Official title: A Study of the Differences Between Submental Ultrasonography (SUS) and Assessment by Speech-Language Pathologists (SLP) for Nasogastric Tube Removal

NCT number: 202411050RINC

Document date: December 30, 2025

Study Protocol

Participants

The research was performed at the 7th floor Integrated Medicine wards of National Taiwan University Hospital from February to December 2025. All 26 Taiwanese patients were stabilized acute illness (post-acute) without any nasogastric (NG) tube before this admission and referred to our team. The inclusion and exclusion criteria were shown below in Table 1.

Inclusion criteria	**Exclusion criteria**
Adults aged 18 and above	Impaired consciousness
	Long-term NG use, before this admission
Nasogastric (NG) tube use in this admission	Oxygen mask or mechanical ventilation
	Excessive drooling or frequent aspiration
Non-stroke stabilized acute illness status	Oral or head and neck surgery history
	Patient refusal

Table 1. Inclusion and exclusion criteria

The submental ultrasonographic examination and speech therapists' swallowing assessments were performed once when the participants agreed to join the study. The Research Ethics Committee of National Taiwan University Hospital approved the study protocol and all participants provided written informed consent. IRB number: 202411050RINC.

This study was a randomized controlled trial (RCT), 26 patients with NG agreed to join initially. After their agreement, the patients were randomly distributed to either submental ultrasonography group (SUS) or speech therapist group (ST). Each two groups would undergo submental ultrasound examination and speech therapist's assessment, but the criteria for entering oral feeding training and NG removal will be followed by their group. As the SUS group for entering oral feeding training and NG removal, the criteria would be maximum hyoid bone displacements over 1.38 cm; while the ST group would base on the speech therapist's assessment

forms to determine pass or fail. If the patients fail to pass the criteria no matter in SUS group or ST group, they would undergo routine swallowing rehabilitation and keep NG feeding after discharge. The RCT flowchart is showed in Figure 5 .

