# Impact of Patient Education on Interdialytic Weight Gain and Blood Pressure in Patients Undergoing Hemodialysis

# Rini Thainery Padinchare Veetil<sup>1</sup>, Janardhan Kamath<sup>2</sup>, Uday Venkat Mateti\*<sup>1</sup>

<sup>1</sup>Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Paneer, Deralakatte, Mangaluru, INDIA.

<sup>2</sup>Department of Nephrology, K.S. Hegde Academy, Justice K.S Hegde Charitable Hospital, Nitte (Deemed to be University), Deralakatte, Mangaluru, INDIA.

# **ABSTRACT**

Objectives: To assess the impact of patient education on Interdialytic Weight Gain (IDWG) and Blood Pressure (DBP) in patients undergoing hemodialysis (HD). Materials and Methods: A Quasi experimental Pre and Post study design was conducted in an outpatient HD unit among 50 patients who were undergoing maintenance HD. The patients were educated by using validated educational material. The data on IDWG, Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) were collected at baseline, 4th week, 10th week and 16th week. The paired sample t-test was applied to assess the mean change in difference from baseline to 16th week with p value less than 0.05 was considered as statistically significant. Results: The mean SBP was significantly reduced from baseline (151.60  $\pm$  19.99 mmHg) to 16<sup>th</sup> week (144  $\pm$  15.70 mmHg) with p value 0.021 in pre HD patients and also in post HD patients from baseline (157  $\pm$  21.65 mmHg) to  $16^{th}$  week (144.62  $\pm$  16.03 mmHg) with p value 0.001. The mean Pre and Post IDWG was significantly reduced after the patient education from baseline (3.44  $\pm$ 1.36 kg) to the end of the study i.e.  $16^{th}$  week (2.76  $\pm$  0.90 kg) with p value 0.001 in the HD session patients. Conclusion: The small group education in patients undergoing HD leads to decrease in IDWG, SBP in Pre and Post-HD sessions patients and DBP in Post-HD session patients significantly from baseline to post education but DBP in Post-HD patients were not reduced significantly.

Key words: Hemodialysis, Interdialytic Weight Gain, Blood Pressure, Patient Education.

# INTRODUCTION

Chronic kidney disease (CKD) is the major public health problem in the world population. Studies were estimated that the incidence rate of ESRD in India to be 229 per million populations and more than 100000 new patients are undergoing renal replacement therapy (RRT) annually. In India only 10% of end - stage renal disease (ESRD) patients receive any one type of RRT due to scare and unawareness.<sup>1</sup>

IDWG is the main problem in patients who are undergoing maintenance HD. IDWG is mainly occurring as a result of excessive intake of salt and water in-between two HD

sessions. It can be seen in 10 - 95 % of HD patients. Excessive fluid and salt intake lead to dyspnea, generalized edema, heart failure (HF), pulmonary edema and ultimately lead to weight gain.<sup>2</sup> IDWG will vary individually and it is 5% less than body weight usually seen in the range between 2 - 3.5 kg.<sup>3</sup> Controlling IDWG is the main problem in patients undergoing maintenance HD. IDWG depend on daily fluid intake and time between HD session and how much urine passes. The UK renal association suggests that the rate fluid removal during HD should be kept in the range of

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### DOI: 10.5530/ijper.51.4s.95 Correspondence: Dr. Uday Venkat Mateti,

Department of Pharmacy Practice, NGSM Institute of Pharmaceutical Sciences, Nitte (Deemed to be University), Paneer, Deralakatte, Mangaluru-575 018, INDIA. Phone no: 8152977460 Email: udayvenkatmateti@ gmail.com



10 ml/kg/hour. However, it is important to notice that the fluid you can remove from your body during HD depend on the excess fluid present in your body. Monitoring IDWG continuously and controlling the fluid and salt intake between dialysis sessions by using alternative ways will help to reduce IDWG.<sup>4</sup>

Like IDWG, HTN is both a reason and consequence of

CKD. Around 50 to 90% of patients on HD were suffering from HTN and were on HTN drugs.5 Controlling blood pressure is a difficult task in patients undergoing HD. It increases the risk of development of left ventricular hypertrophy, HF, stock and other CVS and neurological complications. BP measurements during HD procedure are important method of volume assessment and safety, because BP will varies individually during HD sessions and in-between HD sessions. Dietary salt restriction will help to manage HTN in HD patients.<sup>6</sup> It is evident that patients are facing problems during their dialysis session as they do not show compliance with their diet, salt and fluid consumption plans. This can even lead to complications such as increased IDWG and variation in BP. Systematic patient education can enhance patient's knowledge, behavior and awareness.7 By providing proper counseling, a clinical pharmacist can attain definite improvement in patient's knowledge regarding the different aspects of drugs, disease, lifestyle changes during dialysis.8

