

Prevention of malnutrition in older people during and after hospitalisation: results from a randomised controlled clinical trial

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Abstract

Objective: to prevent the occurrence of weight loss during hospitalisation and following discharge by daily oral supplementation.

Design: in a prospective, randomised, controlled study of 80 patients aged 75 or more, and at risk of undernutrition based on their initial Mini Nutritional Assessment score, patients were randomised into a control group or one receiving oral supplementation. The intervention was a prescription of 200 ml sweet or salty sip feed twice daily (500 kcal, 21 g protein per day) throughout hospitalisation and convalescence. Nutritional status was assessed at baseline and after 2 months using Mini Nutritional Assessment and body weight record.

Results: compliance with oral supplementation was good and daily extra energy intake was 407 ± 184 kcal. On day 60, significant weight loss from upon admission was observed in the control group (-1.23 ± 2.5 kg; $P=0.01$), but not in the supplemented group (0.28 ± 3.8 kg; NS). At the end of the study, Mini Nutritional Assessment scores were higher in the supplemented group than in the control group (23.5 ± 3.9 versus 20.8 ± 3.6 ; $P<0.01$).

Conclusion: use of daily oral supplementation during and after hospitalisation maintains body weight and increases Mini Nutritional Assessment score in patients at risk of undernutrition.

Keywords: aged, dietary supplement, mini nutritional assessment, weight loss

Introduction

The prevalence of undernutrition in geriatric hospital populations is known to be high, ranging between 30 and 60% [1–5]. Undernutrition is associated with depression, infections, sarcopaenia, falls, fractures, reduced autonomy and increased mortality [6–10]. In addition, several studies confirm a deterioration in the nutritional status of elderly during hospital stay and after hospital discharge [1, 11–13]. The provision of nutritional support in physiopathological, surgical and medical situations where malnutrition already exists has received growing attention in the literature [14–17].

The aim of the present randomised, controlled clinical trial was to prevent the occurrence of weight

loss during hospitalisation and following discharge by daily oral supplementation.

Nutritional status was evaluated using the Mini Nutritional Assessment (MNA) which was developed and validated on large representative samples of elderly persons worldwide [18, 19].

Material and methods

The clinical trial, which was approved by the Hospital Ethics Committee, involved a total of 80 patients (61 women and 19 men) hospitalised in the geriatric ward of the Centre Hospitalier de la Citadelle in Liège. All patients, aged 75 or over, admitted for acute conditions

between November 1999 and the end of March 2000 were taken considered for the study. Informed consent was obtained before enrolment in the trial. Exclusion criteria were as follows: patients with a medical condition preventing oral feeding, end-of-life patients, patients with severe dementia (Mini Mental Score <10) [20], patients presenting clinical signs of dehydration or heart failure, and those suffering from diseases requiring special dietary treatment (kidney or liver failure) were discarded from the study.

Within 72 hours of admission [21], patients were given a short-form MNA. If the score obtained was <11, the full MNA questionnaire was completed. The MNA included anthropometric measurements (calf and arm circumferences, height, weight, BMI and weight loss), general assessment (lifestyle, medications, mobility), dietary questionnaires (number of meals, fluid and food intake, autonomy of feeding) and subjective assessments (self perception for health and nutrition) [18, 19]. The MNA identifies persons at nutritional risk, provides information needed for intervention planning and does not require laboratory data. Patients were eligible for the study only if their total MNA score ranged between 17 and 23.5, indicating that they were 'at risk of malnutrition'. Then, patients were randomised into either the control group that did not receive any oral supplementation or the supplemented group that received a standard diet and two oral supplements per day for 2 months. Patient allocation to either group was made using sealed envelopes containing the group code. This was undertaken at latest 72 hours after admission. The supplements used were one Clinutren soup (1 kcal/ml) and one Clinutren 1.5 (1.5 kcal/ml) (Nestlé Clinical Nutrition, Brussels, Belgium), which provided 500 kcal and 21 g of protein per day in a 200 ml cup. Nurses and patients (once at home) kept a daily record throughout the trial of the supplements taken and of spontaneous intakes. Consumption of each portion of supplement and regular meals were measured by direct observation and recorded as all, three quarters, half, one-quarter or none of the portion. There was no placebo, as providing another liquid of similar consistency and color but without nutritional value was not found feasible. In the same way, the study was unblinded. Except the supplementation, the care was identical in the two groups. Demographic and medical data recorded during the inclusion period (from day 0 to day 3), included age, sex, place of origin (home or nursing-home), reason for hospitalisation and therapy. The patients were also weighed in a fasting state without clothes by day 3 at the latest. All patients were also weighed upon hospital discharge and on day 60, whether at home or in their nursing home. The same calibrated electronic chair scale was used for all patients (trademark: Arnold; accurate to 0.1 kg). Height was calculated using the patient's age and knee height (KH) measured in centimeters in accordance with Chumlea's formula: $64.2 - 0.04 \times \text{age} + 2.02 \times \text{KH}$ for men and $84.9 - 0.24 \times \text{age} + 1.83 \times \text{KH}$ for women [22].

