Research Article

Effects of Two Current Great Saphenous Vein Thermal Ablation Methods on Visual Analog Scale and Quality of Life

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Background. The aim of the study is to compare the current two endovenous thermal ablation methods by examining the effects on the visual analog scale (VAS) and the short form-36 quality of life index. Methods. Ninety-six patients who underwent unilateral endovenous thermal ablation of great saphenous vein were included. ClosureFast™ catheters were used in the RFA group and 1470 nm radial fiber laser catheters were used in the EVLA group. Results. The RFA group consisted of 41 patients and the EVLA group consisted of 55 patients. The preoperative baseline characteristics of both groups were similar. On the day of operation, VAS values were 2.8 ± 1.1 in the RFA group and 3.6 ± 1.8 in the EVLA group (p = 0.02). Comparisons of short form-36 parameters in both groups showed them to be similar except the pain detected at postoperative 1st week (48.1 ± 5.4 for RFA, 44.9 ± 7.6 for EVLA, p = 0.04). Conclusion. Results in postprocedural quality of life were found to be similar in both of the techniques. However, in terms of postoperative pain, radiofrequency ablation is still superior to the 1470 nm radial fiber laser catheters.

1. Introduction

According to current guidelines thermal ablation is the first choice of treatment in saphenous vein insufficiency [1, 2]. Among those, radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) are the most commonly used. There is no consensus about the superiority of these techniques. Although lesser pain and complication rate was reported with RFA, using old generation laser catheters in those studies has led to question of the superiority of the RFA [3–6]. Because of this, new studies are needed with the use of new generation catheters with high wave length and new tip designs. Advances in laser catheters may alter the results and end the superiority of the RFA [7–9].

Short form-36 (SF-36®) is frequently used questionary with 36 questions in quality of life analysis. SF-36 uses 8 parameters to detect physical and mental status (physical function, physical role, pain, and general health for physical component; vitality, social role, emotional role, and mental health for mental component) [10]. Visual analog scala (VAS) is used to evaluate pain objectively. The purpose of this study is to compare the postoperative results of two current thermal ablation methods and their effects on VAS and SF-36 quality of life index.

2. Materials and Methods

2.1. Patient Groups. One hundred fifteen patients underwent great saphenous vein (GSV) thermal ablation between February 2013 and March 2016 at our institution. Among them, ninety-six patients undergoing unilateral GSV endovenous thermal ablation were enrolled in the study. Local anesthesia and mild midazolam sedation were used in all patients. Patient with previous deep vein thrombosis, accessory saphenous vein insufficiency, previous venous surgery in the same extremity, peripheral arterial disease (ABI < 0.8), patients with CEAP [11] class C4b and above, and immobilized patients were excluded from the study. The information of the patient was obtained by examining the hospital records. Patients were separated into RFA and EVLA groups.

2.2. Radiofrequency Ablation. The GSV was cannulated percutaneously using an 18-gauge needle with the aid of ultrasound on the knee area. A 6 F introducer sheath (INPUT
2.4. Follow-Up Protocol. Compression treatment was stopped following the control bed resting. It was advised that compression stockings be used and patients were dressed with grade II (23–32 mmHg) compression stockings and they were mobilized. Patients were examined and the pre- and posttreatment CEAP class, venous clinical severity score [12] (VCSS), VAS, and SF-36 quality of life index (Table 1). The success rate was 100% in both groups. The ablated segment was 27 ± 1 cm in the RFA group and 26 ± 1 cm in the EVLA group (p = 0.73). No statistically significant difference was found in the use of amount of tumescent anesthesia between the two groups (380 ± 22 versus 385 ± 18 ml, p = 0.96). The number of mini phlebectomy procedures for local varicose veins was 3.4 ± 0.7 in the RFA group and 3.6 ± 0.7 in the EVLA group (p = 0.3). All of the patients were discharged on the day of the procedure.

