

EXPLORING DOCTORS' VIEWS ON PHGG WITH L-THEANINE: A NATURAL ALTERNATIVE TO LAXATIVES FOR CHILDHOOD CONSTIPATION

Dissertation Submitted to



The IIHMR University, Jaipur

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Master of Business Administration (MBA)

in

Pharmaceutical Management

By

Siddhant Kishor Wankhade

Under the Supervision and Guidance of

Dr. Sudhinder Singh Chowhan

2024

DECLARATION BY STUDENT

I hereby declare that this dissertation titled **Exploring doctors' views on PHGG with l-theanine: a natural alternative to laxatives for childhood constipation** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.



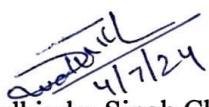
(Signature)

Siddhant Wankhade

Date: 04/07/2024

CERTIFICATE

This is to certify that the dissertation titled **Exploring doctors' views on PHGG with l-theanine: a natural alternative to laxatives for childhood constipation** is a record of the research work undertaken by **Siddhant Wankhade** in partial fulfilment of the requirements for the award of the degree MBA (Pharmaceutical Management) from the IIHMR University, Jaipur under my guidance and supervision and his approach to the research study has been sincere, scientific, and analytical.


Dr. Sudhinder Singh Chowhan

Faculty Guide

IIHMR University, Jaipur

Date: 4/7/24


Dr. Manthan Janodia

School Dean

IIHMR University, Jaipur

Date: 04/07/2024

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Date:

Place:

(Siddhant Wankhade)

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Abstract

Background: Childhood functional constipation (FC) significantly affects children's quality of life and incurs substantial healthcare costs. Traditional treatments include dietary adjustments and laxatives, but there is increasing interest in natural alternatives such as Partially Hydrolysed Guar Gum (PHGG) and L-theanine.

Objective: This study aims to assess healthcare professionals' awareness, perceptions, and experiences regarding the use of PHGG with L-theanine as a treatment for childhood constipation compared to traditional laxatives.

Methods: An exploratory, descriptive study design was used, incorporating primary research through surveys and secondary data analysis. A total of 65 healthcare providers participated in a structured questionnaire evaluating their knowledge and views on PHGG with L-theanine.

Results: Of the respondents, 84.6% were aware of PHGG with L-theanine as a treatment option. Most respondents found it more effective than traditional laxatives, with 53.8% rating it as significantly more effective and 30.8% as slightly more effective. Additionally, 76.9% reported no side effects with PHGG and L-theanine, and 46.2% believed it effectively supports the gut-brain axis. Ease of administration was noted, with 61.5% finding it much easier to administer than traditional laxatives. Satisfaction levels were high, with 53.8% indicating that parents and children were very satisfied with its use. Furthermore, 38.5% strongly agreed that PHGG with L-theanine is a viable long-term solution for managing childhood constipation.

Conclusion: The findings highlight a positive perception among healthcare professionals toward PHGG with L-theanine as a safe and effective alternative to traditional laxatives for childhood constipation. The results emphasize the need for further clinical research, educational initiatives, and the development of evidence-based guidelines to support its integration into paediatric healthcare practice.

Keywords: Childhood constipation, Functional constipation, Partially Hydrolysed Guar Gum, L-theanine, Healthcare professionals, Natural treatment, Gut-brain axis.

Chapter 1: Introduction

Ataraxia Life Pvt. Ltd.

Ataraxia Life, is one of the fastest growing companies in India. We emphasize on attention to detail at every stage of product development, production process and packaging material to ensure integrity in end-to-end value chain. The company has expertise in offering customised solutions to unmet needs of the consumers.

VISION

To improve quality of life by offering healthcare solution with scientific evidence & Improved access.

MISSION

To explore realm of opportunity in the healthcare by means of vertical integration and adding value to all the stakeholders.

Ataraxia Life Pvt Ltd (ALPL) is a nutraceutical & health sciences company operating in the Indian market form last year. Ataraxia is committed to deliver palatable and efficacious therapeutic products which aims to restore the health and nutritional balance across age groups.

