

# Patient Perceptions of Treatments for Functional Bowel Disorders

## ***Abstract***

**Background:** Functional bowel disorders, including irritable bowel syndrome (IBS) are heterogeneous in terms of pathogenesis and presentation. Consequently, the therapies prescribed for the management of symptoms are equally diverse. However, long term and patients' perceptions of the efficacy of these treatments are often not well understood.

**Objective:** To investigate patients' perspectives on efficacy of management practices used for functional bowel disorders, including irritable bowel syndrome (IBS).

**Methods:** A questionnaire was posted to all patients with IBS or functional bowel disease who attended the Allergy Unit, and/or a Private Gastroenterology Practice at Royal Prince Alfred Hospital, between January 1998 and December 1999. Questions focused on medical and alternative therapies trialed by the patient, and the perceived short and long-term efficacy of the therapies. Responses were analysed using Excel and SPSS to perform ANOVAs and t-tests.

**Results:** Data from 97 Patients was analysed. Perceptions of treatment efficacy were very varied. Patients in this study perceived dietary manipulation, mostly in the form of elimination of specific chemicals from the diet, was most effective in reducing symptoms. Medication was also important. Relaxation techniques, although not perceived to be of greatest importance, were a common second choice of therapy. High fibre diets did not rate highly, although data about high fibre diets was incomplete.

**Conclusions:** The perceived efficacy of treatments is personal, and probably reflects the specific mechanisms underlying the symptoms in an individual. Most people have trialed a number of therapies (av. 9.4, range 1-37), before finding one or a combination which works to bring some relief from their symptoms. The large

percentage of patients from both practices rating dietary manipulation as most important for symptom relief suggests food intolerance should be investigated more thoroughly for a substantial subgroup of this population.

## ***Introduction***

Irritable bowel syndrome (IBS) is a functional bowel disorder where pain is relieved by defecation. There is an associated alteration in bowel habit, with features of disordered defecation and distension<sup>[1]</sup>. Not all patients with chronic gastrointestinal symptoms meet the specific symptom criteria for IBS<sup>[2]</sup>.

Irritable bowel syndrome affects between 10 and 25% of the population<sup>[3,4]</sup>, (15-25% of females; 5-20% of males) and appears to be fairly consistent in presentation across countries and all socioeconomic standings<sup>[5]</sup>. In approximately 30% of IBS sufferers, symptoms resolve over time<sup>[6,7]</sup>. A study in the UK following almost 3000 newly diagnosed IBS patients<sup>[8]</sup> found most were young or middle-aged at the time of diagnosis, only 12% being older than 60 years. The majority, (74%) were women, reflecting other studies. Accurate calculation of the rate of IBS is difficult, and although IBS accounts for up to 50% of outpatients presenting to gastroenterologists<sup>[9,10]</sup>, it is suggested only a subgroup of IBS sufferers seek medical attention for their symptoms<sup>[9,11-13]</sup>.

The diagnosis of IBS is generally one of exclusion, made in the absence of other organic causes<sup>[12,14-17]</sup>. A number of sets of criteria have been developed. The Manning criteria<sup>[15]</sup> were developed first and are used most commonly by gastroenterologists, but have been shown in studies to have varying diagnostic value when applied to the male population<sup>[18-20]</sup>. Developed from this, the Rome<sup>[16,21]</sup> criteria (Appendix 1) have come to be accepted as the gold standard for research studies. Patients with IBS often present with additional problems such as fatigue/lethargy, headache, backache, nausea, non-cardiac chest pain, gynaecological problems, urological symptoms and fibromyalgia<sup>[3,22-25]</sup>. Therefore, the use of 'non-colonic' symptoms as a means to a more accurate diagnosis,<sup>[24]</sup> has been suggested. With the inconsistency of definition<sup>[26,27]</sup>, IBS often misdiagnosed<sup>[28]</sup> resulting in some people undergoing needless medical tests and surgery<sup>[28,29]</sup>.

An additional group of patients do not experience pain relieved with defecation, but exhibit a plethora of other gastrointestinal symptoms such as chronic diarrhoea, constipation, flatus or bloating, as well as many of the

non-colonic symptoms listed above. By definition, they cannot be classified as having IBS, and are classified as having functional bowel disease, yet treatment is often similar.

Psychological factors have long been considered as significant in the pathogenesis of IBS and it has been suggested that psychiatric illness may occur in 54% to 100% of patients [12,16,30-38]. Psychological stress has been reported to be associated with health seeking [39,40], as has learned illness behaviours [41]. More than half of those with IBS symptoms report that psychologically stressful events exacerbate symptoms [38-44] and a stressful event which preceded the initial onset of their symptoms [42,44]. Others report a history of abuse preceding their bowel symptoms [45-48]. One study [49] found that symptoms of IBS patients, but not those of patients classified with functional bowel disease, respond to stress.

It is impossible to accurately measure the real cost of IBS. It is a combination of personal cost, such as quality of life, direct financial costs including medical expenses, and indirect costs such as lost work time [49,48,50]. Ramifications to the quality of life and activities of daily living of sufferers [51,52] may include poorer general health, vitality, mental and emotional health, and more sleep disturbances than the average population. These symptoms are perceived to be greater in those who seek health care [53-55].

