ABSTRACT

Background: To find out the influence of intermittent compression therapy using sphygmomanometer on pressure changes and walking ability on individuals affected with peripheral arterial diseases of lower limbs.

Methods: Total thirty patients' age 30 to 70 years post peripheral arterial diseases individuals included for study. These patients were randomly allocated to intervention group (n=15), which underwent a 6- weeks training program & control group (n=15) that received standard care and unsupervised exercise protocol. Primary outcome was change in ABI levels as determined in before and after the intervention program. Secondary outcomes were intermittent claudicating distance and walking capacity as assessed by the walking impairment questionnaire.

Results: Paired sample t- test was used to analyze changes from before and after intervention program. There is a statistically significant (p=0.000) improvement in both experimental group and control group but when compared to control group, experimental group shows improvement in the mean values in all parameters.

Conclusion: In this study the Ankle Brachial Index (ABI), Intermittent Claudication Distance (ICD) and Walking Impairment Questionnaire (WIQ) improved significantly in experimental group than control group by applying the pneumatic compression therapy with the sphygmomanometer and graded walking exercise. Hence, the study recommends that intermittent pneumatic therapy along with graded exercise is most effective in improving Ankle Brachial Index (ABI), Intermittent Claudication Distance (ICD) and Walking capacity in PAD individuals.

Keywords: Peripheral arterial diseases, ankle brachial index, intermittent claudication distance, walking distance, walking impairment questioner, intermittent pneumatic compression therapy.

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Peripheral arterial disease is an occlusive arterial disease which causes inadequate blood flow to the limbs. The disease process is due to formation of atherosclerosis mainly affecting the vascularisation of the lower limbs [1]. The prevalence of peripheral arterial disease in men is slightly higher than in women. Over all prevalence of Indian population is 17.9%.

The underlying pathology of disease is altered vascular mechanics, loss of physical, physiological property of blood vessels, altered neural, hormonal regulation of vascular system. The clinical presentations of symptoms are intermittent claudication, numbness and tingling sensation in legs of peripheral arterial diseases. The ischemia of the lower limbs is classified as functional and critical. The functional ischemia occurs when blood flow is normal at rest but insufficient during exercise presenting clinically as intermittent claudication. The critical limb ischemia is produced when the reduction of blood flow result in perfusion deficit at rest and defined by the presence of pain at rest or trophic lesion in the leg [2].

20 to 50% of peripheral arterial diseases may be asymptomatic 10 to 35% of patients presents with intermittent claudication (aching, pain, cramping, numbness of the calf muscle during exercise, relieved by rest) 40 to 50% of patients present with typical symptoms of claudication involving the calf, thigh, buttock 1% to 2% of patients with critical limb ischemia manifest as tissue loss or rest pain in the limbs with non healing ulcers, necrotic tissue, gangrene, diminished pulses and cool skin temperature of lower extremities. Changes in the color especially on feet, tropic changes, hair loss, brittle nails and muscular atrophy, weakness, numbness or feeling of heaviness in legs, aching burning sensation in the toes and feet during rest and while lying flat may be the signs of ischemia [3].

The functions of vascular system are recorded as pressure changes evaluated through ABI, walking capacity is evaluated through WIQ. Peripheral arterial diseases are treated conservatively with anticoagulants, antihypertensive, anti-cholinesterase drugs. The atherosclerotic blocks are excised surgically. The main principles of physiotherapy are preventive therapy in early mobility phase, therapeutic walking distance, decrease edema, increase mobility, enhance vascularization in sub-acute phase, maintenance phase enhance vascularization and increase strength and endurance of the muscles in chronic phase of PAD [4].

