

Original Research

Nightly Enteral Nutrition Support of Elderly Hip Fracture Patients: A Pilot Study

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Key words: elderly, hip fracture, nutrition support, protein-energy undernutrition, enteral feedings, randomized controlled trial

Objectives: Assess whether postoperative nightly enteral nutrition support improves outcomes of elderly patients with an acute hip fracture

Design: Randomized controlled trial

Setting: A University and a Department of Veteran's Affairs Hospital

Subjects: Adults >64 years of age who underwent surgical repair of an acute hip fracture

Interventions: Subjects randomized to the control (Ctrl) group received standard care while the treatment (Tx) group received standard care plus up to 1,375 Kcal [5,755 kJ/d] of nasoenteral tube feedings each night. When tube feedings had to be discontinued, Tx subjects were asked to drink an equivalent amount of the nutritional supplement each night.

Measures of Outcome: Rate of postoperative complications and 6-month postoperative survival

Results: Fifty-seven patients were randomized to the Tx ($n = 27$, mean age 75.9 ± 7.4 yrs) or Ctrl groups (age 81.7 ± 7.7 yrs). All subjects had reduced volitional nutrient intakes after surgery. During the first week subsequent to surgery, there was no difference between the treatment and control groups in the amount of nutrients that they volitionally consumed during the day. However, the treatment subjects had a greater total daily nutrient intake (Median 5,866 (IQR 5,024 to 7,335) kJ/d vs. 3,965 (IQR 2,968 to 4,664) kJ/d, $p < 0.001$). However, by the second postoperative week this difference was no longer statistically significant. Intolerance to the tube feedings developed commonly. There was no difference between the groups in the rate of postoperative life-threatening complications or mortality within six months subsequent to surgery.

Conclusions: This study failed to confirm findings from a prior study of improved postoperative survival with nutrition support. However, it was conducted on multiple hospital wards which may have contributed to the higher rate of tube-related problems and less nutrient delivery signifying the need for further study.

INTRODUCTION

Protein-energy undernutrition (PEU) is a very common and potentially serious problem among elderly patients hospitalized with an acute hip fracture. Up to 64% of these patients are undernourished at admission or develop serious nutritional deficits while hospitalized [1–10]. Regardless of when PEU develops, it is associated with an increased risk of serious in-hospital complications. The likelihood of developing an adverse clinical outcome increases in direct proportion to the severity of the nutritional deficits [1,3].

Several studies suggest that nutritional support may lower the risk of adverse outcomes among undernourished elderly patients with an acute hip fracture [9–17]. However, each study examined different outcomes and none of the findings have been confirmed. The lack of confirmatory studies has left orthopedic surgeons and other health care providers unconvinced as to the benefits of aggressively monitoring and treating the nutritional deficits of their elderly hip fracture patients. Given the number of elderly patients who fracture their hip each year (approximately 350,000 in 2003) [18], the prevalence of PEU in this population, and the increased risk of morbidity

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associated with poor nutrition, the effectiveness of nutrition intervention to improve outcomes needs to be established.

Nightly enteral nutrition support is one method of bolstering nutrient intake that has been employed with some success in the treatment of older hip fracture patients. In one of the first studies using this approach, Bastow *et al.* found that hip fracture patients provided with nighttime enteral nutrition support during the postoperative period had greater total nutrient intakes and more rapid functional recoveries than did control subjects who received only standard care [11]. More recently, Sullivan *et al.* initiated a series of studies to evaluate further the effectiveness of this form of therapy [16]. Although the first investigation in the series was designed as a feasibility study and included only 18 subjects, it produced several encouraging results. The eight treatment subjects received nasogastric tube feedings over 11 hours each night in addition to standard care. Compared to the controls who received only standard care, the treatment subjects had a nearly 80% greater total nutrient intake for the first seven postoperative days and improved survival (control vs. treatment) within six months subsequent to surgery (50% vs. 100%, $p = 0.036$). In order to confirm these findings and assess the strength of the evidence that postoperative enteral nutrition support lowers the rate of postoperative complications, a larger 'pilot' study was conducted. This report presents the results of this pilot study.

