

Nutritional behaviour and quality of life during oncological polychemotherapy: Results of a prospective study on the efficacy of oral nutrition therapy in patients with acute leukaemia

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Abstract. A total of 29 patients with acute leukaemia were prospectively randomized before starting cytostatic treatment to be nourished either with intensified oral nutrition (intervention group) or *ad libitum* nutritional intake during the whole tumour therapy (median 22 weeks). All received menus of free choice (daily offer of 1.0–2.0 g protein, 30–50 kcal kg⁻¹ body weight (BW)). Beyond this, intervention patients received nutrition education, daily visits by the dietician and record of food intake, as well as a weekly assessment of subjective well-being (linear analogue self assessment 'LASA'). From the LASA items, the factors: 'malaise', 'psychological distress', 'therapy side-effects' were extracted by principal component analysis, and correlated to nutrient intake and nutritional status. At the end of antineoplastic induction therapy, after continuous hospitalization of 10 weeks (median), 31.3% of the controls had regained their initial nutritional status, and 68.8% of the intervention group. Mean daily energy intake was 23.2 kcal kg⁻¹ BW during weeks with weight loss (constant weight: 30.9, weight gain: 39.3 kcal kg⁻¹ BW). Nutritional behaviour correlated with subjective well-being, low intake with complaints of tumour treatment side effects and weight loss with malaise.

Keywords. Acute leukemia, feeding behaviour, malnutrition in cancer, oncological chemotherapy, oral nutrition, quality of life, subjective well-being, supportive tumour therapy.

Introduction

Until now, there is no prospective trial available, which can demonstrate that a good nutritional status may be

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of special benefit for the survival of patients who were treated by cytostatic agents [1]. Therefore artificial nutrition is not a routinely advisable adjunct to oncological chemotherapy. On the other hand, there is enough evidence that loss of appetite and impaired nutritional status are significantly associated with reduced subjective well-being—the so-called 'quality of life' [2,3]. This might be of clinical relevance for tumour patients during very aggressive and long-lasting drug-regimens, which are only partially effective with respect to prolonging life expectancy, for example in the case of acute leukaemias [4,5,6].

Recently, we were able to show that under favourable conditions, oral nutrition can be a successful supportive therapy of drug-treated tumour patients [7]. We now present the results of a prospectively randomized investigation on the efficacy of exclusive oral nutrition during induction and maintenance therapy of patients with acute leukaemia. The study was designed with the trial endpoint 'nutritional status—measured as body weight course' in order to answer the following questions:

1. Can life-threatening malnutrition be prevented by dietetic intervention, without artificial nutrition, even during the stress of antileukaemic treatment?
2. Is daily applied dietetic care (intervention group) superior to standard hospital feeding (control group) with respect to the nutritional status of leukemic patients?

Beside this, we were interested whether nutritional status as well as nutritional behaviour of tumour patients are correlated to subjective well-being or not. In order to prevent a bias on the nutritional behaviour of the control patients (as a consequence of nutritional interviews), this part of the investigation was done only in the intervention group.

Patients

All patients, admitted consecutively to medical departments I and II of Cologne University between 1986 and

Table 1. Characteristics of patients with acute nonlymphocytic leukaemia, and acute lymphocytic leukaemia with intensified oral nutrition as an adjunct to chemotherapy (group A: *ad libitum* nutrition intake, group B: nutritional intervention)

Diagnosis/ Treatment	Number/sex	Medians, ranges		
		Age (Years)	Initial Body Weight (% IBW)	Study period (Weeks)
I. Acute Nonlymphocytic Leukemia				
LAM-A	3f, 3m	50 (35-55)	106.6 (84.6-128.2)	27 (10-44)
LAM-B	4f, 3m	52 (27-58)	89.3 (75.3-117.2)	22 (7-54)
TAD-A	1f, 4m	44 (29-59)	112.3 (75.0-122.4)	8 (4-9)
TAD-B	2f, 1m	29 (18-50)	86.4 (86.2-98.7)	22 (19-32)
II. Acute Lymphocytic leukemia				
Ulm-A	3f, 2m	21 (19-26)	96.9 (89.3-114.4)	38 (15-47)
Ulm-B	3f, 3m	27 (17-58)	106.6 (73.5-145.3)	29 (8-50)

f = female, m = male, LAM/TAD/Ulm = chemotherapy-protocols
IBW = Ideal body weight.

