

Six-year follow-up of patients with functional bowel disorders, with and without previous psychotherapy

Sechs-Jahres-Nachuntersuchung bei Patienten mit funktionellen Magen-Darm-Störungen mit und ohne vorherige Psychotherapie

Abstract

Introduction: Long-term follow-up studies in patients with functional bowel disorders are rare.

Methods: Of 85 patients with functional bowel disorders diagnosed in 2000, forty-eight patients responded to a postal questionnaire 6 years later (2006).

Results: Gastrointestinal symptom severity was similar to that at the initial diagnosis. Anxiety and depression (HADS) were significantly decreased, however, depending on previous psychotherapy (PT) experience. Men but not women that had participated in PT exhibited reduced symptoms more pronounced than did patients without PT.

Discussion: Anxiety and depression may determine consulting behaviour, but this appears unrelated to intestinal symptoms and their severity. Short-term PT contributes to long-term well-being especially in men.

Keywords: functional gastrointestinal disorders, irritable bowel syndrome, psychotherapy, depression, anxiety, follow-up

Zusammenfassung

Hintergrund: Langzeitstudien bei Patienten mit funktionellen Magen-Darm-Störungen sind selten.

Methoden: Von 85 Patienten mit funktionellen gastrointestinalen Erkrankungen, die im Jahr 2000 diagnostiziert wurden, waren 48 sechs Jahre später bereit, einen postalischen Fragebogen auszufüllen.

Ergebnisse: Zum Zeitpunkt der Nachuntersuchung waren die gastrointestinalen Beschwerden vergleichbar zum Zeitpunkt der Erstuntersuchung, aber Ängstlichkeit und Depression waren signifikant niedriger, in Abhängigkeit vom Umstand, ob in der Zwischenzeit Psychotherapie stattgefunden hatte. Insbesondere Männer profitierten von der Psychotherapie und zeigten reduzierte Symptombelastung im Vergleich zu Patienten, die keine Psychotherapie erfahren hatten.

Diskussion: Die psychischen Komorbiditäten (Angst und Depression) scheinen das Konsultationsverhalten zu beeinflussen, aber von den gastrointestinalen Symptomen und deren Schwere unbeeinflusst zu sein. Kurzzeitige Psychotherapie trägt zu langfristigem Wohlbefinden bei, vor allem bei Männern.

Introduction

Since the 1983 “landmark paper” by Svedlund et al. [1], many published studies have shown that a combination of psychotherapy (PT) and medical treatment or PT alone is more effective than conventional medical management alone in the treatment of patients with functional gastrointestinal (GI) disorders (irritable bowel syndrome, IBS; functional dyspepsia, FD). – (For a survey, see the reviews by Talley et al. [2], Soo et al. [3], Lackner et al.

[4], and Ford et al. [5].) A recent Cochrane meta-analysis by Zijdenbos et al. [6] however, concluded that psychological interventions may be slightly superior to usual care or waiting list control, but the clinical significance of this was regarded as debatable, and the sustainability of effects as questionable. Most PT studies have followed their patients for a few months and up to 1 year after therapy, and long-term follow-up studies are rare [7], in contrast to data from other clinical conditions [8], [9], [10]. Among the exceptions is the report by Schwarz et

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al. [11] of a 4-year follow-up of cognitive-behavioural therapy (CBT) and a similar study from another group [12] that followed patients up to 4 years after CBT, and 15 patients were followed for more than 2 years. Also, a 6-year follow-up after hypnotherapy was reported in more than 200 patients [13].

A different approach is taken by long-term “natural course of disease” studies that followed patients for a prolonged period of time without specific treatments. In IBS and other functional bowel disorders, the 12-year follow-up of patients by Halder et al. [14] may serve as one example; others are the 5-year follow-up study by Harvey et al. [15], the 6-year follow-up study by Neal et al. [16], and a study by Owens et al. [17] showed some degree of symptom improvement over time independent of a systematic trial intervention, in up to 40% of cases. These authors did not record psychopathology in their sample and their symptom data therefore, cannot be correlated to psychopathology.

