Abstract

**Background:** The great saphenous vein (GSV) is a continuation of the dorsal venous arch in the foot. It travels anterior to the medial malleolus and ascends in the superficial fascia along the medial aspect of the lower extremity and drains into the deep system via the saphenofemoral junction. The aim of this work was to compare between Radiofrequency ablation and mechanochemical ablation of GSV reflux regarding post operative pain, pigmentation, ulcer, hospital stay and rapid return to work.

**Methods:** This was a prospective randomized clinical trial that was conducted on 60 patients diagnosed with GSV reflux in Department of surgery - vascular unit of Benha University Hospitals to compare between radiofrequency ablation and mechanochemical ablation. Patients were divided into two groups: Group A: 30 patients who were treated with mechanochemical ablation, Group B: 30 patients who were treated with radiofrequency ablation. **Results:** There was no significant difference in post-operative outcomes (recovery time, return to work and failure of procedure) between the studied groups. There was no significant difference in postoperative complications between the studied groups. In follow up, there was no significant difference in patient satisfaction between the studied groups. But VAS Score was significantly higher in RFA group than MOCA group. **Conclusion:** Mechanochemical ablation is associated with less postoperative pain compared with Radiofrequency ablation. Although Pigmentation after procedure was significantly higher in Mechanochemical ablation group than Radiofrequency ablation group, Mechanochemical ablation and Radiofrequency ablation are both related to an improvement in quality of life.

**Key words:** Radiofrequency Ablation; mechanochemical Ablation; Great Saphenous Vein Reflux

**Introduction:**

Chronic venous disease is a common condition, which affects both men and women with the prevalence rate of 30%–50%. This has led to significant health spending, and about 1%–2% of healthcare budgets have been spent for venous disease in European countries. Great saphenous vein (GSV) reflux is the most common site of reflux accounting for about 80% of all reflux sites. GSV ablation is recommended to improve symptoms and quality of life of patients (1).

High ligation and stripping of the great saphenous vein (GSV) has been the gold standard for GSV incompetence for more than 100 years. Surgery is performed under general or spinal anesthesia and is related to a high recurrence rate of 18 to 40% after five years. In addition, surgery may lead to significant postoperative symptoms (particularly pain and hematoma) and carries a risk of injury to the saphenous nerve (2).

Endovenous techniques have been developed for the treatment of varicose veins. Endovenous laser ablation (EVLA) and radiofrequency ablation (RFA) are now widely accepted techniques and are frequently used in practice. They are related to less hematoma, pain, and superior cosmetics and earlier resumption of normal activities and work when compared to traditional surgical stripping. Thermal ablative modalities, however, carry the risk of damaging the surrounding tissues of the vein. For this reason, patients are treated with tumescence anesthesia, which requires multiple punctures around the vein. Despite the use of tumescence anesthesia there are still a subset of patients who have postoperative pain, which can last for weeks (3).

Mechanochemical endovenous ablation (MOCA), using the ClariVein® device (Vascular Insights, Madison, CT, United States), uses a rotating wire in a catheter to create mechanical damage to the endothelium of the vessel. At the same time, a sclerosant is infused at the end of the catheter, causing chemical damage to the vein wall. With MOCA, the vein wall is not heated and tumescence anesthesia is redundant. Subsequently complications that occur in thermal ablative modalities such as pain, hematoma, induration and nerve injury could be reduced (4).

The safety and efficacy of MOCA was shown in the first human study. In this study, 30 patients with primary GSV insufficiency were treated using sodium tetradecyl sulfate (Sotradecol). At six months the anatomical success was 97%. After a follow-up period of two years, 27 of the 28 (anatomical success 96%) treated GSV were occluded. Several reports have confirmed the efficacy of MOCA, with occlusion rates varying from 94 to 97%. No major complications such as deep vein thrombosis, pulmonary embolism or nerve injury were observed in all previous studies. Moreover, MOCA was associated with lower post-procedural pain and faster recovery than RFA (5).

The aim of this work was to compare between Radiofrequency ablation and mechanochemical ablation of GSV reflux regarding post operative pain, pigmentation, ulcer, hospital stay and rapid return to work.

**Patients and Methods**

This study aimed to compare between Radiofrequency ablation and
mechanochemical ablation of GSV reflux regarding recent advances in this field.

This study was conducted in the Department of surgery’s vascular surgery unit of Benha University Hospitals.

Approval of Ethics Committee in the Faculty of Medicine, Benha University was taken before preceding the study.

