Effect of Intradialytic Aerobic Exercises on Renal Failure Patients and Correlation Between Outcomes: A Randomized Controlled Trial

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ABSTRACT

Background: Most patients with renal failure depend on hemodialysis with deterioration in physical performance and biochemical markers; although intradialytic exercises have rarely been used it can be very effective. **Purpose:** This study aimed to examine the effect of intradialytic aerobic exercises on physical performance and biochemical markers and correlation between outcomes after the intervention. **Subjects &Methods:** Fifty seven patients with chronic renal failure were randomly allocated into two groups, 29 patients in the experimental group received intradialytic aerobic exercises with the dialysis treatment and 28 patients in the control group received just stretching exercises with the dialysis. Both the groups were receiving therapy three times per week for 12 weeks. Following assessments (6-minutes walking test, sit to stand test as well as serum analysis of urea, creatinine and albumin; and calculating the dialysis efficacy Kt/v) were done before and after treatment. **Results:** The experimental group showed a statistically significant improvement in median values of all the measured variables post-treatment ($P<0.001$); except of albumin ($P = 0.487$); and showed positive correlation between 6 minutes walking test and dialysis efficacy ($P=0.040$) and negative correlation between sit to stand test and dialysis efficacy ($P=0.022$).**Conclusions:** Based on these results, this study proved that intradialytic aerobic exercises were effective in improving physical performance and biochemical markers and dialysis efficiency in patients with chronic renal failure.

Key words: physical activity; kidney function; functional level.

INTRODUCTION

End-stage Renal Disease (ESRD) is almost or complete and irreversible loss of kidney function requiring renal replacement therapy (RRT) through dialysis or transplantation to provide alternation of kidney function that is insufficient to maintain life [1]. Dialysis is the diffusion of molecules in solution across a semipermeable membrane along an electrochemical concentration gradient; it's performed 3 times per week for 4–6 hours /session [2].

Population-based studies show that chronic kidney disease (CKD) epidemiology differs by gender, affecting more women than men, especially with regard to stage G3 CKD. Women show a greater symptom severity than men, women have greater severity of uraemic symptoms than men and a lower perceived quality of life [3]. A low activity level in dialysis people cause muscle disuse, muscle atrophy, myopathy, decreasing of physical ability or physical capacity which affects quality of life negatively and increases mortality [4].

For people receiving hemodialysis (HD), the most appropriate time to perform exercise is during the dialysis session [5]. Intradialytic exercises (IDE) lead to increase hemodialysis adequacy, exercises capacity, and quality of life of hemodialysis patients [6].

Aerobic training is defined as cardiovascular conditioning lead to enhance the aerobic metabolic capacities of muscle cells, improving circulation, muscle tissue capillarization, cardiac output, and enhance muscle's endurance [7]. Cycling is the most famous form of IDE [8].

The Kt/Vurea indicates the urea clearance at time of HD session per unit of urea distribution volume [9]

The purpose of HD is removal of intracellular compartment as albumin, creatinine, urea, and phosphate which are decreased by constriction of the peripheral circulation at the time of hemodialysis, resulting in low HD adequacy so the intradialytic aerobic exercises for the lower limbs is suggested to improve the cardiac output and peripheral circulation causing vasodilation and larger surface area facilitating the perfusion and improving dialysis efficiency [10]. IDE is safe and is recommended to enhance Kt/V, VO2 peak and physical performance [11].

Intradialytic exercises for patients receiving maintenance HD have not been considered in most dialysis centers because of clinical limitations [12]

Exercises proved its importance in HD patients, it can be done at several times and modalities such as resisted exercise and aerobic exercise or combined resistance and aerobic exercises [13].Lately, exercises during HD session have become more common and proved its safety [14].

The purpose of this study is to apply intradialytic aerobic exercises in hemodialysis patients (HDP), in order to improve physical performance and biochemical markers. We, therefore, aimed to design an intradialytic exercises training program to improve the implementation of this practice and determine its impact on physical performance and biochemical markers in HDP.

Material and methods:

Study design

This randomized controlled parallel study followed the new CONSORT Statement, which was conducted according to the Declaration of Helsinki and complied with all regulations and confirmation that written informed consent was obtained from all participants before active enrollment with a full explanation of the study purpose and procedures. This study was performed at Hemodialysis Unit Al-Hussein University Hospital in Cairo.

