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Upper Esophageal Sphincter Augmentation Reduces Pharyngeal Reflux in Nasogastric Tube-Fed Patients

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Abstract

Aspiration of gastric refluxate is one of the most commonly observed complications among long-term nasogastric tube (NGT) fed patients. Upper esophageal sphincter (UES) pressure barrier is the main defense mechanism against pharyngeal reflux of gastric contents.

Objective—To investigate the efficacy and safety of the UES assist device (UES-AD) in preventing gastric reflux through the UES in long-term NGT fed patients.

Methods—We studied ten patients (90.6±3.4 yrs, 4F) with dysphagia caused by stroke or dementia that were fed for 0.5–5 yrs (median 3 yrs) by NGT. External pressures of 20–30 mmHg were applied by using a handmade UES-AD, which was started two hours after the beginning of NGT infusion and was alternated between periods of two hours on and two hours off, for a total of 12 hours. Placement of the impedance sensors within the UES was guided by high-resolution manometry. Trans-UES and intra-esophageal reflux events were recorded by using 24 hour combined pH-impedance measurements.

Results—No aspiration pneumonia events were noted in the period one month before or during the study in any of the cohort. Baseline UES pressure averaged 17.5±9.4 mmHg and was increased to 38.9±11.9mmHg after application of UES-AD. Overall frequency of trans-UES reflux decreased significantly with UES-AD compared to without (0.8±0.9 vs 3.3±2.8, p<0.05 for the 12-hour study period). There was no effect of UES-AD on esophageal reflux events (7.4±4.4 vs 6.4±3.0, p>0.05).

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Conflict of interest: Dr. Reza Shaker is the inventor and patent holder of the Reza Band and has an interest in Somna Therapeutics.

Dr. Shaker had a major role in the study concept and design, interpretation of the data, funding and supervision of the project, and development of the manuscript. Dr. Jiao had a major role in the study concept, data acquisition, and preparation of the manuscript. Dr. Mei had a major role in the study concept, data acquisition, interpretation of data, and preparation of the manuscript. Dr. Sanvanson had a major role in the study concept and preparation of the manuscript. Dr. Liang had a major role in the preparation of the manuscript. Dr. Dai had a major role in the data acquisition. Dr. Fu had a major role in the data acquisition. Dr. Wu had a major role in the data acquisition.

Level of evidence: 4

Conclusion—UES-AD significantly decreases the number of trans-UES reflux events and can potentially reduce the aspiration risk associated with NGT feeding.

Keywords

Aspiration; pharyngeal reflux; impedance monitoring

Introduction

Aspiration of gastric contents and aspiration pneumonia associated with tube feeding constitute a significant management problem among the elderly patients with deglutitive failure requiring non-oral feeding^{1–3}. Despite various approaches to modify the risk factors including post-pyloric delivery of perfusate beyond the stomach^{4–6}, avoidance of bolus feed^{7–9} and positional adjustment during and after feeding^{10, 11}, aspiration remains a significant challenge in this patient group^{6, 11, 12}. Indeed, the incidence of aspiration pneumonia in tube fed patients is reported between 7% and 62%^{13–16}, with a mortality rate of 17–62%¹⁷. Among various tube-feeding techniques, nasogastric tube (NGT) feeding has the added disadvantage by disturbing the protective mechanism of the lower and upper esophageal sphincters against reflux^{18–20}.

The main mechanism of gastroesophageal reflux in this patient population is likely related to the increased number of inappropriate transient lower esophageal sphincter relaxations (TLESRs) in the setting of increased gastric volume/content. After entry of gastric content into the esophagus, there remains two mechanisms for containing the refluxate in the esophagus and preventing its entrance into the pharynx, which is a prerequisite for aspiration. These are secondary peristalsis and contractile response of the upper esophageal sphincter (UES) to the presence of refluxate in the esophagus, i.e. esophago-UES contractile reflex^{21, 22}. The function of esophago-UES contractile reflex and secondary peristalsis in elderly tube-fed patients has not been systematically studied. However, judging by the prevalence of aspiration pneumonia in this population, it seems that in some of these patients, the function of esophago-UES contractile reflex may be impaired and inadequate for prevention of trans-sphincteric flow of the refluxate and its entry into the pharynx.

In order for pharyngeal reflux to occur, the refluxate must traverse the UES high-pressure zone (UESHPZ), we hypothesized that artificial increase in UES pressure might prevent the trans-sphincteric retrograde flow of the gastroesophageal contents in these patients. Therefore, the aim of the present study was to determine the effect of enhancing the UES resting pressure barrier by an externally applied assist device on the frequency of trans-sphincteric retrograde flow during NGT feeding in patients with deglutitive failure.

