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Original article

The outcomes of long term home enteral nutrition (HEN) in older patients with severe dementia

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SUMMARY

Background and aims: European and international guidelines advice against initiating tube-feeding in patients with severe dementia. These recommendations are based on studies with important methodological limitations that evaluated the benefits of artificial nutrition in patients with percutaneous endoscopic gastrostomy almost exclusively in terms of the prolongation of survival. The aims of this study were to assess the harmful effects of home enteral nutrition administered via the nasogastric tube and percutaneous endoscopic gastrostomy in patients with advanced dementia in terms of mechanical, gastrointestinal and metabolic complications, to estimate the survival, to explore the risk factors for mortality and to compare the outcomes of patients with advanced dementia with those of patients without dementia.

Methods: The retrospective observational study was carried out on 585 consecutive patients of the mean age of 85.6 ± 6.9 years. They were treated using home enteral nutrition from 2010 to 2015 according to follow-up protocols adopted by the Clinical Nutrition Unit of an Italian geriatric research hospital (IRCCS-INRCA, Ancona). Incidence rates of mechanical, gastrointestinal and metabolic complications and survival rates in patients with severe dementia were compared to those in patients without dementia. The Cox proportional hazards model was used to evaluate the mortality risk factors.

Results: There was no difference between the incidence rates of complications in patients with severe dementia and those in patients without dementia. The incidence of mechanical complications was 1.35/1000 days for patients without dementia vs. 1.53/1000 days for patients with dementia ($p = 0.270$), the incidence of gastrointestinal complications was 1.30/1000 days for patients without dementia vs. 1.35/1000 days for patients with dementia ($p = 0.984$) and the incidence of metabolic complications was 0.36/1000 days for patients without dementia vs. 0.35/1000 days for patients with dementia ($p = 0.252$). The Kaplan Mailer analyses showed that there was no evidence to support the theses on poorer prognosis of survival of patients with dementia (median survival was 193 days for patients without dementia vs. 192 days for patients with dementia, ($p > 0.05$)). The female gender, advanced age, nasogastric tube, diabetes mellitus and chronic renal failure were identified as risk factors. Subjects whose Geriatric Nutritional Risk Index values were higher had a lower risk of mortality.

Conclusions: The discussion on the appropriateness of enteral nutrition in patients with severe dementia is still open. Our results show that, if there is a medical prescription for tube-feeding and a patient's surrogate decision-makers express free and informed consent to the tube-feeding of the patient, enteral nutrition should not be contraindicated a priori if the patient has severe dementia. Regular follow-up is mandatory to guarantee adherence to the therapy and achieve its initial aims and to ensure that the principles of beneficence and nonmaleficence are respected.

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1. Introduction

Guidelines on nutrition in dementia, which several scientific societies have published, generally advice against initiating enteral nutrition (EN) in patients with advanced dementia. However, they suggest that the decision for or against that nutritional intervention should be made on an individual basis [1–3]. If there are medical indications/prescriptions for the therapy, the proper procedure entails informing patients and/or their caregivers about the patients' general prognoses and the potential benefits and risks of the therapy, and letting them express their consent based on the detailed and truthful information provided [4]. The problem is that the available scientific evidence on the risks and benefits of EN in patients with severe dementia is still incomplete, and even the guidelines of scientific societies are formulated based on such reduced evidence. Numerous points of criticism may be made regarding this evidence. The evidence is available almost exclusively with reference to the survival of patients with severe dementia, which does not seem to improve when they are treated with EN via percutaneous endoscopic gastrostomy (PEG) [5–7]. Although the follow-up practices adopted after the positioning of the PEG tubes may significantly influence the outcomes of the therapy, none of the studies that analyze the survival of patients with dementia treated with EN describe them. There is very limited evidence regarding patients on long-term EN with a nasogastric tube (NGT) although in some countries, such as Italy or Spain, such patients are very common [8,9]. What's more, none of the results are from clinical trials, which represent the gold standard for judging the benefits of any medical treatment. It is difficult to imagine controlled trials on the effects of tube-feeding (TF) in patients with dementia being carried out in the future since the control groups without nutritional support would be unethical. However, numerous other gaps could be addressed. New evidence of the harmful effects of EN complications and that of the achievement of goals other than mere survival should be gathered. Such evidence is necessary to investigate whether the principles of beneficence and nonmaleficence are respected when patients with severe dementia are treated using feeding tubes. This retrospective observational study was performed on geriatric patients treated with long-term home enteral nutrition (HEN) by Clinical Nutrition Unite of an Italian geriatric research hospital (INRCA, Ancona), with aim to provide information on the complications of HEN therapy - mechanical, gastrointestinal and metabolic - in patients with advanced dementia. The incidence rates of different complications of HEN therapy and the mortality rates of patients with and without dementia were compared. The risk factors for mortality in old patients on long-term HEN were identified.

