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Original Research Article

Drug utilization pattern and selected biochemical parameters in pre- and post-hemodialysis state in the end stage renal disease patients: a cross sectional study at a tertiary care hospital

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ABSTRACT

Background: Chronic kidney disease can progress to end-stage kidney failure (ESRD), which is fatal without artificial filtering (dialysis) or a kidney transplant.
Methods: The ESRD patients of either gender age >18 years who were diagnosed by nephrologist as ESRD and are on haemodialysis regularly included for the study.
Results: The blood urea, serum creatinine, phosphorous, potassium levels were reduced significantly in post – haemodialysis condition, but, there was not much weight reduction after haemodialysis. Serum albumin, serum sodium and blood haemoglobin levels were almost unchanged in post – haemodialysis state. There was no significant difference between the pre and post haemodialysis parameters- serum Na+ serum albumin and blood hemoglobulin. Out of 75 ESRD patients, almost all patients 74 (98.7%) prescribed tablet Livogen, 73 (97.3%) patients given Inj. EPO, 55 (73.3%) tab Nicardia, 54 (76%) tab Sodamint, 43 (57.3%) capsule Alpha D3, 40 (53.3%) tab Shelcal. While between 12 (16%) to 20 (26%) patients prescribed tab Nodosis, tab Metoprolol, tab Febuget, tab Ecosprin, and tab Rantac. Only 1 (1.3%) to 9 (12%) patients received tablet Augmentin, tab Arkamine, tab Carvedilol, tab Para 500, tab Atorvas, Human mixtard, tab Calcicard, tab Minipress XL, tab Dytor, and tab Clopilet.
Conclusions: The available two models of treatment, i.e., haemodialysis and poly pharmacy at hospital setup to face the challenges associated with the ESRD, and even outcome after application of both these two models of therapies did not provide optimal normal healthy life status to ESRD patients.

Keywords: ESRD, Haemodialysis, Poly-pharmacy, Drug utilization pattern

INTRODUCTION

Chronic kidney disease, also known as chronic kidney failure, is a major health issue in the world. In India, the overall prevalence of chronic kidney disease is 17.2% which was reported by the SEEK India cohort. Chronic kidney disease (CKD) results from partial or total loss of kidney function. When the kidney function is low, they cannot effectively filter wastes and excess fluid from blood. Adults (41-60 years) and elderly people (60+ years) have more risk to suffer from chronic kidney disease than the other age groups. To stratify the severity of chronic kidney disease the National Kidney Foundation developed criteria as part of its kidney disease outcomes quality initiative (NFKKDOQI^{TM}), this stratification considers the estimated glomerular filtration rate (eGFR) as the chief criteria. Chronic kidney disease can progress to end-stage kidney failure, which is fatal without artificial filtering (dialysis) or a kidney transplant. End stage renal disease (ESRD) is the last stage (stage V) of chronic kidney disease, that is, the kidneys are functioning at less than 15% of their normal capacity.[2]

Haemodialysis is the most common medical intervention method to postpone the consequences of the ESRD. A typical haemodialysis schedule is 2 or 3 sessions per week, for 3-5 hours per session. Haemodialysis is essential for the ESRD patient to filter waste, remove extra fluid and to maintain electrolyte balance.[3]

Patients with ESRD are associated with other co-morbid diseases like diabetes mellitus, hypertension, coronary artery diseases and infections adding to the complexity and need for multiple drug therapy, consequently risk of drug interactions, medication dosing errors, and high incidence of adverse drug events, which results in increase morbidity and mortality, as well as an increase in the cost of health care. There is limited evidence on the prescribing trends in ESRD patients from India.[4]

This study offers an insight into the prescribing trends in ESRD patient which can help to identify, evaluate and minimize prescription errors and thereby decrease the burden of the disease.

Objectives

- To find out drugs utilization pattern in the ESRD patients.
- To compare pre- and post – haemodialysis effects on the biochemical parameters, like blood urea, serum creatinine, serum Na+, serum K+, serum calcium, serum phosphorous, serum albumin, blood hemoglobulin and body weight in the ESRD patients.

METHODS

Ethical approval

The study was initiated after getting ethical approval from Institutional Ethics Committee (Human Studies), IECHS.

