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A prospective study on prevalence of intradialytic complications and its management in the department of nephrology of tertiary care multispeciality teaching hospital

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Abstract---Background: Renal dysfunction has been more common during the last two decades, with an estimated 11-13 % prevalence. Hemodialysis is one of the most widely utilized medical procedures globally, with over two million patients undergoing regular hemodialysis yearly. Intradialytic complications are critical since they affect patients' quality of life, mortality, and morbidity. Therefore, it is important to monitor hemodialysis patients for complications during dialysis and understand the management strategy for various intradialytic complications. Methodology: prospective observational study conducted for the period of six months. Irrespective of gender, age between 18-85 years with selected co-morbidities included in the study. Patients general demographic data, Personal history including adverse habits, occupation, food habits, also collected. All the collected data were evaluated with Microsoft Excel 2010, SPSS (v26.0), and GraphPad Prism software (V.8.2.0). Chi-Square test was utilized to determine the association between variables. Results: out of 245 patients, 30 (12.24 %) patients had intradialytic complications where 20 (66.67%) of them were male, and 10 (33.34%) were female. intradialytic complications like hypertension (HTN), Hypotension, Vomiting, Headache, shortness of breath were commonly found. Fever and vomiting were also present. When comparing to other complications, hypertension (50%) was found to be more prevalent, followed by headache (13.33%) and hypotension (13.33%). The drugs

used to manage these intradialytic complications are Hydralazine Hydrochloride Injection USP (20mg/ml), Labetalol Hydrochloride Injection USP (5mg/ml), Ondansetron Injection, USP (2mg/ml), Paracetamol (150mg/ml) Injection, and 50% Dextrose Injection USP (0.5g/ml). Conclusion: The prevalence of intradialytic complications in our study was 12.24%. During dialysis, there are possibilities of occurrence of mild to very severe complications. So, preventive measures and other dialysis precautions are always highly recommended.

Keywords---Hemodialysis, Dialysis, Intradialytic complications, End stage renal disease, Dialysis complication.

Introduction

Renal dysfunction has been more common during the last two decades, with an estimated 11-13 % prevalence.^[1] It could be related to an increase in the prevalence of diabetes mellitus (DM), glomerular diseases, hypertension, kidney stone disorders, and the use of OTC drugs. Hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation are the three most effective treatments for people with end-stage renal disease (ESRD).^[2] Hemodialysis is one of the most widely utilized medical procedures globally, with over two million patients undergoing regular hemodialysis yearly ^[3]. The procedure can be done in almost three to five hours, and it is performed two to three times per week.^[4] Although hemodialysis is a safe technique, acute intradialytic complications do occur. Hypotension, nausea and vomiting, muscle cramps, headache, fever, pruritus, and chills are the most common complications. Hypotension is linked to several complications. Life-threatening consequences, such as arrhythmias and other cardiovascular issues, only occur in a small percentage of cases.^[5] Intradialytic complications are critical since they affect patients' quality of life, mortality, and morbidity ^[6]. Therefore, it is important to monitor hemodialysis patients for complications during dialysis and understand the management strategy for various intradialytic complications. This prospective observational study was done to identify the prevalence of intradialytic complications and understand its management options.

Methodology

This prospective observational study was carried out in the SRM Medical College Hospital and Research Centre, Tamil Nadu, for six months.

All the patients of age between 18-85 years irrespective of gender diagnosed with end-stage of renal disease under dialysis and patients with co-morbidities like diabetes, hypertension, heart disease included in the study. Patients who were not willing to consent, with age <18 years, Pregnant and lactating women were excluded.

Data collection

Permission to conduct the study was obtained from the Department of Nephrology. Used the data collection form, specially designed for this study to enter all the patient's information, including demographic details (Patient name, Age, Gender, Weight, Height, IP number, Date of Dialysis, Personal history including adverse habits, occupation, food habits, Frequent illness). In the form, there was the provision to enter laboratory tests, diagnoses, the number of drugs given, and the duration of therapy.

Data analysis

All data were evaluated with Microsoft Excel 2010, SPSS (v26.0), and GraphPad Prism software (V.8.2.0). The discrete variables were reported as percentages, whereas the continuous data were represented as mean and standard deviation. The unpaired t-test (student's t-test) was used to figure out the mean difference. The Chi-Square test was utilized to determine the association between variables.

Results

Totally 245 patients were enrolled in this study, where 155 (63.26%) were male, and 90 (36.73%) were female, as given in table 01. The male and female ratio was 31:18. Male patients were found to be more common than female patients in this study. The overall population's mean age was found to be **54.51±15.86** years. The Mean age of males and females was **56.29±15.10** years and **51.44±16.72** years, respectively, as in table 02. The difference was found to be statistically significant, as per unpaired t-test [$t = 2.3291$ ($P = 0.0207$)].

