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COMPRESSIVE THERAPY SIDE EFFECTS DURING THE TREATMENT OF VENOUS LEG ULCERS

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Venous ulceration arises as an end stage of chronic venous insufficiency. The application of an adequate level of compression therapy is the gold standard of treatment. The study to assess the frequency of complications from compression therapy used to treat venous ulcerations of the lower limbs, in relation to age and the level of compression applied. The study included 102 outpatients with venous ulceration treated at the Niš University Clinical Center's Clinic of Dermatovenereology. Ulcers were monitored within 24 weeks from the start of treatment. There were two groups of patients, ≥ 65 years old and < 65 years old, divided into two subgroups in relation to the degree of compression therapy. The following were monitored: sex, age, body mass index, area, localization and number of ulcerations, degree of granulation tissue and fibrin in the ulceration, presence of dermatitis, lipodermatosclerosis, infection, and duration of the disease. It was found that there was a statistically significant difference in the number of previous ulceration episodes, the size of the ulcerations and the duration of the disease between the examined groups. Additionally, a difference was found in the level of pain in relation to the degree of compression, as well as the risk of paresthesia in relation to age. A higher degree of compression therapy in both age groups led to an increase in the rate of patients with paresthesia and a higher level of pain sensitivity. The study showed no statistically significant risk of superficial necrosis and skin discoloration related to the age of patients.

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Key words: *venous ulcer, compressive therapy, paresthesia, pain*

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Introduction

Venous ulceration arises as an end stage of chronic venous insufficiency (1). Applying an adequate level of compression therapy in treating venous ulcerations is equally essential for both patients and doctors. Compression therapy is associated with several potential risks and problems; however, there are no clear guidelines about contraindications, risk factors, or complications. Complications such as allergic skin reactions, eczema, paresthesia, and skin necrosis are rare (2). However, they represent a big problem because they prevent the application of compression therapy and thus compromise this type of therapy as one of the most important methods of treating venous ulcerations of the lower extremities.

Aim

This study aimed to assess the frequency of problems associated with compression therapy in the treatment of lower extremity venous ulcers in relation to age and compression level.

Material and Methods

The study involved 102 outpatients with venous ulceration treated at the Dermato-venerologyClinic of University Clinical Center Niš. Ulcers were monitored over 24 weeks from the start of treatment.

Before inclusion in the study, all patients underwent a color Doppler ultrasound (CDU) evaluation of the venous and arterial systems of the legs. Each patient's brachial-malleolar-ankle pressure index (ABPI) was also measured. CDU confirmed the venous origin of the ulcers. Patients with venous ulcers (VU) larger than 3 cm^2 and a disease duration exceeding three months were included in the trial. Patients with ABPI less than 0.8, with present heart failure (ejection fraction below 35%), pregnant women, patients with malignant diseases or diabetes, and those on immunosuppressive or corticosteroid therapy were excluded from the study. Patients with ulcerations associated with cutaneous vasculitis, pyoderma

gangrenosum, or other neutrophilic dermatoses were also excluded. The following patient data were monitored: sex, age, body mass index (BMI), ulcer size, localization and number of ulcers, degree of granulation tissue and fibrin in the ulcer, presence of dermatitis, lipodermatosclerosis, and ulcer infection, as well as disease duration. Groups were formed using simple randomization, by computer-generated random sorting of the patient list. Based on age, patients were divided into two groups: those 65 years and older formed the study group, while those under 65 years of age were the control group. Each group was further subdivided according to the degree of compression therapy applied in VU treatment. The first subgroup included patients treated with class III compression therapy, exerting a pressure of 35–40 mmHg. The second subgroup consisted of patients who received an additional elastic bandage over the class III compression device, resulting in a pressure exceeding 45 mmHg. Local treatment of ulcers involved the use of antiseptics and antibiotics. The standard regimen included wound debridement, with dressings changed from daily to weekly depending on exudate levels. After debridement and dressing application, the ulcer was bandaged. The first and second layers consisted of gauze without pressure. For the third layer, in the first subgroup, a tubular compression system was used to exert 30–40 mmHg on the ankle, with reduced pressure on the calf. In the second subgroup, an elastic bandage was applied via a tubular compression system, similarly exerting 30–40 mmHg. The bandage was applied spirally with 50% overlap in the supine position and with the foot in dorsiflexion. An elastic bandage measuring 15 cm in width and 5 m in length was utilized. Patients were advised to walk for 30 minutes after bandage application. Following wound healing, patients were instructed to continue using the class III tubular compression device to prevent recurrence.

