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Original article

The new ESPEN diagnostic criteria for malnutrition predict overall survival in hospitalised patients

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SUMMARY

Background: In 2015 the European Society for Clinical Nutrition and Metabolism (ESPEN) presented new consensus criteria for the diagnosis of malnutrition. Whereas most previous definitions were based on involuntary weight loss and/or a low BMI, the ESPEN definition added Fat Free Mass Index (FFMI) to the set of criteria.

Aim: To study the predictive value of the new ESPEN diagnostic criteria for malnutrition on survival, with specific focus on the additional value of FFMI.

Methods: Included were 335 hospitalized adult patients of the VU University Medical Center Amsterdam (60% female, age 58 ± 18 y). Three sets of criteria for malnutrition were used to study the predictive value for survival: Dutch definition for malnutrition, ESPEN diagnostic criteria for malnutrition and ESPEN diagnostic criteria for malnutrition without FFMI criterion. The association between malnutrition and three-months and one-year overall survival was analyzed by log rank tests and Cox regression. In multivariate analyses, adjustments were made for gender, age, care complexity and length of stay.

Results: Ninety patients (27%) were classified as malnourished by any of the sets of criteria; malnourished patients had significant lower survival rates than non-malnourished patients at three months (84% vs 94%; $p = 0.01$) and one year (76% vs 87%; $p = 0.02$). After adjustments, malnutrition remained significantly associated with three-months survival for the Dutch definition for malnutrition (HR:2.25, $p = 0.04$) and the ESPEN diagnostic criteria for malnutrition (HR:2.76, $p = 0.02$). Malnutrition remained significantly associated with one-year survival for the ESPEN diagnostic criteria for malnutrition (HR:2.17, $p < 0.02$) and the ESPEN diagnostic criteria for malnutrition without FFMI (HR:2.66, $p < 0.01$).

Conclusion: The new ESPEN definition for malnutrition is predictive for both three-months and one-year survival in a general hospital population, whereas definitions without FFMI are predictive for either three-months or one year survival.

1. Introduction

Over the few last decades malnutrition has become a generally recognized care problem, affecting 17–25% of patients across health care settings [1–3]. Malnutrition has serious adverse consequences. Previous research has shown associations between malnutrition and a decreased muscle and immune function, impaired quality of life, decreased wound healing and reduced functional status [2]. In addition, studies have shown associations between malnutrition and survival [4–7].

Comparison between studies and recognizing patients at nutritional risk is hampered by the lack of a uniform definition of malnutrition. Most definitions for malnutrition are based on recent involuntary weight loss and/or a low BMI [8–10]. However, the amount of weight loss, the timespan for losing weight and BMI cut-off points differ between definitions. In addition, some definitions also contain questions on appetite, fatigue or quality of life [7,8]. For decades, the Dutch have used percentage of weight loss and/or a low BMI [10] to identify malnourished patients.

The European Society for Clinical Nutrition and Metabolism (ESPEN) has recently put forward a consensus definition for malnutrition with the aim to reach uniformity between countries

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and between studies [11]. In accordance with the Dutch definition, patients with a low BMI are defined malnourished with this new consensus definition. However, in contrast to the Dutch definition, the ESPEN diagnostic criteria for malnutrition only define a patient malnourished if he has lost weight in combination with a low BMI or a low fat free mass index (FFMI). This study investigates the predictive value of the new ESPEN diagnostic criteria for malnutrition on survival [11], with specific focus on the additional value of FFM, and in comparison to the previously used Dutch definition based on BMI and weight loss only.

2. Methods

2.1. Data collection

In the present study, a cross sectional study cohort of hospitalized patients was used for analyses. The study design was in accordance with the Declaration of Helsinki and approved by the institutional review board of the VU University Medical Centre (Trial ID: NTR210) [8]. All included patients gave written informed consent. All included patients underwent a nutritional assessment at the first day of admission to hospital.