2. Materials and methods

2.1. Settings and sample population

INRCA's ethics committee approved the study protocol in compliance with Italian national rules and standards for ethical research conduct. Data on 585 patients (26% male, 74% female, mean age 85.6 ± 6.9 years) whom the Clinical Nutrition Unit of INRCA geriatric hospital treated with HEN in the period of 2010–2015 was analyzed. HEN therapy was provided to patients according to INRCA's protocol [10]. The nutrition is administered via NGT or PEG. Patients enrolled in the study received, on average, 20–25 kilocalories and 1–1.5 g of proteins for each kg of body weight. The number of kcal and amount of proteins provided were determined based on the patients' metabolic requirements and the underlying diseases [11]. Disease-specific tube-feeding formulas were used. Following the protocol, upon the patients' discharge from the hospital, the caregivers who would assist them at home (family members or informal caregivers who were not sanitary staff) were trained to implement HEN therapy in the community [12]. The caregivers were trained to use the infusion pump, to use and store the enteral feeding formulas, to administer drugs and water through an enteral feeding device and to manage the tube site. Trained nurses followed up on patients in their homes or nursing homes once monthly. The home visiting staff performed examinations and assessments of each patient according to a specific protocol. During each home visit, the home visiting staff performed an electrocardiogram, an assessment of body weight, blood pressure measurement, a determination of the presence of and an appraisal of pressure ulcers and glycemia measurement using a glucometer. In the shared protocol, the conditions and cut-off values for the diagnoses of different complications of HEN therapy were defined. Gastrointestinal complications were defined as follows: constipation (closed alvus for more than 3 days despite the use of constipation medications), diarrhea (loose and watery bowel movements [stools], with more than 4 stool emissions a day), vomiting and/or esophageal regurgitation. Metabolic complications were defined as follows: hyperglycemia (glycemia >200 mg/dL) and hypoglycemia (glycemia <80 mg/dL) based on fingerstick blood samples collected during each home visit; hypernatremia (blood sodium >148 mmol/L) and hyponatremia (blood sodium <136 mmol/L) based on the results of blood examinations; hyperkalemia (blood potassium >4.9 meq/L) and hypokalemia (blood potassium <3.6 meq/L) and high blood urea nitrogen levels (>405 mg/dcl) and dehydration based on clinical signs, such as oliguria (<400 mL urine/day). The hospital physician specialized in clinical nutrition undertook the prevention and treatment of gastrointestinal complications – constipation, diarrhea, vomiting and/or esophageal regurgitation – and metabolic complications – hyperglycemia and hypoglycemia, hypernatremia and hyponatremia, hyperkalemia and hypokalemia, high blood urea nitrogen levels and dehydration – after it was informed of them by the home visiting staff informed. When the tube-related complications – displacement, occlusion and breakage, infection around the wound exit site and the presence of granulation tissue – arose, home visiting staff diagnosed them and, when possible, addressed them directly at the patients' homes. All the data that the staff gathered on patients' conditions during home visits was recorded in case report schedules on a dedicated internet database, together with information on eventual hospital visits (frequency and reasons), hospitalizations (frequency, diagnoses and length of hospital stays), and the results of blood tests that were performed during the previous month. The case report schedules can be consulted in real time by the hospital physician and dietician who, when it's necessary, may intervene immediately for the therapy modification and/or interruption.