The digestive side effects (bloating, nausea, diarrhoea, constipation and abdominal pain) were noted upon hospital discharge and on day 60. A follow-up visit was planned on day 60, when an MNA was carried out. Data were collected by two different physicians. The inter-observer agreement of the MNA scale was assessed in a previous study (Kappa score=0.51) [23].

Statistics

The study sample size of 80 patients was determined by a power calculation to detect a difference in mean weight change of 1 kg after 2 months in favour of the supplemented patients (one-sided test) with a power of 80% and a significance level of 5%. Results were expressed as mean \pm SD or as proportions for categorical variables. Within group mean differences were assessed by either Student's paired *t*-test or Wilcoxon signed rank test. Between groups mean values were compared by either unpaired *t*-test or Mann-Whitney U-test. Proportions were compared by the classical chi-squared test. Time-related data were also analysed by general linear mixed models (GLMM). Changes in the parameters at hospital discharge or after day 60 were expressed either in units or as percentages from values recorded at baseline (admission). Results were considered to be significant at the 5% critical level ($P < 0.05$).

Results

To enrol 80 patients in the study, a total of 99 eligible patients (56.3% of all admissions) were needed since 19 did not consent to participate. Among the 80 patients enrolled in the study, 39 received the oral supplements and 41 did not. The baseline characteristics of the two groups (see Table 1) were similar, as expected from the randomisation. The reasons for hospitalisation were distributed as follows: falls (47.0%), secondary pulmonary infection (15%), cognitive deterioration (10%) and depression (7.5%). At the end of the study, two patients had died in each group. Five patients included in the protocol group discontinued the nutritional support during the first 2 weeks because of the intensity of the intervention. They were nevertheless included in the 'intention to treat' analysis.

The length of stay was comparable in the two groups (19.8 ± 15.1 days in the control group and 21.2 ± 10.1 days in the supplemented group; $P=0.19$). Likewise, no significant difference was noted regarding the patient's destination at hospital discharge (home: 65% in the control group *versus* 66.7% in the supplemented group; $P=0.15$). Three patients in the control group and four patients in the supplemented group were re-hospitalized (two for falls with fracture).

On day 60, data were available for 35 patients in the control group and 34 patients in the supplemented group

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Table 1. Baseline characteristics of the 80 patients included either in the control group or in the supplemented group

| | Control <i>n</i> =41 | Supplemented <i>n</i> =39 | Total <i>n</i> =80 | <i>P</i> -value |
|--------------------------|----------------------|---------------------------|--------------------|-----------------|
| Age (years) | 78.8 ± 6.1 | 81.5 ± 7.6 | 80.1 ± 6.9 | 0.09 |
| Sex M/F | 8/33 | 11/28 | 19/61 | 0.20 |
| Height (m) | 1.56 ± 0.01 | 1.57 ± 0.08 | 1.57 ± 0.07 | 0.46 |
| Weight (kg) | 65.6 ± 13.7 | 61.7 ± 13.0 | 63.7 ± 13.4 | 0.20 |
| BMI (kg/m ²) | 26.9 ± 5.4 | 24.8 ± 4.5 | 25.9 ± 5.1 | 0.07 |
| Origin: home | 35 (85.4%) | 32 (82.1%) | 67 (83.8%) | 0.69 |
| No. of drugs | 5.80 ± 2.3 | 5.47 ± 2.5 | 5.64 ± 2.4 | 0.55 |
| MMS | 21.7 ± 6.6 | 20.5 ± 7.8 | 21.1 ± 7.2 | 0.44 |
| MNA | | | | |
| Screening score | 8.95 ± 1.7 | 8.31 ± 1.6 | 8.64 ± 1.6 | 0.08 |
| Global evaluation | 11.2 ± 1.5 | 11.6 ± 1.5 | 11.4 ± 1.5 | 0.24 |
| Total score | 20.2 ± 2.4 | 19.9 ± 2.0 | 20.1 ± 2.2 | 0.62 |

