# How should this patient with repeated aspiration pneumonia be managed and treated?—a proposal of the Percutaneous ENdoscopIc Gastrostomy and Tracheostomy (PENIIGhT) procedure

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**Abstract:** Cerebrovascular accident (CVA) is commonly seen among the elderly with a substantial proportion of patients suffering from long-term dysphagia and/or an inability to protect their airway. This potentially imposes on them an increased risk of malnutrition and aspiration pneumonia. In this article, we present a patient with malnutrition and dysphagia secondary to CVA. We propose a procedure for which we will name the Percutaneous ENdoscopIc Gastrostomy and Tracheostomy (PENIIGhT) procedure for placement of percutaneous endoscopic gastrostomy (PEG) and tracheostomy tube (TT) at the same time. The medical literature was systematically reviewed for both PEG and tracheostomy, aiming to provide the state-of-the-art evidence for clinical use of the PENIIGhT procedure. In clinical practice, the PENIIGhT procedure is indicated for patients who are expected to have prolonged swallowing disturbance and mechanical ventilation. Some prediction tools and scores can be helpful to identify such groups of patients. Patients with poor neurological outcomes who require prolonged maintenance of life are also good candidates for the PENIIGhT procedure.

**Keywords:** Percutaneous ENdoscopIc Gastrostomy and Tracheostomy (PENIIGhT); dysphagia; stroke; percutaneous endoscopic gastrostomy (PEG)

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#### **Clinical scenario**

An 82-year-old man with dysphagia due to cerebrovascular accident (CVA) presented to the emergency department with complaints of cough and fever for 3 days. The clinical history and imaging confirmed aspiration pneumonia presumably due to impaired airway protection. In addition to his acute presentation, the patient appeared malnourished. Further history revealed that the patient had not been able swallow food normally since his CVA event. The pneumonia progressed rapidly to hypoxic respiratory failure requiring endotracheal intubation and mechanical ventilation. A nasogastric feeding tube was placed within 24 hours after intubation and enteral nutrition was initiated. After 10 days treatment, the patient's fever resolved and he was able to be weaned to minimal ventilator settings. Imaging revealed resolution of his pulmonary infiltrates and blood routine profile had returned normal. Despite these improvements, his underlying dysphagia remained unchanged. How should this patient be managed and treated? Should we simply discharge him, leaving him at high risk of aspiration pneumonia and malnutrition?

#### Why is this question important?

Dysphagia resulting from central nervous system (CNS)

disease is common (1-3). The most common causes of CNS driven dysphagia are ischemic and hemorrhagic CVA (4), intracranial infection, degenerative diseases and autoimmune disorders affecting the CNS. With the aging population, a substantial proportion of elderly patients are at risk for cerebrovascular disorders, which may greatly compromise the autonomic nervous system of the oropharynx (i.e., bulbar function) (5,6). Consequently, the passage of food along the digestive tract is compromised which can lead to recurrent aspiration and subsequent pneumonitis or pneumonia. Management of patients with chronic aspiration can be quite challenging and include nasogastric tube (NGT) feedings, percutaneous gastrostomy tube placement [percutaneous endoscopic gastrostomy (PEG)], jejunal tube placement and medical management. NGT placement has been a longstanding technique aimed at providing enteral nutrition for these patients. However, its adverse effects include nasal wing, chronic sinusitis, gastrooesophageal reflux (GER), and aspiration pneumonia. More recently, clinicians have adopted the use of PEG tube placement in an effort to overcome this problem, however PEG tube placement has not been shown to decrease aspiration events or mortality (7).

Patients with stroke or other CNS disorders may require tracheostomy tube (TT) placement. Data would suggest that approximately 1.3% of patients status-post CVA underwent TT (8). In some cases, patients with post-CVA may require airway protection due to compromised bulbar function, decreased airway protective reflexes, muscle weakness, and a weak cough. As a result, they cannot reliably clear secretions or maintain a patent airway (9,10). In this situation, TT placement allows for transition from mechanical ventilation (MV) to tracheal collar while maintaining airway patency. Placement of a TT also allows for direct access to the airway and improved suctioning from the lower airways (11). In addition, data suggests that patients are more comfortable with TT than with endotracheal intubation (12), allowing for earlier discontinuation of analgesia and sedation, which is helpful in facilitating patients to awaken, be weaned from ventilation, and begin early mobilization regimens (13,14).

The timing of PEG and TT placement remains controversial with evidence existing that PEG placement is often delayed. The time from onset of CVA and decision to insert PEG was 10 days, and the time between decision and PEG insertion was 12 days (4). Such delay may significantly impair nutritional status of stroke patients with dysphagia, as guidelines recommended early initiation of enteral nutritional support for the critically ill (15,16). There is also evidence 3721

that early tracheostomy (ET) can improve patient-important outcomes such as mortality, duration of MV and ICU length of stay (14), however this remains controversial (17). Based on this we propose the combined placement of PEG and TT in the same setting as the Percutaneous ENdoscopIc Gastrostomy and Tracheostomy (PENIIGhT) procedure. This procedure is indicated for patients with recurrent aspiration pneumonia due to bulbar dysfunction or coma. The idea to perform PEG and tracheostomy simultaneously is not new (18-20), which has been shown to expedite recovery of these patients (21). In the next section, we systematically review the literature to obtain the stateof-the-art evidence to support our concept.

#### Who will benefit from the PENIIGhT procedure?

Patients with persistent swallow disturbances for 1 month after the onset of stroke are eligible for insertion of PEG. Concomitantly, the patient should have impaired cough reflex that they cannot reliably clear secretions from the airway. In clinical practice, high gugging swallowing screen (GUSS) grade (22), dysphonia, an abnormal gag reflex, impaired voluntary cough, incomplete oral-labial closure, a high NIHSS score, or cranial nerve palsies should alert the care team to the risk of dysphagia (23-25). However, a preserved gag reflex may not indicate safety with swallowing (26). The clinical scenario described earlier is often encountered in elderly patients after CVA.

We suggest that the criteria in selecting patients for the PENIIGhT procedure are the need for long-term MV and airway protection and swallowing disturbance. In patients with severe traumatic brain injury, Mandaville and colleagues established a model to predict probability of long-term (>6 weeks) swallowing disturbance. The model contains variables age, Initial Ranchos Los Amigos (RLA) score, TT and initial aphonia (27). A mathematical equation was derived for the prediction purpose:

 $\exp[-0.097 + 0.03 \times age - 0.497 \times RLA + 1.846 \times trach + 0.786 \times aphonia]$ [1]  $1 + \exp[-0.097 + 0.03 \times age - 0.497 \times RLA + 1.846 \times trach + 0.786 \times aphonia]$ 

More recently, Faigle and colleagues developed the GRAVo scoring system for prediction of the need for PEG placement in patients with intracranial hemorrhage. The name GRAVo represented the four components of the scoring system: Glasgow coma scale (GCS), Race, Age and Volume. The authors stated that "Points for the GRAVo score were assigned as follows: 2 points for GCS  $\leq 12$ , 1 point for black race, 2 points for age >50 years, and 1 point for ICH volume >30 mL, with a maximum of 6 points. The PEG placement rates for

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Search strategy				
Search (dysphagia[Title/Abstract]) OR swallowing disorder[Title/Abstract]	21,437			
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 Table 1 Search strategy in PubMed

patients with a score of 0 to 1, 2 to 3, and 4 to 6 were 8.7%, 19.6%, and 63.0%, respectively." (28). There are many other tools being used for prediction of PEG placement, and components of these tools included age, 24-hour National Institutes of Health Stroke Scale, race and body mass index (29-31).

Similarly, many efforts have been made to predict patients who need tracheostomy (32,33). The stroke-related early tracheostomy score (SET score) was estimated within 24 hours after admission and consisted of neurological function, neurological lesion and general organ function/ procedure (11). The TRACH Score was defined by radiological scale (RScale) and Glasgow Outcome Score (GOS) (34). However, there is no tool for the prediction of patients requiring both tracheostomy and PEG, which is an area in need of further investigations.

#### **Evidence for PEG**

#### Search strategy and study selection

Electronic database of PubMed was searched from inception to September 28, 2016. There was no language restriction. The searching strategy consisted of key terms related to the PEG, dysphagia, and randomized controlled trials (RCTs). Detailed searching strategy in PubMed was shown in *Table 1*.

Studies that met the following criteria were considered eligible: (I) RCTs investigating efficacy and safety of PEG; (II) the study was conducted in adult patients with dysphagia. The following citations were excluded: (I) animal and/or experimental studies; (II) observational studies; (III) study setting was in the ward or community; (IV) reviews and commentaries.

If there were systematic reviews in the field, we adopted the results of the most updated systematic review as the evidence. The use of available systematic reviews might help to avoid repeated work, without compromising the quality of the present review. We also tried to identify eligible articles published after the search time period used in the most updated systematic review.

#### Results

The initial search identified 19 citations and 1 systematic review (7). There are no new RCTs published after that time. As a result, we adopted this systematic review as the most updated evidence.

A total of 11 RCTs were included in the systematic review (Table 2) (35-45). Four trials explicitly stated they included patients with CVA complicated by dysphagia (36,38,41,42). Overall, the intervention failure occurred less frequently in the PEG group than in the NGT group (RR: 0.18; 95% CI: 0.05 to 0.59). However, there was no difference on mortality (RR: 0.86; 95% CI: 0.58 to 1.28), or aspiration pneumonia (RR: 0.70; 95% CI: 0.46 to 1.06). With respect to nutritional status, PEG was able to improve mid-arm circumference (MD: 1.16; 95% CI: 1.01 to 1.31) and level of serum albumin (MD: 6.03; 95% CI: 2.31 to 9.74). The intervention favored PEG over NGT on quality of life measures (EuroQol, RR: 0.03; 95% CI: 0.00 to 0.29), discomfort (RR: 0.03; 95% CI: 0.00 to 0.29), altered body image (RR: 0.01; 95% CI: 0.00 to 0.18) and social activities (RR: 0.01; 95% CI: 0.00 to 0.18).

#### Comments

Malnutrition is common among patients post-CVA, and has been shown to be an independent predictor of poor outcomes (46-48). Thus the prompt initiation of enteral nutrition is of paramount importance. Current evidence and practice favors PEG over NGT placement for patients with swallowing disturbances. Although some major outcomes such as mortality, aspiration pneumonia cannot be reduced (7). Placement of a PEG tube has also been show to improve the nutritional status and quality of life in patient with chronic aspiration secondary to dysphagia (49). The timing of PEG insertion is another important issue that requires consideration. Several guidelines have recommended PEG placement (50-53), but there is no specific recommendation

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Studies	Participants	Exclusion	Sample size	Follow-up
Baeten, 1992 (35)	Neurological problem; ENT tumors; surgical problem	Contraindication for either method	90	17.9±19.9 days
Bath, 2000 (36)	Ischemic and hemorrhagic stroke	Orogastrointestinal disease concurrent severe illness, coagulopathy, pre-morbid dependency, severe dementia, psychiatric illness	19	3 months
Corry, 2008 (37)	Head and neck tumor	Refusal to participate	42	6 months
Dennis, 2005 (38)	Recent stroke (<7 days)	Subarachnoid hemorrhage	321	6 months
Douzinas, 2006 (39)	Patients on MV for >10 days; or persistent VAP	Unstable hemodynamic state, administration of morphine, atropine, theophylline, barbiturates, and cisapride, and a past history of GER or hiatal hernia	39	20 days
Elbadawy, 2014 (40)	Closed traumatic severe brain injury in need for prolonged MV who continued to have a GCS <8 after initial stabilization	History of known respiratory disease, thoracic trauma, multiple traumatic injuries including abdominal or spinal trauma, massive or untreatable loculated ascites, previous abdominal surgery, uncorrected coagulopathy	60	NR
Hamidon, 2006 (41)	Patients with acute ischaemic stroke and persistent dysphagia for 7 or more days	NR	23	NR
Norton, 1996 (42)	Acute CVA with persisting dysphagia for 8 or more days, in need for sedation and prolonged mechanical ventilation	Patients with a previous history of gastrointestinal disease which would preclude siting a gastrostomy tube or who were unfit for upper gastrointestinal endoscopy and IV sedation	30	6 weeks
Park, 1992 (43)	Longstanding (4 weeks or more) dysphagia due to neurological disease	Dementia; mechanical lesions causing obstruction of the oesophagus or stomach; active intra-abdominal inflammation including inflammatory bowel disease or pancreatitis; history of partial gastrectomy, reflux oesophagitis, or intestinal obstruction; and presence of ascites, notable hepatomegaly, severe obesity, coagulopathy, untreated aspiration pneumonia, and major systemic disease including malignancy and respiratory, liver, or renal failure	40	28 days
Sadasivan, 2012 (44)	Patients with advanced stage 2 or 3 squamous cell carcinoma of the head and neck	Patients with early stage 1 or 2 head and neck cancer	100	6 months
Yata, 2001 (45)	Dysphagic patients	NR	82	NR

RCTs, randomized controlled trials; PEG, percutaneous endoscopic gastrostomy; NGT, nasogastric tube; ENT, ear, nose and throat; MV, mechanical ventilation; VAP, ventilator-associated pneumonia; GER, gastrooesophageal reflux; GCS, Glasgow coma scale; NR, not reported; CVA, cerebrovascular accident.

regarding the timing of PEG placement. Although PEG placement is considered a low risk procedure, PEG placement at acute phase is associated with worse outcomes in comparison to NGT (54,55). Thus, in our experience 3 or 4 weeks can be allowed for the recovery of swallowing ability before considering PEG.

#### **Evidence for TT placement**

#### Search strategy and study selection

Electronic database of PubMed was searched from inception to September 28, 2016. There was no language restriction. The search strategy consisted of key terms related to the tracheostomy and RCTs.

Studies that met the following criteria were considered eligible: (I) RCTs investigating the timing of tracheostomy; (II) the study was conducted in adult patients requiring MV and/or airway protection. The following citations were excluded: (I) animal and/or experimental studies; (II) observational studies; (III) study setting was in the ward or community; (IV) reviews and commentaries.

If there were systematic reviews in the field, we adopted the results of the most up-to-date systematic review as the evidence. We also tried to identify eligible articles published after the search time period used in the most updated systematic review.

#### Results

The initial search identified 307 citations. We identified one systematic review from Cochrane database which focused on the timing of tracheostomy in the critically ill (56).

In critically ill patients, Andriolo and colleagues identified eight RCTs (56). They defined ET as 2 to 10 days after intubation, and late tracheostomy (LT) was defined as >10 days after intubation. The pooled results showed that ET as compared with the late group had lower risk of death (RR: 0.83; 95% CI: 0.70 to 0.98; P=0.03). The number needed to treat for an additional beneficial outcome (NNTB) was around 11. Also, the probability of discharge from the ICU was higher at day 28 in the ET group (RR: 1.29; 95% CI: 1.08 to 1.55; P=0.006; NNTB  $\approx$ 8). In systematic review restricting to patients with acute brain injury, McCredie VA employed the same definitions of early and LT and found that ET reduced long-term mortality (RR: 0.57; 95 % CI: 0.36 to 0.90; P=0.02). For other secondary outcomes, ET reduced ICU length of stay (MD: -2.55 days; 95% CI: -0.50 to -4.59; P=0.01; n=326) and duration of MV (MD: -2.72 days; 95 % CI: -1.29 to -4.15; P=0.0002; n=412) (14). However, the timing (early versus late) TT placement is controversial. There is evidence from systematic reviews that ET had no significant effect in clinical outcomes compared to that of the LT/prolonged intubation (PI) group (57,58). Others suggested that ET may shorten the duration of sedation (17). In patients with subarachnoid hemorrhage ET was associated with fewer respiratory adverse events (59). Given the conflicting results of current studies, more investigations are needed, with standard definition of timing and homogeneous study population.

#### Comments

The beneficial effects of ET versus LT are controversial. There is evidence suggesting that early (<10 days) tracheostomy is beneficial for patients intubated and expected need of MV for at least 2 weeks (60). However, others showed no significant effect in clinical outcomes with ET versus LT. For some elderly stroke patients, they may not need MV but tracheostomy is required to keep a patent airway.

#### Conclusions

Approximately 10% of the patients requiring long-term MV may eventually undergo tracheostomy (61-63), with slightly more than half also needing PEG placement for enteral nutrition (64). Although there is evidence that early PEG placement is associated with increased risk of death, for a subgroup of patients with recurrent aspiration pneumonia after stroke the use of the PENIIGhT procedure may not only aid in providing adequate enteral nutrition but also in the suctioning of airway secretions. For some patients with dismal neurological outcome, the family members can never make a decision to stop treatment. The PENIIGhT protocol may be able to aid in expediting patient transfer to other levels of care (65). Some experts proposed that placement of both PEG and TTs at the same time had the potential for decreased costs, anesthesia exposure, procedural times, ventilator times, and ICU days (64). That said, the PENIIGhT protocol has not been validated by well-designed RCTs, and requires further investigation (66). Selection of appropriate patients is the core to making the PENIIGhT protocol clinically useful. Patients should be expected to have prolonged swallowing disturbance

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and mechanical ventilation. Some prediction tools can be helpful to make clinical decision and consultation. Patients with poor neurological outcome who require prolonged maintenance of life are good candidates for the PENIIGhT procedure.

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## Footnote

*Conflicts of Interest*: The authors have no conflicts of interest to declare.

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