Study design

It was a cross sectional study at the tertiary care hospital.

Study population and study location

ESRD patients who were admitted for haemodialysis in the Department of Nephrology at a tertiary care hospital.

Sample size

Seventy five (75) ESRD patients.

The minimum sample size to be considered for the study is equal to $\frac{z^2 \times p(1-p)}{e^2}$ where $z = 1.96$ for confidence level of 95%, $e = 0.05$ for estimation error of 5%, and $p = 0.008$ as the prevalence rate of ESRD patients is 0.8% which was reported by the SEEK India cohort.[1]

On calculation we get that sample size must be 13 approximately. Since there were many ESRD patients undergoing dialysis at the facility, the sample size was chosen to 75 and also that the data was collected from the case sheets and haemodialysis register without interfering the treatment after obtaining proper approval from Nephrology Department, so there was no wastage of resources.

Inclusion criteria

ESRD patients of either gender age more than 18 years who were diagnosed by nephrologist as ESRD and are on haemodialysis regularly included for the study.

Exclusion criteria

The incomplete data of the ESRD patients of either gender age below 18 years excluded from the study.

Informed consent

Since, it was an observational study, and the data was collected from the case sheets and Haemodialysis register without interfering the treatment after obtaining proper approval from Nephrology Department, so technically, we were not concerned with the ESRD participants directly, thus, no need to take the consent.

Data collection

The ESRD patient's data like their age, sex, biochemical parameters, as Blood urea, serum creatinine, serum Na+, serum K+, serum calcium, serum phosphorous, serum albumin, blood hemoglobin and drugs being utilized were noted from the patient's case sheet and from the haemodialysis register (pre – and post-haemodialysis) after getting proper permission from the Head of Department of Nephrology. The weight of the patient was measured before and after haemodialysis using standard weighing machine in kilograms. Study participant's data were noted on the prepared data collection sheets accordingly.

Data collection duration

The data were collected from 1st May, 2018 to 25th August, 2018.

Data was collected in a predesigned proforma sheet (as given in Table 1).

Statistical analysis

All the data were arranged systematically on Microsoft Excel sheets 2013 and statistical analysis were done by using authentic OpenEpi.info online free available software. We calculated percent, mean value, standard deviation (S.D.), and level of significance (p value) were calculated by applying two tailed t–test. We had

estimation error as 5% and with the confidence level of 95%.

RESULTS

According to the inclusion criteria, we analysed data of the seventy five patients who were suffering from ESRD and were on haemodialysis.

Demographic profile

Out of the 75 patients, majority (82%) of the patients were male and 18% were female. And nearly two-third (61.33%) of the patients were in the age group of 41-60 years, 22.7% were over the age of 60 and 16% of the patients were in the age group 18-40 (Figure 1).

Pre– and post– haemodialysis laboratory reports status

There was not much weight reduction after haemodialysis. Serum albumin, serum sodium and blood haemoglobin levels level were almost unchanged in post – haemodialysis state. While blood urea, serum creatinine, phosphorous, potassium levels were reduced significantly after haemodialysis, and serum calcium level was increased significantly after haemodialysis (Table 1).

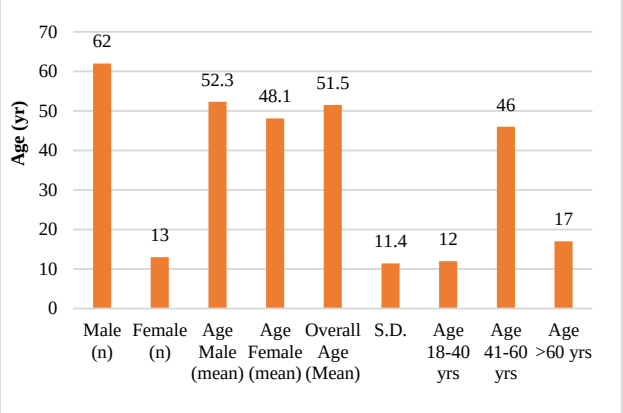

Figure 1: Distribution of age and gender of the ESRD patients.

Table 1: Pre and post–haemodialysis laboratory reports.

