The Effect of Fiber Supplementation on Irritable Bowel Syndrome: A Systematic Review and Meta-analysis

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- OBJECTIVES: Fiber has been used for many years to treat irritable bowel syndrome (IBS). This approach had fallen out of favor until a recent resurgence, which was based on new randomized controlled trial (RCT) data that suggested it might be effective. We have previously conducted a systematic review of fiber in IBS, but new RCT data for fiber therapy necessitate a new analysis; thus, we have conducted a systematic review of this intervention.
- METHODS: MEDLINE, EMBASE, and the Cochrane Controlled Trials Register were searched up to December 2013. Trials recruiting adults with IBS, which compared fiber supplements with placebo, control therapy, or "usual management", were eligible. Dichotomous symptom data were pooled to obtain a relative risk (RR) of remaining symptomatic after therapy as well as number needed to treat (NNT) with a 95% confidence interval (CI).
- RESULTS: We identified 14 RCTs involving 906 patients that had evaluated fiber in IBS. There was a significant benefit of fiber in IBS (RR=0.86; 95% CI 0.80–0.94 with an NNT=10; 95% CI=6–33). There was no significant heterogeneity between results (*P*=0%, Cochran *Q*=13.85 (d.f.=14), *P*=0.46). The benefit was only seen in RCTs on soluble fiber (RR=0.83; 95% CI 0.73–0.94 with an NNT=7; 95% CI 4–25) with no effect seen with bran (RR=0.90; 95% CI 0.79–1.03).
- CONCLUSIONS: Soluble fiber is effective in treating IBS. Bran did not appear to be of benefit, although we did not uncover any evidence of harm from this intervention, as others have speculated from uncontrolled data.

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INTRODUCTION

Irritable bowel syndrome (IBS) is a relatively modern term (1) for a lower gastrointestinal (GI) symptom complex that has been described for centuries, with notable figures such as Beethoven possibly suffering from this disorder (2). Fiber supplementation has a long history in the management of functional lower GI disorders, although, more recently, there has been caution expressed in the use of fiber in IBS as it may exacerbate certain symptoms in some patients (3). We have previously conducted a systematic review of fiber supplementation in IBS and found that there was RCT evidence that this approach did reduce overall IBS symptoms, particularly with psyllium-based products (4). This was based on small studies that usually had an unclear risk of bias and hence the quality of evidence was low (5). Since then, further randomized controlled trial (RCT) evidence (6) has been published. We have therefore updated our systematic review on fiber supplementation in the treatment for IBS.

METHODS

Search strategy and study selection

A search of the medical literature was conducted using MEDLINE (1946 to December 2013), EMBASE, and EMBASE Classic

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Box 1. Eligibility criteria

Randomized controlled trials Adults (participants aged > 16 years) Diagnosis of irritable bowel syndrome (IBS) based on either a clinician's opinion or meeting specific diagnostic criteria (Manning, Kruis score, Rome I, II, or III). Compared fiber supplementation with placebo or no therapy. Minimum duration of therapy 7 days. Minimum duration of follow-up 7 days. Dichotomous assessment of response to therapy in terms of effect on global IBS symptoms or abdominal pain following therapy (Preferably patient-reported, but if this was not available then as assessed by a physician or questionnaire data.).

Box 2. Data extraction methodology

Outcome of interest: improvement in global irritable bowel syndrome (IBS) symptoms preferable; if not reported then improvement in abdominal pain.

Reporting of outcomes: patient-reported preferable; if not available then investigator-reported.

Time of assessment: upon completion of therapy.

Denominator used: true intention-to-treat analysis; if not available then all evaluable patients.

Cutoff used for dichotomization: any improvement in global IBS symptoms or abdominal pain for Likert-type scales, investigator-defined improvement for continuous scales; if no investigator definition was available we used ≥ 1 s.d. decrease in symptom score from baseline to completion of therapy (we assessed whether the use of any decrease in symptom score from baseline to completion of therapy altered our analysis).

(1947 to December 2013), and the Cochrane central register of controlled trials. RCTs examining the effect of supplementing the diet with fiber in adult patients (over the age of 16 years) with IBS were eligible for inclusion (Box 1). We contacted the authors of studies that evaluated functional GI disorders that could have included IBS, but did not report this group of patients separately. Similarly, we contacted original investigators of studies that did not report dichotomous data but were otherwise eligible for inclusion in the systematic review to explore whether these data were available.

