RANDOMISED CONTROLLED TRIAL

Polidocanol Plus Glucose Versus Glucose Alone for the Treatment of Telangiectasias: Triple Blind, Randomised Controlled Trial (PG3T)

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WHAT DOES THIS PAPER ADD?
Sclerotherapy is the treatment of choice for telangiectasias in the lower limbs; however, there is no consensus regarding the optimal sclerosing agent. The use of 0.2% polidocanol + 70% hypertonic glucose has been proven to be a safe and more effective option than 75% hypertonic glucose alone. This association of sclerosing agents constitutes an important alternative to the sclerosing agents currently used.

Objective: The aim of this study was to compare the effectiveness and safety of two sclerosing agents used to treat telangiectasias in the lower limbs: 0.2% polidocanol + 70% hypertonic glucose (HG) *vs.* 75% HG alone.
Methods: A prospective, randomised, triple blind, controlled, parallel group trial with patients randomly assigned in a 1:1 ratio between January and December 2015, with a two month follow up, from a single academic medical centre in Brazil, was carried out. Participants were women aged 18–65 years with telangiectasias on the lateral aspect of one thigh, classified as C1EpAsPn who underwent sclerotherapy in a single session with 0.2% polidocanol + 70% HG or 75% HG alone to treat the telangiectasias on an area limited by a rectangular template. The primary effectiveness endpoint was elimination of 75% of the telangiectasias within 60 days *vs.* the pre-treatment pattern. The length of vessels was measured on images obtained before and after treatment using ImageJ software. Safety outcomes were analysed immediately, 7 days, and 60 days after the treatment, and included pigmentation.
Results: A total of 115 patients were included, 98 of whom completed the study. Sclerotherapy with 0.2% polidocanol + 70% HG was significantly more effective than with 75% HG alone to treat telangiectasias in the target area (82.2% *vs.* 63.9%; $p < .001$); considering a minimum improvement of 75%, there was a 0.49 risk reduction (95% confidence interval 0.24–0.98; $p = .047$). No severe adverse events occurred in either group. Pigmentation was the most common minor adverse event and was significantly shorter in length in the group treated with 0.2% polidocanol + 70% HG (median 0 cm *vs.* 0.5 cm, respectively; $p = .033$).
Conclusion: Polidocanol 0.2% plus 70% HG had better results than 75% HG alone in sclerosing telangiectasias. No severe adverse events occurred. Pigmentation occurred in both groups and was shorter in length in the group treated with 0.2% polidocanol + 70% HG.

Keywords: Glucose solution, Hypertonic, Polidocanol, Sclerosing solutions, Sclerotherapy, Telangiectasias, Veins
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INTRODUCTION

Telangiectasias are veins with a diameter of less than 1 mm, located in the dermis, mostly in the lower limbs, which cause cosmetic discomfort and, in some cases, localised pain, itching, or burning.[1,2] They present a reddish or bluish colour, and can be divided into four morphological types: simple or linear; arborised; spider; and papular.[3,4] Telangiectasias affect > 80% of subjects and are more common in

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females.[5,6] The treatment of this mild venous abnormality can be done by sclerotherapy, electrocoagulation, or laser ablation.[7–12] Sclerotherapy is the most frequent procedure used for telangiectasias; however, there is no consensus on the best choice of sclerosing agent among a range of options.[8,13–16] The ideal sclerosing agent should induce venous ablation by spasms, thrombosis, and fibrosis, with a low rate of adverse events.[13,17] Much has been discussed about how to optimise the results of sclerotherapy and have sustained results at least in the medium term; however, despite consensus for the treatment of telangiectasia, the ideal sclerotherapy agent remains unknown.[18]

Reticular veins, also called feeder veins (as large as 3 mm in diameter), visible to the naked eye or hidden in the subcutaneous tissue, can be associated with the resistance of telangiectasias to sclerotherapy, so other treatments have been advocated by some.[19,20] Combinations of sclerosing agents including mixtures of hypertonic saline (HS), hypertonic glucose (HG), glycerin, polidocanol, polyiodinated iodine, and others have been used over time with no consensus about the results.

