

Nightly Enteral Nutrition Support of Elderly Hip Fracture Patients: A Phase I Trial

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

Objective: This non-blinded randomized controlled trial was the first phase of a planned series of investigations designed to test the efficacy of aggressive post-operative enteral nutrition support to decrease the rate of post-operative complications or improve long-term outcomes in specifically defined subgroups of elderly patients who have sustained a hip fracture requiring surgery.

Methods: Eighteen patients (17 males) were randomized to the treatment (eight male subjects) or control groups. The control group (mean age 76.5 ± 6.1 years) received standard post-operative care. Subjects in the treatment group (mean age 74.5 ± 2.1 years) received 125 cc/hour of nasoenteral tube feedings over 11 hours each night in addition to standard post-operative nutritional care.

Results: Both the treatment and control groups had reduced volitional nutrient intakes for the first 7 post-operative days ($3,966 \pm 2,238$ vs. $4,263 \pm 2,916$ kJ/day [948 ± 535 vs. 1019 ± 697 kcal/day], $p=0.815$), but the treatment subjects had a greater total nutrient intake ($7,719 \pm 2,109$ vs. $4,301 \pm 2,858$ kJ/day [1845 ± 504 vs. 1028 ± 683 kcal], $p=0.012$). On average, treatment subjects were tube fed for 15.8 ± 16.4 days. There was no difference between the groups (treatment vs. controls) in the rate of post-operative life-threatening complications (25 vs. 30%, $p=1.00$) or in-hospital mortality (0 vs. 30%, $p=0.216$). Mortality within 6 months subsequent to surgery was lower in the treatment group compared to the controls (0 vs. 50%, $p=0.036$).

Discussion: We conclude that nightly enteral feedings are a safe and effective means of supplementing nutrient intake. The greatest impact of nutrition support may be to reduce mortality.

INTRODUCTION

Up to 64% of elderly patients hospitalized with an acute hip fracture are protein-energy undernourished at admission or develop serious nutritional deficits while hospitalized [1–8]. These undernourished patients are at increased risk of developing serious in-hospital complications, the likelihood of developing a complication increasing exponentially in relation to the severity of the nutritional deficits [1,3–9]. Despite these facts, elderly hip fracture patients rarely receive a complete nutritional assessment [4,10,11]. Consequently, their nutritional deficits are usually not recognized and only rarely is

adequate treatment provided [4,10–12]. Several studies suggest that aggressive nutritional support targeted to these undernourished patients may be beneficial both in terms of rectifying their nutritional deficits and improving their clinical outcomes [5–7]. 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 increasing number of elderly patients who fracture their hip each year (the incidence is expected to double by the year 2011) [13], the prevalence of

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protein-energy undernutrition in this population, and the increased risk of morbidity associated with poor nutrition, the efficacy of nutrition intervention to improve outcomes needs to be established.

This study was the first phase of a planned series of investigations designed to test the efficacy of aggressive post-operative enteral nutrition support to decrease the rate of post-operative complications or improve long-term outcomes in specifically defined subgroups of elderly patients who have sustained a hip fracture requiring surgery. The specific objectives of this non-blinded randomized controlled trial were to refine a nutrition intervention protocol and to establish the feasibility of testing the efficacy of the intervention in subsequent studies.

METHODS

Patients

Subjects were recruited from the J. L. McClellan VA hospital, a 550 bed University affiliated acute care facility. 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 nonosteoporotic 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 recruitment goal for the study was set at 18 subjects. This sample size was felt to be adequate to test the feasibility of the protocol. Although supporting literature did not exist, it was hoped that this sample size would also be adequate to demonstrate a trend toward improved clinical outcomes with treatment and thus provide the basis for determining sample size for a larger, more definitive investigation.

Subjects were evaluated for possible study entry at the time of their admission to the hospital. Due to limited resources, only patients admitted Monday through Friday were considered candidates. Each recruit received oral and written explanations of the nature of the study and the possible risk 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 post-operative 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 evaluated. Calorie counts were completed daily on all subjects. The enteral feedings were terminated when volitional intake exceeded 90% of estimated requirements for 3 consecutive days.