METHODS

Subjects

Subjects were recruited from the orthopedic wards of a 267-bed University Hospital and an affiliated 208-bed Department of Veteran's Affairs (VA) Hospital. The criteria for inclusion were an age over 64 years and an acute femoral neck or intertrochanteric fracture which required surgical intervention. Subjects were excluded if they were incapable of giving informed consent and did not have a legal guardian; if they had sustained a pathological fracture (due to cancer or other non-osteoporotic pathologies) or significant trauma to other organ systems (e.g., multitrauma from a motor vehicle accident); or, if they had metastatic cancer, cirrhosis of the liver, a contraindication to the use of enteral feedings (e.g., severe short bowel syndrome), or organ failure which rendered the proposed intervention inappropriate.

The primary objective of the study was to provide the basis for determining the sample size required to test the hypothesis that nightly enteral nutrition support decreases the rate of postoperative complications of elderly patients with an acute hip fracture requiring surgery. To meet this objective, the recruitment goal for the study was set at 58 subjects. This sample size was estimated to provide an 80% power to detect a 20% or greater reduction in complications at a two-tailed significance of $p = 0.30$. Confirming the findings from the first

study that nutrition support improved six-month-postoperative mortality was a secondary objective.

Subjects were evaluated for possible study entry at the time of their admission to the hospital. Each recruit received oral and written explanations of the nature of the study and the possible risks involved prior to signing an informed consent, in accordance with the ethical standards of the Subcommittee on Human Studies, Little Rock VA Hospital, and the Human Research Advisory Committee of the University of Arkansas for Medical Sciences. Randomization occurred only after a subject was cleared for surgery and scheduled for operation within 18 hours. Subjects determined to be nonsurgical candidates prior to randomization were dropped from the study.

Study Design

As described in greater detail below, all subjects completed periodic clinical and nutritional assessments. Subjects randomized to the control group received standard care while the treatment group received standard care plus postoperative nightly enteral feedings. The amount of nutrients which the subject consumed was the primary concern, not the route of delivery. Both oral supplementation and tube feeding methods were utilized in an attempt to reach each treatment subject's nutritional requirements. Calorie counts were completed daily on all subjects. The enteral feedings were terminated when volitional intake was within 480 Kcal of estimated nutritional requirements for at least 2 consecutive days or the subject was discharged from the hospital.

Admission Assessment

An initial assessment was completed within 24 hours of admission which included: 1) a concise social, nutritional, and functional status history obtained by a standardized series of questionnaires administered to each subject or the primary caregiver; 2) a complete list of all primary and secondary diagnoses recorded in the current hospital chart and old medical records; 3) a neuropsychological evaluation using the Mini-Mental State Exam [19]; and, 4) a complete clinical and laboratory nutritional assessment including serum secretory protein concentrations and cholesterol. The admission assessment and postoperative monitoring protocol were developed and validated in the prior feasibility study and are described in detail elsewhere [16,20]. The APACHE illness severity instrument was completed using available clinical data [21]. The Katz Index of Activities of Daily Living (ADL) scale was used to assess functional status [22]. The Katz Index was scored on a three-level scale (e.g., 0 = independent, 1 = human help, 2 = totally dependent) with total scores ranging from 0 (independent) to 12 (totally dependent).

Postoperative Treatment Regimen

Standard Care. As explained below, all study subjects (both treatment and control) had their nutrient intakes monitored on a daily basis. Subjects who were randomized to the control group received standard postoperative care. The research team did not make recommendations regarding their nutrient needs and the results of the daily calorie counts were not provided to the attending health care team.

Nutrition Intervention. Unless they refused, all subjects who were randomized to the treatment group had a small-bore feeding tube placed within 12 hours subsequent to surgery, usually in the recovery room. Placement of the tube was confirmed by x-ray. The goal was to have the tubes advance into the small bowel. However, subjects who were assessed to be at low risk for aspiration (i.e., they did not have a history of aspiration, had an intact gag reflex, and a clear sensorium) and had positive bowel sounds were cleared to be started on a nightly feeding protocol if the tube was in the stomach or distally.

