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Randomized control trials

Tight Calorie Control in geriatric patients following hip fracture decreases complications: A randomized, controlled study☆

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SUMMARY

Background & aims: Optimizing nutritional intake has been recommended for geriatric patients undergoing hip-fracture surgery. Whether nutritional support guided by repeated measurements of resting energy requirements (REE) improves outcomes in these patients is not known.
Methods: A randomized, controlled, unblinded, prospective, cohort study comparing provision of energy with a goal determined by repeated REE measurements using indirect calorimetry, with no intervention. Oral nutritional supplements were started 24 h after surgery and the amount adjusted to make up the difference between energy received from hospital food and measured energy expenditure.
Results: 50 Geriatric patients were included in the study. Patients in the intervention group ($n = 22$) received significantly higher daily energy intake than the control group ($n = 28$) (1121.3 ± 299.0 vs. 777.1 ± 301.2 kcal, $p = 0.001$). This was associated with a significantly less negative cumulative energy balance (−1229.9 ± 1763 vs. −4975.5 ± 4368 kcal, $p = 0.001$). A significant negative correlation was found between the cumulative energy balance and total complication rate ($r = -0.417$, $p = 0.003$) as well as for length of hospital stay ($r = -0.282$, $p = 0.049$).
Conclusion: We have demonstrated that nutritional support actively supervised by a dietician and guided by repeated measurements of REE was achievable and improved outcomes in geriatric patients following surgery for hip fractures. Clinicaltrials.gov Identifier: NCT017354435.

1. Introduction

Hip fractures remain a significant health risk in the elderly population in western society. Thus, in the United States, the mean annual number of hip fractures in 2005 was 957.3 per 100 000 for women and 414.4 for men.[1] These injuries degrade quality of life and increase both morbidity and mortality.[1,2] One of the factors which might influence the outcome of these patients is their nutritional status. In this regard, up to half of elderly patients with hip fractures are already malnourished on admission to hospital and protein energy malnutrition appears to be more common in older patients with hip fractures than age-matched controls.[3,4] In addition to the effects of preexisting under nutrition, lean body mass may be further depleted by the inflammatory response to injury, which leads to a catabolic state characterized by nitrogen loss and insulin resistance. This is evident immediately after the injury and may continue for up to 3 months after surgery. Finally, under nutrition may be further aggravated by lower than required intake of energy during the hospital stay.

This state of under nutrition may impact on outcome. Negative effects include muscle wasting and weakness, impairing mobility and predisposition to decubitus ulcers and pulmonary complications (including atelectasis and pneumonia) as well as impaired immune responses further predisposing to an increase in post-operative infections.[5,6]

Non-standard abbreviations: IC, indirect calorimetry; ONS, oral nutritional supplements; MAC, mid-arm circumference; CIRS-G, Cumulative Illness Rating Scale for Geriatrics; CCI, Charlson's comorbidity index; FIM, Functional Independence Measure; MMSE, Mini-Mental State Examination; MNA, mini-nutritional assessment; CAM, Confusion Assessment Method.

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It is therefore important to determine whether these adverse outcomes may be modified by active nutritional interventions. In this regard, a recent Cochrane review of nutritional supplementation for hip fracture aftercare in older people concluded that there was only weak evidence for the effectiveness of protein and energy feeds.[2] In these studies, energy requirements were typically based on the use of weight-based formulae which may not necessarily capture the different metabolic profile seen in patients following injury compared to those undergoing elective procedures.

We have recently demonstrated encouraging results on the outcome of critically ill patients whose energy requirements were determined by repeated measurements of resting energy expenditure (REE).[7] To our knowledge, no study has examined longitudinal REE in the immediate postoperative course in this patient population. We therefore undertook the present study to evaluate whether nutritional support guided by repeated measurements of REE improved outcomes in geriatric patients following surgery for hip fractures and compared this to usual nutritional therapy.

2. Subjects and methods

2.1. Subjects

This study was conducted in the ortho-geriatric unit of the Department of Geriatrics, at the Rabin Medical Center in Petah Tikva, Israel, over a period of 20 months (from May 2010 to December 2011). The study was approved by the local institutional review board and written informed consent was obtained from all participants prior to randomization. Consecutive patients older than 65 years who were admitted to the unit following hip fracture within 48 hof the injury and in whom orthopedic surgery was considered the treatment of choice. Patients were excluded if they presented to hospital >48 hafter the injury, were receiving steroids and/or immunosuppression therapy; in the presence of active oncologic disease, multiple fractures, diagnosed dementia or in the event that patients required supplemental nasal oxygen which precludes the measurement of REE.

