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Clinical validation of Ayurveda treatment on patients of chronic kidney disease

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Abstract

Introduction: Chronic kidney disease (CKD) had emerged as a global threat worldwide spawning significant concerns in the life of an affected person thereby resulting in life of misery, but with timely screening, early detection, early intervention it can be managed through Ayurveda system of medicine thereby withholding the disease progression to end stage renal disease which is involving significantly higher mortality rates. On the contrary, conventional therapy significantly contributes towards the cost of patient care and have its own implications & limitations. Therefore alternate remedies for curing and impeding the disease manifestation are being embraced worldwide. In Ayurveda, CKD may be considered as Mutravaha srotas vikar occurring due to the derangement of Tridoshas (three biological humours; Vata, Pitta, and Kapha), Agnimandya (weak digestive fire) and Srotosanga (obstruction in microchannels of Mutravaha srotas).

Aim and objectives: A clinical study to evaluate the effect of Ayurveda Preparations in management of CKD.

Materials and method: A clinical study was conducted on 50 CKD patients at OPD of Karma Ayurveda Hospital, Delhi Patients were prescribed T.Renal KFT, T.Renal Plus, T. Nephra Plus, T.Renal Win , T.Renal Care for about 30 days. All the patients were clinically assessed before and after treatment. Changes in signs & symptoms, serum creatinine, uric acid, blood urea and haemoglobin were observed, thereafter observations were statistically evaluated.

Result: These preparations are capable of giving relief in symptoms like appetite, reducing swelling, nausea, breathlessness, weakness, body ache and sleep quality, but these also impart good improvement in biochemical parameters in a short time span. Statistical analysis depicted significant reduction in mean serum creatinine levels (29.7%, p=0.000), mean uric acid levels (14.3%, p=0.02), mean blood urea levels (32.3%, p=0.000), whereas mean hemoglobin levels were risen marginally (3.6%, p=0.54).

Conclusion: Ayurveda preparations depicted par excellence in the disease management of CKD by virtue of their rasayana action, augmenting agni, removing srotodushti and balancing the tridoshas. Such improvements are indicative of positive signals for achievement of much better results provided the treatment is administered for sufficient time period. Hence it clearly support the fact that Ayurveda treatment modality possess great potential for the management of CKD, thereby imparting a better quality of life.

Keywords: Ayurveda, Chronic kidney disease, CKD**,** Mutravaha Srotas.

Introduction

Chronic kidney disease (CKD) is defined as a progressive declining renal functions over the period of three months or more. Kidneys may get damaged due to physical injury or any other disease such as diabetes mellitus or high blood pressure, henceforth unable to filter blood and perform other activities. The disease is associated with decreased glomerular filtration rate (GFR) & proteinuria.[1,2]

The disease CKD depicts significant irreversible reduction in the nephron number, denoting CKD stages 3-5. It further progresses towards, the end-stage renal disease corresponding to the stage 5 CKD depicting accumulation of toxins, fluid & electrolytes, which are otherwise normally excreted by the kidneys thereby resulting in uremic syndrome. This syndrome may progress to death if the toxins aren't cleared by renal replacement therapy (RRT), using dialysis or kidney transplantation. Renal replacement therapy rates are inversely related to socioeconomic status (SES) in developed countries.[3]

The risk factors for CKD include hypertension, diabetes mellitus [4] , autoimmune disorders, old age, family history of kidney disease, previous episode of acute renal failure, the presence of proteinuria or structural abnormalities of the urinary tract. In western countries, diabetes and hypertension account for over 2/3rd of the cases of CKD.[5] In India too, diabetes and hypertension account for nearly 40–60% cases of CKD.[6] It depicts signs and symptoms of oedema, weakness , anaemia, loss of appetite, breathlessness, nausea , weight loss etc. Disease manifestation further enhances the mortality and morbidity due to its vascular[7] complications thereby resulting in cardiovascular, cerebrovascular events and further disease progression leads to an end-stage kidney failure thereby increasing the socioeconomic burden of the society and contributing as 12th leading cause of death, thereby accounting for 1.1 million deaths, worldwide.[8,9]

Taking into Consideration such high prevalence of disease i.e. in India it is noted to be 13.8% which itself is very high; early detection, evaluation and preventive management stands as a key to delay the disease progression and to prevent adverse outcomes.

Chronic kidney disease has emerged as a worldwide public health problem depicting poor outcomes and high cost.[10] Over 1 million people worldwide have to undergo dialysis and in India nearly 90% patients cannot afford the dialysis cost .CKD has doubled in the last 15 years thereby depicting huge burden on the life expectancy of the patients as well.[11]

Ayurveda treatment modality offers promising results in management of CKD. With timely Ayurveda intervention in the early stages of the disease, disease progression may be haulted. Whereas in the latter stages while progressing to an End Stage Kidney Disease, the disease progression may be retarded. Further reinforcement of education including timely screening, dietary management, and early medication becomes very much

essential in disease management for appropriate self-care and better quality of life. [12]

Materials and Methods

All the patients were selected from the OPD of Karma Ayurveda Hospital.

Criteria for inclusion

1. Patients with clinically positive history of CKD, depicting the clinical features of CKD such as raised serum creatinine and blood urea etc. were included.
2. The patients having diabetes were included in the study.
3. The patients having hypertension were included in the study.
4. The patients with/without dialysis were included in the study.

Criteria for exclusion

1. Multiple myeloma
2. Clinically non responding patients
3. Patients with added complications.
4. Patients less than 20 yrs. of age and more than 80 yrs. of age

Plan of study and management

1. The patients were treated in OPD.
2. A total of 50 patients (SAMPLE SIZE-50) were taken for the study.
3. The patients were treated with the following drugs:
   - ✓ T.Renal KFT
   - ✓ T.Renal Plus
   - ✓ T. Nephra Plus
   - ✓ T.Renal Win
   - ✓ T.Renal Care
4. The patients were kept on normal healthy diet.
5. No interference was done with the doses of the antihypertensive, anti-diabetic drugs of the patients.

Preparation of medicines

Medicines were prepared under expert supervision from Seva sadan Ayurveda pharmacy, UP.

Duration of the treatment: The duration of the treatment was 1 month.

Assessment of the results

1. All the patients were clinically assessed before and after treatment.
2. Changes in symptoms, serum creatinine, uric acid, blood urea and hemoglobin levels were observed.
3. Observations were evaluated statistically

Results and Observations

The Age of patients varied from 20 to 80 years, of them 12% were aged 20-39, 56% aged 40-59 and remaining 32% aged 60 and above. 68% patients included in the study were males, 52% depicted hypertension, 28% were diabetic and 4% also had other associated diseases. Among all, 26% had history of dialysis, 16% depicted family history of CKD.A total of 36% were vegetarians, 22% were alcoholic, 50% depicted Vata-Pita prakriti and 50% depicted weight loss.

