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Original Article

Internal Medicine Section

Subjective Global Assessment and Quality of Life in Hemodialysis Patients- A Clinical Observational Study

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ABSTRACT

Introduction: Malnutrition is a prevalent problem in patients undergoing haemodialysis. Malnutrition is strongly associated with increased morbidity and mortality in these patients. Early detection and intervention is the key to prevent significant morbidity and mortality.

Aim: To assess the nutritional status of Maintenance Haemodialysis (MHD) patients by anthropometry, biochemical measurements, Subjective Global Assessment (SGA), Malnutrition Inflammation Score (MIS). Also, to assess the correlation between SGA, MIS and WHO SF 36 scores which measures the Health Related Quality of Life (HRQOL).

Materials and Methods: This was a clinical observational study which included 60 stable maintenance haemodialysis patients. The patients who were on haemodialysis for atleast 3 months and who fulfilled the inclusion criteria were selected randomly and studied over a period from January 2017 to January 2019. They underwent nutritional status assessment by anthropometry i.e., Body Mass Index (BMI), Mid Arm Circumference (MAC), triceps Skin-Fold Thickness (SFT) and biochemical tests i.e., S.creatinine, S. albumin, S.cholestrol, S.total iron binding capacity (TIBC), S.ferritin, S.transferrin saturation. All the patients were subjected to SGA, MIS and SF 36 questionnaires. They were divided into 3 groups based on SGA scores: well nourished, mild to moderately malnourished and moderate to severely malnourished. Biochemical tests, anthropometric parameters, MIS scores were compared between these three groups using Analysis of variance (ANOVA) test to find out if there was any significant difference. Pearson's correlation was performed to find the degree of correlation between SGA, MIS and WHO SF 36 scores. The p-value less than 0.05 were considered significant.

Results: In the present study, 55% were diabetics and 86.7% were hypertensive. 53.3% of the patients had a dialysis vintage of <30 months (Mean±SD: 44.33±38.52). Based on SGA scores, 20% were in well-nourished group, 63.3% of patients were in mild to moderate malnourished group and 16.7% were in moderate to severely malnourished group. Patients who were moderate to severely malnourished had significantly lesser anthropometric measurements compared to other groups. (p-value for BMI=0.001, MAC=<0.001, TSF=0.003). While studying Biochemical parameters we found that those with moderate to severe malnourishment had significantly lesser S.albumin (p-value=0.001), S.cholestrol (p-value=0.038), S.creatinine (p-value=0.005), S. transferrin (p-value=0.047) saturation. There was no significant difference with respect to S.ferritin (p-value=0.993) and TIBC (p-value=0.921). Those with moderate to severe malnourishment had higher MIS scores (p=<0.001). All quality of life aspects, physical and mental component summary and total scores (except bodily pain) had a significant difference with SGA and MIS parameters (p<0.001). All the quality of life parameters (except bodily pain) had a significant negative correlation with SGA and MIS scores. Overall (Total) SF 36 scores also had a significant negative correlation with SGA (r=-0.785) and MIS scores (r=-0.604).

Conclusion: MIS, SGA and HRQOL SF 36 are cost-effective, simple to use, bedside and readily available tools for nutritional assessment of MHD patients. Patients with poor nutrition have a poor physical and mental quality of life. Hence, it becomes important for us to identify such patients and intervene earlier, in order to improve their quality of life and also reduce morbidity which in turn helps in reducing mortality. This can be effectively carried out by using these simple and cost-effective questionnaires across all MHD units on a periodic basis to monitor their progress towards achieving better health goals.

Keywords: Dialysis, Malnutrition, Mental health, Physical health

INTRODUCTION

Protein Energy Malnutrition (PEM) is prevalent in haemodialysis population due to various reasons such as anorexia (reduced intake), infection (reduced immunity), inflammation (increased protein breakdown), metabolic acidosis (increased protein breakdown) [1]. It leads to increased mortality and morbidity in this maintenance haemodialysis population [2]. There are various validated methods to assess the nutritional status. Some of the traditional methods used are anthropometric measurements [3] like Height, Weight, BMI, Triceps SFT, MAC. Biochemical parameters like serum Albumin, serum Colesterol, serum Creatinine and Transferrin are also used [2]. S.Albumin is a predictor of poor dietary protein intake [2]. Hypoalbuminemia is also common in infection, inflammation and stress which is more prevalent in haemodialysis patients [2]. S.Creatinine is a marker of dietary protein intake and skeletal muscle mass [2]. S.Cholestrol levels are predictors of mortality [2]. There is an increasing risk of mortality as the serum cholesterol rises above the range of 200-300 mg/dL or decreases below 150 mg/dL [2].