Table 2. Comparison of control patients and supplemented patients 60 days after inclusion in the study

| | Control <i>n</i> =35 | Supplemented <i>n</i> =35 | <i>P</i> -value |
|--|----------------------|---------------------------|-----------------|
| MNA | | | |
| Screening score | 9.80 ± 2.4 | 11.1 ± 2.6 | 0.04 |
| Global evaluation | 11.0 ± 1.9 | 12.4 ± 1.8 | 0.002 |
| Total | 20.8 ± 3.58 | 23.5 ± 3.9 | 0.004 |
| Caloric intake (kcal/day) | – | 407 ± 184 | |
| Protein intake (g/day) | – | 16.9 ± 7.5 | |
| Spontaneous intake (excl. supplements) | (<i>n</i> =10) | (<i>n</i> =16) | |
| Caloric (kcal) | 1049 ± 253 | 1492 ± 386 | < 0.01 |
| Protein (g/day) | 37.2 ± 9.9 | 52.5 ± 14.1 | < 0.01 |

(see Table 2). The MNA screening score ($P=0.04$), global evaluation score ($P=0.002$) and total score ($P=0.004$) were all significantly higher in the supplemented group. All but the 5 patients already described took both supplements during the entire 60-day period, yielding adequate compliance with the nutritional support prescribed. The average daily caloric and protein intakes from the nutritional support during the 60-day period were 407 ± 184 kcal/d (range from 223–500 kcal/d) and 16.9 ± 7.5 g of protein/d (range from 9.4–21 g/d), respectively. Smaller oral intake was observed on certain days due to medical reasons rather than patients finding the supplement unpalatable. The spontaneous intakes of kcal and protein (excluding supplements) were calculated for 10 control patients and 16 supplemented patients and were found to be significantly higher in the supplemented group: 1492 ± 386 kcal *versus* 1049 ± 253 kcal ($P<0.01$) and 52.5 ± 14.1 g/d *versus* 37.2 ± 9.9 g/d ($P<0.01$). At the end of the study, minor side effects like loss of appetite ($n=2$), nausea ($n=2$) and diarrhea ($n=1$) were noted for 5 patients in the supplemented group.

The changes in body weight observed in both groups after 60 days are given in Table 3. Patients of the control group lost on average 1.23 ± 2.5 kg ($P=0.01$) or $1.73 \pm 4.2\%$ ($P=0.02$) of their baseline weight. Conversely, patients of the supplemented group showed a weight increase of 0.28 ± 3.8 kg ($0.68 \pm 7.1\%$), but this change was not statistically significant ($P=0.6$). When comparing the two groups, mean weight changes were found to be

Table 3. Comparison of weight change after 60 days in control and supplemented patients

| | Control <i>n</i> =35 | Supplemented <i>n</i> =34 | <i>P</i> -value |
|--------------------|-------------------------|------------------------------|-----------------|
| Weight change (kg) | -1.23 ± 2.5^a | 0.28 ± 3.8 | 0.09 |
| Weight change (%) | -1.73 ± 4.2^a | 0.68 ± 7.1 | 0.05 |

^aStatistically significant change ($P<0.05$) between Day 0 and Day 60

just significantly different when expressed in terms of percent of baseline ($P=0.05$).

Discussion

The prevalence of protein-energy undernutrition is high in hospitalized geriatric populations [1–4, 24]. The benefits of oral supplementation in malnourished older people, both in hospital and at home, has been clearly established in the literature: improvement in anthropometric and biological parameters [14], improvement in functional status [13] and MNA score [25], together with a simultaneous decrease in morbidity [15], mortality [24] and length of stay [14, 7]. Recently, Potter *et al.* [26] have demonstrated that prescribing sip feed supplements in the medicine prescription chart during hospital stay reduces weight loss. Nevertheless, the criteria for prescribing oral supplementation are still unclear as shown by a recent retrospective study, ranging from

weight loss and abnormal blood test results to whether or not the patient or his/her family is requesting it [27]. In the same way, in a recent French survey (F. Arnaud-Battandier, personal communication), at discharge, 2/3 of the patients ($n=2144$) were either at risk of under-nutrition (38.3%) or malnourished (31.3%) using the MNA.