In this study, we found that out of 245 patients, 30 (12.24 %) patients had intradialytic complications where 20 (66.67%) of them were male, and 10 (33.34%) were female (see table 03). The age groups of patients who developed intradialytic complications were analyzed, and the mean age was found to be **51.87±12.66** years. The Mean age of males and females was **52.75±12.92** years and **50.1±12.59** years, respectively and the difference was not statistically significant. (Unpaired t-test, $t = 0.5339$ ($P = 0.5976$)). (Refer table 04).

The BMI was calculated for all the 30 cases in which 11 patients (36.66%) were overweight, five (16.66%) were underweight, and 14 patients (46.66%) were in the normal BMI range as given in table 05.

The food habit of these 30 patients was also taken into account, and it was found that among 30 patients, the majority of the patients (86.67%) were taking non-vegetarian food. In contrast, the remaining 13.34 % were vegetarians. (Table 06).

Out of these 30 patients, 16 patients (53.34%) were found to had adverse habits. All of them are male, and none of the female patients had any adverse habits. Out of 20 male patients, six (30%) were smokers, two (10%) were alcoholics, and eight (40%) were both smokers and alcoholics. (Table 07).

Hb levels were measured in these 30 cases. In these 30 patients, only 11 patients (36.67%) were found to be in the range of 10-13g/dl. The mean Hb value was found to be 7.80 ± 2.78 , which shows that most of the CKD patients have anemia. The Chi-square test reveals that there is no association between gender and hemoglobin level. [$\chi^2 = 2.922$ (P=0.232)] (table 08).

The frequent illness faced by these intradialytic complicated patients were analyzed. It was observed that 11 patients (36.67%) were had headaches, nine (30%) had a fever, seven patients (23.34%) suffered from stomach Pain, and three (10%) were having chest pain frequently, as given in table 09.

The types of drinking water used by these patients were analyzed and found that 11 patients (36.67%) were drinking Home purified water, 9(30%) were drinking Mineral Water, 3 (10%) patients were drinking Well Water, and seven patients (23.34%) were drinking Ground Water as shown in table 10.

Out of 30 patients, the occupation of 11 patients (36.67%) was reported as business, three patients (10%) were doing security jobs, six female patients (20%) were homemakers, two patients (6.67%) were Drivers, five (16.67%) patients were Engineers and three (10%) patients were daily labors. (See table 11)

During dialysis, the pulse rate was measured, and 14 patients (46.67%) were found to have normal pulse rate, and the remaining 16 (53.34%) were above the normal range as given in table 12. Similarly, the blood pressure was also observed where 25 (83.34%) patients were found to have high Blood Pressure (BP), four patients (13.33%) were found with normal BP, and only one patient (3.33%) had low BP, as shown in Table 13

In these 30 cases, intradialytic complications like hypertension (HTN), Hypotension, Vomiting, Headache, shortness of breath were commonly found. Fever and vomiting were also present. The number of patients and percentage for each complication is shown in Table No: 14. When comparing to other complications, hypertension (50%) was found to be more prevalent, followed by headache (13.33%) and hypotension (13.33%). The drugs used to manage these intradialytic complications were given in table 15. It was found that all the drugs used to manage these complications were given through the IV route during dialysis except for nebulizers for breathing difficulty.

Table 01: Gender wise distribution

Gender	No. of patients (n = 245)	Percentage
Male	155	63.26%
Female	90	36.74%

Table 02: Age and gender-wise description

Age in years	Male (n=155)	Female (n=90)	Total(n=245)
18-28	10 (8.34%)	13 (14.44%)	23 (9.39%)
29-39	13 (10.84%)	12 (13.33%)	25 (10.2%)

40-50	25 (20.84%)	10 (11.11%)	35 (14.28%)
51-60	38 (31.67%)	22 (24.44%)	60 (24.49%)
61-70	39 (32.5%)	24 (26.67%)	63 (25.71%)
71-80	30 (25%)	9 (10%)	39 (15.91%)

*Mean age of male and female was 56.29±15.10 years and 51.44±16.72 years
Mean age of the total population was 54.51±15.86 years
Unpaired t-test, t = 2.3291 (P = 0.0207)