1988 for induction treatment of acute lymphocytic or nonlymphocytic leukemia (ALL/ANLL), were asked to participate in the trial if they fulfilled the following criteria: undesired weight loss of more than 5% of the original body weight within 3 months before cytostatic treatment, and/or actual weight below 90% ideal body weight; age: between 17 and 60 years; planned therapy according to the regimens LAM-6 [8] without m-AMSA-application, TAD-9 [9], Ulm-protocol [10]: subgroups LAM, TAD, ULM. Exclusion criteria: metabolic diseases; renal or liver insufficiency; need for artificial nutrition.

During these 2 years, 38 patients fulfilled the given criteria, seven of them refused to participate, two died within 4 weeks after entering the study. The characteristics of the remaining 29 patients are shown in Table 1. Three patients had to be treated with two complete induction courses of LAM-6 and Ulm-protocol (patients L-B 3, 4, 7 are identical with patients U-B 4, 5, 6); that is why 32 treatment periods were investigated in 29 patients.

All patients received menus of free choice instead of the standardized hospital meal, with a daily offer of 1.0-2.0 g protein, 30-50 kcal kg⁻¹ BW, depending on their pretreatment nutritional status (<90% ideal body weight: 2 g protein/50 kcal; <110%: 1.4 g/35 kcal; >120%: 1 g/30 kcal). Patients were randomized within the subgroups before starting induction therapy to receive this diet either *ad libitum* (A=control group), or (B=study group): 'intensified oral nutrition' diet as group A plus dietetic intervention as described below.

The study phases were defined in the following way:

1. 'total study period' = day 1 of induction therapy until planned or premature end of maintenance chemotherapy;
2. 'induction period' = day 1 of induction therapy to the day before first demission from hospital after consolidation therapy was completed. Patients

were taken from the study, when artificial nutrition became necessary or on patients' demand.

Dietetic intervention

Patients in the study group were visited daily by a registered dietician, with the following aim: Assessment of nutritional status and nutrition behaviour; calculation of nutrient requirements; composition of menu and diet modification—if necessary; nutrition education for patients and relatives; daily assessment of nutrient intake; daily patient motivation; assessment of therapy-side effects, doctor's information on drug treatment for emesis, oral mucositis, diarrhoea; assessment of patients' subjective well-being; menu-composition for out-patient phases.

Assessments

1. *Nutritional status (Groups A, B)*. The nutritional status of all patients was assessed by means of body weight courses, measured daily under standardized conditions and quantified as percentage of Broca weight [11]. From these data we calculated: the weekly occurring weight changes (% of pre-week BW); the lowest BW (% initial BW); final BW (% initial BW); the weeks with and without weight loss (see Table 2). We did not use plasma proteins, skinfold- or arm muscle circumference assessment as nutritional indicators, because of their lack of specificity and validity—especially in tumour patients [11,12].

2. *Clinical course (Groups A, B)*. Assessment of days with body temperature >38.5°C, of amount of complete remissions, and of mortality during the study period. As mentioned above, the primary research aim was to study the effect of the dietetic intervention globally on changes of the nutritional status. Even though the assessment of nutrient intake and subjec-

Table 2. Intensified oral nutrition, during chemotherapy of the acute leukaemias: Courses of body weight during induction treatment (Group A=without, Group B=with dietetic intervention)

