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A Study on Adequacy of Hemodialysis and Quality Of Life in Esrd Patients

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Abstract: *Hemodialysis is a process of purifying the blood of a person whose kidneys are impaired. The objective of the study is to assess the efficacy/adequacy of Hemodialysis by calculating the Kt/V ratio (ideal value= 1.4) and URR ratio (65%) (KDOQI) and to evaluate the quality of life of the patient based on the KDQOL sf 36 questionnaires. This is an observational study conducted for a period of seven months in a quaternary care hospital. 496 Hemodialysis data were collected. The adequacy of Hemodialysis dose was calculated using Kt/V and URR standards. The quality of life was evaluated by KDQOL SF 36 questionnaires and the relationship between the Hemodialysis adequacy and the quality of life of the patients were drawn. Of the 496 data collected, 321 (64.71%) were found to be adequate and 176 (35.48%) inadequate. 70 Hemodialysis patients evaluated by KDQOL SF 36 questionnaires, 7 were found to have the quality of life score below 50. The adequacy of the Hemodialysis dose and the quality of life of the patient was found to have a direct correlation. The patients with adequate Hemodialysis dose (by Kt/V and URR standards) are found to have an improved KDQOL score i.e. above 50 percent and there by better quality of life.*

Keywords: *Adequacy,Hemodialysis dose, Glomerular Filtration Rate, Quality of Life.*

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I Introduction

Chronic Kidney Disease (CKD), also known as chronic renal insufficiency, progressive kidney disease, or nephropathy, and it is defined as the presence of kidney damage or decreased Glomerular Filtration Rate (GFR) for 3months or more[1]. CKD is a progressive disease that eventually leads to renal failure called End-Stage Renal diseases (ESRD). Early detection, management and treatment of CKD are fundamental factors in minimizing morbidity and mortality associated with CKD. CKD is associated with several risk factors namely advanced age, family history, diabetes mellitus, hypertension and tobacco smoking[2].

The severity of CKD is classified from stage 1 to 5 depending on the level of Glomerular Filtration Rate(GFR): Stage 1: >90ml/min with proteinuria, Stage 2: 60-89ml/min with proteinuria, Stage 3: 30-59ml/min, Stage 4: 15-24ml/min and stage 5: <15ml/min [3].

1.1 Epidemiology

Chronic glomerulonephritis and chronic interstitial nephritis were reported to be the most common cause of ESRD in India. It is important to appreciate that the clinical spectrum of CKD in India is different from the western world. The average age of ESRD population India is 50 years; this is approximately 20 years less than that reported in the USRD and some European countries. In India, it has been recently estimated that the age adjusted incidence rate of ESRD to be 229 per million population and >100,000 new patients enter renal replacement programme annually.

Recent studies say that hypertension and diabetes are the major aetiology of CKD[10]. In 2003, the American Heart Association (AHA) stated CKD is a major risk factor for cardiovascular disease[11]. Accordance to the kidney disease outcomes quality initiative (KDOQI) of the National Kidney Foundation (NKF), 2002, CKD guidelines CKD is due to either damage to kidney or its GFR is less than 60ml/min/1.73m2 for more than 3months including or excluding the proof of kidney damage[8]. Cockcroft-Gault (CG) equation and the Modification of Diet in Renal Disease Study (MDRD) are the best method to estimate GFR [11-21].

The initial injury develops to increased renal damage. The mechanism of these renal damage is not clearly known but it includes following: (1) Glomerular hyper-filtration: the increase in workload of remaining left out nephrons results in complete fail, (2) Nephrosclerosis: systemic hypertension and intra renal hypertension, (3) Immunologic Damage: by basic renal lesion, (4) Proteinuria: can cause tubular and interstitial damage, (5) External protein load and fat load[22]. **Renal dialysis** [3-7]

Dialysis is a procedure that is substituted for many of the normal duties of the kidneys. it is an artificial method of maintaining the chemical balance of the blood when the kidneys have failed. The term dialysis refers to the process in which the components of the blood are separated using a semipermeable membrane.

The effectiveness of dialysis depends on both its duration and efficiency.

Two main types of dialysis are available are 1. Hemodialysis and 2. Peritoneal dialysis.

Hemodialysis is a process where the blood is cleansed of impurities by cycling the blood through a machine called dialyser, and back into patient via catheter. Hemodialysis involves the pumping of the patient's heparinized blood through the blood compartment of the dialysis filter at a rate of 300 to 600 ml/min.