The salient aspects of the present trial were, at first, the way in which patients likely to benefit from nutritional support (during their hospital stay and at home during convalescence) were selected, and next, the demonstration that effective prevention of weight loss can actually be achieved. Selection was actually based on the MNA score, which allows for the identification of subjects at risk of undernutrition, but whose weight or blood test results may not yet have changed [28]. In the same way, the low cost as well as the performance speed of the MNA scale make it an interesting tool in clinical practice. The patients with an MNA score <17 were excluded from the study design because it appears unethical to have a control group of severely malnourished patients who need a more aggressive nutritional support either orally or by tube feeding. Weight was chosen as the primary marker of any change in nutritional status, despite its potential drawbacks (water retention without oedema, errors of measurements), since it is the simplest parameter to measure at home or in a nursing home by the attending physician, the patient or his/her family. We observed that, without any special nutritional management, the patients lost on average $1.73 \pm 4.2\%$ of their weight after 60 days, while the weight of the patients in the supplemented group remained stable. The preventive value of oral supplementation appears therefore to be the major finding of this trial. Larsson *et al.* [24] demonstrated a reduction in weight loss in the supplemented group in a randomised geriatric population after 8 and 26 weeks when compared to a control group. These authors also concluded that the most important benefits of nutritional support can be anticipated when it is prescribed for the prevention of deterioration in the nutritional status of patients who are not undernourished upon admission. Likewise, a study by Lauque *et al.* [25] found that the elderly patients in a nursing home, who were classified as at risk of under-nutrition by the MNA, increased both their weight and MNA score after 2 months of oral supplementation. In our study, bodyweight was not analysed in terms of body composition. Woo *et al.* [16] showed that the loss in bodyweight affected body fat, unlike Constans [1], who observed a decrease mainly in the lean body mass.

The analysis of the spontaneous intake confirmed that this was maintained despite oral supplementation. Most studies also note an increase in intake without loss of appetite [13, 15, 16, 25, 27] even in hospitalised elderly patients during the acute phase of disease [17]. Conversely, other authors noted low acceptability [29, 30]. As Volkert has shown [13], if acceptability is good in hospital, it will also be good after hospital discharge.

Oral supplements therefore play an important role in increasing energy and nutrient intake because of their ease of use, and preparation and, above all, their low volume.

In this study, the MNA score of the supplemented group increased significantly after 2 months (4.0 ± 4.3 , $P < 0.01$), while MNA scores in the control group remained unchanged. A recent study by Lauque *et al.* [25] also showed an increase in the total MNA score of the supplemented group as compared to the control group in a group of patients at risk of undernutrition. These authors therefore recommended the use of the MNA device as a screening tool which can also be used as a follow-up tool during the nutritional intervention phase [25].

Conclusions

The prescription of oral supplementation upon admission to hospital in patients shown by the MNA to be at risk of undernutrition has a beneficial effect on the patient's outcome. In this context, the MNA scale proved to be a useful and necessary tool for evaluating the nutritional status at the bedside, for selecting elderly patients at risk of undernutrition but with normal biometric and biological levels, and for assessing the treatment's effect. The absence of any systematic management of nutritional support led after 60 days to a significant weight loss of 1.7%, while the weight of supplemented patients remained stable both upon hospital discharge and in the convalescence period. The maintenance of body mass in this frail elderly population should limit the physiopathological consequences of undernutrition, such as risk of falling and loss of functional autonomy. Oral supplements are well accepted and tolerated, while providing a significant caloric and protein intake in a small volume.

Key points

- Hospitalisation of many older patients is associated with deterioration in nutritional status.
 - The MNA scale was used to select older patients who were at risk of undernutrition.
 - Oral supplements were well accepted and tolerated.
 - The weight of the supplemented patients remained stable both upon hospital discharge and in the convalescence period.
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Received 19 June 2002; accepted in revised form 24 December 2002