The ethical committee of Faculty of Physical Therapy, Cairo University approved the study with code number P.T.REC/012/003158.

Participants

This study was conducted on 60 female patients on hemodialysis for more than 3 months medically and psychologically stable, their ages ranged from 40-50 years, body mass index (BMI) ranged from 25-29,9kg/m^2.

Patients with Cognitive impairment, stroke, coronary artery disease, heart failure, uncontrolled hypertension (systolic blood pressure (SBP) >230 mmHg and diastolic blood pressure (DBP) >120 mmHg), uncontrolled diabetes (fasting glucose>300 mg/dl), infectious diseases, chest diseases, active smokers, patients with peripheral vascular disease in the lower limbs such as deep vein thrombosis or thromboangiitis were excluded from the study.

Measurement procedures

History of the patients was carefully taken to collect data about their general conditions, physical activity and current medication. The procedures of this study were divided in the following main parts:

1- Preparatory Procedures:

All medical and demographic data of subjects was collected, the basic vital signs of all patients were monitored (BP, temperature, Heart rate (HR), and respiratory rate). The patients were taught to stop the exercises and notify the researcher if they feel or complain from any of the criteria of potential discontinuation of the exercises as: dizziness, giving an hypotension episode, witnessing fainting, headache, palpitations, arrhythmias, nausea, vomiting, anxiety, dyspnea, chest pain, joint pain, muscle cramps or muscle pain, exhaustion or excessive fatigue, or if a repetitive disturbance (alarm) of the HD procedure occurred and any other adverse effects.

2-Anthropometric measures:

BMI in kg/m^2 and Weight in kg by Toshibh electronic scale, Height in a meter by tape measurement.

3-Physical performance:-

A) -6 Minutes walking test (6MWT): It was taken place in a20-meters corridor with marks every meter. Every patient was asked to walk as much as she can in 6 minutes in the 20 m corridor, the standard order that was given to the patients was, “Walk as far as possible for 6 minutes, but don't run or jog". Patients could use any assisted aid that they already use in everyday life. They could rest when they need and begin later [15].

b) - Sit to stand to sit (STS-10) it assist the duration (in seconds) to finish 10 repetitions to sit down and stand up from a chair. Patients were asked to do the test “as fast as possible,” it begin and end with patient in the chair. Patients were beginning the test by putting their hands on their opposite shoulder and sitting with their back straight [15].

3-Biochemical markers:-

A- Blood samples was collected by nurses and analyzed by a laboratory. At beginning and 12 weeks after the procedure, blood samples were collected after at least 12 hours of fasting, and before the dialysis session, analysis the concentrations of urea (g/L), creatinine (mg/L) and albumin (g/L).

B- Dialysis efficacy was calculated as follows

$$spKt/V = -\ln(R\_0.008t) + (4 - 3.5 \times R) \times UF/W$$

R is the ratio of pre- to post-HD concentration of blood urea nitrogen (BUN), t is dialysis session length (in hours), UF is amount of ultrafiltration (L) during the given HD session, and W is post-HD weight (kg) [16].

Treatment procedures

Group A:

29 patients received 30-min aerobic exercises sessions at the first 2 hours of the dialysis session, 3 times each week for 12 weeks, using a horizontal cycle ergometer. The exercises session consisted of three phases: warming up, conditioning, and cooling down.

-The warming-up phase included 5 min of stretching of the lower extremities and low-load aerobic exercises at an intensity of 8-9 of 20 on the Borg Rate of Perceived Exertion (RPE) scale [17].

-The conditioning phase involved 20 min of moderate intensity aerobic exercises with 12–14 RPE. The patients were encouraged to increase the rate of rotation if the Borg scale values beneath 12 and decrease the rate of rotation if the values were beyond 14. Patient's BP and HR were evaluated and recorded at the start of the exercises session and after 15 minutes; exercises weren't taken place or get stopped when the BP ≥200 mmHg SBP and/or 110 DBP, or ≤100 mmHg SBP and/or 50 mmHg DBP [18]. At the cooling down phase, patients exercise lightly with no resistance at an intensity of 8–9 on the RPE scale [19].

Figure (1): Intradialytic cycling exercise.

Group B:

28 participants received stretching exercises of lower extremities (hamstring and calf muscles) in dialysis sessions and medical treatment.

