J Nutr Health Aging. 2018;

© Serdi and Springer-Verlag International SAS, part of Springer Nature

EFFECT OF A MINIMAL-MASSIVE INTERVENTION IN HOSPITALIZED OLDER PATIENTS WITH OROPHARYNGEAL DYSPHAGIA: A PROOF OF CONCEPT STUDY

A. MARTÍN[1], O. ORTEGA[1,2], M. ROCA[3], M. ARÚS[3], P. CLAVÉ[1,2,4]

1. GI Physiology Laboratory, CIBERehd CSdM-UAB, Hospital de Mataró. Barcelona, Spain; 2. Centro de Investigación Biomédica en Red de Enfermedades Hepáticas y Digestivas (CIBERehd), Instituto de Salud Carlos III. Barcelona, Spain; 3. Department of Dietetics and Nutrition, Hospital de Mataró. Barcelona, Spain; 4. Fundació Institut de Investigació Germans Trias i Pujol, Badalona, Spain. Corresponding author: Pere Clavé Civit, MD, PhD Surgeon. Principal Investigator. Associate Professor of Surgery Universitat Autònoma de Barcelona. +34 937417700 ext. 1046. Fax: +34 937417733. e-mail: pere.clave@ciberehd.org

Abstract: *Background:* Oropharyngeal dysphagia (OD) is a newly defined geriatric syndrome that causes nutritional and respiratory complications in older hospitalized patients. Following hospital discharge, OD also causes hospital readmission and mortality in this population. *Objective:* Our aim was to assess the effect of a minimal-massive intervention (MMI) in reducing nutritional and respiratory complications in older hospitalized patients with OD. *Design and participants:* An open label trial was performed on 186 hospitalized older patients (>70y) with OD; 62 of these patients with OD were treated with the MMI and paired by sex, age, functionality, comorbidities and body mass index with two controls. *Intervention:* The MMI consisted of: a) fluid thickening and texture-modified foods, b) caloric and protein supplementation; and c) oral health and hygiene recommendations during hospitalization and following discharge. The control group followed the standard clinical practice without MMI. *Measurements:* Main study outcomes were hospital readmissions, respiratory infections, nutritional status and survival after 6 months follow up. *Results:* Both groups had similar advanced age (84.87±6.02MMI and 84.42±5.31 years), poor functionality (Barthel 59.51±26.76 MMI and 58.84±26.87), and high comorbidities (Charlson 3.00±1.60 MMI and 3.06±1.45). Main results showed that MMI improved nutritional status (MNA 9.84±2.05 pre-MMI vs. 11.31±2.21 post-MMI; p=0.0038) and functionality (Barthel 62.34±25.43 pre-MMI vs. 73.44±25.19 post-MMI; p=0.007). In addition MMI decreased hospital readmissions (68.8 readmissions/100 persons-year (28.1–109.38) MMI vs. 190.8 (156.0–225.7); p=0.001), respiratory infections (12.50 readmissions/100 persons-year (0–29.82) MMI vs. 74.68 (52.86–96.50); p=0.002), and increased 6-month survival (84.13% MMI vs. 70.96%; p=0.044). *Conclusions:* Our results suggest that a MMI in hospitalized older patients with OD improves nutritional status and functionality and reduces hospital readmissions, respiratory infections and mortality. MMI might become a new simple and cost-effective strategy to avoid OD complications in the geriatric population admitted with an acute disease to a general hospital.

Key words: Swallowing disorders, deglutition, aged, geriatrics, and oral hygiene.

Background

Oropharyngeal dysphagia (OD) is a swallowing dysfunction recognized by the World Health Organization that can include tracheobronchial aspirations (1). OD can cause severe complications among older patients and it is a predictor for poor prognosis and mortality: hospitalized patients with OD have increased length of hospital stay, increased readmissions for respiratory infections, more complications, increased consumption of healthcare resources, higher rates of institutionalization at discharge and increased mortality (2–5). OD has been recently recognized as a geriatric syndrome by two relevant scientific European Societies (European Society for Swallowing Disorders and European Union Geriatric Medicine Society) as it is very prevalent in older patients, is related to multiple risk factors, causes various precipitating diseases with poor outcomes and needs a multidisciplinary team to be treated (6).

We have found that prevalence of OD among older patients admitted with an acute disease to a general hospital is very high (47.4%) (7). OD is related to the development of severe complications that originate from two main alterations: i) impaired safety of swallow, or the incapability to protect the respiratory airway effectively, is caused by a slow neural response associated with delayed laryngeal vestibule closure (8, 9). Tracheobronchial aspirations cause respiratory complications, including aspiration pneumonia in up to 50% of cases, with an associated mortality of up to 50% (10, 11). OD is also an independent risk factor for lower tract respiratory infection (LTRI) (12) and increases the risk of readmission for pneumonia and aspiration pneumonia by 80% and by 400% respectively (3). ii) impaired efficacy of swallow is characterized by the inability to ingest the necessary amount of nutrients and liquids to be well nourished and hydrated and is caused by impaired propulsion forces due to weakness of the swallowing muscles and sarcopenia13 causing malnutrition and dehydration (9, 14). The relationship between OD and malnutrition has been well described in community (12, 15), and in hospitalized (7) and institutionalized older patients (16) showing poor clinical outcome and higher rates of mortality.

Aspiration pneumonia occurs when colonized material from the oral cavity is aspired into the lungs and pneumonia develops in patients with swallowing disorders (17, 18). Its pathophysiological mechanism in this phenotype of patients

Received February 5, 2018
Accepted for publication February 6, 2018

has been studied by our group (13, 19, 20) and is related to three main risk factors: a) impaired safety of swallow, causing the aspiration of respiratory pathogens to the airway; b) impaired nutritional status, leading to malnutrition, impaired immunity and frailty; and c) poor oral health (OH) and hygiene, associated with oral colonization by respiratory pathogens (20–22). Several interventional studies aiming to improve oral hygiene of older patients have significantly reduced the incidence of respiratory infections and pneumonia (23–31). However, it is necessary to treat these three main risk factors simultaneously with minimal-massive interventions (MMI). The aim of this kind of intervention is to maximize the number of patients treated because of the high prevalence of OD in this population, with simple and cost-effective measures based on the best scientific evidence (21). MMI is based on compensatory interventions such as fluid and food texture adaptation (32) to avoid aspirations; nutritional supplementation (33) to improve nutritional status, and oral hygiene, to reduce the load of respiratory pathogens from the oral cavity (6,20,21).

