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Recanalization After Radio-frequency Ablation (RFA) in Limb Varices at Dr. Cipto Mangunkusumo and Fatmawati General Hospitals from 2015- 2017

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Abstract

Introduction. Ligation in upper location and stripping of the varicose veins, enfacing high incidence of failure, recanalization. Endovascular surgery is a modality used to treat limb varicose. However, the recanalization following the procedure was never evaluated.

Method. We ran a cohort study on subjects with reflux of the great saphenous vein treated by RFA. Following the RFA procedure, the evaluation proceeded using ultrasound within the first three weeks.

Results. A total of 77 subjects were analysed for recanalization post-RFA. Recanalization was found in one subject (1.3%), partial recanalization in 6 subjects (7.79%), and no recanalization in 70 subjects (90.9%). No significant difference between the diameter of the great saphenous vein with the procedure ($p < 0.001$).

Conclusion. We concluded that RFA is effective in treating limb varicose. In addition, we found there is no association between recanalization and age, sex, and body mass index statistically.

Keywords: *vein varicose, recanalization, radiofrequency ablation*

Introduction

Pathological changes of various veins leading to reflux requiring surgical intervention, namely resection of the pathologic superficial veins. The procedure is ensuring the sufficient venous flow.¹⁻⁶ Nonsurgical treatment such as pharmaceutical therapy and gradual compression using stocking may reduce the symptom but does not causative. In the earliest 20th century, the treatment of limb varicose comprises the procedure of the ligation of the great saphenous vein at the femoral junction, stripping vein, sclerotherapy, and the phlebectomy.¹

Nowadays, there is an alternative method of therapy for limb varicose, which is the minimal invasive intravenous surgery by ablation of the pathologic vein. This ablation method indicated to treat reflux both on the saphenous-femoral junction and the great saphenous vein.^{2,3} Another alternative is minimal invasive therapy, such as radio-frequency ablation (RFA), which introduced in the United States, 1999. The method used thermal energy to do vein ablation in varicose. The success rate to occlude of the great saphenous vein using such an approach is about 90.9%.⁷ However, reported relapse post RFA manifested in the recanalization after four months is about 4.8%.⁸ The ligation of a vein in the upper segment, in addition to the stripping of varicose, enfacing a high incidence of failure, it is about 20-30%. On the other hand, the recurrence of the varicose is about 30-40%.¹

The mechanism of limb varicose is the reflux of the incompetence of the veins valve — the most located found in the saphenous veins. Normally, the diameter of the great saphenous vein is about ≤ 4 mm. Reflux may occur as the diameter up to > 7 mm.⁹ A reflux, defined as the contra flow of a normal vein ≥ 1 second after manual pressure of limb in vascular ultrasound;¹⁰ defends vein contra-flow resulting in blood stuck in superficially distal veins and an increase of hydrostatic vein pressure.^{1,2}

In Indonesia, endovascular surgery in varicose limbs firstly performed in 2010. So far, there is no evaluation of the success rate reported, neither the recurrence of RFA. Thus, a study carried out aimed to evaluate the recanalization following the RFA procedure.

Method

This study is a descriptive analytic one, which used a cohort design conducted in dr. Cipto Mangunkusumo General Hospital (CMGH) and Fatmawati General Hospital (FGH) in 2018. The population is all those with reflux of the great saphenous vein treated using RFA from 2015-2017. Those who met the following criteria included: underwent the first RFA procedure for more than three weeks and the subject willing to be examined using the vascular USG imaging for the recanalization. The USG examined by the certified trainee of the vascular surgeon. The prevalence of recanalization in the

RFA based on the criteria of Rasmussen, i.e., $4.8\% \approx 5\%$. With score of $Z\alpha = 1.96$, $p = 0.05$, $q = 1-p = 0.095$ and $d = 0.1$. The calculated minimal sample size was 19. These variables subjected to analysis using Kolmogorov–Smirnov and Anova test. The study approved by The Committee of Ethic Faculty of Medicine, Universitas Indonesia, No. 846/UN2.F1/ETIK/2017, and Research Unit of dr. Cipto Mangunkusumo General Hospital No. LB.02.01/2.210/60/2018.

Results

There were 77 subjects enrolled and analyzed for recanalization post RFA procedure. Out of these subjects, 44 (57.1%) were females; the mean age was 52.49 ± 12.62 years old. The median BMI was 25.4 (19.48–34.80). The subjects were characteristic as seen in table 1. Following a minimum of 3 weeks of treatment, a total recanalization found in 1 subject (1.3%), partial recanalization in 6 subjects (7.79%), and nil in 70 subjects (90.9%).

