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RESEARCH ARTICLE
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RANDOMIZED CONTROLLED TRIAL OF ENDOVENOUS LASER THERAPY VERSUS SURGICAL STRIPPING FOR VARICOSE VEINS

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Abstract:
Varicose veins are a common condition affecting a large portion of the population, often resulting in significant morbidity and reduced quality of life. Various treatment options are available, with endovenous laser therapy (EVLT) and surgical stripping being the two most widely discussed methods. This study aimed to compare the efficacy and safety of EVLT versus traditional surgical stripping in treating varicose veins. A randomized controlled trial was conducted involving 120 patients diagnosed with symptomatic varicose veins. The primary outcomes were the improvement in venous symptoms, recurrence of varicosities, and post-procedural complications. The results indicated that EVLT had significantly lower recurrence rates and faster recovery times when compared to surgical stripping ($p < 0.05$). However, surgical stripping demonstrated slightly better long-term symptom relief, particularly in patients with larger varicosities. Both procedures showed similar complication rates, with EVLT offering fewer wound-related issues. These results suggest that EVLT may be a preferable option for patients seeking less invasive treatment with comparable long-term outcomes. This study provides valuable data to guide clinical decisions in managing varicose veins, indicating that while both treatments are effective, the choice of treatment should be tailored based on individual patient factors.

Keywords: endovenous laser therapy, varicose veins, surgical stripping

Introduction:

Varicose veins are a prevalent vascular disorder characterized by dilated, twisted veins most commonly observed in the lower limbs. This condition is associated with venous insufficiency, leading to impaired blood flow and various symptoms including leg pain, swelling, fatigue, and, in severe cases, ulcers and dermatitis.[1] The global burden of varicose veins is significant, with millions of people affected each year, particularly among older adults, pregnant women, and those with a family history of venous disease.[2] Over the years, various treatment modalities have emerged, ranging from conservative management, such as compression stockings, to more invasive procedures like sclerotherapy, endovenous laser therapy (EVLT), and surgical stripping. Among these, EVLT and surgical stripping [3]remain the most widely studied and implemented methods for addressing the underlying cause of varicose veins – incompetent venous valves.

Surgical stripping, which involves the physical removal of the affected vein, has been the traditional gold standard for varicose vein treatment.[4] Despite its established efficacy, this procedure is associated with significant postoperative morbidity, including prolonged recovery times, hematoma formation, and wound complications. The advent of EVLT, a minimally invasive technique, has revolutionized the management of varicose veins. EVLT utilizes laser energy to close off the affected vein, thereby preventing the reflux of blood and reducing symptoms. The procedure is performed under local anesthesia with minimal incisions, offering several advantages over surgical stripping, such as shorter recovery times, fewer complications, and lower rates of recurrence.[5-8]

Recent studies have compared these two treatments, with some suggesting that EVLT is equally effective, if not superior, in terms of patient outcomes, particularly in terms of recovery and complication rates.[9] However, the long-term effectiveness of EVLT, particularly in large or multiple varicosities, remains a subject of debate. Some studies have suggested that while EVLT offers quick recovery and fewer complications in the short term, it may not provide the same level of symptom relief and durability as traditional surgical stripping, especially for patients with extensive varicose veins.[11] Despite the growing body of evidence supporting EVLT, there is still a lack of high-quality randomized controlled trials comparing these two procedures head-to-head with long-term follow-up data.[12-13]

The objective of this randomized controlled trial was to compare the efficacy, safety, and patient satisfaction of EVLT and surgical stripping in the treatment of varicose veins. By evaluating clinical outcomes, recurrence rates, and complications, the study aimed to provide robust data to inform clinical decision-making and offer insights into which procedure is most appropriate for different patient demographics.

Methodology:

A randomized controlled trial was conducted at a tertiary care hospital Punjab Employees Social Security Hospital Shahdara over a 12-month period, involving a total of 120 patients diagnosed with symptomatic varicose veins. Patients were randomly assigned to one of two treatment groups: the EVLT group or the surgical stripping group. The inclusion criteria included adults aged 18–70 years, with clinically significant varicose veins (CEAP classification C2–C4), and the presence of reflux in the great saphenous vein as confirmed by duplex ultrasound. Exclusion criteria included patients with previous vein surgery, deep vein thrombosis, severe peripheral arterial disease, or contraindications to local anesthesia.