As current standard clinical practice is undertaking the prevention, evaluation and treatment of these main risk factors in older patients with OD in the majority of centers, the aim of this proof of concept (POC) study is to assess the effects of a MMI directed at assessing and treating OD, malnutrition and oral health in hospitalized older patients with OD and following hospital discharge.

Material and methods

Experimental design

We designed a quasi-experimental open label trial to evaluate whether the MMI could improve functional and nutritional status and reduce overall readmissions, readmissions for LTRI and pneumonia and mortality after 6 months discharge in older hospitalized patients with OD. The study included one visit in the acute geriatric unit (AGU) of Hospital de Mataró during hospitalization, and a second visit six months after discharge at the Dysphagia Unit at Hospital de Mataró. During study visits we assessed dysphagia, clinical characteristics, nutritional status and oral hygiene of the participants. At 6 months follow up we assessed readmissions and survival by reviewing the electronic medical history of the patients. Results of patients treated with MMI were compared with a retrospective control group from the same hospital unit paired by 5 variables: age, sex, comorbidities, functional status and body mass index (BMI). Each patient treated with MMI was paired with 2 controls.

Study population

Between March and July 2014 we prospectively screened for OD 364 consecutive patients from the AGU of the Hospital de Mataró. Of these, 74 had oropharyngeal dysphagia and 62 signed the informed consent form. Inclusion criteria were to be ≥70 years old and to have OD according to the volume-viscosity swallow test (V-VST) (34). Exclusion criteria were patients with severe dementia (GDS≥6) (35), patients discharged from the intensive care unit, patients with severe functional dependence (Barthel Index (BI) ≤40) (36) and patients with low survival probability (Walter score ≥ 6) (37). In addition, we retrospectively recruited 124 control patients from the same hospital unit from a database of 3000 patients discharged over the previous 5 years and paired them (2 controls for each case) with the intervention group (n=62) by sex, age, comorbidities (Charlson index), functionality (Barthel Index), and body mass index.

All patients were informed about the study and gave their written consent. The study protocol was approved by the ethics review board of the Hospital de Mataró (code IMM2013-14) and was conducted following the principles and rules of the Declaration of Helsinki. ClinicalTrials.gov registration code: NCT02396992.

Health status and comorbidity assessment

An overall geriatric assessment was carried out as soon as possible after admission to the AGU by a multidisciplinary team of geriatricians, specialist nurses and dieticians. Data was collected as follows: (i) sociodemographic data, (ii) comorbidities using the Charlson Comorbidity Index (CCI) (38), (iii) functional capacity according to the BI (36) and (iv) frailty according to the Fried criteria (39).

Clinical diagnosis of OD

OD was clinically assessed during hospitalization by trained nurses using a validated test, the V-VST (34). The methodology used to perform this clinical test has been previously described (34,40). The V-VST is a clinical tool used to assess swallowing safety and efficacy. The test includes several volumes (5, 10 and 20 mL) and viscosities (nectar, thin liquid and pudding) in combination with a pulse-oxymeter to detect silent aspirations (oxygen desaturation ≥3%) (Nellcor™ Bedside SpO_2 Patient Monitoring System, Medtronic Corporation, USA). Patients with impaired efficacy and/or safety of swallow were included in the study and were followed up. Thicken Up thickener (Nestlé, Spain) was used to perform the V-VST. The V-VST was performed by the same team of experienced nurses from the AGU who conducted the clinical assessment during the entire study. The-V-VST has a sensitivity of 88% for impaired safety of swallow (100% for aspirations) and a specificity of 65% (34).

Nutritional evaluation

Nutritional evaluation was performed by a dietitian using the Mini-Nutritional Assessment short-form (MNA-sf) (41) during hospitalization and at 6 months follow up. The MNA-sf classifies patients over 65 years of age into three main categories according to a determined nutrition score: 12-14, well nourished; 8-11, at risk of malnutrition; and 7 and below, malnourished (41). Body mass index (BMI) was also measured

for all the patients.

Oral health assessment

Oral examinations were performed by a trained nurse and included teeth count, oral hygiene according to the simplified Oral Hygiene Index (OHI-S) (42) and oral health habits using a simple questionnaire (43) that included tooth-brushing frequency, use of mouthwashes, use of dentures and last visit to the dentist. This evaluation configuration had been used previously by our group to assess oral hygiene in older patients with OD (20,43). Poor oral health and high prevalence of colonization of oral cavity by respiratory pathogens in frail older patients with OD was also previously described by our group (20,43).

The MMI is based on the minimal evidence-based therapeutic measures that can be applied to the maximal number of patients and consists of:

Study intervention

Minimal Massive Intervention

(i) Fluid thickening and texture modification according to the results of the V-VST, including a) general recommendations for patients with OD; b) rheological adaptation for liquids including volume (5, 10 and 20mL) and viscosity (nectar and pudding) if necessary; and c) texture-adapted diets based on traditional food (texture E and texture C according to the British Dietetic Association44 taking into account the specific requirements for older patients established in previous studies (1750 kcal/day, 70.36g/day protein, 63.8g/day lipids and 220g/day carbohydrates) (33). These diets consisted of 14 days of complete menus (5 intakes per day) for the MMI patients and can be found in a recent doctoral thesis from our group (45).

(ii) Nutritional supplementation (caloric and proteic) according to the results of the MNA-sf, given to malnourished or patients at risk of malnutrition during hospital admission and follow-up period. The supplements used were natural products (legumes, cookies, olive oil, nuts, honey, marmalade, dried fruit, cereals and sauces) as described in a recent doctoral thesis from our group (45).

