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A Prospective Study to Assess the Glycemic Pattern of Patients Undergoing Hemodialysis in End Stage Renal Disease, to Find Out the Influence of Glucose Levels on Serum Potassium and Impact of Patient Counselling on Patient's Quality of Life

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ABSTRACT

Background: Chronic kidney disease (CKD) is recognized as a major health problem. Numbers of prevalent CKD patients continues to rise, reflecting the growing elderly population and increasing numbers of patients with diabetes and hypertension.

Objectives: To assess the glycemic pattern, serum potassium levels and impact of counselling in patients undergoing maintenance hemodialysis in end stage renal disease.

Methods: Out of patients undergoing maintenance hemodialysis in dialysis unit, 53 patients were recruited for the study as per sample size calculation. The dialysis is done with glucose free dialysate solution. The glucose profile of patients was monitored before, during and within 1 hour after dialysis period by using glucometer On Call Plus. The patients were reviewed after a month for follow up according to each of their dialysis schedule. Serum potassium levels will also be monitored to assess the impact of glucose levels on it. A structured interview with patient or care giver was conducted by using questionnaire to elicit information about their lifestyle and dietary habit. Also, the impact of kidney disease in their daily life using KDQOL^{TM}-SFv1.3 questionnaire was also assessed. Proper counseling about drugs and diet was given to the patients, by using validated Patient Information Leaflet. The counseling was provided during the waiting hours for dialysis session. The datas were statistically analyzed using SPSS v (22.0).

Results: Average age of study population was 60.8±13.32 years. The mean value of glucose levels on blood before the start of dialysis was higher (192.8±88.6) in comparison to glucose levels during intra dialysis and post dialysis. The values of glucose levels during dialysis were slightly higher (155.5±46.2) than post dialysis. Frequency of patients having potassium levels between 3.5-5.5 mEq/L that is 56.6% and those showing levels above 5.5mEq/L that is 43.4%.56.6 % of patients showed levels between 3.5-5.5mEq/L and 43.4 % showed levels above 5.5mEq/L. It was found that the result was statistically insignificant. Mental health was one among the significantly affected domain and an average score was increased to be 62.5±14.59% (p=0.0015). An average score of physical health was also increased and it was statistically significant.

Conclusion: Diabetic patients were more prone to hyperglycaemia than non-diabetic patients. Patients with diabetes may experience hypoglycaemia after dialysis and can be prevented by giving a mid-dialysis snack and through continuous monitoring of glucose levels on dialysis days. The present study has revealed that there is significant correlation between physical health, mental health and kidney function, whenever there is problem in kidney physical and mental health get affected.

Keywords: Hemodialysis,Hyperglycemia,Hypoglycemia, KDQOL

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I. INTRODUCTION

Chronic Kidney Disease (CKD) is characterized by a progressive deterioration in kidney function ultimately leading to irreversible structural damage to existing nephrons. Kidney Disease Outcome Quality Initiative defines CKD as kidney damage or a reduced glomerular filtration rate (GFR)<60ml/min/1.73m² for three months or more irrespective of the cause.[1,2] Dialysis makes it possible to continue living with chronic kidney disease for many years or even decades. There are two main types of dialysis known as hemodialysis and peritoneal dialysis. Hemodialysis is the most used type of dialysis. In this method blood is transported out of the body through tubes and cleaned in a machine using dialysis fluid. [3,4]

Major initiation factors for CKD include diabetes mellitus, hypertension and glomerular nephritis and progression factors include hypertension, diabetes mellitus, proteinuria, smoking, hyperlipidaemia.[5] Strict glycaemic control is clearly indicated to improve diabetic management, reduce proteinuria and slow the rate of decline in eGFR. High protein consumption accelerates the progression of diabetic nephropathy presumably because of increased glomerular hyper filtration and intraglomerular pressure. Maintaining consistent glycemic control is difficult in patients with End Stage Renal Disease (ESRD) because the disease causes many changes in glucose metabolism, insulin resistance, secretion and degradation, whereas hemodialysis treatment results in changes to drug metabolism.[6,7]

Factors that are associated with an increased risk of haemodialysis-induced hypoglycaemia include use of glucose-free dialysate, glucose loss during dialysis, decreased renal gluconeogenesis and alterations in metabolic pathways. Factors that are associated with haemodialysis-associated hyperglycaemia and other glucose disarrays in patients with ESRD include insulin resistance, removal of insulin by haemodialysis and secretion of counter regulatory hormones.[8] The uraemic toxin pseudouridine, which accumulates in the circulation of patients with renal failure, has been reported to impair insulin-mediated glucose utilization in muscle. Patients with ESRD show increased serum levels of the gluconeogenic hormones glucagon and parathyroid hormone as well as resistance to the anabolic hormones insulin, growth hormone and insulin-like growth factor-1.Vitamin D deficiency, obesity, metabolic acidaemia and inflammation also contribute to insulin resistance in advanced CKD.[9]

