Original Research Paper

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SHORT TERM COMPARATIVE OUTCOME ANALYSIS OF QUALITY OF LIFE BETWEEN ENDOVENOUS LASER AND RADIOFREQUENCY ABLATION TREATMENT MODALITIES FOR VARICOSE VEINS TREATMENT AT TERTIARY CARE CENTRE

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ABSTRACT Varicose vein is an important cause of morbidity worldwide. Endovenous laser therapy (EVLT) or radiofrequency ablation (RFA) treats venous reflux with less morbidity, improved cosmetic results and faster recovery with high patient satisfaction. Aim of the study is to compare the Quality of life between EVLT and RFA procedures by using health status score (SF-36) and Aberdeen Varicose Vein Questionnaires.

Methods: This Prospective non-randomized Interventional study was conducted in department of General Surgery of a Medical University, Lucknow after ethical clearance. Patients of age >18 years, diagnosed as primary varicose vein on duplex Doppler Ultrasonography, willing for EVLT or RFA procedure for varicose vein treatment were included in the study. Two groups were made, group 1 (EVLT) and group 2 (RFA), each enrolled 20 patients. Assessment of Quality of life was done by using health status score (SF-36) and Aberdeen Varicose Vein Questionnaires preoperatively and up to 3 months in follow up after the procedure.

Results: In Group 1, EVLT and in Group 2, RFA was performed. The health status scores(SF-36) were significantly increased in both groups at postoperative day 1, day 7 and 3 month after treatment as compared to pre-operative scores. The health status scores (SF-36) were significantly higher in group 2 (RFA) as compared to group 1 (EVLT) at postoperative 3 month except General Health and pain health status score. Moreover, the health status scores were statically insignificant in group 2 (RFA) and group 1 (EVLT) at Pre-operative, Post-operative day 1 and day 7, except GH health status score. The average quality of life using AVOQ was significantly improved post-operatively to 3 month follow-up in group 1 and group 2.On Comparison of average quality of life (AVOQ) in between Group 1 (EVLT) and Group 2 (RFA), at pre-operative, post-operative day 1, day 7 and 3 month, average quality of life were 1.37±0.82, 1.12±0.69, 0.46±0.59 and 0.04±0.06 in group 1 and 1.42±0.67, 1.32±0.65, 0.61±0.62, and 0.01±0.03 in group 2, respectively. The average quality of life (AVOQ) was not significantly different in between group 1 and group 2.

Conclusion: The General health status score assessed by SF-36 questionnaire was significantly higher in group 2 (RFA) as compared to group 1 (EVLT) at postoperative day 1, day 7 and 3 month. The average quality of life assessed by AVVQ was found to be similar in both groups. So both treatment modalities are effective in improving the QOL over a period of time based on Aberdeen system, however, SF 6 has shown some edge to RFA as compared with EVLT.

KEYWORDS : varicose vein , Endo venous laser treatment(EVLT),Radiofrequency ablation (RFA).

INTRODUCTION

Varicose vein is an important venous disorder affecting 20–60% of individuals around the world. It is classified as either primary or secondary. Primary varicose veins are caused due to intrinsic abnormalities of the venous wall and valves, while the secondary varicose veins are due to obliteration of lumen of vein. It is classified into various grades (1, 2).

It is diagnosed on physical examination, and confirmed by duplex ultrasound scanning, which is the gold standard test. A retrograde flow that lasts for more than 500 milli sec is considered to be positive for reflux and would indicate the presence of varicose veins. Computerized tomography (CT) Venography and magnetic resonance imaging (MRI) are helpful in identifying suspected proximal obstructions, such as obstruction in pelvic system or iliac vein.[3]

Treatment varies according to the type of pathology. In case of saphaneo-femoral valve (SFJ) Incompetency, treatment aimed at SFJ closure, occlusion of the great saphenous vein (GSV) and management of perforators using various methods. One of these methods is either Endovenous laser therapy (EVLT) or RFA which has been introduced recently for the treatment of varicose veins and for decreasing postoperative complications and provide early recovery than with conventional open surgery(stripping and ligation of vein). All studies have compared early complications (4-8).