The First 1000 weeks is the most crucial period for the new-born, Health care practitioners & parents. At Ataraxia we are committed to make the difference with the best-in-class solutions in order to fulfil the unmet needs. On the other hand, Modern & urban lifestyles give rise to nutritional imbalances and poor health habits that result in loss of wellness, extending to illness. Ataraxia, aims to address these imbalances through therapeutically efficacious and innovative solutions and shift the focus in Health sciences from ILLNESS to WELLNESS.

Certifications and Collaborations



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Childhood Constipation

Childhood functional constipation (FC) is characterized by infrequent and painful bowel movements, fecal incontinence, stool withholding behavior, and occasionally passing large stools. It is a significant global health issue found in both developed and developing nations. Children suffering from constipation endure various symptoms that adversely affect their quality of life, often overlooked by healthcare systems. The economic impact is substantial, with considerable public expenditure on hospital admissions, emergency room visits, and regular clinic appointments to manage recurrent symptoms.

Epidemiology

Functional constipation (FC) is a prevalent functional gastrointestinal disorder (FGID) in childhood, exhibiting consistent prevalence worldwide over the last two decades. Variations in reported prevalence are influenced by differing definitions used rather than by age or gender. Notably, FC appears less prevalent among Asian children compared to their American and European counterparts, potentially influenced by dietary habits, cultural practices, and toilet training norms.

The association between socioeconomic status and FC remains debated. While several studies indicate no significant correlation with parental education levels, family income, or parental employment status, a study from Nigeria suggests a higher prevalence among children from lower social classes. Family history of FC and general health issues among family members are also noted as contributing factors in epidemiological studies.

Risk factors for constipation

Several factors contribute to the development of functional constipation (FC), all of which ultimately result in anorectal dysfunction and retention of feces in the colon and rectum, leading to the passage of infrequent, hard, and painful stools. FC is considered a disorder involving interactions between the gut and the brain.

Risk factors for childhood FC can be broadly categorized into two main groups: centrally mediated factors and gut-related mechanisms. These factors encompass various influences that impact gastrointestinal function and the neural regulation involved in defecation processes. Understanding this risk factor is crucial for addressing and managing childhood constipation effectively.

Management of childhood constipation

The management of constipation involves five components.



Fig 1: Five components in the management of functional constipation.

<i>Types of laxatives</i>	<i>Name of laxative</i>	<i>Dose</i>	<i>Mechanism of action</i>	<i>Side effect</i>
Osmotic laxatives	Polyethylene glycol	0.5–1 g/kg/day	Large inert molecule which retains intraluminal water	Nausea and bloating
	Lactulose	<1 year 2.5 mL BD 1–<5 years: 2.5–10 mL BD 5–20 years 5–20 mL BD	Nonabsorbable synthetic disaccharides product which retains intraluminal water	Bloating and abdominal discomfort
	Lactitol	200–400 mg/kg/day	Synthetic monohydrate product which retains intraluminal water	Mild bloating
Stimulant laxatives	Sodium picosulfate	2.5–10 mg per day up to 4 years 2.5–20 mg per day up from 4–18 years	Converts into active metabolite by intestinal bacteria which increases the peristalsis	Nausea, crampy abdominal pain, occasionally loose motions

Table 1: Commonly used laxatives and dose used in children and their mechanism of action.

Chapter- 2: Literature Review

Childhood constipation is a common condition, with prevalence rates ranging from 0.8% to 28%. Nearly half of the children experience relapse after successful treatment. Current recommended treatments for functional constipation include toilet training, a high-fiber diet, and long-term use of oral laxatives. Dietary fiber is crucial for childhood health, particularly in promoting regular bowel movements. Two small randomized controlled trials have demonstrated that glucomannan, a non-absorbable fiber gel polysaccharide, positively impacts defecation frequency and stool consistency in constipated children. A recent double-blind randomized controlled trial compared the efficacy of a dietary fiber mixture with lactulose, concluding that both treatments are equally effective.