The present trial was a modification of the Zuccarelli[21] proposal, which used 66% glucose and 0.5% polidocanol with good results. The current study was designed to compare the effectiveness and safety of 0.2% polidocanol + 70% HG *vs.* 75% HG alone for the treatment of telangiectasias in a single session with a two month follow up,[22] based on previous results with reticular veins.[23]

MATERIALS AND METHODS

Study design

A randomised, controlled, prospective, triple blind, parallel group, phase IV clinical trial was conducted at a single university medical centre in Brazil. From January 2015 to November 2016, consecutive patients with lower limb telangiectasias were assigned, in a 1:1 ratio, to undergo sclerotherapy in a single session with either 0.2% polidocanol + 70% HG (2 mg/mL polidocanol + 700 mg/mL glucose [group 1]) or 75% HG alone (750 mg/mL glucose [group 2]), in order to diminish 75% of the telangiectasias in 60 days. These sclerosing agents are commercially available in Brazil (Health Tech Laboratory, São Paulo, Brazil). The trial protocol has been previously published,[22] and the Consolidated Standards of Reporting Trials (CONSORT) checklist is available in Supplement 1. The trial has been registered on ClinicalTrials.gov (NCT02657252).

Participants

Eligible participants were women aged 18–65 years who had telangiectasias on the lateral aspect of one thigh, classified as mild venous disease (C1EpAsPn), and were willing to attend the appointments. Exclusion criteria were signs of superficial or deep venous insufficiency on duplex ultrasound (DUS), pregnancy or puerperium, allergy to sclerosing agents, restricted mobility, peripheral arterial disease, uncontrolled systemic disorders, dermatitis at the treatment site, asthma, migraine, previous deep venous thrombosis (DVT) or family history of DVT, thrombophilia or any hypercoagulable state, and use of anticoagulants.

Ethics

All patients signed an informed consent form that had been approved by the Internal Review Board of the Botucatu Medical School, São Paulo State University (UNESP; protocol 4127-2012), in accordance with the principles of the Declaration of Helsinki, ISO14155, and guidelines for Good Clinical Practice.

Randomisation

Participants were randomly assigned using web based randomisation software (Stat Trek, http://stattrek.com/statistics/random-number-generator.aspx), to one of two treatment groups. The computer generated allocation sequence was kept by an independent nurse who prepared sealed opaque envelopes that were sequentially numbered, and who was unaware of the patient name or the physician who was performing the procedure.

Masking

Treatment allocation was masked by a nurse who prepared a syringe containing 5 mL of the medication, in a separate room, identified only by the patient's protocol number. Both medications were in liquid form and identical in appearance when inside the syringes (colourless, odourless, and with similar viscosity). Participants, study personnel, and evaluators were all blinded to the allocation.

Interventions and procedures

All patients underwent DUS to assess the superficial and deep venous systems.

The treatment area was defined as a 150 cm^2 (15 cm long × 10 cm wide) rectangle on the lateral aspect the thigh of only one limb. One Velcro® fastening cloth template containing a centimetre scale was made and positioned 5 cm above the line of the knee joint, with the lower/anterior apex on the lateral patella.

The target area of the lower limb was photographed before and after treatment using a high definition digital camera (D7000 Nikon AF-S Lens 18–105 mm). The images were obtained under natural light with the patient 0.6 m from the camera.

All sclerotherapy procedures were carried out by the same experienced physician (blinded to the solutions). The maximum volume per puncture was 0.3 mL, and punctures were done until whitening of the veins was seen in the area of interest.

Patients were given the following instructions: (1) contact the research team if they had oedema or any problems; (2) to apply a cream containing 0.5% sodium heparin to treat bruising (twice a day for two weeks, 30 g/patient [Health Tech Laboratory, São Paulo, Brazil]); (3) not to expose the treated leg to sunlight during the study period; and (4) to

attend the scheduled follow up visits. No restrictions on physical activity were directed and no therapeutic compression was employed.

