

## **Chronic Venous Insufficiency: prevalence and effect of compression stockings**

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### **Abstract**

**Introduction:** Chronic venous insufficiency (CVI) is a common disease affecting mainly lower limbs and significantly influencing the quality of life. This study aims to estimate the prevalence of CVI in the Qassim Region and test the effectiveness of compression stockings as an intervention option.

**Methods:** A cross sectional study was conducted to assess the prevalence of CVI among patients visiting primary health care (PHC) centers in the Qassim Region. CVI patients were diagnosed and classified using the clinical, etiologic, anatomical, and pathophysiological (CEAP) scale. They were randomly divided into two groups, one using compression stockings and the other standard medical therapy. A clinical follow up was done using multiple scale system including CEAP scale. Data analysis was performed using SPSS.

**Results:** Among the 226 screened patients, 138 (61.1%) were diagnosed as having CVI (69% female and 45% male,  $p < 0.001$ ). Compared to the baseline, both the clinical and venous scores for CVI at the follow-up were significantly lower among patients using compression stockings,  $p = 0.002$  and  $p = 0.003$ , respectively. Regression analysis suggested that, after controlling for age, sex and body mass index, compliance was the main factor responsible for a significant reduction in the clinical score among CVI patients.

**Conclusions:** Chronic venous insufficiency is very common in the Qassim Region. Compression stockings are highly effective in improving clinical symptoms and signs of CVI.

### **Trial registration:**

This study is registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT02050061).

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### Introduction:

Chronic Venous Insufficiency (CVI) commonly affects lower limbs with a prevalence ranging between 25-40% and 10-20% in women and men, respectively. The annual incidence is 2-6% in women and 1.9% in men.<sup>(1-4)</sup> The caveat however is the way CVI is defined, which would have an effect on these statistics. Studies carried out in Saudi Arabia, Bawakidet al<sup>(5)</sup> estimate a prevalence of 45.6%, which is much higher than the rates in Western countries. Increased exposure to risk factors including the opulent lifestyle is the likely incriminating factor.

Among the many assessment tools developed for this study, the descriptive clinical, etiological, anatomical, and pathophysiological findings (CEAP classification) was found to be the most appropriate for diagnosis and classification of CVI.<sup>(6, 7, 8)</sup>

Conservative treatment of CVI mainly relies on compressive stockings<sup>(4)</sup> They exert a graded pressure that reduces the ambulatory venous pressure in the lower limbs. The fall in ambulatory venous pressure is directly proportional to the compression that also explains the beneficial effects to patients with venous ulceration in limbs.<sup>(9, 10, 11)</sup>

However, no data are available on CVI for Saudi Arabia covering early stages of the disease, in the perspective of life style of the affected population and the suitability of management interventions. This study therefore aims to estimate the prevalence of CVI in the Qassim region along with the testing of effectiveness of compression stockings to control the condition.

### Methods:

**Study design:** The study was conducted in two phases:

**Phase 1:** A cross sectional descriptive study to identify CVI cases and estimate their prevalence in patients visiting the primary health care centers;

**Phase 2:** A prospective interventional study meant to evaluate the impact of stockings as an intervention to control signs and symptoms of CVI patients diagnosed during the first phase;

### Study site and population:

Seven PHC centers were randomly selected for this study in Buraidah and Unaizah, two large cities of the Qassim region. All adult patients visiting the selected PHC centers were asked for their consent to be screened for CVI. The first 100 patients clinically diagnosed as CVI were asked to participate in the second phase of the study. Informed consents were obtained from all participants.

**Exclusion criteria:** Children, pregnant women and patients who refused to participate or give informed consent were excluded.

**Phase 1:** This was a cross sectional study of patients attending the selected PHC centers of the Qassim region that lasted for six months, from October 2011 to March 2012, screening 226 patients for CVI. All patients were interviewed using a screening questionnaire designed to make clinical diagnosis of CVI. The most recent scale for CVI assessment was used for identification of the disease. It included the clinical severity, etiology or cause, anatomy and pathophysiology, i.e. the CEAP scale<sup>6</sup>. Each patient found positive for CVI was offered the option to participate in the second phase of the study. We aimed to recruit 100 patients of CVI.

**Phase 2:** Following completion of the first phase, we randomly divided the 100 CVI patients, who had agreed to participate in Phase II, regardless of their CEAP class into two groups; one to receive compression stockings (SIGVARIS™) and the other standard medical therapy. Each group comprised fifty patients. Compression stockings were issued free of charge to the relevant group from a store in Buraidah City. The other group receiving standard therapy was encouraged to exercise and avoid prolonged standing posture.

The questionnaire enquired about the basic demographic data, symptoms and signs of CVI, and presence of chronic diseases such as diabetes, hypertension and cardiac conditions. Focused physical examination of the lower limb for signs of CVI was also performed. CEAP class, score, and venous severity score were also determined for all patients to assess

the severity. All CVI patients were instructed about risk factors, symptoms, grades and approach to management. Finally, 30 CVI patients were given the SF36 questionnaire<sup>(12)</sup> to assess their quality of life index.

#### Follow Up:

Telephonic follow up of all 100 CVI participants, in whom the evaluator was blinded about the participant's prior answers and group allocation, was done. At the end of the follow up questionnaire, compliance to and practicality of compression stockings was assessed, if applicable. The compliance assessed by asking whether the participant collected stockings from the store, used it regularly and noticed the effect of the stockings (i.e. good, not comfortable or neutral). The patient was also asked if he/she would recommend compression stockings to others with the same problem.

The study protocol was previously reviewed and approved by the Research Committee of Qassim University and Medical Education and Research Center in Qassim region, Ministry of Health.

