Metamucil as an additional source of dietary fiber: impact of the quality of healthcare professionals' recommendations on users' experience

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Abstract. – OBJECTIVE: Metamucil® is a fiber supplementation formed by 100% natural psyllium. This study, conducted in Italy, assessed the impact of quality of pharmacists' instruction to use this product on subjects' adherence to and overall satisfaction with this test product.

SUBJECTS AND METHODS: Open-label post-marketing study involving adult subjects who had purchased Metamucil® (follow-up: 14 ± 7 days). Information was collected using questionnaires dedicated to the participating subject and pharmacy.

RESULTS: In total, 1480 subjects and 182 pharmacies returned their questionnaires. The mean age of the subjects was 49 years, two-thirds were female and 87% went to the pharmacy with problems related to bowel movements. The median daily dose taken over the 21-day period was 1. Adherence to the test product was associated with the quality of pharmacist's counseling (p = 0.005). Similarly, satisfaction with the tested product was associated with the quality of counseling (p < 0.001). Consumers' satisfaction was also associated with the quality of pharmacist's explanation of the benefits of the test product (p < 0.001) and with adherence (p < 0.001). 93% and 83% of subjects, respectively, stated the ease of use and their overall satisfaction with the test product, with 73% of subjects agreeing that they would continue using it. Similar findings were observed in subjects who had previously taken the most commonly used branded fiber supplements containing either partially hydrated guar gum or psyllium in the previous 6 months. 92% of pharmacists stated they would recommend Metamucil® for bowel regularity and 90% as it provides multiple benefits.

CONCLUSIONS: Pharmacists' counseling is associated with consumers' adherence and satisfaction to Metamucil®. A large proportion of subjects were satisfied and would continue taking the tested product as a fiber supplement.

Key Words:

Counselling, Dietary fibers, Metamucil, Nutritional supplementation.

Introduction

The health benefits of fiber intake have been well-studied and are now recognized by many health organizations or scientific societies such as the World Health Organization¹, the US Department of Health and Human Services², the European Food Safety Authority³, and the Italian Society for Human Nutrition⁴.

The benefit of fiber as a bulk-forming laxative for treating occasional constipation or for maintaining regular bowel activity has been appreciated for many years⁵. Other health benefits of dietary fibers have been documented in a number of meta-analyses of controlled studies, although benefits may vary according to the specific type of fiber. Documented health benefits include reduced risk of cardiovascular disease (specifically from cereal or vegetable sources and rich in insoluble type fiber)⁶, improved glycemic control (especially soluble fibers)⁷, and diminished incidence of breast (soluble fibers), esophageal, gastric and, potentially, colon cancer (fruit and cereal fibers)8-11. Given these benefits, the World Health Organization recommends a fiber intake of 16-24 g/day1 and the Italian Society for Human Nutrition recommend an intake of at least 25 g/day⁴. However, available reports from Western countries - including Italy - are consistent in showing that fiber intake with diet is below the recommended levels¹²⁻¹⁵.

Nutritional supplementation does have a major role in correcting non-optimal nutritional habits and helps maintain a good health status¹⁶⁻¹⁸. Fiber supplements, therefore, can be important in helping meet the recommended daily fiber intake⁵. Fiber sources vary in their chemical and physical properties as well as in their specific effects on human health. Fibers are characterized by solu-

bility (i.e., the ability to dissolve in the gastrointestinal tract), viscosity (i.e. the ability to thicken or form a gel when mixed with fluids), and fermentability (i.e., degree to which the fiber is degraded by bacteria in the colon forming gases and short chain fatty acids). Fibers found in fruits, vegetables, whole grains and each fiber supplement vary in these features.

Well-grounded evidence has shown the health benefits of the soluble viscous fiber in psyllium husk, a natural source of dietary fiber that is derived from the seeds of *Plantago ovata*¹⁹⁻²⁵. Metamucil®, launched in Italy in 2014, is a food supplement brand with fiber from 100% natural psyllium and is currently distributed in pharmacies without medical prescription.