PT efficacy has been shown to be independent of the type of PT applied, the duration of treatment and other differentiating variables [4]. If at all, variables predicting treatment success were identified in relation to clinical symptom severity (with the most severe symptoms predicting less success) and psychopathology (the higher the psychic comorbidity the better the PT response). A recent analysis by Lackner et al. [18] investigating moderators of treatment success came to conclude that PT directly affects gastrointestinal symptoms rather than being mediated via improvement of psychological well-being. However, many PT treatment reports are often lacking appropriate control groups and may be regarded as providing inappropriate evidence for efficacy of PT [2], [3], [4], [5], [6].

In a recently published paper from our group [19] we could show that one of the mediators of PT treatment success is the patients' motivation to undergo PT. However, whether patients were asked for their motivation or whether motivation was measured on psychometric test scales would not predict their actual behaviour to accept PT when this was offered. In our study, only a minority of patients (19%) accepted the offer of undergo psychotherapy. We followed the patients from this cohort six years later and asked for their current symptoms and psychological profiles to compare those that had undergone PT to those that did not. However, we acknowledge that our design resembles rather that of “natural history” studies than of “long-term psychotherapy outcome” studies.

Methods

Patients

Consecutive patients with symptoms suggestive of functional gastrointestinal disorders who were seen between January 1999 and December 2000 were included into the study. The Ethics Board of the University Hospital

Heidelberg had approved the study; all patients gave written informed consent prior to participation.

All patients were seen in the gastroenterologic outpatient clinic by a gastroenterologist, who suggested another consultation by a medical doctor trained in internal and psychosomatic medicine because of the nature of their symptoms. This physician recommended psychotherapy in all cases after the consultation.

In cases of symptoms suggestive of FGD, routine gastroenterological diagnostic procedures [20], [21] were used to exclude an organic origin of symptoms. Patients self-rated the presence and severity of the following GI symptoms – in accordance with the Rome definition of functional GI disorders [22] – and related symptoms. All symptoms were rated between 0 = not at all present and 4 = very strong. A questionnaire asked for the patients' actual social and biographic background (education, profession, current family situation, current employment status/retirement), medical history (current medication, frequency of doctor visits, inpatient treatments), and previous psychotherapy. They were also asked whether they had consulted doctors, psychotherapists, and alternative medicine practitioners since the initial evaluation. In addition, patients received a psychometric test battery including the Giessen Somatic Complaints Scale (GSB) [23], [24], and the German version of the Hospital Anxiety and Depression Scale (HADS) [25], [26].

Psychotherapy

Patients were offered to participate in a 10-session group therapy (90 min/session weekly) within the setting of the GI hospital. Following the assessment of individual therapy goals according to the *Goal Attainment Scaling* [27], patients were informed about the disease, prognosis, diagnosis and current state of therapy, learned to conduct a symptom diary, and to perform muscle relaxation training according to *Jacobson*. They learned to identify symptom-provoking situations, and to develop and exercise individual problem solving strategies, and behavioural alternatives to cope with stress. They also were instructed in nutritional and dietary management of symptoms. To include the familial environment and problems into treatment, family members were invited for an initial assessment and for one group therapy session. As reported previously [19], 16 patients of the initial cohort participated in a 10-hour supportive educational psychotherapy according to a published scheme [28].

Patients who underwent psychotherapy in the last 6 years received either cognitive behavioral psychotherapy or psychodynamic psychotherapy because these methods are paid by the German health care insurances. 1/3 had weekly sessions, and nearly 30% had psychotherapy for one year. 1/4 of patients consulted alternative medicine practitioners.

Giessen Somatic Complaints Scale (GBB)

The GBB scale [23], [24] is used to record the bodily complaints of patients with somatic disorders. It allows distinguishing between organically generated symptoms and subjective complaints.

