nutritionDay in Intensive Care Units worldwide

Applicant & Research director:

Prof. Dr. Michael Hiesmayr, MSc CEDAS - Center for Medical Data Science Institute of Medical Statistics Medical University Vienna Spitalgasse 23 A-1090 Vienna Austria

Tel: +43-1-40400-74940 Email: michael.hiesmayr@meduniwien.ac.at

Coworker & Partner Medical University Vienna:

Prof. DI Dr. Peter Bauer, CEDAS - Center for Medical Data Science Institute of Medical Statistics

Prof. Dr. Martin Posch, CEDAS - Center for Medical Data Science Institute of Medical Statistics

Dr. Silvia Tarantino, CEDAS - Center for Medical Data Science

Institute of Medical Statistics

Dr. Arabella Fischer, division of cardiac thoracic vascular anaesthesia and intensive care

Dr. Cecilia Veraar, division of cardiac thoracic vascular anaesthesia and intensive care

Dr. Karin Schindler, Internal medicine, Div. Endocrinology and Metabolism

Dr. Christian Schuh, ITSC Medical University of Vienna

Partner Organisations: European Society for Clinical Nutrition and Metabolism (ESPEN) European Society for Intensive Care Medicine (ESICM MEN section)

Summary

The aim of this research project is to run a multi-centre cross-sectional multinational audit about nutritional care and outcome in ICUs worldwide.

Background & Significance

Nutrition care is an integrated part of any ICU treatment(1). Nevertheless, there are several aspects of nutritional care where little consensus exists and where practical implementation may vary between ICUs(2). Disagreement exist about the tolerable energy deficit(3), the route of administration(4), the actual energy needs(5), the composition of artificial nutrition given and the role of specific nutrients such as glutamine(6), arginine, omega-3 fat or micronutrients. (7-9)

An ICU patient presents a number of nutritional challenges. The case mix of patients admitted may range from those admitted electively after major elective surgery to those admitted as emergencies after some surgical catastrophe, major trauma, sepsis or respiratory failure (10,11).

About 30% of all patients in hospital are undernourished (7, 8). The majority of these patients are already undernourished when admitted to hospital and in many patients, undernutrition develops further while in hospital (12). It has been shown that a relevant energy deficit develops usually in the first week in the ICU and is related to an increased complication rate(13). Nevertheless, recent data indicate that 70% of measured energy expenditure is associated with best outcome in ICU patients(14). Nutrition care guidelines in ICU were developed and published in 2019 (1) including progressive nutrition over several days during ICU stay and they recommend higher protein supply than previously reported.

Enteral nutrition is the preferred way of feeding the critically ill patient and an important way of counteracting the catabolic state induced by severe illness(15). Enteral nutrition should be given to all ICU patients who are not expected to be taking a full oral diet within three days(16). Artificial nutrition should be started within the first 24h using a standard high-protein formula. During the acute and initial phases of critical illness an exogenous energy supply in excess of 20-25 kcal/kg BW/day should be avoided. During recovery instead, the aim should be to provide values of 25-30 total kcal/kg BW/day. Supplementary parenteral nutrition remains a reserve tool and should be given only to those patients who do not reach their target nutrient intake on enteral nutrition alone(16). Parenteral nutrition is often used in patients with gastro-intestinal intolerance.

The target caloric intake depends on the specific situation and changes for example for patients with sepsis or trauma. It is very important to identify the patient's needs to determine the energy requirement. The use of stress factors may introduce substantial error into estimations of energy expenditure, since there is no definitive guide as to the stress factors that should be used in different clinical situations.

Specific aims

The aim of this project is to increase knowledge and awareness about nutrition of ICU patients among the staff by evaluating nutrition care on a European and International level. Consecutively knowledge and best practice information will be shared with the participating institutions and associations. The results of the survey will be disseminated to increase the clinical interest in nutrition. By drawing attention to health care services and approaches to patient feeding, hospitals could adopt a health promoting approach to patient care complementing the current curative approach.

