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Clinical Science of Nutrition is an international, peer-reviewed, open access journal. It publishes research articles, reviews, case reports, and letters to the editor on all aspects of nutrition and dietetics.

Clinical Science of Nutrition is a triannual journal that is published in English in April, August, and December.

Abstracting and indexing

Clinical Science of Nutrition is covered in the following abstracting and indexing databases;

- TR-Index
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Aims and Scope

The journal aims to contribute to the literature by publishing high impact content and become one of the leading publications of the field while functioning as an open discussion forum on significant issues of current interest. Clinical Science of Nutrition also aims to have significant input in emphasizing the increasing importance of clinical nutrition in Turkey and the region, identifying the effects of differences between societies on study results in a clearer way and converting clinical applications into scientific publications as well as forming a bridge between West and East.

The scope of Clinical Science of Nutrition includes original research articles, review articles, case reports, conference reports, and letters to the editor as well as editorials, abstracts from international and national congresses, panel meetings, conferences and symposia. As an online-only publication, in addition to traditional manuscript submissions, Clinical Science of Nutrition is also able to process video, audio and interactive software submissions. Authors are encouraged to submit their content in the most appropriate medium to best convey their findings to the audience of Clinical Science of Nutrition.

The journal covers all aspects of nutrition and dietetics including prevalence of malnutrition and its effects on clinical results; nutritional support and delivery methods and their advantages and disadvantages; nutritional support products and their side effects; immune system and nutritional support; ERAS protocol and nutritional support; home parenteral and enteral nutrition; nutrition support teams and their necessity, challenges and potential solutions of nutritional support.

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Prevalence and presence of sarcopenia and sarcopenic obesity in female breast cancer patients

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ABSTRACT

Objective: This study aimed to evaluate prevalence and clinical correlates of sarcopenia and sarcopenic obesity in breast cancer patients

Methods: A total of 50 female patients with histopathological diagnosis of breast cancer were included in this prospective 6-month observational study. Data on patient age, anthropometrics, bioelectrical impedance analysis, physical activity level and blood biochemistry were recorded. Sarcopenia was assessed using preoperative computed tomography (CT) findings, while obesity in sarcopenic patients was identified based on BMI (Body mass index) and fat percentage values.

Results: Obesity, sarcopenia and sarcopenic obesity was evident in 50%, 50% and 20% of patients, respectively. None of the parameters studied, including age, laboratory results, BIA (bioelectrical impedance analysis), or anthropometric findings, showed a significant correlation with the degree of sarcopenia in the overall study population, as well as in patients with sarcopenia and those with sarcopenic obesity.

Conclusion: The findings suggest that sarcopenia is prevalent in half of breast cancer patients before radiotherapy, with concomitant obesity in 40% of sarcopenic patients. Therefore, assessing body composition using CT imaging is essential to recognize sarcopenic obesity earlier and prevent the combined hazards of obesity and depleted muscle mass in breast cancer patients.

Keywords: Breast cancer, nutrition, obesity, sarcopenia, sarcopenic obesity

INTRODUCTION

Weight gain is frequently encountered during antineoplastic treatment among patients with breast cancer and associated with decreased quality of life and increased risk for recurrence and shortened survival.[1-3] In addition, weight gain in patients with breast cancer is considered distinctive in terms of occurrence of gain in weight without concomitant gain or even with loss in lean body mass (LBM), a pattern consistent with sarcopenic obesity.[4-6]

Although obesity has been extensively evaluated based on well-defined body mass index (BMI) criteria in several population studies for obesity, body composition in patients with obesity has been addressed by few studies despite the likelihood of variability in body composition across the BMI spectrum, increasing the likelihood of patients with sarcopenia to be under-reported.[7]

This seems notable given that sarcopenia, a generalized and progressive loss of skeletal muscle mass and muscle function, has emerged as a potential novel marker for risk assessment in the surgical oncology population, given its association with poor clinical outcomes in patients with cancer.[8-10] In fact, sarcopenia is considered to occur in one out of three patients with newly diagnosed breast cancer and to be under-recognized in patients with non-metastatic breast cancer[11], even though it has been

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associated with greater treatment toxicity and a shorter time to tumor progression.[7,12,13]

Hence, early nutritional and body composition assessment is considered to provide valuable prognostic information in patients with breast cancer.[14,15] Given that the shifts in body composition cannot be captured using body weight or BMI measures, use of body composition modalities such as bioelectrical impedance analysis, dual-energy X-ray absorptiometry (DXA) and computed tomography (CT) has been recommended to further elucidate the relationships between body composition and breast cancer outcomes.[4,16,17] Also, CT using a single slice at the level of the third lumbar vertebra (L3) is considered a more sophisticated and precise methodology in assessment of muscle mass.[4,17,18]

Although the maintenance of adequate body weight in relation to body composition is considered amongst the favorable prognostic factors in survivors of any type of cancer[19,20], the concomitant sarcopenia in obese patients with breast cancer may be masked by the excess fat mass despite its association with poorer prognostic outcomes in patients with obesity.[20-22]

Main Points

- Weight gain is a common issue in breast cancer patients, often reducing their quality of life while increasing the risk of recurrence and potentially shortening survival. However, weight gain is typically accompanied by the loss of muscle mass, which may indicate the presence of sarcopenic obesity.
- Sarcopenia has emerged as a new marker for risk assessment in breast cancer patients. This study reveals that more than half of breast cancer patients have sarcopenia, and around 40% of these individuals are obese.
- Traditional measures like body weight or BMI may be insufficient for assessing body composition. More sensitive methods like computerized tomography (CT) scans are crucial for evaluating muscle mass and detecting sarcopenia in overweight and obese patients.
- While this study didn't establish a strong link between physical activity and the presence or degree of sarcopenia, it emphasizes the importance of not disregarding the potential benefits of regular exercise in increasing muscle mass.
- In conclusion, this research lays the groundwork for a better understanding of the complex relationship between obesity, muscle mass, and breast cancer, contributing to the development of treatment strategies for breast cancer patients. It underscores the importance of precise body composition measurements in assessing the combined risks of obesity and muscle loss in breast cancer patients.

This study was therefore designed to determine the prevalence and clinical correlates of sarcopenia and sarcopenic obesity in patients with breast cancer by evaluating body composition across the BMI spectrum.

MATERIALS AND METHODS

Study Population

A total of 50 female patients with histopathologic diagnoses of breast cancer who were admitted for radiotherapy were included in this prospective 6-month observational study conducted at a tertiary care center. Fifty consecutive patients with breast cancer aged over 18 years were included in the study. All were given chemotherapy either in an adjuvant or neoadjuvant setting before initiation of radiotherapy, and surgical treatment was performed to all patients. None of patients had metastatic disease. No palliative treatment was given. The intent of treatment was curative in each patient.

Written informed consent was obtained from each subject following a detailed explanation of the objectives and protocol of the study, which was conducted in accordance with the ethical principles stated in the Declaration of Helsinki and approved by the institutional ethics committee (E-18-1868).

Study Parameters

Data on patient age, anthropometrics (body weight (kg), height (m), BMI (kg/m^2)), bioelectrical impedance analysis (BIA; body fat percentage (%), body water percentage (%), visceral fat ratio, bone mass (kg), muscle mass (kg), basal metabolic rate (BMR; kcal), metabolic age), handgrip strength (kg) , physical activity level and blood biochemistry (prealbumin (g/L), albumin (g/dL), vitamin D (ng/mL) and C-reactive protein (CRP, mg/L)) were recorded in each patient. Sarcopenia was assessed using computed tomography (CT) findings, and obesity in patients with sarcopenia was identified based on BMI and fat percentage values.

Patient age and laboratory findings were evaluated according to BMI, sarcopenic obesity, and body fat percentage, and correlations between the degree of sarcopenia and study parameters were assessed in sarcopenia and sarcopenic obesity groups along with the univariate analysis for factors associated with the presence and degree of sarcopenia.

CT-based Sarcopenia Diagnosis

Simulation CT was performed for radiotherapy planning using a CT scanner (GE Bright Speed) without iodine-based contrast material administration. Cross-sectional surface measurements of the psoas muscle, paraspinal

muscles (erector spinae muscles, quadratus lumborum muscle), and abdominal wall muscles (transversus abdominis muscle, external and internal oblique muscles, and rectus abdominis muscle) at the upper end of third lumbar vertebrae (L3) were performed. All CT images were then transferred to a workstation (Eclipse contouring system) for further quantitative computed tomography (QCT) analysis for sarcopenia, which was performed by the same radiation oncology specialist. A single slice at L3 vertebra was selected for sarcopenia assessment. Total skeletal muscles volumes were measured in terms of cm^3. To evaluate sarcopenia, the L3 skeletal muscle index was calculated by dividing the total cross-sectional muscle area by the squared height (cm^2/m^2). Sarcopenia was defined based on previously described cut-off values for women (38.5 cm^2/m^2).[23,24]

Bioelectrical Impedance Analysis (BIA)

Body composition (body fat percentage, body water percentage, visceral fat ratio, bone mass, muscle mass (cm^2)) and physical activity level was measured using a Tanita BC-532 Body Composition Analyzer (Tanita, Tokyo, Japan). For the BIA measurements, the subject stood in an upright position with bare feet on the analyzer footpads. The impedance between the two feet was measured while an alternating current (50 kHz and ~200 μA) passed through the lower body. Body composition parameters were computed with this impedance value.

Hand Grip Strength Measurement

The three measurements were obtained via the digital hand dynamometer (Baseline Smedley Digital Hand Dynamometer Model 12-0286) from the dominant hand and the mean value was recorded as the hand grip strength in kilograms (kg).

Obesity

Patients with sarcopenia with BMI (≥30 kg/m^2) or high/very high body fat percentage were considered to have sarcopenic obesity.

Statistical Analysis

Statistical analysis was made using the IBM SPSS Statistics for Windows, version 20.0 (IBM Corp., Armonk, NY). Student's t-test, the Kruskal–Wallis test, and the Mann–Whitney U test with Bonferroni correction and analysis of variance (ANOVA) were used for the analysis of numerical data. Data are expressed as mean± standard deviation (SD), percentage (%) and median (min-max) where appropriate. $p<0.05$ was considered statistically significant.

RESULTS

Overall Characteristics

Overall, obesity was evident in 25 (50%) patients according to BMI assessment, and body fat percentage was very high in 23 (56.0%) patients. Sarcopenia was diagnosed in 25 (50.0%) patients. Sarcopenia alone (without obesity) was detected in 15 (30.0%) patients, obesity alone (without sarcopenia) was seen in 15 (30.0%) patients and sarcopenic obesity was present in 10 (20.0%) patients. Overall, 10 (20%) patients had neither sarcopenia nor obesity (Table 1).

Prealbumin and albumin levels were abnormal in 10 (20.0%) and 2 (4.0%) patients, respectively (Table 1).

Study Parameters According to BMI, Sarcopenic Obesity and Body Fat Percentage

Physical activity level was significantly lower in obese vs. normal weight patients ($p=0.005$) and in patients with very high and high body fat percentages than in those with low or normal body fat percentages ($p<0.001$) (Table 2).

Handgrip strength was similar in patients with sarcopenic obesity and those without sarcopenic obesity (41.3 ± 23.1 kg vs. 36.7 ± 17.2 kg, $p=0.490$). No significant difference was noted in prealbumin, albumin, CRP, and vitamin D levels with respect to BMI, sarcopenia, and body fat percentage (Table 2).

Correlations between Degree of Sarcopenia and Study Parameters

No significant correlation of degree of sarcopenia was noted with age, laboratory, BIA or anthropometric findings in the overall study population, in patients with sarcopenia and in patients with sarcopenic obesity (Table 3).

Univariate Analysis for the Factors Associated with the Presence and Degree of Sarcopenia

None of the parameters studied including age, laboratory, BIA or anthropometric findings was associated with the increased risk for the presence or degree of sarcopenia (Table 4).

Table 1. Overall characteristics			
Anthropometrics			
BMI (kg/m^2) category, n(%)			
Underweight (<18.5)			1 (2.0)
Normal (18.5-24.9)			11 (22.0)
Overweight (25.0-29.9)			13 (26.0)
Obesity (≥30)			25 (50.0)
Bioelectrical impedance analysis			
Body fat percentage, n(%)	Low		1 (2.0)
	Normal		9 (18.0)
	High		12 (24.0)
	Very high		28 (56.0)
Body water percentage (%),mean(SD)			14.8±5.3
Visceral fat ratio, mean(SD)			3.0±0.3
Muscle mass (kg), mean(SD)			43.6±5.2
Bone mass (kg), mean(SD)			2.3±0.3
Basal metabolic rate (kcal), mean(SD)			1398.8±165.0
Metabolic age, mean(SD)			45.7±8.6
Sarcopenia assessment			
Sarcopenia			
Absent			25 (50.0)
Present			25 (50.0)
Sarcopenia and/or obesity			
Sarcopenic obesity, both (+)			10 (20.0)
Only sarcopenia (+)			15 (30.0)
Only obesity (+)			15 (30.0)
None			10 (20.0)
Laboratory findings			
Prealbumin (g/L)	Mean(SD)		0.2±0.0
	n(%)	Normal	40 (80.0)
		Abnormal	10 (20.0)
Albumin (g/L)	Mean(SD)		4.5 ± 0.3
	n(%)	Normal	48 (96.0)
		Abnormal	2 (4.0)
Vitamin D (ng/mL), median(min-max)			14.3(4.7-93.7)
CRP (mg/L), median(min-max)			3(0.9-27.0)

Table 2. Patient age and laboratory findings according to BMI, sarcopenic obesity and body fat percentage

	BMI (kg/m2)a					Sarcopenic obesity			Body fat percentage					
	Underweight (n=1)	Normal (n=11)	Overweight (n=13)	Obese (n=25)	p[1]	Absent (n=40)	Present (n=10)	p[2]	Low (n=1)	Normal (n=9)	High (n=12)	Very high (n=28)	p[1]
Age (years)	43.0±0.0	57.0 (31.0-89.0)	52.0 (32.0-78.0)	53.0 (37.0-69.0)	0.254	53.3±12.7	57.3±9.9	0.357	43.0 ±0.0	67.0 (34.0-89.0)	47.0 (31.0-67.0)	53.0 (37.0-78.0)	0.110
Prealbumin (g/L)	0.2 ± 0.0	0.2 ± 0.0	0.2 ± 0.1	0.2 ± 0.0	0.691[3]	0.2±0.0	0.2±0.0	0.396	0.2±0.0	0.2±0.0	0.2±0.0	0.2± 0.0	0.741[3]
Albumin (g/L)	5.4±0.0	4.7±0.3	4.5±0.3	4.5± 0.3	0.131[3]	4.5±0.4	4.4±0.3	0.195	5.4±0.0	4.4±0.4	4.6±0.3	4.5±0.3	0.335[3]
Vit D (ng/mL)	23.8±0.0	15.0±11.7	16.1± 9.5	20.2±18.0	0.566[3]	16.8± 9.2	25.4±26.2	0.567	23.8±0.0	12.7±8.0	17.2±13.5	20.0±16.8	0.310[3]
Physical activity	7.0±0.0	5.0 (2.0-6.0)	2.0 (2.0-6.0)	3.0 (2.0-6.0)	**0.005**	3.5±1.4	2.9 ± 1.2	0.264	7.0±0.0	5.0 (5.0-6.0)	3.0 (2.0-5.0)	3.0 (2.0-3.0)	**<0.001**

Data are expressed as mean± SD or median (min-max)
aunderweight: <18.5 kg/m^2; normal :18.5- 24.9 kg/m^2; ; overweight: 25.0- 29.9 kg/m^2, obese: ≥30 kg/m^2
[1]Kruskal Wallis test and Mann Whitney U test with Bonferroni correction (significance for difference p=0.008), [2]Student's t test, [3]ANOVA test

Table 3. Correlations between degree of sarcopenia and study parameters overall and in sarcopenia and sarcopenic obesity groups

		Degree of sarcopenia		
		Overall (n=50)	Patients with sarcopenia (n=25)	Patients with sarcopenic obesity (n=10)
Physical activity degree	r	0.038	0.250	0.060
	p	0.792	0.228	0.869
	n	50	25	10
Muscle mass (kg)	r	0.031	-0.320	-0.309
	p	0.830	0.119	0.385
	n	50	25	10
Handgrip strength (kg)	r	0.046	-0.192	-0.079
	p	0.750	0.357	0.829
	n	50	25	10
Bone mass (kg)	r	0.024	-0.319	-0.352
	p	0.866	0.120	0.319
	n	50	25	10
Prealbumin (g/L)	r	0.030	-0.204	-0.140
	p	0.838	0.329	0.699
	n	50	25	10
Albumin (g/L)	r	-0.125	-0.186	-0.418
	p	0.386	0.372	0.229
	n	50	25	10
Vitamin D (ng/mL)	r	0.045	0.231	0.758
	p	0.758	0.267	0.011
	n	50	25	10
CRP (mg/L)	r	-0.056	0.021	0.563
	p	0.700	0.921	0.090
	n	50	25	10
Age (years)	r	-0.028	0.012	0.267
	p	0.845	0.955	0.455
	n	50	25	10
BMI (kg/m2)	r	0.207	-0.260	-0.055
	p	0.150	0.210	0.881
	n	50	25	10
Body fat percentage (%)	r	0.207	-0.151	0.006
	p	0.148	0.471	0.987
	n	50	25	10
Body fluid ratio (%)	r	-0.211	0.090	-0.127
	p	0.142	0.668	0.726
	n	50	25	10

Table 3. Continued

		Degree of sarcopenia		
		Overall (n=50)	Patients with sarcopenia (n=25)	Patients with sarcopenic obesity (n=10)
Visceral fat ratio (%)	r	0.164	-0.190	0.280
	p	0.255	0.362	0.434
	n	50	25	10
Basal metabolic rate	r	0.067	-0.328	-0.309
	p	0.645	0.109	0.385
	n	50	25	10
Sarcopenia rate	r	1	1	1
	p			
	n	50	25	10

Table 4. Univariate analysis for the factors associated with the presence and degree of sarcopenia

	Presence of sarcopenia[a]					Degree of sarcopenia[b]				
	Type III Sum of Squares	[c]df	Mean Square	[d]F	Significance	Type III Sum of Squares	[c]df	Mean Square	[d]F	Significance
Corrected Model	4.137a	17	0.243	0.931	**0.548**	718.739a	17	42.278	0.927	**0.553**
Intercept	0.053	1	0.053	0.204	**0.655**	93.34	1	93.345	2.046	**0.162**
Age (years)	0.222	1	0.222	0.851	**0.363**	17.58	1	17.580	0.385	**0.539**
BMI (kg/m^2)	0.540	1	0.540	2.066	**0.160**	139.49	1	139.493	3.057	**0.090**
Body fat percentage (%)	0.078	1	0.078	0.298	**0.589**	141.42	1	141.417	3.100	**0.088**
Body fluid ratio (%)	0.154	1	0.154	0.590	**0.448**	139.72	1	139.722	3.062	**0.090**
Visceral fat ratio (%)	0.097	1	0.097	0.371	**0.547**	73.16	1	73.158	1.603	**0.215**
Muscle mass (kg)	0.586	1	0.586	2.241	**0.144**	28.71	1	28.708	0.629	**0.433**
Physical activity degree	0.113	1	0.113	0.432	**0.516**	191.66	1	191.664	4.201	**0.049**
Handgrip strength (kg)	0.014	1	0.014	0.054	**0.818**	0.245	1	0.245	.005	**0.942**
Bone mass (kg)	0.093	1	0.093	0.356	**0.555**	23.82	1	23.820	0.522	**0.475**
Basal metabolic rate	0.537	1	0.537	2.055	**0.161**	22.04	1	22.044	0.483	**0.492**
Metabolic age (years)	0.070	1	0.070	0.268	**0.608**	12.60	1	12.597	0.276	**0.603**
Prealbumin (g/L)	0.869	1	0.869	3.325	**0.078**	24.87	1	24.874	0.545	**0.466**
Albumin (g/L)	0.092	1	0.092	0.353	**0.556**	2.30	1	2.305	0.051	**0.824**
Vitamin D (ng/mL)	0.190	1	0.190	0.725	**0.401**	0.05	1	.054	0.001	**0.973**
CRP (mg/L)	0.428	1	0.428	1.639	**0.210**	21.04	1	21.044	0.461	**0.502**
Error	8.363	32	0.261			1459.97	32	45.624		
Total	25.00	50				73443.15	50			
Corrected Total	12.50	49				2178.70	49			

[a]R Squared = 0.331 (Adjusted R Squared = -0.024) [b]R squared = 0.330 (Adjusted R squared = -0.026) [c]df=degree of freedom [d]F=F-distribution

DISCUSSION

Our findings in patients with breast cancer prior to radiotherapy revealed sarcopenic obesity in 20% of the study population, and either sarcopenia or obesity was present alone in 30% of patients. Physical activity levels were significantly lower in obese vs. normal weight patients, and were similar in patients with vs. without sarcopenic obesity. None of the parameters studied including age, laboratory, BIA or anthropometric findings was associated with an increased risk for the presence or degree of sarcopenia in patients with sarcopenia or sarcopenic obesity in the univariate analysis.