The literature search was performed as part of a broader exercise to inform an update of the ACG monograph on the management of IBS. Specifically, studies on IBS were identified with the terms *irritable bowel syndrome* and *functional diseases, colon* (both as medical subject heading (MeSH) and free text terms), and *IBS, spastic colon, irritable colon,* or *functional* adj5 *bowel* (as free text terms). These were combined using the set operator AND with *dietary fiber, cereals, psyllium, sterculia, karaya gum* (both as MeSH terms and free text terms), or the following free text terms: *bulking agent, psyllium fibre, fibre, husk, bran, ispaghula,* or *wheat bran.*

Articles in any language were eligible and were translated when appropriate. Abstracts were also eligible, and conference proceedings from United European Gastroenterology Week and Digestive Diseases Week between 2001 and 2013 were hand-searched to identify potentially eligible studies published only in abstract form. We also performed a recursive search of the literature from the bibliographies of all relevant studies retrieved from the electronic search. Two masked reviewers assessed potentially relevant articles using predesigned eligibility forms, according to the prospectively defined eligibility criteria (**Box 1**). We resolved any disagreement between investigators by consensus.

Outcome assessment

The primary outcome was defined as global improvement in IBS symptoms. If this was not available then improvement in abdominal pain was taken as the primary outcome. When more than one definition was provided for improvement in the primary outcome, the most stringent definition with the lowest placebo response rate was taken. Secondary outcomes included quality of life and adverse events.

Data extraction

Two reviewers independently recorded data from eligible studies onto a Microsoft Excel spreadsheet (XP professional edition; Microsoft, Redmond, WA). In addition to the primary outcome (**Box 2**), the following clinical data were extracted for each trial: setting (primary, secondary, or tertiary care-based), number of centers, country of origin, type of fiber supplementation, duration of therapy, total number of adverse events reported, criteria used to define IBS, primary outcome measure used to define symptom improvement or cure following therapy, duration of follow-up, proportion of female patients, and proportion of patients according to predominant stool pattern. Data were extracted as intention-to-treat analyses, with all dropouts assumed to be treatment failures, whenever trial reporting allowed this.

Assessment of risk of bias

Two independent reviewers assessed the risk of bias using the Cochrane handbook risk of bias tool (7). This evaluates the method of randomization, whether allocation was concealed, method of blinding, the completeness of follow-up, whether there was evidence of selective outcome reporting, and other biases.

EVIEW

Data synthesis and statistical analysis

Global IBS symptoms or abdominal pain persisting with intervention compared with control was expressed as a relative risk (RR) with 95% confidence intervals (CIs). Data were pooled using a random-effects model (8) to allow for any heterogeneity between studies. Adverse events data were also summarized with RRs. The number needed to treat and the number needed to harm, with 95% CIs, were calculated from the reciprocal of the risk difference of the meta-analysis.

Heterogeneity between studies was assessed using both the P-statistic with a cutoff of \geq 50% and the χ^2 -test with a P value < 0.10, used to define a significant degree of heterogeneity (9). When the degree of statistical heterogeneity was greater than this between trial results in this meta-analysis, possible explanations were investigated using subgroup analyses according to type of intervention, trial setting, criteria used to define IBS, whether method of randomization or concealment of allocation was reported, level of blinding, and risk of bias of included trials. We compared individual RRs between these analyses using the Cochran *Q*-statistic. These were exploratory analyses only and may explain some of the observed variability, and hence the results should be interpreted with caution.

Review Manager version 5.1.4 (RevMan for Windows 2008, the Nordic Cochrane Centre, Copenhagen, Denmark) and StatsDirect version 2.7.7 (StatsDirect, Sale, Cheshire, UK) were used to generate Forest plots of pooled RRs and RDs for primary and secondary outcomes with 95% CIs, as well as funnel plots. The latter were assessed for evidence of asymmetry, and therefore for possible publication bias or other small study effects, using the Egger test (10), if there were 10 or more eligible studies included in the metaanalysis (11).

RESULTS

The search strategy identified a total of 343 citations, of which 29 were evaluated and 14 were eligible for the systematic review (**Figure 1**). The agreement between reviewers regarding eligibility for inclusion in the review was perfect (κ -statistic = 1.0). This update of our previous systematic review and meta-analysis on fiber in IBS (5) identified an additional two studies (6,12), which increased the number of patients included in the analysis substantially.

