

Establishment of the Screening Scale on the Aspiration Risk of Patients Receiving Enteral Nutrition

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Research

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Abstract

Purpose

To establish a set of screening scale on the aspiration risk applicable to patients receiving enteral nutrition, determine the threshold of the scale and evaluate the scale's reliability-validity.

Methods

Firstly, the screening scale on the aspiration risk of patients receiving enteral nutrition was mainly formed through literature search, expert brainstorming and consultation. And then a retrospective analysis was undertaken by investigating 484 patients in the intensive care unit of 19 tertiary hospitals around China from May 2019 to June 2019. Reliability-validity test on the screening scale concerning the potential aspiration risk among the vulnerable patients was performed. The items in the scale were assigned with scores through expert evaluation method. At last ROC curve was used to evaluate the diagnosis threshold of such scale.

Results

A screening scale on the aspiration risk of patients receiving enteral nutrition was established, including general conditions of patients, primary disease and the accompanying symptoms, treatment strategies, and et al. The Cronbach's a coefficient, interrater reliability, content validity index interval, and the content validity index of such scale were 0.922, 0.920, 0.812-1.000 and 0.944 respectively. All the items in the scale were presented in the form of scores with a total of 12 points. The ultimate diagnosis threshold, sensitivity and specificity were 8 points, 0.800 and 0.627 respectively.

Conclusion

The screening scale on the aspiration risk of patients receiving enteral nutrition was shown to provided precise evaluation of the potential aspiration risk of such patients with compelling sensitivity and specificity, which deserved more clinical studies to confirm its value in other patient populations in the future.

Introduction

It was recommended that enteral nutrition should be and implemented as early as possible within 24–48 hours in the patients with critically ill, if the patients' digestive system is normal[1–3]. As an important way of nutritional support, enteral nutrition is proved to relieve the severity of diseases, reduce the comorbidities, shorter the hospitalization time and improve the prognosis [4]. However, it was also reported that during the enteral nutrition period, 59.1% patients were complicated with at least one kind of

complications[5], among which, the most serious complication is aspiration. It is reported that the rate of enteral nutrition relevant aspiration is up to 40% [6]. Aspiration can lead pulmonary complications, including serious lung injury and acute respiratory distress syndrome. It can prolong the hospitalization time and increase the mortality [7]. Therefore, how to identify the high-risk factors of aspiration in patients with enteral nutrition and screen out the high-risk patients is an urgent problem to be solved.

A previous study had evaluated dysphagia and aspiration pneumonia in elderly hospitalization stroke patients [8], however, it was lack of specificity and sensitivity on the aspiration associated with enteral nutrition. Therefore, in this study, based on literature research, expert opinion, and multi-center retrospective analysis, we established the screening scale on the aspiration risk of patients receiving enteral nutrition, determine the threshold of the scale and measure the reliability-validity.

Methods

Aspiration Scale

Firstly, PubMed, Cochrane databases, and Web of Science databases were searched from Oct. 2009 to Oct. 2019, using the keywords “enteral nutrition”, “aspiration”, “aspire”, “aspiring”, “factor”, “evaluation” without language restrictions. We compiled 12 items for aspiration risk assessment based on physical condition, underlying disease, and treatment intervention in patients who aspirate. Secondly, we invited experts to develop the preliminary aspiration scale. Expert inclusion criteria: engaged in intensive care, medical treatment, teaching, management and scientific research for more than 10 years. Finally, 15 experts were selected, with an average age of 47.2 ± 7.4 and experience of 22.8 ± 4.3 years. There were two rounds of consultation, each lasting for two weeks. The first round is used to screen items that meet the assignment > 4.0 and the coefficient of variation < 0.2 . The second round determined the weight of each item according to experts’ experience. Finally, according to the experts and the clinical feasibility of the scale, we established the preliminary aspiration scale.

Aspiration Scale Pre-Detecting

The language expressions of items in the scale were modified through pre-detecting, and the expression was matched for the habits of clinical nurses. Random sampling was used to select 20 patients, who met the inclusion criteria in the intensive medicine department of a 3A hospital in Shanghai. Aspiration scale for risks of enteral nutrition aspiration was determined (Table 1).

