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RESEARCH ARTICLE

COMPARATIVE STUDY OF SURGICAL LIGATION AND STRIPPING VERSUS ULTRASOUND GUIDED FOAM SCLEROTHERAPY IN THE MANAGEMENT OF PRIMARY VARICOSE VEINS

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Abstract

Background: Characterized by dilated, tortuous superficial veins, primary varicose veins represent a common and often debilitating chronic venous disorder. For decades, surgical ligation and stripping (SLS) has been considered the traditional gold standard for the definitive management of symptomatic primary varicose veins. In response to the desire for less invasive treatment modalities and driven by technological advancements, ultrasound-guided foam sclerotherapy (UGFS) has emerged as a widely adopted alternative for primary varicose veins.

Methods: A prospective, observational study was conducted among 120 subjects which compared surgical stripping (n=60) versus ultrasound-guided foam sclerotherapy (n=60) for primary varicose veins. Procedures were detailed. Outcomesincluding Venous Clinical Severity Score, recurrence, complications and satisfaction were assessed at 1, 3, 6, 12 months. A p value of <0.05 was considered statistically significant.

Results: Both treatments improved VCSS scores, but the UGFS group had higher scores at day 7 (p=0.029). In the first week, surgical patients had increased discomfort. After one month, UGFS reported increased pain ratings. The two groups' mean varicosity assessments did not alter much after treatment. VDS scores improved considerably for the UGFS group at 7 days. At 1- and 3-month follow-ups, the surgical group had higher VDS scores. The surgical group had higher seventh-day problems such discomfort, bruising, stitch infection, seroma, and hematoma.

Conclusion: Foam sclerotherapy has emerged as a safe, promising, and dependable treatment for varicose veins, characterized by convenience of administration, no need for hospital admission, absence of anaesthetic risks, little disruption to daily activities, fast return to work, and comparable efficacy to surgical intervention.

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Introduction:-

Primary varicose veins represent a common and often debilitating chronic venous disorder, affecting a substantial portion of the adult population globally, with prevalence estimates ranging from 10% to 30%.(1,2) Characterized by dilated, tortuous superficial veins, this condition typically arises from valvular incompetence within the superficial venous system, predominantly involving the great saphenous vein (GSV) or small saphenous vein (SSV).(3) Beyond cosmetic concerns, varicose veins can lead to a spectrum of symptoms including pain, heaviness, itching, swelling, and cramping, which significantly impair a patient's quality of life. Progression of the disease can result in more severe complications such as skin changes, thrombophlebitis, venous ulceration, and even bleeding, posing considerable healthcare burdens.(4)

For decades, surgical ligation and stripping (SLS) has been considered the traditional gold standard for the definitive management of symptomatic primary varicose veins.(5) This invasive procedure involves the surgical disconnection of the saphenofemoral or saphenopopliteal junction (ligation) and the physical removal of the incompetent saphenous vein (stripping). While demonstrably effective in eliminating the refluxing segment and alleviating symptoms, SLS is associated with potential drawbacks such as general anesthesia requirements, larger incisions, longer recovery times, significant post-operative pain, ecchymosis, and a risk of complications including nerve injury, hematoma, and infection.(6,7)

In response to the desire for less invasive treatment modalities and driven by technological advancements, ultrasound-guided foam sclerotherapy (UGFS) has emerged as a widely adopted alternative for primary varicose veins.(8) This endovenous technique involves injecting a sclerosant mixed with air to form a foam directly into the incompetent vein segment under ultrasound guidance. The foam displaces blood, allowing the sclerosant to contact the vein wall, causing endothelial damage, fibrosis, and eventual occlusion of the vein. UGFS offers several advantages over traditional surgery, including being a minimally invasive, office-based procedure, often performed under local anesthesia, with reduced recovery time and potentially fewer immediate complications.(9)