Recent pre - and post - haemodialysis laboratory reports - Mean value, S.D. and p value									
	Weight Kgs	**Albumin (g/dl)**	**Urea (mg/dl)**	**Creatinine (mg/dl)**	**Calcium (mg/dl)**	**Phosphorous (mg/dl)**	**Potassium (mmol/dl)**	**Sodium (mmol/dl)**	**Hb (g/dl)**
Pre - haemodialysis mean (S.D.)	59.57 (10.97)	3.5 (0.5)	98.5 (30.3)	8.9 (2.7)	8.5 (1.0)	4.6 (1.3)	5.1 (1.0)	137.1 (5.2)	7.3 (1.6)
Post-haemodialysis mean (S.D.)	57.1 (10.94)	3.6 (0.6)	43.1 (23.8)	4.8 (2.6)	9.4 (1.4)	3.5 (1.3)	3.9 (1.2)	137.5 (4.7)	7.9 (1.8)
P value (two - tailed)	0.17	0.27	0.0001	0.0001	0.0001	0.0001	0.0001	0.6	0.03

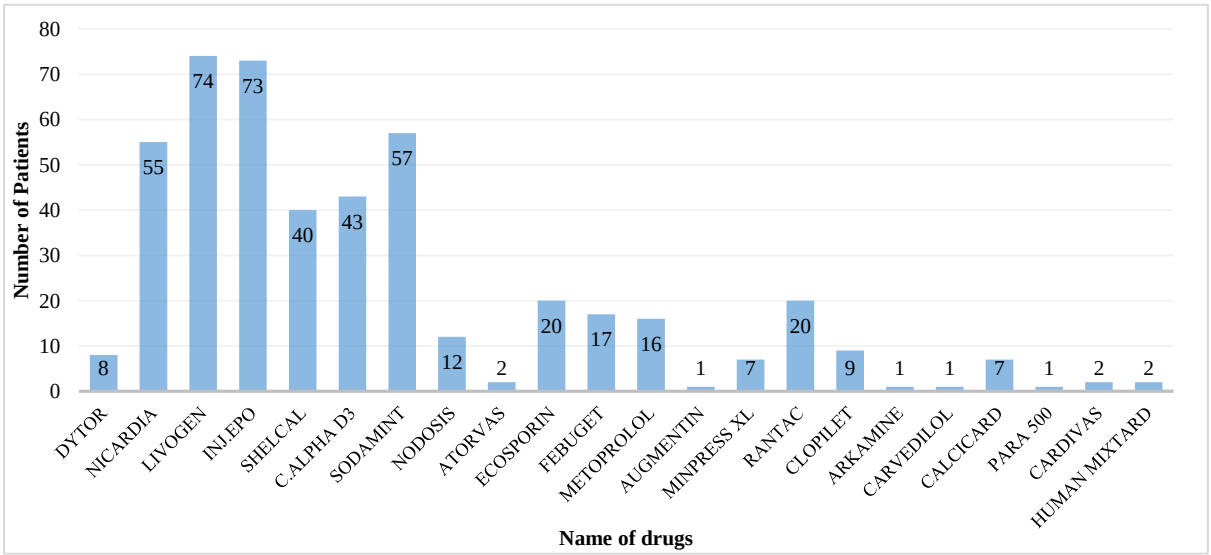

Figure 2: Number of ESRD patient used drug.

