Novelty Journals

ISSN 2394-7330

International Journal of Novel Research in Healthcare and Nursing
Vol. 7, Issue 3, pp: (390-407), Month: September - December 2020, Available at: www.noveltyjournals.com

The Effect of Physical Rehabilitation on Patient's Functional Status after Lower Extremities Arterial Bypass Surgery

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Abstract: **Peripheral artery disease is a worldwide health challenge and a major cause of morbidity and mortality. After lower extremity (LE) bypass surgery, patients may remain have limited functional abilities. The role of exercise in improving the postoperative walking performance had not adequately investigated. Aim: The study aims to determine the effect of physical rehabilitation on the patient's functional status after LE bypass surgery. Method: A Quasi-experimental design with Pre and Post Test was used for the current study. The study was carried out at the vascular surgery department at Alexandria Main University Hospital and the vascular surgery outpatient clinic. Subjects: It comprised a convenience sample of 40 patients who were planned for LE bypass surgery. They were divided into two equal groups: rehabilitation and control. Tools: Two tools were used 1) Socio-demographic characteristics and biomedical data interview schedule and 2) The Walking Impairment Questionnaire (WIQ). Results: There were no statistically significant differences between the study groups WIQ pretest scores (t=0.035-p=0.972), while at 3 months follow-up statistically significant differences in the posttest scores were found in favor of the rehabilitation group (t=4.13- p<0.001). Conclusion: The implementation of the physical rehabilitation program after LE bypass may be a promising intervention for those patients to restore their walking performance. Recommendations: Integrate the physical rehabilitation program into the comprehensive management after LE bypass surgery and it should be considered when updating clinical guidelines**

Keywords**: Arterial bypass surgery, Exercise, Functional status, Lower extremities, Physical rehabilitation, Revascularization.**

I. INTRODUCTION

Peripheral artery disease (PAD) is a worldwide public health challenge and a major cause of morbidity and mortality [1]. It is one of the manifestations of generalized atherosclerotic disease which is characterized by a partial or complete failure of the arterial system to supply the peripheral tissue with oxygenated blood[2, 3]. As similar to that of any other cardiovascular disease (CVD), well-known risk factors for PAD are male gender, age, smoking, diabetes mellitus, hyperlipidemia, and hypertension. The risk of developing PAD can be predicted by age. Its prevalence accounts for 12–14% of the general population and is estimated to present in up to 20% of patients older than 75 years [1, 4-6].

Lower extremity arterial disease (LEAD) is categorized into asymptomatic PAD, intermittent claudication (IC) and atypical leg pain, acute limb ischemia (ALI), and chronic limb ischemia, also known as critical limb ischemia (CLI)[7]. Asymptomatic patients do not have typical IC symptoms. Claudication is defined as fatigue, discomfort, or pain in the lower extremities (LE), usually, the calves, which is reproducibly brought on by exercise and alleviated by rest. CLI is defined by chronic ischemic rest pain, nocturnal recumbent pain, or ischemic skin lesions that may include ulcers or frank gangrene [8, 9]. Symptoms of CLI usually are existing for a minimum of 2 weeks. ALI manifests with a sudden decrease in limb perfusion causing an immediate threat to limb viability. The presentation can happen up to 2 weeks from the onset of symptoms. ALI may manifest with the "6 Ps" of pain, paralysis, paresthesia, pulselessness, poikilothermia, and pallor[8].

PAD is associated with limited physical capacity and impaired functional status (FS) [10]. Because of pain, patients often avoid physical activity (PA), especially ambulation, which leads to an additional decline in FS [11]. Precise clinical assessment supports decisions on management strategy and should objectively assess the severity of the ischemia and a need for revascularization[2]. Comprehensive management to reduce cardiovascular risk is necessary for all PAD patients. Besides, those with IC should receive therapy focused on improving walking ability, functional capacity, and patient-reported outcomes[12].

Additionally, CLI and lifestyle-limiting claudication can be treated with an endovascular intervention such as angioplasty to open the artery or with vascular surgery to bypass the arterial blockage using an artery from elsewhere in the patient's body. In some patients, a combination of endovascular and surgical interventions may be beneficial[13]. Bypass surgery is indicated when angioplasty has been failed or is unsuitable after proper imaging [9, 14, 15]. Both angioplasty and bypass surgery have shown a limb salvage rate of 80% at 3 years [13].

Postoperatively, patients anticipate that are that they will be free of pain and walk wel as l, but functional activity may still be restricted because of decreased confidence and muscle wasting a result of several factors, including hospitalization and prolonged recumbencas despite successful surgical treatment [16, 17]. Delay in the recovery in daily life activities involves an additional burden on health care resources. Traditional outcome measures, focusing only on technical "success", are usually considered poor predictors of functional outcome, whereas from a rehabilitative point of view, general mobility and ambulatory status, reflecting functional performances, are considered basic determines of outcome after surgery [17]. Unfortunately, advice on the benefit of an exercise program usually are not offered, despite the benefits shown in surgical and post bypass patients [16].

Supervised Exercise Therapy (SET) is recommended as an initial treatment for PAD and IC before any endovascular or open revascularization[9, 14, 18]. Clinical trials have consistently demonstrated that treadmill-based SET is beneficial in improving walking ability as assessed by graded treadmill testing and to be effective in patients with PAD both with and without classic symptoms of claudication ([19]. For example, in the 21 studies included in a meta-analysis by Gardner et al (1995), SET resulted in a significant mean improvement in graded treadmill testing among the studies[20]. This is supported by a meta-analysis by Fakhry et al (2012) summarized the results of 25 randomized clinical trials of supervised walking therapy in 1054 patients with PAD and claudication symptoms [21]. However, several barriers including the insufficiency of centers and physician referral, high transportation cost, and scarce coverage of medical insurance, restrict the PAD patients from participating in SET [12, 22-25].

