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ENDOVENOUS ABLATION Vs OPEN SURGERY FOR THE TREATMENT OF VARICOSE VEINS –A COMPARATIVE STUDY

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ABSTRACT :

Background : Varicose veins are a common problem and one of the most prevalent medical disorders affecting approximately 10 to 40% of the general population. The lower limb venous system is classified into the superficial system, the perforator and communicating systems and the deep system. This study compares the outcome of the management of truncal varicose veins in a series of patients presenting to our tertiary care referral centre over a period of one year. The traditional conventional open surgical technique is compared with that of the latest and the newest minimal access endovenous ablative procedures.

Methods: The study was designed as a Prospective studyn 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)..The patients with varicose vein attending the Surgery OPD of Mookambikai Medical College and Hospital, Kanyakumari 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.

Results: 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.
In our study the incidence of parasthesia was higher in HL/S group (19.56%) compared to RFA (3.7%) and EVLA (8.3%) where as the other study from literature showed higher incidence in RFA (23.3%) and EVLA (2%) compared to HL/S (13.9%)8,21.

Conclusion: study shows that the short term efficacy and safety of endovenous ablation and open

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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.

Keywords: Varicose vein,Radio frequency abalation, endovenous ablation and open surgery.

INTRODUCTION:

Varicose veins are a common problem and one of the most prevalent medical disorders affecting approximately 10 to 40% of the general population. The lower limb venous system is classified into the superficial system, the perforator and communicating systems and the deep system. In most of the cases the varicose veins of lower limbs are due to superficial venous incompetence which results in the development of truncal varicosities. This occurs in 32% of women and 40% of men (Edinburg Vein Study). Varicose veins are classified as primary and secondary varicose veins. About 60 to 70% of primary varicose vein develop due to Sapheno Femoral Junction (SFJ) incompetence and Great Saphenous Vein (GSV) reflux while in about 10% it is due to Sapheno Popliteal Junction (SPJ) and Small Saphenous Vein (SSV) incompetence.

Asymptomatic superficial venous reflux occur in 39% of cases and present as cosmetic problem alone, but in the rest of the cases it presents with symptoms such as restless leg, discomfort, ache, heaviness, pain, swelling, hyper pigmentation and eczematous skin changes, ulcers, bleeding, superficial thrombophlebitis and disability such as talipes equino varus.

Treatment of varicose veins is for three main reasons. In the first instance, treatment is to prevent occurrence of complications, such as bleeding, edema, eczema, lipodermatosclerosis and leg ulcers. Leg ulcer treatment is intense and sincere perseverance and endurance is required from both the patient and physician side. It is very expensive owing to its chronicity the duration of treatment required is prolonged. Leg ulcers have a major impact on patients' social life as reflected by the health related quality of life (HRQOL). Secondly, varicose vein treatment also relieves symptoms caused by varicose veins, such as heaviness, tired legs and cramps. Cosmetic reasons are the third reason for treatment.

Treatment begins with the abolition of venous reflux and thereby reducing ambulatory venous hypertension, which is the key point for successful treatment. This can be achieved by surgical ablation or by endovenous ablation of saphenous vein reflux.

Surgical ablation in the form of high ligation of SFJ and stripping of GSV is more than a century old and is considered the gold standard. Lot of innovations in the treatment of varicose veins has developed with the aim of reducing the morbidities associated with the standard surgical procedure. Among them are the endovenous ablations with radio frequency ablation, laser ablation and foam sclerotherapy.

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Though the endovenous ablation techniques are a decade old, there are only a few studies in the international literatures comparing these procedures with that of the conventional surgical procedure. Also the national literatures have reported only the case series in the individual endovenous procedures and no comparative study appears to be available so far.

This study compares the outcome of the management of truncal varicose veins in a series of patients presenting to our tertiary care referral centre over a period of one year. The traditional conventional open surgical technique is compared with that of the latest and the newest minimal access endovenous ablative procedures.

AIM AND OBJECTIVES 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.

