Review paper

The role and therapeutic effectiveness of *Plantago ovata* seed husk (psyllium husk) in the prevention and non-pharmacological treatment of gastrointestinal diseases. Part 1. Clinical use of psyllium husk in the treatment of irritable bowel syndrome, ulcerative colitis, and colorectal cancer

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Abstract

Plantago ovata is a common medicinal plant widely cultivated in tropical regions of the world. The outer seed coat of *P. ovata*, obtained by cleaning the seeds, contains soluble and insoluble fibre in a ratio of 7:3, making products containing *P. ovata* husk an ideal source of health-beneficial fibre. The results of clinical trials demonstrate the therapeutic efficacy of psyllium husk for various gastrointestinal disorders. It has also been documented that psyllium ingestion exhibits antioxidant, immunomodulatory, antiproliferative, anticancer, and antiviral effects. Such pleiotropic effects of *P. ovata* husk are related to the presence in its composition of arabinoxylan, which forms a gel in an aqueous environment, as well as bioactive compounds and their metabolites. This article presents the evidence available in the literature on the therapeutic potential and possible mechanisms of action of psyllium in the treatment of irritable bowel syndrome and ulcerative colitis, and prevention of colorectal cancer.

Introduction

In 2002, the Institute of Medicine published a definition of dietary fibre that distinguished between dietary fibre (indigestible carbohydrates and lignin found in plants) and functional fibre (isolated, indigestible carbohydrates that exhibit beneficial physiological effects in humans) [1]. Under the current definition, fibre supplements (and fibre added to foods) must have clinically proven health benefits to be considered "functional fibre". The beneficial physiological effects formulated by the U.S. Food and Drug Administration include the following: lowering cholesterol levels, lowering blood glucose levels, reducing energy intake, lowering blood pressure, improving bowel movements, and improving mineral bioavailability [2, 3]. According to the criteria adopted by the FDA, the existence of clinical evidence of only one of the aforementioned physiological effects is sufficient for a fibre to be credited and labelled as a functional fibre. Meanwhile, for *Plantago ovata* husk, evidence of therapeutic efficacy has been shown, in numerous clinical studies, for 5 of the 6 effects listed above (regulation of bowel movements, lowering cholesterol, improving glycaemic control, reducing energy

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intake/weight loss, and lowering blood pressure due to weight loss) [4–11]. What is more, *P. ovata* husk is the only natural source of fibre that provides as many as 5 major health benefits identified by the Food and Drug Administration. In addition, consumption of psyllium husk has also been shown to provide measurable clinical benefits in other conditions such as ulcerative colitis, irritable bowel syndrome, diarrhoea caused by enteral feeding, chronic constipation, chronic diarrhoea, haemorrhoids, and type 2 diabetes [4–11]. It is worth noting that psyllium husk is the only fibre recommended by the American College of Gastroenterology for the treatment of irritable bowel syndrome [12]. Similarly, Experts of the Polish Society of Gastroenterology, in their recommendations for the management of irritable bowel syndrome published in 2018, suggest a diet rich in soluble fibre in all types of IBS [13].

The biological activity of *P. ovata* husk is related to the presence in its composition of the following:

- a highly branched, gel-forming arabinoxylan in aqueous environments,
- bioactive compounds along with their primary and secondary metabolites such as short-chain fatty acids, amino acids, polyphenols, flavonoids, alkaloids, terpenoids, phenolic acid derivatives, and iridoid glycosides [4-7, 14–19].

The following section of the article presents the evidence available in the recent literature on the therapeutic potential and possible mechanisms of action of psyllium in the treatment of irritable bowel syndrome and ulcerative colitis, and the prevention of colorectal cancer.

Therapeutic effect of *Plantago ovata* husk in irritable bowel syndrome

Psyllium husk is the only fibre recommended by the American Society of Gastroenterology for the treatment of irritable bowel syndrome (IBS) [12]. Clinical evidence available in the literature confirms that psyllium extracted from *P. ovata* can reduce painful symptoms and normalise stool consistency in patients with IBS in both diarrhoeal and constipated forms [20–23]. Bijkerk *et al*. in a study conducted in a group of 275 patients diagnosed with IBS evaluated the effect of psyllium husk and bran consumption on the clinical course of the disease [20]. For this purpose, the cited authors randomly assigned eligible patients to 3 groups. The first group consisted of patients (n = 85) receiving psyllium 10 g/day, 97 other patients consumed wheat bran 10 g/day, and the last group of 93 patients received placebo. The duration of the study was 12 weeks [20]. In the first month of the experiment, the percentage of patients who responded was statistically significantly higher in the group consuming psyllium than in the placebo group (57% vs. 35%). Also, in the second month of follow-up, a higher percentage of patients with clinical improvement were those in the psyllium-treated group (59% vs. 41%). In the third month of treatment, the observed difference between the number of patients reporting symptom relief in the psyllium group (46%) and the number in the placebo group (32%) was not statistically significant. The authors of the described experiment also noted that the dropout rate was highest (46%) in the group receiving wheat bran, and the most common reported reason for dropping out was exacerbation of IBS symptoms, probably caused by mechanical irritation of the intestinal mucosa by coarse wheat bran particles [7, 20]. Another reason for the exacerbation of IBS symptoms in the group receiving wheat bran may have been an increase in bacterial fermentation processes in the intestine associated with the high content of poorly absorbed, easily fermentable oligo-, di-, and monosaccharides and polyols (FODMAPs) in wheat bran [24]. According to the recommendations of the Polish Society of Gastroenterology, wheat bran is not recommended as a source of fibre in the diet of patients with IBS [13]. Clinical studies available in the literature show that as many as 52–86% of patients report significant relief of IBS symptoms after eliminating FODMAPs from the diet [24]. This is because a diet low in FODMAPs reduces microbial fermentation with less gas production and fewer osmotic metabolites, leading to relief of IBS symptoms, mainly bloating and abdominal pain [24].

The therapeutic benefits of psyllium husk in IBS patients were also reported by Prior and Whorwell in a clinical study conducted in a group of 80 patients [21]. In the cited study, psyllium husk therapy, at a dose of 10 g/day, proved effective in relieving IBS symptoms in 82% of patients [21]. In the placebo group, clinical improvement was noted in 53% of patients ($p < 0.02$). In the placebo group, there were no changes in bowel movements, while a statistically significant reduction in constipation was observed in psyllium-treated patients ($p = 0.026$). In addition, psyllium consumption significantly improved the overall well-being of the patients studied [21].

The mechanism described in the literature for the therapeutic effect of *P. ovata* in the course of IBS, among other things, is the alteration of colonic environment, which is due to the ability of psyllium to promote the growth and proliferation in the intestinal lumen of probiotic bacteria [7, 25], with a secondary increase in the production of endogenous short-chain fatty acids (SCFAs): acetic, propionic, and butyric [7, 26, 27]. Bacteria in the colon fermenting psyllium produce SCFAs, which act as signalling molecules that modulate

many physiological processes [28]. Low intake of soluble dietary fibre has been shown to result in a reduction of SCFA concentrations in the body. Results of clinical studies available in the literature indicate that *Plantago* polysaccharides regulate the growth of *Bifidobacterium* in the stool in a baseline microbiota-dependent manner [7, 26, 27]. It was also shown that consumption of psyllium husk resulted in a significant increase in *Faecalibacterium* ssp., *Lachnospira*, and *Phascolarctobacterium*, i.e. microorganisms associated with the production of short-chain fatty acids [26]. Numerous studies have shown that SCFAs are a major source of energy for colon cells and have significant effects on intestinal homeostasis, energy metabolism, and modulation of the immune response [28–31]. The potential mechanism for the beneficial effects of SCFA in IBS is through the following: (1) altering chemotaxis and phagocytosis, (2) inducing reactive oxygen species, (3) altering cell proliferation and function, (4) inducing anti-inflammatory, anti-tumour, and antimicrobial effects, and (5) altering intestinal integrity [28–30]. Impaired intestinal integrity plays a key role in the pathogenesis of IBS. Additionally, butyrate or propionate supplementation has been shown to modulate intestinal permeability and alleviate the discomfort associated with IBS patients [28, 31]. SCFAs enhance intestinal barrier integrity through several mechanisms, including induction of IL-18 secretion, release of antimicrobial peptides, and production of mucins by intestinal epithelial cells. In addition, SCFAs have been shown to increase the expression of tight junction proteins, strengthening the physical barrier against pathogens [28].

Therapeutic effect of *Plantago ovata* husk in the course of ulcerative colitis

A small number of studies have also evaluated the ability of psyllium husk to maintain remission in ulcerative colitis [25, 32]. Treatment with psyllium has been shown to be beneficial in maintaining remission of the disease. The study authors suggest that the therapeutic effect is the result of increased production of endogenous short-chain fatty acids in the gut. Psyllium supplementation alleviated colonic damage in HLA-B2712 transgenic rats and the observed effect was associated with decreased levels of certain pro-inflammatory mediators (nitric oxide, leukotriene B4, tumour necrosis factor α) and correlated with increased amounts of SCFAs, which may act synergistically in inhibiting the production of pro-inflammatory mediators [25]. The results noted in animal model studies are consistent with clinical observations. In an open randomised, multicentre study conducted among 105 patients with ulcerative colitis in remission, it was shown that *P. ovata* supplementation (10 g twice daily) was comparably effective in maintaining emissions as mesalamine therapy [32]. It was concluded that this effect may be the result of an increase in butyric acid after psyllium supplementation.

Plantago ovata husk supplementation reduces colon cancer risk

The results of biological as well as clinical studies available in the literature indicate that psyllium consumption reduces the risk of colorectal cancer [33–36]. Citronberg *et al.*, in a large prospective clinical trial involving 75,214 participants, evaluated the association between colorectal cancer incidence and the following: constipation, use of laxatives without fibre, and use of laxatives with fibre (including but not limited to psyllium husk) [36]. The authors, during a follow-up of 8 years, showed that the risk of colorectal cancer increased in proportion to the amount of non-fibre laxatives taken. At the same time, there was a reduction in the risk of colorectal cancer in users of fibre-based laxatives (such as psyllium) [36]. The results of Citronberg *et al.* are consistent with those of 2 previously published studies, which found that high-fibre use was inversely correlated with colorectal cancer (CRC) risk [37]. Additionally, Jacobs and White noted that all commercial laxatives except fibre were associated with an increased risk of CRC [38].

The mechanisms by which psyllium inhibits carcinogenesis are well understood and are due to protective effects on intestinal structure and the reduction of inflammatory mediators such as TNF-α and NO [25, 39]. As previously described, psyllium husk increases faecal weight, shortens intestinal transit, and reduces the concentrations of carcinogens present in the colon by diluting them as well as binding and thus neutralising them in the mucogel-like structure that psyllium forms when combined with water [33]. *Plantago ovata* husk's ability to inhibit bacterial β-glucuronidase activity has also been described, which secondarily reduces the hydrolysis of glucuronide-conjugated carcinogens [40]. It is also known that psyllium provides a nutrient substrate for colon bacteria and a substrate for the production of short-chain fatty acids, which exert anticancer effects by reducing faecal mutagenicity [41, 42]. In addition, butyric acid in the distal colon decreases cell proliferation and induces apoptosis, which ultimately inhibits the transformation of colon epithelial cells into cancer [42].

Dosage – recommended intake of *Plantago ovata* husk

The most commonly indicated dose of psyllium husk showing therapeutic effect in clinical trials is the

amount of 10–15 g/day, taken in divided doses (3 × daily at about 3.4–5 g) before main meals [43]. The Polish Society of Gastroenterology recommends a soluble fibre intake of 10–25 g/day to reduce overall IBS symptoms [13]. It is recommended that *P. ovata* husk therapy for all indications other than constipation be started gradually, with a single daily dose of 3.4 g/day for the first week, and then increased by one daily dose each subsequent week until the therapeutic goal is reached (i.e. about 10.2 g/day) [43]. *Plantago ovata* husk supplements can also be used in larger amounts (with safety precautions) to supplement a poorly varied diet with beneficial fibre. According to a 2003 WHO expert opinion, adult fibre intake should be above 30–40 g/day [44, 45]. This recommendation stems from preventive health measures aimed at preventing gastrointestinal disorders and metabolic diet-related diseases. In 2020, NIZP-PZH experts set dietary fibre intake standards for the Polish population in accordance with European dietary standards (EFSA 2017) [44, 45]. Depending on age, the standard of sufficient intake (adequate intake, AI) of dietary fibre for children over 1 year of age is 10–21 g/day, which, according to European experts, corresponds to an amount of fibre of 2 g/MJ (8.4 g/1000 kcal). The standard for sufficient fibre intake for adults (≤ 65 years) is 25 g/day and 20 g/day for the elderly (> 65 years), after adjusting the intake in the oldest age group according to individual medical and dietary indications [44, 45]. Both AI values for fibre (25 and 20 g/day) should be interpreted as the "minimum intake level", advising patients to consume more fibre (30–40 g/day).

Plantago ovata husk supplementation safety information – possible side effects

Researchers are pondering the safety of long-term psyllium husk supplementation in terms of its effect on the bioavailability of nutrients from the gastrointestinal tract and thus the nutritional status of quality patients. It was thought that psyllium supplementation may translate into impaired absorption of fat-soluble vitamins (A, D, E, and K). It has also been suggested that psyllium may bind minerals in its mucilaginous-gel-like structure, e.g. calcium, potassium, magnesium, zinc, and iron. However, the results of clinical studies available in the literature show that supplementation with *P. ovata* husk is safe, well tolerated, and does not adversely affect the gastrointestinal bioavailability of vitamins and minerals. Solà *et al.* determined the effects of an 8-week intake of 10.5 g/day *P. ovata* husk, by 28 men (age: 61.4 ±8.6 years) with ischaemic heart disease, among others, on selected laboratory parameters, i.e. magnesium, calcium, iron, ferritin, haemoglobin, vitamin A and E, and prothrombin time (as an indirect indicator for assessing vitamin K levels) [8]. No clinically or statistically significant differences were observed in the results of the laboratory parameters analysed. Similarly, Sierra *et al.* reported no adverse effect of 6-week psyllium supplementation (14 g/day) on serum levels of minerals and vitamin A and E in a group of 20 patients with type 2 diabetes (12 men and 8 women) [9].

Another aspect related to the safety of psyllium as a functional ingredient in supplements is the degree of processing and purity of these products [10]. The FDA issued a statement that the use of psyllium husk in dietary supplements and food products in the amount necessary to achieve the desired therapeutic effect (i.e. 10.2 g/day) was safe and legal when using *P. ovata* husk with a high degree of purity, a minimum of 95% [46].

When describing the safety issues of *P. ovata* husk, attention should also be paid to possible inhalation or gastrointestinal allergic reactions after ingestion or contact with products containing psyllium. Lantner *et al.* published a case report of an anaphylactic reaction in a 60-year-old woman after ingesting breakfast cereals containing psyllium [47]. The only previous contact of the described woman with psyllium was in the course of her work as a nurse, while dispensing a laxative containing psyllium to patients. The patient was confirmed to be allergic to psyllium by the results of point skin tests and specific IgE levels [47]. Examples of occupational asthma associated with psyllium exposure through dust inhalation or skin contact have also been described [48]. A review of the literature suggests that health care workers, pharmaceutical workers, and especially those directly involved in the production of psyllium preparations may be at increased risk of allergic reactions due to frequent inhalation exposure to the allergen [48].

In addition, it should not be forgotten that protein contamination with other allergens (e.g. sesame, mustard) can occur during the manufacturing process of supplements / food products. Therefore, physicians, pharmacists and consumers should be aware of potential allergic reactions, including anaphylaxis after consuming supplements/food products containing psyllium. The FDA, referring to the allergenicity of psyllium husk, has indicated that the purity of psyllium husk is an important safety criterion in this aspect as well. Therefore, the FDA has set a required purity criterion of at least 95% (with protein content ≤ 3%) [46].

The U.S. Food and Drug Administration has also identified the possibility of oesophageal or intestinal obstruction as important, related to the safety of psyllium consumption [46]. Supplementation of psyllium without adequate fluid intake can cause a lack of prop-

er passage of the ingested dose of the product, and its swelling in the upper gastrointestinal tract can block the throat or oesophagus, which in turn will result in choking. Therefore, it is essential to inform patients about the possible side effects of consuming the product with an inadequate amount of fluids [46]. Each dose of *P. ovata* husk should be consumed after dissolving the product in an appropriate amount of liquid (approximately 150–200 ml). In addition, to avoid complications, it is recommended that the patient drink another glass of water after consuming a dose. Psyllium should not be consumed if the patient has difficulty swallowing [43].

Conclusion and perspective

Plantago ovata husk is a natural plant product high in water-soluble fibre and numerous bioactive compounds that exert a number of positive health (clinical) effects. Only a soluble nonfermenting, gel-forming fibre has been clinically proven to provide all of the health benefits typically associated with a fibre supplement. *P. ovata* husk has been extensively researched for its potential health benefits and its potential use in the treatment and prevention of gastrointestinal diseases. It seems that psyllium husk preparations deserve attention as a natural dietary supplement for use in the nutrition of patients with gastroenterological disorders, because they are inexpensive, generally safe, and show positive clinical results in a short period of time. The therapeutic properties of *P. ovata* husk described in this article may be helpful to clinicians in making effective recommendations for patients with irritable bowel syndrome or ulcerative colitis and in patients at risk for colorectal cancer.

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Ethics approval

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Conflict of interest

The authors declare no conflict of interest.

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