In a systematic review of 35 studies in 6894 patients with cancer, the prevalence of pre-therapeutic sarcopenia was reported as 38.6% in the overall study population and 25.5% in patients with breast cancer, being significantly and independently associated with postoperative complications, chemotherapy-induced toxicity and poor survival in patients.[25] Also, when compared with other studies that reported the prevalence of sarcopenia in women with stage IV breast cancer (25%)[12], and in patients with operable breast cancer (14%)[7], our findings seem to indicate much higher rates for sarcopenia (50%) in patients with breast cancer prior to radiotherapy.

The prevalence of sarcopenic obesity in our patients (20%) seems closer to previously reported rates in patients with operable breast cancer (14%)[7], and in patients with solid tumors of the respiratory and gastrointestinal tract (15%)[24]. Sarcopenic obesity was also reported to be evident in 25% of postmenopausal women without a history of cancer[26] along with much higher rates (95%) reported in survivors of breast cancer.[27]

Nonetheless, obesity was not present in 60% of patients with sarcopenia in the current study, supporting data from a past study among patients with operable breast cancer that indicated a significant association between sarcopenia and BMI category, with a higher percentage of patients with sarcopenia having a normal BMI.[7] However, the presence of concomitant obesity in 40% of our patients with sarcopenia is important given that sarcopenic obesity is considered an independent predictor of cancer survival[24], along with poorer prognosis in patients with sarcopenia with elevated vs. normal BMI.[7,24,28] This may be due to adverse factors associated with excessive adipose tissue such as insulin resistance and chronic inflammation.[7]

However, it should also be noted that in patients with operable breast cancer with normal BMI, an unexpectedly better prognosis and better toleration of chemotherapy toxicity was reported in patients with vs. without sarcopenia[7], in contrast to studies that indicated shorter survival times and greater treatment toxicity associated with sarcopenia in other cancer populations[24,28,29] and patients with metastatic breast cancer.[12] Thus, authors suggested the inclusion of patients with early-stage breast cancer (and thus recognition of sarcopenia through a CT scan early in the course of disease) to be a potential reason for the remarkable benefit associated with sarcopenia in their study[7], decreasing the likelihood of diminished muscle mass as a result of the cancer cachexia syndrome.[30]

Notably, our findings indicated the presence of sarcopenia in half of the patients with breast cancer, among which obesity accompanied in 40%. This seems to emphasize the role of the assessment of body composition and the use of CT-based sarcopenia diagnosis as a sensitive test for identifying occult sarcopenia in overweight and obese patients who might otherwise remain unrecognized and devoid of necessary treatment in the clinical setting[31], Hence, body weight assessment per se seems to be insufficient in this regard.[7,24]

Similarly, in a population-based study of patients with solid tumors of the respiratory and gastrointestinal tract, a large proportion of obese patients with cancer (15%) were reported to be affected by sarcopenia, and obesity was indicated likely to mask sarcopenia.[24] This seems notable given that sarcopenic obesity represents a worst-case scenario because it involves the hazards of both obesity and depleted muscle mass simultaneously, and is associated with an increase in the number and severity of complications in patients with breast cancer.[4,24,32]

Indeed, in a past study with 166 patients with metastatic breast cancer receiving first-line palliative chemotherapy, low muscle mass (LMM) and low muscle attenuation (LMA), which reflect low muscle quantity and low muscle quality, respectively, were reported in 66.9% and 59.6% of patients, and sarcopenic obesity was evident in 7.2% of the study population.[33] The authors also noted a significant association of LMA but not LMM or sarcopenic obesity with overall survival.[33]

In a systematic review of body composition changes in women treated for breast cancer, the authors reported no changes in LBM in five of nine trials on LBM within 3-4 years of diagnosis and treatment, despite losing body weight and fat mass in one study.[4] Notably, in a 24-week dietary intervention trial among patients with breast cancer, an average of 6.1 kg loss of body weight was reported to be accompanied by a simultaneous loss of LBM, but an increase in the prevalence of sarcopenic obesity from 10% at baseline to 18% at trial completion.[34]

Although BMI and body weight are easily obtained prognostic endpoints, they fail to accurately estimate potentially important changes in lean or adipose tissues.[4] Hence, given the recent imaging studies in other cancer populations highlighting the variability in LBM across the BMI spectrum[12,24,28], the prognostic significance of the interaction between body weight and adiposity in patients with breast cancer merits further investigation.[4] Moreover, given the identification of highest rates of LBM depletion in the earliest postmenopausal years[35], the likelihood of menopausal status to be a moderator of body composition is considered, along with a need for further investigation, to separately address the natural increases in adiposity and decreases in lean tissue in premenopausal and post-menopausal patients with breast cancer.[4]

Although certain cancer types (i.e. colorectal cancer) and patient age over 65 years were reported to be associated with increased susceptibility to sarcopenia in a past study among patients with respiratory and gastrointestinal cancer[24], our findings revealed that none of the parameters studied including age, laboratory, BIA or anthropometric findings was associated with an increased risk for the presence or degree of sarcopenia in patients with sarcopenia or sarcopenic obesity in the univariate analysis.

In elderly populations, sarcopenic obesity is considered to be an independent predictor of disability, and obese patients with vs. without sarcopenia were reported to have poorer self-assessed functional status and restricted activities of daily living.[36] Resistance exercise is considered likely to offer improved lean mass in the breast cancer population.[27,37,38] However, physical activity level was not associated with presence of either sarcopenic obesity or sarcopenia and also the degree of sarcopenia in our patients. Strikingly, our findings revealed no significant difference in CRP, prealbumin, albumin, and vitamin D levels with respect to the presence of obesity, sarcopenia or sarcopenic obesity in patients with breast cancer. Nonetheless, the interaction between obesity and sarcopenia in patients with breast cancer needs further investigation considering confounding factors such as disease stage, menopausal status, and previous treatments in the assessment of combined hazards of obesity and depleted muscle mass in patients with breast cancer.

Certain limitations of this study should be considered. First, due to its observational nature and the non-randomized group allocation, the likelihood of main selection bias and confounding is possible. Second, although the current study provides data on real-life clinical practice, the potential lack of generalizability seems another important limitation due to the relatively small sample size. Third, the lack of data on menopausal status is another limitation because of the likelihood of menopausal status acting as a moderator in body composition changes, which otherwise would extend the knowledge achieved in the current study.

CONCLUSION

In conclusion, our findings revealed sarcopenia in half of patients with breast cancer prior to radiotherapy and concomitant obesity in 40% of patients with sarcopenia. This emphasizes the crucial role of the assessment of body composition using CT imaging rather than body weight and BMI-based assessments alone in the earlier recognition of sarcopenic obesity to prevent combined hazards of obesity and depleted muscle mass in patients with breast cancer. None of the potential risk factors studied in our population, including patient age, BIA or anthropometric findings was associated with an increased risk for either the presence or degree of sarcopenia in patients with sarcopenia or sarcopenic obesity. However, the body composition changes in patients with breast cancer and the prevalence and prognostic role of sarcopenic obesity needs to be further investigated, particularly in terms of subgroups stratified by ongoing treatment, variability in muscle mass across the BMI spectrum, and menopausal status.

Ethical approval: The study was approved by the Ethics Committee of Ankara Numune Training and Research Hospital (E-18-1868, date: 26.06.2018).

Informed consent: Written informed consent was obtained from all patients who participated in this study.

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The relationship between weight stigma, self-esteem, and life satisfaction in individuals seeking bariatric surgery*

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ABSTRACT

Objective: Stigma is a mark that defines some people, devalues, and causes them to be distinguished from others in society. Obesity is among the diseases that might cause discrimination and stigmatization. This study aimed to evaluate the relationship between weight stigma, self-esteem, and life satisfaction in people with a bariatric surgery history.

Method: This cross-sectional study was evaluated in 250 individuals [147 female (58.8%) and 103 male (41.2%)] with a mean age of 34.35 ± 7.46 years. Descriptive characteristics, the factors leading to bariatric surgery, self-esteem, and life satisfaction scores were collected with a questionnaire. Linear regression models for the life satisfaction scale were analyzed. Statistically, $P < 0.05$ values were considered significant.

Results: The postgraduates had lower life satisfaction than high school and undergraduate students (P=0.001); the non-smokers had higher life satisfaction than smokers or who quit smoking (P=0.036) and also non-alcoholics had higher life satisfaction than the other groups who consume alcohol or quit consuming (P=0.000). The self-esteem of the non-smokers was higher than smokers or who quit smoking (P=0.000). The postoperative body weight loss of the individuals was 93.8 ± 31.3 kg. Accordingly, most of the individuals (98.4%) applied for surgery because of a "fear of health problems", 98.8% of the individuals were "experiencing exclusion or discrimination at school or work", 99.2% of the individuals were "feeling insecure about the opinions of others" and "being blamed by people for weight problems". The self-esteem score of the overweight group was higher than the group with normal BMI values (P=0.012). According to the regression model, weight loss and self-esteem were among the determinants of life satisfaction (P=0.000).

Conclusion: The current data suggest that strategies to reduce stigma behavior should be developed in addition to lifestyle interventions, including dietary approaches, in the treatment of obesity. It is necessary to conduct follow-up studies on this subject, which span the time before and after bariatric surgery.

Keywords: Bariatric surgery, weight stigma, self-esteem, life satisfaction

INTRODUCTION

Obesity is a chronic disease characterized by the accumulation of excess fat in the body, leading to various complications[1,2] and has become a significant public health problem with its increasing prevalence, health costs, and negative effect on physical and psychological health.[2,3] According to the World Health Organization (WHO), about 13% of the world's adult population has obesity.[4] In Turkey, 39% of adults are overweight, and 30.3% are with obesity.[5]

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Lifestyle changes, including diet and physical activity, are the basis of obesity treatment and pharmacological and surgical therapies also follow these.[6] Bariatric surgery has been considered a standard and an effective treatment option for morbid obesity in recent years, and it is effective in improving long-term survival and controlling obesity-related comorbidities.[7] Studies have indicated that bariatric surgery positively affects body image, life quality, and depressive symptoms.[8,9]

Self-esteem is a central construct in clinical, developmental, personality, and social psychology, and research on the subject of self-esteem's function in psychological functioning dates back many years.[10] Rosenberg (1965) defined self-esteem as a generally positive evaluation of the individual's self and defined high self-esteem as self-respect and self-worth.[11] The metabolic effects of obesity on diabetes, asthma, and cardiovascular diseases are known. However, there is less data on the impact on psychological conditions such as mental state, anxiety, depression, and self-esteem.[12] Literature suggests that people with obesity generally have lower self-esteem, and negative attitudes and behaviors about their body weight are a factor in studies on obesity and self-esteem.[13,14] Another study stated that dissatisfaction with their bodies was a factor in the low self-esteem of people with obesity.[15] These results suggest that self-esteem is associated with different situations in people with obesity. Life satisfaction describes an individual's general judgment that life is well.[16] Health conditions, work environment, and well-being affect life satisfaction.[17] Life satisfaction is also associated with body weight control in young adults.[18] Compared to individuals with average body weight, young adults with obesity have lower life satisfaction.[14]

Stigma is a mark that defines some people, devalues, and causes them to be distinguished from others in society.[19] It is described as dehumanizing those who go through socially different circumstances by making them appear different from other members of the social system.[20] Obesity is among the diseases that cause discrimination and stigmatization by society. Individuals with obesity are excluded and marginalized by society and judged by certain stereotypes due to their excess weight.[21]

Main Points

- Individuals with obesity may be subject to stigmatization by society.
- Stigmatizing behavior can affect the success of obesity treatment, quality of life and self-esteem.
- It is very important to include stigma behavior in examining the causes and consequences of obesity.

The treatment of obesity should include weight loss, improved health and maintenance of well-being. There is a need for a holistic approach accompanied by body weight loss, which is the focal point in obesity management. In this respect, it is important to address the reasons that lead individuals to lose body weight in obesity as a whole, as well as to raise social awareness and to improve the treatment of the disease and preventive health services.[2] Studies on people with obesity revealed that experiences of stigmatization, shifts in self-worth, and quality of life all have an impact on people's wellbeing. Furthermore, those who experience weight stigma have lower self-esteem, which leads to body dissatisfaction and psychological stress.[22] Self-esteem, body dissatisfaction, a desire to be "normal", and stigma might be among the factors that encourage individuals to undergo bariatric surgery.[23-27]

This information suggests that self-esteem, life quality, and stigma are interrelated in people with obesity, and this interaction may affect the treatment approach of individuals with obesity. In the view of literature, we aimed to investigate the presence of stigma, self-esteem and life satisfaction in people with obesity who undergo bariatric surgery history, and present possible reasons related to stigma that conduct people to surgery.

METHODOLOGY

Sample Selection

This cross-sectional study was conducted between January and February 2022 among 250 participants [147 female (58.8%) and 103 male (41.2%)] living in Turkey with a history of sleeve gastrectomy. Individuals who were communication platform members including people with a bariatric surgery history, were invited to the study by a general surgeon using an online questionnaire. The purpose and method of the study were explained to the individuals online through bariatric surgery patient groups and 267 volunteers were reached. The data of 250 individuals who answered the survey questions were analyzed. Individuals who had bariatric surgery and were literate enough to answer the survey questions were included in the study.

Data Collection

The individuals who volunteered to take part in the study gave their electronic consent. The sociodemographic characteristics of the individuals, their knowledge of health and bariatric surgery, the factors leading to bariatric surgery, the situations faced by the individuals related to stigma before applying for bariatric surgery, anthropometric measurements (body weight and height), self-esteem and life satisfaction were evaluated with a questionnaire. Based on research on the stigmatization of people with obesity in the literature, a section was

developed to identify the circumstances that people will encounter before deciding to apply for bariatric surgery.

Rosenberg Self-Esteem Scale

The Rosenberg Self-Esteem Scale was used in this study to assess the participants' self-esteem.[11] The scale measures how much each person values oneself. The short form used in this study consists of 10 items (five positive statements and five negative statements) and is a 4-point Likert-type scale. The scale was developed by Morris Rosenberg (1965). The Turkish adaptation study was carried out by Çuhadaroğlu (1986).[28] After inverting the items, a high overall scale score denotes high self-esteem.[29] In this study, the Cronbach alpha value for the scale was 0.700.

Satisfaction with Life Scale

In this study, life satisfaction was evaluated with the Satisfaction with Life Scale. The scale consists of five items on a 5-point Likert-type scale. Diener et al. established it in 1985 to evaluate life satisfaction[30], and Dağlı and Baysal adapted it into Turkish in 2016.[31] Higher scores of the scale are associated with higher satisfaction with life. In this study, the Cronbach alpha value for the scale was 0.762.

Statistical analysis

IBM SPSS Statistics for Windows 21.0 (IBM Corp., Armonk, NY, USA) was used to analyze statistical data. Continuous data were presented as Interquartile Range (IQR), median (minimum-maximum), and the categorical data were presented as the number (N) and percentage (%). The normality of the quantitative data was assessed using Kolmogorov-Smirnov test. For the non-parametric paired groups, Mann-Whitney U test was used, while the Kruskal-Wallis test was used to compare more than two groups. The continuous variables examined for Pearson correlation. Linear regression model was used to determine correlations between the variables of self-esteem, life satisfaction, and weight loss (kg). Statistically, $P < 0.05$ was regarded significant.

RESULTS

The distribution of descriptive characteristics of the individuals and the distribution of these characteristics according to their self-esteem and life satisfaction scores are given in Table 1. A total of 147 female (58.8%) and 103 male (41.2%) individuals with a mean age of 34.35 ± 7.46 years (data not shown in the tables), were included in this study. Moreover, 50.4% of individuals had a bachelor's degree, and 54.8% were single. According to the participants' employment status, 31.6% were civil servants. The high school graduates had higher life satisfaction than the undergraduates and graduates (P=0.001); the non-smokers (P=0.036) had higher life satisfaction than smokers and who quit smoking; non-alcoholics (P=0.000) had higher life satisfaction than whom drink alcohol or quit drinking. The self-esteem of those who don't smoke was higher than smoker and who quit smoking (P=0.000) (Table 1). Duration after surgery was 8.12±5.3 years (data not shown in the tables).

The distribution of information about the disease and surgical history of the individuals is presented in Table 2. The most common chronic diseases in the individuals were arthritis (97.2%), sleep apnea (96.8%), asthma (89.8%), and cardiovascular disease (82.8%).

"Worrying about body weight-related health problems" was among the reasons that led patients to surgery at a high rate (98.8%). Of the patients, 90.8% reported receiving professional support for diet therapy, and 99.6% stated, "if I do not follow a diet plan after surgery, they will return to my pre-surgical weight". The patient's mean postoperative body weight was 93.8 ± 31.3 kg and most of the patients didn't gain weight after bariatric surgery (data not shown in the tables). Physicians (85.2%), social media (66.4%), and friends (43.2%) were the resources to refer to surgery patients (data not shown in the tables).

The distribution of the patients regarding the feeling of stigma in society before surgery is presented in Table 3. Accordingly, most of the individuals (98.4%) applied for surgery because of a "fear of health problems". The vast majority (99.2% and 98.8%, respectively) had difficulties before surgery due to "experiencing difficulties in physical environments" and "experiencing exclusion or discrimination at school or work environment". The individuals confirmed the items, "feeling insecure due to the opinions of others" (98.6%), "Being blamed by people for of weight problems" (99.2%), "not being invited to social environments such as meetings or events" (98.4%), with high percentages.

The distribution of the individual's life satisfaction and self-esteem scores according to their body mass index (BMI) class is summarized in Table 4. Accordingly, the self-esteem score of the overweight group was higher than the group with normal BMI value (P=0.012).