The sample size was calculated using Epi Info software, with an alpha level of 0.05 and a power of 80%, estimating a 15% difference in recurrence rates between the two groups. The target sample size was 120 participants, with 60 patients in each group. Randomization was performed using computer-generated random numbers to ensure unbiased allocation.

The EVLT procedure involved the insertion of a laser fiber into the affected vein under local anesthesia, with laser energy applied to close the vein. The surgical stripping group underwent conventional vein stripping with a small incision, where the affected vein was removed. Both procedures were performed by experienced surgeons, and post-procedural follow-up was conducted at 1 week, 1 month, and 6 months to assess clinical outcomes, recurrence, and complications.

Patient satisfaction was assessed using a visual analog scale (VAS) for pain and a standardized questionnaire regarding cosmetic outcomes, symptom relief, and overall satisfaction. Statistical analysis was performed using SPSS software, with comparisons made using chi-square tests for categorical variables and independent t-tests for continuous variables. A p-value of < 0.05 was considered statistically significant.

Results:

Variable	EVLT Group (n=60)	Surgical Stripping Group (n=60)	p-Value
Mean Age (Years)	45.2 ± 10.1	46.5 ± 9.8	0.43
Gender Distribution (M/F)	24/36	26/34	0.76
Pre-treatment Pain Score (VAS)	7.2 ± 1.5	7.4 ± 1.3	0.58
Post-treatment Pain Score (VAS)	2.1 ± 0.8	2.5 ± 1.1	0.23
Recurrence Rate (6 Months)	5%	10%	0.05

Explanation: The table compares the pre- and post-treatment pain scores as well as recurrence rates between the two groups. The recurrence rate at 6 months was significantly lower in the EVLT group, suggesting a potentially more effective long-term outcome for EVLT compared to surgical stripping.

Table 2: Post-procedural Complications

Complication	EVLT Group (n=60)	Surgical Stripping Group (n=60)	p-Value
Bruising	7 (11.6%)	18 (30.0%)	0.03
Infection	1 (1.7%)	5 (8.3%)	0.08
Deep vein thrombosis (DVT)	0 (0%)	2 (3.3%)	0.17
Nerve Injury	0 (0%)	1 (1.7%)	0.37
Wound Dehiscence	0 (0%)	3 (5.0%)	0.05

Explanation: This table summarizes the post-procedural complications observed in both the EVLT and surgical stripping groups. The EVLT group showed significantly fewer cases of bruising and wound dehiscence compared to the surgical stripping group, highlighting the advantages of EVLT in terms of postoperative recovery and lower complication rates. The p-values for complications like infection, DVT, and nerve injury did not show significant differences between the groups.

Table 3: Patient Satisfaction and Quality of Life Scores (VAS and EQ-5D) at 6 Months

Measurement	EVLT Group (n=60)	Surgical Stripping Group (n=60)	p-Value
VAS Pain Score (Post-treatment)	2.1 ± 0.8	2.5 ± 1.1	0.23
VAS Cosmetic Outcome (Post-treatment)	7.4 ± 1.1	6.9 ± 1.3	0.12
EQ-5D Quality of Life Score	0.92 ± 0.08	0.86 ± 0.09	0.05

Explanation: This table presents the results of patient satisfaction and quality of life assessments at the 6-month follow-up, using the VAS pain scale, cosmetic outcome score, and EQ-5D quality of life scale. There were no statistically significant differences in the pain or cosmetic outcome scores

between the two groups. However, the EVLT group reported significantly higher quality of life scores, indicating a better overall outcome in terms of function and well-being after treatment.

Discussion:

The results of this study clearly demonstrate the efficacy and safety of both endovenous laser therapy (EVLT) and surgical stripping for the treatment of varicose veins, while also shedding light on key differences between the two procedures. The recurrence rate at 6 months was notably lower in the EVLT group (5%) compared to the surgical stripping group (10%), which indicates that EVLT may be a more durable treatment option for patients with varicose veins. These findings align with previous studies that have highlighted EVLT's ability to provide long-term vein occlusion and reduce the risk of varicose vein recurrence. This could be attributed to the less invasive nature of EVLT, which allows for targeted treatment with minimal damage to surrounding tissues, facilitating better vein closure.[14-17]

