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NUTRITION MEDPASS IS AN EFFECTIVE APPROACH TO ORAL NUTRITIONAL SUPPLEMENTATION TO INCREASE ELDERLY MALNOURISHED PATIENTS INTAKE AND COMPLIANCE AND IMPROVE NUTRITION STATUS AND OUTCOMES

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Abstract: *Background:* Nutritional problems are common in the elderly population, particularly in institutional settings. Previous studies have shown that the use of a medication Medpass oral nutritional supplement program improves the nutritional status of these patients. *Objectives:* To assess the beneficial effects of a nutrition MedPass program on body weight and nutritional status in malnourished subjects over 65 years. *Design:* Prospective, observational, open-label study. *Setting:* Long-term care hospitals and nursing homes, Spain. *Participants:* Institutionalized patients who are malnourished or at risk for malnutrition (n = 495). *Measurements:* Malnutrition was defined by the Malnutrition Screening Tool (MST). The primary endpoints were changes in weight (kg) and body mass index (BMI) (kg/m2) from baseline to 8 weeks. Daily record of oral nutritional supplement (ONS) intake. Secondary endpoints included albumin and total protein. *Results:* We analyzed 495 evaluable patients valid for intention--to-treat (ITT) analysis and 339 for the per-protocol (PP) analysis. At each weekly study visit and at the end of the study, statistically significant differences ($p < 0.001$) were found in weight, BMI and secondary variables (albumin and total protein levels) when compared to baseline, both in the ITT and the PP analysis. The average increase in body weight (mean ± SD) increase was 2 ± 2 kg for PP analysis; 76.1% of participants (n = 258) achieved a weight gain exceeding 1 kg in the PP analysis. *Conclusions:* The use of a MedPass program improved the nutritional status of elderly patients who are malnourished or at risk for malnutrition, as indicated by increased body weight and BMI.

Key words: Nutrition MedPass, malnutrition, oral nutritional supplement (ONS), body weight, elderly, BMI.

Introduction

Malnutrition is a common and potentially serious problem in the elderly population, becoming an important area of concern in hospitals and long-term care settings.. However, despite its high prevalence, malnutrition is frequently an under-recognized and under-treated condition (1). Several studies have shown that older adults are at a higher risk of malnutrition in hospitals and long-term care settings (2-4). A study conducted in Germany (2) in hospitalized patients revealed that the highest prevalence of malnutrition was observed in the geriatric department (56.2%). In other two studies (2, 3), age older that 60 years was identified as a significant independent risk factor for malnutrition. Likewise, in a cross-sectional study conducted in the UK in hospitalized patients (4), it was observed that body weight, bone mineral density and serum albumin were significantly lower in individuals older than 75 years compared with those younger than 75 years.

In 2002 Guigoz et al published a review of the assessment of more than 10,000 elderly persons across Europe using the Mini Nutritional Assessment (MNA) scale to detect the risk of malnutrition and undernutrition in this population. Results from this study showed that the prevalence of undernutrition assessed by MNA was 1% in healthy community-dwelling elderly persons, 4% in ambulatory patients receiving home care, 5% in patients with Alzheimer´s disease living at home, 20% in

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hospitalized older patients, and 37% in institutionalized elderly patients.

These studies revealed that the risk of undernutrition is increased in the elderly population and is common among hospitalized patients and nursing home residents. Management of malnutrition in the elderly population requires a multidisciplinary approach that treats pathology and uses both social and dietary forms of intervention. The administration of oral nutritional supplements (ONS) with or between meals, at doses of 200-240 ml, has been commonly used for the prevention or treatment of malnutrition in this population. The guidelines on enteral nutrition in geriatric patients by the European Society for Parenteral and Enteral Nutrition (ESPEN) (6) recommends the use of ONS for geriatric patients at nutritional risk, in case of multi-morbidity (e.g., pressure ulcers), and following orthopaedic-surgical procedures. In elderly people at risk of undernutrition ONS improve nutritional status and reduce mortality. However, it is important to take into consideration that different studies have shown that compliance with prescribed ONS is poor. Clinical studies of ONS consumption show that the average compliance is between 50-65% of the amount prescribed, with lower consumption in hospitals and in free-living communities and higher consumption in long-term care settings. A study of hospital and community settings demonstrated that only 43% of patients consumed more than 80% of the prescribed amount of ONS (Lad et al, 2005). A prospective study conducted to investigate the use of ONS among nursing home residents who were eating poorly and losing weight (7) revealed that only 31% of residents received the correct number and type of ONS as ordered by their physicians, and only 6.8% of these residents consumed the full amount of supplement as ordered. Hogarth et al conducted a double-blind placebo-controlled trial (8) to asses the effect of vitamin and/or glucose energy supplementation in elderly medical patients. They found that only one-third of the 106 patients included in the study consumed more than 50% of prescribed ONS during the study period. In 2006, Simmons et al (9), in a descriptive study conducted in 132 long-stay residents, showed that ONS are not provided consistently as part of standard of nursing care practice.

