Effect of Lifestyle Modification on Functional Ability and Outcomes for Patients with Lower Limb Ischemia

[1]Entisar G. Shabaan and [2]Safaa M. Hamed

[1]Department of Medical and Surgical Nursing,
Faculty of Nursing, Aswan University, Aswan, Egypt
[2]Department of Medical and Surgical Nursing,
Faculty of Nursing, Benha University, Benha, Egypt

Abstract: Lower limb ischemia (LLI) associated with significant morbidity, mortality and activity impairment. LLI patients have poor baseline function, loss of functional status and ability to live independently with a risk of amputation if LL is not revascularized. This study aimed to investigate effect of lifestyle modification on functional ability and outcomes for patients with LLI. Design: Quasi-experimental design was utilized in this study. *Setting*: The study was carried out at the Vascular and Surgical departments at Benha University Hospital. During the period from the beginning of March 2019 till the beginning of March 2020. *Sample*: Purposive sample of 120 patients to be at the end of study period (Intervention group 60 & control group 60). *Tools*: Three tools used to collect the study data. These are structured interview questionnaire regarding the patients' demographic characteristics, medical data, assessment symptoms sheet and Patient knowledge regarding LLL, Lifestyle and Activiy of Daly living (ADL) checklist. Compliance Supervised exercised program *Results*: showed that there was highly statistically significant difference in term of increased knowledge level among the intervention group compared to controls, as well as a significantly improvement changes in symptoms assessment, a higher level of independence in performing ADL, besides, a higher mean score of supervised exercise program compliance among intervention group compared to controls. Conclusion: Implementing life style modification and supervised exercise program for patients with LLI was effective in improving their pain, pulse palpation odema redaction and knowledge about disease process. Also, performing ADL as well as its effectiveness in improving the functional ability and patient outcome among intervention group than in control group.

Key words: Lower Limb Ischemia · Daily Activities · Functional Ability · Patients Outcomes

INTRODUCTION

LLI patients have a tremendous disease burden, with poor baseline function, loss of functional status and ability to live independently. In addition, the ischemic pain resulting from CLI causes impaired functional status and strongly associated with multiple co-morbidities resulting in increased risk of death, complications and amputation [2].

Patients with LLI frequently impairment of sleep and walking performance, or even inability to walk and leading to decreased quality of life, as will as feelings of loss of control and social isolation [3].

Approaches in LLI include conservative management, LL revascularization or amputation. Considering the functional repercussions of LLI, these patients should be approached by a multidisciplinary team during hospitalization periods. Therefore, this study proposed to establish a consensus of specialists directed to plan of care for patients with LLI, pre- and post- LL revascularization [4].

LLI Patients should receive a comprehensive treatment plan that includes a structured exercise program with recommended lifestyle modifications to reduce ischemic events and improve functional status and relieving signs and symptoms and preserving tissue are the primary goals for treating LLI [5].

Coresponding Author: Entisar Gaad-Elmoula Shabaan, Department of Medical and Surgical Nursing, Faculty of Nursing, Aswan University, Aswan, Egypt. Tel: +01006846565.

Nursing care of patients with LLI or at risk for amputation should include education about tobacco and smoking cessation and managing hypertension, diabetes and dyslipidemia. This includes complince to medications as prescribed, ensuring adequate nutrition, skin care and tight glycemic control [6].

Patient oriented outcome the end points of the study, such as health related functional status, are essential in defining optimal treatment options for the patients with LLI. This area of research remains in its infancy, but will become increasingly important as the population of patients with LLI and treatment options for these patients continue to expand [7].

Significance of the Study: From previous studies the LLI frequently are accompanied by threatening ischemic are worsening in limb perfusion causing a potential complication, with a risk of amputation if LL is not revascularized [6]. Statistics in vascular and surgical departments at Benha University hospital. in year 2019 reported that, the number of patients admitted with LLI, was 172, of them 60 or 70 patients with ALI Benha University Hospital Record [8].

This study could be beneficial in many ways; lifestyle modification and exercise is beneficial to all Patients with LLI should receive a comprehensive lifestyle and risk factors modification and patient performed normal ADL, also supervised exercise program, to reduce ischemic events and improve functional status.

Operational definition:
Functional Ability: Meaning life style and ADL for patient's LLI.

Patients' Outcomes: are intended in this study to measure assessment symptoms (Pulse palpation, Auscultation for femoral bruits, inspection of legs and feet, pain scale and edema).

Aim of the Study: This study aimed to investigate the effect of the lifestyle modification on functional ability and outcomes for patients with lower limb ischemia.

Research Hypotheses
H1: Improve knowledge level for patients with LLI among study group than control.

H2: Improve of functional ability (life style and ADL) for patients with LLI among study group than control.

H3: Improve of outcomes level for patients with LLI among study group than control.

H4: Significant improvement in mean score of supervised educational program compliance for patients with LLI among study group than control.

MATERIALS AND METHODS

Research Designed: A quasi experimental research design (pre/post study/control) was used in this study.

Study Variables: The independent variable is lifestyle modification while the dependent variable is performing supervised exercise program and ADL.

Setting: The study was carried out at the Vascular and Surgical departments at Benha -University Hospital.

Sample: A purposive sample of 120 adult patients (45 males and 85 females study and control groups) who suffered from LLI was admitted to Vascular and Surgical departments at Benha University Hospital.

The Inclusion Criteria: Were as follows: Adult male and female patients, their age ranged between 20 to 65 years old, recent admission with lower limb ischemia and able to communicate and cooperate with the researcher.

The Exclusion Criteria: Included with previous surgery or gangrene, other medical problems and muscle-skeletal deformity that may interfere with perform normal daily activities.