During Hemodialysis, a patient's anticoagulated blood and an electrolyte solution (dialysate) are perfused through a dialyser (artificial kidney) to opposite side of a semi permeable membrane; metabolic waste products are removed from the patient's blood by diffusion down its concentration gradient into the dialysate. The blood and dialysate flow in opposite directions to maximize the concentration gradient for toxin exposure to the membrane. The rate of removal of toxins from the blood is influenced by blood and dialysis flow, membrane characteristics and properties of toxin being removed [1]. Solutes from the blood are removed through diffusion and convention or ultra-filtration.

1.2 Hemodialysis Dose and Adequacy [23]

Adequacy of Hemodialysis should be periodically checked – normally once a month. Blood is sampled at the start of dialysis and at the end. The level of urea in the two blood samples are then compared.

Two methods are generally used to assess dialysis adequacy, **URR** and **Kt/V.**

1.2.1 URR (Urea Reduction Ratio)

The URR is one measure of how effectively a dialysis treatment removed waste product from the body and is commonly expressed as a percentage.

For the Hemodialysis to be adequate URR should be greater than or equal to **65%**.

$$URR = \left(1 - \frac{\text{post-BUN}}{\text{pre-BUN}}\right) \times 100$$

URR is calculated by the following formula:

1.2.2 Kt/V

Kt/V is another way of measuring dialysis adequacy. In this measurement,

K-stands for the dialyzer clearance, the rate at which blood passes through the dialyzer, expressed in millilitres per minute (mL/min).

t-stands for time.

Kt-the top part of the fraction, is clearance multiplied by time, representing the volume of fluid completely cleared of urea during a single treatment

V-the bottom part of the fraction, is the volume of water a patient's body contains.

For the Hemodialysis to be adequate Kt/V should be greater than or equal to **1.4**.

Daugirdas Formula used to calculate Kt/V

$$Kt/V = -\ln\left(\frac{\text{post-BUN}}{\text{pre-BUN}} - 0.03\right) + \left(4 - 3.5 \times \frac{\text{post-BUN}}{\text{pre-BUN}}\right) \times \frac{UF}{\text{weight}}$$

1.3 Health Related Quality of Life.

Quality of life (QOL) is a broad multidimensional concept that usually includes subjective evaluations of both positive and negative aspects of life.

Health-related quality of life (HRQOL) is an individual's or a group's perceived physical and mental health over time.

On the individual level, this includes physical and mental health perceptions and their correlates, including health risks and conditions, functional status, social support, and socioeconomic status. On the community level,

HRQOL include resources, conditions, policies, and practices that influence a population's health perceptions and functional status.

HRQOL questions about perceived physical and mental health and function have become an important component of health surveillance and are generally considered valid indicators of service needs and intervention outcomes. Self-assessed health status also proved to be more powerful predictor of mortality and morbidity than many objective measures of health. HRQOL measures make it possible to demonstrate scientifically the impact of health on quality of life, going well beyond the old paradigm that was limited to what can be seen under a microscope.

Generally speaking, assessment of HRQL represents an attempt to determine how variables within the dimension of health (e.g., a disease or its treatment) relate to particular dimensions of life that have been determined to be important to people in general (generic HRQL) or to people who have a specific disease (condition-specific HRQL). [10]

Most conceptualizations of HRQL emphasize the effects of disease on physical, social/role, psychological/emotional, and cognitive functioning. Symptoms, health perceptions, and overall quality of life are often included in the concept domain of HRQL.

Outcomes Study Short Forms (SF-12 and SF-36), the Sickness Impact Profile, and the Quality of Well-Being Scale. The SF-36 measures are now used by the Health Care Financing Administration (HCFA) and the National Committee for Quality Assurance's Health Plan Employer Data and Information Set (HEDIS) to help evaluate the quality of care in managed care plans and other health care applications. While these measures have been widely used and extensively validated in clinical settings and special population studies, their length often makes them impractical to use in population surveillance.

To meet the need for a standard set of valid HRQOL measures that could be used in our national health surveillance system, a collaborative program was initiated in 1989 by the Division of Adult and Community Health (DACH) in the CDC's National Centre for Chronic Disease Prevention and Health Promotion (NCCDPHP). This HRQOL surveillance program received its initial direction and guidance from several planning meetings that included representatives of state and local chronic disease and health promotion programs, relevant academic disciplines, and survey researchers[28].

