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EVALUATION OF NUTRITION AND TREATMENT APPROACHES IN CYSTIC FIBROSIS DISEASE WITH STATISTICAL ANALYSES

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ABSTRACT

Objective: Cystic fibrosis (CF) is a complex genetic disorder with severe effects on respiratory health and nutritional status. This study aimed to evaluate the nutritional status and treatment approaches of children diagnosed with CF at Tripoli University Hospital, Libya..

Materials & Method: A cross-sectional study was conducted between March 2024 and May 2024 including children aged 7–17 years with CF. Nutritional status was assessed using body mass index (BMI), lung function was evaluated by forced expiratory volume in the first second (FEV1), and quality of life was measured using the Short Form Sickness Perception Scale (SF-SPS) and the Modified Wisconsin Cystic Fibrosis Quality of Life Questionnaire (MWCFC-Q).

Results: Among the participants, 48.5% were aged 14–17 years and 56.8% were male. A total of 34.9% were underweight with a BMI below 18.5 kg/m². Lung function assessments revealed that 57.4% of patients had FEV1 values between 70–90%, indicating mild obstruction. The mean scores of SF-SPS and MWCFC-Q were 20.94 and 21.20, respectively. Low BMI was significantly associated with reduced lung function and lower quality of life scores.

Conclusion: The study highlights the strong relationship between nutritional status and health outcomes in children with CF. Undernutrition adversely affects lung function and quality of life, emphasizing the need for integrated nutritional support and targeted treatment strategies in CF management.

Keywords: Cystic fibrosis, CFTR gene, Disease perception scale, Genetic diseases, Quality of life questionnaire

1. INTRODUCTION

Cystic fibrosis (CF) is an autosomal recessive genetic disorder that causes a progressive deficiency in the function of the exocrine glands and affects many functions of the body. It leads to the accumulation of a thick and sticky layer of mucus in the organs, affecting especially the lungs but also the pancreas, liver and intestines. It is one of the most common chronic lung diseases among children and young adults and is a genetic disorder that can result in death. Pseudomonas and Staphylococcus often cause pneumonia, making the disease fatal (1). CF is caused by a mutation in the gene encoding the cystic fibrosis transmembrane conductance regulator (CFTR) protein. This protein ensures the passage of chloride ions across the cell membrane. Its deficiency leads to impaired production of sweat, digestive juices and mucus, and the disease develops when both alleles are recessive. Researchers have discovered and described more than 1500 mutations related to this disease. Less than 1% of these mutations are due to chromosomal rearrangement mutations, while the majority are small deletions or micromutations (2).

The CF Genetic Analysis Consortium has now reported more than 1700 CFTR mutations, the majority of which are rare. However, the F508del mutation is the most common CF allele worldwide, with an average frequency of 66% on Caucasian CF chromosomes, ranging from 87% in Denmark to 26% in Algeria (3). CF is a disease affecting multiple organs and is associated with a variety of characteristic symptoms. These symptoms include abnormal sweat tests, pancreatic dysfunction, endocrine failure, chronic obstructive pulmonary disease (COPD) with bronchiectasis and recurrent infections. Other clinical manifestations may include azoospermia, gallstones, diabetes, pancreatitis, chronic liver disease and nasal polyps. These are just some of the possible symptoms of the disease and often patients also experience malnutrition and growth retardation. It is estimated that 10% to 15% of babies born to mothers with CF will have meconium ileus, which occurs during labor and is caused by obstruction of the intestines at the level of the terminal ileum. While diagnosis can be difficult to determine, improvement has been achieved over the years thanks to advances in understanding the biology of the disease and innovative treatment (4).

Investigation and treatment of the nutritional status of CF patients has a significant impact on clinical outcomes, which has been demonstrated by several experiments (5). Screening of infants, which symbolizes the beginning of the treatment process, is the first step in making an accurate examination. Many studies have shown that early diagnosis and treatment

can improve lung function and growth characteristics, leading to improved quality of life. These findings support the importance of early diagnosis and treatment techniques (6).