Despite the growing popularity and perceived benefits of UGFS, a robust body of comparative evidence is essential to critically evaluate its efficacy, safety profile, and long-term outcomes relative to the established SLS. While numerous studies have reported promising short-to-medium term results for UGFS, concerns regarding its long-term recurrence rates, potential for skin staining, and varying efficacy based on foam concentration and injection technique remain.(10,11) Conversely, improvements in surgical techniques and perioperative care continue to refine the outcomes of SLS. Therefore, a comprehensive comparative study is imperative to provide clearer guidance for clinical practice, aiding surgeons and patients in making informed decisions regarding the optimal management strategy for primary varicose veins. This study aims to directly compare the clinical efficacy, recurrence rates, complication profiles, and patient satisfaction between surgical ligation and stripping and ultrasound-guided foam sclerotherapy in the management of primary varicose veins.

Materials and Methods:-

Study Design and Setting

This was a prospective, observational study conducted at a tertiary care hospital. The study was initiated following the ethical committee approval and after obtaining written informed consent from the study participants. Patients diagnosed with symptomatic primary varicose veins meeting the eligibility criteria were randomly allocated into two parallel groups to receive either surgical high ligation and stripping or ultrasound-guided foam sclerotherapy. The study aimed to compare the clinical outcomes, recurrence rates, complication profiles, and patient satisfaction between these two treatment modalities over a 12-month follow-up period.

A total of 120 patients diagnosed with primary varicose veins were enrolled in the study. Patients were randomly allocated into two equal groups: Group A (n=60): Underwent high ligation and great saphenous vein stripping. Group B (n=60): Received ultrasound-guided foam sclerotherapy (UGFS).