2.2. Data collection

Data on diseases and on diagnoses of dementia and its severity were collected from patients' records. To perform dementia assessments neurologists used Clinical Dementia Rating scores (CDR). The CDR is a five-point scale that may be applied to Alzheimer's disease and related dementias [13]. It assesses different domains of patients' cognitive and functional performances by means of a semi-structured interview. Dementia severity is classified using scores ranging from 0 (no dementia) to 5 (terminal dementia). Baseline data, gathered for all participants at the beginning of the HEN therapy, included standard demographic data (age, gender, living conditions), information on nutrition therapy (reasons for starting HEN, administration routes) and body mass index (BMI).

Patients were assessed for the nutrition-related risk of morbidity and mortality using the Geriatric Nutritional Risk Index (GNRI) [14]. Values lower than 82 on this index indicate a major risk of death or complications within 6 months due to patients' nutritional status, values from 82 to 92 indicate a moderate risk, values from 92 to 98 indicate a low risk and values $\geq$ 98 indicate the absence of risk. On the occasion of the nutritional assessment, for all patients the degree of disability and functional impairment was measured also by the Karnofsky index. This index allows to assess the ability of pts to perform activities of daily living and their prognosis. Its score ranges from 10 to 100. The scores from 80 to 100 indicate that pt needs no special care, from 50 to 70 that pt is able to care for most personal needs and need varying amount of assistance while the scores that range from 10 to 40 indicate that pt is unable to care for self but requires equivalent of institutional or hospital care and that the disease may be progressing rapidly [15,16].

Information on the frequencies and types of complications associated with HEN therapy, frequency, duration and reasons of hospitalizations, in particular the frequency of the diagnoses of aspiration pneumonia during hospitalizations and the outcomes of the HEN therapy (death, moving from tube-feeding to oral feeding, moving from enteral to parenteral nutrition and changing the provider) were extrapolated from patients' report schedules, which were available on the dedicated internet database of the Clinical Nutrition Unit.

2.3. Data analyses

For the purposes of this retrospective observational study, patients were categorized in two groups: those with severe dementia and those without dementia. Descriptive statistics were used to describe patients' characteristics. Shapiro–Wilk test was performed to test whether continuous variables were distributed homogeneously or non homogeneously. Following this analyses the statistical methods were selected (mean values ± standard deviation or median values and range). Categorical variables were expressed as absolute values and relative frequencies. The two-sample *t*-test, Mann–Whitney and chi-square test ($\chi 2$ test) were used to compare the two groups' baseline characteristics. The prevalence of different complications of HEN therapy were calculated for the total sample and for the two categories of patients. The incidence rates of complications were compared for the two groups of patients. Survival was analyzed using the Kaplan–Meier method. The comparison of subgroups was examined using the log rank test. The Cox proportional hazards analysis was used to assess which variables were correlated with survival. All tests for significance used a two-sided *P*-value of 0.05. Data collected were subjected to analyses through STATA (StataCorp, College Station, TX, USA).

3. Results

The characteristics of 585 geriatric patients (74% females, 26% males, mean age 85.6 ± 6.9), whom INRCA's Clinical Nutrition Unit treated with HEN in the period 2010 to 2015, are described in Table 1. All patients with dementia who were enrolled in this study had CDR $\geq$4. For 83.2% of the patients, the reason for starting the HEN therapy was severe dysphagia (92.3% in patients without dementia vs. 77.3% in patients with dementia; p = 0.000). For the remaining 16.8%, the TF was prescribed because of anorexia. The mean Karnofsky values of the two groups show that both demented and non demented patients had very high level of functional impairment and were therefore comparable, independently from the condition of being demented. The BMI values of patients with dementia were lower and their nutritional statuses were more compromised. The GNRI values of the two groups of patients also partially confirmed that the prognoses of patients with dementia due to their nutritional status were poorer than those of patients without dementia (mean GNRI of 80.5 ± 9.7 in patients with dementia vs. 84.7 ± 10.1 in patients without dementia; p = 0.000).