(iii) Oral health intervention consisting of recommendations on tooth brushing with the Modified Bass technique (46,47), at least once a day, and the use of chlorhexidine 0.12% mouthwashes, at least twice a day. Patients who had dentures were advised to remove them, brush them and clean them with chlorhexidine 0.12%.

Instructions on the intervention were given orally during hospitalization and reinforced on discharge by a specialist nurse and dietitian and supported by educational material.

Control group intervention

Control patients received the standard hospitalization recommendations that were not applied systematically and not in a standardized way according to individual clinical criteria (19).

Follow-up visits and clinical outcomes

Follow-up visits were performed in the outpatient department of the hospital 6 months after discharge. During this visit, a specially trained nurse assessed OD (V-VST) and oral health status (OHI-S) and a dietitian assessed nutritional status (MNA-sf). Compliance with the recommendations given on discharge was checked and reinforced if necessary. Four outcomes associated with OD were assessed: a) hospital readmissions expressed as readmissions/100 persons-year (3), b) lower respiratory tract infections (LRTI), c) pneumonia, and d) 6-month mortality after discharge. LRTI and pneumonia were determined from the electronic medical records of the patients. Survival was determined by reviewing the electronic clinical records for intra-hospital deaths or by telephoning patients who failed to attend the follow-up visits (3,4).

Data analysis

Categorical variables were presented as relative and absolute frequencies and analyzed with the chi-square test or the Fisher exact test. Continuous variables were presented as mean ± standard deviation and analyzed with the Mann-Whitney U test or the t-test. Survival curves were used to evaluate 6-month mortality after discharge. The incidence rate was used to calculate the accumulated readmissions during the follow-up period3. Results were described and interpreted according to the obtained P values. Statistical significance was accepted if P values were less than 0.05. Statistical analysis was performed using GRAPHPAD PRISM 6 (San Diego, CA, USA).

Results

Basal status

Prevalence, health status and comorbidities

According to the V-VST, prevalence of OD in the cohort of patients from the AGU was 25.51% (74/364). Those with OD that accepted to receive the MMI (62) had a mean age of 84.87±6.02 years, presented a high number of comorbidities, impaired functional status, frailty (80.65 %), risk of malnutrition or malnutrition (74.19%), and impaired quality of life (QoL) with an EQ-5D-3L of 0.68±0.11 and a self-perception of QoL of 53.15±22.50 out of 100 (Table 1).

Swallowing evaluation

According to the V-VST, 6.45% (4) of patients with OD included in the MMI presented only impairments in safety of swallow, 19.35% (12) presented only efficacy impairments and 74.19% (46) both safety and efficacy impairments. The most prevalent sign of impaired safety of swallow was voice change in 56.45% of patients, and that of efficacy was pharyngeal residue in 51.61%. Safety impairment signs were more prevalent in thin liquid series (93.02%) than in

higher viscosity series such as nectar (22.58%) and pudding (3.23%) (p<0.0001). According to the V-VST, 48.39% patients needed thickeners to compensate their alterations (40.32% were prescribed to nectar viscosity and 8.06% at spoon thick viscosity).

Table 1

Demographic, functional and nutritional characteristics of the study population that received the MMI during hospitalization

N	62
Age (Years)	84.87 ± 6.02
Sex (♀)	47%
Charlson	3±1.60
0	0.00
1-2	37.10 (23)
3-4	38.71 (24)
≥5	24.19 (15)
BI	59.51 ± 26.76
Independent [100] (%)	9.67 (6)
Mild dependence [95-60] (%)	41.94 (26)
Severe dependence [<60] (%)	48.39 (30)
Fried	3.33±1.16
Robust (%)	0.00
Pre-frail (%)	19.35 (12)
Frail (%)	80.65 (50)
MNA-sf	9.97±1.96
Well-nourished (%)	25.81 (16)
At risk (%)	59.68 (37)
Malnourished (%)	14.52 (9)
BMI (Kg/m2)	26.84±4.86
EQ-5D-3L (QoL)	0.68±0.11
Self-perception QoL (%)	53.15±22.50

BI: Barthel Index; BMI: Body Mass Index; MNA-sf: Mini Nutritional Assessment short form; EQ-5D: Euro Quality of Life 5 dimensions.

Nutritional status

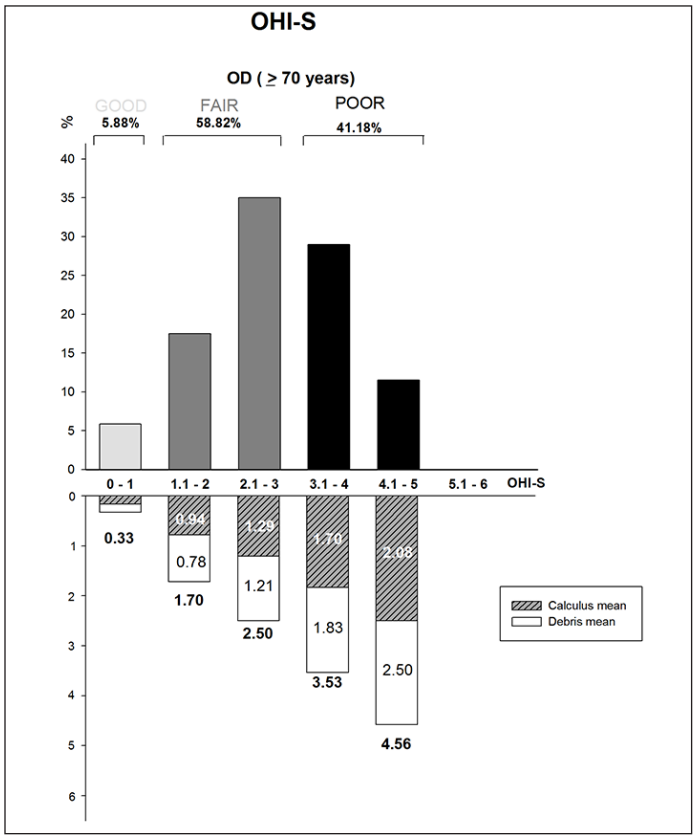
With regard to nutritional status during hospitalization measured with the MNA-sf, up to 74.19% of patients in the MMI group with OD were at risk of malnutrition (59.68%) or malnourished (14.52%) with a mean MNA-sf score of 9.97±1.96 (Table 1). BMI was normal for this age range.

