Psychotherapy or paroxetine did not reduce abdominal pain, but may improve quality of life in irritable bowel syndrome

Creed F, Fernandes L, Guthrie E, et al. ***The cost-effectiveness of psychotherapy and paroxetine for severe irritable bowel syndrome.*** *Gastroenterology 2003;**124**:303–17.*

Sources of funding: Medical Research Council of the UK and North Western Region Health Authority.

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QUESTION: In patients with severe irritable bowel syndrome (IBS), is psychotherapy or paroxetine more effective than usual care for reducing abdominal pain, and improving health related quality of life (HRQL), without incurring additional costs?

Design

Cost effectiveness analysis of a randomised (allocation concealed*), blinded (clinicians, {data collectors, data analysts, and data safety and monitoring committee}†),* controlled trial with follow up at 3 and 15 months.

Setting

7 gastroenterology clinics in the UK.

Patients

257 patients 18–65 years of age (mean age 40 y, 80% women) who met Rome I criteria for IBS, had symptoms for >6 months, failed to respond to "usual" medical treatment (antispasmodics and laxatives or antidiarrhoeal medication given for ≥3 mo), had severe abdominal pain (visual analogue scale >59), had no contraindication to psychotherapy or paroxetine, and were able to complete the study questionnaires. Follow up was 88% at 3 months; at 15 months, 90% of patients completed pain scores.

Intervention

Patients were stratified by hospital and by pain severity and allocated to psychotherapy (n=85), oral paroxetine, 20 mg daily (n=86), or usual care by a gastroenterologist or general practitioner (n = 86) for 3 months. 3 therapists administered psychotherapy, which consisted of encouraging patients to discuss symptoms, explore emotional factors, and identify the links between them. After 3 months, all groups received usual care for up to 15 months.

Main cost and outcome measures

Abdominal pain severity, physical component of the HRQL (measured by the SF-36), and direct healthcare costs (assessed by 1997–98 UK prices and reported in US dollars [£1 = $1.6]).

Main results

Analysis was by intention to treat. The groups did not differ in severity of abdominal pain at 3 or 15 months or improvement in the physical component of HRQL at 3 months (table). Both psychotherapy and paroxetine led to improvement on the physical component of HRQL at 15 months (based on 75% patient follow up and 96% imputation analysis) (table). Overall healthcare costs did not differ for paroxetine or psychotherapy relative to usual care.

Conclusions

In patients with severe irritable bowel syndrome, psychotherapy or paroxetine did not reduce abdominal pain but may improve quality of life at 15 months. Costs did not differ.

*See glossary.
†Information provided by the author.

Psychotherapy or paroxetine v usual care in irritable bowel syndrome at 3 months‡

Outcomes	Mean change from baseline: Psychotherapy	Paroxetine	Usual care	Difference in mean change from baseline (95% CI)
Abdominal pain at 3 months	−16.1	—	−11.4	4.7 (−4.2 to 13.6)
	—	−20.6	−11.4	9.2 (0 to 18.4)
Abdominal pain at 15 months	−15.0	—	−15.6	0.6 (−8.8 to 10)
	—	−16.3	−15.6	0.7 (−8.2 to 9.6)
Physical component of HRQL at 3 months	2.2	—	−0.5	1.7 (0.2 to 5.2)
	—	2.4	−0.5	1.9 (−0.2 to 6)
§Physical component of HRQL at 15 months	5.0	—	−0.2	4.8 (2.8 to 7.6)
	—	5.3	−0.2	5.1 (3.1 to 7.9)

‡HRQL=health related quality of life. Difference in mean change from baseline, and CI calculated from data in article. §Calculated from imputed data provided by author.

COMMENTARY

Selective serotonin reuptake inhibitors (SSRIs) are commonly prescribed in IBS but their efficacy is unknown. The study by Creed *et al* showed no difference between paroxetine and psychotherapy for IBS symptoms, which was consistent with another recent small, randomised placebo controlled trial using fluoxetine.[1] In the absence of other randomised placebo controlled trials, the cost effectiveness study by Creed *et al* comparing paroxetine to usual care is arguably premature, and usual treatment likely represents a very heterogeneous group. Any improvement in quality of life measures with paroxetine or psychotherapy could simply reflect greater contact with healthcare personnel in those groups.[2]

The study had other limitations. Firstly, the patients could not be blinded to the treatment allocation. Secondly, the generalisability of the findings to less severe cases is debatable because enrolment was limited to patients with severe abdominal pain and refractoriness to usual medical treatments. In addition, the study was powered to detect differences in abdominal pain that were not observed. A global disease specific outcome such as adequate IBS symptom relief would have allowed more useful comparison with other studies in the field.[3]

At 1 year, direct healthcare costs were less for psychotherapy than usual treatment, whereas no difference was observed between paroxetine and usual treatment. The cost results may also have been limited because 25% of the total sample did not complete the SF-36 assessment at 15 months, and a wide variability of cost data existed in the usual treatment group. Sensitivity analyses would have been useful to account for these factors.

Although other studies have suggested that psychotherapy is valuable for IBS[4], we do not believe the evidence is convincing that either SSRIs or psychotherapy are superior to usual care in either relevant symptom relief or cost for IBS.

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3 Cremonini F, Delgado-Aros S, Camilleri M. Efficacy of alosetron in irritable bowel syndrome: a meta-analysis of randomized controlled trials. *Neurogastroenterol Motil* 2003;**15**:79–86.
4 Spanier JA, Howden CW, Jones MP. A systematic review of alternative therapies in the irritable bowel syndrome. *Arch Intern Med* 2003;**163**:265–74.