Sample Size: Was estimated using the Epi info 7 statistical programs based on the previous year's statistical report of admission to the vascular and surgical departments at Benha universty Hospital from the statistical department, 2019 at 90% confidence level and acceptable margin of error 5%. The total sample size was 172. One hundred and twenty patients consented to participate in the study. They were divided randomly into two equal groups (study and control) and each group was containing 60 patients.

Tools of Data Collection
Three Tools Are Used for Data Collection for this Study.
Tool (I): Structured Interviewing Questionnaire: It developed by the researchers based on reviewing the current literature; Smith and Field [9], used to assess

patients' demographic characteristics and medical data. It divided into four parts as follows:

Part I: Socio-demographic Data: Such as the patient's ID, age, gender, occupation and cohabitation.

Part II: Medical Data: related to patient's risk factors, severity of disease, level of disease, leg side of disease, degree of patient dependence.

Part III: Symptoms Assessment Contains (Pre & Post): adopted from (7) it include: distal pulse palpation, auscultation femoral bruits, pain scale and edema.

Part VI: Structured Knowledge Questionnaire (Pre/post-Test): It is developed by the researchers after reviewing related recent literatures of Herman, Gornik and Barrett [10]. It was used to assess patients' knowledge related to ischemic diseases (definition, causes, types, signs and symptoms, diagnosis, treatment and protection from its complication) and personal care activities.

Scoring System: All knowledge variables weighted according to the items included in answer to each question. One point was given for each correct answer and zero was given to the incorrect one, contained 40 points. A score of more than 50 % consider satisfactory knowledge,> 50% consider unsatisfactory knowledge.

Tool (II): Lifestyle and Activity of Daily Living (ADL) checklist (Pre- Post test): It was adapted from Halperin, Halperin, Levine and Al-Khatib [11] and modified by the researchers to suit the aim of the current study. To assess patient functional abilities to perform ADL independently and life style modification. Use the checklist to detect problems in performing ADL and to plan care accordingly. It was translated into Arabic and it includes 12 questions sub-items regarding the ability to perform specific activities as wearing elastic socks, skin inspection, suitable shoes, etc. Each activity was evaluated on a scale of 0- 4 and the results were summed (0 = for complete assistance, 1= needed some assistance, 2 = with difficulty, 3 = mild compromise, 4 = normal).

Tool (III): Compliance Supervised Exercised Program: It was adapted from Halperin, Levine and Al-Khatib [11] and modified by the researchers to suit the aim of the current study. It includes physical activity the first part is pertinent to exercises (range of motion exercises). The second part was Mobility activities: Patient

independent with exercise and walking. The total Supervised exercised compliance score was Impaired physical activity was given a score of (1) and full physical activity was given a score of (2).

Teaching Material (Booklet): The general objective of the instruction was to help patients with LLI to regain normal live. The educational instruction was developed by the researchers based on the knowledge and practices needs in a form of printed Arabic booklet. The booklet was adopted from Herman, Gornik and Barrett [10]. Then the instruction was reviewed by a panel of experts before its implementation. Using simple Arabic language and different illustrated pictures to facilitate understanding of its contents.

Administration Approval: Official permission letters were obtained from the head of the vascular and surgical departments at benha University hospital to conduct the research.

• The first tool (structured interview questionnaire) was developed by the researcher after extensive review of the relevant literature. The tool (I) was tested for content validity by five experts of academic medical and nursing staff at Aswan &Benha University. Modifications were done accordingly and then the tool was designed in their final format and tested for reliability using internal consistency for the tool measured using Cronbach alpha test, the tools were approved to be reliable (0.86) (Acceptable alpha $\geq$ 0.8).

Data Collection: Data were collected from March 2019 till the beginning of March 2020. The data collection was done through the following phases:

Preparatory Phase (Assessment Phase): The researcher interviewed the patients with LLI who admitted to vascular and surgical department to explain purpose and nature of the study and get their oral consent to participate in the study. Categorization of the patients into two groups (study and control) (60 patients for each) was done.

Implementation Phase: Patients in the study group were interviewed individually by the researcher in the preoperative period at the vascular and surgical departments for twice and received two sessions for about 40 minutes for each. The first session started by

explaining the purpose and nature of the study and the objectives of the session then includes oral and written instructions.

The researchers assessed the patients' knowledge by written pre-test. The developed health education about lifestyle and risk factors modifications was implemented individually for the study group in the vesicular, nurses and physical medicine department. The educational instructions about lifestyle modification, ADL was performed for patients with LLI in the form of 4 scheduled sessions pre discharge, immediately post discharge and at one month, three months' post discharged.

After each session, there was 10 minutes for discussion and giving feedback. Reinforcement of teaching was performed according to patient's needs to ensure their understanding. Patients in the study group were encouraged to use the affected limb in ADL and were encouraged to perform Passive Range-of-Motion Exercises.

In discharge day; discharge plan was taught to the subject. It includes Assess legs and feet for indications of LLI**.** Ask patient about pain, if known pain, assess more often. Evaluate skin: color, hair, shiny, thin, edema. Written booklet was given to the patients. Before patients discharged post -discharge knowledge test was done. A control group patient matched to the study group never had pre- discharge instruction during the study period, but instructions given at the end of the study time.

Evaluation Phase: Evaluation of the instructions success was based on the patients' compliance. This evaluation was done two times for symptoms and three for compliance. Discharge compliance instruction was completed from the participant by utilizing telephone call during first and three months after discharge, because of difficulties for patients in moving and transferring. Feedback and follow up visit at outpatient clinic during one and third months.

Statistical Analysis: Statistical Package for Social Science (SPSS), version 21 was for statistical analysis of the data. The following tests were used, arithmetic mean as an average, describing the central tendency of observations. The frequency and percentage of observations and repeated measures, ANOVA was used to measure the change over time for the studied variables.

