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Impact of a Staged Enteral Nutrition Nursing Pathway Based on Dynamic Assessment of Tolerance and Aspiration Risk vs Usual Care on Feeding Intolerance in Older Adult Patients With Acute Ischemic Stroke and Dysphagia: A Single-Center Randomized Controlled Trial

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Background: Older adult patients with acute ischemic stroke have dysphagia and require early post-pyloric enteral nutrition, yet feeding intolerance and unstable energy delivery remain common, and practical pathways that integrate tolerance and aspiration risk are lacking. This trial evaluated whether a dual-axis staged nursing pathway, compared with usual care, was associated with lower feeding intolerance and better nutritional delivery.

Material/Methods: This single-center, parallel, 1: 1 randomized controlled trial enrolled older adult patients with acute ischemic stroke and dysphagia with post-pyloric nasoenteric tubes placed. The intervention group received a staged nursing pathway, and the control group received usual care. The primary outcome was 7-day feeding intolerance; secondary outcomes were time to ≥80% of target, target-achieving days, aspiration-related pneumonia, and safety. Analyses were intention-to-treat.

Results: Compared with control, the intervention group had a lower 7-day risk of feeding intolerance (adjusted RR 0.61, 95% CI, 0.47-0.81; *P*=0.003); faster attainment of at least 80% of energy target (adjusted HR 1.65, log-rank *P*<0.001); target-achieving-day proportion was higher (difference 0.16, Holm-adjusted *P*=0.001); risk of aspiration-related pneumonia was lower (adjusted RR 0.54, Holm-adjusted *P*=0.041); and difference in feeding-related hypoxemia was not significant (*P*=0.189). No between-group differences were observed in tube displacement, upper gastrointestinal bleeding, or electrolyte disturbances (all *P*>0.05). Subgroup/sensitivity analyses were consistent.

Conclusions: A staged nursing pathway driven by dynamic dual-axis assessment was associated with lower feeding intolerance and earlier, more stable nutritional delivery in the context of post-pyloric feeding, without increasing short-term safety events.

Keywords: Critical Pathways • Deglutition Disorders • Enteral Nutrition • Ischemic Stroke

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Introduction

Acute ischemic stroke is a major cause of disability and death among the older adult population, and dysphagia is common in the early phase of stroke, which can rapidly lead to inadequate intake, dehydration, and malnutrition and increase the risk of aspiration-related pneumonia [1,2]. For patients who cannot safely take oral nutrition, enteral nutrition is the first-line clinical nutrition support strategy [3]. In populations at high risk of aspiration, a post-pyloric nasoenteric tube can reduce reflux and aspiration of gastric contents to some extent, but it does not eliminate abdominal distension, diarrhea, vomiting, and failure of feeding advancement caused by post-stroke gastrointestinal hypomotility, stress responses, bed rest, and medication effects [4,5]. The first week after stroke is a key window for energy delivery and the occurrence of complications, and nursing processes primarily govern feeding initiation, advancement, positioning, and interruption management, the quality of which directly affects the continuity and achievement of energy delivery [6]. Existing enteral nutrition management often uses a fixed starting rate and then accelerates empirically [7]. Assessments of tolerance often focus on single symptoms or indices such as gastric residual volume, which are inadequate to reflect intraday fluctuations in intestinal responses among patients with stroke and are not adapted to the monitoring characteristics of post-pyloric feeding [8]. Aspiration risk fluctuates dynamically with changes in patient level of consciousness, airway secretion burden, and the frequency of nursing procedures [9], yet clinical pathways often do not translate risk stratification into executable rate-adjustment and positioning strategies, with nursing decisions relying more on personal judgment; pump stoppage and restarting occurring repeatedly; and actually delivered energy remaining persistently below the prescription [10]. Most prior studies are from general critical care or mixed populations, and targeted randomized controlled evidence is lacking for older adult patients with acute ischemic stroke and dysphagia who use post-pyloric nasoenteric tubes. Standardized nursing algorithms that account for both tolerance and aspiration risk are also lacking. In this study, we developed a staged enteral nutrition nursing pathway driven by dynamic assessment of tolerance and aspiration risk and conducted a single-center randomized controlled trial in the stroke unit, with participants restricted to patients receiving post-pyloric nasoenteric feeding. The primary objective was to evaluate its effect on early feeding intolerance. The secondary objectives were to assess nutritional delivery efficiency, aspiration-related events, and short-term safety. We hypothesized that, compared with usual care, the pathway would reduce feeding intolerance and improve nutritional delivery efficiency without increasing short-term safety events.

Material and Methods

Study Design

This study was a single-center, parallel-group, 1: 1 randomized controlled trial. The study was conducted in the geriatrics department (ward 4) of our hospital. The study period was from January 1, 2024, to March 31, 2025. The protocol was approved by the institutional ethics committee of our hospital (approval No.: 2023-087), and written informed consent was obtained from the participants or their legal representatives. The trial was registered in the Chinese Clinical Trial Registry (ChiCTR2300067930).

Participants

The inclusion criteria were as follows: age 65 years or older; onset of acute ischemic stroke within 72 hours and confirmed by imaging; bedside assessment by a speech-language therapist indicating dysphagia and confirmation by fiberoptic endoscopic evaluation of swallowing; a nasoenteric tube already placed with the tip located 20 to 40 cm beyond the pylorus; planned initiation of enteral nutrition immediately after enrollment; mean arterial pressure of 65 mmHg or higher; and no use of medium-to-high–dose vasoactive agents (norepinephrine ≤0.1 μg/kg/min).

The exclusion criteria were as follows: imaging or clinical evidence of intestinal obstruction, intestinal ischemia, or active gastrointestinal bleeding; acute pancreatitis or high-output enterocutaneous fistula; prior short bowel syndrome; 5 or more watery stools within 24 hours before enrollment; gastrointestinal anastomosis or major surgery within the past month; anticipated inability to complete observation within 7 days (planned transfer or palliative care); continuous parenteral nutrition of at least 12 hours before enrollment; and participation in other interventional clinical trials.

The withdrawal or termination criteria were as follows: the participant or proxy withdrawing consent; occurrence of a serious adverse event requiring permanent discontinuation of enteral nutrition; discovery after randomization of non-eligibility for inclusion/exclusion criteria; and objective reasons that preclude execution of study-related procedures. Whenever possible, safety outcomes were recorded after a participant's withdrawal.

