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Original Article

Percutaneous radiologic gastrostomy in patients with amyotrophic lateral sclerosis: A safe and effective technique

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ABSTRACT

Background: Percutaneous radiologic gastrostomy (PRG) was considered as an alternative technique for long-term enteral nutrition, and the current study is aimed to evaluate the feasibility and safety of this technique in patients with amyotrophic lateral sclerosis (ALS) at a single medical center. **Methods:** From July 2017 to October 2020, a total of 14 patients underwent PRG with ALS were included in this retrospective study with a median age of 64.0 years, and 78.6% were male. The procedure comprised a dilation of the stomach via a nasogastric catheter, followed by puncture and gastrostomy tube placement under fluoroscopic guidance. The technical success rate and clinical outcomes were recorded over 3 months following the procedure.

Results: The technical success rate was 100%. During the follow-up period, minor complications were reported in 2 of patients (14.3%) including superficial skin infection and early tube block. Neither major complications nor mortality were observed. Body mass index of the patients increased significantly from $16.4 \pm 2.1 \text{ kg/m}^2$ to $17.1 \pm 2.0 \text{ kg/m}^2$ ($t = -13.77$; $P < 0.001$), and the albumin level increased significantly from $37.5 \pm 2.3 \text{ g/L}$ to $41.8 \pm 1.6 \text{ g/L}$ ($t = -8.82$, $P < 0.001$).

Conclusion: PRG is a relatively safe and effective method for ALS patients, and deserves widespread clinical acceptance.

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Keywords: Amyotrophic lateral sclerosis; Deglutition disorders; Gastrostomy; Interventional radiology

Introduction

Amyotrophic lateral sclerosis (ALS) is a neurodegenerative disorder characterized by a progressive decline of motor functions at the spinal and bulbar level, which probably causes malnutrition, aspiration pneumonia, and finally contributes to the death of patients due to the atrophy of respiratory and medullary muscle.¹

The timely enteral nutrition could provide sufficient nutrition supply and thus improve the quality of life and survival time.^{2–4} A gastrostomy tube can be placed surgically, endoscopically, or fluoroscopically. The surgical approach is rarely performed because of the much invasive techniques, complication rates, and cost.^{5,6} Percutaneous endoscopic gastrostomy (PEG) was traditionally recommended for tube insertion, nevertheless, this procedure has its limitations in patients with respiratory impairment and masseter spasticity.^{7,8} Recently, percutaneous radiologic gastrostomy

(PRG) was considered as a simple alternative technique for enteral nutrition with less stimulation of the pharynx and no sedation requiring.^{5,9,10} Several studies reported that PRG has been shown to provide a similar success rate as PEG, with potential benefits of increased patient convenience and decreased procedure times and equipment costs.^{11,12} However, the reports on using PRG for ALS patients were limited, and this technique has not gained enough clinical acceptance, thus, further studies on this technique for ALS patients are required.

The present study is aimed to evaluate the feasibility and safety of PRG tube placement in ALS patients at a single medical center over 3 months of follow-up.

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Table 1 General Characteristics of the Study Patients

Characteristic	PRG (n = 14)
Age (yr)	64.0 ± 18.0
Sex (male : female)	11 : 3
Disease period (mo)	24.8 ± 10.0
Weight loss from diagnosis	
< 10%	0 (0)
10%–20%	9 (64.3)
> 20%	5 (35.7)
Body mass index (kg/m ²)	16.4 ± 2.1
ALSFRS-R score	22.4 ± 3.3
Forced vital capacity (%)	
> 50	2 (14.3)
30–50	8 (57.1)
< 30	4 (28.6)
Preoperative albumin (g/dL)	37.5 ± 2.3
Underlying disease	
Hypertension	4
Cardiovascular disease	1
Nephritis	2

Values are presented as mean ± standard deviation, number only, or number (%).

PRG, percutaneous radiologic gastrostomy; ALSFRS-R, the revised amyotrophic lateral sclerosis functional rating scale.

Methods

Patients

This retrospective study has been approved by the institutional review board of the First Affiliated Hospital of Nanjing Medical University and the informed consent of the procedure was signed by every patient and the data collection consent was waived (IRB no. 2020-SR-200). Of the patients diagnosed with ALS, 14 patients who underwent PRG in our center from July 2017 to October 2020 were enrolled, excluding 2 patients with incomplete clinical data. Among them, 11 were male and 3 were female, and the median age was 64.0 years (range, 42–74 years). The mean disease period was 24.8 ± 10.0 months. The patient characteristics are summarized in Table 1.

Procedure for insertion

Before the procedure, all ALS patients were required to fast at least 6 hours. Procedures were performed by two interventional radiologists with over 10 years of experience under fluoroscopic guidance. No sedation was used and no prophylactic antibiotics were administered. As a preliminary, diazepam (10 mg) combined with raceanisdamine (10 mg) was injected intramuscularly to relieve the anxiety and gastrointestinal spasm of patients.