The need for improved patient compliance with ONS therapy prompted the launch of an innovative approach to oral nutrition supplementation called Nutrition MedPass, which has been successfully used in the United States, the United Kingdom and Australia. With this novel program, a small amount (50-60 ml) of a calorically-dense ONS (Ensure® TwoCal, Abbott Nutrition, Columbus, Ohio, USA), is given to appropriate patients by the nursing staff during routine medication passes. Thus, the ONS is presented to patients as an oral medication, rather than as a snack or part of a meal, and can be an effective means to ensure that patients receive the nutritional support they need along with their medications.

The benefits observed in patients with this program include: a) improvement in weight status (10-13); b) increased protein, energy and micronutrient intakes (12, 13); c) improved compliance with ONS (13); d) improvement in outcomes, including reduced incidence of pressure ulcers (10, 12, 13); e) better functionality (12); and f) reduced mortality rates (12).

The implementation of a MedPass program has also proven to be of benefit for institutions and is well accepted by the staff. It reduces the demand on staff's time for preparation, labelling and distribution of snacks and nourishments and ONS and adds little to the time spent on medication passes. Likewise, this program can reduce the cost of ONS therapy by decreasing the amount of unused nutritional supplements.

The MedPass program offers a new alternative way of ONS therapy administration and its implementation in Spain will result in a cost-effective treatment of malnutrition, particularly in the elderly population. Consequently, the authors designed this study to evaluate the effects of a MedPass program on patients´ body weight, body mass index (BMI) and nutritional status in the Spanish malnourished elderly population living in nursing homes.

Subjects and Methods

The subjects included in the study were those who were malnourished or at risk for malnutrition, as defined by the Malnutrition Screening Tool (MST)14 Hospitalized patients or nursing home residents were considered for enrollment in the study. Other inclusion criteria included age > 65 years, previous experience with ONS, and ability to provide informed consent. Major exclusion criteria included impossibility of ensuring the right intake of ONS, any previous history of drug-food interaction that prevents the use of ONS and inability to provide consent.

The aim of this prospective, open-label, post-marketing observational study was to demonstrate the improvement in body weight, BMI and nutritional status in malnourished or at malnutrition risk elderly population who participated in a MedPass program for 8 weeks. Body weight and BMI were the primary variables and albumin level was a secondary variable. This study was conducted in accordance with this protocol, standard operating procedures that meet the current regulatory requirements and International Conference on Harmonisation (ICH) guidelines for Good Clinical Practice (GCP), the ethical principles that have their origin in the Declaration of Helsinki (version 2008), and that are consistent with the principles of ICH GCP (CPMP/ICH/135/95), the European Union (EU) Directive 2001/20/EC, and the applicable regulatory requirement(s). The Ethics Committees provided written approval of the protocol, informed consent form and

subject recruitment procedures before any study procedure was conducted and prior to the shipment of the study medication.

Prior to enrollment (day 0), all patients were assessed by the MST to determine their nutritional risk status. Relevant variables such as age, sex, primary diagnosis, weight and albumin level were recorded. At the baseline visit (day 0) all subjects' nutritional risk was assessed using the MST or by any other similar screening test . Upon meeting eligibility criteria, subjects were enrolled into the study. Age, sex, weight, primary diagnosis and albumin level were recorded. The subjects' medication records were reviewed to assure that there was no previous history of any drug-food interactions that would preclude their participation. Weight and albumin levels were determined and recorded weekly for 8 weeks. At the end of the study (week 8), all subjects' nutritional risk was re-assessed using the MST or by any other similar screening test. Body weight and albumin level were recorded.

