


Adequacy of protein and calorie delivery according to the expected calculated targets: a day-by-day assessment in critically ill patients undergoing enteral feeding

Adam Fabiani¹ | Lorella Dreas¹ | Enzo Mazzaro¹ | Elena Trampus² |
Michela Zanetti² | Antonella Calabretti³ | Giuseppe Gatti¹ | Gianfranco Sanson² 

Abstract

Background: In critically ill patients requiring mechanical ventilation for longer than 48–72 h enteral nutrition (EN) should be started early. Because EN alone may be unable to reach the target nutritional requirement, supplemental parenteral nutrition (PN) should be administered. This study aimed at describing the daily rate of administered calories and proteins according to the expected calculated targets. The impact of calorie adequacy, deficit or excess on relevant clinical outcomes was explored.

Methods: A retrospective cohort study was conducted in 217 patients undergoing cardiac surgery, admitted postoperatively in intensive care unit and undergoing EN. The effective intake provided via EN, PN, oral nutritional supplements (ONS) and nonnutritional calories (NNC) was documented for a maximum of 20 days. The administered/required calorie and protein ratios ($Kcal_{A/R}$, $Prot_{A/R}$) were calculated daily. Patients receiving 80%–100%, <80% or >100% of $Kcal_{A/R}$ and $Prot_{A/R}$ were identified. The association between mean $Kcal_{A/R}$ between days 4–7 and 30 days' mortality was explored.

Results: A mean $Kcal_{A/R}$ ratio of $92.0 \pm 40.6\%$ was ensured between days 4 and 20. During days 4–7 the 80%–100% calorie target was achieved in 26.9% of patients, whereas 44.9% were below and 28.2% over this range. EN contributed 47.1% and PN 41.2% to the total energy intake. An increase in 30-day mortality risk was documented for patients exceeding 100% of $Kcal_{A/R}$ ratio (adjusted-hazard ratio [HR] 5.2; 95% confidence interval [CI] 1.123.9; $p = 0.035$).

Conclusions: Despite a preliminary estimate of nutritional requirement, a steady daily optimal 80%–100% $Kcal_{A/R}$ was not ensured for all patients. EN contributed only partially to both energy and protein intakes so that PN was largely used to achieve the desired nutritional targets.

KEYWORDS

cardiac surgery, critical care, enteral feeding, nutritional requirement

Key points

- In critically ill patients requiring prolonged mechanical ventilation, inadequate nutritional support may worsen inflammation, hypermetabolism and catabolism, and thus negatively affect the outcome.
- The present investigation provides new evidence in describing the daily specific contribution of all nutritional sources to total nutritional requirements in postoperative cardiac surgery patients undergoing enteral nutrition.

INTRODUCTION

Patients undergoing cardiac surgery are at a particular risk for multifactorial hypermetabolic state and catabolic stress resulting in increased energy requirements (ER), as they regularly experience a complex systemic inflammatory response syndrome induced by factors such as surgical trauma, extracorporeal circulation, ischaemia/reperfusion injury, haemodilution and blood loss.¹⁻³ Moreover, they are exposed to the risk of multiple organ dysfunctions requiring prolonged life-supporting treatments, resulting in prolonged mechanical ventilation and longer intensive care unit (ICU) stay.¹ In this clinical setting, possible concomitant nutritional deficits may further worsen inflammation, hypermetabolism and catabolism. Thus, an early nutritional support should be considered for all patients having an ICU stay of more than 48 h, as this condition may lead to a high risk of malnutrition. However, full application of this recommendation in clinical practice is challenging because of some relevant criticalities burdening daily decision-making.

No dedicated guideline exists to guide the perioperative nutrition support for patients undergoing cardiac surgery. Similarly, no clear consensus exists regarding the optimal nutritional targets to reach in critically ill patients.⁴ Although determining a patient's ER before starting nutritional support is strongly recommended, the suggested indirect calorimetry (IC)⁵ is challenging from both practical and economic points of view.⁶ Similarly, predictive equations developed for estimating ER are accurate only in metabolically and haemodynamically stable, mechanically ventilated patients.⁷ Consequently, in daily practice international guidelines recommend – in the absence of IC – a minimum approach based on a simple weight-based equation estimating a fixed daily amount of 20–25 kcal and 1.2–2 g protein per kilogram of body weight at the acute phase of critical illness.^{8,9}