After that, the stomach was probed with a 0.035-inch guidewire and a 5-Fr catheter (Cook Medical, Bloomington, IN, USA) to allow air insufflation (300–600 mL) under fluoroscopic control. The abdomen was prepped and draped in a sterile fashion, and ultrasonography was used to confirm that no other organs such as the liver or transverse colon were intervening between the stom-

Fig. 1. The Funada gastrostomy device. It has two 20-gauge needles with a snare which selected for fish-hook or dropped stomachs and a 3-0 monofilament nylon suture. After penetrating, a snare is taken out through one needle and a nylon suture through the other needle is inserted into the snare. Then, the suture is caught by the snare and the device is pulled up while keeping it.

ach and the abdominal wall.

Local anesthesia was administered to the abdominal wall (2% lidocaine), and the puncture site (the mid-distal body of the stomach to avoid the gastric major arterial branches) was determined via fluoroscopic examination of the insufflated stomach. The two-needle Funada gastrostomy devices (Create Medic, Yokohama, Japan) were then used to penetrate the abdominal wall and gastric wall. The nylon suture is inserted via one needle and the suture is snared and pulled up via the other (Fig. 1). Afterward, a T-fastener gastrostomy via a single needle (Create Medic) was pierced vertically to access the gastric lumen, and the placement was confirmed with air aspiration and contrast injection. Finally, a 15-Fr gastrostomy tube (Create Medic) was advanced into the stomach through the sheath. The retention balloon was dilated by injecting 2 to 3 mL sterilized distilled water. Repeat contrast injection was used to confirm the tube placement (Fig. 2).

After the procedure, normal saline was infused intravenously to ensure proper hydration, and tubes were not used for 24 hours to deter against possible risk of cutaneous and intraperitoneal leakage. Next, a nutrient solution was given according to the pre-determined formula diet, and a semi-supine position was used to promote digestion and reduce aspiration. Besides, the tube should be flushed with clean water for 30 to 50 mL after each feed. Further imaging was only performed if clinically indicated, including suspicion of tube malfunctioning or dislodgement. Gastrostomy sutures were removed at 3 weeks when the access site was evaluated, and the replacement was performed every 6 months.

Follow-up and definition

Information of each patient was extracted from individual medical records and obtained by phone calls to patients, or primary care providers. The technical success, complications, and clinical outcomes were analyzed.

In the present study, technical success was accomplished when the gastrostomy tube was effectively placed into the stomach and the correct function of the feeding tube was achieved. Complications were subdivided into major and minor categories, which are described in Table 2. Major complications were defined as those requiring surgery or hospitalization, causing permanent adverse

Fig. 2. PRG with tube placement. The patient was a 46-year-old male with ALS. (A) A nasogastric tube was placed to allow air insufflation under fluoroscopic control; (B) the two-needle Funada gastropexy device was placed percutaneously to bring the anterior stomach wall into contact with the interior abdominal wall; (C) a T-fastener gastropexy via a single needle was used to access the gastric lumen; (D) a 15-Fr gastrostomy tube was placed and contrast was injected via the tube for confirmation. PRG, percutaneous radiologic gastrostomy; ALS, amyotrophic lateral sclerosis.

Table 2 Classification of Complications

Minor	Major
<ul style="list-style-type: none"> ◆ Superficial infection ◆ External leakage (not requiring repeat procedure) ◆ Tube blockage or migration (not requiring specific local treatment) ◆ Hemorrhage (not requiring suturing or transfusion) ◆ Pain (transient) 	<ul style="list-style-type: none"> ◆ Deep infection/bacteremia ◆ External leakage (requiring repeat procedure) ◆ Tube blockage or migration (requiring repeat procedure) ◆ Hemorrhage (requiring suturing or transfusion) ◆ Pain (persistent) ◆ Aspiration or peritonitis

sequelae, even death.¹³ Minor complications were defined as those requiring either minor or no treatment and resulting in no permanent sequelae.¹³ For clinical outcomes, we have investigated body mass index (BMI) and the albumin of patients at the end of the follow-up period.

Statistical analysis

All statistical analyses were conducted using IBM SPSS software ver. 19.0 (IBM Corp., Armonk, NY, USA). Normally distributed data were expressed as means $\pm$ standard deviations, while non-normally distributed data were presented as the inter-quartile range. Differences in measurement data were evaluated using the *t* test. Categorical data were presented as frequencies. A *P*-value <

Table 3 Technical Results (*n* = 14)

Variable	Value
Technical success rate (%)	100
Procedure duration (min)	20.0 (16.7)
Fluoroscopy time (min)	4.4 (2.2)
Duration of hospital stay (day)	2.0 (1.3)

Values are presented as mean (standard deviation).