Statistical analysis

Data analysis was performed using the following: Jandel SigmaStat version 2.0, for Fisher's exact test, Mann–Whitney rank sum test, and t-test. Comprehensive Meta-Analysis version 3.0, for calculating OR (odds ratio) with confidence interval (CI - Confidence interval 95%): Cox regression model for cross analysis of independent predictors (predictor variables) in all examined groups in relation to treatment, 2.2 Cox regression model for risk analysis of cases (< 65 years and ≥ 65 years) versus controls (< 65 years and ≥ 65 years).

Results

Out of the examined number of patients, there were 25 patients < 65 years in the subgroup with class III compression, while the < 65 years subgroup with class III+ consisted of 26 patients. The subgroup of elderly patients with class III compression consisted of 25 patients, and the subgroup of elderly patients with class III+ compression consisted of 26 patients. In all subgroups, the female gender was somewhat more represented. There was a statistically significant difference in previous episodes of ulcerations ($p < 0.05$) in groups with moderate pressure aged < 65 vs. ≥ 65 years. There was also a statistically significant difference in the size of the ulcer for the following groups: moderate pressure age < 65 vs. ≥ 65; ($p < 0.05$) moderate pressure age ≥ 65 vs. high pressure ($p < 0.05$); duration of the ulcer for the following groups: moderate pressure age < 65 vs. ≥ 65 ($p < 0.01$) (Table 1).

Pain sensitivity (Table 2) to compression therapy was monitored in < 65 years and ≥ 65 years' patients with class III and III+ compression therapy. A pain scale ranging from 0 to 10 was used. The highest pain level was in ≥ 65 years of patients with class III+ standard value ± SD (5.61 ± 1.39). The Mann–Whitney rank sum test determined a statistically significant difference ($p \leq 0.001$) between A, < 65 years III vs. < 65 years III+; B, ≥ 65 years III vs. ≥ 65 years class III+.

Localized complications associated with the use of compression therapy were monitored in patients aged under 65 and 65 years and older, who were receiving class III and III+ compression therapy. Using Fisher's exact probability test, it was determined that there was no statistically significant difference in the percentage of patients with paresthesia aged < 65 years and those ≥ 65 years treated with class III and III+ compression therapy (Figure 1).

Table 1. Baseline characteristics of patients by groups

Variable	**< 65 years, class III n = (25)**	**< 65 years class III+ n = (26)**	**≥ 65 years, class III n = (25)**	**≥ 65 years, class III n = (26)**	p
Gender					
Male	12 (48%)	12 (46%)	11 (44%)	12 (46%)	ns
Female	13 (52%)	14 (54%)	14 (56%)	14 (54%)	ns
BMI (mean ± SD)	30.40 ± 1.86	30.43 ± 1.58	29.94 ± 1.83	30.15 ± 1.65	ns
Previous episodes of ulceration (n%)	15 (60%)	16 (61.54%)	23 (92%)	22 (84.61%)	< 0.05 (class III < 65 vs. ≥ 65)
History of deep vein thrombosis (n%)	11 (44%)	10 (38%)	10(40%)	12 (46%)	ns
Number of ulcers (n%)	22 (88%)[a]; 3 (12%)[b]	22 (85%)[a]; 4 (15%)[b]	19 (76%)[a]; 6 (24%)[b]	21 (81%)[a]; 5 (19%)[b]	ns
Duration of ulcer disease (yrs ± SD)	6.59 ± 3.80	7.52 ± 4.79	11.56 ± 6.30	9.81 ± 6.78	< 0.01 (class III < 65 vs. ≥ 65)[c]
Size of the ulcer (cm^2) (mean ± SD)	17.84 ± 12.26	16.96 ± 10.39	11.8 ± 6.06	16.96 ± 10.80	< 0.05 (class III < 65 vs. ≥ 65)[c]; < 0.05 (class III ≥ 65 vs. class III+)[c]
Dermatitis n (%)	13 (52%)	10 (38%)	13 (52%)	16 (61%)	ns
Lipodermatosclerosis n (%)	11 (44%)	19 (73%)	7 (28%)	9 (35%)	< 0.05 (class III+ < 65 vs. ≥ 65)[d]
Infection n (%)	17 (68%)	13 (50%)	18 (72%)	19 (73%)	ns

BMI, body mass index; ns, not significant; aone ulcer; btwo ulcers; cMann–Whitney test; dChi–square test