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 care giver; 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 [14]; and 4) a complete clinical and laboratory nutritional assessment including anthropometric measurements and a determination of serum secretory protein concentrations (albumin and transferrin), cholesterol, and total lymphocyte count. The admission assessment and post-operative monitoring protocol was developed and validated in prior studies and are described in detail elsewhere [9,15]. The APACHE illness severity instrument was completed using available clinical data [16].

The Katz Index of Activities of Daily Living (ADL) scale was used to assess functional status [17]. 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). As previously reported, our testing of this modified Katz scale found it to be highly reliable and valid [9].

Post-Surgical 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 post-operative 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: One of the primary purposes of this study was to test and refine the post-operative feeding protocol. Initially, all subjects who were randomized to the treatment group had a small-bore feeding tube placed in the operating room. In order to determine the optimal method for tube placement, four subjects had their tubes placed in the

recovery room. In all cases, placement of the tube was confirmed by x-ray in the recovery room. 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 cleared to be started on the feedings, all subjects received 1375 cc of polymeric enteral formula (Promote®, Ross Laboratories, 85.8 g protein, 4,314 non-nitrogenous kJ [1,031 kcal]) over an 11-hour period (125 cc/hour via enteral feeding pump) beginning at 7 p.m. each night. In addition to the nasoenteral tube feedings, they received standard post-operative nutritional care and received three meals each day. The orthopedic surgeons wrote all of the diet orders for the daytime meals. The nasoenteral tube remained in place until the subject volitionally consumed greater than 90% of predicted nutrient requirements for at least 3 consecutive days or was discharged from the hospital. The study personnel determined the supplement requirements for each study subject. Total daily energy requirements were estimated based on the Harris-Benedict equation (BMR) plus an activity and stress factors [18].

Standard nursing procedures were followed in caring for subjects who were receiving enteral feedings. If diarrhea developed after the tube feedings started, the quantity of the feeding provided each night was decreased and an evaluation for other causes of diarrhea initiated. Once the diarrhea was controlled, the tube feedings were slowly increased to tolerance. To prevent the feeding tubes from becoming clogged, the tubes were flushed with 30 cc of water every 4 hours and whenever medications were given through the tubes. If the feeding tube was proximal to the pylorus, gastric residuals were checked every 4 hours.

Postoperative Monitoring and Assessment

Repeat Clinical Assessments. The laboratory parameters identified above were 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 patient 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 as described elsewhere [9,15]. 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 patient from receiving all of the nutrients ordered. Subsequent to discharge, all subjects were followed by return orthopedic clinic visits and phone interviews for 6 months.

Monitoring Nutrient Intake. All study subjects had their nutrient intakes monitored by the research team on a daily basis. As described elsewhere [19], 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 patient'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 patient database. The software program derives the nutrient analysis using a food nutrient database based on modified USDA 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 feasibility study, the goal was to identify possible trends in the data and to detect problems that might arise in the conduct of a larger study which would influence the validity of the analyses. The data were analyzed using the SAS Institute software [20]. The unpaired t-test was used to compare group means for continuous variables [21]. The results are reported as means, standard deviations, and p-values for the contrasts of interest. Differences in proportions between treatment and control groups were evaluated using univariate chi-squared or Fisher's exact tests.

RESULTS

Recruitment

During the 5-month period of recruitment, 18 subjects (17 males) were determined to be eligible for study entry. All 18 consented to study participation and were randomized to either the treatment (eight subjects) or control group. The baseline characteristics of each group are contrasted in Table 1. Subjects from the treatment group tended to have slightly fewer functional limitations prior to their fracture (pre-admission Katz Index of ADL score), were more cognitively intact (Mini Mental State Exam score), and less likely to be admitted from a nursing home (0 vs. 30%, $p=0.216$) compared to controls. However, none of these comparisons reached statistical significance. Compared to the control group, the treatment subjects had significantly longer average surgical and anesthesia times. Roughly equal proportions of each group required an endoprosthesis for repair of their hip fracture (37.5 vs. 40%, $p=1.00$).

