

THE EFFECTIVENESS OF INTERMITTENT PNEUMATIC COMPRESSION IN PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY

KRONİK VENÖZ YETMEZLİĞİ OLAN HASTALARDA İNTERMİTTANT PNÖMATİK KOMPRESYON TEDAVİSİNİN ETKİNLİĞİ

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SUMMARY

The purpose of this study was to determine the effects of intermittent pneumatic compression (IPC) in patient with chronic venous insufficiency of the lower limbs. Twenty female patients were randomly allocated into two groups, an IPC group and a control group. Both groups received physiotherapy which consisted of lower extremity exercises, walking exercise on a treadmill and manual massage of the lower extremities for a period of four weeks. In addition, patients in IPC group were treated with a sequential pneumatic compression device for thirty minutes daily, five days a week. Assessment parameters were leg pain at rest, leg pain during ambulation and limb heaviness according to visual analog scale (VAS); limb girth measurements at the ankle, calf and thigh levels; maximal and mean blood flow velocities at the popliteal vein measured by a Duplex ultrasound. VAS scores decreased significantly after treatment in both groups but the differences were significantly more in IPC group. There was a significant decrease in limb girth at all levels in IPC group while the only significant change in the control group occurred at the ankle. Although decrease in ankle girth was more in IPC group than the control group, the difference was not statistically significant. Statistically significant increase in maximum and mean popliteal vein blood velocities were observed in IPC group while no significant change occurred in the control group. These data suggest that IPC is effective in patients with chronic venous insufficiency.

ÖZET

Bu çalışmanın amacı alt ekstremitelerde kronik venöz yetmezliği olan hastalarda intermittant pnömatik kompresyon (IPC) tedavisinin etkinliğini araştırmaktır. Yirmi kadın hasta, IPC grubu ve kontrol grubu olarak rastgele iki gruba ayrıldı. Her iki gruba dört hafta süreyle alt ekstremitelerde egzersizleri, koşu bandında yürüme egzersizi ve alt ekstremitelerde manuel masajından oluşan fizyoterapi programı uygulandı. IPC grubuna ise ek olarak günde 30 dakika, haftada beş gün olmak üzere pnömatik kompresyon tedavisi uygulandı. Değerlendirme parametreleri istirahat sırasındaki bacak ağrısı, ambulasyon sırasındaki bacak ağrısı ve bacakta ağırlık hissinin vizuel analog skalaya (VAS) göre değerlendirilmesi; ayak bileği, baldır ve uyluk düzeylerinde bacak çevre ölçümleri; Duplex ultrason ile ölçülen popliteal ven maksimum ve ortalama kan akım hızları idi. Tedavi sonunda VAS skorları her iki grupta da azalmakla birlikte, IPC grubundaki azalma istatistiksel olarak anlamlı derecede daha fazlaydı. IPC grubunda bacak çevre ölçümlerinde tüm düzeylerde anlamlı azalma olduğu halde, kontrol grubunda anlamlı azalma sadece ayak bileği çevresindeydi. Ayak bileği çevresindeki azalma IPC grubunda daha belirgin olmakla birlikte iki grup arasındaki fark istatistiksel olarak anlamlı değildi. IPC grubunda popliteal ven maksimum ve ortalama kan akım hızlarında anlamlı artış olmasına rağmen kontrol grubunda anlamlı değişiklik gözlenmedi. Bu veriler kronik venöz yetmezliği olan hastalarda IPC tedavisinin etkili olduğunu düşündürmektedir.

INTRODUCTION

Chronic venous insufficiency (CVI) affects a large proportion of individuals and causes substantial morbidity and medical expenditure. It is more prevalent in industrialized nations (1). The pathophysiological basis of CVI is venous hypertension in the lower extremities that occurs as a consequence of incompetent valves in the deep veins of the leg (2). The chief clinical manifestations of CVI are dilated veins, edema, leg pain, skin pigmentation, subcutaneous fibrosis, dermatitis, and ulceration (3,4). The extent to which these occur is related to both the site of anatomic involvement (superficial and/or deep system) and the severity of disease (3).

Leg elevation and vascular compression therapy are the mainstay of medical treatment for CVI. Vascular compression therapy includes elastic wraps, elastic stockings and intermittent pneumatic devices (2). Other treatment methods available are oral drugs (5), exercise (5-9) and massage (8, 10, 11). Surgical management is most often preserved for severe or medically refractory CVI (2).