Baseline Pathological Profile**:** Data(Table:1)suggested that mean serum creatinine levels were 6.76(Sd=3.46); lower 4.85(3.97) at below age of 40 years and high as 7.30(2.99) aged 40-59. Mean Serum creatinine levels were also higher among patients with positive family history of disease (CKD), with mixed diet takers, with history of diabetes, and significantly higher among patients with history of dialysis ($p<0.001$) and hypertension ($p<0.035$). Although no significant difference had been noted in levels of Uric acid and blood urea except patients with history dialysis had significantly higher (mean+SD) levels (194.1+ 94.7) than (119.8+48.6) among with no history of dialysis. Mean (SD) levels were (11.2+2.0 vs. 8.72+2.1, p=0.02)

significantly higher among patients with Kapha Vata/Pita-Kapha prakiti than in Vata-Pitta/Kapha.

Improvement in Associated Symptoms: All the patients were questioned about associated symptoms. Among CKD patients Significant complete cure was achieved in symptoms of appetite, swelling, nausea, breathlessness and feeling of weakness (P<0.05) but in other symptoms only mild to moderate relief was noticed. The qualitative improvement could be seen in severity of appetite (97.1%, p=0.000), 100% improvement is noted in severity of swelling, nausea, breathlessness, feeling of weakness, urine Froth, burning micturition, hematuria, body pain and reduction in sleep in 86.4% patients (Wilcoxon Sign Rank test, p<0.001).**Table-1**

Improvement in Hematological parameters:

Significant improvement was observed in mean serum creatinine levels (29.7%, p=0.000), mean uric acid levels (14.3%, p=0.02), mean blood urea levels (32.3%, p=0.000) but mean hemoglobin levels were risen marginally by 3.6%; from 9.13 to 9.45,p=0.54. **It was observed that in CKD patients serum creatinine levels declined by 50-75% in 8% (4 out 50), 25-50% in 38% (19/50) and upto 25% in 54% patients.**

Further analysis revealed good (decline by >2 points) improvement in serum creatinine levels in 32% (16/50), Moderate (>1-2 points) improvement in another 32% but mild (up to 1 point) improvement in 36% cases of CKD. Improvement of varying degrees was seen in all CKD patients irrespective of history of hypertension, diabetes, positive family history or alcohol intake Nevertheless significant improvement was observed in patients with history of dialysis. Among 13 patients with dialysis history; 69.2 % (9) depicted good improvement, 23.1 % (3) moderate and 7.7% (1) as mild (p=0.003) improvement. Improvement in uric acid levels were also seen in 73.1 % (19/26) the patients with all associated symptoms and 71.1% (27/38) improvement (>5 points) in patients in blood urea levels. **(Table-2, 3, 4)**

Discussion

CKD is specific type of renal disease, spawning significant concerns in the life of an affected person thereby resulting in life of misery. Many a time's even dialysis hardly gives any relief. It is observed that Ayurveda preparations are not only capable of giving relief in symptoms like appetite, reducing swelling, nausea, breathlessness, weakness, body ache and sleep quality, but these also depict good improvement in Serum creatinine levels, Uric acid and Blood urea levels in a short time span of about 30 days. Such improvements are positive signals for much better achievement provided the treatment is administered for sufficient time period.

According to Ayurveda, CKD involves the Mutravaha Srotas. The characteristic manifestations of vitiation of these channels are voiding of too much urine or complete cessation of urine and occasionally or frequently passage of thick urine associated with pain It has a complex vyadhi sankar hence for the treatment of CKD on Ayurveda principles, it is necessary to identify the nature of disease in terms of its component such as Dosha (~humour), Dushya (~part which is affected),and Adhishtana (~abode). CKD is clearly depicting the impairment of renal function due to the derangement of Tridoshas (~three humours; Vata, Pitta, and Kapha), with predominance of Vata dosha, (leading to degeneration) and kapha dosha (leading to blockage of channels), Agnimandya (~weak digestive fire), involving Srotosanga (~obstruction in microchannels of Mutravaha srotas), and Vimarga gamana. Hence it is utmost essential to break the pathogenesis for achieving the desired results. Thus, the treatment of CKD aims at the enhancing the digestive fire, balancing the vitiated Doshas, diuresis ,control of excessive salt & water

retention, Sroto shuddhi and Rasayana chikitsa; which will be further leading to an improved nutritional status thereby acting at the levels of Rasa, Agni, and Srotas.[13]

Administration of Ayurveda preparation such as T.Renal KFT, T.Renal Plus, T. Nephra Plus, T.Renal Win , T.Renal Care contain a blend of certain key ingredients possessing variable properties & actions efficacious in management of CKD such as Vayvidanga (Embelia ribes), depicting Anti-inflammatory[14], rasayan, deepan pachan[15], Pushkarmool depicting shothahara[16], Harad (Terminalia chebula), Baheda (Terminalia bellirica) depicting nephro-protective[17], mutrakricchahar[18], Amla (Emblica officinalis), Punarnava (Boerhaavia diffusa) ,Mandoor Bhasma depicting Pandurogahar[19,20], Shothahar[21], Gokshura(Tribulus terrestris) depicting vrikkvikarhar[22], Kali Mirch (Piper nigrum) depicting Analgesic[23], Anti-inflammatory, agnideepak[24], Chitrak depicting Rasayan[25], Analgesic, Antioxidant, Anti-inflammatory[26] activities.

Hence these formulations render par excellence in treatment of CKD by breaking the disease pathogenesis owing to unique actions of its ingredients .

In the present study 56% of patients aged 40-59yrs and remaining 32% aged 60 and above, as it is evident that CKD becomes more common with increasing age. After the age of 40, kidney filtration begins to fall by approximately 1% per year[27] Males constituted 68% as in men higher testosterone levels tend to cause a decline in kidney function.[28] 2% patients depicted past history of hypertension and it is observed that high rate of hypertension tends to be associated with declining glomerular filtration rate (GFR),[29] Whereas, 28% had history of diabetes clearly depicting the fact that metabolic changes associated with diabetes are leading to glomerular hypertrophy, glomerulosclerosis, tubulointerstitial inflammation and fibrosis thereby compromising kidney functions.[30] 26% patients had history of dialysis, depicting there progress towards end-stage renal disease (ESRD).[31]Family History was evident in 16% patients depicting kidney disease runs in families.[32] 62% patients consumed mixed diet indicating the fact that consumption of high amounts of protein leads to an increased intraglomerular pressure thereby causing glomerular hyperfiltration ultimately damaging the glomerular structure and causing CKD disease manifestation.[33]

Improvement in associated Symptoms: Statistical analysis suggested that all the patients with mild symptoms were completely cured. Patients with moderate severity improved to normal levels (about 5-20%) and rest to mild levels. All the patients with severe symptoms also improved to normal, mild or moderate severity. Therefore, the Ayurveda intervention has shown significantly high level of improvement on symptoms associated with CKD.