Submental ultrasonographic examination and measurement

Protocol for submental ultrasonographic examination

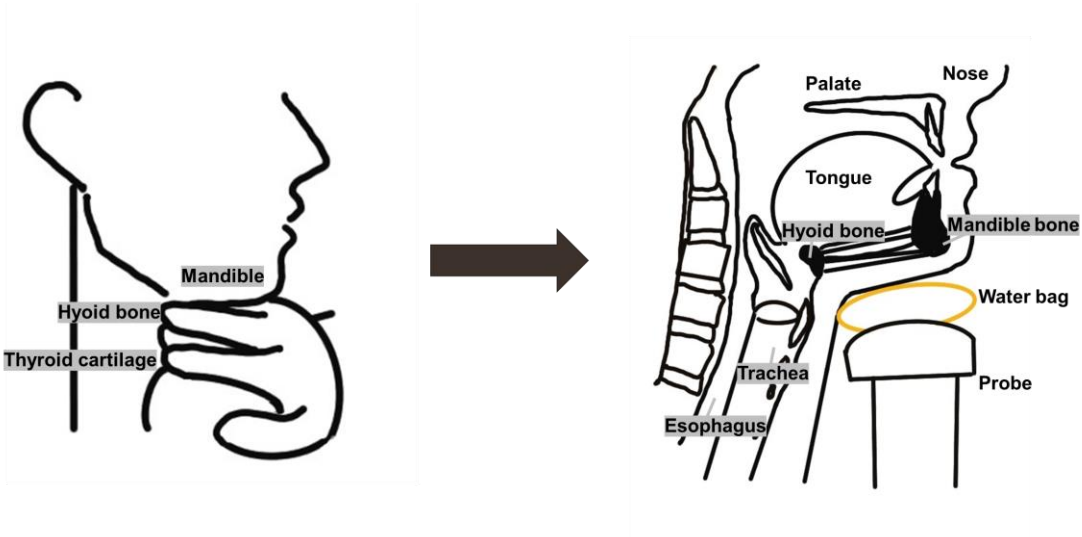


Figure 1. RSST and submental ultrasonographic examination

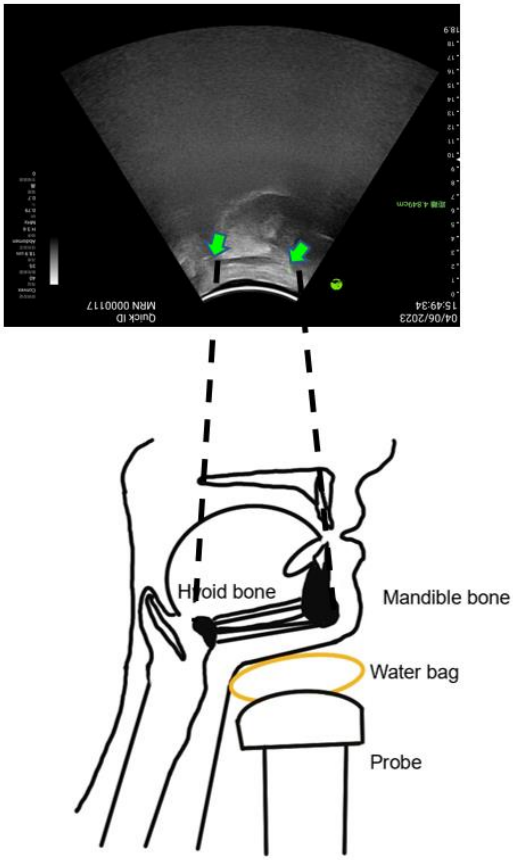
Shown in fig 1, participants were examined in upright position and kept the mandible vertical with the neck. First, RSST (repetitive saliva swallowing test) was performed by the examiner for initial assessment. (Cut-off value was feeling swallowed motion three times in thirty seconds.) (Oguchi et al., 2000) Then, a self-designed water-filled bag (150 ml water in a small size glove) was placed on ultrasound probe to keep stable when examined. (as the picture shows) Placed the probe in the midsagittal plane in the submental area. Asked patients swallow their saliva and recorded the hyoid bone displacement. Repeated three times for each examiner to take mean maximum hyoid bone displacement value.

Images Measurement

The wireless ultrasound machine used in this study was a LeSono Ultrasound Imaging System LU710L (Leltek Inc., New Taipei City, Taiwan) with a 5.0 MHz convex transducer in grayscale 2-dimensional mode, in combination with a Galaxy Tab S7 FE 5G SM-T736B (Samsung Electronics Co., LTD, Taipei, Taiwan). Record each examination as videos and using the internal distance measurement tool in ultrasound image software to measure hyoid bone

displacement = distance between the shadows created from the mandible and the hyoid bone (at rest, neutral)-(during swallowing). Take the maximum displacement of each assessment. Set cut off values, 1.38 cm to determine the patient pass (>1.38cm) or fail (<1.38 cm), which was based on our previous pilot study. The examples were in figure 2 and 3.

Figure 2. submental ultrasonographic image and anatomical structures



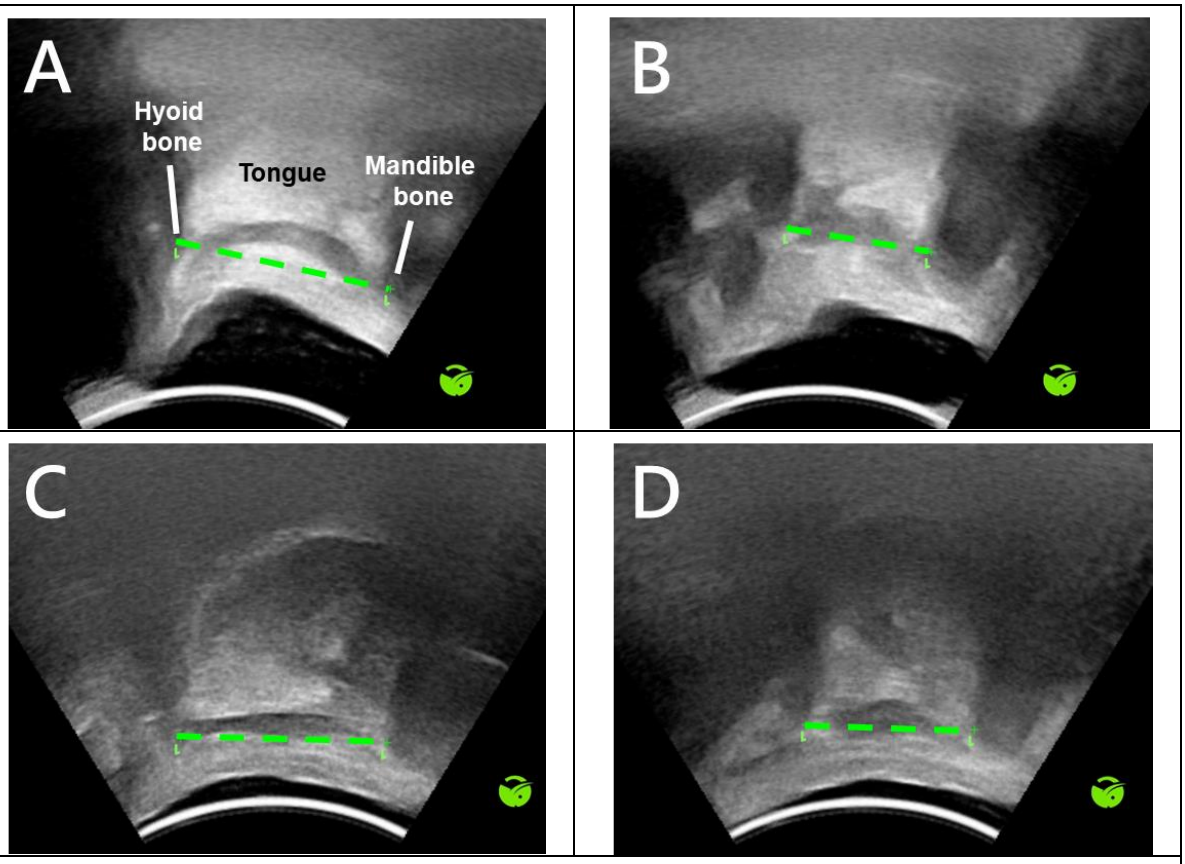


Figure 3. Ultrasonographic examples of pass and fail results
Length Measurement: The green dash-line
A, C: at rest, neutral position
B, D: Maximum muscle contraction during swallowing

Fig A, B: Patient passed the criteria
Maximum displacement(neutral-swallowing) = 5.067-3.365 = 1.702 cm
Fig C, D: Patient failed to the criteria
Maximum displacement(neutral -swallowing) = 4.849-3.926 = 0.923 cm

Speech therapists' swallowing assessments

Two well-trained, licensed speech therapists were invited to assess the patients' swallowing function using a protocol developed by the Department of Physical Medicine and Rehabilitation at National Taiwan University Hospital. The speech therapists first evaluated the patients' cooperation and level of consciousness, followed by an objective examination of the oral-motor mechanism, including the lips, cheeks, jaw, and tongue. Next, for the swallowing test, they provided small amounts of water or thickened liquids, or asked the patients to swallow their saliva, to observe their swallowing performance. Key observations included a prolonged oral phase, delayed swallowing reflex, reduced laryngeal elevation, choking, and the presence of a wet voice.

Each observation was coded on a 0–2 (impaired to normal) point scale, yielding a total possible score of 10.

Based on these findings, the speech therapists determined whether the patient passed or failed the assessment for initiating oral feeding training for NG tube removal. In addition, they provided rehabilitation strategies and exercises for the patients.

Oral feeding training

Oral feeding training protocol was based on The International Dysphagia Diet Standardisation Initiative (IDDSI) framework. Once the patients passed the criteria of their group, they will start to try oral feeding training for 2 to 5 days. The protocol was shown in table 2, following the order of IDDSI 2 to 4 to 5. After the sixth meal was done, and no chocking occur, NG could be removed. If chocking recurred several times, the training would stop and defined as training failure, and the patient remained feeding by NG.

	Order		Annotations
IDDSI 2 (thicken water)	100ml①	200ml②	Add Food Thickener
IDDSI 4	100ml③	200ml④	Adjust tube feeding amount to keep the Total Daily Energy Expenditure
IDDSI 5	100ml⑤	200ml⑥	Remove NG after passing these meals without chocking

Table 2. Oral feeding training protocol

Statistical analysis Plan

Method

All statistical analyses were performed using the SPSS 27 (IBM Corporation, Armonk, NY, USA). Group differences for all parameters were compared using Kruskal-Wallis H test (age, gender, GCS, Barthel Index). The correlations of three swallowing evaluation methods, SUS, RSST, and SLP assessments were analyzed by Fisher's Exact Test and Spearman's rank correlation. The mean maximum displacement of hyoid and mandible bone was the predictors for swallowing function and swallowing times measured in RSST were all collected to plot the receiver operating characteristic (ROC) curve. The optimal cut-off value of the ROC curve was determined by Youden index.

Flow chart of the trial