The mean follow-up was 11 ± 8 months in the RFA group and 14 ± 9 months in the EVLA group. Six months’ follow-up was achieved in all the patients studied (100%), while 10 patients (20%) did not show up on their first-year control. During the follow-up period, 4 (1%) patients in the RFA group and 0 (0%) patients in the EVLA group died. Most of the patients (80%) did not show up on their second-year control. The number of patients who developed complications was 2 (0.85%) in the RFA group and 6 (11%) in the EVLA group had complications (p = 0.05). None of the patients had skin burns or deep venous thrombosis. The distribution of developing complications according to the groups is listed in Table 2. The recurrence rate was 1 (2.4%) in RFA group and 2 (3.6%) in the EVLA group (p = 0.73). Two of the patients were treated with high ligation and one was treated with foam sclerotherapy.

3. Results and Discussion

3.1. Results. Ninety-six patients were included in the study. The RFA group consisted of 41 patients and the EVLA group consisted of 55 patients. The mean age was 46 ± 12 in the RFA group and 45 ± 10 in the EVLA group. Most of the patients in both groups consisted of female patients. At the saphenofemoral junction level, the diameter of the GSV was 9.8 ± 2.5 mm in the RFA group and 9.5 ± 2.7 mm in the EVLA group. Preoperative VCSS was 4.3 ± 1.7 in the RFA group and 4.4 ± 1.2 in the EVLA group and VAS was 5 ± 2 in the RFA group and 5.1 ± 1.8 in the EVLA group. Most of the patients in both groups were in class C2–C3. There was no significant difference between groups in terms of age, gender, comorbid disease, preoperative CEAP class, VCSS, GSV diameter, VAS, and SF-36 quality of life index (Table 1).

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### Table 1: Comparison of preoperative variables of the groups: There is no significant difference between two groups.

| Variable                  | RFA (n = 41) | EVLA (n = 55) | p value |
|---------------------------|--------------|---------------|---------|
| Age                       | 46 ± 12      | 45 ± 10       | 0.77    |
| Female/male               | 27/14        | 38/17         | 0.73    |
| Comorbidities             |              |               |         |
| Hypertension (%)          | 6 (14.6)     | 7 (12.7)      | 0.78    |
| Diabetes (%)              | 3 (7.3)      | 4 (7.3)       | 0.99    |
| CAD (%)                   | 2 (4.9)      | 3 (5.5)       | 0.90    |
| Others (%)                | 3 (7.3)      | 5 (9.1)       | 0.75    |
| CEAP class                |              |               |         |
| C1 (%)                    | 1 (2)        | 1 (2)         | 0.83    |
| C2 (%)                    | 24 (59)      | 34 (61)       | 0.74    |
| C3 (%)                    | 15 (37)      | 19 (35)       | 0.83    |
| C4a (%)                   | 1 (2)        | 1 (2)         | 0.83    |
| GSV diameter (mm)         | 8.8 ± 2.5    | 9.5 ± 2.7     | 0.22    |
| VCSS                      | 4.3 ± 1.7    | 4.4 ± 1.2     | 0.60    |
| Preop VAS                 | 5 ± 2        | 5.1 ± 1.8     | 0.83    |
| SF-36 parameters          |              |               |         |
| Physical function         | 48.5 ± 7.1   | 47.7 ± 6.6    | 0.39    |
| Physical role             | 50.2 ± 9.8   | 48.6 ± 10.4   | 0.43    |
| Pain                      | 43.5 ± 9.7   | 43.1 ± 7.8    | 0.75    |
| General health            | 50.3 ± 8     | 49.5 ± 7.0    | 0.27    |
| Vitality                  | 53.4 ± 7.5   | 52.8 ± 9      | 0.75    |
| Social role               | 49.1 ± 9     | 49 ± 8.4      | 0.79    |
| Emotional role            | 50.9 ± 10    | 50.7 ± 10.5   | 0.92    |
| Mental health             | 46.8 ± 8     | 46.5 ± 9.2    | 0.58    |
| Physical component score  | 46.4 ± 8.8   | 44.8 ± 7.8    | 0.31    |
| Mental component score    | 50.5 ± 9.3   | 50.6 ± 9.2    | 0.92    |

CAD: coronary artery disease, VAS: visual analog scale, VCSS: venous clinical severity score, GSV: great saphenous vein, and SF-36: short form-36.