#### Statistical Analysis:

Statistical Package Social Science; SPSS version 17 software (SPSS Inc. Chicago, Illinois, USA) was used for data entry and processing. We used chi-square test, ANOVA and linear regression to assess the impact of compression stockings on the clinical and venous scores of CVI before and after the intervention.

#### Results:

Among the 226 adult patients who agreed to be screened, 138 (61.1%) were diagnosed to have CVI (69% in females and 45% in males,  $p < 0.001$ ). CVI was more common in women than men (69% versus 45%,  $p < 0.001$ ). See table 1 for demographics of our cohort. Although, we could not elicit risk factors for the development of CVI, we found statistically significant difference in trending towards CVI in the female gender, obesity, hormonal therapy and presence of comorbidities such as diabetes and hypertension. These statistical differences were not necessarily to be of clinical relevance.

**Table 1: Demographics/risk factors in relation to CVI**

	CVI, n=138	No CVI, n=88	P value
Age (mean, yrs)	43,9	32.8	<0.001
Female gender	75.4%	52.3	<0.001
Occupation			
Housewife/Retired	63 %	28.4%	
Teacher/reporter/soldier	14.5%	12.5%	
Doctor/Nurse	0.7%	3.4%	
Office work	14.5%	14.8%	
Student	7.2%	40.9%	
Obesity	53.6%	18.2%	<0.001
Hypertension	28.3%	8.0%	<0.001
Diabetes	31.2%	11.4%	<0.001
Hormonal therapy	44.2%	19.3%	<0.001
Previous history of DVT	2.9%	3.4%	0.558

We randomly divided the 100 CVI patients (who consented to participate in Phase II; see details above in the Methods Section) into two groups of 50 each: compression stockings and standard therapy. Compared to the baseline, both the clinical and venous scores for CVI at the follow-up stage were significantly lower among patients using compression stockings,  $p=0.002$  and  $p=0.003$ , respectively. The result was significant even though only half of the participants in the treatment group were compliant with instructions, i.e. they received and used the compression stockings as

directed. The remaining patients did not collect compression stockings. The main reason for not obtaining compression stockings was quoted as lack of transportation. The result was the study having two uneven groups: 25 in the treatment group and 50 in the control group.

Regression analysis suggested that, after controlling for age, sex and body mass index, the compliance was the main factor responsible for a significant reduction in the clinical score among CVI patients (Table 2).

**Table 2: Pre- and post-scores of intervention groups**

	Compression Stocking Group, n=25	Control Group, n=50	P value
CEAP Clinical Score, mean:			
Baseline	2.52	1.62	0.006
One month follow up	0.48	2.61	<0.001
Venous Score, mean:			
Baseline	3.1	2.4	0.032
One month follow up	0.38	3.1	<0.001

CEAP: clinical, etiological, anatomical, and pathophysiological

As stated earlier, 50% of patients in the treatment group did not use compression stockings. The main reason for non-compliance was the lack of transportation from Unaizah to Buraidah as most of the participants were females (75%) and their symptoms were not severe enough to feel the urge for a trip to Buraidah to pick up free compression stockings. Nevertheless, the observed benefits were statistically significant, even though the clinical conditions were worse in the treatment group at the baseline.

#### Discussion:

Our study showed that the prevalence of CVI is 61% in our sample. This figure is not far from the research already done in Saudi Arabia.<sup>(5)</sup> The numerically higher prevalence in our study may be driven by the higher number of female population in our sample. As expected the female gender is associated with a higher prevalence than male (69% versus

45%). This is a well-known association seen in many other studies.<sup>(4,13, 14)</sup>

Our study showed an increased prevalence of CVI in housewives/retired individuals, which could be related to their relative inactivity and sedentary life style, or in some cases to prolonged periods of standing. Similar studies showed increased prevalence of varicose vein in occupations which require prolonged standing,<sup>(4)</sup> although a lack of association has also been reported by others.<sup>(13)</sup> Studies have also shown that CVI is commonly associated with decreased physical activity.<sup>(6)</sup>

The pathophysiology and clinical manifestations of CVI rely on the result of blood flow back into other veins and pooling in the leg tissues, causing swelling and sometimes varicose veins. Chronic blood stasis and migration of red blood cells extravascularly lead to hemolysis and hemosiderin deposition in the subcutaneous tissues. Wear and tear in the subcutaneous tissue of lower limbs leads to scarring and open

sores especially in the ankle area. Compression stockings exerting moderate pressure 20-30 mmHg prevent such stasis in the lower limb. By exerting a graduated compression between ankle and calf; they induce a reduction in the ambulatory venous pressure in the affected limb. The greater the degree of graduated compression, the greater the fall in ambulatory venous pressure leading to 'lighter' legs.<sup>(15)</sup> So it is beneficial to wear stockings in occupations that require prolonged standing such as hotel receptionists, teachers and airport attendees.

In our study, we found compression stockings as highly effective in improving symptoms and quality of life, which has also been shown by other studies.<sup>(9, 10, 16)</sup> Given the high prevalence of CVI and the effectiveness of compression stockings, our results suggest a large-scale study that could guide policy makers to recommend such simple and non-invasive intervention, such as compression stockings during working hours as part of health and safety regulations.

The limitations of our study include a large female cohort; 50% compliance to the use of compression stockings and a small sample size. This highlights the need for a research study with relatively wider geographical and demographic scope the results of which could inform a wide range of curative and preventive programs at the national level.

### Conclusion:

Chronic venous insufficiency is very common among adult patients attending PHC centers in the Qassim Region, and is relatively higher in obese women. Compression stockings are highly effective in improving clinical symptoms and signs of CVI.

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