**Type of the study:**
Prospective interventional study.

**Patients:**
This study included 60 patients diagnosed with GSV reflux, the patients are randomized into 2 groups, randomization done with card test.

**Inclusion criteria:**
- Age >18 years old.
- Sex: Both males and females are included
- Primary GSV incompetence & Reflux.

**Exclusion criteria:**
- Allergic to sclerosant.
- History of deep venous thrombosis.
- Peripheral arterial disease (ABPI < 0.8).
- Pregnant and lactating.
- Anticoagulation with warfarin.
- Vein diameter < 3mm or > 15mm.

**Ethical consideration:**
- Approval of the study protocol by an Ethical Scientific Committee of Benha University was obtained.
- Informed verbal and written consent was obtained from the patients before enrollment in the study.

**Methods:**

**Patients were subdivided into:**
- **Group (A):** 30 GSV reflux patients who were treated with Radiofrequency ablation.
- **Group (B):** 30 GSV reflux patients who were treated with mechanochemical ablation (Flebogif catheter).

**All patients were subjected to:**
An informed consent was taken from every patient.

**Complete history taking:**
- Personal history, Any complaint, Obstetric history, Menstrual history, Past medical and past surgical history and Family history.

**Complete physical examination:**

**General examination:**
- Vital signs (Blood pressure, Temperature, Heart rate, Respiratory rate),
- Signs of (Pallor, Cyanosis, Jaundice and Lymph node enlargement).

**Operative intervention of group(A) who are treated with radiofrequency ablation:**
Local tumescent anesthesia or spinal anesthesia, all patients were positioned supine with leg slightly flexed abducted and externally rotated leg to make the GSV more accessible.

The RFA procedure involves using a catheter electrode to deliver a high-frequency alternating radiofrequency current that leads to venous spasm, collagen shrinkage and physical contraction. The patient’s leg is prepped with antiseptic solution and draped in a sterile fashion. With ultrasound guidance, the vein is cannulated, and local tumescent anesthetic is then injected around the target venous segment. The catheter is then introduced through a sheath. The radiofrequency current is then delivered, resulting in circular homogeneous denaturation of the venous collagen matrix and endothelial destruction at a temperature of 110–120°C. Venous segments 3–7cm in length are treated in 20-second cycles. Patients are instructed to wear 20–30 mm Hg graduated elastic compression stockings for at least 14 days.

**Operative intervention of group(B) who are treated with mechanochemical ablation:**
spinal anesthesia, all patients were positioned supine with leg slightly flexed abducted and externally rotated leg to make the GSV more accessible.

No tumescent anaesthesia, sedation or antibiotics were required. All procedures were performed under ultrasound guidance with local anaesthesia (10ml, bupivacaine and Xylocaine mixture) injected at the site of puncture.

We introduce a short micropuncture 5Fr intro-ducer sheath below knee, via Seldinger technique into either the GSV or SSV ultrasound guided and flushed with saline. The flebogif catheter tip was inserted through the sheath and the tip of the dispersion wire positioned 5cm distal to the Sapheno-femoral junction or Sapheno-popliteal junction. Then the catheter was advanced on the wire to that point, the wire then removed, the five arms of the working part with sharp hooks on the ends were released and directed toward the wall of the vein and scarification of the vein was performed by withdrawing the system with continuous movement to the site of the puncture. The withdrawal speed is approximately 5cm/s and the volume of the injected foam amounted to 1mL/5cm of vein. For veins with a diameter of 15mm, 2% polidocanol was used, and for veins of larger diameter 3% polidocanol.

Post-operative, the patients were advised to wear compression stockings second grade for min-imum of ten days.

**All patients were followed for:**
1. Operative time.
2. Hospitalization.
3. Recovery time.
4. Quick return to work.
5. Patient satisfaction.
6. Complication:
   - Post intervention pain
   - Pigmentation

Patients treated with radiofrequency ablation. Figures (1-4)

**Before**

![Before](image1)

![Before](image2)

Fig 1

Ultrasound guided needle insertion

Fig 2
Introduction of sheath

Sheath inserted

Fig 3

Before          After

Fig 4

Before          After
Patients treated with mechanochemical ablation. Figures (5-7)

Before

Fig 5
Sample size:
This study base on study carried out to calculate the sample size by considering the following assumptions: 95% two-sided confidence level, with a power of 80%. & a error of 5% odds ratio calculated= 1.115. The final maximum sample size taken was 60. Thus, the sample size was increased to 60 cases to assume any drop out cases during follow up. 30 were treated with Radiofrequency ablation and 30 were treated with mechanochemical ablation.
Statistical analysis:
Data collected throughout history, basic clinical examination, laboratory investigations and outcome measures coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 22). According to the type of data qualitative represent as number and percentage, quantitative continues group represent by mean ± SD, the following tests were used to test differences for significance; difference and association of qualitative variable by Chi square test ($X^2$). Differences between parametric quantitative independent groups by t test. P value was set at <0.05 for significant results & <0.001 for high significant result.

