ORIGINAL RESEARCH

Outcomes of diabetic patients treated with dialysis: Complications and quality of life

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ABSTRACT

Background: Diabetes is one of the most prevalent metabolic disorders affecting the population globally and affects multiple organ systems. Diabetes is also one of the most common causes of ESRD (end-stage renal disease) globally. **Aim:** The present study aimed to comparatively assess the outcomes in diabetic subjects managed with dialysis to non-diabetic subjects. **Methods:** The study assessed 266 hemodialysis maintenance subjects prospectively for 14 months. In all the included subjects, hemodialysis exit, hospitalization, and cause of death were assessed and compared to non-diabetic subjects. **Results:** In 266 subjects, diabetes was reported in 40.97% (n=109) subjects. In diabetic subjects, significantly worse SF36 scores, high LDL and serum triglycerides, lower iPTH, low serum albumin, high CRP, higher cardiovascular morbidities, lower dialysis duration, and higher age were seen compared to non-diabetic subjects. Hazard risk of death was 1.9 times higher in diabetics compared to non-diabetics. Death secondary to cardiovascular diseases with infection and other causes was 80% in diabetics and 54% in non-diabetics. The annual admission rate was also significantly higher in diabetics. **Conclusions:** The present study concludes that HRQOL (health-related quality of life) and clinical outcomes were much worse in diabetic subjects compared to non-diabetic subjects on hemodialysis which is primarily attributed to the higher frequency of cardiovascular diseases.

Keywords: Cardiovascular diseases, diabetes mellitus, hemodialysis, outcomes, quality of life

INTRODUCTION

Diabetes is one of the most prevalent metabolic disorders affecting the population globally and affects multiple organ systems. Diabetes is also one of the most common causes of ESRD (end-stage renal disease) globally including in developing countries like India. In the United States alone, nearly 45% of End Stage Renal Diseases are attributed to the etiology of Diabetes mellitus.[1]

Diabetic nephropathy is defined as the presence of proteinuria which is more commonly seen in subjects with type 1 diabetes mellitus. However, subjects with type 2 diabetes mellitus also show the presence of proteinuria and diabetic nephropathy as complications of diabetes. Diabetic nephropathy is also seen in subjects presenting with secondary forms of diabetes mellitus such as subjects following pancreatectomy and pancreatitis when diabetes mellitus has a longer duration and glycemia level is high enough to proceed to diabetic complications.[2]

Nearly 25-30% of subjects with diabetes mellitus present micro microalbuminuria following a mean duration of diabetes for 15 years and less than half of these subjects proceed to macroalbuminuria which is also known as overt nephropathy. Following the development of overt nephropathy, a considerable number of subjects develop ESRD (end-stage renal disease) at the rate of 4% to 17% at 20 years and nearly 17-30% after the initial diagnosis of diabetes mellitus and such subjects need hemodialysis for survival and maintenance of renal function.[3]

In recent times, the incidence of subjects that require diabetic nephropathy that require hemodialysis has reduced with the advancement of medical management of diabetes, particularly in developed countries. It can also be attributed to widespread education and the use of reno-protective measures in subjects with diabetes.[4]

In diabetic subjects on maintenance dialysis, the outcomes are worse compared to non-diabetic subjects having end-stage renal diseases secondary to glomerular diseases and hypertension depicting the marginal improvement following the recent literature data. The better outcomes of hemodialysis are seen in

young diabetic subjects with no cardiovascular diseases as comorbid factors.[5]

The present clinical study aimed to assess the death rate, comorbidities, quality of life, and characteristics in diabetic subjects on maintenance hemodialysis in the institute. The study also compared the outcomes and characteristics of hemodialysis diabetic subjects to non-diabetic subjects.

MATERIALS AND METHODS

The present prospective clinical study aimed to comparatively assess the outcomes in diabetic subjects managed with dialysis to non-diabetic subjects. The study population was the subjects admitted to the institute and were on hemodialysis. Informed consent was taken from all the subjects in written and verbal format before study participation and after explaining the detailed study design to the participants.

The study included 266 subjects on maintenance hemodialysis who were from both genders. The inclusion criteria for the study were diabetic and non-diabetic subjects on maintenance hemodialysis for a minimum of 2 weeks, were of age 18 years or more, and gave consent for study participation. The exclusion criteria for the study were subjects that were not willing to participate in the study.

