

Prevention of varicose ulcer relapse: a cohort study

Prevenção de recidiva de úlcera varicosa: um estudo de coorte

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Keywords

Nursing care; Clinical nursing research; Recurrence; Varicose ulcer/prevention & control

Descritores

Cuidados de enfermagem; Pesquisa em enfermagem clínica; Recidiva; Úlcera varicosa/prevenção & controle

Submitted

July 8, 2015

Accepted

January 18, 2016

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DOI

<http://dx.doi.org/10.1590/1982-0194201600003>



Abstract

Objective: Determine the relapse rate of varicose ulcer and check the association between relapse and prevention measures adopted.

Methods: Cohort study involving 50 patients over 18 years of age post-healing of varicose ulcer monitored over ten years. Relapse was assessed through direct inspection during the clinical assessment, and the preventive measures used were informed by the patient. Pearson's chi-square test was used with $p \leq 0.05$.

Results: Relapse of varicose ulcer corresponded to 62.2%, mostly in women, followed by elderly, illiterate and retired people. The following combination was effective to prevent relapses: use of compressive stockings, rest and application of moisturizer.

Conclusion: The relapse rate of varicose ulcer was high and the main combination of preventive measures applied was the use of compressive stockings, rest and application of moisturizer.

Resumo

Objetivo: Determinar a taxa de recidiva de úlcera varicosa, e verificar a associação entre recidiva e medidas de prevenção adotadas.

Métodos: Estudo de coorte com 50 pacientes maiores de 18 anos com úlcera varicosa pós-cicatrização acompanhados durante 10 anos. A recidiva foi avaliada por meio de inspeção direta durante a avaliação clínica, e as medidas de prevenção usadas foram informadas pelo paciente. Utilizou-se o teste qui quadrado de Pearson, sendo significante $p\text{-value} \leq 0,05$.

Resultados: A recidiva de úlcera varicosa foi de 62,2%, a maioria em mulheres, seguida por idosos, analfabetos e aposentados. Mostrou-se medida eficaz na prevenção de recidivas o seguinte conjunto: uso da meia de compressão, repouso e aplicar creme hidratante.

Conclusão: A taxa de recidiva de úlcera varicosa foi elevada e as principais medidas de prevenção aplicadas em conjunto foram usar meia de compressão, repousar e aplicar creme hidratante.

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Conflicts of interest: no conflicts of interest to declare.

Introduction

Different pathological conditions or health problems can cause the appearance of a leg or foot ulcer, which can become chronic when not healed within four to six weeks. Its main etiology has been associated with peripheral vascular disease of lower limbs, mainly venous insufficiency, leading to the formation of varicose ulcer, also called stasis ulcer or phlebostatic ulcer.^(1,2)

Varicose ulcer is important in the public health context because it affects people of different age ranges and causes socioeconomic problems. It affects the patient's lifestyle due to the need for outpatient visits for dressing change, chronic pain and unpleasant smell due to the exudate the wound produces. The patient needs health care frequently, causing absence from work, early retirement and economic burden for the institutions, due to the drop in productivity.^(3,4)

The varicose ulcer problem involves multiple aggravating factors, characterized as recurrent. These include low socioeconomic conditions to maintain the preventive practices, difficult access to specialized services and patients' low education. The relapse rate of varicose ulcers is around 30% in the first year after the cure, and increases to 78% after two years.⁽⁵⁾

In the United States, varicose ulcers also constitute one of the main health problems, because they affect the quality of life and come with high costs and extended treatment. The estimated treatment cost ranges between US\$1.9 and 3.5 billion, and each patient demands approximately US\$40 thousand for treatment. An estimate published in 2007 appoints that about seven million people around the world presented chronic venous problems in the lower limbs, three million of whom evolved to venous ulcers.⁽⁶⁾

In Brazil, epidemiological prevalence and incidence data related to this problem are scarce and no official estimates are found in the national or regional context. Nevertheless, scarce research data exist, like in the city of Botucatu, State of São Paulo, where a prevalence of 1.5% of cases of active or healed varicose ulcer was found.⁽⁷⁾

The findings by Finlayson et al. on varicose ulcer relapse evidenced a median monitoring period of 24 months (interval between 12 and 40 months) and a relapse rate of 68%. This study also demonstrates that a history of cardiac illness is a risk factor for recurrence, while raising the leg, physical exercise and compressive stockings can prevent it.⁽⁸⁾ Recurrence rates of varicose ulcers, even after several years, still tend to increase, indicating the need for new strategies after the varicose ulcer is cured.

