# "A COMPARATIVE STUDY BETWEEN SCLEROTHERAPY AND ENDOVENOUS ABLATION THERAPY IN MANAGEMENT OF VARICOSE VEINS"

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#### **ABSTRACT**

**Background:** Sclerotherapy and endovenous laser ablation (EVLA) have emerged as alternative treatments to surgery for patients with varicose veins, but uncertainty exists regarding their effectiveness in the medium to longer term.

**Objectives:** To compare the clinical effectiveness, outcome, complications, recurrence and post operative improvement in CEAP classification in patients treated with EVLA and Sclerotherapy.

**Methods:** This is a prospective study. All patients fulfilling inclusion criteria with varicose veins in Krishna Hospital & Medical Research Centre, Karad will be included in the study

**Results:** More than 80% of the study population was classified as C2 or C3 venous disease. After 1 and 1/2 year, the anatomic success rate was highest after EVLA, followed by sclerotherapy. The complication rate was low and comparable between treatment groups. All groups showed significant (P < .001) improvement of quality of life and Chronic Venous Insufficiency 72.10% of patients with C2 class showed an improvement of the "C" of the CEAP classification.

**Conclusion:** Endovenous ablation therapy has shown high improvement with the outcomes such as hospital stay, or post operative complications. It can be concluded that the endovenous ablation therapy is an effective method to cure varicose vein which taken significantly higher time for complication of the wound. Compared to sclerotherapy, and apart from signs and symptoms endovenous ablation therapy is an effective therapy which should be used in the management of varicose veins.

Keywords: Endovenous laser ablation, Sclerotherapy, CEAP classification

### Introduction

A disorder known as varicose veins is characterised by elongated, convoluted, and dilated veins in the leg. It is defined by blood flowing backward via this dysfunctional valve. Leg varicosities were first described around 1550 BC, and their correlation with trauma, childbearing age, and "standing too much before monarchs" was established in the 1600s AD. The causes of varicose veins risk factors include women's sex, pregnancy, lengthy periods of standing, and due to phlebitis.

The Trendelenberg surgery, vein stripping, stab avulsion, sclerotherapy, and minimally invasive techniques including radio frequency ablation and endovenous laser therapy are some of the therapeutic options for varicose veins. Based on the cause, varicose veins are divided into primary and secondary forms.

Primary varicose veins result from laxity and valvular dysfunction in the venous wall caused by genetic or developmental abnormalities. Primary varicose veins are the most typical cause for isolated superficial venous insufficiency. Secondary varicose veins develop as a result of valve system malfunction brought on by pelvic tumours, pregnancy, DVT, or other non-traumatic proximal venous blockage. When the valves of the deep and perforating veins are damaged, chronic venous stasis results.

This study was done to compare the results of two treatment modalities, namely foam sclerotherapy and stab avulsion as the treatment for perforator incompetence.

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# Aims and Objectives

#### Aim:

To compare the most effective treatment modality for lower limb varicose vein between endovenous ablation and sclerotherapy.

### **Objectives:**

- To compare the outcome in patients treated with endovenous ablation and sclerotherapy
- To compare post operative success, return to work, hospital stay, improvement in HRQoL score in endovenous ablation and sclerotherapy
- To study complications and recurrence
- To study post operative improvement in CEAP classification.

Material and Method

### **SOURCE OF DATA-**

This is a prospective study. All patients fulfilling inclusion criteria with varicose veins in Krishna Hospital & Medical Research Centre, Karad will be included in the study.

#### METHOD OF SELECTION-

#### **Inclusion Criteria-**

- Patients above the age of 18 years ,both male and female.
- Patients with primary SFJ incompetence.

## **Exclusion Criteria-**

- Patients with recurrent varicose veins
- Patients with arterial diseases, haematological disorders, extensive perforator incompetence, significant cardiovascular disease
- 2. **SAMPLE SIZE**
- 3. STUDY DESIGN:

## **EXAMINATIONS-**

- Clinical examination of varicose veins.
- Bidirectional Doppler velocity study.
- Duplex imaging/colour flow imaging.

