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CME

Fiber for the Treatment of Hemorrhoids Complications: A Systematic Review and Meta-Analysis

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OBJECTIVES: To evaluate the impact of laxatives on a wide range of symptoms in patients with symptomatic hemorrhoids.

METHODS: We searched using the following sources: MEDLINE, EMBASE, CINAHL and CENTRAL, BIOSIS, AMED, Papers First and Proceedings; study authors, industry, and experts in the field. We included all published and unpublished parallel group randomized controlled trials comparing any type of laxative to placebo or no therapy in patients with symptomatic hemorrhoids. Two reviewers independently screened studies for inclusion, retrieved all potentially relevant studies, and extracted data on study population, intervention, prespecified outcomes, and methodology.

RESULTS: Seven trials randomized 378 patients to fiber or a nonfiber control. Studies were of moderate quality for most outcomes. Meta-analyses using random effects models suggested that fiber has an apparent beneficial effect. The risk of not improving/persisting symptoms decreased by 47% in the fiber group (RR = 0.53, 95% CI 0.38–0.73) and the risk of bleeding by 50% (RR = 0.50, 95% CI 0.28–0.89). Studies with multiple follow-ups, usually at 6 wk and at 3 months, showed consistent results over time. Results are also compatible with large treatment effects in prolapse, pain, and itching, but even in the pooled analyses confidence intervals were wide and compatible with no effect (RR = 0.79, 95% CI 0.37–1.67; RR = 0.33, 95% CI 0.07-1.65; and RR = 0.71, 95% CI 0.24–2.10, respectively). One study suggested a decrease in recurrence. Results showed a nonsignificant trend toward increases in mild adverse events in the fiber group (RR = 6.0, 95% CI 0.57–64.8).

CONCLUSIONS: Trials of fiber show a consistent beneficial effect for symptoms and bleeding in the treatment of symptomatic hemorrhoids.

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INTRODUCTION

Symptomatic hemorrhoids are a common medical condition with a prevalence ranging from 4.4% in the general population, to 36.4% in general practice (1), and an increased prevalence during pregnancy and in the postpartum (1). While experts have usually divided internal hemorrhoids into four categories depending on the degree of prolapse (I–IV), some authors recommend that they now base their classification on the presence or absence of bleeding or prolapse (2). The pathophysiology is not completely understood; structural and/or vascular changes are involved (3) and chronic straining is inconsistently associated (4).

Minimizing constipation, and the prolonged straining that may be associated, is one of the main purposes of lifestyle measures and medical treatment for symptomatic hemorrhoids. The initial approach aims to increase the amount of water and fiber in the diet, or to introduce a laxative. Constipation may be due to low fluid intake (5), but the effectiveness of increasing fluid intake as a treatment for constipation remains unknown. Dietary fiber intake has been positively associated with increases in bowel movement frequency and fecal mass among individuals with occasional or mild constipation (6, 7). Other types of laxatives (stimulant laxatives, osmotic agents, and fecal softeners) have proved effective for the treatment of constipation in randomized trials (5, 8–10) but the poor methodology of these studies weakens inferences about treatment effect.

Several small clinical trials have evaluated the effect of fiber compared with placebo in patients with hemorrhoids (11, 12). Authors of narrative reviews (13, 14) and clinical practice guidelines (15–17) have found the evidence

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inconclusive, but have still recommended use of fiber due to its safety and low cost (13). To establish the strength of the available evidence, we conducted a systematic review of the impact of laxatives on a wide range of symptoms in patients with symptomatic hemorrhoids.

METHODS

We began by constructing a protocol that readers can obtain by correspondence with the first author.

Eligibility Criteria

We selected all published and unpublished parallel group randomized controlled trials of patients with symptomatic hemorrhoids comparing any type of laxative to placebo or no therapy, with any of the following outcomes recorded: individual or global symptom improvement, number of recurrences in a time period, change in the degree of prolapse, need of surgical treatment, or other adverse effects. We also included crossover trials and quasi-randomized methods of treatment allocation. We contacted authors to provide additional data and details about the key validity issues. There were no language restrictions.