However, there is insufficient literature to make evidence-based recommendations on the most effective fiber sources for treating constipation. One promising fiber source is partially hydrolyzed guar gum (PHGG), known for its low viscosity and complete fermentation in the colon. To our knowledge, no studies in the English literature have investigated the use of PHGG for childhood constipation. This study aims to evaluate the therapeutic role of PHGG in children with chronic constipation and compare its effects with lactulose treatment.

Functional gastrointestinal disorders (FGIDs) are characterized by a range of chronic or recurrent gastrointestinal (GI) symptoms that vary with age and are not attributable to structural or biochemical abnormalities. Chronic abdominal pain (CAP) is the most prevalent condition within FGIDs, typically functional in nature, with no objective evidence of an underlying organic disorder. The term recurrent abdominal pain (RAP) was first introduced in pediatric literature to describe a condition in which children experience at least three bouts of pain, severe enough to affect activities, over a period of at least three months.

In 1999, the Pediatric Rome Working Group introduced standardized symptom-based criteria for pediatric FGIDs with the publication of the Rome II criteria. In 2006, the “Rome Committee” defined new diagnostic criteria (Rome III) for pediatric FGIDs, differentiating functional abdominal pain (FAP) from dyspepsia and irritable bowel syndrome (IBS), noting that FAP involves pain at a different site with normal bowel habits.

The exact prevalence of CAP in children is not known, but it seems to account for 2%-4% of all pediatric office visits. Several studies suggest that 13% of middle-school students and 17% of high school students experience weekly abdominal pain. According to these criteria, IBS is an FGID characterized by abdominal pain or discomfort, accompanied by altered bowel habits (constipation, IBS-C; diarrhea, IBS-D; or alternating).

It has been shown that several factors, especially psychological factors, dietary habits, and frequency of exercise, are associated with the onset and course of IBS. The term “functional” is conceptual rather than real, as the pathogenesis can be correlated with alterations in visceral sensitivity, increased intestinal permeability, chronic inflammation, and genetic predisposition. Pharmacotherapy generally cannot be recommended for children with FAP, except in the context of clinical trials, and drugs should only be given in exceptional cases. Up to 40% of children undergo alternative or complementary therapies such as reassurance, phytotherapy, dietary restrictions, or homeopathy, though the benefits of such methods have not been documented by controlled clinical trials.

The beneficial effects of water-soluble dietary fibers have received attention as complementary therapy in FGIDs, especially in FAP and IBS, due to their ability to modify bowel patterns, accelerate oral-to-anal transit, decrease intracolonic pressure, and alleviate pain. Partially hydrolyzed guar gum (PHGG) is a vegetal, water-soluble, non-viscous, non-gelling dietary fiber derived from guar gum, a water-soluble, viscous, gelling polysaccharide found in the seeds of the guar plant. The saccharide component of guar gum is galactomannan. An adult open trial by Parisi et al. showed that PHGG supplementation is followed by a decrease in IBS symptoms, such as abdominal pain and bowel habit changes. Feldman et al., in a small, prospective, randomized, double-blind, controlled trial, revealed that fiber supplementation can improve symptoms in children with FAP. Despite this, there have been no recent randomized controlled trials (RCTs) published to support the use of fiber in the treatment of CAP in a pediatric population.

Partially hydrolyzed guar gum dietary fiber is well recognized for its numerous health benefits. In the present study, we aimed to investigate the effects of partially hydrolyzed guar gum on constipation, intestinal microbiota, and mental health in healthy subjects. In this randomized, parallel, double-blind, and placebo-controlled study, enrolled healthy men and women took either 3 g/day (T3) or 5 g/day (T5) of dietary fiber for eight consecutive weeks, compared to a placebo (T0). Fecal characteristics, fecal microbiota, defecation characteristics, and quality of life (QOL) were assessed through questionnaires.

The results revealed a significant reduction in fecal potent harmful mucolytic bacteria in the T3 and T5 groups compared to the T0 group. The defecation frequency, excretory feeling, and scores on sleep and motivation questionnaires also improved in the dietary fiber intake groups, with a significant difference observed in the T5 group compared to the T0 group. In summary, the consumption of partially hydrolyzed guar gum dietary fiber effectively suppressed potent harmful mucolytic bacteria, which could be associated with improvements in constipation-related symptoms and mental health, specifically in terms of sleep and motivation, among healthy subjects.