2.2. Study population and design

The prospective collected sample used in this survival study consisted of patients who were admitted to the general internal wards or the general surgical wards of the VU University Medical Centre during the periods April 2002 until October 2002, and February 2003 until June 2003 [8]. The general internal wards consisted of the specialisms: general internal medicine (21.8%, n = 73), gastroenterology (11.9%, n = 40), rheumatology (7.2%, n = 24) and other (4.2%, n = 14). The general surgical wards consisted of the specialisms: surgical oncology (37.3%%, n = 125), surgical gastroenterology (16.7%, n = 56) and other (0.9%, n = 3).

Included were patients aged 18 or above who were expected to be admitted for at least 24 h. Patients were excluded if they were not able to give informed consent, if they were not a resident of the Netherlands, if they could not be weighed, if they had missing values on measurements for fat free mass index (FFMI), or when patients were lost to follow-up within 1 year after inclusion [8].

To study the predictive value of malnutrition on survival, three sets of criteria for malnutrition were used: the Dutch definition for malnutrition [10] the ESPEN diagnostic criteria for malnutrition [11] and the ESPEN diagnostic criteria for malnutrition without the FFMI criterion (Table 1) [11]. All three variables (Dutch definition for malnutrition, ESPEN diagnostic criteria for malnutrition and ESPEN diagnostic criteria for malnutrition without the FFMI criterion) were dichotomized; a patient was or was not malnourished according to the set of criteria for malnutrition.

Dutch definition for malnutrition [10] – This set of criteria for malnutrition was described by the Dutch Malnutrition Steering Group (DMG) as 'a loss of muscle and fat mass following severe nutritional deficiency, with or without inflammation'. Patients were classified as malnourished if they met at least one of the following criteria: weight loss of more than 5% in the last month and/or more than 10% in the last six months and/or a low BMI (<18.5 kg/m^2 (<65 y) or <20 kg/m^2 (>65 y)) (Table 1).

ESPEN diagnostic criteria for malnutrition [11] – The consensus statement proposed by an international expert group was formulated to 'provide a consensus-based minimum set of criteria for the diagnosis of malnutrition independent of clinical setting and etiology, and to unify international terminology'. The set of criteria includes not only weight loss and BMI, but also fat free mass index (FFMI). The ESPEN diagnostic criteria for malnutrition consist of three subgroups. The first subgroup includes all patients with a BMI lower than 18.5 kg/m^2. The second subgroup includes all patients with weight loss of more than 10% (indefinite of time) or more than 5% over the last three months and a BMI <20 kg/m^2 or <22 kg/m^2 in patients under or above the age of 70, respectively. The third subgroup includes all patients with weight loss of more than 10% (indefinite of time) or more than 5% over the last three months and a FFMI of <15 kg/m^2 and <17 kg/m^2 in females and males, respectively.

ESPEN diagnostic criteria for malnutrition without FFMI [11] – To be able to study the additional value of FFMI in the ESPEN consensus definition, the analyses were also carried out with the ESPEN diagnostic criteria for malnutrition without the parameter of FFMI; i.e. low BMI (<18.5 kg/m^2) or the combination of weight loss and low BMI depending on age (<20 or 22 kg/m^2).

Patient characteristics, i.e. age, gender, Body Mass Index (BMI), FFMI, weight loss, care complexity (INTERMED) and length of hospital stay (LOS) were collected as described below [8]. These last two characteristics, care complexity and LOS, were expected to be potential confounders for the association of malnutrition with survival, and therefore included.

2.3. Measurements

All measurements were taken on the day of admission to the hospital. Patients were weighed to the nearest kg using a calibrated scale (SECA 880) [8] Patients' height was self-recorded, or measured to the nearest cm using a fixed-wall stadiometer (SECA 220) when a patients' height was unknown [8]. Body Mass Index (BMI) was calculated as weight divided by height in meters squared (kg/m^2). Unintentional weight loss during the last month and last six months was inquired [8].