Patient selection

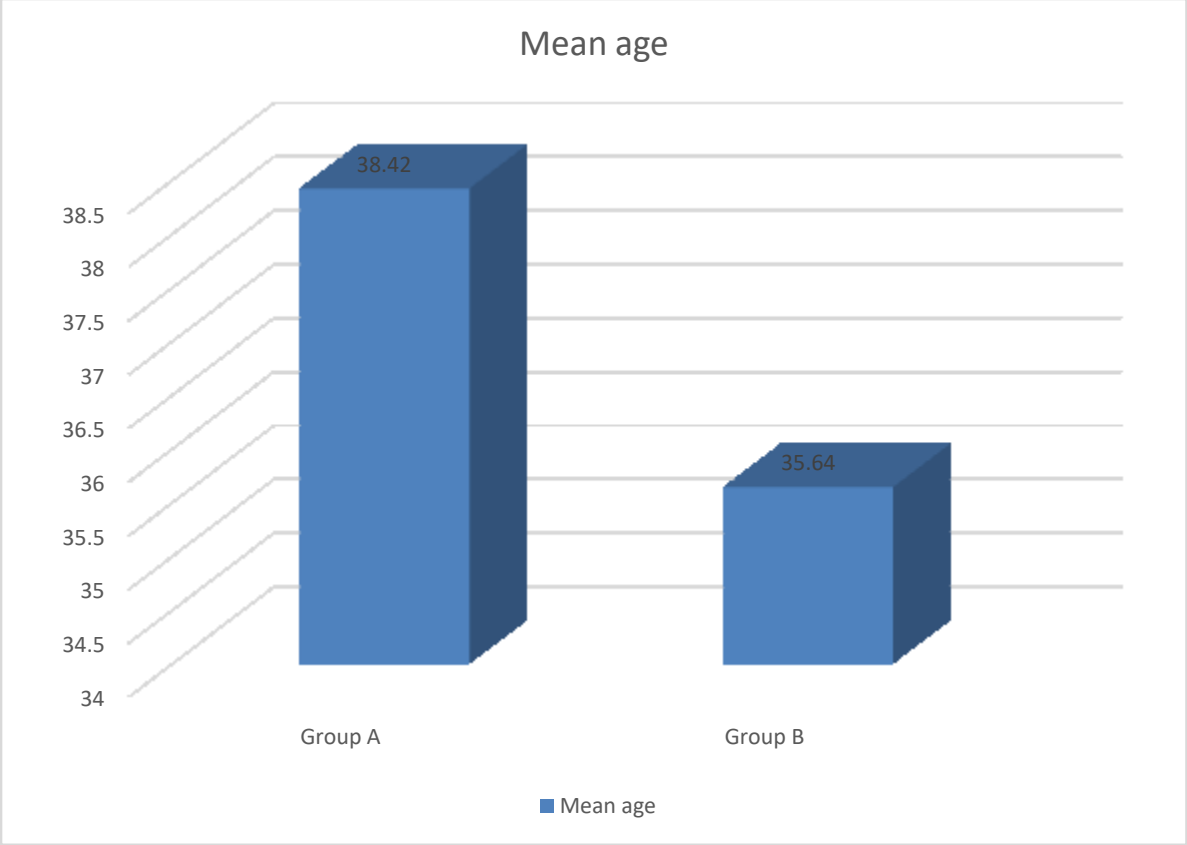
Inclusion criteria

1. All adults (>18 years of age) clinically diagnosed with primary varicose veins (C2-C4 based on the CEAP classification) and willing to participate in this research were included in the study.

Exclusion criteria

1. Varicose veins due to a history of deep vein thrombosis (post-thrombotic syndrome), arteriovenous fistulae, or pelvic congestion syndrome.
2. History of previous surgery, sclerotherapy, or endogenous thermal ablation for varicose veins in the limb designated for the study
3. Pregnancy or lactation
4. Coagulopathies, severe systemic diseases, uncontrolled diabetes mellitus
5. Severe cardiac failure, severe renal or hepatic impairment
6. Active malignancy, or other life-limiting comorbidities
7. Severe arterial disease
8. Thrombophilia

Figure 1:- Mean age of the study population.



Methodology:-

Group A: High Ligation and Great Saphenous Vein Stripping

Detailed duplex ultrasound mapping of the entire saphenous system, limb marking, and pre-operative assessment were performed. The procedure involved a groin incision for high ligation of the GSV at the saphenofemoral junction with division of tributaries, followed by stripping of the incompetent GSV segment (typically to the knee or mid-calf) using an intraluminal stripper. Compression bandaging was applied immediately post-surgery, gradual ambulation was encouraged, and analgesics were prescribed. Patients were advised to wear graduated compression stockings for a specified period (e.g., 4-6 weeks).