Overall efficacy of fiber supplementation in the treatment of IBS

There were 14 RCTs (6,12–24) involving 906 patients. A summary of the eligible trials is given in **Table 1**. The majority of trials did not differentiate between the type of IBS patients recruited, with only five studies providing data on this (6,12,21–24), two of which recruited only IBS-C patients. (23,24). The proportion of women in trials ranged between 20 and 90%. Ten trials were double-blind (6,13,15–18,20–23), two were single blind (14,24), and two were open label (19,12), but only four reported adequate methods of randomization (6,14,15,12) and only one described adequate concealment of allocation (6). Only one trial was at low risk of bias (6),



Figure 1. Flow diagram of assessment of studies identified in the updated fiber and irritable bowel syndrome (IBS) systematic review and metaanalysis.

with two at high risk (19,12); the remaining were unclear. Eleven trials used a "clinical diagnosis" of IBS supplemented by negative investigations to define the condition, with only one study using the Manning criteria combined with negative investigations (20), one the Rome I criteria combined with negative investigations (24), and one the Rome III criteria (12).

There was a statistically significant effect in favor of fiber compared with placebo (RR of IBS not improving=0.86; 95% CI 0.80-0.94, **Figure 2**) with an number needed to treat of 10 (95% CI=6-33). There was no significant heterogeneity between results (I^2 =0%, Cochran Q=13.85 (d.f.=14), P=0.46). Subgroup analysis showed no major differences in efficacy according to duration of therapy, definition of IBS, and various quality criteria, including the proportion of subjects followed up, whether the study was double-blind, whether the method of randomization was stated, and whether the study had a low, unclear, or high risk of bias (**Table 2**).

Bran vs. soluble fiber

Six studies used bran in a total of 441 patients (6, 12, 13, 18, 19, 23), seven studies used ispaghula husk in a total of 499 patients (6,15–18,21,22), and the remaining studies used "concentrated fiber" (23), or linseeds (12). Bran had no statistically significant effect on the treatment of IBS (RR of IBS not improving=0.90; 95% CI 0.79–1.03, P=0.14; **Figure 2**), but ispaghula was effective in treating IBS symptoms (RR of IBS not improving=0.83; 95% CI 0.73–0.94, P=0.005; **Figure 2**). The number needed to treat with ispaghula was 7 (95% CI 4–25). Numerically the risk ratio was not