Table 5 presented the relationship between life satisfaction and various variables with the regression model. Accordingly, weight loss (P=0.000) and self-esteem (P=0.000) were among the determinants of life satisfaction.

Table 1. Descriptive characteristics of individuals and the distribution of these characteristics according to self-esteem and life satisfaction scores

Variables	Total N (%)	Self-esteem			Life satisfaction		
		IQR	Median (Min-Max)	p	IQR	Median (Min-Max)	p
Gender							
Male	103 (%41.2)	1	4 (2-5)	0.239*	3	16 (10-21)	0.386*
Female	147 (%58.8)	0	4 (0-5)		4	17 (5-20)	
Marital status							
Married	78 (%31.2)	0	4 (0-5)	0.622^	3.25	16 (5-20)	0.410^
Single	137 (%54.8)	1	4 (2-5)		3	17 (6-21)	
Divorsed	35 (%14.0)	0	4 (3-5)		2	16 (12-19)	
Education							
High school	75 (%30.0)	0	4 (3-5)	0.328^	3	17 (10-20)[a]	**0.001^**
Undergraduate	126 (%50.4)	0	4 (0-5)		3	17 (6-21)[a]	
Postgraduate	49 (%19.6)	1	4 (2-4)		4	15 (5-20)[b]	
Smoking							
Yes	24 (%9.6)	1	4 (2-5)[ab]	**0.000^**	2.75	16 (11-20)[ab]	**0.036^**
Never	74 (%29.6)	1	4 (2-5)[a]		3	17 (10-20)[a]	
Quit	152 (%60.8)	0	4 (0-4)[b]		4	17 (5-21)[b]	
Alcohol							
Yes	2 (%0.8)	-	3.5 (3-4)	0.274	-	9 (8-10)	0.000^
Never	163 (%65.2)	1	4 (0-5)		2	17 (5-21)	
Quit	85 (%34.0)	0	4 (2-5)		4	15 (11-20)	

p<0.05, IQR: Interquartile Range, Data are given as IQR, median (minimum-maximum) and number (N) and percent (%). *The difference between groups was evaluated with the chi-square test. ^ Intergroup difference assessed by Kruskal Wallis. The differences between groups are shown with bold. a-b: There is no difference between groups with letters in the same column

DISCUSSION

Obesity treatment includes different factors, such as dietary intervention, other lifestyle changes and well-being. Self-esteem, life satisfaction, and the feeling of stigma might affect well-being of individuals with obesity. The current study questioned factors related to individuals' self-esteem, life satisfaction, and weight stigma.

In this study with 147 females (58.8%) and 103 males (41.2%), there was no statistically significant difference between self-esteem and life satisfaction scores according to gender. Similar to the current study, Torre-Cruz et al. (2021) reported no difference between the self-esteem and life satisfaction scores according to gender.[32] In another study, males were shown to have higher life satisfaction and self-esteem scores than females.[33] Although, there is no relationship between gender and self-esteem in this study, there has been debate regarding the findings of a literature review that examined gender variations in self-esteem.[34] It is well-established that there is a two-way relationship between marital status and self-esteem which affects social life.[35] According to marital status, there was no statistically significant difference between self-esteem and life satisfaction scores. While there was no difference between the self-esteem scores according to education level, the high school graduates had higher life satisfaction than the undergraduates and graduates. The non-smokers (P=0.036) had higher life satisfaction than smokers or who quit smoking and non-alcoholics (P=0.000) had higher life satisfaction than the other groups who consume alcohol or quit consuming. The self-esteem of those who don't smoke was higher than the non-smokers or who quit smoking. These outcomes alligned with the research conducted by Tesler et al. (2018), which's findings consistent with their intervention study.[36] Accordingly, alcohol and cigarette consumption decreased, and life satisfaction increased in individuals who were intervened with to reduce risky behaviors. There was statistically significant difference between

Table 2. Distribution of information about the disease and surgical history				
Variables	**Yes**		**No**	
	N	**%**	**N**	**%**
Chronic diseases				
Arthritis	243	97.2	7	2.8
Sleep apnea	242	96.8	8	3.2
Asthma	207	82.8	43	17.2
Cardiovascular disease	190	76.0	60	24.0
Gastro-esophageal reflux disease	198	79.2	52	20.8
Venous stasis disease	106	42.4	144	57.6
Hypertension	93	37.2	157	62.8
Non-alcoholic steatohepatitis	77	30.8	173	69.2
Urinary incontinence	32	12.8	218	87.2
Diabetes	27	10.8	223	89.2
Pickwick syndrome	21	8.4	229	90.4
Obesity-hypoventilation syndrome	1	0.4	249	99.6
	Agree		**Disagree**	
	N	**%**	**N**	**%**
Reasons leading to surgery				
Worrying about body weight-related health problems	247	98.8	3	1.2
Dissatisfaction with physical appearance	249	99.6	1	0.4
Thinking that surgery will be good for health	247	98.8	3	1.2
Pre-surgical weight loss applications				
Having a diet before surgery	246	98.4	4	1.6
Getting professional support for diet therapy	227	90.8	23	9.2
Taking medication with doctor's advice	197	78.8	53	21.2
Weight loss with exercise alone	179	71.6	71	28.4
Exercising with diet	146	58.4	104	41.6
Expectations for surgery				
Surgery enables weight loss without exercise	57	22.8	193	77.2
Surgery enables weight loss without diet	56	22.4	194	77.6
It is impossible to lose weight with surgery	248	99.2	2	0.8
If I do not follow a diet plan after surgery, I will return to my pre-surgery weight.	249	99.6	1	0.4
Data are given as numbers (N) and percentage (%).				

the self-esteem and life satisfaction scores according to employment status and social security categories.

Evaluating chronic diseases of the individuals almost all of the participants had arthritis, sleep apnea, asthma, and cardiovascular disease; and almost half of them had gastroesophageal reflux disease, venous stasis disease, and hypertension. The prevalence of chronic diseases increases with obesity and people with obesity are at risk for these diseases.[37,38] Accordingly, the high prevalence of chronic diseases determined according to the study's results was consistent with the literature. Individuals with a BMI of >35 kg/m^2 must have at least one of these diseases to be candidates for bariatric surgery (Table 2).[39] A total

Table 3. Distribution of body weight stigma related issues in the patients before surgery				
Variables	**Agree**		**Disagree**	
	N	**%**	**N**	**%**
Individual attitudes				
Fear of health problems	246	98.4	4	1.6
Feeling guilty about their weight	187	74.8	63	25.2
Education and working life				
Experiencing difficulties in physical environments (classrooms and offices etc)	248	99.2	2	0.8
Experiencing exclusion or discrimination at school or work	247	98.8	3	1.2
Difficulty in communicating at work or school outside of recruitment				
Experiencing the negative impact of weight on issues (applying for a job, promotion, workload or assigning important tasks etc)	246	98.4	4	1.6
Experiencing unfortunate and demoralizing situations in their education life	246	98.4	4	1.6
Attitudes of healthcare providers				
Inability to benefit from health services	77	30.8	173	69.2
Encountering negative attitudes	71	28.4	179	71.6
Not receiving medical support due to the attitude of healthcare professionals	29	11.6	221	88.4
Social environment attitude				
Benefiting from opportunities designed for people with obesity in daily life	182	72.8	68	27.2
Feeling insecure about the opinions of others	248	99.2	2	0.8
Being blamed by people for of weight problems	248	99.2	2	0.8
Calling others in different ways due to their weight other than their name	243	97.2	7	2.8
Not being invited to social environments	246	98.4	4	1.6
Having problems at the gyms while exercising	211	84.4	39	15.6
Embarrassment of being around others because of weight issues	243	97.2	7	2.8
Having problems in family and friend relationships	244	97.6	6	2.4
Data are given as numbers (N) and percentage (%).				

Table 4. Distribution of life satisfaction and self-esteem scores according to BMI				
BMI	**Self-esteem**		**Life satisfaction**	
	IQR	**Median(Min-Max)**	**IQR**	**Median (Min-Max)**
Normal	0	4.00 (0-5)[a]	4	16.00 (7-20)
Overweight	1	4.00 (2-5)[b]	3	16.50 (6-20)
Obese	1	4.00 (2-4)[ab]	3	17.00 (5-21)
p		0.012*		0.879
*p<0.05, IQR: Interquartile Range Data are given as IQR, median (minimum-maximum). The difference between the groups was evaluated with the Kruskal Wallis test. a-b: There is no difference between groups with letters in the same column				

of 99.6% of the individuals declared that they did not experience any post-operative body weight gain. Odom et al. (2010) and King et al. (2020), draw attention for the weight regain after bariatric surgery, which poses a risk in terms of comorbidities.[40,41] They pointed to the weight stigma, apart from metabolic complications, after surgery. Accordingly, individuals who had metabolic surgery or weight loss endure self-stigma in the form of internalized weight bias and stigmatizing due to the remarks from family, friends, and healthcare professionals.[42] In another study,

Table 5. Linear regression model for prediction of life satisfaction scale

	Coefficients B	Std error	STD B	p	R	R2	F
Self-esteem score	1.152	0.236	0.355	0.000	0.251	0.266	17.648
BMI (kg/m^2)	-0.31	0.610	-0.32	0.605			
Weight loss (kg)	-0.34	0.005	-0.415	0.000			

Dependent: Life satisfaction, Predictors: (Constant), Age (years), Self-esteem score, duration after surgery (years), Body weight loss (kg). Adjusted: Age and duration after surgery

participants (n= 5, 33-59 years and n=15, 63-72 years) who have undergone bariatric surgery and the resulting body transformations reported being judged for choosing an "easy way out" to lose weight.[43] The follow-up of the patient's body weight is crucial in terms of self-esteem, life satisfaction, and a sense of stigma, even if the recovery of the body weight loss was not shown in this study. Participants in the study expressed strong agreement with the factors that led to the stigma they faced prior to surgery. These factors fell into four categories: personal attitudes, education and career, attitudes of healthcare providers, and attitudes of the social environment This indicates that individuals in society are highly exposed to the feeling of stigma. Self-esteem and life satisfaction scores, which were questioned about regarding the post-operative condition of the individuals, indicate the change in the general well-being of the individuals. Raves et al. (2016) reported that weight loss has an impact on stigma and patients who had bariatric surgery may also experience the feeling of stigma by health professionals, which worsens post-operative dietary behavior.[44] In this study, 11.6% of the participants declared that they gave up receiving medical support due to the "attitude of healthcare professionals" was. These findings imply that people should also consider these factors that influence their decision to have bariatric surgery. According to the Himmelstein et al. (2022) there are still a number of questions regarding patient care after bariatric surgery including how weight bias may affect the decision to seek follow-up care and whether or not patients who undergo bariatric surgery adhere to their expectation of less stigmatizing healthcare encounters.[42] These results and inferences suggest that healthcare professionals should be informed about stigma.

The general well-being of individuals with obesity is impacted by the interaction between life satisfaction and self-esteem.[30] According to a study with a large cohort (n=1,465,219) life satisfaction was lower in individuals with obesity and slightly overweight. It is also known that low self-esteem is associated with body weight.[45] After classifying the individuals in this study according to their self-esteem, those with high self-esteem had higher life satisfaction. In the regression model, self-esteem was found as a determinant of life satisfaction. Li et al. (2012) similarly found a correlation, but in a different population, between life satisfaction and self-esteem in university students.[46] The present study results were consistent with the literature.

This study has some strengths and limitations. First, stigma is a critical issue, and this is the first study on stigma in a specific group in Türkiye. Secondly, a high sample number has been reached in a particular sample. Our limitation is that we included only people who have sleeve gastrectomy history. Another limitation is we evaluated stigma and some questions from some studies' results, so this measurement is not a validated tool.

CONCLUSION

The results of this study provide essential data on pre-surgery stigma, post-surgical self-esteem, and life satisfaction in individuals undergoing bariatric surgery. Based on available data, it is recommended that in addition to lifestyle interventions such as modifying dietary habits to treat obesity, strategies to lessen stigma should be developed, society should be made aware of the causes of obesity, and a thorough investigation of the sociological factors that lead people to bariatric surgery should be conducted. It is necessary to perform follow-up studies on this subject, that span the time before and after bariatric surgery.

Ethical approval: The study was approved by the Ethics Committee of Ondokuz Mayıs University (Number: B.30.2.ODM.0.20.08./829).

Informed consent: A written conset was obtained by acceptin to answer the online form.

Author contributions: Concept – Z.U.,M.S.M.Ç.,N.C.U.; Design – Z.U.,M.S.M.Ç.,N.C.U.; Supervision – Z.U.,M.S.M.Ç.,N.C.U.; Resources – Z.U.,M.S.M.Ç.,N.C.U.; Materials – Z.U.,M.S.M.Ç.,N.C.U.; Data Collection and/or Processing – Z.U.,M.S.M.Ç.,N.C.U.; Analysis and/ or Interpretation – Z.U.,M.S.M.Ç.,N.C.U.; Literature Search – Z.U.,M.S.M.Ç.,N.C.U.; Writing

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Evaluation of the effect of parenteral nutrition on mortality and morbidity in hospitalized patients with non-variceal upper gastrointestinal bleeding

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ABSTRACT

Objective: Nutritional support products should preferably be administered orally whenever possible, with rare exceptions, one of which is gastrointestinal bleeding. In our study, we examined the effects of parenteral nutrition support, which we have recently introduced in the treatment of patients with gastrointestinal bleeding, on the hospitalization duration and mortality-morbidity of these patients.

Methods: We analyzed the patients admitted to the Internal Medicine Service with non-variceal upper gastrointestinal bleeding in our study. Patients were retrospectively analyzed in two groups, based on the years in which total parenteral nutrition (TPN) was initiated (2016-2017) and not initiated (2012-2013). Hospitalization durations and discharge methods were compared between the two groups.

Results: Our study included a total of 369 cases after screening and application of our exclusion criteria. 35.5% of these cases received TPN, while 64.5% did not. When evaluated based on the TPN administration status after stabilizing the Rockall score of the patients, as well as considering the need for erythrocyte suspension (ES), fresh frozen plasma (FFP) replacement, and length of hospital stay, the length of hospital stay was significantly longer in those receiving TPN compared to those who did not.

Conclusion: Although TPN may be the preferred choice in patients with upper gastrointestinal bleeding for whom oral nutrition is not suitable, our study suggests that this preference not only does not lead to a reduction in the number of blood and blood product replacements but also prolongs the hospital stay. While it is believed that complications of nutritional support with TPN may contribute to this result, our retrospective study did not provide data on this. Comprehensive prospective studies are needed on this issue.

Keywords: Parenteral nutrition, non-variceal upper gastrointestinal bleeding, mortality

INTRODUCTION

Upper gastrointestinal (GI) bleeding is defined as bleeding into the lumen from any region between the upper sphincter of the esophagus and the ligament of Treitz.[1] Gastrointestinal bleeding is a clinically significant condition characterized by high mortality, high diagnostic and treatment costs, often requiring hospitalization, and sometimes intensive care, requiring multidisciplinary management.

Approximately 80% of upper GI bleeding stops spontaneously and requires only supportive treatment.[2] The remaining 20% is severe and refractory enough to be stopped with medical and surgical treatment. Thirty percent of patients with upper GI bleeding experience recurrent bleeding within the first 48 hours after hospital admission, and the risk of recurrence increases with the severity of the initial bleeding.

Various scoring systems have been used in studies of

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upper GI bleeding to assess risk and prognosis. These scoring systems are generally based on medical history and physical examination. The Rockall score is a system based on five variables designed to predict the risk of rebleeding and mortality. The Rockall Scoring System (RS) evaluates age, shock symptoms, accompanying diseases, endoscopic diagnosis, and the course of the last bleeding.[3] Blatchford and colleagues, in their study, aimed to detect early the risk of re-bleeding and mortality by evaluating factors such as blood urea level on admission, Hb level, heart rate, systolic blood pressure, the presence of syncope or melena, chronic liver disease, and heart failure. This scoring system, which is called the Glasgow Blatchford Score (GBS), is considered a system that can guide clinical practice in patients with upper GI bleeding.[4]

Studies comparing the two methods revealed that the GBS is just as good as, if not more than, the RS at predicting death from gastrointestinal bleeding.[5] The GBS has been found to be more accurate in predicting the need for endoscopic or surgical procedures as well as transfusions.[6]

In this disease, which requires close monitoring, nutritional assessment is necessary in addition to treatment. While nutritional support products should preferably be administered orally, one of the rare exceptions is gastrointestinal bleeding. Nutrition support provided intravenously is called parenteral nutrition.[7,8] However, there are insufficient data on how parenteral nutrition affects the prognosis and mortality of these patients.

In patients whose oral feeding is compromised, parenteral nutrition support is considered an indication.[7,8] In our hospital, total parenteral nutrition (TPN) has been implemented in the treatment of patients with non-variceal upper gastrointestinal bleeding in recent years, whereas intravenous glucose infusion was applied in previous years. This study will retrospectively examine the effects of parenteral nutrition support, which we have started to implement in these patients in recent years, on the hospitalization duration and mortality-morbidity of the patients.

Main Points

- A total of 369 patients with non-variceal upper gastrointestinal bleeding were included in the study, with 131 of the cases recieving total parenteral nutrition and 238 of the cases not recieving it.
- Total parenteral nutrition usage did not lead to a decrease in the number of blood and blood product replacements or in mortality.
- Total parenteral nutrition recieving group ended up having prolonged hospital stay.

MATERIAL AND METHOD

This study was conducted by retrospectively reviewing the files of patients admitted to the Internal Medicine Clinic of Health Sciences University, Umraniye Training and Research Hospital, between 2012-2013 and 2016-2017, due to non-variceal upper gastrointestinal bleeding. The study protocol was approved by the Ethics Committee of Health Sciences University with approval number 48865165-302.14.01.

A total of 369 patients were included in the study, with 131 cases receiving TPN and 238 cases not receiving TPN. Patients with gastrointestinal malignancies, variceal bleeding, or bleeding related to portal hypertension were excluded from the study. Patients who did not undergo gastroscopy were not included in the study. Patients with comorbidities such as chronic kidney disease and congestive heart failure were included in the study.

Patient records were examined for age, gender, comorbidities, hospital admission and discharge laboratory findings, endoscopic findings, examination findings, treatments, discharge methods, and the number of blood and blood product replacements. Patient records were scanned, Rockall and Glasgow-Blatchford scores were calculated based on clinical and endoscopic findings, and Forrest classification was performed. The Rockall scoring system is shown in Table 1, the Blatchford scoring system is shown in Table 2, and the Forrest classification is also presented.

Forrest Classification

1a: Active bleeding in a gushing fashion.

1b: Active bleeding in the form of leakage.

2a: Visible vein that cannot bleed.

2b: Adherent clot.

2c: Flat pigmented lesion.

3: Clean-bottomed ulcer.