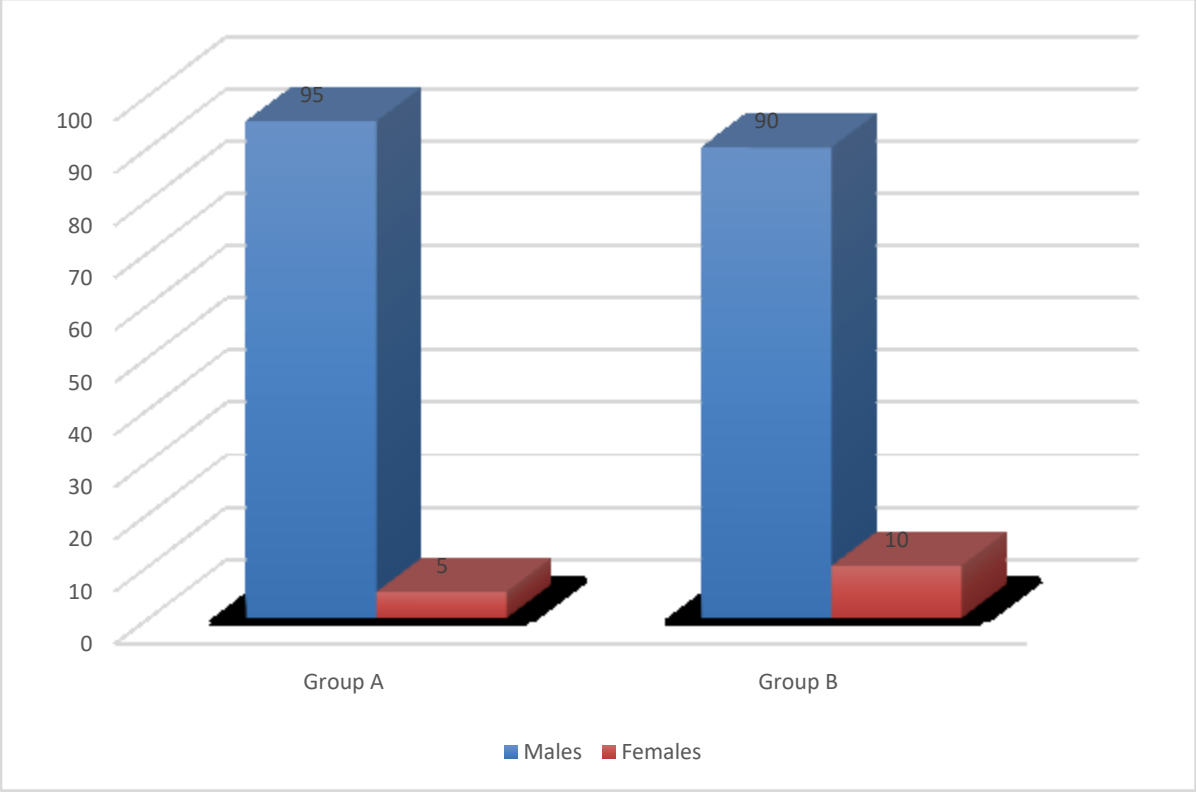
Group B: Ultrasound-Guided Foam Sclerotherapy (UGFS)
Detailed duplex ultrasound mapping of the entire saphenous system and limb marking were performed. Polidocanol foam was prepared using the Tessari method (1 part polidocanol to 4 parts air) immediately prior to injection. The foam was injected directly into the incompetent saphenous vein segment under continuous real-time ultrasound guidance, starting from the most proximal point of reflux. Digital compression was applied distal to the injection site to aid foam distribution. Immediate compression bandaging and application of graduated compression stockings were carried out. Patients were encouraged to ambulate immediately. Post-procedure ultrasound was performed within 24-48 hours to confirm occlusion and rule out DVT.

Baseline demographic data and clinical characteristics were recorded for all patients. Follow-up assessments were conducted at 1, 3, 6, and 12 months post-procedure. The Venous Clinical Severity Score was assessed at each follow-up visit. This validated, 10-item questionnaire covered pain, oedema, claudication, skin changes, and ulceration, providing a quantitative measure of disease severity and treatment effectiveness.

Statistical analysis
Data were entered into a Microsoft excel and analyzed using SPSS v27.0. Baseline characteristics between the two groups were compared using independent t-tests for continuous variables and Chi-square tests for categorical variables. A p-value < 0.05 was considered statistically significant.

Results:-
The mean age of the study population in group A was 38.42 ± 8.45 years and in group B was 35.64 ± 11.42 years. In the group A there were 57 (95.0%) males and in group B there were 54 (90.0%) males.

Figure 2:- Gender distribution of the study population.



Both treatment methods shown comparable efficacy in enhancing VCSS scores, with the UGFSgroup showing better VCSS scores at 7th post operative day (p=0.029).

Table 1:- Comparison of mean VCSS scores in both the groups.

VCSS Score	Group A (N = 60)	Group B (N = 60)	P value
Pre Op	7.63±2.14	7.79 ±3.14	0.893
7th day post Op	4.31 ± 2.50	3.25 ± 1.15	0.029
1 month post Op	1.84 ± 1.02	1.44 ± 1.32	0.749
3-month post Op	1.78 ± 0.87	1.37 ± 0.89	0.169

Figure 3:- Graph representing mean VCSS scores in both the groups.