The median duration of HEN therapy was 193.5 days in patients without dementia and 141 days in patients with dementia and these difference was close to significance (p = 0.055). The ranges of the duration of therapy were very wide for both groups (min: 1 day, max: 2190 days). During the study period, a total of 234.586 days of HEN therapy were provided to patients, with a total of 4.094 HEN-related complications registered. Complications of HEN therapy did not occur in 164 patients (28.0%), while 355 patients (60.7%) registered more than two complications. The most frequent complications were mechanical complications which represented 55.3%

Table 1
Descriptive analysis of baseline sociodemographic and clinical parameters in the whole sample and in demented and non demented patients - relative frequencies (%) and mean values (±SD).

	Total sample (n = 585)	Dementia (n = 365)	No Dementia (n = 220)	p
Age, Mean ± SD^	85.6 ± 6.9	86.0 ± 6.8	84.9 ± 7.1	0.051
Female Gender**	74.4%	75.9%	71.8%	0.275
Living condition**				
Home	54.2%	49.0%	62.7%	0.001
Nursing home	45.8%	51.0%	37.3%	
Karnofsky, Mean ± SD*	42.2 ± 7.2	41.8 ± 7.2	43.1 ± 7.1	0.061
Comorbidities**	74.8%	73.0%	77.8%	0.199
Neurologic Disease (other than Dementia)**	34.7%	3.6%	86.4%	0.000
Diabetes Mellitus Type 2**	18.3%	13.7%	25.9%	0.000
Heart Failure**	45.3%	42.7%	49.6%	0.109
Chronic Renal Failure**	8.7%	9.9%	6.8%	0.206
Cancer**	3.4%	0.8%	7.7%	0.206
BMI±SD*	20.6 ± 3.7	20.0 ± 3.7	21.5 ± 3.7	0.000
GNRI t0, Mean ± SD^	82.1 ± 10.1	80.5 ± 9.7	84.7 ± 10.1	0.000
Reason for starting HEN**				
Dysphagia	83.2%	77.3%;	92.3%;	0.000
Anorexia	16.8%	22.7%	7.7%	
Route of administration**				
PEG	26.4%	23.6%	31.2%	0.043
NGT	73.6%	76.4%	68.8%	
Duration of HEN, Median (min, MAX)	174 (1; 2190)	141 (1; 2190)	193.5 (1; 2190)	0.055

Notes: * T-test, ** Chi-square test, *** Wilcoxon rank-sum test, ^ Mann–Whitney.

Table 2
Number of demented and non demented patients who registered at least one complication during HEN therapy, incidence and 95% confidence interval of different complications during HEN therapy (IR for 1000 days/person).

Complications	Total sample			Dementia			No dementia			p*
	n.	Incidence	95% CI	n.	Incidence	95% CI	n.	Incidence	95% CI	
Mechanical	345	1.47	1.32–1.63	132	1.35	1.14–1.60	209	1.55	1.34–1.76	0.270
Gastrointestinal	316	1.35	1.21–1.50	127	1.30	1.09–1.54	184	1.35	1.17–1.56	0.984
Metabolic	82	0.35	0.28–0.43	35	0.36	0.26–0.50	47	0.35	0.26–0.46	0.252

Notes: *Log-rank test of equality.

of the total. In particular, the tube displacement represented 48% of mechanical complications, followed by granulation tissue (17%) and infection of insertion site (16%). The prevalence of gastrointestinal complications due to patients' intolerance or adverse reactions to the nutrition formula represented 34.9% of the total. The main gastrointestinal complication was the constipation (almost 50% of total gastrointestinal complications), followed very closely by diarrhea (almost 40% of total gastrointestinal complications). The metabolic complications represented less than 10% of the total whereas the hyperglycemia represented 96% of total metabolic complications. No significant differences were found in the prevalence rates of complications between the two groups (data not shown). Given the substantial differences in duration of the patients' therapies, the incidence rates of their complications were compared.