The various modes of exercises like active exercises, free exercises, aerobic exercises, facilitatory techniques are adopted to activate muscle action. The risk factors are regulated by applying stockings/ crepe bandage. The blood circulation is enhanced through pneumatic compression therapy techniques, various studies have proved the effectiveness of active exercises, treadmill walking, walking, pneumatic compression therapy in regulating risk factors of PAD but prolonged usage of pneumatic compression therapy is found to be practically not possible as it is expensive and equipment is unavailable in all level of hospitals care. Sphygmomanometer is an adjunct of pneumatic compression therapy which can be used to regulate blood circulation and edema. The equipment is easily accessible and economically low expensive and safe. Hence, the aim of study is to find out the influence of intermittent compression therapy using sphygmomanometer on pressure changes and walking ability on individuals affected with PAD of lower limbs.

**METHODOLOGY**

Thirty patients with age between 30 to 70 years old individuals who were diagnosed as PAD in cardiothoracic OP and pranadanum ward in Sri Venkateswara Institute of Medical Science University, Tirupati, Andhra Pradesh were taken up for the study. The study design adopted for the study is experimental design, prospective randomized controlled trial, selection of sample, the hospital investigations, data recording etc., were conducted during a period of 6 weeks. Sphygmomanometer and stethoscope is utilized to assess the ankle brachial index (ABI) in the patients with peripheral arterial diseases. Walking impairment questioner is utilized to assess the walking ability, walking distance, walking speed. Sphygmomanometer is utilized for the treatment purpose alternate adjuvant of pneumatic compression unit. The sample of peripheral arterial diseases patients with ABI less than 0.95 > .5, diagnosed PAD, age more than 30 years< 70 years, both genders were included in the study. The samples of PAD patients are following criteria were excluded from the study, chronic obstructive pulmonary diseases, ABI less than 0.5, Ischemic ulceration, Symptoms of angina, Gangrene, Arthritis

The sample of 30 subjects was divided in to two equal halves by using simple lottery method. All the subjects met the inclusive criteria,

**INTERVENTION PROTOCOL**

The samples under control group are advised to undergo graded walking exercises a pamphlet is given to the sample size with the protocol period of 6 weeks. The samples were evaluated for ABI, walking distance and walking ability before intervention. Exercise protocol is advised as mentioned in the table to continue and re-assessed after 6 weeks of intervention.
Compression therapy by using sphygmomanometer and graded walking exercises protocol in experimental group:

After initial base line evaluation samples were prescribed sphygmomanometer compression therapy along with graded walking exercises for a period of 6 weeks. The patients were trained to receive the compression therapy for a week and asked to continue the same at home for 4 weeks to method of applying compression therapy is clearly explained and demonstrated for 2 weeks in hospital. The values are recorded before and after the intervention protocol.

**COMPRESSION THERAPY PROTOCOL:**

- **Session:** 2 sessions per day
- **Repetitions:** 10 repetitions done for one session
- **Treatment duration:** 20 minutes
- For one repetition inflated pressure are given as follow.

| Time | Pressure raises |
|------|----------------|
| 1st 20 sec. | 40 mm of hg |
| 40 sec | 50 mm of hg |
| 60 sec | 60 mm of hg |

Table: 2 Compression therapy protocol

Compression therapy by using sphygmomanometer in experimental group:

A well documented method to increase arterial leg inflow in patients with peripheral arterial disease is compression therapy. The rapid rise of the cuff pressure in this therapy assists with emptying of the vascular blood of the extremities and allows oxygenated blood to move down the limbs delivering nutrients to deprived tissues. Platelet derived growth factors, nitric oxide will also increases after compression. Growth factors helps in forming new capillaries and nitric oxide will shows positive effects on the cells in the inner layers of arteries, which can improve blood supply.

**STUDY ALGORITHM**

![Flow chart showing treatment algorithm](image)

RESULT

There is a statistically significant (p=0.000) improvement in both variables from baseline to sixth week in experimental group and control group.