Table 03: Gender wise distribution of Intradialytic Complicated patients

Gender	No. of Patients (n=30)	Percentage
Male	20	66.67%
Female	10	33.33%

Table 04: Age-wise distribution of intradialytic complicated patients

Age in years	Male (n=20)	Female (n=10)	Total (n=30)
18-28	1(5%)	0	1(3.33%)
29-39	3(15%)	3(30%)	6(20%)
40-50	2(10%)	1(10%)	3(10%)
51-60	8(40%)	4(40%)	12(40%)
61-71	6(30%)	2(20%)	8(26.67%)

Mean age of males and females was 52.75±12.92 years and 50.1±12.59 years
Mean age of the total population was 51.87±12.66 years
Unpaired t-test, t = 0.5339 (P = 0.5976)

Table 05: BMI distribution of intradialytic complicated patients

Gender	Overweight	Underweight	Normal weight
Male (n=20)	6(30%)	2(10%)	12(60%)
Female (n=10)	5(50%)	3(30%)	2(20%)
Total (n=30)	11 (36.66%)	5 (16.67%)	14 (46.67%)

*Reference Value:
Underweight = Below 18.5, Normal =18.5-24.9, Overweight = 25.0-29.9, Obese =30.0 and above

Table 06: Food Habit of Intradialytic complicated patients

Gender	Veg	Non-Veg
Male (n=20)	2(10%)	18(90%)
Female (n=10)	2(20%)	8(80%)
Total (n=30)	4 (13.34%)	26 (86.67%)

Table 07: Adverse Habits of Intradialytic complicated patients

Gender	Smoking only	Alcohol only	Both	No Adverse Habits
Male (n=20)	6(30%)	2(10%)	8(40%)	4(20%)
Female (n=10)	0	0	0	10 (100%)
Total (n=30)	6 (20%)	2(6.67%)	8(26.66%)	14 (46.66%)

Table 08: Hemoglobin level of Intradialytic complicated patients

Hemoglobin Range g/dl	Male (n= 20)	Female (n=10)	Total (n=30)
3-5	3 (15%)	4(40%)	7 (23.34%)
5.1-9	8 (40%)	4(40%)	12 (40%)
9.1-13	9 (45%)	2(20%)	11 (36.67%)
Mean value of Hb = 7.80±2.78 g/dl Chi square value, $\chi^2 = 2.922$ (P=0.232) *(Reference value Male=13.8–17.2 g/dl, Female=12.1–15.1 g/dl)			

Table 09: Frequent Illness facing by intradialytic complicated patients

Frequent Illness	No of Patients (n=30)
Headache	11 (36.67%)
Fever	9 (30%)
Stomach Pain	7 (23.34%)

Chest Pain	3 (10%)
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Table 10: Type of drinking water using by intradialytic complicated patients

Type Drinking Water	No of Patients (n=30)
RO Water	11 (36.67%)
Mineral Water	9 (30%)
Well Water	3 (10%)
Ground Water	7 (23.34%)

Table 11: Occupation of Intradialytic Complicated Patients

Occupation	No of Patients(n=30)
Business	11 (36.67%)
Security	3 (10%)
House Wife	6 (20%)
Driver	2 (6.67%)
Engineer	5 (16.67%)
Daily labors	3 (10%)

Table 12: pulse rate during dialysis

Range(72/min)	No of Patients (n=30)
low pulse rate	0
Normal pulse rate	14 (46.67%)
High pulse rate	16 (53.34%)

Table 13: Blood pressure during dialysis

Range	No of patients (n=30)
low Blood Pressure	1 (3.33%)

Normal Blood Pressure	4 (13.33%)
High Blood Pressure	25 (83.34%)

Table 14: Intradialytic complications

Complication	Male (n= 20)	Female (n=10)	Total (n=30)
Hypertension	10(50%)	5(50%)	15(50%)
Hypotension	2(10%)	2(20%)	4(13.33%)
Headache	3(15%)	1(10%)	4(13.33%)
Fever	1(5%)	0	1(3.33%)
Shortness of Breath	3(15%)	0	3(10%)
Vomiting	1(5%)	2(20%)	3(10%)

Table 15: Drugs Used for Management of Intradialytic Complications

No. of patients	Intradialytic Complications	Management Drugs
15	Hypertension	1) Hydralazine Hydrochloride Injection USP (20mg/ml). 2) Labetalol Hydrochloride Injection USP (5mg/ml).
03	Shortness of breathing	1) Thiamine Hydrochloride Injection (5ml). 2) Asthalin Respules (0.5ml) + 03% NS 5ml.
03	Vomiting	1) Vancomycin Hydrochloride Injection USP (500mg). 2) Gentamicin Injection USP (40mg/ml). 3) Ondansetron Injection, USP (2mg/ml).
04	Headache	1) Paracetamol (150mg/ml) Injection. 2) Sulbactam & Cefoperazone Injection

		(1.5g).
04	Hypotension	1) 50% Dextrose Injection USP (0.5g/ml). 2) Polybion Injection (2ml). 3) Erythropoietin Injection BP 2000 IU /ml
01	Fever	1) Gentamicin Injection USP (40mg/ml). 2) Paracetamol Injection (300mg/ml).