Statistical Analysis

The data were analyzed using the Statistical Package for Social Sciences (SPSS) version 21 for Mac (SPSS Inc., Chicago, IL, USA). Descriptive statistics are presented as numbers and percentages for categorical variables, and mean, standard deviation, and median for numerical variables. Homogeneity was assessed using Levene's test, and $p > 0.05$ was considered indicative of homogeneity. The distribution of continuous variables was assessed using the Kolmogorov-Smirnov normality test ($p > 0.05$)

Table 1. Rockall risk scoring system		
Variables		**Score**
A. Age	≥ 80	2
	60-79	1
	< 60	0
B.Shock	Hypotension, systolic blood pressure < 100 mmHg	2
	Tachycardia, systolic blood pressure ≥ 100 mmHg and pulse > 100 beats/min	1
	No shock, systolic blood pressure ≥ 100 mmHg and pulse < 100 beats/min	0
C. Concomitant disease	Renal failure, liver failure, metastatic cancer	3
	Heart failure, ischemic heart disease, other major comorbidity	2
	No major comorbidities	0
D. Endoscopic diagnosis	Upper gastrointestinal cancer	2
	Peptic ulcer, erosive disease, esophagitis	1
	No lesion, Mallory Weiss tear	0
E. Endoscopic finding of new bleeding	Ulcer with clear base, flat pigmented spot	0
	Blood in the upper GI tract, active bleeding, visible vein, clot	2

Table 2. Glasgow-Blatchford risk scoring		
Parameters	**Values**	**Score**
Urea	>6,5 <8,0	2
	>8,0 <10,0	4
	>10,0 <25	4
	>25,0	6
Hemoglobin	>12 <13	1
Male	>10 <12	3
	<10	6
Female	>10 <12	1
	10>	6
Systolic blood pressure	100-109	1
	90-99	2
	<90	3
Other markers		
Pulse(minutes)	>100	1
Presentation with melena		1
Presentation with syncope		2
Liver disease		2
Cardiac failure		2

or skewness and kurtosis test, and acceptance as normal distribution was within ±1.5.

For pairwise independent group comparisons of numerical variables, the Independent T-Test was used when the assumption of normal distribution was met, and the Mann-Whitney U Test was used when the assumption was not met. The Wilcoxon Test was used for numerical variables in paired dependent cases. After fixing the Rockall value, recalculation was performed using the ANCOVA test. For categorical variables, Pearson's chi-square ($\chi 2$) or Fisher's chi-square test was used for multiple and pairwise group comparisons when the chi-square condition was met. The statistical significance level was set at a 95% confidence interval, with a p-value of less than 0.05.

RESULTS

In the retrospective analysis, all patients underwent esophagogastroduodenoscopy and the etiology of gastrointestinal bleeding was not identified in 20.6% of patients. Among the patients, 34.7% had no history of medication use, while 65.3% were on medication. Nonsteroidal anti-inflammatory drugs (NSAIDs) were identified as the etiological agents in 23.6% of the patients, acetylsalicylic acid (ASA) in 14.4%, smoking in 13.6%, warfarin in 10.6%, clopidogrel in 2.7%, and new oral anticoagulant drugs (NACs) in 2.2%. Furthermore, 12.2% of the patients had concomitant use of more than one drug that could contribute to the etiology.

In terms of age, the mean age was 56.8 years in the non-TPN and 60.3 years in the TPN- group, with no statistically significant difference between the groups.

Regarding gender distribution, 33.3% of the cases were female, and 66.7% were male, with no statistically significant difference between the groups.

Smoking status showed that 77.5% of the patients were non-smokers, and 22.5% were smokers, with no statistically significant difference between the TPN and non-TPN groups.

Among the patients, 48.8% had no chronic disease, 13% had one additional chronic disease, and 38.2% had two or more chronic diseases. The non-TPN group had a higher rate of patients with no chronic disease, which was statistically significant ($p<0.05$). In contrast, the TPN-receiving group had a higher rate of patients with two or more chronic diseases, which was also statistically significant ($p<0.05$). However, there was no statistically significant difference between TPN receipt status and the presence of one chronic disease, no chronic disease, or two or more chronic diseases ($p>0.05$).

According to the Rockall risk stratification system, 39.3% of the cases were classified as low risk, 60.2% as medium risk, and 0.5% as high risk. When comparing the groups according to the Rockall risk stratification system, 47.5% of those not receiving TPN were low risk, 52.1% were medium risk, and 0.4% were high risk. Among those receiving TPN, 24.4% were low risk, 74.8% were medium risk, and 0.8% were high risk. In TPN recipients, the ratio of medium risk to low risk was higher compared to non-recipients, and this ratio was statistically significant ($p<0.05$). There was no statistically significant difference between high-risk and low or medium-risk groups ($p>0.05$) (Table 3).

Evaluation of Groups According to the Forrest Classification System

According to the Forrest classification system, 0.8% had negative ulcers, 30.4% had erythematous pangastritis, 32.3% had Forrest 3, 10.3% had Forrest 2C, 10% had Forrest 2B, 6.7% had Forrest 2A, 7.8% had Forrest 1B, and 1.7% had Forrest 1A. Mallory-Weiss syndrome was present only in the non-TPN group with 10 cases. When evaluated according to the Forrest classification system, no statistically significant difference was observed between the groups ($p>0.05$).

Of the cases, 95.1% were discharged, 0.5% had fatal outcomes, and 4.3% were transferred to the intensive care unit. When evaluating the groups based on discharge, fatal outcome, and intensive care unit admission status, 97.1% of those not given TPN were discharged, 0.4% had fatal outcomes, and 2.5% were admitted to the intensive care unit. Among TPN recipients, 91.6% were discharged, 0.8% had fatal outcomes, and 7.6% were admitted to the intensive care unit. There was no statistically significant difference in the mode of discharge based on TPN status ($p>0.05$) (Table 4).

The mean Rockall score and Glasgow-Blatchford scores were higher in TPN recipients compared to non-TPN recipients, and this difference was statistically significant ($p<0.05$) (Table 5).

When evaluating the length of stay, TPN recipients had a longer stay compared to non-TPN recipients, and this difference was statistically significant ($p<0.05$). There was no statistically significant difference between TPN recipients and non-TPN recipients in terms of ES and FFP replacement needs ($p>0.05$) (Table 6).

DISCUSSION

In this study, a retrospective analysis of a patient group consisting of 369 individuals with a diagnosis of non-variceal upper gastrointestinal bleeding was conducted. The files of patients admitted with this diagnosis were thoroughly examined to determine whether there is a

Table 3. Evaluation of groups according to Rockall scoring system

		TPN		
Rockall	**Total**	**Not received**	**Received**	**P**
Low Risk	39,3% (145)	47,5% (113)	24,4% (32)	0,0001
Medium Risk	60,2% (222)	52,1% (124)	74,8% (98)	
High Risk	0,5% (2)	0,4% (1)	0,8% (1)	>0,05
Chi-square test				

Table 4. Evaluation of groups according to the mode of exit of patients

		TPN		
Output Type	**Total**	**Not received**	**Received**	**p**
Discharge	95,1% (351)	97,1% (231)	91,6% (120)	0,063
Exitus	0,5% (2)	0,4% (1)	0,8% (1)	
Intensive Care Unit	4,3% (16)	2,5% (6)	7,6% (10)	
Total	100% (369)	64,5% (238)	35,5% (131)	
Chi-square test				

Table 5. Evaluation of groups according to Rockall and Glasgow-Blathcford scores			
	TPN		
	Not received	Received	
Parameters	Mean ± SD	Mean ± SD	p
Rockall	2,62±2,02	3,77±2,04	0.000
Glasgow Blathcford	10,23±3,59	11,32±3,68	0.006
Independent T Test			

Table 6. Evaluation according to TPN receipt status after fixing rockall score, blood and blood products replacement need, and length of stay				
		TPN		
		MEAN±SD		
Parameters	Number (n:463)	Not received	Received	p
ES Requirement	238/131	1,96±0,1	2,25±0,13	0,098
FFP Requirement		0,32±0,06	0,46±0,08	0,184
Length of Hospitalization Days		4,96±0,20	6,59±0,27	0,0001
ANCOVA Test				

difference in mortality and morbidity between cases treated with TPN (patients from 2012 to 2013) and those not treated (patients from 2016 to 2017).

The retrospective nature of the study is a limitation due to the potential information gaps in the records, and this should be considered when interpreting the findings. Additionally, being a high-volume tertiary research hospital may have affected the data on blood and blood product replacements, especially since most patients being treated in the emergency department before admission. This is also a point that needs to be taken into account.

As no tests were performed to assess the nutritional status of patients, our inability to provide an evaluation on this aspect in the discussion is another limitation of our study due to its retrospective nature.

Rapid assessment and management of patients with upper GI bleeding is critical. Intravenous fluids, along with red blood cell transfusion at a hemoglobin threshold of 70–80 g/L are advised for all patients with GI bleeding. Proton pump inhibitors (PPIs) should be given at the start of resuscitation. After resuscitation, endoscopy should be performed within 24 hours, albeit in high-risk patients, such as those with hemodynamic instability, although early endoscopy may be considered. Significant reductions in rebleeding rates, blood transfusion needs, length of hospital stay, surgical times, and mortality are achieved through endoscopic hemostasis.[9]

Following endoscopic treatment, patients at a high risk of rebleeding should be kept nil and admitted to the hospital for a minimum of 72 hours. Within 72 hours, the majority of high-risk lesions turn into low-risk lesions, and most rebleeding happens during this period.[10] It is also recommended to start EN early as it does not associated with higher rebleeding and mortality compared to delayed EN in patients with GI bleeding, but decreases the length of hospital stay. Early EN should be recommended as the preferred nutrition routine in patients at low risk of rebleeding.[11]

For many years, PN was prescribed only to individuals who cannot handle the severe side effects of EN, namely abrupt hyperglycemia and infectious problems. Its application has expanded due to the availability of an all-in-one PN admixture and the optimization of substrate composition, especially lipid emulsions. Comparable complications rates with EN and PN nutrition therapy have been reported in recent studies. As a result, in addition to total GI failure, other issues including inadequate EN, malabsorption, or certain needs that cannot be met with EN feeds are now included in the list of indications for PN.[8]

For patients, for whom oral nutrition is unavailable, parenteral nutrition support is considered a definite indication.[7] ESPEN guidelines on enteral nutrition (EN) state that inadequate nutrient supply will result in inadequate nutrition within 8-12 days after admission to surgical and/or intensive care units. To prevent inadequate

nutrition and associated side effects, EN should be given to all ICU patients who are not expected to complete a full oral diet within three days. For all patients whose normal nutrition is not expected within three days, PN should be given within 24-48 hours if EN is contraindicated or if they cannot tolerate it.

When PN was initially introduced, its primary ingredient was glucose.[12] As safer and less inflammatory lipid emulsions were developed, the carbohydrate content, and consequently, the frequency of hyperglycemia of the formulas decreased. By limiting glucose variability, reducing hypoglycemic events, controlling absolute blood glucose concentrations, or prolonging the duration in a normal range, total parenteral nutrition improves glucose control.[13] Observational studies in recent years have also demonstrated the benefits of high protein delivery to intensive care patients. Nicolo et al. discovered that achieving more than 80% of desired protein intake reduced mortality and length of stay.[14] Zusman et al. conducted a retrospective observational study on critically ill patients and discovered a linear relationship between protein intake and decreased mortality, with a 1% reduction in mortality for each gram of protein consumed.[15]

In line with these recommendations, our hypothesis was concluded that the application of TPN instead of intravenous glucose infusion in patients with upper GI bleeding may be a practice that reduces mortality and morbidity, and shortens the hospital stay through nutrition.

The only difference in the treatment process of patients hospitalized with non-variceal upper gastrointestinal bleeding at our hospital between 2012-2013 and 2016-2017 was that, starting in 2015, we began administering total parenteral nutrition at a daily rate of 25-30 kcal/kg instead of a daily 75-gram/day intravenous glucose infusion.

In our study, 95.1% of cases were discharged, 0.5% had fatal outcomes, and 4.3% were transferred to the intensive care unit. When the groups were evaluated based on discharge, fatal outcomes, and intensive care unit admission status, no statistically significant difference was observed in the mode of discharge between the groups.

When the TPN and non-TPN groups were compared based on the Forrest classification, no statistically significant difference was observed, although TPN recipients had a statistically significantly higher average score according to the Rockall and Glasgow-Blatchford scoring systems. It was thought that this result was reached as a result of including all patients admitted with a diagnosis of non-variceal upper gastrointestinal bleeding, excluding those with gastrointestinal malignancy, in our retrospective study. In line with this result, covariance analysis (ANCOVA) was applied to control the pre-test Rockall scoring to compare length of hospital stay, discharge modalities, and blood product replacement needs.

When evaluated based on TPN receipt status after fixing the Rockall score, ES, TDP replacement need, and length of stay, the length of hospital stay was higher in TPN recipients compared to non-recipients, and this difference was statistically significant. There was no statistically significant difference between TPN recipients and non-recipients in terms of ES and FFP replacement needs. Contrary to our hypothesis that TPN application would have a positive effect on mortality, we found a result that did not support this, and we also observed a prolonged hospitalization, contrary to our hypothesis that it would decrease.

PN-associated complications may be categorized as metabolic, infectious, and mechanical. It can cause hyperglycemia, hypertriglyceridemia, electrolyte imbalances particularly phosphorus and potassium, hepatobiliary complications, and infectious complications.[16] It is believed that the longer length of stay in the TPN group is due to TPN complications, although our retrospective study could not obtain data to support this. Multicenter prospective studies in the future may provide more information on the subject.

CONCLUSION

In cases where oral nutrition is inappropriate in patients with upper gastrointestinal bleeding, TPN can be the first line choice instead of intravenous glucose support. In line with the studies conducted, our study, based on the hypothesis that TPN application may be a practice that reduces mortality and morbidity in patients with upper GI bleeding and shortens length of stay through nutritional support, found that this preference not only did not lead to a decrease in the number of blood and blood product replacements or in mortality, but also resulted in prolonged hospital stay in our group of patients receiving TPN.

This result is thought to be due to complications of nutritional support with TPN, although our retrospective study could not obtain data to support this. Conducting multicenter prospective studies on the subject would be beneficial."

Ethical approval: The study was approved by the Ethics Committee of Health Sciences University (Number: 48865165-302.14.01).

Informed consent: Written informed consent was obtained from all patients who participated in this study.

Author contributions: Concept – O.K.; Design – O.K.; Supervision – S.B.; Materials – O.K.; Data Collection and/or Processing – O.K.; Analysis and/or Interpretation – M.T., S.B.; Literature Search – M.T., S.B.; Writing Manuscript – M.T.; Critical Review – S.B.

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Complications of pediatric enteral nutrition at home: a systematic review of quantitative research

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ABSTRACT

Objective: Identifying complications related to enteral nutrition at home in children is important in terms of establishing standard discharge education and training programs to support parents in managing complications. The study aimed to synthesize current evidence on the complications of pediatric enteral nutrition at home.

Methods: The study was conducted according to PRISMA recommendations. Eight databases were reviewed between 2012 and 2022 in Turkish, German, and English languages. Articles were assessed in three stages: title, abstract, and full text. The review included 18 studies that met all the inclusion criteria. The Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instruments were used to assess the quality appraisal of the studies.

Results: A total of 18 studies with 19,531 children were included from 14 countries. The outcome measures were major and minor complications with pediatric enteral nutrition at home. 11 of the 18 papers included were retrospective studies on complications of PEG. In studies reporting the overall rate of major complications ranged from 0% to 14.3%, and the most common complications were reoperation (2.64%-12.4%), and gastrocolic fistula/perforation (0.9%-3.8%). In studies reporting the overall rate of minor complications, the rate ranged from 16.4%-73.6% and the most common complications were infection (8.2%-31.9%), dislodgement (1.6%-21%), skin granulation (4%-50.4%), and vomiting (1%-49.89%).

Conclusion: This systematic review reveals that the rate of complications in pediatric enteral nutrition at home cannot be underestimated. Healthcare providers should plan their practice considering these complications to support parents in managing complications of pediatric enteral nutrition at home.

Keywords: Complications, home enteral nutrition, enteral feeding, children

INTRODUCTION

Sufficient energy and critical nutrients are required for optimal growth and development in children.[1] In addition, nutrition has a pivotal role in the prevention of several diseases.[1-3] However, it is estimated that 25% of children have some degree of nutritional deficiency, with 3%-10% having severe feeding problems.[4-6] In a study of 39,674 children in the United States, gastrointestinal diseases were the primary cause of nutritional issues in children, with malnutrition, developmental and behavioral conditions, as well as neurological impairments constituting additional contributing factors.[4] Oral feeding is considered the optimal method for providing nutrition. Nevertheless, in cases where the gastrointestinal system is operational but oral energy and nutritional requirements cannot be adequately met, Enteral Nutrition (EN) is employed. The European Society for Pediatric Gastroenterology Hepatology and Nutrition (ESPGHAN) defines EN as the delivery of medical nutritional products into the stomach, duodenum, or jejunum through oral means, an intermediate tube, or an artificial opening.[7] While the Feeding Tube Awareness Foundation highlights various conditions necessitating enteral feeding in children, the

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predominant indication for EN is neurological disorders that compromise essential functions such as sucking, swallowing, and chewing. Common symptoms in children requiring EN include insufficient oral nutrient intake, developmental delays, challenges with absorption and digestion, increased nutritional requirements, and nutrient loss.[8]

The European Society for Clinical Nutrition and Metabolism (ESPEN) practical guideline recommends that patients who require home enteral nutrition (HEN) for a short period of time (up to 4-6 weeks) can receive it through a nasal feeding tube.[9] The ESPGHAN position paper recommends percutaneous endoscopic gastrostomy (PEG) when non-oral nutritional supplementation is expected to be required for more than 3-6 weeks or when trans-nasal tube feeding is unsafe.[10] Research has indicated that HEN support following discharge can effectively preserve or even increase body weight and nutritional parameters. Additionally, there is a notable improvement in the quality of skeletal muscle mass within the body composition.[11]

With growing recognition of the significance and advantages of enteral nutrition (EN), its administration has become increasingly important. Although it is commonly used and has many advantages, minor and major complications may occur in the early and late stages.[12,13] It has been reported that admissions to the pediatric emergency unit for minor complications are common, particularly throughout the EN process.[14,15] It has been stated that the caregivers who received treatment from the pediatric emergency department for complications were different, and they were unable to receive professional support.[16,17] According to the literature, parents with EN experience complications at home care and are unsuccessful in managing complications.[17-19] In this context, identifying the complications experienced by caregivers and patients due to EN is critical for planning care and discharge education. It is thought that the identification of currently prevalent complications of in EN would shed light on future planning and promote the sustainability of supportive care for EN at home. Nurses have a primary role in providing and maintaining EN support. In conclusion, identification of common complications may help to identify the needs of children and parents as well as to develop appropriate nursing care interventions and discharge education. In addition, there is no systematic review in the literature examining the studies on complications experienced in children with HEN. Therefore, this systematic review aimed to synthesize the current evidence on complications of pediatric enteral nutrition at home.

Main Points

- The most common major complication in pediatric enteral nutrition at home is reoperation related to enteral tubes.
- The most common minor complications reported were skin infection, leakage, granulation tissue, and vomiting.
- If children with complex care needs are to be cared for safely at home, the provision of services at home must be improved to support families.
- Adequate and accessible allied health services are important to support patients receiving enteral nutrition at home.

Study question

What are the complications of pediatric enteral nutrition at home?

METHODS

Study Design

This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines.[20] It was also reported according to the PRISMA statement[21] and it was registered in the International Prospective Register of Systematic Reviews database (PROSPERO) (Registration no: CRD42022329008).

Eligibility Criteria

The Population, Intervention, Comparison, and Outcome (PICO) framework was used to guide the study selection.[22] It has been emphasized that when structuring a clinical question, all four elements must receive clear and focused elaboration: the patient or problem (P), the intervention or exposure (I), the relevant comparison intervention or exposure (C), if applicable, and the specific clinical outcome of interest (O).[23] The eligibility criteria for this study are explained in Table 1.