Because an oral diet is seldom feasible in these populations, an artificial support should be started early (within 48 h) preferably via enteral nutrition (EN), aiming at progressively reaching the estimated calorie and protein targets by 3 days from ICU admission. Indeed, it is well known that a possible energy deficit during these first days of ICU stay plays an important role in ICU and hospital outcomes, including increased mortality rate and acquired infections in long-staying ICU patients.¹⁰ However, EN alone may be unable to reach the established nutritional requirement.¹¹ In these cases, parenteral nutrition (PN) and oral nutritional supplements (ONS) should be added early, between days 3 and 7.¹²

The actual ability to ensure the established daily nutritional requirements is still a challenging aspect of nutrition in critically ill patients, despite both under-feeding and overfeeding have been shown to result in

increased incidence of complications (e.g., infections, organ failure), longer hospital stay and higher mortality.⁴ Only a few studies reported the effective daily energy and protein intake in patients undergoing cardiac surgery,¹³⁻¹⁶ and none described in detail the nutritional strategies through which the total nutritional intake was provided.

The main aim of the present study was to describe in detail the nutritional support as the daily rate of administered calories and proteins according to the expected calculated targets in a population of postoperative cardiac surgery subjects. Moreover, the association between early calorie deficit or excess and relevant clinical outcomes was explored as a secondary study objective, taking into account possible confounders such as the preoperative surgical risk and the duration of the provided EN.

MATERIALS AND METHODS

Study design, setting and population

This was a retrospective cohort study conducted in the cardiac surgery unit, University Hospital of Trieste. The unit admits almost 600 patients/year who need cardiac surgery procedures and who are always admitted postoperatively to the cardiac surgery ICU. Overall, in the study setting, compared to an expected mortality of 6.6% as predicted by EuroSCORE II the actual 30-day mortality was 2.9%. Early discontinuation of mechanical ventilation (by 24 h) and early discharge from ICU (by 48–72 h) are expected for most patients, so that EN is needed only in a minority of patients having prolonged mechanical ventilation and longer ICU stay. All consecutive patients admitted in the ICU from January 2012 to May 2018 were considered for enrollment. Inclusion criteria were: (1) age ≥ 18 years; (2) undergoing postoperative EN. Patients with ICU length of stay (LOS) of < 72 h were excluded.

Energy and protein intake

As a study ward policy, in the absence of contraindications artificial nutritional support was always started as EN 48–72 h after ICU admission. EN was given via an EN tube. Based on the treating physician decision, EN could be integrated with oral nutritional supplements (ONS; sterile liquids, semisolids or powders providing macro- and micronutrients) and/or PN if patients were unable to cover individual energy and protein requirements because of conditions such as feeding intolerance, severe haemodynamic instability, excessive gastric residual volume (GRV), digestive haemorrhage or ileus.

For the study purposes, the actual nutritional intake was documented starting from the day of ICU admission

TABLE 1 Examples of daily calorie intake calculation

Source	Energy content ^a (kcal/100 ml)	Given volume (ml/day)	Discarded GRV (ml/day)	Actual intake (ml/day)	Actual intake (kcal/day)
EN	157.0	960.0	130.0	830.0	1303.1
PN	120.0	1360.0	/	1360.0	1632.0
ONS	123.0	100.0	/	100.0	123.0
NNC	20.0	44.0	/	44.0	8.8

Abbreviations: EN, enteral nutrition; GRV, gastric residual volume; NNC, nonnutritional calories; ONS, oral nutritional supplements; PN, parenteral nutrition.

^aSpecifically considered for each nutritional source.

and continued until ICU discharge or the start of oral diet (i.e., when the patient started to feed through the mouth without the enteral tube), for a maximum of 20 consecutive days. Calories administered without nutritional aims (NNC) such as glucose and propofol were computed as well. For all considered nutritional sources (i.e., EN, PN, ONS and NNC), daily energy (kcal/day) and protein (g/day) intakes were then determined by calculating the calorie/protein values of effectively administered formulas as a proportion of the known amounts of calories and protein provided by a standard volume (e.g., 100 ml). For nutrition administered via gastric tube (i.e., EN and ONS) the overall actual administered volume (and the consequent calorie and protein intake) was calculated after subtracting the discarded GRV (e.g., administered EN: 1500 ml/day; discarded GRV: 250 ml/day; actually administered EN: 1250 ml). Table 1 shows some examples of how daily energy intakes have been computed; similar criteria have been adopted for daily protein intake.