Table 2. Pain sensitivity in all groups

Pain sensitivity	Score	Mean ± SD	Mode
< 65 class III	0–10	2.84 ± 1.11	2
≥ 65 class III	0–10	3.24 ± 1.05	3
< 65 class III+	0–10	5.46 ± 0.95	2
≥ 65 class III+	0–10	5.61 ± 1.39	3
Comparisons	A***, B***		

*p ≤ 0.05, **p ≤ 0.01, ***p ≤ 0.001 (Mann–Whitney test)
(A, < 65 class III vs. < 65 class III+; B, ≥ 65 class III vs. ≥ 65 class III+; C, < 65 class III vs. ≥ 65 class III; D, < 65 class III+ vs. ≥ 65 class III+)

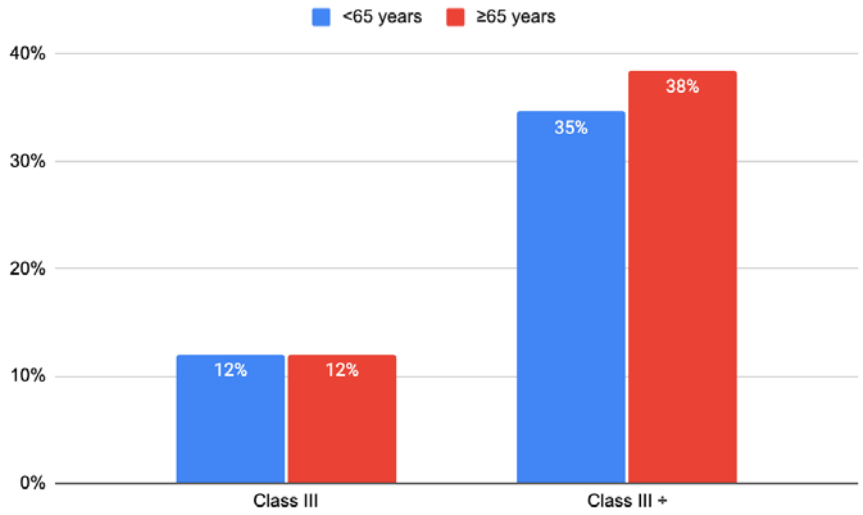


Figure 1. Percentage share (%) of patients with paresthesia < 65 years and ≥ 65 years, classes III and III+

The Cox regression model (OR, 95% CI) revealed a significant statistical risk of paresthesia in elderly patients treated with compression therapy class III + compared to class III, with an odds ratio (OR) of 4.58 (1.08–19.38; 95% CI; p = 0.039). This risk was not observed in patients under 65 years old treated with class III+ vs. class III compression therapy (Table 3).

The Fisher's exact probability test showed that there was no statistically significant difference between the groups of patients aged < 65 and ≥ 65 treated with class III and III+ compression treatment for superficial skin necrosis (Figure 2).

The Cox regression model (OR, 95% CI) was used to confirm that there was no statistically significant risk of superficial skin necrosis in patients aged ≥ 65 years treated with class III+ compared to class III compression therapy, as well as in patients aged < 65 years treated with class III+ compared to class III compression therapy (Table 4).

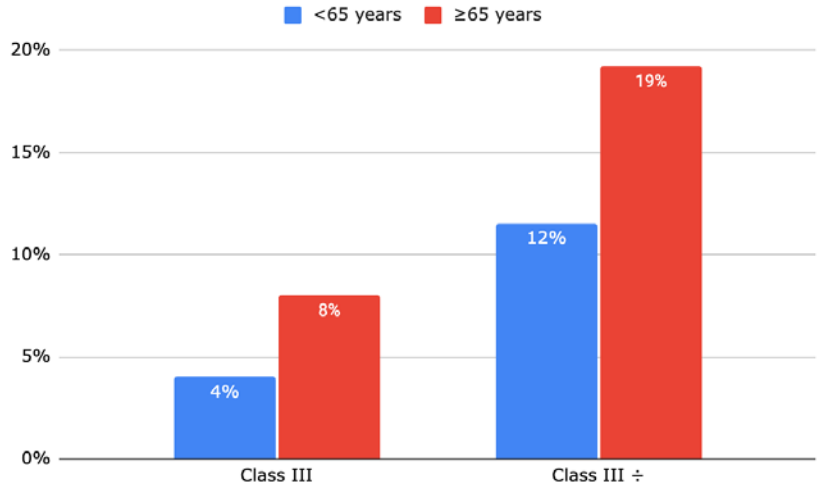
A statistically significant difference (p ≤ 0.05) in the percentage of skin discoloration was seen between patients aged < 65 and ≥ 65 who received class III+ compression therapy (Graph 3).