Hospital Anxiety and Depression Scale (HADS)

The HADS [25], [26] is a fourteen-items instrument to assess anxiety and depression in patients with somatic diseases; the German version (HADS-D) was developed for use in general medicine.

Follow-up

In 2006, all patients included in the initial study were mailed a set of tests and questionnaires; these included the GI symptom rating scale, the GBB, and the HADS. Patients who did not respond within 2 weeks after mailing were followed by telephone survey to identify the reason for their non-responsiveness.

Evaluation and statistics

Social and medical history data were analysed in a qualitative and quantitative fashion. Symptom severity was scored by adding the presence and severity of 11 GI related symptoms (abdominal pain, bloating, feeling of distension, feeling of incomplete evacuation, diarrhoea, undigested food in stool, mucus in stool, constipation, loss of appetite, nausea) that were rated between 0 (not present) and 4 (severe). Psychometric data were scored according to the standards of the respective tests. Change in marital and professional status was noted if present; in addition, we assessed whether patients had experienced PT in-between the two evaluation points, and computed the total number of patients with PT experience.

Clinical symptom scores and psychometric scores were compared within patients by 2x2 repeated-measure ANOVAs using time (pre, post) as within-factor and gender (male, female) as between factor. PT (yes, no), change of marital status (yes, no) and retirement (yes, no) as between-subject factors that were added individually to post-hoc explore their contribution to GI and psychometric symptoms changes over time.

Association between repeated measures of individual tests were evaluated by Pearson's correlation coefficient. All data reported are mean \pm SD. All tests were performed using the SPSS Version 13 statistical package on an IBM PC; for all tests, the level of significance was set at 5%.

Results

Of the initially evaluated 85 patients (49.1 years, 61:24 females:males) with the diagnosis of "somatoform autonomic disorder of the upper gastrointestinal tract" (ICD-

10 F.45.31, n=13) or "somatoform autonomic disorder of the lower gastrointestinal tract" (ICD-10 F.45.32, n=40) or both (n=32), 48 (56%) were available for the follow-up investigation. However, excluding those with missing contact addresses, those that had received other diagnoses, and one patient who had died, response rate was 48/69 (70%) (Figure 1).

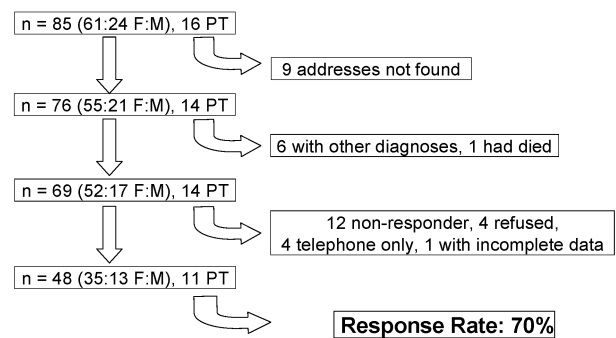


Figure 1: CONSORT chart of patient inclusion/exclusion. Response rate was 58% based on the initial recruitment and 70% based on the number of patients who were accessible for follow-up evaluation.

Socio-demographic and clinical characteristics of the 48 patients are summarized in Table 1. Patients who participated in the follow-up were not different from those who did not with respect to their psychological profiles at the initial investigation. As can also be seen, patients who had participated in initial PT (n=11) were not different from those who had not; the same holds true when all patients with PT experience (initially as well as over the 6 years follow-up, see below) (n=31) were compared to those who did not.

It was noted that 13 patients had changed their family status during the follow-up period; in 10 cases they changed from single to married, and in one case each from married to separated, from married to re-married, and from married to widowed. Sixteen patients were retired or semi-retired at follow-up compared to one subject at the initial assessment. Three patients had finished school in-between, 6 more had upgraded their professional qualification.

Nearly all patients in both groups had been seen by general practitioners and/or specialists since the initial evaluation, and 1/3 had consulted one or more alternative practitioner. In addition, 25 patients (5 males, 20 females) had been in PT in-between (7 on an inpatient basis, 14 as outpatients, and 4 with both), and 14/25 were cases in which PT had not been experienced at the time of the initial evaluation. At follow-up, 31 patients (64.6%) (8 males, 23 females) had collected PT experience over the 6 years.

