

Survey to evaluate efficacy and tolerability of Unienzyme with Methylpolysiloxane (MPS) in African population with digestive disorders

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Abstract

Functional gastrointestinal disorders (FGIDs) can be defined as frequent and recurrent gastrointestinal complaints involving different locations of the digestive system that other conditions cannot better explain after a careful medical evaluation.

Key words: gastrointestinal disease; global distribution; dyspepsia

Introduction

Functional gastrointestinal disorders (FGIDs) can be defined as frequent and recurrent gastrointestinal complaints involving different locations of the digestive system that other conditions cannot better explain after a careful medical evaluation [1]. Dyspepsia consists of heterogeneous group of symptoms that are localized in the epigastric region and can be broadly defined as pain or discomfort that is centred in the upper abdomen (particularly the epigastrium) [2]. It is a common symptom of gastrointestinal disease with global distribution [3].

This condition represents a substantial economic burden [4]. The reported prevalence of functional dyspepsia is high. Johnsen et al, in a Norwegian population-based survey, found the lifetime prevalence of functional dyspepsia to be 23% in men and 18% in women [5].

Functional dyspepsia is associated with increased health-care requirement, and impaired quality of life as well as higher rates of absenteeism from employment, lower productivity at work, missed leisure time, reduced activity around the house, and greater medical and prescription medicine costs per year [4].

Though dyspepsia is common globally, there is a lack of evidence from the African, sub-Saharan African setting including the prevalence, and factors associated with its presence and severity. The prevalence of about 10 to 15% is observed in population of Rwanda [6].

Role of enzymes in Functional dyspepsia

Though the exact cause of functional dyspepsia is unknown, transient deficiency in digestive enzymes is one of the contributing factors in functional dyspepsia. These are the enzymes which break down fats, proteins and carbohydrates and are produced and secreted by

gastrointestinal system. By breaking down the complex molecules into simpler molecules, these enzymes help in digestion and assimilation of nutrients [7]. There are several enzyme supplements currently used in clinical practice for management of digestive disorders. In combination, these supplements improve digestion. Since multiple enzymes are involved in the process of digestion of complex food materials, it is required to supply combination of digestive enzymes to facilitate digestion of each type of food i.e. fats, carbohydrate and proteins. Such supplements are aimed at better digestion of ingested food and also aimed at improving and simplifying the steps of digestion and absorption. The multienzyme preparation "Unienzyme" is a fixed dose combination (FDC) which contains Fungal Diastase (alpha amylase) and Papain as the major constituents apart from simethicone, activated charcoal and nicotinamide. The combination acts as supplemental enzymes to those secreted by the body.

Fungal diastase mainly contains alpha amylase which assists in the assimilation of heavy carbohydrates and has maximum activity at a pH of around 5. Papain has a wider range of proteolytic activity and is active in both acid and alkaline media. Simethicone decreases the intestinal gas formation and also eliminates the gas from breath or through flatus. Activated charcoal adsorbs the gas formed in the lower gastrointestinal tract. Nicotinamide in this combination plays the role as a co-enzyme for the carbohydrate and protein metabolism which catalyse the oxidation-reduction reactions for respiration at cellular level.

Since majority of patients require long term symptomatic treatment for functional dyspepsia, we undertook a survey to evaluate the efficacy, tolerability as well as other parameters such as duration of treatment, time to get relief from symptoms etc.

1.Methods

The survey was conducted between July 2023 to October 2023 in Africa specifically in Tanzania and Zambia. The questionnaire was developed for doctors who were prescribing Unienzyme with MPS to their patients for gastrointestinal disorders and who consented to participate in the survey.

A total of 105 doctors participated in this survey.

No.	Questions
Q.1	For which Indications do you prescribe Unienzyme with MPS
Q.2	What dosage of Unienzyme do you recommend for patients with these complaints
Q.3	Do you prescribe any other drug enzyme preparation along with Unienzyme MPS?
Q.4	Have you prescribed Unienzyme with MPS in post operative digestive disorders? [Yes/No] If yes, please specify the type of surgery
Q.5	What is the duration of treatment given in the indication mentioned in Question 1?
Q.6	What is the average duration of treatment to get complete relief from symptoms?
Q.7	Have you used Unienzyme MPS in any other indication apart from those listed in question 1 and 4?
Q.8	How would you rate the efficacy of Unienzyme with MPS in terms of overall treatment satisfaction?
Q.9	How would you rate the overall tolerability of Unienzyme with MPS?
Q.10	Comments/Suggestions/Inputs if any

Results

The survey was conducted from July 2023 to October 2023.

A total of 105 doctors participated in this survey. Of which, 38.0% doctors prescribed Unienzyme in mild to severe and 48.6% doctors prescribed in mild to moderate digestive disorders respectively. Few doctors (10.4%) doctors prescribed in moderate to severe digestive disorders.

The recommended dose is to prescribe 1 tablet of Unienzyme with MPS twice a day post meal which was prescribed by 63.8% of participating doctors.

