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Recommendations and Appropriate Solutions to Difficulties During the Endovenous Radiofrequency Ablation Process for Lower Limb Varicose Veins Management

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ABSTRACT:

Background: Endovenous radiofrequency ablation (EVRFA) is a highly effective, minimally invasive treatment for lower limb varicose veins, though operators frequently encounter intraoperative challenges that require real-time problem-solving. This study aims to document these specific intraoperative challenges using the ClosureFAST™ system and evaluate the efficacy of standardized corrective strategies on procedural success and patient outcomes.

Methods: A cohort study was conducted involving 480 patients who underwent a total of 680 great saphenous vein (GSV) ablations between April 2013 and October 2020. The study recorded ten predefined procedural challenges including misleading duplex imaging, venous spasm, tortuous segments, and superficial veins alongside the specific corrective measures deployed. The primary endpoint was technical success, defined as complete segmental occlusion confirmed by duplex ultrasound at 6 months.

Results: The most frequent intraoperative challenges encountered were ineffective first-cycle RFA (97.9%), tortuous or recanalized segments (20.8%), superficial vein courses (20.8%), and venous spasm (12.5%). Applying targeted corrective actions—such as on-table duplex re-mapping, anesthetic and positional adjustments to abolish spasm, phased ablation via dual punctures, and focused manual compression—successfully overcame these hurdles. Ultimately, technical success at 6 months was achieved in 99.4% of the treated veins (676/680). Furthermore, standardizing the protocol significantly reduced mean procedure times from 55 to 42 minutes, with zero major adverse events reported.

Conclusion: Implementing systematic, algorithmic corrective measures for common EVRFA challenges minimizes complications and significantly enhances procedural efficiency. This standardized approach provides a highly reproducible framework that ensures patient safety and maximizes the technical success rates of endovenous thermal ablation.

INTRODUCTION

Varicose veins primarily affect the superficial venous system of the lower limbs, and are a common manifestation of chronic venous insufficiency (CVI) **[1]**.

Historically, high ligation and great saphenous vein (GSV) stripping were the main care options, while being effective in decreasing patients' complaints, these invasive procedures required considerable tissue dissection of the groin, longer-than-normal recovery, and had greater risk of postoperative morbidity than their minimally invasive counterparts **[2].**

Compared with more invasive procedures, minimally invasive treatments like endovenous thermal ablation (EVTA) which encompassed radiofrequency ablation (RFA) and endovenous laser ablation (EVLA) became first-line therapies over the past 20 years. These therapies provided a high degree of efficacy with much lower rates of pain, downtime, and complications overall **[3, 4, 5].**

The ability of RFA to thermally ablate incompetent veins by thermally-controlled closure, carries excellent safety profiles and a rapid symptom relief has thus made RFA very popular **[6].** When compared to both surgical stripping and EVLA, RFA demonstrated a more rapid return to daily life, fewer hematomas and less periprocedural pain. Additionally, RFA minimizes the likelihood of induration, skin burns and other post-procedural adverse events by avoiding the high-energy peaks associated with some laser systems **[7].**

With good patient satisfaction and occlusion rates greater than 90% EVLA is a feasible option. Nevertheless, it is also associated with a higher incidence of superficial thrombophlebitis, post-operative ecchymosis, and perivenous pain, which is generally thought likely depending on anatomical factors and energy density **[8, 9].**

Although RFA guidelines are widely available, the intraoperative experience can still pose significant challenges, especially with navigating the catheter, sheer attachment, or even tumescence distribution. These challenges often require the operator to make decisions in the moment in real time, and there still seems to be a lack of published material supporting and systematically describing these situations and evidence-based responses **[10, 11]**.

Aim of work

The purpose of this prospective cohort study is to document and assess the intraoperative challenges faced during endovenous radiofrequency ablation (RFA) for lower limb varicose veins using the ClosureFAST™ system. This study will also evaluate the efficacy of the strategies used to overcome these difficulties, determine the effect of those strategies on procedural success and patient outcomes, and help increase both the feasible conduct of RFA and successful outcomes in a practical clinical context.

METHODS

Study Design and Setting

This retrospective cohort study was performed at Badr university hospital to primarily evaluate intra-operative difficulties faced while performing radiofrequency ablation (RFA) of lower limb varicose veins, and to assess the effectiveness of the prompt corrective actions taken to readdress such issues. Patients were recruited, and data collected, from April 2013 to October 2020, after having obtained ethical approval from the Institutional Scientific Research Ethical Committee, and in line with standard ethical principles. The study was operated according to the declaration of Helsinki IORG registry number: IORG0011670 serial: 60-2-26.

Study Population

Inclusion Criteria

- Patients aged 18 years or older.
- Patients diagnosed with refluxing great saphenous vein (GSV) confirmed by duplex ultrasound.
- Patients scheduled for RFA using the ClosureFAST™ system.
- CEAP Classification (C2–C5)

Exclusion Criteria

- Patients with successful sheath insertion and ablation without any intraoperative difficulties.
- Patients refusing to provide informed consent.
- High-risk patients unsuitable for RFA due to comorbid conditions.