Fat Free Mass Index (FFMI) was calculated using Bio Impedance Analysis (BIA, Xitron 4000, Xitron technologies, San Diego, CA, USA) [12]. Four adhesive electrodes (3M Red Dot T, 3M Health care, Borken, Germany) were placed on the non-dominant side of the patient, two on the wrist and two on the ankle [12]. A low imperceptible electrical current was sent through the patients' body. The Geneva equation [13] was used (reactance and resistance at 50 kHz)

Table 1
The three sets of criteria for malnutrition.

	Body Mass Index (BMI)	Fat Free Mass Index (FFMI)	% Weight Loss (WL)
Dutch definition for malnutrition [10]	<18.5 kg/m^2 (<65 y) <20 kg/m^2 (>65 y)	X	>5% in last month >10% in 6 months
ESPEN diagnostic criteria for malnutrition [11]	≤18.5 kg/m^2 <20 kg/m^2 (age <70 y) <22 kg/m^2 (age ≥70 y)	<17 kg/m^2 ♂ <15 kg/m^2 ♀	>5% in last 3 months >10% (indefinite time)
ESPEN diagnostic criteria for malnutrition without FFMI [11]	≤18.5 kg/m^2 <20 kg/m^2 (age <70 y) <22 kg/m^2 (age ≥70 y)	X	>5% in last 3 months >10% (indefinite time)

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to calculate the FFM (kg), from which the FFMI was calculated by the equation: FFMI (kg/m^2) = FFM (kg)/height [2] (m^2) [8]. For interpretation of the FFMI, the cut-off points of the ESPEN consensus definition were used: <15 kg/m^2 and <17 kg/m^2 in females and males, respectively.

A validated questionnaire (INTERMED) [12] was used as an observer-rated instrument to establish care complexity. This questionnaire contained four domains (biological, physiological, social and health care). Each consists of five questions that were rated zero to three points, which resulted in a potential range of zero to sixty points. A cut-off score of more than twenty points was determined as an optimal score in detecting patients who were at risk of a longer LOS and poor quality of life (QoL) at discharge [12]. LOS was calculated in days, from admission to hospital until discharge or death during admission after the first day of admission. Because LOS was not normally distributed, it was log transformed for analyses [12].

2.4. Study endpoints

The endpoints of this study were overall three-months and one-year survival, calculated from the day of admission to hospital, dichotomized into 'alive' or 'deceased'. Survival data was collected in January 2015. Survival data were derived using two different sources: the electronic patient database of the VU University medical centre and/or municipality databases. Overall survival was defined as the time elapsed between the date of admission and the date of death (by any cause), or if the patient was still alive 1 year after the inclusion in the study.

2.5. Statistical analysis

Statistical analyses were conducted using IBM SPSS Statistics 22. The characteristics of the total study population and three sets of criteria for malnutrition, i.e. Dutch definition for malnutrition, ESPEN diagnostic criteria for malnutrition and ESPEN diagnostic criteria for malnutrition without FFMI criterion, were presented as frequencies (%), mean ± standard deviation (SD), or median and interquartile range (IQR) as appropriate.

Survival analyses were conducted by Kaplan Meier curves and Cox regression analyses. Kaplan Meier curves (survival rates) were performed for each of the three sets of criteria for malnutrition: the Dutch definition for malnutrition, the ESPEN diagnostic criteria for malnutrition, and the ESPEN diagnostic criteria for malnutrition without FFMI. Log rank tests were applied to test differences in survival rates between malnourished and not-malnourished patients, at three months and one year, for each set of malnutrition criteria. Cox regression analyses (HR, 95% CI and p-value) were then performed to determine the association between each set of criteria and three-months and one-year overall survival. In the multivariate analyses adjustments were made for potential confounders: age, gender, care complexity (INTERMED) and LOS. For all analyses a statistical significance at the level of $p < 0.05$ was used.

3. Results

The original study population consisted of 349 patients; 14 patients were excluded for reasons of loss to follow-up (n = 5) or double inclusion because of readmission (n = 9), resulting in a study sample of 335 patients of which 60% were female. The mean age was 57.8 years (Table 2). In total 90 patients (27%) were classified as malnourished, according to at least one of the sets of criteria for malnutrition. The overlap of patients between the three definitions for malnutrition is shown in Fig. 1.