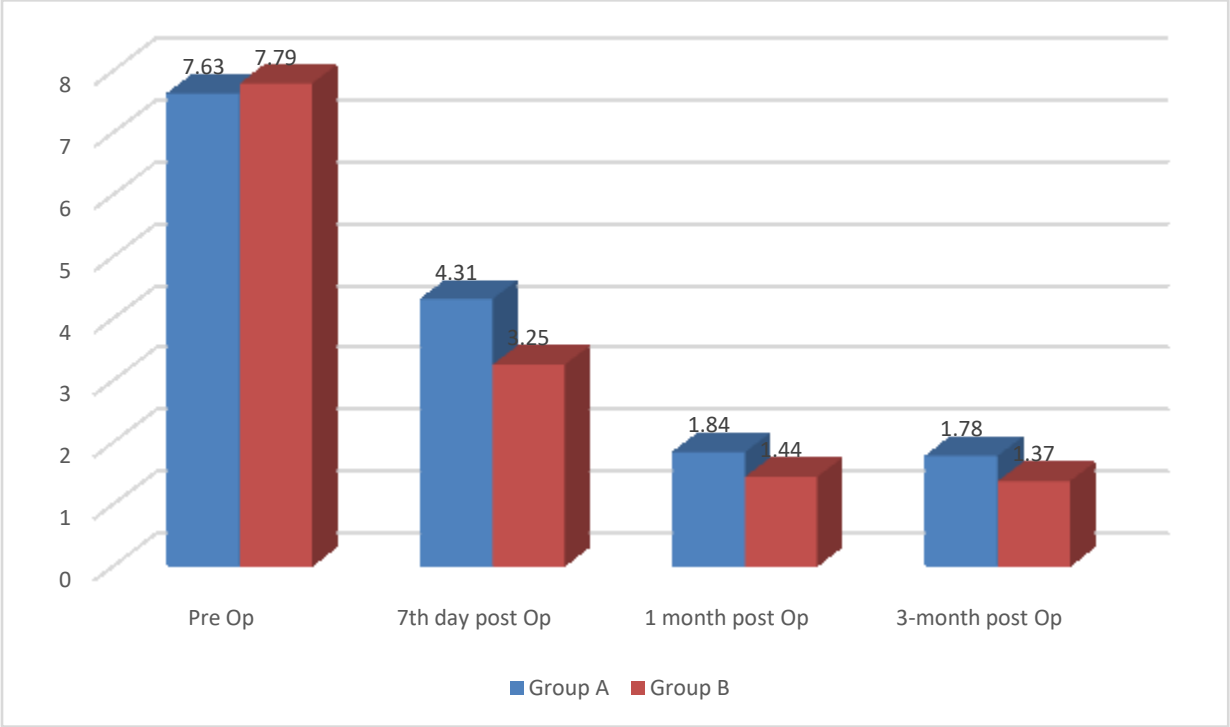


Table 2:- Change of mean VCSS scores in both the groups.

VCSS Score	Group A (N = 60)		P value	Group B (N = 60)		P value
	Before	After		Before	After	
7th day	7.63 ± 2.14	4.31 ± 2.50	<0.001	7.79 ± 3.14	3.25 ± 1.15	<0.001
1 month	7.63 ± 2.14	1.84 ± 1.02	<0.001	7.79 ± 3.14	1.44 ± 1.32	<0.001
3 month	7.63 ± 2.14	1.78 ± 0.87	<0.001	7.79 ± 3.14	1.37 ± 0.89	<0.001

Looking at pain scores it was observed that, preoperative pain scores were similar in both the groups. Post procedure the pain was found to be more in the surgery group compared to the UGFS group during the first week. Later at one month, the pain scores were found to be higher in group B following UGFS.

Considering the varicosity score, pre-operative ratings were not similar, and the Surgical group had a higher number of patients with significant varicosities in their legs ($p = 0.001$). Following therapy, there was no statistically significant change in mean varicosity ratings between the two groups. Varicosity ratings decreased markedly in both groups before and after therapy ($p < 0.000$)

Venous oedema was found to be resolved satisfactorily in both the groups post the procedure. But there was no statistically significant difference in the venous oedema scores in both the groups ($p = 0.584$). But the odema scores reduced significantly in both the groups before and after the treatment.