2.2. Interventions

In this unblinded study, eligible patients were randomly assigned to 2 groups, within 48 h of the injury and prior to surgery: the tight calorie (intervention) group and the control group. Randomization was performed using a concealed, computer-generated program. RA enrolled participants and assigned them to interventions while YB enrolled patients but was blinded to the intervention. The tight calorie group received calories with an energy goal determined by repeated REE measurements using indirect calorimetry (IC) (Fitmate, Cosmed, Italy) which was based on hospital-prepared diets (standard or texture-adapted). Oral nutritional supplements (ONS) were started 24 h after surgery and the amount adjusted to make up the difference between energy received from hospital food and measured energy expenditure. These ONS were provided in the form of Ensure plus (Abbott Laboratories) containing 355 kcal/237 ml and 13.5 g protein or Glucerna (Abbott Laboratories) containing 237 kcal/237 ml and 9.9 g protein/237 ml. The patient, family and caregivers were educated regarding the importance of nutritional support and more attention was given to personal food preferences. The control group received usual hospital food (standard or texture-adapted) and a fixed dose of ONS if already prescribed prior to hospitalization. Hospital prepared diets provide a mean of 1800 kcal and 80 g of protein in the event that the meals are completely eaten by the patients.

All patients were treated in the same unit and perioperative care including antibiotic and thrombosis prophylaxis was identical in both groups.

2.3. Measurements

All patients underwent IC measurements after a fasting period of at least 6 h at three time periods: on admission to the study, between 24 and 48 h following surgery and on the 7th day of the study. Measurements were performed by an experienced nurse or dietician, the device was automatically calibrated before each measurement and the REE was recorded after 15 min.

The nutrient intake of each patient was monitored by the research team on a daily basis. Twenty-four hour food diaries were filled in by the medical staff, family and caregivers. All meals had a known energy and protein content and the proportion of each component consumed was calculated using a food data base program. In addition, the amount of ingested ONS was noted by the medical staff. Before surgery, grip strength in the dominant arm was measured with a hand-grip dynamometer (JAMAR®) with the highest of 3 measurements being recorded. Midarm circumference (MAC, cm) was measured on the first day of the study using a non-stretchable flexible tape perpendicular to the long axis of the non-dominant arm.

2.4. Data collection

On admission and during hospitalization, demographic, laboratory and clinical data were collected from patients, caregivers and patient files, where appropriate. The BMI was derived from body weight which was measured during hospitalization using seat scales, and height which was calculated according to measured recumbent knee height.[8] Biochemical parameters including serum glucose, albumin, lymphocyte count and creatinine levels, were collected at 3 time points: before surgery, 24 h after surgery and on the 7th study day. Energy balances were assessed daily by calculating the difference between the most recently measured REE and the same day energy intake. Cumulative energy balance was assessed at either day 14 or at discharge from the geriatric department and included the preoperative period. Comorbidity was assessed retrospectively with the Cumulative Illness Rating Scale for Geriatrics (CIRS-G)[9] and the Charlson's Comorbidity Index (CCI).[10] The Functional Independence Measure (FIM) scale was used to assess pre-facture functional ability[11] and the Mini-Mental State Examination (MMSE) was used for the assessment of cognitive function.[12] Nutritional status of the patient was assessed on the first day of the study using the Mini Nutritional Assessment (MNA),[13] a validated, sensitive, reliable tool for use in the elderly. The MNA score distinguishes between elderly patients with adequate nutritional status ($MNA > 23.5$), those at risk of malnutrition (MNA between 17 and 23.5) and those with protein-calorie malnutrition ($MNA < 17$).

2.5. Outcome measures

The primary outcome was the presence of postoperative complications and hospital length of stay. Secondary outcomes included energy intake and calculated energy balance.

Patients were examined daily by the research nurse and attending physician for the presence of postoperative complications. These included surgical complications (such as local bleeding or the need for repeat surgery); infectious complications, including pneumonia (based on clinical symptoms and signs and positive chest radiograph), urinary tract infection (based on clinical symptoms and signs and positive urinary cultures) and wound infections