0.05 was considered statistically significant.

Results

Technical and clinical results

In the present study, the technical success rate was 100%. The median procedure duration from nasogastric tube placement to gastrostomy tube placement was 20.0 minutes (range, 8.7–37.3 minutes). The median duration of radiation exposure was 4.4 minutes (range, 2.6–7.0 minutes). All patients were successful to feed within 2 days after the procedure, and the median duration of hospitalization was 2.0 days (range, 1–6 days) (Table 3). After the timely enteral nutrition, BMI of the patients increased significantly from 16.4 ± 2.1 kg/m² to 17.1 ± 2.0 kg/m² (*t* = -13.77, *P* < 0.001), and the albumin level increased significantly from $37.5 \pm$

Fig. 3. The changing level of plasma albumin.

2.3 g/L to 41.8 ± 1.6 g/L ($t = -8.82$, $P < 0.001$) (Fig. 3, 4).

Complications

During the follow-up period, no mortality and major complications were observed. Minor complications occurred in 2 of patients (14.3%). One case with superficial skin infection was treated with topical silver nitrate and the other one developed partially tube blockage within 1 month and was relieved by flushing with forceful saline (Table 4).

Discussion

This single-center study was designed to evaluate the short-term outcome of ALS patients after PRG placement. In the present study, we found that PRG is a safe and effective alternative option for enteral feeding. The technical success rate of the procedure was 100%, and the nutrition conditions of patients were improved with an increasing BMI and albumin level. No mortality and major complications were observed during the follow-up period. Moreover, the incidence of minor complications after the procedure was 14.3%, which was consisted of the range of 2.9% to 36.0% reported in the previous PRG studies.^{10,13–16}

ALS is a fatal syndrome that can lead to progressive weakness of the bulbar, limb, thoracic and abdominal muscles. The maintenance of adequate nutrition remains an important goal in the management of ALS.⁵ Enteral feeding is the preferred route of nutrition, as it provides greater immunological and nutritional benefits compared to parenteral feeding.^{17,18} Meanwhile, enteral access can facilitate the delivery of medications in these patients who are unable to swallow.¹⁹

Nowadays, percutaneous gastrostomy techniques have generally replaced an open surgical approach for the administration of enteral nutrition in patients with impaired swallowing and dysphagia.^{5,9,10} While the endoscopic approach was widely used, the procedure was not recommended in patients with moderate or severe respiratory impairment (that is, with a forced vital capacity of less than 50%).⁷ Meanwhile, Stavroulakis et al²⁰ reported that morbidity was 3.4% to 25% one month following PEG in ALS patients with worsening respiratory function. To overcome this limitation, the use of non-invasive positive pressure ventilation (NIPPV) would be vital.²¹ However, it is difficult for patients to adapt to NIPPV, as it needs prolonged training and is not well tolerated.

Interventional radiology has played a main role in the technical evolution of gastrostomy.^{13,22} The technical superiority of PRG

Fig. 4. The changing level of body mass index (BMI).

Table 4 Complications (n = 14)

Complication	Number
Minor complications	
Superficial skin infection	1
Partially tube blockage	1
Major complications or death	0

are as follow: (1) increasing patient convenience and decreasing procedure times and costs; (2) less risk of asphyxia and respiratory failure with no sedation requiring; (3) avoiding the gastrointestinal fistula for presenting the anatomical relationship directly; (4) undertaking patients who failed in PEG.^{23,24} Lee et al²⁴ reported that PRG is more advantageous than PEG because it avoids the insertion of a relatively large-bore endoscope orally. Moreover, previous studies also confirmed that PRG represents the technique of choice in ALS.^{1,10}

An important finding is that no adverse events of aspiration were reported. According to a previous study, aspiration occurred more frequently with PEG than PRG, and this may result from the need for more sedation and the endoscopic technique used during PEG. Moreover, major complications such as severe bleeding, severe infection, and tube dislodgement did not occur. Only two minor complications of superficial skin infection and early tube blockage were relieved by conservative treatment.

To our knowledge, several key points of the technique should be noted. First, make sufficient air insufflation to keep the stomach snug against the anterior abdominal wall to avoid penetrating the surrounding organs accidentally. Second, pay more attention to the puncture depth and avoid injuring the posterior wall of the stomach. Finally, pull the tube out of the abdominal wall with a certain tension to make the balloon stick close to the gastric wall to achieve the desired effect.

The present study had some inherent limitations. First, the sample size of the study is small and the follow-up time was 3 months, hence, further studies with more patients are required to confirm the long-term results. Moreover, there still needs a prospective study with a controlled comparison of the two techniques to fully define the role of PRG in the treatment of dysphagia in ALS patients.

We conclude that our retrospective study identified that PRG is safe and effective for the management of dysphagia in ALS patients, which deserves more clinical acceptance.

Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

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