable health.

Costs

Societal costs during the 1yr follow-up period were assessed and valued in accordance to the Dutch guidelines for pharmacoeconomic research [12] including direct and indirect medical costs as well as indirect non-medical costs. Both FM-related and other costs were included, since it is sometimes difficult to distinguish one from the other.

Table 1 lists all direct and indirect costs that were included in the analysis, presenting the method of valuation, the cost per unit and its source. Most cost prices were obtained from Dutch standard prices as described in the Dutch manual for costing by Oostenbrink et al. [13]. This manual was designed to increase standardization in costing methodology among studies. Prices of 1999 as stated in the cost manual of Oostenbrink et al. [13] were converted to the price level of the year 2000 using the price index rate for the Dutch health care sector of 2.6% (obtained from Statistics Netherlands).

The cost of the spa treatment programme was based on the costs of thalassotherapy, travel expenditures, accommodation and overhead costs including staff expenses. Total costs were estimated at €1526 per patient. A second calculation was made in which package deals because of group discount and 2007 airfares were taken into account. This way the total costs of spa treatment were estimated at €1125. Both prices were applied in the analysis.

Absenteeism from work was calculated by using the friction cost method. This method is based on the idea that the amount of production lost due to disease depends on the time span employers need to restore the initial production level. Hence, this method assumes that production losses are confined to the period needed to replace a sick worker. This ‘friction period’ is limited to a maximum of 123 days [13, 14]. Domestic help was classified into three categories. Professional domestic care (provided by professional home care organizations and reimbursed by health insurance), paid household help (privately paid, not reimbursed) and informal care (unpaid help from relatives or friends). Informal care was limited to a maximum of 28 h/week.

Statistical analysis

Results are expressed as quality-adjusted life years (QALYs). QALYs are an accepted measure for resource allocation decisions involving different treatments and patient populations. A QALY is a composite index that includes effects in terms of both quality of life (utility) and the duration of time in such a health state [9]. Therefore, the time-integrated summary score, the area under the curve (AUC) of the utilities, was calculated to define the quality of life per period (0–6 months and 0–1 yr), based on the assumption that utilities followed a linear course over time between the assessments. Between-group differences in QALYs were analysed per period by Student’s t-test for unpaired observations.

The costs are presented as arithmetic means (±S.D.) per patient per group. The between-group differences in resource use were analysed per period by Mann–Whitney U-test. Mean incremental costs per patient and study period were calculated and 95% CI were estimated using double-sided bootstrapping.

The incremental cost utility ratio (ICER) was calculated by dividing the extra costs for the intervention group by the extra QALYs derived from it. The ICER is expressed as costs per QALY gained. The 95% CIs of the ratios were estimated with bootstrapping. Costs and effects were not discounted as the time horizon of this study was less than 1 yr and no modelling beyond the observed period was done.

Results

Data from 128 of the 134 patients (96%) could be used for analysis (55 SPA and 73 UC). The excluded patients (three from SPA and three from UC-group) completed <50% of the cost diaries. However, they did not differ from the study group.
Table 2. Demographic characteristics and resource use 6 months prior to the study start of the 128 patients who completed the cost questionnaires: comparison between the spa treatment (SPA) and usual care (UC) group

<table>
<thead>
<tr>
<th>Resource use</th>
<th>SPA (n = 55)</th>
<th>UC (n = 73)</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner (GP), visits [mean (s.d.)]</td>
<td>4.0 (4.3)</td>
<td>3.3 (2.7)</td>
<td>0.7 (2.6)</td>
</tr>
<tr>
<td>Specialists, visits [mean (s.d.)]</td>
<td>1.2 (2.2)</td>
<td>1.7 (2.5)</td>
<td>0.5 (2.3)</td>
</tr>
<tr>
<td>Paramedical professionals, visits [mean (s.d.)]</td>
<td>13.3 (15.1)</td>
<td>12.5 (16.1)</td>
<td>0.8 (16.1)</td>
</tr>
<tr>
<td>Alternative medicine (%)</td>
<td>35</td>
<td>30</td>
<td>5</td>
</tr>
<tr>
<td>Hospitalisation [days, mean (s.d.)]</td>
<td>4.5 (0.7)</td>
<td>5 (5.4)</td>
<td>0.5 (5.4)</td>
</tr>
<tr>
<td>Professional domestic care [h/week, mean (s.d.)]</td>
<td>0.5 (1.4)</td>
<td>0.5 (1.3)</td>
<td>0.0 (1.3)</td>
</tr>
<tr>
<td>Paid household help [h/week, mean (s.d.)]</td>
<td>0.5 (1.1)</td>
<td>0.8 (1.7)</td>
<td>0.3 (1.7)</td>
</tr>
<tr>
<td>Informal care [h/week, mean (s.d.)]</td>
<td>4.5 (7.8)</td>
<td>4.1 (6.1)</td>
<td>0.4 (6.1)</td>
</tr>
</tbody>
</table>

*Maximum possible range is 1 (elementary school) – 6 (university).