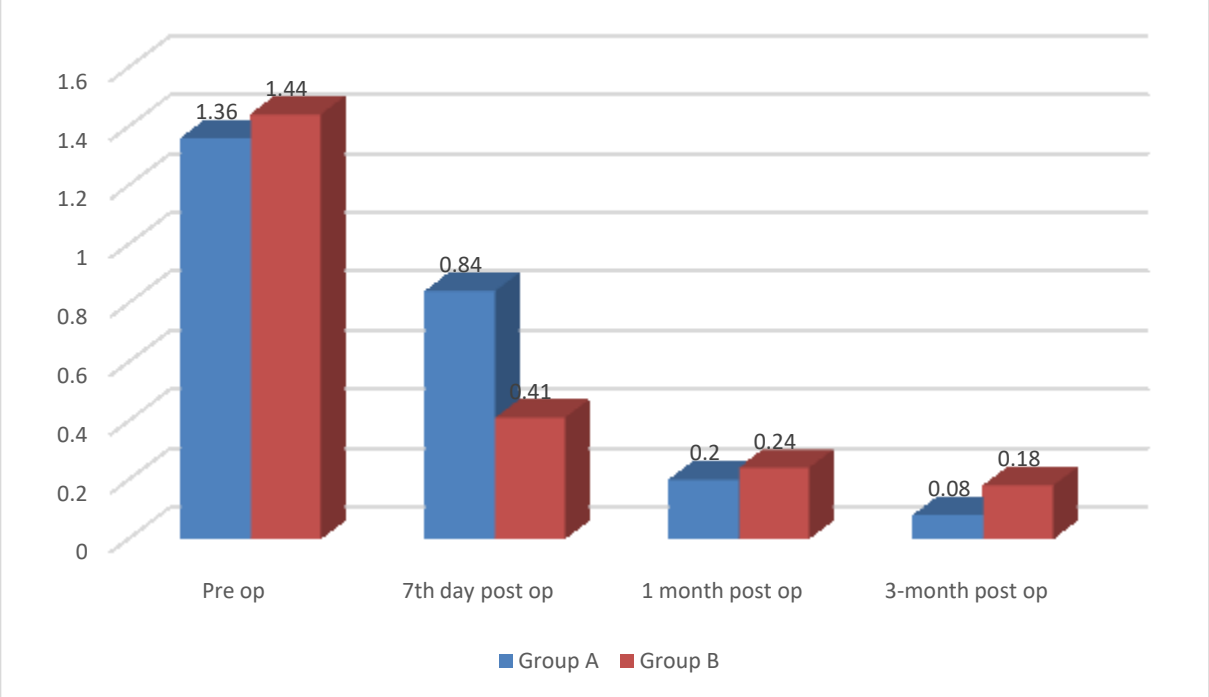
Pigmentation score was found to be better in the UGFS groups at one month (p = 0.041) and at three months (p = 0.04) compared to the surgery group.
The need for compression stockings in both groups was same pre-operatively (p = 0.847) and until the seventh post-treatment day (p = 0.247). At the one-month follow-up, a substantially greater number of patients in the UGFS group were using compression therapy (p = 0.024).

Venous disability score
The VDS scores were similar in both groups prior to the initiation of therapy (p = 0.823). The UGFS group exhibited substantially superior enhancements in VDS scores at the first follow-up on the seventh day (p = 0.014). However, by the conclusion of one and three months, the scores favoured individuals who had surgery (p = 0.042 and 0.012 respectively) (Table 3). VDS scores were markedly decreased in both groups (p <0.001).

Table 3:- Mean VDS scores in both the groups.

VDS scores	Group A (n = 60)	Group B (n = 60)	P value
Pre op	1.36 ± 0.28	1.44 ± 0.36	0.823
7th day post op	0.84 ± 0.31	0.41 ± 0.20	0.014
1 month post op	0.20 ± 0.02	0.24 ± 0.08	0.042
3-month post op	0.08 ± 0.04	0.18 ± 0.06	0.012

Figure 4:- Comparison of mean VDS scores in both the groups.



The mean procedure time for group A was 110.34 ± 14.23 but the mean time in case of group B (UGFS) was 32.4 ± 3.36 mins. This difference in mean time of the procedure was statistically significant. The mean hospital stay was also found to be higher in group A (35.2 ± 4.54 hours) compared to group B (2.4 ± 0.6 hours). This difference was also statistically significant.

