Wiadomości Lekarskie
Medical Advances

VOLUME LXXVI, ISSUE 9, SEPTEMBER 2023
Official journal of Polish Medical Association has been published since 1928

ISSN 0043-5147
E-ISSN 2719-342X

INDEXED IN PUBMED/MEDLINE, SCOPUS, EMBASE, EBSCO, INDEX COPERNICUS,
POLISH MINISTRY OF EDUCATION AND SCIENCE, POLISH MEDICAL BIBLIOGRAPHY

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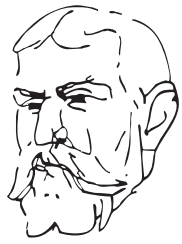
ALUNA Publishing



Memory of
dr Władysław
Biegański

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The journal Wiadomości Lekarskie is cofinanced under Contract No.RCN/SN/0714/2021/1 by the funds of the Minister of Education and Science

Wiadomości Lekarskie
Medical Advances

Distribution and Subscriptions:
Bartosz Guterman prenumerata@wydawnictwo-aluna.pl
Graphic design / production:
Grzegorz Sztank fajne.work

Publisher:
ALUNA Publishing
ul. Przesmyckiego 29,
05-510 Konstancin – Jeziorna
www.wydawnictwo-aluna.pl
www.wiadomoscilekarskie.pl
www.wiadlek.pl

CONTENTS

ORIGINAL ARTICLE

MINI-INVASIVE TREATMENT METHODS OF SPIDER VEINS: SCLEROTHERAPY AND RADIOFREQUENCY THERMOCOAGULATION

DOI: 10.36740/WLek202309113

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ABSTRACT

The aim: This study was conducted to compare the results of spider vein: sclerotherapy or radiofrequency thermocoagulation.

Materials and methods: The study included 52 patients with spider veins, who were randomized into two treatment groups: sclerotherapy or radiofrequency thermocoagulation. Treatment outcomes were assessed using: a self-assessed questionnaire, CIVIQ 20 questionnaire, computer evaluation of images, registration relapses complications, negative manifestations, and intensity of the pain syndrome.

Results: Both methods showed a statistically significant difference in the quality of life indicators before and one month after treatment ($p<0.001$ for both groups). Radiofrequency thermocoagulation showed a greater impact on the patient's quality of life ($p = 0.003$). The average length of spider veins in the treatment area decreased the most with radiofrequency thermocoagulation (by 92.1%), slightly less after sclerotherapy (by 73.4%) ($p < 0,01$).

Conclusions: Both treatments have shown good results for spider veins and were reasonably safe with few negative manifestations. Radiofrequency coagulation better eliminates small veins, less than 0.3 mm.

KEY WORDS: sclerotherapy, radiofrequency thermocoagulation, telangiectasias, spider veins, venous disorders

Wiad Lek. 2023;76(9):1992-1999

INTRODUCTION

Today, a lot of attention is paid to aesthetic problems, such can be the appearance of spider veins on the lower limbs, especially in young people. According to the American Venous Forum (2008), spider veins are found in 50% of the adult population on at least one limb. Spider veins occur in two-thirds of patients before the age of 25, and increase in incidence with age [1, 2].

The pathogenesis of the appearance of telangiectasias, or the so-called spider veins, cannot be considered completely understood today. From the surgeon's point of view, the most reasonable explanation for their occurrence is venous reflux [1, 3]. Most cutaneous spider veins are abnormalities of the horizontal vascular skin plexus or capillary loops. Spider leg veins are composed of a feeder vessel and ectatic venous sprouts in the reticular dermis [2]. However, there are other points of view: hormonal changes, increased intra-abdominal pressure, hereditary features of the structure of venous vessels [4, 5].

Due to the minimal changes in the venous system, patients who are concerned about the specified cosmetic defects really agree only to the least traumatic treatment methods and most often hope for a positive result from percutaneous laser ablation. It is known that telangiectasias on the face are very well amenable to such treatment, but when they are localized on the limbs, the effect is expensive and questionable [2, 4]. Today, the gold standard in the treatment of spider veins, according to most scientists, is sclerotherapy, as it combines such positive features as minimal invasiveness, high cosmesis, lack of surgical risk, a short period of rehabilitation and does not require hospitalization of the patient [4, 6-8]. For more than twenty years of using this method as the main method of treating telangiectasia, researchers have noted a number of its complications and negative side effects. Complications are primarily caused by the introduction of a foreign substance into the body - a sclerosant, which can cause local and general reactions. Complications of sclerotherapy are divided into minor (local) and severe (systemic). Systemic complications of sclerotherapy in the treatment of spider veins are extremely rare (0.01%). These are predominantly anaphylactic reactions.