After final inclusion, detailed history was recorded from all the subjects followed by clinical examination. Also, the samples were collected for laboratory examination following the aseptic and sterile method of sample collection. A preformed structured questionnaire was made for all the subjects to collect demographic, clinical, and laboratory data for all the participants. The subjects were then followed for 14 months with the follow-up range of 15 days to 14 months. In all the study subjects, exit from the hemodialysis unit including death and cause of hospitalization was noted. The last follow-up was taken as the last visit or the time when the subject left the hemodialysis unit owing to transplantation, shift to peritoneal dialysis and renal recovery.

The subjects shifted to other wards and were followed there. The cardiovascular disease presence was assessed in all the subjects and the diagnosis of congestive heart failure was confirmed following the echocardiographic criteria. CAD (coronary artery disease) was considered when subjects were on pharmacological management for CAD diagnosed with stress myocardial perfusion imaging, dobutamine stress echocardiography, or coronary angiography, PCI (percutaneous coronary intervention), or underwent CABG (coronary artery bypass graft).

HRQOL (health-related quality of life) was also assessed in all the subjects using the SF 36 (36-item short-form health survey) that assessed SF 36 scores and two dimensions and eight scales of MCS (mental component summary) and PCS (physical component summary) following the scoring algorithm.[6,7]

The data gathered were analyzed statistically using SPSS software version 21.0 (IBM Corp., Armonk, NY, USA) using the Fisher exact test and chi-square test to compare the categorical variables. To compare continuous variables, a t-test, ANOVA (analysis of variance), and Mann-Whitney U test was used. The hazard ratio was also assessed. The data were expressed in mean and standard deviation and frequency and percentage. The significance level was considered as $p<0.05$.

RESULTS

The present prospective clinical study aimed to comparatively assess the outcomes in diabetic subjects managed with dialysis to non-diabetic subjects. The study included 266 subjects on maintenance hemodialysis who were from both genders. Among 266 subjects, 109 were diabetics and 157 were non-diabetics. The mean age was significantly higher in diabetics at 62.4±11.4 years compared to 53.3±16.5 years in non-diabetics with $p<0.001$. The gender has a non-significant difference in the two groups with $p=0.08$. Hemodialysis vintage was significantly higher in non-diabetics with $p=0.01$. Vascular access type was tunneled CVC in 22.01% (n=24) subjects with diabetes and 15.92% (n=25) in non-diabetics, AVG was used in 5.50% (n=6) diabetics and 7.64% (n=12) non-diabetics, and AVF in 69.72% (n=76) diabetics and 73.88% (n=116) non-diabetics respectively depicting non-significant difference with $p=0.17$. BMI of >25-30 and >30 was significantly higher in diabetics compared to non-diabetics with $p<0.001$ as shown in Table 1.

Table 1: Demographic data of study participants

Characteristics	Diabetes (n=109)	Non-diabetes (n=157)	p-value
Mean age (years)	62.4±11.4	53.3±16.5	<0.001
Gender			
Males	58 (53.21)	94 (59.87)	0.08
Females	51 (46.78)	63 (40.12)	
Hemodialysis vintage[2]	21 (10-540	28 (11-72)	0.01
Vascular access type			
Tunneled CVC	24 (22.01)	25 (15.92)	0.17
AVG	6 (5.50)	12 (7.64)	
AVF	76 (69.72)	116 (73.88)	
BMI			
≤18.5	3 (2.75)	9 (5.73)	<0.001

>18.5-25	50 (45.87)	96 (61.14)	
>25-30	39 (35.77)	42 (26.75)	
>30	17 (15.59)	10 (6.36)	

Concerning the laboratory parameters, it was seen that single pool Kt/V was significantly higher in non-diabetics with 1.31±0.19 compared to diabetics where it was 1.25±0.17 with p=0.001. Creatinine levels were also significantly higher in non-diabetics with 9.1±2.5 compared to 7.4±2.2 in diabetics with p<0.001. CRP levels were significantly higher in diabetics compared to non-diabetics with p=0.001. However, albumin levels were significantly higher in non-diabetics with 3.91±0.33 g/L compared to 3.84±0.33g/L with p<0.001. HDL was significantly higher in non-diabetics, whereas, LDL was significantly higher in diabetics with p=0.03 for both. Triglycerides in serum were also significantly higher in diabetics with p<0.001. iPTH was significantly higher in non-diabetics with 372 pg/mL compared to 270 pg/mL in diabetics with p<0.001. Phosphorus levels were significantly higher in non-diabetics with p=0.004 as summarized in Table 2. Pre-dialysis BUN, Hemoglobin, calcium, potassium, cholesterol, ferritin, transferrin, iron, and alkaline phosphate levels in the serum of diabetics and non-diabetics showed statistically non-significant differences (Table 2).