Table 1
The coordination index of expert indicators in the two rounds of consultation

| Quantity of rounds | Quantity of experts | Quantity of items (piece) | Wvalue | χ^2 | P value |
|--------------------|---------------------|---------------------------|--------|----------|---------|
| Round 1 | 15 | 12 | 0.138 | 21.793 | 0.023 |
| Round 2 | 15 | 10 | 0.112 | 31.445 | 0.002 |

Aspiration Scale Detecting

This was a retrospective cohort study. Participants of intensive care unit of nineteen 3A-hospitals from May to June 2019 included. Inclusion criteria: 1) Patients received enteral nutrition therapy; 2) hemodynamic stability; 3) admission time > 2 days; 4) patients or their families agreed with Informed consent. Exclusion criteria: 1) severe infection; 2) patients with gastrointestinal hemorrhage. 484 cases, including 280 males and 204 females, were collected in this study. The age was 42.78 ± 8.15 year. The hospitalization time was from 3 to 63 (12.30 ± 4.21) days. Among them, 129 cases were given assisted ventilation support. Clinical data of the enrollers were reviewed, including physical condition, underlying diseases and treatment, and the aspiration scale was used to assess the aspiration risk of patients who met the inclusion criteria.

Diagnostic criteria for aspiration [9]: 1) irritant choking cough or blood oxygen saturation decreases; 2) obvious shortness of breath, lung moist rale; 3) intratracheal aspiration of gastric contents; 4) inflammatory reactions such as bronchospasm and thickening of lung texture can be seen by imaging examination. In the process of this clinical research, matron and clinicians had provided training and answered questions to ensure scientific and effective screening methods.

Evaluation of the aspiration scale

The reliability and validity of the aspiration scale was investigated. The internal consistency reliability of the scale was evaluated by Cronbach's α coefficient. The Inter-rater reliability was evaluated by intra-group correlation coefficient (ICC). Twenty patients were randomly selected, and the researchers and nurse screened patients for aspiration risk. ICC was used to calculate and compare the results of the two evaluators. The content validity index is used to reflect the content validity of the scale.

Statistical analysis

All statistical analyses were performed using SPSS version 20.0 software (SPSS Inc., Chicago, IL, USA.) Continuous variables were shown as mean \pm standard deviation (SD), when normally distributed and with equal variances. Categorical data were summarized as frequency counts and percentages and measured with Chi-square or Fisher exact statistic test. The expert's positive coefficient was described by the recovery rate of the consultation table. The concentration of expert opinions was showed by mean \pm standard. The coordination degree of expert opinions was described by coefficient of variation and coefficient of coordination (Kendall's W); ROC curve and Youden index (YI) value were used to find the diagnostic threshold of the scale. P value < 0.05 is considered to be significant.

Results

Contents of the screening scale on the aspiration risk of patients receiving enteral nutrition

The expert activity was presented by effective recovery rate of expert consultation questionnaire. Fifty questionnaires were distributed respectively in each round of the expert consultation and all 30 questionnaires were recovered with an effective recovery rate of 100%. The coordination index of expert indicators was principally reflected by the coefficient of variation and coordination coefficient (Kendall's w). The coordination index of expert indicators in the two rounds of consultation was shown in Table 1. In combination of the screening results, expert modified suggestions in the 2 rounds of consultation and the opinions by our group members, 4 items in the 2 rounds of consultation were modified and 2 items were deleted (one of which was combined with another item). The ultimate 10 items in the primary scale were finally obtained. For the 10 items from the 3 dimensions, the mean values of the degree assignment by the experts were all more than 4.0, and the coefficient of variation was less than 0.2. The screening scale on the aspiration risk of patients receiving enteral nutrition was ultimately formed after modification of expression and wording according to the pretest, which was shown in Table 2.

Table 2
Screening scale on the aspiration risk of patients receiving enteral nutrition

| Primary indexes | Secondary indexes | Concentration degree of expert opinions(xs, points) | Coefficient of variation | Weight of the primary indexes | Weight of the secondary indexes |
|---------------------------------------|--|---|--------------------------|-------------------------------|---------------------------------|
| General conditions of the patient | Age > 65 or < 10 | 4.44±0.53 | 0.119 | 0.35 | 0.22 |
| | Body position: low slope lying position (< 30 °) or prone position | 4.98±0.58 | 0.116 | | 0.25 |
| | Consciousness: coma or GCS ≤ 8 points or RASS score 4– 5 points | 4.63±0.51 | 0.110 | | 0.23 |
| | Dysphagia: water swallow test ≥ grade II | 4.66±0.60 | 0.129 | | 0.25 |
| Diseases and the accompanied symptoms | Primary diseases: gastroparesis, gastroesophageal reflux, craniocerebral disease, apoplexy, Parkinson's disease, myasthenia gravis, spinal cord injury, neuromuscular disease, large area burn, asthma, post total laryngectomy, post esophageal cancer surgery or associated abnormalities: electrolyte disorder, blood glucose abnormality, sepsis, decreased physical endurance and weakness. | 4.88±0.49 | 0.100 | 0.33 | 0.48 |
| | Symptoms: gastric residual volume > 500 ml, nausea and vomiting, frequent cough, abdominal distention | 4.76±0.54 | 0.113 | | 0.52 |
| Treatments and intervention | Drugs: opioid analgesics, muscle relaxants, vasoactive drugs, gastric emptying drugs | 4.72±0.58 | 0.123 | 0.32 | 0.24 |

| Primary indexes | Secondary indexes | Concentration degree of expert opinions(xs, points) | Coefficient of variation | Weight of the primary indexes | Weight of the secondary indexes |
|-----------------|---|---|--------------------------|-------------------------------|---------------------------------|
| | Supportive treatment: ☒ artificial airway (tracheal intubation, tracheotomy, oropharyngeal airway); ☒ mechanical ventilation (invasive / noninvasive ventilation); ☒ fiberbronchoscopy; ☒ gastroscopy; ☒ physical therapy; ☒ sputum suction; ☒ turning over | 4.96±0.47 | 0.095 | | 0.3 |
| | Infusion route: indwelling nasogastric tube with diameter ≥ 6 mm | 4.63±0.32 | 0.069 | | 0.23 |
| | Infusion method: intermittent injection | 4.54±0.39 | 0.086 | | 0.23 |

The weight and assigned scores of the dimensions and items of the aspiration risk screening scale

The weight of the indexes in the scale was presented in Table 2. Considering the clinical utility of the scale, the assigned values were determined by the research group as following. The primary indexes were each assigned as 4 points. The secondary indicators corresponding to the basic condition, including age, body position, consciousness and dysphagia, were assigned as 1 point for each index. The scores of the secondary indicators corresponding to the dimensions of disease and accompanying symptoms (primary disease or associated abnormal condition and symptoms) assigned as 2 points for each index. The scores of the secondary indexes corresponding to the treatment intervention dimension, including drugs, supportive treatment, infusion route and infusion method, were assigned as 1 point for each index.

The diagnosis threshold of the aspiration risk screening scale

The area under the ROC curve was 0.749 ($P= 0.003$) (Fig. 1). The area > 0.7 indicated that the diagnosis criteria possessed high accuracy. From Table 3, the maximum value of YI, sensitivity and specificity were 0.427, 0.800 and 0.627 respectively. Accordingly, the diagnosis threshold of the scale was determined by the group members as 8.5 points. Considering that the diagnostic purpose of this scale was risk screening which put more emphasis on the sensitivity, the ultimate diagnosis threshold was specified as 8 points.

Table 3
Coordinates of the curve

| Positive if greater than or equal to | sensitivity | 1-specificity |
|--------------------------------------|-------------|---------------|
| 1.00 | 1.000 | 1.000 |
| 2.50 | 1.000 | .995 |
| 3.50 | 1.000 | .954 |
| 4.50 | .971 | .893 |
| 5.50 | .971 | .843 |
| 6.50 | .914 | .772 |
| 7.50 | .829 | .622 |
| 8.5 | .800 | .373 |
| 9.50 | .543 | .167 |
| 10.50 | .286 | .061 |
| 11.5 | .171 | .015 |
| 13 | .000 | .000 |

Reliability-validity analysis of the aspiration risk screening scale

Internal consistency of reliability

The Cronbach's α coefficients of the 3 dimensions of the scale including general conditions of patients, primary disease and the accompanying symptoms, and treatment, were respectively 0.892, 0.912 and 0.896. While the Cronbach's α coefficient of the summary scale was 0.922, indicating the high internal consistency of the results and fine reliability.

Interrater reliability

The ICC values of the interrater reliability among the 2 evaluators from the 3 dimensions were respectively 0.901, 0.960 and 0.961. The total ICC of the scale was 0.920.

Validity analysis

According to the results of the second round of expert consultation, the content validity indicated that the content validity index of the scale was 0.944 and the range of content validity index of the items was 0.812-1.000. All the items in this scale were factors influencing aspiration during enteral nutrition, and

came from the present studies and the experience of clinician, which could well reflect the conception of aspiration and possessed fine surface validity.

Discussion

Aspiration is considered as one of the main reasons leading to prolonged hospitalization time and increased mortality in patients receiving enteral nutrition, as it could cause aspiration pneumonia, asphyxia or death [1]. It is the consequence resulted from the participation and exertion of multiple elements. Although many studies have widely investigated the risk factors of aspiration [9–11], one previous study has indicated that the ICU nurses possessed a low understanding of aspiration [12]. To identify the occurrence of aspiration in patients with enteral nutrition and to take effective measures as early as possible is of great importance to improve the quality of nursing and ensure the safety of patients. Wu et al. has established the risk assessment system of aspiration in ICU patients based on the expert consultation[13], however, the threshold of aspiration was not defined.

In this study, with literature research of the risk factors leading to aspiration during enteral nutrition, expert brainstorm and expert consultation, the screening scale on the aspiration risk of patients receiving enteral nutrition was established and the diagnostic threshold was defined. This scale has good clinical pertinence, makes up for the blank of screening tool for intestinal nutrition aspiration, and can effectively promote the improvement of clinical quality.

The reliability of the scale refers to the content of internal consistency of the measuring results. The Cronbach's α coefficient of the screening scale on the aspiration risk of patients receiving enteral nutrition is 0.922, which indicates the high internal consistency of the measuring results and fine reliability. The items were evaluated and modified according to expert consultation. The results showed that the content validity and the range of the content validity index of the items were 0.944 and 0.812-1.000 respectively, which were higher than the recommended values [14], and indicated the good content validity of the scale. Simultaneously, with the large-scale literature research, expert brainstorm and the clinical experience, the risk factors influencing aspiration during enteral nutrition were induced and summarized and the primary item tank was ultimately obtained. These items were capable of reflecting the conception of aspiration and provided fine surface validity.

According to the ROC curve analysis, the area under the ROC curve was 0.749 with $P = 0.003$, which indicated a high diagnostic value of the scale. Based on the theory of the best critical point, the diagnosis threshold of aspiration during enteral nutrition was defined as 8.5 points. The diagnostic sensitivity and specificity at this critical point are respectively 0.800 and 0.627. Considering that the assignments of the scale are all integers while the moderate decreasing of the diagnosis threshold can add sensitivity of the scale with the quality specificity being ensured, the diagnosis threshold of the scale was ultimately adjusted to 8 points, which is conducive to maintaining the evaluation authenticity of the scale. When the assessment results ≥ 8 points, there is a risk of aspiration for the patient receiving enteral nutrition.

Conclusion

The established “Screening scale on the aspiration risk of patients receiving enteral nutrition” is capable of identifying the risk factors influencing aspiration during enteral nutrition directly and conveniently. In this study, the diagnosis threshold as a total of 8 points is defined of the scale, and a series of relevant factors influencing aspiration during enteral nutrition are also clarified. It is of great clinical significance to decrease the incidence of the aspiration during enteral nutrition and improve the implementation quality and level of clinical enteral nutrition.

Declarations

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Competing interests

The authors declare that they have no competing interest.

Authors' contributions

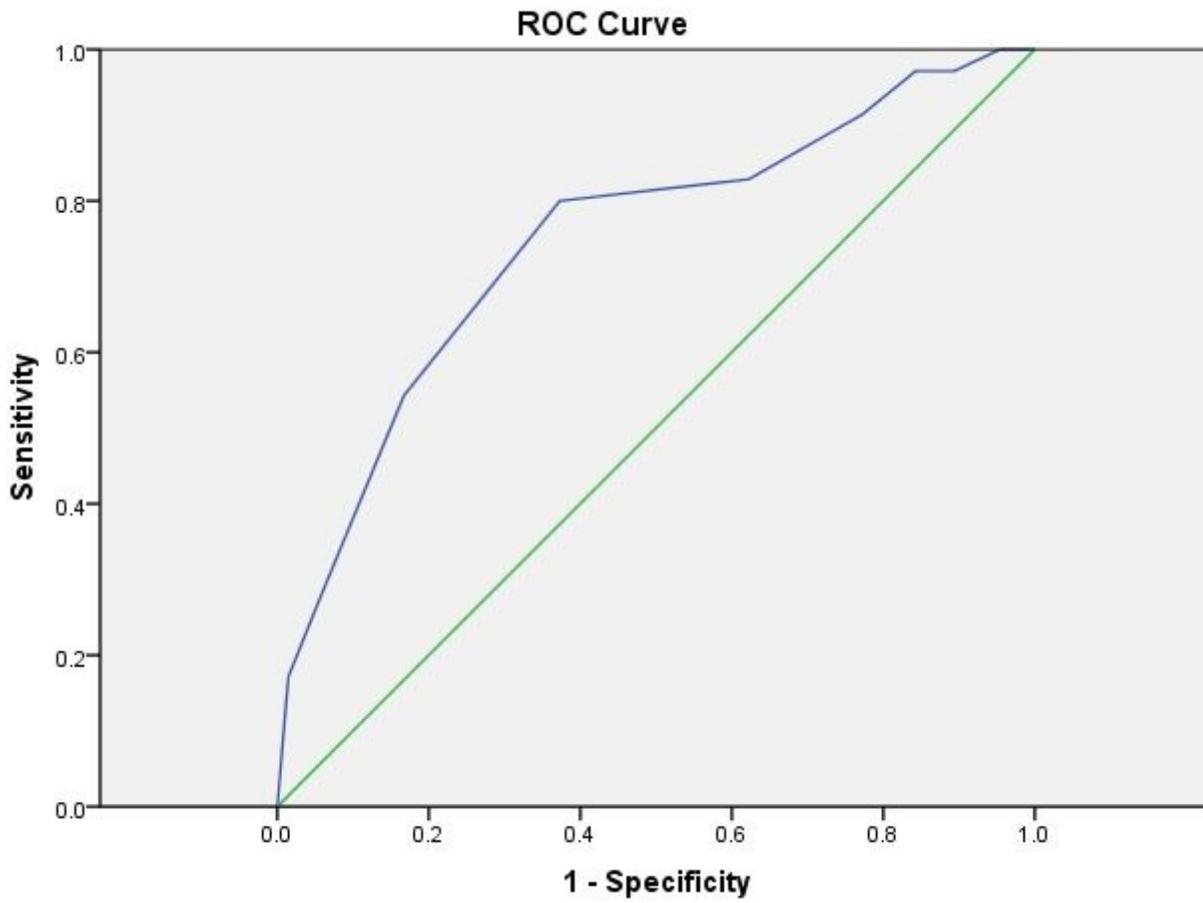
Conception and design: Shao XP and Yan YL. Study coordination: Hu SL. Inclusion and clinical data collection: Shao XP, Yan YL, Yan PW, Li YY, Qi Q, Li YY, Ye XH, Gao L, Huang HY and Hu SL. Analysis of data: Shao XP and Hu SL. Interpretation of data: Shao XP and Hu SL. Drafting and writing of manuscript: Shao XP and Hu SL. Revision of manuscript: Yan YL, Yan PW, Li YY, Qi Q, Li YY, Ye XH, Gao L, and Huang HY. Given final approval of the manuscript: Shao XP, Yan YL, Yan PW, Li YY, Qi Q, Li YY, Ye XH, Gao L, Huang HY and Hu SL.

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Figures



Diagonal segments are produced by ties.

Figure 1

ROC curve of the aspiration risk screening scale