A total of 30 subjects were invited on to this study, they were randomly allocated to the intervention group (n=15), and control group (n=15)

| Parameters | Group       | N  | Mean ± Std. Error | t-value | DF  | p-value |
|------------|-------------|----|-------------------|---------|-----|---------|
| ABI        | Control Pre | 15 | 0.59±0.068        | 0.59    | 8.407 | 14 | 0.000  |
| ABI        | Control Post| 15 | 0.66±0.058        | 0.66    |       |       |       |
| ABI        | Experimental Pre | 15 | 0.56±0.016        | 0.063   | 13.484 | 14 | 0.000  |
| ABI        | Experimental Post| 15 | 0.77±0.016        | 0.062   |       |       |       |
| ICD        | Control Pre | 15 | 138.00±12.880    | 49.886  | 10.832 | 14 | 0.000  |
| ICD        | Control Post| 15 | 190.00±15.119    | 58.354  |       |       |       |
| ICD        | Experimental Pre | 15 | 149.33±9.231     | 35.750  | 13.916 | 14 | 0.000  |
| ICD        | Experimental Post | 15 | 299.33±9.127    | 35.349  |       |       |       |
| WIQ        | Control Pre | 15 | 35.14±2.124      | 8.225   | 16.185 | 14 | 0.000  |
| WIQ        | Control Post| 15 | 36.78±2.131      | 8.232   |       |       |       |
| WIQ        | Experimental Pre | 15 | 41.82±1.501     | 10.355  | 27.860 | 14 | 0.000  |
| WIQ        | Experimental Post | 15 | 78.60±2.348    | 9.093   |       |       |       |

Table 3: Pre and post mean and std. error values of ABI, ICD, WIQ which shows significant increase in post therapeutic values.

| Parameters | Groups       | N  | Mean ± Std. Error | t-value | p-value |
|------------|--------------|----|-------------------|---------|---------|
| ABI        | Experimental | 15 | 0.20±0.015        | 7.044   | 0.000   |
| ABI        | Control      | 15 | 0.08±0.009        |         |         |
| ICD        | Experimental | 15 | 150.00±10.779     | 8.305   | 0.000   |
| ICD        | Control      | 15 | 52.00±4.801       |         |         |
| WIQ        | Experimental | 15 | 41.82±1.501       | 10.355  | 0.000   |
| WIQ        | Control      | 15 | 21.19±1.309       |         |         |

Table 4: Comparison between the groups

To compare the results between the groups of control and experimental group, paired t-test was selected. The mean and std. error values of ABI, ICD and WIQ are given. There is found to be significant improvement in experimental group than control group.
There was a significant difference between experimental group and control group in ABI in PAD individuals

Graph 1: Graphical representation of post mean value of ABI between experimental and control groups

There was a significant mean difference value of pre and post value of ICD between experimental group and control group of PAD individuals

Graph 2: Graphical representation of mean difference of ICD between experimental and control groups of PAD

There was a significant difference of WIQ values between experimental group and control group of PAD individuals

Graph 3: Graphical representation of mean difference value of WIQ between experimental group and control group of PAD individuals

DISCUSSION

The result of analysis of the study generally shows significant improvement in physiological and functional characteristics of the experimental group over the control group individuals. The results of each of the outcomes are comparatively evaluated with earlier works.

In the present study it has been reported that the effect of graded walking exercises (control) in PAD individuals has shown there is no significant difference between the pre (0.59±0.59) and post (0.66±0.066) intervention value of ABI in control group. On the other hand, intermittent compression therapy and graded walking exercises had shown significant difference between the pre (0.56±0.0063) and post intervention (0.77±0.662) values of ABI in experimental group. The mean percentage change of ABI values has shown significant difference between 0.08 (control group) and 0.20 (experimental group).

Earlier studies by Joaquin Deharo et al reveals that 2hours of daily IMC on the calf provided by the FM220 device used by patients with peripheral artery disease at home for 3 months has significantly increased claudication distance and is associated with objective improvement is limb perfusion. Clinical benefits are observed within a month of treatment of objective evidence [5].