Home-based walking exercise (H-BEx) is a promising alternative to SET [26]. Patients who are unable or unwilling to participate in SET may choose H-BEx intervention, which is effective in patients with PAD [18, 19]. Therefore, H-BEx programs have recently obtained attention in vascular medicine because they potentially overcome many of the obstacles associated with SET [12]. Several randomized controlled trials (RCTs) assessed the walking performance of structured home exercise (SHE) programs on PAD health outcomes. However, conclusions drawn from these trials are conflicting[26-28]. The 2016 American College of Cardiology (ACC) and American Heart Association (AHA) guidelines recommended identifying the best community- or home-based exercise programs for patients with PAD and the role of such exercise programs before or in addition to revascularization [18].

There is a dearth of studies investigating the effects of SHE when combined with surgical revascularization. Two studies evaluate the effect of SHE after an early rehabilitation phase and 18-20 days of treadmill based SET. The two studies included only patients with femoropopliteal (FP) bypass and prove the efficiency of these combined programs in improving walking performance [29, 30]. Since the hospital stay for vascular treatment is often a very short period throughout the whole disease process, nursing care needs to focus on supporting these patients in their environments. Therefore, knowledge of which domains of promotive and preventive should be continued over a longer period is important for the rehabilitation of these patients [31]. To fill this practice gap and meet the rehabilitative need of patients after LE bypass surgery, a walking based- SHE program was developed that follows an inpatient phase of physical rehabilitation. The results of the study can be used to guide the health care providers including the nurses in patient's rehabilitation after LE surgery, thereby improve patients' function and prevent disabilities. The program also will offer a low-cost intervention to the patient in their home.

AIM OF THE STUDY:

The study aims to determine the effect of physical rehabilitation on the patient's FS after LE bypass surgery.

RESEARCH HYPOTHESIS:

Patients undergoing arterial bypass surgery of the lower extremities who participate in the physical rehabilitation program exhibit high FS performance than those who do not.

II. MATERIALS AND METHOD

MATERIALS

Design: A quasi-experimental research design was used for this study.

Setting: The study was carried out at the vascular surgery department at Alexandria main university hospital and the vascular surgery outpatient clinic.

Subjects: A convenience sample of 40 patients who were planned for lower extremities arterial bypass surgery were included in the study using. Participants were divided into two equal groups (rehabilitation group and control group).

Tools of the study: the data was collected using the following tools:

***Tool (1): Socio-demographic characteristics and biomedical data interview schedule for the patient undergoing lower extremities arterial bypass surgery*:**

This tool was developed by the researcher after a review of the related literature [32-37]. It consisted of two parts as follows:

Part 1: Patients' Socio-demographic Characteristics: It gathered information about the patient's age, gender, marital status, educational level, employment, financial condition and residence area, and living environment (number of floors in the home, use of stairs versus elevator, the patient was living alone or with others)

Part 2: Patients' Clinical Data: it consisted of two sections as following:

Section 1: Associated comorbid conditions and PAD risk factors, this part gathered data about PAD risk factors and associated comorbid conditions including hypertension, cardiovascular disease, hyperlipidemia, diabetes mellitus, smoking status, body mass index (BMI). Hypertension was defined as a clinic BP >140/90 mm Hg or current use of antihypertensive drugs. Dyslipidemia was defined as total cholesterol >240 mg dl or the current use of anti-hyperlipidemic medications. Diabetes mellitus was defined by the current use of anti-diabetic medications and/or a history of previous diagnosis[38]. The BMI was calculated by a person’s weight in kilograms divided by the square of height in meters. BMI below 18.5 was considered underweight, 18.5 – 24.9 was a normal or healthy weight, 25.0 – 29.9 was overweight and BMI OF 30.0 and above was obese[39].

Section 2: History of the current illness: it gathered data about:

- The past history of the current illness; this included data about the onset of the disease and the previous treatment for the vascular condition (e.g. Lifestyle modification and cardiovascular risk reduction, pharmacological treatment, endovascular or surgical revascularization,….etc).

- The present history of the current illness; this included data about current diagnosis, the anatomical region of the lesion, duration of the surgery, surgical technique, and the graft type.

Tool 2: The Walking Impairment Questionnaire (WIQ):

The WIQ was first developed by Regensteiner et al (1990) [40]. The English translation of the French version of the WIQ adapted by [41] was used in this study. It is a simple self-administered, valid, reliable, and sensitive disease-specific

International Journal of Novel Research in Healthcare and Nursing
Vol. 7, Issue 3, pp: (390-407), Month: September - December 2020, Available at: www.noveltyjournals.com

instrument for assessing the functional status of PAD patients for available treatment options including exercise training, peripheral bypass surgery, endovascular therapy, and many types of medications[11, 19]. This tool contained 14 items that contributed to 3 subscales [11, 19, 42, 43]:

- The distance subscale included 7 statements to assess the degree of difficulty in walking specific distances (ranging from walking indoors to 20 meters (m), or 500m).

- The speed subscale included 4 statements to assess the degree of difficulty in walking about 300m at specific speeds ranging from walking slowly to jogging/ running.

- The stair-climbing subscale included 3 statements to assess the degree of difficulty climbing-specific numbers of flights (each flight equal 14 steps) of stairs ranging from one to three flights of stairs.

Scoring of the WIQ:

The scoring of the three subscales was similar. The participants answered each item on a graded Likert scale from zero to four (4 = no difficulty, 3 = slight difficulty, 2 = some difficulty, 1 = much difficulty, and 0 = unable to do). This graded score was multiplied by a pre-specified weight for each distance, speed, or number of stair flights. Scores weighted based on the difficulty of the task (e.g., the weight for “walk slowly” is 1.5 whereas for “run” is 5. Each subscale score ranged from 0-100 with lower scores indicating the lower performance of each subscale. The overall and combined (distance and stair) scores were calculated as the average of the subscales' scores. The patient's FS was categorized as follows [44].

- A score of 43 or less of the overall WIQ score was identified as low performers.

- A score of more than 43 or less than 70 of the overall WIQ score was identified as moderate performers.

- A score of 70 or higher of the overall WIQ score or a Score of 76 or higher of a combined distance and stair score was identified as high performers.

METHOD:

The study was accomplished as follows:

- Written approval was obtained from the Alexandria Main University Hospital administrative authority to collect the data after explaining the aim of the study.

