

Effects of elastic stocking on quality of life of patients with chronic venous insufficiency

An Italian pilot study on Triveneto Region

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Aim. Even though compression therapy is the most recommended treatment for chronic venous insufficiency (CVI) in the national and international guidelines, its application, at least in Italy, is lower than the estimated need from the prevalence of CVI in the epidemiological studies. Since we believe that the measurement of the impact of compression therapy on quality of life (QoL) could improve the compliance for this precious treatment, we carried out this study on 50 patients with CVI.

Methods. Fifty patients (23 CEAP C₂ and 27 C_{3-4,5}), selected within a larger study on QoL in CVI, received a prescription for compression therapy. Before treatment and 4 months afterwards, the patients received the instrument for QoL assessment (MOS SF-36; CIVIQ-2; Euro-QoL 5D and a visual analogue scale). The score scales have been adjusted to poorest QoL as 0 and best QoL as 100.

Results. Baseline QoL of patients in class C₂ did not show significant difference with the healthy Italian Population, except for the physical role item. The patients in class C_{3-4,5} showed significant reduction of QoL. After 4 months all the items of the utilized instrument showed significant improvement (from P<0.01 to P<0.04 for SF-36; from P<0.099 to P<0.006 for other instruments) in all CEAP classes.

Conclusion. The study unquestionably shows that the compression therapy improves the QoL of patients with CVI, and should be included in the CVI treatment covered by the Public National Health Insurance. Finally, the QoL measurement could be utilized as the scientific method to assess the effectiveness and efficacy of different therapeutic devices.

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Key words: **Bandages - Compression therapy - Venous insufficiency - Quality of Life - CEAP classification.**

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Even if both national and international guidelines for chronic venous insufficiency (CVI) suggest compression therapy with the highest grade of recommendation,¹⁻⁴ its application, at least in Italy, is lower than the estimated need from the prevalence of CVI in epidemiological studies.

There are different causes behind this low prescription rate: the low compliance of the patients and, probably, the fact that often doctors do not give a resolute indication.

In over 20 years of teaching vascular medicine, our team has always recommended that compression is a therapy and, similar to medications, it has its own indications and contraindications. Compression therapy utilizes different devices for the acute phase (bandage) and for the maintenance therapy (stocking), with specific posology (the stretch degree for the bandage, and compression class for the stocking).

In a recent search in Medline Database, we found 180 papers when searching for "elastic stocking and CVI", 300 papers when searching for "elastic stoking and venous disease", and 600 papers (including acute deep vein thrombosis (DVT), sepsis and other leg diseases) when searching for "compression therapy and venous disease".

Searching for "compression therapy and quality of life" (QoL) we found only 8 papers that included the treatment of fracture or metastatic bone disease, whilst searching for "elastic stocking and QoL" we found only 4 papers. Two of them were about lymphedema. The first, concerning the lymphedema postmastectomy, utilized a QoL assessment instrument in the cancer therapy. The

TABLE I.—Baseline scores of SF-36 items of patients with chronic venous insufficiency receiving prescription for elastic stocking.

		Physical functioning	Physical role	Bodily pain	General health	Vitality	Social functioning	Emotional role	Mental health
IHP over 50 y	Mean	79.10	72.53	68.31	60.08	58.71	76.33	69.66	63.18
CEAP class C2	Mean	82.25	67.94	66.06	59.76	62.94	70.44	66.47	71.94
	SD	14.59	32.89	16.31	18.03	15.32	14.04	29.13	16.23
P<		NS	P<0.001	NS	NS	NS	NS	NS	NS
CEAP class C3-4-5	Mean	41.31	54.55	47.09	40.64	46.97	60.00	58.73	55.91
	SD	15.38	30.86	24.00	21.74	23.58	26.10	25.48	17.70
		P<0.0001	P<0.0001	P<0.001	P<0.001	P<0.001	P<0.01	P<0.001	P<0.01

IHP: Italian healthy population over 50.

P values: Student's t-test for paired data, between scores of Italian Healthy Population and two groups of enrolled patients.

second did not indicate the utilized instrument. Of the two remaining papers, one asks for further studies about the follow-up of DVT and QoL to find objective criteria for diagnosis of post-thrombotic syndrome, and the latter underlines the opportunity of the health-related QoL to assess the effectiveness of new tools for the treatment of venous ulceration.⁵

In spite of the high number of papers about the effectiveness of elastic stocking in CVI, none has been published about the impact of compression therapy on QoL of patients with CVI. We believe that measuring the impact that compression therapy has on QoL could improve the doctor's and patient's compliance for this precious treatment. This paper refers to the results obtained in 50 patients with CVI.