Since 2007, in order to facilitate benchmarking in ICUs, we use a multi-lingual data acquisition tool to determine actual nutrition care in an ICU's.

Research questions:

- 1. Determine the association between severity of illness and reasons for admission on the preferential use of enteral or parenteral nutrition.
- 2. Determine the amount of calories and proteins supplied associated with better and worse outcomes
- 3. Association of specific nutrients, such as protein and omega-3 fatty acids, multi-vitamins, trace elements, glutamine on outcome
- 4. Timing of the start of enteral and parenteral nutrition
- 5. Association of oral nutrition in ICU patients with outcome
- 6. Comparison of world regions in the practice of ICU nutrition
- 7. Association of mobilization practices in ICU on patient's outcome
- 8. Association of diagnoses and comorbidities profiles of ICU patients with nutrition care and outcomes
- 9. Association of respiratory care with nutrition care and outcomes
- 10. Association of Delirium, RASS score
- 11. Prevalence of refeeding syndrome (Laboratory Values)
- 12. Describe the practice of prokinetic therapy

Preliminary research & research synergies

The nutritionDay project was developed by a group of ESPEN members at the Medical University of Vienna, where a small team build up a network, which now includes some hundred hospitals and different professional groups involved in nutritional care. Many professionals involved in the actual nutritionDay project for wards are directly or indirectly involved in nutritional care in the ICU. Our intention is to use this existing network of competence and experience for the development of a specific NutritionDay for the ICU.

Research design & methods

The audit has 5 parts:

- Part I: structure and organisation of the ICU (sheet 1)
- Part II: patient's status at admission and medical history (sheet 2)
- Part III: treatments received in ICU
- Part IV: patient's nutritional care (precisely on nutritionDay and with less precision for the preceding days).
- Part V: patient's outcome 60 day in hospital

All data are retrievable from the routine ICU documentation. No tests or investigations are necessary for conducting the audit. In patients able to communicate, 7 questions about wellbeing (hunger, thirst, mood) are directly asked to the patient.

The questionnaires are available for each participating country in the national language. The questionnaires are freely accessible in a web-based download. Upon participation, units enter anonymous collected data into the

nutritionDay database available at <u>www.nutritionday.org</u> upon successful registration. On nDay Data collection and transfer comply with the General data protection Regulation (GDPR)(17). All information and necessary training for participation can be accessed electronically.

Inclusion criteria: all patients present in the ICU on the data collection days. Ventilated and non-ventilated patients should be included in the audit.

Exclusion criteria: patients are excluded from data collection if below 7 years or above 100 years of age or if the legal representatives of the patient express refusal based on the displayed unit information (see unit announcement sheet).

Representative sample of 20-30 patients in a given ICU is obtained by 3 consecutive cross-sectional samples. The interval between the cross-sectional data collection will be 6 days. The week day for data collection is Thursday in the first week, Wednesday in the second week and Tuesday in the third week. Patients are only included once.

This workload appears to be feasible even in busy ICU's if the workflow has been well designed and adequate preparation was possible.

Variables:

Structure of the ICU:

- ICU size, ICU staff, type of ICU, structure of nutrition therapy

Patient-oriented information:

<u>At admission:</u>

-Reasons for admission, diagnosis and comorbidities, severity of illness (SAPS 2 score),

At nutritionDay:

-severity of illness (SOFA score), level of nursing care (NEMS score), level of sedation (RASS score), history of infection within the last 10 days in ICU, level of organ support, level of care

Nutrition care:

-nutritional approaches, reasons for interrupting nutritional support, oral feeding, patient feeling and wellbeing, type and amount of enteral and parenteral nutrition, additional pharmaco-nutrition.

Patient's outcome at day 60 after nutritionDay:

-ICU length of stay, hospital length of stay, transfer to other hospital, discharge home, readmission to hospital, ICU readmission, surgery, death.