The efficacy of intermittent pneumatic compression (IPC) in the prevention of deep vein thrombosis (DVT) is well documented (12,13). IPC reduces venous stasis by promoting venous blood flow (14-16) and it stimulates fibrinolytic activity (15, 17). It has also been found to be an effective modality of treatment for venous ulceration (18, 19). Ginsberg et al used IPC in patients with severe postphlebotic syndrome and observed dramatic improvement in symptoms and functional status of all of the five patients studied (20). In another study by Kessler et al, quantitative subjective scores for total symptomatology were improved in most of the patients with CVI (21). The purpose of this study was to determine the effects of a treatment protocol which consisted of IPC and physiotherapeutic measures in patients with CVI, and to compare IPC plus physiotherapy with physiotherapy alone.

MATERIALS AND METHODS

Twenty female patients with symptomatic CVI of the lower limbs over a period of at least 6

months were included in the study. Patients having congestive heart failure, acute pulmonary edema, peripheral arterial disease, cutaneous infections, and a history of recent DVT were excluded. Patients were randomly allocated into two groups, an IPC group and a control group. Each group consisted of ten patients.

At the beginning of the study, patients were asked to evaluate leg pain at rest, leg pain during ambulation and limb heaviness by using a visual analog scale (VAS) of 10 cm length. The degree of edema formation was assessed by measuring limb girth at the ankle, calf and thigh levels. Ankle girth was measured over the medial malleol; calf girth was measured at 15 cm distal to patella; and thigh girth measurements were performed at 10 cm proximal to patella. Venous system of the lower extremities of the patients was examined by duplex ultrasound (Toshiba SSH-140 A, Tokyo, Japan) in order to rule out any venous obstruction and to obtain maximal blood flow velocity and mean blood flow velocity at the popliteal vein. Ultrasonographic imaging was performed by a radiologist. Patients were examined while lying in prone position with the knees flexed to 10-15°, after 5 minutes of rest. The duplex probe contained a 7.5 MHz transducer. The sample volume length was maintained at 50 to 75% of the vessel diameter.

In both groups patients received physiotherapy which consisted of lower extremity exercises, walking exercise on a treadmill and manual massage of the lower extremities for a period of four weeks. In addition, patients in the IPC group were treated with a sequential pneumatic compression device (Automatic Compression System Medomer, ITO Co, Ltd, Japan). Each of the lower extremities was treated for thirty minutes daily, five days a week for four weeks. The device, which had four chambers inflating sequentially, was adjusted to apply a pressure of 45 mmHg. The durations of the inflation and deflation phases were 12 seconds and 2.4 seconds, respectively.

Lower extremity exercises included gluteal and quadriceps isometric exercises, active hip and knee flexion/extension, ankle dorsiflexion/

plantar flexion, and straight leg raising. The patients were instructed to perform ten repetitions of each exercise three times a day. Walking exercise on a treadmill (Marathon 472, Enraf Nonius, Netherlands) was performed with a rate of 3km per hour, thirty minutes daily, five days a week. Manual massage was also applied five days a week.

All of the clinical and radiologic assessments were repeated at the end of four weeks. Statistical analysis was performed by using Wilcoxon test for comparison within the groups and Mann-Whitney U test for comparison between the groups. Significance was accepted for $p \leq 0.05$.

RESULTS

Demographic characteristics of the patients are presented in Table 1. There were no significant

Table 1. Demographic characteristics of patients*

	IPC group N=10	Control group N=10
Age (yr)	53.10±10.18	56.10±12.28
Height (cm)	161.20±4.26	160.90±4.60
Weight (kg)	69.60±11.86	65.20±16.17
Body Mass Index (kg/m ²)	26.70±4.29	24.90±5.36

IPC: Intermittent pneumatic compression.

* $p > 0.05$

significant differences in age, height, weight and body mass index between the two groups ($p > 0.05$). Two patients in IPC group and three patients in control group had been working as nurses and all of the remaining patients were housewives. Also, there were no significant differences in terms of pretreatment VAS scores for pain and limb heaviness, girth measurements, and popliteal vein blood velocities between the two groups ($p > 0.05$). None of the patients had a history of DVT or thrombophlebitis. Some patients had minimal hyperpigmentation, especially over the medial malleol but none of them had an active or healed ulcer.

VAS scores for pain and limb heaviness, girth measurements, and popliteal vein blood velocities before and after treatment in IPC group are summarized in Table 2. The intensity of pain at rest, pain during ambulation and limb heaviness decreased significantly after treatment ($p < 0.001$). Limb girth at the ankle, calf and thigh levels also decreased significantly ($p < 0.05$; $p < 0.001$; $p < 0.001$, respectively). Statistically significant increase in maximum and mean popliteal vein blood flow velocities were observed after treatment ($p < 0.001$).

Results in control patients are summarized in Table 2. The intensity of pain at rest, pain during ambulation and limb heaviness decreased significantly after treatment ($p < 0.001$; $p < 0.001$;

Table 2. Results in both groups receiving intermittent pneumatic compression (Mean±Standard deviation).