Improvement in Hematological parameters: Serum creatinine, Urea, Uric acid, Haemoglobin levels were taken into consideration. Serum creatinine is considered as a convenient index of kidney function, being produced as a by-product of muscle metabolism and is elevated with significant reduction in the glomerular filtration rate.[34] Uric acid, is the end-product of purine metabolism.[35] Urea is a nitrogenous waste produced as a by-product of the metabolism of proteins excreted in urine.[36] Anaemia/ falling haemoglobin levels is a common complication in chronic kidney disease (CKD), and is associated with a reduced quality of life, and an increased morbidity and mortality.[37]

Statistical analysis revealed good (decline by >2 points) improvement in serum creatinine levels in 32% (16/50), Moderate (>1-2 points) improvement in another 32% but mild (up to 1 point) improvement in 36% cases of CKD.

Although improvement of varying degrees is seen in all CKD patients irrespective of associated history of hypertension, diabetes, positive family history, alcohol addiction but significant improvement observed in patients with history of dialysis. Among 13 patients with dialysis history; 69.2 % (9) had shown good improvement, 23.1 % (3) moderate and 7.7% (1) as mild (p=0.003). Improvement in Uric acid levels is also seen in 73.1 % (19/26) the patients with all associated symptoms and 71.1% (27/38) improvement (>5 points) in patients in Blood urea levels.

Hence it is evident from results that in spite of factors like history of hypertension, history of diabetes, family history and alcohol addiction, good improvement in symptoms and laboratory marker are evident.. Further, it is very important to note that in patients with history of dialysis, improvement in all symptoms along with hematological parameters is significantly high. Keeping in view, further analysis suggest, that in patients with history dialysis and initial Sr. creatinine levels above 5, Sr. creatinine levels declined by 41.5% after treatment than 21.3% with dialysis history.

Conclusion

Choosing an intelligent lifestyle, timely screening, timely intervention, one may cope up with such an ebbing crisis[38], rewarding oneself with healthfulness. Hence the clinical study supports the fact that Ayurveda treatment modality possess great potential for CKD management, relieving the signs & symptoms of patients thereby imparting a better quality of life.

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Legend Tables and Figures

Table 1: Percent Symptomatic improvement

Clinical Symptoms	% with Symptoms (N=50)		McNemar χ^2 Test	Significance (Yes/NO)	Dynamics of Qualitative percent Change (n1/n)								
	BT	AT	P-Value		Normal to Symptomatic	Mild to Normal	Moderate to		Severe to			% Improvement in severity	*Z-test, p-value
							Normal	Mild	Normal	Mild	Moderate		
Appetite	70.0	56.0	0.039	Yes	6.7 (1/15)	100.0(1/1)	30.8(4/13)	69.2(9)	14.3(3/21)	61.9(13)	23.8(5)	97.1(34/35)	5.22, 0.000
Swelling	72.0	52.0	0.002	Yes	0	100.0(3/3)	22.7(5/22)	77.3(17)	18.2(2/11)	45.5(5)	36.3(4)	100.0(36/36)	5.44, 0.000
Nausea	58.0	18.0	0.000	Yes	0	100.0(14)	20.0(1/5)	80.0(4)	44.4(4/9)	55.1(5)	0	100.0(28/28)	4.78, 0.000
Breathlessness	62.0	44.0	0.004	Yes	0	100.0(4/4)	20.0(4/20)	80.0(16)	16.7(1/6)	33.3(2)	50.0(3)	100.0(31/31)	5.07, 0.000
Urine Froth	72.0	64.0	0.125	No	0	100.0(3/3)	0(0/17)	100.0(17)	6.3(1/16)	50.0(8)	43.8(7)	100.0(36/36)	3.00, 0.003
Burning Micturition	18.0	08.0	0.063	No	0	100.0(5/5)	0(0/4)	100.0(4)	0	0	0	100.0(9/9)	3.00, 0.003
Hemeturia	2.0	0	1.0	No	0	100.0(1/1)	0	0	0	0	0	100.0(1/1)	1.00, 0.317
Weakness	92.0	80.0	0.031	Yes	0	100.0(5/5)	5.0(1/20)	95.0(19)	0(0/21)	52.4(11)	47.6(10)	100.0(46/46)	6.23, 0.000
Body Pain	80.0	70.0	0.063	No	0	100.0(3/3)	5.0(1/20)	95.0(19)	5.9(1/17)	35.3(6)	58.8(10)	100.0(40/40)	5.89, 0.000
Sleep Disorder	44.0	36.0	0.125	No	0	60.0(3/5)	5.9(1/17)	88.2(15)	0	0	0	86.4(19/22)	4.26, 0.000
								*Wilcoxon Sign Rank test					

Table 2. Decline in mean laboratory parameters from baseline(BT) to after treatment(AT)

	N	BT	AT	BT-AT	SE (BT-AT)	t-test	p-value	95%CI (L-U)	Percent Improvement
Serum Creatinine	50	6.76	4.75	2.01	0.307	6.56	0.000	1.40-2.63	29.7
Uric Acid	27	7.06	6.05	1.01	0.409	2.48	0.020	0.17-1.85	14.3
Blood Urea	38	140.9	95.4	45.5	10.40	4.38	0.000	24.49-66.63	32.3
Haemoglobin	19	9.13	9.45	+0.33	0.523	0.63	0.540	-(1.42)-0.77	3.6

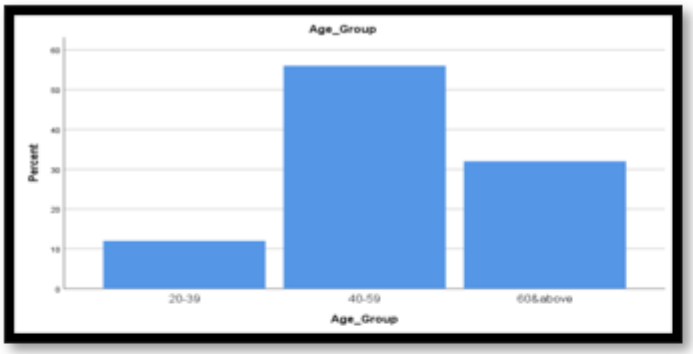
Table. 3. Improvement in Serum creatinine, Uric Acid and Blood urea levels