Among the local complications, pain at the injection site, local swelling, erythema, blisters, hemorrhages, local skin necrosis, and residual hyperpigmentation are the most common. According to various researches, the frequency of local complications ranges from 7% to 30% of cases [1, 3, 6, 7, 9]. Many sclerosant agents have been used but a perfect sclerosant that is complication free and 100% effective has not yet been developed. All sclerosants represent a compromise between efficacy and toxicity [2, 10].

The main disadvantage of sclerotherapy is the high frequency of relapses. Mandatory wearing of compression stockings after a treatment session causes a negative reaction of the patient and complicates the procedure in the summer season. It is technically impossible to sclerose vessels with a diameter of less than 0.3 mm because they are smaller than the diameter of the thinnest needle [3, 4, 9]. This impairs the cosmetic effect, especially in patients with a very extensive network of telangiectasias. The described factors encourage researchers to search for alternative methods of treating spider veins [11].

Now the attention of surgeons is once again attracted by hardware, coagulation techniques. These techniques were already used in the 1990s, but were forgotten due to a number of shortcomings of the technology of that time. Modern technologies, such as radiofrequency coagulation, are safer, more controlled and devoid of those disadvantages, which allows it to be used for the treatment of spider veins. This technique consists in the coagulation of blood vessels by introducing into their lumen micro needle - tungsten electrodes with a diameter of 0.2-0.3 mm. The coagulation of the vein takes place with a current of 3 MHz. The main difference between modern coagulation techniques is what is used an insulated micro needle with beveled tip. The sheath of biocompatible material covers the entire portion of the needle except the beveled tip to prevent exposure of the shaft to adjacent tissue and to minimize collateral damage [2, 12, 13].

THE AIM

The study aimed to compare the results of spider vein treatment depending on which treatment method was used: sclerotherapy or radiofrequency thermocoagulation.

MATERIALS AND METHODS

The study was conducted in accordance with the guidelines of the institutional review board and the tenets of the Declaration of Helsinki were followed and in accordance with the recommendation of International Council for Harmonization Good Clinical Practice. Informed consent was provided by all patients in the study.

From September 2018 to October 2022, 118 consecutive patients were assessed for the eligibility.

All patients in the study underwent ultrasound examination during the initial evaluation. In addition to ultrasound, vessels were visualized in the infrared spectrum of light using the Vein Finder device. The purpose of ultrasound was to detect horizontal and vertical reflux in the system of the great saphenous vein, involvement in the pathological process of malleolar region and saphenofemoral junction, as well as the spider veins feeding vessels. The examination in infrared light complemented ultrasound to find smaller feeding vessels. Patients in whom venous reflux was detected were not included in the study, since in such a case surgical intervention is advisable.

We included 52 patients with spider veins in the CEAP/C1 phase. Sixty-six patients with great saphenous vein reflux with or without involvement of malleolar region and/or saphenofemoral junction, with feeder veins larger than 1 mm, with prior surgical interventions on the veins of the lower extremities, who had sclerotherapy or laser sessions performed to the target localization, using antithrombotic medications, with allergies, pregnant, breastfeeding, with any type of skin problems were excluded.

Remaining 52 patients were randomized to receive either sclerotherapy (Group 1) or radiofrequency thermocoagulation (Group 2). The method of treatment was chosen by randomizing all patients into two groups of 26 patients using a random number table generated in the STATISTICA 13 program.

The first group included 26 patients who underwent sclerotherapy with liquid 0.5%-1% polidocanol. During the procedure, anesthesia was not used. The procedure followed by immediate topical cooling with ice packs and compression. In the post-procedural period, this group of patients received compression therapy by using compression stockings of the II compression class for 3 weeks.