In the study population, 305 patients (91%) were still alive after three months and 280 patients (84%) were still alive after one year. Malnourished patients, by any of the three sets of criteria, had significantly lower survival rates at both time points than non-malnourished patients (three months 84% vs 94%; $p = 0.01$ and one year 76% vs 87%; $p = 0.02$). This was significant for all three sets of criteria, as illustrated by Kaplan Meier survival curves for one-year survival shown in Fig. 2 (Dutch definition for malnutrition, $p = 0.02$; the ESPEN diagnostic criteria for malnutrition, $p < 0.001$; the ESPEN diagnostic criteria for malnutrition without FFMI, $p < 0.01$).

Survival rates for malnourished versus non-malnourished patients, specified for each set of criteria, are shown in Table 3. According to the Dutch criteria for malnutrition, 90 patients (27%) were malnourished. These patients had significantly lower survival rates than non-malnourished patients at both time points (three months 84% vs 94%; $p = 0.01$ and one year 76% vs 87%; $p = 0.02$). According to the ESPEN diagnostic criteria for malnutrition 49 patients (15%) were malnourished. These patients had significantly lower survival rates at both time points than non-malnourished patients (three months 80% vs 93%; $p < 0.01$ and one year 65% vs 87%; $p < 0.001$). When the ESPEN diagnostic criteria for malnutrition were applied without the FFMI criterion, 36 (11%) patients were identified as malnourished. These patients had significantly lower survival rates for one-year survival (67% vs 86%; $p < 0.01$), but not for three-months survival (83% vs 92%; $p = 0.08$).

In multivariate analysis with adjustments for confounders, the results for the three sets of criteria were attenuated but remained significant (Table 4), except for one-year survival using the Dutch definition for malnutrition ($p = 0.15$) and three-months survival using the ESPEN diagnostic criteria for malnutrition without FFMI ($p = 0.10$).

4. Discussion

The present study provides insight into three sets of criteria for malnutrition, the Dutch definition for malnutrition, the ESPEN diagnostic criteria for malnutrition and the ESPEN diagnostic criteria for malnutrition without FFMI, and their association with short term overall survival in a general hospital population. After adjustment for confounders, the Dutch definition for malnutrition and the ESPEN diagnostic criteria for malnutrition were both associated with three-months survival. The ESPEN diagnostic criteria for malnutrition and the ESPEN diagnostic criteria for malnutrition without FFMI were associated with one-year survival. The findings from this study contribute to the on-going discussion on defining an optimal set of malnutrition criteria for worldwide use. More validation studies are probably required before a final definition is adopted.

The relation between malnutrition and survival has been described in previous studies. In the study by Lim et al. (2012) [7] a significant difference for one-year survival ($p < 0.001$) in malnourished versus non-malnourished patients was shown. In the study of Agarwal et al. (2013) [6], which showed a comparable percentage of malnourished patients to this study, a significantly higher risk of three-months (in-hospital) mortality in malnourished patients was found. The study by Correia et al. (2003) [5] also showed that malnutrition is an independent risk factor that significantly contributes to overall survival, after adjustments for reason of admission and cause of death, which was not taken into account in the present study. However, none of the aforementioned studies used body composition measurement in their diagnosis of malnourishment.

Sarcopenia, loss of muscle mass due to aging and disease, has been increasingly recognized as a predictive parameter for poor

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Table 2
Clinical characteristics of the study population.