# **MATERIALS AND METHODS**

## Study design, site and Ethical approval

Quasi – experimental Pre and Post study was conducted in an out-patient HD unit of Nephrology Department of Justice K.S. Hegde Charitable Hospital, Mangaluru for the study duration of eight months (August 2016 to March 2017). Prior to the initiation of the study, ethical approval was obtained from Institutional Ethical Committee (Ref No: INST.EC/EC/66/2016-17), Mangaluru.

# Study criteria

The study inclusion criteria are based on patients undergoing HD continuously in the age group between 18-75 years with a written informed concern, patients of either gender, patients who are undergoing minimum two HD sessions per week, and patients who are not receiving official education about fluid consumption during the study. The study exclusion criteria includes patients who have any mental problems such as dementia or delirium, pregnant and lactating women and patients who are not willing to participate in the study.

# Development, validation and readability testing of Patient Information Leaflet (PIL)

The content of PIL includes the information on fluid, thirst and salt management. An expert committee consisting of a nephrologist and academic pharmacists validated the content of the PIL. The validated PIL was translated into Kannada and Malayalam language by using a 3-step process of forwarded translation, backward translation and patient testing and it was also tested for Flesch Reading Ease (FRE) and Flesch – Kincaid Grade Level (FKG) readability tests in Microsoft officeword 2010. The Baker Able Leaflet Design (BALD) was used to obtain layout and design of the PIL. Three months' time duration was taken for the development final of PILs.

# Sample size calculation

The sample size required for this pre and post study was calculated based on the formula mentioned in the similar study by Mateti UV et al., 9

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{d^2} + 2$$

 $\sigma$  = 2, Z  $_{_{1-\alpha/2}}$  is 1.96 (for  $\alpha$  = 5%), Z  $_{_{1-\beta}}$  is 0.84 for 80% power and d = 0.8  $\sigma$  is the mean of the two standard deviations d is the minimum significant difference in the two groups

The minimum sample required for study is 40.

# **Data collection process**

The demographic details such as age, gender, educational status, employment status, domiciliary status, height, weight, BMI, duration of CKD, duration of HD, co-morbid conditions and number of medications per prescription were obtained from the patient's medical records. The IDWG and BP readings were also collected at the different time intervals after obtaining informed consent form from the patients.

# **Patient education**

The patient education was provided to all the eligible patients after the baseline assessment of IDWG and BP. The educational sessions were provided regularly at 4<sup>th</sup>, 10<sup>th</sup> and 16<sup>th</sup> week of HD sessions. During the educational sessions, the patients were educated about the fluid, thirst and salt management along with indication, dose, administration time, and common side effects of medications and motivated for importance of adherence to regular HD sessions and medications. These patients were also provided the validated PIL based on the preferred language.

### Assessment of outcomes

For each time point, the average eight preceding readings of IDWG, SBP and DBP were recorded at baseline, 4<sup>th</sup> week, 10<sup>th</sup> week and 16<sup>th</sup> week for each patient.

IDWG was calculated by using the below mentioned formula <sup>6</sup>

IDWG = Pre hemodialysis weight – Post hemodialysis weight

Mean arterial pressure (MAP) was also calculated by using below mentioned formula <sup>10</sup>

$$MAP = ((SBP-DBP)/3 + DBP)$$

# Statistical analysis

Descriptive statistics was used to summarize the demographic characteristics of the patients. Pre and post educational IDWG, BP and MAP of the HD patients were analyzed by using paired student t test with p value less than 0.05 was considered as statistical significant. The mean change in IDWG, BP and MAP of the HD patients at different time points were analyzed by using repeated measures of ANOVA with p value less than 0.05 was considered as statistical significant. The data was analyzed by using Statistical Analysis Package for Social Science (SPSS) version 16.0.

# **RESULTS**

# Readability assessment of PIL

The readability was assessed by using FRE and FKG tests and their readability scores were 61.3 and 8.3 respectively.

### **BALD** assessment scores of PILs

The BALD scores of PILs were calculated based on the standard criteria and the scores for English, Kannada and Malayalam leaflets were 24, 25 and 26 respectively.

