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Effect of intradialytic aerobic exercise on dialysis adequacy, inflammatory, biochemical markers and quality of life; a double-blind randomized clinical trial study

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Abstract

Introduction: Despite ongoing advancements in dialysis techniques, patients undergoing this treatment often experience impaired physical performance. Intradialytic exercise has shown potential in improving dialysis adequacy, biochemical markers (calcium and phosphorus), and quality of life for these patients.

Objectives: This study aimed to investigate the effect of intradialytic exercise on various factors including dialysis efficacy, biochemical markers, quality of life, and physical performance among individuals undergoing hemodialysis.

Patients and Methods: A single-center randomized clinical trial was conducted to investigate the effects of a 6-month exercise program on 30 end-stage renal disease patients who were receiving hemodialysis (HD) treatment for at least six months. The patients were randomly assigned to either the experimental group (n = 16) or the control group (n = 14). The experimental group received a 30-minute intradialytic exercise session three times a week, during the first 2 hour of HD. Blood samples were collected at baseline, as well as at the end of six months of the exercise program, for biochemical measurements. Additionally, the sit-to-stand 10 (STS-10) test and KDQOL-36 scale were completed at the beginning and end of the study to assess the participants' quality of life.

Results: There were no significant differences between the control and intervention groups in baseline demographic and biochemical characteristics. The results of the STS-10 test showed a noteworthy increase in muscle strength at the end of six months for the exercise group ($P<0.05$). The prescribed intradialytic exercise led to an improvement in Kt/V and C-reactive protein (CRP) levels, although the improvement was not statistically significant ($P=0.06$). No significant changes were observed in biochemical parameters and the level of quality of life between the two groups after six months ($P>0.05$).

Conclusion: It can be concluded that an intradialytic exercise program is a safe and effective complementary intervention, with the potential for improvement in physical ability.

Trial Registration: The trial protocol was approved by the Iranian Registry of Clinical Trials (identifier: IRCT20080916001256N2; https://en.irct.ir/trial/43662; Ethical code: IR.MUMS.MEDICAL.REC.1399.110).

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Keywords: Exercise, Hemodialysis Quality of life, Dialysis efficacy, Chronic kidney disease

Introduction

In chronic kidney disease (CKD) hypertension, electrolyte disturbance, and toxin accumulation are common, and they all may be associated with cardiovascular and hematologic complications.

When these problems are coupled with emotional disorders like depression, which is a common comorbidity in CKD patients, it leads to a decline in physical performance and overall quality of life (1-5). Moreover, these patients often endure long periods of sedentary behavior while receiving hemodialysis (HD) each week.

Recent growing evidence showed that a minimum activity of 20-30 minutes per dialysis session improved various factors, such as Kt/V (2,6,7), serum creatinine (2,8-12), potassium, phosphorus, blood urea (2,12), and quality of life (QoL) (2,5,9).

Numerous studies have demonstrated that intradialytic exercise effectively enhances physical performance in patients, as assessed by the sit-to-stand 10 (STS-10) test (1,4,5,9), alongside a significant strength increase in lower extremities' muscles (10). Furthermore, riding a stationary bike decreases the number of hypotension episodes during dialysis, and results in reduced blood pressure throughout the remainder of the day (4), as well as improving left ventricular systolic function (11). All of these can result in a reduced need for antihypertensive drugs (13). In

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Implication for health policy/practice/research/ medical education

This study investigates the effectiveness of intradialytic exercise on dialysis efficacy, biochemical markers, and physical performance in individuals undergoing hemodialysis. A 6-month exercise program was conducted on 30 end-stage renal disease patients receiving hemodialysis treatment. The patients were randomly assigned to an experimental group (n = 16) or a control group (n = 14). The experimental group received a 30-minute intradialytic exercise session three times a week during hemodialysis. The results showed a significant increase in muscle strength at the end of 6 months in the exercise group. In conclusion, intradialytic exercise is a safe and effective complementary intervention that has the potential to improve physical ability in patients undergoing hemodialysis.

addition, some studies showed that intradialytic exercise reduces inflammatory factors interleukin-6 (IL-6), C-reactive protein (CRP) (1,4,8), and bone loss (1,14).

