Research on morbidity and mortality in advanced dementia has provided a greater recognition of end-of-life decisions and has appropriately raised questions about the value of percutaneous endoscopic gastrostomy (PEG) tube placement in the setting of terminal illness. This research, and the increased level of awareness regarding the risks and benefits of PEG placement, arrives at a critical juncture of modern healthcare and the aging of America. It has been estimated that a Baby Boomer turns 50 every 7.6 seconds, and medical technology offers us the promise of increasing hospital survival for an aged population with multiple co-morbidities (1). It is apparent that the demand for PEG placement will increase dramatically in the setting of increased hospital survival in a population that may no longer be able to meet their most basic nourishment and hydration needs. However, specialized enteral feedings and PEG placement in a compromised population introduces risks, and there is a limited body of evidence to establish when the risks of feeding tube placement may outweigh the benefits of providing adequate nutrition.

The evidence-based findings from every other facet of medical practice demonstrate that there are no safe assumptions. Enteral feedings should meet the same criteria for improved outcomes in morbidity, mortality and quality of life that are demanded of any other medical practice. A critical understanding of current evidence and its limitations, is vital for healthcare practitioners. Without this understanding, practitioners are unable to provide the most up to date and accurate information to their patients (and their caregivers) so that informed decisions about the benefits and risks of feeding tube placement can be made.

Reviews on the merits of PEG placement such as the one by Doctor Plonk in his preceding article, provides a valuable synopsis of recent studies and offers thoughtful viewpoints worthy of consideration. However, there are a number of limitations to the available studies and this editorial will highlight several of these limitations in the interest of a balanced discussion of PEG placement.

Much of the available research is observational in nature. Such data are useful for demonstrating or validating associations, but they cannot be used to prove that the association is causative. Selection bias is inherent in all observational research. One means of selection bias that is noteworthy in any studies of PEG placement, is nutrition status. Patients are frequently not considered for tube feeding or PEG placement until malnutrition has sufficiently advanced and it becomes readily apparent to the caregivers or physicians. Nutrition status is difficult to adequately control due to the lack of any single indicator that accurately reflects the degree of malnutrition. Albumin is well established as an inverse acute-phase reactant,
and has little correlation with recent nutrition intake (2). Although malnutrition is well established as a factor that significantly increases infection risk and complications from procedures, it is only one factor (3,4). One must consider that a recommendation or referral for PEG placement is not made in every patient, nor are patients selected to receive a PEG in a random fashion—the fact is, there is no way to control for all of the factors involved with selection into that group without randomization.

Selection bias is also evident when discussing the risk of aspiration associated with nasogastric or PEG feeding. Those patients referred for tube feeding are at increased risk of aspiration, compared to those patients who are able to eat by mouth, due to their underlying severity of disease and co-morbidities. PEG feedings cannot protect against aspiration of oral and pharyngeal secretions, but nasogastric or PEG feedings may offer protection from aspiration of oral intake in those patients with documented dysphagia as seen in acute stroke (5). In a group of elderly patients who had an abnormal swallowing function, placement of a PEG tube was associated with increased survival at 36 months, compared to those who continued oral intake (6). In order to achieve a true understanding of the risks associated with enteral feeding it is important for authors of reviews to differentiate between risk of aspiration of oral intake due to dysphagia, aspiration in intubated critically ill patients, and aspiration due to inability to manage oral/pharyngeal secretions. It is equally important to note how aspiration is defined—or not—within each study.

Another consideration in any discussion of aspiration risk with enteral feedings is the protocol used for enteral feeding. Supine positioning during enteral feeding is a documented risk factor, and yet this is rarely discussed, or controlled for, in evaluation of aspiration risk with PEG feeding (7,8). Factors such as failure to elevate head of bed, inadequate oral care, and rapid bolus of large-volume feedings are all known to increase the risk of reflux or aspiration in this population (9–11). Studies that provide enteral feeding in a manner that may increase the incidence of adverse events (feeding while supine, large bolus’, etc.) may not represent the true risk/benefit ratio for all patients, in all institutions.