In literature, there are many studies on the effect of nutrition and therapeutic approaches in cystic fibrosis disease. Ede and Köseoğlu (7) revealed the importance of medical nutrition therapy principles and nutrition therapy in cystic fibrosis disease in their review study. Vandevanter et al. (8) summarized structural abnormalities and dysfunctions in the digestive and respiratory systems in children under 6 years of age with CF by reviewing studies published between 1990 and 2014. The study showed that the health status of children diagnosed early through newborn screening was better than those diagnosed symptomatically. The results consistently demonstrated that CF-related growth retardation and airway abnormalities begin at birth and the disease progresses throughout childhood.

Yürük (9) examined the findings of 60 patients admitted to the Pediatric Infection Outpatient Clinic of Balcalı Hospital of Çukurova University Faculty of Medicine with the diagnosis of CF and found problems such as insufficient absorption of nutrients, vitamin and mineral deficiency, inadequate weight gain and growth retardation. Mailhot et al (10) stated in their review that the management of CF has changed significantly with the use of modulators targeting the CFTR gene defect. They stated that this change has reshaped the demographics, prognosis and treatment approaches of CF, including nutritional management. The study focused on the lifelong nutritional management of people with CF in the era of CFTR modulation, addressing various nutritional challenges that require individualized interventions. Mariotti Zani et al (11) studied the effects of malabsorption-induced malnutrition on growth and nutritional status in patients with CF. The study highlighted the importance of a high-calorie diet, pancreatic enzyme therapy and fat-soluble vitamin supplementation. In addition, CFTR modulators have been reported to contribute to improvements in weight gain, BMI and lung function. The challenges of transforming CF into a treatable chronic disease were also discussed. Bailey et al (12) analyzed the impact of food insecurity screening and local food access on nutritional status in CF patients using data from the US CF Patient Registry 2019. They found that in children, food insecurity screening at each visit reduced the odds of being underweight by 39%, while living in a food desert was associated with lower weight and lower BMI percentiles. Buyuksahin et al (13) investigated the factors affecting bone mineral density in children and adolescents with CF.

In this study, we investigated the effects of nutrition and treatment methods and the relationships between these methods in children with CF aged 7-17 years in Libya. The article is organized as follows. In section 2 presents the materials and methods used in the study, in section 3 presents the findings of the study and section 4 summarizes and discusses the results.

2. MATERIAL AND METHOD

Study Design

This study was carried out in a descriptive design to examine the effects of nutrition and treatment methods and the relationships between these methods in children diagnosed with CF aged 7-17 years.

Study Population and Sample

The study population consisted of all patients (300) diagnosed with CF at the University Hospital of Tripoli, Libya. The sample size was determined using G power analysis. The power analysis accepted a mean effect size of 0.55. The error limit α was set at 0.05 and the power limit (1-β) was set at 0.95. In the analysis performed in G-power 3.1.9.4, it was calculated that the required sample size was 169. The sample was selected as a non-probability sample of 169 male and female CF patients admitted to the Tripoli University Hospital who were younger than 17 years of age. In addition, CF patients with other chronic diseases or psychiatric disorders were excluded from the study.

Data Collection

The study was conducted between March and May 2024 to collect data from CF patients. Data collection was conducted through questionnaires and personal interviews. The questionnaires usually took 20 to 30 minutes to complete. The researcher benefited from the training and guidance received from the mentor during the data collection process. Personal information form, CF Symptom Progression Questionnaire (CF-SPS) and Mountain West Cystic Fibrosis Consortium Questionnaire (MWCFC-Q) were used to collect research data to determine the socio-demographic characteristics of the patients.

Socio Demographic Data Form

A personal information form was used to determine the sociodemographic characteristics of CF patients. This form included age, gender, body mass index, forced expiratory volume in one second (FEV1) variables.

Mountain West Cystic Fibrosis Consortium Questionnaire (MWKFC-Q)

The Mountain West CF Consortium Questionnaire (MWKFC-Q) was developed by McDonald and colleagues and used to assess food insecurity in pediatric CF patients living in the western United States (14). This questionnaire also assesses childhood hunger and the short form of the 12-month food security scale created by the Food and Nutrition Service of the US Department of Agriculture (15). The scale consists of 10 questions on a five-point Likert scale. The total score range is between 0 and 40 and Cronbach's alpha value is 0.706.