Due to the shift of the intercellular fluids to the intravascular space in the involved muscles, the clearance of urea improves (12,15). Additionally, the movement of ions, such as potassium and phosphate, from the intracellular compartment to the interstitial space enhances the effective removal of waste ions (16).

Continuous physical activity increases circulating progenitor cells (CPCs), which play an essential role in the endothelial repair of the damaged arteries. It is reported that the number of CPCs are much lower in HD patients. However, studies suggest that aerobic intradialytic exercise increases CPCs significantly (17), which can potentially result in an expedited cardiac function improvement for patients with a recent history of myocardial infarction.

Objectives

This study aimed to assess the effect of intradialytic exercise on dialysis efficacy, biochemical markers, quality of life, and physical performance among HD patients.

Patients and Methods

Study design

In this randomized clinical trial, a total of 36 dialysis patients with a minimum of six months' history of receiving HD, three times a week for four hours were enrolled in the study.

Inclusion and exclusion criteria

Patients were excluded if they had active angina pectoris, experienced a myocardial infarction in the last month, had congestive heart failure of grade III-VI, chronic hyperkalemia before dialysis, active liver disease, musculoskeletal limitations, amputation of lower limbs and toes, malignant hypertension unresponsive to treatment, recent surgery within the past month, severe peripheral neuropathy, dementia, malignancy, active inflammatory disease, parathyroid hormone (PTH, parathormone) >1000 pg/mL, history of femoral bone fracture, poorly controlled diabetes mellitus, previous administration of immunosuppressive drugs, fever above 38 degrees, hemodynamic disorders, cerebrovascular diseases, active lung diseases such as chronic obstructive pulmonary disease, cardiac ejection fraction less than 45%, and hemoglobin (Hb) <10 g/dL.

Sampling

Detailed information regarding the benefits and risks of the study, as well as the management of potential hazards, was thoroughly explained to the patients. They were informed of their right to withdraw from the study at any time without impacting their ongoing treatment process. To ensure their understanding and agreement, the patients were required to complete informed consent forms. All patients were examined one week before the start of the study to assess their eligibility to enter the study. Participants were asked to perform the STS-10 test before the start of HD treatment. The STS-10 is a measure of lower-extremity strength that assesses the time it takes for an individual to complete 10 repetitions of sitting down and getting up from a chair (18). The patients were asked to have their arms crossed while doing the STS-10 test to avoid using their hand strength in getting up. A stopwatch was conducted to measure the STS-10 test duration. Maximum heart rate was calculated using the Karvonen formula (60% of maximum power) for each patient.

Randomization

For the block randomization method, blocks of 4 were randomly assigned to either the control group or the intervention group using randomization.com.

Blinding

It was planned to be double-blind study but due to the clinician's role in the clinic. Despite efforts, the clinician's awareness of the treatment allocation might have inadvertently influenced data collection and patient interactions. This potential bias needs consideration when interpreting the study findings, highlighting the challenge of implementing blinding in such clinical settings.

Quality of life and dialysis adequacy definition

World Health Organization (WHO) defines quality of life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

Kt/V, like URR (urea reduction ratio), is a measure of dialysis adequacy. K = clearance—the amount of urea your dialyzer can remove (liters/minute) t = time—the duration of treatment (minutes) V = volume—the amount of body fluid (liters)

Intervention

The intradialytic exercise was prescribed for 10 to 15

minutes a day during the first 2 hours of the HD session, three times a week for 12 weeks. Once patients were connected to a HD machine, vital signs were examined and documented. If the vital signs were stabilized, the patients would then start cycling in a supine position. During the initial five minutes, patients were instructed to cycle at a lower intensity to warm up. Over the next 20 minutes, patients were asked to ride a bicycle according to a Borg scale of 12-16. During the last five minutes, they rode a bicycle at a slower speed to cool down. The blood pressure and heart rate of patients were measured and recorded every 15 minutes during cycling, as well as at the end of the exercise.