Methods

Participants

We studied 10 patients 87 to 94 years of age (mean 90.6±3.4 years, 4 Female) who received long-term care in the Geriatric ward of Peking University First Hospital and were receiving NGT feeding due to severe dysphagia due to stroke or advanced dementia. The diagnosis of

stroke or dementia were made clinically and confirmed by imaging studies. All of the patients were fed by similar size feeding tubes with the outer diameter of 4.52–4.72mm and the inner diameter of 3.15–3.30mm (Nutricia Flocare, CH14–110 PUR tube). The period of NGT feeding ranged from 0.5 to 5 years with median duration of 3 years. The enteral feeding rate was controlled at 70–80 ml/hour with a total volume 1200–1500 ml/day (1200–1600 kcal/day). On average, patients received continuous feeding through a NGT about 15-hours/day. The feeding tube was removed and replaced through the alternate nostril once a month. To simplify the protocol, the study was performed on the day when the participants were due for feeding tube exchange. To reduce gastro-esophageal reflux injury, all these patients were on daily proton pump inhibitor or histamine 2 receptor antagonist therapy.

UES Assist Device

External cricoid pressure was applied by using a handmade UES Assist Device (UES-AD), which comprised of an elastic band and a cushion ($5 \times 3 \times 2.5$ cm) placed on the cricoid cartilage and secured around the neck using the Velcro fastener. The design allows for bridging the vital organs of the neck to avoid vascular compression. The UES-AD was calibrated by an External Pressure Sensor™ (Somna Therapeutics, Glendale, WI) to confirm the 20–30 mmHg external pressures.

High-Resolution Manometric (HRM) Evaluation of the UES

A solid-state manometric assembly with 36 circumferential sensors spaced at 1 cm intervals (outer diameter, 4.2 mm) was used (Given Imaging, Los Angeles, CA) to locate the UES and measure the resting UES pressures and UES pressures assisted with external cricoid pressure. After at least 6 hours of overnight fasting, 10 patients underwent trans-nasal placement of the manometric catheter following topical 2% lidocaine application until the tip of catheter was in the distal esophagus. After a 10-minute adaptation period, the UESHPZ was determined and the resting pressure was measured and the assisted UES pressure was recorded after application of external cricoid pressure of 20–30 mmHg by the UES-AD.

pH/MII Evaluation of Reflux

Trans-UES and esophageal reflux events were recorded by using a 24-hour combined pH-multichannel intraluminal impedance catheter (pH/MII, Given Imaging, Los Angeles, CA), which was calibrated at pH 4 and pH 7 before use. After the measurement of the UES pressure with high-resolution manometry (HRM), the pH/impedance catheter and nasogastric (NG) tube were inserted with the aid of 2% lidocaine jelly. The pH/impedance catheter was adjusted so that at least 2–3 impedance sensors were across the UESHPZ, which was determined by HRM (Figure 1). The location of pH sensor is about 10 cm below the UES. A chest X-ray was then taken to confirm the location of the NG tube and impedance sensors (Figure 1). Esophageal reflux was defined as a retrograde 50% drop in impedance starting distally and propagating to at least the more proximal impedance measuring segment. The trans-UES reflux event was defined as trans-UES impedance drop 50% from baseline, preceded by intra-esophageal impedance drops (Figure 2a). Intra-esophageal reflux event was defined as esophageal impedance drop 50% from baseline without trans-UES impedance drops (Figure 2b).

Study Protocol

Application of UES-AD was started two hours after the beginning of NGT infusion and was alternated between periods of two hours on and two hours off, for a total of 12 hours (Figure 3). The number of trans-UES reflux events and intra-esophageal reflux events were calculated for each of the 2-hour periods and summed as a total. The patients were alternated every four hours between right or left lateral decubitus position with head elevated at 30 degrees. The right or left lateral decubitus positions were equally distributed between UES-AD on and off periods. Two gastroenterologists experienced in esophageal pH-impedance analysis and interpretation were assigned to data analysis. One of these physicians was blinded to the study protocol. The study was approved by the Ethics Committee of Peking University First Hospital.

Statistical Analysis

Data for the UES and lower esophageal sphincter (LES) resting pressures were expressed as mean $\pm$ SD. The paired *t*-test was used for comparison of UES resting pressures between with UES-AD and without UES-AD conditions. Descriptive statistics were used to quantify the frequency of the reflux events. The Wilcoxon-signed rank test was used for non-parametric comparison of reflux events between with UES-AD and without UES-AD conditions. $P < 0.05$ was considered statistically significant. To evaluate the agreement of identifying impedance events between the two observers, the intra-class correlation coefficient was calculated.

Results

The average BMI of the patients was 22.8 ± 3.4 kg/m². UES-AD was well tolerated by all patients. No aspiration pneumonia events were noted in the period one month before or during the study in any of the patients.