- Patients with prior surgical interventions for varicose veins in the same limb.
- Vein diameter range (exclude GSV > 2 cm if difficult to ablate effectively with RFA).

Sample Size

A total of 480 patients, involving 680 GSV ablations, will be included.

Preoperative Assessment

All patients underwent a thorough preoperative assessment in the outpatient clinic approximately one to three weeks prior to the planned radiofrequency ablation (RFA) procedure. The plan was to verify the diagnosis, determine suitability for RFA, and set a full baseline of data for follow-up.

A full clinical history was taken with the following observations focused on the chief complaint, duration of symptoms, and evidence of classical signs of chronic venous insufficiency, such as symptoms of leg pain or heaviness, visible varicosities, edema, night cramps, pigmentation and history of ulceration. Patients were specifically questioned about previous treatments, including compression therapy, sclerotherapy, or surgical interventions.

Medical history included screening for diabetes mellitus, hypertension, chronic kidney disease, deep vein thrombosis, and cardiovascular or pulmonary comorbidities. Medication history was carefully reviewed, with particular attention to the use of anticoagulants or antiplatelet agents, which may influence perioperative management. Social history, including smoking status, physical activity level, and hours spend standing or walking at work, were recorded to identify any potential risk factors associated with the surgery.

All patients were subjected to a full physical examination including general examination and lower limb focused vascular examination. The vitals, blood pressure, heart rate, respiratory rate, and temperature were documented. During the local examination, limb swelling, areas of skin changes (i.e., hyperpigmentation, eczema, and lipodermatosclerosis), varicose vein staging, and active, healed ulcers were considered. The peripheral pulses were examined thoroughly, and tenderness or local signs of inflammation concerning phlebitis were noted.

Duplex venous ultrasound (DUS) performed with the patient in standing position, a high resolution linear transducer (7.5-10 MHz) was used. The dorsal veins and the superficial and deep veins of both limbs were evaluated for valve competence and reflux in the great saphenous vein (GSV), small saphenous vein (SSV) and perforators. Reflux defined as retrograde flow lasting longer than 0.5 second, following distal augmentation.

The GSV diameter was recorded in accordance with standard anatomical landmarks: 3 cm below the saphenofemoral junction (SFJ), mid-thigh, and below the knee. Duplex mapping was undertaken in B-mode and color Doppler at angles of insonation of 45°–60° as per normal practice, in order to ensure the signal quality was robust and reproducible. The reporting was documented in standardized vascular charts, with diagrammatic vein mapping.

Laboratory investigations were undertaken within 1 week of surgery and included: a complete blood count (CBC); serum creatinine; blood urea nitrogen (BUN); liver function tests; international normalized ratio (INR); activated partial thromboplastin time (aPTT); and a coagulation profile. These laboratory investigations were all used to establish baseline organ function, and to rule out undiagnosed coagulopathies and calculate anesthetic risk. All patients who had either an elevated INR or renal impairment were had a perioperative optimization with the internal medicine service.

Informed written consent was obtained after explaining to patients the procedure that was to be undertaken, the benefits, risks, possible complications, and alternative options. Patients were advised to cease anticoagulant medications with medical oversight 5-7 days before the procedure if clinically deemed appropriate. Compression stockings were prescribed preoperatively to assess tolerance and to inform the patient of post-operative use. Finally, photographs of the lower limbs were taken to document pre-treatment varicosities for future comparison during follow-up.

Intervention:

All procedures were completed in the operating theatre under strict aseptic conditions. The patient was positioned supine on the operating table with the leg externally rotated (approximately 15°) at the hip to facilitate adequate access to the medial aspect of the thigh. The lower limb was then prepped from the groin to the ankle and draped in a sterile fashion.

Using ultrasound guidance, the great saphenous vein (GSV) was accessed at a location distal to the knee, usually in the junction of the upper and middle third of the leg. A longitudinal approach was utilized where the probe was targeted at a 45° angle to visualize accurately the venous puncture. Access was confirmed by Doppler visualization. The venous puncture and access guidewire were then confirmed via Doppler trajectory. Then a 7 French (Fr) introducer sheath was inserted.

The ClosureFAST™ RFA catheter was then advanced through the sheath and located in the vicinity of 2 cm distal to the saphenofemoral junction (SFJ), as confirmed by real-time imaging ultrasound. Great care was taken to ensure that we did not place the catheter tip too close to the SFJ, which could cause heat-related injury to the deep venous system. After completing this step, we administered tumescent anesthesia along the entire length of the target vein. This procedure involved infiltrating a solution of 500 ml of cold normal saline (4°C), 20 ml of 1% lidocaine, and 1 ml of epinephrine (1:100,000) perivenously using a 21G spinal needle in case of performing procedure under local anesthesia. We used only cold normal saline infiltration in case of doing procedure under regional or general anesthesia. The goal of tumescence was to provide a thermal barrier to adjacent tissues, reduce vein diameter, and achieve local anesthesia. The infiltration was performed under ultrasound guidance at 1–2 cm intervals along the course of the GSV, ensuring circumferential distribution around the vein.