Recent studies in the USA and UK [3,48,52], found IBS patients had significantly more work absenteeism and doctor's visits per year than those without these symptoms. Most had cut down on working hours, changed jobs, turned down promotions, altered their schedule or lost work due to their IBS symptoms. A fiscal cost analysis in 1995 showed that median health care costs for community IBS patients was almost 1.8 times that of control subjects without bowel symptoms [56].

The mechanism of IBS involves the interaction of numerous factors [57,58] including underlying psychological distress [59], altered gut motility and function through involvement of both the peripheral and central nervous systems [27,59-74], altered sensory functions of the intestine [17,75-77], food malabsorption, intolerance and allergy [78-84] and possibly altered gut flora [85] and immune function [86]. There is also speculation about other factors including increased colonic gas production [87-90]. Consequently, management of patients once

diagnosed is based on the institution of therapeutic regime(s) which are individualised and based on the perceived mechanisms in operation, which appear to be unique to the individual [12] and relatively stable over time [91]. The major focus of the therapy for these patients is to reassure them of the absence of serious underlying disease, and to point out that the therapies are aimed at alleviating the discomfort suffered rather than providing a cure [12].

Dysfunction in more than one of these systems may be operating in any one individual. Therefore, a combination of therapies is often used. Therapies may include:

- ◆ Dietary manipulations such as adjustment of water or fat intake, consumption of probiotics [92], avoidance of 'windy' foods, fibre manipulation [93-96], lactose-free diets [97,98], and elimination diets for various food intolerances including gluten, amines, salicylates, preservatives and other additives. [99-101].
- ◆ A study in the UK [8] found that 86% of newly diagnosed IBS patients were prescribed some kind of drug treatment. The most common drugs prescribed were antispasmodics (70% of patients) [101,103], followed by laxatives (14% of patients). Anxiolytics [104] and antidiarrhoeal [67,105,107] drugs were more likely to be prescribed to older patients. Most patients prescribed drugs began treatment within a week of diagnosis. Drugs were more likely to be prescribed to female and elderly patients than to younger men. Other drugs prescribed include antidepressants [108,109], gastric secretion inhibitors [110], prokinetic agents (modulate gut motility) [111-114], sodium cromoglycate (appears to decrease gastrointestinal permeability) [115,116], (and has met with mixed reports of efficacy in treating food allergy/intolerance [117-123]), and others [124,125].
- ◆ Alternative therapies used include peppermint oil [126-134], reported to have antispasmodic properties [135] and Chinese herbal medicine [136-140].
- ◆ Psychotherapy is suggested as useful for some patients, including hypnotherapy [141-146], insight-orientated therapy [147,148], cognitive therapy [149,150], and relaxation therapy [151]. Multi-component therapies, combining psychotherapies and other therapies have also been trialed [152-157].

- ◆ Other management practices may include education classes <sup>[158]</sup> which involve several facets including information about the disease, etc, or exercise.

Although the above therapies are frequently prescribed, the long-term efficacy of many of these is unclear. Variable diagnostic criteria, poor study design (often too short, insufficient 'washout' time between crossovers, lack of randomisation, controls or blinding, etc), and a large placebo effect in this group have resulted in a limited amount of unequivocal study data, and difficulty comparing data from different studies <sup>[132,160-161]</sup>.

Functional bowel disorders are a major problem, to both to the individual, and to the wider community. Improvement in symptoms has been shown to result in improved quality of life <sup>[162]</sup>. Thus, the quest for answers on how best to manage this group have important ramifications. The aim of this retrospective study is to further investigate, using a self-administered questionnaire, the different therapies used in a selected cohort of patients with IBS and other functional bowel disorders, and evaluate the therapies from a patient-perceived long-term perspective.

## **Methods**

### **Ethics Approval**

Approval was sought and granted by the Ethics Review Committee of the Central Sydney Area Health Service (RPAH Zone). All subjects gave written, informed consent, which included patient record access.

### **Patient Selection**

Patients were selected for inclusion in the study if they had attended the Allergy Unit of Royal Prince Alfred Hospital (RPAH), Sydney, or a Private Gastroenterology Practice associated with RPAH aged 18 or over, between January 1998 and December 1999, with either IBS or functional bowel symptoms.

Five hundred and fifty six consecutive patients were included, 214 from the Allergy Unit, and 342 from the Gastroenterology practice. The questionnaire was posted to patients during August, 2000, and those returned by 1 October, 2000 were included in the results.

### **Questionnaire Design**

The questionnaire (Appendix 2) was based on a design previously used with IBS patients by the Allergy Unit, updated to reflect current requirements. No validation process was undertaken of the questionnaire before use. Questions called for a mixture of closed and open responses and included

- ◆ Date of first visit to the Clinic, age, gender
- ◆ Perceived symptom frequency and severity at the time of presentation to the Allergy Unit or Gastroenterologist, and again at the time of completing the questionnaire. Patients were asked to score each symptom they have experienced on scales of:
  - ◆ **severity** - 0 (none), 1 (mild), 2 (moderate) or 3 (severe),
    - *Mild*: The patient is aware of the symptom, but it is easily tolerated.
    - *Moderate*: This symptom is enough to cause interference with daily life or usual activity.

- *Severe*: This is incapacitating with inability to work or to take part in usual activities
- ◆ **frequency** - 0 (never), 1 (less than once per month), 2 (monthly), 3 (weekly) or 4 (daily).
- ◆ Past medical, relaxation and alternative therapies trialed, whether still in use and perceived effectiveness over time;
- ◆ Perceived effects of dietary modifications and results of food elimination trials, both in the past, and on advice from the Allergy Unit;
- ◆ Patient ranking of relative effectiveness of therapies trialed.