There are a few questionnaires which are simple, convenient and cost-effective strategies that can be easily used by the nursing staff or dialysis technicians at the bedside for assessment of nutritional status [3].

Three such questionnaires are SGA [4,5], MIS [6] and Health Related Quality Of Life Short Form 36 Index (WHO HR QOL SF 36) [7]. Assessment of the nutritional status of the haemodialysis population is very essential in order to intervene at an early stage and prevent significant hospital admissions, morbidity and mortality [3].

Thus, the primary objective of the study was to assess the nutritional status of stable MHD patients by anthropometric

methods, biochemical methods, MIS and compare them with SGA scores.

Secondary objective was to correlate SGA, MIS which assesses the nutritional status with the SF 36 scores which measures the HRQOL of these patients.

MATERIALS AND METHODS

This was a clinical observational study conducted at the Institute of Nephro-Urology, Victoria Hospital campus, Bengaluru and Maintenance haemodialysis unit of Manipal Hospital, Bengaluru from January 2017 to January 2019. The study was approved by the Institutional Ethics Committee vide reference number (320-27135-151-203498).

We studied 60 stable outpatients on MHD selected randomly over a period of 2 years, who fulfilled the inclusion criteria. Informed consent was obtained from all the patients.

Inclusion criteria

- Age between 18 to 85 years
- Haemodialysis for at least 3 months
- Ambulatory and receiving an oral diet.

Exclusion criteria

- Hospitalisation in last 3 months prior to the beginning of the study due to severe illness, sepsis, shock, multiple organ failure, coma or surgical conditions.
- Symptomatic Acquired Immunodeficiency Syndrome (AIDS), cirrhosis with encephalopathy, severe congestive heart failure, unstable or new onset angina pectoris, chronic pulmonary disease, and current hospitalisation.

Patients who fulfilled the inclusion criteria were evaluated for the following:

1. Collection of demographic data: Age, gender, co-morbidities (diabetes and hypertension), duration of dialysis. Similar dialysers were used. Each session of HD was of 210-240 minutes.

2. SGA: This bedside tool includes medical and weight histories, change in dietary intake, gastrointestinal symptoms, functional status, and physical examination. Each component is subjectively graded creating an overall score. Score of ≤10=normally nourished, 11-20=mild to moderately malnourished, or >20=moderate to severely malnourished. Scores range from 7 to 35. Higher scores depict poorer level of nutrition [8].

3. Anthropometry measurements: BMI, MAC, SFT. BMI was calculated using height and weight of the patient. BMI=Weight in kg/Height in m^2, expressed as kg/m^2. All the measurements were taken at the end of dialysis by a single investigator. Triceps SFT was measured using a skin fold caliper. An inch-tape was used to measure the MAC. An average of three measurements was taken as the final value.

4. Biochemical tests: S. Albumin, total Cholesterol, S.Ferritin, S.Transferrin saturation, TIBC and S.Creatinine as measured from predialysis fasting blood sample.

5. MIS: Derived from SGA score. It is scored from

1. medical history such as gastrointestinal symptoms, dietary intake, change in weight
2. presence of co-morbidities
3. physical examination such as signs of muscle wasting
4. BMI
5. Laboratory parameters like S. Albumin

Scores range from 0 to 30. Higher scores depict poorer state of nutrition [6].

6. **SF 36:** is a self-report measure of HRQOL. Responses to items can be computed into an eight-domain profile of scores: Physical Functioning (PF), Role Limitations-Physical (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Limitations-Emotional (RE), and Mental Health (MH). Additionally, physical and mental component summary. Scores range from 0 to 100. Higher scores depict better QOL [7].

The questionnaires were readout to the patients and their results were recorded by a single investigator. The physical examination of the patients was conducted by the same investigator at the same time. Biochemical parameters were obtained from the hospital MRD.

STATISTICAL ANALYSIS

Descriptive and inferential statistical analyses were carried out in the present study. Continuous data were presented as (Mean±SD) and categorical measurements were presented as numbers (percentage %). Significance was assessed at 5% level of significance.

Analysis of variance (ANOVA) was used to find the significance of study parameters between three or more groups of patients. Pearson's correlation between study variables was performed to find the degree of relationship, Pearson's correlation co-efficient ranging between -1 to 1. The p-value less than 0.05 were considered significant. The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

RESULTS

A total of 60 patients were enrolled in the study. Majority of patients (41/60) were in the 51 to 70 years age group [Table/Fig-1].

