European Geriatric Medicine (2020) 11:191–194
https://doi.org/10.1007/s41999-020-00292-4

EDITORIAL

Enteral nutrition in advanced dementia: an unresolved dilemma in clinical practice

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Published online: 28 January 2020

Enteral Nutrition (EN), also named Tube feeding (TF), refers to nutrition therapy where enteral nutrition formula is delivered to gastrointestinal tract of an individual, mostly via nasogastric tube (NGT) or percutaneous endoscopic gastrostomy (PEG). Clinical practitioners' decisions concerning EN in patients with specific clinical conditions are directed by clinical practice guidelines. Clinical guidelines are statements and recommendations based on the best scientific evidence or consensus among experts whose aim is to increase the quality of the care and to decrease the variation in clinical practice by linking the professional services to quality standards [1]. The higher is the strength of the scientific evidence on which each statement and recommendation is based, the higher is the importance of respecting it.

The most relevant recommendations on EN in patients with severe dementia are provided by the American Geriatric Society (AGS) in its Feeding Tubes in Advanced Dementia Position Statement from 2014 and by the European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines on nutrition in dementia from 2015 [2, 3]. Both AGS and ESPEN advise not to initiate EN in patients with severe dementia mostly based on results of studies which showed that EN is not associated with longer survival in these patients [4–15]. Moreover, according to studies cited in the AGS statement, EN does not improve the nutritional status in subjects with severe dementia, it causes excessive use of restraints and it is ineffective in preventing and treating pressure ulcers (PU) and aspiration pneumonia. Despite the recommendations, the use of EN in patients with severe dementia, who always develop swallowing difficulties, is very controversial. Clinicians often do not agree that PEG placement is contraindicated in advanced dementia and they believe that enteral feeding may prevent aspiration pneumonia, weight loss and pressure sores in these subjects. Therefore, EN is still commonly used in clinical practice [16, 17]. This attitude is supported by the criticism that many authors and scientists expressed about the quality of the scientific evidence used to draft the recommendations [18, 19].

Indeed, the studies on which recommendations are based have several weaknesses and new evidence, which suggests that the recommendations against initiating EN in severe dementia should probably be less categorical, has been produced only recently.

The main critics that may be moved to recommendations concerns the methodological limitations of the studies used to draft them. These studies are not prospective randomised controlled clinical trials which are the gold standard for any medical decision but, instead, they are observational studies whose validity is limited. Other important methodological limitations of the studies have been highlighted by Samson and, more recently, by Lynch [18, 20]. Both authors pointed out that the studies used to draft the recommendations were mostly plagued with selection bias. Clinical outcomes of tube fed patients with advanced dementia were compared with outcomes of patients whose swallowing problems were less severe and who were still able to eat by mouth. The outcomes of different groups of patients were obviously influenced by their different clinical conditions and nutritional regimens and, although some authors attempted to correct this selection bias, the outcomes of different groups are incomparable.

Furthermore, none of the studies provided information on consequences and complications of PEG positioning and on

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their impact on overall outcomes. None of them described the characteristics of follow-up programmes and practices which are unavoidably associated with outcomes of the therapy. The conditions of patients with advanced dementia are severe but these subjects are not necessarily near the end of life so that the outcomes of EN therapy, just as the frequency of EN-related complications and the possibility to resolve them promptly, are strongly dependent on characteristics of the services provided and on the frequency and accuracy of outpatient visits. No information on training of formal and informal caregivers is given either, although it is well known that caregivers have a fundamental role in the management of patients treated with EN at home or in institutions.

Selection bias and inaccurate methodologies are just two of the numerous issues which impact negatively the quality of the evidence used to draft recommendations on EN in severe dementia.