Monitoring

The appointments were scheduled as follows: (1) screening visit for patient selection; (2) visit for venous DUS; (3) visit to collect clinical data, obtain pre-treatment images, and do the single session treatment (day 0); (4) seven day follow up visit to collect clinical data (day 7); and (5) return visit 60 days after treatment for final evaluation and final post-treatment image (day 60). All patients were asked to complete a questionnaire of dissatisfaction with the disease and procedure related pain (day 0), using a visual analogue pain scale (VAPS; ranging from 0 (no pain) to 10 (worst possible pain).

Participants who failed to attend the treatment or follow up visits after three attempts at telephone contact were also excluded, and the reasons recorded.

All outcomes of effectiveness and safety were predicted to be analysed in the "per-protocol" basis.

Baseline characteristics

Patient baseline characteristics were compared in the groups, such as age, body mass index, lifestyle, smoking, comorbidities, family and personal history of varicose veins, morphology of telangiectasias, baseline vein measurements, skin phototype classified according to Fitzpatrick classification,[24] and history of pregnancies.

Outcome measures

Descriptive data of the treatment sessions were compared between the groups, including number of punctures, volume of medication used, and intensity of treatment related pain (VAPS), oedema, local thrombosis, thrombus evacuated by puncture, haematoma, telangiectatic matting, and presence of pigmentation. Other adverse events were also investigated, including minor general or local transient reactions (allergies, scars, vasovagal reactions, nausea, metallic taste, and scotomas) and severe adverse events (hospitalisation, incapacitation, need for operations, chest pain, transient neurological abnormalities, anaphylaxis, accidental arterial puncture, tissue necrosis, DVT, pulmonary embolism, and death).

Measurement methods

To assess the results of length (cm) of the telangiectasias, feeder veins, and pigmentation, one new methodology of objective measurement in photographs was employed, using the segmented line tool in ImageJ.[23] The linear measurements were obtained before (D0) and after treatment (D60). The lines were measured in pixels (the diameter line was defined to one pixel − without volume) and converted to centimetres (1 cm on the ruler attached to the cloth mould was the base of the calculation). Each image was analysed by two independent experienced vascular surgeons, who were blinded to the groups.

Primary end point

The primary effectiveness end point was to quantify the percentage of telangiectasia elimination in a single session of sclerotherapy according to the pre-treatment pattern. Percentage improvement was calculated by the difference between the total length (cm) in D0 and the residual length (cm) in D60, divided by the total length (cm) in D0.

Secondary end points

Data improvement was also presented in absolute length value of obliterated telangiectasias in centimetres (calculated by the difference between the total length in D0 and the residual length in D60). The improvement in the visible feeding veins (also treated in the same conditions) was presented as absolute length (cm) and proportional (%) reduction.

Pigmentation, defined as a brown line or spot in the path of treated vessels, was measured as previously described, carefully evaluating the images comparatively at D60, by the same two blind evaluators, in absolute length (cm) and in percentage related with the total vessels.

Statistical analysis

Based on an expected percentage rate of improvement of telangiectasias of 75% *vs.* 50% in patients treated with polidocanol 0.2% + glucose 70% *vs.* glucose 75%, a significance level of 5%, and power of 80%, the necessary sample size was calculated to be 55 per group. It was decided that at least 115 patients should be randomised.