Partially hydrolyzed guar gum (PHGG) alleviates symptoms in constipation-predominant irritable bowel syndrome (IBS) and may possess prebiotic properties. However, the relationship between PHGG effectiveness and patient characteristics has not been explored. This study aims to examine the impact of PHGG on symptom relief in constipation-predominant IBS, considering factors such as gender, age, and body mass index (BMI).

Chapter-3: Methodology

Articles and research papers were reviewed and selected according to specific criteria. Numerous articles were evaluated, and a field survey was conducted. A total of 65 healthcare providers responded to the survey.

Research Questions:

- a) Are you aware of Partially Hydrolysed Guar Gum (PHGG) and L-theanine as a treatment option for childhood constipation?
- b) How effective do you find PHGG with L-theanine in relieving constipation symptoms in children compared to traditional laxatives?
- c) Have you noticed any side effects in children using PHGG with L-theanine for constipation compared to those using traditional laxatives?
- d) How effective do you believe the combination of PHGG with L-theanine is in supporting the gut-brain axis in children with constipation?
- e) How easy is it to administer PHGG with L-theanine to children compared to traditional laxatives?
- f) How satisfied are the parents and children with the use of PHGG with L-theanine for constipation management compared to traditional laxatives?
- g) Do you believe PHGG with L-theanine is a viable long-term solution for managing childhood constipation compared to traditional laxatives?

Objective:

The primary objective of this methodology is to investigate doctors' viewpoints on the use of partially hydrolysed guar gum (PHGG) with L-theanine as an alternative to traditional laxatives for childhood constipation. The objectives include assessing doctors' awareness and perceptions of PHGG with L-theanine, evaluating their understanding of its safety and efficacy compared to conventional treatments, and examining current prescribing practices. Additionally, the study seeks to identify barriers and facilitators influencing doctors' decision-making, compare their attitudes towards PHGG with L-theanine versus traditional laxatives. Furthermore, it aims to explore doctors' experiences with patient satisfaction and compliance when using PHGG with L-theanine for childhood constipation.

Material and Methods:

Study Design: The study employs an Exploratory with Descriptive study design to assess the market.

Setting: This study will involve primary research aimed at gathering data from surveys, legal documents, regulatory documents, and existing reports.

Study Population: Healthcare providers.

Sampling Technique: Non-Probability Convenient Sampling

Sample Source: Primary and Secondary research sources

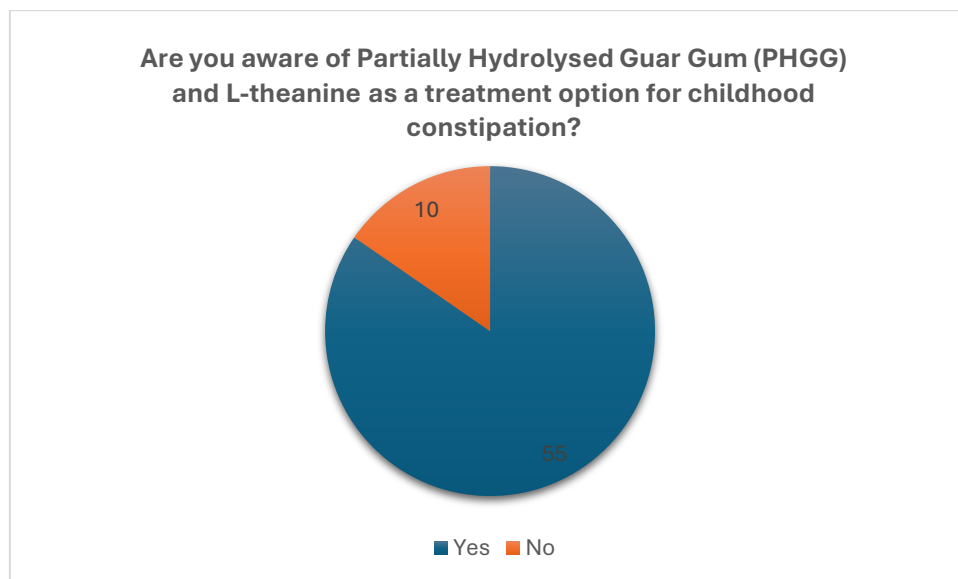
Data Analysis Plan:

Surveys and reports will be analyzed using MS Excel, if necessary.