Cystic Fibrosis Symptom Progression Questionnaire (CF-SPS)

Norrish et al (16) developed a ten-item symptom progression scale commonly associated with pulmonary exacerbation in CF. These items include seven respiratory items and three general items. The respiratory items are cough frequency, child's condition when coughing, description of coughing fits, sputum volume, sputum color, breathing effort and short, shallow, rapid breathing. General items are activity level, normal appetite and recent changes in appetite. Responses to each item are scored on a Likert scale from 1 to 35.

Data Analysis

The independent variables of the study were age, sex, BMI, forced expiratory volume in one second (FEV1) and the dependent variables were the Mountain West CF Consortium Questionnaire (MWKFC-Q) scale score and the CF Symptom Progression Survey (CF-SPS) scale score. In the statistical analysis phase of the study, frequency analysis, means comparison tests and correlation analysis were performed. Skewness and kurtosis coefficients were used to assess the suitability of the data for normal distribution. Parametric tests were used to compare means, in accordance with the normal distribution of the data. Depending on the number of groups, the t-test or one-way ANOVA (F-test) was preferred. The margin of error for the evaluation of the results of the statistical analyses was set at 5%. SPSS 26 (IBM 2023) was used for the analyses.

Ethics

The necessary approval was obtained prior to the study to meet the ethical requirements for research. Ethical approval was obtained from the Ethics Committee of Nesama General Hospital, Ministry of Health, Libyan State (Reference No: 2023/110).

3. RESULTS

Firstly, frequency analyses of the demographic characteristics of patients diagnosed with CF were presented. In frequency analyses, percentage (%) and frequency (n) values of the groups were shown together. The age variable in the study was obtained as both qualitative and quantitative variables. Summary statistics were calculated for the quantitative variable. Table 1 shows the socio-demographic characteristics of patients.

Of the patients diagnosed with CF, 48.5% were aged 14–17 years and 56.8% were male. Regarding body mass index, 34.9% of the patients were underweight, 21.3% were normal/healthy weight, 28.4% were overweight, and 15.4% were obese. Additionally, 57.4% of the patients were classified as having mild obstruction according to the forced expiratory volume in one second (FEV1) variable (Table 1).

When reliability analyses were performed for the MWKFC-Q and KF-SPS scales used in the study, the Cronbach's alpha values of the scales were found to be 0.706 and 0.704, respectively, and the scales were found to be reliable. Scales with a Cronbach's alpha value greater than 0.6 are generally considered reliable. In this context, it can be said that the internal consistency of the scales used in the study is good. In reliability analysis, Cronbach's Alpha (α) coefficient varies between 0 and 1; 0.00-0.40 is considered as low reliability, 0.40-0.60 as moderate reliability, 0.60-0.80 as high reliability and 0.80-1.00 as high reliability (17). Table 2 presents summary statistics of the MWKFC-Q scale score variable and the CF-SPS scale score variables.

The mean score of the MWCFC-Q scale was found to be 21.20 and the mean score of the CF-SPS scale was found to be 20.94 in patients with CF. In addition, as the skewness and kurtosis values for both scales were found to be between ±1.96 values at the 5% significance level, it can be said that the data were normally distributed (18) (Table 2).

In this part of the study, the MWCFC-Q scale score variable was taken as the dependent variable, and it was examined whether it showed a statistically significant difference according to socio-demographic characteristics (Table 3).

A statistically significant relationship was found between age, gender, BMI and MWCFC-Q scale score ($p<0.05$). When the pairwise comparison results were analyzed, the MWCFC-Q scale scores of the patients in the 7–10 age range were higher than those of the patients in the 11–13 age range. In addition, the MWCFC-Q scale scores of patients aged 14–17 years were higher than those of patients aged 11–13 years. According to the BMI variable, the MWCFC-Q scale scores of underweight patients were higher than those of normal/healthy, overweight, and obese patients (Table 3).

The comparison of the total score of the CF-SPS scale according to patient characteristics is presented in Table 4.

A statistically significant association was found between BMI and CF symptoms (CF-SPS). Participants with obesity had higher CF symptom scores compared to those in other BMI categories ($p < 0.05$) (Table 4).

The relationship between the total scores of the MWCFC-Q scale and the CF-SPS scale and patient characteristics is presented in Table 5.

