

Empowerment and patient-centered care: A therapeutic educational project for patient with venous ulcers. A pilot study

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ABSTRACT

This project involved conception, validation and testing of a paper training tool, developed for the patient accessing the nursing clinic because of its venous leg ulcer. A multi-professional Team designed and validated a five item questionnaire concerning the disease awareness, the need for therapy and the knowledge of some basic pathophysiology contents. The questionnaire was submitted to the enrolled patients before and after a training intervention in order to test its effectiveness (pre-post test without control group). An analysis of the effect of the intervention was carried out by testing the Pre-Post Intervention mean scores variation. Our primary efficacy endpoint tested is statistically significant ($p < 0.001$) for the selected sample: Pre-I mean 6.22 (95% CI 5.22-7.21) Post-I mean 10.83 (95% CI 10.59-11.06). According to scientific literature, this pilot study has enabled the wound care nurse to make the importance of implementing patient knowledge clear in order to achieve a targeted customized intervention. The training intervention, perfectible as well as structured, must be considered as a starting point for further future developments.

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INTRODUCTION

The venous ulcers of the lower limbs represent an extremely disabling chronic problem; they weigh on the affected subject from the clinical, psychological and social point of view.^{1,2}

More than 70% of the ulcerative lesions of the lower limbs are venous.³⁻⁵

The risk of developing chronic venous insufficiency and injuries increases with age. Given the demographic trend of the population, the trend will be to have an increasing number of patients affected by this disease.⁶⁻⁸

The vascular venous ulcer of the lower limbs is characterized by a slow healing and the high rate of recurrence; this justifies the health and social costs, often significantly high.^{6,8,9}

The estimated rate of recurrence of lower limb ulcers varies from 67% to 80%. The appropriateness and effectiveness of the treatment path, therefore, go through the proper treatment of injuries, timely intervention on lifestyle and correction of the underlying etiological factors.^{10,11}

The care of the patient suffering from vascular lesions of the lower limb must be carried out by a multidisciplinary team, composed of different professional figures, who with their skills collaborate to optimize the treatment path.¹²⁻¹⁶ According to the literature examined, the expert in Wound Care is the figure that best suits the role of supervisor and coordinator of the entire team of professionals.¹² To play a fundamental role in the treatment of venous ulcers of the lower limbs is the empowerment of the patient, the awareness that the patient has of himself and his condition of health and his active participation in the treatment process.

Empowerment takes the form of health education and the promotion of self-management.^{17,18}

Health education is a systematic, continuous, structured and patient-centered learning process.

It must be structured, organized and provided to all patients with a variety of means. It is aimed at helping the patient and caregiver to understand the nature of the disease and the need for treatment.

The possibility for the patient to have synthetic written information and indications with a language weighed on the target and available at any time encourage compliance and improve the outcome.¹⁹⁻²⁴

The paper brochure that contains information about the pathology of which you are affected, standards of conduct and lifestyles is well suited to represent a potential training tool to support the team that takes care of the patient.^{7,25-28}

So, starting from what we learned in the literature it was decided to design and experiment a paper training booklet dedicated to the patient with venous vascular lesions of the lower limbs who regularly accessed the nursing clinic of the District of Macerata-Asur Marche AV3, in order to verify the effectiveness of this training tool in the course of care.

EPIDEMIOLOGY

Lower limb ulcers represent a serious clinical and social problem with a prevalence ranging between 0.1% and 1% in the general population.

Epidemiological data collected from international literature are often discordant, due to the variability of the criteria used in several recent prevalence surveys. In Europe the prevalence of lower limbs Chronic Venous Disease (MVC) ranges between 10 and 50% in the adult male population and between 50 and 55% in the female one.