1.3.1 SF36 Questionnaire

The Short Form (36) Health Survey is a 36-item, patient-reported survey of patient health. The SF-36 is a measure of health status and an abbreviated variant of it, the SF-6D, is commonly used in health economics as a variable in the quality-adjusted life year calculation to determine the cost-effectiveness of a health treatment. The original SF-36 came out from the Medical Outcome Study, MOS, done by the RAND Corporation. Since then a group of researchers from the original study released a commercial version of SF-36 while the original SF-36 is available in public domain license free from RAND. A shorter version is the SF-12. If having only adequate physical and mental health summary scores is of interest, "then the SF12 may be the instrument of choice"[29].

1.3.2 Scoring

The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability. The higher the score the less disability i.e., a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability.

The eight sections are: Vitality, Physical functioning, Bodily pain, General health perceptions, Physical role functioning, Emotional role functioning, Social role functioning and Mental health.

Uses of SF-36 questionnaire is as follows: Evaluating individual patient's health status, Researching the cost-effectiveness of a treatment, Monitoring and comparing disease burden.

Limitations include: The survey does not take into consideration a sleep variable, the survey has a low response rate in the >65 population[28,29].

II Material And Methods

Study site:

The study was conducted at BGS Global Hospital a quaternary care super speciality hospital located at Kengeri, Bengaluru.

Study design: Observational study.

Study duration: Six months.

Inclusion criteria

1.Patients undergoing ambulatory Hemodialysis for 4 months and above.

2.Both male & female patients from all age groups were enrolled in the study.

Exclusion criteria
1.Patients who are not willing to participate and consent in the study were excluded.
2.Patient with acute illness

Source of data collection:
The data necessary for the study was collected by;
1.Patients Hemodialysis case files
2.Interviewing Hemodialysis patients, their care takers and health professionals.

Ethical approval: This study was approved by Institutional Ethical Committee of PES College of Pharmacy.

Study procedure:

The data collection form was prepared by referring patient dialysis file. The main aim of the study was to find out ADEQUACY OF HEMODIALYSIS AND QUALITY OF LIFE IN ESRD PATIENTS. The dialysis data dating back to 2015 as well as of ongoing dialysis were included. The main entries required for the Kt/V and URR calculations were post and predialysis BUN, pre and post dialysis weight, duration of the dialysis, ultrafiltration volume. The adequacy of the each Hemodialysis data collected were calculated and entered.

The health related quality of life of 70 patients were assessed by handing out the KDQOL SF-36 questionnaires. This is a very significant tool in the assessment of the quality of life provided by RAND health. The south-Indian language (kannada) version of the questionnaire was prepared by consulting the RAND translation tools as directed by the RAND health through e-mail. The patients were informed of the benefit and importance of study. Any assistance in filling the questionnaire was provided to the patient and caretakers.

Data collection form:

The data collection form was developed by referring available literatures. It includes patient demographics, date of dialysis, laboratory results like Pre-Dialysis Weight, Post-Dialysis Weight, Difference in weight, Duration, Serum Creatinine, Pre-BUN, Post-BUN, Erythropoetin, Ultra Filtration. Finally, the data collection form includes Kt/V and URR to check the adequacy of Hemodialysis.

Documentation:
1.The data collected from the patients were documented.
2.The adequacy of Hemodialysis was calculated by ***Med India Kt/V calculator***.
3.The KDQOL SF36 score was calculated by touchcalc.com provided by RAND INSTRUMENTS
4.For further analysis it was entered to the Microsoft excel sheet.

III Result Analysis

1.The general demographics of ambulatory Hemodialysis patients were categorised and evaluated.
2.The prevalence of inadequate Hemodialysis was calculated.
3.The correlation between the quality of life and the Hemodialysis dose was assessed.
4.The relation between the biochemical parameter, serum creatinine and the delivered Hemodialysis dose was drawn.

- **Result**

A total of 497 Hemodialysis data was collected during the study from August 2016 to March 2017.

Table 1: Males, Females and Total Dialysis Data.

Adequacy Type	Number of patients	Number of Males	Number of Females
Adequate	321	208	112
Inadequate	176	143	33
Total	497	351	145

Diagram 1:

Fig 1 represents total males, females and total dialysis data in the study and the number of them adequate and inadequate.

Table 2 : Age distribution of subjects.

Age Interval	Adequate	Inadequate	Total
0-20	4	3	7
20-30	25	17	42
30-40	49	29	78
40-50	83	34	117
50-60	88	58	146
60-70	42	27	69
70-80	28	10	38
80 & Above	0	0	0

Diagram 2:

Fig 2: Graph representing the number of ESRD patients undergoing routine Hemodialysis in different age groups.