# **Baseline data of HD patients**

A total number of 50 patients were included in the study based on the inclusion and exclusion criteria. Out of 50 patients, three patients did not complete the full educational sessions and two patients were expired during the study period. At the end of the study, 45 HD patients were completed the full 16 weeks of patient educational sessions.

Out of 50 patients, male patients (n=33) outnumbered the female patients (n=17) and the mean age of the HD patients was  $49.82 \pm 11.71$  years. Most of the patients were unemployed (72%) due to their disease condition and 38% were illiterate in the study. Majority of HD patients were from rural area background (n=34).

According to the Asian classification of BMI, majority of the HD patients had normal or lean BMI (36%). In the present study, most of the HD patients were undergoing 3 HD sessions/week. Most of the HD patients had the history of CKD in the range from 21 to 40 months (42%) and 52% of them were undergoing HD for less than 20 months. The demographic details such as age, gender, employment status, educational status, duration of HD/ week, BMI, history of CKD and vintage of HD in patients are presented in the Table 1. The study shown that, the family history (82%) of CKD was one of the main risk factor for the development of CKD in the study population. It was noticed that 100% of HD patients were suffering from HTN. The risk factors and co-morbidities of HD patients are presented in the Table 2.

# Change in pre and post educational IDWG in HD patients

The mean IDWG in the HD patients was significantly reduced after the patient education from baseline (3.44  $\pm$  1.36 kg) to the end of the study i.e.  $16^{th}$  week (2.76  $\pm$  0.90 kg) with p value 0.001. The mean IDWG in the HD patients was significantly reduced at different time points from baseline to  $4^{th}$  week,  $10^{th}$  week and  $16^{th}$  week with p value 0.001 are presented in the Table 3.

# Change in pre and post educational SBP in Pre-HD session patients

The mean SBP in the Pre-HD session patients was significantly reduced after the patient education from baseline (151.60  $\pm$  19.99 mmHg) to the end of the study i.e.  $16^{th}$  week (144.84  $\pm$  15.70 mmHg) with p value 0.021. The mean SBP in the Pre-HD session patients were significantly reduced at different time points from baseline to  $4^{th}$  week,  $10^{th}$  week and  $16^{th}$  week with p value 0.007 are presented in the Table 3.

# Change in pre and post educational SBP in Post-HD session patients

The mean SBP in the Post-HD session patients was significantly reduced after the patient education from baseline (157.05  $\pm$  21.65 mmHg) to the end of the study i.e.  $16^{th}$  week (144.62  $\pm$  16.03 mmHg) with p value 0.001. The mean SBP in the Post-HD session patients was significantly reduced at different time points from baseline to  $4^{th}$  week,  $10^{th}$  week and  $16^{th}$  week with p value 0.001are presented in the Table 3.

# Change in pre and post educational DBP in Pre-HD session patients

The mean DBP in the Pre-HD session patients was not significantly reduced after the patient education from

Table 1: Demographic details of HD patients						
Demographic details		Number of patients (n = 50)	Percentage			
Gender	Male	33	67%			
	Female	17	33%			
Age group (Years)	18 – 29	2	4%			
	30 – 39	10	20%			
	40 – 49	11	22%			
	50 – 59	13	22%			
	60 – 69	14	28%			
Employment status	Employed	14	28%			
	Unemployed	36	72%			
	Primary school	14	28%			
Educational status	10 <sup>th</sup> standard	11	22%			
Educational Status	Pre-University	5	10%			
	Degree	1	2%			
	Illiterate	19	38%			
	Underweight (<18.5)	17	34%			
BMI range	Normal or lean (18.5-22.9)	18	36%			
( Kg/ m²)	Over-weight (23-24.9)	10	20%			
	Obese (> 25)	5	10%			
	>20	12	24%			
History of CKD in HD	21-40	21	42%			
patients	41-60	10	20%			
(Months)	61-80	2	4%			
	81-100	3	6%			
	101-120	2	4%			
	>20	26	52%			
Vintage of HD (Months)	21-40	18	36%			
	41-60	4	8%			
	61-80	2	4%			
Domiciliary status	Rural	34	68%			
	Urban	16	32%			
Sessions of HD per week	3 HD/week	3	6%			
	2 HD/ week	47	94%			

BMI-Body mass index; HD-Hemodialysis

baseline (86.78  $\pm$  7.85 mmHg) to the end of the study i.e.  $16^{\text{th}}$  week (86.45  $\pm$  5.49 mmHg) with p value 1.000. The mean DBP in the Pre-HD session patients was not significantly reduced at different time points from baseline to  $4^{\text{th}}$  week,  $10^{\text{th}}$  week and  $16^{\text{th}}$  week with p value 0.357are presented in the Table 3.