EVLT and RFA result in complete obliteration of the GSV lumen, with rates of varicose vein recurrence and clinical severity scores equivalent to those seen in open surgery. Currently, both EVLT and RFA are used in managing Varicose Vein (8, 9). There are some scoring systems to assess the quality of life after surgery for Varicose Vein, such as SF-36 [ref]. A new scoring system Aberdeen Varicose vein questionnaire was started in 1993 which is specific for Varicose vein . There are limited studies which have evaluated the QOL on the basis of Aberdeen Varicose vein questionnaire. There is no study which has compared the QOL using Aberdeen Varicose vein questionnaire and SF 36 after using EVLT and RFA.

This study was conducted to comparatively evaluate the QOL based on Aberdeen Varicose vein questionnaire and SF 36 after using EVLT and RFA.

MATERIALAND METHODS

It was a prospective, non randomized interventional study conducted in Department of General Surgery, of a medical University. It was approved by the Institutional Ethical committee (Ref.code:97th ECM II B-Thesis/P86).

All patients older than 18 years, diagnosed as primary varicose and having SFJ incompetency wiling for the procedure, were included in the study. The patients having secondary varicose vein (pregnancy, Pelvic Tumor, Deep Vein Thrombosis), huge varicosity not fit for either EVLT and RFA, dearranged coagulopathy, medically unfit, financial constraints, deep vein reflux, and children were excluded. CEAP (clinical severity, etiology, anatomy and path physiology) classification was utilized prior to the procedure [ref]. The primary end

point of the study was comparative evaluation of the QOL based on Aberdeen Varicose vein questionnaire and SF 36 after using EVLT and RFA. All patients received perivenous tumescent anesthesia (consisting 10 ml 2% lignocaine, 500 ml 0.9% isotonic solution (+4^{0}C), 10 ml 8.4% sodium bicarbonate, and 0.5 mg adrenaline).

In group 1, patients received EVLT, Endovenous laser energy was delivered using BioLitec diode laser machine, ELVeS, 1470nm laser, 600 microns, double ring, radial and generator was set at continuous signal mode of power delivery of 8 watt and 80 joules of energy. The laser fiber was withdrawn at every 1cm after ablating vein for 10 sec after listening to a beep sound. The procedure was performed from knee up to 2 cm below the SFJ (USG guided).

In group 2, patients received RFA .Endovenous radiofrequency ablation was also performed from knee up to 2 cm below SFJ. Catheter was passed through seldinger technique. Radiofrequency heat was delivered at a temperature of 85^{0}C. Radiofrequency [CR45i device and catheter (F care system)] energy was applied to the saphenous vein as 25 W each 2 cm from the distal part of the SFJ (50 W/cm).In both the groups, below knee GSV, varicosities, and incompetent perforators were treated by USG guided foam sclerotherapy. After the procedure crepe bandage was applied.

The Aberdeen Varicose Veins Questionnaire (AVVQ) is a disease explicit survey that estimates Health related quality of life (HRQOL) for patients with varicose veins. The Questionnaire comprises 13 inquiries identifying with all parts of the issue of varicose veins. The survey has a segment where the patients can demonstrate diagrammatically the distribution of their varicose veins. There are questions identifying with the measure of pain experienced, ankle swelling, and utilization of help stockings, impedance with social and domestic activities, and the cosmetic effects of varicose veins. The survey is scored from 0 to 100, with the manikin diagram contributing up to 20 focuses relying upon the degree of varicose vein. Here 0 represents patient with no proof of varicose veins and 100 represents the most extreme issues related with varicose veins.

The SF-36 questionnaire is a standardized procedure for the assessment of health related quality of life (HRQOL) which have total 36 questions and quality of life analyzed in 8 domains: Physical function (PF), General health (GH), Emotional roles (RE), social function (SF), Bodily pain (BP), role of limitation due to physical health or physical role (RP), energy or vitality (VT) Emotional well being or psychological status (MH). The answers were categorized in the form of scores in the way recommended from RAND, transforming them into linear analogue score of 0 to 100, where 100 indicated optimal health. This was calculated by using SF-36 health survey scoring questionnaire demonstration version 1 available at http:www.sf-36.org/demos/SF-36.html.