VAS	IPC group (n=20)		Control group (n=20)	
	Before treatment	After treatment	Before treatment	After treatment
Pain at rest	5.80±2.30	2.85±1.63**	5.90±1.74	4.50±1.70**
Pain during ambulation	5.90±2.14	3.15±1.69**	6.75±1.94	5.35±1.87**
Limb heaviness	6.00±1.74	3.40±1.98**	6.70±2.10	5.30±1.75*
Girth measurements (cm)				
Ankle	25.55±1.28	25.12±1.22*	26.40±1.82	26.22±1.70
Calf	37.12±3.06	36.55±2.82**	37.17±4.31	36.90±4.26
Thigh	49.32±3.45	48.60±3.49**	48.40±6.99	48.70±7.05
Popliteal vein blood velocity (m/s)				
Vmax	0.125±0.017	0.151±0.020**	0.137±0.032	0.136±0.038
Vmean	0.103±0.014	0.125±0.016**	0.111±0.024	0.115±0.029

IPC: Intermittent pneumatic compression.

Vmax: Maximum popliteal vein blood flow velocity.

Vmean: Mean popliteal vein blood flow velocity.

* $p < 0.05$, ** $p < 0.001$

$p < 0.05$, respectively). There was a statistically significant decrease in ankle girth ($p = 0.05$). Although there was a decrease in calf girth and an increase in thigh girth, these differences did not reach statistical significance ($p > 0.05$). Popliteal vein blood flow velocities did not change significantly ($p > 0.05$).

When two groups were compared, the differences in VAS scores for pain at rest, pain during ambulation and limb heaviness were significantly more in IPC group than the control group ($p < 0.001$; $p < 0.05$; $p < 0.05$, respectively). Although decrease in ankle girth was more in IPC group than the control group, the difference was not statistically significant ($p > 0.05$).

DISCUSSION

The pathophysiological basis of CVI is venous hypertension in the lower extremities that occurs as a consequence of incompetent valves in the deep veins of the leg. The diagnosis is usually clear from the history and physical examination, but various noninvasive and invasive testing modalities are available to assist in the evaluation (2).

Numerous epidemiologic studies have demonstrated that CVI is more prevalent in women than in men (22-24). All of the patients included in our study were female as most of the patients with CVI were female.

It is demonstrated that CVI is a major problem in subjects with a standing position at work (25). Housewives are also exposed to prolonged standing position during housework and this can explain why most of the patients in our study were housewives.

Elevation of the legs and exercise to strengthen the calf musculature provide considerable relief of signs and symptoms of the venous problems in many patients (6). Active exercises of the lower extremities and walking exercise are also recommended (9,26).

IPC has usually been used for the prevention of DVT in patients at risk for thromboembolic complications (12, 13). It has also been used successfully for the treatment of lymphedema (27).

Smith et al used IPC four hours a day in 21 patients having venous ulcers for a minimum of 12 weeks. Patients were studied until the ulcer healed or for a total period of three months. The median rate of ulcer healing was 19.8% area per week (18). McCulloch et al examined the effects of IPC on the healing rates of ulcers in patients with CVI in a prospective, controlled study. Both experimental and control groups received local wound care followed by application of an Unna boot. In addition, subjects in the experimental group received IPC twice weekly for one hour each session. They obtained a healing rate of 0.08 cm² per day for control subjects and 0.15 cm² per day for experimental subjects (19).

In a study by Kessler et al, 19 patients with symptoms of CVI were treated with IPC in two hour sessions twice weekly for 13 weeks. Quantitative subjective scores for total symptomatology were improved in 84% of the patients (21). In our study, the intensity of pain at rest, pain during ambulation and limb heaviness decreased significantly after treatment in both groups but the differences were significantly more in IPC group than the control group.

We could not find any other study investigating the effect of IPC on measurements of lower limb girth in patients with CVI. We observed significant decrease in limb girth at the ankle, calf and thigh levels in IPC group while the only significant change in the control group occurred at the ankle. Although decrease in ankle girth was more in IPC group than the control group, the difference was not statistically significant.

Keith et al examined the effect of IPC on peak venous velocity in the superficial femoral vein by using a duplex imaging system in normal volunteers and postoperative patients. The use of IPC boots significantly increased the peak venous velocity relative to rest (14). Malone et al also obtained similar results in healthy volunteers and patients with severe post-thrombotic venous disease (16). In the present study, statistically significant increase in maximum and mean popliteal vein blood

flow velocities were observed after treatment in IPC group while no significant change occurred in the control group.

In conclusion, treatment with IPC for thirty minutes daily for four weeks in patients with

CVI provide improvement in symptoms, decrease in edema and increase in venous blood velocity. Further studies are needed to determine the duration of treatment effects and the optimum frequency of treatment sessions.

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