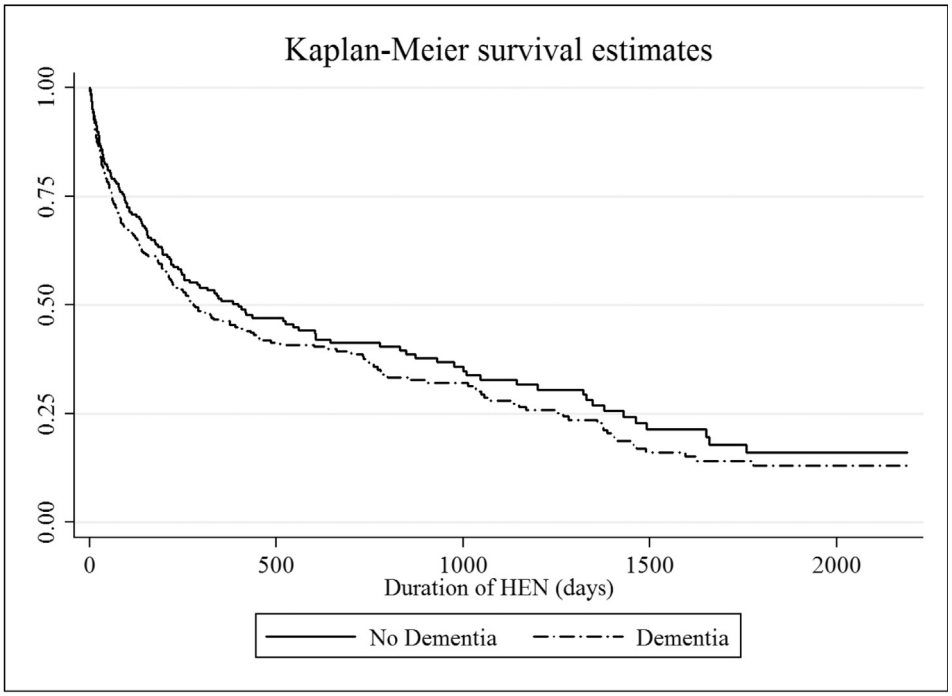
As is shown in Table 2, no differences were found between the incidence rates of the different categories of complications of HEN therapy in patients with dementia and in those without dementia.

The hospitalizations for HEN therapy complications were 15% of total hospitalizations without significant differences for demented and non demented patients. Following the analyses of the hospital diagnoses, it was found that the incidence rate of the aspiration pneumonia (the main risk factor for mortality in old tube-fed patients) was quite low and it didn't differ between the two groups (0.174 in patients without dementia vs. 0.279 in patients with dementia; $p = 0.972$).

For 60.9% of patients enrolled in the study, death interrupted the HEN therapy. Almost 7% of patients moved from TF and resumed full oral nutrition. Among the patients who resumed oral nutrition there were 58% of patients with severe dementia who were on HEN only temporarily, for reasons different then dementia (acute states, food refusal etc.), and who were promptly moved to oral feeding when that was possible thanks to the follow up visit. Another 1.4% of patients moved from EN to parenteral nutrition, while 4.2% of patients moved to another provider. Figure 1 shows the Kaplan–Meier survival curves in relation to dementia. Statistical significance of the curves was estimated through the log-rank test of equality. No significant difference was found between the survival of patients with dementia and that of patients without dementia (median survival = 193 days in patients without dementia vs. 192 days in patients with dementia).

The Cox proportional hazards analysis was performed to assess which variables were correlated/associated with the survival of old patients in long-term HEN.

This analysis showed that dementia was not an independent risk factor for mortality in elderly patients on HEN (Table 3). By



Notes: Log-rank test of equality of survivor functions p=0.196

Fig. 1. Kaplan–Meier survivor function assuming duration of HEN as exposition time and death as failure endpoint.

Table 3
Cox proportional hazards model assuming duration of HEN as exposition time and death as failure endpoint.