Statistical analysis:

Data were analyzed using the Statistical Package for Social Sciences (SPSS), version 25 (IBM, Chicago, Illinois, USA).The Shapiro–Wilk test was used to examine whether the data were normally distributed. Continuous data were expressed as median (interquartile range; 25th percentile–75th percentile) and range for non-normally distributed data. The Mann-Whitney U-test was used to compare differences between two independent groups (for non-normally distributed data). Additionally, Wilcoxon's sign rank test was used to compare outcomes in the same group before and after the intervention. Finally, Spearman rank correlation coefficient (r) was used for the study of the association between physical performance and biochemical markers after 12 weeks of the intervention for each group. A Spearman correlation coefficient (r) is ranged between -1 and +1 that indicates to which extent two variables are linearly related. P-values < 0.05 were considered statistically significant.

Results

Sixty females with renal failure were included in this study. Three participants didn't complete the study (one participant died from each group and one had to be excluded from the group B due to chest infection). Thus, data was analyzed for 57 participants (29 in group A and 28 in group B) who completed all assessments and training.

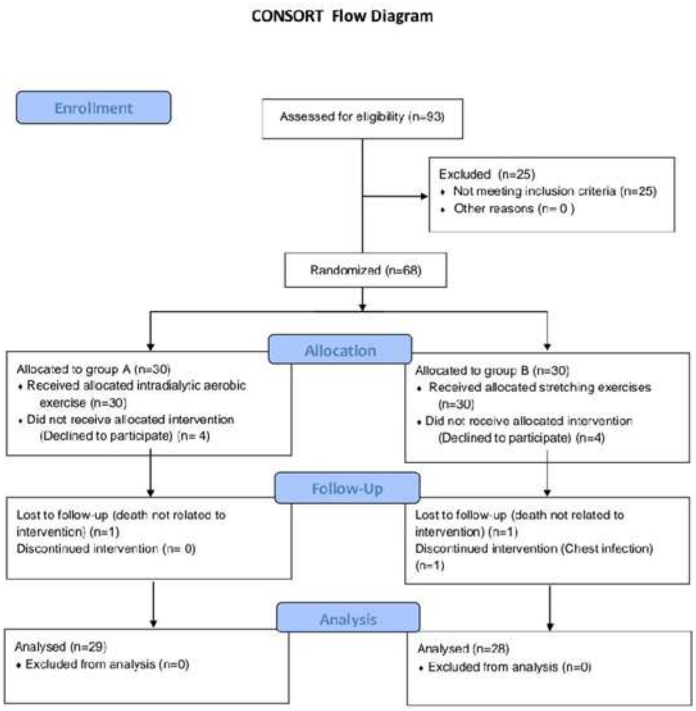

Figure (2): Flow diagram of study participant

There were no statistically significant differences between the two groups regarding age, height, weight, BMI, 6-MWT, Sts, albumin, creatinine, urea, and Kt/V at baseline where P >0.05, are shown in Table (1).

Table (1): Baseline characteristics of study participants.

Characteristics		**All (n= 75)**	**Group (A) (N=29)**	**Group (B) (N=28)**	**z**	***P*-value [a]**	**Significance**
Age (yrs)	**Median (IQR)**	47.00(43.00-49.00)	47.00(45.00-49.00)	45.50(42.00-49.00)	-1.003	0.316	NS
	Range	40.00-50.00	40.00-50.00	40.00-50.00			
Weight (kg)	**Median (IQR)**	69.90(65.00-75.10)	68.80(64.15-75.00)	72.35(66.33-75.58)	-1.660	0.097	NS
	Range	60.00-79.00	60.00-79.00	63.30-78.80			
Height (m)	**Median (IQR)**	1.60(1.57-1.63)	1.59(1.56-1.63)	1.60 (1.58-1.64)	-1.009	0.313	NS
	Range	1.51-1.69	1.51-1.69	1.54-1.69			
BMI (kg/m^2)	**Median (IQR)**	27.30(26.00-28.80)	27.20(25.90-28.55)	27.95((26.70-28.90)	-1.230	0.219	NS
	Range	25.00-29.50	25.00-29.50	25.00-29.50			
6-MWT (m)	**Median (IQR)**	211.00(204.50-223.50)	210.00((206.00-221.50)	211.50(204.00-230.00)	-0.560	0.576	NS
	Range	200.00-250.00	200.00-243.00	200.00-250.00			
Sts-10 (Sec)	**Median (IQR)**	48.00(45.00-51.05)	48.00(45.00-50.05)	48.00(44.25-52.75)	-0.096	0.923	NS
	Range	40.00-59.00	42.00-55.00	40.00-59.00			