Low-quality evidence is also available concerning the impact of tube feeding on nutritional status of patients with severe dementia. According to most authors, the EN therapy is inefficient in improving nutritional status in these subjects. Peck is the only author whose study offers different and contrasting results [13]. However, studies used to draft the recommendations were all performed few years ago when the indicators of nutritional status such as albumin levels, the haematocrit and cholesterol levels or some single anthropometric indicators like BMI or weight loss were used [11–14]. Nowadays, the validity of these indicators has been questioned and new evidence should be collected using the proper tools and criteria for the nutritional assessment, such as ESPEN Consensus Statement or GLIM criteria [21, 22].

The argument concerning the restraint use as an inevitable companion of EN also does not find a solid support in the scientific literature [13, 14]. Data on the frequency of restraints' use in this specific population are scarce, based on small studies and the information is prevalently gathered among old, frail subjects, independent of the condition of being demented [23]. Different authors considered different types of restraints which are commonly used for patients' safety independent of the condition of being treated with EN. Some very important information was scarcely available when guidelines were edited. For example, even though in some countries, the NGTs are used for long-term tube feeding, almost all available information was for patients with PEG. Very incomplete, if any, was also the information on enteral formulas used. Although the overall benefit of EN therapy concerns not only the survival and the improvement of the nutritional status but also the patient's quality of live (QoL), no information on this issue is still available for patients with severe dementia.

Other evidence has been provided only after the publication of the guidelines. Relatively to the issue of PU, there is new evidence demonstrating the ability of special, enriched, formulas to improve PU healing compared with standard formulas [24]. As far as harms of EN are concerned, until very recently, the evidence on the safety of EN, measured in terms of mechanical, gastrointestinal and metabolic complications, was not available for tube-fed patients with severe dementia. Different authors reported on the frequency of complications of EN but they analysed data collected in different populations [15, 25, 26]. Some new evidence was made available on this issue by our study which compared the incidence rates of mechanical, gastrointestinal and metabolic complications in 585 consecutive patients and found no difference between the incidence rates of complications in patients with dementia and patients with similar characteristics but without dementia [27]. New evidence on the correlation between EN and aspiration pneumonia is also available. While until recently, the EN was considered by most authors as a risk factor for aspiration pneumonia in patients with severe dementia [13, 14, 28], some recent studies showed that, on the contrary, there is no difference in the frequency of aspiration pneumonia among tube-fed patients with severe dementia and tube-fed patients without dementia and that aspiration pneumonia can even be prevented by the means of EN in patients with dementia [27, 29].

Finally, from the ethical standpoint, in recent years, it has been recognised that more attention should also be paid to personal feelings and wishes of patients and caregivers. Family members frequently believe that food and water are basic human needs and should be provided no matter what, and they report that this was also the belief of patient in earlier phases of life. This issue becomes particularly sensitive when patients who are not able to make their healthcare decisions do not have advanced healthcare directive or a surrogate decision maker indicated by power of attorney or court and it is unclear whether the clinicians should decide about artificial nutrition and hydration, just like for other medical treatments [30].

In conclusion, there seems to be reason and the need for a critical revision of the recommendations on EN in patient with advanced dementia. The studies performed in the recent years do not overcome the main methodological limitations which characterised previous studies, but they certainly offer some new evidence which should be considered. Ethical aspects have been recognised as very important to be taken into account during the decision-making process. While no prospective randomised trials will ever be available for the obvious ethical reasons, new, carefully planned, prospective observational studies on larger populations should be performed to clarify the risk benefit ratio of EN in these patients. In our view, data collection and production of new evidence should be strongly recommended if the gap between the clinical practice and scientific recommendations has to be overcome. Solid evidence is also crucial for clinicians to provide objective information to caregivers and

surrogate decision makers on which to base their ethical decisions. In the meanwhile, the overall decision-making process should be personalised as much as possible and any generalisation should be avoided.

Authors' contribution Conceived the study PO. Supervision PO. Data search and analyses NJP. Wrote the original draft NJP. Edit and comment on manuscript PO, NJP and AC.

Funding This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethics approval and consent to participate Not applicable.

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