Once the subject was cleared to be started on enteral feedings, the study feeding protocol was initiated. The subject's total daily caloric requirement was calculated based on the Harris-Benedict equation plus activity and stress factors [23] and used as the subject's 'target intake'. The subject received standard postoperative care with the orthopedic surgeons writing all diet orders for the daytime meals with the usual advancement to 3 meals each day. As described below, complete calorie counts were obtained each day from which the subject's total volitional caloric intake for that day ('volitional intake') was determined. The subject's 'nutrient deficit' for the day ('target intake' minus 'volitional intake') was calculated each evening. Nightly enteral feedings were initiated with a nutritionally complete, lactose-free, polymeric enteral formula (Promote[®], Ross Laboratories) that contained 1,000 Kcal [4,187 kJ], 62.5 gms protein (25% of calories), 26 gms fat (23% of calories), and 130 grams carbohydrates (52% of calories) per liter. On the first night after the feeding tube was placed, the subject was provided enteral feedings at a rate of 50 cc/hr over an 11 hour period beginning at 7 pm (i.e., a total of 550 cc of enteral formula, 34.5 gms protein). If the subject tolerated the tube feedings, the rate was increased by 25 cc/hr each night to either: (a) a maximum of 125 cc/hr over an 11 hour period beginning at 7 pm; or, (b) the subject's 'nutrient deficit' was reached. For example, if the subject's 'target intake' was calculated to be 2,100 Kcal and his 'volitional intake' was 1,400 Kcal, the enteral feeding rate that night was set to 64 cc/hr for a total of 700 cc over 11 hours, which equaled his 'nutrient deficit' (i.e., 2,100–1,400 Kcal).

As necessary to insure subject safety and comfort, the rate of the enteral feedings was temporarily decreased by 25–50 cc/hr or discontinued. The nasogastric tube remained in place until the subject's 'nutrient deficit' was less than 480 Kcal for at least 2 consecutive days or the subject was discharged from

the hospital. Subjects who had a 'nutrient deficit' between 240–480 Kcal were asked to drink one or two cans (240 Kcal/can) of supplement each night.

Standard nursing procedures were followed in caring for subjects who were receiving enteral feedings. At any point that the subject refused the feeding tube, the subject was switched to the oral feeding arm of the study. The subject's 'nutrient deficit' was calculated in the same manner. However, instead of receiving the supplements via nasogastric feeding tube, the subject was coached to drink the targeted amount of supplement each night. It was not possible to quantitate the amount of coaching provided. As desired by the subject, flavor packets were added to the supplement to make it more palatable. In the final analysis, all subjects remained in the group to which they were originally assigned by the randomization procedure (i.e., as per 'intent to treat').

Postoperative Monitoring and Assessment

Repeat Clinical Assessments. The laboratory nutritional assessment was repeated the day after surgery and again every 7 days until the subject was discharged. To identify complications, all subjects were monitored daily from admission until hospital discharge. Monitoring included chart reviews, interviews with the ward team, and daily subject examinations by the study nurse and physician. To avoid subjective observer bias, each post-admission complication was defined both qualitatively and quantitatively using rigid objective criteria based on standard clinical assessment parameters. These criteria and the protocol used for the outcomes monitoring was developed, validated, and utilized in previous outcome assessment trials as described elsewhere [16,20,24,25]. Record was also made of all occurrences of feeding tube displacement or obstruction, the amount and severity of any diarrhea, and any factors which prevented the subject from receiving all of the nutrients ordered. Subsequent to discharge, all subjects were followed by return orthopedic clinic visits and phone interviews for six months.