Patients regimen	Pretreatment BW (% Broca)	Lowest BW (% PTr. BW)	Study week	Post-treatment BW (% PTr. BW)	Study week	Weight gain (% lowest BW)
LAM 6-Protocol						
LA 1	107.8	90.0	10	90.0	10	0
LA 2	105.4	96.0	5	96.0	11	0
LA 3	84.6	93.4	6	97.6	8	4.5
LA 4	119.3	93.2	7-8	93.8	9	0.6
LA 5	98.5	96.9	4	100.0	8	3.2
LA 6	128.2	77.7	9	77.7	9	0
LB 1	101.6	93.2	4	95.0	7	1.9
LB 2	87.5	90.9	3	98.1	9	7.9
LB 3	85.9	96.3	4-6	98.4	10	2.2
LB 4	89.3	89.0	3	106.2	9	19.3
LB 5	106.0	93.9	3	99.3	10	5.8
LB 6	117.2	88.5	3	92.2	9	4.2
LB 7	75.3	94.4	3	98.8	6	4.6
TAD 9-Protocol						
TA 1	122.4	84.8	4	84.8	4	0
TA 2	103.7	89.7	7	89.7	7	0
TA 3	112.3	87.2	7	90.5	9	3.8
TA 4	116.7	85.1	9	85.1	9	0
TA 5	75.0	97.6	6	100.7	8	3.1
TB 1	86.2	91.2	11	95.0	13	4.2
TB 2	98.7	92.8	6-7	92.8	7	0
TB 3	86.4	93.9	6	94.1	7	0.3
Ulm-Protocol						
UA 1	89.3	92.7	3	113.2	14	22.1
UA 2	96.9	97.7	3	100.8	11	3.2
UA 3	106.7	89.8	7	90.5	14	0.8
UA 4	114.4	84.5	13	84.5	13	0
UA 5	95.7	91.1	5	93.9	15	3.1
UB 1	119.0	94.5	3	94.9	10	0.5
UB 2	145.3	90.4	5	93.5	11	3.5
UB 3	109.2	96.8	6	99.0	12	2.3
UB 4	103.9	95.3	3	101.5	15	6.6
UB 5	93.7	92.7	5	97.8	10	5.4
UB 6	73.5	96.8	3	100.4	8	3.7

PTr. BW = Pretreatment body weight.

tive well-being exclusively in the intervention group is problematic, this proceeding seemed to be necessary in order to avoid a bias regarding nutritional behaviour of the control group, originating from nutritional questionnaires. That is why the following data were collected only in patients of the intervention group.

3. *Nutrient intake (Group B)*. Calculation of the weekly non-protein energy intake from the daily assessed data (kcal kg⁻¹ IBW, medians of daily intake). Patients' weekly nutrient intakes were correlated with changes of BW and with parameters of subjective well-being.

4. *Evaluation of subjective well-being (Group B)*. Patients had to self-assess their well-being on linear analogue scales weekly [13] using standardized questionnaires with 16 questions, characterizing the typical

complaints of leukaemic subjects during tumour-therapy [14,15]:

During the last week

... I was not (rated 0)/I was very intensively (rated 10) suffering from:

weakness, helplessness, sorrow, unrest, anxiety, hopelessness, anorexia, nausea, amesis, pain, taste disturbances, stomatitis.

During the last week: my quality of life, my health, my physical feeling ... was not (rated 0)/was very intensively (rated 10) impaired.

From the weekly assessed LASA-items (means, standard-deviations, minima and maxima: see Table 3), 3 dimensions ('factors') characterizing the patients' subjective well-being were extracted with the help of principal component analysis [16] performed with the SPSS 'factor' program [17] (Table 4).