Majority of the Hemodialysis data and the highest percentage of inadequate Hemodialysis were found to be lying in the age group of 50-60 years having 88 adequate and 58 inadequate patients.

Table 3: Kt/v Analysis

Category	Number of patients	Percentage
<1.4 (Inadequate)	120	24.10 %
>or= 1.4 (Adequate)	377	75.85 %
Total	497	100 %

Diagram 3:

Fig 3 :- represents the number of adequate (n=377) and inadequate (n=120) Hemodialysis doses by kt/v analysisKt/V value of 1.4 is considered as the reference standard. The Hemodialysis doses with Kt/V above 1.4 are considered as adequate.

Category	Number of Patients	Percentage
<65% (Inadequate)	167	33.60 %
>or= 65% (Adequate)	330	66.39 %
Total	497	100 %

Table 4: URR (Urea Reduction Ratio) Analysis

Diagram 4:

Fig 4: Represents the number of adequate (n=330) and inadequate (n=167) Hemodialysis doses by URR analysis. URR value of 65% is considered as the reference standard. The Hemodialysis doses with URR above 65% are considered as adequate

Table 5: Comparison of KDQOL with Kt/v and URR.

KDQOL SF36SCALE	kt/V	URR
0.7	1.5	65%
0.7	1.5	68%
0.7	2.1	73%
0.8	1.8	74%
0.8	1.9	82%
0.7	1.7	71%
0.7	2	74%
0.6	1.8	72%
0.7	1.9	79%
0.5	0.9	55%
0.8	1.9	81%
0.8	1.8	79%
0.7	1.8	68%
0.8	1.9	73%
0.62	1.6	64%

0.8	2.2	81%
0.8	2.1	78%
0.8	2.3	81%
0.55	1.23	59%
0.52	1.3	60%
0.6	1.67	73%
0.69	1.68	73%
0.73	1.69	74%
0.44	0.94	49%
0.63	1.53	66%
0.79	1.75	75%
0.73	1.8	70%
0.78	1.87	72%
0.69	1.43	59%
0.72	1.71	67%
0.75	1.68	69%
0.78	1.6	67%
0.62	1.42	58%
0.77	1.84	76%
0.79	1.81	75%
0.7	1.68	72%
0.88	2.44	85%
0.7	1.66	71%
0.3	0.78	42%
0.88	2.66	83%
0.69	1.52	64%
0.57	1.31	58%
0.69	1.53	70%
0.79	1.52	75%
0.77	1.42	67%
0.78	1.51	70%
0.45	1.08	52%
0.73	1.72	75%
0.78	2.04	81%
0.72	1.67	74%
0.78	1.96	73%
0.73	1.42	68%
0.78	2.07	71%
0.79	1.85	67%
0.69	1.78	69%
0.7	1.58	71%
0.73	1.42	68%
0.72	1.54	66%

Diagram 5:
Fig 5: :- Correlation between KDQOL with Kt/v and URR. Adequate Hemodialysis dose corresponds to high KDQOL score.

IV Discussion

Hemodialysis (HD) constitutes the most common form of Renal Replacement Therapy. There is a strong correlation between HD dose and clinical outcome. The adequacy of Hemodialysis have a profound impact on the quality of life (QOL) and health resource utilisation. Quantification of the dialysis dose is an essential element in the management of chronic HD treatment because the adequacy of the Hemodialysis dose delivered have a direct relationship with the patient morbidity and mortality.

The aim of this work was to evaluate HD adequacy in patients with ESRD in the Hemodialysis unit at BGS Hospital, Kengeri, Bengaluru to identify the prevalence and courses of in adequate HD among those patients and impact of adequacy on other parameters such as the health related quality of life.

In a similar research conducted by Adas H, etal,, in a Palestinian hospital, single-pool kt/v and URR of 64 patients were calculated.the targets based on National Kidney Foundation Disease Outcomes Quality Initiative (KDOQI) Cliniacal Practice Guidelines were Kt/v ≥1.2 and URR ≥65%. The research showed similar outcomes and results.[43]

- **Patient Demographics**

This study was carried out over a period of 6 months from July 2016 to march 2017 involving 496 Hemodialysis cases. The data collected includes Hemodialysis cases starting from 2015 as well as the fresh ongoing dialysis during the period of study. It was essential that the subjects enrolled in the study is on regular ambulatory Hemodialysis dose for over 4 months, as the patient need to be accustomed to the regular Hemodialysis routine (usually 3times a week). Any subjects presenting with an acute illness were ruled out of the study in order to obtain a more focused observation. As any sepsis, infection or acute conditions like respiratory and gastric diseases can show an inadequate Hemodialysis dose without pertaining to any of the general factors that normally results in Hemodialysis inadequacy.