Albumin (g/L)	**Median (IQR)**	4.15(3.97-4.34)	4.20(3.99-4.38)	4.04(3.89-4.20)	-1.613	0.107	NS
	Range	3.59-4.90	3.59-4.90	3.65-4.90			
Creatinine (mg/L)	**Median (IQR)**	7.40(6.90-8.25)	7.81(6.69-8.50)	7.00(6.90-8.01)	-1.246	0.213	NS
	Range	6.17-8.90	6.19-8.90	6.17-8.90			
Urea (g/L)	**Median (IQR)**	120.50(114.75-137.90)	121.00(113.50-142.75)	120.25(118.00-136.35)	-0.232	0.817	NS
	Range	102.00-150.00	110.80-150.00	102.00-150.00			
Kt/V	**Median (IQR)**	0.98(0.90-1.03)	1.00(0.901-.06)	0.92(0.89-1.00)	-1.536	0.125	NS
	Range	0.70-1.20	0.78-1.20	0.70-1.10			

Data presented as Median (IQR: interquartile range) and range (Min-Max)

(NS: Not significant).

Table (2) shows a significant increase in median 6-MWT in the group (A) post 12 weeks of the intervention from 210.00 m at baseline to 261.00 m (P<0.001); whereas in the group (B), it increased from 211.50 m to 213.50 m (P=0.031). As both groups significantly improved, group (A) was significantly increased after 12 weeks of intervention compared to group (B) (P<0.001).

Regarding the STS-10 value, group (A) demonstrated a significant decrease after 12 weeks of intervention (P<0.001), but there were no significant changes in the group B). Also, a significant difference was detected between the two groups).

Creatinine and urea concentrations were significantly decreased in the group (A) compared to group (B) after 12 weeks of intervention (P <0.001 and =0.008, respectively).

Group (A) showed a significant decrease in the median of albumin level whereas no change occurred in the group (B) (P=0.545). However, there was no significant difference between the two groups regarding albumin level (P =0.487).

Regarding Kt/V level, group (A) showed a significant increase whereas no change occurred in the group (B). In addition, group (A) had a significantly higher Kt/V level than group (B) (P< 0.001)

Table (2) shows a significant increase in median 6-MWT, in the group (A) after 12 weeks of intervention compared to group (B) (P<0.001).

Variable	**Group (A) (N=29)**		***p*-value a**	**Group (B)(N=28)**		***p*-value a**	***p*-value b**
	Pre-interventio	**Post-interventio**		**Pre-interventio**	**Post-interventio**		

	n	n		n	n		
6-MWT (m)	210.00(200.00-243.00)	261.00(236.00-290.00)	**<0.001***	211.50(200.00-250.00)	213.50(202.00-250.00)	**0.031***	**<0.001****
STS-10 (Sec)	48.00(42.00-55.00)	41.00(35.00-48.00)	**<0.001***	48.00(40.00-59.00)	48.00(40.00-59.00)	0.074 (NS)	**<0.001****
Albumin (g/L)	4.20(3.59-4.90)	4.16(3.50-4.62)	**<0.001***	4.04(3.65-4.90)	4.03(3.70-4.87)	0.545(NS)	0.487(NS)
Creatinine (mg/L)	7.81(6.19-8.90)	6.10(4.50-7.62)	**<0.001***	7.00(6.17-8.90)	7.01(6.10-8.70)	**0.012***	**<0.001****
Urea (g/L)	121.00(110.80-150.00)	111.00(99.00-138.00)	**<0.001***	120.25(102.00-150.00)	119.50(100.00-150.00)	**0.010***	**0.008****
Kt/V	1.00(0.78-1.20)	1.20(0.90-1.30)	**<0.001***	0.92(0.70-1.10)	0.90(0.70-1.10)	0.096(NS)	**<0.001****

Data presented as Median (Min-Max).

[a]: Wilcoxon's sign rank test. [b]: Mann-Whitney U-test.

*: statistically significant at $P<0.05$ according to Wilcoxon's sign rank test.

**: statistically significant at $P<0.05$ according to Mann-Whitney U-test.

NS: Not significant.