Oral health and hygiene

Of the MMI patients group, 40.32% (n=25) presented edentulism and wore full dentures, and 16.12% (n=10) used a partial denture. The following results are for dentate patients: mean number of teeth was 17.44±9.42; mean OHI-S value was 2.75±1.11 and a high prevalence of patients (41.18%) had a poor (OHI-S 3 - 6) and fair (OHI-S 1.1 - 3) (58.82%) oral hygiene status according to the OHI-S (Figure 1). In addition, composition of teeth coverage according to the OHI-S was very similar between its two components (50% dental plaque and 50% calculus) (Figure 1). Regarding clinical evaluation of oral health, 60.86% of dentate patients presented caries (4.64±4.10 teeth with caries per patient). Finally, according to the oral health habits questionnaires, only 61.3% patients reported cleaning their teeth or dentures at least once a day and only 38.7% of them used mouthwashes once a day too.

Figure 1

Oral Health Index-Simplified (OHI-S) results on admission from patients receiving the minimal-massive intervention (upper graph) and difference between plaque and calculus composition in each cathegory of the OHI-S (lower graph). OD: oropharyngeal dysphagia



Effect of MMI

Functionality and frailty

Barthel pre-admission in MMI patients was 78.03±18.11. This score decreased significantly for the acute disease process during admission to 62.34±25.43 (p<0.001) and improved at the end of the follow-up period to 73.44±25.19; p=0.007. Categorization of the Barthel Index showed that the percentage of independent patients increased after intervention (18.75% on admission vs. 40.63% after 6 months) (p=0.0112) (Table 2). We

also found that MMI improved frailty status during the follow-up period (Fried score: 3.53±0.95 vs. 3.06±1.44; p=0.0574), and the categorization on Fried Index showed a lower percentage of frail patients after MMI (87.5% vs. 65.62%; p=0.0746) (Table 2).

Table 2
Summary of the clinical effects of the Minimal-Massive Intervention

	ADMISSION	6 MONTHS	p-value
Functional capacity (BI)	62.34±25.43	73.44±25.19	0.0070
Independent (%)	18.75 (6)	40.63 (13)	0.0112
Low dependence (%)	75 (24)	50 (16)	
Severe/Total dependence (%)	6.25 (2)	9.37 (3)	
Frailty (Fried)	3.53±0.95	3.06±1.44	0.0574
Robust (%)	0	0	0.0746
Pre-frail (%)	12.5 (4)	34.38 (11)	
Frail (%)	87.5 (28)	65.62 (21)	
Nutritional Status (MNA-sf)	9.84±2.05	11.31±2.21	0.0038
Well-nourished (%)	21.87 (7)	65.63 (17)	0.0013
At risk (%)	59.38 (19)	31.25 (10)	
Malnourished (%)	18.75 (6)	3.13 (1)	
BMI	27.76±4.42	28.52±4.39	0.2045
Oral Health (OHI-S)	2.76±0.27	2.06±0.24	0.095
Plaque index	1.38±0.20	0.82±0.19	0.0695
Calculus index	1.37±0.17	1.23±0.1	0.5475
EQ-5D-5L (QoL)	0.69±0.11	0.71±0.12	0.3608
QoL self-perception (%)	47.81±22.82	62.57±18.30	0.0086

BI: Barthel Index; MNA-sf: Mini Nutritional Assessment short form; BMI: Body Mass Index; V-VST: Volume-Viscosity Swallowing Test; OHI-S: Oral Health Index Simplified; EQ-5D: Euro Quality of Life 5 dimensions.

Nutritional status

According to the MNA-sf, the nutritional status of patients significantly improved after the MMI (MNA-sf score: 9.84±2.05 vs. 11.31±2.21; p=0.0038) (Figure 2). In addition, the proportion of well-nourished patients improved during follow up from 21.87% on admission to 65.63% at 6 months; p=0.0013) (Figure 2). In contrast, we did not find any significant differences regarding the BMI (Table 2).

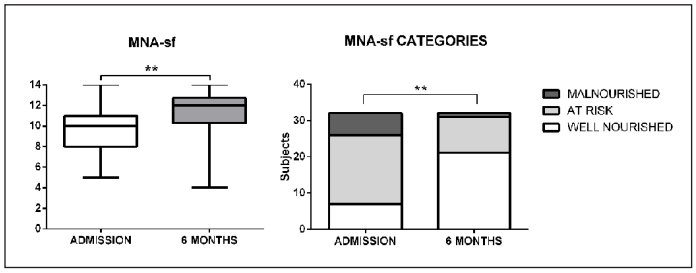
Oral health and hygiene

According to the OHI-S, there was an improvement trend in oral hygiene status (2.77±0.27 on admission vs. 2.06±0.24 at six months; p=0.095). Regarding the dental plaque component of the OHI-S, there was a clinically relevant decrease after MMI (1.382±0.20 vs. 0.83±0.19; p=0.0695) but not in the case of calculus (1.369±0.17 vs. 1.230±0.11, ns) (Table 2).

Quasi-experimental study

After the pairing between controls and cases, no statistically significant differences were found between groups regarding patient characteristics. Mean age of the 124 controls was 84.42±5.31 (47% women), mean Charlson comorbidity index was 3.06±1.45 and mean Barthel index was 58.84±26.87. Nutritional status was also similar; in the control group we found similar results, with a prevalence of patients at risk of malnutrition of 66.34% and 20.79% of patients presenting malnutrition.

Figure 2
Mini nutritional assessment short-form (MNA-sf) and MNA-sf categorized on admission and after 6 months in patients receiving the minimal-massive intervention.



*p<0.05; ** p<0.01; *** p<0.001.

