VENOUS LEG ULCER-PATIENT COMPLIANCE TO TREATMENT AND IMPACT ON QUALITY OF LIFE

R. Bistreanu
M. Teodorescu

ABSTRACT: Venous ulceration is the most undesirable consequence of exposure to the elevated venous pressure associated with chronic venous insufficiency (CVI). Approximately 1% of the population are at significant risk for development of venous leg ulcer and the incidence of pathology increases among the elderly population. Ulcers often take years to heal and a major problem among patients is compliance to treatment (surgical or conservative), especially to long-term regimes. Applying compression bandages or stockings is considered essential in venous leg ulcer treatment. These bandages or stockings need to be worn as long as there is evidence of venous disease, stockings need to be worn as long as there is evidence of venous disease, (in a five years period). We also evaluated a group of 142 patients examined in ambulatory unit of the same clinic. Demographic data, the cause of venous insufficiency, ulcer characteristics, comorbidity and patient compliance were studied. Adherence to treatment protocol (physician supervised) significantly decreased the time to healing and prolonged the time to recurrence. About the impact of disease on quality of life, there are questionnaires and methods to analyze this, but the challenge is to move from a focus on wound management to understanding the specific needs of each individual within the context of their life. The influence of ulcer treatment on quality of life depends of appropriate wound management to understanding the specific needs of each individual within the context of their life. The influence of ulcer treatment on quality of life depends of appropriate time of surgical intervention and of patient compliance with complex therapy (dressing, stocking, medication and physical exercises).

Keywords: venous leg ulcer, patient compliance, life quality

ULCERUL VENOS DE GAMBĂ - COMPLIANŢĂ PACIENTULUI LA TRATEMENT ŞI IMPACTUL PE CALITATEA VIEŢII.

Rezumat: Ulecraţia venaosă este consecinţa cea mai severă a expunerii la hipertensiunea venaosă din insuficienţa venaosă cronică. Riscul de a dezvolta ulcer venos de gamba este prezent la circa 1% din populaţie, incidenta bolii crescând la vârstnici. Vindecarea leziunii poate necesita uneori luni sau ani, iar o problema majoră este complianţa la tratament (chirurgical sau conservator), în special pentru terapile pe termen lung. Aplicarea bandajelor compresive sau a ciorapilor elastici este considerată esenţială în tratamentul ulcerului venos de gambă. Compresoterapia se menţine atât timp cât există semne de boală venaosă, ceea ce însă nu adesea pentru toată viaţa. Ulcerul venos de gambă are şi un impact major asupra vieţii cotidiene, datorită durerilor, tulburărilor de somn, problemelor financiare, iar mobilitatea pacienţilor si capacitatea de muncă se reduc. Menţionăm și izolarea socială (prin teama de traumatisme) sau imaginea negativă de sine. Studiul nostru a fost efectuat pe un lot de 105 pacienţi cu ulcer venos de gamba, internaţi în Clinica 1 Chirurgie a Spitalului Judeţean Timişoara într-o perioadă de 5 ani. Am evaluat, de asemenea, 142 pacienţi examinaţi în cadrul ambulatoriului aceleiaşi clinici, urmărind datele demografice, etiologia bolii, caracterele ulecraţiei, comorbidităţile şi complianţa pacienţilor. Acceptarea protocolului terapeutic a adus pacientului scurtarea timpului de vindecare şi prevenirea recurvenţei. În ceea ce priveşte impactul bolii asupra calităţii vieţii, sunt chestionare şi metode specifice de analiză, dar provocarea este de a merge de la înghierea unei leziuni către înţelegerea bolii în contextul individului. Impactul tratamentului ulcerului asupra calităţii vieţii depinde de momentul intervenţiilor chirurgicale şi de complianţa pacientului la terapia complexă (pansamente, compresie, medicaţie, exerciţii fizice).

Received for publication: 24.03.2009
Revised: 06.04.2009

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“If you do what I say and follow it closely, your ulcer will heal” -Robert Linton

INTRODUCTION

Chronic leg ulcers are those ulcers which appear under the knee and cannot be healed in 6 weeks or longer. Leg ulcer of different origin disable about 1% of general population; 15% of them are older than 70 years (1). Venous ulceration is the most severe expression of chronic venous insufficiency (from varicose disease or post-thrombotic syndrome), with important consequences on life quality and high cost in health care system. The evolving technology of non-invasive evaluation of vascular disorders continues to refine our knowledge of the anatomy and pathophysiology of the extremity with ulcer. Despite of the wide availability and application of modern dressing material, therapies with pressure bandages and stockings, new medication specific for venous system, the treatment of ulcer remains a long and expensive process, especially when a cause of the ulceration cannot be eliminated. The role of surgical intervention on superficial or deep venous system is essential. After this pathogenic surgery, large ulcers benefit of autodermoplasty (skin grafting). Patient compliance with the prescribed treatment protocol (in hospital or ambulatory) was evaluated to determine the influence on healing or recurrence of ulcer. We try to analyze not only medical baseline of disease, but also its human part: pain, social isolation, decreased mobility, restriction in work capacity.