After tumescence was performed, segmental ablation was carried out using the ClosureFAST™ catheter, which provides controlled radiofrequency energy of 120°C for heating segments of 7 cm. Each heating segment was ablated for 20 seconds with incremental withdrawal of the catheter under ultrasound guidance. Manual compression was applied during ablation cycling to achieve contact of the catheter and the vein wall and to induce transmural thermal injury.

Upon ablation completion, the sheath and catheter were removed, and manual pressure was used for hemostasis at the puncture site. Compression dressing was then applied to the access point. The patient was fitted for thigh-high Class II graduated compression stockings (20–30 mmHg), which the patient was instructed to wear continuously for the first 48 hours then during the daytime for 2 weeks. Monitoring of vital signs persisted throughout the operation. Otherwise, intraoperative sedation was not utilized beyond local anesthesia, unless unanticipated patient discomfort or anxiety warranted mild sedation, which occurred under the anesthesiologist's supervision. The length of the procedure varied from 20 to 40 minutes, and depended on the vein length, tortuosity, or added technical challenges.

Patients and Methods

From April 2013 to October 2022, 480 consecutive patients (mean age 45 ± 12 years, 58% female, mean BMI 27 ± 4 kg/m², CEAP C2–C4) with symptomatic great saphenous vein reflux were enrolled at Badr university Hospital, Cairo, Egypt. A total of 680 incompetent veins underwent EVRFA under ultrasound guidance with the 6-Fr ClosureFast™ catheter. Patients were randomized into two arms: Group A (n = 80) initially consented to receive no anesthesia, while Group B (n = 400) received periprocedural sedation or spinal/general anesthesia.

Pre-procedure duplex scans were reviewed on site. Immediately before access, all patients underwent a repeat intra-operative duplex to confirm target anatomy (duplicated GSV, accessory veins, diameter, tortuosity, perforators). Ten predefined procedural challenges were recorded, along with corrective measures:

1. Misleading pre-operative duplex
2. Venous spasm impeding visualization or puncture
3. Vasovagal reactions during access attempts
4. Repeated sheath-insertion failures
5. Adjacent multiple incompetent veins
6. Tortuous or partially recanalized segments
7. Superficial vein course (<1 cm from skin)
8. Acute friable thrombus formation

9. Ineffective first-cycle RFA near SFJ due to cool inflow

10. Suboptimal ultrasound probe positioning

Primary endpoint was technical success—defined as complete segmental occlusion on duplex at 6 months. Secondary endpoints included procedure abortion rates, conversion to open surgery, thermal skin injury, venous thromboembolism, number of RFA cycles per vein, and complication rates. Statistical analyses compared outcomes before versus after implementation of corrective strategies, with significance set at $p < 0.05$.

RESULTS

Patient and Procedural Characteristics

Mean pre-ablation venous diameter was 6.4 ± 1.3 mm. Baseline demographics and CEAP distribution were similar between groups (all $p > 0.2$).

Incidence of Technical Challenges and Corrective Actions

1. **Misleading Duplex (n=18; 3.8%)** Originally missed duplicated GSV (n=7), accessory anterior branches (n=6), or extra-axial varicosities with perforator reflux (n=5). On-table duplex re-mapping averted mistargeting in all cases.

2. **Venous Spasm (n=60; 12.5%)** Occurred predominantly in Group A (50/80; 62.5%) during initial puncture attempts. General or spinal anesthesia, operating-room warming, and ante-Trendelenburg positioning abolished spasm in 100% of subsequent attempts.

3. **Vasovagal Attack (n=1; 0.2%)** One Group A patient developed transient bradycardia during multiple cannulation trials; prompt IV fluids, midazolam, and glycopyrrolate reversed symptoms. Only one procedure was aborted (0.2%).

4. **Sheath-Insertion Failures (n=28; 5.8%)** Tortuous or sclerotic veins resisted 7-Fr sheath advancement. Wire-assisted placement by experienced interventional radiologists and perivenous nitroglycerin (100 µg in 10 mL saline) succeeded in 27 cases; one required surgical conversion (0.2%).

5. **Multiple Adjacent Veins (n=25; 5.2%)** In 20 patients with dual refluxing veins punctured at similar levels, pre-emptive dual-sheath placement prevented compression of the secondary vein by tumescent anesthesia.

6. **Tortuous/Recanalized Segments (n=100; 20.8%)** Ninety-three cases were navigated via ultrasound-guided catheter manipulation with limb repositioning. One required a hydrophilic 0.018-inch guidewire; six underwent staged ablation via dual punctures (proximal and distal).

7. **Superficial Veins (n=100; 20.8%)** Veins <10 mm from skin, especially around the knee, were insulated by high-pressure, multi-site tumescent injection and segmental ablation—avoiding any thermal injury or post-procedural hyperpigmentation.

8. **Friable Thrombus (n=3; 0.6%)** Upon thrombus detection at catheter tip, sheath advancement cranial to the thrombus and cranio-caudal ablation prevented embolization; no PE or DVTs occurred.