Readmissions and survival

After the follow-up period, patients following MMI showed statistically significant differences presenting lower rates of overall readmissions for any cause (readmissions/100 persons-year (68.8 (28.1–109.38) vs. 190.8 (156.0–225.7); p=0.001)), and readmissions due to LTRI (readmissions/100 persons-year (12.50 (0–29.82) vs. 74.68 (52.86–96.50); p=0.011)) and readmissions for any other diseases (readmissions/100 persons-year for other causes (37.5 (7.49 – 67.51) vs. 104.55 (78.73 – 130.37); p=0.011)) (Table 3). No differences were found for readmissions for pneumonia which were very low in both groups (Table 3). Moreover, when we analyzed survival rates, we found a significant higher survival rate in the group who had received MMI compared with the control group after the 6-month follow-up period (84.13%vs. 70.96%; p=0.044) (Figure 3).

Discussion

The main results of this proof of concept study confirm that our hospitalized older patients with OD have advanced age, high comorbidities, severe functional dependence, frailty, impaired nutritional status, and poor oral health status and are at high risk of severe dysphagia complications. All this findings are in accordance with the definition of OD as a geriatric syndrome by a recent publication (6). In addition, the clinical outcome of the control group of older hospitalized patients with OD receiving standard treatments was very poor, presenting very high readmission rates and mortality after 6 months follow

up similar to that found in previous studies (3,4,7). In contrast, the MMI caused a significant improvement in functional and nutritional status and perceived QoL, a significant decrease in general hospital readmissions and readmission for LTRI, as well as increased survival after 6 months. Our results suggest that OD can be treated with simple and effective multimodal compensatory protocols such as the MMI, a cost-effective intervention that could be of great relevance in the future in the management of these hospitalized older patients with OD, avoiding complications and improving clinical outcomes.

Table 3

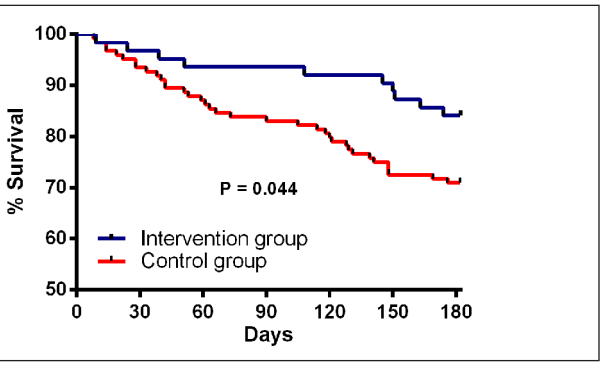
Incidence Rate and Incidence Rate Ratio for different types of readmissions between the study (MMI) and control group

	Incidence Rate: Readmissions/100 persons-year (95% CI)	Incidence Rate Ratio (95% CI)	p-value
All readmissions		2.78 (150 – 5.15)	0.001
MMI	68.8 (28.1 – 109.38)		
Controls	190.8 (156.0 – 225.7)		
Readmissions for PN		0.62 (0.16 – 2.40)	0.4468
MMI	18.75 (0 – 39.97)		
Controls	11.62 (3.01 – 20.22)		
Readmissions for LRTI		5.97 (1.45 – 24.63)	0.0020
MMI	12.50(0 – 29.82)		
Controls	74.68 (52.86 – 96.50)		
Readmissions for other causes		2.79 (1.21 – 6.44)	0.011
MMI	37.5 (7.49 – 67.51)		
Controls	104.55 (78.73 – 130.37)		

PN: Pneumonia; MMI: Minimal-Massive Intervention; LRTI: Lower Respiratory Tract Infections.

Figure 3

Survival rate after 6 months follow up between control and intervention (MMI) groups (2 controls per case)



OD has been recently defined as a geriatric syndrome due to its high prevalence in older patients, its relationship with multiple risk factors, precipitating diseases and poor outcomes, and the need for a multidisciplinary team in its treatment (6) as we have found in our study population. Prevalence of OD in our population of polymorbid hospitalized older patients with moderately impaired functionality (BI=59.51±26.76) was 25.51% (74/364). Previously, we found a strong association between impaired functional status and prevalence of OD among hospitalized older patients (3,4). Two previous studies in the same hospital unit, showed a prevalence of OD of 47.4% in older patients with poorer functional capacity (BI=24.71±25.31) (7) and 55.5% in hospitalized older patients with pneumonia (BI=22.4±27.1) (4). In the present study our population was selected according to functional capacity (BI >40) to optimize treatment compliance. We also found a high percentage of older patients with OD presenting malnutrition or risk of malnutrition (74.19%), even higher than in the two previous studies done at the same hospital (82.6% and 91.2%) (4,7). This high prevalence of patients malnourished or at risk of malnutrition underlines the importance of assessing the nutritional status in these older patients with OD and the importance of nutritional adaptation and supplementation to avoid malnutrition and its subsequent complications. Another relevant factor in OD management is the assessment and treatment of oral health, as previous studies found a close relationship between oral health and hygiene, colonization by respiratory pathogens and the development of respiratory infections and aspiration pneumonia (20,48–50). In this study, we found poor oral health and high prevalence of edentulism, similar to previous studies from our group (20,43), indicating the lack of awareness and treatment of oral health and the high concentration of oral bacteria among older patients with OD.

