Hemodynamic Effect and Safety of Intermittent Sequential Pneumatic Compression Leg Sleeves in Patients With Congestive Heart Failure

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ABSTRACT

Background: Pneumatic leg sleeves are widely used after prolonged operations for prevention of venous stasis. In healthy volunteers they increase cardiac function. We evaluated the hemodynamic effects and safety of intermittent sequential pneumatic compression (ISPC) leg sleeves in patients with chronic congestive heart failure (CHF).

Methods and Results: We studied 19 patients with systolic left ventricular dysfunction and CHF. ISPC leg sleeves, each with 10 air cells, were operated by a computerized compressor, exerting 2 cycles/min. Hemodynamic and echocardiographic parameters were measured before, during, and after ISPC activation. The baseline mean left ventricular ejection fraction was 29 ± 9.2%, median 32%, range 10% −40%. Cardiac output (from 4.26 to 4.83 L/min; $P = .008$) and stroke volume (from 56.1 to 63.5 mL; $P = .029$) increased significantly after ISPC activation, without a reciprocal increase in heart rate, and declined after sleeve deactivation. Systemic vascular resistance (SVR) decreased significantly (from 1,520 to 1,216 dyne-s/cm^5; $P = .0005$), and remained lower than the baseline level throughout the study. There was no detrimental effect on diastolic function and no adverse clinical events, despite increased pulmonary venous return.

Conclusions: ISPC leg sleeves in patients with chronic CHF do not exacerbate symptoms and transiently improve cardiac output through an increase in stroke volume and a reduction in SVR. (*J Cardiac Fail 2014;20:739−746*)

Key Words: Laparoscopy, surgery, transthoracic echocardiography, pneumatic sleeves.

The application of pneumatic sleeves on the lower extremities improves venous circulation and prevents venous stasis in postoperative patients. The intermittent sequential pneumatic compression (ISPC) sleeves (made of 10 air cells) were originally designed for treating severe limb edema (elephantiasis), and were recently shown to improve cardiovascular hemodynamics during positive pressure pneumoperitoneum (PP) that is required during laparoscopic operations.[1] Hemodynamic derangements (such as reduced venous return, stroke volume, and cardiac output and increased systemic vascular resistance [SVR]) may follow PP and prohibit its use in patients suffering from cardiovascular disease.[2−11] ISPC and pneumatic sleeves that were activated to create pressure equilibration were shown to be effective in elimination of undesired systemic and visceral hemodynamic changes associated with PP.[1,12−14] Decreased sympathetic autonomic activity during laparoscopic operations may be an additional mechanism explaining the reduced SVR caused by the 10-cell ISPC sleeve.[15]

A recent publication claimed that the use of 3-cell sequential pneumatic sleeves may decrease cardiac output and increase SVR in healthy volunteers.[16] Because of insufficient

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information regarding the cardiovascular effects of ISPC during PP, we recently conducted a study measuring echocardiographic indices during ISPC application in healthy subjects.[17] We demonstrated an improvement in cardiac activity as expressed mainly by increased cardiac output and decreased SVR without an accompanying increase in heart rate.[17]

However, owing to increased venous return and a possible increase in pulmonary blood flow that may be associated with activation of sequential pneumatic devices, application of ISPC leg sleeves might be deleterious and unsafe in the growing population of elderly postoperative patients, particularly patients with congestive heart failure (CHF). We therefore decided to evaluate the safety and cardiovascular effects of activation of 10-cell ISPC sleeves in patients with systolic CHF.

Methods

Every participant gave informed consent to be included in the study, which was approved by the local Ethics Committee. All patients had clinical symptoms of chronic CHF. Inclusion criteria included New York Heart Association (NYHA) functional class II–III and left ventricular ejection fraction (LVEF) ≤40% as assessed by transthoracic echocardiography (TTE). We excluded patients who could not sign an informed consent, had unstable angina, were <30 days after myocardial infarction or therapeutic coronary intervention, had NYHA functional class I or IV, had oxygen saturation (as measured by pulse oxymetry) <90% on room air, or had chronic lung disease. We also excluded postoperative patients to avoid their unnecessary mobilization for study purposes. The study was conducted in the cardiology outpatient clinic, and each patient was accompanied throughout the process by both a senior cardiologist and an anesthesiologist. Heart rate, blood pressure, and pulse oxymetry were measured every 5 minutes throughout the study. Each subject was connected to the ISPC device (Lympha-press, Mego-Afek AC, Afek, Israel) soon after arriving in the procedure room. Each leg was wrapped in a pneumatic sleeve from the tip of the toes to the proximal thigh below the inguinal region. Each sleeve was composed of 10 air cells, separately connected by an inflation tube to a computerized compressor, aimed to inflate the sleeves sequentially to a maximal pressure of 50 mm Hg, at a rate of 2 cycles/min (separated by a short interval), to enable maximal venous refilling before any successive pneumatic squeeze. Inflation pressure was not adjusted to account for varying body size, and we used the same inflation pressure that was used in our previous studies,[13–15,17] in which we have noted the cardiovascular advantages of the pneumatic sleeves.