Out of the total 496 Hemodialysis data collected (there were 351 males and 145 females) the age distribution of the subjects showed that majority of the patients belonged to 50 to 60 years. The gender disparities may be due to diet, kidney and glomerular size, differences in glomerular hemodynamic, and the direct effects of sex hormones. The factors leading to kidney diseases like diabetic nephropathy, proteinuria progresses at a higher rate in males that in females.48

Regardless of the underlying cause of kidney disease, the elderly are at a higher risk for further kidney injury and therefore progression of the disease. major risk factors for progression include Hypertension and Diabetes, which is common in the elderly. Additionally, the elderly are at high risk for progression of kidney injury. High prevalence of comorbid diseases, such as prostatic hypertrophy or congestive heart failure, medications and medical interventions commonly used for treatment of comorbid condition may either cause or predispose kidney injury 49

- **Adequacy of Hemodialysis**

The normalised treatment ratio, Kt/V i.e. the ratio of the [urea clearance × time product] to total body water and the URR (urea reduction ratio) are widely accepted measures of dialysis dose. Kt/V determined by single-pool urea kinetic modelling continues to be the preferred, most precise and accurate measure of dialysis. The target HD dose and its relationship with minimum dose which, in-light of HEMO study findings, remain 1.2 Kt/V units per dialysis for patients dialysed 3 times per week. Data from the HEMO study also revealed a coefficient of variation within patients of approximately 0.1 Kt/V units therefore, the previous target of 1.3 was considered too low to grant 95% confidence that the dose will not decrease to less than1.2 per dialysis, the target dose was increased to 1.4 per dialysis.

In this study, out of the total 496 Hemodialysis data collected, 321 dialysis i.e. 64.58% were found to have achieved the adequate target dose. 176 dialysis i.e.35.41% were measured as inadequate by the Kt/V and URR standards. The inadequate dialysis fails to give the patient the targeted blood clearance and there by lesser outcome of the renal replacement therapy.

Out of the 351 male dialysis data 143 dialysis i.e. 40.74% showed inadequate dialysis dose and 208 i.e. 59.25% dialysis were adequate and delivered the targeted dialysis dose. Percentage of inadequate dialysis dose in females was comparatively less. 33 out of 145 i.e. 22.75% failed to achieve the target HD dose and 112 i.e. 77.24% were found to be adequate by both Kt/V and URR. This gender disparity may have aroused due to the differences in size, body mass indices and body water content.

The age distribution patterns of HD show that majority of the ESRD patients undergoing routine dialysis belongs to 50 to 60 years. The prevalence of inadequate Hemodialysis occurrence is generally found to be increased with the progression of age. In this study, 146 dialysis belonged to the age group of 50 to 60 years, with 58 inadequate and 88 adequate.

3.Delivered Hemodialysis dose and serum creatinine

The biochemical parameters like serum albumin, creatinine, ferritin and urea levels are expected to have dependency on the delivered Hemodialysis. In this study it was observed that the patients who received the adequate Hemodialysis dose presented better serum creatinine levels as indicated by fig—

Adequacy of Hemodialysis and Quality of Life in ESRD Patients (QOL)

The health-related quality of life of 70 HD patients were evaluated by KDQOL SF36 Questionnaires. Dialysis adequacy was significantly associated with quality of life (QOL) in Hemodialysis patients. Out of the 70 patients interviewed and scored on a scale of 100, 13 showed below average scores i.e. less than 50. The correlation between the HD dose delivered and the QOL score shows that QOL is generally less when the HD dose is inadequate. patient with Kt/V levels greater than or equal to 1.4 and URR levels greater than or equal to 65% had better QOL as measured by significantly higher scores.

V Conclusion

In conclusion, our study demonstrates that dialysis adequacy is significantly associated with health-related quality of life in Hemodialysis patients. Hence quantification of the dialysis dose is an essential element in the management of chronic Hemodialysis treatment because the adequacy of the dose has a profound effect on patient morbidity and mortality. Hence our study establishes that an adequate delivery of Hemodialysis dose (as measured by Kt/V and URR) is a crucial determinant in clinical outcome of chronic HD patients.

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