Statistics and analysis methods

Data will be presented as percentages with 95% confidence intervals. In general data will be aggregated first at unit level and thereafter at country level. The level of aggregation is indicated for each analysis separately. Data referring to units as well as data for multivariate analysis will include only patients from ICUs that included on nutritionDay a minimum of six patients. Individual countries will only be reported if a minimum of six participating ICUs

fulfilled the inclusion criteria to protect anonymity of participating ICUs. Variation between countries will be assessed by considering countries as homogeneous and by considering units as random factor. Percentages will refer to the total population present in the ICU.

In addition to the univariate analysis, a multivariate analysis will be performed. The analysis will include age in categories of 10 years with mean age 60-70 a as reference, gender (reference female), BMI in WHO categories with BMI 18.5-25 as reference, duration of stay in the ICU before nutritionDay in three categories for the first week, one for the second week and the last category for 2 weeks and longer, comorbidities as cancer with metastasis, heart failure or any other less frequent comorbidities (cancer therapy, haematological cancer, cirrhosis, aids) reasons for being dependent on ICU care (abdominal, burns, cardiac, neurological, pulmonary, septic, trauma and other), surgery before ICU admission, severity of illness at admission based on SAPS II score in quintiles, , actual severity based on the SOFA, artificial ventilation, renal replacement therapy and 6 world regions (North America, Latin America, Eastern Mediterranean, Europe A as reference, Europe B).

For the multivariate analysis of the starting day of artificial nutrition we considered either countries or year of participation as effect modifier. Only countries with a sufficient number of participant (n=66) to let the model converge will be included in the country analysis. Preference for EN, PN, oral nutrition in contrast to the other nutrition modalities will be analysed with logistic regression where unit were considered clusters. The start day of EN or PN will be determined with multivariate linear regression including only risk factors already present at ICU admission (age, BMI, gender, comorbidities, surgery before admission, reasons for ICU admission and severity of illness (SAPS 2) at ICU admission.

The outcome evaluation for discharge, transfer and death will be done in a competing risk multivariate model (Fine and Gray model) with the same covariates as described above.

Due to the cross-sectional sampling design of nutritionDay estimates of proportions and durations may be biased and should be interpreted with care. The same applies for effect estimates in multivariate models which may also be affected by sampling related bias.

Statistical analysis will be done in R 3.3.1 or STATA 15.1.

Ethical aspects and data protection:

The project "nutritionDay in the ICU" has two ethical aspects. Firstly it is an ethical obligation to address malnutrition of hospitalised patients as a safety issue. Secondly the anonymity of the participating unit and all assessed patients is always protected.

Data safety

All anonymous data from ICU patients are transferred via the nutritionDay data collection web-interface and are stored on a server at the Medical University of Vienna. Automatic regular backup is performed daily.

Access to Data entry is protected by two random number passwords which protect the identity of the participating center and of the unit.

Benefit to patients and healthcare system

First there will be a harmonised set of data collection questionnaires in all languages that can be used for regular benchmarking of ICU's (e.g. annual intervals). ICU will be able to communicate and compare performance at world regions level.

Second there will be a multi-lingual electronic data collection tool that will facilitate the data transfer into a database on ICU nutrition Care.

Third the knowledge transfer between the nutritionDay for wards and ICU's will be a step towards a continuous nutrition care plan throughout hospitalisation.

References

1. Singer P, Blaser AR, Berger MM, Alhazzani W, Calder PC, Casaer MP, et al. ESPEN guideline on clinical nutrition in the intensive care unit. Clin Nutr. 2019;38(1):48-79.

2. Bendavid I, Singer P, Theilla M, Themessl-Huber M, Sulz I, Mouhieddine M, et al. NutritionDay ICU: A 7 year worldwide prevalence study of nutrition practice in intensive care. Clin Nutr. 2017;36(4):1122-9.

3. Arabi YM, Reintam Blaser A, Preiser JC. Less is more in nutrition: critically ill patients are starving but not hungry. Intensive Care Med. 2019;45(11):1629-31.