The Cox regression model (OR, 95% CI) was used to evaluate whether there was a statistically significant risk of skin discoloration in patients aged ≥ 65 years treated with class III+ vs. III compression therapy compared to patients aged < 65 years treated with the same therapy (Table 5).

Table 3. Predictor variables (paresthesia) in the ≥ 65 years old/< 65 years old III+ compared to the ≥ 65 years old/< 65 years old III included in the Cox regression model (OR, 95% CI)

Variables	Odds ratio	Lower limit	Upper limit	Z-Value	p-Value	(OR, 95% CI)
≥65 years III+/III	4.583	1.084	19.383	2.069	0.039	
<65 years III+/III	3.882	0.909	16.582	1.831	0.067	

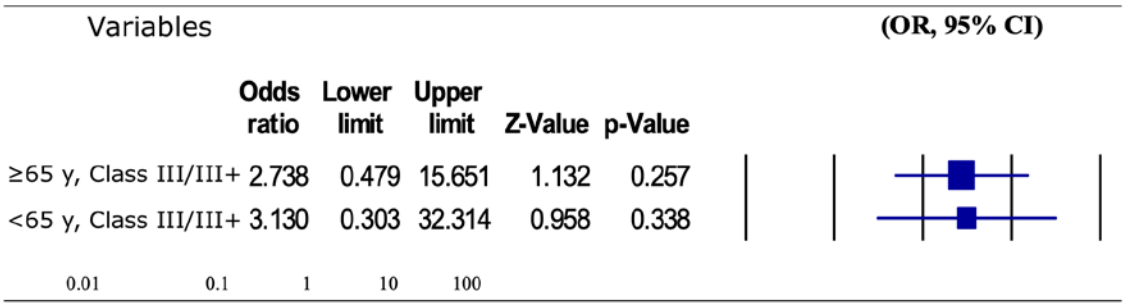
OR, Odds Ratio; CI, Confidence Interval; Z-value, test statistic from regression model; p-value, probability value

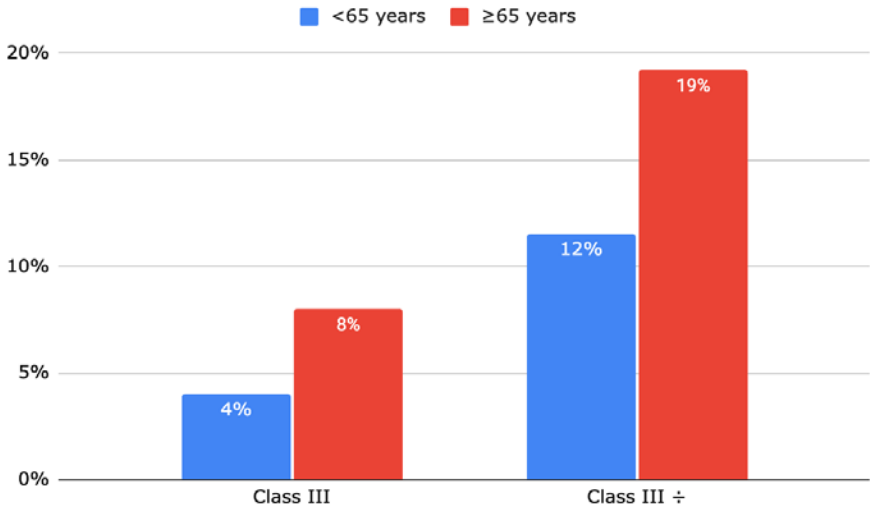


n.s. (Fisher's exact test)

Figure 2. Percentage (%) of patients with superficial skin necrosis < 65 years and ≥ 65 years, classes III and III+

Table 4. Predictor variables (superficial skin necrosis) in the ≥ 65/<65 class III+ compared to the ≥ 65/< 65 class III, included in the Cox regression model (OR, 95% CI)