RESULTS

Table (1) shows socio-demographic characteristics of patients with LLI, it was observed that, regarding their age 74% of study group & 64.0% of the control group were at age 35 <50 and more than half (74% & 76.7%, respectively) of both groups were females as well as, (58.33 &75.0 %) respectively were house wife. Moreover (90.0 %& 76.7%) were living with family, with a non-significant difference between both groups at the beginning of the study.

Table 1: Comparison between the study and control groups regarding their demographic characteristics (N= 120).

Socio-demographic characteristics.	Intervention group baseline (N=60)		Control group (N=60)		Ch. square	P-value
	N	%	N	%		
Age:						
▪ 35 <50	41	74	42	64.0	1.436	0.274
▪ 50 <65	10	16.7	8	13.33		
▪ >65	9	6	10	16.7		
Mean ± SD=	44.67±4.87		35.52±5.72		2.451	0.382
Gender:						
▪ Male	19	26	16	33.3	1.652	0.426
▪ Female	41	74	44	76.7		
Occupation:						
▪ Government employee.	9	15.0	0	00.0	1.324	0.121
Student	6	10.0	6	10.0		
▪ House wife.	35	58.33	45	75.00		
▪ Manual Workers	10	16.67	9	15.0		
Cohabitation:						
▪ Living alone	6	10.0	16	33.3	1.643	0.351
▪ Living with family	54	90.0	44	76.7		

Chi-square test statistically

-Independent t-test * Significant difference at p-Value< 0.05

Table 2: Comparison between the patients in study and control groups according to their illness-related data (n= 120)

Items	Intervention group baseline N=60		Control group N=60			
Patients Risk factors:	N	%	N	%	Chi-square	P- value
Smoking	44	73.33	38	63.3		
Hypercholesterolemia	10	16.7	8	13.3		
Hypertension	23	38.33	20	33.3		
Diabetic	25	41.7	23	38.33		
Vascular diseases	10	16.7	9	15.0		
Mean ±SD=	20.03±3.16		8.7±1.92		1.665	0.416
Severity of disease:						
Intermittent claudication	41	68.3	35	58.3		
Ischemia rest pain	7	11.7	10	16.7		
Ischemia ulcers	25	41.7	20	33.3		
Ischemia gangrene	23	38.33	15	25.0		
Mean ±SD=	47.03±4.66		85.07±41.37		1.214	0.471
Level of disease:						
Iliac	2	3.3	0	0.00		
Femoral (above knee)	7	11.7	8	13.3		
Distal (below knee)	41	68.3	40	66.6		
Combination	10	16.7	12	20.0		
Mean ±SD=	53.62±6.55		87±10.79		0.756	0.388
Leg side of disease:						
nilateral	54	90.0	55	91.7		
Bilateral	6	10.0	5	8.33		
Mean ±SD=	98.65±4.5		88.09±5.97		2.406	0.623
Degree of patient dependence:						
Complete	56	93.3	53	88.3		
Partial	4	6.7	7	11.7		
Mean ±SD=	53.61±2.18		42.83±3.56		1.851	0.286

Independent t-test * Significant difference at p. value <0.05, ** Significant difference at p. value <0.01.

Table (2) clarifies that there was no statistically significant difference between both control & intervention groups regarding their illness-related data, with more than two thirds (73.33% & 63.3%, respectively) had smoker with the severity of disease among (68.3% & 58.3%, respectively) of both groups was Intermittent claudication, level of disease were Distal (below knee) in more than half of them (68.3% & 66.6%, respectively), which led to leg side of disease (Unilateral) among (90.0% & 91.7 %, respectively). Moreover, the majority of both groups (93.3% & 88.3%, respectively) were completely dependent."

Table (3) revealed that, there was no significant statistical difference between both groups regarding the patients' symptoms related to changes in parameters of distal pulse palpation, auscultation femoral bruits, pain and edema before intervention, to be statistically significantly different Immediate post intervention, after one and three months of its implementation in term of improvement changes in parameters of distal pulse palpation, auscultation femoral bruits among the intervention group than in control group.

As shown in Table (3), there was no significant statistical difference between both groups regarding their knowledge about LLI before intervention, to be a highly statistically significantly different in term of increased knowledge level among intervention group throughout the following study periods (immediate period, after one month and three months of intervention).

The obtained data in Table (5) clarifies that, there was no significant statistical difference between both groups regarding their performing ADL before intervention, to be a highly statistically significantly different Immediate post intervention, after one and three months of its implementation in term of improvement in the level of independence in personal care activities, mobility activities and foot care among the intervention group compared to control group.

Table (6) illustrated that, there were highly statistically significant difference between study and control groups during pre, immediate post intervention, after one month, three months in relation to supervised exercise program, lifestyle and overall compliance.

Table 3: Comparison between patients in study and control groups according to their symptoms assessment pre, immediate post intervention, after one moths & after third months of intervention (n= 120)

Symptoms	Intervention group baseline				Control group				t- test (P-value) (1)	t- test (P-value) (2)	t- test (P-value) (3)	t- test (P-value)(4)
	Pre Mean ±SD	Immediate post intervention Mean ±SD	after one month Mean ±SD	after three months Mean ±SD	Pre Mean ±SD	Immediate post intervention Mean ±SD	After one month Mean ±SD	After three months Mean ±SD				
Distal pulse palpation	8.21±8.87	9.58±9.22	3.50±9.61	8.59±1.51	7.21±8.89	6.58±14.22	5.50±9.71	8.59±7.13	1.487 (0.308)	63.457 (0.001**)	60.512 (<0.003**)	56.453 (<0.041*)
Auscultation for femoral bruits	5.62±3.14	8.51±7.40	8.51±2.54	8.51±12.83	71.82±7.14	96.51±2.82	8.51±22.81	8.41±2.82	0.654 0.364	56.442 (0.010*)	53.541 (<0.002**)	50.452 (<0.010*)
Edema	12.37±2.98	35.13±2.32	37.27±3.23	15.37±2.88	13.47±3.08	22.03±4.24	21.23±8.54	11.47±4.06	0.643 (0.396)	44.743 (0.044*)	41.643 (<0.001**)	38.853 (<0.003**)
Pain	8.13±1.48	10.03±1.79	89.63±6.43	22.23±1.33	7.1±1.4	9.13±1.53	84±10.82	19.33±1.21	3.556 0.066	63.765 0.024	60.634 (0.185*)	54.488 (<0.010*)

Independent t-test * Significant difference at p. value <0.05, ** Significant difference at p. value <0.01.