The inclusion criteria for this study encompassed both observational and experimental research articles published in English, German, or Turkish language between January 2012 and March 2022. These articles had to focus on the age group of children aged 0 to 18 years and involve home enteral nutrition for a minimum duration of one month.

The study's exclusion criteria encompassed the following: qualitative studies, grey literature sources, studies without accessible full-text, articles published in languages other than English, Deutsch, or Turkish, articles published before January 2012, research focused on oral enteral and parenteral nutrition, hospital nutrition, adults, or animals, conference abstracts, case studies, and literature reviews; all of which were excluded from consideration.

Table 1. Eligibility criteria of the study	
Criteria	**Eligibility**
Population (P)	The systematic review included the studies on child between 0 to 18 years feeding with enteral nutrition. The search strategy included child, children, pediatric and synonyms and related mesh terms. The studies on older children, adults and animal studies were excluded.
Exposure/ Intervention (I/E)	The systematic review included the studies related to difficulties, challenges, problems with home enteral nutrition. The reported problems not directly related to home enteral nutrition will be excluded
Comparison (C)	Not applicable
Outcomes (O)	The main outcome is problems/ challenges/complications of home enteral nutrition. Problems identified by health professionals, primary caregivers, parents, or children were examined.

Categories of Results

The main focus of this study is to evaluate the challenges faced by children who undergo tube insertion and subsequently receive home enteral nutrition. The goal is to offer valuable information that can support nurses in tailoring discharge instructions for parents, particularly in recognizing and dealing with relevant complications in their educational and counseling initiatives. This systematic review integrates data from quantitative studies to fulfill its objectives.

Sources and Search Strategy

To obtain a comprehensive overview of the available literature and to identify the most appropriate keywords, a preliminary scoping search was conducted on the PubMed and CINAHL databases. Following this initial search, both researchers meticulously explored the databases using various keywords and their synonyms to refine the search terms. In this comprehensive systematic review, we thoroughly searched eight electronic databases, including Cochrane, Ovid MEDLINE, CINAHL, PubMed, Scopus, Web of Sciences, ULAKBİM - National Academic Network and Information Center, and the National Thesis Center. Our search encompassed articles published between January 1, 2012, and January 1, 2022, in order to gather a comprehensive body of relevant literature. The search strategy involved screening titles and abstracts using keywords and Medical Subject Headings (MeSH) terms. A summarized version of the search strategy is outlined in Table 2. During the screening process, the following keywords were combined using the Boolean operator 'AND': "children" OR "pediatric", "enteral feeding" OR "enteral nutrition", "problems", "difficulties", "complication", "home enteral nutrition." These searches were conducted in English, German, and Turkish languages. The search string utilized for MEDLINE, PubMed, Scopus, Cochrane, Web of Science, CINAHL, and Ovid MEDLINE is provided in the Supplementary Data section.

Data Management and Screening Process

The process of study selection and data extraction was rigorously and impartially carried out by two reviewers. Each reviewer worked independently and blindly to the other's decisions, while remaining aware of journal titles, study authors, and institutions. To streamline the process, we utilized EndNote version 20.1, a reference management software, to identify and eliminate duplicate citations across the eight databases. In order to maintain data validity and ensure high quality, we employed standardized and predefined data extraction forms. Both reviewers initially evaluated the titles and abstracts of the studies retrieved by the search strategy, adhering to the predefined eligibility criteria. For studies that either met the inclusion criteria or couldn't be definitively

Table 2. Search concepts			
Concept 1	**Concept 2**	**Concept 3**	**Concept 4**
"Child" [Mesh] OR Children OR "Pediatrics" [Mesh] OR Pediatric	Gastrostomy OR "Gastrostomy" [Mesh] OR Gastrostomies OR "Enteral Nutrition" [Mesh] OR Enteral Feeding OR Home enteral nutrition	Gastrostomy OR "Gastrostomy" [Mesh] OR Gastrostomies OR "Enteral Nutrition" [Mesh] OR Enteral Feeding OR Home enteral nutrition	2012 OR 2013 OR 2014 OR 2015 OR 2016 OR 2017 OR 2018 OR 2019 OR 2020 OR 2021 OR 2022
Each concept combined with "AND"			

excluded based on the abstracts alone, full-text reports were obtained and further screened against the inclusion criteria. Subsequently, the findings of both reviewers were compared, and any disparities were resolved through discussion until a consensus was reached. To transparently document and report our screening process, we adopted a PRISMA flowchart to outline the outcomes of these procedures.

Data Extraction

Two authors, RS and HP, independently reviewed the articles against the eligibility criteria and quality assessment tools. The process of article selection is meticulously detailed in Figure 1 of the PRISMA flowchart. Initially, a comprehensive search across eight databases yielded a total of 3,940 articles. After removing 2,217 duplicate articles, we were left with 1,723 unique articles that underwent an initial screening based on their titles and abstracts. Subsequently, 1,700 articles that were unrelated to the study's subject matter were excluded, resulting in 23 full-text articles that were further assessed for relevance by the researchers. After a thorough evaluation, these 23 potential articles were subjected to a quality assessment. Five articles were excluded from the study following the quality assessment due to low quality scores. Ultimately, a total of 18 articles were deemed suitable for inclusion and are presented in this research, as summarized in Table 3.

The protocol for this systematic review, including all planned statistical analyses, was registered in PROSPERO before data collection. This proactive step was taken to prevent data-driven analyses and selective reporting and to ensure that all findings, not just statistically significant ones, are reported. Additionally, we have diligently adhered to all the requirements outlined in the current PRISMA guideline when preparing the publication of this systematic review.

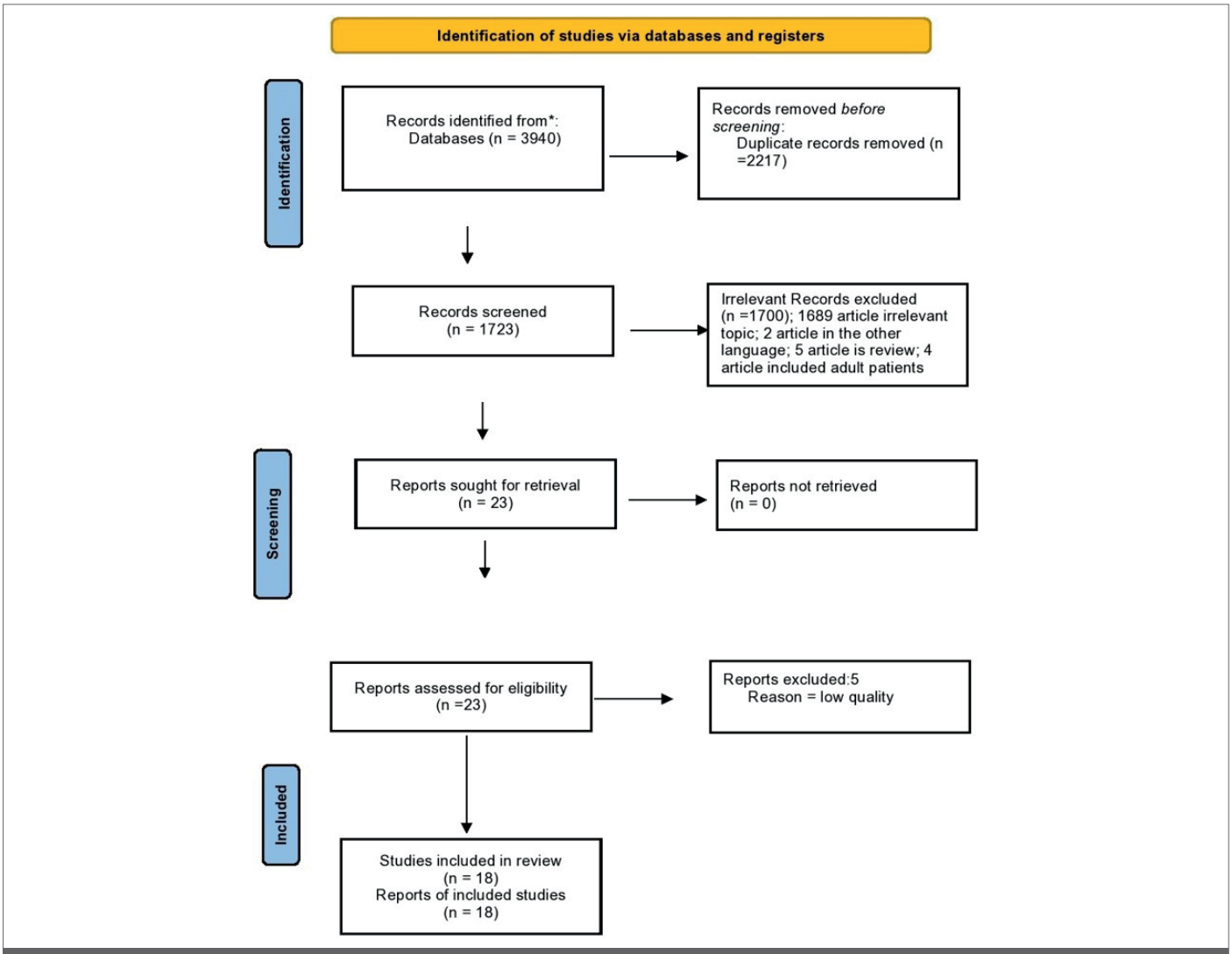

Figure 1. PRISMA flow chart of the research

Table 3. Summary of the included studies

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Landisch et al., 2016, USA	Cross-sectional	183 infants <1 year	Neurologic deficit=25.14% Pulmonary compromise=26.78% Cardiac diagnosis=80.60% Renal insufficiency=8.17% Ventriculoperitoneal shunt=2.20% Peritoneal dialysis catheter=0.57%	PEG and LG	2011–2015	Three months	Major=6.6% Minor= 38.8%	Gastrocolic fistula= 3.8% Reoperation= 12.4% Cellulitis=27.3% Skin granulation=50.4% Pneumonia=7.7% Early tube dislodgement (<6 weeks)=7.6% Late Tube Dislodgement (>6 weeks)=12.4%
Ronning et al., 2017, USA	Retrospective Cohort	161 children 1 months-17 years	Failure to thrive =41.94% Congenital heart disease =9.68% Cystic fibrosis =5.45% Total pancreatectomy auto-islet transplant =9.68% Bone marrow transplant =5.45% Short gut syndrome=12.9% Oesophageal atresia=16.13%	GT and GJT	2007–2012	Not reported	Major=0 Minor= 57.8%	Dislodgement=19.88% Clogging=4.35% Leaking=1.61%
McSweeney et al., 2015, USA	Retrospective Cohort	591 <6 months	Neurologic disorder=45.0% VP shunt=2.9% Metabolic/genetic disorder=27.4% Cardiac disease=18.3% Prematurity=17.9% Cancer=13.0% Oropharyngeal malformations=7.5% Cystic fibrosis=6.8% Other=4.7%	PEG	2006-2010	Not reported	Major= 10.5% Minor= 16.4%	Peritonitis=9.30% Skin granulation=0.33% Perforation=0.33% Pneumoperitoneum=0.17% Infection= 16.24% PEG tube dislodgement= 4.57%
Fascetti-Leon et al., 2012, Italy	Cross-sectional	239 children 10 days–25 years	Neurological impairment=79% Primary myopathy=6.2% Other dysphagia=3.3% Cystic fibrosis=2.5% Metabolic disorders=2% HIV infection=0.8% Miscellaneous=5.8%	PEG	2004-2007	1, 3, 6, 12, and 24 months after the procedure.	Major= 3.3% Minor= 47.7%	Gastrocolic fistula=2.5 % Haemorrhage=0.4% Peritonitis=0.4% Dislodgement=1.6% Granulation= 43.93 Infection=18.5% Leakage=16.8%

PEG: Percutaneous Endoscopic Gastrostomy, LP: Laparoscopic Gastrostomy, GT: Gastrostomy Tube, GJT: Gastrojejunostomy Tube, NG: Nasogastric Tube, LAG=Laparoscopic Gastrostomy, PEG-J: Gastro-Jejunostomy, VAG: Video-Assisted Gastrostomy, ETF: Enteral Tube Feeding

Table 3. Continued

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Işık et al., 2021, Turkey	Cross-sectional	91 children 1 months-18 years	Neurological diseases=76.9% Metabolic diseases=20.9% Cystic fibrosis=2.2%	PEG	2014-2019	6 months to 5 years	Major= 3.3% Minor= 37.4%	Intraabdominal abscess=1.1% Peritonitis=1.1% Buried bumper syndrome=1.1% Over skin granulation=15.4% Tube blockage=6.6% External leakage=6.6% Tube degradation=4.4% Tube dislodgement=4.4%
Pahsini et al., 2016, Austria	Cross-sectional	425 children <18 years	Complicated premature birth =23.1% Congenital malformation Of the heart=12.7% Congenital metabolic disease=2.4% Malformation/disease of the GIT=15.3% Genetic syndromes/ Chromosomal abnormalities=23.5% Failure to thrive=6.8% Neurological conditions=8% Malformation/disease of the respiratory tract=5.4% Oncology and hematology=0.9% Renal problems=1.9%	NG and PEG	2009-2013	Not reported	Not reported	Nausea=14.8% Vomiting=49.89% Retching and gagging=56% Extreme nervous perspiration=7.5% Loss of appetite= 45.2% Local skin granulation tissue=5.2% Skin irritations=1.9% Sweating=7.53% No hunger=45.18%
Krom et al., 2019, Netherlands	Cross-sectional	279 children <17 years	Congenital abnormalities=42% Perinatal problems=38% Neurologic diseases=16% Others=4%	Gastrostomy Nasogastric Duodenal Jejunostomy Jejunal	2010-2014	Not reported	Not reported	Vomiting=36.6% Lack of appetite=28.7% Gagging=28.7% Nausea=26.2% Coughing=18.3% Arching=6.5% Skin irritation=34.5% Fibroma =31.6% Infection=13.0%

PEG: Percutaneous Endoscopic Gastrostomy, LP: Laparoscopic Gastrostomy, GT: Gastrostomy Tube, GJT: Gastrojejunostomy Tube, NG: Nasogastric Tube, LAG=Laparoscopic Gastrostomy, PEG-J: Gastro-Jejunostomy, VAG: Video-Assisted Gastrostomy, ETF: Enteral Tube Feeding

Table 3. Continued

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Hajjat et al., 2017, USA	Retrospective Cohort	43 children <18 years	Neurologic disorder= 58% Genetic/metabolic disorder=26% Cardiac defect=16% Prematurity =14% Eosinophilic esophagitis =5% Chronic lung disease=9% Chronic renal disease=9% Oncology diagnosis=5% Cystic fibrosis=2% Immune deficiency=2% Oral/facial abnormality=7%	low-profile non-balloon GT	-	10 years	Not reported	Dislodgement= 14% Leakage=31% Tube breakdown=11% Bleeding=1%
Franken et al., 2015, Netherlands	Retrospective Cohort	300 patients median age of 2.66 years (IQR 1.28–7.44)	Neurologically impaired=75 % Others=25%	LAG	2004-2011	Median follow-up time was 2.63 years	Major= 2.0% Minor= 73.6%	Postoperative dehiscence of stomach wall=1.3% Intraoperative bleeding=0.3% Postoperative omental herniation=0.3% Skin hyper granulation=44% Stomal infection=24.7% Leakage=24% Dislodgement=21% Obstruction=6.3% Non-closure of gastrostomy site=4% Ectopic gastric mucosa=2.7%
Kidder et al., 2021, USA	Cross-sectional	49 children 1 month and 20 years	Pediatric oncology patients	PEG and PEG-J	2000-2026	6 months	Major= 10% Minor= 28.8%	Cellulitis=24% Buried bumper syndrome=10% Dislodgement=2% Peritonitis=2%
Di Leo et al., 2019, Italy	Cross-sectional	84 children <18 years	Cerebral palsy=66.7% Genetic disorder=15.5% Metabolic or other=10.7% Oesophageal atresia=7.1%	PEG	2003-2017	Not reported	Major= 14.3% Minor=20.2%	Surgical revision=3.6% Occlusion=2.4% Buried bumper syndrome=2.4% Dumping syndrome=5.9% Dislocation=11.9% Granuloma or skin infection=8.3%

PEG: Percutaneous Endoscopic Gastrostomy, LP: Laparoscopic Gastrostomy, GT: Gastrostomy Tube, GJT: Gastrojejunostomy Tube, NG: Nasogastric Tube, LAG=Laparoscopic Gastrostomy, PEG-J: Gastro-Jejunostomy, VAG: Video-Assisted Gastrostomy, ETF: Enteral Tube Feeding

Table 3. Continued

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Khalil et al., 2017, USA	Cross-sectional	322 infants <37 weeks	Prematurity=55.9% Central nervous system=38.1% Cardiovascular system=25.0% Respiratory system=44.0% Gastrointestinal system=40.5% Genetics/metabolic=16.7% Renal=8.3 Other=34.5%	NG and GT	2009-2013	6 months	Major= 6% Minor=Not reported	Inadvertent removal/ misplacement=13.98% Broken/malfunctioning tube=5.28% G-tube site issues=5.59% Infection issues=3.73% Apparent life-threatening event=1.86% Aspiration pneumonia=0.93% Constant fussiness=0.31% Vomiting=0.31% Gastroesophageal reflux=0.31% Gastric outlet obstruction=0.31% Visceral perforation=0.31% Enterocutaneous fistula=0.31%
Mason et al., 2018, Utah	Retrospective Cohort	682 children <18 years	Malnutrition=10.3% Failure to thrive=54.5% Dysphagia=35.2%	GT	2012-2016	Not reported	Major= 8.3% Minor=22%	Tube dislodgment=5.13% Hospital readmission=2.79% Reoperation=2.64% Sch abscess=1.03% Surgical site infection=8.50%
Sakamoto et al., 2021, Japan	Cross-sectional	89 children <16 years	Cerebral damage in the neonatal period or infancy=75.61% Genetic or chromosomal anomaly=12.20% Metabolic disorder=4.88% Adrenoleukodystrophy=6.10% Mitochondrial disease=1.22%	VAG	2006-2015	Over 2 years	Not reported	Skin granulation tissue=38.41% Leakage=15.24% Skin trouble=15.24% Infection=6.09% Vomiting=7.31% Ileus=0.61% Peritonitis=0.61% Dumping syndrome=0.61%

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Table 3. Continued

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Khdair Ahmad et al., 2020, Jordan	Cross-sectional	25 children 1-18 years	Neurological=84% Ventriculo-peritoneal shunt=12% Hematological=44% Genetic/metabolic diseases =24% Respiratory conditions other than Cystic fibrosis =20% Cystic Fibrosis=8% Malignancy=4% Others=8%	PEG	2017-2019	Not reported	Major= 4% Minor=32%	Internal leak and peritonitis=4% Site infections=24% Tube dislodgements=12% Tube degradation=12% Over skin granulation=4%
Hansen et al., 2017, Denmark	Cross-sectional	229 children <16 years	Neurological disorders=49.3% Malformations of the gastrointestinal tract=10.5% Malignancy=19.2% Miscellaneous=17.9% Renal disease=5.2% Cardiac disease=3.9% Short bowel syndrome=2.6% HIV/AIDS=0.4%	PEG	2000-2012	36 months	Not reported	Grade 2, Skin infection=14.4% Infection=11.8% Miscellaneous=5.2% Dislodgement=4.4% Dysfunction of gastrostomy and/or gastrointestinal tract=2.2% Bleeding=1.7% Gastrocolic fistula=0.9% Peritonitis=0.9% Grade 1, Skin infection and/or irritation=31.9% Clogging of tube=3.5% Other=3.5%
Goldin et al., 2016, USA	Retrospective Cohort	15 642 children <18 years	Neurologic only=19.5% Cardiac only =8.3% Respiratory only =6.7% Congenital or genetic only=5.9% Cardiac + congenital or genetic=5.0% Cardiac + respiratory=4.9% Neurologic + congenital or genetic=4.5% Neurologic + cardiac=3.0% Cardiac + respiratory + congenital or genetic=2.8% Malignancy only =2.7%	GT	2010-2012	30 days	Not reported	Infection=27% Mechanical complication=22% Replacement=19%