### Table 2: Postoperative complications: There is no significant difference between two groups.

| Complications (%) | RFA (n = 41) | EVLA (n = 55) | p value |
|-------------------|--------------|---------------|---------|
| Hyperpigmentation | 4 (10)       | 6 (11)        | 0.85    |
| Endurance (%)     | 1 (2.4)      | 2 (3.6)       |         |
| Paresthesia (%)   | 2 (4.9)      | 3 (5.5)       |         |
| Cellulitis (%)    | 1 (2.4)      | —             |         |
| Skin burn (%)     | —            | 1 (1.8)       |         |
| DVT (%)           | —            | —             |         |

The improvements in the postoperative CEAP classifications were shown in Table 3. In the first week, it was observed that the majority of the patients in both groups tended to be in the class C0-C1 and this clinical improvement was maintained throughout the follow-up period. In both groups, mean VCSS were found to decrease compared to preoperative level in the first week, but significant improvement was observed at the 3rd month (Figure 1). The delay in correction was due to mandatory compression therapy applied to all patients during the first postoperative week. When the mean VCSS obtained during follow-up were compared, no significant difference was found between the two groups.

The VAS value determined on the day of operation was 2.8±1.1 in the RFA group and 3.6±1.8 in the EVLA group. The difference between the two groups was statistically significant (p = 0.02) (Figure 2).

Changes in the SF-36 quality of life index parameters following the operation are shown in Table 4. When the two groups were compared, it was seen that all parameters were similar except for the pain that was observed at 1st week (48.1±5.4 for RFA and 44.9±7.6 for EVLA, p = 0.04). When the effect of ablation on the quality of life was examined, similar changes were observed for both methods (Tables 1 and 2). In the first week, physical function, physical role, and social role parameters decreased significantly, but general health, emotional role, and mental health parameters did not change significantly in both groups. Viability increased significantly in both groups but the improvement in the pain parameters was significant in the RFA group and was not significant in the EVLA group (p = 0.03, p = 0.13). It was found that the physical component score decreased and the mental component score increased significantly in both groups. At the third month of evaluation, it was observed that the decrease in physical function, physical role, and social role disappeared in both of the groups and that the preoperative values were significantly exceeded. The general health parameters were significantly increased in both
Table 3: Postoperative changes of the CEAP clinical classification of the patients: both of the groups consist of mostly class C1-C3 patients. Postoperative improvements for the CEAP clinic class were maintained during follow-up.

|        | Preop  | 1st week | 3rd month | 6th month | 1st year |
|--------|--------|----------|-----------|-----------|----------|
|        |        |          | RFA (n = 41) |
| C0 (%) | 0 (0)  | 14 (34)  | 14 (34)   | 21 (52)   | 8 (62)   |
| C1 (%) | 1 (2)  | 26 (64)  | 26 (64)   | 18 (44)   | 4 (30)   |
| C2 (%) | 24 (59)| 0 (0)    | 0 (0)     | 1 (2)     | 0 (0)    |
| C3 (%) | 15 (38)| 0 (0)    | 0 (0)     | 0 (0)     | 0 (0)    |
| C4a (%)| 1 (2)  | 1 (2)    | 1 (2)     | 1 (2)     | 1 (4)    |
|        | EVLA (n = 55) |
| C0 (%) | 0 (0)  | 25 (45)  | 25 (45)   | 32 (58)   | 17 (63)  |
| C1 (%) | 1 (2)  | 27 (49)  | 28 (51)   | 21 (38)   | 9 (33)   |
| C2 (%) | 34 (61)| 0 (0)    | 1 (2)     | 1 (2)     | 0 (0)    |
| C3 (%) | 19 (35)| 2 (4)    | 0 (0)     | 0 (0)     | 0 (0)    |
| C4a (%)| 1 (2)  | 1 (2)    | 1 (2)     | 1 (2)     | 1 (4)    |

Figure 1: Postoperative changes for VCSS of both groups: similar improvements were detected for VCSS of both groups during follow-up (VCSS: venous clinical severity score).