Glucose readily cross the dialysis filter and lead to negative and positive balances depending on concentration gradient across the membrane. Dialysis solutions do not contain glucose and thereby cause loss of blood glucose in the dialysis effluent. [10,11] Other factors include poor food intake, reduced insulin excretion and reduced gluconeogenesis. Insulin is said to be removed from blood and filtered during dialysis, especially when high flux dialysers are used which can effect on post hyperglycemia.[12] Using glucose-based dialysate fluid, giving snacks during dialysis as per diet instructed by physician, reducing predialysis anti-diabetic medications in patients experiencing hypoglycemia may help to prevent glycemic fluctuations.[13]

Potassium (K^+) is the most abundant intracellular cation, with >98% of total body K^+ (approx. 4,000 mEq) being intracellular and <2% (70–80 mEq) extracellular.Hyperkalemia is one of the common electrolyte disorders in patients with CKD. Decreased glomerular filtration and tubular K^+ secretion, often coupled with a generous dietary K^+ intake, are the major causes.[14] Symptoms and signs of hyperkalemia vary widely from nonspecific muscle weakness to paresthesia, paralysis, cardiac arrhythmias, and cardiac arrest.Electrocardiogram may show peaked T waves, prolonged PR interval, loss of P waves, widening of QRS complex, arrhythmias, and sine waves. Importantly, ECG changes are not sensitive for hyperkalemia. CKD patients can develop life-threatening hyperkalemia without accompanying typical EKG changes.[15]

Management of hyperkalemia is based on clinical scenarios. For mild-tomoderate ($[K^+]$ <6.5 mEq/l) and asymptomatic hyperkalemia, a combination of dietary K^+ restriction (<75 mEq/day) and kaliuresis (loop and thiazide diuretics) is generally effective. Medications with hyperkalemic potentials should be modified when appropriate.[16]For severe and symptomatic hyperkalemia, the patient should be monitored and intravenous calcium administered for myocardium stabilization. Temporizing measures to shift K^+ into the cells such as albuterol inhalation, intravenous regular insulin with glucose or dextrose infusion, and isotonic $NaHCO_3$ (when metabolic acidosis is present) are appropriate. Kayexalate and kaluretic diuretics can be used when there is no contraindication. Hemodialysis is effective for

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patients with advanced kidney dysfunction or refractory to conservative measures.[17]

The Kidney Disease Quality of Life (KDQOL) survey is a kidney diseasespecific measure of HRQOL. The first version contained the Medical Outcomes Study 36 (MOS SF- 36) as a generic chronic disease core, plus items relevant to patients with kidney disease, such as symptoms, burden of illness, social interaction, staff encouragement, and patient satisfaction.[18] Blood pressure control and a better glycemic control are necessary to slow down the disease progression and to prevent the further complications in CKD. Hence it is very important in proving information about the lifestyle modifications, dietary regulations and the importance of medication adherence.

II. METHODOLOGY

An observational study was conducted in patients undergoing maintenance hemodialysis in end stage renal disease. The study period was four months. The study was conducted in Dialysis unit of Cosmopolitan Hospital, PG Institute of Health Science and Research in Thiruvananthapuram, Kerala.

INCLUSION CRITERIA

- Patients above the age of 18 years.
- End stage renal disease patients on hemodialysis among which both diabetic and nondiabetic patients were included

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EXCLUSION CRITERIA

- Patients who are not willing
- Pregnant women

A Prospective-observational study was conducted in patients in Dialysis unit of Cosmopolitan Hospital, who are undergoing maintenance hemodialysis in end stage renal disease. The target sample size was 53. Patients were screened and recruited in the study after satisfying predefined inclusion and exclusion criteria. The study period is four months and was conducted after getting the clearance from the Institutional Ethical Committee.

A written informed consent was taken from dialysis patients as per ICMR Biomedical Research Guideline Format. Patients were provided with a copy of informedconsent form and a patient information sheet regarding the purpose, benefits, risks and protocol of the study. All information relevant to the study was collected from case records by using a suitably designed proforma and direct interview with patients using questionnaires. All the scales were translated into local language (Malayalam) of the patient.Patients were requested to answer the questionnaire and were provided with counselling regarding the disease, drugs and lifestyle modifications using PIL, which was provided in English and local languages (Malayalam).

Out of patients undergoing maintenance hemodialysis in dialysis unit, 53 patients were recruited for the study as per sample size calculation. The glucose profile of patients was monitored before, during and within 1 hour after dialysis period by using glucometer On Call Plus. The dialysis is done with glucose free dialysate solution. Serum potassium levels was also monitored.

A structured interview with patient or caregiver was conducted by using questionnaire to elicit information about their life style and dietary habit. Also the impact of kidney disease in their daily life using **KDQOL-SF™ 36** questionnaire was assessed. Proper counselling about diet was given to the patients, by using validated PIL. The counselling was provided at each visit to the dialysis centre and the changes in the score was recorded. The outputs were statistically plotted.

The KDQOL-SF™ 36 questionnaire used is a validated questionnaire that contains 36 items health survey. Symptoms or problems 12 items, effect of kidney disease on daily life 8 items, burden of kidney disease 4 items, general health, limitations due to physical health, limitations due to emotional problems. A high score will indicate better QOL and 100 represent perfect health while zero indicates death. A score will be given to each response and finally the average will be taken with the help of previously designed SAS software program. Quality of life before and after counselling also was assessed. One follow up was taken according the each patient's dialysis schedule.

