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Endovenous Ablation Vs Open Surgery for the Treatment of Varicose Veins –A Comparative Study

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I. AIM OF THE STUDY

The purpose of this study was to compare the pre procedural, intra procedural and post procedural assessments and thereby evaluate the efficacy of treatment with endovenous technique in comparison with open technique for abolishing primary superficial venous incompetence and thereby bringing about clinical improvement.

MATERIAL AND METHODS

STUDY DESIGN: The study was designed as a Prospective study comparing procedure related complications and patient recuperation between those undergoing conventional high flush ligation of SFJ (Trendelenburg procedure) and GSV stripping (HL/S) with those undergoing GSV obliteration with endovenous thermal ablation procedure (i.e.) Radio Frequency Ablation (RFA) or LASER ablation (EVLA).

DURATION: January 2012 to January 2014

SETTING: The patients with varicose vein attending the Vascular Surgery OPD of Govt. Stanley Medical College and Hospital, Chennai were enrolled for study. All symptomatic patients were admitted and evaluated with proper clinical history, thorough clinical examination and duplex evaluation. Based on inclusion and exclusion criteria patients were selected and treated accordingly.
The study was approved by the Ethics Committee of the institution.

INCLUSION CRITERIA:

1) Patients in the age group between 20 to 80 years
2) Both males and females were included
3) Patients with varicosity of GSV with grade II reflux and above of the sapheno femoral junction
4) Patients with venous ulcer with GSV varicosity (i.e) CEAP classification C_2 to C_6 (i.e) $C_{2\text{-}6}\, E_P\, A_S\, P_R$.

EXCLUSION CRITERIA:

1) Patients with secondary varicose veins due to previous DVT.
2) Patients with recurrent varicose veins
3) Patients with perforator incompetence alone
4) Patients with segmental reflux
5) Female patients with pregnancy
6) Congenital anomalies (E.g.) Klippel Trenaunay Syndrome (KTS)
7) Patients with GSV diameter greater than 1.2cm
8) Patients with ABI less than o.9
9) Patients with general co- morbid conditions like CCF, CRF, open PTB and those mentally unfit to comprehend and give consent to the course of treatment.

II. INVESTIGATION PROTOCOL:

Rutherford et al described the Venous Clinical Severity Score (VCSS). There are 10 descriptors namely pain, varicose vein, venous edema, skin pigmentation, inflammation, induration, ulcer number, ulcer duration, ulcer size and compressive treatment each of which is ranked as 0 (absent), 1(mild), 2(moderate), or 3(severe). The possible scores are in the range of 0 to 30. The signs and symptoms were recorded using this VCSS score.

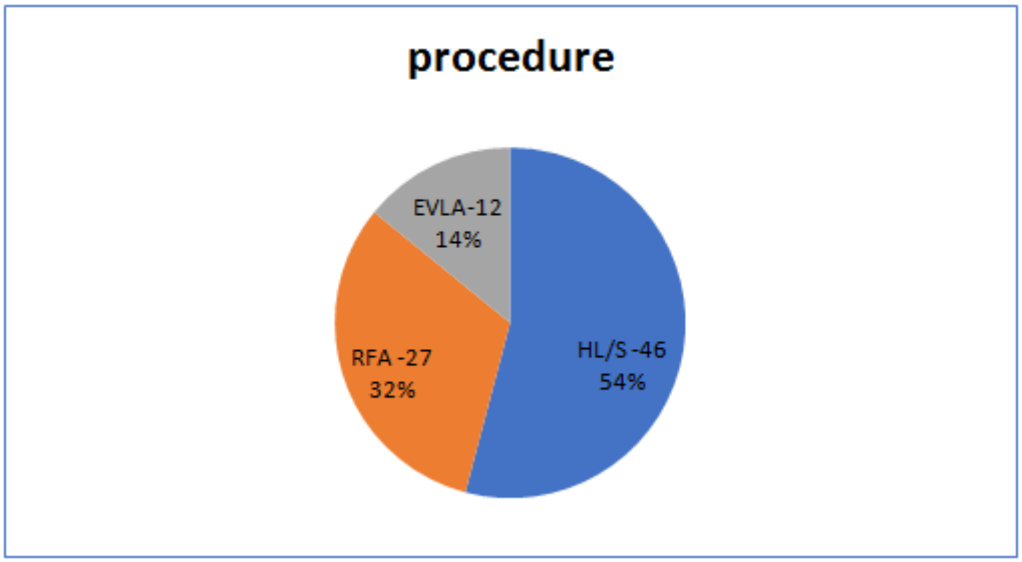
Also the CEAP classification was applied for varicose vein description which includes the clinical, etiological, anatomical and pathological nature of the disease. Duplex examination was used to record duration of SFJ reflux and diameter of GSV 3 cm below SFJ, at mid thigh and just below knee. Duplex examination was also done to rule out deep venous thrombosis and deep vein reflux. Also base line investigations were performed to identify the risk factors and get them fit for surgery.