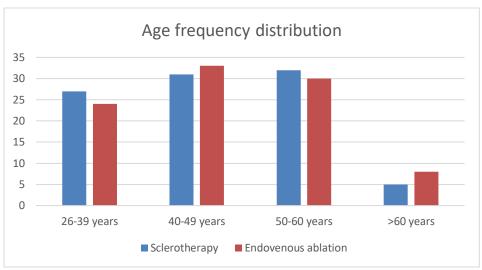
### Observations and Results

All the patients fitting the inclusion criteria were included in the study. Total 190 patients were included in the study for the study duration. In both the groups 95 patients each were randomly allocated.

| Procedure   | Sclerotherapy | Endovenous ablation |
|-------------|---------------|---------------------|
| Sample size | N=95          | N=95                |

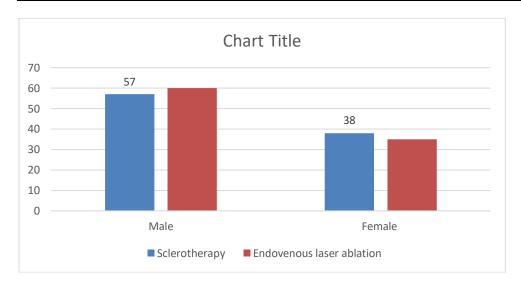
#### Age distribution:

| 8           |               |                     |
|-------------|---------------|---------------------|
| Age group   | Sclerotherapy | Endovenous ablation |
| 26-39 years | 27 (28.42%)   | 24 (25.3%)          |
| 40-49 years | 31 (32.63%)   | 33 (34.73%)         |
| 50-60 years | 32 (33.68%)   | 30 (31.57%)         |
| >60 years   | 5 (5.3%)      | 8 (8.4%)            |
| Total       | 95            | 95                  |



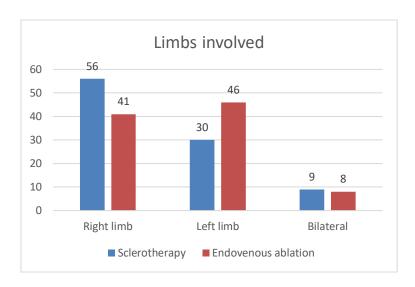
# Gender distribution:

| Gender | Sclerotherapy | Endovenous ablation | Total       |
|--------|---------------|---------------------|-------------|
| Male   | 57 (60%)      | 60 (63.15%)         | 117 (60.9%) |
| Female | 38 (40%)      | 35 (36.84%)         | 73 (39.1%)  |
| Total  | 95            | 95                  | 190         |



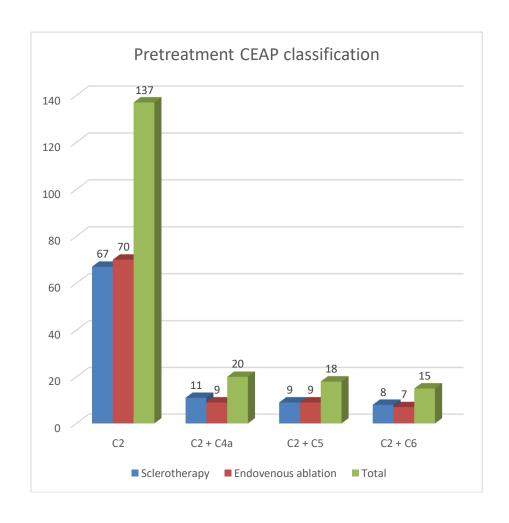
# Limbs involved:

| Limbs involved | Sclerotherapy | Endovenous ablation |
|----------------|---------------|---------------------|
| Right          | 56 (58.9%)    | 41 (43.15%)         |
| Left           | 30 (31.57%)   | 46 (48.42%)         |
| Bilateral      | 9 (9.5%)      | 8 (8.4%)            |
| Total          | 95            | 95                  |



# **CEAP** classification:

| CEAP classification | Sclerotherapy | Endovenous ablation | Total        |
|---------------------|---------------|---------------------|--------------|
| C2                  | 67 (70.5%)    | 70 (73.68%)         | 137 (72.10%) |
| C2 + C4a            | 11 (11.57%)   | 9 (9.5%)            | 20 (10.52%)  |
| C2 + C5             | 9 (9.5%)      | 9 (9.5%)            | 18 (9.47%)   |
| C2 + C6             | 8 (8.42%)     | 7 (7.36%)           | 15 (7.89%)   |
| Total               | 95            | 95                  | 190          |