### ***Data processing and analysis***

Data was coded and entered into a Microsoft Excel 97 (Microsoft Corp, USA) spreadsheet. The respondents' patient files were perused to ensure data was as accurate and complete as possible. When recording responses to treatments, only a definite indication of improvement was taken as a 'yes'. Blanks were treated as a 'no' response. Graphs were then generated from the spreadsheet data. Perceived symptom changes (severity and frequency), treatments trialed and their perceived current efficacy, age, clinic attended and gender were all used for further analysis using SPSS software (Version 6.1, SPSS Inc, Chicago, USA). Due to the small numbers of people using each specific therapy, results were pooled under the general headings of the questionnaire for analysis (ie medication, relaxation therapy, natural therapy, exercise, fibre, dietary modifications, and elimination diet). ANOVA tests were performed to determine variance between the data in terms of:

- ◆ age, gender or clinic attended with perceived symptom outcomes (frequency and severity);
- ◆ age, gender or clinic attended with therapies trialed and perceived symptom outcomes;
- ◆ perceived symptom outcomes (frequency and severity) and perceived current effects of therapies.

Analysis was done based on attendance at a particular clinic, as many of the patients attending the Allergy Unit had seen other Gastroenterologists in the past, and the cohort attending both was too small for unique analysis. Student's t-tests were done to determine significant differences between the populations who did/did

not undertake the elimination diet in terms of symptom frequency and severity. Other qualitative data was taken from open-ended responses on the questionnaire.

### ***Allergy Unit Elimination Diet***

The Allergy Unit elimination diet <sup>[99,100]</sup> excludes all moderate and high sources of chemicals known to cause reactions in sensitive individuals, including salicylates, amines, chemical additives (colours, preservatives, flavours and antioxidants), both naturally occurring and added. If symptoms settle, challenges of these chemicals are taken, as double blind capsule challenges and/or foods to determine chemical sensitivity.

## **Results**

### ***Response Rate***

Of 556 questionnaires posted, 138 (24.8%) were returned. Thirty-one were no longer at that address, one patient was deceased, and another declined to participate owing to poor memory. One hundred and eight questionnaires (19.4%) were returned completed. Eleven were excluded from analysis due to incomplete symptom data, resulting in a total of 97 questionnaires for analysis, 58 having attended the Allergy Unit, and 55 the Gastroenterology Practice (16 attended both).

### ***Age and gender of patients***

Females comprise 70.1% of the sample. Average population age was 43.2 years and while the ranges of age are similar across groups (Appendix 3), distribution was skewed with women (average 41.1 years) on average younger than men (average 48.1 years). Women attending the Allergy Unit were on average younger (average 38.8 years) than those attending the Gastroenterology Practice (average 43.4 years). As age, gender or practice attended had little statistical significance in terms of therapy outcomes, these were not controlled for in further analyses (data not shown).

### ***Medical Tests***

The majority of patients (90.1%) have undergone some form of medical testing to rule out other organic disease (Appendix 4), the most common being colonoscopy/biopsy (71%) followed by endoscopy (67%). On average, patients have undergone 3.3 (Allergy Unit) or 3.5 (Gastroenterology Practice) tests. Comments in patient records of most of those from the Gastroenterology Practice who did not undergo tests suggested they were not warranted based on the presenting symptoms.

### ***Symptom Perception***

Average patient perception decreased for all symptoms over the study period (Appendix 5), severity by 31% and frequency by 30% for all symptoms combined. Average length of time from onset of symptoms to the

present could not be calculated due to a poor response to this question. Initial symptom perception was significantly worse in those who undertook the elimination (cramp, fatigue, and headache severity; diarrhoea, constipation, headache, stomach pain, mouth ulcer, wind, fatigue, distension, and cramp frequency, ( $p < 0.1$ ) than in those not undertaking the diet (data not shown).

Increasing age was correlated significantly with an increase in frequency of diarrhoea ( $r = 0.2596$ ,  $p = 0.012$ ) and severity of mouth ulcers ( $r = 0.2925$ ,  $p = 0.004$ ), and approached significance with an increase in severity of bloating ( $r = 0.1737$ ,  $p = 0.096$ ), and a decrease in frequency of fatigue ( $r = -0.1746$ ,  $p = 0.094$ ). (Appendix 14)

There was significant correlation between being male and an increase in frequency of bloating, ( $r = 0.2184$ ,  $p = 0.032$ ) and significance was approached with increased severity of bloating ( $r = -0.1820$ ,  $p = 0.074$ ), decreased frequency of pain on defecation ( $r = -0.1771$ ,  $p = 0.083$ ), a decrease in ulcer severity ( $r = -0.1733$ ,  $p = 0.090$ ), and a decrease in vomiting frequency ( $r = -0.1723$ ,  $p = 0.091$ ).

### ***Therapies Tried***

The number of therapies trialed was not significantly correlated with the sum of the symptoms scores for an individual. Average number of therapies trialed was 9.4 (range 1-37). Patients often reported therapies as having initial benefit, but after a period of time the therapy appeared to lose effectiveness. The length of benefit of these therapies could not be determined as these questions were often not answered.