Feeding Tube Placement and Initiation of Feedings

Six of the eight treatment subjects had small-bore feeding tubes placed in the operating or recovery rooms. The tubes had tungsten weighted tips and were advanced blindly (i.e., without

Table 1. Admission and Surgical Statistics (Means±SD) for the Study Subjects

Admission parameters	Group		p-Value
	Treatment (n=8)	Control (n=10)	
Age (years)	74.5±2.1	76.5±6.1	NS
Mini Mental State exam score ¹	21±5	15±12	NS
Pre-admission Katz Index of ADL score ²	0.4±0.7	3.0±4.1	NS
APACHE score	9.3±3.8	9.0±2.6	NS
# of inadequately controlled problems ³	2.6±2.1	3.3±2.0	NS
# of stable problems ³	3.0±2.8	3.9±2.7	NS
# of prescription medications ⁴	5.3±2.9	7.4±3.7	NS
Total # of medications ⁴	6.6±3.4	8.7±3.7	NS
Albumin (g/L)	32.3±10.3	35.2±5.8	NS
Transferrin (g/L)	2.01±0.85	2.48±0.93	NS
Cholesterol (mmol/L)	4.13±1.39	4.62±1.38	NS
Body mass index (kg/m ²)	24.1±4.8	24.1±7.8	NS
Weight as a percentage of ideal (%)	102.1±19.8	104.4±32.5	NS
Weight as a percentage of usual weight (%) ⁵	93.9±7.6	99.4±7.2	NS
Biceps skinfold (mm)	7.4±4.4	9.7±8.5	NS
Surgical parameters			
Days from admission to surgery	2.2±1.3	1.4±1.4	NS
Anesthesia time (minutes)	232.5±48.8	171.3±27.8	0.004
Surgical time (minutes)	166.3±44.7	116.8±23.6	0.018

¹ Mini Mental State exam score has a range from 0 to 30 [14]. Scores below 24 suggest delirium, dementia, or severe depression.

² Functional status 1 month prior to study admission based on caregiver recall and measured using the Katz Index of Activities of Daily Living score [17]. Scores ranged from 0 (independent) to 12 (totally dependent) [9].

³ 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).

⁴ Number of medications patient received during first 24 hours subsequent to admission.

⁵ Usual weight was obtained from review of old records as defined previously [9].

fluoroscopy) with the stilets in place. Gastric motility agents (e.g., erythromycin) were not used. After appropriate tube placement was confirmed by x-ray, the stilet was removed and the patient was cleared to be started on feedings. In all but one case, the tubes curled up in the stomach when initially placed. Although various methods were utilized to promote spontaneous tube passage into the small bowel after feedings were initiated, in all five cases the distal end of the tube remained in the stomach for greater than 36 hours. Two of these subjects developed a post-operative ileus necessitating a delay in the initiation of the feedings; in one case the feedings were started

the day after surgery and in the other, on the third post-operative day. The later subject had severe dysphagia and was assessed to be at high risk for aspiration. His feeding tube had to be manually passed into the small bowel endoscopically after repeated attempts to place the tube using standard procedures failed. Several of the subjects who were fed into the stomach complained of mild bloating and anorexia in the early morning, most notably on the first 3 post-operative days. Checks for gastric residuals were consistently negative. All subjects tolerated the feedings once the distal end of the feeding tube passed into the small bowel.

A trial was conducted using two of the treatment subjects to determine if they could orally ingest the supplements and thus avoid the use of the feeding tubes. Both subjects readily consumed three 240 ml cans of the supplement per night (720 cc total), but neither was able to drink more. Based on these results, a decision was made to limit further attempts at oral feeding only to patients who refused to have a feeding tube placed or replaced. All subsequent treatment subjects in this study had feeding tubes placed without problems.

