Implementation and Analysis of a **Free Water Protocol in Acute Trauma and Stroke Patients**

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BACKGROUND Free water protocols allow patients who aspirate thin liquids and meet eligibility criteria to have access to water or ice according to specific guidelines. Limited research is available concerning free water protocols in acute care settings.
OBJECTIVES To compare rates of positive clinical outcomes and negative clinical indicators of a free water protocol in the acute care setting and to continue monitoring participants discharged into the hospital system's rehabilitation setting. Positive clinical outcomes were diet upgrade, fewer days to diet upgrade, and fewer days in the study. Negative clinical indicators were pneumonia, intubation, and diet downgrade.
METHODS A multidisciplinary team developed and implemented a free water protocol. All eligible stroke and trauma patients (n = 104) treated over a 3-year period were randomly assigned to an experimental group with access to water and ice or a control group without such access. Trained study staff recorded data on positive outcomes and negative indicators; statistical analyses were conducted with blinding.
RESULTS No significant group differences in positive outcomes were found (all *P* values were > .40). Negative clinical indicators were too infrequent to allow for statistical comparison of the 2 groups. Statistical analyses could not be conducted on the small number (n = 15) of patients followed into rehabilitation, but no negative clinical indicators occurred in these patients.
CONCLUSIONS Larger-scale studies are needed to reach decisive conclusions on the positive outcomes and negative indicators of a free water protocol in the acute care setting. (*Critical Care Nurse*. 2019;39[3]:e9-e17)

Patients who sustain a stroke or traumatic brain injury often experience dysphagia, or difficulty swallowing, as a secondary complication. Evidence suggests that 37% to 78% of patients with stroke, 20% to 70% of patients with acute traumatic brain injury, and up to 30% of patients with spinal cord injuries in the United States receive a diagnosis of dysphagia.[1-6]

Dysphagia is associated with increased risk of aspiration and aspiration pneumonia, which often necessitates complex decision-making by the medical team.[7-9] Patients who aspirate all consistencies are often advised to ingest nothing by mouth. Patients who aspirate thin liquids are commonly advised to

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consume thickened liquids, particularly if compensatory strategies are ineffective.[10-12] Patient feedback and nonadherence have suggested that patients may be dissatisfied with thickened liquids.[13] Accordingly, in 1984 a speech-language pathologist (SLP) working in conjunction with physicians and dietitians developed an alternative approach known as the Frazier Water Protocol or the Free Water Protocol (FWP), in which patients who meet eligibility criteria are provided access to water or ice according to specific guidelines.[14,15] Although the developers of the FWP noted that water generally has a relatively neutral pH and low levels of bacteria and that it plays a crucial role in hydration for body functions, the FWP has generated controversy because of limited direct evidence concerning its risks and benefits. Advocates of restricting access to water argue that the increased viscosity of thickened liquids allows for the extra time and control required to swallow without aspiration, making this a safer management approach.[16-18] By contrast, advocates of the FWP argue that water's unique characteristics, coupled with the existence of specialized lung cells (aquaporins) that absorb water into the bloodstream, make the risk of aspiration pneumonia low and that the potential benefits of the FWP may therefore outweigh the risks.[19]

Advocates of the FWP argue that water's unique characteristics make the risk of aspiration pneumonia low.

To date, 7 studies of the FWP in the rehabilitation setting have been published.[1,20-25] Of these, 6 did not reveal elevated rates of aspiration pneumonia in participants on free water protocols. One study, however, showed lung complications, including aspiration pneumonia, in 6 of 42 participants (14%) randomized to a group with access to water but no lung changes in the control group (n = 34).[21] The investigators noted that the 6 participants affected by lung complications had neurodegenerative disease and were immobile or had low mobility. In addition to research studies, 2 systematic reviews of the FWP, which included the studies above, have been reported. One review found no significant difference in the risk of pneumonia in patients on the FWP who implemented behavioral safety strategies and patients who consumed thickened liquids only.[18] The authors of the other review concluded that the FWP does not appear to increase the risk of lung complications for those in inpatient rehabilitation settings and suggested the need for studies of the FWP in other settings.[26]