### ***Medications***

Sixty eight percent of the sample reported being prescribed a range of drugs directly for their gut symptoms or for stress relief (Appendix 6). Seventy three percent of those taking drugs reported them initially effective, and 44% reported continued effectiveness. If medication was prescribed, patients reported an average of 2.7 types prescribed in the past. These patients reported still taking an average of 1.1 drugs, with an average of 0.8 types having benefit at the time of the questionnaire. Drug types reported as prescribed, in rank order, were reflux/stomach ulcer medication (50% of all patients), antispasmodics (31%), laxatives (18.6%), antidiarrhoeals (16.5%), antidepressants/anxiolytics (13.4%), prokinetics (13.4%), and a range of other types.

Significant correlation was seen between increasing age and both number of medications prescribed ( $r=0.2227$ ,  $p=0.032$ ), and current perceived effectiveness of medications ( $r=0.2371$ ,  $p=0.022$ ). No significance was found between the number of medications currently perceived effective and any decrease in symptom severity or frequency. However, there was significant correlation between prescription of medication and improvement in nausea severity ( $r=-0.2003$ ,  $p=0.049$ ).

### ***Relaxation Therapies Tried***

Just over 30% of the sample have used relaxation therapies, and almost 80% of these perceive ongoing benefit from these therapies (Appendix 7). If a patient trialed relaxation therapies, they reported an average of 3.2 types of therapies (range = 1-7). These included time out (13.4% of the total group), exercise (13.4%), decreasing workload (12.4%), meditation, (11.3%), deep breathing (11.3%), positive thinking (10.3%), stress relaxation classes (8.4%) and a range of other behaviours. Significant correlation was found between perceived effectiveness of relaxation techniques and improvement in both constipation frequency ( $r=-0.4633$ ,  $p=0.023$ ) and severity of bloating ( $r=-0.4958$ ,  $p=0.014$ ). Significance was approached between perceived relaxation technique effectiveness and improvement in constipation severity ( $r=-0.4029$ ,  $p=0.051$ ).

Patients most commonly reported relief for headaches, diarrhoea, constipation and pain. Some patients suggested these therapies did not directly help their bowel symptoms, but the stress relief enables them to better cope with their symptoms. A question asking those who have trialed relaxation therapies to rank them in order of perceived benefit was not well answered, and an overall ranking therefore was not possible.

### ***Natural Therapies***

Just over half the patients (53%) reported having tried some sort of natural therapy, with an average of 2.0 types (range = 1-6). These included herbal remedies (42% of all patients), massage (16%), meditation (10%), aromatherapy (7%), and a range of others. Only 30% of those trialing natural therapies reported an ongoing benefit from the therapy (Appendix 8). It was not possible to calculate the average length of time of therapy benefit for those who initially perceived benefit but no longer do so, as this question was infrequently

answered. There was some discrepancy among patients in reporting of meditation and antibiotic therapy, as they appeared under several therapy categories, and thus they were considered at face value as reported.

Patients most commonly reported an improvement in bloating, pain, constipation and stress where these therapies were reported as useful.

Significant correlation was found between perceived effectiveness of natural therapy and improved severity of diarrhoea ( $r = -0.2068$ ,  $p = 0.042$ ), and between the perceived benefit of natural therapies and improvement in the frequency of cramp ( $r = -0.2825$ ,  $p = 0.005$ ), and wind ( $r = -0.2791$ ,  $p = 0.006$ ). Significance was approached between perceived effectiveness of natural therapy and improvement in both pain on defecation ( $r = -0.1901$ ,  $p = 0.062$ ), and fatigue severity ( $r = -0.0482$ ,  $p = 0.071$ ). Females ( $r = -0.2366$ ,  $p = 0.020$ ) were more likely to have tried these therapies and there was a tendency against trying them with increasing age ( $r = -0.2561$ ,  $p = 0.013$ ).

### ***Exercise***

Fifty two percent of patients reported using exercise for bowel symptoms (Appendix 9), with about half of these (26%) perceiving sustained benefit. Of those trialing exercise, they reported an average of 1.6 different types trialed (range = 1-3) and an average weekly exercise time of 4.1 hours. Walking was by far the most common type trialed (37% of all patients). Other forms of exercise reported included jogging (10%), aerobics (8%), yoga (8%), swimming (6%) and a range of other exercises. Two patients reported ceasing exercise as they felt it exacerbated symptoms. Several others have ceased due to problems not associated with bowel symptoms. Symptoms commonly cited as relieved by exercise are constipation, bloating, pain and non-colonic symptoms such as depression and stress. A number of patients reported continued use of exercise for general health and well-being either independent of bowel symptoms or despite lack of efficacy for bowel symptoms.

Use of exercise for symptoms (but not outcome) was found to be significantly negatively correlated with age ( $r = -0.1808$ ,  $p = 0.083$ ). Perceived benefit of exercise was correlated with improvement in both constipation frequency ( $r = -0.2115$ ,  $p = 0.038$ ) and cramp severity ( $r = -0.2001$ ,  $p = 0.049$ ). Significance was approached

between perceived benefit of exercise and severity of constipation ( $r=-0.1820$ ,  $p=0.074$ ), vomiting ( $r=-0.1891$ ,  $p=0.064$ ), stomach pain ( $r=-0.1920$ ,  $p=0.060$ ), mouth ulcers ( $r=-0.1952$ ,  $p=0.055$ ) headaches ( $r=-0.1835$ ,  $p=0.072$ ), and fatigue ( $r=-0.1700$ ,  $p=0.096$ ), and frequency of cramps ( $r=-0.1989$ ,  $p=0.051$ ).

### ***Fibre***

Although 63.9% of patients reported trialing an increase in fibre in their diet (Appendix 10), baseline fibre intake figures are not known. Just over half (53%) of those people trialing fibre reported still finding it effective. Vegetables were the most commonly cited form of fibre increase (44% of all patients), followed by fruit (39%), and other forms of fibre. Bran (22% of patients), and pulses/lentils (21%) were the least trialed forms of fibre. As the question on specific type and amount by which fibre had been increased was poorly answered, it is not possible to assess what level of fibre constituted an 'increased fibre diet', or what is currently ingested. Some patients (11) reported already having a high fibre diet and therefore further increase in fibre was not warranted. Several reported fibre exacerbating their symptoms or were advised to reduce fibre. One patient noted that as she had diarrhoea predominant symptoms, there was no use in increasing fibre.

From the reported data, there is significant correlation between perception of benefit of an increased fibre diet and improvement in severity of constipation ( $r=-0.2727$ ,  $p=0.007$ ), and a correlation approaching significance between perceived benefit of fibre and men ( $r=0.1965$ ,  $p=0.054$ ).

### ***Dietary Modifications***

Almost 80% of the patients have trialed dietary modifications and almost 60% of those perceived ongoing benefit (Appendix 11). Dietary modifications included milk-free (43% of all patients), increased water (34%), wheat-free (31%), vitamin supplements (27%), probiotics (27%), avoidance of 'windy foods' (21%), yeast free (18%), and a range of other modifications. Scant information was reported for quantities of probiotics consumed or water drunk.

The main sources of dietary advice came from health professionals, naturopaths and the media. Of the 92 reports from these sources,

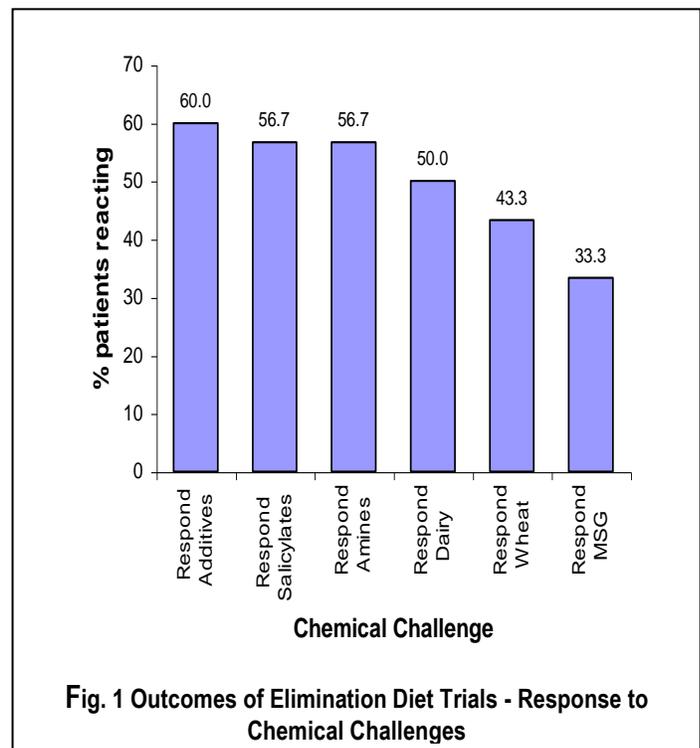
- ◆ 36 were from health professionals, with an ongoing benefit in 58% of cases (compared with an average of 47% ongoing benefit across all modifications trialed),
- ◆ 28 were from the media (books, magazines, radio, TV), with an ongoing benefit in 43% of cases, and
- ◆ 27 were from naturopaths, with an ongoing benefit in 30% of cases.

Patients most often reported an improvement in bloating, wind and diarrhoea where a modification was perceived as beneficial. Dietary modifications were significantly correlated with an improvement in wind severity ( $r=-0.2111$ ,  $p=0.038$ ) and rash frequency ( $r=-0.2372$ ,  $p=0.019$ ), and approached significance for improvement in diarrhoea frequency ( $r=-0.1698$ ,  $p=0.096$ ).

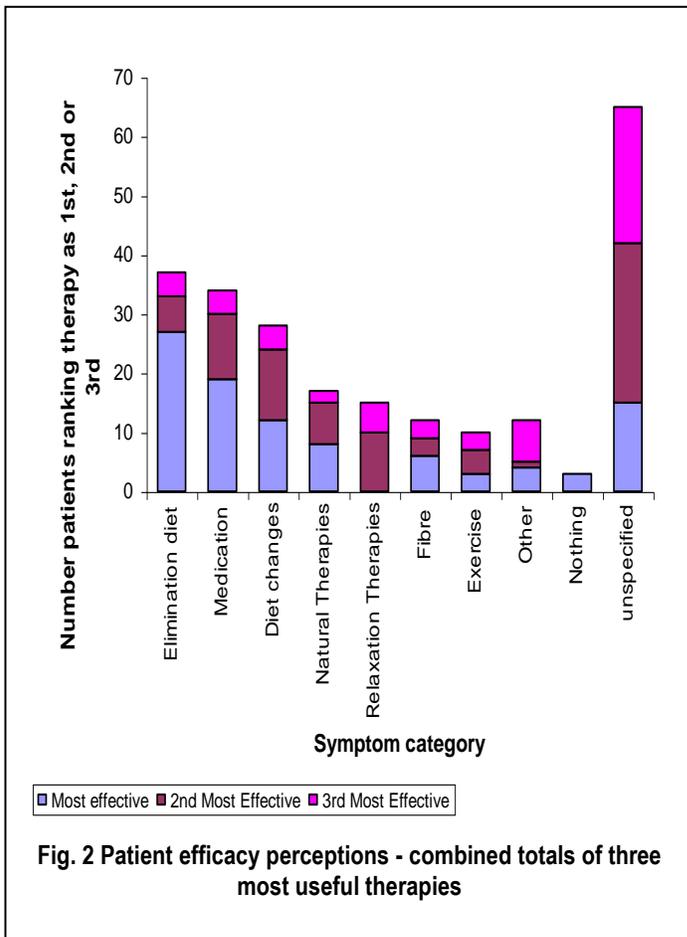
### **Attendance at Allergy Unit/Elimination Diet**