Chronic venous insufficiency is the main cause of development of ulcerative lesions for a percentage of cases ranging between 70 and 80%.²⁹

In Europe almost 70% of afflicted patients are affected by classes CEAP C0 and C1, about 25% are in C2 and C3 with varices and/or edema; 5% of patients can be stratified C4 to C6.³⁰⁻³²

The long diagnostic-therapeutic process, the significant loss in working time and the impact on the quality of life feed cause-specific health cost.³³⁻³⁵

The prognosis of ulcers is generally not favorable as far as taking a long time to heal and relapsing with great ease: about 50-75%, indeed, repairs in 4-6 months, while 20% of them remains active at 24 months; 8% exist even after 5 years.³⁶

Considering just elderly population, the prevalence is about 1.7%, while the incidence is around 1.42%.³⁷

Most patients are treated by local health services and about half of them require home care.³⁸

In Italy the prevalence of lower limb ulcers in the general population is around 1%. About 22% of cases concern young people, but the affected increase with aging. About 3-4% of the population over the age of 65 suffer from an ulcer and about 75% are afflicted by three or more diseases; this condition could hamper the recovery. In about 75% of cases lower limb ulcers have venous origin; 21% occur bilaterally and with a marked tendency to recurrence within 5-10 years.³⁵⁻³⁸

MATERIALS AND METHODS

The trial was authorized by the Macro-structure Director of the Health District of Macerata and agreed with patients enlisted by means of a special written information and consent form; the study design also provided a validation of a training tool and a questionnaire. These were designed and validated by a multiprofessional team composed of a psychologist, a wound care expert nurse, a wound care dermatologist, a wound care vascular surgeon, a general medical practitioner, a physiatrist, a Health District physician of the nursing clinic (promoter of the study) and a graphic designer.

The training tool is a paper booklet, consisting of a graphic part with stylized and elementary images with a notional part, built with a non-technical language and thought about the target audience.

The questionnaire consists of five items, which investigate the patient's awareness of own disease and treatments; it also verifies the knowledge of some basic pathophysiological concepts.

The questionnaires, the informative notes and the informed consents have been illustrated and delivered always from the same nurse near the surgery of the difficult wounds. The educational material was provided to each patient at the time of recruitment to the study sample. The same nurse also took care about health education proposing it to patients already managed by the nursing clinic and in possession of the inclusion criteria provided by the study design. The interview happened in a dedicated room with a table and two chairs next to each other so as to ensure both the privacy of the person and a two-way communication, enhancing the availability to listen and comparison.

Study design

Pre-post test without control group.

Sample

Subjects enrolled in the study: All patients suffering from venous and mixed injuries of the lower limbs already attending the Nursing Clinic of the Health District of Macerata and all patients followed in Home-Care setting

from 05/06/2019 to the period 07/31/2019 who have signed an informed consent to participation in the study, of any age, gender, nationality and educational level, without a caregiver.

Subjects excluded from the study: Patients belonging to the Nursing Clinic of the Health District of Macerata and followed in Home-Care setting, suffering from skin injuries other than those covered by the study protocol; patients who need a caregiver and patients who have not signed the informed consent.

Statistics

An analysis of the effect of the intervention/training tool on the variation of the scores obtained in the study was carried out; the statistical significance was tested by a queue t-test for paired data. The data has been processed by XIStat Software.

RESULTS

The sample of patients meeting the study inclusion criteria is composed of n=20 patients aged 42 to 88 years. Two subjects were eliminated because not-responders at the post intervention training questionnaire.

The sample in the study consists of n=10 women (55.6%) and n=8 men (44.4%). 94.5% of patients (n=17)

are Italian, n=1 patient is Ukrainian (5.5%). 88.9% (n=16) of the patients were tested in the outpatient area, while for 2 patients (11.1%) the nurse performed the training tool and administered the questionnaire at home.

Table 1 set out the distribution of ages by gender of patients enrolled in the study, while educational level is shown in Figure 1.

Figure 2 describes the distribution of the Pre-intervention (Pre-i) and Post-formative (Post-i) scores.

An analysis of the impact of the intervention/training-tool on the variation of the scores obtained was carried out by means of a one-queue t test for paired data (Table 2).

DISCUSSION

The collected data during the period May 6th 2019 - July 31st 2019 pointed out the effectiveness of a training intervention applied to a selected sample of patients followed by the Nursing Clinic in the District of Macerata - ASUR Marche AV3.