The relationship between the MWCFC-Q scale and CF-SPS scale scores and patient characteristics was analyzed using the Pearson correlation coefficient. The analysis showed a low positive correlation between age and the CF-SPS scale score, and a moderate positive correlation with the BMI variable. In addition, negative low correlations were found between the MWCFC-Q scale and age, BMI, and FEV1 variables (Table 5).

4. DISCUSSION

The results of this study are in line with other studies in literature. The study included a total of 169 participants, 90 of whom were male, and this finding coincides with the study (19), which states that 55% of men have CF. It is also consistent with data from the Cystic Fibrosis Foundation (20), which shows that most CF patients in the United States are male. Most participants were aged 14-17 years, which is consistent with studies (21), which reported that most of their sample was younger than 17 years. The mean MWKFC-Q score obtained in the study was 21.20, which supports the findings of (14) and (21), which revealed a high prevalence of food insecurity. A possible reason for this high score is that most of the participants did not adhere to specific dietary regimes or dietary supplements. A statistically significant effect was observed between CF-SPS scores and body mass index. This finding is consistent with previous studies (22–26) which revealed a strong relationship between the development of CF symptoms

and BMI. It is considered as a possible reason for this finding that CF patients cause malnutrition by affecting the digestive system and this leads to low BMI. In the study, a higher rate of malnutrition was found in the 7-10 age group compared to other age groups. This result is consistent with a study in Brazil, which found that young age is an indicator for malnutrition (27) but is inconsistent with the findings of (23), which stated that malnutrition increases with age. This difference may be explained by the idea that maintaining nutritional status with age may be associated with milder diseases and that later onset of the disease may have a positive effect on nutritional status. When the relationship between gender and nutritional status was analyzed, a statistically significant effect was observed; it was determined that males had more malnutrition problems than females. This finding agrees with a study conducted in Bahrain (28), which indicated that gender is a risk factor for malnutrition in children with CF. It is also consistent with another study in Brazil (27), which found that male gender was an independent factor associated with malnutrition. Looking at the relationship between body mass index and nutritional status, it was observed that most cystic fibrosis patients were underweight (< 18.5 kg/m²). This result is consistent with previous studies (29,30), which indicate that CF patients are generally underweight. It is thought that being underweight may be due to patients having changed their diet to reduce the long-term complications of CF or following dietary guidelines set by their doctor. However, this result is inconsistent with studies reporting that CF patients are overweight (5,19,31), as some patients pay more attention to nutrition, and this increases BMI. In addition, the presence of weight gain among the side effects of the drugs used may have led to an increase in BMI in some patients.

5. CONCLUSION

The results showed that the largest group of CF patients were young people aged 14-17 years with a rate of 48.5% and 56.8% of the patients were male. 34.9% of the participants were underweight, with a body mass index (BMI) below 18.5 kg/m². Furthermore, 57.4% of the patients had mild obstruction of forced expiratory volume in one second (FEV1) (FEV1: 70-90). The mean total CF-SPS score was 20.94 and the mean MWKFC-Q score was 21.20. In addition, it was observed that there was a significant relationship between CF-SPS score and BMI, and CF patients who were underweight experienced an increase in disease symptoms. Significant effects were also found between age, gender and BMI and MWKFC-Q score. This study recommends that CF patients should have regular doctor visits to monitor their health status and growth. Periodic check-ups are necessary to monitor lung function and general health indicators. Regular exercise should be performed to improve respiratory capacity and physical

fitness; activities such as swimming and walking should be favored. Furthermore, educating the child and his/her family about the nature of the disease and the importance of adherence to treatment is of great importance for the adoption of a healthy lifestyle..