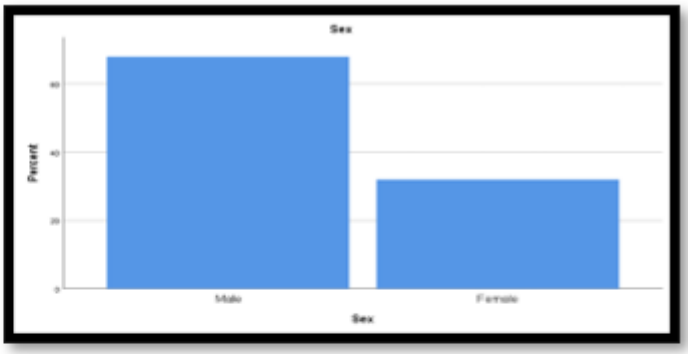
	Associated Symptoms	Improvement in Serum Creatinine levels (mg/dl) (N=50)					
			N	Mild (≤1)	Mod. (1-2)	Good (>2)	χ2
	All		50	18	16	16	
	History of Hypertension:	Yes	26	11	5	10	0.131

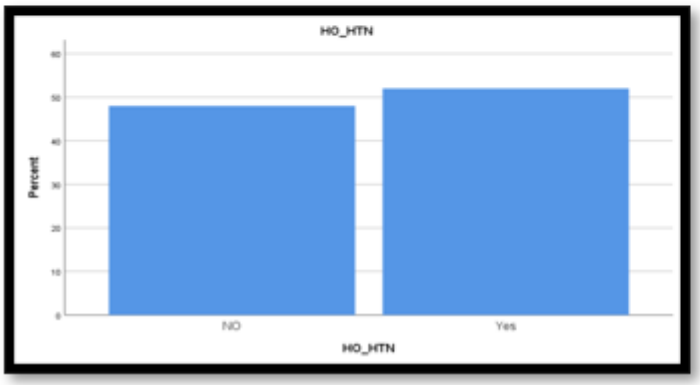
		No	24	7	11	6	
	History of Diabetes	Yes No	14 36	3 15	4 12	7 9	0.207
	History of Dialysis	Yes No	13 37	1 17	3 13	9 7	0.003
	Family History	Yes No	8 42	2 16	3 13	3 13	0.778
	Alcohol Intake	Yes No	11 39	5 13	3 13	3 13	0.761
		Improvement in Uric Acid levels (mg/dl)					
				No ≤0	Mild (>0-1)	Good (>1)	
	All		26	7	11	8	
	History of Hypertension	Yes No	11 15	3 4	3 8	5 3	0.303
	History of Diabetes	Yes No	8 18	1 6	4 5	3 7	0.509
	History of Dialysis	Yes No	7 19	3 4	1 10	3 5	0.179
	Family History	Yes No	5 21	2 5	2 9	1 7	0.733
	Alcohol Intake	Yes No	4 22	1 6	3 8	0 8	0.158
		Improvement in Blood Urea levels (mg/dl)					
				No ≤5	Mild (>5-25)	Good >25	
	All		38	11	6	21	
	History of Hypertension	Yes No	19 29	4 7	4 2	11 10	0.459
	History of Diabetes	Yes No	11 27	4 7	1 5	6 15	0.679
	History of Dialysis	Yes No	10 28	2 9	1 5	7 14	0.550
	Family History	Yes No	7 31	1 10	3 3	3 18	0.131
	Alcohol Intake	Yes No	6 32	3 8	1 5	2 19	0.424

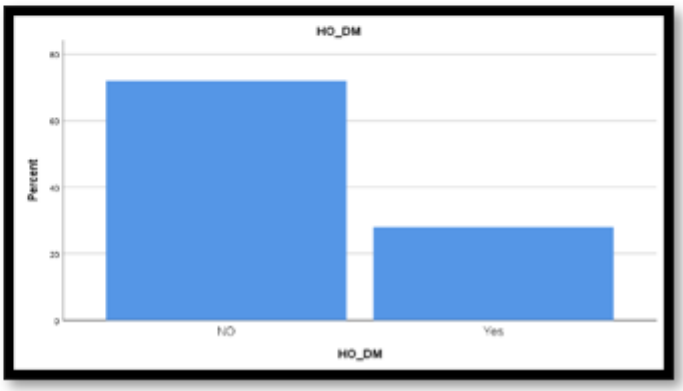
Table. 4: Percent decline in Serum creatinine levels after Ayurveda treatment							
				Serum Creatinine levels			
SN				% decline in Serum Creatinine			
			N	Upto 25	25-50	50-75	P-value
	All		50	27	19	4	
1	History of Hypertension	Yes	26	15	10	1	
		No	24	12	9	3	
2	History of Diabetes	Yes	14	8	6	0	0.423
		No	36	19	13	4	
3	History of Dialysis	Yes	13	3	7	3	0.010
		No	37	24	12	1	
4	Family History: Yes NO	Yes	8	4	4	0	0.562
		No	42	23	15	4	
5	Alcohol Intake	Yes	11	6	4	1	0.984
		No	39	21	15	3	
P-values are $\chi 2$ based at 2 Degrees of Freedom							