	HR	(95% C.I.)
Dementia (ref. No Dementia)	1.00	0.57–1.75
Route of administration NGT (ref. PEG)	1.71	1.29–2.26
Female gender (ref. Male)	1.62	1.26–2.07
Living at home (ref. Nursing Home)	1.11	0.89–1.38
Age	1.04	1.02–1.06
GNRI	0.98	0.97–0.99
Neurological diseases other than Dementia (ref. No)	0.91	0.52–1.60
Diabetes Mellitus Type 2 (ref. No)	1.43	1.09–1.86
Heart Failure (ref. No)	1.20	0.96–1.49
Chronic Renal Failure (ref. No)	1.73	1.19–2.52
Cancer (ref. No)	1.37	0.68–2.74

contrast, the following variables were identified as risk factors for mortality in elderly people who were treated with HEN: age, female gender, the administration of therapy by NGT and the presence of pathologies such as DM2 and chronic renal failure. Higher GNRI values at baseline were identified as constituting a protective factor.

4. Discussion

Although one of the main concerns about the HEN therapy is the occurrence and management of its complications, the evidence on these issues is very limited in the literature. The aim of the present study was to assess the harms of the HEN therapy in patients with advanced dementia and to compare the outcomes of this patients with the outcomes of subjects without dementia. After we compared the incidence rates of mechanical, gastrointestinal and metabolic complications of HEN therapy in the two groups of subject, we found no difference, i.e. no major risk of HEN complications, in patients with dementia who were receiving the HEN according to our standardized follow-up protocol. Given the novelty of these information, it was not possible to compare our results with the results of other studies. In our study, the median survival of patients with severe dementia treated with EN was 192 days versus 193 days for artificially fed patients without dementia and there was no a significant difference in the survival of the two groups. What is more, in patients who were tube fed for some temporary impairments (dysphagia, anorexia, post stroke…), there was an improvement of dysphagia and hyporexia and some of them returned to oral feeding. In 1997 and 1998, Mitchel et al. published the results of studies showing that there was no difference in survival between tube-fed nursing home residents with severe cognitive impairment and similar residents who were not tube-fed, and that there were no specific risk factors associated with feeding-tube placement [17]. In 2001, Meier et al. found that the median survival time was 195 days for subjects with feeding tubes versus 189 days for those without feeding tubes [7] and that feeding tubes in patients with dementia had no significant influence on survival; rather ethnicity and prior residence in a nursing home influenced survival. The study of Jaul et. all showed that the median survival time in dementia patients with NGT was significantly increased (250 days) compared to that in orally fed patients (40 days), but, after controlling for comorbidities, this correlation became insignificant [18]. However, all these authors compared the survival of demented patients to whom the nutrition was provided by different administration routes (PEG and/or NGT vs. mouth) while in our study the comparison is between tube fed patients with and without diagnosis of dementia.

