The relationship between somatisation and outcome in patients with severe irritable bowel syndrome

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

CRD summary
This study examined the clinical and economic impact of three treatments for patients with severe irritable bowel syndrome, which were brief interpersonal psychotherapy, paroxetine, and usual treatment. These were assessed for four quartiles of somatisation score. Both psychotherapy and antidepressants were cost-effective for patients with marked somatisation. The study was based on a valid approach, which makes the authors’ conclusions more robust. However, the methods were published elsewhere and were not extensively reported.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the clinical and economic impact of three treatments for patients with severe irritable bowel syndrome (IBS), which were brief interpersonal psychotherapy, paroxetine, and treatment as usual. The aim was to assess the cost-effectiveness of these treatments according to the severity of somatisation score.

Interventions
The three treatment strategies were brief interpersonal psychotherapy (eight sessions), the selective serotonin re-uptake inhibitor antidepressant paroxetine (20mg daily for three months), and treatment as usual by a gastroenterologist and a general practitioner.

Location/setting
UK/primary and secondary care.

Methods
Analytical approach:
This economic evaluation was based on data derived from a single study with a one-year time horizon (Creed et al 2003, see 'Other Publications of Related Interest' below for bibliographic details). The authors did not explicitly report the perspective.

Effectiveness data:
The clinical evidence came from a published randomised controlled trial (RCT), which was carried out at seven gastroenterology clinics. The outcomes were assessed at baseline and at 15 months of follow-up, which was 12 months after the end of treatment. A psychiatrist, who was blind to the treatment group, assessed the severity of depressive symptoms. The key clinical endpoint was the Short Form (SF-36) physical component summary (PCS), which was a composite score of several scales (physical functioning, role limitation, bodily pain, and health perception). A regression analysis was undertaken to consider the potential impact of confounding factors. The sample included 257 patients, with follow-up data for 225 patients. The sample was divided into four quartile groups on the basis of the patients’ baseline somatisation score, with 65 patients in the most severe group.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
No summary benefit measure was used. The primary clinical outcome was the change in health status measured using the SF-36 PCS.

Cost data:
The analysis of costs included the following items: in-patient days, other hospital attendances, primary care contacts, domiciliary care services, medications and alternative therapies, travel and additional patient expenditures related to IBS, and productivity losses due to either illness or clinic attendance. The costs for health services came from National Health Service reference costs. Productivity costs were based on the patient’s wage and days lost. The resource use was based on case notes and hospital records of patients enrolled in the RCT (economic data were available for 249 of the 257 patients). The cost for two time periods, which were the 12 months prior to baseline and the 12 months after the end of treatment, were compared. All costs were in UK pounds sterling (£) and the price year was not reported.

Analysis of uncertainty:
Not investigated.

Results
Considering the whole sample, the PCS scores at 15 months were 36.6 (standard error, SE: 2.2) for psychotherapy, 35.5 (SE: 1.9) for antidepressant, and 26.4 (SE: 2.7) for usual treatment (adjusted p=0.014).

Patients in the quartile with the highest baseline somatisation score improved their health status more with psychotherapy or antidepressant than those who received usual care. At 15 months, for this highest quartile, the average change in adjusted PCS score compared with baseline values was 6.9 (SE: 2.2) with psychotherapy, 4.4 (SE: 1.9) with antidepressant, and -5.0 (SE: 2.8) with usual treatment (p=0.009).

The differences between the treatment groups in the quartiles with lower baseline somatisation scores did not reach statistical significance. At follow-up the mean SF-36 PCS scores (adjusted for baseline scores) were not significantly different, for all four somatisation quartiles (the groups had become more similar).

In the highest quartile, the total adjusted costs over the year following the end of treatment were £1,092 (SE: 487) in the psychotherapy group, £1,394 (SE: 443) in the antidepressant group, and £2,949 (SE: 593) in the usual treatment group (p=0.050). In all the other quartiles, the differences in costs among the three treatments did not reach statistical significance at one year and the data were only presented graphically.

Authors’ conclusions
The authors concluded that psychotherapy and antidepressants in patients with severe IBS, with marked somatisation, were cost-effective.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear. Psychotherapy and antidepressants were also valid comparators in other health care settings. The authors did not provide a clear description of the usual care, although more information may have been available in the report of the primary RCT.

Effectiveness/benefits:
The clinical evidence came from a RCT, which is usually considered to be a valid source of evidence, given the strengths of its design, which should reduce the potential impact of selection bias and confounding factors. This RCT was further strengthened by its blinded design and the use of extensive statistical tests to adjust the clinical outcomes for baseline factors. The length of follow-up appears to have been appropriate. The exclusion criteria for patient enrolment in the trial were reported. The RCT was published elsewhere, so some aspects of the clinical assessment were not reported. The primary clinical endpoint was estimated using a validated instrument.

Costs:
The economic viewpoint was not explicitly stated, but the types of costs included suggest that a societal perspective was taken. A breakdown of the cost categories was provided but the unit costs, resource quantities, and the price year were...
not reported. Most of the details on the economic analysis were presented in a previous economic evaluation. Statistical analyses of the costs were appropriately performed to adjust the totals for baseline differences.

**Analysis and results:**

The costs and benefits were not synthesised as a cost-consequences analysis was performed. The findings were clearly presented and discussed. The issue of uncertainty was not investigated. The authors acknowledged some limitations of their analysis, such as the small sample sizes for the quartiles and the fact that the results should be limited to patients with severe IBS.

**Concluding remarks:**

The study was based on a valid approach, which makes the authors’ conclusions more robust. However, the details of the methods were published elsewhere and were not extensively reported in this paper.

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**Other publications of related interest**


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**MeSH**

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