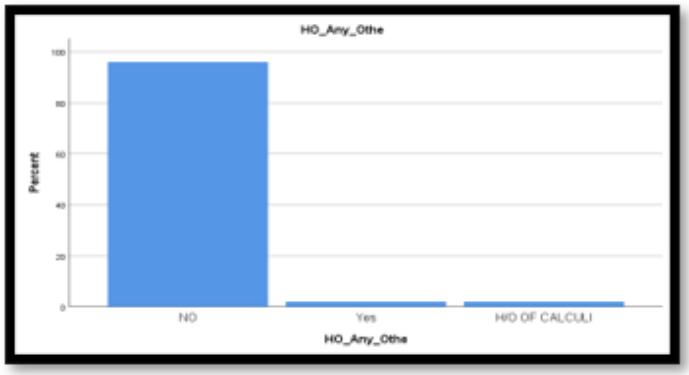
Figure 1: Demographic data

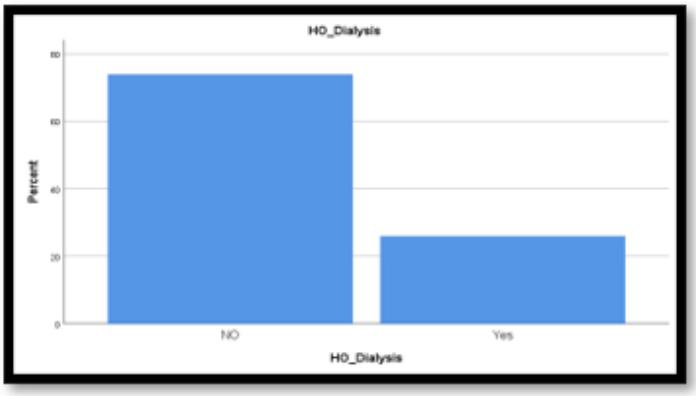


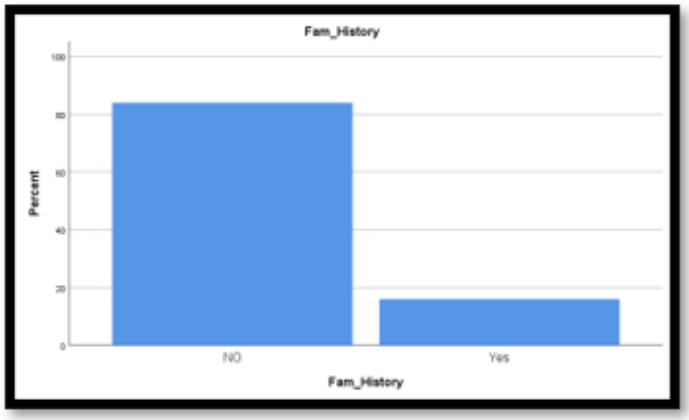


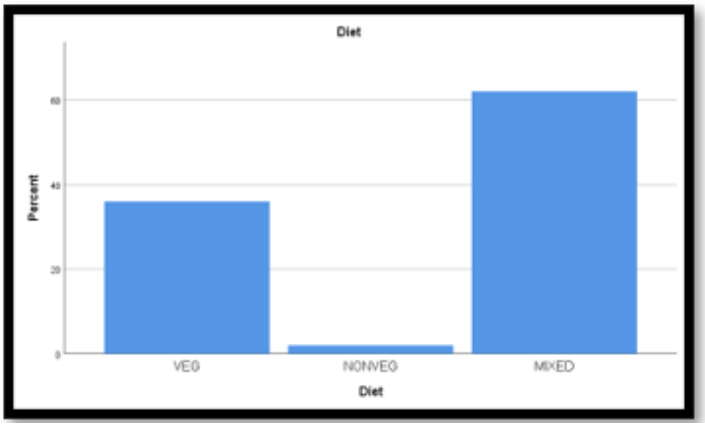


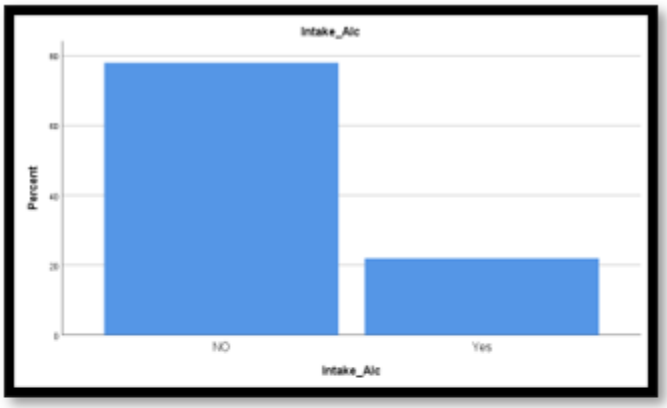


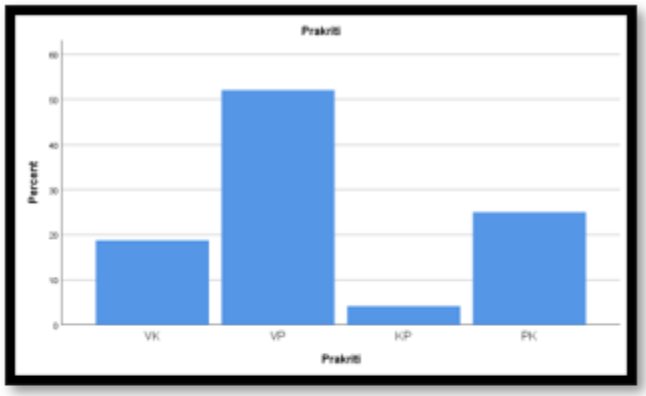