	Total population	Dutch definition for malnutrition	ESPEN diagnostic criteria for malnutrition	ESPEN diagnostic criteria for malnutrition without FFMI
n/N n (%)	335/335 (100%)	90/335 (27%)	49/335 (15%)	36/335 (11%)
Female n (%)	201 (60%)	57 (63%)	34 (69%)	27 (75%)
Age (years)				
Mean ± sd	57.8 ± 17.7	61.4 ± 19.0	64.2 ± 20.7	64.8 ± 22.3
BMI (kg/m^2)				
Mean ± sd	24.8 ± 4.6	22.0 ± 4.1	19.6 ± 2.6	18.3 ± 1.8
≤18.5 n (%)	19 (6%)	19 (21%)	19 (39%)	19 (53%)
>18.5–25 n (%)	168 (50%)	48 (53%)	29 (59%)	17 (47%)
>25–30 n (%)	100 (30%)	18 (20%)	1 (2%)	0 (0%)
>30 n (%)	48 (14%)	5 (6%)	0 (0%)	0 (0%)
FFMI (kg/m^2)				
Mean ± sd	16.9 ± 2.5	15.6 ± 2.5	14.1 ± 1.5	13.8 ± 1.5
<P5 n (%)	142 (42%)	46 (51%)	34 (69%)	27 (75%)
<P10 n (%)	160 (48%)	50 (56%)	34 (69%)	27 (75%)
Length of stay				
Median (Q1–Q3)	8.0 (5.0–13.0)	9.5 (6.0–15.0)	12.0 (6.0–16.0)	11.5 (6.0–17.0)
Weight loss (%)				
Mean ± sd	2.2 ± 8.5	11.7 ± 8.0	12.8 ± 8.7	13.4 ± 8.7
Care complexity (n/N)	319/335	88/90	49/49	36/36
High care n (%)[a]	36 (11%)	19 (22%)	12 (25%)	11 (31%)

[a] High care complexity is defined as a score >20 points.

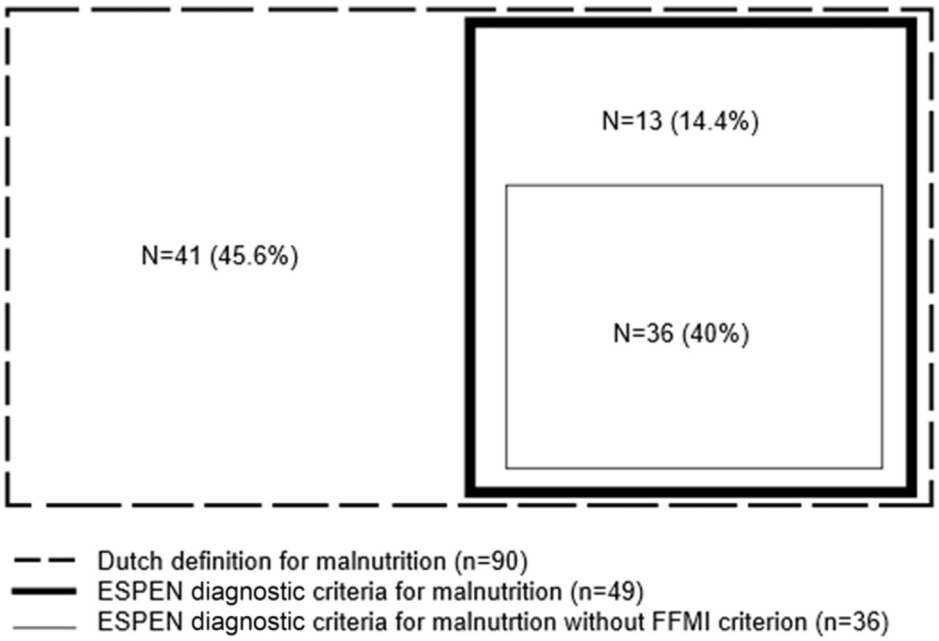

Fig. 1. Overlap of patients between three sets of criteria for malnutrition. Malnourished patients (n = 90) according and classified into one or more of the three sets of criteria for malnutrition.

clinical outcome [14]. Sarcopenia can be caused by reduced energy and protein intake, insulin resistance, changes in hormone levels, decreased physical activity, inflammation or chronic illness [14]. Sarcopenia is an emerging clinical challenge in our ageing population and is associated with negative health outcomes such as falls [15,16], impaired standing balance [17], physical disability [18,19] and mortality [20,21]. This has been the rationale for the ESPEN consensus group to include a measure of FFMI in its diagnostic criteria. The choice to include this measure has been justified by the present study, as only the ESPEN diagnostic criteria including FFMI were predictive for both three-months and one-year survival.