Results of Feeding Intervention and Clinical Outcomes

All subjects had reduced volitional nutrient intakes for at least the first 7 days subsequent to surgery. There was no difference in average daily volitional nutrient intake between the treatment and the controls (3,966±2,238 vs. 4,263±2,916 kJ/day [948±535 vs. 1019±697 kcal/day], $p=0.815$) during the first 7 post-operative days. During this period, the treatment subjects' average daily enteral feeding (3,749±1,155 vs. 38±113 kJ/day [896±276 vs. 9±27 kcal/day], $p<0.001$) and total nutrient intake (7,719±2,109 vs. 4,301±2,858 kJ/day [1845±504 vs. 1028±683 kcal/day], $p=0.012$) was significantly greater than that of the controls. These figures include the two treatment subjects who were given a trial of oral supplementation, the two treatment subjects who had delays in starting the feeding protocol, and one control subject who received enteral feedings for several days. On average, treatment subjects were tube fed for 15.8±16.4 days (±SD). No complications related to the nasoenteral tube feedings occurred in the treatment group and the nightly feedings did not induce significant diarrhea.

As shown in Table 2, there was no difference between the groups in the rate of post-operative complications, post-operative life-threatening complications, rate of discharge to an institution, or in-hospital mortality. Among those discharged alive, the treatment subjects tended to be slightly less debilitated (Table 3). However, none of the comparisons reached statistical significance. Three subjects (one treatment and two controls) developed their first life-threatening complication prior to or during surgery. For the three subjects who died in the hospital, the average time from surgery to death was 22.7 days (range 3 to 48 days).

Table 2. Comparison of Clinical Outcomes

Clinical Outcome	Group		p-Value
	Treatment (n=8)	Control (n=7)	
Post-operative complication ¹	88%	80%	NS
Post-operative life-threatening complication ²	25%	30%	NS
Rate of discharge to an institution	50%	57%	NS
In-hospital mortality	0%	30%	NS
Six-month mortality	0%	50%	0.036

¹ Percentage of subjects who developed one or more complications subsequent to surgery. Some of the subjects who developed post-operative complications also had complications prior to or during surgery.

² Percentage of subjects who developed one or more life-threatening complications subsequent to surgery.

Table 3. Discharge Statistics (Means±SD) for the Study Subjects Discharged Alive

Discharge Parameters	Group		p-Value
	Treatment (n=8)	Control (n=7)	
Mini Mental State Exam score	19±10	13±14	NS
Katz Index of ADL score ¹	4.1±3.7	5.9±4.3	NS
# of inadequately controlled problems ²	0.9±1.1	1.4±1.1	NS
# of stable problems ²	5.4±4.5	5.7±2.2	NS
Total # of medications ³	4.6±1.8	5.0±2.8	NS
Length of stay (days)	38.2±36.9	23.7±20.0	NS
Albumin (g/L)	28.6±6.3	26.7±2.9	NS
Transferrin (g/L)	2.01±0.42	1.70±0.93	NS
Cholesterol (mmol/L)	3.86±0.62	4.25±0.98	NS

¹ Functional status at discharge measured using the Katz Index of Activities of Daily Living score [17]. Scores ranged from 0 (independent) to 12 (totally dependent) [9].

² As described in Table 1.

³ Number of medications patient prescribed to take after discharged.

Mortality within 6 months subsequent to surgery was lower in the treatment group compared to the controls (Table 2). Of the subjects still alive at 6 months, there was no difference between treatment and controls with regards to functional status or percentage requiring institutional care.

DISCUSSION

There are a number of important findings from this study. Most notably, the study demonstrates the feasibility of conducting a scientifically sound randomized trial of nutrition intervention in a population of elderly subjects undergoing surgical repair of an acute hip fracture. Of the patients evaluated and found to be eligible for study entry, 100% agreed to participate. All subjects knew they had a 50% chance of being randomized

to the treatment group when they consented to enter the study. With few exceptions, all of the subjects were very frail, and most had evidence of preexisting potentially serious nutritional deficits. As found in prior studies of this population, complications were frequent and long-term outcomes were generally poor. The study did not have the power to test the effectiveness of the intervention to reduce short-term complications. However, the findings provide the basis for a larger trial of nutrition support in this population.

In this study, there were no intervention-related complications (including enteral nutrition induced diarrhea) and the nightly feedings did not diminish daytime appetite. Feeding via nasogastric tube was the most effective method of delivering nutrients, although oral supplementation was also effective and may be the preferred method in some patients in who do not tolerate tubes. These findings are consistent with those of other studies which also found nightly enteral feedings to be of benefit in undernourished frail elderly patients [1,5,7,22].