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Table 3. Continued

Author, Year, Country	Study Type	Sample	Patients' Disease	Type of Enteral Nutrition	Study Period	Duration of Follow Up	Complication	Types of Complication
Wiernicka et al., 2021, Poland	Randomize controlled trial	97 children 1 month to 18 years	Feeding disorders=47% Cerebral palsy=17% Encephalopathy=9% Central nervous system defect=4% Epilepsy=4% Cystic fibrosis=4% Other = 15%	PEG	2015-2016	12 months	Major= 6.1% Minor=32%	Displacement=3.1% Status epilepticus=1% Arrhythmia=1% Death=1% Pneumoperitoneum=1% Bleeding=1% Reddening around stoma canal=10.4% Leakage of gastric contents=6.3% Vomiting=14.6% Nausea=3.1% Regurgitation=5.2% Constipation=1% Infectious complications=8.2%

PEG: Percutaneous Endoscopic Gastrostomy, LP: Laparoscopic Gastrostomy, GT: Gastrostomy Tube, GJT: Gastrojejunostomy Tube, NG: Nasogastric Tube, LAG=Laparoscopic Gastrostomy, PEG-J: Gastro-Jejunostomy, VAG: Video-Assisted Gastrostomy, ETF: Enteral Tube Feeding

For the purpose of quality assessment, we employed the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instruments (JBI–MAStARI), specifically tailored to evaluate randomized controlled trials (RCTs)[24], cross-sectional research[25], and the JBI critical appraisal checklist for cohort studies.[25] The JBI critical appraisal checklist is tailored to the specific type of study being assessed, with variations in the number of questions depending on the study design. It comprises 13 questions for Randomized Controlled Trials (RCTs), while analytical cross-sectional studies involve 8 questions, and cohort studies entail 11 questions. In the case of RCTs, data quality is assessed by assigning one point for each applicable item, allowing for a maximum achievable score of 13. Similarly, analytical cross-sectional studies are scored with one point for each relevant item, resulting in a maximum score of 8. For cohort studies, data quality is appraised by awarding one point for each pertinent item, leading to a maximum possible score of 11. Respondents are required to answer all questions with 'Yes,' 'No,' 'Unclear,' or 'Not Applicable.' To ensure objectivity, two authors, RS and HP, independently evaluate each study and determine a risk of bias grade. The final score for each paper is then calculated as a percentage, with quality ratings falling into three categories: 'good' (80%–100%), 'fair' (50%–79%), and 'low' (< 50%)[26] (Table 4, 5, 6). Five studies were excluded because of the low-quality scores.

Data Synthesis and Analysis

Data collection was conducted by two independent researchers, RS and HP, who utilized a standardized form to compile the following information: 1) author, publication year, and study location; 2) study type; 3) characteristics of the study population; 4) specific medical conditions affecting the patients; 5) the specific type of enteral nutrition employed; 6) study duration and timeline; 7) duration of patient monitoring for complications; and 8) documented complications. Throughout the synthesis process, we utilized data extraction tables and incorporated the PICO framework elements from each study. These tools were employed to categorize and consolidate studies, facilitating the process of data synthesis and the integration of research findings. As part of the data synthesis process, the outcomes of the individual studies were thoroughly scrutinized. Given the diverse array of research types encompassed in this review, a descriptive analysis approach was adopted to effectively summarize the research results. Consequently, the research findings were concisely summarized through the application of descriptive analysis techniques.

Ethical considerations

Ethical approval was not deemed necessary for the conduct of this systematic review.

RESULTS

Study Characteristics

In this systematic review, a total of 18 articles were subjected to detailed examination. These studies were conducted in nine different countries, including the United States of America (USA; n = 8), Denmark (n = 1), Jordan (n = 1), Japan (n = 1), Türkiye (n = 1), the Netherlands (n = 2), Italy (n = 2), Poland (n=1), and Austria (n = 1). The sample sizes of these studies varied, ranging from 25 to 15,642 participants, ultimately encompassing a total of 19,531 children.

Three studies were conducted with infants[27-29] and fifteen studies[12,30-43] were conducted with children and adolescents. One study investigated complications of home enteral nutrition in pediatric oncology patients[30] and other studies investigated children with other diseases.[12,27-29,31-43] Most studies have investigated the complications of home enteral nutrition in children with neurological, genetic/chromosomal, metabolic, systemic, and nutritional disorders.

One study was conducted as an RCT[12], six studies were cohort[28,32,34-37], and 11 studies were cross-sectional.[27,29-31,33,38-43] Seven studies examined complications of PEG, one study examined complications of all enteral tubes[31], one study was related to PEG and LG[27], one study was related to Gastrostomy Tube (GT) and Gastrojejunostomy Tube (GJT)[32], one study was related to NG and PEG[33], three studies were related to GT[34-36], one study was related to Laparoscopic Gastrostomy (LAG)[37], one study was related to PEG and Gastro-Jejunostomy (PEG-J)[30], one study related to Nasogastric Tube (NG) and GT[29], and one study related to Video-Assisted Gastrostomy (VAG)[38].

In the included studies, it was determined that there was no standard time for follow-up of complications after tube placement. Landisch et al.[27] followed up in 3 months, Fascetti-Leon et al.[40] followed up in 1, 3, 6, 12, and 24 months after the procedure. Işık et al.[41] followed up for 6 months to 5 years, Hajjat et al.[36] followed up for 10 years, Franken et al.[37] followed up for about 2.63 years, Kidder et al.[30], and Khalil et al.[29] followed up in 6 months, Sakamoto et al.[38] followed up over 2 years, Hansen et al.[43] followed up 36 months, Goldin et al.[34] followed up in 30 days and Wiernicka et al.[12] followed up in 12 months. Seven studies did not report the following duration of complication after the enteral feeding tube placement (Table 3).

Quality Appraisal of the Included Reviews

The Joanna Briggs Institute critical appraisal tools were employed for the reviews. Both authors conducted evaluations on all the articles, and the quality of each paper was assessed by calculating a percentage score. Quality ratings were categorized as follows: 'good' (with a score falling within the range of 80%–100%), 'fair' (scores between 50%–79%), and 'low' (scores below 50%). Notably, four of the studies achieved a 'good' quality rating.[28,31,36,39] Of the studies assessed, 14 received a 'fair' quality rating based on the evaluation using the Joanna Briggs Institute critical appraisal tools. These studies scored within the range of 50% to 79% on the quality assessment (Table 4, 5, 6).

Table 4. Appraisal of methodological quality of the cross-sectional studies

Study Reference	Methodological Items								Quality Score
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	
Landisch et al., 2016, USA	Y	Y	Y	Y	N	N	Y	Y	%75
Fascetti-Leon et al., 2012, Italy	Y	Y	Y	Y	N	N	N	Y	%62.5
Işık et al., 2021, Turkey	Y	Y	N	Y	N	N	Y	Y	%62.5
Pahsini et al., 2016, Austria	Y	Y	N	N	Y	N	Y	Y	%62.5
Krom et al., 2019, Netherlands	Y	Y	Y	Y	N	N	Y	Y	%75
Kidder et al., 2021, USA	Y	Y	Y	Y	Y	N	N	Y	%75
Di Leo et al., 2019, Italy	Y	Y	Y	Y	N	N	Y	Y	%75
Khalil et al., 2017, USA	Y	Y	N	Y	Y	N	Y	N	%62.5
Sakamoto et al., 2021, Japan	N	Y	Y	Y	Y	N	Y	Y	%75
Khdair Ahmad et al., 2020, Jordan	Y	Y	Y	Y	Y	N	Y	Y	%87.5
Hansen et al., 2017, Denmark	Y	Y	Y	Y	N	N	Y	Y	%75

Y-Yes, N-No, U-Unclear, NA-Not Applicable

Table 5. Appraisal of methodological quality of the randomized controlled studies

Study Reference	Methodological Items													Quality Score
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	
Wiernicka et al., 2021, Poland	Y	N	Y	N	N	N	Y	N	Y	Y	Y	Y	Y	%61.54
Y-Yes, N-No, U-Unclear, NA-Not Applicable														

Table 6. Appraisal of methodological quality of the cohort studies

Study Reference	Methodological Items											Quality Score
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	
Hajjat et al., 2017, USA	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	%100
Mason et al., 2018, USA	Y	Y	Y	Y	N	N	Y	Y	Y	Y	N	%72.73
Goldin et al., 2016, USA	Y	Y	N	Y	Y	Y	Y	Y	N	N	N	%63.64
Ronning et al., 2017, USA	Y	N	Y	N	N	Y	Y	Y	Y	N	N	%54.55
McSweeney et al., 2015, USA	Y	Y	Y	Y	Y	Y	Y	Y	N	N	Y	%81.82
Franken et al., 2015, Netherlands	Y	Y	Y	N	N	Y	Y	Y	N	N	N	%54.55
Y-Yes, N-No, U-Unclear, NA-Not Applicable												

Complication Features

Major and minor complications were reported in 12 out of 18 studies. In studies reporting the overall rate of major complications, the rate ranged from 0%-14.3%. The most common major complications were reoperation (2.64%-12.4%), gastrocolic fistula/perforation (0.9%-3.8%), and peritonitis (0.4%-9.30%). The least common major complications were postoperative dehiscence of the stomach wall (1.3%), death (1%), intraabdominal abscess (1.1%), and postoperative omental hernia (0.3%).

In articles reporting the overall rate of minor complications, the rateo ranges from 16.4% to 73.6%. The most common minor complications were infection (8.2%-31.9%), dislodgement (1.6%-21%), skin granulation (4%-50.4%), vomiting (1%-49.89%), nausea (3.1%-26.2%), leakage of gastric contents (6.3%-31%), cellulitis (24%-27.3%), reddening around the stoma canal (10.4%-24.7%), buried bumper syndrome (1.1%-10%), and clogging (3.5%-4.35%). The least reported minor complications were ectopic gastric mucosa (2.7%) and stitch abscess (1.03%).

DISCUSSION

This systematic review highlights the importance of acknowledging the rate of complications associated with pediatric enteral nutrition administered at home. Many of the studies included in this review predominantly relied on retrospective cross-sectional analyses of hospital records. These comprehensive investigations consistently shed light on the occurrence of minor complications, some of which are preventable. Although EN and PEG insertion are generally considered safe procedures in pediatric patients and are widely utilized, it is imperative to recognize that complications can indeed arise. Minor complications, including tube obstruction, leakage from the tube edges, tube dislocation, and peristomal infections, were found to be notably prevalent, with reported rates spanning from 16.4% to 73.6%. These minor complications, while less severe, can have a significant impact on the well-being of pediatric patients and should not be underestimated. In contrast, major complications, such as aspiration, peritonitis, bleeding, and pneumoperitoneum, occurred at a lower frequency, with rates of approximately 0% to 14.3% for each of these more serious complications. While these major complications are less common, they demand close attention and swift intervention when they do occur due to their potential for severe consequences. This review emphasized the importance of continuous monitoring and careful management of pediatric patients receiving enteral nutrition at home, with particular emphasis on strategies to prevent minor complications.

Peristomal skin infections are the most common minor complications in pediatric enteral nutrition. Our study results corroborate this observation, revealing a notable incidence of peristomal skin problems. These issues encompassed leakage, which occurred in approximately 6.3% to 31% of cases, hyper granulation tissue on the skin, observed in roughly 4% to 50.4% of cases, and peristomal skin infections, with reported rates ranging from 3.73% to 31.9%.[42-44] Furthermore, our findings indicate that approximately 8.6% of pediatric patients sought medical attention in the pediatric emergency department within

30 days of tube insertion, primarily due to complications related to the procedure.[14,45] These statistics underscore the immediate impact of complications associated with tube insertion. Notably, reports suggest that around 73% of patients experience minor complications in the early post-insertion period, while 5% of patients develop complications in the late period.[15] These findings emphasize the significance of vigilance and prompt intervention in the management of complications related to pediatric enteral nutrition. It is crucial for healthcare providers to be prepared to address peristomal skin problems and other potential complications, particularly in the early stages following tube insertion, to ensure the well-being of pediatric patients in their care.

In this study, major complication rate ranged from 0% to 14.3%. Notably, reoperation emerged as one of the most frequently encountered major complications, with reported rates spanning from 2.64% to 12.4%. Gastrocolic fistula or perforation was another significant major complication, with incidence rates ranging from 0.33% to 3.8%. These findings showed the potential for major complications in the context of pediatric enteral nutrition, while also highlighting the variability in their occurrence across the included studies. It emphasizes the need for careful monitoring and proactive management to mitigate the impact of these complications on the well-being of pediatric patients undergoing HEN. All these findings underscore the considerable significance of complications associated with enteral nutrition, particularly the challenges families face in preventing and managing these complications. It is evident that discharge education plays a vital role in a patient's recovery process, as it has the potential to reduce both the frequency and severity of complications that may arise following the procedure.[41] Schweitzer et al. (2014) demonstrated that the implementation of a systematic and family-centered interdisciplinary approach to caregiver education has a significant positive impact on patient care and outcomes.[46] Similarly, according to Pars & Soyer, enhancements in caregivers' knowledge reduced anxiety levels, and diminished burden have been associated with a decrease in the occurrence of common, minor, and preventable complications.[19] Based on moderate-quality evidence (III-IV B), it is clear that standardized discharge education plays a crucial role in facilitating a smooth transition to home for patients. This is achieved by reducing psychosocial and economic stress, primarily through the active involvement of families in the treatment process.[19,42] The available evidence, predominantly of moderate quality (III-IV B), strongly indicates that gastrostomy tube (g-tube) complications are prevalent and often result in unplanned healthcare utilization. It is imperative to address these common complications, such as dislodgement, leaking, and clogs, as they play a critical role in a patient's recovery. Effective management of these complications can substantially reduce both the frequency and severity of post-procedure complications.[41] Caregivers who did not receive standardized, evidence-based discharge education were found to have significantly higher rates of complications, including issues like infections and clogs. This underscores the importance of providing caregivers with structured and evidence-based guidance during the discharge process to enhance patient care and reduce the risk of complications.[19,42] This systematic review aimed to address a gap in the existing literature concerning the essential components of pediatric home enteral nutrition and enteral tube education. The results obtained from this review underscore the importance of comprehensive and high-quality education for caregivers, including nursing staff. Furthermore, these findings align with the existing literature, emphasizing that multidisciplinary and standardized discharge education not only reduces anxiety and complications but also enhances caregiver knowledge. This highlights the critical role of such education in improving patient outcomes in the context of pediatric home enteral nutrition.[15]

Limitations of the Study

This study has several limitations that should be acknowledged. Firstly, the included studies had diverse indications for the disease, and it is important to note that wound healing may be influenced, particularly in oncology patients, those using corticosteroids, and individuals with suppressed immune systems. Secondly, various factors, such as the individual's diagnosis, medication usage, the type and size of the enteral feeding tract, and the use of prophylactic antibiotics, can impact the occurrence of peristomal skin infections. Third, because most of the included studies were based on hospital records, few studies described complications by families. In this case, it constitutes the limitations of the study results. There is a need for studies with a high level of evidence in which confounding factors are controlled, complications of individuals are evaluated with valid and reliable measurement tools, and patients are followed up prospectively. Lastly, the follow-up period for symptoms that may occur at home in pediatric patients varies between 1 month and two years in the studies. This difference in follow-up time limits the interpretation of the timing of complications.

Strength of the Study

The strength of this systematic review lies in its comprehensive analysis of the complications associated with pediatric HEN. It provides a thorough examination of the existing literature on this critical topic, offering valuable insights into the prevalence and types of complications encountered in children receiving enteral nutrition at home. The review encompasses a wide range

of studies conducted in various countries, which enhances the generalizability of the findings. Additionally, the inclusion of both major and minor complications, along with an assessment of the quality of the included studies, contributes to the robustness of the review's conclusions. The study's implications for practice emphasize the importance of educating caregivers and healthcare professionals about the management of complications related to HEN access, ultimately promoting better patient outcomes. This systematic review fills a significant gap in the literature and provides essential information for healthcare providers, caregivers, and researchers involved in pediatric enteral nutrition care. Priorities include handovers from hospital to community, training for family carers, provision and expertise of services in the community and availability and reliability of equipment.

CONCLUSION

This review represents the first attempt to investigate the complications associated with pediatric home enteral nutrition comprehensively. The outcomes of this study highlight the need for more robust research, encompassing both retrospective and prospective studies. The prevalence of minor complications observed in the studies underscores the significance of equipping all individuals involved in the care of home enteral nutrition (HEN) patients with fundamental knowledge of access tube management. Moreover, it is of utmost importance for families to receive comprehensive discharge training, as well as ongoing home follow-up to ensure the well-being of HEN patients and minimize the occurrence of complications.

Future research in the field of pediatric home enteral nutrition should prioritize prospective studies, measurement tool development, patient-related factors, education programs, device comparisons, long-term follow-up, psychosocial impacts, multidisciplinary collaboration, and cost-effectiveness analyses. These research avenues can contribute to better care for pediatric patients receiving home enteral nutrition and enhance the management of complications in this population.

IMPLICATIONS FOR PRACTICE

HEN is a critical component of care for patients facing various underlying conditions that hinder their ability to meet their nutritional needs through regular eating alone. The provision of long-term enteral access is essential for those who cannot achieve their energy or protein requirements solely through regular eating, especially in the home setting. Several methods are available for establishing enteral access, and the choice should be tailored to the patient's characteristics. Despite the development of minimally invasive techniques for accessing enteral nutrition, long-term complications continue to be a concern both in terms of nature and frequency. To optimize outcomes in the HEN setting, it is crucial to have dedicated multidisciplinary teams and well-informed patients who actively participate in their care. Complications related to enteral access are issues that healthcare professionals from various disciplines may encounter at different points in the healthcare system. Therefore, it is imperative that all those who may be involved in the care of HEN patients possess fundamental knowledge about the management of access tubes.

Complications related to these devices can be challenging, especially when they occur in the home setting as opposed to a hospital environment. The key to achieving positive outcomes for patients receiving HEN lies in having specialized multidisciplinary teams and maintaining close follow-up. Nonetheless, all healthcare providers should have a foundational understanding of the common complications associated with HEN access and how to initiate their management. This systematic review underscores the significance of complications associated with pediatric enteral nutrition at home, emphasizing that these should not be underestimated. It highlights the importance of developing and implementing future strategies to support parents in effectively managing complications related to pediatric enteral nutrition care in the home setting.