Nutritional requirements

For each enrolled patient, the daily nutritional requirement was estimated considering a fixed amount of 1.2 g/kg as daily protein intake¹⁷ and 25 cal/kg of body weight as a standard average daily caloric target, according to the above-cited equation. For these calculations, the patients' actual body weight (as assessed soon before surgery) was considered, except for obese subjects (body mass index [BMI] >30 kg/m²) for which an adjusted body weight (i.e., ideal body weight¹⁸ and 50% of the excess body weight) was used.¹⁹

Collected variables

The following data were collected from the clinical documentation:

- socio-demographic characteristics (gender and age),
- Charlson comorbidity index (CCI), to describe the comorbidity condition,²⁰
- EuroSCORE II, calculated at patient's hospital admission to predict the cardiac surgery-related risk of death,²¹
- length (from incision to skin closure time) and type of the surgery,
- length of extra corporeal circulation,
- length of mechanical ventilation.

Study endpoints

As a primary study endpoint, we analysed the relationships between the daily administered and required calorie and protein ratios (Kcal_{A/R} and Prot_{A/R}, respectively) to document the adequacy of nutritional support. According to previous literature, a ratio of 80%–100% Kcal_{A/R} and Prot_{A/R} was established as a daily target to ensure an adequate nutritional intake while avoiding under- or overfeeding.¹⁰ Accordingly, three categories of patients were defined, depending on whether they received 80%–100%, <80% or >100% of Kcal_{A/R} and Prot_{A/R}. Moreover, the achievement of at least 80% of Kcal_{A/R} and Prot_{A/R} ratios between days 4 and 7 of ICU stay was considered as a relevant clinical endpoint to avoid an 'early caloric and protein deficit' condition.¹⁰

The association between mean Kcal_{A/R} between days 4 and 7 and all-cause mortality (either during hospital stay or after discharge) within 30 days from ICU admission was explored as secondary endpoints.

Ethics

The study was approved by the Regional Bioethics Committee (protocol number: 8566-2019) and was conducted according to the Declaration of Helsinki. At hospital admission, all enrolled patients or their legal representatives authorised the use of their anonymised clinical data for research purposes.

Data analysis

Descriptive statistics was reported as means and standard deviations for continuous variables, whereas absolute numbers and percentage were used for categorical variables. The difference between the means was analysed using the unpaired Student *t*-test, after determining whether equal variance could be attributed to the subgroups according to Levene's test. One-way analysis of variance (ANOVA) was applied for all comparisons between the subgroups. The nominal variables were described as a number and

percentage, and analysed with contingency tables and the χ test.

After excluding patients with an ICU LOS of <7 days (as the Kcal_{A/R} between days 4 and 7 was considered for this analysis), survival analysis was adopted to explore the 30-day risk of death according to the defined Kcal_{A/R} categories. Observations were right-censored after 30 days from ICU admission. Crude evaluation was carried out by comparing Kaplan–Meier curves, and differences in survival rates between subgroups were assessed with log-rank test. Adjusted comparison was performed by fitting a multivariable Cox proportional-hazards model. Given the low number of events per variable, a limited number of covariates supposed to act as potential confounders (i.e., BMI, surgery-related risk of death and total duration of artificial nutritional support) were included to adjust the model. Results were reported as hazard ratios (HRs) with relative 95% confidence intervals (CI) and *p*-values.

All statistical analyses were performed using the software IBM SPSS Statistics, version 24.0 (IBM Corp.), setting an α level of *p* < 0.05 for statistical significance.

RESULTS

During the study period, 3398 patients were admitted to the cardiac surgery ICU and were therefore considered for enrollment. Among them, 217 (6.4%) underwent EN and were included in the study. None of them had an ICU LOS of <72 h. The main characteristics of the enrolled population at baseline are described in Table 2.

Nutritional intake

The mean daily nutritional intake provided during a patient ICU stay is described in Figures 1 and 2. All patients had an extremely low caloric intake and received no protein during the first 2 days of ICU stay, receiving the only nutritional support as NNC. Thereafter, nutritional support increased gradually starting from day 3, including both EN, PN and ONS (the latter giving a marginal contribution). In days 4–7, the target of at least 80% of Kcal_{A/R} was achieved by 40.3%, 59.9%, 68.2% and 70.7% of subjects, whereas at least 80% of Prot_{A/R} by 22.7%, 37.3%, 49.2% and 50.0% of patients, respectively. In the time-span comprised between days 4 and 20 of ICU stay, a total Kcal_{A/R} ratio of 92.0% ± 40.6% was ensured on average. Based on these results, we also compared the ability to reach the minimum target of 80% Kcal_{A/R} and Prot_{A/R} ratios during the ‘acute’ (1–10 days) or ‘prolonged’ (from 11 up to 20 days) period of ICU stay. A statistically significant lower rate of patients reached both the minimum 80%