Relative to mortality risk factors, we found that dementia was not an independent risk factor for the mortality of older patients treated with HEN. This finding is in accordance with the results of numerous studies. In 2008, Gaines et al. also found that patients with dementia or severe cognitive impairment did not have a shorter survival time than patients whose cognitive function was not compromised [19]. In 2008, Hohagi et al. published the results of their study on 311 Japanese geriatric patients, which suggested again that elderly patients with dementia did not have a poorer prognosis after PEG positioning than the cognitively preserved elderly [20]. The results of a 2013 study by Shintani also showed that the survival periods of patients with PEG on home parenteral nutrition were twice those of patients in the self-feeding oral-intake group despite lower serum albumin levels, compromised swallowing and cognitive function and high levels of dependence at the beginning of home care [21]. Gaines et al. found that the risk factors for 30-day mortality after PEG positioning were the patients' age and serum albumin levels while in the study of Hohagi et al. a poorer prognosis in demented patients was correlated to male gender, advanced age, a low serum albumin level, chronic heart failure, and subtotal gastrectomy. In our study, a poorer prognosis of patients treated with HEN was correlated to gender (and it was higher for females), age, GNRI, DM 2 and chronic renal failure. We also found that patients with NGT (73,6% of our patients) had a 71% higher probability of death compared to patients with PEG. The scientific evidence suggests indeed that patients with NGTs have a poorer prognosis. According to that evidence, there are no statistical differences in the mortality, complications and pneumonia between pts with PEG and those with NGT, while the intervention success and survival are worse in pts with NGT [22]. The results of some our analyses, not presented in this study, suggest that the prognosis of our patients with NGT is even worse than that suggested by the scientific evidence, both with reference to the complications of the HEN therapy and to survival. It may be surprising therefore such a high prevalence of NGTs in our clinical practice but there are numerous reasons for that. In the first place, according to our protocol the PEG positioning may be practiced only for patients who have a legal guardian which is the case only for the minority of Italian elderly subjects. But what is more, we assist patients much older than those enrolled in the studies used to provide the scientific evidence, patients whose clinical conditions and cognitive status are very compromised. In fact, in our patients the anesthesia and surgery represent significant mortality risk factors and the gastrostomy tubes are placed only if there is intolerance to NGTs, in patients who have been administered the HEN by NGT for more than 60 days, while the tubes are always placed by pull method aided by endoscopy and never surgically [23–25]. Patients who have been elected for placement of the PEG are those whose overall conditions are less compromised. Hence, the major risk of mortality associated with the NGT must be interpreted also in the light of this consideration.

When dealing with such very old and frail patients the goal of extending the survival may not be as important as that of extending the survival of younger patients. In older patients it becomes of primary importance to improve their quality of life, to avoid complications and to satisfy their and their caregivers' spiritual and ethical needs and beliefs. Both the benefits and the risks of the therapy should be assessed during the decision making process based on the best scientific evidence which is still scarce [26–28]. Therefore, the main contribution of this study is in providing the missing evidence on mechanical, gastrointestinal and metabolic complications in very old patients on HEN and in showing that their prevalence and incidence are not higher in patients with severe dementia when compared to non-demented patients. No patient with severe dementia should be precluded a priori from possibly benefitting from TF [29,30].

Our results must certainly be interpreted also based on the characteristics of our follow-up methodologies. The prevention and management of the complications of HEN therapy were indeed

strictly related to the frequency and quality of the follow-up visits. During therapy, the goals of treatment may change, or it may turn out that the principles of beneficence and nonmaleficence are no longer being respected: under those circumstances, the therapy has to be interrupted. Very frequently, some modifications in therapy are necessary to prevent or address complications or, as was the case for 7% of our patients, therapy may be interrupted to enable patients to engage in oral feeding. Patients whom the Clinical Nutrition Unit of INRCA followed up received one monthly visit by nurses who regularly updated the hospital staff. This allowed the modification or interruption of the therapy as soon as the associated risks rose or when the therapy wasn't necessary any more. This study is only one step forward in the enrichment of the scientific knowledge needed to ensure a more rational decision-making approach, based on evidence, in the field of clinical nutrition of the elderly, especially those with advanced dementia. In this study we considered only mechanical, gastrointestinal and metabolic complications of HEN therapy while numerous other discomforts should also be addressed (difficulties in repositioning NGTs, restrains, caregiver burden…). The costs of the service which provides a regular monthly follow up visit during the whole duration of the therapy should also be assessed in order to evaluate the possibility to adopt similar organizational models in other regions and countries and to estimate the transferability of our results.

Statement of authorship

Orlandoni Paolo conceptualized and designed this study, he drafted and critically revised the manuscript and approved its final version. Nikolina Jukic Peladic assisted Orlandoni Paolo for study design, assisted with data analyses and interpretation, drafted the manuscript, critically revised it, wrote and approved its final version. Mirco di Rosa performed statistical analyses and participated in interpretation of results, he critically revised the manuscript and approved its final version. Claudia Venturini participated in data collection, critically revised the manuscript and approved its final version. Claudia Cola, Debora Sparvoli, Natascia Giorgini, Donata Fagnani and Redenta Basile participated in data collection and approved the manuscript final version.

Conflicts of interest

None declared.

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