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Original Article

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A R T I C L E I N F O

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SUMMARY

Background & aims: Strategies to treat malnutrition lack practicability in the hospital setting. The present study aimed at developing and evaluating a routinely manageable concept for an improved nutritional care of malnourished in-hospital patients. *Methods:* A randomized controlled intervention study was conducted. 132 risk patients defined by Nutritional Risk Screening 2002, were randomized to individualised nutrition support (intervention group [n = 66]) or standard hospital care (control group [n = 66]). Body weight, plasma vitamin levels, quality of life, complications, antibiotic therapies, readmissions and mortality were assessed. *Results:* Nutrition interventions led to higher intakes (mean [standard deviation]) in energy (1553)

[341] kcal vs. 1115 [381] kcal, p < 0.001) and protein (65.4 [16.4] g vs. 43.9 [17.2] g, p < 0.001). Intervention patients (n = 66) kept their body weight in comparison to control patients (n = 66; 0.0 [2.9] kg vs. -1.4 [3.2] kg, p = 0.008). Positive effects on plasma ascorbic acid level (46.7 [26.7] µmol/l vs. 34.1 [24.2] µmol/l, p = 0.010), SF-36 function summary scale (37 [11] % vs. 32 [9] %, p = 0.030), number of complications (4/66 vs. 13/66, p = 0.035), antibiotic therapies (1/66 vs. 8/66, p = 0.033) and readmissions (17/64 vs. 28/61, p = 0.027) were recorded.

Conclusions: Malnourished patients profit from nutrition support regarding nutrition status and quality of life. They have fewer complications, need fewer antibiotics and are less often re-hospitalised. © 2010 Elsevier Ltd and European Society for Clinical Nutrition and Metabolism. All rights reserved.

1. Introduction

In line with earlier data collected in other EU countries,^{1,2} the first multi-centre cross-sectional study in German hospitals brought evidence forward that every fourth adult patient at admission is already malnourished or has a risk of becoming malnourished during hospital stay.³

^{*} Conference presentation: Some of the data were presented as a poster at the 31th Congress of the European Society for Clinical Nutrition and Metabolism (ESPEN), Vienna 2009 and in a talk at "nutrition2009" in Zurich in 2009.

* Corresponding author. Tel.: +41 61 925 2187; fax: +41 61 925 2804. *E-mail address*: remy.meier@ksli.ch (R. Meier). An insufficient nutritional status judged by low BMI, for example, is associated with a worse adherence to therapies, higher complication rates, a lower quality of life, restrictions in functionality, and, thus, higher morbidity and mortality rates. Moreover, malnourished survivors stay longer in hospitals which increase average treatment costs for these in-patients approximately threefold.^{4–6} Therapeutic efforts to optimize the nutritional status during hospital stay are, thus, mandatory, both to improve patient outcome and to decrease costs for the health care systems.⁶

The first step towards approaching this goal is the evaluation of the nutritional status in routine clinical setting. Although validated and easy manageable screening tools like the Nutritional Risk Screening 2002 (NRS-2002⁷) are available, only few hospitals in Europe routinely screen the nutritional status of their patients at admission and/or during hospital stay. One important reason might be that efficacious and validated "pathways" for treatment are not available in hospitals.⁸

The aim of the present study was, thus, to develop and evaluate a routinely manageable concept for an improved nutritional care of malnourished in-hospital patients.

Abbreviations: 25-OH-D₃, 25-Hydroxycholecalciferol; CG, control group; IG, intervention group; ITT, Intention-To-Treat-population; LOS, length of stay; NRS-2002, Nutritional Risk Screening 2002; ONS, oral nutritional supplement; PAL, physical activity level; REE, resting energy expenditure; SF, stress factor; SF-36, quality of life Short Form 36 Questions Score; TEE, total energy expenditure.

2. Patients and methods

2.1. Study design

The study was conducted as a randomized controlled intervention trial between January 2007 and November 2007 (intervention period; follow up until June 2008) until a sufficient number of patients had been recruited (see statistics). The study protocol was approved by the ethic committee of the University of Basel/ Switzerland. All patients were informed about study objectives and procedures and signed written informed consent before inclusion.

During the study period, all adult patients consecutively admitted to the general medical ward at "Kantonsspital Liestal" hospital were screened for nutritional risk using the NRS-2002 questionnaire.⁷ Exclusion criteria were: no informed consent, terminal condition, expected stay <5 days (judged by physician), previous participation in this study, patient on starvation, on parenteral nutrition, and/or being on dialysis. Patients with a nutritional risk (NRS score \geq 3) were recruited and randomized according to a computer-generated randomization list to the intervention group (IG) or the control group (CG) receiving either individualised nutritional support for 5 to maximum 28 days (IG) or standard hospital care (CG). Patients with an initial score <3 were re-evaluated weekly during the study's intervention period and asked for participation in case a nutritional risk developed during hospitalisation.