Both SF-36 questionnaire and AVVQ were converted to Hindi language (Mother language) with help of Google translator. Questionnaire were given to patients and followed on mobile by third person.

Follow-Up:

All the patients were followed up at baseline (before intervention) and Post-operative Day 1, Day 7, 1 month, and 3 months in terms of QOL, assessed by (SF-36 and AVVQ) questionnaire.

STATISTICALANALYSIS

All the data was entered into Microsoft excel sheet and results were analyzed using the Statistical Package for Social Sciences (SPSS) 21.0 version for Windows. The sample size calculated, assuming 0.05 level significance and 90% power. Considering any dropouts, we had enrolled 20 patients in each group. The Chi-square test was used to compare the categorical or dichotomous variables. The unpaired Student's *t*-test was used to compare discrete variables between group 1 (EVLT) and group 2 (RFA). The Analysis of variance (ANOVA) test was used to analyze more than two variables. The p-value of <0.05 was considered significant. The data has been presented as mean ± SD and frequency.

RESULTS

The mean age in groups 1 and 2 was 29.65±10.52 (range 16 to 54 years) and 37.70±11.74 (range 18 to 58) respectively (p> 0.05). The statistical difference as per sex was also not significant (table 1).

Table 1. Comparison of health status scores for patients pre-operative, post-operative day 1, day 7, and at 3 month Control Group and after treatment in between Group 1 (EVLT) and Group 2 (RFA)

Health Status Scores		Control Group		Group 1 (EVLT)		Group 2 (RFA)		p-value			
		Mean	±SD	Mean	±SD	Mean	±SD	Mean difference	Control VS EVLT	Control VS RFA	EVLT VS RFA
PF	Pre-operative	99.86	0.36	62.75	24.89	74.25	17.79	6.5	-	-	0.101
	Post-operative day 1	99.86	0.36	71.60	19.91	78.50	16.87	6.90	<0.001	<0.001	0.244
	Post-operative day 7	99.86	0.36	82.25	18.18	90.50	10.12	8.25	<0.001	<0.001	0.084
	Post-operative 3 month	99.86	0.36	92.15	10.97	99.00	3.08	7.85	0.001	0.149	0.011
RP	Pre-operative	100.00	0.00	56.25	32.15	56.25	47.21	0	-	-	1.00
	Post-operative day 1	100.00	0.00	64.73	27.57	69.65	36.72	4.92	<0.001	<0.001	0.634
	Post-operative day 7	100.00	0.00	78.00	20.91	87.50	20.68	9.50	<0.001	<0.002	0.157
	Post-operative 3 month	100.00	0.00	88.58	19.00	100.00	0.00	11.42	0.002	-	0.011*
RE	Pre-operative	100.00	0.00	59.95	35.32	53.35	45.14	6.60	-	-	0.610
	Post-operative day 1	100.00	0.00	68.50	28.40	65.60	36.88	2.90	<0.001	<0.001	0.782
	Post-operative day 7	100.00	0.00	80.90	20.04	84.20	23.89	3.30	<0.001	<0.001	0.639
	Post-operative 3 month	100.00	0.00	89.90	14.13	100.00	0.00	10.10	0.001	-	0.003
Energy/ Fatigue	Pre-operative	96.18	4.69	68.00	14.99	74.25	13.60	6.25	-	-	0.175
	Post-operative day 1	96.18	4.69	78.90	12.44	79.35	13.10	0.45	<0.001	<0.001	0.912
	Post-operative day 7	96.18	4.69	85.85	8.44	89.25	10.42	3.40	<0.001	<0.001	0.264
	Post-operative 3 month	96.18	4.69	93.80	6.83	95.75	6.34	1.95	0.169	0.789	0.355
Emotional well being	Pre-operative	95.50	5.02	68.80	14.83	73.20	10.87	4.40	-	-	0.291
	Post-operative day 1	95.50	5.02	73.90	18.19	78.20	9.04	4.30	<0.001	<0.001	0.350
	Post-operative day 7	95.50	5.02	85.45	8.92	86.90	8.74	1.45	<0.001	<0.001	0.607
	Post-operative 3 month	95.50	5.02	91.55	7.88	94.75	8.93	3.20	0.039	0.712	0.237
SF	Pre-operative	99.86	0.36	61.55	17.22	68.25	9.41	6.70	-	-	0.135
	Post-operative day 1	99.86	0.36	73.10	14.35	73.00	8.40	0.10	<0.001	<0.001	0.979
	Post-operative day 7	99.86	0.36	81.48	12.42	82.70	8.63	1.22	<0.001	<0.001	0.719
	Post-operative 3mth	99.86	0.36	90.15	10.10	99.40	2.68	9.25	<0.001	0.376	<0.001
Pain	Pre-operative	100.00	0.00	60.40	28.25	74.15	25.08	13.75	-	-	0.112
	Post-operative day 1	100.00	0.00	80.00	16.98	80.05	19.06	0.05	<0.001	<0.001	0.993
	Post-operative day 7	100.00	0.00	87.65	12.91	89.70	12.42	0.49	<0.001	<0.001	0.612
	Post-operative 3 month	100.00	0.00	95.00	11.36	100.00	0.00	5.0	0.024	-	0.056
GH	Pre-operative	93.32	6.93	59.50	13.37	55.00	16.06	4.50	-	-	0.342