The understanding of these problems can help medical stuff to provide more sensitive care.

MATERIAL AND METHODS

Our study has been performed on a group of 105 patients with venous leg ulcer, admitted in 1st Surgical Clinic of County Hospital Timisoara (between 2002-2006). We also evaluated a group of 142 patients examined in ambulatory unit of the same clinic. Patients referred were initially evaluated by a surgeon with a complete history and physical examination. Items of interest included a history of deep venous thrombosis, venous ulceration, arterial occlusive disease, past surgery for arterial or venous disease, diabetes, cancer, arthritis, dermatitis, neuropathy, local trauma and infection. Clinical evaluation included the location of the ulcer, the depth (superficial, deep), the quantity (single, multiple) and the area. Additional information includes the appearance of the ulcer bed, the amount and character of drainage, the appearance of the lower limb (edema, erythema, dermatitis) and the degree and character of discomfort. Ankle/brachial index was performed to exclude ischemia as a cause for the ulceration. When indicated, radiographs were obtained to exclude bone and deep tissue infection. Non invasive studies to confirm the diagnosis of venous insufficiency include venous duplex ultrasonography to obtain images of valvular incompetence and postthrombotic changes such as venous occlusion, recanalization and collateral formation.

In some cases, phlebographic evaluation was necessary to clarify these aspects. The patient compliance is very good with the diagnostic protocol, but things are changing with adherence to treatment.

We have also studied the impact on life quality, comparing our findings with literature review, to describe in a better way leg ulcer-related problems among patients.

RESULTS

In the group of admitted patients (105 ), we found these characteristics:

- median age: 65 years at women, 56 years at men
- distribution by sex: 57% women, 43% men

<table>
<thead>
<tr>
<th>TABLE 1. Comorbidity to patients with venous ulcer.</th>
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<tbody>
<tr>
<td>DISEASE</td>
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<tr>
<td>--------------------------</td>
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<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Obesity</td>
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<tr>
<td>Arthritis and arthrosis</td>
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<tr>
<td>Diabetes mellitus</td>
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<tr>
<td>Cardiac disease</td>
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<tr>
<td>Peripheral arteriopathy</td>
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</tbody>
</table>
- history of venous disease: varicose veins 51%, deep venous thrombosis 20%
- medical insurance: majority of patients benefits of basis level, but 55% are retired and 30% of people at active age are unemployed.

We analyzed also associated diseases, because of impact on results and compliance with therapy. The situation of comorbidity is presented in table 1.

Patient compliance with surgical treatment was good, 85 from 105 patients were treated in this way: most of them by venous surgery (superficial and/or perforating veins, sclerotherapy), and others received skin grafting. Many patients understood the importance of pathogenic surgery, with direct impact on vein incompetence. Interventions on venous system were performed before ulcer’s local surgery(2). Table 2 presents the situation of performed operations.

About conservative treatment, we noticed dressings, compressotherapy, micronised flavonoids (per os) and sometimes antibiotics.

Patient adherence to compression therapy improves the micro circulation and the effectiveness of the calf muscle pump. It also prevents the occurrence of edema and reduces the development of skin changes, especially after deep venous thrombosis (3). Compression is applied by means of bandages or therapeutic elastic stockings. It is important that stockings be replaced regularly to ensure adequate compression. Physical activity, through walking and leg exercises, combined with an adequate use of compression therapy is essential in treatment (4).

In a group of 142 patients examined in ambulatory unit, we tried to estimate the level of adherence to compression therapy. Table 3 presents results with stockings and/or bandages.

The presentation of findings about the impact on life quality is organized according to the following five core domains: effect of leg ulceration on the (1) physical, (2) occupational, (3) social, (4) psychological domain and (5) impact of leg ulcer treatment.

1. Impact of leg ulceration on the physical domain

The physical domain encompasses numerous aspects of pain as well as pruritus, swelling, discharge, malodour and various aspects related to mobility. With regards to pain, including intensity, the influence of pain on physical activities, sleep, analgesic therapy and the coping strategies to reduce pain are described.