The second group included 26 patients who underwent radiofrequency thermocoagulation of spider veins using the Dr. Oppel ST-501 (Sometech, South Korea). Punctures were performed in the vein projection introducing into their lumen micro needle - tungsten electrodes with a diameter of 0.2-0.3 mm. Coagulation of the vein took place at a current of 3 MHz. No anesthesia was used during the procedure. Compression therapy in the post-procedure period was not carried out, as this treatment technology does not require it.

According to the recommendations of the European guidelines for sclerotherapy in chronic venous disorders, a self-assessed cosmetic outcome and a visual

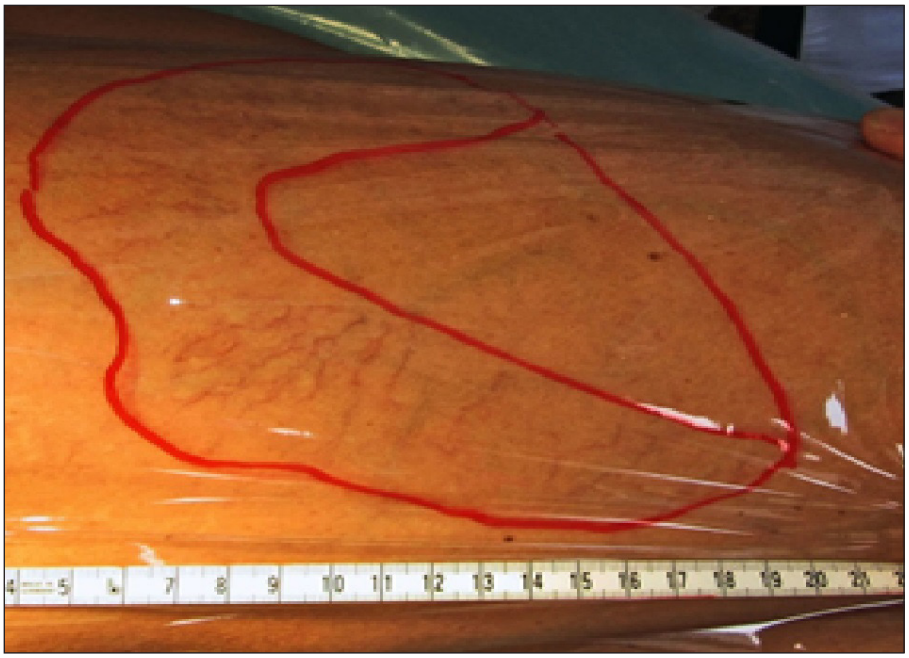

Fig. 1. Photographing the contours of the area of spider veins

Fig. 2. Segmentation of spider veins to calculate their total length in the treatment area

Fig. 3. Remains of spider veins on the periphery of the sclerosing zone one week after treatment (the zone of residual vessels is circled in red)

Table I. Patient`s self-assested cosmetic outcome

Self-assested cosmetic outcome	Group 1 n=26	Group 2 n=26	p
Better	15 (57.7%)	22 (84.6%)	0.035*
Same	10 (38.5%)	4 (15.4%)	0.062
Worse	1 (3.8%)	0	0,317

Notes: Group 1: sclerotherapy; Group 2: radiofreguency thermocoagulation.
Comparison of the data between the groups was carried out using Wilcoxon two-sample test for independent samples.
*There is significance difference

Table II. Comparison of the GIS index in patients with spider veins

	Group 1 n=26	Group 2 n=26	p
Pre- GIS	86.96±4,8	88,35±4,4	0.196
GIS 1 month after procedure	98.5±1.3	99.55±0.7	0.003*
GIS 6 month after procedure	98.31±1.4	99.23±0.9	0.007*

Notes: Group 1: sclerotherapy; Group 2: radiofreguency thermocoagulation
Comparison of the data between the groups was carried out using the Student"s test for independent samples.
*Average values differ at significance level

Table III. The total length of spider veins depending on the treatment

№	Evaluation period	The total length of spider veins			
		Group 1 n=26		Group 2 n=26	
		M ± σ (mm)	p	M ± σ (mm)	p
1	Before treatment	701,3 ± 225,8	$p_{1-2} < 0,01$*	670,2 ± 254,8	$p_{1-2} < 0,01$*
2	1 month after treatment	187,8 ± 56,79	$p_{1-3} < 0,01$*	53,01 ± 25,04	$p_{1-3} < 0,01$*
3	6 month after treatment	197,7 ± 56,26	$p_{2-3} = 0,97$	59,31 ± 27,35	$p_{2-3} = 0,99$