# Change in pre and post educational DBP in Post-HD session patients

The mean DBP in the Post-HD session patients was significantly reduced after the patient education from baseline (88.42  $\pm$  7.40 mmHg) to the end of the study i.e.  $16^{\rm th}$  week (86.13  $\pm$  6.01 mmHg) with p value 0.019. The mean DBP in the Post-HD session patients was not significantly reduced at different time points from

Details		Number of patients (n = 50)	Percentage
	Family history	41	82%
	Pre-alcoholic	3	6%
	Pre-smoker	1	2%
	Pre-alcoholic and smoker	-	-
	Obesity	2	4%
	Nature of job	3	6%
Risk factors	Type 2 DM	14	28%
	Hypertension	19	38%
	Cresentric-glomerulonephritis	1	2%
	Diabetic nephropathy	3	6%
	Acute pancreatitis	1 14 n 50	2%
	Unknown	14	28%
	Hypertension	50	100%
	HTN retinopathy	5	10%
	Type 2 DM	14	28%
	Diabetic retinopathy	4	8%
	Diabetic nephropathy	3	6%
	Diabetic neuropathy	1	2%
	IHD	7	14%
Co-morbidities	Parkinsonism	1	2%
	Anemia	45	90%
	COPD	2	4%
	Endocarditis	1	2%
	Hepatitis B	1	2%
	Hyperthyroidism	2	4%
	GERD	1	2%
	UTI	1	2%

GERD - Gastro esophageal reflux disease, UTI - Urinary tract infection, IHD - Ischemic heart disease

Table 3: Change in pre and post educational outcomes at different time points in HD patients								
Outcome	Baseline (Mean ± SD)	4 <sup>th</sup> Week (Mean ± SD)	10 <sup>th</sup> Week (Mean ± SD)	16 <sup>th</sup> Week (Mean ±SD)	p value			
IDWG (Kg)	3.44 ± 1.36	3.10 ± 1.11	3.01 ± 1.02	2.76 ± 0.90	0.001			
SBP in Pre-HD (mmHg)	151.60 ± 19.99	150.28 ± 18.13	147.26 ± 17.53	144.84 ± 15.70	0.007			
SBP in Post-HD (mmHg)	157.05 ± 21.65	152.73 ± 20.02	149.73 ± 16.04	144.62 ± 16.03	0.001			
DBP in Pre-HD (mmHg)	86.78 ± 7.85	87.08 ± 6.14	85.87 ± 5.96	86.45 ± 5.49	0.357			
DBP in Post-HD (mmHg)	88.42 ± 7.40	86.55 ± 6.89	86.66 ± 5.32	86.13 ± 6.01	0.031			
MAP in Pre-HD (mmHg)	108.38 ± 11.60	108.84 ± 9.81	106.13 ± 9.13	105.91 ± 8.35	0.070			
MAP in Post-HD (mmHg)	111.34 ± 12.19	108.02 ± 11.05	107.51 ± 8.57	105.28 ± 8.46	0.001			

IDWG- Interdialytic weight gain; SBP- Systolic blood pressure; DBP-Diastolic blood pressure; MAP- Mean arterial pressure

baseline to 4<sup>th</sup> week, 10<sup>th</sup> week and 16<sup>th</sup> week with p value 0.031 are presented in the Table 3.

# Change in pre and post educational MAP in Pre-HD session patients

The mean MAP in the Pre-HD session patients was not significantly reduced after the patient education from baseline (108.38  $\pm$  11.60 mmHg) to the end of the study i.e.  $16^{th}$  week (105.91  $\pm$  8.35 mmHg) with p value 0.105. The mean MAP in the Pre-HD session patients was not significantly reduced at different time points from baseline to  $4^{th}$  week,  $10^{th}$  week and  $16^{th}$  week with p value 0.070 are presented in the Table 3.

# Change in pre and post educational MAP in Post-HD session patients

The mean MAP in the Post-HD session patients was significantly reduced after the patient education from baseline (111.34  $\pm$  12.19 mmHg) to the end of the study i.e.  $16^{th}$  week (105.28  $\pm$  8.46 mmHg) with p value 0.003. The mean MAP in the Post-HD session patients was significantly reduced at different time points from baseline to  $4^{th}$  week,  $10^{th}$  week and  $16^{th}$  week with p value 0.001are presented in the Table 3.