Table 2: Laboratory data in the study participants

Laboratory parameters	Diabetes (n=109)	Non-diabetes (n=157)	p-value
Single pool Kt/V	1.25±0.17	1.31±0.19	0.001
Pre-dialysis BUN (mg/dl)	56.0±12.9	56.3±13.5	0.84
Creatinine (mg/dl)	7.4±2.2	9.1±2.5	<0.001
Hemoglobin (g/dL)	10.4±1.2	10.4±1.4	0.07
CRP (mg/L)	3.82 (1.52-8.32)	2.27 (0.92-5.15)	0.001
Albumin (g/L)	3.84±0.33	3.91±0.33	<0.001
Calcium (mg/dl)	8.6±0.4	8.6±0.5	0.95
Potassium (meq/L)	5.0±0.4	4.9±0.4	0.08
HDL (mg/dl)	35.7±7.3	37.5±8.9	0.03
LDL (mg/dl)	82.3±24.3	77.3±23.6	0.03
Cholesterol (mg/dL)	151±33	145±36	0.14`
Triglycerides (mg/dL)	165±89	137±65	<0.001
Ferritin (ng/mL)	405±245	444±293	0.13
Transferrin (µg/dL)	251±56	246±57	0.43
Iron (µg/dL)	66±37	69±33	0.51
iPTH (pg/mL)	270 (148-418)	372 (171-705)	<0.001
Alkaline phosphatase (IU/L)	281 (211-363)	322 (197-447)	0.09
Phosphorus (mg/dL)	5.0±0.9	5.4±1,0	0.004

For the parameters of quality of life in study subjects, it was seen that the role-emotional component was significantly higher in non-diabetics with 59.9±35.6 compared to diabetics where it was 50.3±34.9 with p=0.007. Vitality, general health, role physical, physical functioning, SF 36 scores, mental component summary, physical component summary, and mental health were significantly higher in non-diabetic subjects compared to diabetics with significant results and p=0.01, 0.02, 0.002, <0.001, <0.001, 0.004, 0.003, and 0.04 respectively. However, a non-significant difference was seen in social functioning and body pain in diabetics and non-diabetics with better results in non-diabetics and p=0.12 and 0.71 respectively as shown in Table 3.

Table 3: Quality of life components in diabetic and non-diabetic study subjects

Quality of life parameters	Diabetes (n=109)	Non-diabetes (n=157)	p-value
Role-emotional	50.3±34.9	59.9±35.6	0.007
Social functioning	47.7±29.0	52.5±30.2	0.12
Vitality	44.5±25.7	50.4±26.4	0.01
General Health	46.7±21.0	51.5±23.9	0.02
Body pain	60.2±31.7	61.3±31.0	0.71
Role-physical	43.0±30.5	52.2±30.5	0.002
Physical functioning	40.0±31.1	52.6±29.3	<0.001
SF 36 score	45.5±20.7	52.5±20.3	<0.001
Mental component summary	49.1±20.9	55.1±22.0	0.004
Physical component summary	46.9±21.6	53.6±21.4	0.003

Mental health	55.9±27.5	61.1±25.3	0.04

Cardiovascular diseases had a significantly higher prevalence in diabetics compared to non-diabetics where the clinical peripheral vascular disease was seen in 56.88% (n=62) diabetics and 0.63% (n=1) non-diabetic subjects with p<0.001. Cerebrovascular accidents were reported in 16.51% (n=18) diabetics and 7.64% (n=12) non-diabetics depicting a non-significant difference with p=0.002. Congestive heart failure was seen in 36.69% (n=40) diabetics and 16.56% (n=26) non-diabetic subjects which was significantly higher in diabetics with p<0.001. Coronary artery disease (CAD) was significantly higher in diabetics compared to non-diabetics with p<0.001 (Table 4).

Table 4: Cardiovascular diseases in diabetic and non-diabetic study subjects

Cardiovascular comorbidities	Diabetes n=109 (%)	Non-diabetes n=157 (%)	p-value
Clinical peripheral vascular disease	62 (56.88)	1 (0.63)	<0.001
Cerebrovascular accident	18 (16.51)	12 (7.64)	0.002
Congestive heart failure	40 (36.69)	26 (16.56)	<0.001
CAD			
Stent	8 (7.33)	6 (3.82)	<0.001
Medical therapy	43 (39.44)	27 (17.19)	
None	39 (35.77)	112 (71.33)	
CABG	19 (17.43)	12 (7.64)	