Search Strategy

We searched OVID versions of MEDLINE (1966 to April Week 2, 2005), EMBASE (1980 to 2005 Week 17), CINAHL (1982 to April Week 4 2005), limiting our searches to randomized controlled trials using a maximally sensitive strategy (18). We modified these searches for other databases as CENTRAL (the Cochrane Central Register of Controlled Trials, The Cochrane Library, issue 2, 2005) BIOSIS, AMED (Allied and Alternative Medicine Database), Papers First and Proceedings. Two reviewers screened reference lists from all retrieved articles and from reviews and clinical practice guidelines to identify additional studies (13–16). We sought additional trials from pharmaceutical companies and experts in the field. We also searched for on-going trials in the Meta Register of Controlled Trials (mRCT), U.S. NIH register, and the Register of the Center for Clinical Trials and Evidence-Based Healthcare.

Data Abstraction

Two reviewers (E.M., P.A.) independently screened studies for inclusion, retrieved all potentially relevant studies, and extracted data on study population, intervention, prespecified outcomes, and methodology from included trials. In both phases, we resolved disagreements by consensus between reviewers, if unsolved after contacting study authors. We used Cohen's κ to assess agreement between the two reviewers on the selection of articles for inclusion (19).

Validity Assessment

We extracted methodological information for the assessment of internal validity (20): existence and method of generation of the randomization schedule, and method of allocation concealment (21); blinding of caregivers and outcomes assessors; number and reasons of patients lost to follow-up; and use of validated outcome measures.

Quantitative Data Synthesis

Trials did not consistently use similar symptom measures; all of them, however, recorded the proportion of patients either free of symptoms, with symptom improvement, or still symptomatic. We considered outcomes of patients free of symptoms and patients with symptomatic improvement as equivalent, and pooled each outcome of interest based on the *a priori* expectation of a similar magnitude and direction of treatment effect.

We present results as the relative risk and risk difference of being symptomatic or persisting symptoms. We calculated pooled risk differences for being symptomatic/persisting symptoms for the different outcomes. Studies varied in their duration of follow-up, the number of discrete measurements they made, and the timing of their first follow-up measurement. Investigators' first follow-up measurement occurred from 6 wk to 3 months—we used this first measurement for all our pooled analyses. In studies with multiple follow-ups we compared the different estimates across each study. We calculated the pooled relative risks of re-treatment, patient satisfaction, need for additional treatment, and adverse effects.

We undertook the analysis using the intention-to-treat principle, including all patients in the study arm to which they were originally allocated. We used Review Manager 4.2 (The Cochrane Collaboration, Oxford, UK) to aggregate data for each outcome using a random effects model (22). We present all pooled effect estimates with 95% confidence intervals; all p values are two sided.

In crossover studies, we analyzed the data in the same way as for parallel group studies, comparing treatment periods to control periods. We tested for between-study heterogeneity for each pooled comparison using the Cochran Q statistic. We also report the I^2 statistic, which is the proportion of the total variation among studies that is likely to be explained by between-study heterogeneity rather than chance (23). Irrespective of the results of the formal statistical test for heterogeneity, we tested whether our *a priori* hypotheses could explain variability in the magnitude of treatment effects across studies. For each hypothesis, we tested the difference in estimates of treatment effect between the two subgroups using a Z test and considered $p < 0.05$ to be statistically significant (24).

Our *a priori* hypotheses to explain heterogeneity were: (1) severity: smaller treatment effect in hemorrhoids grade III–IV compared to grade I–II; (2) condition: smaller treatment effect in thrombosed hemorrhoids *versus* nonthrombosed; (3) intervention: smaller treatment effect in studies that used another treatment for hemorrhoids in both treatment arms (*e.g.*, venotonic in both arms comparing fiber *versus* no fiber or placebo) (4) methodology: smaller treatment effect in studies with adequate allocation concealment and in studies with appropriate blinding of caregivers and smaller treatment effect in cross-over compared to parallel trials.

An expanded version of this review will appear in the Cochrane Library.

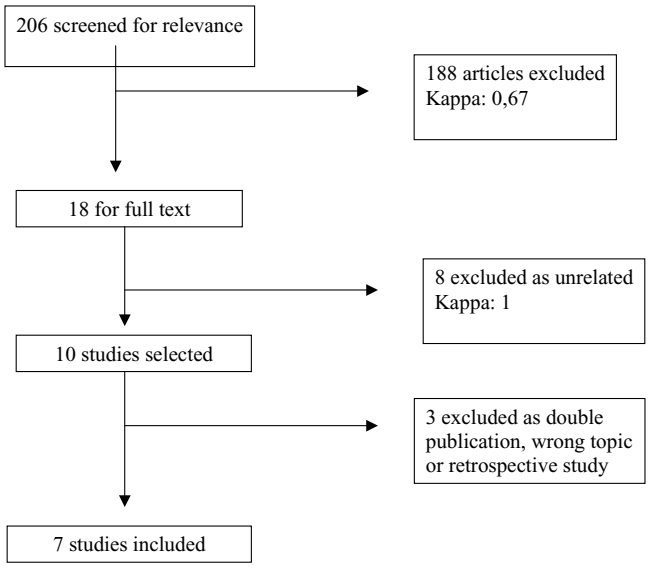

Figure 1. Flowchart of search results.