# **DISCUSSION**

In our study, most of the HD patients were in the age group of 60 - 69 years (28%) and the mean age of the study population was  $49.82 \pm 11.71$  years. Our study results are in contrast to the study conducted by Rahman M *et al.*, where the mean age of the HD patients was  $59.7 \pm 15.8$  years. <sup>10</sup> In addition, the results reported by Lopez- Gomez *et al.*, showed that the mean age of the HD patients was  $60.6 \pm 14.5$  years which is contradicted to our study results. <sup>4</sup> This may be due to the fact that, older population have the higher risk for developing ESRD.

In our study, 38% of the patients were illiterates, 28% had primary school education and higher education. These results were contradicted to the study conducted by Oshvandi K *et al.*, where they showed that most of the patients had high school education (26.2%).<sup>7</sup> As per the study result of Sharaf AY *et al.*, most of them had bachelor's degree (26.7%).<sup>11</sup> These results were not in comparison with the present study results.

The mean BMI of the study population was 20.21± 4.1 kg/m². These findings were contradicted to the study carried out by Lopez-Gomez MJ *et al.*, in their study population BMI was 23.8 ± 3.4 kg/m².4 In our study, most of the patients are undergoing maintenance HD of 2 times per week (94%). The study results of Lopez-Gomez MJ *et al.*, and Oshvandi K *et al.*, finding were

not comparable to our results where it was showed that the subjects routinely preformed 3 HD/ week (100% Lopez-Gomez MJ *et al.*, and 81% in Oshvandi K *et al.*).<sup>4,7</sup> This is mainly due the financial problem during patient's treatment period.

In the present study, family history of CKD was found to be the major risk factor for HD patients (82%). This finding was contradicted to the study conducted Lopez-Gomez *et al.*, and Rahman M *et al.*, in their study chronic interstitial nephropathy (26.1%) and diabetes (34%) were the most common co-morbidities observed.<sup>4,11</sup>

Another important finding in the study was 100% of the HD patients had HTN (100%) as co-morbidity followed by anemia (90%). These results were consistent with the study conducted by Sharaf AY *et al.*, and Santos SFF *et al.*, where most of the HD patients were suffered from HTN as co-morbidity.<sup>11,12</sup>

The mean IDWG at baseline was  $3.44 \pm 1.36$  kg, at 4<sup>th</sup> week  $3.10 \pm 1.11$ kg, at 10th week  $3.01 \pm 1.02$  kg and at  $16^{\text{th}}$  week  $2.76 \pm 0.90$  kg in the current study. From this, it is evident that IDWG significantly decreased from baseline to 16th week after the patient education (p value 0.001). These findings were in line with the results of the study performed by Oshvandi K et al., in which it was found that the mean IDWG of HD patients was  $3.64 \pm 0.88$  kg before education and was decreased to  $1.34 \pm 0.61$  kg and  $1.71 \pm 0.72$  kg in one week and one month after the education respectively, with p value 0.001.7 The present study findings were also coincides with the results of Sharaf AY et al., where it was found that the mean IDWG was significantly reduced after the educational programs. The mean IDWG in the Sharaf AY et al., study was  $4.39 \pm 0.63$  kg before education and was reduced to  $3.71 \pm 0.78$  kg after the education with p < 0.001. The study results of Ryu H et al., also comparable with the present study where, IDWG was significantly reduced after educational program before education (22.5%) to after education (7.46 %) with p value 0.001.13

In this study, the mean SBP in Pre-HD patients was significantly reduced after the patient education from baseline (151.60  $\pm$  19.99 mmHg) to end of the study i.e.  $16^{th}$  week (144.84 $\pm$ 15.70 mmHg) with p value 0.021. Also the mean SBP in Post-HD patients was significantly reduced from baseline (157.05  $\pm$  21.65 mmHg) to the end of the study i.e.  $16^{th}$  week (144.62  $\pm$  16.03 mmHg) with p value 0.001. As per the study of Oshvandi K *et al.*, the mean SBP in HD patients before education was 139.7  $\pm$  16.45 mmHg and significantly reduced to 129  $\pm$  12.16 mmHg (1 week) and 129  $\pm$  11.51 mmHg (1 month) after education with p value 0.001.7 Inrig JK

et al., reported that, for every 1% increase in percentage IDWG was associated with 1 mmHg increase in Pre-HD SBP (p < 0.0001) and 0.65 mmHg decrease in Post-HD SBP with p value < 0.0001 these findings were contradicted to our study results.<sup>14</sup>