Statstical analysis of data

Data were fed to the computer and analyzed using SPSS software package version 22.0. Qualitative data were described using number and percent. Quantitative data were described using mean, standard deviation, and median. A calculated P value <0.05 is considered to be statistically significant. The association between qualitative

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study variables was assessed by Chi-square test and unpaired t-test was used for comparison of two independent groups.

III. RESULTS

AGE DISTRIBUTION

Age in years	Frequency(n)	Percentage(%)
≤50	10	18.9
51 – 60	14	26.4
61 – 70	15	28.3
>70	14	26.4
Total	53	100

Table 1: Age group distribution

Table 1 shows frequency distribution of patients undergoing haemodialysis in end stage renal disease. 18.9% of the patients were in the age group below 50, 26.4 % of the patients were in the age group of 51-60, 28.3% of the patients were in the age group of 61-70 and 26.4% of the patients were in age group above 70. Average age of study population was 60.8±13.32 years. Fig 1 represents distribution of patient's age in years.

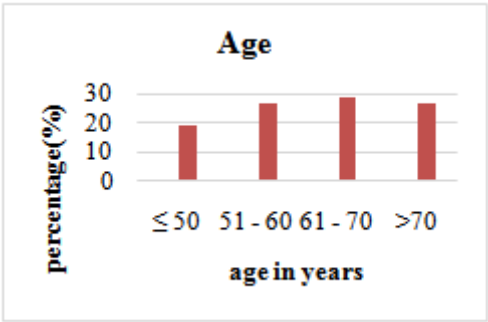

Fig1: Age group distribution

GENDER DISTRIBUTION

Table 2: Gender distribution

Gender	Frequency	Percent
Female	16	30.2
Male	37	69.8
Total	53	100

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Table 2 represents the frequency distribution of patients according to gender. Out of 53 patients, 16 were female and remaining were male. Fig 2 represents distribution of patients according to gender.

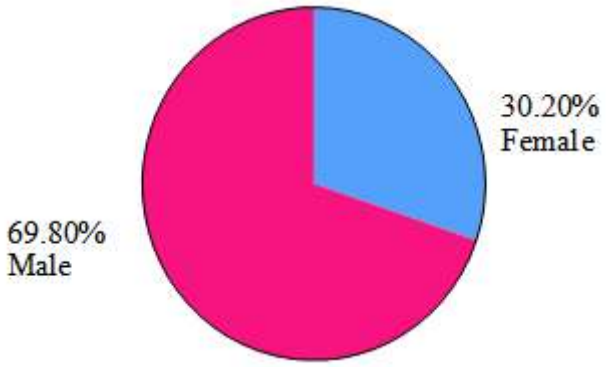

Fig 2: Gender distribution

DIALYSIS SESSIONS

Dialysis session	Frequency(n)	Percentage (%)
Morning	19	35.8
Afternoon	19	35.8
Evening	15	28.3
Total	53	100

Table 3: Distribution of patients attending dialysis session atdifferent times of a day

Table 3 shows frequency distribution of subjects attending dialysis in different times of the day. Out of 53 patients, 19 patients attended morning session, 19 subjects attended afternoon session and 15 subjects attended evening session. Fig 3 represents distribution of patients attending dialysis session at different times of a day.

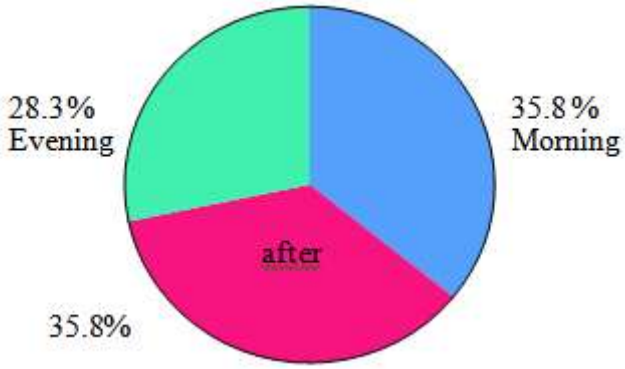

Fig 3: Frequency distribution of subjects attending dialysis session at different times of a day

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DISTRIBUTION OF PATIENTS EXPERIENCING DIFFICULTIES DURING DIALYSIS

Symptoms	Frequency(n)	Percent(%)
Hypotension	21	39.6
Muscle Cramps	21	39.6
Shortness of breath	11	20.8

Table 4: Distribution of patients experiencing difficulties during dialysis

Table 6 represents the frequency distribution of patient's difficulties during dialysis session. 39.6% of patients had hypotension, 39.6% of patients had muscle cramps and 20.8% of patients experienced shortness of breath. Fig 5 represents distribution of patients experiencing difficulties during dialysis.

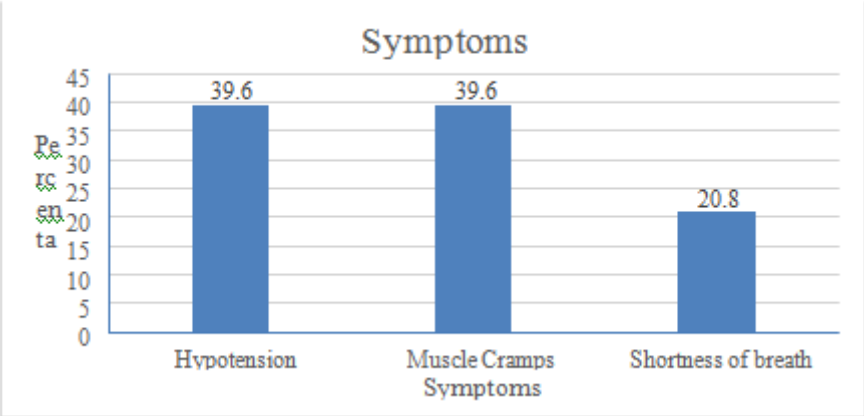

Fig 4: Distribution of patients according to difficulties experienced during dialysis

MEAN GLUCOSE LEVELS ON PRE-DIALYSIS, INTRA-DIALYSIS AND POST DIALYSIS

Duration	N	Minimum (mg/dl)	Maximum (mg/dl)	GRBS (mg/dl)	
				Mean	Sd
Pre dialysis	53	70	486	192.8	88.6
Intra dialysis	53	84	293	155.5	46.2
Post dialysis	53	74	234	130.3	39.1
Total	53	228	1013	478.6	173.9

Table 5: Mean glucose levels on pre dialysis, intra dialysis and post dialysis(Baseline)

Table 5 represents the mean value of glucose levels on blood before the start of dialysis was higher (192.8±88.6) in comparison to glucose levels during intra dialysis and post dialysis. The values of glucose levels during dialysis were slightly higher (155.5±46.2) than post dialysis. Fig 5 represents the mean glucose levels on pre-dialysis, intra dialysis, and post dialysis.

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Fig5: Mean glucose levels on pre dialysis, intra dialysis and post dialysis(Baseline)

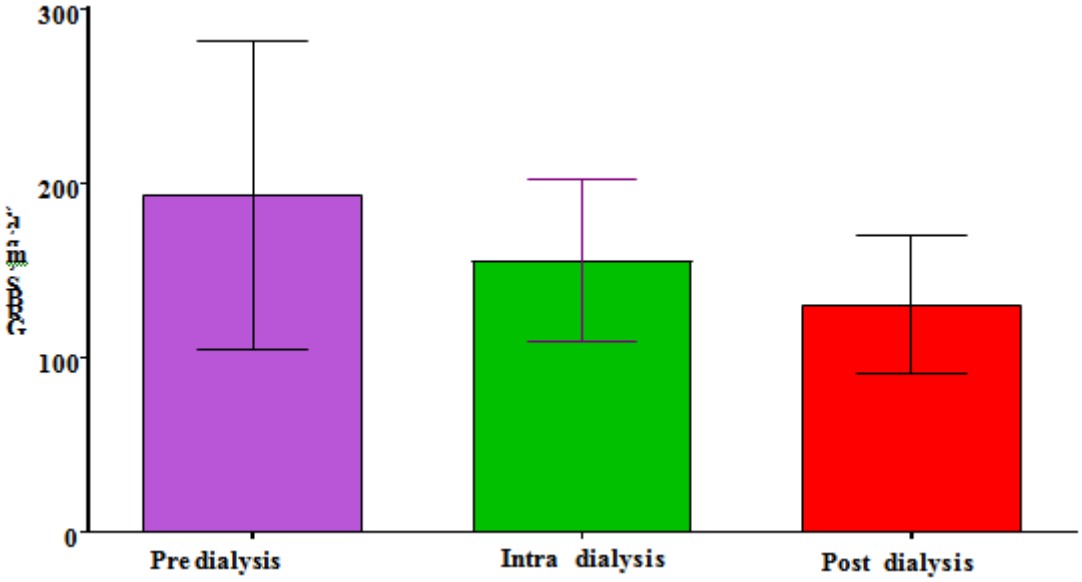

Table 6: Mean glucose levels on pre-dialysis, intra-dialysis and post dialysis (Follow up)

Duration	**N**	**Minimum (mg/dl)**	**Maximum (mg/dl)**	**GRBS (mg/dl)**	
				Mean	Sd
Pre dialysis	53	90	399	179.7	63.5
Intra dialysis	53	80	213	148.1	35.7
Post dialysis	53	84	196	130.8	33.1
Total	53	254	1008	458.6	132.3

Table 6 ,the mean value of glucose levels on blood before the start of dialysis was higher (179.7±63.5) in comparison to glucose levels during intra dialysis and post dialysis. The values of glucose levels during dialysis were slightly higher (148.1±35.7) than post dialysis. Fig 6 represents the mean glucose levels on pre dialysis, intra dialysis and post dialysis.