Student's *t* test or the non-parametric Mann—Whitney test was used to compare continuous parameters. Fisher's exact test or the chi square test was used to compare categorical parameters. The groups were compared using Goodman's test for multinomial populations to establish the sizing association or homogeneity in contingency tables. Interclass correlation coefficients (ICCs) were calculated to assess interobserver reproducibility of measurements. Continuous parameters were expressed as mean and standard deviation or median and interquartile range, and categorical parameters were expressed as absolute and relative frequencies. The Kolmogorov—Smirnov test was used to test the normality. For clinical relevance, risk ratio (RR) and the number needed to treat (NNT) was calculated for the main end point, considering at least 75% improvement. All statistical analyses were conducted using STATA, version 11.0 (StataCorp, College Station, TX, USA), and the level of significance was set at 5% ($p < .05$). The statistician who performed the results analysis was blinded to the sclerotherapy agents used in the groups (characterising the triple blinded study).

RESULTS

From January to December 2015, 308 patients were accrued. One hundred and fifteen were randomised, 58 to group 1 (0.2% polidocanol + 70% HG) and 57 to group 2 (75% HG alone). Seventeen patients were excluded because they did not attend the scheduled appointments. Fig. 1 shows one example of the treatment. Fig. 2 shows the study flow chart and the reasons for exclusion.

The demographic characteristics of the study participants are given in Table 1. No significant differences between the groups were found, except for sedentary lifestyle and hypothyroidism. Morphological analyses of the telangiectasias showed that most patients presented linear (71.4%) and arboriform telangiectasias (24.5%), with no statistical difference between the groups ($p = .49$). The presence of feeder veins was noted in 48 of 98 patients (49%), with no significant difference between the groups ($p = .68$).

Table 2 shows data concerning the procedure, procedure monitoring, and follow up for both groups; adverse events were considered for primary and secondary end points. No significant differences were found between the groups for parameters evaluated during treatment or for the monitoring parameters, except for an unintentional difference in the mean volume of solution used, 2.3 mL in group 1 and 2.0 mL in group 2 ($p = .049$). There were no major adverse events in either group.

Considering the number of patients that had pigmentation, there was no significant difference between the groups (41.2% [group 1] *vs.* 59.6% [group 2]; $p = .068$). To analyse the relevance of pigmentation, the perception of the patient was evaluated and no statistical difference was found (15.7% [group 1] *vs.* 29.8% [group 2]; $p = .095$), however, if relevance was defined by at least 2.0 cm of linear pigmentation in ImageJ, there was a statistical difference in favour of group 1 (15.7% [group 1] *vs.* 34.0% [group 2]; $p = .035$) (Table 2)

Primary end point

There was high correlation between the two observers and the pictures analysed with ImageJ (ICCs of 0.95—0.99); therefore, all results were analysed by the mean of the results found by both observers.

Table 3 describes the main effectiveness outcome. These results of proportional improvement favoured group 1 (0.2% polidocanol + 70% HG) (median, 82.2% [group 1] *vs.* 63.9% [group 2]; $p < .001$). Considering a minimum improvement of 75% of telangiectasias elimination *vs.* the pre-treatment pattern, the RR was 0.49 (95% confidence interval [CI] 0.24—0.98; $p = .047$) and the NNT was 5.4 (95% CI 2.8—70.7).

Secondary end points

Table 3 also describes all the secondary end points and safety. The results of effectiveness are also presented by the absolute reduction in length (cm) of telangiectasias, which was significant, favouring group 1 (30.9 cm [group 1] *vs.* 24.1 cm [group 2]; $p = .044$). Considering improvement of all vessels (feeder veins and telangiectasias) in percentage (76.8% [group 1] *vs.* 57.3% [group 2]; $p < .001$) and in absolute length (37.1 cm [group 1] *vs.* 27.7 cm [group 2]; $p = .014$), the results statistically favoured group 1. There was a statistically significant improvement in the percentage of reticular veins, favouring group 1 (94.5% [group 1] *vs.* 47.2% [group 2]; $p = .023$). There was no significant

