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CRC – IRB Proposal
November 21, 2012

The Effect of an Educational Supplement for Surrogates on the Rate of PEG Tube Placement in Patients with Advanced Dementia

A. Study Purpose and Rationale

Approximately 4 million people in the United States suffer from dementia with numbers projected to increase to 13.2 million by year 2050.[1,2] Dementia is a leading cause of morbidity in the elderly and one of the main causes of death in the U.S. Unlike the dying process during acute illness, patients with advanced dementia experience a gradual and prolonged cognitive and functional decline, with the final stages of the disease marked by dysphagia and poor oral intake in nearly 90% of patients.[3] Patients develop indifference and resistance to food, in addition to failure to appropriately coordinate the act of chewing with subsequent swallowing of the food bolus. This leads to weight loss, malnutrition, aspiration, and recurrent hospitalizations from the nursing home, faced with the critical and controversial treatment decisions regarding feeding (ie. tube feeding versus hand feeding).

After percutaneous endoscopic gastrostomy (PEG) tubes were first introduced in the early 1980s for feeding children with brain damage, they became an increasingly common procedure for adult patients who are unable to swallow or maintain adequate nutrition. For decades they have been routinely utilized for long-term feeding in the elderly with cognitive impairment. The perceived benefits by physicians and surrogate decision makers included improved survival, improved quality of life, better nutritional status, and reduced risk of complications such as aspiration pneumonia. However, recently there has been a growing body of literature and studies questioning the benefit of feeding tubes in patients with advanced dementia. Many studies, including a recent Cochrane review, have found that PEG tubes do not prolong life or increase survival rates.[4-8] Feeding tubes have not been shown to improve nutritional status, weight gain, overall function, or wound healing. They also do not decrease the risk of aspiration and may actually lead to increased rate of aspiration pneumonia.[4,6,9,10] Furthermore, the quality of life of patients may be adversely affected due to the known complications associated with PEG tube placement including aspiration, peritonitis, hemorrhage, tube migration, gastrocolocutaenous fistula, and wound infection. For patients with dementia, they are more likely to pull the PEG tube causing them to dislodge, requiring re-admissions for PEG replacement, frequent use of physical restraints, and deprivation of the social interaction and pleasure surrounding meals.[4,11]

Despite the mounting evidence discouraging the use of PEG tubes in advanced dementia patients, they are still being placed with high frequency. Currently, over 200,000 PEG tubes are placed annually in the United States[12] with approximately 30% of them in patients with dementia[13], and the prevalence of PEG tubes among nursing home residents with advanced cognitive impairment remains high between 18% - 40% [3,14,15]. Multiple studies have investigated the factors leading to high rates of PEG placement and identified the current barriers to decreasing the procedure rate in the dementia population. Results found a tenfold variation in the prevalence of PEG tubes in those with dementia across the

United States, with New York being among the highest. This discrepancy was found to be correlated to regions with higher rates of health care transitions.[17] Also, approximately 75% of PEG tubes are inserted in acute-care settings, with higher rates occurring in larger hospitals with high ICU use.[18] Current barriers to decreasing PEG tube placement rate include the physician's knowledge of the current literature, in addition to personal beliefs regarding tube feeding and advanced dementia. Additionally, the caregivers of those with advanced dementia are confronted with this difficult decision, however are not equipped with the knowledge of chronic enteral feeding. Families struggle with the decision due to the widely held notion that eating is part of caregiving, with growing concern that their loved one is loosing weight and may suffer from hunger or thirst. Unfortunately, research suggests that surrogates are offered little information to answer these questions and many physicians only address procedural risk without discussing long-term outcomes or alternatives such as hand feeding. Lastly, the referring physician faces outside pressures including reimbursement and influences from secondary entities including consultants, nutritionists, and the nursing home.[19,20]

Two prior studies have investigated the impact of educational interventions to reduce the rate of PEG tube placements in patients with advanced dementia. Campbell et al. designed an intervention for physicians, consisting of explicit recommendations to withhold PEG tube and provide advice about PEG tube non-benefit to the referring physician. No patients in the experimental group received a PEG tube, however the difference was not statistically significant.[21] Swaminath et al. initiated both a physician and patient/surrogate education and counseling intervention led by geriatricians. In this study there was a statistically significant 50% decline in the rate of feeding tube placement associated with the intervention.[22] Both of these studies improved physician awareness and were designed as retrospective chart reviews, comparing records before and after the intervention. Currently, there are no randomized control trials looking at an intervention that is family focused to reduce the rate of PEG tube placements, given the significant weight that is placed on the surrogate to make the final decision. The purpose of this study will be to investigate the effect of an educational DVD designed for surrogates, illustrating the short and long-term risks, benefits, and alternatives of PEG tube placement for patients hospitalized with advanced dementia. This intervention, developed to aid in family decision-making, may serve as a replicable tool to potentially improve the informed consent process and end-of-life care across hospitals.