Figure 2: Comparison of mean preoperative and operative day VAS between two groups: preoperative VAS was similar for both groups, but operative day VAS in RFA group was significantly lower than in EVLA group (VAS: visual analog scale).

3.2. Discussion. When the findings are examined, it can be said that both ablation methods have similar high clinical success and low complication rates. In the first week postoperatively, SF-36 resulted in a decrease in both physical component and social role scores, but, in later controls, the quality of life was found to be above preoperative levels in almost all parameters. The only significant difference between the groups was the severity of pain experienced after ablation. In the RFA group on the day of operation, the pain assessed by VAS was significantly lower than in the EVLA group (Figure 2). A significant difference was found between the two groups in the SF-36 quality of life index pain parameter on the first week and it was found that this difference between the two groups disappeared in later controls (Table 4). These results suggest that in our study group RFA caused less pain on the operation day and that this advantage continued for the first postoperative week. As is known, the level of evidence for retrospective studies is lower than that for prospective randomizations. However, the
Table 4: Postoperative changes for SF-36 parameters: postoperative changes for the quality of life index are similar for both groups except pain parameter in the first week.

| SF-36 parameters     | RFA (n = 41) | EVLA (n = 55) | p value |
|----------------------|--------------|---------------|---------|
|                      | 1st week     |               |         |
| Physical function    | 43.6 ± 6.7   | 43.3 ± 6.8    | 0.99    |
| Physical role        | 39.3 ± 7.2   | 38.0 ± 8.7    | 0.39    |
| Pain                 | 48.1 ± 5.4   | 44.9 ± 7.6    | 0.04    |
| General health       | 50.5 ± 8     | 50.2 ± 7.5    | 0.58    |
| Vitality             | 54 ± 7.5     | 53.8 ± 8.9    | 0.85    |
| Social role          | 46 ± 8.3     | 44.2 ± 8.9    | 0.27    |
| Emotional role       | 50.4 ± 10    | 48.6 ± 11.7   | 0.53    |
| Mental health        | 46.8 ± 7.8   | 46.9 ± 8.5    | 0.61    |
| Physical component score | 41.7 ± 5.6 | 40.4 ± 6.6    | 0.30    |
| Mental component score | 52 ± 8.3   | 51.3 ± 9.3    | 0.41    |
|                      | 3rd month    |               |         |
| Physical function    | 54.1 ± 5     | 54.3 ± 3      | 0.55    |
| Physical role        | 55.5 ± 2.6   | 55.4 ± 2.2    | 0.58    |
| Pain                 | 62 ± 2.5     | 60.1 ± 5      | 0.13    |
| General health       | 51.9 ± 7.7   | 51.1 ± 7.0    | 0.37    |
| Vitality             | 56.2 ± 6.8   | 55.6 ± 7.7    | 0.60    |
| Social role          | 51.8 ± 6.5   | 52.2 ± 6.9    | 0.50    |
| Emotional role       | 51.7 ± 9     | 51.5 ± 9.4    | 0.96    |
| Mental health        | 47.7 ± 7     | 47.5 ± 8      | 0.73    |
| Physical component score | 56.6 ± 4.7 | 56 ± 3.6      | 0.18    |
| Mental component score | 49 ± 7.3   | 49 ± 8.2      | 0.96    |
|                      | 6th month    |               |         |
| Physical function    | 54.6 ± 4.6   | 54.6 ± 3.2    | 0.66    |
| Physical role        | 55.7 ± 1.8   | 55.6 ± 2.4    | 0.98    |
| Pain                 | 61.7 ± 2.5   | 61.2 ± 3.7    | 0.71    |
| General health       | 53.1 ± 7.6   | 52.5 ± 7.0    | 0.38    |
| Vitality             | 56.4 ± 6.6   | 56.8 ± 7.8    | 0.95    |
| Social role          | 52.1 ± 6.1   | 53 ± 6.3      | 0.34    |
| Emotional role       | 53 ± 7.6     | 51.7 ± 8.6    | 0.27    |
| Mental health        | 48.5 ± 6.6   | 48.7 ± 7.9    | 0.86    |
| Physical component score | 56.8 ± 4.4 | 56.6 ± 3.6    | 0.32    |
| Mental component score | 50.7 ± 7   | 50 ± 8.1      | 0.96    |
|                      | 1st year     |               |         |
| Physical function    | 55.6 ± 2.5   | 55.2 ± 2.3    | 0.50    |
| Physical role        | 56.2 ± 0.1   | 55.6 ± 1.3    | 0.85    |
| Pain                 | 61.1 ± 3     | 60.9 ± 3.6    | 0.96    |
| General health       | 55.2 ± 8.1   | 53.6 ± 8.1    | 0.55    |
| Vitality             | 56.7 ± 6.3   | 57.9 ± 7.6    | 0.53    |
| Social role          | 53.8 ± 4.7   | 54.8 ± 5.2    | 0.43    |
| Emotional role       | 52.9 ± 8.8   | 53.1 ± 6      | 0.79    |
| Mental health        | 48.7 ± 4.3   | 49.5 ± 7.4    | 0.72    |
| Physical component score | 57.8 ± 3.1 | 57 ± 3.4      | 0.39    |
| Mental component score | 50.3 ± 6.4  | 51.4 ± 7.6    | 0.72    |