To prevent relapse, it is important for the patient to be knowledgeable and skilled and to receive support for the adoption of effective self-care measures. In the recent publication by the *Wound, Ostomy and Continence Nurses Society*[®] (WOCN[®]), the recommendations to prevent varicose ulcer relapse include compressive therapies, adjuvant therapies (surgery), medication and educative actions, particularly: dressing compressive stockings before getting out of bed; change the stockings regularly, every three to six months; the use of stockings that correspond to the leg diameter and length, verified by a professional or trained person; not smoking; adopting a healthy diet and controlling one's body weight; avoiding mechanical traumas in the injured leg and raising the legs above the level of the heart several times per day.⁽⁹⁾

Deepening the knowledge on relapse-related aspects and adopting preventive measures are essential to support health services' elaboration of protocols and guidelines, in a contextualized manner, within the patients' historical and social reality. Therefore, this study was developed to determine the relapse rate of varicose ulcers and to verify the association between relapse and the adopted preventive measures.

Methods

A retrospective cohort was conducted between 2003 and 2013 at a dermatology outpatient clinic of a large teaching hospital in Belo Horizonte, the state capital of Minas Gerais, Brazil. The

data were collected between August and December 2013, when all patients who were discharged up to 2003, after the cure of the varicose ulcer, were interviewed.

Relapse is defined as the reappearance of a disease after a period of convalescence or an asymptomatic interval as a result of an external reinfection or a new exposure to the causal agent. In this study, the emergence of a varicose ulcer after complete healing was considered as relapse.

The participants' eligibility criteria were: being over 18 years of age; attending the dermatology outpatient clinic of the university hospital and having been discharged from this service up to 2003 with a healed varicose ulcer and having received guidelines according to the service protocol to prevent relapse based on the recommendations of the *Wound, Ostomy and Continence Nurses Society* (WOCN)⁽⁹⁾; and attending the service during the data collection period. All patients who were discharged from the service up to 2003 with a healed varicose ulcer agreed to participate in the study and signed the Free and Informed Consent Form.

As a dependent variable, the varicose ulcer relapse was selected and, as independent variables, the professional activity and the relapse prevention measures (daily use of class 2 stockings with compression of 30 to 40mmHg up to the region of the kneecap; stocking change every six months; daily rest of two hours in the morning and afternoon, keeping the legs raised 15cm above the heart level; daily application of moisturizer on the lower limbs after removing the stockings), as recommended by the WOCN⁽⁹⁾.

A form was used to characterize the participants (age, sex, marital status, education and retirement) and relapse (duration of occurrence and location of the ulcer). The data on the wound and measures adopted to prevent relapse were collected through a conversation between the researcher and the patient. The existence of the varicose ulcer was confirmed through direct inspection. It took between 20 and 40 minutes to collect data from each patient.

The data were analyzed using *Statistical Package for the Social Sciences* (SPSS), version 16.0. Descriptive analyses were developed with absolute and relative frequencies, means, besides the analysis of combinations of the preventive measure variables. To identify the factors associated with the prevention of varicose ulcer relapse, for statistical analysis, Pearson's chi-square test was used. Significance was set as p-value ≤ 0.05 .

The study was reported in the Research Ethics Committee (COEP), Universidade Federal de Minas Gerais under number - 6908.

Results

Among the 50 patients, 31 (62.2%) presented relapse of the varicose ulcer. The majority (76.0%) was female; ages ranged between 26 and 85 years and the median was 69 years; 54.0% were elderly people (60 years or older), 40.0% were married and the remainder (60.0%) widowed, single or divorced; 60.0% were functionally illiterate. Retired people were predominant (42.0%). Patients with ulcer relapse were mostly (71.0%) female, over 59 years of age (54.9%), with a predominance of married people (38.7%). The majority (80.6%) was functionally illiterate, and almost half (45.2%) of the people were retired (Table 1).

No statistical association was found between the variables sex, age, marital status, instruction level, professional activity and retirement and relapse. Each participant presented a single relapse of varicose ulcer during the investigated period and the length of occurrence varied between one and more than 24 months (mean 7.9 months) after being discharged with a cured injury. Five (16.1%) patients had a relapse after one month, and relapse two years after the discharge (32.2%) was predominant. The predominant region (45.2%) of the relapse cases was the medial and lateral malleolus (Table 2) and the left leg was the most affected (70.0%) by the relapse.