Notes: Group 1: sclerotherapy; Group 2: radiofreguency thermocoagulation
Comparison of the indicators in dynamics was carried out using Student"s test for related samples.
*Average values differ at significance level

Table IV. Negative manifestations and local complications encountered with various methods of treating spider veins

Complication	Group 1 n=26		Group 2 n=26		p
	n	% of patients in the group	n	% of patients in the group	
Pain at the site of the injection	6	23,1	9	34,6	0.365
Local swelling	4	15,4	0	0	0.039*
Erythema	2	7,7	2	7,7	1
Hemorrhages	1	3,8	0	0	0.317
Residual hyperpigmentation	2	7,7	0	0	0.153
In total	15	57,7	11	42,3	0.276

Notes: Group 1: sclerotherapy; Group 2: radiofreguency thermocoagulation
Comparison of the data between the groups was carried out using Wilcoxon two-sample test for independent samples.
*There is significance difference

assessment of the intervention area are sufficient to assess the treatment results [3].

In order to objectively evaluate the effect of different treatment approaches on spider veins, they were photographed with a calibrated Panasonic DMXLC15 digital camera under standard conditions (distance, lighting and no optical magnification). The contours of the area where the venous «spiders» are located

were outlined with a felt-tip pen on a transparent film applied to the skin. Bone anatomical structures were used for correct positioning of the film before and after treatment. A centimeter tape located along the zone allowed to obtain results in millimeters during computer processing of the images. (Fig. 1).

Images were analyzed using ImageJ/Fiji 1.46r J scientific image analysis software, which is available in the public domain [14]. The total length of the vascular network formed by spider veins in a certain area was calculated (Fig. 2).

The results of the treatment were evaluated at the 1st and 6th month after the treatment session. The main end point of the study was the relapse of spider veins. Relapse was considered the restoration of patency of telangiectasias in the area of therapy, as well as repeated visualization of ≥ 40%. Computer evaluation of images was performed with measurement of the total length of spider veins before and after treatment.

All complications and negative manifestations that occurred during or after the procedures were registered.

Since many patients noted unpleasant pain during the treatment, it was analyzed separately intensity of the pain syndrome on the 0–5 Numeric Rating Scale, which is often used in pain management [15].

Patients cosmetic satisfaction was also recorded on the 1st and 6th months (better/same/worse compared to the preprocedural state).

Satisfaction with treatment results was also objectively assessed using the 20-item Chronic Venous Disease quality-of-life Questionnaire (CIVIQ 20), in order to compare average scores, absolute scores were converted to a GIS index [16].

Statistical analysis was performed using Statistica 10 (Serial Number: STA999K347150-W) and MedStat. Data distribution normality was checked using the Shapiro-Uilk criterion. Normally distributed indicators were given as $M_0 \pm \sigma$, indicators whose distribution differed from the normal one, such as intensity of the pain syndrome according to the 0–5 Numeric Rating Scale, were given as M_0 (Q_1; Q_3). A comparison of the data with abnormal distribution between the groups was performed using Wilcoxon two-sample test. A comparison of the data with normal distribution was carried out using the Student"s test for independent samples, and Student"s test for related samples. The confidence intervals given in the article were constructed for the confidence level of 95%.

RESULTS

In total, only 4 patients were male, and the mean age of the study population was 39.4 ± 8.3 years. The study groups did not differ in terms of the mean age, body mass index, and the number of spider veins.

Patients' self-assessed satisfaction ratings of cosmetic outcomes were found to be higher compared to the baseline in both groups ($p < 0.001$). This cosmetic satisfaction was found to be higher in Group 2 compared to that reported by the patients in Group 1 ($p = 0.035$), (Table I).

The data obtained using the CIVIQ 20 questionnaire were also analyzed. The mean GIS of the patients before the procedure was 86.96±4,8 in Group 1 and 88,35±4,4 in Group 2. One month after the procedure, this indicator increased significantly up to 98.5±1.3 in Group 1 and 88,35±4,4 in Group 2 ($p<0.001$ for both groups). At the same time, quality of life indicators did not change significantly in the six-month period compared to the one-month period ($p = 0.30$).

The GIS comparison between Group 1 and Group 2 is shown in Table II.