Results:
There was no significant difference in procedure data (length of vein treated, duration of procedure, and need for hospitalization) between the studied group.

Regarding the type of anesthesia used, there was no significant difference in general anesthesia between both groups. Spinal anesthesia was significantly higher in RFA group than MOCA group (p <0.001) and local anesthesia was significantly higher in MOCA group than RFA group (p <0.001).

Intraoperative VAS score was significantly higher in RFA group than MOCA group (p <0.001) Table (1).

There was no significant difference in post-operative outcomes (recovery time, return to work, and failure of procedure) between the studied groups Table (2).

Table (1): Procedure data in the studied groups

<table>
<thead>
<tr>
<th></th>
<th>MOCA (n =30)</th>
<th>RFA (n =30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anesthesia</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General</td>
<td>0 (0%)</td>
<td>1 (3.33%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Spinal</td>
<td>1 (3.33%)</td>
<td>19 (63.33%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Local</td>
<td>29 (96.67%)</td>
<td>10 (33.33%)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td><strong>Length of vein treated (cm)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>40.6 ± 13.9</td>
<td>36.3 ± 14.8</td>
<td>0.254</td>
</tr>
<tr>
<td>Range</td>
<td>15 - 61</td>
<td>11 - 53</td>
<td></td>
</tr>
<tr>
<td><strong>Duration of procedure (min)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>13.8 ± 7.8</td>
<td>14.1 ± 11</td>
<td>0.903</td>
</tr>
<tr>
<td>Range</td>
<td>5 - 45</td>
<td>4 - 65</td>
<td></td>
</tr>
<tr>
<td><strong>Intraoperative VAS score</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>2.9 ± 1</td>
<td>4.1 ± 1.5</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Range</td>
<td>2 - 5</td>
<td>2 - 6</td>
<td></td>
</tr>
<tr>
<td><strong>Need for hospitalization</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (3.45%)</td>
<td>2 (6.67%)</td>
<td>1.000</td>
</tr>
<tr>
<td>No</td>
<td>29 (96.67%)</td>
<td>28 (93.33%)</td>
<td></td>
</tr>
</tbody>
</table>

*Statistically significant as p ≤0.05, MOCA: Mechanochemical ablation, RFA: Radiofrequency ablation, VAS: Visual analogue scale.
Table 2: Postoperative outcomes in the studied groups

<table>
<thead>
<tr>
<th></th>
<th>MOCA (n =30)</th>
<th>RFA (n =30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recovery time (days)</td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 (0 – 1)</td>
<td>2 (1 – 2)</td>
<td>0.068</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 – 5</td>
<td>0 – 6</td>
</tr>
<tr>
<td>Return to work (days)</td>
<td>Median (IQR)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 (0 – 4)</td>
<td>2 (1 – 5)</td>
<td>0.411</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 – 12</td>
<td>0 – 13</td>
</tr>
<tr>
<td>Failure of procedure</td>
<td>Failure</td>
<td></td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>1 (3.33%)</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

MOCA: Mechanochemical ablation, RFA: Radiofrequency ablation.

Table 3: Postoperative complications after 1 week in the studied groups

<table>
<thead>
<tr>
<th>Postoperative complications</th>
<th>MOCA (n =30)</th>
<th>RFA (n =30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigmentation</td>
<td>8 (26.67%)</td>
<td>1 (3.33%)</td>
<td>0.026*</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>5 (16.67%)</td>
<td>8 (26.67%)</td>
<td>0.532</td>
</tr>
<tr>
<td>Ulcers</td>
<td>1 (3.33%)</td>
<td>0 (0.0%)</td>
<td>0.567</td>
</tr>
<tr>
<td>Superficial thrombophlebitis</td>
<td>7 (23.33%)</td>
<td>5 (16.67%)</td>
<td>0.748</td>
</tr>
<tr>
<td>Hematoma</td>
<td>5 (16.67%)</td>
<td>6 (20%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Erythema</td>
<td>1 (3.33%)</td>
<td>2 (6.67%)</td>
<td>1.000</td>
</tr>
<tr>
<td>No complications</td>
<td>19 (63.33%)</td>
<td>23 (76.67%)</td>
<td>0.398</td>
</tr>
</tbody>
</table>

MOCA: Mechanochemical ablation, RFA: Radiofrequency ablation.