MATERIALS AND METHODS:

The study was designed as a Prospective studyn 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)..The patients with varicose vein attending the Surgery OPD of Mookambikai Medical College and Hospital, Kanyakumari 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 are Patients in the age group between 20 to 80 years , Both males and females were included,Patients with varicosity of GSV with grade II reflux and above of the sapheno femoral junction, 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 are Patients with secondary varicose veins due to previous DVT,Patients with recurrent varicose veins,Patients with perforator incompetence alone,Patients with segmental reflux,Female patients with pregnancy,Congenital anomalies (E.g.) Klippel Trenaunay Syndrome (KTS),Patients with GSV diameter greater than 1.2cm,Patients with ABI less than o.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.

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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.

The three procedures in this study were done under regional anesthesia.The surgical procedure of High ligation (Trendelenburg procedure) and GSV stripping was performed through a groin skin crease incision of 4 to 6 cm, with flush ligation of SFJ and division of GSV and all its tributaries near the saphenofemoral junction. The exit of the stripper was at the below knee level or at the ankle if the varicosity extended to the lower leg. The stripper was retrieved through the groin wound with simultaneous application of elastic compression bandage.

In the other arm which included the RFA and EVLT, procedures were performed under duplex guidance. The GSV was accessed by percutaneous puncture with the 7Fr puncture kit or by means of a small cut down at just below knee or in the upper calf. The catheter or the fiber tip was placed 2 cm distal to the SFJ or just distal to the superficial epigastric vein. Tumescent anesthesia, approximately 250- 300ml per treatment, was administered peri venously in the saphenous canal under USG guidance.
Radio frequency ablation (segmental ablation) was performed using VNUS CLOSURE FAST system. The EVLA procedure was performed using 1470nm diode laser (BIOLITEC) using continuous mode with 11 to 12W of energy and pull back of 80J/cm. Both RFA and EVLA were performed in limb elevated position.In both the groups the stab avulsion technique was used to treat the leg perforators and branch varicosities.

Post operative follow up was done within 72 hours, 1 month, and 6 month and at 1 year. Each visit included clinical examination, duplex ultra sound examination and documentation of CEAP staging and VCSS.In the RFA and EVLA group, the criteria for technical success was considered as obliterated great saphenous vein with lack of flow and absence of saphenous vein was considered as success in HL/S group. Treatment failure or recanalization of great saphenous vein was defined as any open part of the treated vein segment more than 5 cm length. The complication was regarded as minor if no separate treatment was required and major if they required additional treatment or prolongation of hospital stay or led to permanent adverse event. The post operative pain was analyzed using Visual Analogue Scale from 0 to 10 and analgesics prescribed accordingly.

Statistical analysis was done using the statistical package for social sciences (SPSS).Different statistical methods were used as appropriate. Mean ± SD was determined for quantitative data and frequency for

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categorical variables. The independent t- test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p- value < 0.05 was considered significant.

RESULTS:

Patients were enrolled from January 2023 to January 2024 and the follow up was continued till January 2024. 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.

TREATMENT DISTRIBUTION

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

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

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

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

78% (n=66) of treated patients had varicose vein alone that were symptomatic. The symptom included restless legs, heaviness, leg ache or edema of ankles towards evening which subsided on overnight rest. There was no case of varicose vein operated for cosmetic reason alone. Of the 7 patients with active ulcer one patient underwent HL/S, 3 patients underwent RFA and 3 patients underwent EVLA. The sizes of the ulcer were between 2-4 cm averaging 3 cm. The average time taken for ulcer to heal was 3 weeks to 3 months. There was no ulcer recurrence in the one year period of follow up.

In technique comparisons, vein access of the distal extent of saphenous vein in the leg was with cut down in all the 46 (100%)limbs in HL/S group and in 46% (18 of 39) of limbs in endovenous group. The other 21 limbs in endovenous group were accessed via percutaneous puncture of GSV in the calf using 7Fr puncture kit under ultra sound guidance Procedural complications were infrequent in both the treatment groups. Phlebectomies of superficial leg varicosities were performed by stab avulsion technique in all patients in both the groups.
Immediate success on the day of treatment was reported in 100% of all treated groups.
The complications and adverse events were evaluated in the peri operative period.

COMPLICATIONS AND ADVERSE EVENTS

	HL/S	RFA	EVLA	P-Value

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complications	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		

The peri operative complications were observed maximally in the HL/S group (P value=0.0001). All patients had induration and tenderness in the groin wound from the immediate post operative period to 2 to 3 weeks post op. The same was not a complaint in the endovenous group as no incision was made at the groin.