Radiofrequency thermocoagulation has a greater impact on the patient's quality of life. There was a significant difference in GIS between the two groups after the procedure in both evaluation periods ($p = 0.003$ and $p = 0.007$, respectively).

Computer evaluation of images of areas with spider veins before and one month after treatment proved that both methods effectively eliminate them ($p < 0.01$ for both groups compared to the baseline). After 6 months, the total length of telangiectasias increases slightly but is not statistically significant ($p = 0.97$ and $p = 0.99$, respectively). The results are shown in Table III.

The average length of telangiectasias one month after the procedure decreased the most with radiofreguency thermocoagulation from 670,2 ± 254,8 mm to 53,01 ± 25,04 mm (by 92.1%), slightly less after sclerotherapy from 701,3 ± 225,8 mm to 187,8 ± 56,79 (by 73.4%). A statistically significant difference between the reduction in the length of the vascular network as a result of radiofreguency thermocoagulation and sclerotherapy was revealed at the level of significance $p < 0,01$. Comparison of the data between the groups was carried out using the Student"s test for independent samples.

After sclerotherapy, the distal parts of the spider veins often remained unobliterated. Additional direct puncture of them due to the small diameter of vessels (less than 0.3 mm) was practically impossible (Fig. 3). This worsened the overall cosmetic effect of sclerotherapy.

At the same time, radiofrequency thermocoagulation with a tungsten electrode with a diameter of 0.2 mm was effective even at the minimum settings of power and pulse duration (10 W, 1/8 s).

In the group of patients who underwent sclerotherapy, 3 (11.5%) relapses of the disease were registered within a month, and another 5 relapses (19.2%) within 6 months. in the group of patients who underwent thermocoagulation, 1 (3.8%) relapse was detected within a month, and 5 more (19.2%) relapses after 6 months. The difference between groups is not statistically significant (p = 0.941). Comparison of the data between the groups was carried out using Wilcoxon two-sample test for independent samples.

Analysis of the spectrum of negative manifestations and complications that occurred in patients of both groups showed that most often patients complained of pain at the injection site, and objectively, a fairly long-lasting local swelling was determined (Table IV). The difference in the frequency of complications in the examined groups is not statistically significant (p = 0.276). But in Group 1, local swelling was more common (p = 0.039).

The intensity of the pain syndrome in the Group 1 of patients who underwent sclerotherapy according to the 0–5 Numeric Rating Scale was M_0=0,31($Q_1$0; $Q_3$1), in the Group 2 M_0=0,5 ($Q_1$0; $Q_3$1). Comparison of the data between the groups was carried out using Wilcoxon two sample test. The difference between the groups was not statistically significant, (p = 0,658). However, it is worth noting that patients during thermocoagulation more often complained of more intense pain. But none of them required additional anesthesia.

DISCUSSION

There are several treatments, such as sclerotherapy, laser, intense pulsed light, microphlebectomy and thermoablation, but none is established as preferable [17].

The basic principles of treatment of varicose veins - elimination of venous reflux and removal or ablation of dilated venous vessels - have remained unchanged for a long time [1]. However, the technical means of their implementation have changed significantly over the last decade and the transformation process continues [2, 7]. This is due to the researchers' efforts to make the perioperative period or conservative treatment sessions less uncomfortable for the patient, to improve the cosmetic result of the interventions, while not increasing the risk of recurrence of varicose veins. At the same time, it is desirable not to increase the cost of treatment significantly. In our study, we tried to compare the gold standard of spider vein treatment, sclerotherapy, with the more modern and less common technique, radiofrequency thermocoagulation.

In the case of spider vein correction, success will depend on the choice of method that will provide a cosmetic result that will meet the patient's expectations to the greatest extent.

In our study, we confirmed the high efficiency of both methods in the treatment of spider veins. And we also identified some advantages of radiofrequency thermocoagulation. Almost every step of the sclerotherapy is operator-dependent from the choice of concentration of the sclerosing agent to the technique of its administration or from preparation of the field to the post-procedural follow-up [2, 6]. With radiofreguency thermocoagulation, the effect depends on the device and its settings. It can be argued that this procedure is performed under hardware control, which makes it safer. The main limitations of these methods are the reduced efficacy with increased vessel diameters and depth, and the problems experienced in selectively delivering energy to the vein during epidermal application [12].