Materials and methods

Within a pilot study on QoL in CVI carried out in the Triveneto Region (Veneto, Trentino Alto Adige and Friuli Venezia Giulia), we enrolled 112 patients consecutively seen in 10 Vascular Laboratories by 14 angiologists or vascular surgeons (Appendix). The patients were informed about the target and modality of the study, and gave their informed consent.

Each patient received a preliminary Mini-Mental State Examination (MMSE).⁶ Two people with a MMSE lower than 24 were excluded from the study.

One hundred and ten patients received the QoL questionnaires, and were asked to fill out it in complete self-administration, helped by the nurses only if required.

The utilized instruments have been:

- the SF-36 (a generic questionnaire and the most utilized instrument to assess QoL; it has 8 items, 4 physical ones (physical activity, physical role, bodily pain, general health) and 4 psychomental ones (vitality, social activity, emotional role, mental health)).⁷⁻⁹ The results are reported with a single score for each item;

- the CIVIQ-2 questionnaire, a specific instrument for venous diseases with 20 questions;^{10, 11} the results are reported as global index score (GIS);

- two utility measurement instruments, the Euro-QoL 5D and the visual analogue scale;¹² the results are reported as a single score. The score scales of all questionnaires have been adjusted to reflect the poorest QoL as 0 and the best QoL as 100.

After answering the questionnaire the patients underwent a clinic and instrumental examination to assess the diagnosis according to the CEAP criteria.^{1, 8} The class C criteria have been assessed as clinical (visible and palpable) categories. The class E has been assessed by clinical history. The A and P criteria have been assessed by echo-duplex examination (reflux, obstruction, superficial, deep and perforator veins) following the criteria of the consensus statement on the investigation of CVI.¹

Sixty patients received the same questionnaires 30 days after the first administration to evaluate the test-retest reliability.

Seventy patient (38 classified in the CEAP class C2 and 32 in the class C3-4-5) received a prescription of elastic stocking, according to the recommendation of the guidelines of Italian College of Phlebology.²⁻⁴ After 4 months, the patients came back to the Vascular Lab, and were asked to fill out a new copy of the questionnaires. The four

TABLE II.—Changes of the physical and mental scores of SF-36 after 4 months of compression therapy.

CEAP class	Physical health scores								
	PF		PR		BP		GH		
	Before	After	Before	After	Before	After	Before	After	
C2	Mean	82.25	85.06	67.94	85.88	66.06	76.35	59.76	64.12
	SD	14.59	16.76	32.89	22.45	16.31	18.56	18.03	16.45
	P<	0.2546		0.0142		0.0042		0.1395	
C3-4-5	Mean	41.31	55.91	54.55	68.27	47.09	68.82	40.64	49.36
	SD	15.38	17.29	30.86	23.45	24.00	21.36	21.74	21.49
	P<	0.0196		0.0906		0.0022		0.0567	

CEAP class	Mental health scores								
	V		SF		RE		MH		
	Before	After	Before	After	Before	After	Before	After	
C2	Mean	62.94	67.35	70.44	76.44	66.47	88.46	71.94	73.18
	SD	15.32	12.64	14.04	13.92	29.13	18.13	16.23	11.47
	P<	0.1132		0.0574		0.0050		0.3153	
C3-4-5	Mean	46.97	55.45	60.00	71.59	58.73	65.07	55.91	61.09
	SD	23.58	20.43	26.10	26.27	25.48	30.27	17.70	18.16
	P<	0.0759		0.0339		0.2692		0.0469	

TABLE III.—Changes of global score index of CIVIQ-2 questionnaire, Euro-QoL 5-D and visual analogue scale, after 4 months of compression therapy.

CEAP class		CIVIQ-2		Euro QoL 5-D		VAS	
C2	Mean	76.54	84.56	78.58	88.91	71.18	74.71
	SD	14.45	12.82	16.16	13.66	13.64	15.66
	P<	0.0063		0.0083		0.0996	
C3-4-5	Mean	54.20	63.18	55.48	59.79	49.55	53.64
	SD	19.33	21.65	35.64	30.34	17.95	22.48
	P<	0.0285		0.3131		0.1065	

months time frame has been chosen because several questions of the questionnaires are related to the health status of the previous 4 months.

Missing data

Several patients have been withdrawn and not considered in the final analysis: 6 because of incomplete filling of questionnaires at baseline, and 20 because of no-show during the follow-up.

The final available data are related to 104 patients for baseline analysis of QoL, published separately,¹³ and 50 patients (23 CEAP class C₂ and 27 CEAP classes C₃₋₄₋₅) with QoL measurement before and after 4 months of compression therapy.