According to these results, and the fact that the world population is aging, and the prevalence of OD is thus increasing, an optimal intervention to treat these patients should be of massive application, with easy and simple tools, multidisciplinary and cost-effective. This intervention, such as the MMI, should be based on the avoidance of the main risk factors to develop serious dysphagia complications. There are few studies on this kind of interventions in the literature. One of the biggest problems in implementing a treatment program is compliance; although our intervention was minimal, 32.5% of patients did not fully follow the recommendations. The current therapeutic approach to treat OD is to use thickeners to compensate efficacy and safety impairments as has been recently reviewed (32). However, this strategy is not generally well accepted by users (51) and it has been associated with decreased QoL (51, 52). The literature describes a 48% to 56% adherence to this treatment, lower in ambulatory care than institutionalized care (53, 54). According to this data, and considering that the MMI is based on compensation, our compliance rate should be considered as normal for this kind of intervention. In contrast, a recent systematic review cautioned against routine use of modified liquids citing uncertain beneficial effects on critical outcomes, decreased patient preferences, weight loss and dehydration, especially with thickened fluids with high viscosity (55). These results

are not supported by our study given the positive results obtained regarding nutritional improvement, reduction of general readmissions and readmissions for LRTI and increased survival in the intervention group. We must take into account that our intervention was multifactorial covering several risk factors for the development of complications and this should be considered when interpreting its effects. However, although that it is true that adaptation of fluids with thickeners is not well accepted by patients, our previous studies and a revision by the ESSD show the strong therapeutic effect of increasing bolus viscosity in this population (13, 20, 32, 40, 56, 57). In addition, increasing the viscosity with xanthan-gum-based thickeners does not increase the risk of oropharyngeal residue, as modified-starch-based thickeners does (56, 57). These results highlight the need to develop more evidence-based studies and to develop new thickening agents with better therapeutic properties, palatability, and more aligned to patient preferences in order to increase compliance, and reduce dehydration, weight loss and risk of aspiration. According to our previous data and the results of this study, we believe that fluid adaptation should be a fundamental part of the management of older patients with OD with therapeutic interventions like the MMI. In addition, texture modified food adaptation is another important part of OD management to avoid choking. In our study, we develop an initial concept named "triple adaptation of solids" (rheological and textural, caloric and proteic, and organoleptic) in order to make traditional food appropriate for our patients. This approach will be improved and developed in future studies (45).

After 6 months of the MMI, we found very positive clinical effects: first, a significant improvement in functional status between hospitalization and follow-up and second, in nutritional status. These improvements could be attributed to the normal process of recovery from acute diseases that is generally accompanied with functional improvement but also to the nutritional intervention during the MMI, indicating that malnutrition can be improved or reversed in these older patients with an appropriate nutritional approach based on traditional food. This branch of the MMI is really important because the relationship between OD and malnutrition has serious implications on health status, immunity, functionality, sarcopenia and frailty (7, 9, 33, 58). A previous study of our group on a similar population showed that both OD and malnutrition are independent risk factors for one-year mortality after discharge (OR=1.675 (1.2–2.3) and OR=1.7 (1.2–2.4) respectively) and the worse prognosis is for patients with both conditions (7). Another publication showed that malnutrition is associated with prolonged length of stay, higher treatment costs and increased morbidity and mortality (59). Regarding oral hygiene, we observed a non-significant improvement in the OHI-S after the MMI in the plaque index (not in calculus), suggesting a reduction in the oral bacterial load. Despite this improvement, it is important to have a periodical professional dental cleaning to achieve significant results, due to the poor oral health and hygiene habits of older patients (43). While dental plaque is a soft bacterial biofilm that can be removed by mechanical tooth brushing (60), calculus (mineralized plaque) needs a professional dental cleaning to be eliminated. A systematic review found that tooth brushing and oral hygiene had a preventive effect on mortality caused by pneumonia in hospitalized and nursing home older patients (31) highlighting the importance of proper oral health and hygiene. The importance of a periodic professional oral hygiene has been recommended in a revision concluding that oral health services should be an essential component of primary geriatric healthcare (61).

Finally, the most important result of this POC study was that patients that completed the MMI presented lower incidence of readmissions for any cause and for LTRI compared with the control group, indicating the effectiveness of the MMI through the combined effect of its three main components (prevention of aspiration, nutritional improvement and reduction of oral bacterial load). An observational prospective study on older patients admitted to an AGU found that OD patients had approximately 80% higher risk of readmission due to pneumonia and 400% due to AP and/or bronchial aspiration than those without OD (3). In the OD group, they described a lower incidence of general readmissions for 100 patients/year (95.5 (91.1–99.9) than our control group. This difference can be attributed to the high functional deterioration, frailty and comorbidities presented by our patients. The incidence found for readmissions of MMI patients was lower than that of controls, emphasizing the importance to assess and treat swallowing impairments with fluid adaptation, malnutrition, and oral hygiene in older patients with OD as early as possible during hospitalization. Survival at 6 months also significantly increased for patients from the MMI group.

The main limitation of this study was the experimental design as the best way to validate the effect of an intervention is to use a randomized clinical trial. However, our intention was to carry out a POC study to assess the effect of the MMI as we did not find previous studies on simultaneous interventions on OD, malnutrition and oral health. In addition, the control group was not selected in the same period of time as the intervention but was recruited from the same hospital unit and paired with the cases taking into account five different clinical variables.

Conclusions

The increase in life expectancy is leading to a future health challenge that will demand change to the usual standards of clinical practice. Our results show that patients that completed the MMI improved their functional and nutritional status due to fluid and solid food adaptation and nutritional supplementation through a multimodal management strategy. Consequently, there was a reduction in hospital readmissions, LTRI incidence and mortality. Taking into account the importance of oral health in the pathophysiology of aspiration pneumonia and confirming that our oral intervention was not effective (there

was no significant reduction in the OHI-S), we believe that a professional oral hygiene should be applied for future interventions. For this reason and to validate the MMI it is still necessary to develop a randomized clinical trial, with a greater number of patients and improved oral hygiene treatment including professional care, in order to prove these results and to establish the definitive basis for a standardized MMI strategy.

Conflict of interest: The authors declare no conflicts of interest.

Funding: This study was funded by the Acadèmia de Ciències Mèdiques de Catalunya i Balears, filial del Maresme, and by the Centro de Investigación Biomédica en Red en el Área de Enfermedades Hepáticas y Digestivas (CIBERehd), Instituto de Salud Carlos III.

Acknowledgements: We would like to thank the support and collaboration during the study to the Nurse Department of the AGU and the Department of Odontology of the Hospital de Mataró. We thank to Mrs. Jane Lewis for the English review of the manuscript.

Author contributions: AM performed the research, did the data analysis and wrote the paper. OO designed the study, performed the research and wrote the paper. MR and MA did the nutritional evaluation of the patients. PC designed the study and wrote the paper. All authors reviewed and commented on subsequent drafts of the manuscript.

