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# Is Polydextrose a Beneficial Supplement for Gastrointestinal Health and Maintenance of a Healthy Body Weight?

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**Is polydextrose a beneficial supplement for gastrointestinal health and maintenance of a healthy body weight?**

Katharine Reilly, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science  
In  
Health Sciences- Physician Assistant

Department of Physician Assistant Studies  
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## ABSTRACT

**Objective:** The objective of this selective EBM review is to determine if polydextrose is a beneficial supplement for gastrointestinal health and maintenance of a healthy body weight

**Study Design:** Review of three English language primary randomized controlled studies Published from 2000-2011.

**Data Sources:** All studies were double blind randomized control trials and found using one search+ and EBSCO host through the PCOM library webpage.

**Outcomes measured:** The outcomes measured in each study were based on subjective evaluations of ease of defecation, ease of stool passage, and feelings of fullness.

**Results:** Only one of the three studies found a clinically significant difference between the control and experimental groups. Ease of stool passage was found to be significantly easier when polydextrose was used as a dietary supplement when compared to placebo.

**Conclusions:** The role of polydextrose in maintenance of a healthy body weight remains unclear, as it did not significantly increase feelings of satiety when compared to a placebo. It may be beneficial in gastrointestinal health, as one study found ease of stool passage was significantly increased when polydextrose was added to their diet. However another study found no difference between the control and experimental groups, therefore further research must be done to clearly understand the ability of polydextrose to promote gastrointestinal health.

**Key Words:** Polydextrose, fiber, health benefits

## INTRODUCTION

Over the past two decades research has revealed the importance of fiber in one's diet. Fiber has been proven to be an essential dietary component that has been shown to protect against constipation, obesity, diverticulitis, and even colon cancer<sup>1</sup>. New products are now on the market that utilize synthetic fiber to increase the amount of total fiber in products that would otherwise would not provide a significant amount of one's suggested daily fiber intake; one common synthetic fiber product used is polydextrose<sup>2</sup>. The food ingredient polydextrose is a synthetic polymer of glucose<sup>2</sup>. It is indigestible and was classified as a soluble fiber by the U.S Food and Drug Administration<sup>2</sup>. It is used by many different food manufacturers to increase the fiber content of food, decrease calorie content and replace sugar and fat in food products<sup>2</sup>.

The relevance of this study to the PA profession and PA practice relates to the overwhelming prevalence of obesity and other conditions that fiber has been proven to be protective against. Maintaining a healthy body weight is a challenge for many individuals throughout the United States. The CDC estimates that over one-third of Americans are obese (35.7%) and a large percentage of obese individuals struggle with weight related health issues, such as Diabetes Mellitus type 2, cardiovascular disease, and certain types of cancer<sup>3</sup>. Fiber has been shown to help control blood sugar levels due to its ability to slow the absorption of sugar to help maintain healthy blood glucose levels, protecting against Type 2 diabetes mellitus<sup>1</sup>. Fiber has also shown to be effective in protecting against cardiovascular disease – the number one killer of men and women in the United States. Fiber has been shown to lower low-density lipoprotein cholesterol levels, protecting against plaque build-up in blood vessels, decreasing one's risk of hypertension and other major cardiovascular diseases<sup>1</sup>. Fiber is also vital in colon health and promoting

regular bowel movements<sup>1</sup>. Dietary fiber increases the bulk of stool and softens stool, making stool easier to pass and decreasing ones risk of constipation<sup>1</sup>. It can also help those with loose watery stools by bulking up loose stools and avoiding malnutrition or dehydration<sup>1</sup>.

Since research has revealed the dietary benefits of fiber, many consumers now buy products with synthetic fiber to increase overall dietary fiber intake. However, with the increasing popularity of fiber supplementation in processed foods, many American's are abandoning natural sources of fiber like fruits and vegetables. Polydextrose is a common source of fiber in products like granola bars and instant oatmeal, which are being consumed by millions of Americans on a daily basis<sup>4</sup>. The question this paper asks is: is synthetic fiber, specifically polydextrose, a beneficial supplement for gastrointestinal health and maintenance of a healthy body weight? This paper evaluates three double blind, randomized, controlled trials that assess the nutritional and health benefits of the food ingredient polydextrose.

#### OBJECTIVE:

The objective of this paper is to determine if polydextrose is a beneficial supplement for gastrointestinal health and maintenance of a healthy body weight.

#### METHODS:

Three randomized controlled trials (RCT) were assessed for this review. All trials were double blind, randomized, controlled trials consisting of healthy adult volunteers over the age of 18. Each study used daily ingestions of  $\geq 12$ g of polydextrose as an intervention and the comparisons were: visually matched placebos in 2 of the trials and soluble maize fiber in one. They outcomes measured were the ease of stool

passage/defecation and feelings of satiety. Key words used to research this topic were polydextrose, health benefits, weight loss, colon health. All articles were published in English in peer reviewed journals. All articles were researched using PubMed and COCHRANE via One Search on the PCOM library webpage. Articles were selected depending on relevance to the clinical question and if they included patient oriented outcomes (POEMS). Inclusion criteria were RCT studies that were double blind. Exclusion criteria during my search were subjects under the age of 18 and those diagnosed with syndromes, diseases, or illness. Statistics reported and used were measured using patient response. Ease of stool passage/defecation was measured using self-report on a scale from -3 →3 and a scale of 1-5. Feelings of satiety was measure using a one hundred millimeter continuous line visual analog scale.

Table 1: Demographics and Characteristics of Included Studies

Study	Type	# pts	Age (yrs.)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Ranawana (2012)	Double blind RCT	26	18-45	Healthy males with a BMI between 18.5 and 30 kg/m (Squared), age between 18-45	Those with medical conditions/syndromes, taking medicines that effect appetite or the GI tract	2 subjects	Regimen of 12g of PD 1 hour prior to lunch
Vester Boler (2011)	Double blind RTC	21	20-40 yrs.	Healthy males between the ages of 20-40	The female gender, Opposition to any of the mentioned inclusion criteria	5 subjects	A Regimen of 21g of polydextrose per day
Zhong (2000)	Double blind RTC	120	M: n=32.9 yrs. F: n=29.4	Healthy volunteer with no history of heart,	no history of heart, lung, kidney, liver, or metabolic disease	None	Regimen of 12g of PD QD

			yrs.	lung, kidney, liver, or metabolic disease			
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**OUTCOMES MEASURED**

The outcomes measured in these studies were focused on patient oriented evidence, basing the results on outcomes that would be important to the patients. This was measured having subjects rate the ease of passing stool/defecation or feelings of satiety on subjective scales and results were presented as means ± standard deviations. P values were computed to determine overall significance.

**RESULTS:**

Table 2: Significant P-Values from Reviewed Studies

Study	Outcome Measured	P-value
Zong, Bang-yao, et al. (2000)	Ease of defecation	P < 0.01
Ranawana, Muller et al. (2012)	Feelings of fullness	P > 0.05
Vester Boler, Rossoni et al. (2011)	Ease of stool passage	P > 0.05

In the first study (Zong et al., 2000) a placebo controlled, double-blind and randomized study design was utilized to evaluate the effect of polydextrose on bowel function, specifically ease of defecation measured subjectively by subject reports<sup>5</sup>. One hundred and twenty subjects were assessed, deemed appropriate for the study, and answered questions about bowel habits. The feeding phase, which consisted of polydextrose intake in the experimental group and placebo intake in the control group lasted from day 0- day 28<sup>5</sup>. During the feeding phase, each subject had to report foods

consumed at each meal, the amount consumed at each meal, daily activities, and any adverse reactions from the polydextrose<sup>5</sup>. The polydextrose was a powder supplement dissolved in warm water, delivered to the subjects in a double blind setting<sup>5</sup>.

Ease of defecation was assessed by subject report on a subjective scale of -3 to 3<sup>5</sup>. The results are presents as mean values +/- a standard deviation and P-values were computed using Dunnett's multiple (pairwise) comparison procedure to determine differences between the control and experimental group<sup>5</sup>. SAS was used for analysis<sup>5</sup>.

The results revealed that subjects that consumed 12g of polydextrose per day vs. a control group who consumed no polydextrose found that polydextrose had a significant, positive effect on the ease of defecation in subjects (see table 2)<sup>5</sup>. Not only were results significantly different in the experimental group vs. the control group, but subjective ease of defecation scores differed significantly within the experimental group before consuming the polydextrose and after<sup>5</sup>.

The second study (Ranawana et al., 2012) utilized a repeated-measures randomized blind crossover design. Twenty six healthy males consumed a 400 gram smoothie that contained 12g of polydextrose in the experimental group and 0g of polydextrose in the control group<sup>6</sup>. Subjective ratings for fullness were obtained before drinking the smoothie, and 15, 30 and 45 minutes after drinking the smoothie<sup>6</sup>.

One hundred millimeter continuous line VAS was utilized to measure subjective feelings of fullness<sup>6</sup>. The lines were anchored at the left and right with opposing statements for feelings of fullness<sup>6</sup>. The statistical package for the social sciences (SSPS) version 17 was used to analyze data from this study<sup>6</sup>.

The results of this study indicate that there was no significant difference between the control group and the experimental group when it came to subjective reports. Changes in the rating for fullness were comparable for both control and treatment groups<sup>6</sup>.

The final study consisted of 21 healthy adult subjects in a double-blind, placebo-controlled cross-over study<sup>7</sup>. Subjects were randomly assigned one of two fibre sources or no supplemental fibre during each period in a Latin-square design<sup>7</sup>. This review assesses the results pertaining to the control group compared to the experimental group who received polydextrose. The fiber was delivered in a rice cereal bar that either contained 0g of fiber or 7g of fiber through polydextrose<sup>7</sup>. Ease of stool passage was ranked on a five-point scale ranging from 1 (very easy) to 5 (very difficult)<sup>7</sup>.

The data collected in the study was analyzed using the SAS mixed models procedure and the GLIMMIX procedure of SAS was used to compare non-continuous survey data<sup>7</sup>. Results indicated that that ease of stool passage did not significantly differ between the control group and the experimental group<sup>7</sup>.

#### DISCUSSION:

As previously mentioned in the introduction, the market for supplemental fiber has rapidly expanded in the past decade with polydextrose being one of the most common supplements found in fiber labeled products<sup>2</sup>. The studies analyzed in this review yield mixed results on whether polydextrose is beneficial to gastrointestinal health and maintenance of a healthy body weight.

The results of ease of stool passage and defecation varied between the two studies analyzed. One study found a significant increase in ease of defecation with supplementation with polydextrose, while the other study noted comparable results in

ease of stool passage between the experimental group and the control group. These conflicting results unfortunately lead to an unclear answer of whether or not polydextrose is beneficial to one's gastrointestinal health in terms of ease of defecation and stool passage.

One issue with these studies is that all results concerning ease of stool passage is based on self-report. Any study relying on self-report depends on similarity of subjects and establishing a clear, standardized baseline for each subject. However, it is impossible to determine each subject's definition of ease vs. difficulty pertaining to stool passage, as this personal definition varies between each individual. What one subject may rate as "very difficult", another may rate as "moderately difficult." A more clear or in depth assessment of ease of stool passage or defecation may have led to more dependable results. For example, if ease of stool passage was broken down into more detailed aspects such as time spent defecating, presence of straining, presence of pain, etc. – results may have been more consistent. Had both studies clearly explained to subjects exactly what each score associated with ease of defecation entailed in a detailed, fact based manner the results would most likely be more similar, and most definitely more reliable.

When discussing the ability of polydextrose to aid in the maintenance of a healthy body weight, this study focused on its ability to increase feeling of satiety and fullness when compared to food lacking supplemental fiber. The study analyzed in this review found no significant difference in subjective ratings on feelings of fullness in subjects that received the polydextrose vs. subjects that received no supplemental fiber. However, again it is noted that subjective data is difficult to standardize between subjects. While only patient oriented outcomes were assessed in this review, it was found in another

aspect of this study that on average, each subject that received the polydextrose ate on average 102 calories less at a lunch buffet than the subjects that did not receive the polydextrose. This implies that the subjects may have not been able to accurately interpret and rate feelings of satiety and fullness, or possibly these results could suggest that polydextrose increases feelings of satiety more during consuming meals rather than before them. Overall, the study seemed to have a disconnect between the subjective reports on feelings of fullness and the objective data on how much each subject ate after receiving the polydextrose or the placebo, which leads to an unclear answer of whether polydextrose is beneficial in maintenance of a healthy body weight.

#### CONCLUSION:

Based on the studies analyzed in this review, polydextrose was not effective in increasing feelings of satiety in subjects when compared to a control. This statement conflicts with a common belief that polydextrose and other synthetic fibers contribute to healthy weight maintenance by increasing the intensity and duration of feelings of satiety. While this review only considered subjective data, these results that polydextrose is not effective in increasing satiety, and therefore its ability to promote healthy body weight is still controversial.

In terms of promoting digestive health, this review concluded with mixed results on the ability of polydextrose to increase the ease stool passage and defecation. Surprisingly, the study that utilized more grams per day of polydextrose did not find that ease of defecation differed between groups, while the study that provided only 12g of fiber in the experimental group noted a significant change in bowel habits and ease of defecation. This could be due to differences in the populations selected, as the study that

had significant results used only Chinese subjects of both genders and the comparable study only used male subjects, with the majority of subjects being American. Overall, more research must be conducted to establish a stronger understanding of the ability of polydextrose to aid in gastrointestinal health by easing stool passage.

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