Table 3. Self-assessment of subjective well-being during intensive oral nutrition of antileukaemic treated patients (group B): A LASA-means, B. Nutritional parameters

Parameter	n	Means	SD	Min	Max
A. LASA-Items					
Impaired quality of life	198	2.6	3.0	0	10
Impaired health	198	2.8	2.9	0	10
Impaired physical feeling	198	2.6	2.9	0	10
Weakness	199	1.9	2.6	0	10
Helplessness	196	1.1	2.0	0	10
Sorrow	199	1.3	2.0	0	10
Unrest	199	2.0	1.9	0	10
Anxiety	198	1.4	2.3	0	10
Hopelessness	196	0.9	1.9	0	10
Sleepiness	192	5.0	1.9	0	10
Pain	198	1.8	2.8	0	10
Nausea	198	2.2	2.8	0	10
Anorexia	197	3.3	3.3	0	10
Emesis	197	1.4	2.4	0	10
Taste disturbances	191	2.4	3.1	0	10
Stomatitis	197	1.6	2.7	0	10
B. Nutritional Parameter					
Medians of weekly energy intakes (kcal/kg IBW)	209	31.0	14.0	0	61.0
Weekly assessed body weight (% IBW)	210	100.0	17.5	71	161.0

(SD)=standard-deviations; (Min)=—minima; (Max)=—maxima; N=number of assessments; kcal/kg IBW=kcal per kg ideal body weight.

Factor 1—'Fatigue/malaise'. Deriving from the items: impaired quality of life, impaired health, impaired physical feeling, weakness, helplessness, unrest, pain, anorexia.

Factor 2—'Psychological distress'. (helplessness, sorrow, unrest, anxiety, hopelessness; stomatitis).

Factor 3—'Tumour-therapy-side-effects'. (nausea, anorexia, emesis, taste disturbances).

Baseline values of these 'quality-of-life-factors' obtained from 180 tumour patients, and the factors' test statistical properties are described in detail elsewhere [14,15]. For a total of 156 weeks of 13 patients, the identified factors of subjective well-being were correlated with the absolute BW, the weekly BW changes, the weekly energy intake, the type of tumour therapy and the patients' estimation of food quality.

Statistics

Differences between the groups and subgroups were tested to be significant at a level of $P < 0.05$ using the Wilcoxon's Mann-Whitney U -test. Because of the significantly differing outcomes of patients in the TAD-groups (see below: Results), statistical evaluation of subjective well-being was restricted to the patients under LAM- and Ulm- protocols. Correlations between quality of life and nutritional parameters were calculated only for periods of complete hospitalization (induction treatment) in order to standardize the patients' social surroundings.

Principal factor analysis was calculated with the

help of the SPSS-program using the following steps: 1. z-transformation of the LASA-values (mean: 0, SD: 1), 2. generation of a factor matrix using principal factors, 3. varimax rotation of principal factors (see Table 4). Correlations between LASA-items or principal factors of subjective well-being and energy intake or changes of body weight are described by Spearman's rank correlation coefficients. For testing the coefficients' statistical significance the two-tailed Student's t -test was used for: $n > 30$; and for $n < 30$ the Ferguson-test.

Results

The complete mean study period was 25.5 weeks without significant differences between the subgroups—except for those with the TAD-regimen: LAM-6-protocol median = 22 (range 6–54), Ulm = 36 (range 8–50), TAD = 9 (range 4–32). The induction periods were completed as preplanned in all cases, except for 1 TAD-A.

There were no differences regarding septic episodes; days with body temperatures above 38.5°C were as follows: LAM-A/B = 13/11 (6–29/8–21; medians—ranges); TAD-A/B = 11/11 (11–14/8–13); ULM A/B 2/2 (0–10/0–12). Complete remission after the induction phase was diagnosed in two out of six LAM-A patients, two out of seven LAM-B; two out of five TAD-A, three out of three TAD-B; three out of five ULM-A, and three out of six ULM-B patients. To all patients, cystostatic drugs were given in the preplanned dosage. No patient died earlier than 2 weeks after the end of the study.