(1) The difference in the mean score of symptoms assessment before intervention implementation between both intervention and control groups.

(2) The difference in the mean score of symptoms assessment immediately post intervention implementation between both intervention and control groups.

(3) The difference in the mean score of symptoms assessment after one month of intervention implementation between both intervention and control groups.

(4) The difference in the mean score of symptoms assessment after three months of intervention implementation between both intervention and control groups.

Table 4: Comparison of knowledge between both studied groups throughout different study periods (before, immediate, after one month and three months) of intervention, intervention group (n=60) and control group (n=60)

Total Knowledge Level	Intervention group baseline (N=60)								Control group (N=60)								Chi-square (P- value) (1)	Chi-square (P- value) (2)	Chi-square (P- value) (3)	Chi-square (P- value) (4)
	Pre		Immediate post intervention		Post one month		Post third month		Pre		Immediate post intervention		Post one month		Post third month					
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%				
Satisfactory Knowledge	6	10.0	58	96.6	57	95.0	55	94.0	7	11.6	5	8.3	6	10.0	0	0.00	0.462 0.645	32.684 (<0.001**)	31.645 (<0.0022**)	39.663 0.041*
Unsatisfactory Knowledge	54	90.0	2	3.3	3	5.0	5	8.3	53	88.4	55	94.0	54	90.0	60	100.0	0.456 0.564	45.523 0.020*	41.543 (<0.003**)	39.534 0.010*

*unsatisfactory level < 50 %, Satisfactory level = 50 **significant at P. values ≤ 0.05.

(1) The difference in the mean score of knowledge before intervention implementation between both intervention and control groups.

(2) The difference in the mean score of knowledge during immediate post- intervention implementation between both intervention and control groups

(3) The difference in the mean score of knowledge after one month of intervention implementation between both intervention and control groups

(4) The difference in the mean score of knowledge after three months of intervention implementation between both intervention and control groups

Table 5: Comparison of life style and activities of daily living between both studied groups throughout measurement periods (before, Immediate post intervention, after one month and after three months) of intervention. Intervention group (n=60) and Control group (n=60)

Items	Intervention group baseline (N=60)				Control group (N 60)				t- test (P-value) (1)	t- test (P-value) (2)	t- test (P-value) (3)	t- test (P-value) (4)
	Pre	Immediate post intervention	Post one month	Post third month	Pre	Immediate post intervention	Post one month	Post third month				
1.	Personal care activities: Patient's ability to perform normal daily activities required to meet basic needs											
Anticoagulant drugs compliance	17(28.3%)	35(58.3%)	38(63.3%)	55(91.6%)	18(30%)	20(33.3%)	22(26.6%)	15(25.0%)	0.546 (0.135)	52.765 (0.006**)	48.543 (0.009**)	40.513 (<0.001**)
Wearing elastic socks	10 (16.66%)	40 (66.6%)	55 (91.6%)	50 (83.3%)	5 (8.33%)	13 (22.6%)	25 (41.6%)	9 (15.0%)	0.654 0.862	65.308 0.058*	63.546 0.002**	58.436 <0.001**
Performing skin inspection	12(20.0%)	38(63.3%)	50(83.3%)	15(25.0%)	4(6.6%)	15(25.0%)	17(28.3%)	13(22.6%)	0.786 0.408	48.547 4.053	39.561 6.481*	30.651 0.004*
Performing dressing, bathing & toileting care	18(30.0%)	35(58.3%)	32(53.3%)	5(8.33%)	5(8.33%)	10(16.6%)	20(33.3%)	4(6.6%)	0.345 0.273	49.875 (0.064*)	43.815 (<0.001**)	33.658 (<0.001**)
2.	Mobility activities: Patient independent with exercise and walking											
Changing in Claudication Onset Distance pain-free (Meters)	9(15.0%)	25(41.6%)	40(66.6%)	50(83.3%)	15(25.0%)	12(20.0%)	13(22.6%)	12(20.0%)	0.651 0.436	53.612 0.084*	49.675 (<0.001**)	40.658 (<0.001**)
Changing in Peak Walking Distance pain-free (Meters)	13(22.6%)	55(91.6%)	38(63.3%)	45(75.0%)	2(3.3%)	10(16.6%)	5(8.3%)	9(15.0%)	0.631 0.135	61.671 0.032**	45.678 0.003**	42.488 (<0.001**)
Stairs up	15(25.0%)	45(75.0%)	53(88.3%)	55(91.6%)	4(6.6%)	5(8.33%)	5(8.33%)	13(22.6%)	0.432 0.862	60.540 2.576	60322 5.845	52.431 0.003*
3.	Domestic activities: Foot Care											
Moisturizing cream and nail care.	12(20.0%)	10(16.66%)	55(91.6%)	57(97.6%)	3(5.0%)	7(11.33%)	2(3.3%)	12(20.0%)	0.732 0.408	78.311 0.050*	71.453 (0.001*)	65.487 (<0.001**)
preventing abnormal pressure points	9(15.0%)	45(75.0%)	50(83.3%)	53(88.3%)	6(10.0%)	2(3.3%)	3(5.0%)	8(13.3%)	08128 0.135	54.373 0.013*	48.654 0.044*	39.563 (0.004**)

- Independent t-test * Significant difference at p- value <0.05, ** Significant difference at p- value <0.01.

(1) The difference in the mean score of life style and activities of daily living before intervention implementation between both intervention and control groups.

(2) The difference in the mean score of life style and activities of daily living during intervention implementation between both intervention and control groups

(3) The difference in the mean score of life style and activities of daily living after one month of intervention implementation between both intervention and control groups.

(4) The difference in the mean score of life style and activities of daily living after three months of intervention implementation between both intervention and control groups.

Table 6: Mean score between study and control groups regarding to supervised exercise program compliance, lifestyle compliance and overall compliance (N= 120).

| | Intervention group baseline | | | | Control group | | | | | | |
Variables	Pre X± SD	Immediate post intervention X± SD	After one month X± SD	After third month X± SD	Pre X± SD	Immediate post intervention X± SD	after one month X± SD	after third month X± SD	t- test (P-value) (1)	t- test (P- value) (2)	t- test (P- value) (3)	t- test (P- value) (4)
Supervised exercise program compliance	44.21± 8.89	51.85± 7.33	94.58± 14.22	88.59± 17.13	41.04± 6.37	84.58± 14.23	41.85± 7.34	42.03± 6.87	2.645 0.282	56.459 (32.864)	51.654 (<0.001**)	49.672 (<0.003**)
Lifestyle	32.50± 9.71	60.67± 19.23	42.65± 8.45	84.14± 5.154	31.37± 8.97	72.68± 16.34	31.76± 7.65	30.67± 8.99	5.642 1.823	48.651 (0.724*)	42.536 (<0.004**)	39.472 (<0.010*)
Overall compliance	71.62± 17.14	78.59± 17.40	82.68± 16.11	96.51± 22.89	72.22± 18.25	43.03± 6.76	71.89± 16.17	70.67± 19.12	8.456 0.195	66.453 (<0.003**)	61.654 (<0.003**)	60.456 (<0.003**)

* **significant at P. values ≤ 0.05.

(1) The difference in the mean score of supervised exercise program compliance before intervention implementation between both intervention and control groups

(2) The difference in the mean score of supervised exercise program compliance during immediate post- intervention implementation between both intervention and control groups

(3) The difference in the mean score of supervised exercise program compliance after one month of intervention implementation between both intervention and control groups

(4) The difference in the mean score of supervised exercise program compliance after three months of intervention implementation between both intervention and control groups

Table 7: Relation between Knowledge level and educational level among study group patients Pre and post intervention (N= 60)

| | Level of education | | | | | | | |
| | Illiterate "n=36" | | Read & write "n=8" | | Secondary level "n=10" | | University level "n=6" | |
Knowledge Level	N	%	N	%	N	%	N	%
Inaccurate Knowledge:								
▪ Pre	25	69.44	6	75.00	7	70.00	4	66.67
▪ Post	4	11.12	7	70.00	9	90.00	5	83.33
Satisfactory Knowledge:								
▪ Pre	11	18.33	1	12.5	2	20.00	1	16.67
▪ Post	33	91.66	6	75.00	8	80.00	4	66.67
Good Knowledge:								
▪ Pre	--	--	1	12.5	1	10.00	1	16.67
▪ Post	34	94.4	6	75.00	8	80.00	5	83.33
X ± SD	2.6700 ±1.334		3.89 ±1.987		2.9800 ±1.543		1.978 ± 2.549	
P- value	Significant at P. values ≤ 0.05.							

Data in Table (7) reveals that, among those pre intervention who don't knowledge, there were illiterate, read & write, secondary level and university level (69.44%, 75 %, 70%, 66.67%), while, post intervention level (11.12, 70%, 90%, 83%.33) respectively. Also (12.5% and 10%,16.67) good knowledge were read & write, secondary level and university level pre intervention and (94.4%, 75%, 80%, 83.33%) post intervention, statistically significant (P ≤0.05.) between pre and post educational level of studied sample and their knowledge level.

DISCUSSION

LLI is a manifestation of peripheral arterial disease (PAD) caused by a critical reduction of blood flow to the lower limb tissues, with a risk of amputation if LL is not revascularized. Patient LLI become dependent because of either, loss of motor function can have a severe impact on an individuals ADL and overall level of functioning [12].

This study aimed to investigate effect of lifestyle modification on functional ability and outcomes for patients with LLI.

As regarding demographic characteristics of the current study showed that more than half of study and control groups of patients age ranged from (35 to 50) years old. This result is contradicting with Criqui and Aboyans [13] who study about "Epidemiology of PAD "present in the prevalence of LLI to increase consistently with age from around 5% at age 45-49 years to 18% at age 85-89 years.

Regarding six of both study and control group, more than half of them were female patients. This finding is consistent with Olinic *et al*. [14] "Epidemiology of LLI ""reported that, study survey identified 109 patients younger than 40 years of age with lower extremity ischemia. Women had a higher prevalence of LLI than men, this because women had the highest rates of diabetes and risk factors of LLI.

As regarding to medical data, more than two thirds (73.33% & 63.3%, respectively) had smoker with the severity of disease among (68.3% & 58.3%, respectively) of both groups was intermittent claudication, level of disease were Distal (below knee) in more than half of them (68.3% & 66.6%, respectively), which led to leg side of disease (Unilateral) among (90.0% & 91.7 %, respectively). Moreover, the majority (93.3% & 88.3%, respectively) was completely dependent. This result was supported by Monaro *et al*. [15] who study" An integrative review of health-related quality of life in patients with LLI " and Ducrocq *et al*. [16] who mentioned that, the highest percentage of patients had diabetes mellitus is associated with an increased risk of peripheral atherosclerosis, history of hypertension, vascular disease and older age.

The researcher of the study found that, patients ages 45 years or older with established live long smoking, coronary artery disease (CAD), cerebrovascular disease, or Prevral Artery Diseases (PAD), diabetic, hypertension, hyperlipidemia, or with at least three atherothrombotic risk factors for LLI. This finding is consistent with Wang *et al*. [17] who mentioned that, smoking cessation has the most positive impact, stopping LLI progression and even improving circulation. These results come in agreement with Salomon *et al*. [18] who study" Impact of Nutritional State on LLI Early Outcomes "concluded that, Smoking can significantly increase the risk for developing LLI and eventually, chronic limb ischemia.

According to Salomon *et al*. [18] studied the inconclusive evidence regarding the impact of nutritional status on the risk, course, prognosis and outcomes of conservative and invasive treatment of LLI. This study is the first to demonstrate prospectively the major importance of malnutrition in the early prognosis of LLI patients.

This finding agreed with Normahani *et al*. [19] who study " perfusion assessment of LLI: Principle for understanding " whose study revealed that, there is a patient with LLI often describe a history of deteriorating claudication, progressing to nocturnal rest pain. Ulceration or gangrene commonly results from minor trauma and complete dependent.

According to Nordanstig *et al*. [20] who study" Walking performance and health-related quality of life endovascular invasive versus non-invasive treatment for intermittent claudication" suggested that, patients with claudication underwent operation only after deterioration of their clinical symptoms, including inability to work or ischemic rest pain and majority of them were only predictors of the need for lifestyle modification in the patients with intermittent claudication.

These results come in agreement with *Okazaki et al*. [21] study about " LLI " documented that, LLI was defined as one or more of the following: Claudication, the most frequent symptom of LLI. The current intermittent claudication with ankle-brachial index of less than 0.9 or a history of intermittent claudication together with a previous.

As regards the patients' symptoms assessment improvement changes in parameters of distal pulse palpation, auscultation femoral bruits, pain and edema among the intervention group than in control group immediate post intervention, after one and three months. The results of the present study were on the same line with Perme *et al*. [22] who study" Early Mobility and Walking for Patients with LLI this study has even shown that a "supervised treadmill structure exercise also increased brachial arterial flow-mediated dilation and improved lower limb edema. Exercise and ambulation may prevent or slow the progression of LLI for study group than control. These findings are supporting the third research hypothesis.

In addition, the results of the present study were on the same line with TASC [23] study about "Consensus for the Management of LLI" mentioned that, symptoms of LLI can be managed non surgically. Treatment focuses on leg elevation and compression to decrease edema, the management of infected ulcers. Also Howard, Banerjee and Fairhead [24] who study" Population-based study of incidence, risk factors, outcome and prognosis of LLI: implications for prevention "reported that the ultimate goals are help to performed life style and risk factors modification is to regain adequate blood flow thus relieving pain, decrease edema, improving function and quality of life and prolonging patient survival.

As regarding knowledge increased level of knowledge among intervention group throughout the following study periods (immediate period, after one month and three months of intervention). On the same line with Soden, Zettervall and Curran [25] study about" regional variation in patient selection and treatment for the LLI compliance" reported that, improvement in the information for the study group, despite the difference in the level of education after the program than before. This finding may be due to practical, comprehensive, concise and clear intervention, active learning methods and explicit learning materials & increased patient's motivation. These findings are supporting the first research hypothesis.

The researchers' opinion that providing knowledge for LLI patient that lead to improves his health and reduces of complications.

This agrees with Kohlma *et al*. [26] who study" Management of LLI recommended knowledge will lead to earlier identification of patients with PAD, improved quality of life and continuity of care for patients with LLI. On the same line with Brahmanandam *et al*. [27] whose study about present expertise staff working with this patients LLI as well as instructions can significantly affect the patients' functional ability and outcomes patients with LLI. These findings were consistent with Misra *et al*. [28] study Guideline on the management of patients with LLI shows that the majority of those patients also did not reach functional independence by the time they were discharged education intervention.

Concerning ADL, improvement in the level of independence in Personal care activities, Mobility activities and foot care among the intervention group compared to control group. Immediate post intervention, after one and three months of intervention implementation which reflect the effectiveness of the instructional content and training exercises for maintaining their functional level, it also involves the caregiver in the educational session that might enhance and empower the patients.

This agrees with Mays *et al*. [29] who study "Assessment of functional status and quality of life in claudication" suggested that people with LLI may need to be directed to specialized exercise program and to make risk factors modifications to their environment in order to handle activities of daily living and to function independently. Also, another opinion from Belkin and Creager, [30] study about" key data elements and definitions for peripheral atherosclerotic vascular disease" recommended that patients who are instructed to increase activity will help to increase their chances of recovery and less complication.

In addition; the results of the present study were on the same line with Douiri, Rudd andWolfe [31] who study "Functional outcome of LLI" reported that, patients with the most LLI exhibited the most severe activity impairment before intervention; however, these were the same patients that exhibited the greatest improvement in ADL and outcomes measured one week after intervention. Age and comorbidities did not influence improvements in this activity. These findings are supporting the second research hypothesis.

Concerning supervised exercise program compliance, lifestyle compliance and overall compliance. The study showed that there was highly statistically significant difference between study and control groups during pre, Immediate post intervention, after one month, three months. This indicates the extent to which the study

group adhered to the instructions and intervention that were given to them before they were discharged from the hospital and also to follow them at home. However, these findings are inconsistent with those of Nordanstig *et al*. [32] ho study" program compliance of the disease-specific health-related quality of life instrument" stated that, A supervised walking-based exercise program should be considered first for all patients because of the low risk and the patients ability improvement in functional activity that is associated with exercise.

In the same context Mays *et al*. [29] mentioned that, Exercise improves not only maximal treadmill walking distance, but also the all ADL and community-based functional ability of patients.

According to Yelnik, Simon and Parratte [33] whose "suggested that, independent levels of functioning have frequently not been achieved in individuals with LLI at the time of discharge instructions. This finding might even be more notice able by the trend toward shorter of the patient's period of follow-up, therefore emphasizing the importance of outpatient follow-up after discharge in order to reach full levels of functional independence.

Also nursing team must be trained on pre-discharge instructions and on the importance and necessity of the instructions that must be shared with patients and their relatives. On the same line Murata *et al*. [34] reported about 64 patients with LLI had their functional ability assessed on admission to discharge this considered live threating complications, as well as needed follow-up education one-year post affected with their relatives.

The results of our study achieve the hypothesis by evaluate the effect of life style modification on functional ability and patient's outcomes for patients with LLI. patients which resulted in improved functional ability and patient's outcomes as well as decrease pain, pulse palpation and odema redaction, decreased claudication, ischemic complication and ability to work.

Finally, based in the study results, significant different in patient's overall compliance at immediately post intervention, one month, three months, matched to study and control groups, this result related to strongly applications of supervised exercise program and risk factors and live study modification pre discharged and follow up.

CONCLUSION

Implementing life style modification and supervised exercise program for patients with LLI was effective in improving their knowledge about disease process and

decrease pain, pulse palpation improved, odema redaction and normal performing ADL as well as its effectiveness in improving the functional ability and patient outcome among intervention group than in control group.

Recommendations: The following recommendations could be inferred from the previously mentioned conclusion;

- Encourage a simple illustrated booklet to patients post LLI includes all therapeutic instructions and threatening complications could help increasing patient's awareness, understanding and perform activities.
- Further future studies should include period of follow up post LLI longer than 3 months, it is suggested to be one years, this period is enough to monitor outcome to maximize the intervention and instruction effect.

REFERENCES

1. Ully Alexia Caproni Correa, Adeliane Almeida Rezende Vida, l, Patric Emerson Oliveira Gonçalves, Erica Regina Ribeiro Sady, Ronald Luiz Gomes Flumignan and Ligia de Loiola Cisneros, 2019. Intrahospital physical therapy for patients with critical lower limb ischaemia: an expert consensus. Fisioter. Pesqui. vol. 26 no. 2 Sao Paulo Apr./June 2019 Epub July 18, 2019. https://doi.org/10.1590/1809-2950/18006426022019.

2. Parmenter, B.J., G. Dieberg and N.A. Smart, 2015. Exercise training for management of peripheral arterial disease: a systematic review and meta-analysis. Sports Med., 45(2): 231-244. Available form https://pubmed.ncbi.nlm.nih.gov.

3. Whayne, T.F. and D. Mukherjee, 2016. Increased Exercise Favorably Modifies Coronary Artery Disease and Peripheral Arterial Disease Outcomes. Curruent Vasclar Pharmacology Journal, 14(5): 458-465. Available form https://pubmed.ncbi.nlm.nih.gov.

4. Aboyans, V., J.B. Ricco, M.E.L. Bartelink, M. Bjorck, M. Brodmann and T. Cohnert, 2017. Guidelines on the diagnosis and treatment of peripheral arterial diseases, in collaboration with the European Society for Vascular Surgery (ESVS). Eur. Heart J., 2017; 39(9): 763-816. doi: 10.1093/eurheartj/ehx095.

5. Linda, B.H. and E. Brenda, 2018. A closer look at lower extremity peripheral arterial disease. Nursing, 48(1): 35-41.

6. Karnabatidis, D.S. Spiliopoulos and D. Tsetis, 2011. Quality Improvement Guidelines for Percutaneous Catheter-Directed Intra-Arterial Thrombolysis and Mechanical Thrombectomy for Acute Lower-Limb Ischemia. Cardiovascular Intervenetion Radiology, 34(6): 1123-1136. Available form https://pubmed.ncbi.nlm.nih.gov.

7. Obara, H., K. Matsubara and Y. Kitagawa, 2018. Acute Limb Ischemia. Annals of vascular diseases, 11(4): 443-448. Available from http://www. doi.org/ at Jun16, 2019.

8. Statistical Records of vascular and surgical departments at Benha University Hospital Record, 2019. The incidence of lower limb ischemia and critical limb ischemia, Benha University Egypt, pp: 1-55.

9. Smith, B. and L. Field, 2018. Nursing Care: An essential guide for nurses and healthcare workers in primary and secondary care. Routledge.

10. Herman, M.D., H.L. Gornik and C. Barrett, 2016. Guideline on the management of patients with lower extremity peripheral artery disease, Circulation J., 69(11): 1465-1508.

11. Halperin, J.L., G.N. Levine and S.M. Al-Khatib, 2016. Further evolution of the ACC/AHA clinical practice guideline recommendation classification system: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J. Am. Coll. Cardiol., 67: 1572-4.

12. Fink, A., J. Kosecoff, M. Chassin and R.H. Brook, 2015. Consensus methods: characteristics and guidelines for use. Am. J. Public Health, 74(9): 979-83.

13. Criqui, M.H. and V. Aboyans, 2015. Epidemiology of peripheral artery disease. Circ. Res., 116: 1509-1526.

14. Olinic, D.M., M. Spinu, C. Homorodean, D.A. Tataru, A. Liew, G.H. Schernthaner, A. Stanek and G. Fowkes, 2018. Epidemiology of peripheral artery disease in Europe: VAS Educational Paper. Int. Angiol, 37: 327-334.

15. Monaro, S., S. West and J. Gullick, 2016. An integrative review of health-related quality of life in patients with critical limb ischaemia. J. Clin Nurs., 26: 2826-2844.

16. Ducrocq, G., P. Amarenco and J. Labreuche, 2013. A history of stroke/transient ischemic attack indicates high risks of cardiovascular event and hemorrhagic stroke in patients with coronary artery disease. Circulation, 127: 730-738.

17. Wang, E., J. Hoff, H. Loe, N. Kaehler and J. Helgerud, 2008. Plantar Flexion: An Effective Training for Peripheral Arterial Disease, European Journal of Applied Physiology, 104: 749-755.

18. Salomon L. Mont, B. Leclerc, M.C. Morgant, G. Besch, A. Laubriet, E. Steinmetz and S. Rinckenbach, 2017. Impact of Nutritional State on Critical Limb Ischemia Early Outcomes Ann. Vasc. Surg J., 45: 10-15. Doi.

19. Normahani, P., N.J. Standfield and U. Jaffer, 2016. Sources of delay in the acute limb ischemia patient pathway. Ann. Vasc. Surg, 38: 279-285. doi: 10.1016/j.avsg.2016.05.118.

20. Nordanstig, J., J. Gelin, M. Hensater, C. Taft, K. Osterberg and L. Jivegard, 2011. Walking performance and health-related quality of life after surgical or endovascular invasive versus non-invasive treatment for intermittent claudication: a prospective randomised trial. Eur. J. Vasc. Endovasc Surg., 42: 220-227.

21. Okazaki, J., D. Matsuda, K. Tanaka, M. Ishida, S. Kuma, K. Morisaki, T. Furuyama, Y. Maehara and J. Vasc Surg, 2018. Analysis of wound healing time and wound-free period as outcomes after surgical and endovascular revascularization for critical lower limb ischemia. Mar, 67(3): 817-825. doi: 10.1016/j.jvs.2017.07.122. Epub 2017 Oct 9. PMID: 29032905

22. Perme, C., C. Lettvin, T.A. Throckmorton, K. Mitchell and F. Masud, 2011. Early Mobility and Walking for Patients with Femoral Arterial Catheters in Intensive Care Unit: A Case Series. Journal of Acute Care Physical Therapy, 2(10).

23. TASC II Working Group, 2017. Inter-Society Consensus for the Management of PAD (TASC II). Japanese College of Angiology transl. Tokyo: Medical Tribune, (in Japanese).

24. Howard, D.P., A. Banerjee and J.F. Fairhead, 2015. Population-based study of incidence, risk factors, outcome and prognosis of ischemic peripheral arterial events: implications for prevention. Circulation J, 132: 1805-15.

25. Soden, P.A., SL. Zettervall and T. Curran, 2017. Regional variation in patient selection and treatment for lower extremity vascular disease in the Vascular Quality Initiative. J. Vasc. Surg. 65(1): 108-118. doi: 10.1016/j.jvs.2016.06.105.

26. Kohlam, D. and M.S. Trigboff, 2013. Management of Lower Extremity Peripheral Arterial Disease: Interpreting the lates Guidelines for Nurse Practitioners, Jornal for Nurse Practitioners, 9(10): 653-660.

27. Brahmanandam, S.M., L.M. Messina, M. Belkin, M.S. Conte and L.L. Nguyen, 2009. Determinants of hospital disposition after lower extremity bypass surgery. Presented at: Vascular Annual Meeting, Scientific Program, Jun 11-14, 2009; pp: 166-7.

28. Misra, S., Shishehbor, H. Mehdi, E.A. Takahashi, Aronow D. Herbert, P. Brewster Luke, Bunte C. Matthew, Kim S.H. Esther, R. Lindner, Jonathan and Rich, Kathleen, 2019. Perfusion Assessment in Critical Limb Ischemia: Principles for Understanding and the Development of Evidence and Evaluation of Devices: A Scientific Statement from the American Heart Association". Circulation. doi:10.1161/. Accessed on September, 2018.

29. Mays, I.P., W.M. Casserly, P.M. Kohrt, M.R. Hiatt and Nehler, 2011. Assessment of functional status and quality of life in claudication J. Vasc. Surg., 53(5): 1410-1421.

30. Belkin, M. and M.A. Creager, 2012. Key data elements and definitions for peripheral atherosclerotic vascular disease, a report of the American College of Cardiology Foundation/American Heart Association Task Force on Clinical Data Standards, Circulation 2012125:395. Accessed on January 28, 2019.

31. Douiri, A., A. Rudd and C. Wolfe, 2012. Prevalence of Poststroke Cognitive Impairment: South London Stroke Register 1995-2010. Stroke. 2013; 44: 138-145; originally published online November 13, 2012; doi: 10.1161/STROKEAHA.112.670844.

32. Nordanstig, J., M.E. Karlsson, C. Pettersson and Wann-Hansson, 2012. Psychometric properties of the disease-specific health-related quality of life instrument, Vascu QoL in a Swedish setting, Health Qual Life Outcomes, 10(1): 45.

33. Yelnik, A.P., O. Simon and B. Parratte, 2010. How to clinically assess and treat muscle over activity in spastic paresis. Journal of Rehabilitation Medicine, 42: 801-7.

34. Murata, N., Y. Soga, O. Iida, Y. Yamauchi, K. Hirano, D. Kawasaki, M. Fujihara and Y. Tomoi, 2015. Complex relationship of body mass index with mortality in patients with critical limb ischemia undergoing endovascular treatment. Eur. J. Vasc. Endovasc Surg. Mar; 49(3): 297-305. doi: 10.1016/ j.ejvs.2014.10.014. Epub 2014 Dec 15. PMID: 25524520.