Ethical standard: ????????

References

1. World Health Organization. International Classification of Diseases (ICD). Geneva; 2010.
2. Altman KW, Yu G-P, Schaefer SD. Consequence of Dysphagia in the Hospitalized Patient. Arch Otolaryngol Neck Surg. 2010;136(8):784.
3. Cabré M, Serra-Prat M, Force L, et al. Oropharyngeal dysphagia is a risk factor for readmission for pneumonia in the very elderly persons: Observational prospective study. Journals Gerontol - Ser A Biol Sci Med Sci. 2014;69 A(3):330-337.
4. Cabre M, Serra-Prat M, Palomera E, et al. Prevalence and prognostic implications of dysphagia in elderly patients with pneumonia. Age Ageing. 2010;39(1):39-45.
5. Almirall J, Rofes L, Serra-Prat M, et al. Oropharyngeal dysphagia is a risk factor for community-acquired pneumonia in the elderly. Eur Respir J. 2013;41(4):923-926.
6. Baijens L, Clave P, Cras P, et al. European Society for Swallowing Disorders - European Union Geriatric Medicine Society white Paper: Oropharyngeal Dysphagia as a Geriatric Syndrome. Clin Interv Aging. 2016;11:1-16.
7. Carrión S, Cabré M, Monteis R, et al. Oropharyngeal dysphagia is a prevalent risk factor for malnutrition in a cohort of older patients admitted with an acute disease to a general hospital. Clin Nutr. 2015;34(3):436-442.
8. Rofes L, Arreola V, Almirall J, et al. Diagnosis and management of oropharyngeal dysphagia and its nutritional and respiratory complications in the elderly. Gastroenterol Res Pract. 2011;2011. pii: 818979.
9. Clavé P, Shaker R. Dysphagia: current reality and scope of the problem. Nat Rev Gastroenterol Hepatol Adv online Publ. 2015;12(5):259-70.
10. Cook IJ, Kahrilas PJ, Bloem B, et al. AGA technical review on management of oropharyngeal dysphagia. Gastroenterology. 1999;116(2):455-478.
11. Clavé P, Terré R, de Kraa M, et al. Approaching oropharyngeal dysphagia. Rev Esp enfermedades Dig. 2004; 96(2):119-131.
12. Serra-Prat M, Palomera M, Gomez C, et al. Oropharyngeal dysphagia as a risk factor for malnutrition and lower respiratory tract infection in independently living older persons: A population-based prospective study. Age Ageing. 2012;41(3):376-381.
13. Rofes L, Arreola V, Romea M, et al. Pathophysiology of oropharyngeal dysphagia in the frail elderly. Neurogastroenterol Motil. 2010;22(8):1-9.
14. Ortega O, Martín A, Clavé P. Diagnosis and Management of Oropharyngeal Dysphagia Among Older Persons, State of the Art. J Am Med Dir Assoc. 2017;18(7):576-582.
15. Serra-Prat M, Hinojosa G, Lõpez D, et al. Prevalence of oropharyngeal dysphagia and impaired safety and efficacy of swallow in independently living older persons. J Am Geriatr Soc. 2011;59(1):186-187.
16. Suominen M, Muurinen S, Routasalo P, et al. Malnutrition and associated factors among aged residents in all nursing homes in Helsinki. Eur J Clin Nutr. 2005;59(4):578-583.
17. Marik PE, Kaplan D. Aspiration pneumonia and dysphagia in the elderly. Chest. 2003;124(1):328-336.
18. Japanese T, Society R. Aspiration pneumonia. Respirology. 2004;9 Suppl 1:S35-7.
19. Ortega O, Cabre M, Clave P. Oropharyngeal dysphagia: Aetiology and effects of ageing. J Gastroenterol Hepatol Res. 2014;3(5):1049-1054.
20. Ortega O, Sakwinska O, Combremont S, et al. High prevalence of colonization of oral cavity by respiratory pathogens in frail older patients with oropharyngeal dysphagia. Neurogastroenterol Motil. 2015;27(12):1804-1816.
21. Ortega O, Martin A, Clave P. Diagnosis and Management of Oropharyngeal Dysphagia Among Older Persons, State of the Art. J Am Med Dir Assoc. 2017; 18(7):576-582.
22. Ortega O, Clavé P. Oral Hygiene, Aspiration, and Aspiration Pneumonia: From Pathophysiology to Therapeutic Strategies. Curr Phys Med Rehabil Reports. 2013;1(4):292-295.
23. Yoneyama T, Yoshida M, Ohrui T, et al. Oral care reduces pneumonia in older patients in nursing homes. J Am Geriatr Soc. 2002;50(3):430-433.
24. Yoneyama T, Yoshida M, Matsui T, et al. Oral care and pneumonia. Oral Care Working Group. Lancet (London, England). 1999;354(9177):515.
25. Tada A, Hanada N. Opportunistic respiratory pathogens in the oral cavity of the elderly. FEMS Immunol Med Microbiol. 2010;60(1):1-17.
26. Tada A, Miura H. Prevention of aspiration pneumonia (AP) with oral care. Arch Gerontol Geriatr. 2012;55(1):16-21.
27. Sorensen RT, Rasmussen RS, Overgaard K, et al. Dysphagia screening and intensified oral hygiene reduce pneumonia after stroke. J Neurosci Nurs. 2013;45(3):139-146.
28. Zuckerman LM. Oral Chlorhexidine Use to Prevent Ventilator-Associated Pneumonia in Adults. Dimens Crit Care Nurs. 2016;35(1):25-36.
29. Scannapieco FA, Yu J, Raghavendran K, et al. A randomized trial of chlorhexidine gluconate on oral bacterial pathogens in mechanically ventilated patients. Crit Care. 2009;13(4):R117.
30. Seedat J, Penn C. Implementing oral care to reduce aspiration pneumonia amongst patients with dysphagia in a South African setting. South African J Commun Disord. 2016;63(1):1-11.
31. Sjögren P, Nilsson E, Forsell M, et al. A systematic review of the preventive effect of oral hygiene on pneumonia and respiratory tract infection in elderly people in hospitals and nursing homes: Effect estimates and methodological quality of randomized controlled trials. J Am Geriatr Soc. 2008;56(11):2124-2130.
32. Newman R, Vilardell N, Clavé P, et al. Effect of Bolus Viscosity on the Safety and Efficacy of Swallowing and the Kinematics of the Swallow Response in Patients with Oropharyngeal Dysphagia: White Paper by the European Society for Swallowing Disorders (ESSD). Dysphagia. 2016;31(5):719.
33. Carrión S, Roca M, Costa A, et al. Nutritional status of older patients with oropharyngeal dysphagia in a chronic versus an acute clinical situation. Clin Nutr. 2017; 36(4):1110-1116.
34. Clavé P, Arreola V, Romea M, et al. Accuracy of the volume-viscosity swallow test for clinical screening of oropharyngeal dysphagia and aspiration. Clin Nutr. 2008;27(6):806-815.
35. Reisberg B, Ferris SH, de Leon MJ, et al. The Global Deterioration Scale for assessment of primary degenerative dementia. Am J Psychiatry. 1982;139(9):1136-1139.
36. Mahoney FI, Barthel DW. Functional evaluation: The Barthel index. Md State Med J. 1965;14:56-61.
37. Walter LC, Brand RJ, Counsell SR, et al. Development and validation of a prognostic index for 1-year mortality in older adults after hospitalization. Jama. 2001;285(23):2987-2994.
38. Charlson ME, Pompei P, Ales KL, et al. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40(5):373-383.
39. Fried L, Tangen C, Walston J, et al. Frailty in older adults: evidence for a phenotype. J Gerontol. 2001;56A(3):M146-M156.
40. Ortega O, Rofes L, Martin A, et al. A Comparative Study Between Two Sensory Stimulation Strategies After Two Weeks Treatment on Older Patients with Oropharyngeal Dysphagia. Dysphagia. 2016;31(5):706-716.
41. Kaiser MJ, Bauer JM, Ramsch C, et al. Validation of the Mini Nutritional Assessment short-form (MNA-SF): a practical tool for identification of nutritional status. J Nutr Health Aging. 2009;13(9):782-788.
42. Greene JC, Vermillion JR. The symplified oral hygiene index. J Am Dent Assoc. 1964;68:7-13.
43. Ortega O, Parra C, Zarcero S, et al. Oral health in older patients with oropharyngeal dysphagia. Age Ageing. 2014;43(1):132-137.
44. The British Dietetic Association and the Royal College of Speech and Language Therapists. National Dysphagia Diet: Standardization for Optimal Care.; 2011.
45. Carrion S. Doctoral Thesis. Fisiopatología de las complicaciones nutricionales asociadas a la disfagia orofaríngea en la población anciana. Universitat Autònoma de Barcelona. 2017. https://www.educacion.gob.es/teseo/mostrarRef.do?ref=1437708.
46. Bass C. An effective method of personal oral hygiene. J La State Med Soc. 1954;106(2):57-73; contd.
47. Bass C. An effective method of personal oral hygiene; part II. J La State Med Soc. 1954;106(3):100-112.
48. Awano S, Ansai T, Takata Y, et al. Oral health and mortality risk from pneumonia in the elderly. J Dent Res. 2008;87(4):334-339.
49. Terpenning MS, Taylor GW, Lopatin DE, et al. Aspiration pneumonia: Dental and oral risk factors in an older veteran population. J Am Geriatr Soc. 2001;49(5):557-563.
50. Gomes-Filho IS, Passos JS, Da Cruz SS. Respiratory disease and the role of oral bacteria. J Oral Microbiol. 2010;2(2010):1-6.
51. Swan K, Speyer R, Heijnen BJ, Wagg B, Cordier R. Living with oropharyngeal dysphagia: effects of bolus modification on health-related quality of life—a systematic review. Qual Life Res. 2015;24(10):2447-2456.
52. Gillman A, Winkler R, Taylor NF. Implementing the Free Water Protocol does not Result in Aspiration Pneumonia in Carefully Selected Patients with Dysphagia: A Systematic Review. Dysphagia. 2017;32(3):345-361.