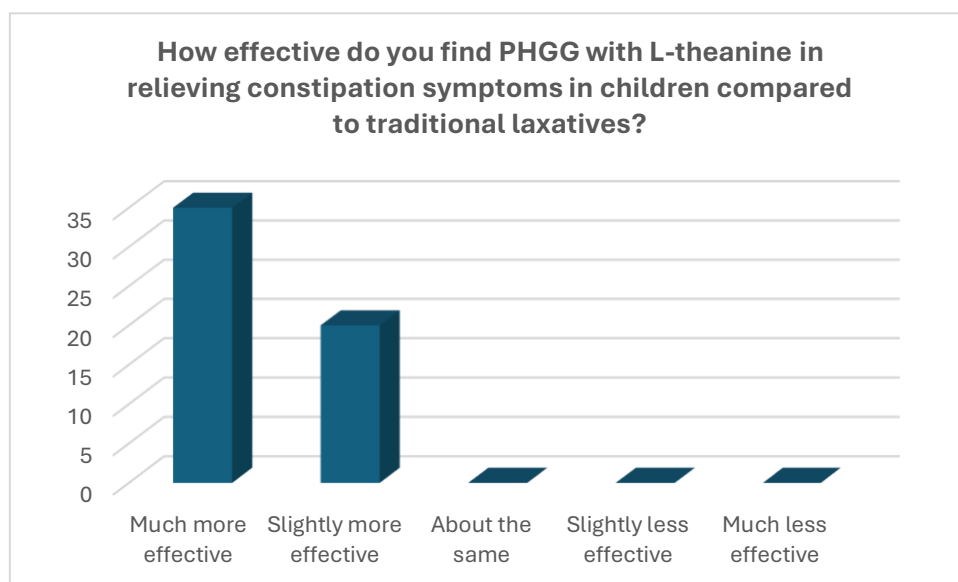
Ethical Considerations:

Considering ethical aspects when conducting research is as important as choosing appropriate research approaches and methods. Since informed consent has been taken from the professionals before asking for the collection of data for Exploring doctors' views on PHGG with l-theanine: a natural alternative to laxatives for childhood constipation also all the secondary data is collected from open sources which do not claim any privacy about the data. Also, the data and study would be used for the academic purpose only.