Pharmacists play a key role in helping individuals improve their diet and their health²⁶⁻²⁸. A semi-quantitative evaluation of pharmacists' counselling can improve the quality of healthcare professional communication and provide therefore additional benefits to patients and clients²⁹. With respect to fiber supplementation, appropriate counseling by the pharmacist may increase patient's adherence and therefore maximize the clinical benefits associated with this nutritional supplementation. However, information on the quality of pharmacists' instruction on how to take fiber supplementation is scant.

This open-label post-marketing study, conducted in Italy, assessed the impact of the quality of pharmacists' instruction to use Metamucil® on subjects' adherence to and overall satisfaction with this product.

Subjects and Methods

Setting and Design

This was a post-marketing study, with an open-label design, which involved subjects who had purchased Metamucil® (white oral powder containing 3.4 g of psyllium husk per serving) from pharmacies in all areas of Italy during the period May 5th-July 31st 2014.

Procedures

After consent to participate, each pharmacy received a participation kit containing the subject inclusion form, pharmacist's questionnaire, subject's questionnaires, and the survey protocol. The pharmacists were trained and instructions were given to explain the procedures of the survey.

Subjects were eligible to this post-marketing assessment if they were at least 18 years of age, decided to use Metamucil® for their own benefit by visiting one of the participating pharmacies and agreed to fill out the questionnaires required by the study. Moreover, to avoid the selection bias of recruiting only subjects with positive experiences with Metamucil®, all subjects had to be first-time users of Metamucil®. Subjects were excluded if they presented known hypersensitivity to ispaghula/psyllium or to any of the other ingredients, had difficulties in swallowing, were deemed ineligible for the tested product by the pharmacist, or if they were not able/willing to complete the study questionnaire. The use of other products to help bowel movements in addition to the tested product was not allowed.

Participating subjects were requested to start taking Metamucil®, one dose per day, then increasing the dosage by one dose per day each week, up to a maximum of three doses per day. Subjects were recommended to take one dose with each meal. Subjects were followed for 14 ± 7 days of Metamucil® use.

Data Collection and Statistical Analysis

Qualitative and quantitative information from both the participating pharmacies and subjects were based on the collection of data from both pharmacy and user questionnaires. The pharmacy questionnaire recorded the pharmacist's details and the experience with the product. The Metamucil® user questionnaire recorded the perceived quality of the instructions received from the pharmacist, the satisfaction with the use of the product and data on product utilization. The questionnaires were then returned to the pharmacist, who then referred them to central data analysis.

Due to the open-label nature of the study, data analysis should be considered descriptive. Two statistical analysis data sets were defined: (1) full analysis set (FAS), which represented the population of recruited subjects who returned their questionnaire; (2) per protocol (PP) population, defined as the subjects of the FAS population who answered "no" to the question "During the assessment period, did you take any product to help with bowel movements in addition to Meta*mucil?*". The FAS was considered the primary dataset, while the PP set was used for a sensitivity analysis. Two secondary analyses were also performed: (1) satisfaction with the tested product in subjects who had previously taken other fiber supplements (namely Benefibra®, a guar gum supplement, and Psyllogel®, a psyllium-based supplement with a different micronization level compared with Metamucil®) to promote regular bowel movements; (2) post-evaluation assessment by participating pharmacists.

The target number of pharmacies to be recruited was calculated to be 300, in order to collect a balanced and representative sample across all regions of Italy.

Descriptive statistics was used to describe continuous and category data; the chi-square test was used to assess the association between pharmacist and subject category responses. A *p*-value < 0.05 was considered statistically significant. SAS software (version 9.4) was used to perform the analysis.

Results

Populations

In total, 1923 subjects were recruited. Of them, 1480 (77%) returned the user questionnaire and were included in the FAS dataset; 1154 (60%) were compliant with the protocol and were included in the PP dataset. Demographic and anthropometric characteristics of subjects are summarized in Table I. In the FAS population, 1225 (87%) patients visited the pharmacy for irregular bowel movements; most subjects had already experienced previous irregular bowel movements (77%), bloating (55%) and abdominal pain (26%). Overweight/obesity were reported in 18% of subjects. The PP population presented similar characteristics (data not shown). In the 6 months before inclusion in the study, 182 subjects (12%) had taken Benefibra® and 119 (8%) Psyllogel®. Of the 300 pharmacies recruited, 182 – located in all Italian areas – returned their questionnaire (Table II).