9. **Ineffective First-Cycle RFA (n=470; 97.9%)** Posterior thigh circumflex inflow cooled the segment, necessitating >2 cycles. Focused manual compression and targeted tumescent under the tributary reduced mean cycles from 2.7 ± 0.6 to 2.1 ± 0.5 ($p < 0.01$).

10. **Ultrasound Probe Optimization** Standardizing to a 7.5–12 MHz linear probe on the sonographer's side with ideal foot-angle tilting improved catheter visualization and decreased fluoroscopy use by 35%.

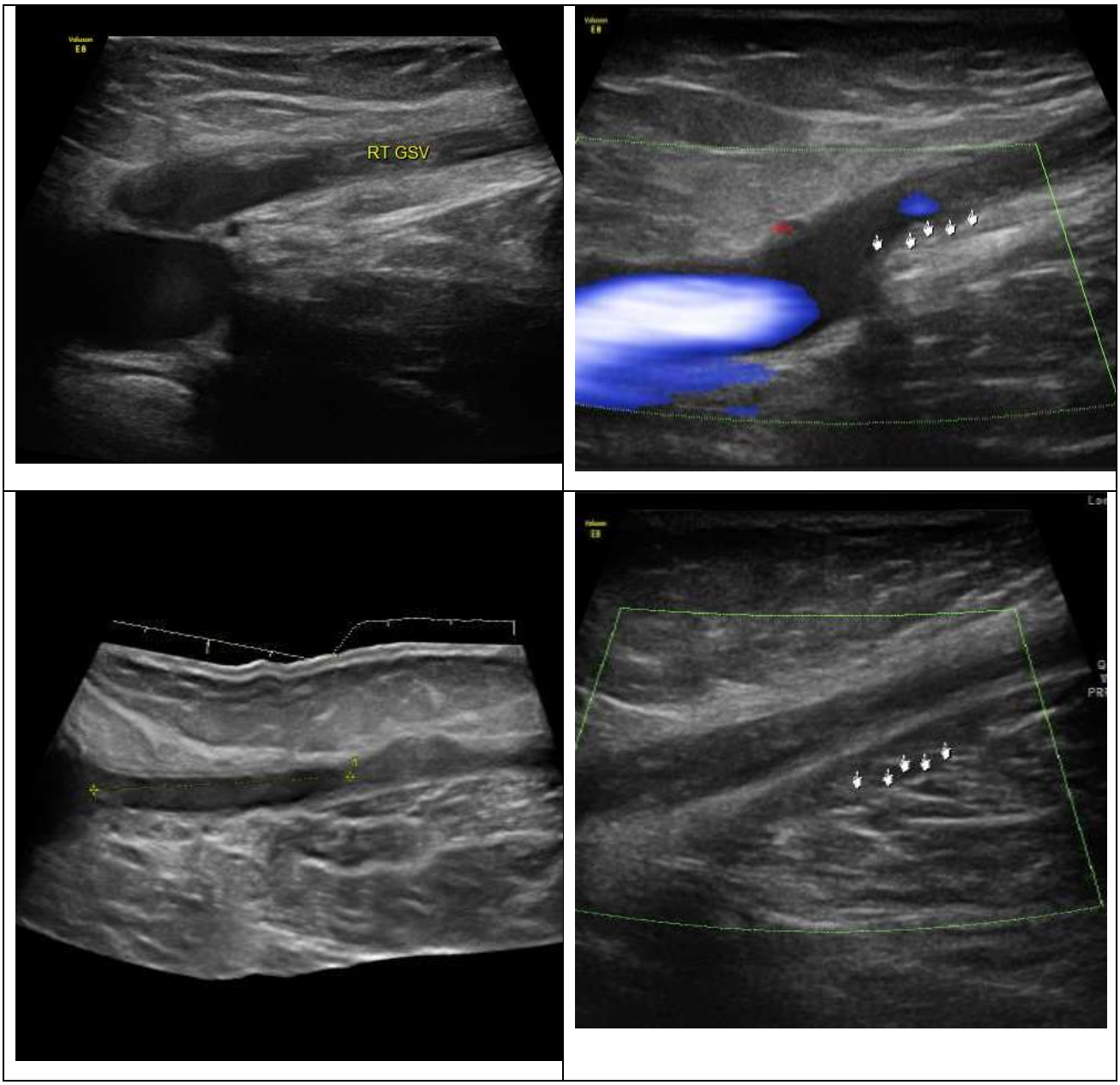
Clinical Outcomes

Technical success at 6 months was achieved in 676/680 veins (99.4%). One conversion to open surgery (0.2%) and one elective abortion (0.2%) were recorded; no major adverse events (skin burns, PE, DVT) occurred. Minor hematomas occurred in 10

patients (2.1%). Mean procedure time decreased from 55 ± 18 min in early cases to 42 ± 12 min after protocol standardization ($p < 0.001$).