So far, only few studies evaluating the validity of the new ESPEN diagnostic criteria for malnutrition have been published. One previous study applied the ESPEN diagnostic criteria for malnutrition without FFMI [22], another one applied the ESPEN diagnostic criteria for malnutrition with FFMI [23]. In our study we analyzed both, the ESPEN diagnostic criteria with and without FFMI, in the same study population. This study suggests that including the FFMI has additional value. If future studies could confirm the additional value of FFMI, ESPEN could perhaps consider to include FFMI in the definition as a mandatory, not as a voluntary measurement, next to weight loss and low BMI. This has implications for daily patient care, as Bio Impedance Analysis (BIA) devices are not yet widely available in all health care settings. Without a BIA measurement 73% (36 of 49) of patients were identified as malnourished according to the ESPEN definition, whereas an additional 13 patients (23%) were identified based on FFMI measurements. This highlights the importance of the BIA measurement as a means to avoid the

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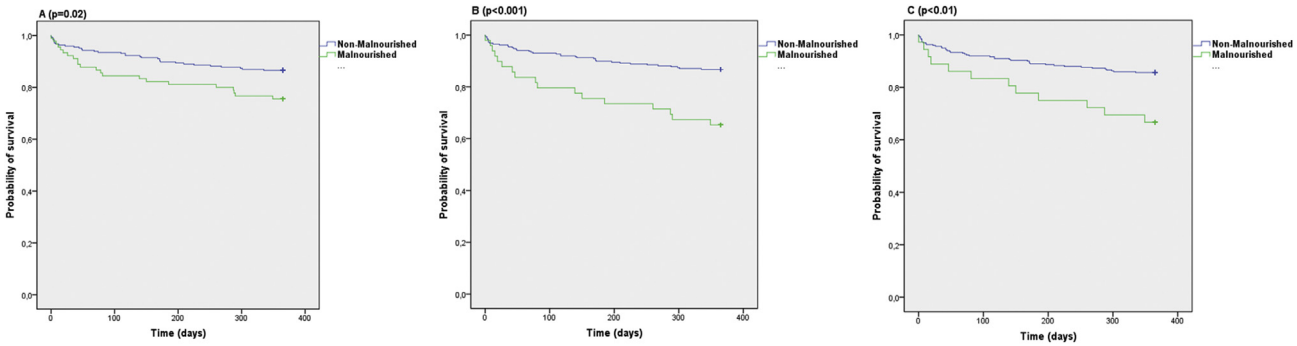

Fig. 2. Kaplan Meier survival curves for three sets of criteria for malnutrition (one-year survival): A) Dutch definition for malnutrition, B) ESPEN diagnostic criteria for malnutrition, C) ESPEN diagnostic criteria for malnutrition without FFMI.

Table 3
Survival rates for malnourished (M) and non-malnourished (NM) patients.

	3-months survival (%)			1-year survival (%)		
	M	NM	p-value	M	NM	p-value
All 3 definitions	84	94	0.01*	76	87	0.02*
Malnutrition definitions						
Dutch definition for malnutrition	84	94	0.01*	76	87	0.02*
ESPEN diagnostic criteria for malnutrition	80	93	<0.01*	65	87	<0.001*
ESPEN diagnostic criteria for malnutrition without FFMI	83	92	0.08	67	86	<0.01*

*Significant differences ($p \leq 0.05$) in overall survival between malnourished and non-malnourished patients (log rank test).

Table 4
Cox regression analyses of the association between different sets of criteria for malnutrition and overall 3-months and 1-year survival.