Adherence and Satisfaction

Overall, 71% of subjects in the FAS population continued treatment for at least 14 days; 12% took at least one daily dose of Metamucil® for three weeks. The median value of doses taken from day 1 to 21 was 1. Figure 1 shows the proportion of subjects who had taken at least one dose of Metamucil®. Most subjects affirmed that Metamucil® was convenient and easy to use; the overall opinion was positive, with 83% of subjects being satisfied with the tested product (Table III). Similar findings were reported in the PP population (data not shown).

Impact of Pharmacists' Recommendations on Adherence and Satisfaction

In both the FAS population (p = 0.005) and the PP population (p = 0.004), adherence to Metamucil® was significantly associated with the quality of pharmacist's counseling (Table IV). Similarly, in both populations, satisfaction with the product was significantly associated with the quality of counseling provided by the pharmacist (p < 0.001 for both populations; Table V).

Consumers' overall satisfaction was also associated with the quality of the pharmacist explanation of the benefits of Metamucil® (p < 0.001 in both populations) and with adherence (p < 0.001 in both populations) (Tables VI and VII).

Table I. Demographic and anthropometric characteristics of participating subjects. Single pieces of information were not available for all subjects.

| | | FAS (N = 1480) | PP (N = 1154) |
|----------------------------------|---|-------------------------|------------------------|
| Age (years) | Mean (SD) | 49 (15) | 48 (15) |
| | Median | 49 | 49 |
| Level of education | Compulsory Education | 309 (21%) | 237 (21%) |
| | College | 612 (42%) | 479 (42%) |
| | University | 520 (36%) | 421 (37%) |
| Reason for going to the pharmacy | Problems with irregular bowel movements Other | 1225 (87%) 189 (13%) | 959 (86%) 158 (14%) |
| Gender | Male | 496 (34%) | 395 (34%) |
| | Female | 962 (66%) | 755 (66%) |
| Weight (kg) | Mean (SD) | 71 (15) | 71 (15) |
| | Median | 69 | 68 |
| Height (cm) | Mean (SD) | 169 (9) | 169 (9) |
| | Median | 168 | 168 |

Table II. Pharmacist specificities. Single pieces of information were not available for all pharmacies

| | | Pharmacies (N = 182) |
|---|---------------------------------|--------------------------------|
| Pharmacy type | Independent Chain Missing | 169 (93%) 9 (5%) 4 (2%) |
| Location | Urban Rural Missing | 156 (86%) 17 (9%) 9 (5%) |
| Number of pharmacists employed | Mean (SD) Median | 5 (2) 4.0 |
| Number of prescription filled per day | Mean (SD) Median | 164 (91) 150 |
| Monthly average of fiber supplement users | Mean (SD) Median | 25 (13) 25 |

Secondary Analyses

Overall, the majority of subjects who previously took either the leading guar gum supplement Benefibra® or the leading psyllium based supplement Psyllogel® in the 6 months before inclusion in the study were satisfied with the tested product Metamucil®, and would intend to continue using this dietary fiber. In addition, the majority of these patients were satisfied with Metamucil® and they would intend to continue it (FAS population; Figure 2). Similar findings were reported in the PP population (data not shown). In

total, 72% of users preferred Metamucil versus the product used most often daily in the 6 months prior to study entry. Specifically, 73% of the subjects who had taken Benefibra® and 64% of those who had taken Psyllogel® in the previous 6 months preferred Metamucil over their previous fiber source.

At the post-evaluation assessment, 92% of pharmacists stated that they were inclined to recommend Metamucil® for bowel regularity; 90% also stated that this product would provide multiple health benefits.

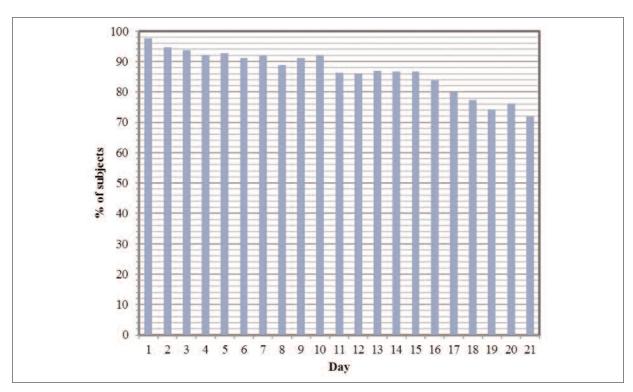


Figure 1. Subjects who have taken at least one dose of Metamucil[®] (FAS population).