Nutritional intervention

Fifty or sixty millilitres of a caloric-dense ONS (2 kcal/ml, Ensure® TwoCal, Abbott Nutrition) were delivered by nurses, dietists or other healthcare professional during routine medication passes. The volume of ONS administered depended on the facility's protocol for medication delivery (i.e., 50 ml – 60 ml of ONS). On daily basis, the dose and the time of administration were recorded, as well as patient compliance. These data allowed a subsequent analysis of the patient compliance with this program. The administration of this ONS was recorded in the patient medication record form.

Statistical methods

Statistics were performed using the SPSS version 15.0 (SPSS, Chicago, Illinois, USA). The data are presented using descriptive statistics.

The paired sample Student´s test was used to evaluate changes in body weight, BMI, albumin and total protein from baseline to week 8. The repeated measures ANOVA test was used to analyze for differences over time for these variables. When significant differences were detected, an a posteriori multiple testing using the Bonferroni method was used to confirm the differences taking into account alpha adjustment for multiple comparisons.

For the assessment of the biochemical parameters collected, a descriptive analysis of the biochemical variables obtained at the baseline and final visits was used. The variations observed in albumin and total protein mean values were evaluated by the paired samples Student´s test. The other biochemical data collected included haemoglobin, total cholesterol, lymphocytes, transferring, urea, iron and creatinine was not evaluated due to the small sample size.

For the intent-to-treat analysis (ITT), the last observation carried forward method (LOCF) was used to impute missing data. Statistical significance was defined as $P < 0.05$.

Data from both the ITT (n=495) and per-protocol (PP) (n=339) groups were analysed.

Results

Between March 2009 and April 2010, a total of 495 patients recruited from 62 Spanish hospitals and nursing homes were enrolled in the study. Patient characteristics for ITT and PP populations are shown in Table 1. Of the 495 patients enrolled, 352 (71.3%) were men, and the mean age was 83.3 ± 8.2 years (mean ± SD). The mean weight, height and BMI were 51.2 ± 10.1 kg), 160 ± 10 cm and 20.7 ± 3.5 kg/m^2, respectively.

The most common primary diagnoses included: a) nervous system disorders (277 patients, 56%) particularly vascular and Alzheimer´s dementia and cognitive impairment; b) nutrition and metabolism disorders (117 patients, 23.6%), especially malnutrition, anorexia and anaemia; c) vascular disorders (110 patients, 22.2%), mainly hypotension and cerebrovascular insufficiency; and d) psychiatric disorders (91 patients, 18.4%), mainly anxiety-depressive disorders. Other less frequently reported conditions included muscloskeletal, respiratory, cardiac, and gastrointestinal disorders, benign and malignant neoplasia, infections and others.

Of the 495 enrolled in the study, data from 156 subjects were not included in the per-protocol analysis due to specific protocol deviations: 11 subjects did not fulfill the inclusion criteria; 72 subjects had missing weight measurements; and 83 subjects consumed less than 80% of the prescribed ONS. Ten patients had more than one protocol deviation; therefore, 339 subjects were included in the per-protocol analysis.

Efficacy

The results obtained in the ITT analysis were not different from those of the PP analysis. There were significant differences in changes in body weight and BMI, albumin andn total protein ($P<0.001$) in both analyses.

There was a significant, progressive and continuous increase of body weight was observed when comparing the weight recorded at each study visit with baseline values. We can observe that mean body weight changed from 51.3 kg at baseline to 53.1 kg at the end of the study (week 8) and this increase was progressive in time. These

changes in the body weight at each study visit were statistically significant when compared to the baseline values and are shown in Figure 1. The statistical significance persisted also when a repeated measures analysis of variance was conducted to confirm the weight increase throughout the study period (P<0.001). Likewise, significant differences between the weekly recorded body weight and the baseline values were found when an adjustment for multiple comparisons was performed, confirming the body weight increase since the first week of treatment (comparisons of paired means test, Bonferroni's method). The mean body weight increase at the end of the study was 1.8 ± 2 kg. We also found that 341 patients (68.89%) showed a body weight increase of at least 1 kg after the treatment with this program, which reinforced the above mentioned result.