C2



C4a



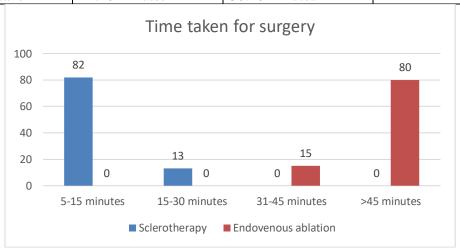






### Time taken for surgery:

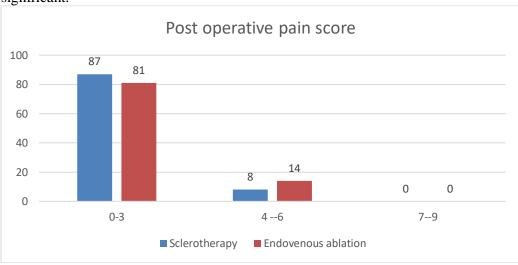
| Time taken for surgery | •             |                     |         |
|------------------------|---------------|---------------------|---------|
| Time taken for the     | Sclerotherapy | Endovenous ablation | P value |
| surgery                |               |                     |         |
| 5-15 minutes           | 82 (86.31%)   | 0                   | < 0.05  |
| 15-30 minutes          | 13 (13.91%)   | 0                   |         |
| 31-45 minutes          | 0             | 15 (14)             |         |
| >45 minutes            | 0             | 80 (86%)            |         |
| Mean time taken        | 12.20 minutes | 50.10 minutes       |         |



Post operative pain according to visual analogue score:

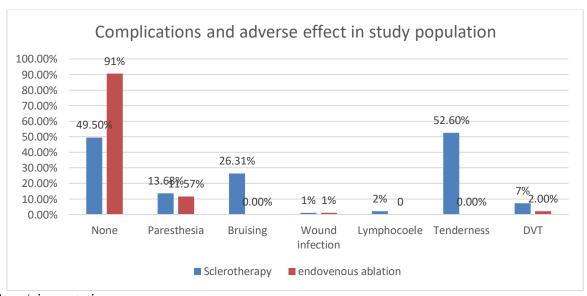
| Pain score      | Sclerotherapy | Endovenous ablation | P value |
|-----------------|---------------|---------------------|---------|
| 0-3             | 87            | 81                  | >0.05   |
| 4-6             | 8             | 14                  |         |
| 7-9             | 0             | 0                   |         |
| Mean pain score | 2.12          | 2.3                 |         |

On the visual analogue score the mean score in sclerotherapy process was 2.12 whereas it was 2.3 in endovenous ablation. P value was more than 0.05 therefore the difference was not statistically significant.



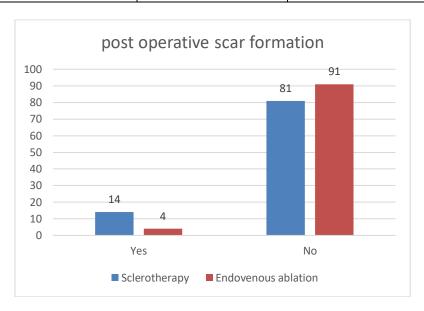
Complications and adverse events:

| Comprisations and adverse events. |               |                     |  |  |
|-----------------------------------|---------------|---------------------|--|--|
| Complications                     | Sclerotherapy | Endovenous ablation |  |  |
| None                              | 47 (49.5%)    | 86 (90.5%)          |  |  |
| Paresthesia                       | 13 (13.68%)   | 11 (11.57%)         |  |  |
| Bruising                          | 25 (26.31%)   | 0                   |  |  |
| Burns                             | 1 (1%)        | 0                   |  |  |
| Wound infection                   | 10 (10.5%)    | 1 (1%)              |  |  |
| Lymphocoele                       | 2 (2%)        | 0                   |  |  |
| Tenderness                        | 50 (52.6%)    | 0                   |  |  |
| DVT                               | 7 (7.3%)      | 2 (2%)              |  |  |