53. Rosenvinge SK, Starke ID. Improving care for patients with dysphagia. Age Ageing. 2005;34(6):587-593.
54. Shim JS, Oh BM, Han TR. Factors associated with compliance with viscosity-modified diet among dysphagic patients. Ann Rehabil Med. 2013;37(5):628-632.
55. Beck AM, Kjaersgaard A, Hansen T, et al. Systematic review and evidence based recommendations on texture modified foods and thickened liquids for adults (above 17 years) with oropharyngeal dysphagia – An updated clinical guideline. Clin Nutr. 2017; pii: S0261-5614(17)30317-5.
56. Rofes L, Arreola V, Mukherjee R, et al. The effects of a xanthan gum-based thickener on the swallowing function of patients with dysphagia. Aliment Pharmacol Ther. 2014;39(10):1169-1179.
57. Vilardell N, Rofes L, Arreola V, et al. A Comparative Study Between Modified Starch and Xanthan Gum Thickeners in Post-Stroke Oropharyngeal Dysphagia. Dysphagia. 2016;31(2):169-179.
58. Carrión S, Verin E, Clavé P, et al. Complications of Oropharyngeal Dysphagia: Malnutrition and Aspiration Pneumonia. In: Ekberg O, ed. Dysphagia Diagnosis and Treatment. Berlin: Springer; 2012:575-599.
59. Norman K, Pichard C, Lochs H, et al. Prognostic impact of disease-related malnutrition. Clin Nutr. 2008;27(1):5-15.
60. Lang NP, Cumming BR, Löe H. Toothbrushing frequency as it relates to plaque development and gingival health. J Periodontol. 1973;44(7):396-405.
61. Yellowitz JA, Schneiderman MT. Elder's oral health crisis. J Evid Based Dent Pract. 2014;14 Suppl:191-200.