TABLE 2 General characteristics of the study population

Age (years)	70.4 ± 10.2
Sex (male)	152 (70.0%)
Body mass index	27.3 ± 5
Charlson comorbidity index	3.5 ± 2.3
Preoperative ejection fraction (%) ^a	51.0 ± 13.4
>50%	142 (66.7%)
31%–50%	46 (21.6%)
21%–30%	18 (8.5%)
≤20%	7 (3.3%)
EuroSCORE II (%)	18.4 ± 20.4
Type of surgery	
CABG	79 (36.4%)
Valvular	41 (18.9%)
Aortic	11 (5.1%)
CABG + valvular	52 (24.0%)
Valvular + aortic	16 (7.4%)
CABG + valvular + aortic	6 (2.8%)
Others	12 (5.5%)
Length of surgery (hh:mm)	5:45 ± 1:54
Undergoing intraoperative ECC	207 (95.4%)
Length of ECC (hh:mm) ^b	2:52 ± 1:13
Intra-aortic balloon pump	82 (38.0%)
Extracorporeal membrane oxygenation	11 (5.1%)
Total calculated energy requirement (kcal/day)	1654.9 ± 283.9
Protein requirement (g/day)	79.4 ± 13.6
Length of mechanical ventilation (days)	14.5 ± 19.8
Length of stay in ICU (days)	25.6 ± 32.5
ICU readmission	39 (18.1%)

Note: *n* = 217 for all variables, except for ^a. CABG, coronary artery bypass graft; ECC, extracorporeal circulation; ICU, intensive care unit.

^a*n* = 213.

^bExcluding off-pump surgery.

Kcal_{A/R} (acute stay: 41.2%; prolonged stay: 65.8%; *p* < 0.001) and the Prot_{A/R} (acute stay: 27.3%; prolonged stay: 44.2%; *p* < 0.001) ratios during the acute period of ICU stay.

Overall, EN contributed 47.1% and PN 41.2% to the total energy intake, whereas ONS and NNC contributed the remaining 11.7%. Regarding protein intake, a mean Prot_{A/R} ratio of 78.9% ± 41.2% was delivered, being 53.2%, 36.5% and 10.3% the contributions of EN, PN and ONS, respectively.