Only 1 study of the FWP in the acute care setting has been published. This study involved 15 patients with dysphagia in a respiratory care unit who were placed on thickened liquids with access to water between meals and were then compared with a retrospective control group of similar patients who had not been given access to water.[27] The results indicated no significant difference in rate of aspiration pneumonia between the control and experimental groups; however, the report provided limited information on how the outcomes were measured. A conference presentation and abstract reporting 2 randomized, controlled pilot studies of patients with stroke (n = 18) or trauma (n = 22) assigned to a control group without access to water or ice or to an experimental group with access to water revealed no significant group differences in positive or negative clinical outcomes.[28,29]

The lack of empirical evidence concerning the FWP, particularly in the acute care setting, provided the rationale for this investigation, in which we randomized participants with dysphagia due to stroke or trauma to a FWP group or to a control group. We compared the groups' rates of 3 clinical outcomes that we deemed positive and 3 clinical indicators that we deemed negative during their

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time in the acute care setting. In a separate analysis, we tracked these outcomes and indicators in a subset of these participants who were discharged into the rehabilitation setting.

Methods

Participating Institutions

We enrolled participants for this study from October 2012 to September 2015 and recruited them from a large urban acute care hospital (> 1000 beds) with a level I trauma center and primary stroke center. A subset of these participants was discharged within the hospital system to inpatient rehabilitation and was followed throughout their rehabilitation stay. We obtained informed consent or assent from each participant or the participant's legally authorized representative. We acquired institutional review board approvals from the hospital system and collaborating university.

Participants

Attending physicians, nurses, or SLPs from the trauma or stroke critical care units or floors identified potential participants. Inclusion criteria were (1) English- or Spanish-speaking individuals aged 18 years and older; (2) admission with a primary diagnosis of acute stroke or acute trauma; (3) admittance to an acute care unit; (4) documented aspiration of thin liquids according to an objective examination (either a fiber-optic endoscopic evaluation of swallowing or a modified barium swallow study) obtained in the standard course of clinical care; and (5) mental status adequate to support oral intake of thin liquids as judged by a certified SLP. Exclusion criteria were (1) secondary diagnosis of congestive heart failure, Parkinson disease, or moderate to advanced dementia as determined by a neurologist; (2) physician-ordered fluid restrictions; (3) documented active oral infection (eg, thrush); and (4) excessive and/or uncomfortable coughing during attempted ingestion of liquids as noted by the SLP during objective or clinical evaluation. Criteria for dismissal from the study were discharge from the hospital system, diet upgrade to thin liquids, and request from the participant or the treating physician for withdrawal from the study.

Eligible patients received modified diets (by mouth or enteral feeding) and dysphagia management consistent with national best practice guidelines and the hospital's standard clinical protocol. This protocol included facilitative oropharyngeal exercises, compensatory strategies, and dietary modifications including thickened liquids during meals and oral medication administration. We also administered to eligible patients the Aspiration Precaution Oral Care Program, which was previously developed and implemented by hospital nursing, SLP, and respiratory therapy teams for nonventilated, non–intensive care unit patients with dysphagia to mitigate hospital-acquired respiratory infections linked to bacterial colonization in the mouth and teeth (Figure 1).[30-37]

After obtaining consent or assent, we randomized participants via odd or even numbers from sealed envelopes into either (1) a control group with no access to thin liquids, including water or ice chips; or (2) an experimental group with access to water and ice chips, according to guidelines specified in the FWP. A physician order for aspiration precautions, modified diet, and/or participant access to ice and water was entered into the medical record. The research SLP placed written precautions concerning group assignment in each participant's room to meet hospital requirements and to ensure adequate communication among all involved in participant care. As a result, blinding of the on-site researchers was not possible.

There were 2 groups: (1) a control group with no access to thin liquids, including water or ice chips; or (2) an experimental group with access to water and ice chips.