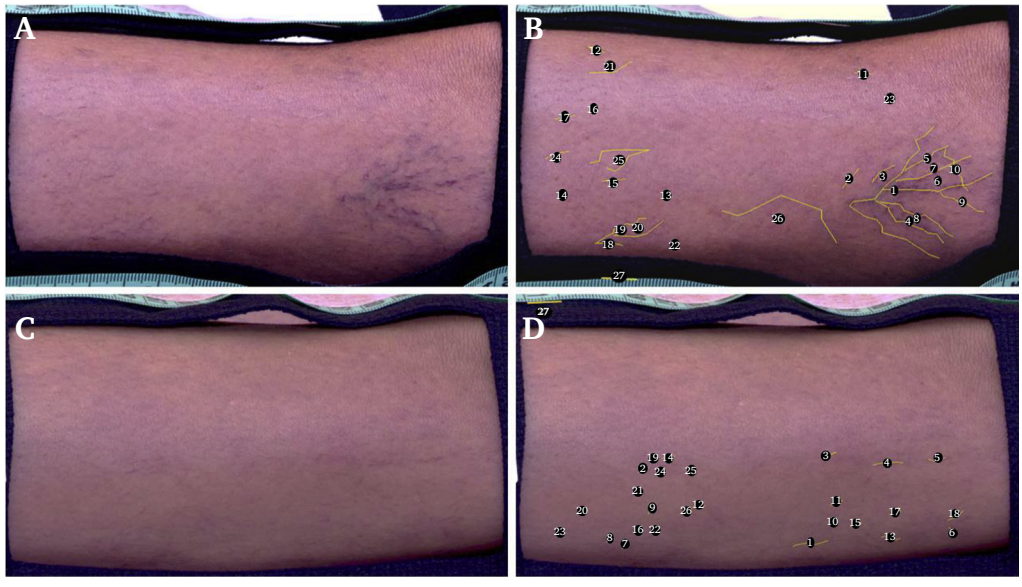

Figure 1. Representative photographs of the telangiectasias treatment area (A, B) before and (C, D) 60 days after treatment with either 0.2% polidocanol + 70% glucose or 75% glucose showing only one site with residual telangiectasias and no pigmentation. (B, D) Yellow lines were drawn over the path of the telangiectasias to perform the measurements with ImageJ and the numbers represent each individual measurement.

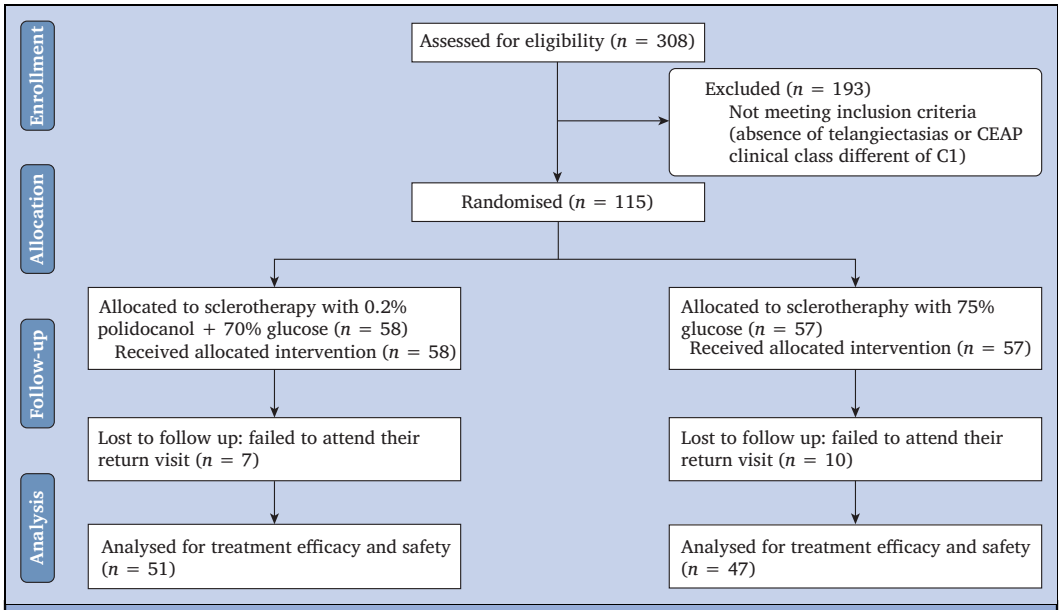

Figure 2. Study flow chart according to Consolidated Standards of Reporting Trials (CONSORT) 2010 flow diagram. CEAP = Clinical-Etiology-Anatomy-Pathophysiology.

difference regarding total length in a sample limited to 48 patients, substantially decreasing the power of the test.