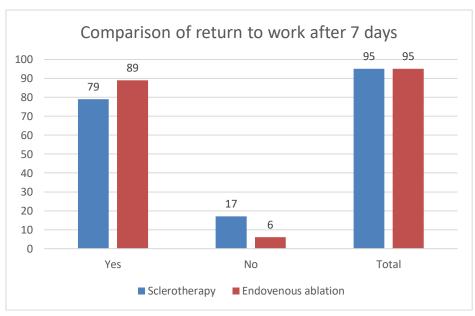
Scar /pigmentation:

| Scar formation | Sclerotherapy | Endovenous ablation |
|----------------|---------------|---------------------|
| Yes            | 14            | 4                   |
| No             | 81            | 91                  |
| Total          | 95            | 95                  |
| %              | 14.73%        | 4.2%                |



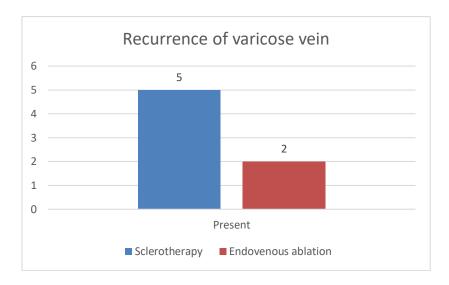
# Return to work in seven days:

| - continue to the continue that the day of |                                   |        |  |  |
|--|-----------------------------------|--------|--|--|
| Return to work in 7 days                   | Sclerotherapy Endovenous ablation |        |  |  |
| Yes  | 79                                | 89     |  |  |
| No   | 17                                | 6      |  |  |
| Total                                      | 95                                | 95     |  |  |
| %age                                       | 83.15%                            | 93.68% |  |  |



# Recurrence:

| Recurrence of varicose vein | Sclerotherapy | Endovenous ablation |
|-----------------------------|---------------|---------------------|
| Yes                         | 5             | 2                   |
| Total                       | 95            | 95                  |
| %                           | 5.2%          | 2.1%                |



# CEAP outcome analysis:

| Measures |               | Pretreatment | 72    | 1 month | 6 months |
|----------|---------------|--------------|-------|---------|----------|
|          |               |              | hours |         |          |
| CEAP     | Sclerotherapy | C2 to C6     | Co    | Co      | Co       |
|          | Endovenous    | C2 to C6     | Co    | Co      | Co       |
|          | ablation      |              |       |         |          |

#### Discussion

Relatively less number of patients were included in C2 + C6 category with 8.42% from sclerotherapy group and 7.36% of endovenous ablation group.

Time taken by the surgeries was also calculated. The Varicose vein is a disorder in which elongated, convoluted and dilated veins are present in lower limb. For the management of varicose veins multiple treatment techniques have been developed.

The present study compared sclerotherapy and endovenous ablation. The study included total 190 participants which were randomly distributed in two groups with two different treatments. That endovenous ablation and sclerotherapy.

95 participants were allocated in either sclerotherapy or endovenous ablation group each.

Majority of the patients in the study population were found in 40-49 year age group and 50-60 year age with 62 patients each. Significant number of patients were present in 26-39 year age group as well.

In the study it was observed that there was male predominance in the study population with total 117 (60.9%) males out of 190 patients whereas only 73 (39.1%) female patients were present in the study population.

During the management of varicose vein the affected lower limbs were anlaysed. It was found during the study compared to left lower limb, right limb was more affected in the sclerotherapy group whereas left lower limb was more affected in the endovenous ablation group. Whereas there was less frequency of bilateral limb involvement.

The limbs were classified according to CEAP classification. This classification is used to assess the chronic venous diseases.

Following is the CEAP classification used to differentiate the affected limbs:

| Grade | Description                            |
|-------|--|
| C0    | No visible or palpable sign of disease |
| C1    | Telangiectasias or reticular vein      |
| C2    | Varicose vein                          |
| C3    | Edema                                  |

| C4a | Pigmentation or eczama                   |
|-----|--|
| C4b | Lipodermatosclerosis or atrophic blanche |
| C5  | Healed venous ulcer                      |
| C6  | Active venous ulcer                      |

It was found that in only C2 class 67 (70.5%) patient were present from sclerotherapy group whereas 70 (73.68%) patients were present in endovenous ablation group. Total 72.10% of the patients included in the study were in C2 category.

11.57% of the sclerotherapy group and 9.5% of endovenous ablation group were categorised into C2 + C4a group.