	Post-operative day 1	93.32	6.93	69.50	13.27	59.25	7.83	10.25	<0.001	<0.001	0.005
	Post-operative day 7	93.32	6.93	77.10	9.39	66.25	6.86	10.85	<0.001	<0.001	<0.001
	Post-operative 3 month	93.32	6.93	85.80	11.55	70.70	11.60	15.10	0.007	<0.001	<0.001

**=Significant (p<0.05), 1= Unpaired t test*

Assessment of General health quality of life using SF -36 questionnaires (Table 2).

Table 2. Aberdeen Varicose Vains Questionnaire (Health Related Quality of Life)

		Group 1 (EVLT)		Group 2 (RFA)			p-value
QOL (AVVQ)		**Mean**	**±SD**	**Mean**	**±SD**	**Mean difference**	
	Pre-operative	1.37	0.82	1.42	0.67	0.05	0.868
	Post-operative day 1	1.12	0.69	1.32	0.65	1.20	0.470
	Post-operative day 7	0.46	0.59	0.61	0.62	0.16	0.541
	Post-operative 3 month	0.04	0.06	0.01	0.03	0.01	0.080

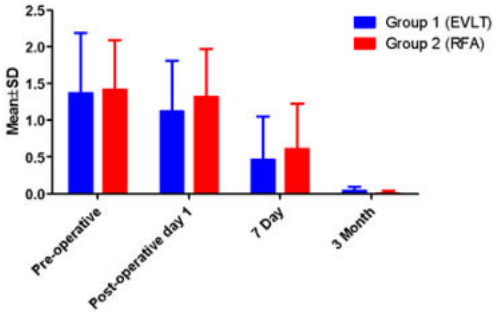

Figure 1. Intergroup comparison of Quality of Life in Group 1 (EVLT) and Group 2 (RFA)

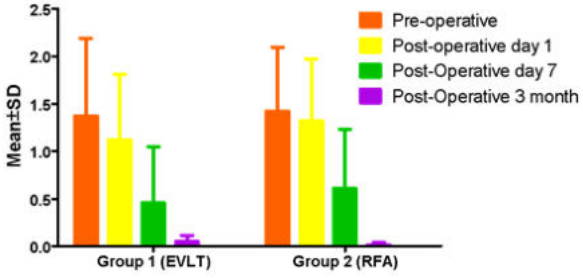

Figure 2. : Intragroup comparison of Quality of Life in Group 1 (EVLT) and Group 2 (RFA) The Comparison of average quality of life in between Group 1 (EVLT) and Group 2 (RFA) at pre-operative, post-operative day 1, day 7 and 3 month

Physical function (PF)
There was no significant (p-value- 0.101,0.244,0.084) difference in PF at baseline , post operative day 1 and post operative day 7 between EVLT (62.75±24.89), (71.60±19.91), (82.25±18.18) and RFA (74.25±17.79),(78.50±16.87), (90.50±10.12) respectively.