Cases:

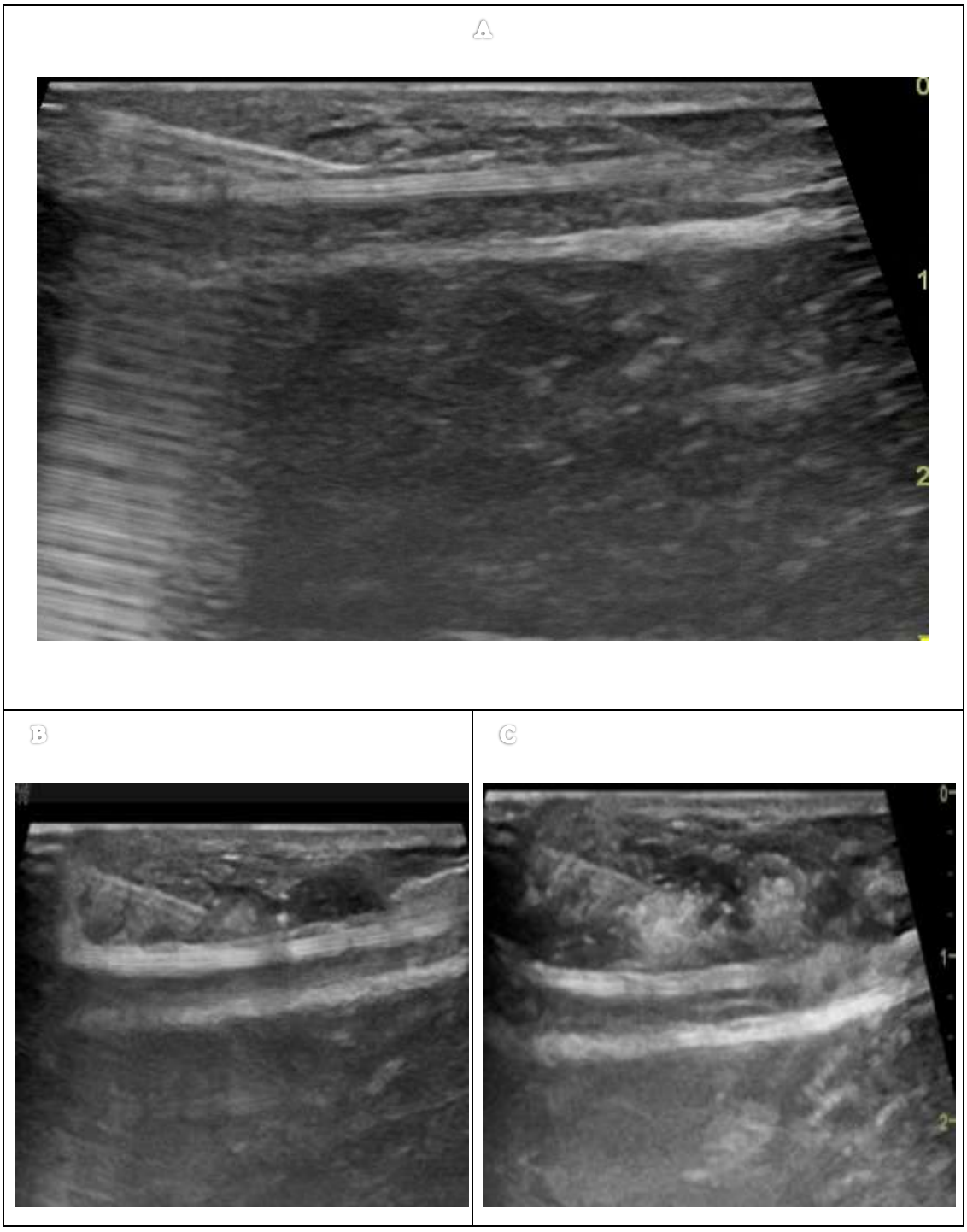
Case 1:



Case 1: Postoperative follow up showing adequately ablated great saphenous veins with no evidence of venous thrombosis or thrombus extension to the femoral vein.