4. Harvey SE, Parrott F, Harrison DA, Bear DE, Segaran E, Beale R, et al. Trial of the route of early nutritional support in critically ill adults. N Engl J Med. 2014;371(18):1673-84.

5. Oshima T, Deutz NE, Doig G, Wischmeyer PE, Pichard C. Proteinenergy nutrition in the ICU is the power couple: A hypothesis forming analysis. Clin Nutr. 2016;35(4):968-74.

6. Andrews PJ, Avenell A, Noble DW, Campbell MK, Croal BL, Simpson WG, et al. Randomised trial of glutamine, selenium, or both, to supplement parenteral nutrition for critically ill patients. BMJ. 2011;342:d1542.

7. McWhirter JP, Pennington CR. Incidence and recognition of malnutrition in hospital. BMJ. 1994;308(6934):945-8.

8. Pennington CR, McWhirter JP. Patients go hungry in British hospitals. Malnutrition is common, unrecognised, and treatable in hospital patients. BMJ. 1997;314(7082):752.

9. Hofman Z, Swinkels S, van Zanten ARH. Glutamine, fish oil and antioxidants in critical illness: MetaPlus trial post hoc safety analysis. Ann Intensive Care. 2016;6(1):119.

10. Reid CL. Nutritional requirements of surgical and critically-ill patients: do we really know what they need? Proc Nutr Soc. 2004;63(3):467-72.

11. Giner M, Laviano A, Meguid MM, Gleason JR. In 1995 a correlation between malnutrition and poor outcome in critically ill patients still exists. Nutrition. 1996;12(1):23-9.

12. Hiesmayr M, Schindler K, Pernicka E, Schuh C, Schoeniger-Hekele A, Bauer P, et al. Decreased food intake is a risk factor for mortality in hospitalised patients: the NutritionDay survey 2006. Clin Nutr. 2009;28(5):484-91.

13. Dvir D, Cohen J, Singer P. Computerized energy balance and complications in critically ill patients: an observational study. Clin Nutr. 2006;25(1):37-44.

14. Zusman O, Singer P. Resting energy expenditure and optimal nutrition in critical care: how to guide our calorie prescriptions. Crit Care. 2017;21(1):128.

15. Reintam Blaser A, Starkopf J, Alhazzani W, Berger MM, Casaer MP, Deane AM, et al. Early enteral nutrition in critically ill patients: ESICM clinical practice guidelines. Intensive Care Med. 2017;43(3):380-98.

16. Heidegger CP, Berger MM, Graf S, Zingg W, Darmon P, Costanza MC, et al. Optimisation of energy provision with supplemental parenteral nutrition in critically ill patients: a randomised controlled clinical trial. Lancet. 2013;381(9864):385-93.

17. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance), (2016).

18. More Nutritional Support on the Wards after a Previous Intensive Care Unit Stay: A nutritionDay Analysis in 136,667 Patients Fischer A, Veraar C, Worf I, Tarantino S, Kiss N, Schuh C, Hiesmayr M. Nutrients. 2023 Aug 11;15(16):3545. doi: 10.3390/nu15163545.

19. Ernährungspraxis auf Intensivstationen: nutritionDay 2007–2021 [Nutrition practices in intensive care units: nutritionDay from 2007-2021].

Hiesmayr M, Fischer A, Veraar C, Mora B, Tarantino S, Weimann A, Volkert D. Med Klin Intensivmed Notfmed. 2023 Mar;118(2):89-98. German. doi: 10.1007/s00063-023-00996-y. Epub 2023 Feb 28. PMID: 36853418; PMCID: PMC9992071.

20. Timing of parenteral nutrition in ICU patients: a transatlantic controversy Veraar C, Geilen J, Fischer A, Sulz I, Tarantino S, Mouhieddine M, Mora B, Schuh C, Singer P, Hiesmayr MJ Clinical Nutrition ESPEN, https://doi.org/10.1016/j.clnesp.2021.08.007.