Quality of life

Results of utilities measured by the SF-6D and VAS are shown in Fig. 1. One and three months after the treatment SPA patients reported better quality of life, but this effect was not significant any more after 6 months. Furthermore, utility scores based on SF-6D were higher than those based on VAS general health.

Differences in time-integrated quality of life (QALYs) between groups and per period are shown in Table 3. Over the 6-month follow-up period, quality of life was higher in the SPA group, measured by the SF-6D as well as the VAS. The between-group difference in the AUC of the SF-6D was 0.02 (P < 0.05), and 0.04 (P < 0.01) based on the VAS-score. Over the 1 yr follow-up period no statistically significant between-group differences were found.

Table 3. Quality of life per period comparing patients of the spa treatment (SPA) and usual care (UC) group

<table>
<thead>
<tr>
<th>Time horizon</th>
<th>SPA</th>
<th>UC</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>OALYs estimated by the SF-6D</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–6 months</td>
<td>0.32 (0.04)</td>
<td>0.30 (0.04)</td>
<td>0.02 *</td>
</tr>
<tr>
<td>0–1 yr</td>
<td>0.61 (0.08)</td>
<td>0.61 (0.07)</td>
<td>0.00</td>
</tr>
<tr>
<td>OALYs estimated by the VAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0–6 months</td>
<td>0.23 (0.08)</td>
<td>0.19 (0.06)</td>
<td>0.04 **</td>
</tr>
<tr>
<td>0–1 yr</td>
<td>0.42 (0.15)</td>
<td>0.39 (0.12)</td>
<td>0.03</td>
</tr>
</tbody>
</table>

Costs

The volumes of health care and non-health care utilization during the 6-month and 1 yr follow-up period are listed in Tables 4 and 5. After 6 months of follow-up a small difference in favour of the SPA group was observed in the number of FM-related visits to general practitioners and specialists (P < 0.05). After 1 yr, this difference was only statistically significant for the number of visits to a specialist (P < 0.05).

The number of hours of domestic care was lower in the SPA group than in the UC group (5 vs 21 h; P < 0.01) after 6 months of follow-up. After 1 yr this difference was still statistically significant (P < 0.05). In the subgroup of patients with a paid job at study start, no between-group differences were found over both follow-up periods with respect to the mean number of sick days due to FM (Table 5).
Mean total costs per patient and treatment group are listed in Table 6. Mean total costs from societal perspective were €3415 per patient for the SPA group and €2105 for the UC group after 6 months of follow-up. The mean incremental costs were €1311 per patient (95% CI −€369 to 2439), balancing the costs of the intervention (thalassotherapy including airfare and lodging). Based on the more realistic cost estimate of €1125 for the spa treatment programme, the mean incremental costs would be €885 per patient (95% CI −€381 to 1790) (data not shown).

Cost–utility

The incremental cost–utility ratio (ICER based on the AUC of the VAS) after 6 months of follow-up was €1311/0.04 = €32775 (95% CI −375000 to 273000) per QALY gained. The uncertainty around the ratio was estimated by bootstrapping and is presented graphically by the cost–utility plane (Fig. 2). This plane shows in which quadrant of the plane the ‘population’ ratio is to be expected. The 95% confidence region surrounding this point estimate spanned all four quadrants of the incremental cost-effectiveness scatter plot, suggesting inconclusive results. Both the upper-right (signifying a treatment effect against higher costs) and upper-left quadrant (no treatment effect against higher costs) were equally represented within the bootstrapped ratios. In a negligible percentage of the bootstrapped results the intervention was cost-saving. The ICER based on the AUC of the SF-6D after 6 months of follow-up was even higher: €1311/0.02 = €65550 (95% CI −684000 to 682000) per QALY gained. Since group differences at 1 yr were not statistically significant the ICER was not calculated for this time horizon.

Discussion

The temporary improvement of quality of life due to an adjuvant course of spa treatment (a combination of thalassotherapy, exercise and patient education) in patients with FM is associated with limited incremental costs of €1311 per patient (or €885, based on the more realistic cost estimate). As the intervention did not result in a noteworthy decrease in health care consumption nor in productivity loss, the incremental costs are in fact the added costs of the spa treatment programme. No conclusions could be drawn from the incremental cost–utility ratio as the 95% CI had a high range.