Most patients used compressive stockings daily (62.0%), rested (62.0%) and applied moisturizer to the lower limbs (74.0%). Among the 31 partic-

Table 1. Demographic characteristics of patients at the time of the data collection and association with ulcer relapse

Variables	Varicose ulcer relapse		Total (n=50) n(%)	p-value
	Yes (n=31) n(%)	No (n=19) n(%)		
Sex				1.133
Male	9(29.0)	3(15.8)	12(24.0)	
Female	22(71.0)	16(84.2)	38(76.0)	
Age range (years)				3.554
20-39	-	1(5.2)	1(2.0)	
40-59	10(32.2)	4(21.1)	14(28.0)	
60-79	15(48.4)	8(42.1)	23 (46.0)	
>80	2(6.5)	2(10.5)	4(8.0)	
No information	4(12.9)	4(21.1)	8(16.0)	
Marital status				0.131
Single	6(19.4)	4(21.1)	10(20.0)	
Married	12(38.7)	8(42.1)	20(40.0)	
Widowed	11(34.5)	6(31.6)	17(34.0)	
Divorced	2(6.5)	1(5.2)	3(6.0)	
Education				6.469
Illiterate	5(16.1)	3(15.8)	8(16.0)	
Functionally illiterate	20(64.5)	10(52.6)	30(60.0)	
Primary education	4(12.9)	3(15.8)	7(14.0)	
Secondary education	-	2(10.5)	2(4.0)	
Higher education	-	1(5.2)	1(2.0)	
Not informed	2(6.5)	-	2(4.0)	
Professional activity and retirement				2.049
Retired	14(45.2)	7(36.8)	21(42.0)	
Housewife	4(12.9)	2(10.5)	6(12.0)	
Domestic servant	8(25.8)	6(31.6)	14(28.0)	
Others	5(16.1)	4(21.1)	9(18.0)	

Table 2. Length and location of the varicose ulcer relapse

Variables	n(%)
Length of relapse (months)	
1	5(16.1)
1.1-3	2(6.5)
3.1-6	4(12.8)
6.1-12	3(9.7)
12.1-18	2(6.5)
18.1-24	5(16.1)
24.1-36	2(6.5)
36.1-48	1(3.2)
48.1-60	1(3.2)
60.1-72	-
72.1-84	3(9.7)
84.1-90	3(9.7)
Total	31(100.0)
Relapse location	
Lower third	12(38.7)
Middle third	5(16.1)
Medial malleolus	9(29.1)
Lateral malleolus	5(16.1)
Total	31(100.0)

ipants who used stockings, 65.0% changed their stockings every six months at most and 19 patients who did not use compressive stockings affirmed that they did not do this because this product was not available (Table 3).

The influence of preventive measures on the varicose ulcer relapse was analyzed (Table 3): use of compressive stockings (p=1.142), stocking change

Table 3. Influence of preventive measures adopted in cases of varicose ulcer relapse

Preventive measures recommended by WOCN®	Patient with relapse		Total (n=50) n(%)	p-value
	Yes (n=31) n(%)	No (n=19) n(%)		
Use of class 2 compressive stockings (30-40 mm Hg)				1.142
Yes	21(42.0)	10(20.0)	31(62.0)	
No	10 (20.0)	9(18.0)	19(38.0)	
Change stockings every six months (n=31)*				0.132
Yes	14(45.0)	6(19.0)	20(65.0)	
No	7(23.0)	4(13.0)	11(35.0)	
Total	21(68.0)	10(32.0)	31(100.0)	
Rest				1.776
Yes	17(34.0)	14(28.0)	31(62.0)	
No	14(28.0)	5(10.0)	19(38.0)	
Application of moisturizer to lower limbs				0.390
Yes	22(44.0)	15(30.0)	37(74.0)	
No	9(18.0)	4(8.0)	13(26.0)	
Use of stockings and rest				0.260
Yes	12(24.0)	6(12.0)	18(36.0)	
No	19(38.0)	13(26.0)	32(64.0)	
Use of stockings, rest and application of moisturizer to lower limbs				0.043
Yes	9(18.0)	5(10.0)	14(28.0)	
No	22(44.0)	14(30.0)	36(72.0)	

*In total, 31 patients used compressive stockings; WOCN® - Wound, Ostomy and Continence Nurses Society®

every six months ($p=0.132$), rest ($p=1.776$) and application of moisturizer to lower limbs ($p=0.390$). The influence of combining these measures was also analyzed: use of stockings and rest ($p=0.260$), use of stockings, rest and application of moisturizer on lower limbs ($p=0.043$).