Subjective assessment of pain was done using Visual Analog Scale from 0 to 10 during the first 10 days and during periodic follow up. The pain score was higher initially and in the subsequent 2 weeks after HL/S compared to endovenous ablation.

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	

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Student – t (Independent samples) Test is applied to calculate the P- ValueThe mean ulcer size was 4cm (n=1) in HL/S, 3cm (n=3) in RFA and 2.33cm (n=3) in EVLA group with rate of ulcer healing of 75%, 83.33% and 82.84% respectively at the end of 1 month and 100% in all groups at the end of 6 months.

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	-

The ultrasound follow up in the post operative period was used to compare the results for length of GSV occlusion, residual patent segments and reflux findings and also the status of deep veins. Absence of GSV and reflux at SFJ was noted in all the treated limbs in HL/S group (100%, n=46). The treatment success was defined as closed great saphenous vein with lack of flow i.e. less than 5cm of proximal patent vein and no reflux in the patent segment in the endovenous group. All the patients in the endovenous group (100%, n=39) fitted into the technical success criteria and remained closed till the end of follow up at the end of one year.

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	-

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	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

DISCUSSION:

The conventional treatment for the patients with symptomatic incompetent superficial veins is best done by removing the refluxing saphenous vein from the saphenofemoral junction to a level at the knee or up to the leg, with individual ligation of the named saphenous branches at the groin. High ligation(Trendelenberg) and stripping is considered to be the standard treatment of varicose veins, as it has highest rate of initial rate of success and lowest rate of recurrence.22,23 Any other alternative techniques to high ligation and stripping of saphenous vein should have the same or a better outcome, without any associated morbidity. The newer techniques are minimally invasive endovascular obliteration of the vein with the radiofrequency or laser generated heating probes placed inside the vein through the percutaneous puncture or by cut down in the upper leg.The aim of our study was to compare the efficacy of the treatment with endovenous technique with the standard open technique (high ligation and stripping) for abolishing superficial venous incompetence and thereby bringing about symptomatic relief.

The study was designed as prospective study with the assessment of operative adverse events and post operative sequelae and recovery of the patient for a short term of one year.In this study, 85 patients were enrolled out of which 74 were males and 11 were females. Though the female incidence with varicose vein is higher in general population, the poor participation of females in our study arm could probably be that they preferred a trial compression therapy during the period of enrollment.

46(54%) patients underwent high ligation and stripping and 39(46%) patients underwent endovenous obliteration by means of radiofrequency ablation [27(32%)] and laser ablation [12(14%)]. The study sample was well matched with the other randomized studies.8,12,13,21 The mean age of incidence was 40±5 years in females and 50±5years in males.8,2Clinical classification of the varicose veins were done based on CEAP classification and among those who underwent treatment 78%(n=66) belonged to C2, 6%(n=5) belonged to C2,4a , 8%(n=7) belonged to C2,5 and 8%(n=7) belonged to C2,6.

In this study, HL/S and endovenous thermal ablation were found to be equally efficient in eliminating the incompetent saphenous vein asdemonstrated by duplex examination within 72 hours of procedure with the success rate of 100%. The similar success rate have been shown in various studies; randomized

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trial comparing endovenous laser ablation of GSV with HL/S in patients with varicose veins: short term results from the American Venous Forum(100%)21, J Vasc Surg.2009: In a meta analysis a success rate of 93.3% for EVLA, 87.5% for RFA and 80.4% for HL/S19, J of cardiovascular surgery 2005(96 to 100%) was observed. The mean follow up period in above literature quoted were between 6 months to 3 years.The occurrence of adverse events was minimum and not different among the groups. Apart from bruising, which was statistically more (P Value=0.0005, <0.05) in the HL/S group (39.95%) compared to RFA (3.7%) and none in EVLA, the bruising event was low in our study compared to other studies which showed 52% in HL/S and 27% in RFA (J Vasc Surg 2003) and 25% and 11% in HL/S and EVLA respectively (J Vasc Surg 2007).4 patients in HL/S (8.69%) and 1 patient in RFA (3.7%) underwent treatment for infection at groin and cut down site respectively. Such infection rate was low compared with another study, where infection was reported in 13.7% of patients after high ligation of saphenous vein [13]. (J R Coll Surg Edinb 1991). The occurrence of lymphocele was high (10.86%) in our study compared to other study (2.8%)(J Vasc Surg 2003) in the HL/S group.