RESULTS

The two reviewers achieved good agreement in the initial selection of trials from the titles for inclusion ($\kappa = 0.67$, 95% CI 0.48–0.85) and excellent agreement on the final stage of inclusion from full text articles ($\kappa = 1.0$) (Fig. 1). Six of the seven authors provided additional information regarding key validity issues.

Seven studies, comparing fiber *versus* placebo, met the inclusion criteria (Table 1). Six were parallel and one of them used a crossed-over design (25). We excluded three retrieved studies for the following reasons: partial duplicate publication (26–28), wrong topic or retrospective study (29). Three of the included studies were abstracts and were both published later in full text (26–28). All trials included adults with symptomatic hemorrhoids (grades I to III) and most patients presented with rectal bleeding as their main complaint. All articles comparing laxatives evaluated the use of fiber *versus* placebo. We did not identify any studies using other types of laxatives.

The apparent quality from the published reports was generally low with little detail provided concerning key validity issues such as allocation concealment. When contacted directly the majority of authors provided additional information that generally indicated they had met methodological criteria (Table 2). This finding is in agreement with recent data suggesting authors typically use concealment of randomization and blinding despite the failure to report these methods (30). None of the included studies used validated questionnaires to assess study outcomes.

Global Ratings

The pooled analysis for overall improvement showed a 47% reduction in the risk of not improving/persistent symptoms (RR = 0.53, 95% CI 0.38–0.73) (Fig. 2) (12, 25, 31, 33). Results were consistent across studies (heterogeneity $p = 0.48$, $I^2 = 0\%$). Pooled risk difference for being symptomatic/persisting symptoms for the overall assessment was 25% (95% CI 0.36–0.13). The range of absolute percentages between trials of those not improved was 0.16 to 0.40 for fiber *versus* 0.23 to 0.61 for placebo.

Bleeding

Four studies (251 patients) that compared fiber to placebo reported bleeding as an individual outcome (Fig. 3) (12, 25, 31, 33). All results showed either a trend or a significant difference in favor of the fiber group. The pooled analysis showed a 50% relative risk reduction in the active treatment arm (RR = 0.50, 95% CI 0.28–0.89). No statistically significant heterogeneity was present but I^2 was moderate ($p = 0.14$, $I^2 = 45.6\%$). Pooled risk difference for being symptomatic/persisting symptoms for bleeding was 0.26 (95% CI 0.44 to 0.07). The range of absolute percentages between trials of those being symptomatic/persisting symptoms was 0.07 to 0.31 for fiber *versus* 0.38 to 0.76 for placebo.

One of the included studies provided the number of bleeding episodes during the first 15 days, from day 15 to 30 and from 30 to 45 days. These data could not be pooled with the rest of the studies as the authors no longer had access to the raw data (11). This study demonstrated a significant benefit in the treatment group compared to placebo but only in the last two periods (5.5 ± 3.2 *vs* 3.1 ± 2.7 days and 5.5 ± 2.9 ($p < 0.05$) *vs* 1.1 ± 1.4 days ($p < 0.001$), respectively). There was no significant difference in the number of patients with hemorrhoids bleeding on contact with the anoscope or finger after 40 days of treatment (RR = 0.13, 95% CI 0.01–2.29) (11).

Prolapse

The pooled analysis of the three studies (223 patients) showed a nonsignificant difference between treatment and placebo for persistent prolapse (RR = 0.79, 95% CI 0.37–1.67) (Fig. 4) (12, 25, 33). Pooled risk difference for being symptomatic/persisting symptoms for prolapse was 0.08 (95% CI 0.22–0.06). The range of absolute percentages between trials of those not improved was 0.03 to 0.35 for fiber *versus* 0.22 to 0.35 for placebo. No statistically significant heterogeneity was present but I^2 was moderate ($p = 0.21$, $I^2 = 35.7\%$) Perez-Miranda *et al.* similarly reported no differences in the degree of prolapse by hemorrhoidal grade within arms compared with baseline.