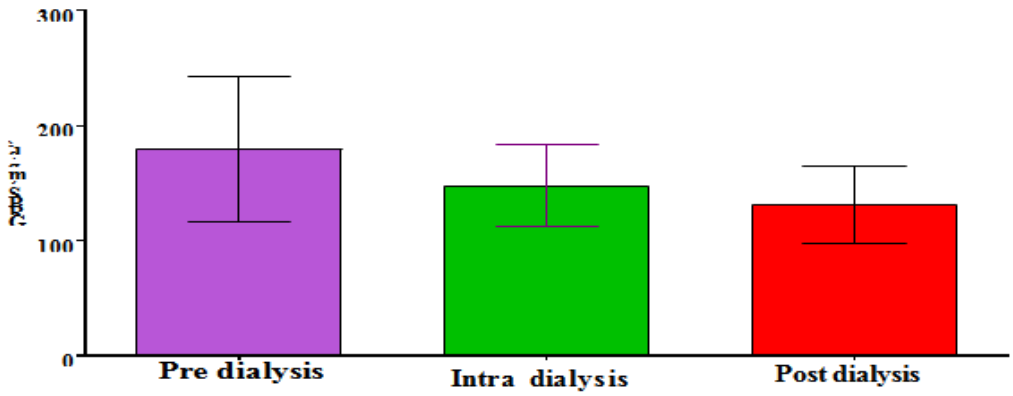

Fig 6: Mean glucose levels on pre-dialysis, intra-dialysis and post dialysis (Follow up)

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GLYCEMIC STATUS ON POST DIALYSIS

Table 7: Glycemic status on post dialysis(Baseline)

GRBS level post dialysis	DM				Total		χ2	df	P
	Yes		No						
	N	%	n	%	N	%			
Hypoglycaemia	5	13.2	4	26.7	9	17	5.458	2	0.004
Normal	15	39.5	9	60	24	45.3			
Hyperglycemia	18	47.4	2	13.3	20	37.7			
Total	38	100	15	100	53	100			

Table 7 represents the glycemic status in post dialysis. The main objective of the study was to assess the glycemic pattern of patients undergoing haemodialysis in end stage renal disease. The GRBS level post dialysis can be hyperglycemic, hypoglycemic or normal. Out of 53 patients 13.2% of diabetic patients and 26.7 % of non-diabetic patients showed hypoglycemia. Thus, a total 17 % showed hypoglycemia. Out of 53 patients 18% of diabetic patients and 13.3 % of non-diabetic patients showed hyperglycemia. Thus, a total 37.7 % showed hyperglycemia. A percentage of 45.3 % patients expressed normal glycemic levels. It was found that the result was statistically significant (P 0.004). Fig .7 represents the glycemic status in post dialysis.

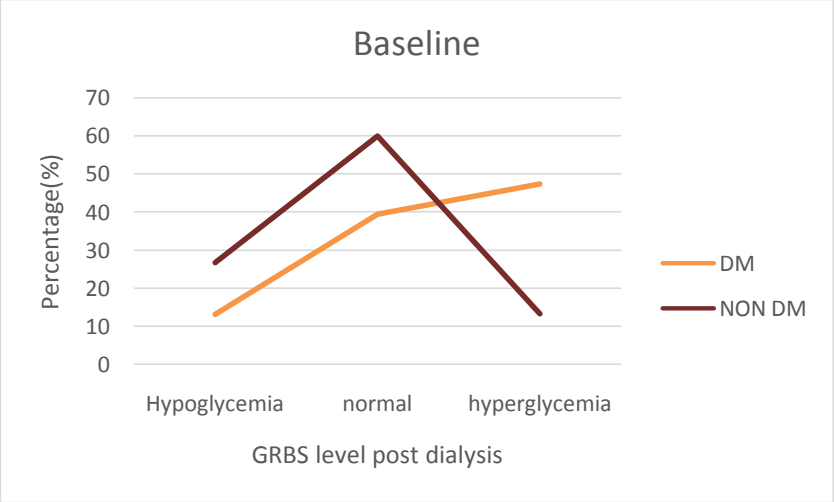

Fig 7:Glycemic status on post dialysis(Baseline)

Table 8: Glycemic status on post dialysis (follow up)

GRBS level Post dialysis (follow up)	DM				Total		χ2	df	p
	Yes		No						
	n	%	n	%	n	%			
Hypoglycemia	4	10.5	3	20	7	13.2			

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Normal	14	36.8	12	80	26	49.1	12.709	2	0.002
Hyperglycemia	20	52.6	0	0	20	37.7			
Total	38	100	15	100	53	100			

Table 8 represents the follow up of glycemic status post dialysis in 53 patients participating in the study. The GRBS level post dialysis can be hyperglycemic, hypoglycemic or normal. Out of 53 patients 10.5% of diabetic patients and 20% of non-diabetic patients showed hypoglycemia. Thus, a total 13.2 % showed hypoglycemia. Out of 53 patients 14% of diabetic patients and 12 % of non-diabetic patients showed hyperglycemia. Thus, a total 49.1 % showed hyperglycemia. A percentage of 49.1 % patients expressed normal glycemic levels. It was found that the result was statistically significant (P 0.002). Fig 8 represents the follow up of glycemic status post dialysis in 53 patients participating in the study.