Role limitation due to physical health (RP)
There was no significant (p-value-1.00,0.634,0.157) difference in RP at baseline ,post operative day 1 and day 7 between EVLT (56.25±32.15), (64.73±27.57), (78.00±20.91) and RFA (56.25±47.21), (69.65±36.72), (87.50±20.68) respectively. The RP was found to be significant (p-value-0.011) at 3 month.

Role limitation due to Emotional problems (RE)
There was no significant difference (p-value-0.610, 0.782, 0.639) in RE at baseline, post operative day 1 and day 7 between EVLT (59.95±35.32), (68.50±28.40), (80.90±20.04) and RFA (53.35±45.41), (65.60±36.88), (84.20±23.89) respectively. The RE was found to be significantly (p-value-0.003) higher in RFA.

Energy/Fatigue
There was no significant difference (p-value-0.175,0.912,0.264,0.355) in Energy/Fatigue at baseline , post operative day 1 , day 7 and 3 month between EVLT (68.00±14.99), (78.90±12.44), (85.85±8.44) (93.80±6.83) and RFA (74.25±13.60), (79.35±13.10), (89.25±10.42), (95.75±6.34) respectively.

Emotional well being
There was no significant difference (p-value-0.291, 0.350,0.607, 0.237) in Emotional well being at baseline , post operative day 1 , day 7 and 3 month between EVLT (68.80±14.83), (73.90±18.19), (85.45±8.92), (91.55±7.88) and RFA (73.20±10.87), (78.20±9.04), (86.90±8.74), (94.75±8.93) respectively.

Social Function (SF)
There was no significant difference in (p-value-0.135, 0.979, 0.719) at baseline, post operative day 1 and day 7 between EVLT (61.55±17.22), (73.10±14.35), (81.48±12.42) and RFA (68.25±9.41),(73.00±8.40), (82.70±8.63) respectively. The SF was found to be significantly (p-value-0.011) higher in RFA (99.40±2.68) than EVLT (90.15±10.10) at post operative 3 month.

Pain
There was no significant (p-value-0.112, 0.993, 0.612, 0.056) difference in pain at baseline, post operative day 1 , day 7 and 3 month between EVLT (60.40±28.25), (80.00±16.98), (87.65±12.91), (95.00±11.36) and RFA (74.15±25.08), (80.05±19.06), (89.70±12.42), (100.00±0.00) respectively.

General health (GH)
There was no significant difference (p-value-0.342,) in GH at baseline between EVLT (59.50±13.37), and RFA (55.00±16.06). The GH was found to be significantly (p-value-0.005, <0.001, <0.001) higher in EVLT (69.50±13.37), (77.10±9.39), (85.80±11.55) than RFA (59.25±7.83), (66.25±6.86), (70.70±11.60) at post operative day 1, day7 and 3 month respectively

Assessment of Quality of lifeusing Aberdeen varicose vain questionnaire (AVVQ) (Tables 2 and 3).
On comparison of disease specific quality of life(AVVQ) between Group 1 (EVLT) and Group 2 (RFA),at the baseline, post-operative day 1, day 7 and 3 month Scores were(1.37±0.82), (1.12±0.69), (0.46±0.59) and (0.04±0.06) in group 1 and (1.42±0.67), (1.32±0.65), (0.61±0.62), (0.01±0.03) in group 2, respectively. The average quality of life was insignificant (p-value- 0.868, 0.470, 0.541, 0.080) in both groups.

DISCUSSION

The commonest age group for varicose veins is between 30 to 50 years (8). It was also noticed by us. Many studies conducted in developed countries show female preponderance (2) however, in our study there was male predominance. It is probably due to lesser number of women working in such conditions.

Comparative outcomes were accounted in the study of **Shepherd et al**[10] between EVLT and RFA patients over a six week period time frame. Middle pain scores were fundamentally lower for Radiofrequency removal patients at 3 and 10 days postoperatively , although the two modalities had comparative results as far as clinical and Quality of life upgrades at about a month and a half.