Table 4. Principal component analysis of LASA-items; factor matrix of varimax rotated principal factors (only correlations above 0.45 are mentioned). Factor 1: 'Fatigue' (% of variance: 50.1), Factor 2: 'Psychological distress' (% of variance: 11.7), Factor 3: 'Tumour therapy side effects' (% of variance: 7.7)

LASA Items	Factor 1	Factor 2	Factor 3
Impaired quality of life	0.8094		
Impaired health	0.8725		
Impaired physical feeling	0.9056		
Weakness	0.7196		
Helplessness	0.6333	0.5056	
Sorrow		0.7979	
Unrest	0.5594	0.6159	
Anxiety		0.7868	
Hopelessness		0.8005	
Pain	0.5338		
Nausea			0.8698
Anorexia	0.4926		0.6350
Emesis			0.8298
Taste disturbances			0.5300
Stomatitis		0.5569	

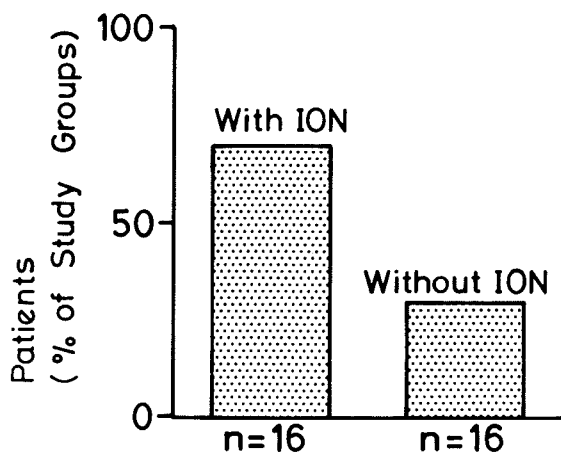


Figure 1. Patients with acute leukaemias *without malnutrition* (% of total pat.) after induction therapy with and without 'Intensified Oral Nutrition (ION)'.

Influence of nutritional intervention on nutritional status

During the period of the first cytostatic drug application (induction treatment) the nutritional status of all patients was highly impaired. This was independent from patients' clinical course and outcome, from therapy type, and from the kind of nutrition intervention (see Table 2). Patients of both study groups experienced an obligatory loss of BW up to the 3rd or even 7th study week. The median weight loss was 8% of the pretreatment weight; one third of all persons lost more than 10%.

It was only after that period of obligatory weight loss, that we could see a superior effect of our dietetic intervention on the nutritional status. Patients of the intervention group under LAM 6-treatment showed

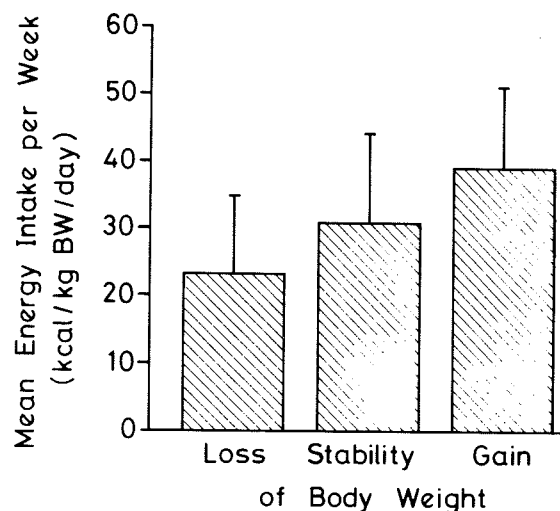


Figure 2. Energy intake (means, SD) of patients with acute leukaemia under oncological polychemotherapy during weeks with weight loss, stable weight, or weight gain (statistical difference between the 3 groups: $P < 0.0001$).

more weeks with weight gain to the end of the induction phase, than those subjects of the control group (weight gain during 33.8% of the whole induction phase in group LAM 6-B, versus 13.2% in group LAM 6-A). The amount of weight gain per week was identical in both LAM-6 groups (mean +2.5% of day 0—body weight on day 7, SD 1.7%). Patients, who had to be treated by the regimens TAD or Ulm, showed no differences between group A and B with respect to the weeks with weight gain (15.9% of the whole induction time for TAD, 24.1 Ulm). In these cases, the dietetic intervention resulted in many more weeks with stable weight (TAD-B: 48.7% of the induction time, versus 18.3% in TAD-A; Ulm-B: 53.1% versus 31.5% in Ulm-A, $P < 0.05$).