III. OBSERVATION AND RESULTS

Patients were enrolled from January 2012 to January 2013 and the follow up was continued till January 2014. Totally 85 cases were enrolled out of which 46 patients underwent high ligation and stripping and 39 patients underwent endovenous ablation. Among endovenous ablation group 27 patients underwent radiofrequency ablation and 12 patients underwent EVLA.

TABLE 1: TREATMENT DISTRIBUTION

	Procedure			**Total**
	HL/S	Endovenous		
		RFA	EVLA	
Cases	46	27	12	85
Total	46	39		85



Of the 85 cases treated 74 patients were males and 11 patients were females. Out of the 74 males, 39 patients underwent HL/S, 23 patients underwent RFA, and 12 patients underwent EVLA. Among the 11 female cases, HL/S was performed in 7 patients and RFA in 4 patients.

TABLE 2: SEX INCIDENCE

Patients	**Procedure**	**Frequency**		**Percent**
Male	HL/S	39	74	87%
	RFA	23		
	EVLA	12		
Female	HL/S	7	11	13%
	RFA	4		
	EVLA	0		
Total		85		100%

SEX INCIDENCE

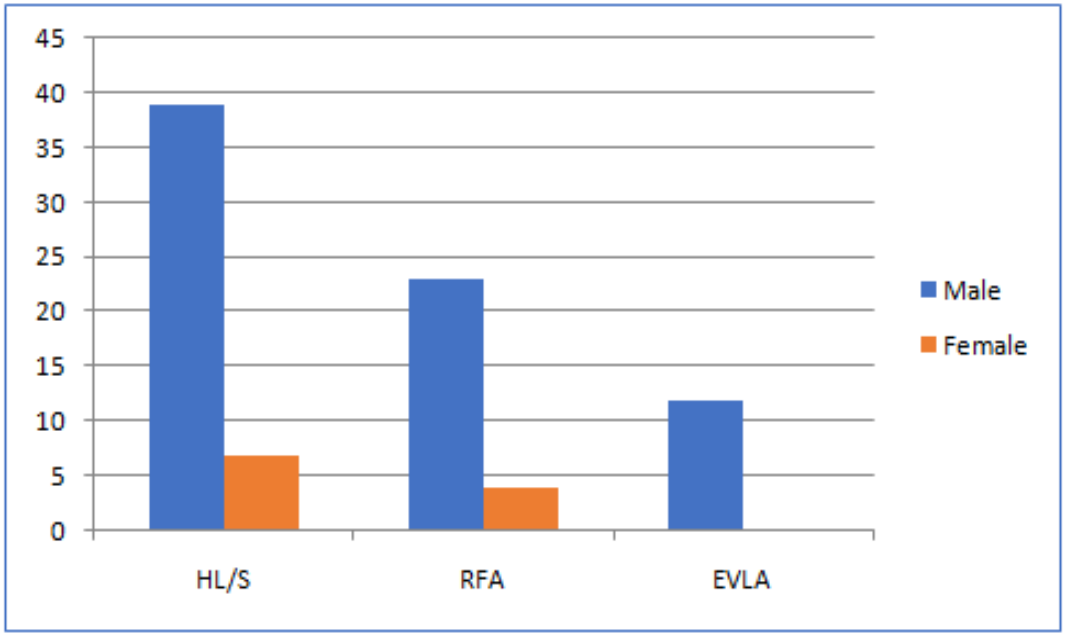
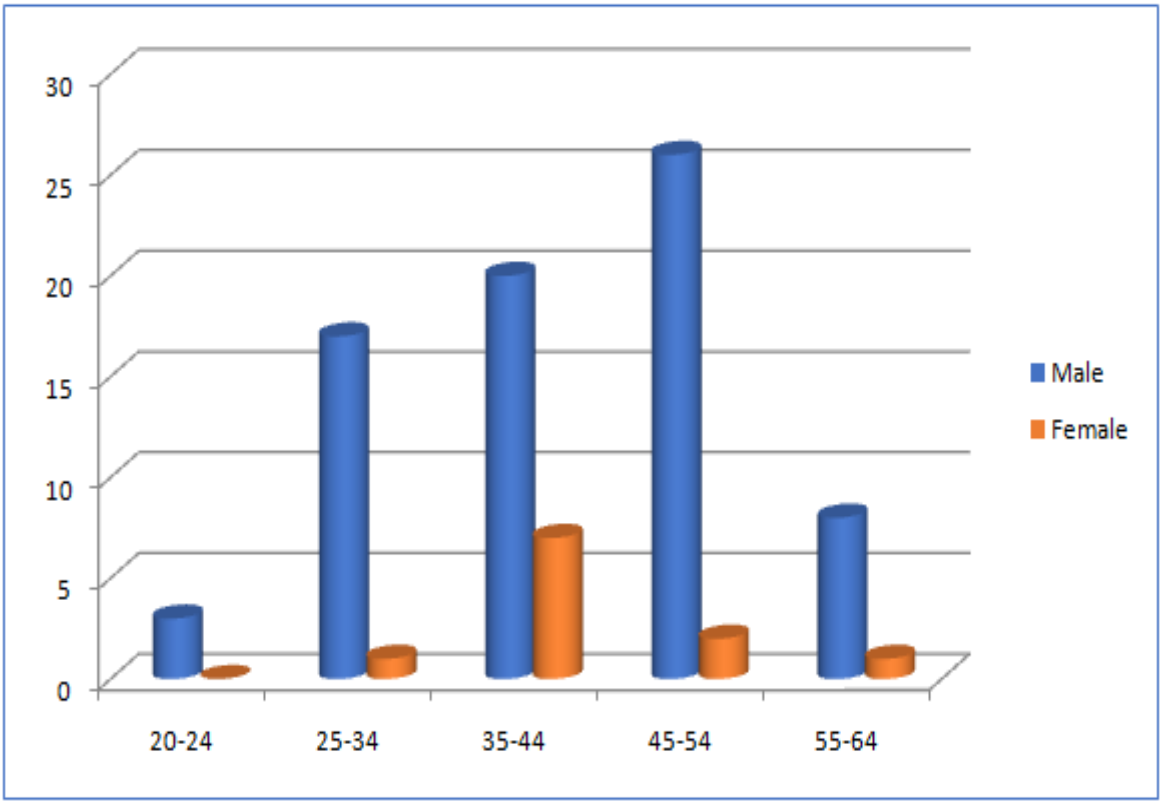


TABLE 3: AGE DISTRIBUTION

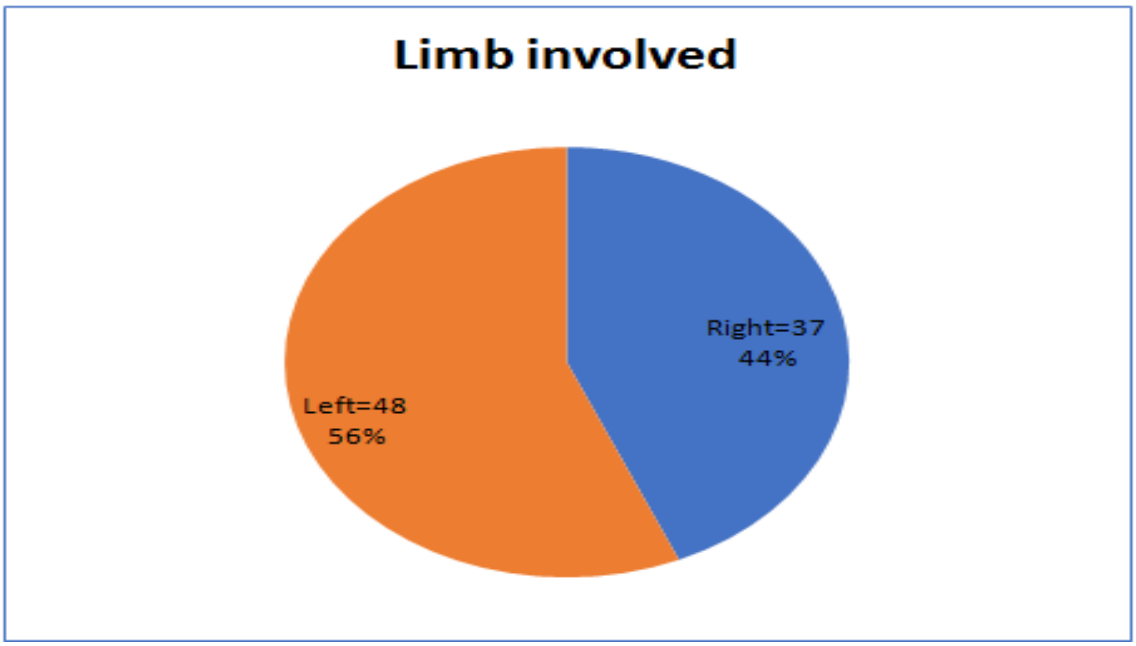
Age in yr	20-24	25-34	35-44	45-54	55-64	Total
Male	3	17	20	26	8	74
Female	0	1	7	2	1	11
Total	3	18	27	28	9	85