Nordon et al[11] compared two modalities of treatment(EVLT & RFA) and found post-operative pain and wounding inside the first seven day stretch of treatment was more awful for Endovenous laser removal in spite of the fact that upgrades in quality of life were measurably comparable for the two modalities at 3 months.

Rasmussen et al[12] recruited 500 patients to compare four treatment modalities, Endovenous laser ablation ,Radiofrequency ablation ,surgical stripping, and Ultrasound guided foam sclerotherapy (125

patients per group) and reported one-year failure rates (i.e., return of GSV reflux) of 5.8%, 4.8%, 4.8%, and 16.3%, respectively. Moreover, Radiofrequency ablation and Ultrasound guided faomsclerotherapy were related with the briefest time for patients to continue typical daily exercises and resumption of work. In general, every one of the four treatment modalities prompted tantamount enhancements in quality of life at 1 year post operatively.

In our study, the health status scores in Group 1 (EVLT) were significantly increased at postoperative day 1, day 7 and 3 month after treatment as compared to pre-operative values. Whereas, only RP was not significantly increased at day 7 after treatment. The Energy/ Fatigue, Social functioning, Pain and GH were significant after 7 day treatment. The median health status score (SF-36) for patient's pre-operative, post-operative day 1, day 7, and at 3 month after treatment was compared with Group 2 (RFA). In group 2(RFA),the health status score were significantly increased at postoperative day 1, day 7 and 3 month after treatment as compared to pre-operative values. Moreover, the health status scores for patients were significantly increased at day 7 and 3 month after treatment as compared to postoperative day 1 . Whereas, PF, RP, RE, Energy/ Fatigue, Emotional wellbeing, Social functioning, Pain and GH were not significantly increased after day 1 treatment.

On comparison of health status scores (SF-36) for patients pre-operative, post-operative day 1, day 7, and at 3 month after treatment in between Group 1 (EVLT) and Group 2 (RFA), the health status scores were significantly higher in group 2 (RFA) as compared to group 1 (EVLT) at postoperative 3 month except GH and pain health status score. Moreover, the health status scores were statically insignificant in group 2 (RFA) and group 1 (EVLT) at Pre-operative, Post-operative day 1 and day 7, except GH health status score. The GH health status score was significantly higher in group 2 (RFA) as compared to group 1 (EVLT) at Postoperative day 1, day 7 and 3 month.

The average quality of life using AVOQ was significantly improved post-operatively to 3 month follow-up in group 1 and group 2.The Comparison of average quality of life in between Group 1 (EVLT) and Group 2 (RFA). The pre-operative, post-operative day 1, day 7 and 3 month average quality of life were 1.37±0.82, 1.12±0.69, 0.46±0.59 and 0.04±0.06 in group 1 and 1.42±0.67, 1.32±0.65, 0.61±0.62, and 0.01±0.03 in group 2, respectively. The average quality of life was not significantly different in between group 1 and group 2.

Similar to our study **Smith et al**[13] the SF-36 scores increased (improvement in function) in all 8 domains of health, reaching significance in 'Mental Health' (P<0.05) and approaching significance in 'General Health' (P =0.066). The scores obtained from the Aberdeen varicose vein questionnaire indicated that there was a highly significant improvement in health related quality of life (P<0.001). At six weeks for both the Aberdeen varicose vein questionnaire and SF-36. With the Aberdeen varicose vein questionnaire scores, there is highly significant improvement in health six weeks after surgery (P<0.001).

The strength of this is that it is one of the first studies where a comparative analysis of Aberdeen and SF 36 has been performed based on EVLT and RFA. This study has attempted to focus on specialized assessment tools for QOL by using Aberdeen. There are certain limitations in this study, such as limited number of patients and shorter duration of study.

CONCLUSION

Both treatment modalities are effective in improving the QOL over a period of time based on Aberdeen system, however, SF 6 has shown some edge to RFA as compared with EVLT. However, Aberdeen system is more specific for varicose veins than SF 36. Further prospective double blind randomized blind studies with more number of patients may show additional advantages of these two treatment modalities and help us to choose an option on better grounds.

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