Table III. Overall satisfaction with Metamucil® (FAS population, N = 1480).

| | Number of subjects n (%) |
|--|--------------------------|
| Convenience and Ease of Use of the Product (Agree/ Strongly agree) | |
| I found it easy to use Metamucil® | 1344 (93%) |
| I was satisfied with the recommendations for taking Metamucil® | 1327 (92%) |
| Overall opinion (Agree/Strongly agree) | |
| I intend to continue using Metamucil® | 1053 (73%) |
| Overall, I am satisfied with Metamucil® | 1192 (83%) |
| I would recommend Metamucil® to a friend or relative | 1082 (75%) |

Table IV. Impact of the quality of pharmacist's counseling instruction on subject adherence to and Metamucil®. FAS Population.

| | | Have you taken at least 1 dose of Metamucil® per day during the assessment period? n (%) | | | | |
|--|--|---|--|--|--|--|
| | | Yes N = 1150 | No N = 242 | Total N = 1392 | | |
| My Pharmacist gave me full instructions on how to use Metamucil® | Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree | 4 (0.3%) 6 (0.5%) 43 (3.7%) 598 (52.0%) 499 (43.4%) | 1 (0.4%) 4 (1.6%) 12 (4.9%) 149 (61.6%) 76 (31.4%) | 5 (0.3%) 10 (0.7%) 55 (3.9%) 747 (53.6%) 575 (41.3%) | | |

p-value Chi-square 0.0054.

Table V. Impact of the quality of pharmacist's counseling instruction on subject satisfaction with Metamucil®. FAS Population.

| | | Overall, I am satisfied with Metamucil® (%) | | | | |
|---|---|---|---|--|---|--|
| | | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
| My Pharmacist gave me full instructions on how to use Metamucil® | Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree | 0 1 (0.1%) 2 (0.1%) 8 (0.5%) 1 (0.1%) | 0 1 (0.1%) 2 (0.1%) 20 (1.4%) 17 (1.2%) | 1 (0.1%) 4 (0.2%) 17 (1.2%) 104 (7.3%) 58 (4.0%) | 1 (0.1%) 4 (0.2%) 28 (1.9%) 540 (37.9%) 331 (23.2%) | 2 (0.1%) 1 (0.1%) 6 (0.4%) 94 (6.6%) 179 (12.6%) |

p-value Chi-square < 0.001.

Table VI. Impact of the quality of pharmacist explanation of product benefits on overall satisfaction with Metamucil®. FAS Population.

| | | Overall, I am satisfied with Metamucil® n (%) | | | | |
|----------------------------------|-------------------------------|---|------------------------|-------------------------------|----------------------------|--------------------------|
| | | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
| My Pharmacist gave | Strongly disagree | 0 | 0 | 1 (0.1%) | 2 (0.1%) | 2 (0.1%) |
| me an explanation | Disagree | 1 (0.1%) | 0 | 4 (0.2%) | 6 (0.4%) | 2 (0.1%) |
| of all the potential benefits of | Neither agree nor disagree | 2 (0.1%) | 3 (0.2%) | 22 (1.5%) | 40 (2.8%) | 8 (0.5%) |
| Metamucil® | Agree Strongly agree | 8 (0.5%) 2 (0.1%) | 24 (1.6%) 13 (0.9%) | 108 (7.5%) 50 (3.5%) | 514 (36.1%) 342 (24.0%) | 91 (6.3%) 179 (12.5%) |

p-value Chi-square < 0.001.

Table VII. Impact of adherence to Metamucil® on the overall satisfaction with this product. FAS Population.

| | | Overall, I am satisfied with Metamucil® n (%) | | | | |
|--|-----------|---|-----------------------|-------------------------------|----------------------------|--------------------------|
| | | Strongly disagree | Disagree | Neither agree nor disagree | Agree | Strongly agree |
| Have you taken at least 1 dose of Metamucil® a day during the assessment period? | Yes No | 7 (0.5%) 5 (0.3%) | 31 (2.2%) 8 (0.5%) | 125 (9.1%) 56 (4.0%) | 735 (53.4%) 145 (10.5%) | 237 (17.2%) 25 (1.8%) |

p-value Chi-square < 0.001.

