MCP techniques in the management of exacerbations of COPD (MATREX)

A randomised controlled equivalence trial to determine the effectiveness and cost–utility of manual chest physiotherapy techniques in the management of exacerbations of chronic obstructive pulmonary disease (MATREX)

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Executive summary

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Executive summary

Background

Manual chest physiotherapy (MCP) techniques, involving chest percussion, vibration and assisted coughing, have long been used in the treatment of respiratory conditions. However, strong evidence for the benefit of this intervention is lacking. Specifically with respect to chronic obstructive pulmonary disease (COPD), a review of the research literature indicates a clear state of clinical equipoise. Traditionally, patients hospitalised with an exacerbation of COPD have been given MCP to assist with sputum clearance. However, uncertainty as to whether it confers either short- or long-term benefits has led to wide variation in practice, with individual clinical preference tending to dictate whether or not a patient receives treatment.

Current clinical guidelines on the management of COPD are unable to provide evidence statements on physiotherapy interventions on account of inherent methodological limitations in existing research. The aim of this study was to address this situation by providing robust evidence on the effectiveness of MCP for this clinical population.

Objectives

To estimate the effect, if any, of MCP administered to patients hospitalised with COPD exacerbation on both disease-specific and generic health-related quality of life. To compare the health service costs for those who either receive or do not receive MCP while in hospital.

Design, setting and interventions

Using a pragmatic, randomised controlled trial design powered for equivalence we compared patients who either received or did not receive MCP while in hospital, in terms of disease-specific quality of life and health-care resource use, in the medium term (6 months), on an intention-to-treat (ITT) basis. The study employed active cycle of breathing techniques (ACBT) in both trial arms. Patients allocated to the intervention arm were guided to perform ACBT while the physiotherapist delivered MCP. For patients allocated to the control arm, the physiotherapist provided instruction on the elements of ACBT and advice on suitable positions to assist with sputum clearance.

Participants

Five hundred and twenty-six participants aged 34–91 years, recruited from four secondary care hospitals between November 2005 and April 2008, were randomised; of these, 372 participants provided evaluable data for the primary study outcome. All persons hospitalised with COPD exacerbation and evidence of sputum production on examination were eligible for the trial providing there were no contraindications to performing MCP.

Main outcome measure

The primary study outcome was COPD-specific quality of life, measured using the St George's Respiratory Questionnaire (SGRQ). An effect size of 0.3 standard deviations in the SGRQ was specified in advance as the threshold for superiority.

The European Quality of Life-5 Dimensions (EQ-5D) questionnaire was employed as an additional generic health-related quality of life measure and used to calculate the quality-adjusted life-year (QALY) gain associated with MCP, compared with no MCP (incremental effect). Physiological outcome measures included the Breathlessness Cough and Sputum Scale (BCSS), the Medical Research Council-Dyspnoea (MRC-D) scale, sputum volume produced during hospitalisation, oxygen saturation at baseline and change in oxygen saturation associated with MCP. In addition, the Six-minute Walk Test (6MWT) was performed on a subsample of participants at one hospital site.

To estimate the incremental cost of MCP to the health service, physiotherapy input (including MCP), hospital admissions, outpatient visits and rehabilitation levels over the 6-month trial period were monitored for each patient. Appropriate unit

costs were assigned to each of these resources. The incremental cost and incremental effect of MCP was subsequently used to estimate the cost-effectiveness of MCP. Per-protocol (PP) analyses were performed for primary and secondary effectiveness end points and for QALYs.

Results

Health-related outcomes

Equivalence was demonstrated with respect to the primary outcome at the primary end point. The ITT analyses indicated no significant difference at 6 months in total SGRQ score [adjusted effect size (no MCP – MCP) 0.03 (95% confidence interval, CI –0.14 to 0.19)], SGRQ symptom score [adjusted effect size 0.04 (95% CI –0.15 to 0.23)], SGRQ activity score [adjusted effect size –0.02 (95% CI –0.20 to 0.16)] or SGRQ impact score [adjusted effect size 0.02 (95% CI –0.15 to 0.18)]. The imputed ITT and PP results were similar. No significant differences were observed in any of the outcome measures or subgroup analyses.

Cost-effectiveness

Compared with no MCP, employing MCP was associated with a slight loss in quality of life (0.001 QALY loss) but lower health service costs (cost saving of £410.79). Based on these estimates, at a cost-effectiveness threshold of λ = £20,000 per QALY, MCP would be estimated to constitute a cost-effective use of resources (net benefit = £376.14), on the assumption that resources could be spent elsewhere in a more efficient manner. There was, however, a high level of uncertainty associated with these results (47.6% chance of making the wrong decision by choosing MCP when λ = £20,000 per QALY) and one could not rule out the possibility that lower health service costs had been due to other factors. Moreover, though the results of the complete case analysis were in line with the base case, it should be noted that less than 50% of respondents provided complete EQ-5D data.

Conclusions

In terms of longer-term quality of life, the use of MCP does not appear to affect outcome in patients hospitalised for COPD exacerbation. Although the cost-effectiveness analysis suggested that MCP was cost-effective, much uncertainty was associated with this finding.

Implications for health care

1. This study addressed the limitations of previous research by standardising the delivery of MCP and obtaining a sample of sufficient size to derive statistically robust results for a patient-orientated, clinically meaningful outcome.
2. This study found no gain in longer-term quality of life when MCP was included in the physiotherapeutic management of acute exacerbation of COPD. However, the findings of this study do not mean that MCP is of no therapeutic value to patients with COPD in specific circumstances.
3. In terms of cost-effectiveness, MCP was associated with lower overall health service costs, with the cost of providing therapy offset by savings associated with fewer hospital admissions among patients assigned to receive MCP. However, interpretation of this apparent saving should be examined in the light of the primary outcome, which demonstrated no evidence of efficacy above normal care. As MCP was not found to be effective, it is difficult to justify providing this therapy on the basis of the results of the cost-effectiveness analysis alone. Furthermore, there is no guarantee that that any cost savings identified would be realised by employing MCP in routine care.
4. This study developed an MCP treatment that reflects professional consensus on best practice. With respect to the essential elements of MCP, it clarifies potential areas of ambiguity and provides a set of clear parameters within which treatment can be given. The high level of adherence to the MCP treatment protocol used in this trial suggests that it would be acceptable among the profession as a generic tool for delivering therapy.

Recommendations for research

With respect to the primary aim of the MATREX trial, further research is not required to demonstrate equivalence between receiving and not receiving MCP. Further research on the level of cost-effectiveness is unlikely to yield gains, as the benefits of both MCP and no MCP were similar and thus the consequences of making the wrong decision are small. As such, the cost of further research is likely to outweigh the value of information that would be gained. However, the findings of this study do not mean that MCP is of no therapeutic value to patients with COPD in specific circumstances.

The research questions arising from this study are listed below in order of priority:

- Is MCP effective for patients with COPD producing high volumes of sputum?
- Can the risk of oxygen desaturation during MCP be predicted?
- Is ACBT effective in treating COPD exacerbation?
- What are the trends over time in admission and survival rates for COPD?
- How can health-related resource use be more accurately identified?

Trial registration

This trial is registered as ISRCTN13825248.

Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 03/13/06. The contractual start date was in March 2005. The draft report began editorial review in May 2009 and was accepted for publication in December 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

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