9.5% of sclerotherapy group and 9.5% of the endovenous ablation group were categorised into C2 + C5 group, time scale was divided into 5-15 minutes, 15-30 minutes, 31-45 minutes and > 45 minutes. The mean time taken by sclerotherapy was less in sclerotherapy compared to endovenous ablation. The mean time taken by sclerotherapy was 12.20 minutes whereas the mean time taken by endovenous ablation is 50.10 minutes. It was observed in the present study that 86.31% of participants from the sclerotherapy group took surgical time between 5-15 minutes whereas 13.69% of the patients took time between 15-30 minutes.

In endovenous ablation group almost 86% of the participants took more than 45 minutes of time from the completion of the surgery while only 15% took time between 31-45 minutes. The difference between completion of surgery was statistically significant with p value <0.05.

During post operative period the pain score was assessed using visual analogue score. Which was divided into three categories, such 0-3, 4-6 and 7-9.

It was found that in the sclerotherapy group 91.57% of the patients experienced lesser pain whereas 85.26% of the endovenous ablation group had pain score between 0-3. The mean pain score was 2.12 for the sclerotherapy whereas it was slightly higher with mean score of 2.3 in the endovenous ablation group. It was observed that the in endovenous ablation group there was slightly higher pain score compared to sclerotherapy group.

There was lower chance of complications in the endovenous ablation group with 86 patients (90.5%) of endovenous group who did not have any post operative complications such as paresthesia, bruising, burns etc. it was also observed that only 47% of the sclerotherapy population did not have any post operative complications. Most commonly paresthesia was present in both the groups with 13.68% in sclerotherapy group and 5.2% in the endovenous ablation group. Also bruising was more common post operative complication with 26.31%. and wound infection was also observed in 10.5% of the sclerotherapy population. Compared to sclerotherapy endovenous ablation had very low post operative complications. Where the % of bruising was nil, and even there was lower possibility of wound infection with only 1% of the patient who had wound infection.

Scar formation during post operative period was observed in the sclerotherapy population. 14 (14.73%) of the patients had scar formation compared to only 4 patients (4.2%) in the endovenous ablation group.

In the present study patients were followed up even after 7 days and the health status of the patients was analysed. It was observed that 83.15% of the patients were able to return to work within 7 days. Compared to 93.68% of the patients in endovenous ablation group who were able to return to work in 7 days. Thereby it was observed that there was difference in the health status of the patient. In the endovneous ablation it can be concluded that there is higher possibility of patient going back to work early compared to sclerotherapy.

During the follow up of the patients it was assessed for the recurrence of this disease. It was found that only in 2.1% the patient had the cases of recurrence in the patients of endovenous laser ablation whereas 5.2% of patients in sclerotherapy had chances of recurrence after the surgery.

The CEAP classification was further analysed post operatively. It was found that in both the study grous the score was divided into categories. For the ranging from C2 to C6. This result was

almost insignificant in both the groups as the pretreatment C2 + C6 which aftet the surgery 72 hours, 1 month and 6 months.

#### Conclusion

- 1. In this study total 190 patients were included with male predominance among the study population.
- 2. Endovenous ablation took approximately 50 minutes to complete the surgical closure.
- 3. Endovenous ablation therapy has shown high improvement with the outcomes such as hospital stay, or post operative complications.
- 4. It can be concluded that the endovenous ablation therapy is an effective method to cure varicose vein which taken significantly higher time for complication of the wound.
- 5. Compared to sclerotherapy, and apart from signs and symptoms endovenous ablation therapy is an effective therapy which should be used in the management of varicose veins.

## **Summary**

The Varicose vein is a disorder in which elongated, convoluted and dilated veins are present in lower limbs. For the management of varicose veins multiple treatment techniques have been developed. The present study compared sclerotherapy and endovenous ablation. 72.10% of the patients included in the study were in C2 category. The mean time taken by sclerotherapy compared to endovenous ablation was also found to be less in both groups.

In endovenous ablation group almost 86% of the participants took more than 45 minutes from the completion of the surgery while only 15% took time between 31-45 minutes. The difference between completion of surgery was statistically significant with p value <0.05. In this study total 190 patients were included with male predominance among the study population. Compared to sclerotherapy 14 (14.73%) of the patients had scar formation compared to only 4 patients (4.2%) in the endovenous ablation group. Thereby it was observed that there was difference in the health status of the patient, suggesting endovenous ablation is better than sclerotherapy.

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