- Pain was described in both quantitative and qualitative studies as the worst thing about having an ulcer (5), despite other important medical problems. A gender analysis revealed that male patients seemed to have more complaints regarding pain than women.
- Pain intensity increases in larger ulcers or in case of patients with low Ankle Brachial Pressure Index (ulcers with arterial aetiology) (6). About 10% of patients surveyed experienced “severe” pain, 19% had “moderate” pain, 38% had “mild” pain, while 33% indicated no pain. Interestingly, patients with leg ulcer duration of more than 2 years experienced

### Table 2. Performed surgical interventions.

<table>
<thead>
<tr>
<th>TYPE OF INTERVENTION</th>
<th>NUMBER OF CASES</th>
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<tbody>
<tr>
<td>a. Superficial vein surgery</td>
<td>38</td>
</tr>
<tr>
<td>b. Perforating vein surgery(classic abord)</td>
<td>5</td>
</tr>
<tr>
<td>c. Subfascial endoscopic perforating surgery(SEPS)</td>
<td>11</td>
</tr>
<tr>
<td>d. Combine superficial and perforating surgery</td>
<td>18</td>
</tr>
<tr>
<td>e. Sclerotherapy</td>
<td>3</td>
</tr>
<tr>
<td>f. Skin grafting</td>
<td>10</td>
</tr>
</tbody>
</table>

### Table 3. Adherence to ambulatory compression therapy.

<table>
<thead>
<tr>
<th>LEVEL OF ADHERENCE</th>
<th>TYPE OF THERAPY</th>
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<tbody>
<tr>
<td></td>
<td>STOCKINGS</td>
</tr>
<tr>
<td>Fully adherent (on a daily basis)</td>
<td>33%</td>
</tr>
<tr>
<td>Moderately adherent (occasionally to regularly)</td>
<td>38%</td>
</tr>
<tr>
<td>Nonadherent (occasionally, considerable shorter)</td>
<td>29%</td>
</tr>
</tbody>
</table>
significantly less pain and were in better general health than patients with a duration of less than 2 years.

- Pain influences physical activities and causes sleeping problems. Ulcer pain restricted physical action such as walking, and was frequently associated with leg and ankle oedema. Moderate and severe pain levels caused interference with normal productive activities. Leg ulcer pain often occurred at night and prevent patients from getting a full night’s sleep, which created a negative state of well-being. Discomfort and pain from the ulcerated leg kept some patients awake, while others woke up when the effect of pain killers lessened. Itching also contributed to patients waking up during the night.

- Analgesics and non-pharmacological therapy. Although pain was the most common cause of functional limitation, not all patients used pain killers. In the study of Hofman et al (7), only half of venous leg ulcer patients with severe pain received morphine-based analgesia and 27% received no analgesia at all. If pain killers were used, in 70% of cases non-steroidal anti-inflammatory drugs were employed. Qualitative research revealed that some patients felt uncomfortable using medication to relieve the nagging ulcer pain, while others did not see any other possibility for managing it. Non-pharmacologic practices for pain management included phytotherapeutic drugs, resting, repositioning of the leg, massage and dressings. Often pain was attributed to the general aging process of the patients.

- Coping strategies for reducing pain and ulcer prevention. Several coping strategies were described in the literature, predominantly in qualitative studies. One strategy to relieve the discomfort caused by pain was getting out of the bed and walking around. Avoiding situation which triggered or exacerbated pain, e.g. standing or walking, was another strategy. Putting the leg in different position or doing massages was described as pain relieving for a while (8). Leg elevation, compression stockings and diuretic therapy were most effectively in reducing swelling, leading to decreased pain levels. When ulcer healing had occurred, patients were often very conscious of preventing further ulcers. Protecting the leg was a mean to maintain some control over the integrity.

- Leg ulceration was often associated with pruritus, discharge and swelling of the leg. Although pruritus was a frequent complaint, some patients interpreted it as a sign of healing, while others construed it as the first alert of recurrence after the ulcer had healed. Malodorous leg ulcer had a negative effect on patients’ social life. The problem was aggravated by foot odour when toe to knee bandages remain in place many days, preventing patient from having a shower. At times, patients reported not leaving their home when the dressings were soaked with fluid from the wound. Mobility restrictions are present in the majority of cases and impairment was significantly aggravated in leg ulcer patients with obesity. As a result of reduced mobility, patients went out less frequently and became more dependent on friends and family members.

2. Impact of leg ulceration on the occupational domain.

Typical items related to the occupational domain included restrictions in carrying out paid employment, the ability to cope with household duties and restrictions experienced by the affected person when engaging in personal hygiene.

- Restrictions in work capacity were experienced particularly among younger patients, correlating with time lost from work and job loss. Employed ulcer patients stated that their work and leisure capacity was restricted, also general health was considered to be good. Activities of housework were impeded for the majority of patients.

- Restrictions in personal hygiene. Leg ulceration also affected the ability to effectively engage in personal hygiene. Many patients reported difficulties in washing and bathing (6). Among the obstacles that prevented patients from conducting personal hygiene was the fear of getting the ulcer wet or spoil.