Table 4: Postoperative complications after 6 months in the studied groups

<table>
<thead>
<tr>
<th>Postoperative complications</th>
<th>MOCA (n =30)</th>
<th>RFA (n =30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pigmentation</td>
<td>2 (6.67%)</td>
<td>0 (0.00%)</td>
<td>0.492</td>
</tr>
<tr>
<td>Paresthesia</td>
<td>2 (6.67%)</td>
<td>1 (3.33%)</td>
<td>1.000</td>
</tr>
<tr>
<td>Recurrence</td>
<td>0 (0.00%)</td>
<td>3 (10%)</td>
<td>0.237</td>
</tr>
<tr>
<td>No complications</td>
<td>26 (86.67%)</td>
<td>27 (90%)</td>
<td>1.000</td>
</tr>
</tbody>
</table>

MOCA: Mechanochemical ablation, RFA: Radiofrequency ablation.

Table 5: Follow up clinical class (CEAP) and VCSS in the studied groups

<table>
<thead>
<tr>
<th></th>
<th>MOCA (n =30)</th>
<th>RFA (n =30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCSS</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.5 ± 1.5</td>
<td>3 ± 1.8</td>
<td>0.302</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>0 - 5</td>
<td>0 - 6</td>
</tr>
<tr>
<td>Patient satisfaction</td>
<td>Mean ± SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>by AVVQ</td>
<td>11.8 ± 3.2</td>
<td>12.9 ± 3.7</td>
<td>0.246</td>
</tr>
<tr>
<td></td>
<td>Range</td>
<td>7 – 19</td>
<td>7 - 9</td>
</tr>
</tbody>
</table>

*Statistically significant as p ≤0.05, MOCA: Mechanochemical ablation, RFA: Radiofrequency ablation, VCSS: Venous clinical severity score, VAS: Visual analogue scale, AVVQ: Aberdeen Varicose Vein Questionnaire. is used as the disease-specific PROM for varicose vein interventions. Data have shown that treatment of varicose veins results in significant improvement in health for patients, with an almost a halving of the AVVQ score compared to preoperative values. Furthermore, patients with the lowest (less severe) pre-treatment scores have been found to benefit least from intervention.
Discussion

There was no significant difference in procedure data need for hospitalization between the studied group.

Sincos et al. showed that RFA allows for a shorter period of hospitalization and absence from work when compared to the conventional stripping Group (6), as previously demonstrated by Lurie et al., and other studies (7).

There was no significant difference in postoperative outcomes (recovery time, return to work and failure of procedure) between the studied groups.

According to Elganzoury et al. reported that Postintervention in the MOCA group 15% of the cases have partially compressible GSV with a flow less than 1 s. Recanalization of one segment about 5 cm in length in MOCA which is less in RFA and Endovenous laser ablation (EVLA) operative time was less in MOCA than RFA and EVLA. Also return to normal activity was faster in MOCA than the other two groups (8).

Van Eekeren et al. demonstrated that MOCA is associated with significantly less postoperative pain and a faster recovery and work resumption, compared with RFA in the treatment of great saphenous incompetence. The observation that patients treated with MOCA resume their work 1 day earlier than patients treated with RFA might have a significant effect on the total health care burden of varicose vein treatment (9).

Our results showed that pigmentation after 6 months procedure was significantly higher in MOCA group than RFA group (p =0.026).

Similarly, Elganzoury et al. reported that hyperpigmentation is higher in MOCA than RFA and EVLA (8).

In the present study, there was no significant difference in postoperative complications (itching, ulcers, superficial thrombophlebitis, hematoma) between the studied groups.

Elganzoury et al. reported that edema, cellulitis, hyperemia, burning pain, and thrombophlebitis are more in the RFA group than the other two groups, whereas infection and nerve injury are more common in the EVLA group. Compression postoperative was less in RFA than the other two groups (8).

Shepherd et al. demonstrated that MOCA is associated with a significant reduction in postprocedural pain after treatment. Pain after endothermal ablation is considerable and probably an underreported complication in the literature. Recent studies have shown less postprocedural pain after RFA compared with EVLA (10).