Illustration of the project, the booklet and administration of the questionnaires required about 40 minutes per patient. Most of the above time was spent reading the fact-sheet, sharing and collecting informed consent.

The analysis carried out that gender, age and educational level have not had a statistically significant impact on the intervention effectiveness. In addition, neither age

Table 1. Distribution of enrolled patients stratified by gender. Mean age, Standard Deviation (SD), median, mode and range.

| N (%) | Age | | | | |
|--------|------------------|----------------------|------|-------|-------|
| | Mean (\pm SD) | Median | Mode | Range | |
| Female | 10 (55.6%) | 72.5 (\pm 11.8) | 74.5 | 81 | 50-88 |
| Male | 8 (44.4%) | 70.37 (\pm 14.11) | 75.0 | - | 42-83 |
| Total | 18 (100%) | 71.56 (12.56) | 74.5 | 81 | 42-88 |

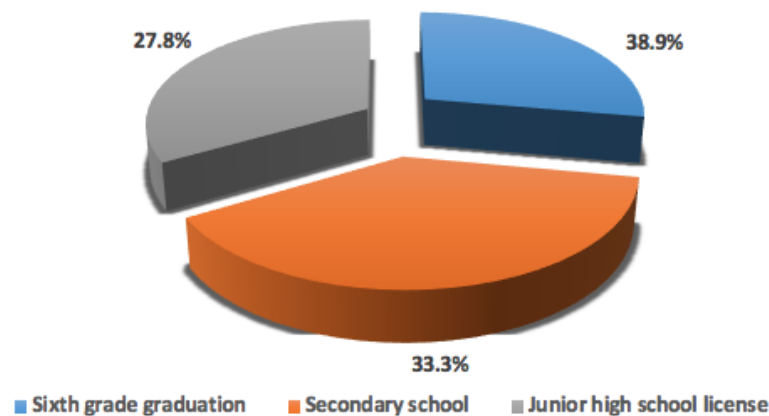


Figure 1. Distribution of the educational level of enrolled patients.

nor schooling were discriminatory for the interest and participation shown by the subject.

As for the disease awareness and some basic patho-physiologic knowledge by respondent patients, clinical history was not overriding: patients with for more than 15 years occurring lesions had neither the first, nor the other.

Our results show an almost complete lack of elementary venous system's anatomic and physiological concepts; unawareness of which ranks as a significant driver leading to venous insufficiency.

This pilot study was affected by several biases.

The first limitation concerns the sample size, restricted due to the available time as laid down by the study dead-

line. A wider time slot would allow to obtain a more representative sample.

A second bias involves the method of questionnaire and training-tool administration as far as just a single wound care skilled operator it has been dedicated for. The opportunity to involve different nurses would allow to check test reproducibility expressed by intra/inter-operator variability.

Besides, the pathology selection likely affected our results: the statistical test was used in an extremely selected sample.

Moreover, the time taken for the administration of the brochure plus questionnaire is not standardized: some pa-

Table 2. Pre-I and Post-I scores. One-queue t-test for paired data.

| Characteristic | Pre-I; mean, median (CI95%) | Post-I; mean, median (CI95%) | <i>p</i> |
|----------------------------|-----------------------------|------------------------------|----------|
| Gender | | | |
| Female | 5.80; 1.99 (4.56-7.03) | 10.8; 0.63 (10.41-11.19) | 0.003 |
| Male | 6.75; 2.38 (5.10-8.39) | 10.88; 0.35 (10.63-11.12) | 0.061 |
| Age | | | |
| < 70 | 6.80; 1.64 (5.36-8.23) | 11.00; 0.0 (0.0-0.0) | 0.232 |
| 71-79 | 5.28; 2.13 (3.80-6.75) | 10.71; 0.75 (10.19-11.22) | 0.033 |
| ≥80 | 6.83; 2.48 (4.84-8.81) | 10.83; 0.40 (10.51-11.15) | 0.660 |
| Educational level | | | |
| Sixth grade graduation | 5.28; 2.13 (3.41-7.14) | 10.71; 0.76 (10.04-11.38) | 0.033 |
| Junior high school license | 6.83; 2.48 (4.81-8.81) | 10.83; 0.40 (10.51-11.15) | 3.125 |
| Secondary school | 6.80; 1.64 (5.36-8.23) | 11.0; 0.0 (0.0-0.0) | 2.232 |
| Total sample | 6.22; 2.16 (5.22-7.21) | 10.83; 0.51 (10.59-11.06) | <0.001 |