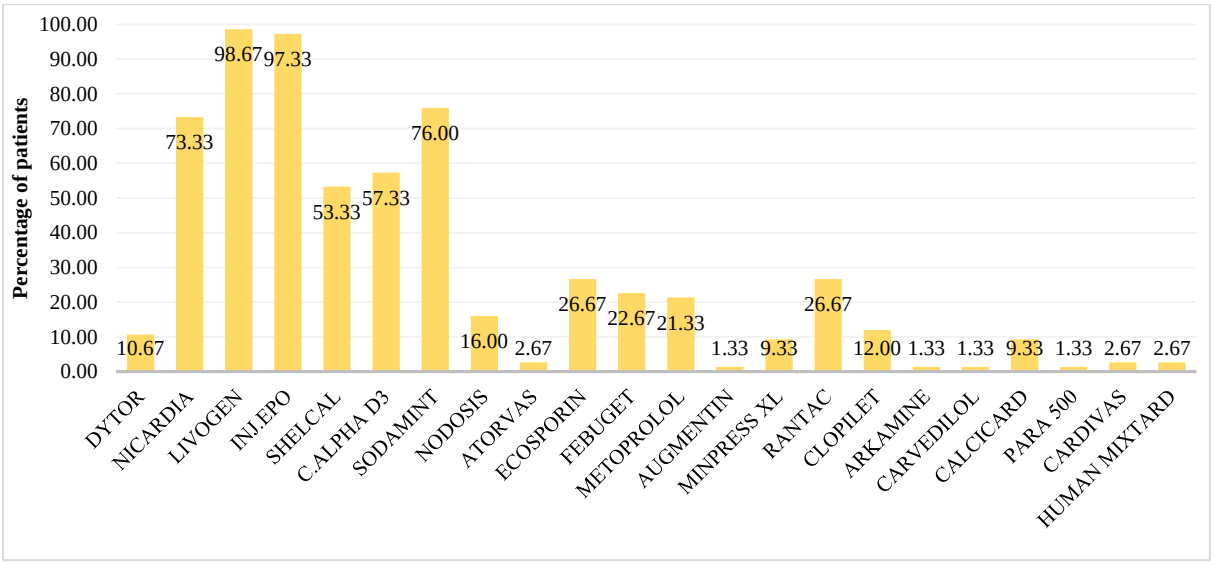

Figure 3: Percent-wise drugs prescribed to the ESRD patients.

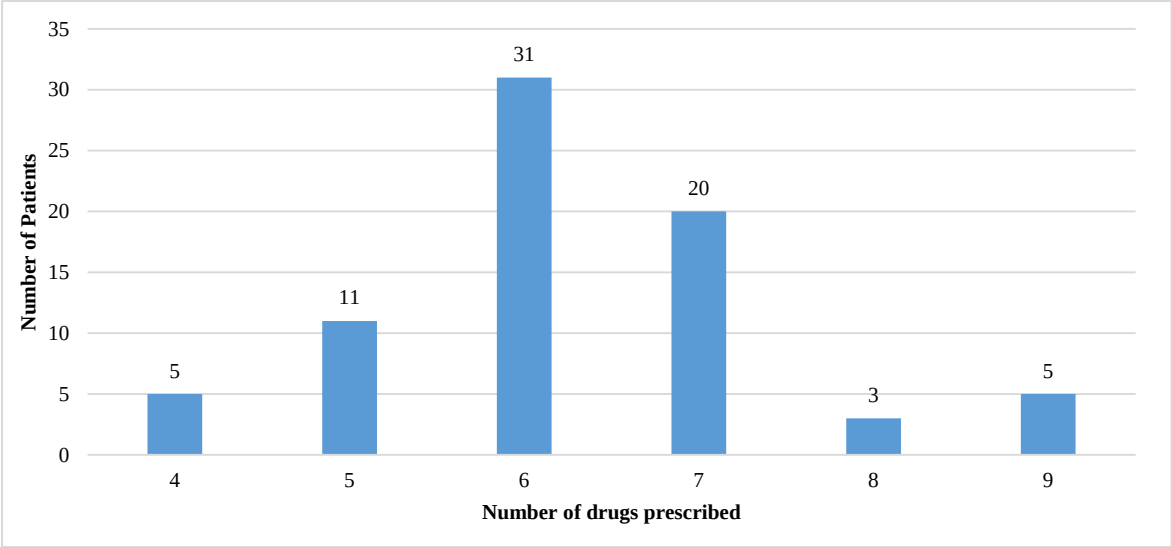

Figure 4: Number of drugs prescribed to the ESRD patients.

Drugs prescribing pattern in ESRD patients

Out of 75 ESRD patients, almost all patients 74 (98.7%) were given tablet Livogen (ingredient ferrous fumarate and folic acid), 73 (97.3%) patients given Inj. EPO (Erythropoietin), 55 (73.3%) tab. Nicardia (nifedipine), 54 (76%) tab. Sodamint (Sodium bicarbonate), 43 (57.3%) capsule Alpha D3 (1, 25 Dihydroxycholecalciferol), 40 (53.3%) tab. Shelcal (calcium) (Figure 2 and 3).