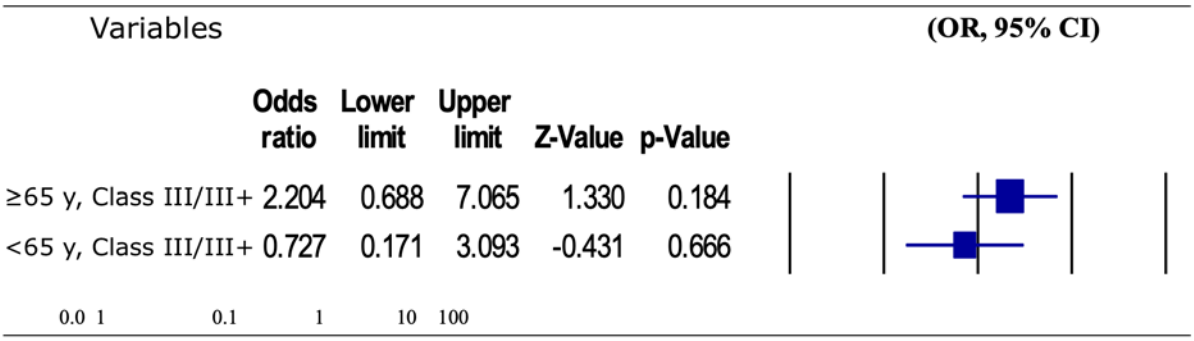




(*p ≤ 0.05) n.s. (Fisher's exact test)

Figure 3. Percentage (%) of patients with skin discoloration aged < 65 years and ≥ 65 years, classes III and III+

Table 5. Predictor variables (discoloration of the skin) in the ≥ 65/< 65 class III+ compared to the ≥ 65/< 65 class III, included in the Cox regression model (OR, 95% CI).



Discussion

Venous ulcerations affect approximately 1% of the global population, with a higher incidence in individuals aged 65 and above. The gender representation ratio indicates a much greater representation of women than men, with a ratio of 3:1 (women to men) (1). Chronic venous ulcerations occur in 0.6–3% of the population over the age of 60, and in patients over the age of 80, the percentage increases by another 5%. Chronic venous ulcerations are a prevalent cause of morbidity, and the prevalence of these ulcerations in communities ranges from 1.9% to 13.1%. (3–6). Ageing and the prevalence of atherosclerosis risk factors like smoking, obesity, and diabetes are believed to heighten the occurrence of ulceration. With a 2.5% mortality rate, over 10% of the population may experience a chronic wound at some point in their lives (5).

Venous ulcerations occur more frequently in patients ≥ 65 years than < 65 years, although the incidence and prevalence of chronic venous ulcerations in patients ≥ 65 years are not well established. Adequate compression therapy remains the gold standard in the treatment of venous ulcers. What cure rate can be expected when applying this type of treatment? The study by Karanikolic V et al. (7) on 102 patients treated with compression therapy showed that a higher degree of applied compression therapy leads to a statistically higher rate of venous healing and significantly faster healing.

Pain sensitivity to compression therapy was monitored in < 65- and ≥ 65-year-old patients with class III and III+ compression therapy. A pain scale ranging from 0 to 10 was used. The highest pain level was in elderly patients with class III+ standard value ± SD (5.61 ± 1.39). The Mann–Whitney rank sum test determined a statistically significant difference ($p \leq 0.001$) between A, participants aged <65 years with stage III disease vs. participants aged <65 years with stage III+ disease; and B, participants aged ≥65 years with stage III disease vs. participants aged ≥65 years with stage III+ disease. The obtained results are consistent with other tests. The study by Hellström et al. (8) on 1,824 subjects with lower extremity ulcerations measured pain intensity during compression therapy. Pain intensity was measured by the Numeric Rating Scale (NRS). Pain level > 5 was present in 34.8% of subjects. Greater pain intensity correlated with the number of ulcerations, so patients with more ulcerations also experienced more intense pain.

A complication that may arise from utilizing a compressive bandage is paresthesia. Fisher's exact probability test was employed to ascertain that the proportion of patients aged < 65 and ≥ 65 years who experienced paresthesia while undergoing compression therapy of classes III and III+ does not differ statistically significantly. However, the Cox regression model showed a statistically significant risk of paresthesia among elderly patients treated with compression therapy class III+ vs. III, OR = 4.58 (1.08–19.38; 95% CI; $p = 0.039$), in contrast to those < 65 years treated with compression therapy class III+ vs. III. One of the relatively common complications of compressive therapy is superficial skin necrosis. Applying Fisher's exact probability test as a Cox regression model, it was concluded that there is no statistically significant difference in superficial skin necrosis between patients under 65 years old and patients aged 65 and above who received class III and III+ compression therapy.