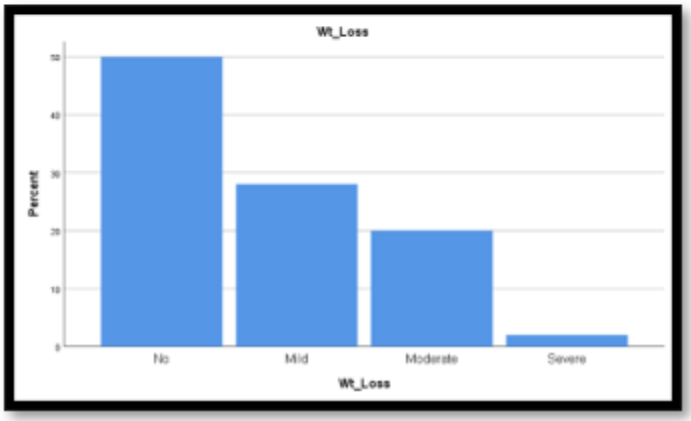


Figure 2: Dynamics of improvement in symptoms

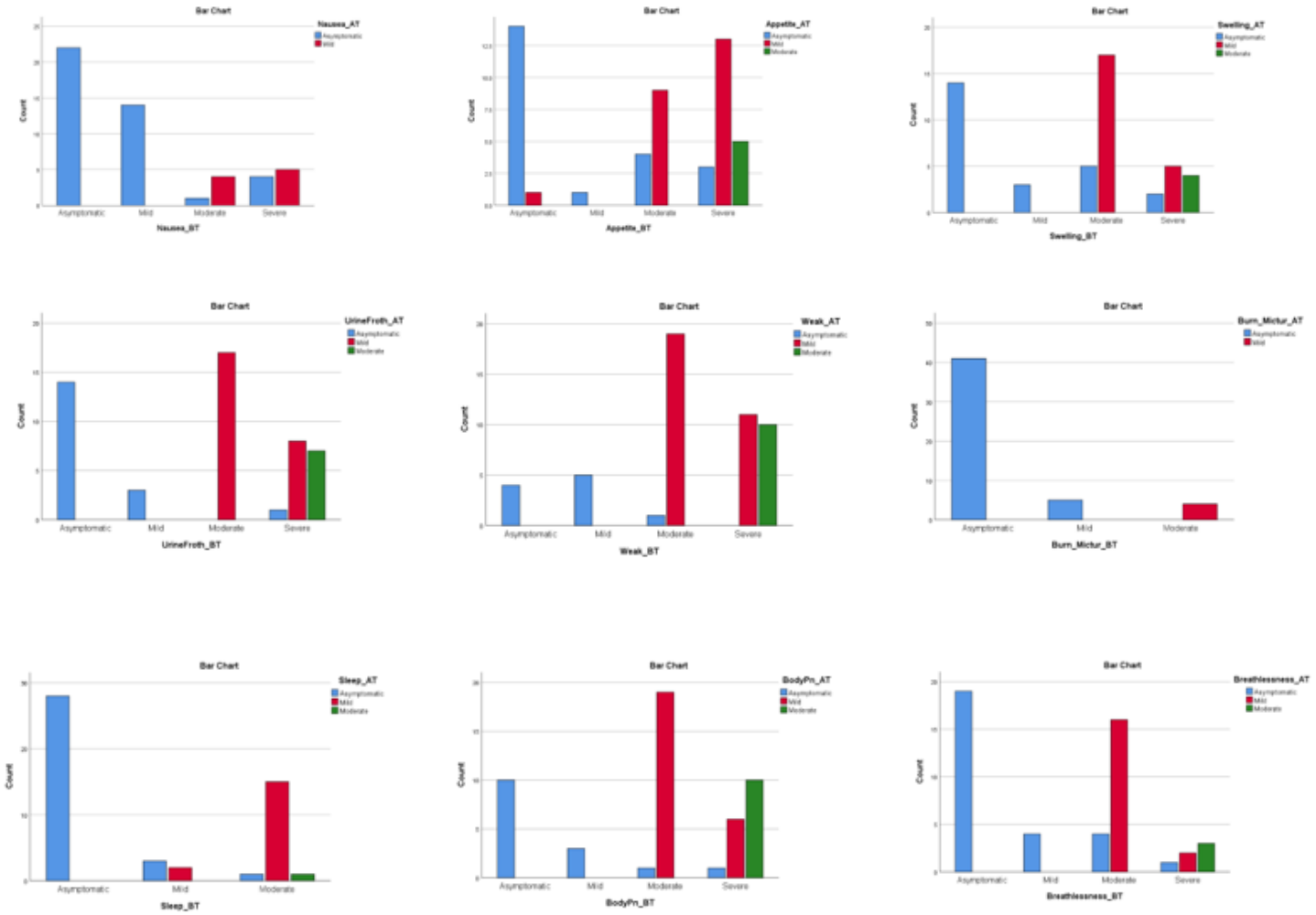
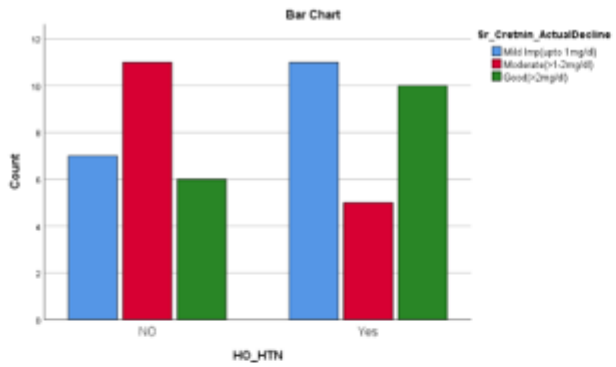
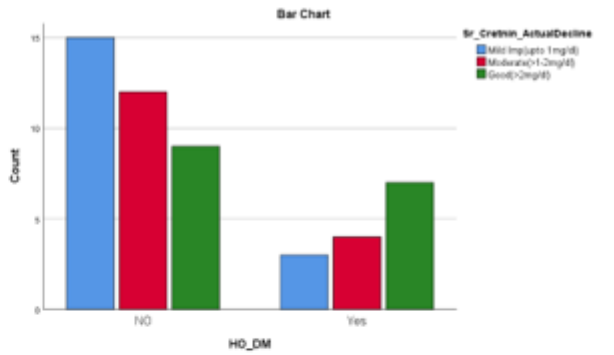
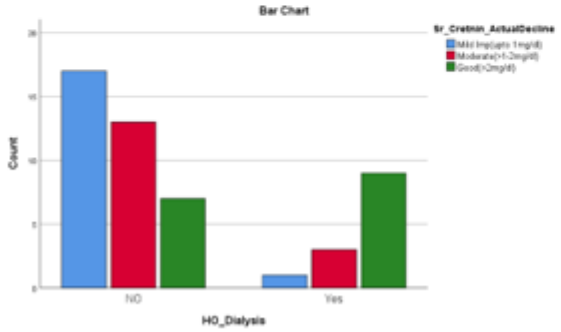
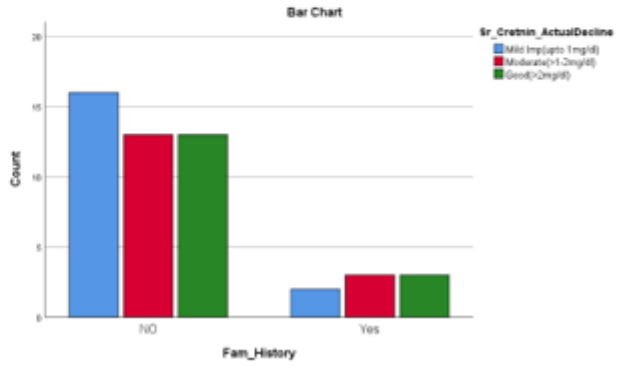