A previous meta-analysis of Healy et al. reported deep vein thrombotic events in 1.7% of patients after treatment with EVLA or RFA. This probably resulted from heat-induced vessel wall injury with thrombotic occlusion (11).

Our recent study revealed that, in follow up, there was no significant difference in VCSS and patient satisfaction between the studied groups.

But VAS Score was significantly higher in RFA group than MOCA group (p =0.039).
The potential benefit of MOCA reported in previous reviews of ClariVein is the reduced intraprocedural and postprocedural pain and, thereby, an earlier return to work (12; 13).

Elganzoury et al. reported that although patient satisfaction in the MOCA and EVLA groups was not significantly different, more patients in the EVLA group expressed satisfaction than in the MOCA group (8).

MARADONA is a multicenter randomized controlled trial that aims for a reduction in postprocedural pain after MOCA compared with RFA, with a similar anatomical and clinical success (4).

The Flebogrif system provides high efficiency, high occlusion rate, and technical success after 3 months of follow-up reaching 96%. The system is also characterized by good cosmetic effect and low complication rate. The procedure performed with the Flebogrif catheter seems to improve quality of life of the patient in the postoperative period (14).

Bootun et al. performed a randomized controlled trial comparing MOCA to radiofrequency ablation (RFA) in 60 patients, looking at intraprocedural pain levels. There was a significantly lower maximum pain score with MOCA (19.3 mm) compared to RFA (34.5 mm) on a 0-100 mm visual analog scale (P < .001). The average pain score was also significantly lower (MOCA 13.4 mm versus RFA 24.4 mm, P = .001). Clinical improvement and quality of life scores were improved with MOCA (15).

Van Eekeren et al. compared MOCA to RFA in a prospective observation study of 68 patients, evaluating postoperative pain levels. MOCA was associated with significantly less pain in the immediate 14-day postoperative period as compared to RFA on a 0-100 mm visual analog scale (4.8 mm versus 18.6 mm, P < .001) (4).

Kim et al. reported that there was a marked reduction in the CEAP class and the VCSS over time in MOCA (16).

Two meta-analyses of MOCA using ClariVein reported anatomic success rates varying from 84.5% to 91.7% after a follow-up period of >6 months but <12 months and 12 months, respectively (17; 18).

Several randomized trials have compared RFA with conventional surgery, endovenous laser ablation and foam sclerosis (19). These studies showed the superiority of EVLA in terms of anatomical success at one to five years after surgery, although newer radiofrequency devices have similar results (20).

Recent studies have shown less postprocedural pain after RFA comparing with EVLA (10, 21).

Van Eekeren et al. found that the mean postoperative pain on the first day was 9 mm on a 0 to 100 mm VAS. The score decreased to a mean of 2 mm, 7 days after MOCA (22).

Elias and Raines reported a 96.7% occlusion rate at 260 days in patients treated with MOCA (23).

Van Eekeren et al. stated that although the VAS was threefold lower in the MOCA group, the procedural pain was not significantly different between the groups (4).

Vasquez and Munschauer examined the results of RFA on venous clinical severity score in 682 limbs treated with RFA. Overall mean baseline venous clinical severity scores were 8.8 at baseline and 3.6 at last follow-up visit, with P < 0.05 (24).

Holewijn et al. showed that MOCA of the GSV results in less postoperative pain, although the absolute difference is small. Clinical success rates were equal to those of RFA at 1- and 2-year follow-up, but with more anatomic failures, especially partial recanalizations (25).

Holewijn et al. showed significantly more anatomic failures at 1 year and 2 years after MOCA compared with RFA, of which a large proportion was partial. Whether the partial recanalizations will be progressive in time and lead to clinical symptoms remains to be seen. Future reinterventions are scheduled, one in the MOCA group and four in the RFA group (25). Prolonged follow-up of these cohorts is therefore crucial, particularly because a further decline may be expected on the basis of an earlier cohort study (26).

When comparing RFA with the new MOCA technique, it seems that MOCA is less painful and patients return to work more quickly. However, after more than two years of follow-up, MOCA has not yet proven to be as capable as RFA in terms of clinical and anatomic results (27).

Conclusion:
Mechanochemical ablation is associated with less postoperative pain compared with Radiofrequency ablation. Although Pigmentation after procedure was significantly higher in Mechanochemical ablation group than Radiofrequency ablation group, Mechanochemical ablation and Radiofrequency ablation are both related to an improvement in quality of life.

References:

