

Original Article

Evidence-based bundled care for patients with dysphagia after severe traumatic brain injury: a randomized controlled trial

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Abstract: Objective: To explore the effect of an evidence-based bundled care model in patients with dysphagia after severe traumatic brain injury (TBI). Methods: This is a prospective randomized controlled study. A total of 60 patients with dysphagia after severe TBI (traumatic brain injury) admitted to the Department of Rehabilitation Medicine were selected and randomly divided into the test group (n=30) and the control group (n=30). Patients in the control group received routine care in the Department of Rehabilitation Medicine, while patients in the test group received evidence-based bundled care on the basis of the treatment of the control group. The improvement of swallowing function (dye test in comatose patients), oral hygiene, and nutritional risk was assessed in both groups. The incidence of adverse events such as aspiration and aspiration pneumonia, as well as the length and costs of hospitalization were compared between the two groups. Results: Compared with patients in the control group, swallowing function of patients in the test group was significantly improved after the care ($P<0.05$), and for comatose patients, the positive rate of Evans blue dye test was markedly reduced ($P<0.05$). Compared with patients in the control group, the oral hygiene of patients in the test group was significantly improved after care, and the nutritional risk scores were also significantly decreased ($P<0.05$). During hospitalization, the total incidence of adverse events, length and costs of hospitalization of patients in the test group were significantly lower than those in the control group ($P<0.05$). Conclusion: Evidence-based bundled care can effectively improve swallowing function and reduce the incidence of nutritional risks and adverse events in patients with dysphagia after severe TBI, which further promotes postoperative rehabilitation of patients.

Keywords: Severe traumatic brain injury, dysphagia, evidence-based, bundled care, swallowing function

Introduction

Traumatic brain injury (TBI) is defined as a severely disabling neurological disease resulting from direct or indirect external forces acting on the brain, with severe TBI patients at the highest risk [1, 2]. With a Glasgow coma scale (GCS) score of ≤ 8 , such patients have high morbidity and mortality rates [2, 3]. Therefore, it has always been a challenge to effectively promote postoperative rehabilitation and improve the long-term prognosis of patients with severe TBI in clinical practice.

Studies have shown that up to 61% of patients with severe TBI may develop dysphagia, which leads to choking while drinking water, aspiration pneumonia, aspiration, malnutrition and

dehydration; seriously impeding nutritional intake, rehabilitation and quality of life of patients, and causing death by suffocation in severe cases [3, 4]. Therefore, rehabilitation care and management for dysphagia in patients with severe TBI are critical for facilitating rehabilitation and prognosis of patients [5]. However, current research on dysphagia is mainly focused on stroke patients [6]. Relevant reports regarding dysphagia in patients after severe TBI are inadequate and lack corresponding guidelines. Also, experimental data of large sample sizes and multi-center studies are insufficient. Therefore, it is urgent to construct a systematic, comprehensive, and multi-layer system for managing dysphagia in patients after severe TBI, in clinical practice.

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Table 1. Baseline data of patients in the two groups ($\bar{x} \pm sd$)

Characteristics	Test group (n=30)	Control group (n=30)	t or χ^2	P
Gender (n (%))			0.659	0.417
Male	18 (60.00)	21 (70.00)		
Female	12 (40.00)	9 (30.00)		
Age (years)	55.2±5.5	54.8±6.2	0.264	0.793
Cases of tracheotomies (n (%))	11 (36.67)	9 (30.00)	0.300	0.584
GCS score (points)	11.83±2.64	11.46±3.13	0.406	0.686
MASA score	71.78±8.45	72.03±8.23	0.116	0.908
Course of disease (d)	49.5±18.4	51.3±21.2	0.351	0.727

Note: GCS: Glasgow coma scale; MASA: Modified Mann's Assessment of Swallowing Ability.