As presented in Figure 1, the activation of ISPC lasted 40 minutes. After TTE measurements without ISPC activation, we activated the pneumatic sleeves, and after 5 minutes we started cardiac assessment which lasted 10 minutes. After an additional 15 minutes (with continuing ISPC activation), we performed a second TTE assessment which lasted another 10 minutes (total ISPC activation time 40 min). Each participant served as his or her own control. Echocardiographic measurements were conducted by experienced echocardiography specialists with the use of ultrasound with a 1–5-MHz transducer (iE33, Phillips Medical Systems, Andover, Massachusetts). During assessments, the patients were in the left lateral decubitus position. Echocardiographic parameters were measured in the parasternal long-axis view and by the apical 2- and 4- chamber view and included the velocity time integral (VTI) of the left ventricular outflow tract (LVOT), ejection fraction, cardiac output, stroke volume, peak velocity of early diastolic atrioventricular flow through the mitral valve (E), peak velocity (flow) during atrial diastolic contraction (A), and deceleration of the E-wave. Cardiac output was calculated by multiplying VTI of the LVOT by heart rate. Fractional shortening of the left ventricle was measured by M-mode still frame, and the E/A ratio was calculated. We also measured heart rate, the area of the right and left atria in the apical 4-chamber view, and the systolic and diastolic dimensions of the left ventricle. The dimensions of the left ventricle were estimated by measuring the distance between the interventricular septum and the posterior wall of the left ventricle in the parasternal long-axis view. Moderate and severe pulmonary hypertension (PHT) was defined according to European Society of Cardiology (ESC) guidelines.[18] Moderate PHT was defined as tricuspid regurgitation (TR) velocity of 2.9–3.4 m/s and systolic pulmonary artery pressure (sPAP) of 37–50 mm Hg with or without additional signs of PHT. Severe PHT was defined as TR velocity >3.4 m/s and sPAP >50 mm Hg with or without additional signs of PHT. Severe mitral regurgitation was defined according to recent ESC guidelines.[19] Color tissue Doppler imaging (TDI) in the apical 4-chamber view sampled the septal region of the mitral annulus. TDI analysis (to assess diastolic dysfunction) included peak early diastolic velocity (TDI velocity and Med E′) and the E/Med E′ ratio [(the ratio of early diastolic mitral inflow (E) to early diastolic mitral annular tissue velocity (E′)]. SVR was calculated according to the relationship between mean arterial pressure (MAP), cardiac output, and central venous pressure (CVP; directly reflected by measuring cubital vein pressure through a 17-gauge intravenous cannula). This method has been previously validated in surgical patients.[20]

Statistical Analysis

Statistical analysis was performed by with the use of computerized SPSS version 19 (SPSS, Chicago, Illinois). Quantitative data were expressed by means, medians, and standard deviations. Qualitative data was presented as frequencies and percentages. Paired-sample *t* test or Wilcoxon signed rank test were used to compare measures between time points when appropriate (evaluating the significance of the mean change in echocardiographic parameters before and after activation of the ISPC device). It was assumed that the differences, calculated for each pair, had an approximately normal distribution. Repeated-measures model was used to evaluate changes over time and was appropriate for MAP and CVP. Multiple comparisons were performed (Bonferroni test) for those measures, and trend over time period was presented for the CVP measure. *P* values of <.05 were considered to be statistically significant.

Results

The patients' clinical characteristics are detailed in Table 1. As presented in Tables 1 and 2, the study population included 19 patients (16 male, 3 female), with an overall mean age of 66.8 ± 10.6 years (median 68, range 48–82). At baseline, the mean LVEF by which the patients were detected was 29 ± 9.2% (median 32%, range 10%–40%). Moderate right ventricular (RV) dysfunction was noted in 32% of the patients, and none had severe RV dysfunction. Severe TR was noted in 1 patient and moderate TR in 5 (26%). Five patients