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Shortages of clinical nutritional components and management strategies

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ABSTRACT

Parenteral nutrition (PN) solution is a medication of high concern due to its intricate drug utilization procedure. It has been reported that since 2010, nearly every component involved in the preparation of PN admixtures has experienced a shortage at least once. Shortages may lead to therapy delays in hospitals, clinics and other health-related facilities or reductions in quality, prompting healthcare providers to recommend alternative treatments, potentially leading to medication errors, negatively influencing patient outcomes, and consume healthcare assets. The causes of medication shortages are diverse and encompass unidentified factors (44%), manufacturing complications (36%), supply and demand imbalances (8%), discontinued product lines (8%), insufficient access to raw materials (4%), and natural disasters. The duration for the resolution of these shortages was inconsistent, with certain product shortages that were resolved experiencing a recurrence, while others persisted for several months to years. The pharmacy department can take the lead in efficiently managing drug shortages by guaranteeing that its institution possesses the essential infrastructure and a clearly outlined management strategy well in advance of any shortages arising. During periods of shortages, it is extremely important to limit the use of nutritional products to patients with valid indications and those with nonfunctional gastrointestinal systems. Effective management of drug shortages, including PN components, necessitates a comprehensive plan and the involvement of an interprofessional team. This team should contribute to the development of the plan and be ready to implement it swiftly in case of a shortage or outage. Once the shortage of PN components is deemed resolved, all rationing and conservation strategies should be halted, as these measures are meant to be employed exclusively during shortages. Once the PN component shortage has been resolved, it is crucial to resume providing the full dosage of PN components to all patients in need of PN therapy.

Keywords: Component, drug shortage, management, parenteral nutrition

INTRODUCTION

Parenteral nutrition (PN) solution is a medication of high concern due to its intricate drug utilization procedure. The measures and precautions, encompassing guidelines, protocols, and support mechanisms, associated with this procedure, play a crucial role in upholding patient safety.[1] Automated compounding devices are employed for the creation of PN in approximately 64% of institutions, particularly those of a larger scale and standardized commercially accessible PN products are utilized in 21% to 43% of institutions.[1]

It has been reported that since 2010, nearly every component involved in the preparation of PN admixtures has experienced a shortage at least once.[2,3] Drug shortages, characterized by an inadequate drug supply, lead to adjustments in the drug preparation processes by the pharmacy and sometimes require the selection of alternative therapeutic options.[4]

In general healthcare providers are contending with a substantial risk to patient well-being and are actively addressing issues related to the availability of PN

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components and product limitations, and are exploring alternative treatment options constantly.[4] However, shortages in medications, such as components for PN, pose a substantial risk to public health and safety while also impacting the healthcare system.[2]

Shortages may lead to therapy delays in hospitals, clinics and other health-related facilities or reductions in quality, prompting healthcare providers to recommend alternative treatments, potentially leading to medication errors, negatively influencing patient outcomes, and consume healthcare assets.[2,4]

The causes of medication shortages are diverse and encompass unidentified factors (44%), manufacturing complications (36%), supply and demand imbalances (8%), discontinued product lines (8%), insufficient access to raw materials (4%), and natural disasters.[2,4]

The duration for the resolution of these shortages was inconsistent, with certain product shortages that were resolved experiencing a recurrence, while others persisted for several months to years.[2]

Administering PN therapy is a notable challenge for healthcare professionals due to the intricate nature of PN as a medication, which could consist of 40 or more distinct components. Among these components, several may face concurrent shortages, further complicating the situation. At every stage of utilizing PN, from prescribing the therapy to a patient to its actual administration, one must take into account the availability of PN components. Unlike antibiotics, there are no substitute treatments available in the absence of PN components, which play a life-sustaining role for many adults, neonates, and pediatric patients.[2] Especially during and after the Covid-19 pandemic period, hospitals experienced a lot of problems due to drug shortages. In this review, our objective is to offer an updated set of fundamental principles to help healthcare experts address the issue of nutrient shortages in patients undergoing PN.

Main Points

- It has been reported that since 2010, nearly every component involved in the preparation of PN admixtures has experienced a shortage at least once.
- Shortages may lead to therapy delays in hospitals, clinics, and other health-related facilities or reductions in quality, prompting healthcare providers to recommend alternative treatments, potentially leading to medication errors, negatively influencing patient outcomes, and consume healthcare assets.
- Staying proactive and prepared for shortages is essential for maintaining patient care standards.
- Effectively managing drug shortages, including PN components, necessitates a comprehensive plan and the involvement of an interprofessional team.

The Importance of Parenteral Nutrition Component Shortages

Medication shortages raise significant patient safety concerns. The likelihood of medication errors increases when a pharmacy modifies the process of ordering, preparing, or dispensing a product or when prescribing practices shift to less familiar alternative agents. This risk is especially pronounced with agents that are less effective, have more adverse effects, or necessitate an uncommon or complicated dosing regimen. When establishing best practices for managing drug shortages, the primary consideration should be the potential effects on patient safety.[5]

Shortages in PN and the limited availability of alternative therapies have compelled certain institutions to take measures such as delaying treatment, adjusting dosages or treatment plans, deferring surgeries, and relocating patients to other facilities.[4]

Besides macronutrients, the absence of other essential components such as electrolytes, micronutrients (vitamins and trace elements) present a significant risk to the patient's nutritional well-being, potentially leading to deficiencies, metabolic abnormalities, and death in severe cases.[3,6]

What to Do in Parenteral Nutrition Component Shortages

The pharmacy department can take the lead in efficiently managing drug shortages by guaranteeing that its institution possesses the essential infrastructure and a clearly outlined management strategy well in advance of any shortages arising. In order to respond efficiently to medication shortages, certain crucial infrastructure components should be established proactively. These include a drug shortage team, a committee for resource allocation, and established protocols for approving substitute therapies and handling ethical concerns.[5]

During periods of shortages, it is extremely important to limit the use of nutritional products to patients with valid indications and those with nonfunctional gastrointestinal systems. Whenever feasible, alternative or accessible products should be utilized to prevent the occurrence of deficiencies. In such shortages, it may be necessary to obtain alternative products like pre-mixed PN solutions and electrolyte solutions. While it's extremely challenging to foresee when a nutritional product might go on shortage, it's crucial to have established formal procedures ready that can be swiftly and effectively put into action in the event of a drug shortage.[4]

Certain international societies, such as the American Society for Parenteral and Enteral Nutrition (ASPEN), the British Association for Parenteral and Enteral Nutrition (BAPEN), and the French Society for Clinical Nutrition and Metabolism (SFNCM), have developed guidelines to prioritize the provision of micronutrients when shortages occur. These societies have determined that enhanced monitoring of vitamins and trace elements is necessary in such circumstances.[6] In response to the recurring shortages of intravenous micronutrient preparations for PN, ASPEN published shortage considerations in 2016 to help clinicians manage these situations. The authors of the publication suggested that clinicians should continuously assess each patient to determine if PN is still necessary and if there is a possibility to provide nutrition orally or enterally. They also advised switching to oral or enteral products whenever feasible. The British Society put forth similar recommendations, including the suggestion to monitor micronutrient levels more frequently than before, particularly if there are any clinical suspicions or concerns regarding micronutrient deficiency. Regardless of the chosen approach, it will be crucial to closely monitor micronutrient levels to prevent complications.[3] During a period of electrolyte and mineral product shortages, clinicians should consider implementing one or more of the following measures:[3,7]

1. Evaluate each patient to determine the necessity for PN and consider providing nutrition through the oral or enteral route if feasible.
2. Consider switching to oral or enteral electrolyte or mineral supplement products if oral or enteral intake is possible (except for patients with malabsorption syndromes or nonfunctioning gastrointestinal tracts). Seek advice from a pharmacist for product details.
3. Acquire an electrolyte and mineral injection supply only in the required quantities. To ensure fair distribution to all patients nationwide, avoid hoarding or stockpiling.
4. Set aside intravenous (IV) electrolyte and mineral products specifically for patients who are receiving PN or those with a documented therapeutic medical requirement for intravenous electrolytes and minerals.
5. Avoid utilizing parenteral electrolyte and mineral injections as supplemental additives in enteral nutrition products.
6. Restrict the use of electrolyte and mineral additives in IV fluids to patients with specific disease states and clinical conditions for which they are medically appropriate.
7. Reevaluate the use of serum electrolyte algorithms or protocols as "automatic" IV electrolyte replacement therapies in patients who are otherwise asymptomatic.
8. Utilize commercially available IV multi-electrolyte and mineral products for replacement therapy whenever feasible.
9. Examine the complete range of PN electrolyte and mineral products available nationwide. While there may be a shortage in one concentration or salt form, there may be availability in another form.
10. Evaluate your PN patient population to ascertain whether a standardized, commercially available PN product with standard electrolytes may be suitable for a subset of your patients. Typically, supplementary components can be incorporated into these products as needed.
11. Analyze your PN patient population to ascertain if a standardized, commercially available multi-electrolyte product may be suitable for a subset of these patients.
12. In the event of extended shortages of IV electrolytes and mineral products, country-specific healthcare authorities such as the Turkish Medicines and Medical Devices Agency may grant temporary approval for the importation of alternative products. These imported products may have varying salts, concentrations, packaging, and labeling compared to products approved in the country. It's important to carefully read the product information of the imported products.
13. Consider reducing or even eliminating the daily quantity of electrolytes added to the PN regimen.
14. Monitoring serum electrolyte concentrations closely.
15. Be vigilant for a potential rise in deficiencies during the ongoing shortages. Enhance your awareness and assessment of signs and symptoms indicative of electrolyte and mineral deficiencies.
16. Consider the possibility of preparing PN at a single, central location, either within a centralized pharmacy or through outsourced preparation, to minimize inventory waste.
17. Facilities and healthcare practitioners must maintain their diligence in adhering to product labeling (e.g., package insert), USP General Chapter <797> Pharmaceutical Compounding—Sterile Preparations guidelines, and federal rules and regulations.
18. Incorporate PN component shortages and outages into your healthcare organization's strategies and protocols for managing medication shortages and outages.
19. Ensure that information regarding severe drug product shortages is reported to the country-specific authorities, such as the Turkish Medicines and Medical Devices Agency.

20. Report any patient-related issues arising from shortages to the Medication Errors Reporting Program.

There are also ASPEN recommendations for electrolyte and mineral shortages which are shown in Table 1.

Besides the electrolyte and mineral, multivitamin and trace element shortages should also be considered for patients with PN. Clinicians should be careful when transitioning from one trace element or multivitamin preparation to another, as the dosages and individual components in each formulation are not standardized. Specific strategies for addressing these shortages include shifting supplementation from IV to enteral administration when possible, limiting the supply to critically ill pediatric or adult patients or those with pre-existing deficiencies, and exploring alternative dosing regimens, such as administering every other day or three times a week. Another option is to reduce the daily dosage by 50%.[4] If supplies of multi-trace and multivitamin preparations are depleted, institutions may consider supplementing individual parenteral vitamin and trace element components as an alternative.[4] Information on the shortage and deficiency symptoms of multi-trace elements and multivitamins are shown in Table 2 and the ASPEN recommendations are shown in Table 3.

When we focus on macronutrients many clinicians view protein as the cornerstone of nutrition therapy because of its crucial role in promoting wound healing, bolstering immune function, and preserving lean body mass. When the supply of amino acids reached critically low levels, the Nutrition Therapy and Pharmacy and Therapeutics Committees endorsed guidelines to limit the use of PN to patients who met the ASPEN criteria. This helped ensure the availability of adequate supplies.[4]

Lipids play a crucial role in PN therapy as they provide essential fatty acids and help reduce the required dose of glucose in the parenteral formulation. Essential fatty acid deficiency (EFAD) is linked to symptoms such as rash and alopecia, which typically manifest after several weeks of lipid-free PN therapy. During the shortage, the administration of lipid therapy in patients on long-term PN can be limited to twice-weekly sessions, typically on Mondays and Fridays, with a maximum daily dose of 50 grams, if they were undergoing therapy for over 14 days or were receiving home PN.[4] In response to the challenges posed by shortages of PN products, practitioners have undertaken a reevaluation of the criteria for PN usage and the timing of administering specific macronutrients such as lipids.[2]

Table 1. ASPEN recommendations for electrolyte and mineral shortages

Component	What to Do	Signs and Symptoms of Deficiency
Calcium	• If inorganic calcium salts are available administer separately from PN.	Irritability, hyperventilation, tetany, other neuromuscular, central nervous system, and cardiovascular symptoms.
Magnesium	• Minimize the use of IV magnesium additives in IV fluids.	Electrocardiogram (ECG) changes, arrhythmias, muscle spasms/tetany, nausea, lethargy, confusion, seizures, coma, and death.
Phosphate	• Consider using the alternate salt IV phosphate as available and balance the sodium and potassium accordingly. • Consider provision of daily IV fat emulsion to all PN patients as clinically appropriate. Note: IV fat emulsions contain 15 mmol/L of phosphate as egg phospholipids. • Reserve phosphates for pediatric and neonatal patients requiring PN.	Impaired diaphragmatic contractility, tachycardia, hypocapnia, respiratory failure, tissue hypoxia, decreased myocardial contractility, paralysis, weakness, paresthesias, neurologic dysfunction, seizures, and death.
Potassium	• Consider using alternate IV potassium salts as available and balance the chloride, acetate, and phosphate accordingly.	Nausea, vomiting, weakness, muscle cramping, constipation, ECG changes, cardiac arrhythmias, sudden death, paralysis, respiratory compromise, and rhabdomyolysis.
Sodium	• Consider using alternate IV sodium salts and concentrations as available and balance the chloride, acetate, and phosphate accordingly. • Consider administering IV medications in 0.9% sodium chloride (normal saline) instead of 5% dextrose in water (D5W) when compatible. • Consider using 0.9% sodium chloride (normal saline) for irrigation with enteral nutrition when patients are on both enteral and parenteral therapy.	Headache, lethargy, disorientation, restlessness, nausea, vomiting, muscle cramps or weakness, depressed reflexes, seizures, coma, and death.

Table 2. Management of some trace elements and vitamins shortage		
Component	**What to Do**	**Signs and symptoms of deficiency**
Vitamin C	• Restrictions may be needed. Patients who may warrant preferred access are those with a nonfunctioning gastrointestinal tract or patients who need high-dose supplementation.	Fatigue, poor wound healing, gingivitis, conjunctival hemorrhages, and ecchymosis
Vitamin B12	• Restrict its use to those patients with malabsorption and severe neurologic manifestations.	Macrocytic anemia, cognitive decline, and neuropathy
Vitamin K	• Oral and enteral administration strongly encouraged whenever feasible. Intravenous use should be reserved for patients with severe or life-threatening bleeding during product disruptions according to the current guidelines.	Problems in the hemostasis that stimulates synthesis of clotting factors II, VII, IX, and X. Problems in bone development and remodeling.
Vitamin A	• Oral and enteral administration encouraged in those patients who require it for wound healing, xerophthalmia, or who are high risk for deficiency.	Detrimental effects on mucosal integrity, immune function, wound healing, and vision.
Chromium	• An administration schedule of three times weekly is likely sufficient to prevent severe deficiency in high-risk patients.	Hyperlipidemia, peripheral neuropathy, encephalopathy, and glucose intolerance
Copper	• Enteral administration is strongly encouraged in patients with functional gastrointestinal tracts. If restrictions are necessary due to future supply disruptions, use in patients with severe deficiencies with clinical manifestations is appropriate.	Anemia, leukopenia, myelopathy, and osteoporosis.
Selenium	• Enteral supplementation is highly encouraged in cases of deficiencies with clinically significant signs or symptoms. Intravenous formulation should be restricted to those symptomatic patients with severe malabsorption syndromes.	Cardiomyopathy, myositis, and muscle cramps
Zinc	• Restrictions of the individual IV formulations should be established for patients with supraphysiologic losses and malabsorption. Oral or enteral administration should be optimized in other clinical scenarios.	Alterations in sight and taste perception, growth and development, immune defense, and wound healing.

Table 3. ASPEN recommendations for vitamins and trace elements shortage
Vitamins
• Use a 13-vitamin product • Use a 12-vitamin product (without vitamin K) if 13-vitamin product is unavailable • In patient on warfarin: • Use a 12-vitamin product (without vitamin K) • Use a 13-vitamin product (with vitamin K) if the 12-vitamin product is unavailable: monitor and adjust anticoagulation • When all options to obtain IV multivitamins have been exhausted, ration IV multivitamins in PN, such as reducing the daily dose by 50% or giving 1 multivitamin infusion dose 3 times a week • If IV multi-vitamins are no longer available, administer individual IV vitamin entities: Thiamine 6 mg, ascorbic acid 200 mg, pyridoxine 6 mg, folic acid 0.6 mg daily, and B12 100e1000 mcg, vitamin K 150 mcg may be given weekly • The use of pediatric IV multivitamins for adults is not recommended
Trace Elements
• When all options to obtain IV adult multi-trace element (MTE) products have been exhausted, ration IV adult MTE products in PN, such as reducing the daily dose by 50% or giving 1 MTE product infusion 3 times a week • Withhold IV adult MTE products from adult patients receiving partial enteral/parenteral nutrition or who can tolerate oral/enteral supplements. • Consider withholding IV adult MTE products for the first month of therapy to newly initiated adolescent and adult PN patients who are not critically ill or have pre-existing deficits • The use of Pediatric and Neonatal IV multi-trace element products for adults is strongly discouraged.