Procedures

The FWP guidelines were modeled after the protocol implemented at Frazier Rehabilitation Center (Table 1). For participants in the experimental group, nursing and allied health staff offered water or ice with supervision as needed throughout each shift. To ensure adherence to FWP protocol guidelines, study investigators used in-services and written material to educate nursing staff on the purpose of the study and implementation of the FWP. Attendance was documented. The research SLP continued to provide individualized education sessions to participants, caregivers, and nurses when necessitated by staff turnover. See Figure 2 for additional information on implementation of the FWP in this study.

Measures

Demographic and Clinical Information. The research SLP entered information from the participant's chart onto the data collection form. Patient information

Step 1:	Discuss the need for a non-ICU oral care policy for patients with dysphagia: • Identify your team, include RN, physician, SLP, and RT champions. • Delineate team roles.
Step 2:	Revise ICU oral care policy to include non-ICU patients with dysphagia[a]: • Review the literature. • Set oral care guidelines. • Develop tracking and documentation forms.
Step 3:	Meet with product vendors to discuss products for non-ICU patients: • Identify products needed, such as oral cleansing and suctioning systems, oral swabs and toothbrush, mouth moisturizer, and Yankauer tip attached to standard suction lines. • Determine frequency of use for each product per day. • Review product cost.
Step 4:	Acquire approval and develop implementation plan: • Schedule meetings to seek approval for aspiration precaution oral care policy (per your facility). • Pilot policy: ◦ Determine appropriate units, floors, and patient population. ◦ Order products on the basis of pilot participant size. ◦ Create compliance tracking documents. ◦ Identify auditors to review compliance.
Step 5:	Implement pilot policy: • RNs, SLPs, and product vendor complete collaborative education to pilot units. • Track compliance on pilot units. • Obtain feedback from medical staff involved in policy implementation. • Modify policy as needed on the basis of compliance and feedback results.
Step 6:	Expand non-ICU oral care policy: • Repeat step 5 for RN units across the hospital.

Figure 1 Aspiration Precaution Oral Care Program implementation process for patients with dysphagia.

Abbreviations: ICU, intensive care unit; RN, registered nurse; RT, respiratory therapist; SLP, speech-language pathologist.
[a] An ICU oral care policy was already established at the time of our study. However, the steps also apply to a newly developed oral care policy (ICU or non-ICU).

Table 1 Free Water Protocol guidelines

1.	All potential participants received a clinical swallow evaluation, which included oral trials of ice and water, by the SLP.
2.	If the potential participant met eligibility criteria (see participant section) and was randomized to the experimental group, the FWP was initiated with a physician's order.
3.	The experimental group received access to ice and water between meals after at least 30 minutes had elapsed since the last oral ingestion.
4.	Water was not given with the administration of medications.
5.	Experimental group participants continued to use swallowing strategies (ie, postural changes, diet modification) per their individualized dysphagia management/treatment plans.
6.	Access to thin liquids other than ice and water was prohibited.
7.	All participants received oral care (per the Aspiration Precaution Oral Care Program).
8.	Participants' water intake was supervised by nursing or educated caregiver if deemed necessary by SLP or physician because of cognitive or physical status.

Abbreviations: FWP, Free Water Protocol; SLP, speech-language pathologist.

included date of admission, age, sex, primary and secondary diagnoses, ambulatory status, current diet, date and type of objective examination confirming aspiration of thin liquids, results of subsequent objective examinations, and date of dismissal from the study. The research SLP also recorded adverse events or significant changes in medical status, which were anticipated because of the severity of illness in this patient population. When a