Figure 3: Improvement in Serum Createnine levels









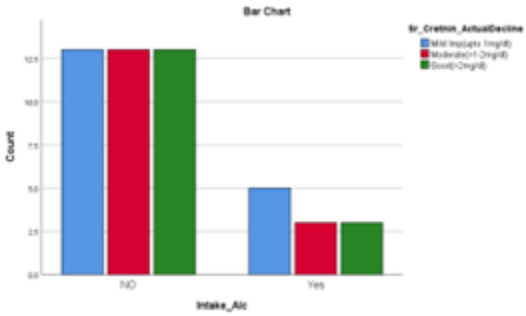


Figure 4: Percent decline in Serum Createnine levels

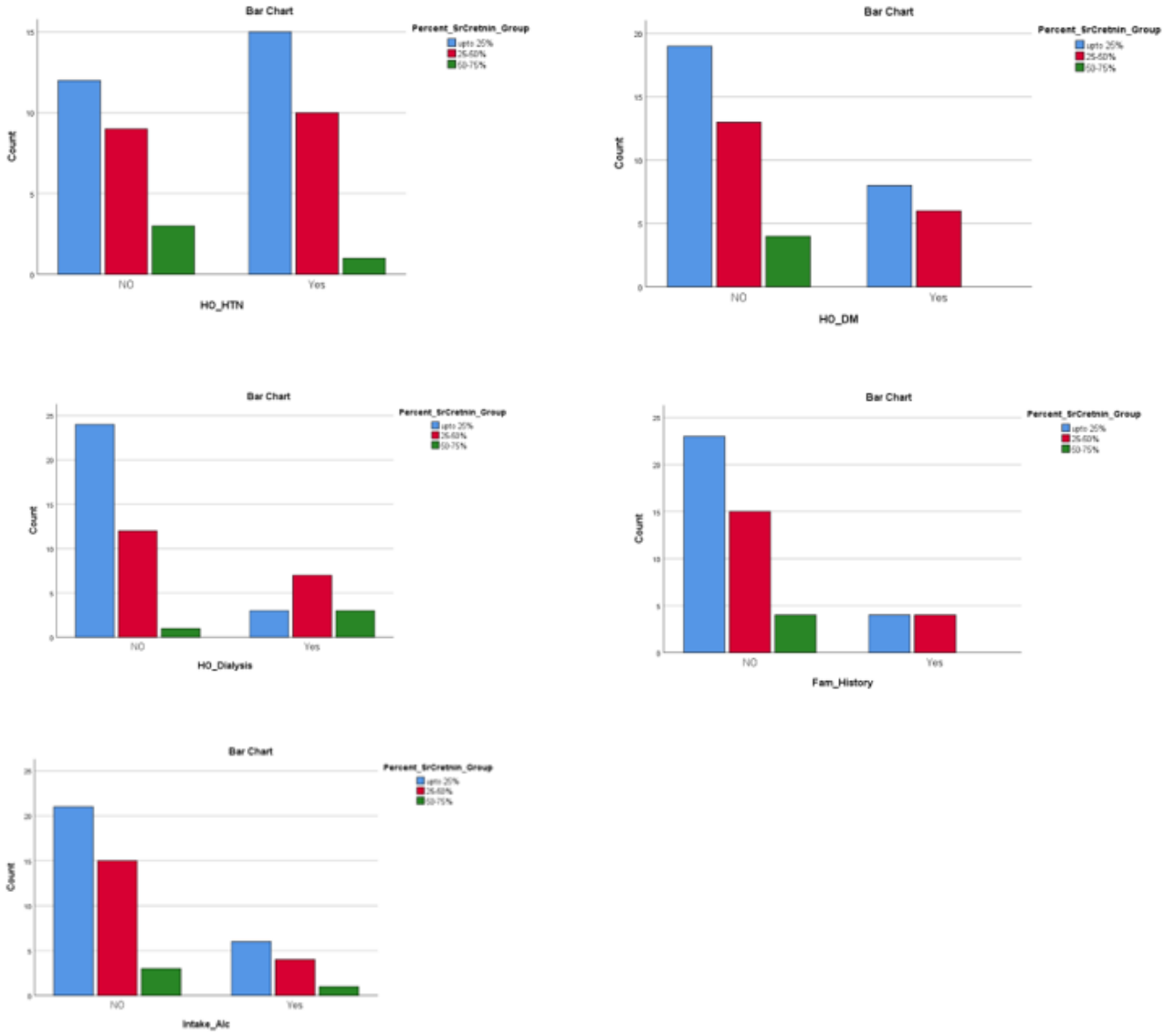
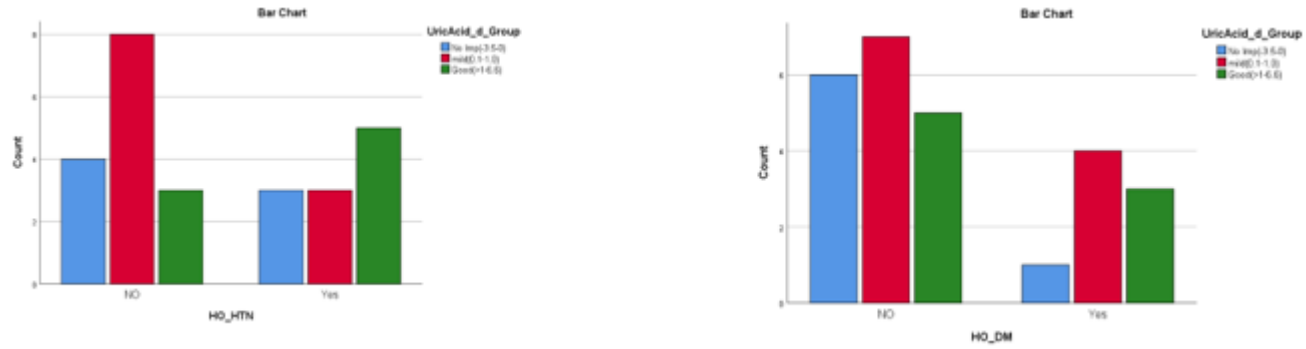