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Tables

Table 1. Sociodemographic characteristics of patients with CF

Variables		**n**	**%**
Age / Years	Mean ±SD 13.39±2.65		
Age	7-10 years	26	15.4
	11-13 years	61	36.1
	14-17 years	82	48.5
Gender	Male	96	56.8
	Female	73	43.2
BMI	Underweight < 18.5 kg/m2	59	34.9
	Normal/healthy weight: 18.5–24.9 kg/m2	36	21.3
	Overweight: 25–29.9 kg	48	28.4
	Obese: > 30 kg/m2	26	15.4
Forced Expiratory Volume in One Second (FEV1)	Normal: FEV1 > 90	12	7.1
	Mid obstruction: FEV1 70–90	97	57.4
	Moderate obstruction: FEV1 40–70	50	29.6
	Severe obstruction: FEV1 < 40	10	5.9

SD= Standard deviation

Table 2. Summary statistics of MWKFC-Q scale score and CF-SPS scale scores of patients with CF

Scales	**Mean**	**SD**	**Median (min.-max.)**	**Skewness**	**Kurtosis**
MWKFC-Q total score	21.20	5.95	22.00(9.00 – 34.00)	-0.050	-0.552
KF-SPS total score	20.94	3.94	21.00 (15.00 – 33.00)	0.705	0.122

SD= Standard deviation, min: Minimum, max: Maximum

Table 3. Comparison of MWKFC-Q scale total score according to patient characteristics

Variables		**Total MWKFC-Q Score**				
		Mean	SD	Test Statistics	p value	Significant Differences
Age	7-10 yaş	273.077	285.334	F=32.651	<0.000*	1>3,1>2,3>2
	11-13 yaş	182.623	488.160			
	14-17 yaş	214.512	589.445			
Gender	Male	208.125	558.440	t= 1.824	0.004*	-
	Female	217.123	640.416			
BMI	Underweight:<18.5 g/m2	243.898	490.959	F=8.002	<0.000*	1>3, 1>4, 1>2 3>4, 3>2, 4>2
	Normal/healthy weight:18.5–24.9 kg/m2	174.722	525.621			
	Overweight:: 25–29.9 kg	208.958	672.322			
	Obese: > 30 kg/m2	196.923	343.825			
Forced Expiratory Volume in 1 Second (FEV1)	Normal: FEV1 > 90	223.333	858.469	F=2.561	0.057	-
	Mid obstruction: FEV1 70–90	220.928	656.709			
	Moderate obstruction: FEV1 40–70	194.000	301.696			
	Severe obstruction: FEV1 < 40	202.000	565.292			

p = Probability value calculated using t-test when two groups and F distribution calculated using One-Way ANOVA when three or more groups; significant if p < 0.05, SD: standard deviation.

Table 4. Comparison of total score of CF-SPS scale according to patient characteristics

Variables		**Total MWKFC-Q Score**				
		Mean	SD	Test Statistics	p value	Significant Differences
Age	7-10 yaş	19.6154	3.25056	F=2.671	0.072	-
	11-13 yaş	20.6721	4.14617			
	14-17 yaş	21.5610	3.91293			
Gender	Male	21.1354	4.09009	t= 0.734	0.967	-
	Female	20.6849	3.76341			
BMI	Underweight:<18.5 g/m2	24.0000	3.40385	F=6.139	<0.000*	1>4, 1>3, 1>2, 4>3, 4>2, 3>2
	Normal/healthy weight:18.5–24.9 kg/m2	19.1923	3.04656			
	Overweight:: 25–29.9 kg	21.7500	3.31555			
	Obese: > 30 kg/m2	22.4375	4.76202			
Forced Expiratory Volume in 1 Second (FEV1)	Normal: FEV1 > 90	19.6000	5.91544	F=1.137	0.336	-
	Mid obstruction: FEV1 70–90	20.7200	3.89576			
	Moderate obstruction: FEV1 40–70	20.9897	3.45254			
	Severe obstruction: FEV1 < 40	22.5833	3.92145			

p = Probability value calculated using t-test when there are two groups and using One-Way ANOVA when there are three or more groups; p < 0.05 is significant, SD: standard deviation

Table 5. The relationship between MWKFC-Q scale total score and CF-SPS scale total score and patient characteristics

Variables		**MWKFC-Q scale**	**CF-SPS scale**
Age	Correlation Coefficient	-0,19	0.176
	p	0.014	0.022
	n	169	169
Gender	Correlation Coefficient	0.075	-0.057
	p	0.332	0.464
	n	169	169
BMI	Correlation Coefficient	-0,257*	0.517**
	p	0.001	0.050
	n	169	169
Forced Expiratory Volume in 1 Second (FEV1)	Correlation Coefficient	-0,177*	-0.124
	p	0.021	0.108
	n	169	169