Bundled care is a nursing program designed to address certain problems of patients, which consists of a series of nursing measures [7]. Each measure has been clinically validated, which can effectively improve patient outcomes. Besides, with these measures working together, the effect of care is further improved. At present, bundled care is widely practiced in the clinical fields of stroke disease, emergency medicine, prevention of nasogastric feeding reflux, pulmonary aspiration, ventilator-associated pneumonia (VAP), and various venous catheterization techniques [7-9]. The clinical characteristics of patients with dysphagia after severe TBI are indwelling of the tracheal tube and gastric tube, and disturbance of consciousness. Considering these features, a comprehensive nursing intervention containing various measures is needed to promote the rehabilitation of patients with dysphagia after severe TBI [10]. Therefore, based on scientific evidence, we developed a bundled nursing program for patients with dysphagia after severe TBI, and observed the effect of such care in the rehabilitation of patients with dysphagia through a randomized controlled design, in the hope of providing a reference for the management of dysphagia after severe TBI in future clinical practice.

Materials and methods

Patients

A total of 60 patients with dysphagia after severe TBI admitted to Qijing No. 1 Hospital between May 2020 and October 2020 were included in the study. The patients were randomly divided into the test group (n=30) and the control group (n=30) by a random number

table. See **Table 1** for general clinical data of the two groups.

Inclusion criteria: (1) Patients met the diagnostic criteria for severe TBI according to the "Guidelines for the Management of Severe Traumatic Brain Injury (Fourth Edition)" issued by the American Brain Trauma Foundation in 2016, and had a GCS score ≤ 8 [11]; (2) Patients had dysphagia within 6 months after the onset of traumatic brain injury in rehabilitation hospitals; (3) Patients did not receive systematic rehabilitation intervention of dysphagia before the study.

Exclusion criteria: (1) Patients had a history of related swallowing diseases; (2) Patients who had severe complications involving dysfunctions of the heart, lung, kidney, and liver; (3) Patients complicated with mental illness; (4) Patients who withdrew from the study, transferred to another hospital or died during intervention; (5) Patients who had incomplete medical records.

Ethical statement

This study conformed to the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Qijing No. 1 Hospital. All patients and their families were informed of the procedures of this study and signed the informed consent.

Bundles of care

Patients in both groups received routine care in the Department of Rehabilitation Medicine, including care of rehabilitation specialties such as; airway, diet, oral hygiene, medication, health, and psychology. Patients in the test group received bundled care on the basis of the treatment of the control group. The details are as follows:

Establishment of bundled care group

The bundled care group consisted of head nurses, primary nurses, speech therapists, physicians in charge, and dietitians in the Department of Rehabilitation Medicine. All members

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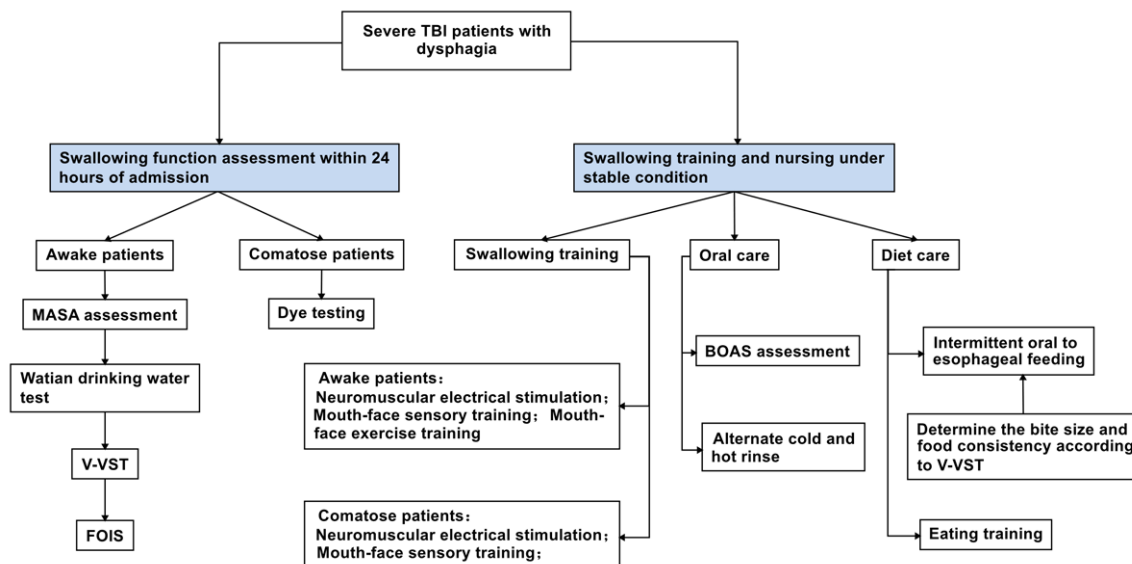


Figure 1. Bundled care program for dysphagia after severe TBI. MASA: Modified Mann's Assessment of Swallowing Ability; BOAS: Beck Oral Assessment Scale; V-VST: Volume-viscosity swallow test; FOIS: Functional oral intake scale.

had 3 to 5 years of specialist experience. A multidisciplinary collaborative care model was employed. The group leader position was assumed by the head nurse of the Department of Rehabilitation Medicine, who was responsible for the management of the group, including group discussion and supervision for the implementation of various bundled care, and quality inspection. The primary nurses were responsible for implementing the bundled care program in patients, monitoring and evaluating swallowing function, closely observing vital signs, and reporting changes in the patient's condition to the doctor. Speech therapists were responsible for specific procedures of oral training. The physician in charge was mainly responsible for clinical therapy and management, and by communicating with primary nurses during the treatment and adjusting the care focus according to the patient's actual conditions, ensuring the best effect of rehabilitation. Dietitians were responsible for nutritional status of patients based on the results of nutritional risk screening and personalized nutritional programs for different patients.

Construction of evidence-based bundled care program

We constructed a bundled care program for patients with dysphagia after severe TBI according to the five steps of evidence-based

care model: identifying problems (Patient/Problem, Intervention, Comparison and Outcome, i.e. PICO strategies), searching, accessing, and applying the literature, as well as evaluating the effects [12, 13]. Relevant literature on patients with dysphagia after severe TBI was systematically retrieved and this included medium- or high-quality literature data. Afterwards, a bundled care program for these patients was scientifically developed according to the conditions of our hospital (Figure 1).

Implementation of bundled care program

Evaluation and monitoring of swallowing function: On the first day in the Department of Rehabilitation Medicine, all patients, either conscious or unconscious, underwent early bedside screening and evaluation. Patients with conscious disturbance who could not receive a comprehensive clinical assessment were monitored for swallowing function on a daily basis, and patients with dysphagia were evaluated regularly.

(1) Conscious patients were evaluated accordingly as follows: a. Modified Mann's Assessment of Swallowing Ability (MASA): Patients with a total score of ≥ 95 were allowed to eat and drink water, and the patient's first drinking profile was observed [14, 15]. Patients with a total score of ≤ 94 were prohibited from consuming food and water temporarily.

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b. Watian drinking water test: The patient was given 300 mL of warm water in a sitting position and observed for grading. Grade I: The patient finished drinking in 1 gulp without choking; Grade II: The patient finished drinking in 2 or more gulps without choking; Grade III: The patient finished drinking in 1 gulp with choking; Grade IV: The patient finished drinking in 2 or more gulps with choking; Grade V: The patient choked constantly and had difficulty drinking all the water. Guidance on eating methods was given to patients graded II and III. For patients graded IV and above, active rehabilitation therapy was given [16].

c. Volume-viscosity swallow test (V-VST): Determined the most appropriate bite sizes and viscosity for patients [17].

d. Functional oral intake scale (FOIS): Patients' ability of food intake was evaluated [18].

(2) Patients with disturbance of consciousness were screened for risk of aspiration by Evans blue dye test: Blue or green food dyes were mixed with water or semi-solid foods and swallowed by the patients [19]. Then the patients were observed for aspiration using sputum suction tube within the tracheal tube for food residue, with the presence of blue-dyed foods representing positive results.

Oral training: When the patients' conditions became stable, oral training was performed, including neuromuscular electrical stimulation, orofacial sensory training, and orofacial exercise training. Patients with disturbance of consciousness did not undergo orofacial motor training.

(1) Neuromuscular electrical stimulation (NMES): VitalStim Therapy System for nerve and muscle stimulation (US) was used for treating the patients. The stimulation intensity was adjusted according to the degree of dysphagia of the patient (0-10 mA), with a constant pulse rate of 80 Hz. By assessing swallowing functions, two output electrodes were placed in different anatomical positions. Meanwhile, the patient was asked to eat or swallow during stimulation. Such stimulation was performed for 30 min per day, 5 days a week [20].

(2) Orofacial sensory training: a. Ice stimulation: The lingual surface, palatal arch, soft palate, the back of tongue, posterior pharyngeal wall and cheeks were stimulated extensively using an iced cotton swab for a long time.