Treatment of small vascular abnormalities of the skin is painful. In our our study, we did not find a difference in the severity of pain syndrome when using different methods. Although patients treated with thermocoagulation more often complained of pain. The sensation and severity of pain during these procedures can be explained by the fact that radiofreguency thermocoagulation refers to thermal treatment methods, so patients during the procedure note a burning sensation due to a local increase in temperature. In addition, the number of contacts of the needle with the skin during thermocoagulation is significantly greater compared to sclerotherapy.

However, it is worth noting that no patient required additional anesthesia during radiofrequency thermocoagulation. Sclerotherapy is also often accompanied by negative feelings, because a chemically active substance is injected. Patients complain of a burning sensation at the injection site, which occurs after the procedure is completed and lasts longer.

The feeling and satisfaction of cosmetic healing is not an objective parameter that can be revealed by biological tests or imaging methods. To objectively evaluate the treatment results, we analyzed the images using the publicly available scientific image analysis software ImageJ/Fiji 1.46r. In contrast to the previously described method of evaluating the surface vascularization of scars [18], the total length of the vascular network formed by spider veins in a certain area was calculated. And we have shown a significant reduction in the length of the vascular network with the use of treatment methods, which proves their effectiveness.

Spider veins are primarily an aesthetic problem. So, in the course of the study, we tried to identify the impact of the proposed methods of treatment on the quality

of life of patients using a questionnaire. CIVIQ-20 is widely used in clinical trials to evaluate post-treatment results in venous diseases [16]. In order to compare the mean scores between dimensions or scales, absolute scores were then converted into an index (GIS). According to this scoring method, improvement in quality of life between two study times is represented by an increase in score. We observed that these GIS in both groups progressed compared to the baseline values independent of the techniques used. However, our results also allow us to state that, radiofrequency thermocoagulation has a greater impact on the patient's quality of life. This may be due to the fact that thermocoagulation gives a faster result. Patients see their veins disappear during the procedure for good, while with sclerotherapy, the veins disappear during the procedure, but in a short time they become brighter, inflamed and filled with microclots. Also, thermocoagulation gives cleaner results, removing even the thinnest vessels [2, 3, 12].

As the results of the study demonstrate, none of the approaches has absolute advantages over the other. The percentage of complications and unwanted effects does not differ significantly in the three groups. We consider it expedient not to contrast them with each other, but to consider the possibility of combining in order to use the advantages of each of them.

Future studies may involve a larger population and have a longer follow-up period. And it is also possible to study the results of treatment with a simultaneous combination of these methods, or the addition of sclerotherapy with radiofrequency thermocoagulation in the long-term period in patients with poor cosmetic satisfaction. The study can be supplemented by a histological analysis of changes in the spider vein when using these methods and their combination.

CONCLUSIONS

1. Patients' self-assessed satisfaction ratings of cosmetic outcomes were found to be higher compared to the baseline ($p = 0.001$). Cosmetic satisfaction was found to be higher in in the group of patients who were treated with radiofrequency thermocoagulation compared to that reported by the patients in group with sclerotherapy ($p = 0.035$).
2. Both methods showed a statistically significant difference in quality of life indicators before and one month after treatment ($p<0.001$ for both groups). At the same time, CIVIQ 20 indicators did not change significantly in the six-month period compared to the one-month period ($p = 0.30$). Radiofrequency thermocoagulation showed a greater impact on the patient's quality of life. There was a significant difference in GIS between the two groups after the procedure in both evaluation periods ($p = 0.003$ and $p = 0.007$, respectively).
3. The average length of spider veins in the treatment area decreased the most with radiofreguency thermocoagulation (by 92.1%), slightly less after sclerotherapy (by 73.4%) ($p < 0,01$).
4. There was no significant difference in relapses and and frequency of complications between the two groups after the procedure ($p = 0.941$ and $p = 0.276$, respectively), but the local swelling was more common after sclerotherapy ($p = 0.039$). There was also no statistically significant difference in the intensity of the pain syndrome ($p = 0,658$).

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Conflict of interest:
The Authors declare no conflict of interest.

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Received: 26.04.2023
Accepted: 06.08.2023

A - Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis, **D** – Writing the article, **E** – Critical review, **F** – Final approval of the article