Malnutrition definitions	3-months survival	1-year survival
Unadjusted		
Dutch definition for malnutrition	2.46, 1.20–5.04, 0.01*	1.94, 1.13–3.32, 0.02*
ESPEN diagnostic criteria for malnutrition	3.08, 1.44–6.59, 0.02*	2.94, 1.70–5.21, <0.001*
ESPEN diagnostic criteria for malnutrition without FFMI	2.17, 0.89–5.31, 0.09	2.55, 1.34–4.83, <0.01*
Adjusted[a]		
Dutch definition for malnutrition	2.25, 1.04–4.89, 0.04*	1.55, 0.86–2.81, 0.15
ESPEN diagnostic criteria for malnutrition	2.76, 1.16–6.11, 0.02*	2.17, 1.16–4.06, 0.02*
ESPEN diagnostic criteria for malnutrition without FFMI	2.14, 0.87–5.25, 0.10	2.66, 1.40–5.10, <0.01*

Hazard ratio's (HR), 95% confidence intervals (95% CI) and p-values for 3-months and 1-year survival.
*Significant differences ($p \leq 0.05$) in overall survival between malnourished and non-malnourished patients.
[a] Adjusted for age, gender, care complexity and LOS.

misdiagnosis of malnourished patients. Since BIA is a simple measurement technique, the measurement is not time-consuming, and the devices are becoming more affordable, we recommend that these devices are increasingly implemented in nutritional assessment.

An often disputed point of discussion is the optimal set of criteria to classify malnutrition. Many definitions contain similar sets of criteria. However, different cut-off points are used for, for example, weight loss and BMI. In our study, the Dutch definition for malnutrition and the ESPEN diagnostic criteria for malnutrition without FFMI, both based on weight loss and BMI, resulted in an 27% and 11% malnutrition rate respectively. Moreover, all patients who were classified as malnourished according to the ESPEN criteria with (n = 49, 15%) and without (n = 36, 11%) the inclusion of the FFMI measurement, were also captured by the Dutch definition for malnutrition (n = 90). The large difference in classification rates between the Dutch definition and ESPEN criteria might be due to a difference in the classification of weight loss. In the Dutch definition, weight loss is an independent criterion, whereas in the ESPEN diagnostic criteria for malnutrition weight loss was only taken into account when combined with low BMI or low FFMI. It can be argued that weight loss as independent criterion should be included in the diagnostic set for malnutrition, because it has been shown to be an independent predictor for survival in many diseases. However, the stricter ESPEN criteria were more predictive for survival in our study.

The population described in this study represents a relevant population of a general hospital, which can be regarded as a strength of our study. Also the variety of specialisms within the study population can be seen as a strength. Another characteristic which favors generalizability is the wide age range (18–96 years) of the patients included.

In the present study it was not possible to adjust for disease severity as a potential confounder. In previous studies, for instance by Stratton et al. (2004) [24] and Correia et al. (2003) [5], disease severity was found to be a confounder in the association between malnutrition and overall survival. However, we did adjust for care complexity, assuming that care complexity is a good indicator of disease severity. The absence of the cause of death can be seen as a limitation, however because of the observational design of the study, those data were not available.

The three sets of criteria for malnutrition which were studied are sets commonly used in hospital practice. However, due to major overlap between the definitions, many patients were classified

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malnourished by more than one definition. In our opinion, the best set of criteria is the set which is best predictive for survival. In this study, the ESPEN diagnostic criteria for malnutrition were predictive for overall three-months and one-year survival. We recommend that our data are confirmed in other clinical patient populations, outpatient populations and community dwelling adults. Moreover, the association between the ESPEN diagnostic criteria for malnutrition and other clinically relevant outcome measures, i.e. mobility, falls, physical functioning, quality of life, cognition, should be studied. It would also be interesting to differentiate between age groups, but this would require a larger study population.

5. Conclusion

In this study we have shown that the new ESPEN diagnostic criteria for malnutrition are predictive for three-months and one-year survival in a general hospital population, and performs better than definitions which do not include fat free mass index. We advocate the implementation of measurements of body composition in the assessment of malnutrition.

Conflict of interest

None.

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