Pain

We pooled two studies evaluating pain or discomfort (12, 32). The pooled estimate showed a nonsignificant trend in favor of fiber (RR = 0.33, 95% CI 0.07–1.65). No statistically significant heterogeneity was present but I^2 was moderate ($p = 0.14$, $I^2 = 53\%$).

Table 1. Characteristics of the Included Studies

Author	Type of Publication	Interventions	Participants	Follow-up	Outcomes	Funding
Broader JH, 1974	Parallel randomized controlled trial. Full text available.	Stercullia *vs* placebo (starch, <20 g/day) Three months of treatment.	40 outpatients with anal bleeding, prolapse or discomfort. Hemorrhoids grade I–III.	Three months	-Bleeding, prolapse, discomfort, and overall impression -Adverse events -Bowel habit	Industry: provided medication, envelopes and travel expenses to present results in meetings*.
Webster DJT, 1978	Cross-over randomized controlled trial. Full text available.	Isphaghula husk (7 g/day) *vs* placebo Two periods of 6 wk of treatment.	67 outpatients with symptomatic hemorrhoids referred to an outpatient surgery clinic Hemorrhoids grade I–III, Age 23–71, 37% women.	Assessment at six and 12 weeks	-Pruritus, prolapse, bleeding, and overall symptoms -Days of laxatives used -Consistency of faces and frequency of defecation -Proctoscopic evaluation	Industry (provided medication)
Foster GE, 1979	Parallel randomized controlled trial. Abstract	Isphagula husk *vs* placebo. One month of treatment.	41 patients with hemorrhoids.	One month	-Overall symptomatic improvement. -Anal and rectal pressure	Not stated
Hunt PS, 1981	Parallel randomized controlled trial. Abstract	Isphaghula husk *vs* placebo. Six weeks of treatment	28 patients with bleeding hemorrhoids. Hemorrhoids grade I–II.	Evaluation at three and six weeks Data provided only at six weeks	-Symptomatic improvement -Proctoscopic improvement -Bowel habit (ease of defecation) -Overall symptomatic improvement -Adverse events*	Industry (minimal)*
Moesgaard F, 1982	Parallel randomized controlled trial. Full text available.	Psyllium seed dietary fiber (20 g/day) *vs* placebo. Six weeks of treatment.	52 outpatients with symptomatic hemorrhoids. Hemorrhoids grade I–II. Mean age 54, 26% of women.	Evaluation at three and six weeks	-Bleeding, pain at defecation, pruritus and/or anal secretion, prolapse, and overall assessment -Adverse events*	Industry (provided medication)
Pérez-Miranda M, 1996	Parallel randomized controlled trial. Full text available.	Plantago ovata (11.6 g/day *vs* placebo (vitamin B preparation) 40 days of treatment	50 outpatients with internal bleeding hemorrhoids referred to colorectal outpatient clinic. Hemorrhoids grade I–IV. Mean age 48, 42% women.	Assessed at 40 days plus patient diary	-Average number of bleeding episodes per time period -Number of congested hemorrhoidal cushions. Hemorrhoids bleeding on contact (during anoscopy) -Degree of prolapse -Adverse events	Undertaken without funding*
Jensen SL, 1988	Parallel randomized controlled trial. Full text available.	Unprocessed bran (20 g/day) *vs* no treatment. 18 months of treatment.	92 patients with hemorrhoids grade III after rubber band ligation. Median age 47, 47% women.	18 months (at 6 months interval)	-Number or recurrences after RBL (symptoms and protrusions) -Severity of symptoms -Laxatives intake -Adverse events	No funding was available*

RBL = rubber band ligation; IT = intention to treat.
* Data provided by authors.

Itching

The two studies that evaluated itching did not find a significant difference between the groups (12, 25) (RR = 0.71, 95% CI 0.24–2.10) One of the studies evaluated a composite outcome with itching and/or anal secretion but authors could not provide the data for its components (12). No statistically significant heterogeneity was present but I^2 was moderate ($p = 0.21$, $I^2 = 36.4\%$) The range of absolute percentages between trials of those being symptomatic/persisting symptoms was 0.03 to 0.40 for fiber *versus* 0.16 to 0.43 for placebo.