The patients in the surgical group resumed their daily activities after a mean of 8.6 ± 2.3 days, whereas those in the UGFS group returned to work the next day (p <0.001). The average analgesic required in the surgical group was 4.21 ± 1.9 days, but in the UGFS group it was 0.84 ±0.65 days (p <0.001).
Early complications seen on the seventh post-operative day, including pain, bruising, stitch infection, seroma, and hematoma, were more prevalent in the surgical group. Late complications seen at the 1-month and 3-month follow-ups included discomfort, pigmentation and neuralgia. No DVT was identified; the other complications were minimal and equivalent across both groups.

Discussion:-

This study was conducted among 120 subjects to compare the clinical efficacy, recurrence rates, complication profiles, and patient satisfaction between surgical ligation and stripping and ultrasound-guided foam sclerotherapy in the management of primary varicose veins.The majority of the subjects in the study were males. This is similar to the study conducted by Jain et al., and Masuda et al., were almost 97.6% and 61.7% were males respectively.(12,13)But most of the foreign authors report a higher prevalence of the disease in females.(14–18)

The majority of our patients were young, with a mean age of 38.42 ± 8.45 years in group A and was 35.64 ± 11.42 years in group B. This is lower compared to the majority of patients in the western world, where most appear in their late 50s and early 60s.(19,20)The increased involvement of men in heavy work which requires prolonged standing may account for the predominance of younger male patients afflicted with the condition.

Astudy conducted by Kakkos et al., indicated that VCSS, VDS, and CEAP clinical scores exhibited comparable sensitivity and were superior for assessing responses to superficial venous surgery.(21) Limited randomized studies have compared UGFS with surgical interventions.(15,16) In our study, the mean VCSS scores for the disease were analogous in both groups prior to treatment initiation. Both treatment modalities demonstrated equivalent efficacy in enhancing the VCSS score at 1 and 3 months; however, patients undergoing UGFS exhibited more significant improvements in total VCSS scores during the early postoperative period at day 7.

In the research conducted by Masuda EM et al., they analysed the alteration in VCSS after foam sclerotherapy and observed that the median score shifted from 8 to 2, indicating a 75% change in score.(13) Iafrati MD et al., compared the alteration in VCSS post-surgery and determined that the mean VCSS shifted from 9.8 to 4.2, indicating a 57% decrease in score.(22) Gloviczki P et al., also analyzed the alteration in VCSS post-surgery and determined that the mean VCSS shifted from 8.93 to 3.98, reflecting a 55% change in score after the therapy.(23) Nevertheless, there is little information explicitly comparing UGFS with surgery based on VCSS and VDS.

Figueiredo M et al. evaluated the outcomes of foam sclerotherapy and surgery based on the Venous Clinical Severity Score (VCSS). He considers just the mean score change in the three components of VCSS—pain, oedema, and inflammation—without accounting for the overall score change. They observed a significant improvement in the average score of each aforementioned component of VCSS in both groups.(15) Our investigation revealed that both techniques were equally helpful in alleviating oedema and discomfort post-treatment.

The literature reveals a scarcity of data to compare the three parameters studied: varicosity, pigmentation, and compression treatment scores. The pigmentation score did not exhibit substantial improvement in consecutive follow-ups. The underlying cause is that skin alterations and lipodermatosclerosis associated with varicose veins are permanent changes, and any substantial improvement requires an extended duration. The need for compression treatment saw substantial alteration within the surgical cohort.

The functional capacity evaluated by VDS indicated that both modalities shown considerable improvement post-treatment and were equally effective. The results were unequivocally inferior to those documented in the research by Masuda et al.(13)This was likely due to the score's heavy reliance on the patient's capacity to do activities. The majority of our patients were daily wage workers who prioritized resuming activities promptly to sustain their families.