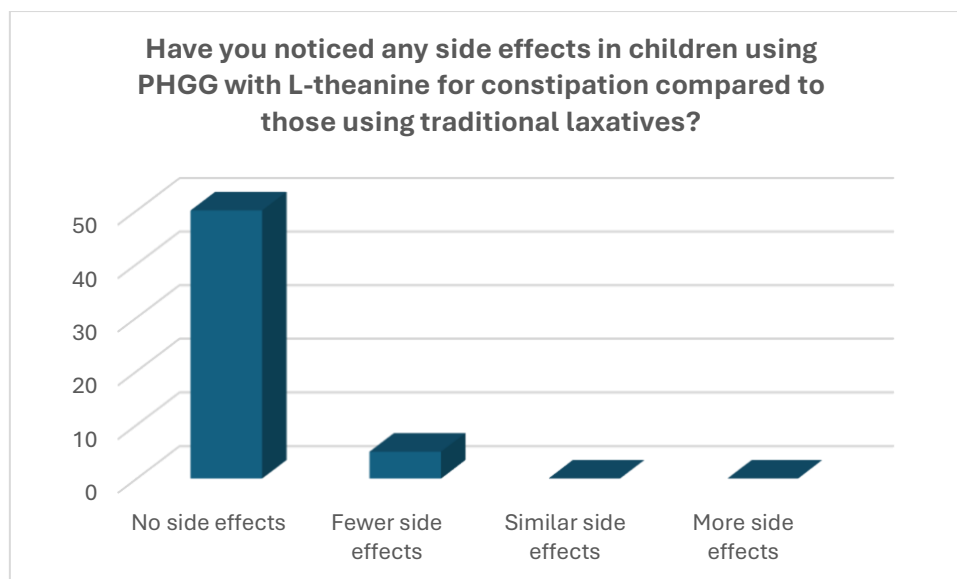
Chapter-4: Result & Discussion



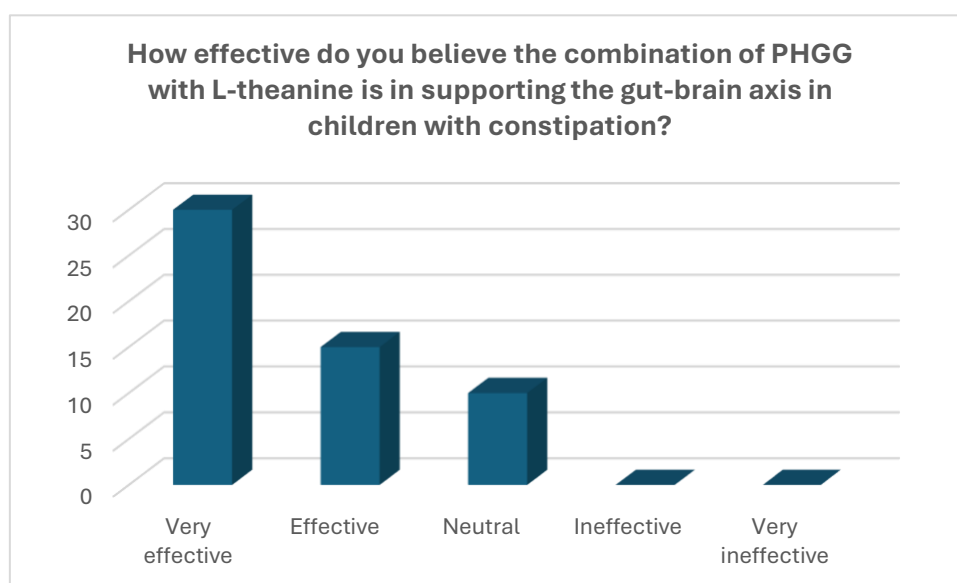
Out of 65 respondents, 55 indicated they were aware of Partially Hydrolysed Guar Gum (PHGG) and L-theanine as a treatment option for childhood constipation, while 10 were not aware.



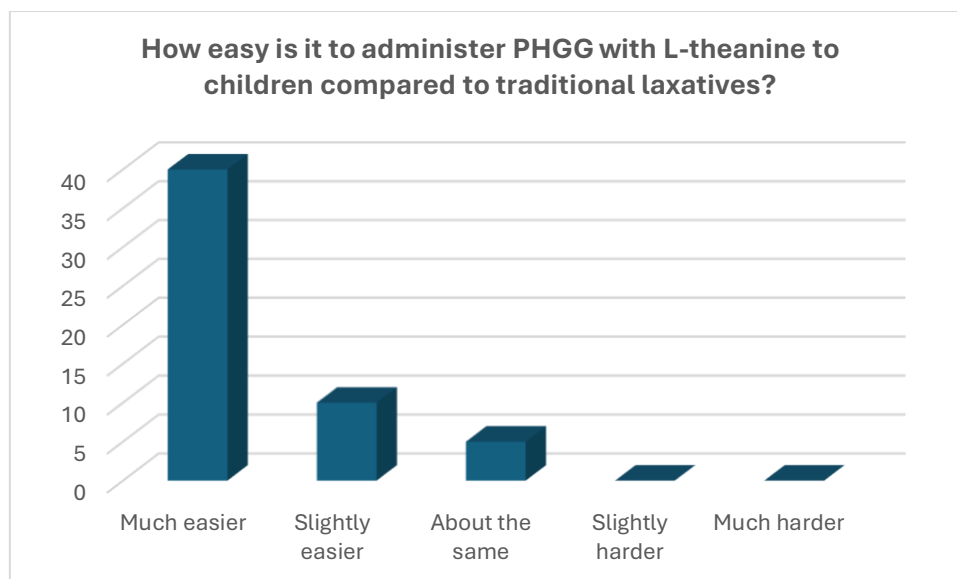
These results indicate that among the respondents, 35 found PHGG with L-theanine to be much more effective in relieving constipation symptoms in children compared to traditional laxatives, while 20 respondents found it slightly more effective.