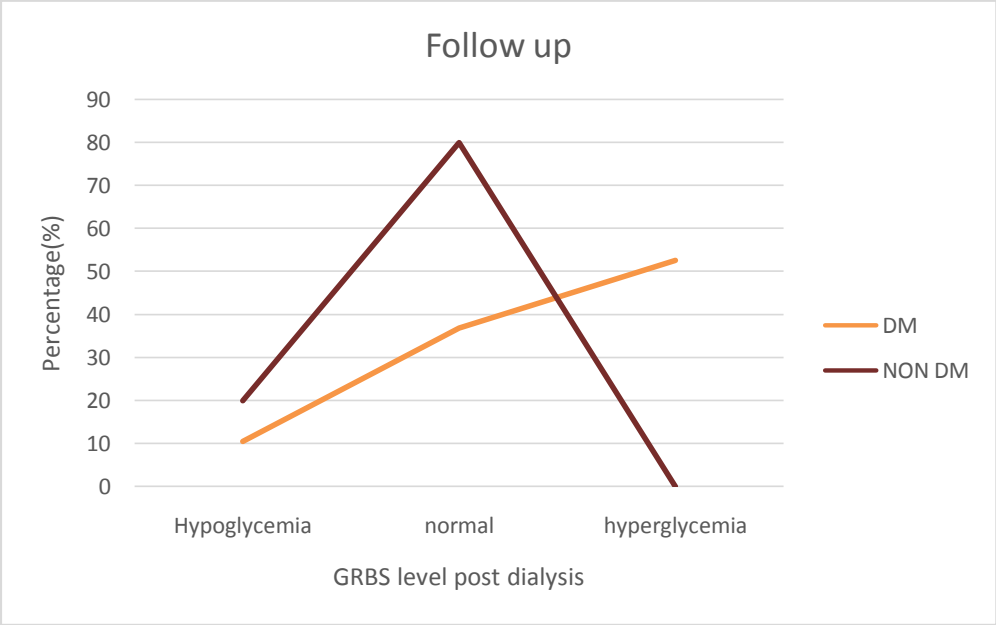

Fig 8: Glycemic status on post dialysis (follow up)

THE INFLUENCE OF GLUCOSE LEVELS ON SERUM POTASSIUM

Table 9: The influence of glucose levels on serum potassium

Potassium (mEq/l)	**DM**				**Total**		**χ^2**	**df**	**p**
	Yes		No						
	N	%	N	%	n	%			
3.5-5.5	20	52.6	10	66.7	30	56.6	0.862	1	0.353
>5.5	18	47.4	5	33.3	23	43.4			
Total	38	100	15	100	53	100			

Table 9 represents the influence of glucose levels on serum potassium. 56.6 % of patients showed levels between 3.5-5.5mEq/L and 43.4 % showed levels above 5.5mEq/L. It was found that

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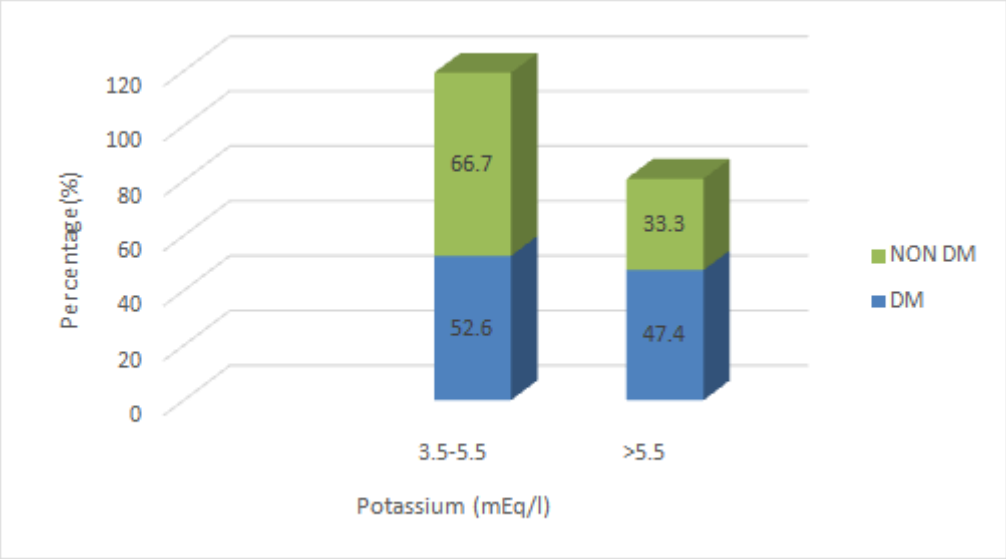
the result was statistically insignificant. Fig 9 represents the influence of glucose levels on serum potassium.

Fig 9 :The influence of glucose levels on serum potassium



POTASSIUM LEVELS

Table 10: Potassium levels

Potassium (mEq/l)	Frequency (n)	Percent (%)
3.5-5.5	30	56.6
>5.5	23	43.4
Total	53	100

Table 10 represents frequency of patients having potassium levels between 3.5-5.5 mEq/L that is 56.6% and those showing levels above 5.5mEq/L that is 43.4%. Fig 10 represents frequency of patients having potassium levels.

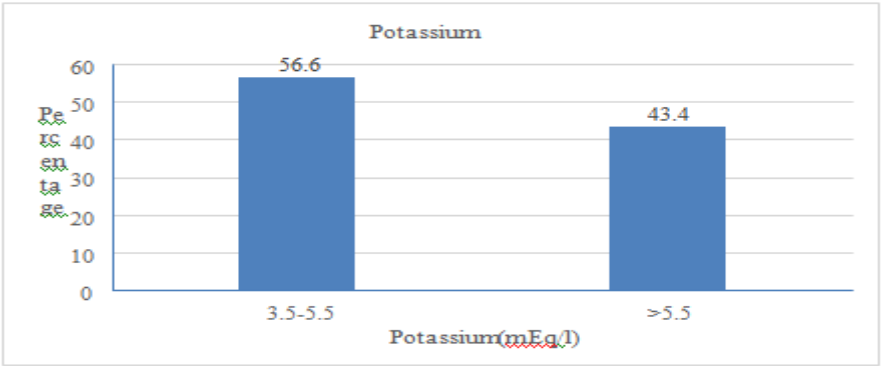


Fig 10: Potassium levels

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OUTPUT OF COUNSELLING ON QUALITY OF LIFE

Table 13: Output of counselling on quality of life

Quality of life	Count (n)	Percentage (%)
Improved	33	62.26
Not improved	20	37.73

The impact of patient counselling on QOL was assessed using **KDQOL™ SF 36(v 2.0)** questionnaire.

Proper counselling about disease and diet was given to the patients at each visit and the effect on patient quality of life was recorded on KDQOL™ SF 36(v 2.0). The 5 domain analysis showed that the quality of life among patients improved. The output was taken at an interval of one month. At the end of the follow up of each patient, preferably after 4 months 33 patients showed improved quality of life. The percentage distribution is illustrated in the table 13 and fig 13.

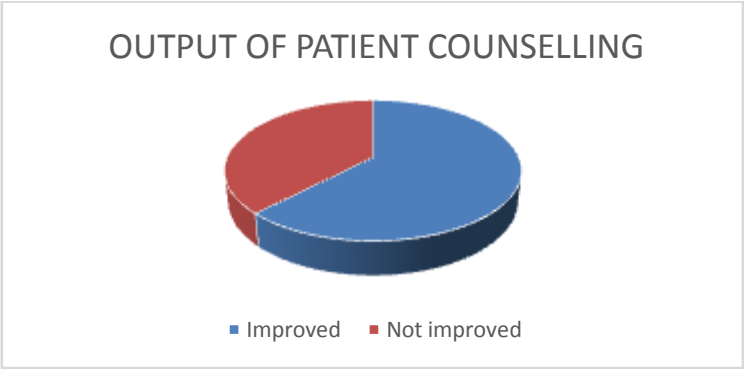

Fig 13:Output of counselling on quality of life

DESCRIPTIVE STATISTICS OF KDQOL-SF 36

it is clear that all domains in the QOL assessing scale were largely affected. Considering the symptoms, it is clear that the patients QOL is very much low and the symptoms are making greatly bad effects on patient's health. The lower score of effect of kidney disease on patient's health related quality of life indicates that there is need to correct the symptoms and the emotional burdens. Overall, the general health status is decreased. The baseline score level was suggestive of the role of patient counselling in patients with CKD to improve their physical and emotional wellbeing.

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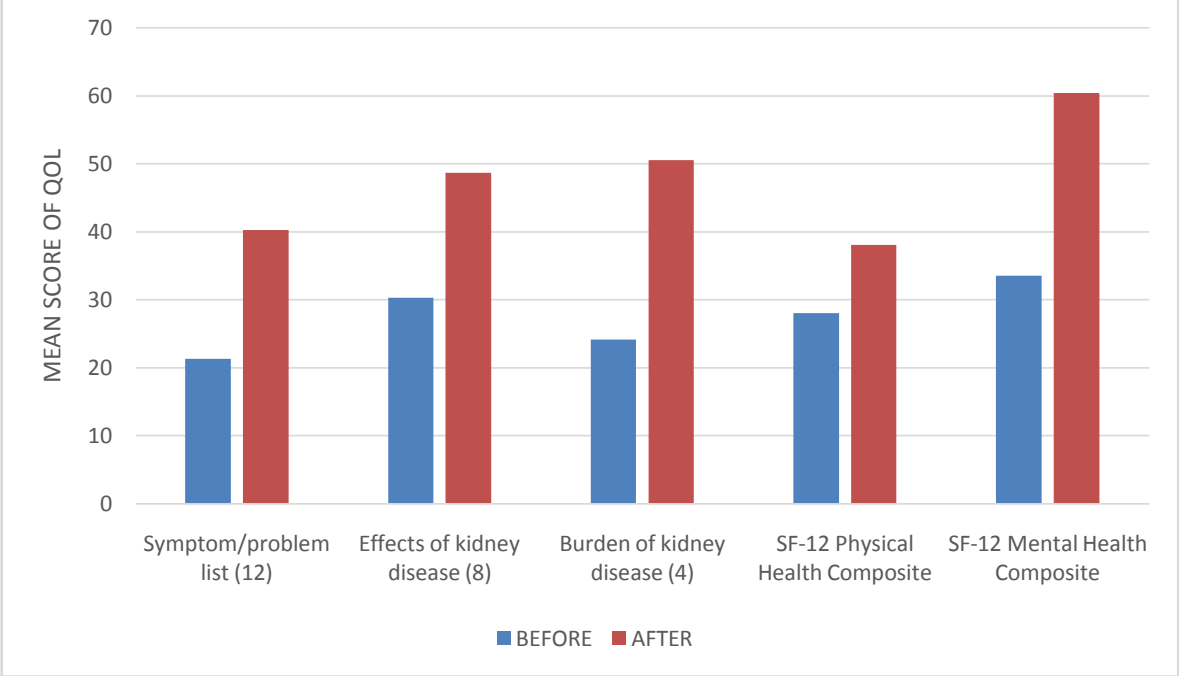