Age in years	No. of patients	%
<40	3	5.0
40-50	7	11.7
51-60	19	31.7
61-70	22	36.7
71-80	8	13.3
>80	1	1.7
Total	60	100.0

[Table/Fig-1]: Age distribution of patients.
Mean±SD: 59.62±11.94 yrs

Out of the total study subjects 65% were males [Table/Fig-2], 55% were diabetics [Table/Fig-3], 86.7% were hypertensive [Table/Fig-4], 53.3% of the patients had a dialysis vintage of <30 months [Table/Fig-5].

Gender	No. of patients	%
Female	21	35.0
Male	39	65.0
Total	60	100.0

[Table/Fig-2]: Gender distribution of patients studied.

Diabetes mellitus	No. of patients	%
No	27	45.0
Yes	33	55.0
Total	60	100.0

[Table/Fig-3]: DM incidence of patients studied.

Hypertension	No. of patients	%
No	8	13.3
Yes	52	86.7
Total	60	100.0

[Table/Fig-4]: HTN incidence of patients studied.

According to SGA, patients were divided into 3 groups as follows: 20% were in well-nourished group, 63.3% of patients were in mild to moderate malnourished group and 16.7% were in moderate to severe malnourished group [Table/Fig-6].

Dialysis vintage (No. of months)	No. of patients	%
<30	32	53.3
30-90	20	33.3
>90	8	13.3
Total	60	100.0

[Table/Fig-5]: Dialysis Vintage distribution of patients studied.
Mean±SD: 44.33±38.52

SGA category (Score range)	No. of patients	%
Well nourished (≤10)	12	20.0
Mild to moderate malnourished (11-20)	38	63.3
Moderate to severe malnourished (>20)	10	16.7
Total	60	100.0

[Table/Fig-6]: SGA Distribution.

As per ICMR, BMI of less than 18.5 kg/m^2 is considered as underweight [2]. Skin Fold Thickness (TSF) depicts the subcutaneous fat [2]. MAC depicts skeletal mass [2]. While studying anthropometric parameters we found that there was a significant difference between the three groups. For BMI (p=0.001), MAC (p<0.001) and for TSF (p=0.003) in the 3 groups according to SGA groups [Table/Fig-7]. Patients with lower BMI scores had higher SGA scores predicting moderate to severe malnourishment. Patients with lesser MAC and lesser skin fold thickness values had higher SGA scores [Table/Fig-7].

Anthropometric parameters	SGA category (Mean±SD)			p-value
	Well nourished	Mild to moderate malnourished	Moderate to severe malnourished	
BMI (kg/m^2)	27.03±6.87	23.06±3.51	19.59±3.10	**0.001****
Mid arm circumference (in cm)	28.13±3.96	25.15±3.15	18.55±2.71	**<0.001****
Skin fold thickness (in mm)	12.62±3.02	11.01±3.67	7.46±2.68	**0.003****

[Table/Fig-7]: Comparison of Anthropometric parameters in relation to SGA category of patients studied.
*statistically significant (p<0.05); **statistically highly significant (p<0.001)

Biochemical tests such as S.albumin, S.cholestrol, S.creatinine and Transferrin Saturation (TSAT) were significantly different between the three groups. For S.albumin (p=0.001), S.cholestrol (p=0.038), S.creatinine= (p=0.005), S.TSAT (p=0.047). Patients with lower serum albumin levels, lower serum cholesterol levels, lower serum creatinine and lower transferrin saturation scores had higher SGA scores [Table/Fig-8].

Variables	SGA category (Mean±SD)			p-value
	Well nourished	Mild to moderate malnourished	Moderate to severe malnourished	
Serum albumin (gm/dL)	3.45±0.73	3.47±0.51	2.67±0.46	**0.001****
Serum cholesterol (mg/dL)	158.25±33.05	140.50±37.33	116.70±39.16	**0.038***
Serum creatinine (mg/dL)	7.95±2.94	7.07±2.13	4.83±1.42	**0.005***
Transferrin saturation (%)	31.99±9.11	25.39±17.80	17.98±5.22	**0.047***
Ferritin (ng/mL)	871.50±1204.17	372.19±344.88	866.90±546.03	0.993
TIBC (microgm/dL)	240.92±48.22	238.05±66.53	230.30±68.05	0.921

[Table/Fig-8]: Comparison of lab parameters in relation to SGA category of patients studied.
*statistically significant (p<0.05); **statistically highly significant (p<0.001)

A significant difference was noted in MIS scores between the three groups (p=<0.001). Patients with higher MIS scores were found in moderate to severely malnourished category [Table/Fig-9].