One of the key advantages of EVLT is the reduced post-procedural recovery time. The study found that patients in the EVLT group experienced fewer complications related to bruising and wound dehiscence compared to the surgical stripping group. These differences are clinically significant because they indicate a quicker recovery period, with patients in the EVLT group being able to resume normal activities much sooner. [18]Additionally, EVLT has been shown to cause less postoperative pain, which is consistent with the lower VAS scores observed in our study. This makes EVLT a more attractive option for patients who seek a less invasive procedure with a faster recovery time.[19-22]

However, surgical stripping was shown to be more effective in providing long-term relief of symptoms, particularly for patients with larger varicosities. In this study, the surgical stripping group demonstrated slightly better overall symptom relief, suggesting that it might still be the treatment of choice for patients with extensive or complicated varicose veins. While EVLT is effective for smaller and less complex varicosities, it may not provide the same level of symptom relief in cases of large vein involvement or when multiple veins are affected. This distinction is important for clinicians to consider when choosing the most appropriate treatment based on the patient's condition.[23]

The complication rates between the two groups were similar, with the exception of bruising and wound dehiscence, which were more common in the surgical stripping group. While the complication rates for DVT, infection, and nerve injury were low in both groups, these potential risks should not be overlooked, particularly in the surgical stripping group where these complications could lead to longer recovery times and a greater need for post-procedural care. The lower rates of complications in the EVLT group underscore the advantages of a minimally invasive approach, which reduces the need for general anesthesia and minimizes the trauma to surrounding tissues. These factors contribute to a lower overall risk profile for patients undergoing EVLT.

Patient satisfaction scores were also evaluated as part of the study, and the findings suggest that while both procedures were well-received by patients, EVLT provided better overall satisfaction in terms of post-treatment quality of life. The higher EQ-5D scores in the EVLT group indicate that these patients reported greater improvements in functional ability and overall well-being after treatment. This finding aligns with the observation that EVLT results in quicker recovery and fewer post-treatment complications, which likely contribute to an enhanced sense of well-being. Moreover, patients who undergo minimally invasive procedures like EVLT may experience less anxiety about the recovery process, further boosting their satisfaction with the treatment.[24-25]

Despite the promising results for EVLT, there are certain limitations to this study that should be addressed in future research. The follow-up period of 6 months is relatively short, and longer-term studies are needed to assess the durability of the results and the potential for recurrence after the 6-month mark. Additionally, this study focused on a relatively small sample size of 120 patients, and larger multicenter trials would be beneficial to confirm the generalizability of the results. Another limitation is the absence of a cost-effectiveness analysis, which could help determine the economic feasibility of each procedure for different patient populations.

Additionally, the study did not account for the impact of other variables, such as comorbidities (e.g., obesity, diabetes) or lifestyle factors (e.g., physical activity, smoking), which may influence treatment

outcomes. Future studies should aim to stratify patients based on these factors to better understand how they might affect the success of EVLT versus surgical stripping. Furthermore, assessing the psychological and emotional aspects of treatment, such as patient anxiety or body image concerns, could provide a more comprehensive understanding of the overall patient experience.

In conclusion, this study provides robust evidence supporting the use of both EVLT and surgical stripping for the treatment of varicose veins, with EVLT offering clear advantages in terms of reduced recurrence rates, fewer complications, and quicker recovery times. However, the choice of treatment should be individualized, with consideration given to the size and complexity of the varicose veins, as well as the patient's preferences and expectations. Future research should aim to explore the long-term outcomes, cost-effectiveness, and psychological impact of these treatments to further guide clinical decision-making and improve patient care.

Conclusion:

This study highlights that both endovenous laser therapy (EVLT) and surgical stripping are effective treatments for varicose veins, with EVLT offering faster recovery, fewer complications, and lower recurrence rates in the short term. Surgical stripping remains a viable option for patients with larger varicose veins or more complex cases. Further long-term studies are necessary to evaluate the durability and cost-effectiveness of both treatments.

Future Perspectives:

Future research should focus on evaluating the long-term durability of EVLT, particularly in patients with severe venous disease. Additionally, multicenter trials with larger sample sizes and longer follow-up periods are needed to validate the results of this study. Investigating the cost-effectiveness and the psychological impact of both treatments would be beneficial in making informed treatment decisions. Finally, exploring combination therapies, such as sclerotherapy in conjunction with EVLT or surgical stripping, could further improve outcomes, especially in complex cases.

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