Pigmentation was evaluated as a safety outcome, and both absolute length (cm) (median, 0 cm [group 1] *vs.* 0.5 cm [group 2], $p = .033$), and percentage related to the treated vessels (median, 0% [group 1] *vs.* 1.5% [group 2]; $p = .027$) were statistically significantly smaller in group 1 (Table 3).

DISCUSSION

Sclerotherapy remains the prevailing treatment for telangiectasias, as it is well tolerated, inexpensive, effective, and safe.[3,8,14,25,26] The ideal treatment should eliminate most of the unwanted veins, through a small number of sessions, present no recurrence or recanalisation, and use a low concentration of sclerosing agents.[27] The most common sclerosing agents used in Brazil are 75% HG alone *and* 0.2% polidocanol + 70% HG, both approved for use by the Brazilian National Health Surveillance Agency (ANVISA).[28] HG is a sclerosing agent readily available in some parts of the world, it is safer and cheaper than others, such as pure polidocanol, which has potential toxicity based on the dosage regimen. The mixture of hypertonic glucose and polidocanol minimises these risks; however, no study has been done to prove its effectiveness and safety in the treatment of telangiectasias. In a previous study, 0.2% polidocanol + 70% HG was proved to be effective in treating reticular veins, probably because the addition of polidocanol to glucose increases its potency, bringing lower risks to the patient owing to the low polidocanol concentration. The same hypothesis was therefore considered for the treatment of telangiectasias.[23] However, the study team does not have enough information about the availability of these sclerosing agents and mixtures in other countries.

The performance of pre- and post-treatment comparative measurements of veins (both telangiectasias and reticular veins) is usually done by subjective assessment of improvement by specialists (2—5 evaluators) who quantify the result based on scores (from 1 — 5 or from 1 — 10). The methodology developed by this group is quite innovative, differing conceptually from other methods.[17,29—32] The use of ImageJ can bring additional benefits in terms of measurement accuracy, with the disadvantage of being extremely laborious.[23] This methodological change has not yet been tested in a direct comparative way with the results available to date.

Previous studies using hypertonic saline, sodium tetradecyl sulphate (STS), polidocanol, and chromed glycerin did not show evidence of higher effectiveness or increased patient satisfaction regarding any sclerosing agent,[29—31,33—37] which was confirmed in a systematic review by Schwartz and Maxwell.[38] In this study, polidocanol 0.2% + glucose 70% eliminated 82.2% of telangiectasias in a single treatment session; this result is close to the 90% found by Goldman *et al.*[17] These authors treated telangiectasias with STS 0.25% or polidocanol 0.5%, finding no statistical difference between them, but at the expense of more pigmentation for STS (63% *vs* 32%).[17]

The pathophysiology of pigmentation has been attributed to iron deposits from microthrombi, skin phototypes IV — VI, a post-procedure inflammatory process, vessel fragility, elevated ferritin level, and other factors.[25,39—41] It is an undesirable adverse event and may cause conflicts in the doctor patient relationship. It is presented in most of the studies as frequent and transient, often disappearing spontaneously within one year in most cases.[25,40] Light or moderate compression therapy is recommended after sclerotherapy as a way to improve results and reduce pigmentation, which correlates with the duration of

Table 1. Baseline characteristics of 98 patients with telangiectasias randomised to treatment with 0.2% polidocanol + 70% glucose (Group 1) or 75% glucose (Group 2)