Manometric Findings

Baseline UES pressure averaged 17.5 ± 9.4 mmHg and was increased by 21.3 ± 4.0 mmHg to 38.9 ± 11.9 mmHg after application of the UES-AD ($p < 0.01$). LES resting pressure averaged 15.2 ± 7.7 mmHg and was not affected by the UES-AD. Three types of manometric esophago-gastric junction (EGJ) morphology were identified in the study group: type I, no separation between the LES and crural diaphragm (CD) in 4 patients; type II, minimal separation (>1 and <2 cm) in 4 patients; and type III, >2 cm separation in 2 patients.

pH/MII Evaluation of Reflux and Trans-Sphincteric Flow

Table 1 and 2 show the frequency of trans-UES and esophageal reflux events in each individual during the study period. There was an average of 13.8 ± 6.5 esophageal reflux events per person during the 12-hour study period. About 3% of the esophageal reflux events detected by impedance were associated with a pH drop below 4.0. Most of the reflux events were non-acidic reflux ($\text{pH} > 5$). During UES-AD on periods, 11% of the esophageal reflux events traversed the UES, compared to 52% during the UES-AD off period ($P = 0.02$, Figure 3). Figure 4 shows the frequency of trans-UES reflux events during each 2-hour period. The overall frequency of trans-UES reflux events decreased significantly with the UES-AD

compared to without the UES-AD. (0.8 ± 0.9 vs 3.3 ± 2.8 , respectively, $p=0.004$, Figure 4). There was no effect of the UES-AD on esophageal reflux events (7.4 ± 4.4 vs 6.4 ± 3.0 , $p>0.05$, Figure 5).

Inter-Observer Concordance

The intra-class correlation coefficient between the two impedance readers was 0.78. The frequency of trans-UES reflux events in each individual and the frequency of trans-UES reflux events during each 2-hour period identified by the blinded second observer are shown in table 3. As seen, although the absolute numbers of measured events (as shown in table 1 and 3) are different between observers, the effect of enhanced UES pressure on reducing the trans-sphincteric flow is similar.

Discussion

In this study, we determined the effect of experimental enhancement of the upper esophageal sphincter pressure barrier on trans-sphincteric retrograde flow of gastric refluxate. To enhance the UES pressure, we used an externally applied handmade device that compressed the UES between the cricoid cartilage and the spine in a controlled fashion delivering a constant pressure of 20–30 mmHg^{23–25}. To monitor the intra-esophageal and trans-UES refluxate flow, we used a multi-site impedance monitoring technique.

Study findings showed that application of the UES assist pressure is associated with significant reduction in the number of reflux events through the UES. This reduction is associated with a significant increase in the UES pressure. Although at the assist pressure level of 20–30mmHg, these events were not eliminated, they were substantially reduced ($P<0.05$). It is conceivable that increasing the assist pressure level will further reduce the trans-sphincteric reflux. Earlier studies^{23–25} have shown that assist pressures as high as 40 mmHg are well tolerated. Therefore, the effect of assist device pressures exceeding 20–30 mmHg merits further investigation.

Airway protection against aspiration of gastric contents is complex and involves two sets of distinct mechanisms: basal and reflex mechanisms^{20, 21}. Basal mechanisms include the resting tone of the LES guarding against entry of gastric contents into esophagus and resting tone of the UES guarding against entry of esophageal contents into the pharynx. Reflex mechanisms can be divided into pre-pharynx and pharyngeal/post-pharynx reflexes. Pre-pharynx reflexes include secondary peristalsis and esophago-UES contractile reflex as well as esophago-glottal closure reflex^{26, 27}. Post-pharynx reflexes are triggered when refluxate enters into the pharynx and include the pharyngo-glottal closure as well as pharyngo-UES and laryngo-UES^{28, 29} contractile reflexes. The function of these reflexes in tube fed patients is not known and awaits systematic study. However, deterioration of some of the aerodigestive tract reflexes has been described in the elderly similar in age to the current study population. These include the esophago-glottal and pharyngo-glottal closure reflexes, pharyngo-UES contractile reflex and secondary peristalsis. Added to the complexities of airway protection in this group of patients is the possible negative role of reflexes such as esophago-UES relaxation reflex and pharyngo-LES relaxation reflex that can be activated by

large volume gastric refluxate induced by tube feeding and result in pharyngeal reflux and aspiration. These issues also require further investigation.

It is noteworthy, that the external UES assist device inducing constant increase in UES pressure independent from these excitatory and inhibitory reflexes, provides a continuous enhanced barrier against trans-sphincteric flow, pharyngeal reflux and potential aspiration. Recent studies in patients with supra-esophageal reflux disease (SERD) and healthy controls have shown that applying the UES-AD on the cricoid cartilage inducing a sustained increase in intraluminal UES pressure between 20 and 30 mmHg prevents pharyngeal entry of simulated esophageal refluxate^{25, 30}.

The present study has several limitations, such as its moderate sample size. Of note, this is the first study using a UES-AD in long-term tube-fed elderly patients. Despite the small sample size, the effect of the UES-AD in reducing trans-UES reflux events was significant. Future studies with a larger sample size are necessary to confirm the current findings. Another limitation of this study is the lack of a second objective method to measure the trans-UES reflux, such as salivary pepsin content. In considering this limitation, it is important to acknowledge that currently there is no standard method to reliably measure pharyngeal reflux. Salivary pepsin concentration, with or without the UES-AD, may provide complimentary information in evaluating the UES-AD in preventing trans-UES reflux. One more limitation of the present study is the short period of study time, i.e., we were not able to evaluate the long-term effect of the UES-AD in preventing aspiration complications, e.g. aspiration pneumonia, in this high-risk group of patients. However, the study was originally designed to quantify the reflux events. Further prospective and randomized studies are required to evaluate this outcome.

In Summary

The UES Assist Device significantly decreases the number of trans-UES reflux events and can potentially reduce the aspiration risk associated with nasogastric tube feeding.

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Figure 1.
The position of impedance sensors and NG tube on the chest X-ray

Figure 2.

Examples of esophageal reflux events traversing the UES (trans-UES reflux, 2a) and without traversing the UES (intra-esophageal reflux, 2b). The trans-UES reflux event was defined as trans-UES impedance drop $\geq 50\%$ from baseline, preceded by intra-esophageal impedance drops. Intra-esophageal reflux event was defined as esophageal impedance drop $\geq 50\%$ from baseline.

Figure 3.

Percentage of esophageal reflux events traversing the UES during each of the 2-hour epochs of the study period and the entire study period. The UES-Assist Device was started 2 hours after the beginning of NGT infusion and kept alternately off and on every 2 hours for a total of 12 hours. *P=0.02

Figure 4.

Frequency of trans-UES reflux events with the UES-AD in place compared to without the UES-AD at each 2-hour period and the entire study period $*P=0.004$. As seen, application of the UES-AD significantly reduced the number of trans-UES reflux events compared to the period that it was not applied.

Figure 5.

Frequency of intra-esophageal reflux events with the UES-AD in place compared to without the UES-AD at each 2-hour period and the entire study period. As seen, UES-AD had no effect on the frequency of gastroesophageal reflux events.

Table 1

frequency of trans-UES reflux on each individual during the study period

Subject	Without UES-AD				With UES-AD			
	0-2h	4-6h	8-10h	total	2-4h	6-8h	10-12h	total
P1	2	0	0	2	0	0	0	0
P2	1	0	1	2	0	0	1	1
P3	0	0	1	1	1	1	1	3
P4	2	3	5	10	0	0	0	0
P5	1	0	1	2	0	0	1	1
P6	0	0	1	1	0	0	0	0
P7	2	3	1	6	1	0	0	1
P8	1	2	1	4	0	1	0	1
P9	2	0	0	2	0	0	0	0
P10	1	1	1	3	0	1	0	1
Average	1.2	0.9	1.2	3.3	0.2	0.3	0.3	0.8

Table 2

frequency of esophageal reflux on each individual during the study period

Subject	Without UES-AD				With UES-AD			
	0-2h	4-6h	8-10h	total	2-4h	6-8h	10-12h	total
P1	7	0	2	9	1	3	1	5
P2	1	0	1	2	2	2	1	5
P3	1	0	2	3	2	1	1	4
P4	3	3	5	11	4	7	1	12
P5	1	0	4	5	4	5	4	13
P6	2	2	3	7	3	4	4	11
P7	2	4	4	10	4	4	3	11
P8	3	2	2	7	3	2	4	9
P9	2	1	1	4	0	0	0	0
P10	1	4	1	6	1	1	2	4
Average	2.3	1.6	2.5	6.4	2.4	2.9	2.1	7.4

Table 3
frequency of trans-UES reflux on each individual during the study period (second observer)

Subject	Without UES-AD				With UES-AD			
	0-2h	4-6h	8-10h	total	2-4h	6-8h	10-12h	total
P1	2	0	0	2	1	0	0	1
P2	1	1	1	3	0	0	0	0
P3	1	0	0	1	1	0	0	1
P4	2	2	2	6	0	0	0	0
P5	1	1	0	2	0	0	0	0
P6	0	0	0	0	0	0	0	0
P7	2	3	1	6	1	0	0	1
P8	2	1	1	4	0	0	1	1
P9	2	0	0	2	0	0	0	0
P10	2	0	1	3	0	1	0	1
Average	1.5	0.8	0.6	2.9	0.3	0.1	0.1	0.5