During the procedure, left and right oral cavity of the patients was stimulated alternatively by slowly moving the swab. The stimulation was discontinued instantly if the patients had vomiting reflex. The treatment was performed for 10 min per day, 5 days a week.

b. Oral vibration stimulation: Inner cheek, tongue, oral cavity and posterior pharyngeal wall of the patients were brushed with a modified vibration stick, in order to stimulate deep sensation of these sites and improve motor coordination of the mouth and face. The treatment was continued for 10 min per day, 5 days a week.

c. Trigger point (K-point) stimulation: The patients were stimulated at K-point by a special teaspoon, cotton stick or finger, in order to facilitate mouth opening and swallowing. The treatment was performed 5 to 10 times per day, 5 days a week.

d. Orofacial relaxation training: Mouth and cheek muscles, including masticatory and suprahyoid muscles, were massaged and relaxed gently. Such treatment was conducted 10 min per day, 5 days a week.

(3) Orofacial exercise training: Orofacial exercise training included exercises of the mandible, lips, tongue, and soft palate. These exercises were performed for 10 min per day, 5 days per week.

Oral care: (1) Oral hygiene assessment: Using a modified Beck Oral Assessment Scale (BOAS), patients were assessed for oral cavity, mainly including presences of sputum adhesion, food residue, ulcers, scabs, inflammation, bleeding, defective teeth, and dental calculus, as well as conditions of the tongue and saliva [21].

(2) Oral care of alternating cold and hot rinse: Alternating cold and hot rinse is applicable for patients with dysphagia or critical illness (patients in coma, on tracheal intubation, or after tracheotomy) graded III or above in Watian drinking water test. By connecting the suction device to a toothbrush, an alternative rinse of cold and hot running water under negative pressure was performed to flush and clear away liquid and residues in the oral cavity. This is conducive to cleaning the oral cavity, and preventing and treating oral diseases. Such oral care of flushing and sucking (washing) was conducted twice a day, in order to exert ade-

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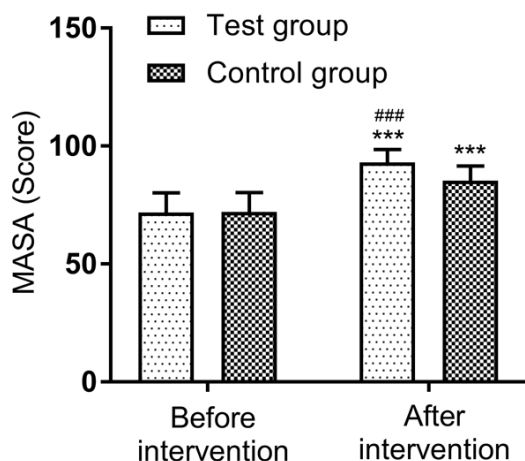


Figure 2. MASA scores before and after intervention in both groups. Compared with that before intervention, *** $P < 0.001$; compared with the control group, ### $P < 0.001$. MASA: Modified Mann's Assessment of Swallowing Ability.

quate stimulation on the mouth, tongue and pharyngeal muscles, reduce swallowing, promote motor recovery, and prevent accidental aspiration.

Diet care: An appropriate eating method was selected according to the actual conditions and functional status of patients. Nasogastric and intravenous nutrition feeding were performed in patients with disturbance of consciousness and dysphagia who could not ingest enough water and calories orally. Evidence-based intermittent oro-esophageal tube feeding was employed. Assessment of swallowing safety and training for food intake were conducted before eating.

(1) Intermittent oro-esophageal tube feeding: An intermittent oro-esophageal tube feeding can maintain normal physiological function of digestive tract and enhance the recovery of swallowing function. It is simple and safe, does not compress the skin and mucous membranes, which can avoid hiccups and gastro-esophageal reflux caused by long-term intubation, without affecting the swallowing training and daily activities of patients. Standard operation of tube insertion is vital. If conditions permit, families and patients can be trained to intubate and inject food. The frequency of injection ranged from 4 to 6 times daily according to the patient's nutrition and digestion, and the amount of each injection was 200 mL to 400 mL.

(2) Food intake training: Bolus volume and food consistency were determined by V-VST results before eating. Eating training was carried out by changing the patient's compensatory head or body posture, food volume, texture and enhancing eating ability.

Outcome measures

Primary outcome measures: MASA scores, grading of Watian drinking water test, positive rate of dye test, and FOIS scores of patients in both groups before and after intervention. Secondary outcome measures: Modified BOAS and Nutritional Risk Assessment 2002 (NRS-2002) scores before and after care, the incidence of adverse events such as aspiration and aspiration pneumonia during hospital stay, the length and costs of hospitalization of patients in both groups.

Statistics

Data analysis was performed using SPSS 23.0 software (SPSS, Inc., Chicago, IL, USA). Enumeration data were expressed as the number of cases (percentage) [n (%)], and examined by chi-square test ($\alpha = 0.05$). Measurement data conforming to normal distribution were presented as mean \pm standard deviation ($\bar{x} \pm sd$). An independent-samples t-test was conducted for comparison between the two groups, and a paired t-test was used for comparison within the same group before and after intervention ($\alpha = 0.05$). $P < 0.05$ was defined as statistically significant.

Results

Baseline data of patients in the two groups

There was no significant difference in gender, age, cases of tracheotomies, GCS scores, MASA scores, and disease course between the two groups (all $P > 0.05$), and they were comparable (**Table 1**).

Effects of bundled care on swallowing function in patients with TBI

Before intervention, there was no significant difference in MASA scores between the two groups ($P > 0.05$). After intervention, a significant increase in MASA scores was observed in both groups ($P < 0.001$), while compared with

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Table 2. Dye test results before and after intervention in the two groups (n (%))

Time	Test group (n=11)	Control group (n=9)	P
Before intervention			0.660 [#]
Positive	9 (81.82)	8 (88.89)	
Negative	2 (18.18)	1 (11.11)	
After intervention			0.015 [#]
Positive	1 (11.11)	6 (75.00)	
Negative	8 (88.89)	2 (25.00)	

Note: [#]Fisher's exact test.

Table 3. Watian drinking water test grading before and after intervention in the two groups (n (%))

Time	Test group (n=19)	Control group (n=22)	P
Before intervention			0.811 [#]
Grade I	0 (0.00)	0 (0.00)	
Grade II	3 (15.79)	2 (9.09)	
Grade III	12 (63.16)	14 (63.64)	
Grade IV or above	4 (21.05)	6 (27.27)	
After intervention			0.010 [#]
Grade I	7 (36.84)	1 (4.55)	
Grade II	6 (31.58)	4 (18.18)	
Grade III	6 (31.58)	13 (59.09)	
Grade IV or above	0 (0.00)	4 (18.18)	
P	0.001 ^a	0.216 ^a	

Note: [#]Fisher's exact test. ^aAs compared with the number of people below grade II in the same group before and after the intervention.

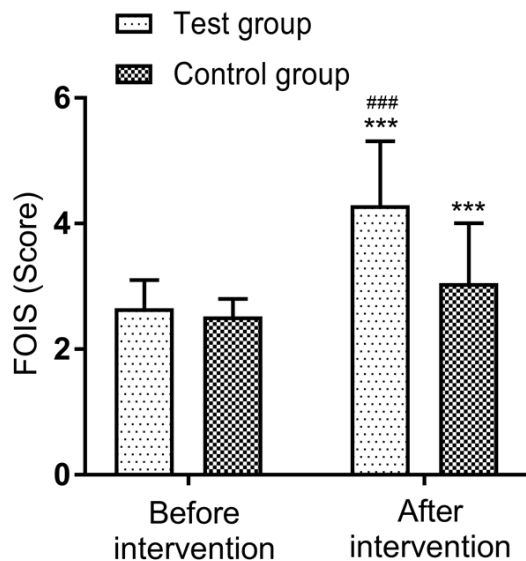


Figure 3. FOIS scores before and after intervention in both groups. Compared with that before intervention, *** $P < 0.001$; compared with the control group, ### $P < 0.001$. FOIS: Functional oral intake scale.

the control group, the MASA scores in the test group were significantly increased ($P < 0.001$, **Figure 2**).

Before intervention, 9 of 11 (81.82%) patients who underwent tracheotomy in the test group had positive results in the dye test. In the control group, 8 of 9 (88.89%) patients who underwent tracheotomy had positive results in the dye test. There was no significant difference in the positive rate between the two groups before intervention (**Table 2**). After intervention, 2 patients in the test group awoke, and 1 of the remaining 9 (11.11%) patients had positive results in the dye test. One patient in the control group awoke, and 6 of the remaining 8 (75.00%) patients had positive results in the dye test. There was a significant difference in the positive rate between the two groups after intervention ($P < 0.05$; **Table 2**).

Before intervention, there was no significant difference in the grading of Watian drinking water test between the two groups ($P > 0.05$). After intervention, the number of people graded II or lower in the Watian drinking water test in the test group was increased significantly ($P < 0.01$), while there was no significant difference in the grading of the test before and after intervention in the control group. Compared with the control group, the grading of the test group in the Watian drinking water test was significantly declined in the test group ($P < 0.05$; **Table 3**).

Before intervention, there was no significant difference in FOIS score between the two groups ($P > 0.05$). After intervention, the FOIS score of both groups was significantly increased ($P < 0.001$), while compared with the control group, the FOIS score was significantly elevated in the test group ($P < 0.001$; **Figure 3**).

Effects of bundled care on BOAS and NRS-2002 scores in TBI patients

Before intervention, there was no significant difference in BOAS and NRS-2002 scores between the two groups ($P > 0.05$). After intervention, BOAS and NRS-2002 scores in the two groups were significantly reduced ($P < 0.05$); while compared with the control group, BOAS and NRS-2002 scores in the test group were significantly decreased ($P < 0.05$; **Figure 4**).

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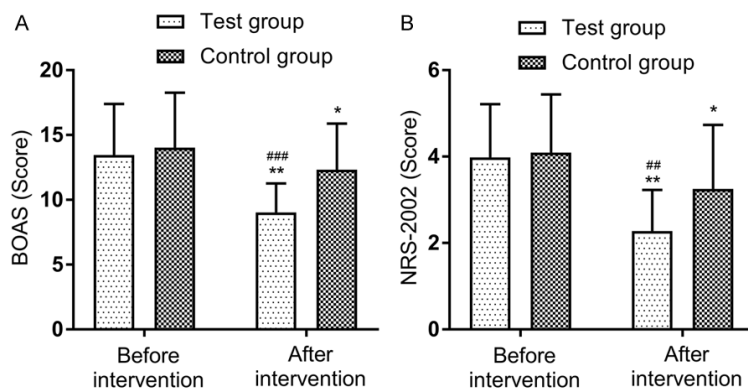


Figure 4. BOAS and NRS-2002 scores before and after intervention in both groups. A: BOAS scores; B: NRS-2002 scores. Compared with that before intervention, * $P < 0.05$, ** $P < 0.01$; compared with the control group, ### $P < 0.01$, ### $P < 0.001$. BOAS: Beck Oral Assessment Scale; NRS: Nutritional Risk Assessment.

Effects of bundled care on adverse events, length and costs of hospitalization in TBI patients

Compared with the control group, the total incidence of adverse events in the test group (6.67% vs. 43.33%) was significantly reduced ($P < 0.01$), and the length and costs of hospitalization were also significantly reduced ($P < 0.001$; **Table 4**).

Discussion

Effective treatment and management of dysphagia are essential for postoperative rehabilitation and prognosis of patients with severe TBI, while there is still a lack of a systematic, comprehensive, and multi-layer management system for dysphagia after severe TBI in current clinical practice [1, 2]. In this study, we established a scientific, evidence-based bundled care program for patients with dysphagia after severe TBI and observed the effect of this care program in patients with dysphagia after severe TBI through a randomized controlled trial.

The results of this study showed that compared with the control group, the MASA scores, grading of Watian water drinking test, and FOIS scores were significantly improved in the test group, and the positive rate of dye test was also significantly reduced in patients with disturbance of consciousness after bundled care. This suggests that an evidence-based bundled care model can effectively improve

swallowing function for patients with dysphagia after severe TBI and is a potentially ideal care management model for dysphagia after severe TBI. We believe that compared with a traditional care model, an evidence-based bundled care model is superior in that: 1. Bundled care for patients with severe TBI is first highlighted in comprehensive assessment and monitoring of dysphagia in patients. At present, clinical early screening for dysphagia is inadequate in patients with craniocerebral injury, and its importance is often neglected, which seriously stalls the pro-

cess to effectively reduce the risk of complications such as aspiration and aspiration pneumonia and promote recovery of patients [22]. We performed an early bedside assessment of swallowing function in severe TBI patients with or without disturbance of consciousness, which is critical for guiding subsequent nursing work [23]. The swallowing function of the patients was comprehensively evaluated by MASA scale, Watian drinking water test, V-VST and FOIS scales, and dietary regimen and nursing measures were personalized for the patients. Patients with a conscious disturbance were evaluated for aspiration risk by dye test, so as to develop corresponding nursing measures. Meanwhile, regular monitoring of swallowing function allows flexible and effective care for the patients. 2. With the bundled care program, we developed effective swallowing function training for patients according to evidence-based recommendations, including NMES, orofacial sensory training and exercise training. NMES is a method of improving muscle function by stimulating nerve or muscle with a low-frequency pulsed current to cause muscle contraction. Currently, it is widely used in the treatment of various neuromuscular diseases and has a significant effect on dysphagia. Orofacial sensory training and exercise training are fundamental for patients with dysphagia in clinical practice. A large number of previous clinical studies have shown that orofacial sensory training and exercise training can remarkably improve dysphagia in stroke patients [24, 25]. Also, the former one is suit-

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Table 4. Adverse events, length and costs of hospitalization in the two groups ($\bar{x} \pm sd$)

Item	Test group (n=30)	Control group (n=30)	χ^2 or t	P
Adverse events (n (%))				
Pulmonary aspiration	0 (0.00)	5 (16.67)		
Aspiration pneumonia	2 (6.67)	8 (26.67)		
Total	2 (6.67)	13 (43.33)	10.756	0.001
Length of hospitalization (d)	25.7±4.9	38.9±8.0	7.673	<0.001
Costs of hospitalization (*10,000 RMB)	2.85±0.16	4.08±0.32	18.831	<0.001

able for patients with consciousness disturbances and can promote recovery of swallowing function. In this study, we found that the swallowing function of comatose patients was also effectively improved by NMES and orofacial sensory training, which reduced the risk of aspiration. Compared with the control group, positive rate of dye test was significantly lowered in the test group (11.11% vs. 75%), which is similar to the conclusions of previous studies [20, 26, 27].

The recovery of swallowing function is of vital importance to reduce the occurrence of complications such as aspiration and aspiration pneumonia in patients [28]. In this study, the number of patients having aspiration or aspiration pneumonia was 0 or 2 respectively in the test group, while the number of such patients was 5 or 8 respectively in the control group. Compared with the control group, the total incidence of adverse events in the test group was significantly reduced (6.67% vs. 43.33%). Besides, during bundled oral care, alternating hot and cold rinse for patients can effectively remove fluid and residue from oral cavity, maintain oral hygiene, induce swallowing, promote coordination of oral muscles, and prevent aspiration [29]. In this way, it can further reduce the risk of complications such as aspiration and aspiration pneumonia in patients.

Also, the nutritional risk of patients with severe TBI was also significantly reduced after bundled care. Compared with the control group, the NRS-2002 scores of patients were significantly lowered after care. We believe that this is not only associated with the recovery of swallowing function, but also related to scientific and effective dietary care measures. During bundled care, we selected appropriate eating patterns according to specific conditions and functional status of patients. Besides, we de-

termined the amount of bolus volume and viscosity of food for patients by V-VST and conducted related eating training, further improving the patient's eating ability and nutrient supply. This was similarly confirmed in related studies [30, 31]. Also, this study showed that through bundled care, that postoperative rehabilitation of patients was greatly accelerated, and the length as well as costs of hospital stay were also markedly reduced.

However, this study is limited in that comatose patients included in both groups were inadequate, which may influence the experimental results. In addition, the differences in the recovery of swallowing function in patients with different disease types need to be further observed. Therefore, more subgroup analyses incorporating a larger sample sizes are needed in the future to further confirm the effectiveness of evidence-based bundled care models.

In conclusion, our research suggests that evidence-based bundled care has prominent value in postoperative rehabilitation care for patients with dysphagia after severe TBI, which can effectively promote the recovery of swallowing function, improve oral hygiene, and reduce nutritional risks and adverse events in patients with dysphagia after TBI, thereby facilitating patients' rehabilitation.

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Disclosure of conflict of interest

None.

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