Figure 5: Improvement in Uric Acid levels



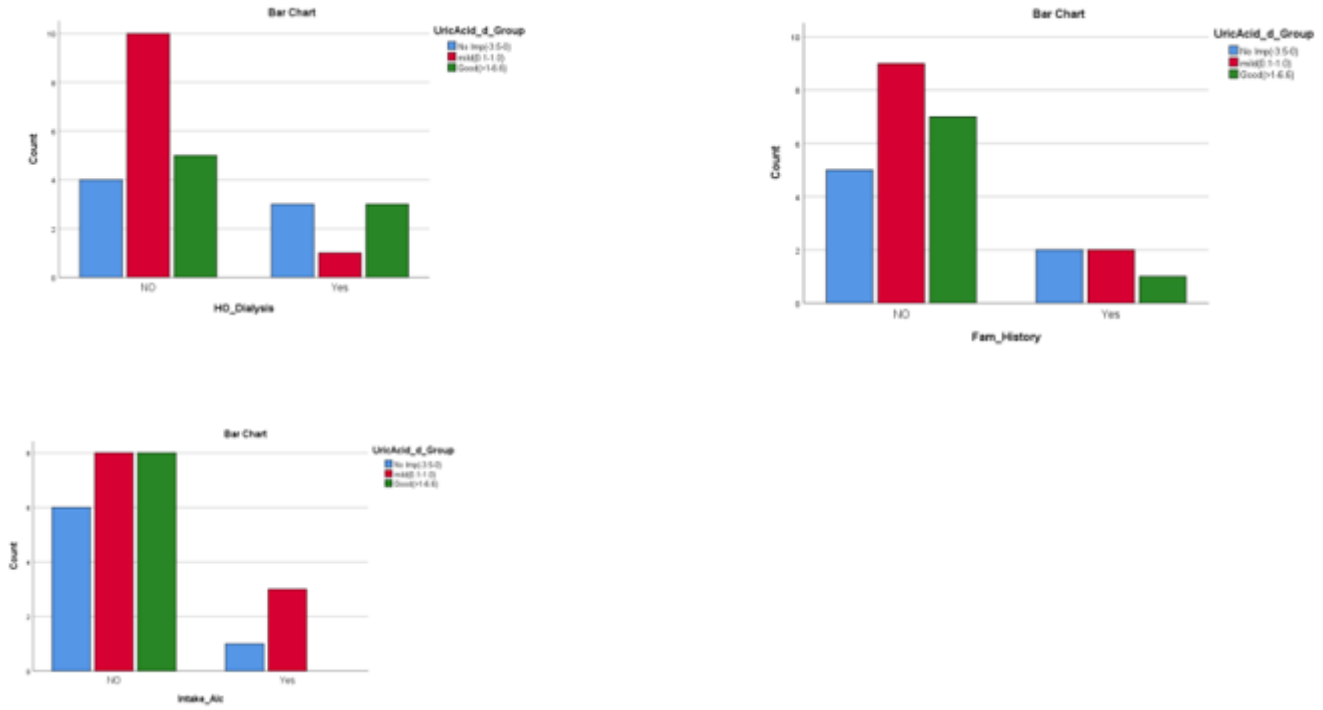
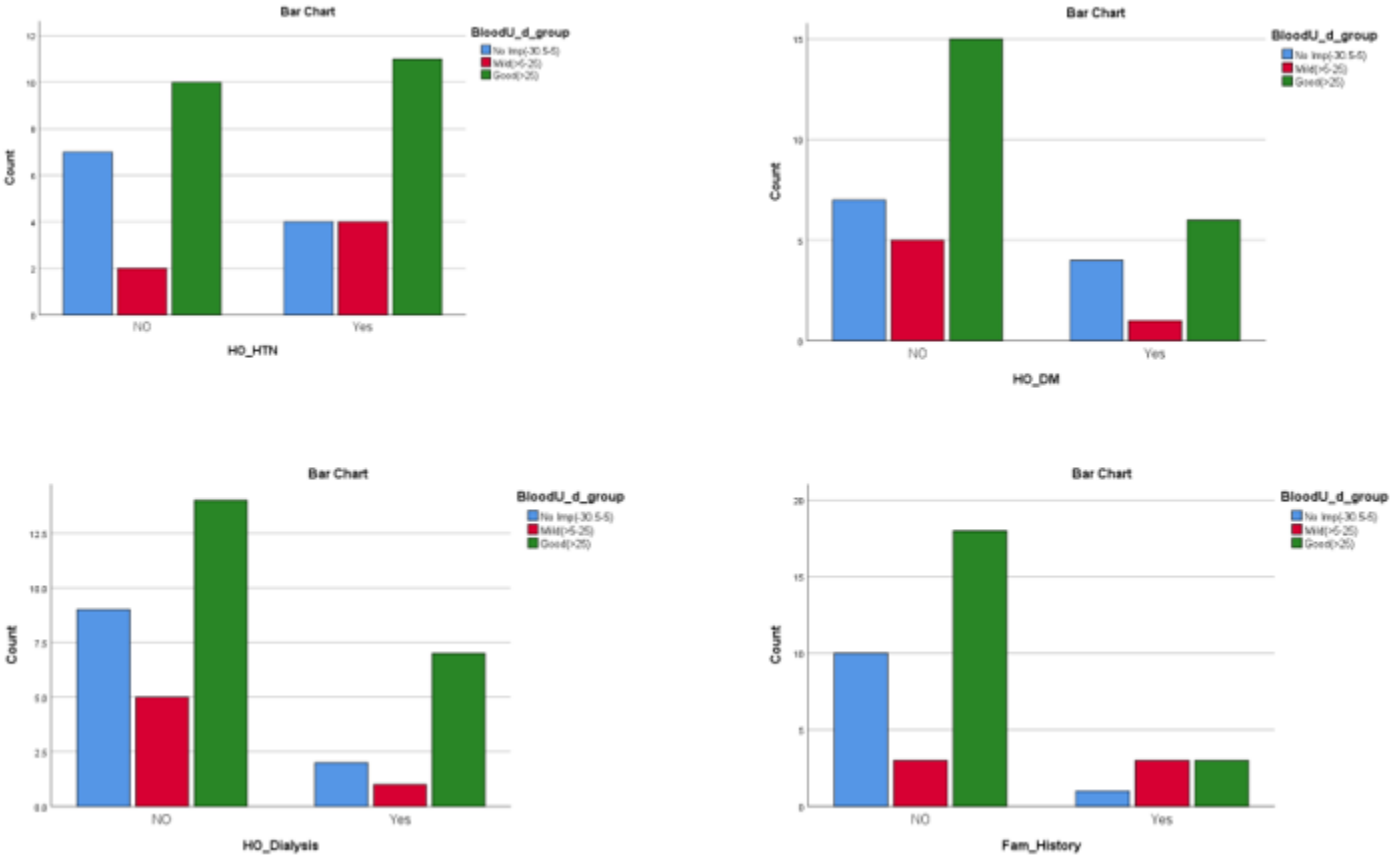


Figure 6: Improvement in Blood Urea levels



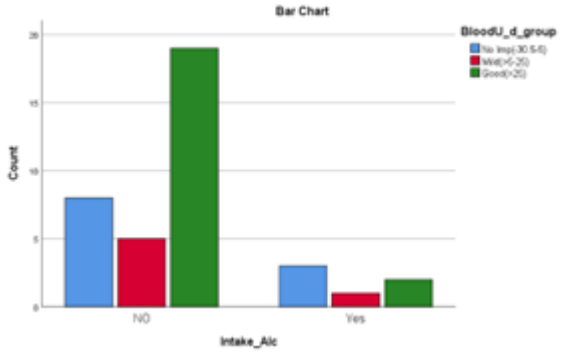


Figure 7: Transformation from symptomatic to Asymptomatic