

## Comparative Study between Injection Sclerotherapy with Polidocanol 1% Versus Injection Sclerotherapy with Polidocanol 1% Followed by Intense Pulsed Light in the Treatment of Lower Limb Minute Varicosities

TALAL A. ABDEL RAHEEM, M.D.; WALEED S. ALDABAANY, M.D.\*; SHREEN ADEL, M.D. and MAI ASHRAF, M.Sc.

*The Departments of Dermatology and Plastic Surgery\*, Faculty of Medicine, Fayoum University, Fayoum, Egypt*

### ABSTRACT

**Background:** Varicose veins are veins that have become enlarged and tortuous. Sclerotherapy is a well-tolerated and highly efficacious treatment for varicose and telangiectatic leg veins. IPL is high-intensity light source, which emit polychromatic light with noncoherent broad wavelength spectrum of 515-1,200nm. The basic principle of IPL devices is a more or less selective thermal damage of the target.

**Patients and Methods:** The present study included 30 female patients with bilateral primary varicosities. All patients subjected to general and local examination and venous duplex ultrasonography to exclude saphenofemoral, saphenopopliteal or any perforator incompetence. Then the patients were categorized in to 2 groups: Group (A) performed injection sclerotherapy with POL 1% only and group (B) performed injection sclerotherapy with POL 1% followed by 4 sessions of IPL on residual very small telangiectasias that couldn't be injected.

**Results:** Our study showed that there was no statistically significant difference between the two groups as regarding the overall patient and physician satisfaction ( $p$ -value  $>0.05$ ).

**Conclusion:** In conclusion we don't advice to follow the injection sclerotherapy by intense pulsed light as it didn't improve the satisfaction neither of the patients nor of the physician.

**Key Words:** Sclerotherapy – Polidocanol – Varicosities.

### INTRODUCTION

Varicose veins (VVS) are veins that have become enlarged and tortuous. This term commonly refers to the veins on the leg. Although VVs can occur elsewhere [1].

Varicose veins are more common in women than men, and are linked with heredity [2]. Other related factors are pregnancy, obesity, menopause, aging, prolonged standing, leg injury, and abdominal straining. Less commonly, but not exceptionally, VVS can be due to other causes, as post

phlebitic obstruction or incontinence, venous and arteriovenous malformations [3].

Sclerotherapy is highly effective treatment for telangiectatic leg veins. Sclerosing solutions act by inducing endothelial damage endosclerosis, which lead to endofibrosis of the treated vessels. Sclerosing solutions can be placed into three broad categories based on their mechanisms for producing endothelial injury: Detergent as sodium tetradecyl sulphate (STS) and polidocanol (POL), Osmotic as hypertonic saline, and chemical irritant solutions as chromate glycerin. Effective sclerotherapy results when the endothelial damage and associated vascular necrosis are sufficient to destroy the entire vessel wall [4].

After review of literatures, we found some studies that evaluated effect of intense pulsed light (IPL) on the leg telangiectasias treatment. Most studies report good result of smaller vessels.

Goldman et al., demonstrated a 90% clearance rate of 159 patients with vessels of  $<0.2$ mm diameter and of 80% in vessels of 0.2-1mm in diameter [5].

Also, Schroeter et al., observed similar results and reported clearance rates of 92.1, 80, and 81% in vessels of  $<0.2$ , 0.2-0.5, and 0.5-1mm diameter in their multi-center study of 40 patients.

Intense pulsed light seems to be most effective for superficial, red telangiectasias less than 1mm [6].

### PATIENTS AND METHODS

This study was conducted over 10 months from March 2014 to January 2015 on outpatient clinic

basis. It was a randomized split study that was carried out on 30 female patients presented to the outpatient clinic of Fayoum University Hospital with bilateral primary minute varicosities, complained from pain, bad cosmetic appearance, or both.

*Patients were categorized into two groups:*

*Group (A):* 20 patients were injected bilaterally with aethoxysclerol (POL) 1% only. Patients received variable number of sessions on each limb (2-4) sessions according to number, size and distribution of varicosity.

*Group (B):* 10 patients were injected bilaterally with aethoxysclerol (POL) 1% followed by 4 sessions of IPL on residual very fine telangiectatic vessels that couldn't be injected.

*Exclusion criteria:*

- Pregnancy and breast feeding.
- History of deep venous thrombosis.
- Sapheno-femoral, sapheno-popliteal or any perforator incompetence.
- Arthritis, severe systemic diseases or medical conditions that prevent active mobilization.
- History of strong allergic conditions and history or current use of anticoagulants.

Full medical history was taken from all patients and detailed clinical examination and Duplex were carried out to detect the distribution of the affected veins (long, short saphenous or haphazard distribution), their Shape (Tubular, saccular, serpentine, reticular, spider) and presence of sapheno-femoral, sapheno-popliteal or any perforator incompetence. And the size of telangiectasias was measured by the scaled lens.

*Technique of injection sclerotherapy:*

- The patient was examined in the standing position. The sites to be injected were marked by skin marker.
- EMLA cream was applied to the skin half an hour before the procedure.
- Injections are performed with insulin disposable needles.
- Sufficient solution was injected in the varicosity to infuse all of its visible branches.
- The sclerosant rubbed immediately post instillation into the surrounding peri-injection vessel area and a pad of cotton was placed over the injection site and the leg was wrapped distally to proximally with an elastic compressive bandage. The bandage was left for 48h.

- The patient was asked to have a rest for about 15 minutes after the session to detect immediate reactions either local (injection site urticaria) or systemic (anaphylaxis). Then the patient was advised to walk about an hour.
- Patients rated pain of injection from 0 (not painful at all) to 4 (extremely painful).
- Treatment sessions (2-4) for varicosity, were spaced at 2-3 weeks intervals for a given vessel to ensure that maximum endosclerosis has occurred and in order to properly assess the results of the preceding treatment session. And assessment points included: (Hyperpigmentation, extravasation necrosis and superficial thrombophlebitis or DVT).
- The patient satisfaction was assessed by asking the patient how much percent she was satisfied from 0-100%.
- The physician rated improvement also by percentage from 0-100%.

*Technique of IPL:*

- EMLA cream was applied to the skin half an hour before the procedure.
- An optical coupling gel needs to be applied.
- Then treatment parameters are introduced on intense pulse light device as follow: 550nm filter, fluence 20J/cm<sup>2</sup>, spot size 10mm x48mm and pulse duration 100 milliseconds.
- Patients received 4 sessions on the residual telangiectasias, with intervals between sessions 3 weeks.
- The patient satisfaction was assessed by asking the patient how much percent she was satisfied from 0-100%.
- The physician rated improvement also by percentage from 0-100%.

## RESULTS

*This study included two groups:* Group (A) 20 patients were treated with sclerotherapy (POL 1%) and Group (B) 10 patients were treated with sclerotherapy followed by IPL sessions. All patients were females with bilateral primary minute varicosities.

*A- Statistical analysis of clinical data:*

- Comparison between both groups as regards clinical data:

*1- Age and number of pregnancies:*

The group (A) ages ranged between 20 to 45 years (mean  $\pm$  SD: 30.1 $\pm$ 7.5) and group (B) ages

ranged between 20-45 years (mean  $\pm$  SD: 29.4 $\pm$ 7.7). Number of pregnancies in group (A) ranged between 0-5 (mean  $\pm$  SD: 1.9 $\pm$ 1.7) and in Group (B) ranged between 0-4 (mean  $\pm$  SD: 1.8 $\pm$ 1.6). There were no statistically significant differences between the two groups as regarding their age and number of pregnancies ( $p$ -value  $>0.05$ ).

## 2- Occupation, family history and history of CCPs:

In the group (A) the number of patients with positive history of occupation with long standing was 13 (65%) and in group (B) was 7 (70%). The number of patients with negative history of occupation with long standing in group (A) was 7 (35%) and in group (B) was 3 (30%). In the group (A) the number of patients with positive family history was 13 (65%) and in group (B) was 8 (80%). The number of patients with negative family history in group (A) was 7 (35%) and in group (B) was 2 (20%). In the group (A) the number of patients with positive history of intake of CCPS was 9 (45%) and in group (B) was 5 (50%). The number of patients with negative history of intake of CCPS in group (A) was 11 (55%) and in group (B) was 5 (50%).

There were no statistically significant differences between the two groups as regarding occupation with long standing, family history of VVs and history of CCPs ( $p$ -value  $>0.05$ ).

## 3- Presenting complaint:

In group (A) 17 patients (85%) presented with cosmetic concern, 5 patients (25%) with pain and 6 patients (30%) with LL edema, and in group (B) 8 patients (80%) presented with cosmetic concern, 3 patients (30%) with pain, and 2 patients (20%) with LL edema. There was no statistically significant difference between the two groups as regarding the complaint ( $p$ -value  $>0.05$ ).

## 4- Course, duration and size of varicosities:

Duration of varicosity in the group (A) ranged between 1 to 20 years (mean  $\pm$  SD: 6.9 $\pm$ 4.9) and in group (B) ranged between 2-20 years (mean  $\pm$  SD: 7.5 $\pm$ 5.9).

The size of injected veins in the right limb in group (A) ranged between 1-4mm (mean  $\pm$  SD: 2.35 $\pm$ 0.98) and in group (B) ranged between 1-4mm (mean  $\pm$  SD: 2.1 $\pm$ 0.87) and in the left limb in group (A) ranged between 1-4mm (mean  $\pm$  SD: 2.4 $\pm$ 1.1) and in group (B) ranged between 1-4mm (mean  $\pm$  SD: 2.3 $\pm$ 1.2).

According to the course of varicosity in group (A) 6 patients (30%) presented with stationary

course and 14 patients (70%) presented with progressive course and in group (B) 4 patients (40%) presented with stationary course and 6 patients (60%) presented with progressive course.

There were no statistically significant differences between the two groups as regarding the duration, the size and the course of varicosity ( $p$ -value  $>0.05$ ).

## 5- Shape of varicosities:

In group (A) 7 patients (35%) presented with spider varicosity, 1 patient (5%) with tubular varicosity, 1 patient (5%) with saccular varicosity, 1 patient (5%) with serpentine varicosity, 4 patients (20%) with reticular varicosity and 6 patients (30%) with mixed varicosity and in group (B) 3 patients (30%) presented with spider varicosity, 1 patient (10%) with saccular varicosity, 4 patients (40%) with reticular varicosity and 2 patients (20%) with mixed varicosity in the right limb.

In group (A) 4 patients (20%) presented with spider varicosity, 2 patients (10%) with tubular varicosity, 1 patient (5%) with saccular varicosity, 4 patients (20%) with serpentine varicosity, 3 patients (15%) with reticular varicosity and 6 patients (30%) with mixed varicosity and in group (B) 2 patients (20%) presented with spider varicosity, 2 patients (20%) with tubular varicosity, 1 patient (10%) with saccular varicosity, 1 patient (10%) with serpentine varicosity, 1 patients (10%) with reticular varicosity and 3 patients (30%) with mixed varicosity in the left limb. There was no statistically significant difference between the two groups as regarding the shape of varicosities ( $p$ -value  $>0.05$ ).

## 6- Site of varicosities:

In group (A) 14 patients (35%) presented with varicosity in the thigh, 4 patients (10%) in the side knee, 14 patients (35%) in the back of knee, 2 patients (5%) in the leg, 1 patient (2.5%) in the thigh and side of the knee and 5 patients (12.5%) in the thigh and leg. In group (B) 7 patients (70%) presented with varicosity in the thigh, 1 patient (10%) in the side of knee, 1 patient (10%) in the back of knee and 1 patient (10%) presented by varicosity in the leg. There was no statistically significant difference between the two groups as regarding the site of varicosities ( $p$ -value  $>0.05$ ).

## B- Statistical analysis of side effects:

### 1- Comparison between both study groups regarding side effects of injection:

As regarding pain, in group (A) 30 patients (75%) didn't suffer from pain at all during the



injection session, 4 patients (10%) suffered from mild pain, 4 patients (10%) suffered from moderate pain and 2 patients (5%) suffered from severe pain and in group (B) 8 patients (80%) didn't suffer from pain, 1 patient (10%) suffered from mild pain, and 1 patients (10%) suffered from moderate pain.

In group (A) the injection complicated with hyperpigmentation in 7 patients (17.5%) and there was no hyperpigmentation in 33 patients (82.5%). In group (B) the injection complicated with hyperpigmentation in 1 patient (10%) and there was no hyperpigmentation in 9 patients (90%).

Injection site urticaria occurred after injection in 8 patients (20%) of group (A) and in 4 patients (40%) of group (B) and there was no incidence of extravascular necrosis, anaphylaxis and DVT. There was no statistically significant difference between the two groups as regarding the side effect of injection ( $p$ -value  $>0.05$ ).

## 2- Frequency of different side effects among patients treated by IPL in group (B):

The frequency of different side effects among patients treated by IPL in the second group was (40%) had erythema, (20%) hypo-hyperpigmentation (10%) scaring and there was no incidence of purpura at all.

## C- Statistical analysis of satisfaction in both study groups:

1- Comparison between the two groups as regarding patient and physician satisfaction before IPL:

In group (A) the patient satisfaction ranged between 30 to 100% (mean  $\pm$  SD:  $0.76 \pm 0.20$ ) about 1 patient (30-50%), 6 patients (50-70%) and 13 patients (70-100%). And in group (B) ranged be-

tween 30-90% (mean  $\pm$  SD:  $0.72 \pm 0.21$ ) about 2 patients (30-50%) and 8 patients (50-90%). Physician satisfaction in group (A) ranged between 20 to 100% (mean  $\pm$  SD:  $0.76 \pm 0.21$ ) about 1 patient (20-50%), 5 patients (50-70%) and 14 patients (70-100%). And in group (B) ranged between 40 to 95% (mean  $\pm$  SD:  $0.72 \pm 0.19$ ) about 2 patients (40-50%) and 8 patients (50-95%). There was no statistically significant difference between the two groups as regarding the patient or physician satisfaction percentage before treatment with IPL ( $p$ -value  $>0.05$ ).

2- Comparison between the two groups as regarding the overall patient and physician satisfaction:

There was no statistically significant difference between the two groups as regarding the overall patient and physician satisfaction ( $p$ -value  $>0.05$ ).

## D- Statistical correlations between patient's and physician's satisfaction and clinical parameters:

1- Correlation between satisfaction and different sites of varicosities:

There was no statistically significant correlation between different sites of injection as regards patient's and physician's satisfaction percentage ( $p$ -value  $>0.05$ ).

2- Correlation between satisfaction and age, number of pregnancies, size and duration of varicosities:

There was a statistically significant negative correlation between mean physician's satisfaction with age, and duration of varicosities ( $p$ -value  $>0.05$ ), and significant positive correlation between mean size of varicosities with both patients and physician satisfaction percentage ( $p$ -value  $>0.05$ ).

Patients' photos before and after treatment in groups A and B  
Group (A):



Fig. (1-A): Patient before injection sclerotherapy.



Fig. (1-B): The same patient after injection sclerotherapy (4 sessions).



Fig. (2-A): Another patient before injection sclerotherapy.

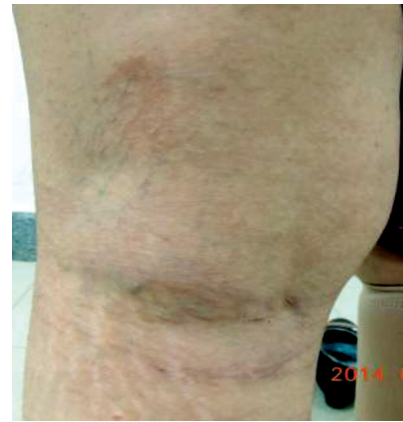


Fig (2-B): The same patient after injection sclerotherapy (3 sessions).

Group (B):



Fig. (3-A): Patient after sclerotherapy and before IPL.



Fig. (3-B): The same patient after IPL (4 sessions).



Fig. (4-A): Another patient after sclerotherapy and before IPL.



Fig. (4-B): The same patient after IPL (4 sessions).

## DISCUSSION

Sclerotherapy is a well-tolerated very effective treatment of varicose and telangiectatic leg veins. POL is one of the most widely used detergent based sclerosing solutions and it has 40-50 years of well-documented history of safety and efficacy [7]. In our study we used POL 1% ampoules for injection

sclerotherapy in both groups and we applied the European safety margin regarding the amount injected per session, that is 2mg/kg (10ml 1% solution in 50kg patient).

In patients with varicosities, beyond the abnormal appearing veins, patients may suffer from pain, altered pigmentation, inflammation, and skin ul-

ceration [8]. However, disfigurement is the most frequent complaint especially in females presented with minute varicosities [9]. In the current study, disfigurement complaint represented 85% of patients in group (A) and 80% of patients in group (B). Pain complaint represented about 25% in group (A) and 30% in group (B), and the third complaint was the lower limb edema which represented about 30% in group (A) and 20% in group (B).

Regarding post sclerotherapy pigmentation, in the comparative study of McCoy et al., between 20% hypertonic saline and POL 1% injection, they stated that hemosiderin deposition and telangiectatic matting are more common with POL 1%, and they referred this complication to the damage of the intima, media and adventitia, with subsequent extravasation of red blood cells into the perivascular tissue resulted in inflammation and hemosiderin staining [10]. Unlike David and Duffy who concluded that POL is less tissue toxic than STS in equal concentrations with much lower incidence of tissue necrosis and hyperpigmentation [11].

In the present study, both groups had small varicosities 1-4mm injected with POL 1% and gave very good results as regarding obliteration of varicosity.

As patient's satisfaction in group (A) ranged between 30-100% (mean  $\pm$  SD:  $0.76 \pm 0.20$ ) and in group (B) ranged between 30-90% (mean  $\pm$  SD:  $0.72 \pm 0.21$ ). Physician's satisfaction in group (A) ranged between 20-100% (mean  $\pm$  SD:  $0.76 \pm 0.21$ ) and in group (B) ranged between 40-95% (mean  $\pm$  SD:  $0.72 \pm 0.19$ ), with residual pigmentation in 17.5% in group (A) and 10% in group (B).

Our results revealed that POL 1% is not painful sclerosant as in the group (A) 75% of patients didn't complain of pain at all, 20% complained of mild to moderate pain and only 5% complained of severe pain during injection while in the group (B) 80% of patients didn't experience pain and 20% complained of mild to moderate pain with injection. Our findings regarding pain were consistent with McCoy et al. [10].

Thrombophlebitis, injection site ulcers, extravascular necrosis and DVT are frequently occurring complications after injection sclerotherapy, and rarely occurring with POL injection. Among the rare but self-limited complications are transient chest tightness and visual disturbances, which commonly occur with ethanolamine oleate more than POL [12,13]. In our study, there were no reported cases of any systemic complication like

visual disturbance, chest tightness, post injection DVT and allergic reaction. We had about 76% patient and physician's satisfaction to POL 1% injection sclerotherapy.

IPL generates non-coherent light with a spectrum of wavelengths ranging from 500-1200nm. Cut-off filters at 515, 550, 570, 590nm are suitable for vascular lesions. These devices produce a variety of fluences, either in single or multiple pulse modes with variable pulse duration and pulse delay. IPL is not a laser but it works according to similar principles. Flexibility in using IPL devices can be provided by computer software, which is not normally available in laser. These devices are able to treat larger areas efficiently and with less discomfort by having a bigger spot size. The longer the wavelength emitted by these devices, the deeper they penetrate into the tissues, thus can improve the clinical efficacy. Splitting the energy into two or three pulses with altered pulse delays can cool the skin between pulses. This results in fewer and negligible side effects [14].

In the current study, we performed 4 sessions of IPL (550 nm filter, fluence  $20\text{J}/\text{cm}^2$ , spot size  $10\text{mm} \times 48\text{mm}$  and pulse duration 100ms) on the post injection residual varicosities in the group (B) and we didn't observe complete clearance in any patient. Transient hyperpigmentation occurred in 20% of the patients, transient erythema noticed in 40% of them and no purpura was detected after IPL treatment.

Sclerotherapy recommended to be as the gold standard for treating uncomplicated cases of leg telangiectasias and Laser/IPL therapy only in resistant forms by Goldman and Raulin [15]. That is exactly was our aim of work for the present study and utilizing IPL instead of Laser was for the lower cost of the latter.

#### Conclusion:

In conclusion we don't advice to follow the injection by IPL in treatment of lower limb minute varicosities, as it didn't improve the overall patient and physician satisfaction ( $p$ -value  $>0.05$ ). Older ages of patients and longer disease duration negatively correlated with physician satisfaction, while sizes of varicose vessels positively correlated with both patient and physician satisfaction ( $p$ -value  $<0.05$ ), in both groups. Thus, the injection sclerotherapy remains the corner stone in the treatment of lower limb small varicosities. However, studies on larger scales are required to further investigate the role of IPL in the treatment of lower limb varicosities.

## REFERENCES

- 1- Eberhardt R.T. and Neglen P.: Chronic venous insufficiency. *J. of Vasc. Surg.*, 111 (7): 2398-409, 2005.
- 2- Andrew T., Spector T. and Jeffery S.: Linkage to the FOXC2 region of chromosome 16 for varicose veins in otherwise healthy, unselected sibling pairs. *Journal of Medical Genetics*, 42 (3): 235-9, 2005.
- 3- Franceschi C.: Pathophysiology of venous insufficiency. *J. of Vasc. Surg.*, 13 (5): 307-310, 1996.
- 4- Tisi P.V. and Beverley C.A.: Injection sclerotherapy for varicose veins (cochrane review) in cochrane library issue 3. Chichester (uk) John wiley and Sons, 2004.
- 5- Goldman M.P. and Eckhouse S.: Photothermal sclerosis of leg veins. *Dermatol. Surg.*, 22: 323-30, 1996.
- 6- Schroeter C.A., Wilder D., Reineke T., Thuerlimann W., Raulin C. and Neumann H.A.M.: Clinical significance of an intense pulsed light source on leg telangiectasias of up to 1mm diameter. *Eur. J. Dermatol.*, 7: 38-42, 1997.
- 7- Jaggi R., John K., Wilde M., Miechel P. and Goldman M.: Comparative trial between foamed and liquid POL and STS in the treatment of VVS and telangiectasias. *Dermatol. Surg.*, 31 (2): 631-635, 2005.
- 8- Eckmann D.M.: Polidocanol for endovenous-microfoam-sclerosant therapy. *Expert OpinInvestig Drugs*, 18 (12): 1919-1927, 2009.
- 9- Weiss R. and Feied C.F.: Varicose Veins and Spider Veins. Downloaded from: <http://emedicine.medscape.com/article/1085530-overview>, 2009.
- 10- McCoy S., Evans A. and Spurrier N.: Sclerotherapy for leg telangiectasia, blinded comparative study of POL and HS. *Dermatol. Surg.*, 25 (7): 381-386, 1999.
- 11- David M. and Duffy M.D.: Sclerosants: A comparative review. *Society of Cosmetic Dermatology and Aesthetic Surgery. Dermatol. Surg.*, 36 (2): 1011-1025, 2010.
- 12- Jia X., Mowatt G. and Burr J.M.: Systematic review of foam sclerotherapy for varicose veins. *B. J. S.*, 94 (4): 925-936, 2007.
- 13- Coleridge P.S.: Foam and liquid sclerotherapy for varicose veins. *Phlebology*, 1 (24): 62-72, 2009.
- 14- Rothfleisch J.E., Kosmann M.K., Levine V.J. and Ashinoff R.: Laser treatment of congenital and acquired vascular lesions: Update on lasers: A review. *Dermatol. Clin.*, 20: 1-18, 2002.
- 15- Goldman M.P. and Raulin C.: Treatment of varicosity with lasers and IPL. *Dermatol. Clin.*, 19 (4): 467-473, 2001.