The cause of exit in hemodialysis subjects was renal function recovery in 0.91% (n=1) diabetic and 0.63% (n=1) non-diabetic subjects. Peritoneal dialysis was the reason for exit from hemodialysis in 0.91% (n=1) diabetics and 1.27% (n=2) non-diabetics. Renal transplantation was caused in 6.42% (n=7) diabetics and 17.19% (n=27) non-diabetics. Death was the cause for exit from hemodialysis in 41.28%% (n=45) diabetics and in 22.29% (n=35) non-diabetics. Continued hemodialysis was caused in 50.45% (n=55) diabetics and 58.59% (n=92) non-diabetics. The difference was statistically significant in diabetics and non-diabetics with p<0.001 as depicted in Table 5.

Table 5: Cause of exit from hemodialysis unit in diabetic and non-diabetic study subjects

Causes of hemodialysis exit	Diabetes (n=109)	Non-diabetes (n=157)	p-value
Renal function recovery	1 (0.91)	1 (0.63)	**<0.001**
Peritoneal dialysis	1 (0.91)	2 (1.27)	
Renal transplantation	7 (6.42)	27 (17.19)	
Death	45 (41.28)	35 (22.29)	
Continued hemodialysis	55 (50.45)	92 (58.59)	

In 45 diabetics deaths and 35 non-diabetic deaths, the cause of death was cachexia with CVD (cardiovascular disease) or infection in 42.22% (n=19) diabetics and in 42.85% (n=15) non-diabetics. Death was because of malignancy in 13.33% (n=6) diabetics and 2.85% (n=1) non-diabetic subjects. Infection was the cause of death in 26.66% (n=12) diabetics and 8.57% (n=3) non-diabetics. Infections with CVD were the reported cause of death in 4.44% (n=2) diabetics and 8.57% (n=3) non-diabetics. Another cause of CVD was the cause of death in 6.66% (n=3) of diabetics and 8.57% (n=3) of non-diabetics. CVD was the cause of death in 2.22% (n=1) diabetics and 8.57% (n=3) non-diabetics. Other unreported causes of death were reported in 4.44% (n=2) diabetics and 20% (n=7) non-diabetics as summarized in Table 6.

Table 6: Cause of death in diabetic and non-diabetic study subjects

Causes of Death	Diabetes (n=45)	Non-diabetes (n=35)
Cachexia with CVD or infection	19 (42.22)	15 (42.85)
Malignancy	6 (13.33)	1 (2.85)
Infection	12 (26.66)	3 (8.57)
Infections with CVD	2 (4.44)	3 (8.57)
Others with CVD	3 (6.66)	3 (8.57)
CVD	1 (2.22)	3 (8.57)
Others	2 (4.44)	7 (20)

DISCUSSION

Among 266 study subjects, 109 were diabetics and 157 were non-diabetics. The mean age was significantly higher in diabetics at 62.4±11.4 years compared to 53.3±16.5 years in non-diabetics with p<0.001. The gender has a non-significant difference in the two groups with p=0.08. Hemodialysis vintage was significantly higher in non-diabetics with p=0.01. Vascular access type was tunneled CVC in 22.01% (n=24) subjects with diabetes and 15.92% (n=25) in non-diabetics, AVG was used in 5.50% (n=6) diabetics and 7.64% (n=12) non-diabetics, and AVF in 69.72% (n=76) diabetics and 73.88% (n=116) non-diabetics respectively depicting non-significant difference with p=0.17. BMI of >25-30 and >30 was significantly higher in diabetics compared to non-diabetics with p<0.001. These data were similar to the studies of Sorensen V et al[8] in 2006 and Kaysen GA et al[9] in 2004 where authors assessed subjects with demographic data comparable to the present study.

It was seen that concerning the laboratory parameters, it was seen that single pool Kt/V was significantly higher in non-diabetics with 1.31±0.19 compared to diabetics where it was 1.25±0.17 with p=0.001. Creatinine levels were also significantly higher in non-diabetics with 9.1±2.5 compared to 7.4±2.2 in diabetics with p<0.001. CRP levels were significantly higher in diabetics compared to non-diabetics with p=0.001. However, albumin levels were significantly higher in non-diabetics with 3.91±0.33 g/L compared to 3.84±0.33g/L with p<0.001. HDL was significantly higher in non-diabetics, whereas, LDL was significantly higher in diabetics with p=0.03 for both. Triglycerides in serum were also significantly higher in diabetics with p<0.001. iPTH was significantly higher in non-diabetics with 372 pg/mL compared to 270 pg/mL in diabetics with p<0.001. Phosphorus levels were significantly higher in non-diabetics with p=0.004. Pre-dialysis BUN, Hemoglobin, calcium, potassium, cholesterol, ferritin, transferrin, iron, and alkaline phosphate levels in the serum of diabetics and non-diabetics showed statistically non-significant differences. These results were consistent with the previous studies of Hayashino Y et al[10] in 2009 and Ravuelta KL et al[11] in 2004 where authors reported comparable laboratory parameters in their study subjects with diabetes and hemodialysis.