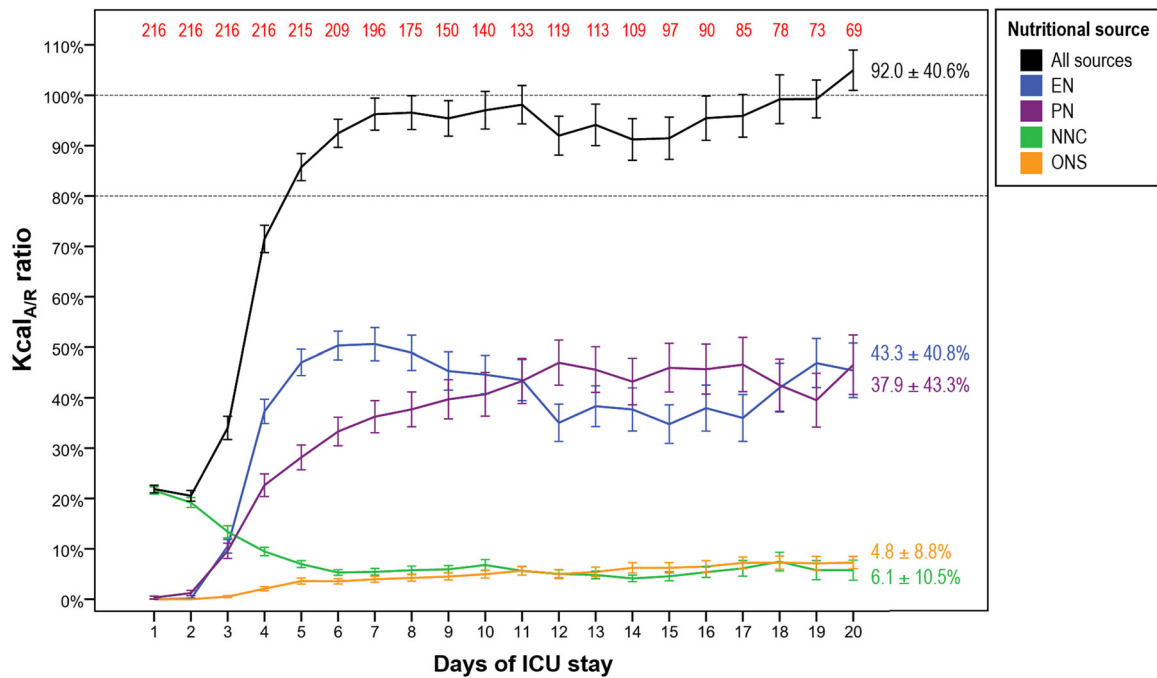


FIGURE 1 Mean daily ratio between calorie administration and request ($Kcal_{A/R}$) according to the nutritional source. Error bars: standard error. Values on bars side: mean \pm standard deviation of the whole period. Dashed lines, upper and lower thresholds of the target $Kcal_{A/R}$; red numbers, subjects enrolled at each consecutive day

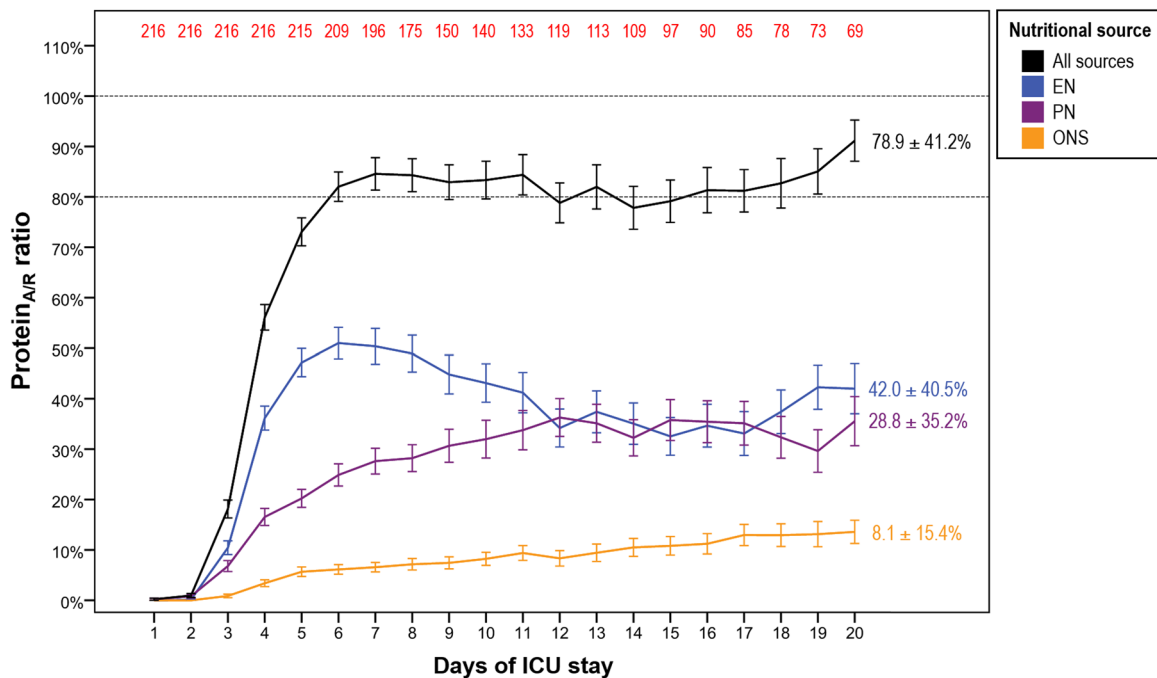


FIGURE 2 Mean daily ratio between protein administration and request ($Prot_{A/R}$) according to the nutritional source. Error bars: standard error. Values on bars side: mean \pm standard deviation of the whole period. $Kcal_{A/R}$, mean daily ratio between calorie administration and request. Dashed lines: upper and lower thresholds of the target $Kcal_{A/R}$. Red numbers: subjects enrolled at each consecutive day

Nutritional intake and outcomes

Overall, 196 patients (90.3%) had an ICU LOS of ≥ 7 days and were considered for the survival analysis. During

days 4–7 of ICU stay, a mean daily energy target of 80%–100% was achieved in 58 patients (26.9%), whereas most participants were below the 80% desired threshold ($n = 79$; 40.3%) and in the remaining 59 (30.1%) the 100%

TABLE 3 Association of study variables with mean daily administered/required calories ratio (Kcal_{A/R})