While, out of 75 ESRD patients, between 12 (16%) to 20 (26%) patients were prescribed tab. Nodosis (sodium bicarbonate), tab. metoprolol, tab. Febuget (febuxostat), tab. Ecosprin (aspirin), and tab. Rantac (ranitidine).

Only 1 (1.3%) to 9 (12%) patients received tablet Augmentin (amoxicillin), tab. Arkamine (clonidine), tab. Carvedilol, tab. Para 500 (Paracetamol 500), tab. Atorvas (atorvastatin), Human mixtard (insulin), tab. Calcicard (nifedipine), tab. Minipress XL (prazosin), tab. Dytor (torsemide), and tab. Clopilet (aspirin+clopidogrel).

Each patient was prescribed drugs with an average of six in numbers. Around 78% of them were prescribed 6 or more drugs (Figure 4).

DISCUSSION

ESRD is the stage V of chronic kidney disease, that is, the kidneys are functioning at less than 15% of their normal capacity. The imbalances of biochemical parameters of the blood are almost restored significantly by haemodialysis.

In the present study, blood urea, serum creatinine, phosphorous, potassium levels were reduced significantly in post haemodialysis condition. In ESRD patients the glomerular filtration rate is less than 15 ml/minute. And this causes the blood urea and creatinine levels to increase. Sarhat et al showed in his study, that there was a significant decrease in the blood urea and creatinine level after the haemodialysis which was high in pre haemodialysis condition in both control and test group.[5]

There was no much weight reduction after haemodialysis. Serum albumin, serum sodium and blood haemoglobin levels were almost unchanged in post-haemodialysis state.

There was no significant difference between the pre- and post-haemodialysis parameters- serum Na^+, serum albumin and blood hemoglobulin.

Pharmacotherapy of ESRD is complex and inevitably requires poly-pharmacy with frequent monitoring of drugs and their dosage adjustments. Polypharmacy is defined as prescription of five or more medications to one patient at one time.[6] Polypharmacy is inevitable in treating end stage renal disease as it mostly is accompanied by a combination of many co-morbid conditions like hypertension, anaemia, mineral bone disorders, diabetes, ulcers etc.

In the present study, out of 75 ESRD patients, almost all patients 74 (98.7%) prescribed tablet Livogen (ingredient: ferrous fumarate and folic acid), 73 (97.3%) patients given Inj. EPO (Erythropoietin), 55 (73.3%) tab. Nicardia (nifedipine), 54 (76%) tab. Sodamint (sodium bicarbonate), 43 (57.3%) capsule Alpha D3 (1, 25 dihydroxy-cholecalciferol), 40 (53.3%) tab. Shelcal (Calcium).

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Many previous researches like, Safar, Michel, et al, Singh, Szczech et al, Parikh, Hwang et al, Tamilselvan, veerapandiyan et al, Yusuf, Howell et al, Xu, et al were also reported in their individual studies that, poly – pharmacy is essential but complex to treat the ESRD with co-morbid conditions to get best outcome.[7-10]

In this study the male subjects predominated (82.6%) like any other study conducted previously on kidney disease. Majority (61.3%) of the patients were in the age group of 40-60 years.

CONCLUSION

To achieve the normal physiological status of the patients who are suffering from ESRD, very challenging task to the healthcare professionals, especially nephrologist. In the present study, all the ESRD patients were on the more than 6 number of medications, and haemodialysis also, to control the blood pressure, reduce volume of body fluid, reduce risk of anaemia, reduce risk of hyperkalaemia, supplement the calcium loss, and simultaneously reduced acidotic conditions by giving sodium bicarbonates as per the clinical needs to the patients, reduced complications of associated with the cardiovascular pathology and diabetes mellitus. The available two models of treatment, i.e., haemodialysis and poly-pharmacy at hospital setup to face the challenges associated with the ESRD, and even outcome after application of both these two models of therapies did not provide optimal normal healthy life status to ESRD.

Limitation of the study

Since, to justify the achievement of the decided objectives in this present study was based on the obtained data from the Patients case-sheet and haemodialysis register without direct communication from the patients. Since, as a MBBS 2nd professional students, I have no authority to involve life – threatening procedure for the haemodialysis and I don't have competency to advice medication to the ESRD patients. So, the limitation of this study is based on the patient's records only.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee from the DSMCH

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