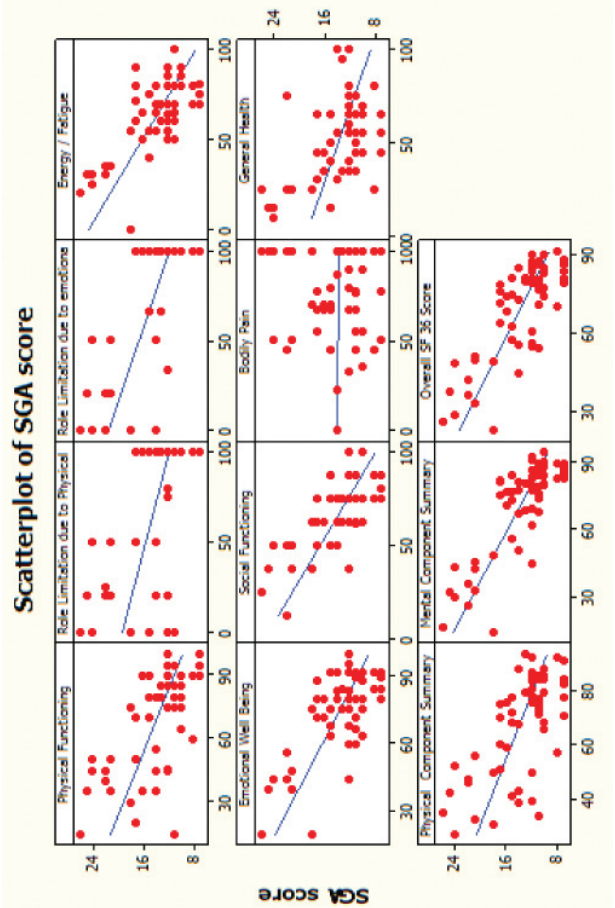
	SGA category (Mean±SD)			p-value
	Well nourished	Mild to moderate malnourished	Moderate to severe malnourished	
MIS	10.83±1.70	15.82±3.12	21.70±8.82	<0.001**

[Table/Fig-9]: Comparison of MIS in relation to SGA category.
*statistically significant (p<0.05); **statistically highly significant (p<0.001)

There was a significant negative correlation between MIS scores and WHO HR-QOL SF 36 parameters. Patients with poor nourishment (higher MIS scores), had poorer quality of life (lesser HRQOL SF 36 scores). Also, there was a significant negative correlation between SGA scores and WHO HR-QOL SF 36 scores. Patients with severe malnourishment (higher SGA scores), had poor quality of life (lesser WHO HRQOL SF 36 scores). However, Bodily pain component had no association with the nutritional status of

WHO QOL SF 36	With SGA		With MIS	
	r-value	p-value	r-value	p-value
Physical functioning	-0.655	**<0.001****	-0.562	**<0.001****
Role limitation due to physical health	-0.593	**<0.001****	-0.441	**<0.001****
Role limitation due to emotional health	-0.706	**<0.001****	-0.510	**<0.001****
Energy/Fatigue	-0.747	**<0.001****	-0.580	**<0.001****
Emotional well being	-0.718	**<0.001****	-0.583	**<0.001****
Social functioning	-0.685	**<0.001****	-0.566	**<0.001****
Bodily pain	-0.010	0.941	0.032	0.810
General health	-0.474	**<0.001***	-0.354	**0.006***
Physical component summary	-0.657	**<0.001****	-0.501	**<0.001****
Mental component summary	-0.806	**<0.001****	-0.623	**<0.001****
Overall SF 36 score	-0.785	**<0.001****	-0.604	**<0.001****

[Table/Fig-10]: Pearson's correlation coefficient (r value) of WHO-HRQOL SF 36 with SGA and MIS.
*statistically significant (p<0.05); **statistically highly significant (p<0.001)



[Table/Fig-11]: Scatter plot depicting SGA score (red dots) and SF 36 scores (blue lines). We can see that except bodily pain, the rest of the parameters depict poor HRQOL (lower SF 36 scores) in patients who are severely malnourished (higher SGA scores).

the patient [Table/Fig-10,11]. Overall SF 36 score had negative correlation with SGA (r=-0.785) and MIS scores (r=-0.604).

DISCUSSION

Malnutrition remains a serious concern in patients on MHD. There is a wide prevalence of PEM in patients on chronic haemodialysis and it is associated with poor QOL [2,9]. The present study study has demonstrated a prevalence of mild to moderate and moderate to severe malnutrition in 63.3% and 16.7% of patients respectively. In a study conducted by Janardhan V et al., 91% were in moderately nourished group of the total haemodialysis population [9]. Majority of the patients were in mild to moderately nourished group similar to our study.