Teams and institutions can adhere to a specific process for managing drug shortages, as illustrated in Figure 1. If this process is functioning as intended, institutions should receive a minimum of 2 weeks' notice before the product is completely depleted.[4]

The operational assessment evaluates both the severity and the expected duration of the shortage. The therapeutic assessment aims to identify the patient populations that will be affected by the shortage and to pinpoint potential therapeutic alternatives for them. The therapeutic assessment should be carried out by a multidisciplinary team comprising physicians, dietitians, pharmacists, nurses, and other relevant clinicians as needed. A comprehensive plan should encompass several key components, including the identification of nutritional alternatives, allocation criteria for the remaining product, revised distribution and administration processes, a cost analysis for the institution, and an evaluation of potential secondary shortages. It's important to note that the management of shortages should not involve stockpiling the product, as this practice is discouraged by professional societies such as the European Society for Clinical Nutrition and Metabolism (ESPEN) and the American Society of Hospital Pharmacists (ASHP).[4]

The concluding phases of the plan encompass communication, education, and implementation. It is

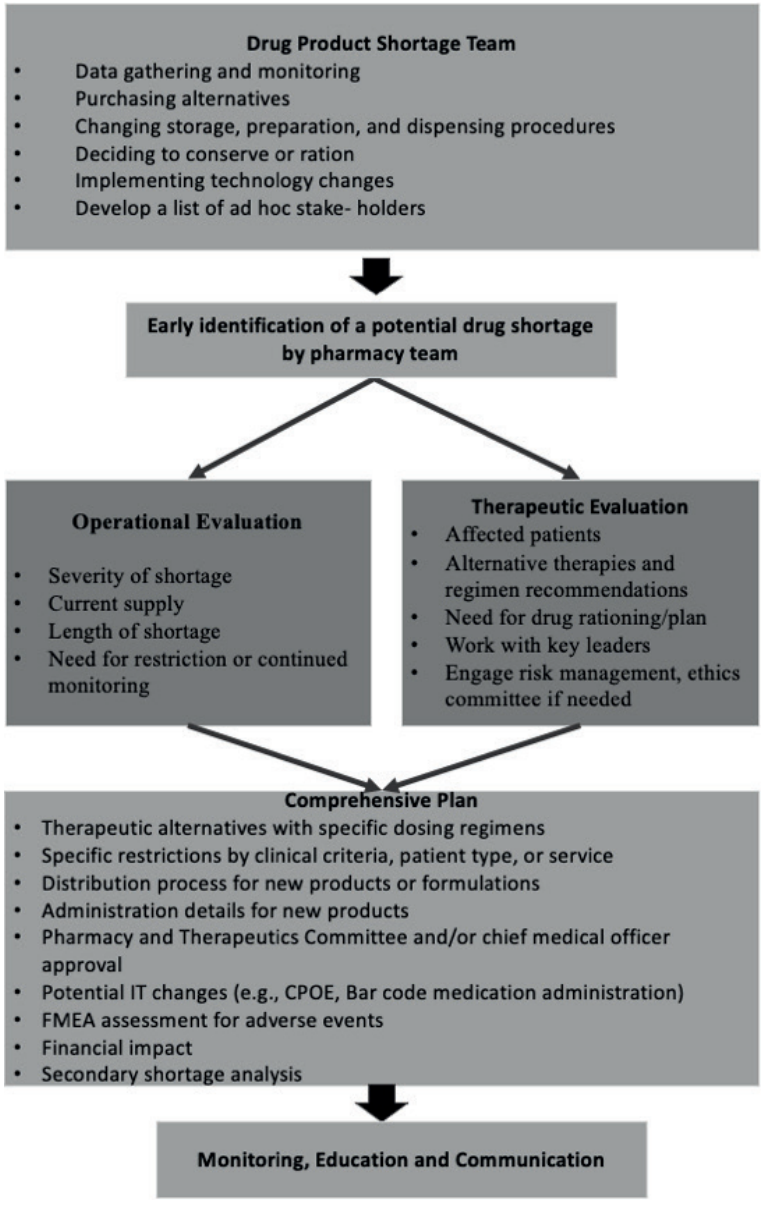

Figure 1. Process for managing drug shortages

crucial to provide education to all disciplines involved before implementing the plan, as shortages can lead to nutritional errors. Errors have been documented as a consequence of alterations in electrolyte or macronutrient concentrations stemming from product shortages. Education is paramount to preventing errors and should be disseminated through various channels, including emails, staff meetings, bulletin boards, websites, dashboards, and in-service training.[4]

Once the shortage of PN components is deemed resolved, all rationing and conservation strategies should be halted, as these measures are meant to be employed exclusively during shortages. Upon the resolution of the PN component shortage, it is crucial to resume providing the full dosage of PN components, and sufficient quantities should be procured to supply these full daily components to all patients in need of PN therapy. The absence of observed adverse events or deficiencies during the rationing of a PN component and the potential cost savings linked to "partial" dosing should not serve as a justification to continue with less than optimal dosing. The focus should always be on providing the best possible care and meeting patients' nutritional needs.[2]

CONCLUSION

Shortages of nutritional products continue to exert a significant impact on patient care. Clinicians should remain informed about both current and past shortages while also preparing for potential shortages of critical nutritional supplements. Staying proactive and prepared is essential for maintaining patient care standards. Institutions should be well-prepared with the knowledge and resources to implement a protocol for managing shortages and identifying therapeutic alternatives when necessary. Effective management of drug shortages, including PN components, necessitates a comprehensive plan and the involvement of an interprofessional team. This team should contribute to the development of the plan and be ready to implement it swiftly in case of a shortage or outage. Collaboration and planning are key to mitigating the impact of shortages on patient care.

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CLINICAL SCIENCE OF NUTRITION
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Effect of video-based education on percutaneous endoscopic gastrostomy tube use duration: A case report

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ABSTRACT

Percutaneous endoscopic gastrostomy (PEG) is a safe, practical, and effective method for enteral nutrition. Minor and major complications may occur after the placement of a PEG tube. In the content of the education provided to caregivers, information should be given about the potential complications and the importance of communicating with the nutrition support team when these issues arise. In this case, we present a patient who was fed through a PEG tube and experienced infections and hypergranulation tissue processes during a thirty-seven-month follow-up, which included one tube replacement. Through this case, we aim to demonstrate that minor complications associated with the PEG tube can be addressed without hospitalization, through collaboration between the patient and the nutrition support team, allowing for an extended period of PEG tube usage.

Keywords: Hypergranulation, infection, percutaneous endoscopic gastrostomy, video-based education

INTRODUCTION

Percutaneous endoscopic gastrostomy (PEG) is the procedure of placing a tube into the stomach to provide enteral nutrition for patients who cannot be orally fed for an extended period when the gastrointestinal system is active.[1] Early and late complications may arise after PEG tube placement, including infection, bleeding, peristomal leakage, tube obstruction, buried bumper syndrome, and inadvertent tube dislodgment.[1,2] Most of these complications can be prevented with proper care. It is crucial for PEG tube care providers, such as nutritional nurses and healthcare personnel, to have adequate knowledge of PEG care, duration of use, and potential complications.

PEG education should be comprehensive, covering both care and potential complications. Practical demonstrations of PEG dressing application should be provided, with caregivers performing the dressing at least once under the supervision of a nurse. Care-related videos should be watched, and caregivers should be informed about the importance of promptly communicating with the nutrition support team when complications arise. Patient discharge should be planned after the completion of these training sessions.

This case aims to illustrate that minor complications of PEG tubes can be effectively managed without hospitalization through the collaborative efforts between the patient and the nutrition team. This approach enables the prolonged use of the PEG tube.

CASE REPORT

Thirty-seven months ago, a 91-year-old bedridden woman diagnosed with cerebrovascular disease underwent her initial PEG tube placement. The patient was discharged ten days after hospitalization. Around one month later, the caregiver observed signs of infection (odorous discharge, redness) at the PEG tube insertion site. The caregiver captured an image of the dressing and shared it with

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the nutrition team doctor, a gastroenterology specialist. Considering the absence of fever and no deterioration in the general condition, the nutrition team doctor prescribed topical antibiotics as the first-line therapy. To facilitate at-home application, the nutrition nurse provided verbal instructions and showed an educational video on topical antibiotic application to the caregiver. This video prepared by the nutrition nurse included wiping the entry site of the PEG tube with povidone iodine gauze and drying it with a new gauze, applying the recommended antibiotic-containing pomade to the gauze cut in Y-shape and placing it under the PEG tube plate. On the fifth day, the caregiver reported no discharge at the PEG tube entry site during a phone follow-up. The PEG tube was replaced after eighteen months of use.

In the thirteenth month following the PEG tube replacement, hypergranulation tissue developed at the insertion site of the new tube (Figure 1). The caregiver was called to the hospital and given a silver nitrate stick to use at home. A training video demonstrating the process of using the silver nitrate stick to burn the hypergranulation tissue was shown to the caregiver. The insertion site of the PEG tube healed after the caregiver applied the silver nitrate stick once a day for two days at home (Figure 2). Currently, the patient is in the nineteenth month of using the replaced PEG tube and plans to continue using it as long as there is no deformation of the tube (Figure 3, 4).

DISCUSSION

The PEG tube was initially introduced by Gauderer in 1980.[1] After PEG tube placement, patients may experience both minor and major complications. Major complications include pulmonary aspiration, peritonitis, perforation, hemorrhage, gastrocolocutaneous fistulas, buried bumper syndrome, and necrotizing fasciitis, while peristomal infection and tube obstruction are the most common minor complications.[2] According to the recommendations of the Society for Nutrition and Metabolism (2022), regular replacement of the PEG tube is unnecessary unless deformation occurs.[3]

Main Points

- PEG is a safe, practical, and effective method for enteral nutrition.
- Effective communication between caregivers and the nutrition nurse eases the management of minor PEG complications.
- With proper care, long-term use of the PEG tube is possible.

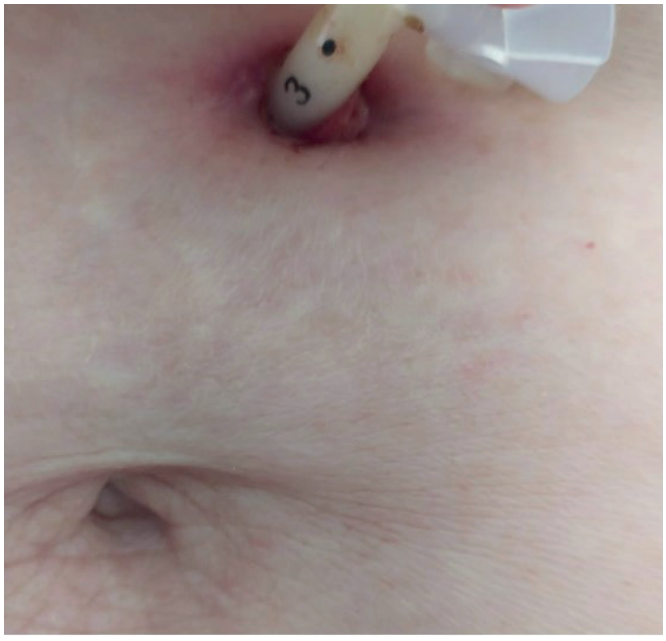

Figure 1. The appearance of hypergranulation tissue at the insertion site of the PEG tube at thirteenth month

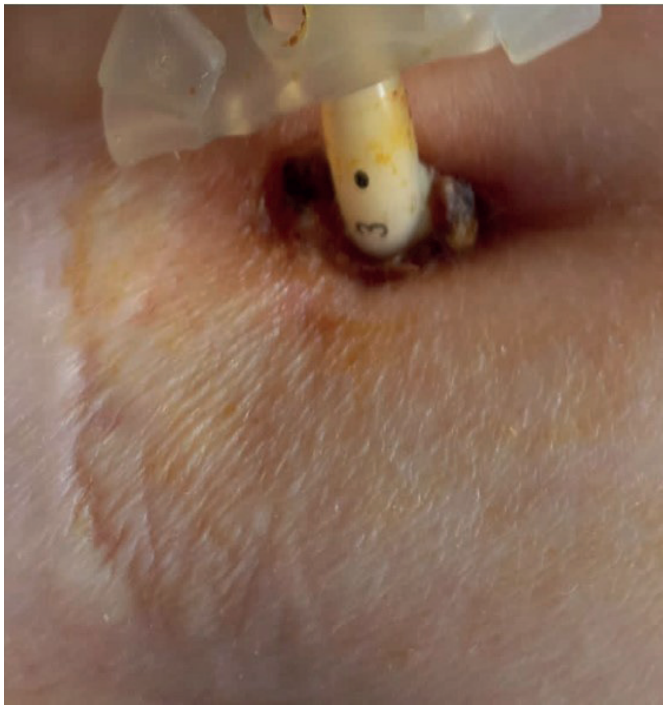

Figure 2. Hypergranulation tissue appearance of the PEG tube entry site burned with silver nitrate

Peristomal infections are prevalent in patients with PEG tubes, particularly in those with diabetes, obesity, malnutrition, and those on chronic corticosteroid or immunosuppressive therapy. Prevention strategies involve wound care and early recognition of signs of infection,

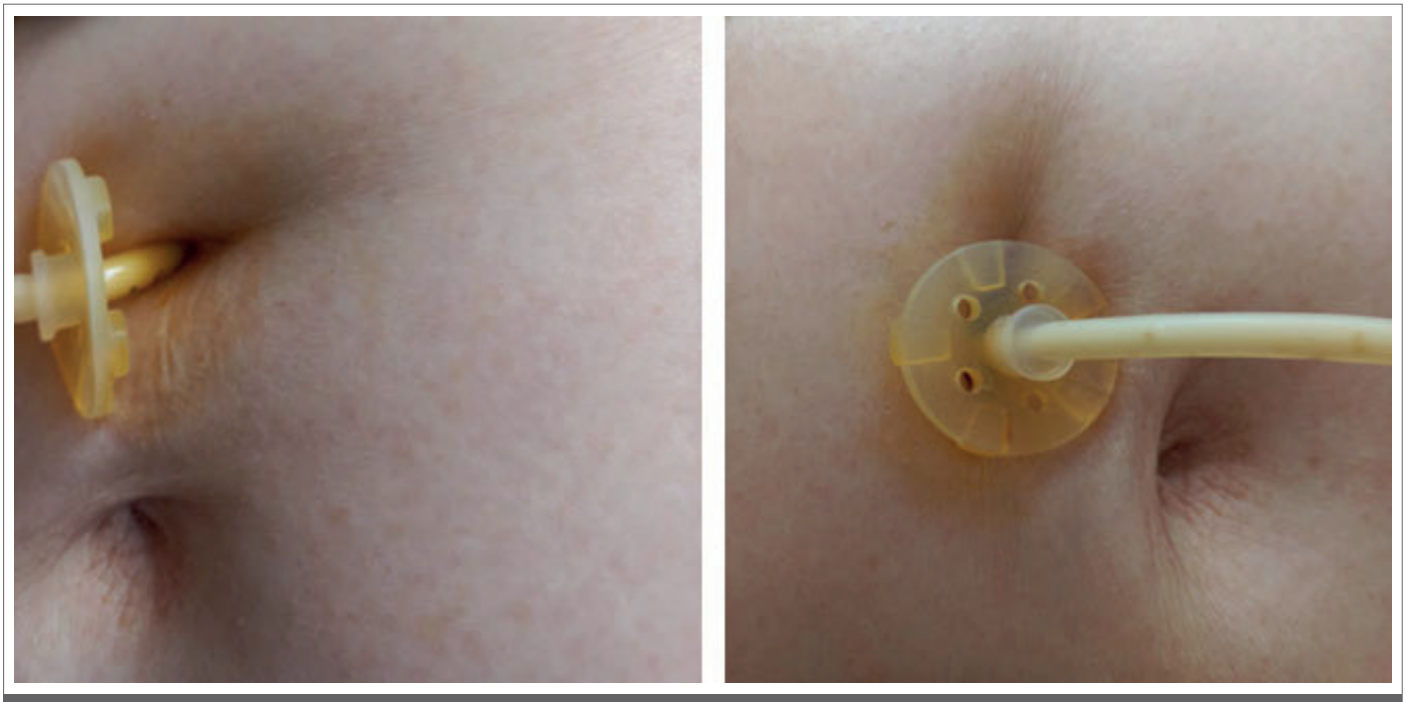

Figure 3, 4. Appearance of the second PEG tube at nineteen month

including odorous discharge, erythema, fever, and pain. Topical antibiotics are recommended for treatment.

Comprehensive education is provided to caregivers of patients undergoing their first PEG tube insertion at our hospital. This includes verbal explanation, a written document, and watching a video demonstrating PEG tube dressing. Additionally, the nutrition nurse performs the PEG dressing in the presence of the caregiver, who then applies the dressing independently one day later. The duration of this PEG care education session is approximately 120 minutes. Caregivers are provided with the contact number of the nutritional support team for any complications that may arise post-discharge.

In the case presented, topical antibiotic dressing was explained verbally and a practical video was shown to the caregiver of the patient, who developed peristomal infection, by the nutrition nurse in the hospital. The content of the infected PEG tube dressing education is as follows; the entry site of the PEG tube is wiped with povidone iodine gauze (gauze that does not leave threads) and dried with a new gauze. The recommended antibiotic-containing pomade is applied to the gauze cut in a Y-shape and placed under the plate of the PEG tube.[3-5]

Hypergranulation tissue is a common complication in patients with a PEG tube, characterized by vascular tissue that bleeds easily and causes pain. The underlying reasons for its development include excessive moisture, friction, leakage, infection, and a foreign body reaction to the PEG tube. Treatment options include applying topical antimicrobial or silver-containing pomade under the PEG tube plate. Alternatively, cauterization directly on the skin with silver nitrate can be performed, typically over a 7–10-day period in combination with topical antibiotics.[3,4]

In this particular case, for the management of hypergranulation tissue, the caregiver was instructed not to apply the silver nitrate stick on healthy skin. Instead, they were advised to touch the stick to the hypergranulation tissue for a few seconds and to do this once a day. A video demonstrating the burning process with a silver nitrate stick was shown to the caregiver. Following the cauterization, it was explained that the dressing should be wiped dry with povidone iodine approximately 4-5 hours later. The patient used the first PEG tube for eighteen months and is currently in the nineteenth month of using the second PEG tube. The expectation is to continue using the same PEG tube as long as it remains free from deformation.

The durability of the PEG tube primarily depends on careful handling, and there is generally no requirement for regular tube changes at fixed intervals. Conditions that may necessitate PEG tube replacement include a deformed tube, buried bumper syndrome, and necrotizing fasciitis.[3,4] Regular assessment and vigilance regarding the tube's condition, along with prompt attention to any signs of potential issues, contribute to prolonging the effective use of the PEG tube.

CONCLUSION

In this case, the complications involved peristomal infection and hypergranulation tissue, both of which were successfully managed in the patient's home environment through communication with the nutritional support team. The effective management of complications underscores the importance of nutrition nurses having sufficient knowledge of PEG care and the management of associated complications.

In order to address complications in patients undergoing PEG tube follow-up, it is crucial to provide comprehensive training to caregivers by nutrition nurses before discharge. Despite the common occurrence of the need for PEG tube replacement at shorter intervals, such as every six months in many cases, this case report demonstrates that a collaborative effort between caregivers and nutrition nurses can enable long-term PEG tube use. The inclusion of written, oral, practical, and video-based components in the education provided to caregivers is essential to ensure the prolonged and successful use of the PEG tube.

Informed consent: Permission was obtained from the patient for the use of the pictures and case presentation.

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Is routine monitoring of gastric residual volume measurement necessary?

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Gastric Residual Volume (GRV) monitoring is a procedure used to assess the nutritional status of patients receiving enteral nutrition in the intensive care unit (ICU).

We read with interest the paper titled "KEPAN Enteral Nutrition (EB) Guide", published in the journal.[1] The sentence you have mentioned in the aforementioned study which is "*In a meta-analysis of five studies [n = 998], it was shown that in patients undergoing mechanical ventilation, GRV examination had no effect on nutritional intolerance [relative risk 0.61, 95% CI 0.51-0.72], mortality [0.97, 95% CI 0.73-1.29] and the frequency of ventilator-associated pneumonia [1.03, 95% CI 0.74-1.44].*" in your study was misspelled due to an overlooked error. The cited study found that "*Compared with monitoring gastric residual volume, not monitoring gastric residual volume decreased the rate of feeding intolerance in critically ill patients (RR = 0.61, 95%CI 0.51–0.72), and did not result in an increment in the rate of mortality (RR = 0.97, 95%CI 0.73–1.29, P = 0.84) or the rate of ventilator-associated pneumonia (RR = 1.03, 95%CI 0.74– 1.44, P = 0.85)*".[2]

In the randomized controlled trial, nutritional goals were achieved faster, and there was no increase in the rate of complications in the group without GRV monitoring. The group with GRV monitoring did not show a significant association between GRV and gastroesophageal reflux disease.[3]

In parallel to the study by Wang *et al*, patients with or without GRV monitoring showed no notable difference between the groups in terms of ICU-acquired infections, duration of mechanical ventilation, length of ICU stay, or mortality rates, according to another study. In addition, the percentage of patients achieving 100% of their calorie target was higher in the group with GRV monitoring.[4]

In another study, GRV monitoring was associated with a reduced incidence of vomiting, whereas no gastric residual volume monitoring was associated with a reduced incidence of unnecessary interruptions of enteral nutrition.[5]

Administration of additional enteral nutrients in people with high GRV can cause aspiration and lead to increased intra-abdominal pressure, which increases the risk of respiratory and circulatory failure as well as intestinal necrosis. It is therefore particularly important to monitor GRV in the early stages of EN feeding, especially in critically ill individuals.[6]

More studies should be done to emphasize the importance of GRV monitoring in critically ill patients.

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