In group (A), 6-MWT had a significant negative correlation with albumin level and had a significant positive correlation with Kt/V after 12 weeks of intervention. However, no significant correlation was observed between 6-MWT and creatinine and urea after 12 weeks of intervention (Table 3). There were a significant positive correlation between STS-10 and albumin and creatinine after 12 weeks of intervention. Also, significant negative correlation was observed between STS-10 and Kt/V value, while no significant correlation was observed between STS-10 and urea concentration. In group (B), 6-MWT and STS-10 were not significantly associated with renal function parameters after 12 weeks of intervention (Table 3).

Table (3): Comparison of 6-MWT, STS-10 and renal function parameters before and after 12 weeks of intervention in both groups.

Group (A)				
Variable	6-MWT		STS-10	
	r	***p*-value**	***r***	***p*-value**
Albumin(g/L)	-0.600	**<0.001****	0.683	**<0.001****
Creatinine (mg/L)	-0.361	0.054(NS)	0.543	**0.002****
Urea(g/L)	-0.171	0.653 (NS)	0.300	0.113(NS)
Kt/V	0.383	**0.040***	-0.423	**0.022***
Group (B)				
Variable	6-MWT		STS-10	
	r	***p*-value**	***r***	***p*-value**
Albumin(g/L)	-0.357	0.062(NS)	0.107	0.587(NS)
Creatinine (mg/L)	-0.186	0.343 (NS)	-0.008	0.966(NS)
Urea(g/L)	-0.331	0.086(NS)	0.314	0.104(NS)
Kt/V	-0.041	0.835(NS)	-0.104	0.597 (NS)

r: Spearman's correlation coefficient.
:*Significant at P<0.05. **: Significant at P<0.01.
NS: Not significant.

DISCUSSION

The current study reflected that intradialytic aerobic exercises improve the physical performance and biological marks. The comparative analysis between the pre and post treatment for HD patients revealed that 6MWT, and kt/v were significantly higher in post treatment HD patients (P-value <0.001) and significantly lower STS, urea, and creatinine (P-value <0.001); In contrast to albumin which showed no statistically significant difference between pre and the post treated HD patients (P-value=0.487).

The study also shows positive correlation between physical performance and dialysis efficacy.

A study carried out by Bae et al., found that after cycling exercises the patients showed significant increase in 6 Minutes walking test (6MWT) which indicate better physical endurance [20].

Reboredo et al. reported that intradialytic aerobic exercise increase physical function as experimental group showed increase in 6MWT from 508.7±91.9 m to 554.9±105.8 m (P=0.001)as well as improving anemia and quality of life and deceasing blood pressure (BP)[21].

Yeh et al., showed that the time the patients needed to complete ten repetitive cycles of sit and stand (STS test) decrease after 12 weeks of IDE[22].

Bohm et al study which based on comparison between 24 weeks intradialytic cycling exercises versus home-based walking program for 24 weeks showed that although there was no significant change in VO2peak or 6MWT between or within study groups, sit to stand test showed a significant improving in both groups which represents improving aspect of physical function [23].

Groussard et al. showed that intradialytic aerobic cycling training is a useful and easy strategy to reduce chronic kidney diseases associated disorders as lipid profile and physical fitness as 6MWT increased significantly in exercise group by (+23.4%, p < 0.001)[24].

Hajbaghery et al. showed that dialysis efficacy increase by 38% when patients perform 15 minutes low intensity

IDE [25]. AIi NH et al reported that the creatinine and serum urea show significant decrease after 6 months of intradialytic aerobic exercise program [26].

Sun et al. reported that exercises during dialysis session improve efficiency of dialysis as kt/v was significantly higher in experimental group compared to control group [27].

In contrast to the above mentioned positive findings, it was reported no significant urea or creatinine decrease in response to intradialytic aerobic exercises by Orcy et al; [28].

Abbreviations

ESRD: End Stage Renal Disease, **RRT:** Renal Replacement Therapy, **CKD:** Chronic kidney failure, **HD:** Hemodialysis **IDE:** Intradialytic exercises, **HDP:** Haemodialysis patients, **BMI:** Body mass index, **SBP:** Systolic blood pressure, **DBP:** Diastolic blood pressure, **BP:** Blood pressure, **HR:** Heart rate **, 6MWT:** 6 Minutes walking test, **STS-10:** Sit to stand to sit, **RPE:** Rate of Perceived Exertion, **IQR:** Interquartile range.

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