3. Impact of leg ulceration on the social domain.

The social domain deals with problems caused by the ulcer that affected people’s social life. These include restrictions regarding leisure time activities, performing as carers and having social contacts with friends and family members.

- Social isolation was a common problem for many leg ulcer patients which was provoked by a combination of circumstances. Possible explanations for social isolation were that patients thoughts constantly revolved around treatment and restrictions in work capacity, which hindered them from making social contacts. Patients were also
hampered in pursuing leisure activities such as gardening, walking or traveling. Some mobility restrictions were self-imposed by patients and further contributed to an increase in the level of helplessness.

4. Impact of leg ulceration on the psychological domain.

The psychological domain includes negative emotional reactions caused by the ulcer, that gave patients a feeling of being controlled by their disease. The majority of patients had a pessimistic vision of the future and experienced alterations in their body image.

- Negative emotional reactions. Psychological problems included the lack of social contact, feelings of depression, reduced will power, helplessness and a sense of uncleanliness. Besides that, feelings of guilt, disappointment and sadness about having an ulcer were expressed during unstructured interviews (9). Patients felt that flag had no control or power over the ulcer when the expected result of healing did not occur.

- Wound healing and vision of the future. The majority of patients interviewed were pessimistic about ulcer healing. They were often resigned when wound healing did not take place within a certain period of time. Patients experienced that typical cycle of ulceration is inevitable, as it was mainly attributed to being part of the aging process or family history. They anticipated healing with a great boost to their morale and improvement in the standard of living.


Leg ulcer treatment was experienced as burdensome and time consuming and patients often relied on help. The treatment regime was received as uncomfortable and patients felt unsatisfied with the care provided. In addition, patient participation, knowledge deficits and patients’ information seeking behavior are also discussed in this domain. Lastly, leg ulcer treatment had an adverse effect on patients’ financial situation.

- Therapy causing discomfort. Wearing dressings and bandages was felt uncomfortable. Therefore some patients took off the bandages to reduce discomfort despite acknowledging that this would interfere with healing. Many patients had a feeling of being trapped by their bandages or felt like a prisoner in their own home. Compression bandages restricted the execution of daily activities and caused other people to draw attention to the leg (10). Qualitative research revealed that leg ulcer treatment such as cleansing and changing the dressing caused pain.

- Patient participation. Patients were likely to accept comprehensive treatment regimes on a short-term basis when healing was within reach. However, compliance diminished on a long-term basis as they gradually came to realise that this was unlikely (11). Sometimes patients were labelled non-compliant when in fact they were unable to incorporate the professionals advice into their every-day lives. At times patients did not comply with treatment protocol as they felt that the current treatment was not in their best interest. Other patients felt guilty when they were unable to comply with therapeutic regimes although they had understood the importance of the suggested regimes.

DISCUSSION

The majority of patients felt that they had very little knowledge of or control over their treatment, with little understanding of the underlying cause of the ulcer. Many attributed leg ulceration to a trauma or to an underlying condition. Patients need more information regarding the cause of venous ulcer, optimal resting position, the benefit of walking, dietary influence on healing. People often stated that they had received conflicting information from different health professionals, which lead to seek alternative treatment and caused difficulties around patient compliance.

Adherence to long-term therapy is defined by the World Health Organization as the extent to which a person’s behavior (e.g. taking medication, following a diet, and/or executing lifestyle changes) corresponds with recommendations from physicians, nurses and physiotherapists.

A purpose of many studies was to explore the perceptions of patients who were labelled as “non-compliant”. Six themes emerged from the data:

1. Lay perceptions of the cause and healing of leg ulceration.
2. Concurrent problems of leg ulcer.
4. Perceptions of healthcare professionals.
5. The need for health education.
6. What is like living with a leg ulcer.

Patients did not have a clear understanding of their condition or treatment regimes. Concurrent problems associated with compression bandaging included pain, leakage of exudate and skin irritation, and these
symptoms adversely affected patients’ lifestyles and contributed to non-compliance. Patients acknowledged that acceptable care was given in the community. However, they said that healthcare professionals misunderstood how their physical and psychological problems affected them, which in turn led to disagreements and disempowerment. Finally, it was apparent that patients were lacking in information relating to their condition and treatment. Non-compliance is a multivariant concept in which both physical and psychological determinants play a key role.

CONCLUSIONS

Most venous ulcers can be expected to heal when patients are enrolled in a physician-supervised care-program. Strict compliance with the treatment protocol (conservative and surgical) significantly decreased the time to healing. Holistic assessment, incorporated health education, physical and psychological support, will provide the foundation of a partnership in care, with effective impact on quality of life.

REFERENCES