Primary endpoints of the study were the average daily energy and protein intake. As secondary parameters the changes in body weight during hospitalisation, number of complications, number of antibiotic therapies due to infectious complications, length of hospital stay, quality of life Short Form 36 Questions (SF-36) Score,⁹ hospital readmission (after six months), mortality (hospital and six months after discharge), compliance with oral nutrition standard supplement consumption and plasma concentrations of 25-OH-D₃, ascorbic acid and glutathione were evaluated.

All baseline measurements were made within 72 h after admission. Body weight was measured in all patients on a chair scale (100 g precision) in light clothes without shoes in the morning. The body weight of patients with oedema was recorded at admission, as was the body weight of patients being dehydrated. Height was asked or taken from the personal identity card. In case height was not available it was measured using a stadiometer (1 cm precision) or (when the patient was not able to stand upright) transposed from knee length measurements.¹⁰ Quality of life was recorded by the SF-36 questionnaire filled out either by the patients themselves or by an experienced interviewer. Venous blood samples were taken after overnight fast by the nurses on duty.

Throughout the study period, intake of medication and the occurrence of complications were recorded daily and confirmed by the physician on duty. Complications were defined as all hospitalacquired unexpected events, i.e. all diagnoses apart from the diagnosis leading to hospitalisation occurring at least 5 days after admission. These include infectious complications (respiratory tract, urinary tract, wound, catheter infection and others) and non-infectious ones (decubitus, wound dehiscence, abscess, respiratory failure, cardiac arrest, insufficiency or arrhythmia, diarrhoea (non-infectious), pneumonia, gastroenteritis, liver and kidney failure, cerebral bleeding, thrombosis and others). Complications were diagnosed and recorded by the physicians (who were not involved in the study). Local guidelines were used in the hospital based on pre-defined formal criteria.

Before discharge (decision of the responsible physician) all baseline measurements were performed again. The actual length of stay (LOSⁱ; based on admission and discharge dates) and the possible LOS (LOS^h; based on admission dates and the physicians

estimate of when the patient was ready for discharged) in the general medical ward and in hospital were calculated.

2.2. Nutritional intervention

Patients of CG received standard nutritional care, including the prescription of oral nutritional supplements and nutritional therapy prescribed by the physician independently of this study and according to the routine ward management.

Patients of IG got individual nutritional care, including a detailed nutritional assessment, individual food supply, fortification of meals with maltodextrin, rapeseed oil, cream and/or protein powder, in-between snacks and oral nutritional supplements. All interventions aimed at meeting the daily energetic requirement according to the individual total energy expenditure (TEE; calculated from resting energy expenditure [REE¹¹] corrected by an individual factor for physical activity level [PAL] and disease [stress factor, SF¹²]). Protein intake was set at 1.0 g/kg body weight. Complications influencing feeding (e.g. nausea) were reported to the ward physician and treatment was optimised (e.g. medication).

Reference menus were weighted to have the detailed size/ weight of each food item and the corresponding energetic and protein contents were calculated (Bundeslebensmittelschlüssel II.3, PRODI[®] database). Food intake was observed during meal times. The consumed part of each food item was visually estimated and recorded. Finally, the total energy/protein intake was calculated with PRODI[®]. In case less than 75% of the portion (i.e. served food at one meal with known energy/protein content) offered had been consumed, energy and protein intake was compensated on a daily basis by supplying either ONS (Resource[®] [Nestlé Nutrition]) or in-between meals in IG. Snacks, drinks and ONS which were additionally consumed were reported by ward staff and the author or asked for with the patient.

Finally, with the help of PRODI[®] database, each daily kcal and protein intake was calculated based on the consumed food items. Energy given by the intra-venous route, e.g. 5% glucose solution, was added to the oral intake.

Compliance of ONS intake (in %) was calculated by taking the amount of ONS consumed divided by the amount the patient should have consumed and multiplied by 100.

Except of energy and protein intake, all outcome data were blinded in terms of that physicians and nurses who were responsible for the outcome did not have access to group allocation.

2.3. Follow-up

Information concerning readmission and 6-months-mortality was obtained by the patients hospital computer register or by calling either the patients themselves or their general practitioners, respectively, six months after discharge.

2.4. Blood sampling and analyses

At admission and before discharge, venous blood was withdrawn into heparinised tubes and directly centrifuged. The plasma aliquots for 25-OH-D₃ and glutathione were frozen at -80 °C. Plasma specimen for ascorbic acid analysis were deproteinized and stabilized using meta-phosphoric acid-perchloric acid solution and stored at -80 °C analysis.

Frozen samples were transported to the central lab in Bonn. Ascorbic acid detection was carried out by HPLC with UV detection.¹³ Analysis of 25-OH-D₃ was achieved by enzymatic immunoassay (ELISA kit from IDS Frankfurt/Germany) and detection of glutathione after separation of metabolites by fluorescence detection.¹⁴

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