B. Study Design and Statistical Analysis

This study is a randomized-controlled trail measuring PEG tube placement rates in patients with advanced dementia who's surrogate views an educational PEG tube DVD compared to those who do not view the DVD. The investigation will not impact or make changes to the current practice of physician-family discussions, and both groups will undergo these standard discussions at the discretion of the primary team. The study subject population will be drawn from adult patients who are admitted to CUMC with advanced dementia. For this investigation the Functional Assessment Staging Tool (FAST), a well-validated standardized tool to evaluate stage of dementia, will be utilized with a score ≥ 7 indicating advanced dementia (Appendix 1).[23] The patients enrolled in the study will include those referred for PEG tube placement or who are undergoing feeding decisions with PEG as a possibility. The patients will then be randomized into the two group arms, those with the

DVD viewing for the surrogate/family and those without the DVD. The primary team will be blinded as to which arm the patient is randomized, to prevent any bias that may influence the standard discussion. After the primary team conducts the standard discussion, the team will notify a research assistant who will accompany the surrogate/family members to a conference room. Those randomized to the DVD arm, will view a 20-minute informational DVD addressing the risks, benefits, and alternatives to PEG tube placement in patients with advanced dementia. The video will discuss value-neutral information regarding chronic enteral feeding through PEG tube and address common family concerns such as survival benefit and quality of life including the lack of hunger and thirst sensation at the end of life. The DVD will be screened by a panel of internists, geriatricians, gastroenterologists, and a medical ethics member for validity and appropriateness in its content. If a patient's advanced directive indicates health care proxy or power of attorney, that person must be present during the DVD viewing. If not, then the health care surrogate is required to be present. Other family members and friends are also welcome to the viewing. Both groups will answer a questionnaire to gather information on the impact and benefit of the DVD, in addition to assessing our current family-physician discussions.

In this study, the primary outcome will be PEG tube placement or no PEG tube placement prior to discharge. Secondary outcomes include analyzing the family's perception of the video and the current family-physician discussions in CUMC. Patients baseline characteristics will also be recorded including: age, gender, race, religion, designated health care proxy, code status/advanced directives, patient's admitting diagnosis, hospital length of stay, disposition (death, home, long-term care, hospice referral), and consultations during hospital stay (nutritionist, speech-language pathologist, geriatrician, gastroenterologist, surgeon, and palliative care including their recommendations regarding PEG tube placement). Between group differences in baseline characteristics will be analyzed using a chi-square test for categorical variables and t-test for continuous variables. Subgroup analysis will be performed for any possible confounders found with significant differences between groups.

Based on the data in the literature, an incidence of approximately 10% of patients with severe dementia undergo PEG tube placement in New York [24], so for our power calculations we will use this value to approximate the proportion of PEG tubes placed in the control group. Previous studies with multidisciplinary intervention, found a 50% decline in the rate of feeding tube placement.[22] Given the less extensive intervention we are proposing for our study, we are aiming for a 40% rate reduction in order to have significant clinical impact. Using a chi-square test analysis with 80% power and alpha = 0.05, with the PEG tube placement rates of 10% and 6% in the control and DVD arms respectively (effect size of 4%) the number of patients required for each group n=770, total n = 1,540.

C. Study Procedure

As part of the study, no procedures will be utilized. The PEG tube procedure is part of a subject's clinical management outside of the study. Percutaneous endoscopic gastrostomy (PEG) is an endoscopic medical procedure during which a tube is passed into the stomach through the abdominal wall, as an alternative to surgical gastrostomy insertion. The

technique takes approximately 20 minutes and requires mild sedation. The subject may experience post-procedure discomfort that is managed with pain medications. Possible complications are reviewed in Section A. Study Purpose. The standard procedure will not be altered in any way or affected by the study.

During the calendar year 2011 the number of PEG tube placements documented on NYP-CUMC Provation (electronic endowriter) was approximately 300. Approx. 30% of all PEG tubes are placed in patients with dementia[13], resulting in 90 per year at CUMC. With a 10% incidence rate in New York[24] of PEG tubes placed in those with advanced dementia, this results in approximately 900 study subjects per year. To reach total n = 1,540, the likely study duration would be 21 months. The duration of each subject's participation extends the length of the patient's hospital stay.

D. Study Drugs
None

E. Medical Device
None

F. Study Questionnaires
In the educational DVD group, the surrogate decision maker will be asked to fill out the following questionnaire to evaluate the effectiveness off the video:

Please circle the statement that best describes how helpful the video was in making your decision about PEG tube placement:

1. *The video was very helpful in making my decision*
2. *The video was somewhat helpful in making my decision.*
3. *The video was not helpful because the doctor already discussed the presented information.*
4. *The video was not helpful because my mind was already made up about my decision.*

All patients in both the DVD group and control group will be asked to fill out the following questionnaire evaluating the standard discussion with the physician:

Please circle the statement that best describes the discussion you had with the doctor about PEG tube placement.

1. *The discussion was very helpful in making my decision.*
2. *The discussion was somewhat helpful in making my decision.*
3. *The discussion was not helpful because my mind was already made up about my decision.*
4. *There was no discussion about PEG tube placement –or- I do not recall the discussion.*

Please answer the following questions.