As a consequence, a higher number of patients of the intervention than of the control group were able to normalize their nutritional status until the end of antileukaemic induction therapy: at that time, only five out of 16 patients of group B showed a body weight below 95% of their prestudy weight, in contrast to 11 out of 16 control patients (Fig. 1). After the end of the induction therapy (e.g., during all in-patient phases for consolidation therapy), only patients with acute lymphocytic leukaemia (Ulm-protocol) could profit from the ongoing dietetic intervention. During 22.8% of all consolidation treatment weeks, intervention patients experienced a mean weight loss of 2.6% per week, compared with 49% treatment weeks for control subjects. Furthermore, B-patients showed weeks with stable weight during 42.4% of the treatment phases, in contrast to only 16.2% for group A.

In the intervention group, the amount of oral nutrient intake and the course of body weight are closely correlated with each other: the mean daily energy intake (calculated as median of one week's daily intake) was 23.3 ± 11.4 kcal kg^{-1} ideal body weight

Table 5. Correlations between weekly reported weight changes, nutrient intake, self-assessed quality of hospital diet and factors of subjective well-being (Spearman's rank correlation)

Parameter/ subj. items	Factors of subjective well-being		
	Weakness (malaise)	Dysphoria (psychol. distress)	Side-effects of TU-therapy
Weight loss (% of last week's body weight)	0.40**	—	—
Energy intake (kcal/kg IBW)	-0.24*	—	-0.40**
Quality of hospital diet (LASA-score)	—	—	-0.50**

IBW = ideal body weight; * $P < 0.01$; ** $P < 0.001$.

during weeks with weight loss, 30.9 ± 13.1 during weeks with stable weight, and 39.3 ± 12.2 kcal during weeks with weight gain ($P < 0.0001$), see Fig. 2.

Nutrition behaviour and subjective well-being ('quality of life')

We found significant correlations between nutrient intake and course of body weight on the one hand, and the factor 'Fatigue/malaise', as well as 'Tumour-therapy-side-effects' on the other hand—quite in contrast to the factor 'Psychological Distress' (see Table 5). Interestingly, the relationship between a reduced nutrient intake and the burden of drug toxicity is much closer than it is between food intake and fatigue—fatigue correlates exclusively with weight loss.

From our data we deduce, that the spontaneous oral food intake and the toleration of hospital food is reduced primarily during phases in which patients suffer from drug toxicity. Anorexia seems to be the predominant reason for reduced food intake (correlation coefficient of $r = 0.47$, $P < 0.0001$), followed by emesis ($r = 0.37$), and nausea ($r = -0.31$). In our patients, mucositis of the oral cavity, the pharynx or esophagus, as well as psychological distress were no problems for oral nutrient intake.

Discussion

Reduced spontaneous food intake, inducing weight loss and malnutrition, is a clinically relevant problem for about half of all tumour patients [18,19]. Especially the toxicity of antineoplastic treatments is generally recognized as a major cause of cancer cachexia [20]. Chemotherapy, as well as surgery and radiation treatment, all have specific adverse effects on the digestive tract or on general metabolism. Learned food aversion is another possible consequence of chemotherapy that can be particularly deleterious, when familiar foods consumed before or during chemotherapy become the object of such aversions [21].