Recurrences or Need for Further Treatment

Only one study comparing fiber with placebo looked at the number of recurrences in the long term (34). Jensen *et al*. reported less overall recurrences in the fiber group (15% *vs* 45%) at 18 months in patients with third-degree hemorrhoids after rubber band ligation (RR = 0.34, 95% CI 0.15, 0.77). During the follow-up period there were fewer recurrent protrusions in the treatment group (10% *vs* 38%) In the same study, the number of rubber band ligations required until disappearance of symptoms was lower in the fiber group (median 2, range 1–4 *vs* 3, range 1–5).

Adverse Effects

The most common adverse effects with fiber consisted of gastrointestinal symptoms, typically starting at the beginning of the study, and were generally not severe enough for patients to stop taking the treatment. Adverse effects were inconsistent with some studies reporting a 50% incidence of bloating, the most common complaint, in the treatment group *versus* none in the placebo group (34). Two of the studies did not observe any adverse effects (information provided by authors) (12, 30). The pooled estimate showed a nonsignificant increase in the number of adverse events in the fiber group (RR = 6.0, 95% CI 0.57–64.84).

Variability in Study Results

In studies that measured symptoms on more than one visit—usually at 6 wk and at 3 months—the results for later time points were similar to earlier time points. Tests for heterogeneity all failed to reach statistical significance, but I^2 ranged from 1.1%, in the overall assessment, to 45.6% (substantial heterogeneity exists when I^2 exceeds 50%). None of our *a priori* hypotheses explained the variability in results between the studies. Crossover estimates for the different outcomes were consistently, though not significantly, closer to 1 than the parallel group estimates, suggesting a potential carry-over effect that decreased the size of the estimate. We found insufficient information in the studies for an adequate evaluation of co-interventions (local treatments, bathing, and compliance with an increase of fiber in the diet). None of these were part of our *a priori* hypotheses to explain heterogeneity.

Table 2. Methodological Quality of Included Studies

Author	Randomization	Allocation Concealment	Blinding	Lost to Follow-Up / IT
Broader JH, 1974	Adequate. Randomization schedule	Adequate*	Patients and observer blinded (Described as double blind) Treatment and placebo looked alike	Yes / Per protocol
Webster DJT, 1978	Adequate. Randomization centrally and placed in sequentially numbered envelopes by sponsor*	Adequate. Sealed envelopes (opened when patient agreed to enter study)*	Surgeons and patients blinded (Described as double blind)*	Yes / Per protocol
Foster GE, 1979	Unclear	Unclear	Unclear (Described as double blind)	Inadequate / Unclear
Hunt PS, 1981	Random list prepared by throwing a coin*	Adequate. Sealed envelopes*	Everyone blinded except Head pharmacist who was aware of the list* (Described as double blind)	Inadequate / Unclear
Moesgaard F, 1982	Adequate. Randomization schedule (table)*	Adequate. Sealed envelopes*	Patients and investigators blinded (Described as double blind)* Treatment and placebo looked alike*	Yes / Yes
Pérez-Miranda M, 1996	Adequate. Computer generated list*	Inadequate*	Endoscopist and analyst blinded* Health providers and patients not blinded*. Patients not aware of therapeutic effect*	Yes / Per protocol
Jensen SL, 1988	Inadequate (by date of referral)*	Inadequate*	Open study Evaluation of follow-up by independent observer	Inadequate / Per protocol

IT = intention to treat.
*Data provided by authors.