Table 3 shows the age group involved in this study. The age group commonly affected both in males and females were found to be in the range of 35 to 55 years.

AGE DISTRIBUTION



85 limbs were treated in85 patients. The study did not have any bilateral limb treated in the same sitting. Of the 85 limbs, 48 involved left and 37 involved right lower limbs.



CEAP CLINICAL CLASSIFICATION:

The varicose vein patients who were symptomatic were categorized according to CEAP classification.

TABLE 4: CEAP CLINICAL STAGING

CEAP	HL/S	RFA	EVLA	Total
C2	37	20	9	66
C2+C4a	4	1	0	5
C2+C5	4	3	0	7
C2+C6	1	3	3	7
Total	46	27	12	85

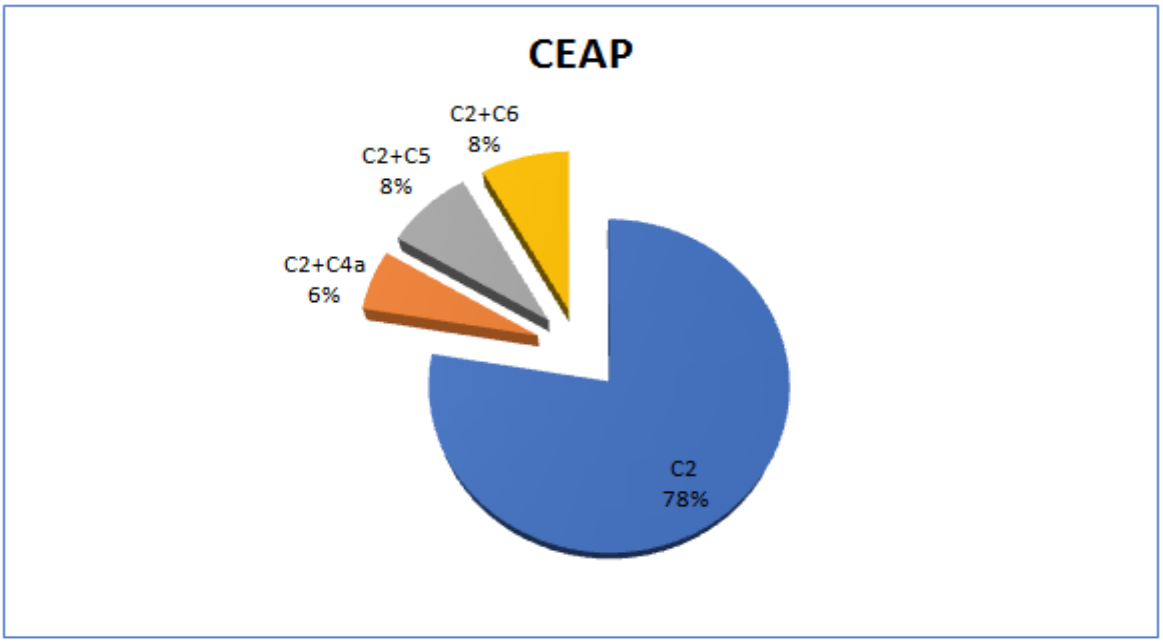
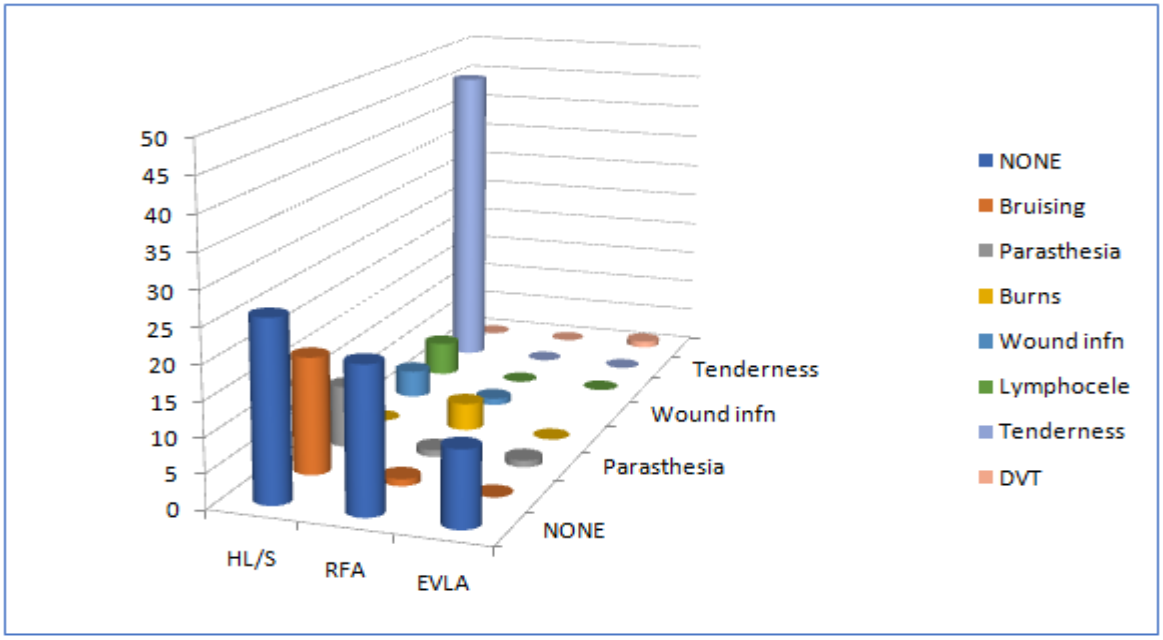


TABLE 6: COMPLICATIONS AND ADVERSE EVENTS

complications	HL/S		RFA		EVLA		P-Value	
	n	%	n	%	n	%	HL/S Vs ENDO	RFA Vs EVLA
None	26	56.5	21	77.7	11	91.6	0.0289	0.3464
Bruising	17	36.95	1	3.7	0	0	0.0005	0.6923
Parasthesia	9	19.56	1	3.7	1	8.3	0.1312	0.6154
Burns	0	0	4	14.8	0	0	0.0110	0.2134
Wound infn.	4	8.69	1	3.7	0	0	0.4406	0.6923
Lymphocele	5	10.8	0	0	0	0	0.1052	-
Tenderness	46	100	0	0	0	0	<0.0001	-
DVT	0	0	0	0	1	8.3	0.0461	0.3077
“pulling”sensation	0	0	13	48.1	3	25		

COMPLICATIONS AND ADVERSE EVENTS:



PLOT OF PAIN SCORE

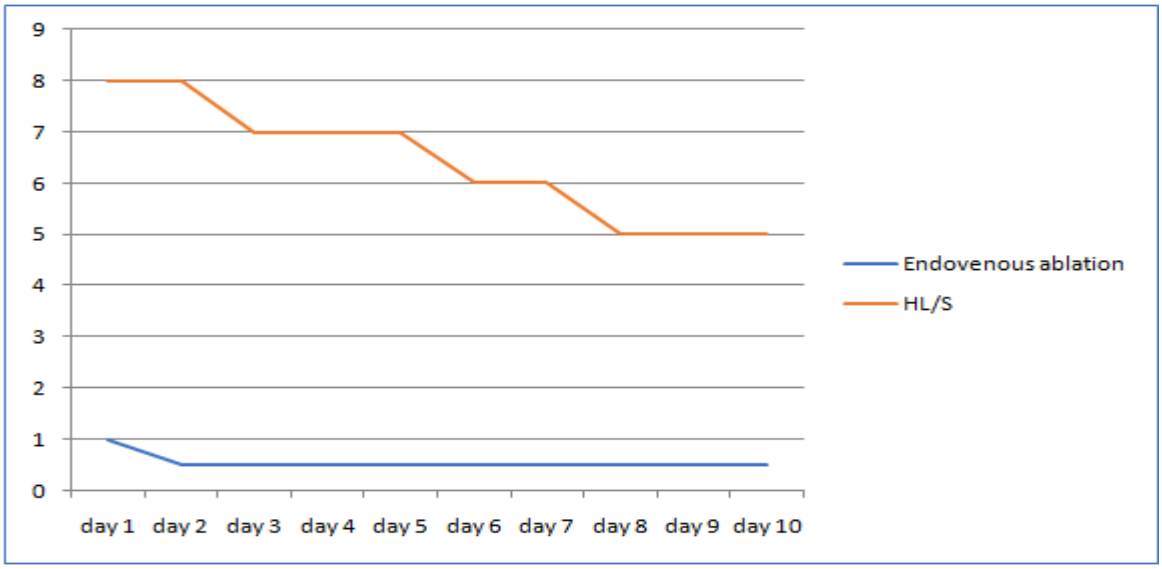


TABLE 7: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
VCSS	HL/S	4.9	-	-	0.8	-
	ENDO	3.1	-	-	0.4	-

Group Statistics at 6 month					
	Group	N	Mean	Std. Dev	P-Value
VCSS	HL/S	46	0.91	0.839	0.005
	ENDO	39	0.41	0.751	

TABLE 8: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
ULCER SIZE	HL/S	4cm	4cm	1cm	0	-
	RFA	3cm	3cm	0.5cm	0	-
	EVLA	2.33cm	2.33cm	0.833	0	-

Statistics		
Ulcer size		
RFA	**N**	**3**
	Mean	**0.6667**
	Median	**0.5000**
	Std. Deviation	**0.28868**
EVLA	**N**	**3**
	Mean	**0.8333**
	Median	**1.0000**
	Std. Deviation	**0.28868**

TABLE 9: OUTCOME ANALYSIS

Measures		Pretreatment	72 hrs	1 month	6 month	1 yrs
CEAP	HL/S	C2 to C6	Co	Co	Co	Co
	ENDO	C2 to C6	Co	Co	Co	Co
VCSS	HL/S	5.4	-	-	0.84	-
	ENDO	3.1	-	-	0.435	-
ULCER SIZE	HL/S	4cm	4cm	1cm	0	-
	RFA	3cm	3cm	0.5cm	0	-
	EVLA	2.33cm	2.33	0.433	0	-
GSV STATUS	HL/S	Varicose veins	absent	absent	absent	Absent
	ENDO	Varicose veins	closed	closed	Closed	Closed

IV. CONCLUSION

This study shows that the short term efficacy and safety of endovenous ablation and open surgery are similar in the treatment of varicose veins.

Endovenous ablation presents with lesser post operative morbidity in terms of post operative pain, bruising and hospital stay which was significantly higher in HL/S group.

Both the treatments are equally safe and efficient in eliminating great saphenous vein reflux, thereby alleviating symptoms and signs of GSV varicosities and improving quality of life.

Symptom reduction and cosmetic improvement after endovenous procedures are slightly better when compared to surgery.

Endovenous procedures can be done as a day care procedure which allows a rapid return to normal activity and also earlier return to work.

Endovenous procedures has lower complication rates than surgery, particularly in respect of saphenous parasthesia wound problems, hematoma formation and bruising.

Although it might appear that EVLA has some advantages over RFA in terms of frequency of complications like bruising, skin burns and "cord like pulling sensation", there is no clear evidence that one or the other should be the preferred procedure.

Given the choice, most patients will choose endovenous procedures instead of an operation with a cut in the groin and vein stripping.

This will become particularly true if the long term outcomes, including the recurrence rates, remain equal.

Considering the ease and comfort of the procedure, with fewer peri procedural complications and equivalent short and midterm results the endovenous procedure definitely has an edge over the traditional open procedure.

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