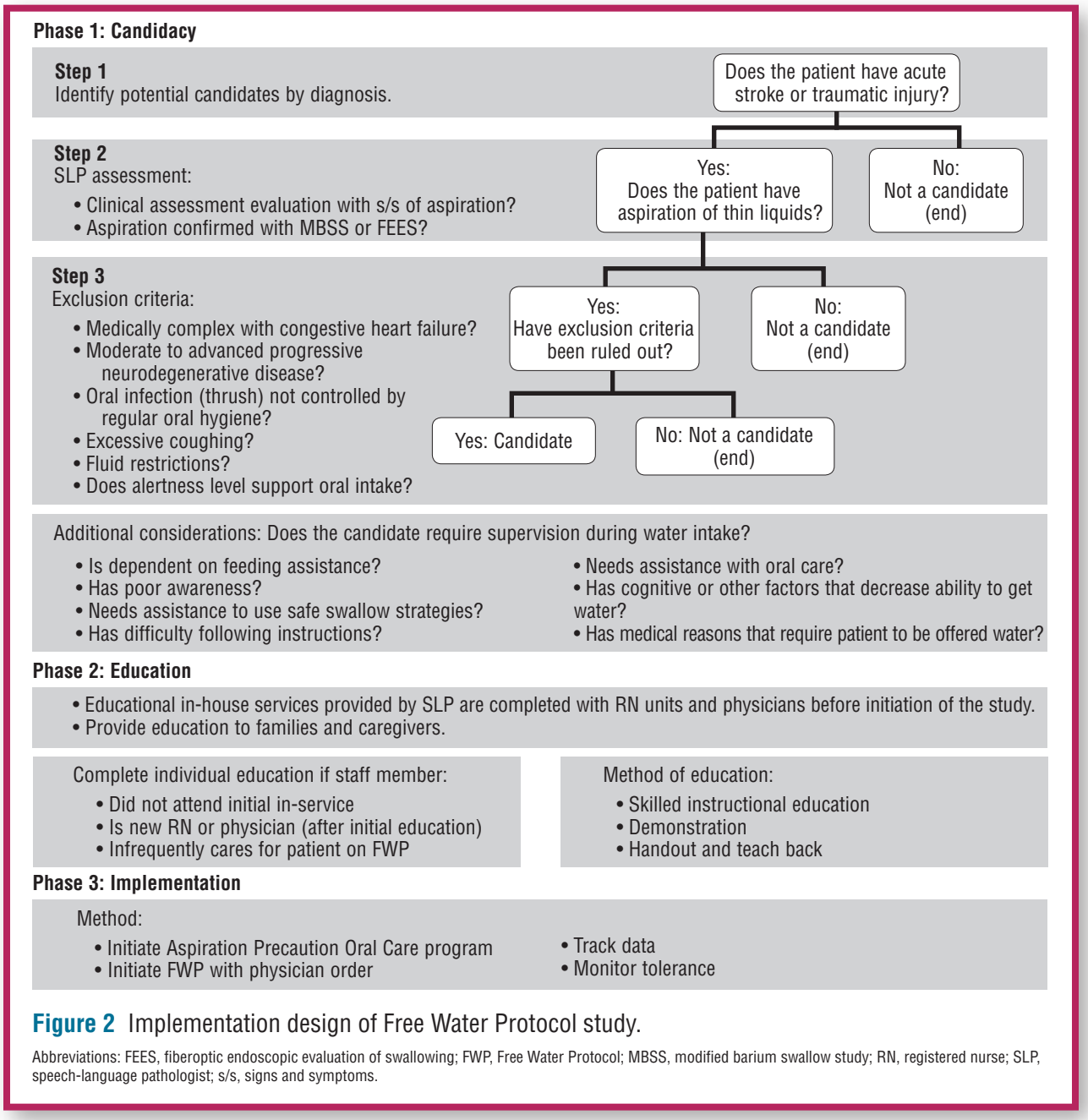

Figure 2 Implementation design of Free Water Protocol study.

Abbreviations: FEES, fiberoptic endoscopic evaluation of swallowing; FWP, Free Water Protocol; MBSS, modified barium swallow study; RN, registered nurse; SLP, speech-language pathologist; s/s, signs and symptoms.

participant's physician documented an adverse event in the medical record, the research SLP recorded the information on the data collection form, and the information was reported to and reviewed by the institutional review board.

Documenting water intake over the course of the study would have been ideal, but limited resources precluded this. Moreover, the hydration status of patients in trauma and stroke units is routinely monitored, and physicians recommend intravenous fluids as necessary. Whether hydration changes in the experimental group resulted from intravenous fluid administration or from increased water and ice intake was thus impossible to determine.[21,38]

Positive Clinical Outcomes and Negative Clinical Indicators. The research SLP recorded positive and negative clinical outcomes daily during the business week. Events occurring during a weekend were recorded on the following Monday.

The 3 positive clinical outcomes were number of diet upgrades, fewer days to a diet upgrade, and fewer days in the study. Data recorded included diet on the date of consent to enter the study, diet upgrades, date of diet

Table 2 Summary of participant information[a]

Characteristic	All (N = 104)	Control (n = 52)	Experimental (n = 52)	*P*
Age, mean (SD), y	54.2 (19.3)	55.1 (19.3)	54.1 (19.5)	.65
Sex				.82
Male	79 (76.0)	39 (75)	40 (77)	
Female	25 (24.0)	13 (25)	12 (23)	
Diagnosis				.52
Stroke	31 (29.8)	17 (33)	14 (27)	
Trauma	73 (70.2)	35 (67)	38 (73)	
Secondary diagnosis				
Pneumonia	18 (17.3)	8 (15)	10 (19)	.60
Dehydration	4 (3.8)	2 (4)	2 (4)	>.99
Patients with tracheostomy speaking valve	42 (40.4)	16 (31)	26 (50.2)	.046

Abbreviations: FWP, Free Water Protocol; SLP, speech-language pathologist.
[a] All values are reported as No. (%), unless otherwise indicated.

upgrade, and number of days between consent and dismissal from the study.

The 3 negative clinical indicators were intubation, pneumonia, and diet downgrade. Dates of intubation and pneumonia diagnosis were confirmed via physician documentation in the medical record. A diagnosis of pneumonia triggered completion of a follow-up form, which included confirmation of the diagnosis via chest radiography or objective examination, reason for the pneumonia (such as aspiration of liquids, solids, or tube feeds) as determined by the physician, and details of oral hygiene such as dependence on caregivers for oral hygiene and nonadherence with the oral care protocol.

Statistical Analysis

We conducted a power analysis with a log-rank test based on a pilot study in which the mean number of days to a diet upgrade was 7 in a control group and 4 in an experimental FWP group. We determined that 80% power with a significance level of .05 would require 53 patients per group.[28,29] We compared patient demographic data, clinical information, positive clinical outcomes, and negative clinical indicators by using *t* tests or Wilcoxon tests for numerical variables, log-rank tests for time to upgrade, and χ^2 or Fisher tests for categorical variables. We used multiple regression analysis to further analyze the positive clinical outcomes for all participants and for participants who received nothing by mouth. We used logistic regression to analyze diet upgrade, the Cox proportional hazards model to analyze days to diet upgrade, and negative binomial regression to analyze days in the study. All models included group assignment, diagnosis group, ambulatory status, and age as independent variables. We set α at .05 for each of these measures. Study personnel who entered, audited, and analyzed the data were all blinded to group assignment. We performed all analyses with data analysis software (SAS 9.4, SAS Institute Inc).

Results

Participants

One hundred six patients consented to participate in the study. Of these, 70% had a trauma diagnosis and 30% had a stroke diagnosis. Two of the 106 participants, both from the experimental group, did not complete the study. Before data collection began, 1 participant was discharged and 1 participant died for reasons unrelated to the study, according to the physician review.

Table 2 shows demographic information and diagnoses of participants in the control and experimental groups. Age, sex, and primary diagnosis were not significantly different between the 2 groups. However, among the secondary diagnoses, the number of patients with a tracheostomy speaking valve was marginally higher in the experimental group than in the control group, suggesting that patients in the experimental group may have been more critically ill than those in the control group.

As expected, adverse events occurred during this study. The adverse events were 4 instances of mucous plugs, 2 changes in neurological status, 1 vertebral artery dissection, and 1 ileus and vomiting. These 7 participants, in conjunction with their adverse events, presented with negative clinical indicators. There were 3 occurrences of

Table 3 Summary of positive and negative clinical indicators, with unadjusted *P* values

	Control (n = 52)	Experimental (n = 52)	*P*
Positive clinical indicators			
Diet upgrade, No. (%)	33 (63)	31 (60)	.69
Days to diet upgrade, median (IQR)	7.0 (6.0–10.0)	7.0 (6.0-10.0)	.78
Days in study, median (IQR)	7.0 (4.0–12.5)	6.0 (2.0-12.5)	.54
Negative clinical indicators			
Pneumonia, No. (%)	0 (0)	0 (0)	NA
Intubation, No. (%)	0 (0)	0 (0)	NA
Diet downgrade, No. (%)	0 (0)	1 (2)	>.99

Abbreviations: NA, not available; IQR, interquartile range.

pneumonia in the experimental group and 2 occurrences in the control group. Physicians attributed these adverse events and negative clinical indicators to participants' medical status rather than to study variables; therefore, the counts are excluded from our experimental and control group comparisons. Of note, 4 of the participants who had adverse events had a trauma diagnosis of spinal cord injury.

A subset of 15 participants, 6 in the control group and 9 in the experimental group, was discharged from acute care to inpatient rehabilitation and was followed until discharge from rehabilitation to collect data along the continuum of care. Seven of these patients (47%) had a trauma diagnosis and 8 (53%) had a stroke diagnosis. The ages of patients in the 2 groups did not significantly differ (mean [SD] ages: control group, 54.5 [26.6] years; experimental group, 54.4 [14.6] years). Men outnumbered women in both the control group (5 vs 1) and the experimental group (7 vs 2).

Primary Results: Acute Care Setting

Positive clinical outcomes did not differ significantly between the 2 groups (Table 3). None of the regression models showed significant differences between the control and experimental groups (Table 4). Patients with trauma were more likely than those with stroke to have a diet upgrade and they also upgraded their diet in fewer days, whether the analysis included all patients or only those who began receiving nothing by mouth. Older age tended to be associated with lower odds of a diet upgrade, although this finding did not reach significance. Among patients who began receiving nothing by mouth, age was significantly associated with more days in the study.

Negative clinical indicators, unrelated to adverse events, were infrequent and did not differ significantly between the 2 groups, but this result must be interpreted with caution because statistical power to detect these infrequent events was likely low. Only 1 diet downgrade occurred, in a patient in the experimental group.

Secondary Results: Rehabilitation Setting

The 15 patients followed through their rehabilitation stays remained in the rehabilitation setting for a mean of 16 days (both groups). Five of 6 participants from the control group (83%) and 8 of 9 participants from the experimental group (89%) experienced a diet upgrade. Of the patients who were receiving nothing by mouth at the onset of the acute setting study, 2 of 3 from the control group (67%) and 9 of 9 from the experimental group (100%) were upgraded to an oral diet in the rehabilitation setting. No participants in either group experienced a diet downgrade, intubation, or pneumonia in the rehabilitation setting.

Among the 15 participants followed into rehabilitation, the mean number of days in the study from acute care admission through rehabilitation was 27. Participants in the experimental group remained in the study for a mean of 22 days; those in the control group remained in the study for a mean of 29 days.

Discussion

Our study compared positive clinical outcomes and negative clinical indicators in 104 participants receiving a standard clinical protocol for dysphagia who were randomized either to have no access to thin liquids or to have access to water and ice under the guidelines of the FWP. We found no significant group differences in the 3 positive indicators. Diet upgrades, median days to diet upgrade, and median days in the study were similar in the 2 groups. With respect to negative clinical indicators, 1 patient in the experimental group experienced a diet downgrade.