Skin necrosis after applying compression therapy has been described in several studies dealing with this problem (9–12), including one Scottish study (13). This Scottish study documented the five-year experience of Scottish surgeons regarding skin necrosis in compression therapy-treated patients with ulcers of the lower extremities. Of 154 surgeons who participated in this study, one-third reported at least one case of skin damage, while 20% of the surgeons who participated in this study had more than one case. Our results are not in conflict with the results of other studies. Our study also showed the presence of superficial skin necrosis, but without statistical significance concerning old age. The ankle-brachial pressure index (ABPI) is used to measure the

condition of arterial circulation in order to administer compression therapy safely. Diagnosis of peripheral artery disease typically requires an ABPI of ≤ 0.90 at rest, with ABPI ≤ 0.50 suggesting significant limb ischemia. Most compression therapy guidelines for people with deep vein thrombosis advocate using compression stockings with a pressure of 23 mmHg (14). Few studies have addressed the adverse effects of compression therapy in patients treated for chronic venous ulceration. The above-mentioned side effects are reflected in the appearance of pain due to applying compression to the extremity, superficial skin necrosis, discoloration and other trophic changes caused by compression therapy. It is essential to point out that the quality of life is crucial for applying a therapeutic procedure. Also, the occurrence of side effects of therapy should be minimized so that this therapeutic procedure can be safely and successfully applied to many patients (15–17). When using a multi-layer compression bandage, and especially when applying a higher level of compression, it is essential to strictly adhere to the instructions for applying this type of therapy. Before using compression therapy, one should strictly consider the state of the arterial system, i.e., the presence of chronic occlusive diseases. All this requires a modern concept and approach to treating patients with chronic venous ulcers. The peculiarities of each patient should be taken into account, and therapeutic procedures should be adjusted according to age, the presence of accompanying chronic diseases, and the state of the venous system of the lower extremities (18–23).

Conclusion

Increasing the intensity of compression therapy in both age groups results in a higher prevalence of patients experiencing paresthesia and increased pain sensitivity. The study found no statistically significant correlation between the age of patients receiving compression therapy and the likelihood of superficial necrosis and skin discoloration.

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NEŽELJENI EFEKTI KOMPRESIVNE TERAPIJE U TOKU LEČENJA VENSKIH ULCERACIJA DONJIH EKSTREMITETA

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Venske ulceracije čine jedno od najčešćih vaskularnih oboljenja među ljudima. Nastaju kao komplikacija hronične venske insuficijencije. Primena adekvatnog stepena kompresivne terapije u lečenju venskih ulceracija predstavlja zlatni standard u terapiji. Cilj ovog istraživanja bio je da se utvrdi učestalost komplikacija kompresivne terapije u lečenju venskih ulceracija donjih ekstremiteta u zavisnosti od starosti i primenjenog stepena kompresije. Ispitivanje je obuhvatilo 102 bolesnika starija od 18 godina sa venskim ulceracijama, koja su se lečila na Klinici za dermatovenerologiju Univerzitetskog kliničkog centra u Nišu. Ulceracije su praćene 24 nedelje od početka tretmana. Bolesnici su na osnovu starosti podeljeni u dve grupe: u prvoj grupi bili su oni sa ≥65 godina, a u drugoj oni sa < 65 godina. Svaka grupa bolesnika bila je podeljena na dve podgrupe na osnovu stepena kompresivne terapije. Kod bolesnika su se pratili pol, starost, *body mass index* (BMI), površina, lokalizacija i broj ulceracija, stepen prisutnog granulacionog tkiva i fibrina u ulceraciji, prisustvo dermatitisa, lipodermatoskleroze i infekcije i dužina trajanja bolesti. Utvrđeno je da postoji statistički značajna razlika u broju prethodnih epizoda ulceracija, veličini ulceracija i trajanju bolesti između ispitivanih grupa. Takođe, uočena je razlika u nivou bola u odnosu na stepen kompresije, kao i rizik od parestezija u odnosu na godine starosti. Za ostale ispitivane parametre nije bilo statističke značajnosti između ispitivanih grupa. Viši stepen kompresivne terapije u obema starosnim grupama bolesnika dovodi do porasta stope bolesnika sa parestezijama i većim nivoom osetljivosti na bol. Ova studija je pokazala da ne postoji statistički značajan rizik od površne nekroze i diskoloracije kože koji bi bio povezan sa starošću bolesnika tretiranih kompresivnom terapijom.

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***Ključne reči**: venske ulceracije, kompresivna terapija, parestezija, bol*