Effectiveness of Intradialytic Stretching Exercises on Prevention and Reduction of Leg Muscle Cramps among Patients undergoing Hemodialysis: Randomized Controlled Trial

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Abstract

Renal replacement therapy is a treatment option for people who have acute or chronic renal failure. A patient with increasing symptoms of renal failure is referred to a dialysis and transplantation center early in the course of progressive kidney disease. Hemodialysis is one of the most widely used dialysis procedures. Muscle cramps are the most common complication experienced by hemodialysis patients that usually develop during and in between hemodialysis therapy. These cramps appear to be the most common reason for the early termination of the hemodialysis session. **Study Design:** Pretest-posttest non-blind randomized controlled trial has been used in the present study to evaluate the effectiveness of Intradialytic stretching exercises on the leg muscle cramps among patients undergoing hemodialysis, from the period of September 5th, 2020 to March 22nd, 2021. **Study Sample:** Non-probability purposive Sample of 60 patients undergoing hemodialysis. The sample is divided randomly into two groups; 30 patients as the study group and the other 30 as the control group. **The setting of the study:** The study is conducted in Al-Najaf City/Al-Najaf Al-Ashraf Health Directorate / Al-Sadder Medical City / The specialized center for kidney diseases and transplantation / Hemodialysis Unit. **Result:** The study result signifies that the level of muscle cramps improved significantly among the study group participants compared with control group.

Keywords: *Stretching Exercises, Muscle Cramps, Hemodialysis.*

Introduction

Chronic kidney disease (CKD) has become a global public health problem with a rising prevalence [(1)]. In 2017, 697.5 million cases of all-stage CKD were recorded, for a global prevalence of 9.1%. The global all-age prevalence of CKD increased 29·3% since 1990. In Iraq, the prevalence of CKD about 3,044,399 cases in 2017 [(2)]. Current international guidelines define CKD as decreased kidney function shown by GFR of less than 60 mL/min per 1·73 m², or markers of kidney damage, or both, of at least 3 months duration, regardless of the underlying cause. End-stage renal disease (ESRD) occurs when a person's GFR falls below 15 mL/min per 173m2, indicating that kidney function is no longer capable of sustaining life over the long term and the patient will rely on one of the renal replacement therapy methods: dialysis or kidney transplantation [(3)].

Hemodialysis is one of the most widely used dialysis procedures. It is a treatment that uses a dialyzer to remove excess fluid, waste materials, and poisonous substances from the blood accountable for the uremic syndrome, and then returns pure and filtered blood to the patient, and prolongs survival [(4–6)]. The client must remain dependent on the periodic hemodialysis sessions for life unless the kidney transplant is done successfully [(4)]. About 9,20,000 people are undergoing hemodialysis

per day in the world, i.e., 7.8 % of the total population [7].

On the other hand, hemodialysis does not fully correct uremia and can be linked to complications arising from the disease itself or the treatment process. Patients are unable to achieve maximum health as a result of these complications, which interfere with certain aspects of their lives. The ability of an individual patient to adapt to medical and psychological pressures is reflected in his or her quality of life. Tiredness, dyspnea, muscle cramps, headaches, pruritus, and joint pain are the six most common symptoms of hemodialysis patients [6].

Muscle cramps are one of the most common physical symptoms experienced by dialysis patients [8]. It is an abrupt involuntary muscle contraction characterized by severe pain that occurs repeatedly in hemodialysis patients. Leg cramps most often affect the calf muscles, feet, toes, and thigh, but they can also affect the arms and hands, in addition to the abdominal muscles [9,10].

Although the exact etiology of muscle cramps is not fully understood, several common triggers have been identified including; hypovolemia, hypotension, dialysate composition, rapid ultrafiltration (UF) [11], disruptions in an electrolyte and mineral metabolisms, such as high serum calcium and phosphorus levels and low sodium, potassium, and magnesium levels in HD patients [12], in addition to the inability to move for three to four hours leads to progressive muscle wasting, and the lack of blood supply and reduced blood flow leads to muscle fatigue and cramping [13]. Such cramps, which affect 33% to 86% of patients, may occur during hemodialysis treatment or at home following dialysis [9,10,14].

Therefore, intradialytic muscle cramps may have serious consequences on patients undergoing hemodialysis, as it represents the most common reason for the early termination of the hemodialysis session. Also, it may lead to a reduction of fluid removal, inadequate clearance of waste products, fluid overload, hypertension, and increased mortality risk Furthermore, muscle cramp negatively affects sleep and patients' quality of life. In severe cases, it may influence a patient's decisions to eventually withdraw from dialysis treatment [15].

So, hemodialysis nurses must be able to recognize complications associated with chronic renal failure, as well as the effectiveness of non-drug treatment options and non-pharmaceutical interventions for these patients [8]. Stretching exercise, strengthening exercise, and oil massage is the most commonly used non-pharmacological therapies in reducing muscle cramps [16]. Patients' compliance with hemodialysis can be improved by reducing muscle cramps, and the quality of life of these patients can be enhanced by increasing the hemodialysis' adequacy. This would also alleviate fears about non-drug options for muscle cramp relief [8].

Methodology

Study Design: Pretest-posttest non-blind randomized controlled trial has been used in the present study to evaluate the effectiveness of intradialytic stretching exercises on prevention and reduction of leg muscle cramps among patients undergoing hemodialysis, from the period of September 5th, 2020 to March 22nd, 2021.

Administrative Agreements and Ethical considerations: The researcher obtained permission from the Ethics Committee of the Faculty of Nursing / University of Kufa, Ministry of Planning/Central Council for Statistics, Al-Najaf Al-Ashraf Health Directorate/ Al-Sadder Medical City. In addition, the researcher also obtained the approval of the muscle cramp questionnaire chart designer to use this tool. Also, in order to respect the principles and desire of the participants in the study, the researcher obtained informed consent from each study participant using the subjects' agreement sheet which formed according to scientific resources such as Roberts and Hyatt, (2019) [17] after explaining the purpose of the study and an emphasis on maintaining the confidentiality of the participant's information.

The Setting of the Study: The study is conducted in Al-Najaf City/Al-Najaf Al-Ashraf Health Directorate / Al-Sadder Medical City / The specialized center for kidney diseases and transplantation / Hemodialysis Unit.

Study Sample: Non-probability purposive Sample of 60 patients undergoing hemodialysis. The sample is divided randomly into two groups; 30 patients as study group are exposed to intradialytic stretching exercises, and the other 30 patients are not exposed to the exercises considered as the control group.

The Study Instrument: This tool consists of three parts:

Part I: Socio-Demographic Data: consists of (6) items, which included residency, gender, age, smoking, educational level, occupational status.

Part II: Clinical Variable: consists of (10) items, which included duration of dialysis treatment, number of hemodialysis session per week, duration of hemodialysis session, frequency of leg muscle cramps per week, site of leg muscle cramps, comorbidity, level of calcium, and body mass index.

Part III: Muscle Cramp questionnaire chart: Adopted with permission from Morris, (2014) [18] to assess the level of muscle cramps during hemodialysis, before and after the intervention. It contains various features of muscle cramps such as the frequency of muscle cramps, duration of muscle cramps, level of pain, temperature, and discomfort which was comprehensively scored as a level of muscle cramps ranging from (0-13).

Score Interpretation: Four scores are used for rating the levels of leg muscle cramps among patients undergoing hemodialysis in terms of no cramps, mild cramps, moderate cramps, and severe cramps. These cramps levels are scored as (0) for no cramps, (1 - 4) for Mild cramps, (5 - 8) for moderate cramps, and (9 - 13) for severe cramps [18].

Reliability of the Study Instrument: Reliability involves the accuracy and reliability of a testing instrument to calculate an interesting variable. Reliability has not been calculated, for the study instrument of the present study because it is a global and stable standard and there are no suggested modifications made by the experts.

Data collection: The Data Collection was done at Al-Sadder Medical City / The specialized center for kidney diseases and transplant / Hemodialysis Unit. 60 patients with muscle cramps during hemodialysis was assigned based on the purposive sampling technique. after that, these patients were randomly allocated into two groups; 30 patients as study group are exposed to intradialytic stretching exercises, and the other 30 patients are not exposed to the exercises considered as the control group. Before Administering the intra- dialytic stretching exercise to the patients, socio-demographic data, clinical data, and muscle cramp status were assessed as a pre-test for both groups. Then the intradialytic stretching exercise was administered to the study group with muscle cramp from the first day. The investigator administered intradialytic stretching exercises to the subjects for 20- 30 minutes twice a week. after that, the post-test 1 muscle cramp was assessed after two weeks of intervention. then, after four weeks of intervention, post-test 2 was assessed, muscle cramp status also was assessed as a post-test for the control group without applying the intra-dialytic stretching exercises.