Variable	Kcal _{A/R} 80%–100% n = 58	Kcal _{A/R} < 80% n = 79	Kcal _{A/R} > 100% n = 59	p-Value
Age (years)	70.6 ± 9.6	71.3 ± 10.4	70.2 ± 10.1	0.809
Sex (male)	42 (72.4%)	60 (75.9%)	31 (52.5%)	0.010
Body mass index	26.6 ± 4.3	27.4 ± 5.3	27.4 ± 5.5	0.556
Charlson comorbidity index	3.8 ± 2.2	3.8 ± 2.4	3.3 ± 2.2	0.302
EuroSCORE II (%)	0.200 ± 0.201	0.164 ± 0.199	0.230 ± 0.224	0.182
Length of surgery (hh:mm)	5:47 ± 1:56	5:34 ± 1:51	6:06 ± 2:01	0.273
Length of ECC (hh:mm)	2:40 ± 1:33	2:36 ± 1:15	2:58 ± 1:13	0.269
Energy requirement (kcal/day)	1631.5 ± 260.5	1745.1 ± 277.8	1497.4 ± 266.3	<0.001
Protein requirement (g/day)	78.3 ± 12.5	83.8 ± 13.3	71.9 ± 12.8	<0.001

Abbreviation: ECC, extracorporeal circulation.

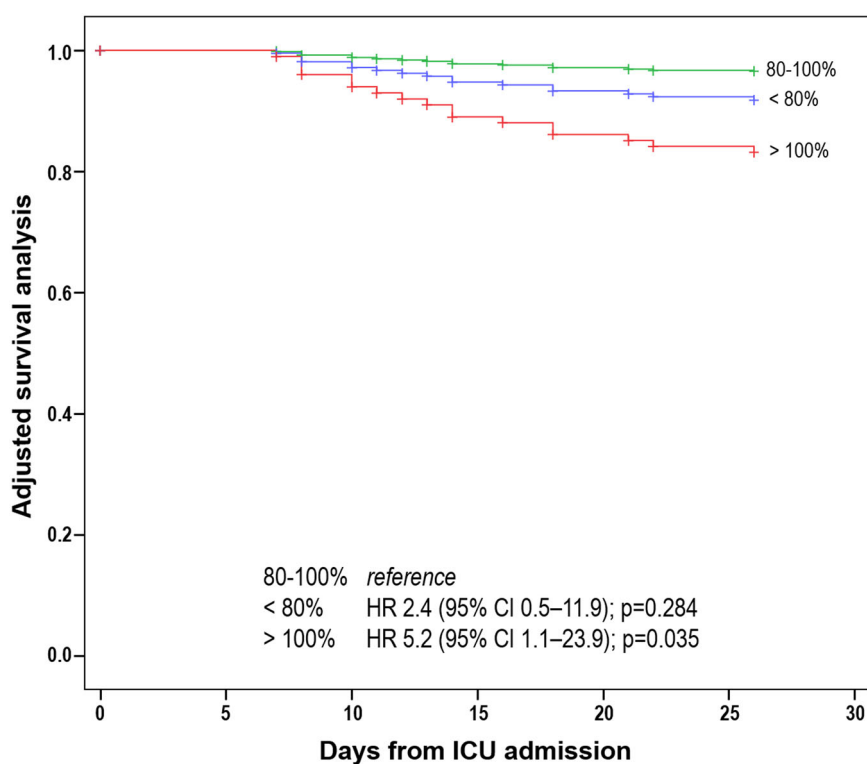


FIGURE 3 Adjusted survival curves (multivariate Cox regression analysis) for patients with a mean ratio between calorie (Kcal_{A/R}) administration and request within (80%–100%), below (<80%) or above (>100%) the expected nutritional target

threshold was exceeded. Table 3 shows the association of study variables with mean daily Kcal_{A/R}.

In the study population, the cumulative 30-day mortality rate was 9.2% (n = 20), compared to an expected mortality of 18.4% according to EuroSCORE II. The risk of death was lower for patients receiving a mean daily energy target of 80%–100% compared with those below or above this target, respectively (log-rank test: p = 0.046). In the multivariable Cox regression model, a significant increase in 30-day mortality risk was detected for patients who received a nutritional intake exceeding >100% of the Kcal_{A/R} ratio (HR 5.2; p = 0.035) (Figure 3).