Baseline characteristics	Group 1 (n = 51)	Group 2 (n = 47)	p
Age* − years	46 (35–50)	41 (34–47)	.12
Female†	51 (100)	47 (100)	1.0
Unilateral disease†	51 (100)	47 (100)	1.0
BMI* − kg/m^2	25.0 ± 4.0	25.2 ± 4.1	.75
Sedentary lifestyle†	30 (59)	17 (36)	.025
Smoking†	5 (10)	2 (4)	.29
Hypertension†	3 (6)	4 (8)	.61
Diabetes†	0 (0)	2 (4)	.14
Dyslipidaemia†	4 (8)	6 (13)	.42
Hypothyroidism†	7 (14)	1 (2)	.046
Family history of varicose veins†	44 (86)	40 (85)	.87
Previous surgery for varicose veins†	12 (23)	7 (15)	.28
Saphenectomy†	7 (14)	5 (11)	.64
Morphology of telangiectasias†,‡			.49
Simple linear	39 (76)	31 (66)	
Arborised	10 (20)	14 (30)	
Spider	0 (0)	0 (0)	
Papular	2 (4)	2 (4)	
Length of telangiectasias§ − cm	41.0 ± 22.4	39.3 ± 19.3	.69
Patients with feeder veins†	26 (51)	22 (47)	.68
Length of feeder veins* − cm	4.3 (0–46.4)	0 (0–37.4)	.72
Total veins length§ − cm	49.5 ± 26.4	47.2 ± 24.1	.65
Skin phototype†,‖			.63
I, II, or III	47 (92)	42 (89)	
IV, V, or VI	4 (8)	5 (11)	
No. of pregnancies*	2.0 (0–3)	2.0 (1–3)	.98

Data are presented as n (%), mean ± standard deviation or median (interquartile range). BMI = body mass index.
* Data did not have normal distribution − non-parametric Mann–Whitney test.
† Goodman's test for multinomial populations.
‡ Adapted from Redisch and Pelzer.[4].
§ Data had normal distribution − Student's t test for independent samples.
‖ Skin phototype according to Fitzpatrick classification.[24].

Table 2. Procedure data, procedure monitoring, follow up, and adverse events for primary and secondary end points for 98 patients with telangiectasias randomised to treatment with 0.2% polidocanol + 70% glucose (Group 1) or 75% glucose (Group 2)

Variables	Group 1 (n = 51)	Group 2 (n = 47)	p
Number of punctures*	23 (19–27)	22 (19–26)	.30
Volume of medication† − mL	2.3 ± 0.6	2.0 ± 0.72	.049
Intensity of treatment related pain − VAPS*	3 (1–5)	3 (2–4)	.41
Current pain > pain at the time of previous treatments‡	2 (12)§	2 (22)§	.48
Oedema in the foot < 4 days‡	3 (6)	3 (6)	.92
Oedema in the calf < 4 days‡	1 (2)	0 (0)	.34
Oedema at the treatment site < 4 days‡	31 (61)	23 (49)	.24
Local thrombosis at 7 days‡	20 (39)	22 (47)	.45
Local thrombosis evacuated by puncture at 7 days‡	20 (39)	22 (47)	.45
Haematoma at 7 days‡	36 (71)	38 (81)	.24
Presence of telangiectatic matting at 60 days‖	14 (27)	18 (38)	.35
Patients with any pigmentation at 60 days‡	21 (41)	28 (60)	.068
Pigmentation noted by the patient at 60 days‡	8 (16)	14 (30)	.095
Any pigmentation that adds up to ≥ 2 cm at 60 days‡	8 (16)	16 (34)	.035

Data are presented as n (%), mean ± standard deviation or median (interquartile range). VAPS = visual analogue pain scale (score 0 [no pain] − 10 [worst pain]).
* Data did not have normal distribution − non-parametric Mann–Whitney test.
† Data had normal distribution − Student's t test for independent samples.
‡ Goodman's test for multinomial populations.
§ Data in parentheses present the total number that had the procedure performed previously.
‖ Chi square test.