Discussion

The use of nutritional supplementation is increasing in Western countries²⁹. Noteworthy, consumers of nutritional supplements often obtain information on these products from non-medical sources rather than from healthcare professional. These sources of information present a risk of abuse, misuse, or poor adherence due to misinformation²⁹. Therefore, the pharmacist healthcare professional can play a crucial role in providing appropriate counseling on the correct use of nutritional supplements and clarify for the consumers the pros and cons of each product²⁹.

The results of the present study suggest the quality of pharmacist's counseling may improve consumers' adherence to the supplementation, thus enhancing the potential for achieving the desired clinical benefits and, improving users' satisfaction. Despite this increasingly-recognized role of the pharmacist, to date limited information on the actual association between high-quality counseling and satisfaction of consumers using nutritional supplements is available.

The participation rate was high (77%), and the majority of consumers included in the study continued Metamucil® for at least 14 days. These results were associated with very high

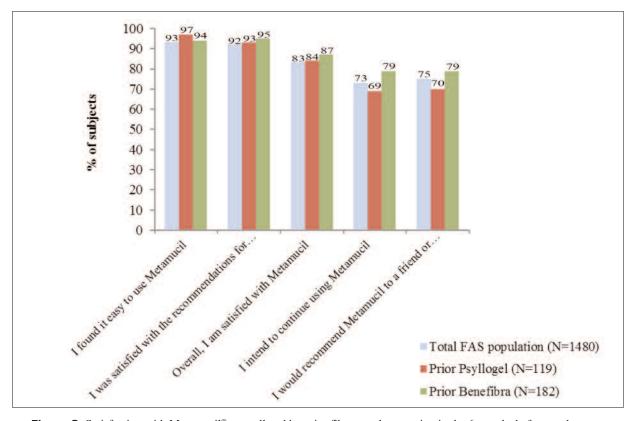


Figure 2. Satisfaction with Metamucil®: overall and by prior fiber supplementation in the 6 months before study entry.

satisfaction of the users towards the tested product (e.g., 93% of consumers found Metamucil® easy to use; 83% were satisfied 73% of consumers intend to continue using this fiber supplement). The pharmacists' opinions, collected at the end of the observation period, were also positive, with the vast majority of the involved pharmacists recommending Metamucil® to ensure bowel regularity, and its additional health benefits. However, it must be acknowledged that no clinical data were collected in this study and therefore no insights on the efficacy of Metamucil® can be drawn from the present analysis. The clinical efficacy of Metamucil® has been assessed in a number of other experimental and clinical studies¹⁹⁻²⁵.

The association of the quality in pharmacist's counseling with consumer adherence and satisfaction with the product was shown by a dedicated statistical analysis; moreover, consumers' satisfaction with results from use was also associated with the quality of the pharmacist counseling on the benefits and usage instructions for Metamucil®. Together, these findings support the importance of the pharmacist's role in providing high-quality, professional counseling to consumers who wish to use nutritional supplements. To this end, dedicated educational efforts targeting pharmacists and aimed at improving both their counseling skills and knowledge of different nutritional supplements could benefit consumers and improve outcomes³⁰.

Although no information on the dosage of previous products nor on the quality of pharmacist' counseling on those product is available, it is also worth noting the satisfaction observed when using Metamucil[®] in subjects who had taken other fiber supplements in the six months prior to study entry were consistent with findings from the overall study population. Moreover, the majority of consumers stated that they would continue using the tested product.

Conclusions

These findings lend additional support to the idea that consumer adherence and satisfaction with Metamucil® can be influenced and improved by pharmacist counseling and quality of the information provided. We speculate that also the counseling of other healthcare professionals (e.g., general practitioners) may have a positive

impact on consumers' experience with Metamucil®; however, further studies are necessary to either confirm or discard this preliminary hypothesis.

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Conflict of Interest

AFG Cicero reported that he has served as consultant for Content Ed Net.

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