Twenty patients had used gastroenterological medication during follow-up (5 proton pump inhibitors, 6 antacids, 3 antispasmodics, 2 antidiarrhoeal drug, some laxatives), and 16 patients had used or used currently antidepressant medication (one patient with a combination of antidepressant and neuroleptic medication).

Table 1: Sociographic and clinical characteristics of the initial and the follow-up sample

		Initial	Follow-up	Patients with PT ¹	Patients with PT ²	Statistics**		
	N (%)	n=85	N=48	N=11	N=31	I – F	F – PT ¹	F – PT ²
Referral	GI outpatient	34	23	3	12	n.s.	n.s.	n.s.
	PSM ⁺ outpatient	2	1	1	1			
	Others outpatient	7	1	0	0			
	Private practice	36	18	5	14			
	Others	6	5	2	4			
Gender	Male	24	13	4	8	n.s.	n.s.	n.s.
	Female	61	35	7	23			
Origin	German	64	41	10	27	n.s.	n.s.	n.s.
	Immigrant	21	7	1	4			
Age	(mean ± SD)	49.1±13.6	49.5±13.9	51.6±13.7	46.7±2.5	n.s.	n.s.	n.s.
Status	Single	29	17	2	13	n.s.	n.s.	n.s.
	Married	42	24	8	14			
	Others	14	7	1	4			
ICD Dx	F45.31	13	8	0	4	n.s.	n.s.	n.s.
	F45.32	39	17	9	15			
	both	31	22	2	12			
	none	2	1	0	0			
SS*	(mean ± SD)	15.5±6.8	14.9±1.2	19.1±5.8	16.8±1.4	n.s.	n.s.	n.s.

+: PSM = Psychosomatic Medicine

*: Symptom Score = sum of 11 GI related symptoms scored between 0 and 4

PT¹: Psychotherapy during the initial study; PT²: psychotherapy within the entire 6 year follow-up period

** : t-test or chi-square, comparing the initial to the follow-up sample (I – F) or patients with and without PT (F – PT¹, F – PT²) to the entire follow-up sample; since the samples overlap, data were corrected accordingly.

Gastrointestinal Symptoms

At the initial evaluation, patients reported an average 15.9±1.1 points on the 0 to 44 symptom scale, while at follow-up, they scored 14.9±1.2 points; this difference was not significant (2x2 ANOVA, not significant). Both measures correlated high and positively: $r=.539$, $p<.001$ indicating that a high symptoms load at the initial evaluation would also be present at follow-up; while many patients had changed symptoms, these changes occurred in both directions. Patients who had undergone PT were equally distributed among them (Figure 2, Table 2).

ANOVA revealed a significant interaction between the factors “time” (pre, post), gender (males, females) with initial PT (yes, no) (significant interaction: $F=4.189$, $p=.047$) (Figure 3) as well as for PT between assessments ($F=4.401$, $p=.042$) indicating that men that had participated in PT reduced GI symptoms more pronounced than women, while this gender difference was not seen in those without PT experience.

Patients who had participated in PT initially showed overall significantly higher symptoms initially as well as at follow-up (main effect of PT: $F=4.678$, $p=.036$) than those who did not. Male patients who had participated in PT during the follow-up period showed lower symptoms at follow-up (significant interaction “time x gender x PT in-between”, $F=4.401$, $p=.042$). Change of marital and job status did not contribute to GI symptoms and symptom changes.

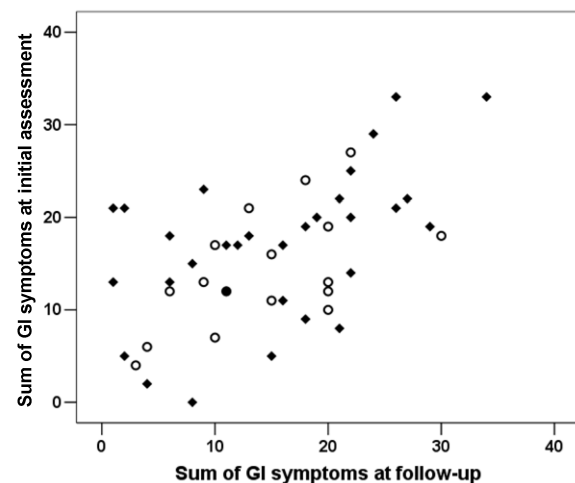


Figure 2: Scatter plot of gastrointestinal symptom scores at initial evaluation and at follow-up. Pearson's correlation coefficient was $R=.539$, $p<.001$. Black diamonds indicate patients who underwent psychotherapy either initially or during follow-up ($n=31$), open circles patients who did not; a black filled circle represents two overlapping cases with and without psychotherapy experience.

Table 2: Psychometric test scores (mean \pm SD) at initial evaluation and at follow-up

		Evaluation (n=48)		Statistics	
		Initial	Follow-up	ANOVA*	Correlation**
SS ⁺	Total	15.9 \pm 1.1	14.9 \pm 1.2	n.s.	R=.539, p<.001
	fatigue	12.3 \pm 6.1	9.5 \pm 5.8	F=5.582, p=.005	R=.505, p<.001
GBB	gastrointestinal	10.4 \pm 4.4	8.1 \pm 5.0	F=9.922, p=.003	R=.345, p=.016
	muscular	11.18 \pm 6.0	11.5 \pm 6.0	n.s.	R=.587, p<.001
	cardivascular	7.0 \pm 5.4	5.3 \pm 4.9	F=4.653, p=.036	R=.713, p<.001
	total	40.1 \pm 16.7	34.4 \pm 18.0	F=7.755, p=.067	R=.628, p<.001
HADS	Anxiety	9.9 \pm 4.3	8.5 \pm 4.6	F=2.903, p=.095	R=.413, p=.003
	Depression	7.9 \pm 4.1	6.8 \pm 4.2	n.s.	R=.454, p=.001

* Repeated measure ANOVA with time (pre, post) as within factor and gender (m,w) as between factors; all effects are min effects of time; for the interaction between time x gender and psychotherapy see text for details.

** Pearson's correlation coefficient for initial versus follow-up measures

+ Symptom score: sum of 11 GI symptoms scored between 0 (none) and 4 (severe)

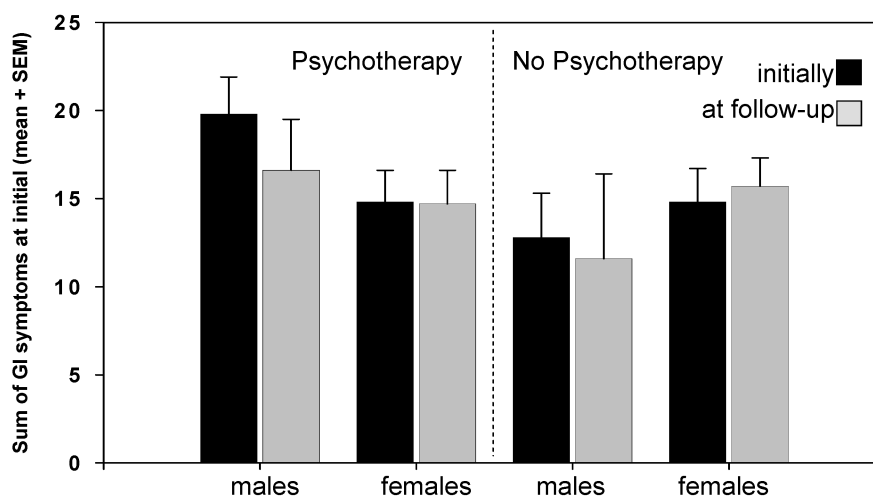


Figure 3: Total gastrointestinal symptom score at initial evaluation and at follow-up by gender and between patients with (n=31) or without psychotherapy (n=17). ANOVA revealed a significant interaction between the factors "time" (pre, post), gender (males, females) and PT (yes, no) (F=4.401, p=.042).

GBB scores

Total GBB scores decreased over time (main effect: F=7.755, p=.067), and were more pronounced for GI symptoms (F=9.922, p=.003) than for fatigue (F=8.585, p=.005), cardiac (F=4.653, p=.036), and muscular symptoms (not significant). PT experience did affect neither of these scores, and neither did change of marital status. Retirement tended to have an independent effect on total GBB scores (main effect: F=3.867, p=.056): Patients who had retired in the interim between initial evaluation and follow-up demonstrated higher overall GBB scores than those who did not.

HADS anxiety and depression

HADS anxiety scores tended to be lower at follow-up, as revealed by repeated measure ANOVA (main effect of time: F=2.903, p=.095).

When PT was entered into the equation a significant interaction between time, gender, and PT occurred (F=4.261, p=.042) with men who had participated in the

PT showing less symptoms. This was due to initial PT (F=4.589, p=.038), while PT experience during follow-up did not contribute to anxiety changes. Change of marital status independently tended to improve of HADS anxiety scores (main effect: F=3.757, p=.059) while retirement did not.

In general, depression scores did not change much over time (Table 2).

Inter-correlations

HADS scores as well as and GBB total score correlated high between the first evaluation and at follow-up (Table 2). All changes of symptoms and HADS and GBB scores between first assessment and follow-up were also significantly correlated (Table 3).

Table 3: Intercorrelations between changes of symptoms (initial assessment minus symptoms at follow-up) over time (all significant)

	GI Symptoms	GBB Global	HADS anxiety	HADS Depress	
GI Symptoms	–	0.001	0.04	0.047	P Values
GBB Global	.448	–	0.026	<0.001	
HADS anxiety	.297	.320	–	<0.001	
HADS depress	.288	.502	.590	–	
Pearson's R					

Discussion

To summarize the findings of our study, we found that 6 years after initial evaluation, patients with functional bowel disorders exhibited a similar number and severity of gastrointestinal symptoms but had substantially improved the anxiety and depression scores. In men but not in women, this decrease in anxiety and a moderate symptom improvement was associated with the participation in psychotherapy 6 years ago or during the follow-up period. However, significant interactions of PT experience were found with gender and overall GI symptoms and GBB and HADS scores, indicating that especially men profited from PT experience in the past. We could not find support for the notion that symptomatic improvements may as well be due to changes in family and professional status, except that the initial symptom burden (in the GBB) was higher in those that had retired at follow-up. While there are many long-term follow-up studies of PT in various clinical conditions [8], [9], [10], only a few of the PT treatment studies with functional bowel disorders report data for more than one year after therapy. Among the few, the report by Schwarz et al. [11] summarizes all measures at a 4-year follow-up of cognitive-behavioural therapy (CBT) in 19 patients to be lower than those obtained prior to treatment, and significant reductions on key IBS symptoms such as diarrhoea, nausea, and flatulence. A similar study from another group [12] reported similar follow-up data for 32 patients after up to 4 years after CBT, and 15 patients were followed for more than 2 years. The sustained response of PT on anxiety symptoms we report at least in men is compatible with these data, but beyond this both study data are not comparable to our assessment here as they both included waiting list controls that received PT after the study termination, and they did not include a no-treatment control group. A different approach in FBD patients is the application of gut-directed hypnosis: Gonsarkonsale et al. [13] reported that from the initial 70% responders to therapy, 80% had persistent symptom improvement up to 5 years later. Improvement was related to quality of life for the entire period with psychological burden, extraintestinal symptoms, and number of physician consultations substantially reduced. Contrary to previous results, age and psychiatric comorbidity had no influence on the success rate. It has been stated before that establishing of unspecific (placebo) effects in clinical trials would require “no treatment” control groups to allow the separation of specific therapy effects from spontaneous variation of

symptoms and from “true” placebo (or unspecific) therapy effects [29]. Such data do – to our knowledge – not exist for psychotherapy trials but can be found in epidemiological samples. In IBS and other functional bowel disorders, the 12-year follow-up of patients by Halder et al. [14] may serve as one example; others are the 5-year follow-up study by Harvey et al. [15], and the 6-year follow-up study by Neal et al. [16]. However, the study by Harvey et al. [15] was based on an IBS definition that does not comply with current or previous IBS definitions [12] and followed only 104 patients who had been treated for IBS. Overall, 68% of patients were reported to be symptom free after 5 years. In a similar study by Owens et al. [17], 112 patients who had been diagnosed having IBS were followed for a medium of 29 (range: 1 to 32) years; IBS patients had a positive prognosis and fewer follow-up visits in case the records contained (among others) information about the patients psychosocial history, indicating a strong physician-patient interaction. The study by Neal et al. [16] followed 192 patients who had previously experienced an episode of acute enteritis to determine, who would develop new IBS symptoms (n=14); hence, their data are non conclusive for our research question. All other studies had a follow-up of mostly 1 year after therapy or diagnosis.

In the largest “natural history” epidemiological study by Halder et al. [14], the authors followed more than 1,300 patients with symptoms of IBS and/or FD for 12 years and found that about 40% of their sample had lost their GI symptoms at follow-up, while 20% had similar complaints and another 40% had changed their predominant complaints from upper to lower GI tracts or reverse. Such a change of diagnostic group had been noted before but for shorter follow-up periods [30], [31] and was attributed to an underlying common pathogenesis of FGD [32]. These authors did not record psychopathology in their sample and their symptom data therefore, cannot be correlated to psychopathology, as we did; but others have reported that psychopathology determines health care-seeking behaviour, symptom severity and duration, and psychological and somatic comorbidity [33], [34], [35]. Unfortunately, our follow-up data do not allow the assessment of such a transition of diagnostic groups. Other limitations of our study are the small sample size (and the low power of the statistical analysis) and the fact that a patient population recruited at a tertiary centre does not represent all patients with functional bowel disorders and may include a subset of patients with high morbidity and longer illness history, but this certainly does apply

also to all other PT studies that were conducted in academic centres. We also do not know whether and to what extent our IBS patients did require medical care for GI symptoms between the initial evaluation and the follow-up; however, we could identify a substantial group of patients who underwent additional psychotherapy sessions, and that contributed to the treatment success as much as the initially PT treatment. As has been reported in the literature, prediction of treatment outcome appears difficult, and may be related to individual features not sampled in our study. Finally, patients may have used antidepressants during the follow-up period in parallel to psychotherapy, and that could have contributed to the reported changes especially with respect to psychological improvements, but was not assessed with our questionnaire.

In summary we conclude that over the course of 6 years GI symptoms in IBS exhibit a rather stable pattern, but at the same time psychological symptoms (somatization, anxiety and depression) improve, especially in those patients who underwent psychotherapy; among them, men profited more. While only 11 patients had agreed to PT during the first phase of the study [9], another 20 underwent PT during the follow-up period. Both the initial symptom load as well as continuous psychological and gastrointestinal symptoms during the follow-up may have motivated patients to take advantage of PT.

As we have stated before [32], patients with functional gastrointestinal disorders are not a homogeneous group of patients even when they enter a specialised tertiary centre. Gender, motivation, psychological strain and severity of symptoms contribute to their health care seeking behaviour, but also to therapy outcome. Further research on therapy effects in subpopulations, stratified for psychological comorbidity, gender, and chronicity of symptoms) is needed to eventually overcome these limitations. In clinical practice short-term multimodal therapy should be offered to motivate patients, in particular male patients who usually have more problems accepting psychotherapy, but – as shown in this study – benefit more than expected once they agree to participate.

Notes

Conflicts of interest

None of the authors declares a conflict of interest.

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