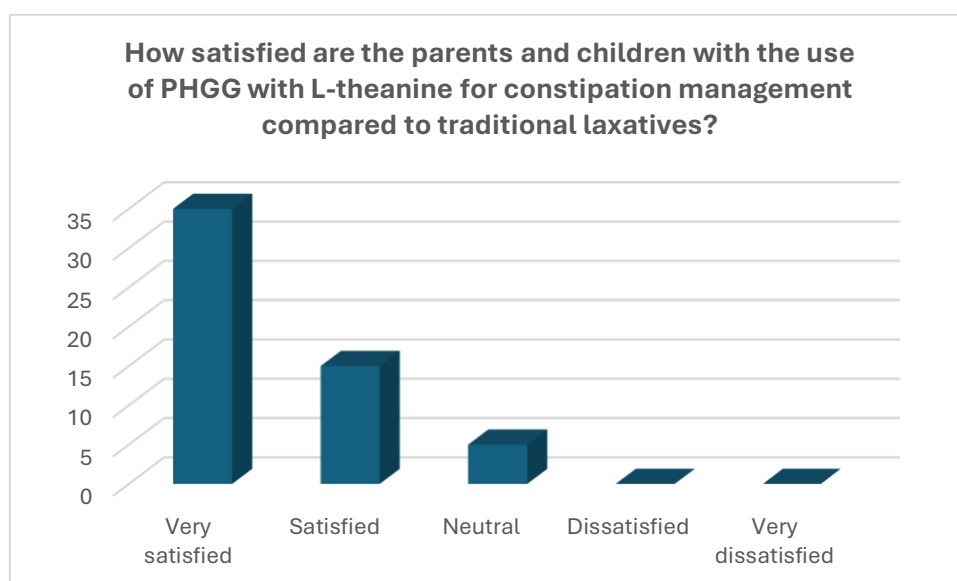
According to the responses, 50 respondents reported no side effects in children using PHGG with L-theanine for constipation compared to traditional laxatives, while 5 respondents noted fewer side effects.



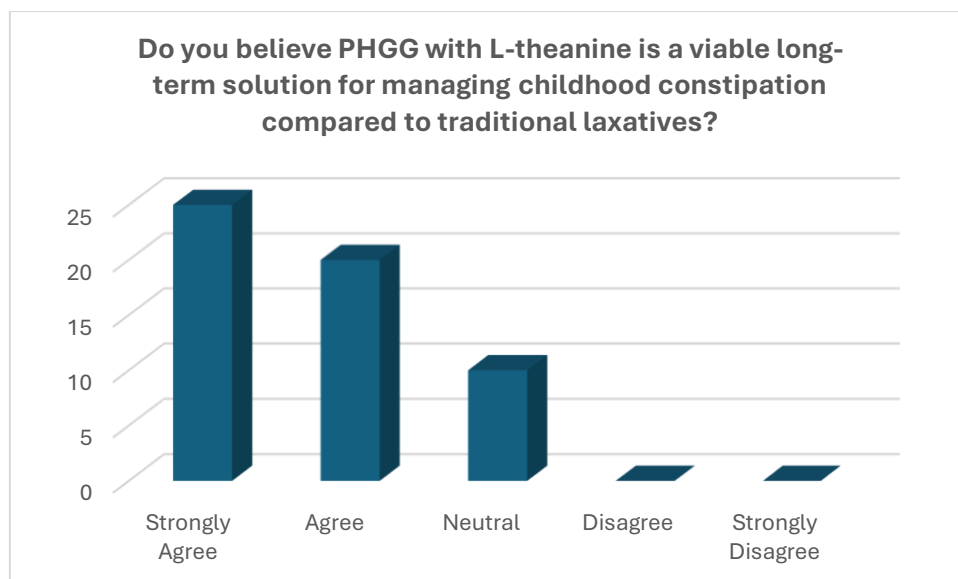
Based on the responses, 30 respondents believed that the combination of PHGG with L-theanine is very effective in supporting the gut-brain axis in children with constipation, while 15 respondents found it effective, and 10 were neutral in their assessment.



According to the responses, 40 respondents found it much easier to administer PHGG with L-theanine to children compared to traditional laxatives, while 10 respondents found it slightly easier.



Based on the responses, 35 respondents reported that parents and children were very satisfied with the use of PHGG with L-theanine for constipation management compared to traditional laxatives, while 15 respondents indicated satisfaction, and 5 were neutral.



According to the responses, 25 respondents strongly agree that PHGG with L-theanine is a viable long-term solution for managing childhood constipation compared to traditional laxatives, while 20 respondents agree with this assessment.

Chapter- 5: Conclusion

The survey findings indicate a positive perception among healthcare professionals towards using Partially Hydrolysed Guar Gum (PHGG) with L-theanine as an alternative treatment for childhood constipation, in contrast to traditional laxatives. A substantial majority of respondents demonstrated awareness of PHGG with L-theanine as a viable therapeutic option for managing constipation in children. This awareness reflects a growing interest within the healthcare community in exploring natural and potentially safer alternatives to conventional medications.

In terms of effectiveness, the survey results reveal strong support for PHGG with L-theanine. Many respondents believe it to be highly effective or effective in alleviating constipation symptoms in children. This perception is reinforced by reports of minimal to no observed side effects associated with PHGG with L-theanine, which contrasts favourably with concerns associated with traditional laxatives.

Healthcare professionals also acknowledge the potential of PHGG with L-theanine in supporting the gut-brain axis, an important consideration in paediatric gastrointestinal health. Additionally, the perceived ease of administration compared to traditional laxatives emerged as a significant factor contributing to its attractiveness among healthcare providers.

The high levels of satisfaction reported by both parents and children using PHGG with L-theanine further validate its acceptance and perceived efficacy in clinical practice. This satisfaction, combined with the belief in its long-term viability for managing childhood constipation, underscores a growing preference for natural treatment options that not only provide symptom relief but also potentially improve overall patient outcomes.

Chapter- 6: Recommendations and Suggestions

- **Further Clinical Research:** Conduct robust clinical trials to validate the safety, efficacy, and long-term effects of PHGG with L-theanine across diverse paediatric populations.
- **Educational Initiatives:** Develop educational programs aimed at healthcare providers to enhance understanding and awareness of PHGG with L-theanine as a treatment option for childhood constipation.
- **Guideline Development:** Establish evidence-based clinical guidelines or protocols for the appropriate use and administration of PHGG with L-theanine in paediatric practice.
- **Patient and Caregiver Education:** Provide comprehensive educational resources to parents and caregivers about the benefits, potential side effects, and proper use of PHGG with L-theanine.

Chapter-7: Limitations of Study

- **Sample Size and Representation:** The survey sample may not fully represent the diversity of healthcare professionals or healthcare settings, potentially limiting how broadly applicable the findings are.
- **Bias and Subjectivity:** Responses could be influenced by individual experiences, personal preferences, or biases, which might affect the objectivity of the reported outcomes.
- **Scope and Depth:** The study primarily focuses on exploring healthcare professionals' perceptions and attitudes. It does not directly assess patient outcomes or long-term clinical efficacy, which could provide a more comprehensive understanding.
- **Methodological Considerations:** Reliance on self-reported data and the survey's cross-sectional nature may introduce recall bias and limit capturing nuanced clinical experiences accurately.

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