The mean DBP in Pre-HD session patients was not significantly reduced after the patient education from baseline (86.78  $\pm$  7.85 mmHg) to the end of the study i.e.  $16^{th}$  week (86.45  $\pm$  5.49 mmHg) with p value 1.000. But the mean DBP in Post-HD session patients was significantly reduced after the patient education from baseline (88.42  $\pm$  7.40 mmHg) to the end of the study i.e.  $16^{th}$  week (86.13  $\pm$  6.01 mmHg) with p value 0.019 in the Post-HD session patients. Whereas, the study result of Oshvandi K *et al.*, the mean DBP of participants was 81.4  $\pm$  6.07 mmHg before education and decreased to 79.7  $\pm$  5.51 mmHg (1 week) and 81.7  $\pm$  5.27 mmHg (1 month) after the education but there is no statistically difference was observed (p value 0.061).9

The present study results revealed that after the patient education, there was a significant reduction in mean IDWG and Pre and Post HD SBP and Pre HD DBP but there was no significant reduction in DBP of Post-HD patients. Santos FFS *et al.*, and Ryu H *et al.*, suggested that repeated patient education preventing abnormal IDWG also control BP in HD patients.<sup>12, 13</sup>

In this present study, the FRE and FKG readability test scores of PIL were 61.3 and 8.1 respectively. These results are contradicted to the study conducted by Mateti UV *et al.*, where the FRE score of the PIL was 64.4 and FKG score of the PIL was 7.3.<sup>15</sup> The studies conducted by Adepu R *et al.*, and Roy RT *et al.*, where the FRE test scores were 80 and 69.9 respectively which was better than our FRE score value. <sup>16, 17</sup> The FKG test score was 7.1 in the study conducted by Roy RT *et al.*, which was almost similar to our study results. <sup>17</sup>

In our study, the design and layout of leaflet was evaluated by BALD criteria and the scores were 24 for English, 25 for Kannada and 26 for Malayalam leaflets. These results were similar to the study conducted by Mateti UV *et al.*, where the scores were similar to Malayalam (26) and Kannada (26) PILs except for English PIL's (25). The mean BALD score was 22 in the study conducted by Adepu R et al. comparing to these results our BALD scores was better. <sup>16</sup>

The study was planned for small group of education; the duration of the study was less to assess the longer-term outcomes and absence of patients in between the educational sessions were the limitations of the study.

# CONCLUSION

The significant reduction of IDWG and SBP in Pre and Post-HD session patients, DBP and MAP in Post-HD session patients was observed from baseline to post education with p value less than 0.05. The DBP and MAP in Pre-HD session patients were not significantly reduced from baseline to the end of the study (post education) with p value >0.05. From these results, it is evident that, by providing proper patient counseling and education by a clinical pharmacist can attain definite improvement in the patient knowledge regarding drugs, disease and lifestyle changes during dialysis and decrease the IDWG and BP in HD patients. Effective education can improve patient's confidence and motivate them to lead a healthy life.

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# **CONFLICT OF INTEREST**

Authors declare no conflict of interest

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# PICTORIAL ABSTRACT Quasi experimental Pre and Post study design Impact of patient education on IDWG, SBP, DBP were collected at baseline, 46 week, 10th week and 16th week The IDWG and SBP in Pre and Post-HD sessions patients and DBP in Post-HD session patients significantly reduced from buseline to post education.

# **SUMMARY**

- A quasi experimental Pre and Post study design was conducted in an out-patient HD unit among 50 patients.
- The patients were educated by using validated educational material in the form of local language PILs.
- The content of PIL includes the information on fluid, thirst and salt management.
- The data on IDWG, SBP and DBP were collected at baseline, 4th week, 10th week and 16th week.
- The IDWG and SBP in Pre and Post-HD sessions patients and DBP in Post-HD session patients significantly reduced from baseline to post education.

### **About Author**



**Dr. Uday Venkat Mateti**, B.Pharm, Pharm.D, RPh, Ph.D is an Assistant Professor and Head of the Dept. of Pharmacy Practice in the esteemed N.G.S.M. Institute of Pharmaceutical Sciences, Nitte University, Mangaluru, India. He obtained Doctor of Philosophy (Ph.D.) degree from Manipal University, Manipal in India in the year 2016. Dr. Mateti's specialized areas are pharmaceutical care, drug safety, pharmacoeconomic modeling, patient-reported outcomes, pharmacoepidemiology and supportive care.

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