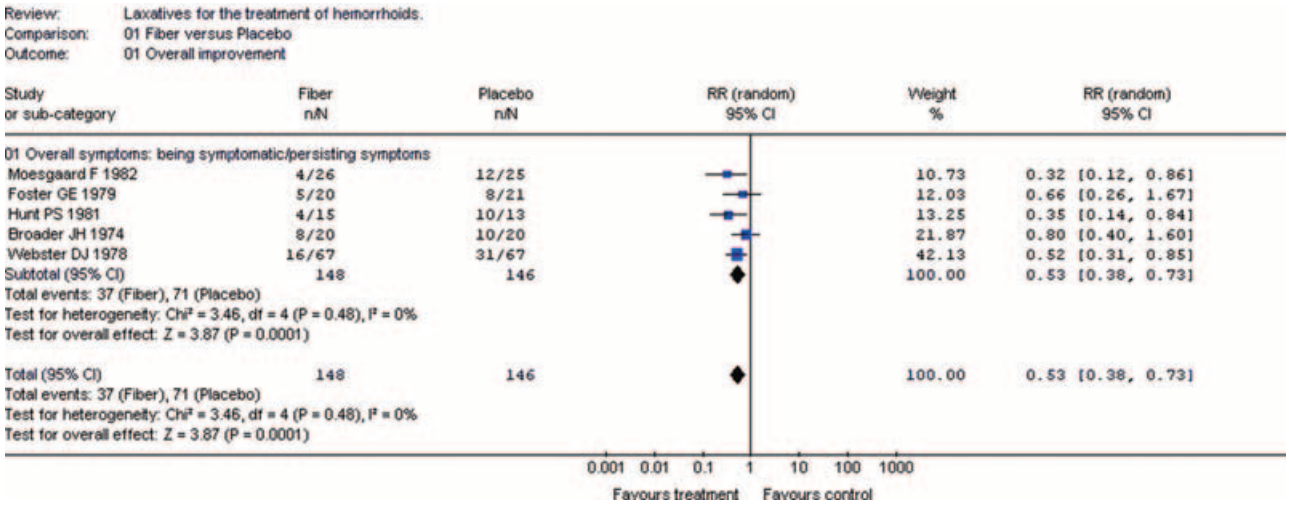

Figure 2. Relative risk of being symptomatic/persisting symptoms for overall improvement.

DISCUSSION

In this systematic review, we found that fiber shows an apparent beneficial effect in the treatment of symptomatic hemorrhoids. The risk of not improving/persisting symptoms decreased by 47% in the fiber group (RR = 0.53, 95% CI 0.38–0.73) and the risk of bleeding showed a significant difference in favor of the fiber too (RR = 0.50, 95% CI 0.28–0.89) We also found that in studies with multiple follow-ups, usually at 6 wk and at 3 months, the results for later time points were very similar to earlier time points. Results are also compatible with large treatment effects in prolapse, pain, itching, but even in the pooled analyses confidence intervals were wide and compatible with no effect (RR = 0.79, 95% CI 0.37–1.67; RR = 0.33, 95% CI 0.07– 1.65; and RR = 0.71, 95% CI 0.24–2.10, respectively). Results showed a nonsignificant trend toward increases in mild adverse events in the fiber group (RR = 6.0, 95% CI 0.57–64.8).

Fiber is generally used in patients suffering from first- and second-degree hemorrhoids, *i.e.*, those with a lesser component of prolapse. Most trials evaluated grade I–II hemorrhoids, and those that included mixed populations failed to provide data according to grade of severity. Although fiber might also be effective in patients with more advanced stages of hemorrhoidal disease, this issue remains largely unaddressed.

For all the major outcomes of this review, we would rate the quality of the evidence as moderate (35). Publication bias and funding remain issues of some concern. We contacted authors and had access to the methodology for the majority of trials, and the information provided improved apparent quality in comparison to the published articles. We found too few trials for the funnel plot to be of use. Our efforts to locate unpublished studies—we contacted authors, experts, and the pharmaceutical industry—and our success—we located two previously unpublished abstracts—make serious publication bias less likely. To the extent that we failed to identify additional unpublished studies with small or absent treatment effects, our results may represent an overestimate of the true underlying effect of treatment. There is evidence