1. The doctor discussed alternatives to PEG tube placement. Yes no unsure
2. Risks of PEG tube placement were discussed. Yes no unsure
3. The doctor made a final recommendation. Yes no unsure

If yes, the recommendation was: *For PEG tube* *Against PEG tube*

F. Study Subjects:
Inclusion criteria:

- Adult patients admitted to CUMC with advanced dementia, using FAST (Functional Assessment Staging Tool) >= 7
- Patients referred for PEG tube placement
- Patients with eating difficulties undergoing treatment decisions regarding feeding with PEG tube as a possibility

Exclusion criteria:

- Advanced directives indicating no artificial hydration and nutrition
- Prior PEG tube placement or current PEG tube in place
- PEG placement for oropharyngeal, laryngeal, or esophageal malignancy, for chronic gastric decompression, or for bowel obstruction.
- Patients without a surrogate or health care proxy present to make medical decisions.

H. Recruitment of Subjects
Multiple departments within NYP-CUMC, including Dept. of Medicine, Gastroenterology, Geriatrics, and Palliative Care, will be informed of the study. The attendings and house staff will be requested to identify patients who meet the inclusion criteria of the study. The primary team will assess if the patient is suitable for the study and then obtain permission from the family member(s) to discuss the study with the research team. The research team will be notified and then approach the family member(s) to explain the study and obtain consent for enrollment in the study. After the primary team completes the physician-patient discussion, the research assistant will be paged to then escort the family member(s) to the conference room.

I. Confidentiality of Study Data
All study subjects will be de-identified with a unique code linked to each medical record number. All study data will be stored in a secure location accessible only to investigators.

J. Potential Conflict of Interest
None

K. Location of the Study
The study will take place at New York Presbyterian Hospital – Columbia University Medical Center, specifically on adult inpatient units.

L. Potential Risks
Potential risks include discomfort and inconvenience while viewing the informational DVD. There may be discomfort in learning about PEG tube placement and complications. This may result in heightened pressure or anxiety associated with the decision process. In the control group, there may be a higher rate of PEG tube placement, resulting in potential complications and discomforts associated with this treatment option.

M. Potential Benefits
Subjects may or may not benefit as a result of participating in the study, however potential benefits include a more comprehensive discussion of the risks, benefits, and alternatives of PEG tube placement for feeding. This may lead to a more complete informed consent process and an improvement knowledge base before making the decision. Potentially, a decreased rate of PEG tube placements may lead to an overall less complications and improved quality of life.

N. Alternative Therapies
The experimental therapy utilized is an educational DVD to supplement the standard physician-family discussions. Currently the main alternative and standard of care are the discussions that will not be altered as part of this investigation. Other alternatives for providing patients with information include pamphlets and written materials. The advantage of a physician discussion is the ability to make it patient specific and interactive, allowing for questions and answers. The disadvantage is the varying degree of knowledge and opinions of each physician, in addition to the limited time physicians have to spend with families. The advantage of written materials include the ability to review the material multiple times, however disadvantages include the propensity to not read the material and the potential for not understanding the material.

O. Compensation to Subjects
There will be no compensation to subjects provided in this study.

P. Costs to Subjects
There will be no costs to subjects participating in this study.

Q. Minors as Research Subjects
There will be no minors enrolled in this study.

R. Radiation or Radioactive Substances
There will be no radiation or radioactive substances used in this study.

Appendix 1.

Functional Assessment Staging of Alzheimer's Disease. (FAST)©

STAGE	SKILL LEVEL
1.	No difficulties, either subjectively or objectively.
2.	Complains of forgetting location of objects. Subjective word finding difficulties.
3.	Decreased job function evident to co-workers; difficulty in traveling to new locations. Decreased organizational capacity.*
4.	Decreased ability to perform complex tasks (e.g., planning dinner for guests), handling personal finances (forgetting to pay bills), difficulty marketing, etc.
5.	Requires assistance in choosing proper clothing to wear for day, season, occasion.
6a.	Difficulty putting clothing on properly without assistance.
b.	Unable to bathe properly; e.g., difficulty adjusting bath water temperature) occasionally or more frequently over the past weeks.*
c.	Inability to handle mechanics of toileting (e.g., forgets to flush the toilet, does not wipe properly or properly dispose of toilet tissue) occasionally or more frequently over the past weeks.*
d.	Urinary incontinence, occasional or more frequent.
e.	Fecal Incontinence, (occasional or more frequently over the past week).
7a.	Ability to speak limited to approximately a half dozen different words or fewer, in the course of an average day or in the course of an intensive interview.
b.	Speech ability limited to the use of a single intelligible word in an average day or in the course of an interview (the person may repeat the word over and over.
c.	Ambulatory ability lost (cannot walk without personal assistance).
d.	Ability to sit up without assistance lost (e.g., the individual will fall over if there are no lateral rests [arms] on the chair).
e.	Loss of the ability to smile.

STAGE••_____

*Scored primarily on the basis of information obtained from a knowledgeable informant and/or caregiver.

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