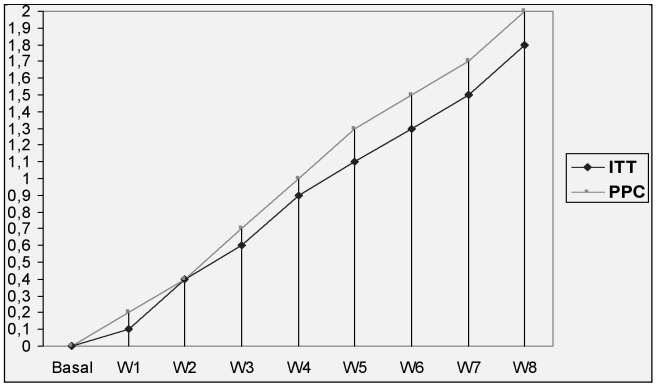

Figure 1. Comparison of weight increase (kg) between ITT and PPC analyses

Similar results were obtained when we evaluated the BMI. Significant differences between the BMI recorded at each visit during the study with regards to the baseline values were observed. The mean BMI varied from 20.7 kg/m2 up to 21.4 kg/m^2 at week 8, with a mean BMI increase at the end of the study of 0.7 ± 0.8 kg/m^2 (see figure 2). The repeated measures ANOVA test used to confirm the increasing trend throughout the study in this variable showed that changes were statistically significant. These differences continued being significant when comparisons of paired means test was performed.

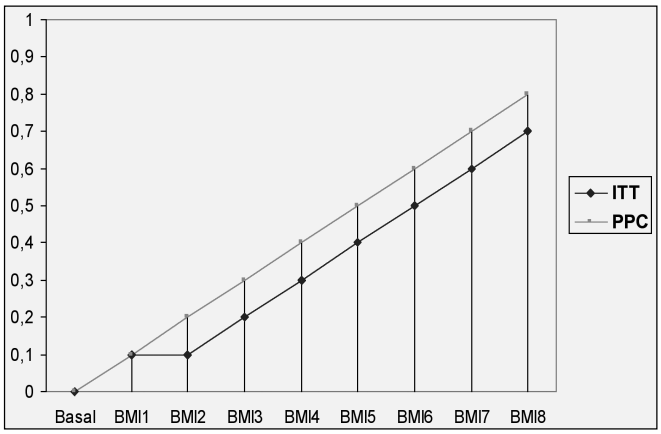

Figure 2. Comparison of BMI increase (kg/m2) between ITT and PPC analyses

The variation of the secondary variables between the baseline and the final visit were only evaluated for albumin and total protein levels, in 468 and 130 patients, respectively. Mean increases of 0.3 ± 0.4 g/dl and 0.4 ± 0.5 g/dl for albumin and total protein levels, respectively, were observed (p<0.001).

The analysis of the compliance with the MedPass program revealed that the patient compliance was good and patients took 95.8% (SD: 19.6) of the prescribed dose during the first 4 weeks and 86.6% (SD: 18.8) during the second four weeks of the study. Investigators also observed that the long-term acceptability of this therapy was good with a minimal difference between the real duration of this therapy and the prescribed duration of therapy (9.7 weeks, [SD: 5.9] versus 9.8 weeks [SD: 5.6], respectively).

Of these 339 patients, 248 (73.2%) were men. Demographical characteristics were similar to those described for the ITT population and are shown in table 1. Mean weight, height and BMI were 51.5 kg (SD: 10.2), 160 cm (SD: 10), and 20.9 kg/m2 (SD: 3.6), respectively.