Table 1. The subjects' characteristics (n = 77)

No	Variable	n (%)	Value
1	Age		52.49 ± 12.62
2	Gender		
	– Male	33 (42.9%)	
	– Female	44 (57.1%)	
3	BMI		25.4 (19.48–34.80)
4.	The diameter of the vein before surgery		6.4(4–16.61)
	– 4-7 mm	51 (66.2%)	
	– > 7 mm	26 (33.8%)	
5.	Recanalization		
	– Total	1 (1.30%)	$\varnothing 4.4$ mm
	– Partial	6 (7.79%)	$\varnothing 3.18 \pm 1.48$
	– None	70 (90.90%)	0(0–12.6)

Kolmogorov–Smirnov study carried out in the assessment of data homogeneity showed a normal distribution of age variable ($p > 0.05$). The other variables showed inhomogeneity. Thus, the ANOVA test used. The diameter before surgery using Chi–square analysis showed a p value of < 0.05 .

Focused on the recanalization, we found a subject out of 44 female subjects 1 with totally recanalized, 40 subjects were no recanalization, and the rest three were partial recanalized. In males, there was no total recanalization found, a total of 30 subjects were no recanalized, and the rest three were partially recanalized. There is no significant association between gender and recanalization.

The average BMI in this study was 25.4. There was no difference within BMI in the group of totally recanalization, partial recanalization, or without any recanalization. From 77 subject, only one subject with an average of BMI is 32 have a total recanalization. On the other hand, 70 subjects with an average BMI of 25.57 do not get any recanalization, and six subjects with an average BMI of 27.54 have partial recanalization.

The median vein diameter of the subject in this study was 6.4 (4–16.61) mm. A total of 75 subjects have a reducing diameter of the great saphenous vein following RFA, at an average of 39.81 mm. Two subjects have an increasing diameter at an average of 8.5 mm. On the statistical analysis we found a significant difference diameter of the great saphenous vein before and after the procedure ($p < 0.001$).

Before surgery, fifty-one subjects with a diameter of vein 4-7 mm, there is no total recanalization, six subjects have partial recanalization,

and forty-five subjects got no recanalization. A total of twenty-six subjects with vein diameter previously > 7 mm, only a subject with pre surgical diameter 8 mm found a total recanalization. On the other hand, the other twenty-five subject found no recanalization.

Table 2. Association within subject character with recanalization state

No	Variable	Recanalization	n	Mean \pm SD	p value	
1	Age	– Total	1	71,00	0.307*	
		– Partial	6	54.50 ± 7.34		
		– None	70	52.06 ± 12.88		
2	Gender	– Total	0		0.099*	
		– Male	– Partial	3		
		– None	30			
		– Female	– Total	1		
		– Partial	3			
	– None	40				
3	BMI	– Total	1	32.01	0.109*	
		– Partial	6	27.54 ± 4.93		
		– None	70	25.57 ± 3.53		
4.	The diameter of the vein before surgery	– Total	0		0.329**	
		– 4 – 7 mm	– Partial	6		
		– None	45			
		– Total	1			
		– >7 mm	– Partial	0		
	– None	25				

*ANOVA test, **Kolmogorov-Smirnov

Table 3. The diameter of the great saphenous vein before and after the procedure

	Median	p Value
Pre-Procedure	6.4 (4-16.61)	0.002*
Post Procedure	0 (0– 12.6)	0.000**

*Kolmogorov-Smirnov study **Wilcoxon

Discussion

RFA is a technique that widely used to treat great saphenous vein reflux. The main advantages of RFA are slight complications, the speed of recovery, and improvement in the quality of life compared to conventional surgery. The energy produced in this procedure will cause denaturation of collagen in the vein wall, then it causes inflammation, then fibrosis, and eventually cause venous wall occlusion. The compression of the venous lumen by a tumescent solution around the catheter tip will increase the energy transfer process and reduce the amount of energy needed.

Besides its high effectiveness, recanalization was reported in 10% of subjects after a follow-up one year later. The following things that can cause recanalization are likely due to the inaccuracy of the technique used, the arrangement of the device (such as the amount of energy used, or the RFA cycle), or the experience of the clinician. Furthermore, the characteristics of the subject are alleged to affect the recanalization process after RFA actions.

Gender differences are related to differences in the prevalence of varicose veins. Women are said to have a higher risk of varicose veins than men. Data from previous studies support this statement, it means there are 25% of women estimated to suffer from varicose veins, and 15% of cases of varicose veins occur in men. Lack of physical activity and the habit of using high heels in women are risk factors for varicose veins.

Consumption of oral contraceptives can interfere with wall veins to relaxation, also a risk factor for leg veins in women.

Related to gender relations to recanalization status, based on previous studies published that gender, magna venous diameter, type of device, and venous length were independent predictors of canalization after endovascular thermal ablation (EVTA). From Total sampling 407 male subjects, 62 subjects showed recanalization. Whereas from 818 female subjects, 68 subjects experienced recanalization after the EVTA action. However, this statement seems to contradict with the study of Nayman et al., Who stated that the low occlusion rate was not associated with gender, and the follow-up time of the saphenous and parve vein post RFA action.¹¹

Based on the results of his analysis, males were more at risk (OR = 1) than females (OR = 0.5) against recanalization. However, the difference in the number of males subjects between the two groups was not significant (p = 0.855). Although there no further explained in the literature about male predominance in the risk of recanalization, the hypothesis is asuming that this was due to a thicker wall in males than females. The results of the study were quite different from the results of this study, where no significant association between gender differences and recanalization status found in the subject.