A total of 18.1% doctors prescribed one tablet once a day post meal. Remaining doctors prescribed 1 tablet thrice a day (3.8%) or 2 tablets twice a day post meal (15.2%).

The duration of treatment varied from 7 days to 1 month. Based on the severity of the disease, 33% doctors prescribed the preparation for a week. Whereas 29 doctors (27.6%) prescribed the preparation for 2 weeks. A

2.Questionnaire

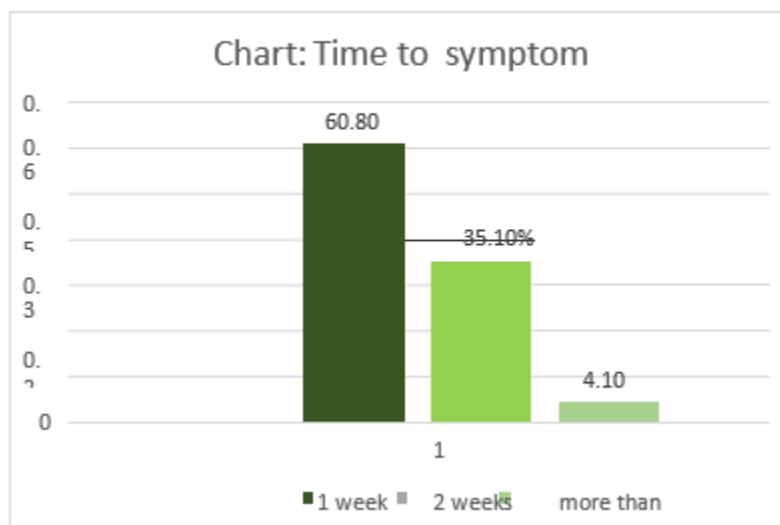
The study questionnaire included 10 objective and/or short answered questions to capture data including indications, dosage, other indications, concomitant enzyme supplement, duration of treatment, time to relief from symptoms, efficacy and tolerability as evaluated by the doctors based on patient's feedback.

few doctors (~ 17%) prescribed it for a month and only 5% for 1 to 2 weeks.

Of the participating doctors, 78 (74.2%) doctors did not prescribe any concomitant enzyme preparation along with Unienzyme MPS. Of the remaining 26.76% patients, 24.76% patients were prescribed a different medicine (proton pump inhibitor, antacid, multienzyme preparation etc.) whereas 1% did not respond to this question. Fifteen doctors (14.28%) prescribed Unienzyme with MPS in post operative digestive disorders (post- gastrectomy or pancreatectomy).

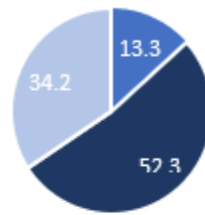
Average duration of treatment to get complete relief from symptoms varied from 1 day to 4 weeks with approximately 61% patients reporting complete relief within 1 week and 35.10% patients reporting complete relief in maximum 2 weeks. Around 4.1% patients reported complete relief within 4 weeks.

Global efficacy and tolerability were assessed using a 5-point scale with 1 being poor and 5 being excellent efficacy/tolerability of the drug.



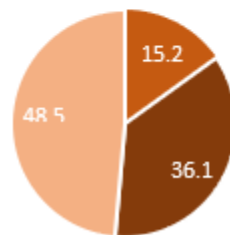
Overall, 86.66% doctors rated the efficacy and 84% doctors rated the tolerability of Unienzyme as very good to excellent.

Chart_ : Overall Global Assessment of Efficacy of



■ Satisfactory ■ Good

Chart_ : Global Assessment of Tolerability of



■ Satisfactory ■ Good

Discussion:

Unienzyme with MPS was prescribed to patients who presented with digestive disorders with complaints of mild to severe indigestion, bloating, lack of appetite, flatulence, abdominal discomfort etc.

While the recommended dose of Unienzyme with MPS is one tablet twice a day and majority of doctors followed the recommended dose, few doctors prescribed the enzyme supplement either 2 tablets twice a day or 1 tablet thrice a day or once a day depending on the severity of their symptoms.

In our study, the average duration of treatment to get complete relief from symptoms varied from 1 day to 2 weeks with 55.7% patients reporting complete relief within 1 week and additional 33.4% patients reporting complete relief 2 weeks. These results coincide with the findings reported by Banka et al (8) wherein maximum number of patients achieved symptom relief in 2 weeks (day 14). Findings about efficacy and tolerability also coincides with the study conducted by Banka et al (8), while the 95.6% patients in their study and 86.66% doctors in our study rated the efficacy from

good to excellent. 94.5% patients in previous study and 84% doctors in this study rated the tolerability of Unienzyme as very good to excellent. The difference could be attributed to clinician's judgement in our study as compared to patients's judgement in previous study.

Conclusion:

The present survey confirmed that Unienzyme is highly efficacious with good tolerability in relieving the symptoms of troublesome functional dyspepsia in African population especially Tanzania, Zambia and neighbouring countries.

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