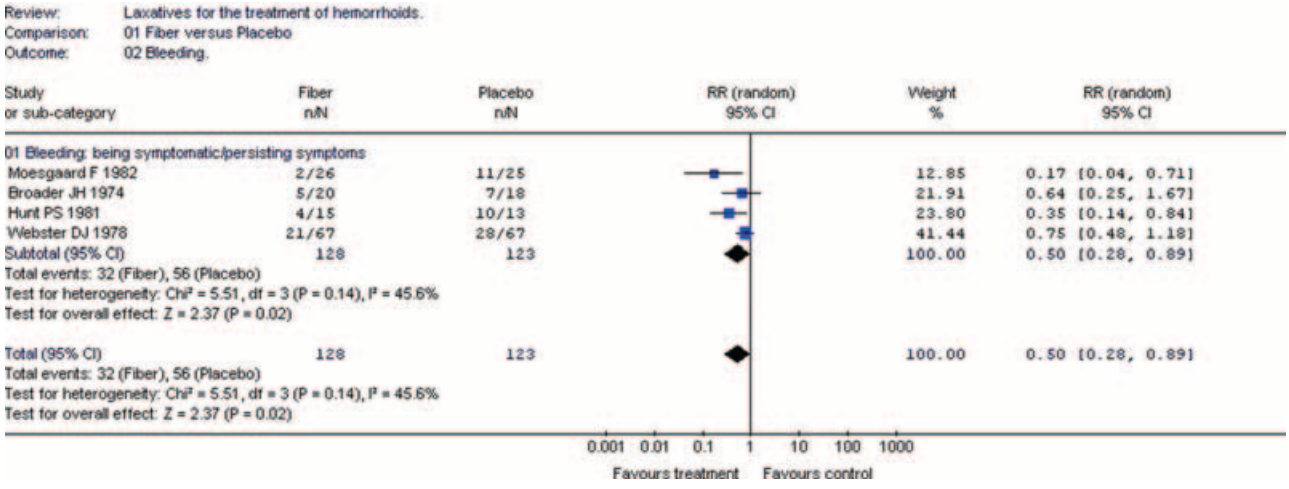

Figure 3. Relative risk of being symptomatic/persisting symptoms for bleeding.

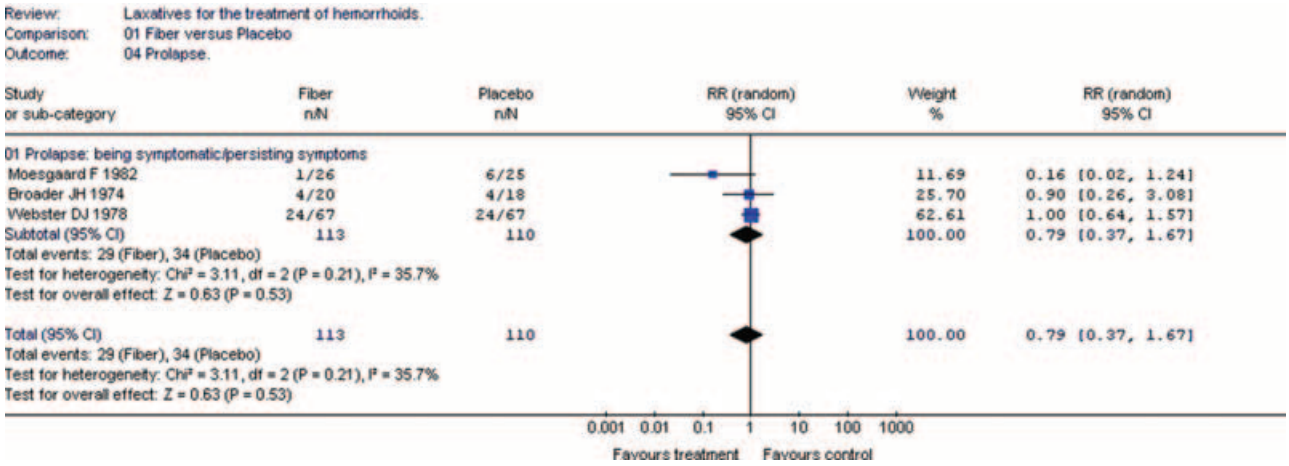

Figure 4. Relative risk of being symptomatic/persisting symptoms for prolapse.

that funding by the pharmaceutical industry can bias results in favor of the intervention of interest (36), however, this kind of funding other than providing the study medication was present in only two of the studies (one of them declared minimal funding). We believe that the limitations outlined above leave inferences concerning the effects of fiber in ameliorating hemorrhoid symptoms moderately strong.

CONCLUSIONS

Fiber is an effective treatment for symptomatic hemorrhoids (overall symptom improvement and bleeding). Results are also compatible with large treatment effects in prolapse, pain, itching, but even in the pooled analyses confidence intervals were wide and compatible with no effect. Moderate study quality leads to moderately strong inferences concerning the benefits of fiber. Thus, while future trials will likely confirm the observed effect, the relatively small number of patients enrolled in trials to date could argue for the need for additional larger trials. Certainly trials that explore head to head comparisons with common first line treatments like venotonics (*e.g.*, flavonoids) or topical treatments (anesthetic and/or steroids) would be informative, and most helpful, if they enrolled relatively large numbers of patients. The use of similar validated scales in future trials would facilitate comparisons and increase the validity of the results.

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