Monitoring Nutrient Intake. All study subjects had their nutrient intakes monitored by the research team on a daily basis. As described elsewhere [26], a standard protocol was used to obtain these daily calorie counts. In brief, the percent of each food item eaten was recorded on a special computer generated form which listed all the items that were on the subject's food tray and the standard serving size of each of the items. The percentages were entered into a computer running a specially designed software package which calculated the calorie count for the given meal and stored the results in a subject database. The software program derives the nutrient analysis using a food nutrient database based on modified U.S.D.A. Handbooks #8 and #456. For subjects receiving enteral feedings, the amount of supplementation received each day was determined based on the readout from the feeding pumps.

Statistics

Since this was a pilot study, the goal was to identify possible trends in the data. The data were analyzed using the SAS Institute software [27]. The unpaired t test was used to compare group means for continuous variables that were normally distributed [28]. Otherwise, the Wilcoxon Rank Sum test was utilized [28]. Differences in proportions between treatment and control groups were evaluated using univariate chi-squared or Fisher’s exact tests.

RESULTS

Recruitment

Between June 1996 and October 1997, 95 patients over the age 64 were admitted with an acute hip fracture to one of the study sites. Of the 64 patients who were eligible, 7 declined the offer to enter the study. The remaining 57 subjects were randomized to either the treatment (n = 27) or control group (Fig. 1). The baseline characteristics and surgical statistics of each group are contrasted in Table 1. Subjects from the treatment group were younger than the controls (75.9 ± 7.4 yrs. vs. 81.7 ± 7.7 yrs., *p* = 0.006). They also tended to be more cognitively intact (i.e., higher Mini Mental State Exam score) and have higher serum albumin and lower APACHE scores at study entry compared to the controls. However, none of these latter comparisons reached statistical significance. Three subjects in each group had their surgery delayed by greater than one week due to complicating medical problems.

Feeding Tube Placement and Initiation of Feedings

Five of the 27 treatment subjects were never started on enteral tube feedings because they either refused tube placement or were not able to tolerate a feeding tube. The remaining 22 subjects had a small-bore feeding tube placed successfully within 12 hours of surgery and were started on enteral feedings. The tubes had tungsten weighted tips and were advanced blindly (i.e., without fluoroscopy) with the stilets in place. Gastric motility agents (e.g., erythromycin) were not used.

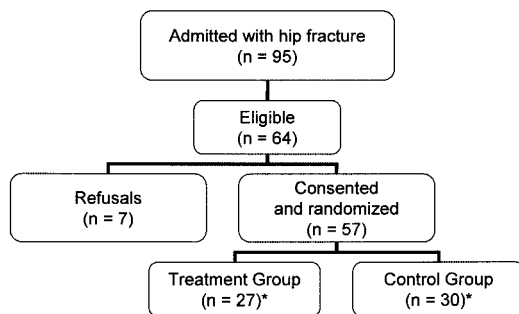


Fig. 1. Study subjects flowsheet. *All 57 study subjects were included in the final analyses.

After appropriate tube placement was confirmed by x-ray, the stilet was removed and the subject was cleared to be started on feedings. Although in 14 cases the first tube inserted passed directly into the third portion of the duodenum or beyond, location of the tube was not a major determinant of the amount of feedings received. In only two cases, the first feeding tube inserted remained in place until the targeted end-point for the nutrition support was reached. In the remaining cases, the tubes were removed (by subject request or inadvertently) on at least one occasion. The number of tube re-insertions varied depending on the need and subject willingness and ranged from 1 to 8 (median 1). In only 5 cases was it possible to continue the nightly enteral tube feedings until the targeted end-point for the nutrition support was reached. When it was no longer possible to provide enteral nutrition support, subjects were asked to drink an equivalent amount of the nutritional supplement each night.