- **Development and content validity of the study tools:**

- Tool 1 was developed by the researcher based on the related literature. Tool 2; the WIQ was translated into the Arabic language.

- The tools (1&2) were submitted to five experts from the Faculty of Nursing, Alexandria University to review and test content validity, and modifications were done based on their suggestions.

- **Rehabilitation program development**: A 2 phase's rehabilitation program table (1 &2) was developed after reviewing the related literature. A booklet containing the content of the program was designed. It was written in a simple Arabic language and supplemented by photos and illustrations to help the patients to understand the content. The booklet was submitted to five experts from the Faculty of Nursing, Alexandria University to review the content, and modifications were done based on their suggestions.

- **Reliability**: Tool 2 was tested for its reliability using Cronbach's coefficient Alpha test, the reliability coefficient was (0.939) which is highly acceptable.

- **Pilot study**: A pilot study was carried out on 10% of patients to test the clarity and applicability of the tools. Necessary modifications were done before data collection for the actual study; those patients were excluded from the study sample.

- **Sampling**: A convenience sample of 40 patients planned for lower extremities bypass surgery were recruited for the study. Recruited subjects were assigned to two equal groups (control group and rehabilitation group).

- Data collection:

- The final drafts of the structured tools were used to collect data to achieve the objective of this study. Data was collected for a period of 7 months starting from July 2019 to January 2020

- Each patient (control & rehabilitation groups) was interviewed by the researcher individually for approximately 30 minutes after explaining the purpose of the study to collect the necessary socio-demographic characteristics and biomedical data using tool 1.

- The FS of each patient in the control and rehabilitation groups was assessed preoperatively using tool 2.

- The control group was exposed only to the routine pre and postoperative hospital care in the ward by the hospital staff.

- Data was collected from the control group initially to prevent data contamination.

- The study group received two phases of physical rehabilitation including an in-patient phase-1 and structured home-based phase-2 physical rehabilitation.

- The day before the surgery, patients in the rehabilitation group were educated about the postoperative exercises and instructions included in the rehabilitation program.

- The in-patient phase-1physical rehabilitation (Table 1) started after the surgery till the patient's discharge. During this phase, diaphragmatic breathing, foot and leg range of motion exercises, and light resistance exercises were used. Patients encouraged to early ambulation out of the bed, walking, and stair climbing training.

Table 1: In-patient phase- 1 physical rehabilitation program

Type	Mode of training	Day	Frequency	Intensity	Duration
'	Diaphragmatic exercise	From the day of operation till discharge	5-10 times every 2 hours while awake	Moderate (RPE of 5-6/10)	-
Range of motion exercise	Foot and leg range of motion (ankle dorsoflextion, and planterflextion, ankle circle and leg raises exercises).	From the day of operation till discharge	5-10 repetitions every 2 hours while awake		-
Muscle-strengthening/ resistance exercise	Knee extensor strengthening without weight Knee flexor strengthening without weight and ankle dorsiflexor/ planter flexor strengthening without weight.#	From the 2nd POD till discharge	5-10 repetitions four sets/ day		-
Ambulation and walking training	Turning and positioning	From the day of operation till being Ambulant	Every 2 hours while awake		2 hours
	Getting out of bed and sitting on a chair.#	From the 1st or 2nd POD till discharge	1-2 times/ day		20-30 min
	Walking# (progress from inside to outside the room)		1-2 times/day		Start with 5 min* and progress as tolerated
	Stair Climbing and Descending#	From the 2nd or the 3rd POD till discharge	Once /day		Start with one step and progress as tolerated

POD: Postoperative day **RPE**: Rate of Perceived Exertion *not including rest periods.

#The first time the training will be done under the researcher's direct supervision.

International Journal of Novel Research in Healthcare and Nursing
Vol. 7, Issue 3, pp: (390-407), Month: September - December 2020, Available at: www.noveltyjournals.com

- During phase -1- rehabilitation an education session was held to given patients instruction regarding the use of assistive devices, weight-bearing restriction, and restricted activities.

- During phase-1, patients were exercised under the researcher's supervision and monitoring

- Before the patient's discharge; an education session was held to educate the patient about the structured 12 weeks phase-2 home-based program (table 2). Patients were instructed to walk 3 to 5 days/ week. Each walking session consisted of a 5–10 min warm-up, walking, and a 5–10 min cool-down. Patients were instructed to start intermittent walking with at least 10 min/ day and progressively increased at least by 5 minutes weekly until a total of 45 minutes of walking was achieved.

- Patients were instructed to exercise with a moderate intensity guided by the Borg's category ratio-scale (CR-10) for the rating of perceived exertion (RPE) between 5-6/10 during phase-1 and phase-2. The Borg's category ratio-scale (CR-10) is a valid and reliable tool that measures the perceived exertion, dyspnea, and pain. It covers an intensity variation from "Nothing at all" (=0) to "Extremely strong, Maximal" (=10)[45].

- Patients and their relatives were taught to identify heavy exertion (RPE >7) so that exercise could be terminated.

- The booklet containing the content of the program was used throughout the rehabilitation process and was given to the patient before discharge

- The patient's relatives were encouraged to be a part of the rehabilitation program and were educated on the importance of the exercise.

- During phase-2 of the rehabilitation program, the researcher made a phone call at the end of each week to review the training goals with the patients and give them guidance and support, and to complete a follow-up diary to assess training frequency and time spent in each of the prescribed training zones.

- The FS of each patient in the control and the rehabilitation group was assessed at the end of the program period using tool 2.

- The patients who did not attend at the time were phone called and a second appointment was made.

Table 2: Structured home-based phase- 2 physical rehabilitation program

Structured home-based program parameters					
Type	**Mode of training**	**Week**	**Frequency**	**Intensity**	**Duration/ Time**
Aerobic Exercise	Home /Community track Walking	1st -	3-5 times#/ week	Moderate (RPE of 5-6/10)	At least 10 min*
		2nd - 4th			15-30 min*
		5-7th			30-45 min*
		8-12th			45-50 min*

RPE: **Rating of Perceived Exertion** *not including rest periods

5 min warm-up phase of stretching the calf, hamstring, and upper limb muscles and 5 min cool-down will precede and follow each session of walking

Data processing and statistical analysis: the collected data were organized, tabulated, and statistically analyzed using SPSS software (Statistical Package for the Social Sciences, version 20, SPSS Inc. Chicago, IL, USA). Qualitative data were described using the number and percent. Parametric quantitative data were described using the arithmetic mean, standard deviation. Non-parametric quantitative data were described using range (minimum and maximum) and median. Comparison between two groups and more was done using the Chi-square test ($\chi 2$) and Fisher's Exact or Monte Carlo correction was used if more than 20% of the cells have expected count less than 5. Marginal Homogeneity Test was used to analyze the significance of the different stages. The student t-test was used to compare the means of the studied sample groups in normally distributed quantitative variables. F-test (ANOVA) was used for normally distributed quantitative variables, to compare more than two groups. Paired t-test, used for normally distributed quantitative variables, to compare the results before and after treatment in the same group. Mann Whitney test (U) was used for abnormally distributed quantitative variables, to compare between two group medians based on independent samples (by ranking). The Wilcoxon signed-rank test is used for abnormally distributed quantitative variables, to compare the data in case of two related samples or repeated measurements on a single sample. Significance was adopted at $p<0.05$ for interpretation of results of tests of significance

Ethical considerations: these included obtaining approval from the ethical committee, Faculty of Nursing, Alexandria University, and written informed consent from the study participants. Also, patients' privacy and data confidentiality was assured. Patients' right to withdraw at any time of research participation was considered and respected.

III. RESULTS

Regarding the socio-demographic characteristics of the study participants, table 3 reveals that the study included 40 patients the majority (92.5%) of them were male and more than half (55%) were more than 60 years old. The participants reported that 67.5% were married, 45 % had a sedentary occupation, and 60% reported that they live in the urban. 45% reported they live between the first and the third floor, 60 % of the total participants used stairs and the majority (90%) was living with others. Also, the table reveals that there was no statistically significant difference between the study groups regarding the socio-demographic characteristics (all P< 0.05).

Table 3: Frequency distribution of study participants according to socio-demographic characteristics

Socio-demographic Characteristics		Study Participants (n=40)		Rehabilitation group (n=20)		Control group (n=20)		Test of sig. (p)
		No	%	No	%	No	%	
Age in year	40-50	5	12.5	3	15	2	10	χ^2=0.559 (^{MC}p=0.824)
	50-60	13	32.5	7	35	6	30	
	More than 60	22	55	10	50	12	60	
	Mean ± SD.	59.68 ± 8.09		58.55 ± 8.44		60.80 ±7.77		t=0.877(0.386)
Gender	Male	37	92.5	19	95.0	18	90	χ^2=0.360 (^{FE}p=1.000)
	Female	3	7.5	1	5.0	2	10	
Marital status	Single	5	12.5	3	15	2	10	χ^2=0.816 (^{MC}p=0.794)
	Married	27	67.5	14	70	13	65	
	Widow	8	20	3	15	5	25	
Educational level	Illiterate	15	37.5	7	35	8	40	χ^2=1.735 (^{MC}p=0.781)
	Basic education	14	35.0	6	30	8	40	
	Secondary education	10	25.0	6	30	4	20	
	Higher education	1	2.5	1	5	0	0	
Occupation	Sedentary occupation	18	45.0	11	55	7	35	χ^2=2.039 (^{MC}p=0.391)
	Non-sedentary occupation	8	20.0	4	20	4	20	
	Retried or does not work	14	35.0	5	25	9	45	
Financial condition	Sufficient	22	55	10	50	12	60	χ^2=0.404 (0.525)
	Insufficient	18	45	10	50	8	40	
Residence area	Urban	24	60.0	11	55	13	65	χ^2=0.417 (0.519)
	Rural	16	40.0	9	45	7	35	
No. of the floor in the home	Ground	11	27.5	5	25.0	6	30.0	χ^2=0.828 (^{MC}p=0.930)
	1-3	18	45.0	10	50.0	8	40.0	
	4-6	8	20.0	4	20.0	4	20.0	
	≥7	3	7.5	1	5.0	2	10.0	

Use of stairs versus elevator at home	Stairs	24	60	14	70	10	50	χ^2=0.829 (0.362)
	Elevators	16	40	6	30	10	50	
Living with whom	Living alone	4	10	3	15	1	5	1.111 (^{FE}p=0.605)
	Living with others	36	90	17	85	19	95	
Total		40	10	20	100	20	100	

χ^2: **Chi-square test** MC: **Monte Carlo** FE**: Fisher Exact** t**: Student t-test**

p: value for comparing between the studied groups

With regard to the associated comorbid conditions and PAD risk factors, table 4 reveals that (47%), (35%), (27.5%) of the study participants had a history of hypertension, cardiovascular disease, and hyperlipidemia respectively. Also, an equal percentage of the participants (50%) reported that were active smokers, overweight, and had diabetes mellitus. Moreover, the table displays that, there was no statistically significant difference between the two groups regarding the associated comorbid conditions and PAD risk factors (all P< 0.05).

Concerning the past history of the current illness; **table 5** indicates that less than half of the participants (42.5%) had the vascular condition for 12-36 months. In respect of the previous treatment for the vascular condition, the highest percent (82.5%) did not participate in lifestyle modification and cardiovascular risk reduction; in contrast, 77.5% of the participants received pharmacological treatment. The minority (15%) and (2.5%) had previous endovascular revascularization and surgical revascularization respectively. Additionally, a minority (2.5%) of them participated in exercise rehabilitation previously and/ or had previous toe(s) amputation. While 10% of the participants reported that they did not receive any previous treatments. Besides the results displayed in the table indicate that there were no statistically significant differences between the two study groups regarding the past history of the current illness (all P< 0.05).

Table 4: Frequency distribution of study samples according to associated comorbid conditions and PAD risk factors:

Associated comorbid conditions and PAD risk factors		**Study Participants (n=40)**		**Rehabilitation group (n=20)**		**Control group (n=20)**		**Test of sig. (p)**
		No	%	No	%	No	%	
Hypertension	Yes	19	47.5	9	45	10	50	χ^2=0.100 (0.752)
	No	21	52.5	11	55	10	50	
Cardiovascular disease	Yes	14	35	5	25	9	45	χ^2=1.758 (0.185)
	No	26	65	15	75	11	55	
Hyperlipidemia	Yes	11	27.5	5	25	6	30	χ^2=0.125 (0.723)
	No	29	72.5	15	75	14	70	
Diabetes mellitus	Yes	20	50	12	60	8	40	χ^2=1.600 (0.206)
	No	20	50	8	40	12	60	
Smoking status	Active smoker	20	50	9	45	11	55	χ^2=0.753 (^{MC}p=0.774)
	Nonsmoker	12	30	6	30	6	30	
	Quitter	8	20	5	25	3	15	
BMI = w	Normal weight	15	37.5	7	35	8	40	χ^2=1.950 (^{MC}p=0.453)
	Overweight	20	50	9	45	11	55	
	Obese	5	12.5	4	20	1	5	
Total		40	100	20	100	20	100	

PAD: **Peripheral Arterial disease** BMI: **Body Mass Index** χ^2: **Chi-square test**

MC: **Monte Carlo** p: p-value for comparing between the studied groups

ISSN 2394-7330

International Journal of Novel Research in Healthcare and Nursing
Vol. 7, Issue 3, pp: (390-407), Month: September - December 2020, Available at: www.noveltyjournals.com

Table 5: Frequency distribution of the study sample according to the past history of the current illness

The past history of the current illness		Study Participants (n=40)		Rehabilitation group (n=20)		Control group (n=20)		Test of sig. (p)
		No.	%	No.	%	No.	%	
Onset of the disease (Month)	<12	16	40	9	45	7	35	χ^2=3.883 (^{MC}p=0.296)
	12-36	17	42.5	8	40	9	45	
	36-60	4	10	3	15	1	5	
	>=60	3	7.5	-	-	3	15	
	Mean ± SD.	29.2±34.22		22.65±17.679		32.75±43.31		t(p)=1.218(0.235)
Previous treatment for the vascular condition								
Lifestyle modification and cardiovascular risk reduction	Yes	7	17.5	4	20	3	15	χ^2=0.173 (^{FE}p=1.000)
	No	33	82.5	16	80	17	85	
Pharmacological treatment	Yes	31	77.5	16	80	15	75	0.143 (^{FE}p=1.000)
	No	9	22.5	4	20	5	25	
Endovascular revascularization	Yes	4	10	2	10	2	10	χ^2=0.00 (^{FE}p=1.000)
	No	36	90	18	90	18	90	
Surgical revascularization	Yes	6	15	2	10	4	20	χ^2=0.784 (^{FE}p=0.661)
	No	34	85	18	90	16	80	
Exercise Rehabilitation	Yes	1	2.5	0	0	1	5	χ^2=1.026 (^{FE}p=1.00)
	No	39	97.5	20	100	19	95	
Toe(s) amputation	Yes	10	25	6	30	4	20	χ^2=0.533 (0.465)
	No	30	75	14	70	16	80	
Not receive any previous treatments	Yes	4	10	2	10	2	10	χ^2=0.00 (^{FE}p=1.000)
	No	36	90	18	90	18	90	
Total		40	100	20	100	20	100	

χ^2: **Chi-square test** MC: **Monte Carlo** FE**: Fisher Exact** t**: Student t-test**

p: p-value for comparing between the studied groups

Regarding the present history of the current illness, **table 6** reveals that all participants were diagnosed with CLI, the majority (87.5%) of them had femoropopliteal bypass surgery. Also, in the majority (87%) the surgery took 180-240 minutes. More than half (52.5%) of them had end-to-side anastomosis, with about two-thirds (65%) of the participants had synthetic graft. Additionally, the table shows that there were no statistically significant differences between the two groups regarding the present history of the current illness (all P< 0.05).

Table 6: Frequency distribution of study samples according to the present history of the current illness

The present history of current illness		Study Participants (n=40)		Rehabilitation group (n=20)		Control group (n=20)		Test of sig. (p)
		No	%	No	%	No	%	
Current Diagnosis	Chronic critical limb ischemia	40	100	20	100	20	100	-
Anatomical region of the bypass surgery	Femoropopliteal	35	87.5	16	80.0	19	95	χ^2=2.291 (^{MC}p=0.414)
	Infra-popliteal	2	5.0	2	10.0	0	0	
	Ilio-popliteal	3	7.5	2	10.0	1	5	
Duration of the surgery (minute)	180-240	35	87	18	90.0	17	85.0	χ^2=1.088 (^{MC}p=1.000)
	240-300	4	10	2	10.0	2	10.0	
	300-360	1	2.5	0	0.0	1	5.0	

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Surgical technique	End to end distal anastomoses	19	47.5	11	55.0	8	40	χ^2=0.902 (0.342)
	End to side anastomoses	21	52.5	9	45.0	12	60	
Graft type	Autologous vein graft	14	35	6	30	8	40	χ^2=0.440 (0.507)
	Synthetic graft	26	65	14	70	12	60	
Total		20	100	20	100	20	100	

χ^2: **Chi-square test** MC: **Monte Carlo**

p: p-value for comparing between the studied groups

Regarding the intragroup Comparison of pre-test and post-test percent scores of functional status for the rehabilitation group (n=20), **table 7** shows that there was a statistically significant difference between the pretest (Mean ± SD= 21.62 ± 10.75) and posttest (Mean ± SD = 64.22 ±12.37) of the total walking impairment percent scores (t=28.344, p <0.001). Moreover, there were significant differences (Z=3.922, p<0.001), (Z=3.925, p<0.001), and (t=16.548, p<0.001) between the pretest and posttest of walking distance, walking speed, and stairs climbing percent scores respectively.

For the control group (n=20), table 8 shows that there was a statistically significant difference between pretest (Mean ± SD= 21.74 ±9.90) and posttest (Mean ± SD = 49.24 ±10.48) of the total walking impairment percent score (t=13.035, p <0.001). Also, there were statistically significant differences (Z=3.920, p<0.001), (Z=3.832, p<0.001), and (t=14.166, p<0.001) between the pretest and posttest of walking distance, walking speed and stairs climbing percent scores respectively.

Table 7: Intragroup comparison of pre-test and post-test percent score of the rehabilitation group functional status

Functional status domain	**Pre-test**	**Post-test**	**Test of sig. (p)**
Walking distance			Z=3.922* <0.001*
Min. – Max.	0.0 – 47.44	38.28 – 87.22	
Median (IQR)	8.03(1.10–19.11)	63.78(55.54–73.9)	
Walking speed			Z=3.925* <0.001*
Min. – Max.	0.0 – 21.74	25.0 – 78.26	
Median (IQR)	7.61(3.26–17.39)	57.61(51.63–65.7)	
Stairs climbing			t=16.548* <0.001*
Min. – Max.	12.50 – 66.67	37.50 – 87.50	
Mean ± SD.	43.33 ± 17.07	72.50 ± 15.85	
Total score			t=28.344* <0.001*
Min. – Max.	7.91– 42.51	39.39 – 84.87	
Mean ± SD.	21.62 ± 10.75	64.22 ± 12.37	

Z: **Wilcoxon signed ranks test** **t: Paired t-test**

p: p-value **for** comparing between pre and post-test *: Statistically significant at p ≤ 0.05

Table 8: Intragroup comparison of pre-test and post-test percent score of the control group functional status

Functional status domain	**Pre-test**	**Post-test**	**Test of sig. (p)**
Walking distance			Z=3.920* <0.001*
Min. – Max.	0.50 – 51.56	25.14 – 75.50	
Median (IQR)	9.06 (7.95–24.68)	53.13(39.84–56.9)	
Walking speed			Z=3.832* <0.001*
Min. – Max.	0.0 – 40.22	21.74 – 67.39	
Median (IQR)	7.61(3.26–17.39)	42.39(32.61–46.7)	

Stairs climbing			
Min. – Max.	16.67 – 62.50	29.17 – 87.50	tp=14.166* <0.001*
Mean ± SD.	36.25 ± 10.65	57.92 ± 13.58	
Total score			
Min. – Max.	8.50 – 44.48	28.97– 68.46	tp=13.035* <0.001*
Mean ± SD.	21.74 ± 9.90	49.24 ± 10.48	

Z: **Wilcoxon signed ranks test** **t: Paired t-test**

p: p-value **for** comparing between pre and post-test *: Statistically significant at $p \le 0.05$

Regarding the intergroup comparison, **table 9** shows that there was no significant difference (t=0.035, p=0.972) in the pretest WIQ total score between the rehabilitation group (Mean ± SD= 21.62 ± 10.75) and the control group (Mean ± SD = 21.74 ± 9.90). Also, there were no statistically significant differences (U=149.5, p=0.174), (U=181, p=0.620), and (t=1.574, p=0.125) between the pretest walking distance, walking speed and stairs climbing percent scores among the two groups respectively.

While the posttest of the WIQ total score was statistically significant higher (t=4.131, p=<0.001) in the rehabilitation group (Mean ± SD=64.22 ± 12.37) than the control group (Mean ± SD=49.24 ± 10.48). Additionally, there were statistically significant differences (U=97.5, p=0.005), (U=61.5, p p<0.001),) (t=3.125, p=0.003) between the posttest walking distance, walking speed and stairs climbing percent scores among the two groups respectively.

Table 9: Intergroup comparison of pre-test and post-test percent scores of the functional status

Functional status domain		Rehabilitation group (n=20)	Control group (n=20)	Test of sig. (p)
Walking distance	**Pretest** Min. – Max. Median (IQR)	0.0 – 47.44 8.03(1.10–19.11)	0.50 – 51.56 9.06 (7.95–24.68)	U=149.5 (0.174)
	Posttest Min. – Max. Median (IQR)	38.28 – 87.22 63.78(55.54–73.9)	25.14 – 75.50 53.13(39.84–56.9)	U=97.50* (0.005*)
Walking speed	**Pretest** Min. – Max. Median (IQR)	0.0 – 21.74 7.61(3.26–17.39)	0.0 – 40.22 7.61(3.26–17.39)	U=181.0 (0.620)
	Posttest Min. – Max. Median (IQR)	25.0 – 78.26 57.61(51.63–65.7)	21.74 – 67.39 42.39(32.61–46.7)	U=61.50* (<0.001*)
Stairs climbing	**Pretest** Min. – Max. Mean ± SD.	12.50 – 66.67 43.33 ± 17.07	16.67 – 62.50 36.25 ± 10.65	t=1.574 (0.125)
	Posttest Min. – Max. Mean ± SD.	37.50 – 87.50 72.50 ± 15.85	29.17 – 87.50 57.92 ± 13.58	t=3.125* (0.003*)
Total score	**Pretest** Min. – Max. Mean ± SD.	7.91– 42.51 21.62 ± 10.75	8.50 – 44.48 21.74 ± 9.90	t=0.035 (0.972)
	Posttest Min. – Max. Mean ± SD.	39.39 – 84.87 64.22 ± 12.37	28.97– 68.46 49.24 ± 10.48	t=4.131* (<0.001*)

t: Student t-test **U: Mann Whitney test** Z: **Wilcoxon signed ranks test**

p: p-value for comparing between the studied groups *: Statistically significant at $p \le 0.05$

With reference to the pretest functional status categories, fig. 1 illustrates that the majority (97.5%) of the studied sample were low performers, with100% of the rehabilitation group, and 95% of the control group were low performers. **Regarding the posttest functional status categories**, fig. 2 displays that less than half (45%) of the studied sample were moderate performers, more than two-thirds (65%) of the rehabilitation group were a high performer, and more than two-thirds (65%) of the control group were moderate performers.

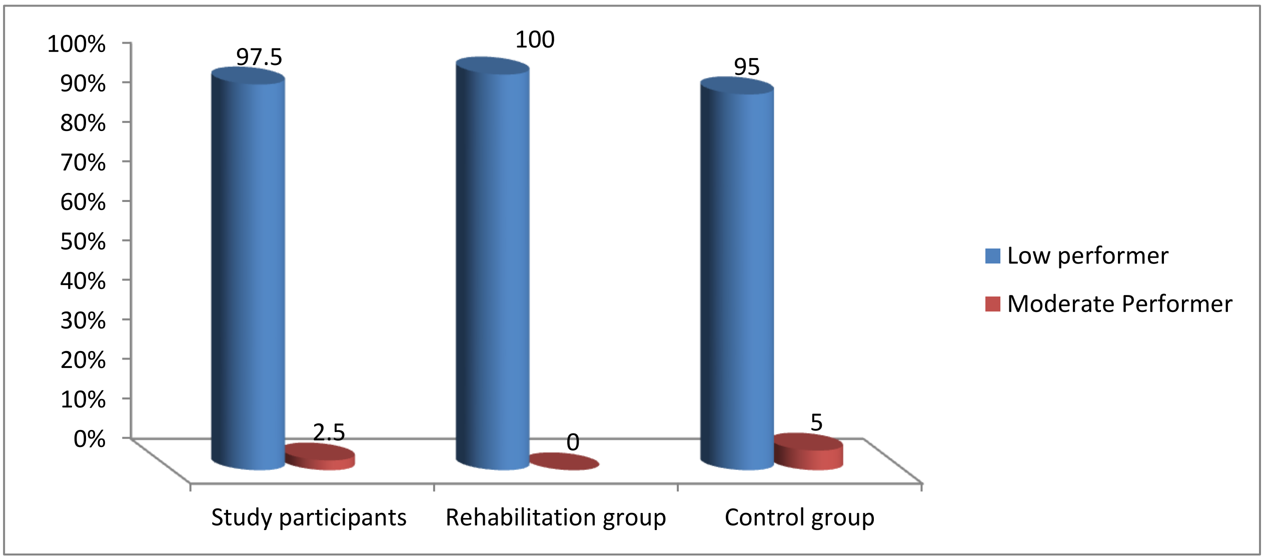

Fig. 1: Distribution of the pretest functional status categories of the study samples

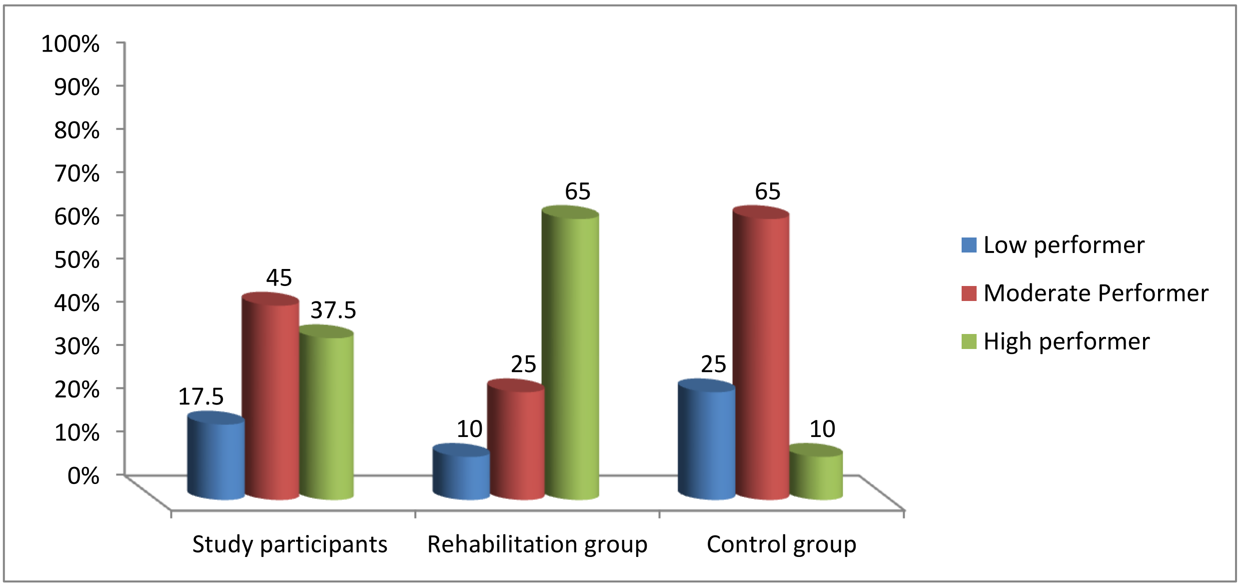

Fig. 2: Distribution of the posttest functional status categories of the study samples

IV. DISCUSSION

The results of the study are promising for patients after LE bypass surgery. Results at 12 weeks follow up demonstrated that both groups (LE bypass + rehabilitation and LE bypass only) achieved significant functional improvement with a significant difference between the groups in favor of the rehabilitation group.

Over recent years there has been a meaningful increase in the use of aggressive endovascular procedures to treat patients with CLI [46, 47]. However, the traditional lower limb bypass remains the gold standard and has been shown to benefit patients in the longer term[47]. Numerous studies have confirmed functional improvements at short and long-term follow-up after LE bypass surgery for CLI[47-55]. However, other studies that investigated the durability of improved functional status and HRQoL concluded that they deteriorate despite successful limb salvage at long-term follow-up [31, 57, 58].

There have been rigorous investigations centered on the effects of exercise in PAD patients with IC and the results imply that exercise is a safe and effective treatment option[59]. Little is known about the effects of exercise therapy after invasive treatment for PAD[31]. The authors reported a positive effect of supervised exercise therapy (SET) on walking distance after endovascular revascularization for IC compared with best medical treatment (BMT) [60-63].

Moreover, there are four RCTs comparing exercise versus BMT in post peripheral bypass surgery which showed similar results of significantly increased walking distance and HRQoL in the postoperative exercise group[16, 29, 30, 64]. Lundgren et al (1989) [64] randomized 75 patients with IC were to three groups (reconstruction alone, reconstruction combined with physical training, or physical training alone). The supervised training program was comprised of three sessions per week of dynamic leg exercise beyond the appearance of leg pain for 30 minutes in each session. Also, the patients were encouraged to exercise during their leisure time. The study identified significant functional improvements in the three groups. However, patients undergoing combination therapy had a significantly improved walking performance at 12 months follow-up[64].

Badger et al (2007) [16] randomized 14 patients after infrainguinal reconstructive surgery to a control group with standard care or exercise group with a SET. In the exercise group, patients walked supervised on the treadmill at 2.0 miles/hour and a 10° gradient for a total of 30 minutes two times per week. The program began 4 weeks after surgery and lasted for 6 weeks. The results of the study noted improvements in the walking distance in the exercise group. Moreover, the improvement in general Health- Short Form (SF-36) questionnaire physical score suggested that both surgery alone and the exercise program enhance the quality of life. Also, the disease-specific WIQ found a significant difference at 6 weeks postoperatively in favor of the exercise group[16].

The other two studies support the findings of the current study were conducted by Jakubseviciene et al., (2014) and Jakubsevičienė et al., (2019). These studies had investigated the effectiveness of an exercise rehabilitation program on the FS and the HRQoL of the patients who underwent femoral-popliteal artery bypass grafting. In the two studies, the patients were assigned into two groups. The two groups received an average of 7 days of early inpatient rehabilitation then each group continued 18 days of SET at a rehabilitation center. The first group received rehabilitation with the usual SEP. After usual SET patients were recommended to continue physical training programs. Whereas the second group received a new SEP developed for PAD patients. The SET included a 5–10 min warm-up followed by lower limb exercises comprised of treadmill exercise, stair climbing, and track walking; and end with a 5–10 min cool-down The intensity of training was based on clinical conditions and established between 60%–85% of the HRmax. After 18 days of the new SEP, the intervention group was assigned to a structured home exercise (SHE); patients were directed to walk for at least 30 min a day, three to five times per week, and to increase their walking time as possible, and to start with a warm-up phase and ending with a cool-down period. Besides, the studied rehabilitees were provided with a physical activity (PA) diary that included instruction on how to complete it. Both groups received optimal pharmacological treatment[29, 30].

(Jakubsevičienė et al., 2014; Jakubsevičienė et al., 2019). In Jakubsevičienė et al (2019) study, patients of the first and second groups who refused stage 2 rehabilitation were assigned to a third group (control group)[30]. These studies revealed that patients participating in a six-month-long physical exercise program had a significantly higher HRQoL after their surgery compared with patients participating in the standard physical activity program and the control group[29, 30].

Home-based exercise preserves the effort, time, and cost associated with travel for SET. Therefore, H-BEx has the potential to be more accessible and acceptable than supervised exercise programs for patients with PAD[65]. Out of the above-mentioned studies, only Jakubsevičiene et.al 2014 and Jakubsevičienė et al 2019 have included a phase of SHE in postoperative rehabilitation. None of them had studied the effect of the SHE exclusively after LE bypass. However, recent studies have provided strong evidence in support of the community- or home-based exercise approach for patients with PAD[18].

Gardner et al., (2011) randomized 119 patients with IC into 3 groups (SHE group quantified with a step activity monitor, SET group, and usual-care control group). The SHE program is designed to be as analogous to the SET as possible. Changes in exercise performance and daily ambulatory activity were compared among the groups. At a 12-week follow-up, the study concluded that the SHE program has high adherence and is efficacious as standard SET in improving claudication measures. Furthermore, it appeared more efficacious in increasing daily ambulatory activity in the community setting than SET[28].

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Collins et al., (2011) randomized 145 patients with diabetes and PAD to a 6-month behavioral intervention versus attention control to assess levels of readiness to participate in the routine walking for exercise. The study concluded that home-based walking intervention did improve walking speed and quality of life in people with diabetes and PAD and clinicians should consider recommending home-based walking therapy for such patients[27].

Gardner et al., (2014) conducted RCT and assigned 180 symptomatic PAD and claudication to 3 groups for 12 weeks: treadmill-based SET, a step watch home exercise program, or a light resistance training group focused on the upper extremities. The study concluded that improvement in the walking abilities was greater in the home exercise program group than in the SET group[66].

The Group Oriented Arterial Leg Study (GOALS trial) tested the ability of a group-mediated cognitive behavioral (GMCB) intervention to help participants with PAD adhere to the SHE, thereby improving their walking performance. Participants were randomized to either GMCB intervention or an attention control group for 6 months [67]. At 6-months follow-up, compared to the control group, patients randomized to the intervention group significantly improved the 6-min walk distance, maximal and pain-free treadmill walking distance, PA level, and patient-perceived walking endurance and speed measured by the WIQ [26]. Results at 12 months follow up concluded that walking exercise intervention that employed GMCB intervention and encouraged regular home-based exercise continued to benefit PAD participants at 12 months follow-up compared to a control group[68].

As the final remark, it noteworthy that a physical rehabilitation program that includes an initial inpatient phase and a subsequent phase of SHE is effective in improving the walking performance after LE bypass. The endorsement of this program for those patients is vital for their management.

V. CONCLUSION

In total 20 patients with CLI participated in the rehabilitation program and 20 patients who did not. Positive effects were found on the functional status in both groups at the12 weeks follow-up. However, the intervention in the rehabilitation group was more efficient compared to the control group in improving the FS after LE bypass surgery. These results may be promising for those patients to restore their walking performance.

VI. RECOMMENDATIONS

Based on the finding of the study, the following recommendations are suggested:

- Integrate the physical rehabilitation program into the comprehensive management after LE bypass surgery for CLI.
- The program should be considered when updating the clinical guidelines.
- The health care team managing patients undergoing LE bypass should incorporate a rehabilitation nurse or physician to help patients to reach their best function and health, and to adapt to an altered lifestyle.
- Moreover, a patient handout that illustrates the postoperative rehabilitation program should be accessible to patients.
- Further large-scale studies are required to verify our promising results.
- A comparative clinical trial to compare the outcome of this physical rehabilitation program with other forms of exercises that have been proven as effective for PAD (e.g SET, resistance training, .….).
- The effect of the program on the physiological function should be evaluated.
- Patient compliance with the rehabilitation program and the factors affecting their compliance should be explored.

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