Results of the Study

Table (1) Summary Statistics of the Socio-Demographic Data related to the Study and Control Groups. (N=60; 30 for each of the study and control groups)

Socio-Demographic Data	Rating And Interval	Study group		Control group	
		Freq.	%	Freq.	%
Age/years	20 - 29	6	20	3	10
	30 - 39	6	20	6	20
	40 - 49	12	40	7	23.3
	50 - 59	4	13.3	8	26.7
	60+	2	6.7	6	20
	Mean	40.57		45.40	
	SD	11.004		11.976	
Gender	Male	21	70	17	56.7
	Female	9	30	13	43.3
Residency	Rural	10	33.3	10	33.3
	Urban	20	66.7	20	66.7
Occupational status	Retired	0	0	5	16.7
	Housewife	8	26.7	13	43.3
	Employee	5	16.7	1	3.3
	Jobless	13	43.3	2	6.7
	Free job	4	13.3	9	30
Smoking	Yes	2	6.7	0	0
	No	19	63.3	25	83.3
	Past Smoker	9	30	5	16.7

Table (1) represents the socio-demographic distribution of the study and control groups. Study results indicate that most of the study group participants (40%) are within (40 - 49) years old, males (70 %), urban residents (66.7 %), jobless (43.3%), and (63.3) of them are non-smokers. The majority of the control group are 40 years old and more (70%), males (56.7%), urban residents (66.7%), housewives (83.3%), and (63.3) of them are non-smokers.

Table (2) Summary Statistics of the Clinical Variables related to the Study and Control Groups

Clinical Variables	Rating And Interval	Study Group		Control Group	
		Freq.	%	Freq.	%
Hemodialysis Duration/Months	<= 12	5	16.7	13	43.3
	13 - 25	9	30	8	26.7
	26 - 38	7	23.3	3	10
	39 - 51	4	13.3	1	3.3
	52+	5	16.7	5	16.7
	Mean	32.03		28.5	
	SD	19.871		30.482	
Session Number/Week	Two times	25	83.3	28	93.3
	Three times	5	16.7	2	6.7
Session Duration	Three hours	8	26.7	6	20
	Four hours	22	73.3	24	80
Cramp Number/Week	Two times	17	56.7	11	36.7
	Three times	8	26.7	14	46.7
	Four times	1	3.3	1	3.3
	Five times	4	13.3	4	13.3
Cramp Site	Calf	28	60.9	25	64.1
	Hamstring	7	15.2	3	7.7
	Soleus	11	23.9	11	28.2
Comorbidities	Diabetes	2	5.6	7	17.9
	Hypertension	23	63.9	23	59
	Ischemic heart disease	5	13.9	2	5.1
	None	6	16.7	7	17.9
Calcium Level	Hypocalcemia	18	60	21	70
	Normal	12	40	9	30
	Hypercalcemia	0	0	0	0
Body Mass Index*	Under weight (< 18.5)	7	23.3	3	10
	Normal (18.5-24)	12	40	15	50
	Over weight (25-29)	9	30	7	23.3
	Obesity (30-34)	2	6.7	5	16.7

*** Scored according to Centers for Disease Control and Prevention, (2020)** [19]

Table (2) demonstrates the clinical variables of the study and control groups. Study results revealed that most of the study group participants underwent 2-year hemodialysis sessions (30%); twice a week (83.3%); 4 hours per session (73.3%), more than half of them experience muscle cramps twice a week (56.7%), (60,9%) in Calf site. in addition. (60%) of the participants had hypertension as a related medical illness, (60%) from Hypocalcemia, the study also points that (40%) of the participant have a normal weight.

Most of the control group participants underwent 1-year or less hemodialysis sessions (43.3%), twice a week (93.3%), 4 hours per session (80%), almost half of them experience muscle cramps 3 times a week (46.7%), (64,1%) in Calf site. In addition. (59%) of the participants had hypertension as a related medical illness, (70%) from Hypocalcemia, the study also points that (50%) of the participant have a normal weight.

Table (3) Levels of Muscle Cramps among Study Group Participants throughout the Three Periods of Measurements (Pre-test, Post-test 1, Post-test 2)

Periods of measurements	Levels of muscle cramps	Freq.	%
Pre-test	No Cramp	0	0
	Mild Cramp	0	0
	Moderate Cramp	17	56.7
	Severe Cramp	13	43.3
Post-test 1 (After two weeks)	No Cramp	22	73.3
	Mild Cramp	8	26.7
	Moderate Cramp	0	0
	Severe Cramp	0	0
Post-test 2 (After four weeks)	No Cramp	27	90.0
	Mild Cramp	3	10.0
	Moderate Cramp	0	0
	Severe Cramp	0	0

Table (3) denote the levels of muscle cramps among study group participants throughout the three Periods of measurements. In the pre-test, more than half of the participants (56.7%) have moderate cramps and (43.3%) with severe cramps. While, in post-test 1, the majority of them (73.3%) with no cramps and (26.7%) with moderate cramps. In post-test 2, the majority of participants have no muscle cramps (90%), while only (10%) experienced mild muscle cramps.

Table (4) Analysis of variance (ANOVA) in levels of muscle cramps among the study group participants throughout Three periods of measurements

Periods of Measurement	N	Mean	Std. Deviation	F	Sig.
Pre-test	30	3.43	.504	277.563	.0001
Post-test 1	30	1.27	.450		
Post-test 2	30	1.10	.305		

Table (4) reveals that there are highly significant differences among study group means score throughout three periods of measurement (pre-test, post-test 1, post-test 2) at p-value less than 0.01 (i.e. Using stretching exercises is an effective way to prevent and reduce muscle cramps).

Table (5) Levels of Muscle Cramps among Control Group Participants throughout Two Periods of Measurements

Periods of measurements	level of muscle cramps	Frequency	Percent
Pre-test	No Cramps	0	0
	Mild Cramps	0	0
	Moderate Cramp	15	50.0
	Severe Cramp	15	50.0
Post-test 1 (After four weeks)	No Cramps	0	0
	Mild Cramps	0	0
	Moderate Cramp	18	60.0
	Severe Cramp	12	40.0

Table (5) illustrates the levels of muscle cramps among control group participants throughout two Periods of measurements. In the pre-test, half of the participants (50%) have moderate cramps and another half (50%) with severe cramps. While, in post-test 1, (60%) of them with moderate cramps and (40%) with severe cramps.

Table (6) Mean Differences in Levels of Muscle Cramps among the Control Group Participants throughout Two Periods of Measurements

Test	N	Mean	Std. Deviation	t-value	Df.	P-value
Pre-test	30	3.50	0.509	1.361	29	0.184
Post-test (After four weeks)	30	3.40	0.498			

Table (6) indicates that there are no statistically significant differences between the control group means throughout two periods of measurement (pre-test, post-test) (i.e. there is no improvement in the patients' muscle cramps levels).

Discussion

After the application of the stretching exercise program throughout the current study, the study concludes that there are highly significant differences among study group means score throughout three periods of measurements (pre-test, post-test 1, post-test 2), This result signifies that the level of muscle cramps improved among the study group participants compared with two periods of measurements for participants in the control group (i.e. Using stretching exercises is an effective way to prevent and reduce muscle cramps).

This study is supported by Chavda and Singh, (2018) [4], who conducted a study entitled: "Intradialytic stretching exercises: A conservative way to reduce muscle cramps". The result of this study showed that the intradialytic stretching exercises enhance blood circulation, depression, and quality of life, in addition to physical function. Patients undergoing hemodialysis also can benefit from an intradialytic stretching exercise to avoid muscle cramps caused by fluid loss during the hemodialysis session.

Also, other authors Salem and Elhadary, (2017) [10] conducted a study entitled: "Effectiveness of Intradialytic Stretching Exercises on Leg Muscle Cramp among Hemodialysis Patients" explained that there was a substantial difference in the severity and frequency of the study participants' leg cramps before and after applying leg stretching exercises, indicating that intradialytic stretching exercise is an efficient method for improving leg muscle cramps among hemodialysis patients.

Conclusion

Based on the study results and the discussion, the study concluded that the participating patients have moderate to severe muscle cramps during the hemodialysis procedure. After the application of the stretching exercise program throughout the present study, a significant improvement in the level of muscle cramps has been reported; therefore, the intradialytic stretching exercise is a simple and efficient technique for reducing and preventing muscle cramps among patients undergoing hemodialysis. That means there is no enough evidence to accept the null hypothesis. Otherwise, the alternative hypothesis is accepted.

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Conflict of Interest: None to declare.

Ethical Clearance: "All experimental protocols were approved and carried out in accordance with approved guidelines".

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