During this study, many of the complications occurred prior to or during surgery and before nutrition support was initiated. In such cases, the nutrition support may have been instrumental in lowering the risk for mortality after the first complication developed. Although the rate of life-threatening complications was the same between treatment and control subjects, all of the deaths occurred within the control group. A larger study is needed to verify this finding.

One of the drawbacks of providing enteral nutrition support is the difficulty of inserting and keeping feeding tubes in place. We found that passing the tubes either in the operating room or recovery could be accomplished without difficulty. Our goal was to advance all tubes into the small bowel. However, when initially placed, most of the tubes curled up in the stomach. As other investigators have found, spontaneous passage of the tubes into the small bowel usually did not occur even by 36 hours. Feeding subjects into the stomach was problematic. Several of the gastrically fed subjects experienced mild abdominal discomfort in the early post-operative period suggestive of poor gastric emptying. Checks for gastric residuals were consistently negative. However, checking residuals through a small-bore feeding tube could have produced false negative results [23]. Several techniques to promote tube passage into the small bowel have been developed, including the use of intravenous erythromycin, manipulating the tube with the stilet in place or under fluoroscopic guidance, and using specialized tubes attached to electromyographic recording devices [24–29]. Further work is needed to determine the usefulness of each of these techniques in this population and the optimal method of keeping the tubes in place once inserted.

This study was modeled after the work of Bastow et al who first reported the potential benefits of nightly enteral feedings in elderly hip fracture patients [5]. In their study, Bastow and coworkers classified the patients as thin, very thin, or normal based on a comparison of their anthropometric measurements to a population norm. Only the thin and very thin subjects were

targeted for intervention. Subjects randomized to the treatment group received a constant amount of enteral feedings each night. Patients who were thin and very thin ate poorly and had prolonged rehabilitation times, which were shortened by supplementary feedings nearly to that seen in the well-nourished controls. There was no significant difference in mortality rates between groups.

As in the study by Bastow et al, we provided the treatment group with nightly feedings at a constant rate. When volitional nutrient intake was determined to be adequate, feedings were discontinued. There was no tapering of nightly feedings as a subject's volitional nutrient intake improved. Whether this is an optimal approach needs to be evaluated. There is also a need to develop better methods of identifying patients who are most likely to benefit from nutrition support, those who are unlikely to maintain an adequate nutrient intake and who are at highest risk for poor clinical outcomes. Bastow et al targeted patients for intervention based on anthropometric measurements whereas we randomized all patients. The accuracy of various targeting criteria to predict post-surgical volitional nutrient intake and complication risk needs to be determined.

There are a number of other issues which need to be addressed in order to determine what constitutes optimal use of nutrition support for elderly patients with a hip fracture. This would include the identification of the most accurate method of assessing the nutrient needs of this population. Various formulas have been derived for calculating resting metabolic rate or estimating total energy and protein needs for the elderly. Nitrogen balance and indirect calorimetry studies are needed to determine the accuracy of these formulations for elderly patients undergoing surgical repair of an acute hip fracture. The optimal time for starting nutrition support also needs to be investigated. In some cases, it may prove advantageous to start nutrition support prior to surgery. It is often the sicker patients and those with the greatest nutritional deficits who have the longest delays prior to being cleared for surgery. For these subjects, starting nutrition support at hospital admission may constitute a more optimal level of nutrition care.

CONCLUSION

The objective of this feasibility study, to provide a working model to test the effectiveness of aggressive nutritional supplementation in elderly patients requiring surgical repair of their hip fracture, was accomplished successfully. We found that patients were willing to enter the study and that nightly enteral feedings are a safe and effective means of supplementing nutrient intake. Although the number of subjects who entered the study is too small to make definitive conclusions, the greatest impact of nutrition support may be to reduce mortality. Subsequent studies are needed to identify which subgroup of hip fracture patients are at greatest risk of nutrition related

complications, and to establish the optimal time to initiate feedings in this high risk group.

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