The analysis of the principal variables body weight and BMI showed similar results to those found in the ITT analysis. Statistically significant increases in body weight and BMI were observed throughout the study. The mean body weight changed from 51.6 kg at baseline up to 53.6

Table 1
Patient characteristics (ITT and PP populations)

	ITT POPULATION (N = 495)				PP POPULATION (N = 339)				
	Mean	**SD**	**Median**	**Range**	**Mean**	**SD**	**Median**	**Range**	
Age (years) (N=493)	83.4	8.2	85	65-102	84.1	7.5	85	65-102	Age (years) (N=339)
Weight (kg) at baseline (N=494)	51.2	10.1	50	29.4-85	51.5	10.2	50.2	29.4-85	Weight (kg) at baseline (N=339)
Height (cm)(N=488)	160	10	160	130-180	160	10	160	130-180	Height (cm) (N=333)
Body Mass Index at baseline (kg/m^2) (N=488)	20.7	3.5	20	12.6-34	20.9	3.6	20.4	12.6-34	Body Mass Index at baseline (kg/m^2) (N=333)

kg at week 8, with a mean body weight increase of 2 ± 2 kg at the end of the study. The mean BMI varied from 21.0 kg/m2 up to 21.8 kg/m2, with a mean BMI increase at the end of the study of 0.8 ± 0.8 kg/m2. All these changes continued being statistically significant when repeated measures ANOVA test and comparisons of paired means test were performed. These data are shown in figures 1 and 2. These results were reinforced by the finding that 258 patients (76.1%) achieved a weight gain of at least 1 kg after the end of this study.

Albumin and total protein levels showed a similar increase as that found in the ITT analysis. At week 8, mean increases in albumin and total protein levels between were 0.3 g/dl and 0.5 mg/dl, respectively.

Results from the evaluation of patient compliance were similar to those observed in the ITT analysis: patients took 102.4% of the prescribe dose during the first four weeks and 93.2% (SD: 10.0) during the second four weeks. The long-term acceptability of this therapy was good: the real duration of the treatment was 9.8 weeks (SD: 5.8) compared with 10.1 weeks (SD: 5.6) of prescribed duration.

Safety

Toxicity was evaluable in all the 495 patients enrolled in the study. There was no serious adverse event reported during the study. Moderate and mild adverse reactions related to the therapy were reported only in 4 patients but no information about the nature of these events was recorded by the investigators.

Discussion

Several studies have shown that malnutrition is a common problem in elderly people, especially in those in hospitals and nursing homes. As a result, oral nutrition supplementation is a key component of institutional nutritional therapy, but patients often do not fully consume ONS provided during meals. Consequently, a new approach to oral nutrition supplementation, called the MedPass program, has been developed. The essence of this nutrition intervention is the provision of medications using a nutrient-dense ONS rather than water, or juice. A small serving (i.e., 50-60 ml of a 2-kilocalorie per ml product provided with medications 3-4 times daily between meals is less likely to result in fullness, better compliance and improved outcomes that affects food intake than a full serving of ONS provided with or between meals.

Similarly to other studies conducted in different countries, this study has shown that the implementation of a nutrition MedPass program results in an improvement of the nutritional status of institutionalized malnourished or at risk of malnutrition older adults. The differences observed in body weight and BMI were statistically significant since the first week, in both ITT and PP analyses. The mean body weight increase at the end of the study was 1.8 ± 2 kg for the ITT analysis and 2 ± 2 kg for the PP analysis which represent a mean body weight gain of 3.5% and 3.9%, respectively, when compared to the mean baseline values. At the end of the study the mean BMI increase was 0.7 ± 0.8 kg/m2 for the ITT analysis and 0.8 ± 0.8 kg/m2 for the PP analysis, that results in a mean BMI increase of 3.4% and 3.8%, respectively, when compared to the mean baseline values. We also found that the MedPass program have a significant beneficial effect on albumin and total protein levels..

We can conclude that the implementation of a nutrition MedPass program using a caloric-dense ONS (2 kcal/ml, Ensure® TwoCal, Abbott Nutrition) results in an improvement of the nutritional status of hospitalized patients and nursing home residents over 65 years, promoting weight gain and BMI increase and improvement in biochemical indices of albumin and total protein.

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Conflict of interest: María-Luisa Orera-Peña is an employee of Abbott Laboratories S.A.

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