In the last few years, several study groups pointed

out that quality of life and nutritional behaviour of tumour patients are closely related. Eating problems are regarded as having higher priority for the subjective well-being of patients under cytostatic therapy than the ability to work, physical fitness or sexual life [3]. Nevertheless, systematic work concerning the relationship between nutritional behaviour and quality of life has so far been of minor interest for clinical investigators. Only Brunig and colleagues [2] were able to publish results of a controlled prospectively undertaken trial, dealing with this problem. In this study, the authors found only slight reduction in spontaneous food intake in cancer patients treated by polychemotherapy or radiation. In that heterogeneous study group impaired nutrition behaviour correlated with diminished subjective well-being; but, in our opinion, these results can hardly be generalized because of the study design. First of all, mostly well-nourished patients were studied. More importantly, instead of continuous assessment of daily food intake, only 48-h dietary records were used, although this method is known to lack validity [22].

In order to get more information about the relationship between nutrition and quality of life, we used antileukaemic polychemotherapy as a model of highly toxic tumour treatment which leads obligatorily to a reduced food intake and weight loss. Furthermore we followed the changes in BW and nutrient intake from week to week. Our check list of subjective well-being items concentrated on those complaints, whose influences on the spontaneous food intake are widely accepted [3,23,24]. We excluded the social aspects of quality of life from our investigation, in order not to overtax patients' compliance to answer the questionnaires.

From the results we deduce that quality of life and nutritional behaviour are correlated with each other. In our opinion the data could lead to the following hypothesis:

1. The amount of spontaneous oral nutrient intake is diminished during those periods in which patients suffer most intensively from the side-effects of tumour therapy.
2. The inadequate nutrient intake is followed by loss of BW with delay (as a consequence of this time lag, the correlation coefficient between energy intake and course of BW is rather low: $r = 0.49$).
3. During periods of intensive weight loss, patients primarily mention the subjective feeling of fatigue/malaise.

In accordance with the results published by Holland [24], we did not find any correlation between the factor 'psychological distress' and nutritional behaviour. We were not able to find any relationship between impaired food intake and increased need of sleep, as discussed by Christensen [25] and Holland [24].

Thus, the keys for the prevention of inadequate food intake, weight loss and—as a consequence perhaps, impaired quality of life—are adequate prophylaxis and

treatment of tumour therapy side-effects. The superior nutritional outcome of the patient group treated by 'Intensified oral nutrition therapy' underlines the necessity of permanent dietetic care of tumour patients during periods of aggressive polychemotherapy [26]. Nutritional counselling was effective in increasing the body weight in the intervention group earlier and more often than in the control group. This interpretation of our study results is based on the fact, that the two groups did not differ with respect to further factors influencing the nutritional behaviour, e.g., duration of sepsis, or individual outcome. Dietetic care failed to prevent the obligatory weight loss during the first month of cytostatic treatment. That is why further studies may be necessary to evaluate, whether the nutritional status can be stabilized together with the patients' subjective well-being by means of artificial nutrition as supportive treatment of induction polychemotherapy.

The energy intake of our patients was closely correlated with the individual course of BW: people who lost weight had a median energy fuel intake amounting to the basal energy expenditure (BEE). During weeks of weight stability (gain), the energy intake was about 1.3 (1.6)-fold BEE, which corresponds with the daily demand of non catabolic (catabolic) patients [27]. So patients with acute leukaemia obviously do not suffer from hypermetabolism during polychemotherapy. These results, together with recently published data on nitrogen metabolism of tumour patients [7] show that—during aggressive antineoplastic pharmacotherapy, most of the cancer patients can be nourished by a normal diet using physiological nutrient amounts, if adequate anti-anorectic treatment is done and if chewing and swallowing are possible [28].

Conclusion

1. Life-threatening malnutrition was prevented in all of our patients even during the stress of antileukaemic treatment by dietetic intervention, without artificial nutrition. That is why this group of patients may not routinely be nourished by artificial access.
2. Daily applied dietetic care is superior to standard hospital feeding with respect to the nutritional status of leukaemic patients.
3. Intensive oral nutrition therapy with continuous dietetic counselling and motivation is an effective adjunct to aggressive antitumour therapy—not only with respect to the nutritional status, but also to patients' quality of life.

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