Cycling was postponed to the next dialysis session if the systolic pressure was > 180 mm Hg and/or <90 mm Hg, or the resting heart rate was more than 120.

Data collection

Tests such as complete blood count (CBC), blood urea nitrogen (BUN), Cr, K, P, serum albumin, intact PTH were taken after 10 hours of fasting. Blood CRP samples were collected prior to the start of the dialysis session. Medications and their respective dosages were recorded at the commencement of the study. The dialysis adequacy (Kt/V) was calculated. The Kt/V can be resolved from the predialysis to postdialysis urea nitrogen ratio (R), the weight loss (UF), session length in hours (t), and anthropometric or modeled volume (V) using the equation; KtV = In (R - 0.008 × t) + (4 - 3.5 × R) × 0.55 UF/V. KDQOL-SF™ version 1.3 scale was completed to assess the quality of life for each participant. Tests were repeated after 6 months from the baseline.

Statistical analysis

The chi-square test was conducted to compare the characteristics of the groups (Tables 1 and 2). Data analysis was performed using SPSS 26 for Windows. Descriptive statistics, including the mean and standard deviation (SD), were calculated for age, gender, duration of time on HD (months), dialysis efficacy (Kt/V), duration of HD (hours), and baseline biochemical data. The Kolmogorov-Smirnov normality test was conducted to examine if variables are normally distributed. Depending on the distribution of variables, parametric or non-parametric (independent t test and/or Mann-Whitney U) tests were used to compare within and/or between-group differences. Statistical significance was determined at a threshold of 0.05 or lower.

Results

Thirty patients completed the study, with 16 in the experimental group and 14 in the control group. Both groups consisted mostly of patients aged between 45 and 70 years. At the beginning of the study, there were no significant differences in demographic and clinical variables between the experimental and control groups, as presented in Tables 1 and 2 and Figure 1.

Table 3 demonstrates the comparison of the difference in biochemical and physical parameters in the pre-study and post-study among patients in the experimental group, test results for the STS-10 showed a noteworthy improvement in muscle strength among participants in the intervention group after 6 months ($P < 0.05$). Kt/V and hs-CRP showed an improvement. However, they were not statistically significant ($P = 0.067$ and 0.064, respectively).

When evaluating the effectiveness of intradialytic exercise on quality of life for the experimental group, significant improvements were observed in the symptom/problem list compartment and the SF-physical health composite, as indicated in Table 4. This suggests that patients in the experimental group experienced enhancements in their quality of life. However, no significant differences were found in the quality of life among patients in the control group ($P > 0.05$). Table 4 displays the quality of life among patients receiving HD in the control group.

Discussion

The current study examined the effectiveness of intradialytic cycling on dialysis efficacy, biochemical markers, and physical performance among HD patients in a real-world setting.

The results indicated that implementing a 6-month intradialytic exercise program led to significant improvements in the average physical performance of the experimental group. These findings are consistent with several prior studies (1,4,5,9,19). Additionally, exercise training resulted in increased lower limb muscle strength, as evidenced by a shorter average time to complete the STS-10 test ($P = 0.001$). This finding is significant because impaired physical performance in the lower extremities is strongly associated with all-cause mortality in these patients (20). Leal et al also observed an exercise-training-induced improvement in handgrip strength, which was linked to reduced inflammation, higher muscle mass, and

Table 1. Demographic baseline characteristics of the participants

	Experimental group (n=16)	Control group (n=14)	*P* value
Age (y)	56.94±14.67	58.36±15.43	0.798[a]
Gender (M/F)	10/6	7/7	0.713[b]
Dialysis duration (h)	3.68±0.51	4.50±1.87	0.172[a]
Body mass index (kg/m^2)	25.98±5.99	27.35±3.35	0.458[a]

[a] Independent sample *t* test; [b] Chi-square test.

Table 2. Biochemical baseline data of participants

	Experimental group (n=16)	Control group (n=14)	*P* value[a]
Kt/V	1.35 ± 0.30	1.39 ± 0.27	0.756
Urea reduction ratio (%)	0.66 ± 0.8	0.68 ± 0.8	0.567
STS-10	23.59 ± 8.26	35.77 ± 18.24	0.131
Hb (g/dL)	12.08 ± 1.94	12.43 ± 1.53	0.588
FBS (mg/dL)	80.25 ± 16.11	79.86 ± 18.08	0.947
BUN before (mg/dL)	116.06 ± 24.55	121.07 ± 40.71	0.682
BUN after (mg/dL)	36.75 ± 11.52	36.21 ± 11.67	0.900
Creatinine (mg/dL)	7.60 ± 2.22	7.62 ± 2.59	0.974
Na (mEq/L)	141.06 ± 4.72	143.00 ± 6.30	0.345
K (mEq/L)	4.90 ± 0.74	5.10 ± 0.84	0.497
Ca (mg/dL)	8.48 ± 0.49	8.22 ± 0.83	0.314
Phosphate (mg/dL)	4.70 ± 1.10	4.82 ± 0.81	0.722
ALP (U/L)	442.58 ± 284.26	585.50 ± 343.38	0.289
Intact parathormone (pg/mL)	528.88 ± 235.50	517.89 ± 404.35	0.927
Albumin (g/dL)	4.32 ± 0.36	4.60 ± 0.43	0.847
Iron (mcg/dL)	165.97 ± 247.86	198.43 ± 2119.47	0.709
TIBC (µg/dL)	288.19 ± 37.73	289.64 ± 22.42	0.901
Ferritin (µg/L)	626.13 ± 573.95	539.71 ± 498.25	0.665
hs-CRP (mg/L)	0.65 ± 0.46	0.81 ± 0.49	0.373

Abbreviations: Hb, Hemoglobin; FBS, Fasting blood glucose; BUN, Blood urea nitrogen; ALP, Alkaline phosphatase; hs-CRP, High-sensitivity C-reactive protein; TIBC, Total iron binding capacity; URR, Urea reduction ratio.
[a] Mann-Whitney or *t* tests were used.

improved survival expectancy in this population (21).

In this study, the researchers compared biochemical markers including serum creatinine, blood urea, serum potassium, calcium, phosphate, and Hb levels between the experimental and control groups. The findings indicated that there were no significant improvements in the levels of these biochemical markers among patients in the experimental group. However, another study by Reboredo et al (22) reported significant improvements in serum phosphate levels. Additionally, Adorati found that intradialytic exercise reduced urea rebound and increased creatinine and phosphate removal. On the other hand, a systematic review of eight trials (23) reported no significant improvement in serum phosphate levels.

In this study, we have found significant improvements in the composite of physical health SF-36 and symptom/problem list scale, while mental health composite did not demonstrate any statistically significant changes, which was consistent with findings of the studies by Ouzouni et al (24) and Zhang et al (25).

Patients in experimental group showed an improvement in dialysis adequacy (Kt/V) with mean difference of 0.31 between baseline and after 6 months of intradialytic cycling in contrast to the control group where Kt/V remain unchanged. However, the difference between control and experimental group was not statistically significant ($P = 0.06$). This finding contrasts with other studies (2,6,7) which showed significant improvement in Kt/V. This can be a result of small sample size.

Markers of chronic inflammation can predict the risk of cardiovascular diseases, which is known to be the most common cause of mortality in HD patients. In this study we studied the effect of intradialytic cycling on hs-CRP, and it was found that the mean level of hs-CRP in intervention group was decreased by 0.14 mg/L, while the control group showed a 0.31 mg/L mean increase. However, this difference was not statistically significant (p=0.06). Previous studies have reported a significant reduction in hs-CRP. Our study did not replicate the findings from other previous studies, where a significant reduction in hs-CRP was found.

Our study was subject to some limitations. Our study was a single center trial with a small sample size, carrying a chance of failing to demonstrate a treatment difference. In addition, admission of patients in hospitals due to fistula repair or other causes led to missing data on several days during the study. It will be necessary to do more research with a larger study population and longer interventions to evaluate the advantages of intradialytic exercise more fully.

Conclusion

The findings of the present pilot study suggest that the recommended intradialytic exercise intervention led to a significant improvement in quality of life without any negative side effects. Additionally, it was observed

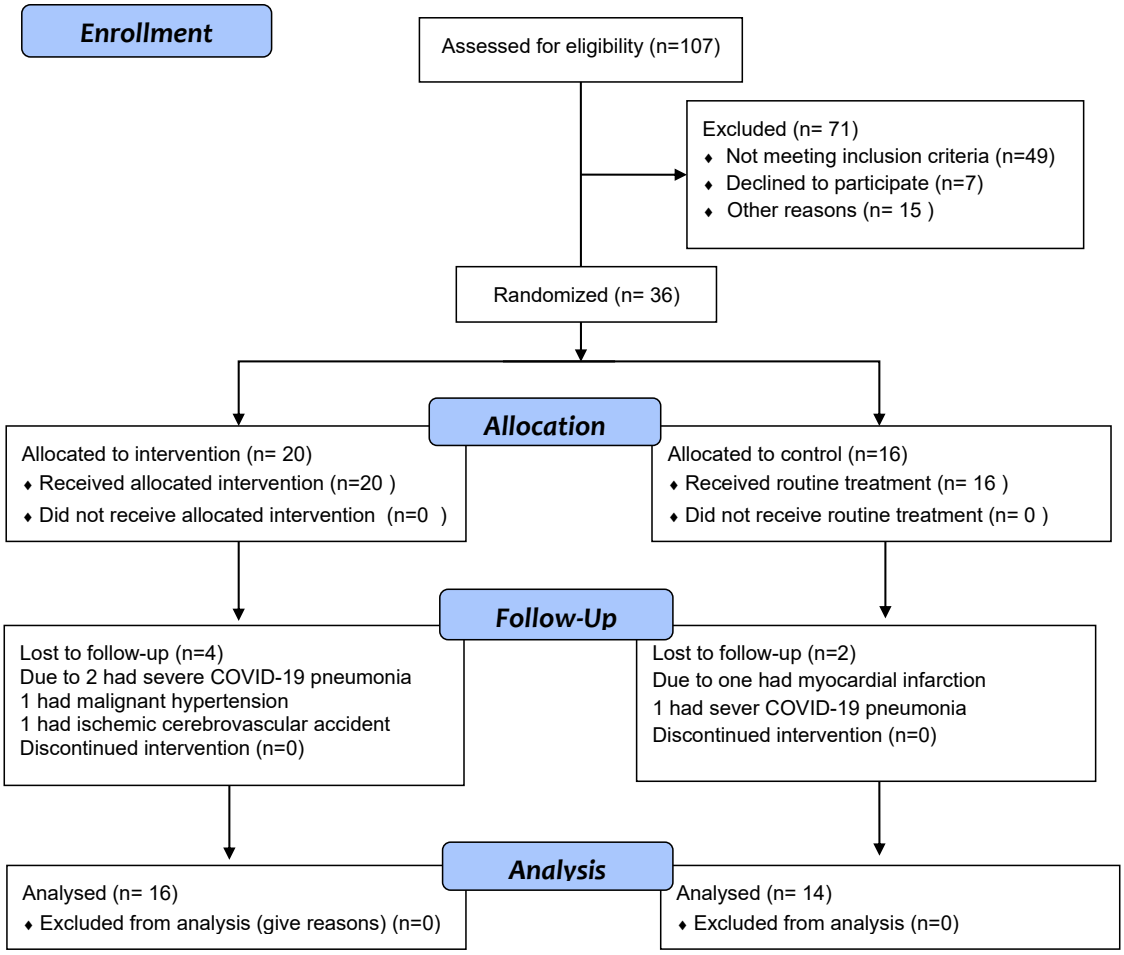

Figure 1. CONSORT flow diagram of the study.

that this exercise program is a safe complementary intervention that does not require the patient to spend extra time. However, the lack of impact on biochemical and inflammatory factors and also dialysis adequacy may be attributed to the limited sample size, indicating the need for more extensive studies in the future.

Limitations of the study

We conducted the study at a single dialysis center, which happened to be the sole facility offering chronic HD services in the city. As a result, the availability of HD patients was limited, potentially resulting in a small sample size and hindering our ability to draw definitive conclusions. Therefore, we recommend a larger, multicenter study to gather more comprehensive data and attain more conclusive findings.

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Authors' contribution

Conceptualization: Arash Sefidgaran.
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Investigation: Natasha Dolatabadian, Arash Sefidgaran.
Methodology: Maryam Hami, Arash Sefidgran.
Validation: Maryam Hami, Arash Sefidgran.
Project administration: Maryam Hami.
Resources: Hamid Taravati.
Supervision: Maryam Hami.
Visualization: Arash Sefidgaran.
Writing–original draft: Maryam Hami, Arash Sefidgran.
Writing–review and editing: Maryam Hami, Arash Sefidgran.

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

The research was conducted in compliance with the principles outlined in the Declaration of Helsinki. The Ethics Committee of Mashhad University of Medical Sciences approved this study (ethical code #IR.MUMS.MEDICAL.REC.1399.110). Before the commencement of the study, all participants voluntarily provided informed consent. The trial protocol was registered in the Iranian registry of clinical trials (identifier: IRCT20080916001256N2;

Table 3. The effect of intradialytic exercise on physical and biochemical markers in the experimental group and comparison with the control group before and after intervention

Group	Median (IQR)	*P* value[a]
FBS (mg/dL)		
Experimental	15.5 (4.5-26.5)	0.901
Control	17.5 (2.75-32.0)	
Hb (g/dL)		
Experimental	-0.8 (-2.3-1.08)	0.708
Control	-0.2 (-1.85-0.43)	
URR (%)		
Experimental	0.09 (-0.01-0.13)	0.176
Control	0.1 (-0.10-0.10)	
Kt/V		
Experimental	0.27 (0.01-0.69)	0.109
Control	0.07 (-0.35-0.39)	
Na (mEq/L)		
Experimental	-1.0 (-8.5-0.75)	0.417
Control	-6.0 (-8.5-1.25)	
K (mEq/L)		
Experimental	0.5 (-0.13-0.98)	0.405
Control	0.3 (-0.5-0.75)	
Ca (mg/dL)		
Experimental	-0.4 (-1.28-0.50)	0.661
Control	-0.35 (-1.05-0.18)	
P (mg/dL)		
Experimental	1.6 (0.42-2.20)	0.467
Control	0.95 (0.50-1.23)	
Ferritin (micg/L)		
Experimental	86 (-370.8-251.8)	0.280
Control	106.5 (-176.5-504.0)	
PTH (pg/mL)		
Experimental	-221.0 (-372- -67.5)	0.105
Control	-81.9 (-188-323)	
Albumin (g/dL)		
Experimental	-0.15 (-0.40-0.10)	0.416
Control	0.00 (-0.30-0.23)	
CRP (mg/L)		
Experimental	-0.10 (-0.38-0.10)	0.162
Control	0.18 (-0.23-0.80)	
STS-10		
Experimental	-2.3 (-5.08-1.70)	0.022
Control	1.5 (-2.25-5.13)	

Abbreviations: Hb, Hemoglobin; FBS, Fasting blood glucose; URR, Urea reduction ratio in hemodialysis; CRP, C-reactive protein; STS-10, Sit-to-stand 10; Hb, hemoglobin.

[a] Mann-Whitney U test was conducted for between-group comparisons.

https://en.irct.ir/trial/43662). Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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