Discussion

WOCN® recommends changing stockings every three to six months to guarantee an excellent compression level.⁽⁹⁾ In this study, relapse occurred in patients who reported changing their compression stockings every six months. Nevertheless, few randomized clinical trials have specifically assessed the impact of compression therapy on the risk of ulcer relapse. In a randomized study developed in a sample of 153 patients whose varicose ulcer was cured after two weeks, distributed in two groups, the reduction of ulcer relapse was associated with the use of compressive stockings. The first group included patients who used compressive stockings (34 to 46mmHg), while the second consisted of patients who did not use compressive stockings. In the assessment, after six months of monitoring, it was verified that the use of the stockings was determinant for the prevention of relapse.⁽¹⁰⁾

Another factor that interferes in the relapse rate of varicose ulcer is the patient's compliance with the use of stocking. High compression stockings (40 to 50mmHg) are less accepted when compared to the medium compression type (30 to 40mmHg).⁽⁹⁾ Consequently, the relapse rate can be higher when the use of high compression stockings is indicated, due to their intolerance. Nevertheless, in a randomized study involving 100 patients after the cure of a varicose ulcer, 50 of whom were using class 1 compressive stockings (20 a 30mmHg) and the remainder class 2 (30 to 40mmHg), it was concluded that, after 12 months of monitoring, the ulcer relapse rate corresponded to 16.1%, without a statistically significant difference in the relapse rate between classes 1 and 2, despite the higher number of re-

lapses in the group of patients using class 1 compressive stockings.⁽¹¹⁾

Based on the systematic review with meta-analysis about the compressive modalities and the healing of the varicose ulcer, it was verified that the compressive effect on the varicose ulcer relapse is still based on low-quality evidence.⁽¹²⁾ The ideal pressure measure of the stocking to prevent relapse remains undefined, in view of difference between the levels in the literature.⁽¹³⁾

Venous insufficiency in the lower limbs is frequent in the general population, in Western countries, and is more common in women and elderly people.⁽¹⁾ In the present study results, ulcer relapse was predominant in female patients, at a rate of 2.5:1.0, without any association between sex and relapse though. Studies suggest a higher prevalence of chronic venous insufficiency and varicose ulcers in women, observing that this disparity decreases with age.⁽¹⁾ The common risk factors for chronic venous insufficiency include family history, multiparity, obesity, history of profound venous thrombosis or thrombophlebitis⁽¹⁴⁾ and others, such as diabetes, heart failure, hypertension, kidney disease and rheumatoid arthritis.⁽¹⁾

More than half of the patients were elderly. This data is similar to other authors' findings, who obtained an annual prevalence of varicose ulcer corresponding to 1.69% among the elderly. This health problem is considered significant for these people^(15,16) and for the health sector, considering that the life expectancy is rising and that, in the next 40 years, the number of elderly people is expected to double.⁽¹⁷⁾

Although no association was found between the instruction level and relapse or the emergence of a new ulcer, patients with a lower level of instruction (illiterate and functional illiterate) were predominant in terms of relapse and the development of a new injury, while patients with secondary and higher education did not present such events. This result can be related to the better understanding of the orientations and the greater adherence to preventive care, such as the habitual use of compressive stockings and moisturizer for example.

Sedentariness or standing or seated work, without alternating with walking, impairs the venous return, influencing the emergence of varicose ulcers. In a Brazilian study undertaken in Fortaleza, the State capital of Ceará, in the Brazilian Northeast, 52% of the participants with varicose ulcer quit working or studying because of the lesion, and about 70% affirmed having experienced losses in daily and leisure activities.⁽⁵⁾ These results differ from the present findings as, at the time of the data collection, among the 50 participants, 58% were professionally active and, among the remainder (42%), although retired, many continued working informally.

Knowledge about the pathogenesis of varicose ulcers has permitted the development of new treatment modalities. Nevertheless, the challenge of impeding their relapse remains. Some authors affirm that most cases of relapse occur within three months after the healing of the wound.⁽⁵⁾ In this study, 80.6% of the patients experienced a relapse in the same period. Five patients relapsed within 30 days, possibly due to the non-adoption of preventive care to avoid the occurrence of edema and, consequently, relapse.