The study results showed that for the parameters of quality of life in study subjects, it was seen that the role-emotional component was significantly higher in non-diabetics with 59.9±35.6 compared to diabetics where it was 50.3±34.9 with p=0.007. Vitality, general health, role physical, physical functioning, SF 36 scores, mental component summary, physical component summary, and mental health were significantly higher in non-diabetic subjects compared to diabetics with significant results and p=0.01, 0.02, 0.002, <0.001, <0.001, 0.004, 0.003, and 0.04 respectively. However, a non-significant difference was seen in social functioning and body pain in diabetics and non-diabetics with better results in non-diabetics and p=0.12 and 0.71 respectively. These findings were in agreement with the findings of Gumprecht J et al[12] in 2010 and Osthus TB et al[13] in 2012 where authors suggested similar quality of life in diabetics and non-diabetics on hemodialysis as seen in the results of the present study.

Concerning cardiovascular diseases had a significantly higher prevalence in diabetics compared to non-diabetics where the clinical peripheral vascular disease was seen in 56.88% (n=62) diabetics and 0.63% (n=1) non-diabetic subjects with p<0.001. Cerebrovascular accidents were reported in 16.51% (n=18) diabetics and 7.64% (n=12) non-diabetics depicting a non-significant difference with p=0.002. Congestive heart failure was seen in 36.69% (n=40) diabetics and 16.56% (n=26) non-diabetic subjects which was significantly higher in diabetics with p<0.001. Coronary artery disease (CAD) was significantly higher in diabetics compared to non-diabetics with p<0.001. These results were in line with previous studies of Ndip A et al[14] in 2010 and Morbach S et al[15] in 2001 where authors also reported a higher prevalence of cardiovascular diseases in diabetics on hemodialysis.

The study results showed that the cause of exit in hemodialysis subjects was renal function recovery in 0.91% (n=1) diabetic and 0.63% (n=1) non-diabetic subjects. Peritoneal dialysis was the reason for exit from hemodialysis in 0.91% (n=1) diabetics and 1.27% (n=2) non-diabetics. Renal transplantation was caused in 6.42% (n=7) diabetics and 17.19% (n=27) non-diabetics. Death was the cause for exit from hemodialysis in 41.28%% (n=45) diabetics and in 22.29% (n=35) non-diabetics. Continued hemodialysis was caused in 50.45% (n=55) diabetics and 58.59% (n=92) non-diabetics. The difference was statistically significant in diabetics and non-diabetics with p<0.001. These findings correlated with Dukkipati R et al[16] in 2010 and Ferreira A et al[17] in 2008 where authors suggested similar reasons for exit from hemodialysis as reported by the authors of the present study.

Concerning death, in 45 diabetics deaths and 35 non-diabetic deaths, the cause of death was cachexia with CVD (cardiovascular disease) or infection in 42.22% (n=19) diabetics and in 42.85% (n=15) non-diabetics. Death was because of malignancy in 13.33% (n=6) diabetics and 2.85% (n=1) non-diabetic subjects. Infection was the cause of death in 26.66% (n=12) diabetics and 8.57% (n=3) non-diabetics. Infections with CVD were the reported cause of death in 4.44% (n=2) diabetics and 8.57% (n=3) non-diabetics. Another cause of CVD was cause of death in 6.66% (n=3) in diabetics and 8.57% (n=3) non-diabetics. CVD was the cause of death in 2.22% (n=1) diabetics and 8.57% (n=3) non-diabetics. Other unreported causes of death were reported in 4.44% (n=2) diabetics and 20% (n=7) non-diabetics. These results were similar to the findings of Spasovski GB et al[18] in

2003 and Charra B et al[19] in 2001 where authors reported similar causes of death in diabetic subjects on hemodialysis.

CONCLUSIONS

Considering its limitations, the present study concludes that HRQOL (health-related quality of life) and clinical outcomes were much worse in diabetic subjects compared to non-diabetic subjects on hemodialysis which is primarily attributed to the higher frequency of cardiovascular diseases.

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