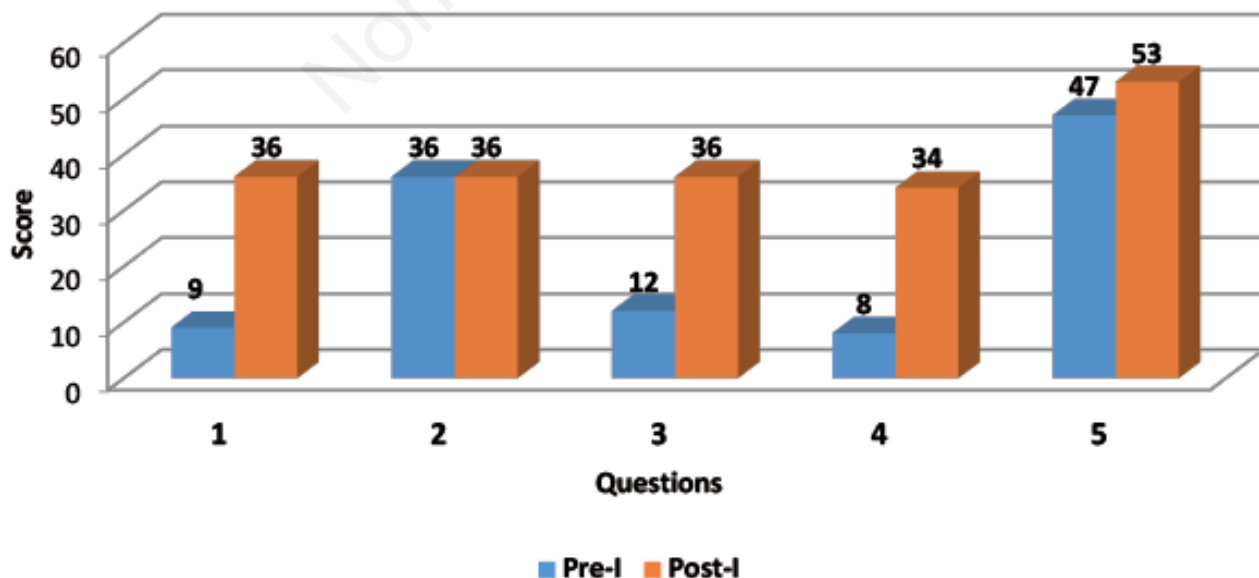


Figure 2. Questionnaire administration: distribution of the Pre-I/Post-I scores.

tient's weak collaboration has led to a necessary times lengthening.

In order to limit the non-responders data, the intervention and the training tool reading coincided with the day in which the outpatient access took place.

Although, in the early stage the nurse dedicated to the administration has had the opportunity to test the feedback of the patient, it was not possible to estimate the effectiveness of the training intervention on the therapeutic compliance in the medium-long term (in line with other reviews).

Finally, it should be noted the lesion-specific characteristics variety and the patient's disease stage array: some of our enrolled subjects were multiple-injured with a very long clinical history, while others of them were at their first outpatient access.

CONCLUSIONS

Patient empowerment and a careful personalized health education handled by a multidisciplinary wound care team are the course of treatment pillars in the continuum of care for the patient affected by lower limbs venous ulcers.

The International Guidelines Recommendations must be customized and shaped, as far as possible, according to the experience of illness, personal life and patient's family condition.

We hope this pilot study will provide other extensive researches about empowerment of the patient suffering from venous lower limb ulcers.

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