There is a tendency to describe the associations found in observational or retrospective studies in a cause and effect manner. One example of attributing cause and effect from an association is describing the results of Mekhail, et al (12) as “PEG placement resulted in more persistent dysphagia,” suggesting that PEG placement might somehow actually cause dysphagia. However, this retrospective trial of patients with head and neck cancer may only demonstrate the ability of experienced clinicians to identify (correctly) those patients with a need for more prolonged tube feedings. The author’s conclusions are that a prospective, randomized trial is necessary to evaluate the observations found.

In some settings, such as that with advanced dementia, randomized trials are not available, and some have suggested that randomized trials of PEG placement in those with advanced dementia would not be ethical. Considering that our best available data—observational, retrospective, or cohort—suggests PEG placement does not improve outcome and may actually be harmful in advanced dementia, (but also recognizing that the nature of current evidence may lead to incorrect conclusions), a randomized trial may not only be ethical, but could be considered ethically necessary. What the limited evidence to date does reveal is that regardless of feeding method, patients with end-stage dementia have a terminal condition with a limited life expectancy (13). However, it is important to realize that younger patients, those with less co-morbidities, and those with milder dementia, do not necessarily fall into the same risks and poor outcomes as those with end-stage or terminal dementia (14). Thus, until data from RCTs do become available, providing decision makers with a realistic set of expectations and outcomes, as well as risks associated with PEG placement in this setting, will allow an informed decision to be made within the context of any advanced directives, or cultural, personal, and ethical beliefs.

There is a need for a balanced approach to discussions surrounding PEG placement. The available literature has raised our awareness that further study is necessary to establish the risk-to-benefit ratio of enteral feedings and feeding tube placement in different clinical scenarios. In an increasingly elderly population with increased incidence of complications of PEG placement, particular attention should be paid to protocols that may lower the risks (15). Recent research suggests that the use of nasogastric feedings for a longer period before a decision is made to place a PEG may be advantageous (16,17). In addition, clinicians should not wait until patients achieve a state of (continued on page 37)
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severe malnutrition before the decision is made to initiate enteral feedings. Those patients with existing malnutrition may need to have severe protein-calorie malnutrition reversed before undergoing elective procedures in order to reduce the complication rate of PEG placement. Future studies that would seek to define the risk-to-benefit ratio of enteral feeding or feeding tube access will need to document the protocols and precautions used in enteral tube placement, as well as the protocols used for enteral feeding so that clinicians can evaluate if the study conditions translate to their actual practice settings.

There is currently no data to support the contention that improved techniques or protocols for PEG placement could change the ultimate outcome of patients, but future research should evaluate this question. Research using oropharyngeal disinfectants, antibiotic regimens and innovations such as use of overtubes during PEG placement may have particular application for an increasingly elderly and compromised population (18). Methods to reduced morbidity and mortality from nasogastric tubes such as fluoroscopic guidance, or devices to detect CO₂ during N-G tube placement decrease the risks associated with inadvertent nasogastric placement into the airway (19,20).

Discussion of the limitations of PEG placement is of paramount importance in the setting of a medical system that encourages increasing use of PEG tubes in populations where there is not strong evidence of outcome benefits. The limitations inherent in the observational, retrospective, or quasi-randomized data that is available limit the strength of the conclusions that can be generated regarding enteral feeding or PEG placement in these patient populations. Non-randomized studies should not be used to generate cause and effect statements, especially when counseling vulnerable populations in what can be life-and-death decisions. Further research is needed to evaluate protocols that will minimize the risks and maximize the benefits for those patients who cannot safely meet their basic nutrition needs via oral intake.

Allowing patients and decision-makers to incorporate unbiased, objective information alongside their individual cultural, personal and religious beliefs is not ambivalence, nor functioning as a technician; it is simply telling the full truth as best we know it—it is the essence of implementing the practice of evidence-based medicine.

References