Figure 15: The mean of KDQOL™ SF 36 in 5 domains before and after counselling.

In KDQOL-SF-36 assessment the highest scores indicate better quality of life, which means 100(score value) indicates free of disease (perfect health) and zero(score value) indicates death. In this study none of the patient attained perfect health, but majority of the patients improved their health status. Mental health was one among the significantly affected domain and an average score was increased to be 62.5±14.59% (p=0.0015). An average score of physical health was also increased and it was statistically significant.

IV. DISCUSSION

Dialysis therapy ameliorates many of clinical manifestations of end-stage renal disease (ESRD) and postpones imminent death. The demographic details of 53 ESRD patients were collected and the quality of life was assessed before and after counseling using KDQOL™ SF 36 (v 2.0) questionnaire. The age group distribution in the study was compared in order to know the frequency of patients and understand the study population. The most common manifestations experienced by these patients during dialysis session were hypotension and muscle cramping followed by shortness of breath. It also has been noticed that, of those diabetes and non-diabetes, males are more likely to develop ESRD as compared to females. This study concluded that diabetic patients were more prone to post dialysis hyperglycemia than non-diabetic patients.

The influence of glucose levels on serum potassium is also observed in this study. End stage renal disease (ESRD) patients rely largely on extra-renal mechanisms and dialysis to maintain potassium homeostasis. Normal potassium (K^+) homeostasis maintains plasma K^+ concentration within a narrow range and is achieved by matching K^+ intake with excretion and ensuring proper distribution between extra- and intracellular fluid compartments. Insulin shifts potassium into cells by stimulating the activity of Na^+-H^+ anti porter on cell membrane, promoting the entry of sodium into cells, which leads to activation of the Na^+-K^+ ATPase, causing an electrogenic influx of potassium. From this study, comparison of potassium levels on both diabetic and non-diabetic was found to be statistically insignificant.

Patient counseling could significantly increase one's medication adherence, knowledge attitude and practice and hence quality of life. Subsequent improvement in medication adherence, QOL, was observed following an effective counseling session provided during the current research. Hence, the provision of effective counseling is found to have a profound impact on promoting better and positive therapeutic outcomes. The limitation of this study includes small sample size and the data collected from the

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patients varies with their diet at the sampling time. This study emphasis that it is important to continuously monitor the blood glucose levels during the dialysis days.

V. CONCLUSION

The glycemic pattern of patients undergoing hemodialysis in end stage renal disease is assessed, the influence of glucose levels on serum potassium is observed and impact of patient counseling on patient's quality of life is studied.The glycemic status of 53 patients is studied. Some patients (17% in baseline study) showed hypoglycemia. This occurs due to dialysis and can be overcome by providing snacks during dialysis along with strict monitoring of blood glucose levels or by using glucose added dialysate. Also prevent taking oral hypoglycemic agents or insulin preparation on dialysis days. Some patients (37.7% in baseline study) showed hyperglycemia. Mostly diabetic patients are prone to be hyperglycemia. This is due to higher sugar levels in the patient. The study result cannot be taken as a reference scale since the glycemic status of each patient varies with their diet, lifestyle and the timing of dialysis sessions.The influence of glucose levels on serum potassium is also observed. As the process of dialysis removes potassium from the body it normalizes potassium levels. In some cases, hyperkalemia occurs due to the potassium efflux as a result of increased osmolality in diabetic patients. During the process of dialysis , one on one personal attention by strict monitoring of glucose levels, providing assurance related to disease condition, aiding the patients in performing mild stretching exercises for improved blood circulation as well as avoid cramps were ensured. Counseling helps the patient in a way that it improves mental health, reduces the occurrence of difficulties experienced during dialysis and also encourages the patient to be aware of their diet and lifestyle as now they are well informed about their disease condition.

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