Lower relapse rates were observed in people using stockings with a higher degree of compression. It was also observed that patients who used moderate compression presented better compliance, while 42% of patients who used class 3 compressive stockings abandoned the treatment and 28% in class 2. The ongoing use of the therapy is emphasized, with the highest level of compression the patient can bear, in order to guarantee the reduction of venous hypertension in the lower limbs, permitting the patient's greater adherence and the reduction of the risk of varicose ulcer relapse.⁽¹⁸⁾

There is evidence on the correct use of compressive stockings to reduce the relapse rate of varicose ulcers. Research results confirm that, within three years, relapse levels were lower in the group of patients wearing high compression stockings, and there was not sufficient evidence to support the selection of different types, brands or lengths of these stockings.⁽¹⁷⁾

The ideal pressure of the compressive stockings varies according to different factors, such as the severity of the patients' vascular conditions, the patient's body weight and length (size) of the affected limb. In practice, it is observed that incorrect stocking pressure can cause skin necrosis, also in the talocrural region, provoking cellulitis or erysipela. As a daily intervention, it should be acknowledged that the use of compressive stocking is not free from potential risks and, therefore, demands correct application and professional accompaniment, especially in patients with frail skin, diabetics, with low immunity and at greater risk of skin damage.⁽¹⁹⁾

In this study, a group of patients was identified who did not use the compressive stockings. The high cost of the stockings can influence the patient's non-compliance with the compressive therapy, in combination with the forgetting of the health professionals' instructions and the difficulty to use the stockings. As regards compliance or not with the use of compressive stocking, among patients with healed ulcers, the perception that the stockings prevent relapse contributed to their use.⁽²⁰⁾

In the literature, recommendations are found for patients with venous insufficiency of the lower limbs to rest with or without using stocking, raising the legs above the height of the heart for two to four hours; raising the lower part of the bed 10 to 15cm; and flex the ankles five to ten times every 30 minutes during the day.⁽²¹⁾ Among these recommendations, 62% of the patients in this study mentioned resting, obtaining 45% of patients without relapse. The analysis of the association between varicose ulcer relapse prevention measures showed a significant difference when a combination of the three measures was adopted: using compressive stockings, resting and applying moisturizer to the lower limbs. Nevertheless, no statistical difference was found between the groups when two associated measures or one isolated measure were applied.

A study proves that to avoid standing for long periods and raising the legs when the patient is sitting can help to improve the venous ulcer and

consequently reduce the edema.⁽¹⁸⁾ No randomized clinical trials were found that compare ulcer relapse with and without limb raising. A prospective longitudinal study indicated that raising the legs for at least one hour was associated with a smaller number of relapses. In this study, the function of the compressive stockings, the high levels of personal independence and the existence of social support were also associated with the reduction of the relapse rate.⁽²²⁾

The results about compliance with ulcer relapse preventive care may have been limited by subjective factors what lifestyle changes are concerned. In this study, these changes referred exclusively to: daily use of compressive stockings, including change; rest; and application of moisturizer. Another limitation was the restriction of the study to a single service. Nevertheless, the results indicated the importance of periodically monitoring the patient after discharge as a result of cure.

The health professionals need theoretical and practical support for them to effectively recommend specific care to patients for the prevention, treatment and relapse of venous ulcer. It is important to continuously train the professionals who take care of patients with varicose ulcers and provide access to the material resources needed, aiming to reduce the existing gap between care practice and scientific evidence.⁽²³⁾

The study results should contribute to encourage professionals to develop research, as questions on the theme are not exhausted. The results should also support the nurses responsible for the prevention and treatment of patients with varicose ulcer. It should be highlighted that the preventive measures should be adopted in combination, and not only in isolation, when they are not effective.

Conclusion

The relapse rate of varicose ulcer was high and the main measures to prevent varicose ulcer applied in combination were the use of compressive stockings,

rest and application of moisturizer. The use of one of these measures alone did not produce the desired result.

Collaborations

Borges EL, Ferraz AF and Carvalho DV contributed to the conception of the study, analysis, interpretation of the data, writing of the paper, relevant critical analysis of the intellectual content and final approval of the version for publication. Matos SS and Lima VLAN contributed to the writing of the article, relevant critical review of intellectual content and final approval of the version for publication.

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