Results of Feeding Intervention and Clinical Outcomes

All subjects had reduced volitional nutrient intakes after surgery. During the first week subsequent to surgery, there was no difference between the treatment and control groups in the amount of nutrients that they volitionally consumed during the day as part of their regularly provided meals (Median 3,429 (IQR 2,596 to 5,338) kJ/d vs. 3,965 (IQR 2,968 to 4,664) kJ/d [Median 819 (IQR 620 to 1,275) Kcal/d vs. 947 (IQR 709 to 1,114) Kcal/d], *p* = 0.370). However, the treatment subjects had a greater total nutrient intake (Median 5,866 (IQR 5,024 to 7,335) kJ/d vs. 3,965 (IQR 2,968 to 4,664) kJ/d [Median 1,401 (IQR 1,200 to 1,752) Kcal/d vs. 947 (IQR 709 to 1,114) Kcal/d], *p* < 0.001) due to the nightly supplementary feedings. These feedings included the nutrients provided by tube and any study-provided supplements that the subjects drank during the night if not being tube fed. Expressed in different terms, the treatment group consumed a larger percentage of their calculated requirements than did the controls (86 ± 28% vs. 63 ± 25%, *p* = 0.002) during the first week.

Twenty-two subjects (10 treatment and 12 controls) had a postoperative length of stay on an acute care ward of greater than 7 days. In the second postoperative week, there was no longer a statistically significant difference in total nutrient intake between the treatment and control groups (Median 6,247 (IQR 4,899 to 8,608) kJ/d vs. 7,005 (IQR 4,049 to 9,479) kJ/d [Median 1,492 (IQR 1,170 to 2,056) Kcal/d vs. 1,673 (IQR 967 to 2,264) Kcal/d], *p* = 0.871). The nightly supplementary nutrient intake of the 10 treatment subjects was offset by a volitional nutrient consumption during the day that was lower than that of the control group (Median 4,786 (IQR 4,116 to 5,179) kJ/d vs. 7,005 (IQR 4,049 to 9,479) kJ/d [Median 1,143 (IQR 983 to 1,237) Kcal/d vs. 1,673 (IQR 967 to 2,264) Kcal/d], *p* = 0.289). However, this difference did not reach statistical significance. Both groups were similar in the second

Table 1. Admission and Surgical Statistics for the Study Subjects

Admission Parameters	Group		<i>p</i> value
	Treatment (n = 27)	Control (n = 30)	
Age (yrs) (mean ± SD)	75.9 ± 7.4	81.7 ± 7.7	0.006
White race, n (%)	24 (89.0)	25 (83.3)	0.547
Male gender, n (%)	20 (74.1)	19 (63.3)	0.384
Admitted to University Hospital (vs. VA), n (%)*	8 (29.6)	10 (33.3)	0.764
Admitted from Nursing Home, n (%)	4 (14.8)	8 (26.7)	0.273
Mini Mental State Exam score, median (IQR)†	20 (8, 27)	13 (5, 23)	0.151
Pre-admission Katz Index of ADL score, median (IQR)‡	1 (0, 7)	2 (0, 5)	0.865
APACHE score (mean ± SD)	9.5 ± 3.1	11.1 ± 4.2	0.120
# of inadequately controlled problems, median (IQR)§	3 (2, 4)	3.5 (2, 5)	0.555
# of stable problems, median (IQR)§	3 (2, 6)	4 (3, 6)	0.419
# of prescription medications, median (IQR)	6 (5, 9)	6 (4, 8)	0.476
Total # of medications, median (IQR)	9 (7, 11)	8 (6, 11)	0.289
Albumin (g/L) (mean ± SD)	35 ± 5	33 ± 4	0.161
Pre-albumin (mg/L) (mean ± SD)	179 ± 46	193 ± 51	0.306
Cholesterol (mg/dL) [mmol/L] (mean ± SD)	166.1 ± 28.6 [4.23 ± 0.74]	176.2 ± 34.1 [4.56 ± 0.88]	0.232
Body mass index (kg/m ²) (mean ± SD)	21.9 ± 3.6	22.2 ± 5.2	0.816
Weight as a percent of ideal weight (%) (mean ± SD)	96.9 ± 18.4	99.1 ± 27.1	0.728
Weight as a percent of usual weight (%) (mean ± SD)	94.5 ± 9.7	96.9 ± 9.9	0.363
Biceps skinfold (mm) (mean ± SD)	6.0 ± 3.3	6.8 ± 3.3	0.368
Surgical parameters			
Days from admission to surgery, median (IQR)	3 (1, 6)	2 (1, 3)	0.178
Anesthesia time (minutes) (mean ± SD)	57.1 ± 16.2	52.9 ± 17.5	0.351
Surgical time (minutes) (mean ± SD)	112.4 ± 37.2	115.4 ± 43.1	0.786
Required endoprosthesis, n (%)	7 (25.9)	12 (40.0)	0.260

* VA = Veteran's Affairs.