In our study the incidence of parasthesia was higher in HL/S group (19.56%) compared to RFA (3.7%) and EVLA (8.3%) where as the other study from literature showed higher incidence in RFA (23.3%) and EVLA (2%) compared to HL/S (13.9%)8,21. Similar incidence of parasthesia in HL/S (15%), RFA (3.8%) and EVLA (7.8%)7 was observed in another study.Burns as a procedural complication occurred in 4 (14.8%) patients in RFA group and none (0%) in EVLA group. Skin burns have been reported in the literature using the 1064nm Nd:YAG laser (Lasers Surg Med 2002) and none with the diode Lasers (early results of various laser ablation studies)2. The incidence of skin burns has been reported as 2-4% in the results of various RFA studies2.Although DVT has been reported in up to 5.6% of laser patients and up to 16% in RFA patients1,2,7 , our study had one incidence of DVT (8.3%) in EVLA group which was managed successfully with anticoagulation.

Post operative pain in the leg was higher after HL/S compared with endovenous procedures as indicated by statistically significant ifferences in pain score as well as by the presence of tenderness (P<0.0001) in all 46 patients who underwent HL/S. The pain was usually located to the thigh. However a paired study comparing EVLA (810nm laser) and HL/S performed with regional anesthesia found no difference in pain between the groups, but the patients indicated more benefit in the leg treated with laser in addition to less bruising and edema (Dermatol Surg 2005). The tumescent fluid placed within the saphenous canal under ultra sound guidance may have probably reduced the immediate post operative pain in the endovenous group as there was no significant difference in pain score in the subsequent follow up visits in both the groups.
Similarly the rate of ulcer healing was observed to be slightly better in the endovenous group with healing rate of 83.33% and 82.84% for RFA and EVLA at the end of one month and 75% in the HL/S group, though they are not statistically significant (P=0.700,
0.05). The rate of ulcer healing was not separately observed in most of the randomized studies as this parameter was included as one of the component of the VCSS. As expected, the VCSS improved similarly in both the groups.

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The mean scores improved significantly (P<0.05) after operation, falling from a mean of 5.4 (range 1to16) and 3.1 (range 1to12) to 0.84 (range 0 to 7) and 0.435 (range 0 to 4) at 6 months in the HL/S and endovenous group respectively.Also the average duration of hospital stay was considerably less in the endovenous group averaging 2 days compared to 7 days in the HL/S group with return to normal activities in less than 2 days in endovenous group and averaging 5 days in HL/S group. The same was observed in other studies where the return to normal activities were 3.5 (0-8) in EVLA and 14 (3-28) days in HL/S groups7 and 0 to 3 days in RFA Vs 3 to 15 days in HL/S group8.

The last decade has seen the evolution of new minimally invasive methods including radiofrequency ablation, endovenous laser ablation and foam sclerotherapy for the treatment of GSV incompetency as an alternative to conventional high ligation and stripping. There are several randomized controlled trials involving these new methods that are available in the literature. There are five RCTs which compare RFA with EVLA. The trials showed similar complication and closure rate in both groups[13]. Kabnick concluded that the most current RFA and jacket tipped EVLA methods and devices are indistinguishable in terms of efficacy and short term results. These procedures present no significant differences from the patient's point of view as the procedure time and use of tumescent anesthesia was same.

The four RCTs comparing radio frequency ablation with high ligation and stripping demonstrated that radio frequency ablation have significant advantages, that included faster recovery, less operative pain, fewer adverse events and improved quality of life scores[8,9,26,27] when compared to conventional stripping.

One RCT compared open surgery Vs EVLA Vs RFA Vs ultrasound guided foam sclera therapy (UGFS)[13]. The study observed better quality of life (SF36), and also lower pain score (P<0.001) and shorter time away from work (P<0.001) in RFA and UGFS groups. Also GSV occlusion was better with HL/S, RFA and EVLA than with UGFS (P less than 0.0001). There was no significant difference in clinical recurrence in all the treatment groups.

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.

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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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