The results have been analyzed using the Student's *t*-test for paired data.

Results

The coefficients of correlation for the test-retest reliability were more than 0.85.

The baseline QoL of the patients of CEAP class C₂ measured by SF-36 did not show significant difference with the normal value of Italian healthy people,¹⁴ except the item physical role. Conversely, the patients of the classes C₃₋₄₋₅ showed a significant reduction of QoL, especially for the physical items, but also involving the general health and vitality (Table I).

After 4 months of compression therapy, the patients of class C₂ showed a significant improvement of the following items: physical role, bodily pain, social functioning and emotional role of SF-36. The statistical significance of different items varies from P<0.01 to P<0.004. The physical functioning, the mental health, vitality and general health of SF-36 did not reach significant value.

The patients of classes C₃₋₄₋₅ showed significant improvement of QoL in all SF-36 items, including general and mental health, but with no significant increase in vitality an emotional role (Table II).

The results obtained by other instruments confirm the general trend of improvement of QoL in the class C2 (GIS $P < 0.006$; Euro-QoL 5-D $P < 0.008$; VAS $P < 0.099$), but in the advanced stages (classes C3-4-5) only the GIS of CIVIQ-2 questionnaire showed a significant changes of the score ($P < 0.028$) (Table III).

Discussion

The general trend of our results unquestionably shows that compression therapy significantly improves QoL of patients with CVI, and increases the strength of its already strong recommendation of the guidelines.

Beyond this general comment on the effectiveness of elastic stockings, our results invite also several clinical comments.

Data from SF-36, physical role, bodily pain and social functioning improve in both groups, class C₂ and class C_{3,4,5}. Physical functioning, general and mental health show significant change in class C_{3,4,5}, but do not in the class C₂. Probably these items are impaired only in the advanced stages of CVI, and in class C₂ the elastic stocking cannot improve what is still good.

There are different comments about the emotional role; this item measures the presence or absence of problems due to the emotiveness of the patient, and their impact on the patient's activities. Probably in class C₂ the impairment of emotional role is low and elastic stocking improves it significantly, whilst in the advanced stages the impairment is significantly worsened and the beneficial effects of compression therapy cannot improve this item significantly. A higher sample size could demonstrate a statistical relevance also for the emotional role; further studies are needed.

In addition, we should underline that doctors did not consider all CEAP class C2 patients enrolled in the pilot study eligible for compression therapy. Comparing the SF-36 items' scores of the patients with elastic stocking prescription and the items' scores of all enrolled C2 patients, we found that the physical role shows a worsened score ($P < 0.01$) in the patients considered eligible for elastic stocking (Table IV).¹⁴ These data suggest that the QoL measurement could help the doctor's expertise for

TABLE IV.—Mean of SF-36 items scores of patients CEAP class C₂, receiving prescription of elastic stocking, and all patients CEAP class C₂ enrolled in the pilot study.¹³

CEAP class	PF	RP	BP	GH	V	SF	RE	MH	P<
C2 (e.st.pr.)	82.24	67.94	66.05	59.76	62.94	70.44	66.47	71.94	
C2 all patients	85.37	80.69	68.06	61.14	55.93	76.74	71.2	65.42	0.19
P<	NS	0.01	0.19	NS	NS	NS	NS	NS	

the prescription of elastic stocking, at least in the dubious cases.

About the other utilized instruments, the best results have been registered by GIS of CIVIQ-2 and Euro-QoL 5-D, in the class C₂. In the class C3-4-5 only GIS showed a significant difference, but lower than the improvement found in class C₂. These results show a higher sensitivity of GIS CIVIQ-2 in comparison to the other utility instruments. Therefore, we must declare a lesser sensitivity of this questionnaire in the advanced stages, probably because the questions of this instrument are calibrated on early stages symptoms rather than on those of the advanced stages of CVI (QoL instrument for RELIEF study, which enrolled patients only in the classes C1-C4).

Conclusions

This study indicates that compression therapy, largely validated in clinical practice, also meets another criteria required by European Medical Agency (EMA) for the drugs and other therapeutic options: the improvement of QoL.

We hope that our paper could contribute to the inclusion of the compression therapy in the CVI treatments covered by the Public National Healthy Insurance, and we also hope that the scientific society and the manufacturing companies could adopt the QoL measurement as a scientific method to assess the efficacy of different devices.

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Appendix

SIAPAV Working Group Quality of Life in Vascular Medicine.

Pilot study on quality of life in patients with chronic venous insufficiency Triveneto Region.

List of participants doctors and vascular laboratories:

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