† Mini Mental State Exam score has a range from 0 to 30 [19]. Scores below 24 suggest delirium, dementia, or severe depression.

‡ Functional status one month prior to study admission based on caregiver recall and measured using the Katz Index of Activities of Daily Living score [22]. Scores ranged from 0 (independent) to 12 (totally dependent).

§ A problem was considered active if it required therapy. Active problems were categorized as inadequately controlled if a new or modified treatment regimen had to be instituted in order to control the problem at admission (e.g. insulin dose modified to control blood sugars). Active problems were considered stable if the treatment regimen for that problem instituted prior to admission did not require modification (e.g. blood sugars stable on usual dose of insulin).

|| Number of medications patient received during first 24 hours subsequent to admission.

¶ Usual weight was obtained from review of old records as defined previously [25].

week with regards to meeting their calculated nutrient requirements. When total nutrient consumption was expressed as a percentage of calculated requirements, there was no difference between the treatment and controls ($96 \pm 43\%$ vs. $95 \pm 40\%$, $p = 0.942$). The within-group variability also did not differ between the groups (F-test for equality of variances, $p > 0.5$).

Although the incidence of diarrhea did not differ between the groups, (18.5 vs. 10.0%, $p = 0.457$), the diarrhea among the treatment subjects was more difficult to control. In two cases, the rate of the tube feedings had to be decreased due to diarrhea. Other than the frequent tube removals, there were no other tube- or tube-feeding-related complications.

As shown in Table 2, there was no difference between the groups in the rate of postoperative complications, postoperative life-threatening complications, rate of discharge to an institution, or in-hospital mortality. The only in-hospital death was a subject in the treatment group who had a serious complication the day of surgery and died 3 days later. At discharge from the acute care hospital, the surviving treatment subjects had higher

serum albumin concentrations and were taking fewer medications than the controls (Table 3). The groups were otherwise comparable in terms of health status at discharge. In contrast to the feasibility study, there was no difference between the groups in mortality within six months subsequent to surgery (Table 2).

DISCUSSION

This intervention trial did not confirm the finding from the feasibility study that enteral nutrition support is an effective method of improving six-month postoperative survival in older patients undergoing repair of an acute hip fracture. The study also failed to produce evidence that the intervention is effective in reducing postoperative complications. The lack of demonstrated effectiveness may be the result of the many problems encountered during the study that prevented most of the intervention subjects from reaching their targeted nutrition goals. Unlike the feasibility study, inadvertent removal of the feeding

Table 2. Comparison of Clinical Outcomes

Clinical outcome	Group		p value
	Treatment (n = 27)	Control (n = 30)	
Postoperative complication, n (%) [*]	18 (66.7)	18 (60.0)	0.602
Postoperative life-threatening complication, n (%) [†]	4 (14.8)	3 (10.0)	0.697
Rate of discharge to an institution, n (%)	25 (92.6)	27 (90.0)	1.000
In-hospital mortality, n (%)	1 (3.7)	0 (0)	0.474
Postoperative LOS (days), Median (IQR) [‡]	7 (5, 13)	7 (5, 10)	0.761
Hospital LOS (days), Median (IQR) [‡]	9 (7, 21)	9 (7, 15)	0.817
Six-month postoperative mortality, n (%)	4 (14.8)	6 (20)	0.734

^{*} Percentage of subjects who developed one or more complications subsequent to surgery. Some of the subjects who developed postoperative complications also had complications prior to or during surgery. The list of potential complications and their definitions is described elsewhere and is also available from the authors upon request [16,20,24,25].

[†] Percentage of subjects who developed one or more life-threatening complications subsequent to surgery.

[‡] LOS = length of stay.