Higher scores of SGA are associated with higher levels of malnourishment [9]. In our study, Patients in moderate to severely malnourished group had lower anthropometric values and lower biochemical parameters such as S.albumin, S.creatinine, S.cholestrol, S.TSAT. The findings are similar to the study by Janardhan V et al., who studied 66 haemodialysis patients in a south Indian tertiary care centre [9]. They demonstrated a significant negative correlation of anthropometric parameters and biochemical parameters such as Serum albumin, TIBC, ferritin and transferrin with the SGA scores. There was no significant difference in TIBC, S.ferritin and nutritional status in the various SGA categories in this study. Study by Janardhan V et al., showed a significant negative correlation between S.Ferritin and SGA categories [9]. Ferritin is also an acute phase reactant [9]. TIBC and Ferritin levels could be confounded by administration of I.V. iron supplements in this study.

In the present study, patients who had severe malnutrition had higher MIS scores. In a study by Zadeh KK et al., haemodialysis patients who were severely malnourished as per MIS scores had higher morbidity and mortality [10]. Malnutrition leads to increase in inflammatory parameters in the body. Inflammation in turn exaggerates malnutrition status, negative nitrogen balance, anorexia and weight loss. Hence both are closely interlinked [11].

There are various ways to assess the nutritional status of a haemodialysis patient, from anthropometric parameters to more complex methods such as Dual-energy X-ray Absorptiometry, bioimpedance assay [3]. But such complex methods are expensive, more time consuming, cumbersome and not always reliable [3]. Hence, SGA was designed to overcome these problems [3,8]. It is easy to use as it does not require any major training [3,8]. It is simple, reproducible, cost-effective and can be performed rapidly at bedside. It categorises patients into just 3 levels of severity of malnourishment [8]. One disadvantage is that it does not consider visceral protein levels [8]. It emphasises more on diet intake and body composition [8]. MIS scores are derived from SGA. They are more objective than SGA. MIS and SGA scores are surrogate markers of malnutrition and inflammation [6].

Nutritional status is likely to influence physical function, emotional well-being and overall quality of life in HD patients, and it also appears from observational studies that there is a strong independent relationship between malnutrition, quality of life and mortality risk in HD patients [6]. The present study also observed that there was a significant decline in the physical and the mental components of the WHO HRQOL SF 36 scores with a decrease in nutritional status of the patients. Patients who were severely malnourished, had poorer physical and mental components of quality of life (except for bodily pain). This finding is of clinical significance since SF 36 is a strong predictor of morbidity and mortality in MHD patients and the importance of HRQOL has been increasingly recognised by the healthcare providers [7]. But till date, the assessment of HRQOL still remains a research domain rather than being a routine practice in clinical arena. Rambod M et al., studied 809 stable HD outpatients and followed them up for 5 years. They concluded that MIS is associated with quality of life and prospective mortality [12]. Bilgic A et al., also demonstrated significant correlation between MIS and poor quality of life [13]. All these study results are similar to the current study results.

To the best of our knowledge this study is the first in India to assess the correlations between SGA, MIS scores and SF 36 HRQOL in Haemodialysis patients in a tertiary care hospital.

Limitation(s)

It is also important to assess whether interventions that improve HRQOL also decrease the risk of death and hospitalisation among haemodialysis patients. Hence, more studies with interventions are required. As the study was conducted using SGA, MIS and WHO HRQOL SF 36 questionnaire, the assessment and results are subjective.

CONCLUSION(S)

Malnutrition is one of the most commonly encountered problems in haemodialysis population as it increases the morbidity and mortality. Though anthropometry and biochemical tests are routinely done, they are incomplete, cumbersome to perform, time consuming, expensive and sometimes yield misleading results. SGA or MIS questionnaires help health care providers to identify patients who are poorly nourished, depressed and in need of physical and emotional support. SF 36 helps to assess the patients physical functioning and emotional well-being which can help the health care providers to assess the functional capacity of patients, recognise the symptoms of mental illness like depression, insomnia and facilitate psychiatric therapy. Also, helps to identify specific health related problems affecting different dimensions of a person's life.

Based on this information, interventions such as intradialytic parenteral nutrition, appetite stimulants, anti-inflammatory drugs, exercise, anabolic hormones can be determined. Patients can be enrolled for diet therapy to ensure adequate intake of calories, protein, salts such as sodium, potassium, phosphorous, calcium and water. We can also monitor the progress of the patients by periodically assessing them. These interventions will help in improving the quality of life and reducing morbidity and mortality of the patients.

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