SF-36: short form-36.

relatively homogeneous formation of the groups (Table 1), the similarity of the factors that can affect the postoperative pain, such as the ablated segment length, the amount of tumescent used, the number of phlebectomy procedures, and the anesthesia protocol increase the reliability of the results.

SF-36 is widely used in assessing quality of life. It is known that particularly physical function, physical role, pain, and general health parameters are in compliance with the severity of venous diseases, while compliance was not great in vitality, social role, emotional role, and mental health parameters that constitute the mental component [1]. Our results confirm these findings. It was observed that the improvement obtained after operation in the physical component parameters did not occur in all of the mental component parameters. Emotional role and mental health parameters were not significantly changed during treatment, and mental component, which is one of the main two components, was worsened at 3rd month, but it was found to increase again back to preoperative levels at 6th-month and 1st-year controls. It can be said that both ablation methods decrease the quality of life temporarily during the first week postoperatively, but it can be assumed that it is improved afterwards...
when we look at the physical component scores. In the mental component scores, the treatment modality does not seem to lead a change when we exclude the early period.

RFA revealed superior results in complication rates and postoperative pain in most of the studies [3–6]. Developments in laser catheters have led to improvements in EVLA results, and it is thought that the new catheters could end this superiority of RFA [7, 8]. However, this hypothesis has not been sufficiently questioned. There is only one study in the literature comparing RFA with current laser catheters. Bozoglan et al. used RFA and 1470 nm radial fiber laser catheter in two different extremities of the same patient and reported that EVLA was superior to RFA in terms of postoperative pain and rate of return to daily activity [9]. Our findings are not compatible with this study. In terms of postoperative pain according to our results, RFA still seems advantageous against the 1470 nm radial fiber laser catheter. Using of a rarely preferred RFA catheter was the drawback of Bozoglan’s study. There could be differences in between RFA catheters as in laser catheters. The higher complication rates in the used catheters versus VNUS ClosureFast are even published in their official web site [13]. No other study comparing two RFA catheters in the literature has been found. It is clear that further studies are needed. On the other hand, it should not be overlooked that the developmental process of laser catheters is still ongoing. It has been shown that better results can be obtained with higher wave length and more different tip designs than 1470 nm radial fiber [14, 15]. While questioning which endovenous thermal ablation method is superior, this should be kept in mind.

4. Conclusions

As a result, two current thermal ablation methods commonly used in the treatment of GSV insufficiency have similarly high clinical success and low complication rates. Both methods provide a significant improvement in the quality of life. In terms of postoperative pain, the superiority of RFA in previous studies seems to be still maintained against 1470 nm radial fiber laser catheters. New randomized multicenter studies are needed to achieve a final result.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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