Author	Design	Participants	Interventions	Methodology	Outcomes
Soltoft <i>et al.</i> (13)	Danish RCT, single center	Author-defined IBS. 59 Patients from tertiary care. 64% female	Miller's bran biscuits vs. wheat biscuits for 6 weeks. Laxatives allowed as rescue medication	Method of randomization and concealment of allocation not stated. Double-blind. 12% Loss of follow-up. No selective reporting	Global assessment of IBS symptoms on Likert scale. Much or slightly improved from baseline symptoms
Manning <i>et al.</i> (14)	English RCT, single center	Author-defined IBS. 26 Patients recruited from tertiary care. 46% Female	60 ml Unprocessed wheat bran or 170 g whole-wheat bread daily vs. low-fiber diet for 6 weeks. Unclear if other IBS medications allowed	Method of randomization stated. Method of concealment of allocation not stated. Investigator- blinded. 8% Loss of follow-up. No selective reporting	Percentage of days on which pain charted by patient in special chart. Improvement in percentage of day's pain charted before and after study
Ritchie and Truelove (15)	English RCT, single center	Author-defined IBS. 100 Patients recruited from tertiary care. 77% Female.	Ispaghula husk vs. placebo for 3 months. Unclear if other IBS medications allowed	Method of randomization stated. Method of concealment of alloca- tion not stated. Double-blind. 4% Loss of follow-up. No selective reporting	Dichotomous assess- ment of IBS symptoms: "improved" or "not improved"
Longstreth <i>et al.</i> (16)	US RCT, single center	Author-defined IBS. 77 Patients recruited from secondary care. 83% Female	Ispaghula vs. placebo for 8 weeks. No other IBS medications al- lowed	Method of randomization and concealment of allocation not stated. Double-blind. 22% Loss of follow-up. No selective reporting	Global assessment of IBS symptoms on Likert scale. Much or a little better from baseline symptoms
Arthurs and Fielding (17)	Irish RCT, single center	Author-defined IBS. 80 Patients recruited from secondary care. 78% Female.	Ispaghula husk vs. placebo for 4 weeks. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. 2.5% Loss of follow-up. No selective reporting	Global assessment of IBS symptoms on Likert scale. Resolved or improved from baseline symptoms
Nigam <i>et al.</i> (18)	Indian RCT, single center	Author-defined IBS. 168 Patients recruited from secondary care. 45% Female	Ispaghula husk vs. placebo for 3 months. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. Apparently no one lost to follow-up. No selective reporting	Dichotomous assessment of IBS: "improved" or "not improved"
Kruis <i>et al.</i> (19)	German RCT, single center	Author-defined IBS. 120 Patients recruited from tertiary care. 62.5% Female	15g wheat bran per day vs. placebo for 16 weeks. No other IBS medications allowed	Method of randomization and concealment of allocation not stated. Unblinded. 17.5% Loss of follow-up. No selective reporting	Global assessment of IBS symptoms on Likert scale. Disappeared or improved from baseline symptoms
Lucey <i>et al.</i> (20)	English RCT, single center	Manning IBS. 44 Patients recruited from tertiary care. 79% Female	Bran biscuits vs. placebo biscuits for 3 months. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. 36% Loss of follow-up. No selective reporting	Total IBS questionnaire symptom score (unclear if validated). Lower score after treatment indicated symptom improvement
Prior and Whorwell (21)	English RCT, single center	Author-defined IBS. 80 Patients recruited from tertiary care. 49% Con- stipation predominant. 90% Female	Ispaghula husk vs. placebo for 12 weeks. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. 29% Loss of follow-up. No selective reporting	Overall improvement in well-being discussed with patient, and rated as "satisfactory" or "unsatisfactory"
Jalihal and Kurian (22)	Indian RCT, single center	Author-defined IBS. 22 Patients recruited from secondary care. 20% Female. 25% had constipation, 75% had diarrhea	Ispaghula husk vs. placebo for 4 weeks. No other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. 9% Loss of follow-up. No selective reporting	Dichotomous assess- ment of IBS: "improved" or "no change"
Fowlie <i>et al.</i> (23)	Scottish RCT, single center	Author-defined IBS. 51 Patients recruited from tertiary care. 100% Constipation predomi- nant or mixed. 65% Female	Concentrated fiber vs. placebo for 3 months. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Double-blind. 14% Loss of follow-up. No selective reporting	Global assessment of IBS symptoms on Likert scale. Generally better from baseline symptoms

Table 1. Characteristics of randomized controlled trials (RCTs) of fiber vs. placebo in irritable bowel syndrome (IBS)

Table 1 continued on following page

Table 1. Continued.

Author	Design	Participants	Interventions	Methodology	Outcomes
Rees <i>et al.</i> (24)	English RCT, number of centers unclear	Rome I IBS. 28 Patients recruited from tertiary care. 100% Constipa- tion predominant. Unclear what proportion were female	10–20g Of coarse wheat bran per day vs. placebo for 8–12 weeks. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation not stated. Patient-blinded. 21% Loss of follow-up. No selective reporting	Patients interviewed using a questionnaire (unclear if validated) asking if any perceived improvement in symp- toms
Bijkerk <i>et al.</i> (6)	Dutch RCT, multicenter	Author-defined or Rome II IBS. 275 Patients recruited from primary care. C 56%, D 25%, M 19% 79% Female	20g Ispaghula husk or 20g bran per day vs. placebo for 12 weeks. Unclear if other IBS medications allowed	Method of randomization and concealment of allocation stated. Double-blind. 40% Loss to fol- low-up. No selective reporting	Adequate relief of IBS- related abdominal pain or discomfort in the last week, with responders defined as those with adequate relief for 2 out of the last 4 weeks
Cockerell <i>et al.</i> (12)	English RCT, number of centers unclear	Rome III IBS. 40 Patients Recruited From Primary And Secondary Care. C 34%, D 37.5% 66% Fe	24g Linseeds per day for 4 weeks vs. no treatment for 4 weeks. Other IBS medications allowed	Method of randomization stated, concealment of allocation not stated. Unblinded. 30% Loss to follow-up. No selective reporting	Decrease of 50 points in the IBS-symptom severity score

	Fiber Placebo or no treatment		Risk Ratio			Risk ratio		
Study or subgroup	Events	Total	Events	Total	Weight	M-H, random, 95% Cl	Year	M-H, random, 95% Cl
Bran								
Soltoft, 1976	17	32	12	27	2.4%	1.20 (0.70, 2.04)	1976	
Manning, 1977	7	14	7	12	1.3%	0.86 (0.42, 1.74)	1977	
Kruis, 1986	29	40	28	40	8.6%	1.04 (0.78, 1.37)	1986	_ _
Lucey, 1987	3	14	4	14	0.4%	0.75 (0.20, 2.75)	1987	
Rees, 2005	6	14	7	14	1.0%	0.86 (0.39, 1.91)	2005	
Bijkerk, 2009	66	97	75	93	23.5%	0.84 (0.71, 1.00)	2009	
Subtotal (95% CI)		211		200	37.2%	0.90 (0.79, 1.03)		•
Total events	128		133					
Heterogeneity: $\tau^2 = 0.00$; χ^2	= 2.76, d	.f. = 5 (<i>I</i>	P = 0.74); / ² = 0%					
Test for overall effect: $Z = 1$.47 (<i>P</i> = 0).14)						
Ispaghula								
Ritchie, 1979	7	12	12	12	2.9%	0.60 (0.37, 0.97)	1979	
Longstreth, 1981	17	37	16	40	2.5%	1.15 (0.69, 1.92)	1981	
Arthurs, 1983	11	40	14	38	1.6%	0.75 (0.39, 1.43)	1983	
Nigam, 1984	13	21	21	21	5.9%	0.63 (0.45, 0.88)	1984	(
Prior. 1987	33	40	37	40	23.8%	0.89 (0.75, 1.05)	1987	
Jalihal, 1990	2	11	3	9	0.3%	0.55 (0.11, 2.59)	1990	
Bijkerk, 2009	60	85	75	93	23.3%	0.88 (0.74, 1.04)	2009	
Subtotal (95% CI)		246		253	60.2%	0.83 (0.73, 0.94)		•
Total events	143		178					
Heterogeneity: $\tau^2 = 0.01$; χ^2	= 7.32, d	.f. = 6 (<i>l</i>	P = 0.29); / ² = 18%					
Test for overall effect: $Z = 2$.80 (<i>P</i> = 0	0.005)						
Linseeds								
Cockerell, 2012	9	27	8	13	1.4%	0.54 (0.27, 1.07)	2012	
Subtotal (95% CI)		27		13	1.4%	0.54 (0.27, 1.07)		
Total events	9		8					
Heterogeneity: not applicab	le							
Test for overall effect: $Z = 1$.75 (<i>P</i> = 0	0.08)						
Fibre (unspecified)								
Fowlie, 1992	10	25	7	24	1.1%	1.37 (0.62, 3.01)	1992	
Subtotal (95% CI)		25		24	1.1%	1.37 (0.62, 3.01)		
Total events	10		7					
Heterogeneity: not applicable	le							
Test for overall effect: $Z = 0$.79 (<i>P</i> = 0).43)						
Total (95% CI)		500		400	100.0%	0.86 (0.80, 0.94)		•
Total aventa	200	505	206	+30	100.0 /0	0.00 (0.00, 0.94)		•
	290		326					
Heterogeneity: $r^{4} = 0.00; \chi^{4} = 13.85, a.f. = 14 (P = 0.46); P = 0\%$								
Less for overall effect: $2 = 3.50$ ($P = 0.0005$)								
i est for subgroup difference	es: χ ² = 3.	95, a.t.	$= 3 (P = 0.27), I^2 = 1$	24.1%				

Figure 2. Forest plot of randomized controlled trials (RCTs) of fiber vs. placebo or no treatment in irritable bowel syndrome (IBS).

Table 2. Subgroup analysis	of randomized controlled ti	and of the vs. placebo in the	5	
Parameter	No. of papers	No. of patients ^a	Relative risk (95% CI)	Heterogeneity
Duration of therapy				
≥12 Weeks	9	529	0.86 (076–0.96)	<i>I</i> ² =13%, χ ² <i>P</i> =0.33
≤8 Weeks	6ь	458 ^b	0.84 (0.69–1.02)	<i>I</i> ² =8%, χ ² <i>P</i> =0.36
Definition of IBS				
Author defined	10	535	0.88 (0.75–1.03)	<i>l</i> ² =25%, χ ² <i>P</i> =0.21
Manning/Rome	4	274	0.85 (0.72–1.00)	<i>I</i> ² =0%, χ ² <i>P</i> =0.59
Completeness of follow				
≥80% Follow	8	378	0.84 (0.67–1.06)	<i>I</i> ² =35%, χ ² <i>P</i> =0.15
<80% Follow	6	431	0.88 (0.79–0.99)	<i>I</i> ² =0%, χ ² <i>P</i> =0.69
Masking				
Double blind	10	635	0.85 (0.75–0.97)	<i>I</i> ² =14%, χ ² <i>P</i> =0.31
Single blind	2	54	0.86 (0.50–1.46)	<i>I</i> ² =0%, χ ² <i>P</i> =1.00
Not blind	2	120	0.81 (0.43–1.52)	<i>l</i> ² =68%, χ ² <i>P</i> =0.08
Randomization				
Adequate	3	228	0.83 (0.69–1.00)	<i>I</i> ² =6%, χ ² <i>P</i> =0.34
Unclear	11	581	0.89 (0.77–1.02)	<i>I</i> ² =12%, χ ² <i>P</i> =0.33
Risk of bias				

Table 2 Subgroup analysis of randomized controlled trials of fiber vs. placebo in IRS

CI, confidence interval; IBS, irritable bowel syndrome.

^aBijkerk *et al.* (6) had two intervention arms, bran and psyllium—only the psyllium arm was used in subgroup analyses.

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^bStudies that provided earlier time points to complete this field were used but this only applied to Bijkerk *et al.* (6). This study was used in both the <8-week and ≥12-week analyses using the 8- and 12-week time point data as appropriate.

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dramatically different between bran and soluble fiber but this is driven by one trial (6). This trial also concluded that soluble fiber was superior to bran, but this is not as apparent in the meta-analysis as there was a statistically significant effect of bran at week 12 but no effect at weeks 4 and 8. Bran was statistically significant at week 12 largely because responders remained stable from weeks 8 to 12, whereas the placebo response fell. When this study (6) was excluded there was no effect of bran on IBS symptoms (RR = 1.02; 95% CI=0.82-1.27). Similarly when week 8 of therapy was used for this trial (6) rather than week 12, there was no trend toward benefit of bran (RR = 0.98; 95% CI = 0.85-1.13).

Safety of fiber

Low Unclear/high

Data on overall adverse events were provided only by six trials (6,18,19,21,23,12). These trials evaluated a total of 566 patients, with 130 (38.8%) of 335 patients receiving fiber reporting adverse events, compared with 63 (27.3%) of 231 in the placebo arms. Overall, there was no statistically significant increase in adverse events with fiber compared with placebo (RR of adverse event = 1.06; 95% CI 0.92-1.22). When only trials that used ispaghula were included in the analysis, the RR of adverse events was 1.14 (95% CI 0.94-1.38), and when only RCTs of bran were considered the RR was 0.97 (95% CI 0.79-1.20).

DISCUSSION

We have updated our previous systematic review and meta-analysis (10) of fiber supplementation as a treatment for IBS. Our previous systematic review identified 12 papers evaluating 591 IBS patients and found that soluble, but not insoluble, fiber was effective in reducing overall symptoms. The monograph that evaluated this systematic review was criticized (25) as it often evaluated small studies of poor quality. Indeed the fiber data it incorporated were based on a relatively small number of participants; thus, the 95% CIs were wide and relied on studies of suboptimal quality with none achieving a low risk of bias. Since the publication of that systematic review (4) there has been another RCT (6) that by itself includes more than half the sample size of the original systematic review. Together with another small trial (12) the updated systematic review suggests once again that soluble fiber is effective in treating IBS symptoms, but with more confidence than previously reported.

0.88 (0.74-1.04)

0.86 (0.75-0.99)

Our conclusion is different from the Cochrane systematic review evaluating fiber in IBS (26). This review found that there was no benefit of either type of fiber in IBS, although there was a trend toward benefit for soluble fiber. This review is now 5 years old and has not included the large trial (6) that was reported subsequently. It is, however, interesting that we had suggested in our previous review (4) that soluble fiber was effective in IBS using the

Not applicable

*I*²=13%, χ² *P*=0.32

same data that the Cochrane review identified (26). We explored the reasons for this and the main explanation is that the Cochrane review used RR of global symptoms improving as their outcome (thus, the RR was usually >1.0), whereas we utilized an outcome measure of RR of global symptoms not improving (thus, the RR was usually <1.0). Although these definitions are simply the inverse of each other, the RRs will not have a simple inverse relationship (a well-known property of RR and why some researchers suggest that the odds ratio is a better summary measure (the odds ratio does behave symmetrically) (27)). Their approach led to greater statistical heterogeneity between studies and wider CIs of the summary statistic, which resulted in a loss of statistical significance. Had they used the same summary statistic as that employed in our paper they would have come to a similar conclusion as our review (4). This emphasizes the fragility of the data before the addition of a further large RCT (6) and thus the benefit of updating the review.

We accepted a broad definition of IBS as many of the papers used clinical definitions of IBS rather than validated approaches. We took this approach, as fiber is often used first line in the community, where definitions such as the Rome criteria are rarely applied (28). The results of our review are therefore more generalizable to the clinical setting that fiber is likely to be used in, but it is possible that some patients may have been included in the trials that did not have IBS according to rigorous definitions. This is likely to bias the results toward the null hypothesis and hence it is reassuring that we still found a statistically, and clinically, significant effect of fiber on IBS symptoms. It is also reassuring to note that fiber had a statistically significant effect on global IBS in one trial (6) that included both patients with a clinical definition and those with a Rome II definition of IBS where the RR of symptom improvement was similar for the Rome II patients (RR of symptom improvement = 1.81; 95% CI = 1.12-2.94) compared with the whole group (RR=1.60; 1.13-2.26). This trial also noted that the magnitude of effect of fiber was similar in IBS-C in comparison with other IBS groups (6). This raises another important limitation of the RCTs in that none formally evaluated the efficacy of fiber in any of the IBS symptom subgroups.

The mechanism of action of soluble fiber is uncertain. It is unlikely that this relates simply to the bulking of the stool, as insoluble fiber has a similar effect on stool bulk (29) but appears to have little impact on IBS symptoms. The site of fermentation of soluble fiber such as psyllium is controversial (30), but fermentation could have an impact on gut function irrespective of the site of occurrence. This could be through an increase in short chain fatty acid production (31), such as butyrate, which provides energy for colonic mucosa cells and acts as an anti-inflammatory agent (32). In addition, short chain fatty acids, or other fermentation products, can act as substrates for gut bacteria and it is therefore possible that psyllium acts as a prebiotic, thus changing the composition of the gut microbiome to a phenotype that promotes gut health and reduces GI symptoms (33). This is true for highly fermentable long chain carbohydrates such as inulin (34), but the effect of psyllium on gut flora needs further study.

We have used a rigorous methodology for this systematic review but should acknowledge the limitations of the fiber data and the conclusions drawn from it. There remains a paucity of high-quality studies, and additional trials using modern designs optimized to reduce bias may affect our estimate of effect size. In particular, studies to evaluate the impact of fiber in specific IBS subgroups may demonstrate different effects in distinct symptom subgroups. Additional weaknesses of existing studies include variations in a number of clinical factors, such as the definition of IBS, settings, and duration of therapy. It is reassuring, however, that subgroup analyses do not suggest that these factors have a major impact on the conclusions of the review.

In summary, our analyses of these data suggest that there is moderate-quality evidence that fiber is effective in IBS. Given that fiber is inexpensive and generally thought to be safe (especially compared with the available drugs approved for IBS), fiber supplementation should remain a useful first-line approach for managing IBS patients.

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CONFLICT OF INTEREST

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Specific author contributions: P.M., E.M.M.Q., B.E.L., A.J.L., Y.A.S., L.R.S., E.E.S., B.M.R.S., and A.C.F. conceived the study. P.M. and A.C.F. collected all data. P.M. and A.C.F. analyzed and interpreted the data. P.M. drafted the manuscript. All authors commented on drafts of the paper. All authors have approved the final draft of the manuscript. Financial support: This study was supported by the American College of Gastroenterology.

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Study Highlights

WHAT IS CURRENT KNOWLEDGE

- Fiber supplementation has been used to treat irritable bowel syndrome (IBS).
- We have conducted a systematic review that indicated this approach may be efficacious but evidence was of low quality.

WHAT IS NEW HERE

- There is now considerably more randomized trial evidence on fiber and IBS.
- Fiber supplementation is effective in improving global IBS symptoms.
- The effect of fiber in IBS appears to be limited to soluble fiber.

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