Discussion

Renal transplantation or dialysis are the two options for RRT in ESRD patients. Hemodialysis is the most widely utilised treatment method on the planet. In-center hemodialysis is cost-effective, but it adds to the socioeconomic burden and causes psychological problems. Hemodialysis devices, technologies, and substances utilised in sessions, such as bicarbonate solution, online hemodiafiltration, and continuous RRT technique, have advanced and modernised in the previous few decades to give the greatest quality of hemodialysis. Intradialytic hypotension's specific mechanism is unknown, although it's thought to be multifactorial due to excessive intradialytic weight gain, quick fluid elimination, cardiovascular system impairment, infections, allergic reactions, high dialysate temperature, low salt, and drugs taken prior to the session.

The male patients (63.26%) were found to be predominant than the female patients (36.73%). The mean age of the CKD patients in the dialysis was found to be 54.51 ± 15.86 . the difference in the mean age between the male and female patients was statistically significant in this study.

Among 245 patients, only 30 (12.24%) had intradialytic complications. The mean age of these patients were 51.87 ± 12.66 . the male predominance in this study is similar to other studies done by saud mohammed raja et al, Co Amira et al. the subset of these patients were analysed.

Patients with normal BMI range were mostly affected with intradialytic complications than overweight patients, which supports the theory that obesity or overweight has the opposite effect in dialysis patients. The analysis of food habits showed that non-vegetarian diet was followed by most of the patients in our study.

Among 30 ESRD patients, only male patients had adverse habits in which most of the patients (46.66%) had no adverse habits. Comparing to alcoholics, no. of smokers was more.

Haemoglobin levels measured in patients involved in this study showed that most of the patients were anemic. The mean value was found to be 7.80 ± 2.78 g/dl which is very low while comparing it to the study done by sahib MM et al, were the Hb levels were 11 ± 1.1 g/dl.

The frequently reported symptoms were headache in most of the patients (36.67%). Antoniazzi AL et al, in 2003 conducted a prospective study to determine the prevalence of headache in hemodialysis patients and reported that most of the patients had frequent headaches.

The type of drinking water consumed by CKD patients must be considered. About 66.67 patients consumed purified drinking water rather than ground water. A study conducted by A Kumar et al, showed that ground water contains more heavy metals and concluded that drinking purified water would be better especially in CKD patients.

The intradialytic complications reported in our study are hypertension (HTN), Hypotension, Vomiting, Headache, shortness of breath, fever, and vomiting. The most encountered complication was hypertension in our study, which was present in 50% of patients, whereas hypotension was the frequently reported complication in studies done by Saud Mohammed Raja et al.^[9] 2020, Prabhakar et al.^[19] 2015, Hasan MJ^[8] 2013, Ali M^[2] 2021. The study done by Co Amira et al.^[7] 2012 showed that hypertension was the most reported intradialytic complication.

The heart rate of most of the patients in the study was high. The increase in heart rate could be due to the changes in the concentration of electrolytes during dialysis. About 83.34% of the patients had high blood pressure during hemodialysis.

In our study, the management of intradialytic complications was based on the underlying cause and guidelines. Hydralazine and labetalol were given to treat intradialytic hypertension in our patients, which are not removable by dialysis procedure^[20]. Jula K et al. study^[21] 2010 says that intradialytic hypertension should be treated by antihypertensive agents that are not removable by hemodialysis. Erythropoietin and polybion injection were given to treat hypotension during dialysis as hypotension may be occurred due to anemia. Erythropoietin is known to increase BP^[21,22,23]

Conclusion

The prevalence of intradialytic complications in our study was 12.24%. This was very low when compared to other similar studies. And also, there were no life-threatening complications and mortality during dialysis in our patients. Less

than ten minor intradialytic complications were only found, which may be due to the low sample size and short duration of the study. But the complications occurred very often, which were managed immediately by suitable medications. However, during dialysis, there are possibilities of occurrence of mild to very severe complications. So, preventive measures and other dialysis precautions are always highly recommended.

The limitations of this study are low sample size and short duration. The Past medical and medication history of patients were not assessed. The risk factors and causes for ESRD of individual patients were not determined. The frequency

and duration of patients on dialysis not seen. The quality of life of ESRD patients on dialysis was not assessed.

Hence, we recommend that the study be done with large sample size and long duration, including the objectives mentioned as limitations above.

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