DISCUSSION

In our cohort, over a time-span up to 20 days most patients reached the optimal 80%–100% Kcal_{A/R} and Prot_{A/R} starting from day 5, and these ratios remained almost steady in the subsequent observation days. However, the wide observed standard deviations suggested a large variability between calculated requirement and actual delivery among several patients. Indeed, only one participant out of three achieved the 80% Kcal_{A/R} ratio within the seventh day of ICU stay, whereas the percentage fell to 50% when considering the Prot_{A/R} ratio. This suggests that a relevant number of patients

experienced an early calorie and protein deficit. This condition tended to persist longer than expected, with the most patients still under 80% of Kcal_{A/R} and Prot_{A/R} ratios up to day 10 of ICU stay. This finding is consistent with previous literature data showing as patients with persistent critical illness were underfed particularly during the first 10 days of ICU stay.²² On the other side, surprisingly, some patients exceeded 100% of estimated requirements: in other words, these patients received a more nutritional support than that established according to their individualised plan. According to our data, exceeding this threshold was not related to having received multiple sources of nutrition. We speculate that the reason could be related to the fact that, despite the intention to provide a personalised calorie and protein intake, in daily clinical practice a tendency to prescribe a standard amount of nutritional support regardless of the expected ER may have occurred. Many literature data have highlighted as in real-life settings the nutritional component of care is burdened by several criticalities involving both the medical and nursing ICU teams (e.g., prescribing undue fasting periods, late involvement of dietitians, insufficient protein and energy, inadequate nurse staffing, poor interprofessional communication), so that nutritional goals are often unmet.^{22–25} A delayed onset of EN, the prescription of inadequate nutritional support (lower or higher than expected), the failure to titrate the administration rate after the initial prescription and the administration of less-than planned EN are frequently encountered situations.^{26–29} Nevertheless, although missing the energy target is a well-known risk factor for negative clinical outcomes in ICU patient receiving EN,³⁰ at present the debate about the optimal nutritional target in critically ill patients is far from being solved. Recent studies showed, for example, that in elderly people the ER might be lower than that expected in younger population.³¹ However, what is clear beyond all is that, in general, many critically ill patients do not receive their appropriate nutritional support, with widely variable proportions of delivered calories.³²

To the best of our knowledge, this is the first study describing in detail the day-by-day contribution of the different nutritional sources—comprising ONS and NNC—to the overall nutritional support in critically ill patients. The contribution of NNC was marginal (6% as a mean, being the sole energy source during the first days after ICU admission), whereas previous studies reported a mean contribution of NNC ranging from 6%³³ to 17%³⁴ of total energy. Only little information is available on the trend of nutrition provision practices during ICU stay. In the present investigation, the early achievement of the desired target of 80%–100% was found to be associated with lower mortality – adjusted for BMI, surgery-related risk of death and the total duration of artificial nutritional support, whereas a higher risk of death was documented in patients below or above this threshold, being the increased risk

statistically significant for patients exceeding the 100% upper limit. This finding is consistent with a previous retrospective study using IC to determine ER, which showed lower mortality at 70%–100% Kcal_{A/R} ratio, while either decreasing below 70% or increasing over 100% this ratio was associated with a progressive increased risk of death.³² Another recent study demonstrated that a suboptimal calorie intake of <80% Kcal_{A/R} ratio on day 4 was associated with higher ICU mortality compared to a higher ratio, however, without considering the possible presence and the impact on patients' outcome of being overfed.¹⁰ Therefore, a negative impact on patients' mortality seems to be associated with both over- and underfeeding when compared to achieving caloric goals.

Interestingly, despite the intention to satisfy a patient's nutritional requirement via the enteral route, overall EN contributed <50% to both energy and protein intakes, with a surprisingly relevant need to fill this gap especially via PN, whose contribution progressively increased up to day 10 of ICU stay and subsequently exceeded that of EN (Figure 1). This finding is in line with previous literature, reporting as a timely supplemental PN may be necessary to achieve full caloric goals in individuals who have 'short-term contraindication' (e.g., gastrointestinal intolerance) to EN, albeit attention should be paid to avoid overfeeding when its administration is not adequately targeted on the measured value.^{35,36} A large multicentric study involving more than 2000 critically ill surgical patients reported that patients were substantially underfed, as they received less of their prescribed calories from EN (33.4%) or from all nutrition sources (45.8%). Interestingly, this finding was even worst in patients undergoing surgery because of cardiovascular or vascular diseases ($n = 417$), in whom EN was less and later used, whereas PN was more largely chosen as a nutritional support.³⁷ However, treatment with a combination of EN with PN led to increased delivery of macronutrients in the acute phase of critical illness, being not inferior to EN alone when considering patients' outcomes.³⁸ Above all, however, nutrition adequacy in ICUs can be increased by adopting feeding protocols.³⁷

Strengths and limitations

The present investigation provides new evidence in describing the daily specific contribution of all nutritional sources to total nutritional requirements in postoperative cardiac surgery patients undergoing EN.