Table 3. Discharge Statistics for the Study Subjects Discharged Alive

Discharge parameters	Group		p value
	Treatment (n = 26)	Control (n = 30)	
Mini Mental State Exam score, median (IQR) [*]	19 (10, 26)	14 (7, 21)	0.189
Katz Index of ADL score, median (IQR) [†]	8 (4, 11)	9 (7, 11)	0.503
# of inadequately controlled problems, median (IQR) [‡]	1 (0, 2)	1 (0, 2)	0.826
# of stable problems (mean ± SD) [‡]	6.8 ± 3.1	7.7 ± 3.3	0.269
Total # of medications (mean ± SD) [§]	5.8 ± 2.6	7.5 ± 3.5	0.050
Albumin (g/L) (mean ± SD)	29 ± 5	25 ± 5	0.002
Pre-albumin (mg/L) (mean ± SD)	167 ± 51	161 ± 69	0.686
Cholesterol (mg/dL) [mmol/L] (mean ± SD)	149.9 ± 35.8 [3.88 ± 0.93]	146.7 ± 36.4 [3.79 ± 0.94]	0.746

^{*} Mini Mental State Exam score has a range from 0 to 30 [19]. Scores below 24 suggest delirium, dementia, or severe depression.

[†] Functional status at study discharge measured using the Katz Index of Activities of Daily Living score [22]. Scores ranged from 0 (independent) to 12 (totally dependent).

[‡] A problem was considered active if it required therapy. Active problems were categorized as inadequately controlled if a new or modified treatment regimen had to be instituted in order to control the problem at admission (e.g. insulin dose modified to control blood sugars). Active problems were considered stable if the treatment regimen for that problem instituted prior to admission did not require modification (e.g. blood sugars stable on usual dose of insulin).

[§] Number of medications patient received during first 24 hours subsequent to admission.

tubes occurred commonly and was probably the biggest obstacle to providing the targeted amount of nutrition support. There were many other patient- and environment-related factors that differed between this study and the feasibility study that may also have contributed to the failure to reach target goals. The feasibility study was conducted on one, geographically defined specialized nursing unit dedicated to orthopedics. Since the time of that study, the hospital environment changed substantially particularly in the VA. Not only did the current study involve another hospital, there was greater dispersion of the subjects to multiple nursing units, postoperative lengths of stay were shorter, the nursing units had greater mixtures of patients, and the nursing staffs appeared to have greater work demands. All of these factors may have resulted in study-related procedures being placed on a lower priority ranking for the nursing staffs. This would have included maintaining the feeding tubes and coaching the intervention subjects to drink the supplement at night if they did not have a feeding tube. Subsequent to the time of the feasibility study, hospitals also implemented policies placing greater restrictions on the use of any form of

patient restraint. Although restraints were never ordered as part of this study, the new restraint policies may have influenced nursing practice with regards to the care of the intervention subjects. Patients who developed postoperative delirium were less likely to be restrained for other reasons, which may have contributed to more tubes being pulled out at night. Given the high incidence of postoperative delirium among older patients with an acute hip fracture, it will be important to identify optimal methods of nutrient delivery for this group of patients [29].

With few exceptions, all of the subjects in this study were very frail. Most also had evidence of preexisting potentially serious nutritional deficits that were exacerbated by a low nutrient intake in the first postoperative week. However, some of the subjects had adequate volitional nutrient intakes within two or three days subsequent to surgery. Since these subjects did not need enteral nutrition support, their inclusion in this study diminished the power of the study to detect benefits of the intervention. In a study of 143 elderly females with an acute hip fracture, Bastow and colleagues used anthropometrics as a means of determining need for nutrition support [1,11]. By

comparing the anthropometric measurements to population standards, each patient was classified as well nourished, thin or very thin. Only the 122 patients classified as thin or very thin were randomized. The 21 well-nourished subjects acted as a second control group. As in the current study, subjects randomized to the treatment group received supplementary nasogastric tube feedings each night starting within 3 days of surgery. Both the randomized and non-randomized control groups received standard care. The well-nourished, non-randomized controls had a significantly greater volitional nutrient intake than either the thin or very thin subjects suggesting that the use of anthropometrics would be an excellent method of targeting patients for nutrition support. However, we did not confirm this finding in the feasibility study. For this reason, we randomized all subjects in the current study. When we examined the nutrient intake of the control subjects in the current study, the lack of an association between anthropometrics and postoperative volitional nutrient intake was again confirmed (data not shown). As this is still an unresolved issue, further study is needed to determine which patients are most likely to have persistently low volitional nutrient intakes subsequent to hip fracture repair. This information would allow nutrition support to be targeted to those in greatest need and most likely to benefit.

By the second postoperative week, the intervention subjects had a somewhat lower average volitional nutrient intake than did the controls. This raises the possibility that the intervention may have caused appetite suppression and a delay in the return to a full volitional nutrient intake in the treatment group. However, this difference between the groups was not statistically significant indicating that it may have been caused by factors other than group allocation. Further investigation of this issue is warranted.

In this study, both oral supplementation and tube feeding methods were utilized in an attempt to reach each treatment subject's nutritional requirements. The amount of nutrients that the subject consumed was the primary concern, not the route of delivery. There were several reasons why this approach was adapted. Of central importance, it was recognized that older patients undergoing surgical repair of an acute hip fracture represent a very heterogeneous population, although most are quite frail and all are acutely ill. It was also recognized that many of these patients maintain very low volitional oral nutrient intakes in the postoperative period [1,9–11,16,30,31]. As has been shown in several studies, nightly enteral nutrition support is an effective method of increasing total caloric intake, at least in some patients of this type [11,12,16,32,33]. The challenge is to select the right candidates for this form of therapy. It is often a major problem keeping the enteral feeding tubes in place, particularly when dealing with older, acutely ill, hospitalized patients such as those with an acute hip fracture [11,34,35]. The limitations in the use of enteral tube feedings in older hip fracture patients would make this approach problematic if the goal was to maximize the nutrient intake of all patients, as was the goal in this study. Likewise, there are pros

and cons to providing liquid nutrient supplements for the patients to drink. Several studies provide evidence of their benefit in the care of older hip fracture patients [10,14,17,33,36]. However, other studies indicate that they too are effective only in select patients [9,13,15,37]. For some patients, they may suppress appetite and lead to a deterioration in nutrient intake [37–39]. Given the literature bias against negative studies, it is not clear how often this is actually the case. By allowing either tube feedings or oral supplementation in this study, it was hoped that at least one approach would be successful in every given treatment subject. Unfortunately, the targeted goal was not fully attained. More work is needed to identify how best to overcome the many obstacles to providing adequate nutrition support to acutely ill older adults.

The study was not powered to examine individual types of complications. However, this may be an important issue. It is possible that nutrition support is only effective in reducing specific types of complications, such as wound dehiscence or soft tissue infections, but has little effect on other outcomes such as cardiovascular complications. Conversely, more needs to be learned about the risks associated with the intervention and the risk-benefit ratios in specific groups of patients. The influence of enteral feedings on glucose metabolism and how this influences outcomes is an example of a potentially important concern of this type that needs more study.

In the feasibility study, six-month postoperative mortality was significantly lower in the treatment group compared to the controls (50% vs. 100%, $p = 0.036$). As indicated in Table 2, the current study intervention was associated with only a non-significant trend toward lower mortality at 6 months. In order to have adequate power to demonstrate conclusively that the intervention reduces mortality by this amount, a much larger study involving over 1700 subjects would be required. Whether a greater relative reduction in mortality can be attained by improving the effectiveness of the nutrient delivery or better patient targeting strategies needs to be determined.

CONCLUSION

This study failed to confirm pilot study findings of improved survival with nutrition support. However, it was conducted on multiple hospital wards which resulted in a higher rate of tube-related problems and less nutrient delivery. Although the intervention has not been shown to be effective in improving outcomes, enough evidence of its efficaciousness exists to warrant further study.

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