The two QALY measures used in this study led to differing conclusions about the effectiveness of the intervention. This can be explained by the fact that conceptual differences exist between the measurement of utilities by the VAS and SF-6D, as they are based on different elicitation methods [15]. The VAS general health is a direct measure of utility representing the individual valuation of a single health state while the SF-6D is a preference-based indirect utility measure representing a summary score of six health states. [11].
Our results showed only a few minor differences in health care consumption. The SPA group reported fewer FM-related visits to doctors. They also reported less paid household help, possibly explained by the better physical and mental condition of the patients [8]. In our study, the overall difference in health-related costs (spa treatment not included) between both groups was not significant. This is in line with previous literature. In a study comparing education and/or social support with no treatment, no differential changes in health care costs were revealed among participants in the experimental and control groups [16]. Goossens et al. [17] reported that the addition of a cognitive component to an educational intervention led to significantly higher health care costs and no additional improvement in quality of life as compared with the educational intervention alone. From these findings, one may assume that the effects of the interventions in these studies were too small to cause any change in health care consumption.

Since health resource use was the same in both groups, sensitivity analysis based on other cost parameters would render the same net result and was therefore not performed. The only cost-related parameter that would directly influence cost-effectiveness is the cost of the spa treatment programme.

In this respect, it should be mentioned that a price estimation of the spa treatment programme of €1526 per patient is rather conservative. It would be more realistic to calculate the price of the spa treatment programme based on 2007 airfares and a 20% group discount, since insurance companies can obtain package deals for large numbers of patients. This would result in an estimated price of €1125 per patient, reducing the incremental costs from €1311 to €810 per patient. Consequently, the ICER would be reduced to €810/0.04 = €20,250 per QALY gained.

On the other hand, our study probably slightly underestimated costs as productivity losses were estimated by the friction costs approach (FCA). Huscher et al. [18] showed that indirect costs differ by a factor of 3, based on whether the human capital approach (HCA) or the FCA is used. However, as no significant between-group differences in absenteeism from work were found, it probably has a limited effect on the incremental costs and thus on the final results.

Among the strong points of our study is its prospective randomized controlled design as well as a minimal loss to follow-up. Subjects were no highly selected patients from a tertiary referral centre, allowing us to generalize the results. Both direct and indirect costs were included in the analysis. This is important, since indirect costs may account for up to 70% of total FM-related costs [6]. We used a randomization-before-consent design, in which control patients only received information concerning their part of the protocol but not the spa treatment. By doing so, we tried to avoid disappointment, which could have negatively influenced patients’ willingness to participate in the study or their reporting of subjective outcome. Although the UC group was thus “blinded” to the intervention, the SPA group could not be blinded, nor were the observers. Even so, from the way that costs were assessed we do not expect the lack of blinding to have significantly influenced our cost-related data.

This is the first study that addresses the cost-effectiveness of spa treatment in patients with FM. Although other multidisciplinary treatment programmes were shown to improve the symptoms of FM [19, 20], evidence of their cost-effectiveness is still lacking [7]. The study by Goossens et al. [17] addressed only the cost-effectiveness of cognitive behavioural therapy in addition to patient education, but not the combination of the two [21].

The cost-effectiveness of combined spa-exercise therapy has been studied in Dutch patients with ankylosing spondylitis [22]. The costs per QALY gained (estimated by the EQ-5D) were €7465 for spa-exercise therapy in Bad Hofgastein, Austria and €18,575 for spa-exercise therapy in a Dutch spa resort. Mean total incremental costs in the intervention groups (€1269 and €1486) were comparable with the incremental costs in our study (€1417) and were mainly explained by the cost of treatment. Furthermore, no important reduction in other health-related costs occurred. Given the similar mean incremental costs per patient in both studies, the higher cost–utility ratio in the present study was due to smaller effects on utilities. However, a direct comparison between studies is difficult, since different measures for utilities were used. It has been shown that the method employed to determine the utility of health states has major effects on the outcome of cost-utility studies [15]. According to Lamers et al. [23] the use of EQ-5D resulted in larger health gains and consequent lower cost–utility ratios although this was studied in patients with mood or anxiety disorders.

Our study aimed at providing information on costs and effects of combined spa treatment in FM. The next question will be whether the incremental costs of this treatment are acceptable. Society should consider whether a temporary improvement in quality of life is worth the incremental costs, given the fact that only a few, if any, effective treatments are available for patients with FM.

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