Baseline assessment and severity stratification (National Institutes of Health Stroke Scale [NIHSS], level of consciousness, comorbidities) were conducted as follows. On the day of enrollment, age, sex, height and weight, blood pressure, glycated hemoglobin, serum albumin, creatinine, and electrolytes were recorded; stroke severity was assessed using the NIHSS; level of consciousness was recorded using the Glasgow

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Coma Scale (GCS); comorbidity burden was recorded using the Charlson Comorbidity Index; and smoking and alcohol history, and history of pulmonary disease and diabetes were recorded.

Randomization, Allocation Concealment, and Blinding

Block randomization generated by an independent statistician using a computer (block sizes of 4 and 6 alternating) was applied, and assignments were made in the order of enrollment; stratification factors were NIHSS scores of less than 15 or 15 or higher, and aspiration risk level at enrollment of low or moderate/high. Allocation was implemented through a centralized, password-protected web system, and the nursing team obtained the allocation result after completion of baseline assessment and signed informed consent. Blinding of nursing staff and patients was not feasible due to the nature of the intervention. To minimize performance, detection, and analysis bias, outcome definitions and adjudication rules were prespecified, care teams were instructed not to disclose allocation during outcome assessment, and the primary endpoint and aspiration-related events were determined by independent assessors not involved in patient care and unaware of group assignment. Further, chest imaging was read and graded by 2 chest imaging experts after removal of group identifiers, with disagreements adjudicated by a third expert. Statistical analyses were conducted by blinded analysts using A/B coding after database lock. Before study initiation, all personnel completed standardized training and assessment. Standardized case report forms and an operations manual were used to ensure uniform data collection, and the quality control team reviewed 3% of samples weekly to verify consistency between source documents and the database. Cross-group interventions were strictly prohibited.

Nasoenteric Tube Placement and Tip Positioning

A qualified physician placed a 10 to 12 Fr polyurethane nasoenteric tube at the bedside under electromagnetic navigation guidance, with the tip positioned in the proximal jejunum or distal duodenum; all participants completed tube placement before randomization, and enteral nutrition was initiated within 6 hours after placement. The post-pyloric position was initially confirmed by an abdominal plain radiograph or the electromagnetic navigation trace, and the distance at the incisors and the external length at the fixation point were recorded and the fixation point was checked daily. If vomiting, persistent abdominal distension, or a change in infusion resistance occurred, the position was reverified. If the tip was found to have migrated back into the stomach, feeding was paused and the tube was repositioned within 12 hours. Both groups used continuous infusion via a volumetric pump with single-use infusion tubing and needleless connectors. Infusion bags and tubing were replaced every 6 hours, and the tube was flushed with 30 mL sterile water every 4 hours, and with 20 mL sterile water after medication administration.

Interventions and Control

Intervention Group Staged Enteral Nutrition Nursing Pathway

For the nutritional assessment and prescription, on the day of enrollment, the energy target was set at 25 kcal/kg/day based on actual body weight. For patients with a body mass index of 28 kg/m^2 or higher, adjusted body weight was calculated as ideal body weight plus 0.25 times the difference between actual body weight and ideal body weight, with ideal body weight defined as 22×height^2 (kg, m^2) [11]. The protein target was 1.2 g/kg/day. An isotonic polymeric formula (1.0 kcal/mL) was used uniformly, and at 08: 00 AM each day the 24-hour prescribed volume and pump rate were verified [12]. The pathway adopted a dual-axis joint decision based on tolerance and aspiration risk, with 3 stages: initiation, advancement, and maintenance. The initiation stage used a low rate with intensive assessments, the advancement stage advanced at preset increments, and the maintenance stage maintained target achievement and managed fluctuations.

For tolerance assessment and aspiration risk management, every 4 hours, abdominal pain, abdominal distension, vomiting, stool frequency and form, bowel sounds, infusion resistance, and vital signs were assessed. Good tolerance required all of the following: no vomiting; change in abdominal circumference from baseline of less than 2 cm and no tenderness; stool frequency of 3 times or less in 24 hours, and Bristol Stool Form Scale of type 5 or lower. There was no unplanned pump stoppage due to gastrointestinal symptoms, and failure to meet any item was judged as limited tolerance. Aspiration risk stratification was performed at enrollment and at 8: 00 AM each day: low risk (GCS ≥13, strong cough reflex, suctioning at intervals >2 hours, no signs of reflux in the past 24 hours), moderate risk (GCS 9-12, weakened cough reflex, or requiring suctioning every 1-2 hours), and high risk (GCS ≤8, endotracheal intubation, or the presence of regurgitation signs in the past 24 hours) [13]. For low risk, the head of the bed was elevated 30° to 45°; for moderate and high risk, the head of the bed was elevated 45° and the pump rate was adjusted 15 minutes before and after turning and suctioning.

For advancement, pause, and rollback, in the initiation stage (0-6 hours), the starting rates were set by risk level of feeding intolerance: low risk 20 mL/h, moderate risk 15 mL/h, and high risk 15 mL/h, with a 50% reduction of the pump rate during turning and suctioning periods [14]. After 2 consecutive assessments demonstrating good tolerance, the protocol proceeded to the advancement stage. In the advancement stage, for low risk, the rate was increased by 10 to 15 mL/h every 4

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hours; for moderate risk, by 10 mL/h every 8 hours; and for high risk, by 5 to 10 mL/h every 12 hours. If limited tolerance appeared at any time point, the protocol was to immediately roll back to the previous successful rate and maintain for 4 hours. If vomiting occurred, abdominal circumference increased by 3 cm or more, or stool frequency was 5 times or greater within 24 hours, feeding was paused for 4 hours, restarted at 10 mL/h, and the rate was not increased within the following 24 hours. In the maintenance stage, after reaching at least 80% of the prescription, the rate was maintained for 24 consecutive hours. If no events occurred, the target was reassessed on day 3 to determine whether it could be increased to 100%. If events occurred, the rate was rolled back according to the previously described rules. Continuous pump infusion was maintained throughout, and bolus feeding was not used. Head-of-bed elevation was routinely at least 30°, and for moderate- or high-risk patients at least 45°. The pump rate was reduced by 50% 15 minutes before turning and suctioning and restored 15 minutes after the procedure. Increases in the pump rate were avoided between 12: 00 midnight and 06: 00 AM. The formula was uniformly an isotonic polymeric formula. If watery stools persisted for 48 hours with a negative stool culture and no use of laxatives, an isotonic peptide-based formula was used. Study drugs were not incorporated into the pathway, and symptomatic treatment was performed by the attending physician according to the hospital formulary and recorded.

Control Group, Usual Care

The control group followed the routine enteral nutrition process of our hospital, with a starting pump rate 25 mL/h. In the absence of vomiting, obvious abdominal distension, or abdominal pain, the rate was gradually advanced to the prescribed target within 48 to 72 hours. If gastrointestinal symptoms occurred, feeding was paused for 4 hours and then maintained at the next lower pump rate for 24 hours. No stratified management based on aspiration risk was performed, and the pump rate was not adjusted during turning and suctioning periods. The remaining nutritional targets, formula, and equipment were the same as in the intervention group.

Standardized Nursing Care and Prohibitions Common to Both Groups

Both groups uniformly implemented head-of-bed elevation at or above 30°, oral care twice daily, and management of airway secretions according to respiratory therapy protocols. A volumetric pump and single-use tubing were used uniformly. Bolus feeding and gravity drip were prohibited, the blood glucose target was 7.8-10.0 mmol/L, using an insulin correction protocol, and proton pump inhibitors were given for stress ulcer prophylaxis. In the event of accidental nasoenteric tube dislodgement, the tube was repositioned within 12 hours and the duration and reason for pump stoppage were recorded.

Outcomes and Operational Definitions

Primary Endpoint: Incidence of Feeding Intolerance Within the First 7 Days

The adjudication window for feeding intolerance was days 1 to 7 after initiation of feeding [15]. An event was recorded if at any time point any of the following criteria were met: (1) vomiting related to feeding and leading to pump stoppage or rate reduction; (2) an increase in abdominal circumference from baseline to 2 cm or greater with tenderness/rigidity, leading to rate reduction or pump stoppage; (3) Bristol Stool Form Scale type 6 to 7 stools 3 or more times within 24 hours or stool volume of 300 mL or more, and leading to rate reduction or pump stoppage, with no use of laxatives in the preceding 24 hours; (4) unplanned pump stoppage due to gastrointestinal symptoms accumulating to 4 hours or more; and (5) due to gastrointestinal symptoms, failure to achieve 60% or more of the prescribed energy by the end of day 4. Pump stoppage due to examination-related fasting or tube displacement was not counted toward feeding intolerance. Events were collected over 7 consecutive days in a daily observation cycle from 08: 00 AM to 08: 00 AM; multiple events on the same day were combined into one, and the most severe item was recorded. For participants discharged early, medical course records were reviewed, and missing data were handled as described. The primary endpoint analysis used only the first event for each participant.

Secondary Endpoints

For nutritional target attainment efficiency, time to target was defined as the number of days from initiation of feeding to the first 24 consecutive hours in which delivered energy reached at least 80% of the prescription; the proportion of target-achieving days was the proportion of days reaching at least 80% within the first 7 days [16]. For aspiration-related clinical events, suspected aspiration-related pneumonia required at least 2 of the following 3 criteria and exclusion of noninfectious pulmonary edema: new or progressive infiltrates on chest imaging; temperature greater than 38.0°C, leukocytes greater than 10×10^9/L, or elevated C-reactive protein [17]; and increased or purulent respiratory secretions. Feeding-related hypoxemia was defined as a decrease in SpO_2 of 3% or more occurring during feeding or within 2 hours after the end of feeding and requiring an increase in oxygen concentration or escalation of oxygen therapy. Safety outcomes were defined as follows: nasoenteric tube displacement referred to imaging or electromagnetic records confirming that the tip had migrated back into the stomach; upper gastrointestinal bleeding referred to

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melena or hematemesis accompanied by a decrease in hemoglobin of 20 g/L or more or requiring transfusion; and electrolyte disturbances referred to serum sodium less than 130 mmol/L or greater than or equal to 150 mmol/L, serum potassium less than 3.0 mmol/L, or serum phosphate less than 0.65 mmol/L, all requiring intravenous supplementation [18].

Process Quality and Execution Consistency Indicators

The pathway adherence rate referred to the proportion of assessments and operations that were completed on time as required. The decision concordance rate referred to the proportion in which actual advancement, pause, or rollback was consistent with the algorithm recommendations. The cumulative duration of unplanned interruptions recorded the total hours of unplanned pump stoppage during the first 7 days and was attributed to gastrointestinal symptoms, tube problems, and examination-related fasting. Nursing workload and resource consumption were measured using the time-motion method, recording the total daily time (minutes) spent on assessments, rate adjustments, oral care, and airway management, with detailed recording of infusion consumables usage.

Data Collection and Quality Control

Data were entered in real time via electronic case report forms, covering baseline, clinical and nutritional records at 08: 00 AM and 8: 00 PM each day, and event forms. Abdominal circumference was measured at the umbilical level at end-expiration, and the average of 2 measurements was taken. Assessors underwent unified training before the study and passed simulated-case assessments. Monthly quality control meetings were held, with a 10% case sample audited for consistency, and retraining was undertaken if Kappa less than 0.8. Two data managers performed double-checking and logical validation, and discrepancies were verified against the original medical records. After database lock, data were exported for statistical analysis. Missing and outlier values were traced or flagged according to predefined rules, with no arbitrary imputation.

Sample Size Estimation

The primary endpoint was a comparison of feeding intolerance incidence within 7 days between 2 independent samples. Routine care audits in the second half of 2023 at our center showed a 7-day feeding intolerance of approximately 45%, and the intervention group was expected to decrease to 28% (absolute risk difference 17%). With α=0.05 (2-sided) and 80% power, the 2-proportion normal approximation indicated that 125 participants per group were required; considering a 10% loss to follow-up or withdrawal, 139 participants were included per group, for a total of 278.

Statistical Analysis

Analysis populations included the intention-to-treat (ITT) set (all randomized and initiated feeding), the per-protocol set (on the basis of ITT excluding major protocol deviations), and the safety set (received at least 1 feeding). The primary endpoint analysis was ITT-based, using the chi-square test and multivariable log-binomial regression (adjusting for age, sex, NIHSS, and baseline aspiration risk) to compare feeding intolerance incidence, reporting adjusted relative risk and 95% confidence intervals (CIs) and providing absolute risk difference and 95% CIs. Missing data for the primary endpoint were handled by multiple imputation (chained equations, 20 imputations, with covariates including baseline and daily assessment variables). Sensitivity analyses used the worst-case assumption (missing in the intervention group treated as events, and missing in the control group treated as non-events) and the per-protocol analysis. The convergence status of each log-binomial model, including models fitted within multiply imputed datasets and complete-case, sensitivity, and subgroup analyses, was checked. Modified Poisson regression with robust variance estimation was defined as the fallback method if convergence failed; in the present analyses, all log-binomial models converged and no fallback estimates were used.

Among secondary outcomes, time to target was estimated using the Kaplan-Meier method, and the Cox proportional hazards model compared between-group differences and tested the proportional hazards assumption. The proportion of target-achieving days was analyzed using beta regression or a 2-sample *t* test (after tests of homogeneity of variance and normality). Aspiration-related pneumonia was reported as risk ratio combined with time distribution. Electrolyte disturbances and tube displacement were described using risk ratio and incidence density, with between-group comparisons by the chi-square or Fisher exact test. Subgroup analyses were prespecified by age (≥80, <80 years), NIHSS (≥15, <15 points), and baseline aspiration risk (moderate/high, low), and interaction *P* values were reported. Additionally, a sensitivity analysis was conducted for the attribution of unplanned pump stoppage (examination-related fasting).

Key secondary endpoints (time to target, proportion of target-achieving days, aspiration-related pneumonia) used the Holm-Bonferroni method to control the familywise error rate at α=0.05; other secondary and safety endpoints presented 95% CIs without multiplicity adjustment. Statistical analyses used R 4.3.2 software, and 2-sided P<0.05 was considered statistically significant.

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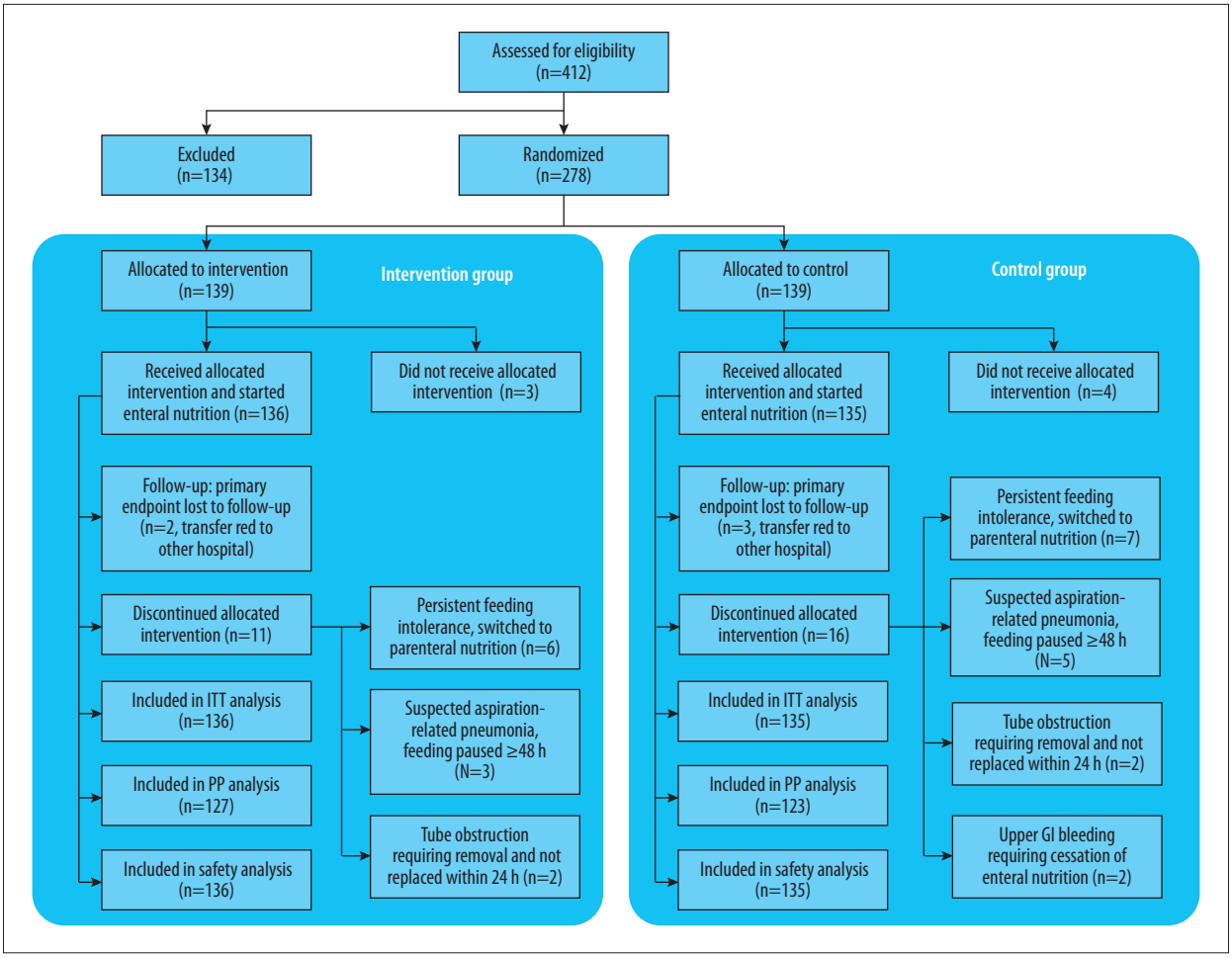

Figure 1. CONSORT flow diagram. ITT indicates the intention-to-treat set (randomized participants who initiated enteral nutrition); PP indicates the per-protocol set (intention-to-treat [ITT] excluding major protocol deviations); the safety set includes participants who received at least 1 enteral feeding; n denotes the number of participants.

Results

Study Population and Baseline Characteristics

A total of 412 patients were screened, and 278 completed randomization, with 139 in each group: 136 in the intervention group and 135 in the control group initiated enteral nutrition and constituted the ITT and safety sets, and the per-protocol sets were 127 and 123 (**Figure 1**). Baseline demographics and disease severity were generally balanced between the 2 groups. The intervention and control groups had similar distributions in age, sex, body mass index, NIHSS, GCS, aspiration risk level at enrollment, and laboratory indices (all standard mean difference [SMD] <0.10), with only a slightly higher Charlson Comorbidity Index (SMD=0.12). Overall, no important baseline imbalance was observed (**Table 1**).

Primary Endpoint: 7-Day Feeding Intolerance

In the multiply imputed ITT set, log-binomial regression showed that the intervention group had a lower incidence of feeding intolerance within 7 days than the control group (27.94% vs 45.19%), with adjusted risk ratio (RR_adj) of 0.61 (95% CI 0.47-0.81, *P*=0.003), indicating a statistically significant difference in the primary endpoint between the 2 groups (**Table 2**).

Secondary Endpoints: Efficiency of Nutritional Target Attainment and Aspiration-Related Events

Kaplan-Meier analysis showed that the time to achieving at least 80% of the energy target was significantly earlier in the intervention group than in the control group (log-rank *P*<0.001). Cox regression (adjusting for age, sex, NIHSS, and baseline aspiration risk level) indicated a faster target attainment rate in the intervention group, with an adjusted hazard ratio of 1.65 (95% CI, 1.25-2.17) (**Figure 2**). Compared with the control

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Table 1. Baseline characteristics.

Variables	Intervention group (n=136)	Control group (n=135)	SMD
Age (years)	76.42±7.83	76.07±7.61	0.05
Female	59 (43.38%)	60 (44.44%)	0.02
Body mass index (kg/m^2)	23.41±3.27	23.58±3.12	0.05
Interval from onset to randomization (hours)	21.6 [14.3, 33.1]	22.1 [14.9, 33.7]	0.03
NIHSS (points)	12 [8, 17]	12 [8, 16]	0.04
GCS (points)	12 [10, 14]	12 [10, 14]	0.03
Endotracheal intubation at enrollment	9 (6.62%)	10 (7.41%)	0.03
Charlson Comorbidity Index (points)	4 [3, 6]	4 [3, 5]	0.12
Aspiration risk at enrollment: low	62 (45.59%)	60 (44.44%)	0.02
Aspiration risk at enrollment: moderate/high	74 (54.41%)	75 (55.56%)	0.02
Serum albumin (g/L)	37.82±3.91	37.55±4.08	0.07
Creatinine (μmol/L)	87.36±24.71	86.93±25.14	0.02
Sodium (mmol/L)	139.27±3.82	139.41±3.79	0.04
Potassium (mmol/L)	4.08±0.47	4.11±0.52	0.06
Current smoking	31 (22.79%)	28 (20.74%)	0.05
Diabetes	40 (29.41%)	37 (27.41%)	0.04
Chronic pulmonary disease	20 (14.71%)	18 (13.33%)	0.04

Standard mean difference (SMD) was calculated using the Hedges method; for binary variables, SMD was based on the difference in proportions between groups divided by the pooled standard deviation. Abbreviations: GCS, Glasgow Coma Scale; NIHSS, National Institutes of Health Stroke Scale.

Table 2. Primary endpoint: incidence of feeding intolerance within the first 7 days.

Item	First feeding intolerance within 7 days
Intervention group	38/136 (27.94%)
Control group	61/135 (45.19%)
Unadjusted RR (95% CI)	0.62 (0.45-0.86)
RD (95% CI)	-17.24% (-28.53%, -5.96%)
RR_adj (95% CI)	0.61 (0.47-0.81)
P value (adjusted model)	0.003

Unadjusted relative risk (RR) and risk difference (RD) used binomial approximations to estimate the 95% CI. Adjusted relative risk (RR_adj) and *P* value were based on log-binomial regression after multiple imputation (chained equations, 20 imputations), with covariates including age, sex, National Institutes of Health Stroke Scale, and aspiration risk level at enrollment.

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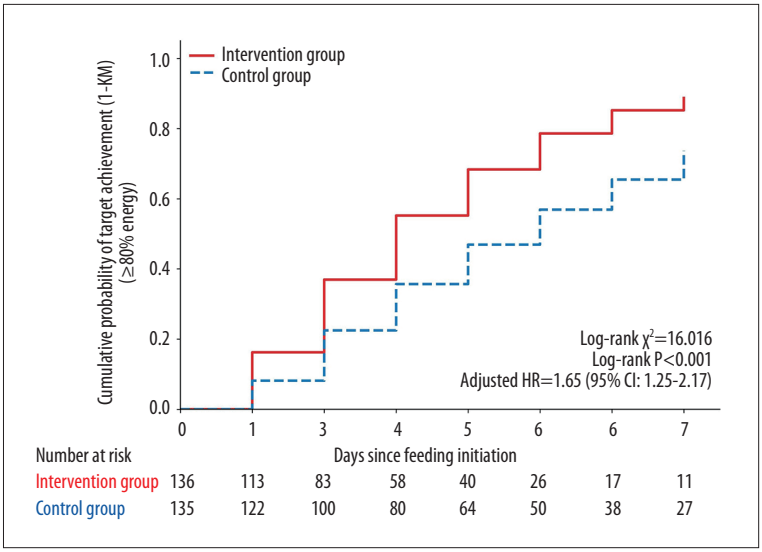

Figure 2. Time to achieve at least 80% energy target (Kaplan-Meier curves, intention-to-treat [ITT] population). The event was defined as the first achievement of at least 80% of prescribed energy intake sustained for 24 hours. Participants were censored at discharge/transfer or at day 7 without the event. Groups were compared using the log-rank test; the hazard ratio (HR) was derived from a Cox proportional hazards model adjusted for age, sex, National Institutes of Health Stroke Scale (NIHSS), and baseline aspiration-risk category; analyses were based on the ITT population.

Table 3. Proportion of target-achieving days, aspiration-related pneumonia, and feeding-related hypoxemia (first 7 days, intention-to-treat [ITT]).

Outcome (first 7 days)	Intervention group	Control group	Effect size (95% CI)	P value
Proportion of target-achieving days (target days/7)	0.58 (0.54-0.62)	0.42 (0.38-0.46)	ΔP=0.16 (0.10-0.22)	P_Holm=0.001
Suspected/confirmed aspiration-related pneumonia (≥1 time)	9/136 (6.62%)	18/135 (13.33%)	RR_adj=0.54 (0.30-0.97)	P_Holm=0.041
Feeding-related hypoxemia (≥1 time)	8/136 (5.88%)	14/135 (10.37%)	RR=0.57 (0.25-1.31)	*P*=0.189

Proportion of target-achieving days: beta regression (logit link, with continuity correction), reporting marginal means and Δ*P*. Pneumonia: log-binomial regression (adjusting for age, sex, National Institutes of Health Stroke Scale, and baseline aspiration risk), reporting adjusted relative risk (RR_adj). Hypoxemia: RR by the Katz method; *P* by Fisher's exact test. The *P* values for the proportion of target-achieving days and pneumonia are Holm-Bonferroni-adjusted 2-sided P values; the *P* value for hypoxemia is unadjusted.

group, the intervention group had a higher proportion of target-achieving days during the first 7 days and a lower risk of aspiration-related pneumonia (both P_Holm <0.05), while the difference in feeding-related hypoxemia did not reach statistical significance (*P*=0.189, unadjusted) (**Table 3**).

Safety, Process Quality, and Feasibility

Using Fisher's exact test and calculating Katz relative risk showed that the between-group differences in the 7-day incidences of nasoenteric tube displacement, upper gastrointestinal bleeding, and electrolyte disturbances were not statistically significant (all *P*>0.05), indicating that no additional short-term safety risk was observed for the intervention pathway (**Table 4**). The quality of pathway execution in the intervention group was generally good. The on-time completion rate of assessments every 4 hours was 94.27%, the concordance rate between advancement/pause/rollback decisions and the algorithm was 93.23%, and the head-of-bed position attainment rate was 91.34%. Other process indicators performed well; the median daily time for assessment-rate adjustment operations was 33.8 minutes/day (**Table 5**). The median cumulative duration of unplanned pump stoppage within 7 days was lower in the intervention group than in the control group (3.6 h vs 6.8 h). In both groups, gastrointestinal symptoms were the main cause, with a higher proportion of stoppages due to gastrointestinal symptoms and tube problems in the control group (**Figure 3**). The 95% CI for the between-group difference in total daily nursing time and number of tube flushes crossed 0, suggesting an uncertain direction of difference for these workload indicators; the 95% CI for the between-group difference in infusion consumables usage did not cross 0, suggesting that the intervention group might have slightly lower usage than the control group (**Table 6**).

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Table 4. Summary of safety outcomes and post-randomization tube-related descriptive indicators.

Event type/indicator	Intervention group	Control group	RR (95% CI)	P value
Nasoenteric tube displacement (confirmed by imaging or electromagnetic records)	7/136 (5.15%)	10/135 (7.41%)	0.69 (0.27-1.77)	0.465
Upper gastrointestinal bleeding (as defined)	3/136 (2.21%)	5/135 (3.70%)	0.60 (0.15-2.44)	0.500
Electrolyte disturbances (at least one of hyponatremia/hypokalemia/hypophosphatemia)	18/136 (13.24%)	22/135 (16.30%)	0.81 (0.46-1.44)	0.498
New endotracheal intubation during the 7-day follow-up among participants not intubated at enrollment	4/127 (3.15%)	5/125 (4.00%)	Descriptive only	Not tested
Time to nasoenteric tube repositioning after displacement, hours, M[IQR]	7.3 [5.6, 9.4]	8.0 [6.1, 10.2]	Descriptive only	Not tested

P values were calculated using Fisher's exact test; relative risk (RR) and 95% CI were calculated using the Katz method. Post-randomization tube-related indicators were reported descriptively only and were not used for inferential comparisons. New endotracheal intubation during follow-up was calculated only among participants who were not intubated at enrollment. Time to nasoenteric tube repositioning referred to the time from confirmed displacement to the first successful repositioning and was summarized only among participants with confirmed tube displacement.

Table 5. Pathway execution consistency and process quality indicators in the intervention group.

Indicator name	Observed value (95% CI)
On-time completion proportion of 4-hourly assessments	94.27% (93.67-94.87)
Concordance rate between advancement/pause/rollback decisions and algorithm	93.23% (92.08-94.38)
Head-of-bed position attainment rate (low risk ≥30°, moderate/high risk ≥45°)	91.34% (CI 90.61-92.07)
Execution rate of pump rate reduction before and after turning and suctioning	86.70% (CI 84.72-88.68)
Zero incidence of "bolus feeding without stopping the pump"	99.26% (CI 95.95-99.87)
Infusion tubing replacement compliance rate	96.48% (CI 95.90-97.07)
Daily time for assessment-rate adjustment operations (minutes/day, M[IQR])	33.8 [27.6, 41.0]

The 95% CI for proportions were calculated using the Wilson method. Daily assessments were performed once every 4 hours, and each patient was expected to undergo 42 assessments within 7 days. The decision consistency rate was calculated based on the recorded advancement/pause/rollback decision events; the postural compliance rate was calculated based on the number of posture assessments. The "pump rate reduction compliance rate" was calculated based on the recorded turning or suctioning events; the zero-incidence rate of "bolus feeding without stopping the pump" was calculated based on the number of patients; feeding tubing replacement was calculated according to the requirement of once every 6 hours. No inferential testing was performed.

Prespecified Subgroup and Sensitivity Analyses

Prespecified subgroup analysis based on log-binomial regression showed that, after stratification by age, NIHSS, and baseline aspiration risk, the direction of the intervention effect on 7-day feeding intolerance was consistent across subgroups (all RR_adj <1), and no significant interaction was observed (all $P>0.05$) (**Figure 4**). Sensitivity analyses using log-binomial regression showed that in the complete-case ITT, worst-case ITT, and per-protocol analyses, the magnitude of the reduction in feeding intolerance risk in the intervention group compared with the control group was consistent (RR_adj=0.58-0.65, all $P<0.01$), suggesting good robustness of the primary endpoint conclusion across different analysis sets/missing-data handling strategies (**Table 7**).

Discussion

Feeding intolerance within 7 days was less frequent in the intervention group, and the difference remained after adjustment for age, sex, stroke severity, and baseline aspiration risk. The group with a slightly higher baseline comorbidity burden still benefited, suggesting that the effect is unlikely to be driven

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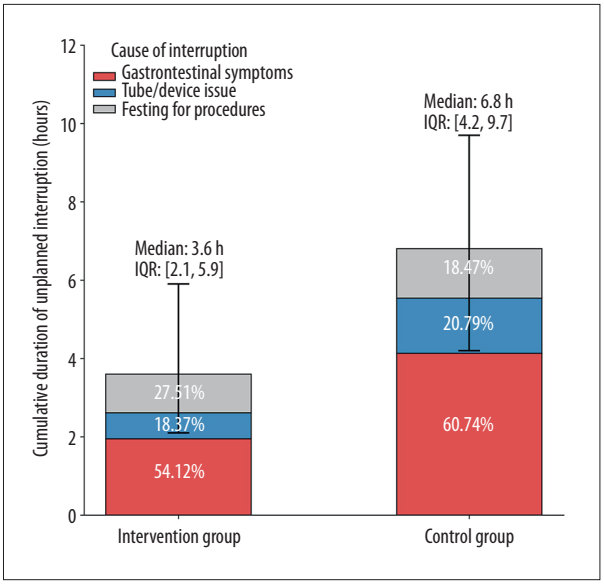

Figure 3. Cumulative duration and causes of unplanned feeding interruptions. Cumulative unplanned feeding interruption time was the total hours over the first 7 days per participant; bar height represents the group median. Stacked segments indicate the proportion of total interruption time attributed to gastrointestinal symptoms, tube/device issues, and diagnostic fasting. Planned interruptions were excluded.

by baseline imbalance. Consistent directions were observed across strata of age, NIHSS, and aspiration risk, and similar effects were found in the complete-case, worst-case missing-data, and per-protocol analyses, indicating robustness of the results. Feeding intolerance triggers rate reduction and pump stoppage, leading to insufficient early energy delivery and increased risks of vomiting, reflux, and aspiration-related complications [19]. Although post-pyloric tube placement reduces reflux related to gastric retention, post-stroke hypomotility, sympathetic activation, bed rest, and medications can still lead to abdominal distension, diarrhea, and failure of advancement [20]. The nursing pathway combined tolerance symptoms and the consequences of pump stoppage and rate reduction into actionable thresholds, and used staged initiation, increment, and rollback rules to adjust when early mild signals appeared, reducing fluctuations in intestinal load and decreasing the cycle of repeated stoppage and re-advancement [21]. After incorporating aspiration risk stratification into the same algorithm, risk control was achieved mainly through positioning management and rate adjustments around nursing procedures, reducing excessive interruptions due to concern about aspiration and making continuous infusion easier to maintain. Prior guidelines emphasize early enteral nutrition and standardized feeding protocols and oppose routine use of gastric residual volume for guidance [22]; existing evidence is mostly from general critical care populations, and randomized evidence is insufficient for older adult patients with ischemic stroke and dysphagia using post-pyloric nasoenteric tubes [23]. This study translated dual-axis dynamic assessment into a replicable pathway and verified its clinical benefit in reducing feeding intolerance, providing methodological support for early enteral nutrition nursing in the stroke unit.

The results of survival analysis and beta regression consistently suggested that the intervention group reached the staged target of the prescribed energy more quickly and maintained greater stability of target attainment during the first 7 days; concomitantly, the cumulative duration of unplanned pump stoppage decreased, and stoppage remained mainly attributable to gastrointestinal symptoms, suggesting that the advantage in target attainment derived more from improved feeding continuity rather than simply increasing the pump rate. The staged pathway translated advancement and rollback into executable rules. The feeding rate was increased by preset increments when tolerance was adequate, and at the first signs of limited tolerance, the rate was immediately reduced or paused briefly, followed by a stabilization period. This approach

Table 6. Nursing workload and resource consumption.

Indicator name	Interventio group	Control group	Between-group difference (95% CI)
Total daily nursing time (minutes/day) M[IQR]	92.7 [74.2, 113.6]	94.8 [77.1, 118.9]	-1.9 (-6.32, 2.24)
Infusion consumables usage (sets/day) Mean (95% CI)	3.86 (95% CI 3.79-3.93)	3.98 (95% CI 3.90-4.06)	-0.12 (-0.21, -0.03)
Number of tube flushes (times/day) M[IQR]	6.9 [6.1, 8.2]	7.3 [6.3, 8.5]	-0.41 (-0.83, 0.02)

Total daily nursing time and number of tube flushes had skewed distributions, and the median difference and 95% CI were estimated using the Hodges-Lehmann method; infusion consumables usage was approximately normally distributed, and the mean difference and 95% CI were estimated using an ordinary least squares linear model. Resource use was measured over 24 hours. *P* values are not reported and no multiplicity adjustment was performed.

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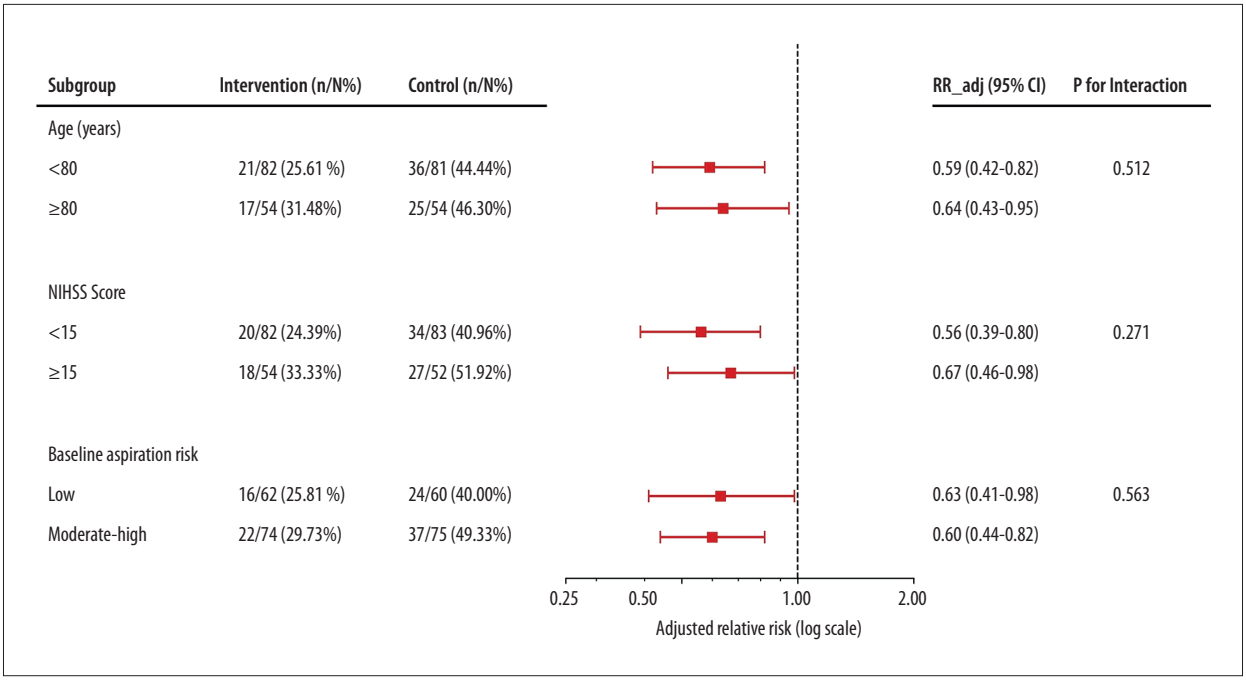

Figure 4. Subgroup analysis of primary outcome. RR_adj represents the adjusted relative risk of 7-day feeding intolerance for the intervention group versus the control group, estimated using log-binomial regression adjusted for age, sex, National Institutes of Health Stroke Scale (NIHSS), and baseline aspiration-risk category. Interaction *P* values were derived from models including treatment-by-subgroup terms. Subgroup analyses were prespecified and exploratory, without multiplicity adjustment.

Table 7. Effect estimates of sensitivity analyses for the primary endpoint.

Analysis set/approach	Analysis sample aize (intervention/control)	RR_adj (95% CI)	*P* value
Complete-case ITT analysis (no imputation)	134/132	0.62 (0.47-0.82)	0.004
Worst-case ITT analysis (missing in the intervention group treated as events, and missing in the control group treated as non-events)	136/135	0.65 (0.51-0.84)	0.006
Per-protocol analysis	127/123	0.58 (0.43-0.77)	0.001

All analyses used log-binomial regression with covariates consistent with the primary analysis (age, sex, National Institutes of Health Stroke Scale, and baseline aspiration risk level). RR_adj denotes adjusted relative risk. *P* values are 2-sided and without multiplicity adjustment.

smoothed changes in intestinal load and reduced secondary intolerance as well as the accumulation of interruptions caused by repeated trial increases of the pump rate [24]. Aspiration risk stratification and management around nursing procedures were embedded into the same process, with proactive pump rate adjustments during turning, suctioning, and nighttime periods, reducing interruptions and restart fluctuations triggered by nursing procedures and decreasing precautionary pump stoppages driven by concerns about aspiration [25]. Continuous infusion was easier to maintain under these rules; the energy gap was bridged by reducing interruptions, thereby shortening the time to first target attainment and increasing the proportion of target-achieving days. Previous studies have indicated that inadequate energy delivery is mainly due to unplanned interruptions rather than insufficient prescriptions [26], and standardized feeding protocols and continuous infusion can improve actual delivery, but simply pursuing rapid advancement may increase intolerance and offset the benefits [27]. Compared with prior evidence predominantly from general critical care populations, in older adult patients with

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ischemic stroke and dysphagia receiving post-pyloric nasoenteric feeding, integrating tolerance thresholds and aspiration-risk nodes into pathway-based decisions and verifying their clinically feasible delivery through complementary indicators—time to target and proportion of target-achieving days—demonstrated improved nutritional management.

Even under post-pyloric feeding conditions, the risk of aspiration-related pneumonia was still observed to be lower in the intervention group, and the difference remained after adjustment for confounders and multiple testing correction. No clear difference was observed in feeding-related hypoxemia, suggesting that short-term hypoxemia is more influenced by baseline pulmonary function, suctioning frequency, and monitoring intensity. Hypoxemia events were mostly transient fluctuations and infrequent, making effect estimates more susceptible to random error. No between-group increases were observed in nasoenteric tube displacement, upper gastrointestinal bleeding, or electrolyte disturbances. Pathway assessment and decision consistency remained high, with the 95% CIs for the between-group differences in total nursing time and number of tube flushes crossing zero, whereas the difference in infusion consumables usage tended to decrease, indicating that risk control mainly resulted from workflow redesign rather than additional manpower input.

Patients with stroke-related dysphagia have impaired airway protection and a high secretion burden, and post-pyloric tube placement only reduces the reflux pathway but cannot eliminate microaspiration [28]. Incorporating aspiration risk stratification with head-of-bed elevation, making rate adjustments before and after turning and suctioning, and avoiding rate increases at night into the algorithm can narrow the window of airway exposure and reduce nursing procedure-induced reflux [29]. After feeding intolerance decreased, the reflux load triggered by vomiting and abdominal distension decreased accordingly, reducing airway exposure from repeated pump stoppage and restart, which is favorable for controlling pneumonia risk [30]. Previous evidence supports that post-pyloric feeding and care bundles such as head-of-bed elevation reduce aspiration complications, but evidence is limited on adding dynamic risk management on top of post-pyloric feeding and verifying it in randomized trials. This pathway translates risk identification, positioning, and rate adjustment into executable rules, providing a replicable practice paradigm for the stroke unit.

Limitations

The single-center design makes the conclusions more closely reflect the staffing structure, training frequency, and equipment configuration of our hospital's stroke unit; when extrapolated to institutions with different nurse-to-patient ratios, different tube placement confirmation procedures, or different nutritional prescription practices, pathway adherence rate and effect size may vary. Blinding of nursing staff and patients was not feasible. Although the primary endpoint and pneumonia were determined by independent assessors, the pathway itself could change nursing behavior and the density of recording, which could introduce performance bias. The primary endpoint adopted a composite definition of feeding intolerance that can reflect clinical decision-making, but the composite items included symptoms and rate reduction and pump stoppage caused by symptoms. Because rate reduction, pump stoppage, and failure to advance feeding were partly clinician- or nurse-driven, non-blinded care may have influenced the threshold for recording or acting on these components, despite prespecified criteria, blinded adjudication, standardized case report forms, and quality-control procedures. The effects of different components on prognosis are not fully equivalent, and the present sample size was insufficient to make adequate inferences about each component separately. Improvements in target attainment efficiency and pump stoppage duration suggest that continuity is an important mediator, but no formal mediation analysis was conducted, and the proportion of the primary effect attributable to reduced pump stoppage could not be quantified. The observation window was limited to 7 days and did not cover the in-hospital cumulative nutritional deficit, sarcopenia, or functional recovery, nor did it assess post-discharge readmission and long-term pulmonary complications, making it difficult to directly address the pathway's effect on long-term outcomes. Future studies should adopt the same algorithm and a standardized training package across multiple centers, predefine major protocol deviations and a minimum acceptable adherence rate, extend follow-up and include more patient-centered outcomes, and incorporate workflow time costs and consumables costs to clarify the resources required for broader implementation and sustainability.

Conclusions

A staged enteral nutrition nursing pathway driven by dynamic assessment of tolerance and aspiration risk, in older adult patients with acute ischemic stroke and dysphagia receiving post-pyloric nasoenteric feeding, compared with usual care, reduced early feeding intolerance and, without increasing short-term adverse events, improved the speed and stability of target attainment in nutritional delivery, shortened the cumulative duration of unplanned pump stoppage, and reduced aspiration-related pneumonia associated with feeding. The effects were consistent in prespecified subgroup and sensitivity analyses, demonstrating robustness. This pathway translates tolerance thresholds and risk nodes into executable advancement and rollback algorithms, combined with positioning and rate adjustments around nursing procedures, with good adherence and operability and without an increase in nursing workload.

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The results indicate that pathway-based decision-making centered on continuity and risk control can improve the quality of early enteral nutrition in the stroke unit.

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Patient Permission/Consent

Written informed consent was obtained from all participants.

Declaration of Figures' Authenticity

All figures submitted have been created by the authors who confirm that the images are original with no duplication and have not been previously published in whole or in part.

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