Nevertheless, it is important to point out as this research presents some limitations that may limit the generalisability of our results. The main one is its retrospective design, characterised by a convenience sample of consecutively admitted patients to a single

cardiac surgery centre, which limits the generalisability of the study findings. Second, although the nutritional intake was calculated with great attention based on the effective administration of each considered nutritional and nonnutritional source as documented by bedside medical records and clinical diaries, some degree of inaccuracy may have occurred, mainly related to a possible inaccuracy in physicians' or nurses' notes in above documentation. Third, the results of survival analysis should be carefully interpreted after considering the limited number of subjects in each Kcal_{A/R} subgroup and the broad confidence intervals for HRs, as expected with a limited number of death events. This limited number of death events suggested to insert only a few covariates in the multivariable model: although EuroSCORE II considers several comorbid conditions, cardiac-related factors and the complexity of surgery, adjusting the model by considering more predictors potentially associated with patient risk of death may have led to different results. Finally, in our study, an observational design with descriptive and correlational aims was used. Therefore, a causative or predictive relationship between the administered/required calories ratio and the explored outcome should be interpreted with caution.

CONCLUSION

The results of the present investigations confirmed previous literature regarding the difficulties related to provide a personalised nutritional support in patients having a prolonged ICU LOS. Moreover, despite the enteral route as the recommended modality to provide nutritional support, a wide integration via PN was observed in our population, contributing to almost half of daily nutritional intake. Strategies aimed at keeping more attention in titrating the daily nutritional targets according to the patient-specific Kcal_{A/R} and Prot_{A/R} ratios may decrease the need of PN integration, thus avoiding overfeeding with a potential positive impact on patients' outcome.

More research with prospective design is needed to explore new, effective strategies to avoid this potential bias through a more precise data collection.

AUTHOR CONTRIBUTIONS

Conception and design: Gianfranco Sanson and Adam Fabiani. *Investigation:* Lorella Dreas, Adam Fabiani and Antonella Calabretti. *Data curation:* Adam Fabiani, Giuseppe Gatti and Elena Trampus. *Data analysis:* Gianfranco Sanson. *Data interpretation:* Gianfranco Sanson, Michela Zanetti and Adam Fabiani. *Draft original writing:* Gianfranco Sanson, Adam Fabiani and Michela Zanetti. *Draft review:* Enzo Mazza and Lorella Dreas. All authors have critically reviewed the manuscript content and have approved the final version submitted for publication.

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CONFLICT OF INTEREST

The authors declare no conflict of interests.

TRANSPARENCY DECLARATION

The lead author affirms that this manuscript is an honest, accurate and transparent account of the study being reported. The reporting of this work is compliant with STROBE guidelines. The lead author affirms that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

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AUTHOR BIOGRAPHIES

Adam Fabiani, MSN, BSN, RN, the Cardiac Surgery Intensive Care Unit, lecturer in clinical surgical nursing and a PhD student in nursing and public health; research interests: vascular access, nutrition and intensive care.

Lorella Dreas, MD, cardiologist, chief of the Cardiac Surgery Intensive Care Unit (retired). Main research interests: surgical risk factors, improvement in patient intensive clinical care and nutritional support, post-operative complications.

Enzo Mazzaro, MD, head of the Cardiac Surgery Unit. He has mastered the most important adult cardiac operations, primarily through a mini-invasive approach. His goal is to minimise rates of complications after cardiac operations.

Elena Trampus, BSN, RN, critical care nurse.

Michela Zanetti, PhD, MD, coordinator of university hospital nutrition team and geriatrician; professor of internal medicine and nutrition; main areas of research: nutrition and metabolism in health and disease.

Antonella Calabretti, food chemistry analyst at the DEAMS Commodity Science Laboratory. Research interests: food safety, antioxidant compounds, chromatographic analytical techniques.

Giuseppe Gatti, MD, at the Cardiac Surgery Unit, researcher. His current projects are ‘Routine bilateral internal thoracic artery use in coronary surgery’,

'Postcardiomy extracorporeal membrane oxygenator'
and 'Predictive scoring systems in cardiac surgery'.

Gianfranco Sanson, PhD, RN, critical care nurse,
associate professor of nursing; main areas of research:
predictive models of outcome in acute illness, clinical
nutrition, standardised nursing languages, health
humanities.