Andrew N. Nocolaides, Kostas Delis clearly demonstrates that IPFCC is an effective treatment in the management of intermittent claudication producing significant improvements both in the walking ability (ICD and ACD) and the arterial hemodynamics in the calf. Follow-up investigation one year after this treatment was completed has shown that the benefits gained are well sustainable [6]. It may be a useful with first line of therapy in patients with disabling claudication who are unfit for major reconstructive surgery. Improved walking on long-term follow-up and experience from different centers may establish a role for this treatment modality in the future [7].

There is an increasing releases of nitric oxide, inside the lying the venous walls, enabling relaxation and improves the pressure flow of the blood [8].

In control group graded walking exercise in PAD individuals has shown that mean percentage of there is significant difference in pre (138.00±49.886) and post intervention of (190.00±58.554) ICD.

In experimental group the intermittent compression therapy graded walking in PAD individuals has shown significant difference between pre (149.33±35.750) and post intervention valve (299.33±35.349) of ICD.

The mean percentage of ICD value as shown 150.00 (42%) in experimental group 52.00 (14.8%) in control group.

In earlier study S.K Kakkos et al; proved that IPC by an augmenting leg perfusion, achieved improvement in walking distance comparable with supervised exercise [9].

Our present study has shown significant improvement of ICD in both experimental (42%) and control (14.8%) intermittent pneumatic compression therapy along with graded walking exercises has lead to regulation of arterial pressure gradient and increases arterial flow in calf muscles [4] although evidence of improve nutrition to muscle tissue [10] and improved performance of the muscle tissue perfusion with increased capilarisation, redistribution of the flow and diffusion based enhancement of arterial venous O₂ extraction is noted [10]. The post intermittent compression therapy and graded walking exercise have induced greater concentration of walking performance and facilitated the aforementioned process in the ischemic exercising muscles.
In control group graded walking exercise in PAD individuals has shown significant differences between the pre \((35.14 \pm 8.225)\) and post \((56.33 \pm 8.252)\) intervention values of WIQ. In experimental group intermittent compression therapy and graded walking exercise in PAD individuals has shown significant difference between pre \((36.78 \pm 8.48)\) and post \((78.60 \pm 9.093)\) intervention values of WIQ.

Sara A. Myers Ms. et al; reported that Initial and absolute claudication distances and WIQ pain, speed, and distance subscales are the measures that correlated the best with the ambulatory limitation of patients with symptomatic peripheral arterial disease. These results suggest the WIQ is the most specific questionnaire for documenting the qualitative deficits of the patient with claudication while providing strong relationships with the quantitative measures of arterial disease. Future studies of claudication, both quantitative and qualitative assessments should be included to adequately assess disease severity and functional status in peripheral arterial disease patients [11-13].

Mary Mc Grae McDermott et al; shows The WIQ is a valid measure of community walking ability in a heterogeneous group of patients with and without PAD. The WIQ discriminates best among patients in the highest and the lowest quartiles of walking speed and endurance [14]. The WIQ is a quantitative measure that best reflects actual ambulatory performance of the PAD patients [14].

This results support with our finding showing that the WIQ is appropriately describes the problems of the patients with PAD. WIQ is related to ICD and ABI individuals with intermittent claudication. The WIQ scores has shown significant increase in the walking endurance speed, distance in the experimental group compared to control group.

**CONCLUSION**

In this study the Ankle Brachial Index (ABI), Intermittent Claudication Distance (ICD) and Walking Impairment Questionnaire (WIQ) improved significantly in experimental group than control group by applying the pneumatic compression therapy with the sphygmomanometer and graded walking exercise. Hence, the study recommends that intermittent pneumatic therapy along with graded exercise is most effective in improving Ankle Brachial Index (ABI), Intermittent Claudication Distance (ICD) and Walking capacity in PAD individuals.

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