Our investigation shown that UGFS required much less time than standard surgery. Additionally, our foam sclerotherapy was an outpatient operation. This parallels other studies that have shown a much shorter duration for UGFS compared to surgical procedures.(15–17,24)

Certain complications were exclusive to the surgical group and not seen in the UGFS group. Complications included suture infection, seroma and hematoma during the one-week follow-up. Figueiredo M et al., during 2009 report infection, hematoma, and suture dehiscence in the surgical cohort at rates of 3%, 7%, and 38%, respectively.(15) In contrast to the findings of Michaels JA et al., who reported a local wound-related complication rate of just 2.4% among patients, our research group exhibited a higher incidence of such issues.(16)
In our research, problems in the foam sclerotherapy group were manageable and temporary, such as pain when walking and soreness, and did not need any active intervention, aligning with previous reports.(25–27) Pain and pigmentation were the two primary complications in the foam group in our investigation, consistent with the

literature. No significant complications were identified in the UGFS group, as corroborated by existing research. Foam sclerotherapy is a relatively safe operation when performed with appropriate ultrasound guidance and meticulous attention.(25–27)
Following foam sclerotherapy, almost all patients were released on the same day following a brief observation period. Following the surgical procedure the patients were discharged only after one day of observation.Iafrati et al. released their patients after 1.3 days.(22) Jain et al released their patients after an average period of 4.5 days, however the rationale for this duration was not provided in the literature.(12)
The mean time to return to regular activities in our research was 8.6 ± 2.3 days for the surgery group and 1 day for the foam group. Bountouroglou DG et al., indicate that the average duration for resuming normal activities was 8 days for the surgical group and 2 days for the foam group.(18) This is very similar to our discovery. Darvall KL et al., discovered that over 50.0% of patients undergoing foam sclerotherapy resumed work within 24 hours, while surgical patients typically required about 4 days to return to work.(24)

The average analgesic required in the surgical group was 4.21 ± 1.9 days, but in the UGFS group it was 0.84 ± 0.65 days. Abela R et al. discovered that 83.0% of patients having conventional surgery need postoperative analgesia, but only 23.0% of patients receiving foam sclerotherapy sometimes required analgesia postoperatively.(17) Darvall KA et al. discovered that after foam sclerotherapy, 70.8% of patients needed no analgesics, in contrast to 24.0% after surgery during the early postoperative period. After one week, only 4.1% of participants in the foam sclerotherapy group continued to need analgesia, in contrast to 30% in the surgery group.(24)

We have conducted doppler follow-up for all patients one month post-operatively. At one month post-operatively, we saw no instances of deep vein thrombosis (DVT) in either group and recorded a 100% obliteration rate of the greater saphenous vein (GSV). Figueiredo M et al. report an obliteration rate of 90% in the surgical group and 78% in the foam sclerotherapy group after six months of follow-up.(15)Bountouroglou DG et al. reported an obliteration rate of 89% in the surgical group and 78% in the foam sclerotherapy group after 12 months of follow-up.(18) The elevated obliteration rate seen in our research may be attributed to the short follow-up duration relative to the aforementioned studies, as well as the use of catheter-guided foam sclerotherapy, which is more effective than traditional sclerotherapy.

Conclusion:-

Foam sclerotherapy has emerged as a safe and effective treatment for varicose veins. This requires no additional setup beyond a Doppler, since duplex ultrasound facilities are accessible at all major hospitals, making the procedure cost-effective. UGFS may be performed as an outpatient procedure under local anesthetic, hence significantly reducing costs and hospital duration.

The therapeutic outcomes, including immediate post-procedure problems, enhancements in severity/disability ratings, recurrence rates, and overall clinical and radiological results, are equivalent to those of surgical care. The treatment was exceptionally gratifying for patients due to its straightforward administration, absence of hospital admission, lack of anesthetic danger, affordability, non-disruption of everyday activities, prompt return to work, and results closely like those of surgical procedures. The method was well tolerated both locally and systemically, with no significant problems, and was very acceptable to the patients. Nonetheless, it is essential to conduct studies including a larger cohort of patients with extended follow-up to reach any definitive conclusions on the potential of this therapy as the gold standard treatment in the future.

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