Attendance at the Allergy Unit is correlated significantly with an improvement in cramp severity ( $r=-0.2008$ ,  $p=0.049$ ), rash frequency ( $r=-0.2250$ ,  $p=0.027$ ), headache frequency ( $r=-0.2764$ ,  $p=0.006$ ) and approaches significance with decreased frequency of stomach pain ( $r=-0.1815$ ,  $p=0.075$ ) and cramps ( $r=-0.1841$ ,  $p=0.071$ ).

Symptoms of approximately 74% of those beginning the elimination diet improved and



approximately 70% completed the process with chemical challenges (Appendix 12). Of those not commencing the diet, reasons for not doing so were varied, including pregnancy, family problems, long work hours, Christmas and 'too hard'. Where food intolerance was determined by double blind capsule challenge and/or food challenge, all participants reacted to at least one (average three, range 1-6) of the six chemical challenges covered by this study (fig. 1). A range of symptoms improved, both colonic as well as non-colonic symptoms such as aches, sinus problems and mouth swelling. The chemicals currently avoided are not



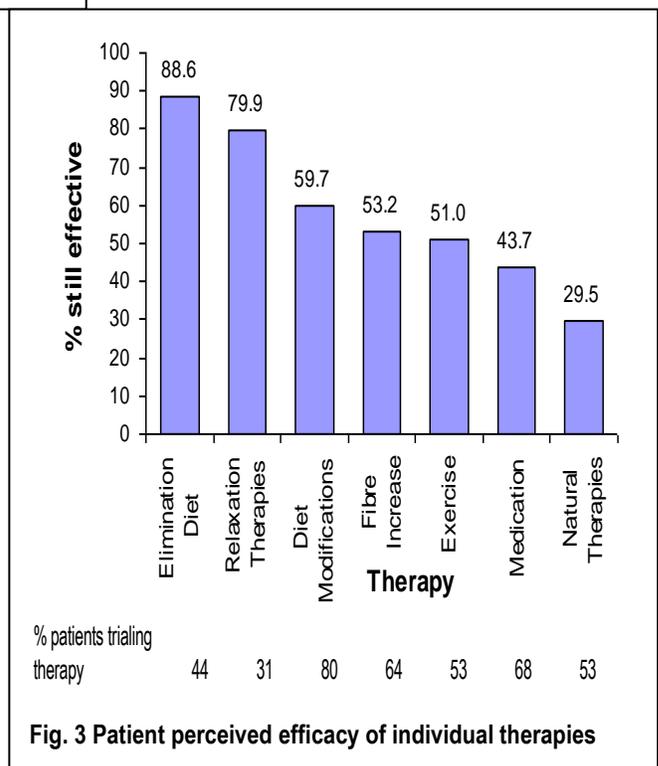
**Fig. 2 Patient efficacy perceptions - combined totals of three most useful therapies**

always the ones to which patients responded in the challenges. A number of Gastroenterology Practice patients were referred to the Allergy Unit, but chose not to attend.

Maintenance of a modified diet after determination of chemical food intolerance is significantly correlated with decreased frequency of nausea ( $r=-0.4633$ ,  $p=0.008$ ) and vomiting ( $r=-0.3080$ ,  $p=0.047$ ) and approaches significance with decreased severity of headache ( $r=-0.2661$ ,  $p=0.089$ ) and vomiting ( $r=-0.2737$ ,  $p=0.079$ ).

### Patient Efficacy Ranking

Fifteen patients did not respond to this question. Three reported nothing helped their symptoms. The therapy perceived to have the single greatest efficacy and combination of first three rankings was the elimination diet (Fig. 2). When considering the practices separately, medication ranks first in efficacy for patients of the Gastroenterology Practice (Appendix 13, Fig. A13 a and b). The effect of food elimination is increased if the 'dietary modifications' rankings are



**Fig. 3 Patient perceived efficacy of individual therapies**

considered (Appendix 13, fig A13c). Of those citing of dietary changes other than the elimination diet, nine have eliminated food constituents such as lactose, salicylates, MSG and caffeine with a perceived improvement in symptoms. Considering the data in this way, the patients from the Gastroenterology Practice also rank dietary modifications first. The 'elimination diet' and 'dietary modifications' also had two of the three highest perceived ongoing efficacy rates when these were calculated on the basis of the number of people trialing each therapy grouping and still finding the therapy effective (fig.3).

## ***Discussion***

### ***Limitations of the study***

There is a selection bias in this study towards those with suspected food intolerance, some of which is removed by comparison of outcomes with the Gastroenterology Practice. There was a greater trend towards improvement in symptoms in those patients attending the Allergy Unit. This may simply be because they were correctly identified to attend based on their presenting symptoms. This bias may limit generalisability of results to the entire population with functional bowel disorders.

Much of the data collected for this study is subjective and retrospective. Subjectivity is an inherent problem in studies of these disorders [163]. Retrospectivity also creates problems as perceptions of, for example, symptom severity will in hindsight, become hazy, and may alter in magnitude. It is therefore also likely that therapies and drugs trialed were under-reported, particularly if they had not been found useful and had been forgotten.

Whether because it was retrospective, or a very long, complicated questionnaire, or another reason altogether, the questionnaire was not well answered, and much objective data such as date of attendance at the clinic or specifics of various trials was missing. Although patient records helped with some of this, many gaps remained. This meant that, for example the length of time therapies have been used could not be calculated. Length of time of 'short-lived effectiveness' may alter significantly the interpretation of loss of effectiveness of therapies, particularly in light of the large placebo effect reported by other studies [132,160-161].

Several patients reported commencement of multiple lifestyle changes at the one time, and attributed symptom improvements to specific changes. These conclusions may or may not be reasonable. It may be that this is the outcome they were told to expect, and so responses have to be taken at face value.

Statistical analysis was done based on attendance at a particular clinic. The scales of severity and frequency of symptoms provided in the questionnaire were used separately as input data. It is not known if these categories accurately represent the degree of distress to the patients. It is also possible that combination of symptom and frequency scores either by addition or multiplication of the two scores may have been a more

valid way of analysing the data. It has been suggested that general quality of life tools such as SF-36 are not ideal for use with this group [51,164]. Consequently, several specific symptom/quality of life assessment tools have been developed for use with this group over recent years [165-170], and combination of one of these with questions on the other data sought may have resulted in better baseline data.

Due to the small numbers of people trialing individual therapies, therapies were pooled for statistical analysis. In some of the categories, such as alternative therapies, those which have reasonable scientific validation, or are moving in this direction (such as Chinese herbs, and peppermint tablets) were grouped with other fringe therapies with little or no scientific testing. This may blunt otherwise significant correlations, or may make a broad therapy grouping appear more valid than it really is.

### ***General Discussion***

For all symptoms, across both patient groups, perceptions of both severity and frequency improved with time. There are several possible explanations for this. Firstly, there is likely to be a significant element of improvement linked to finding an appropriate therapy/ies to alleviate symptoms. Secondly, there is a tendency for symptoms to cycle, and most people seek help when distress is increasing (R. Loblay, pers. com., [171,174]). It is possible that many of these people are currently in a phase where symptoms are not as bad as they were previously. Numerous patients have begun new therapies in recent months and a placebo effect could account for some of the perceived efficacy in these cases [163]. Lastly, in hindsight, symptoms may be remembered as worse than they really were, resulting in greater apparent improvement in symptoms.

The proportion of the study group prescribed medication for their symptoms is in line with previous data [8], as was the fact that older people were more likely to be prescribed drugs [8]. The range of drugs prescribed in this group was also reasonably in line with those described in the literature [67-113,124,125], except for the lack of usage of sodium cromoglycate in the study group. It is hardly surprising that there was significant correlation between number of drugs prescribed and increasing age. There is a general trend towards polypharmacy in the elderly, and some of the bowel-related drugs prescribed to these people are possibly a result of altered gut

function stemming from drugs prescribed for other conditions. If this is the case, it is also understandable that perceived efficacy of drugs in the group is higher as the etiology of the symptoms is better understood.

Some people rated drugs such as vancomycin, flagyl and triple therapy for infections such as *Helicobacter pylori* or *Giardia* as effective only in the short term, as they no longer had need of them. As the underlying mechanisms in an individual are not known, it is understandable that several drugs might be trialed before finding one which works. It has also been suggested that failure of long-term medical treatments is often due to lack of perseverance [175]. Together, these factors may help explain the fact that more than half of those trialing medication no longer consider it effective. Despite this, when patients ranked therapies in order of usefulness, behind food elimination, medication was considered the most effective therapy used. This is possibly because of the large number of people who have trialed medication, or possibly because if a suitable medication is identified, it provides a simple, immediate and ongoing solution.

Although only a small number of the study group trialed relaxation therapies, 80% of those using relaxation therapies perceived ongoing benefit, the second highest of any therapy grouping. Patient reports of symptom relief do not match entirely with those found significant in the statistical analysis. It is quite feasible that, as some patients have reported, it is more a matter of being better able to cope with these symptoms which is the crux of the therapy effectiveness. It may also be that stress exacerbates their symptoms as has been reported in other studies [39,42-44]. Nobody rated relaxation therapies as first in the efficacy ranking. However, almost half of those reporting trialing relaxation therapies ranked it second or third in importance. This would further suggest the important role of managing stress in many of these patients and supports studies suggesting the increased benefit of multi-component therapies combining psychotherapies with other approaches [152-157].

Approximately the same proportion of people reporting the trial and ongoing efficacy of exercise as a relaxation therapy for their symptoms also reported efficacy of exercise directly for symptoms. This is a traditional approach to treating bowel symptoms, particularly constipation. The data from this study would support the notion of using exercise for constipation. Only a small number of people reported exercise in the first three most useful therapies. The comments made by a number of people about exercise not being of benefit to their

symptoms directly, but for general health and well being may potentially be true for others. This may help explain the trend towards improvement in fatigue with perceived exercise benefit.

Increasing fibre and water in the diet is also traditionally a standard suggestion for bowel complaints [93-95,175,176] and yet the literature on high fibre diets is far from unequivocal [96,163,177,178]. It is not possible to make strong conclusions from this study about the efficacy of fibre or water for bowel symptoms. It would be interesting to investigate what patients perceive a high fibre diet to be, the possible benefits of dietary fibre, and the role of water in a high fibre diet. This would be of particular interest in light of comments such as - 'I don't need a high fibre diet as I mostly have diarrhoea'. One person reported they had an increased fibre diet by adding two serves of vegetables to their daily food intake. Another person commented they had increased their water intake to one litre per day, but had not found it effective. (This is still well below the 1.5-2 litres per day recommended, and it is unknown what, if any, other fluid was also being consumed.)

It was noted that several people found fibre increase made symptoms worse. In an earlier paper [96], it was reported that bran, vegetables and especially fruit as a source of fibre often made symptoms worse, although bulking agents and other sources had a neutral/somewhat beneficial effect. The authors go as far as suggesting the routine prescription of fibre for these patients may cause those with otherwise mild symptoms to deteriorate and seek help. The question going begging is: 'Did the fibre exacerbate the symptoms, or was it something else in the foods, such as salicylates, gluten or antioxidants to which these people were sensitive?' This question is pertinent when the high rate of food intolerance in the study group is considered.

A similar question can be raised about the low perceived efficacy rates for the use of Chinese herbs, probiotics, and peppermint, where only about 25% of those trialing these therapies reported ongoing benefit. Recent studies on Chinese herbs [136-140], probiotics [92], and peppermint oil [126-134] have shown promising data on the efficacy of these therapies for subgroups of those with functional bowel disorders. Peppermint, like many herbs, is high in salicylates. It is possible that these therapies were inappropriate for a large proportion of the individuals trialing them. They either did not address the underlying mechanisms, patients may have had intolerance to some of the chemicals present, or they were ingesting a non-pharmacological amount.

Dietary modifications were the most common therapy trialed and covered a wide range of mainstream and fringe behaviours. The improvement seen in 'wind' severity is possibly attributable to those people identifying intolerance to such foods as milk and the 'windy' foods. Bearing in mind the high proportion of those who improved and identified specific food intolerances on the elimination diet, it is likely that those perceiving long term ongoing benefit after trialing elimination of various foods have identified food intolerances for themselves. This trial and error approach, predictable in the search for a solution to symptoms with no obvious underlying cause, may account for apparent low perception of ongoing efficacy. The source of advice may also have a bearing on the efficacy rates of some dietary modifications. It was an interesting finding that, although a number of people perceived the medical profession as giving poor advice or not caring, they were by far the most accurate with their advice on dietary manipulations in terms of ongoing efficacy for bowel symptoms.

Attendance at the Allergy Unit on its own was significant in improvement in some symptoms including severity of cramps and frequency of rash, headache and stomach pain, and there was a trend towards improvement in most other symptoms. It is possible that identification of true allergies, as well as information from doctors and dietitians on food intolerance and possible connection of symptoms with specific foods encouraged people to try manipulating their diet for themselves with good results. This approach has been found in another study <sup>[178]</sup>.

As those who undertook the elimination diet had significantly worse symptoms than the rest of the study group, it is possible that desperation levels are a factor in whether people are willing to undergo the rigours of the diet. Severity of symptoms may also have been a factor which encouraged those referred from the Gastroenterology Practice to the Allergy Unit to follow through. This would support other findings <sup>[25,180]</sup>

The role of food intolerance in the pathogenesis of IBS and other functional bowel disorders is still regarded as controversial <sup>[81]</sup>, is overlooked <sup>[181]</sup> or is considered trivial <sup>[25]</sup>. However, many studies confuse intolerance with true allergy <sup>[81,83,117,182]</sup>, fail to eliminate significant sources of constituents such as salicylates <sup>[101,183]</sup>, or challenged with complex whole foods <sup>[78,183]</sup>. Some more recent studies have recognised that food allergy <sup>[184]</sup> or intolerance <sup>[25,162,180,185,187]</sup> may in fact be an important issue for at least a subgroup of this population. The

rate of people undertaking the elimination diet, completing the challenges, and of response to specific food constituents is similar to those found in other studies on similar patient groups at the Allergy Unit [185].

## ***Conclusions***

This study has taken an introductory 'snapshot' into the efficacy of the treatments in use for IBS and functional bowel disease. The study is unusual in that it is done from the patients' perspective. Probably due to the varied etiology of the syndrome, it is not surprising that the therapies found most useful by individual patients are also very individual. Some patients do indeed perceive that traditional approaches to their treatment, such as medication, fibre and fluids are worthwhile. Stress management appears to be an important adjunct to other therapies for some people. However, 45% of patients ranked food elimination (either by elimination diet or by trial and error) in the top three most useful therapies.

It can be concluded that in this study group, the role of food is important in amelioration of symptoms, contrary to findings in some other studies. It may be time to take a more thorough approach to the role of food intolerance in this group as a whole. A long term prospective study using a validated assessment tool would provide data from which to determine the extent of the role of food intolerance in the individual and generalise to the wider population suffering functional bowel disorders. It would also allow further exploration of the role of other aspects of treatment (eg fibre, exercise) investigated in this preliminary study.

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