Bunnel et al. In 2014 stated that BMI was a statistically significant variable. Each 1 point increase in BMI will increase the probability of about 8.9% of the hazard of recurrent flow. Hager et al. also state that BMI can be one of the factors that can predict the failure of RFA therapy. In the study, subjects with a BMI > 50 had an overall closure rate of about only 37%. This figure was lower than in subjects with BMI <50; it is 66% (p = 0.05). Similar results also occurred in the Timperman et al. study, the success of laser therapy occurred in subjects with an average BMI of 30, while therapeutic failure occurred in subjects with a BMI average of 46 (BMI ranges from 42–55)¹²⁻¹⁴

The results of our analysis related to the relationship between BMI and recanalization status itself showed that there was no significant difference in BMI values between groups with total, partial, or no recanalization status at all. One of the reasons why our analysis shows the result above is because the range of BMI of the subjects studied is not too broad (19.48 - 34.80), where there were no subjects with very high BMI.

The prevalence of varicose veins and age is linear. Prevalence studies in Europe and North America show that varicose veins occur in 20-30% of women, and 10-20% of men and their numbers increase with age in each gender. At the age of 30 years, varicose veins occur in 3% of men and 20% of females and then increase to 40% and 50% at the age of 70 years. Age turned out to affect the increase in venous size also. As age increases, the elasticity of the vein wall will decrease and this becomes one of the predisposing factors for varicose veins.

Those two previous studies reported that age was not significantly associated with the results of RFA actions. The same results also shown in the study of Aurshina et al. Follow-up was done one week after the action, the results showed that

the greatest obliteration failure occurred in the perforator veins (16.6%), followed by accessory veins (p <0.001).¹⁵ However, there was no significant association between age (p = 0.25) and the largest venous diameter (p = 0.69) with the failure of obliteration after RFA. After 13.5 months of follow up, There was also no statistically association between failure of venous obliteration and age (p = 0.73), gender (p = 0.89), and largest vein diameter (p = 0.72).

However, previous studies did not elaborate on the reason why age and gender were not associated with recanalization after the RFA procedure. In this study, a total of recanalization only occurred in 1 subject age of 71 years old, whereas in subjects with an average age of 52 years was no recanalization at all. The Distribution of subjects age data is unequal, where subject age data dominated by subjects aged around 50 years and only a minimal number of elderly, which probably contributes to these insignificant results.

Since 1990, RFA and EVLA have begun to be famous for the treatment of varicose veins. Both of these techniques show similar truncal venous occlusion, although RFA is less commonly associated with post-procedural pain, analgesic needs, and also bruising. Based on a study conducted by Suhartono et al., on the relationship between clinical characteristics of subjects and recanalization after EVLA procedure, the largest the great saphenous vein diameter before surgery (>7 mm) did not have a statistically significant relationship with recanalization after EVLA.¹⁶ However, the study has several limitations, such as the limited number of samples because EVLA is a relatively new procedure for the management of varicose veins in Indonesia, and the subjects are less educated and less informed about the importance of exercising control after venous ablation. Some potential subjects also refused to participate in the study because the location of their residence was far from the hospital or did not feel any complaints of varicose veins they experienced.

The study showed that the great saphenous vein diameter was an independent predictor of post-RFA recanalization. This finding is in line with two previous studies of Bunnel et al., and Desmyterre et al. The study by Desmyterre et al., only occurs in subjects with diameters of saphenous femoral junction (SJF) > 1.1 cm or for the great saphenous troncule diameters > 0.8 cm. the larger the diameter of the great saphenous vein, the higher the energy required for vein closure.^{12,17}

Nayman et al. also showed similar results. In their study of risk factors affecting occlusion rates using the new generation RFA with the ClosureFAST catheter. The increase in the diameter of the great saphenous vein is associated with a low rate of occlusion, but a similar condition not found in the parva vein. Rearrangement of the procedure often needed in subjects with large diameters of saphenous veins. Thus, it is crucial to measure the diameter of the vein before the procedure.

Another study evaluating the relationship between the recanalization and the parva vein stated that one of the variables that significantly affect is the peaks of the speed of reflux before surgery.

Larger diameter veins will be more susceptible to recanalization due to an increase in the amount of intra lumen blood or the distance between the ends of the lesion fibers and blood vessel walls. One hypothesis state that blood in the lumen can absorb light energy from the laser, thus limiting the light transmitted to vascular walls is essential. In this study, the largest diameter of the saphenous venous vein before surgery (>7mm) did not have a statistically significant relationship with post RFA recanalization..

Conclusion

RFA is one of the minimally invasive procedures effective in treating limb varicose. In this study, no association within recanalization and age, gender, body mass index statistically and the diameter of the great saphenous vein.

Disclosure

The author(s) declare have no conflict of interest to disclose

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