Although the groups did not differ significantly in positive or negative clinical outcomes, 8 adverse events

Table 4 Logistic regression results for any diet upgrade, days to diet upgrade, and days in study[a]

Characteristic	Diet upgrade		Days to diet upgrade		Days in study	
	Adjusted odds ratio (95% CI)	*P*	Adjusted hazard ratio (95% CI)	*P*	Adjusted incidence rate ratio (95% CI)	*P*
All patients						
Study group		.40		.87		.82
Control	Reference		Reference		Reference	
Experimental	0.66 (0.25-1.75)		0.96 (0.57-1.61)		0.96 (0.68-1.36)	
Diagnosis group		<.001		.02		.21
Stroke	Reference		Reference		Reference	
Trauma	10.88 (3.56-33.27)		2.58 (1.13-5.88)		1.3 (0.87-1.95)	
Ambulation group		.40		.19		.25
Not ambulatory	Reference		Reference		Reference	
Ambulating	1.56 (0.55-4.40)		1.42 (0.84-2.40)		0.81 (0.57-1.15)	
Age	0.97 (0.95-1.00)	.06	1.00 (0.98-1.01)	.49	0.99 (0.98-1.00)	.14
Patients who started nothing by mouth						
Study group		.35		.89		.61
Control	Reference		Reference		Reference	
Experimental	0.55 (0.15-1.96)		0.96 (0.5-1.84)		0.89 (0.58-1.37)	
Diagnosis group		.03		.32		.86
Stroke	Reference		Reference		Reference	
Trauma	5.10 (1.20-21.76)		1.64 (0.62-4.38)		1.05 (0.62-1.75)	
Ambulation group		.25		.15		.66
Not ambulatory	Reference		Reference		Reference	
Ambulating	2.32 (0.56-9.64)		1.65 (0.83-3.28)		0.91 (0.58-1.40)	
Age	0.96 (0.92-1.0)	.06	1.00 (0.97-1.02)	.62	0.98 (0.97-1.00)	.01

[a] Reference indicates the reference (baseline) category for each variable.

occurred in 7 participants over the course of the study. Four of the 7 participants had spinal cord injuries, and 5 of the 8 adverse events were attributed to these injuries. This finding is consistent with the critical illness and respiratory complications that typify this group of patients. Although these events were deemed to be related to patient diagnosis rather than to the FWP, further investigation of the FWP in this patient population is warranted.

In the subset of participants followed into the rehabilitation setting, our results showed that both the experimental and control groups experienced positive clinical outcomes. As expected, these patients, who were more medically stable than the others, experienced no negative clinical indicators during their stays. This result is consistent with previous research on the FWP in the rehabilitation setting.[1,20-25] Participants in the experimental group showed a trend toward decreased days to discharge from the study, but the small number of participants that were followed precluded statistical testing.

Our results showed that both the experimental and control groups experienced positive clinical outcomes.

Limitations

This study had limitations. Although our sample size was large relative to that of other FWP studies, the power calculation derived from our pilot studies was based on only 1 outcome, the number of days to diet upgrade.[28,29] Because effect sizes in our study were relatively small, statistical power of the study was low despite the size of our sample. Accordingly, additional studies will be needed before conclusions about the FWP can be drawn.

Two other limitations were inherent to studies conducted in the acute care setting: short stays and challenges in blinding on-site research staff to group assignment. Consistent with the short stay that is typical of the acute care setting, participants in this study were monitored for an average of 6 days after enrollment. Although lung changes have been reported as early as 48 hours after FWP implementation, monitoring outcomes over a longer time would be ideal.[20] We tried to address this limitation by following a subset of participants through their rehabilitation stays, but additional evidence is needed. The need to ensure communication and adhere to hospital requirements prevented us from blinding on-site research staff members to participant group, but off-site

staff members, including the principal investigator, research assistants, and biostatistician, were blinded to patient group throughout the study.

Conclusions

The FWP has the potential to enhance patient care in the acute care setting. However, larger-scale studies are needed to reach definitive conclusions on the positive outcomes and negative clinical indicators of the protocol. As with our study, future research will require adherence to oral care and free water protocols and education of multidisciplinary staff members. Communication and collaboration among nurses, physicians, and SLPs will be necessary to monitor participant status across multiple floors and units. Targeting specific acute care populations at varying severity levels, possibly across multiple sites, could further establish an evidence base for evaluating the advantages and disadvantages of the FWP in the acute care setting. CCN

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