Table 3. Outcomes for effectiveness and safety at 60 days after treatment of 98 patients with telangiectasias randomised to treatment with 0.2% polidocanol + 70% glucose (Group 1) or 75% glucose (Group 2)

Outcomes	Group 1 (n = 51)	Group 2 (n = 47)	p
Effectiveness primary outcome			
Percentage of improvement in telangiectasias†	82.2 (64.8–89.2)	63.9 (47.2–74.6)	<.001
Effectiveness secondary outcome			
Length of obliterated telangiectasias* − cm	30.9 ± 17.8	24.1 ± 15.3	.044
Percentage of improvement in telangiectasias + feeder veins*	76.8 ± 18.7	57.3 ± 22.6	<.001
Total obliterated vessels (telangiectasias + feeder veins) in length* − cm	37.1 ± 20	27.7 ± 17.2	.014
Percentage of improvement of feeder veins†	94.5 (59.4–100)	47.2 (19.5–95.7)	.023
Obliterated feeder veins in length† − cm	9.9 (7.0–17.5)	8.6 (3.1–14.1)	.18
Safety outcome			
Pigmentation in length† − cm	0 (0–1.2)	0.5 (0–3.5)	.033
Percentage of pigmentation over percentage of obliterated vessels (telangiectasias + feeder veins)†	0 (0–3.3)	1.5 (0–10.8)	.027

Data are mean ± standard deviation or median (interquartile range).
* Data had normal distribution − Student's t test for independent samples.
† Data did not have normal distribution − non-parametric Mann–Whitney test.

compression use (ideally three weeks).[8,9] However, in a tropical country the adherence to compression treatment by patients whose concern is only cosmetic is quite low compared with those in countries with a milder climate, mainly because of the discomfort generated, and also because they do not like the appearance of the stockings. Therefore, the team chose not to use elastic compression in a preventive way, probably obtaining slightly lower effectiveness and higher pigmentation rates. This study showed that pigmentation was quite common among participants, with no statistical difference for when it was seen by the patient or when noticed in small spots in images. On the one hand, if it is taken into account that, to be visible, these small marks must add at least 2 cm in total length, pigmentation occurred in a smaller number of patients treated with polidocanol 0.2% + glucose 70%, which can be related to the suboptimal results produced by the treatment with HG 75%. On the other hand, although the sample calculation did not take into account patient ethnicity, no direct correlation with skin phototype was seen.

Reticular veins, when intensely related to telangiectasias, can be considered feeder veins, increasing resistance to sclerotherapy treatment, and can be the cause of cosmetic complaints,[20] which justified the treatment options in this study. However, as this was not included within the selection criteria, reticular veins were found in approximately half of the patients, which meant the statistical tests used had a low power, but were assessed in another study.[23]

The discomfort caused by the treatment was evaluated in this study using the VAPS, and pain intensity was considered tolerable and similar for both solutions, which is in agreement with the majority of studies using several sclerosing agents.[29,31,34,36,38]

Therefore, it is possible to infer that this new sclerosing mixture will be a new option in the sclerotherapy routine.

Limitations

The main limitations were that this was a single centre study, an insufficient number of patients to evaluate safety data on a large scale, a large number of losses to follow up, only two specific drugs were tested, the present measurement methodology does not allow a direct comparison with other studies, pure liquid polidocanol and foam were not tested, the follow up was short, compression was not used after treatment, the images were obtained under natural light, and there was no placebo group with a sham procedure.

Conclusion

Polidocanol 0.2% + glucose 70% solution for sclerotherapy of telangiectasias and associated feeder veins were significantly more effective compared with 75% glucose in a 60 day follow up study. No severe adverse events were seen in either group, and the rate of pigmentation in the polidocanol 0.2% + glucose 70% group was less significant than in the other group.

CONFLICTS OF INTERESTS

None.

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