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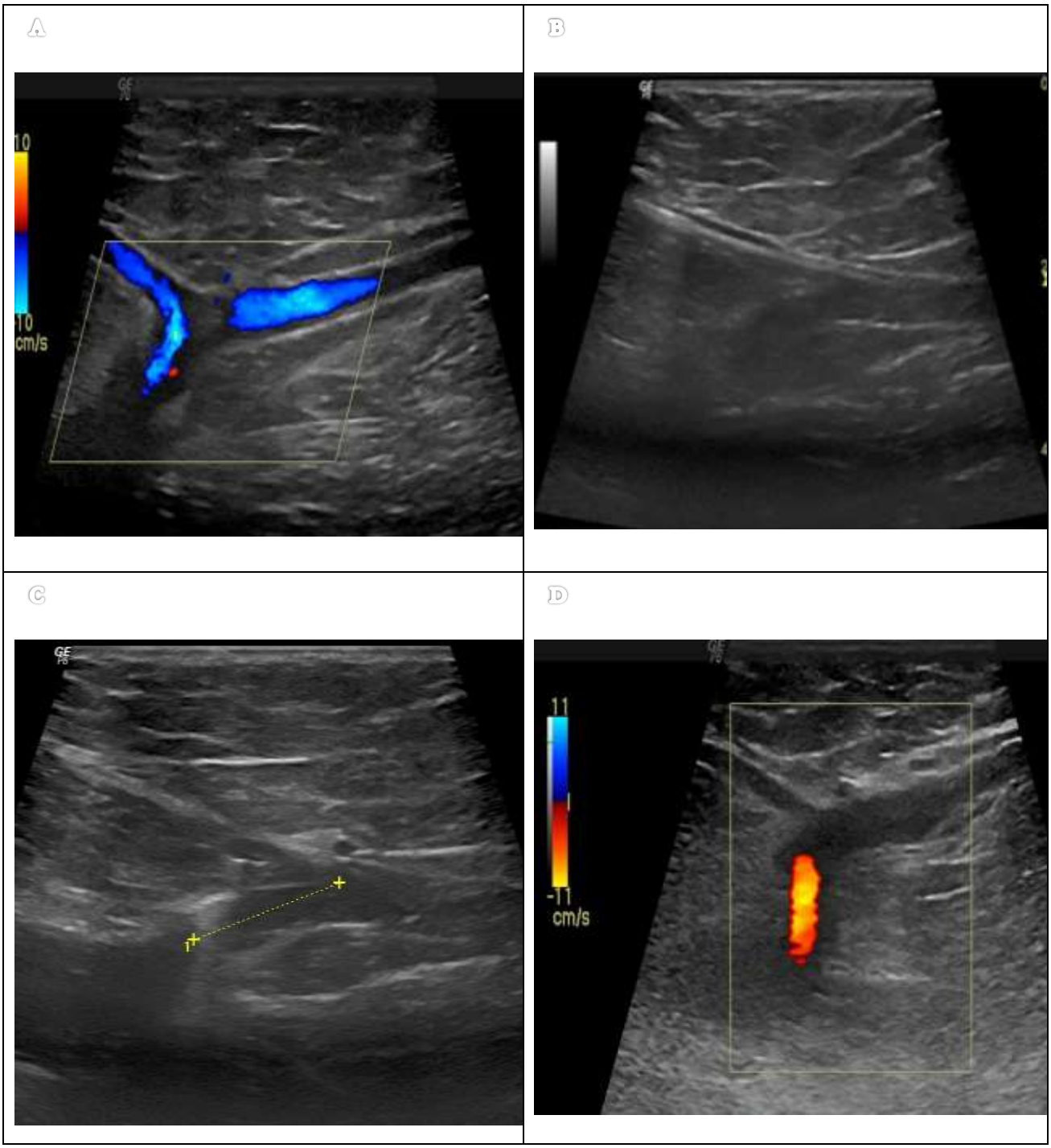
Case 2:



Case 2: Showing very superficial vein close to the skin: A: showing the needle close to the catheter before the injection. B& C: showing the displacement of the vein deep and away from the skin after the injection.

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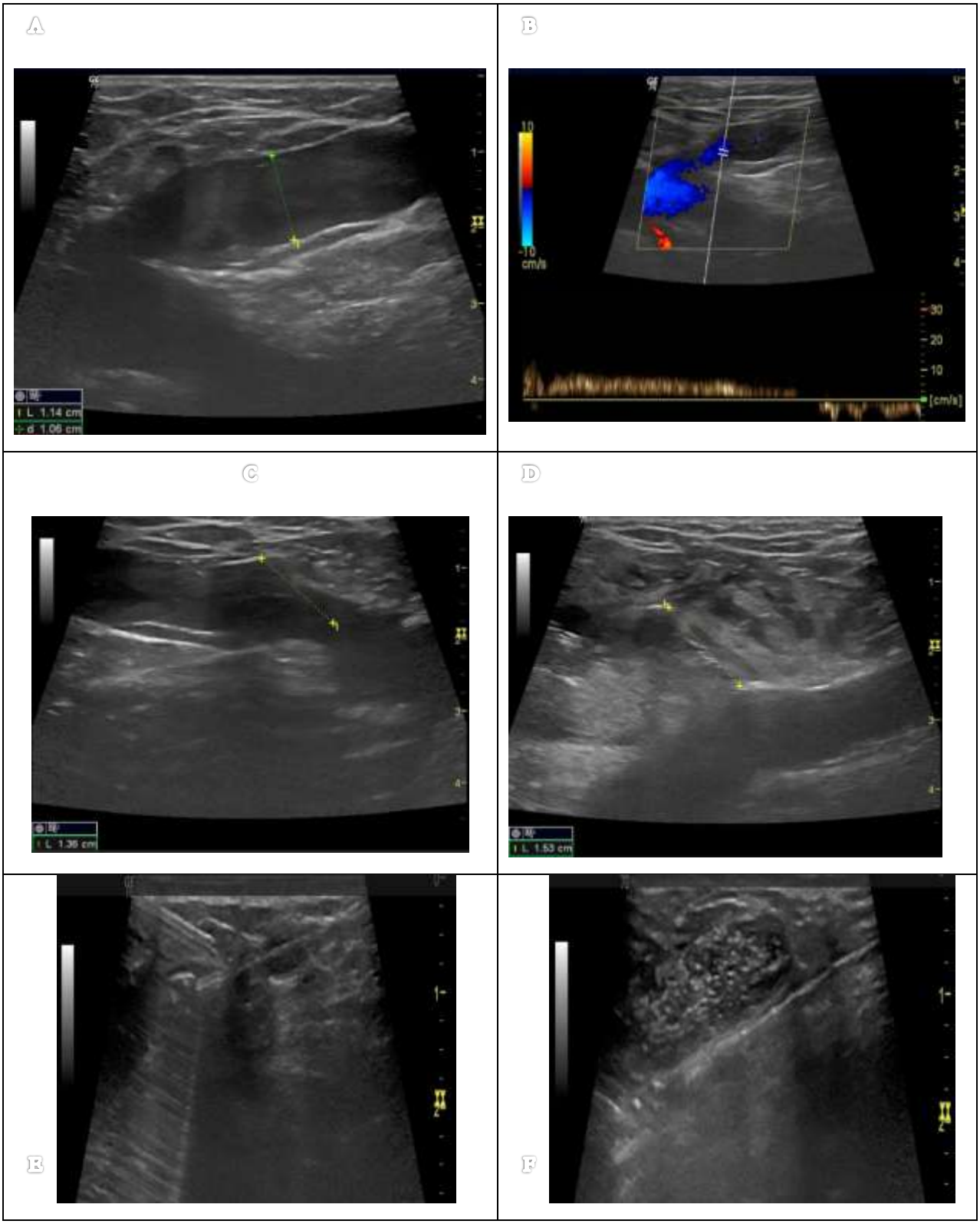
Case 3:



Case 3: Successfully ablated case. A: showing color flow within the SFJ and inferior epigastric vein. B: showing the catheter extending to the inferior epigastric vein. C: showing accepted distance between the catheter tip within the epigastric vein and SFJ. D: showing adequately ablated vein without any thrombus extension to the femoral vein

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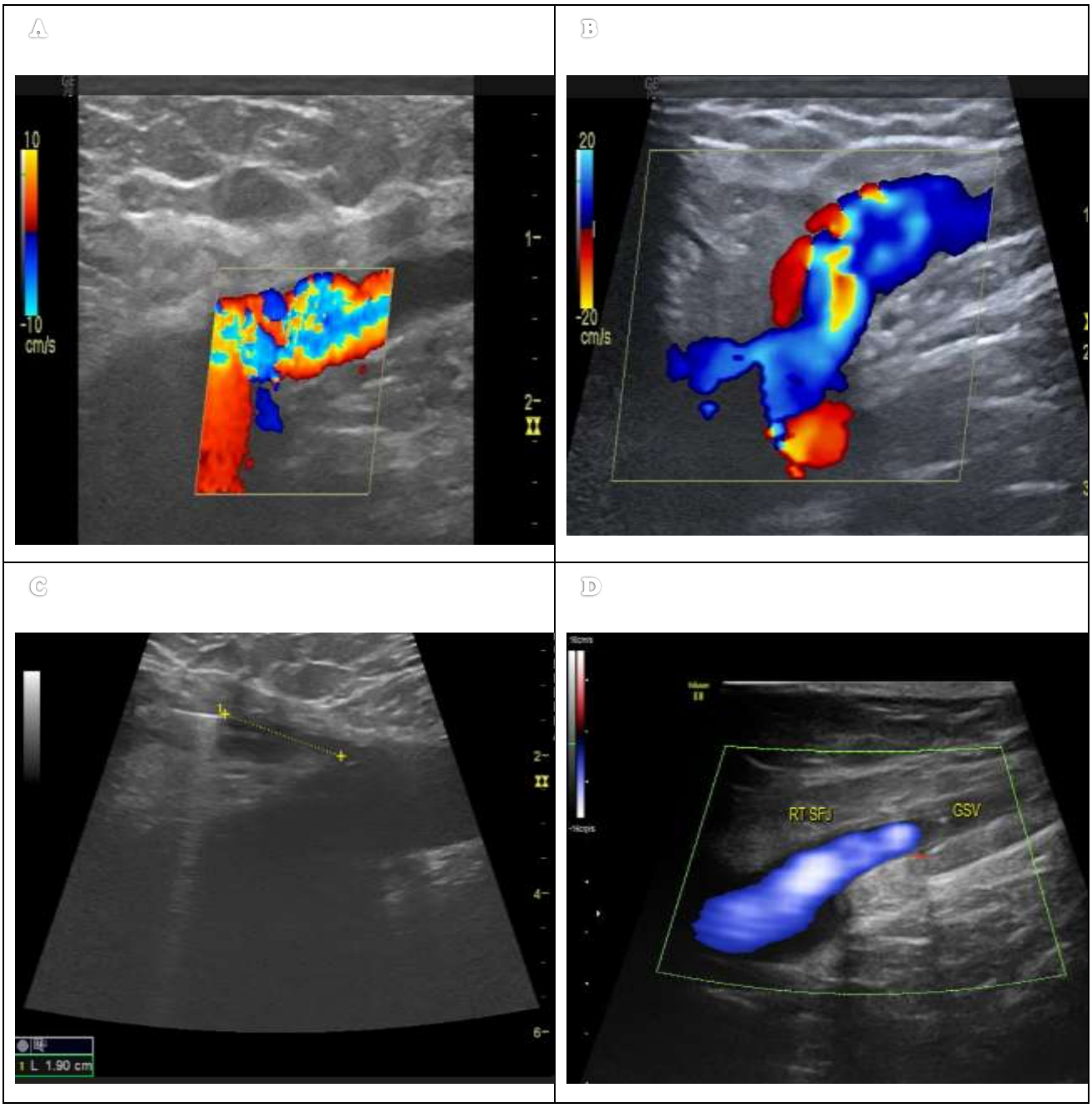
Case 4:



Case 4: With prominently dilated GSV and close to the skin. A: showing prominently dilated vein more than 1cm close to the SFJ. B: showing incompetent SFJ by pulsed wave Doppler study. C&D: showing accepted distance between the catheter

tip and the SFJ before and after tumescent injection. E&F: showing catheter close to the skin and forced injection of large amount of tumescent to separate the catheter from the skin by adequate distance.

Case 5:

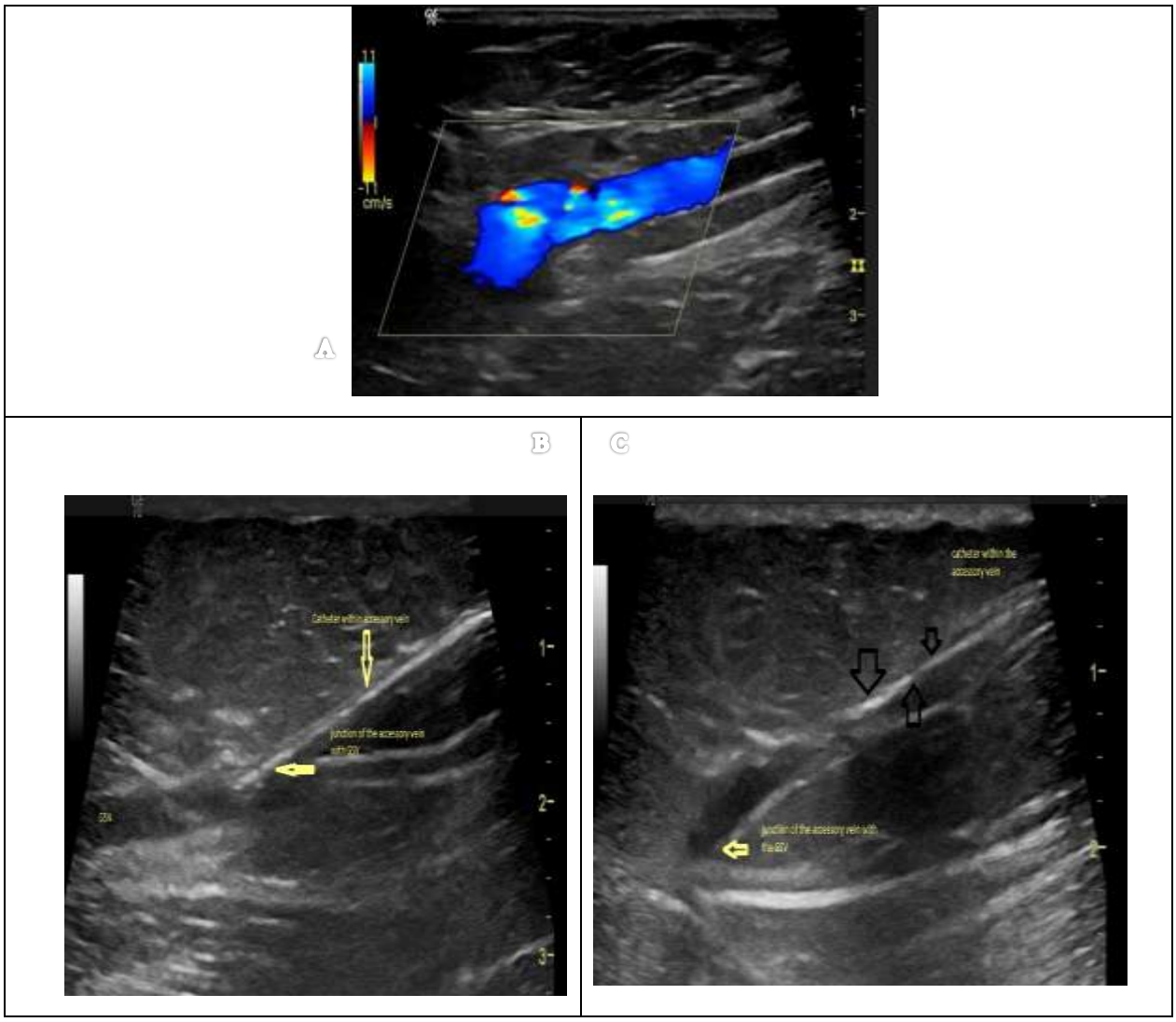


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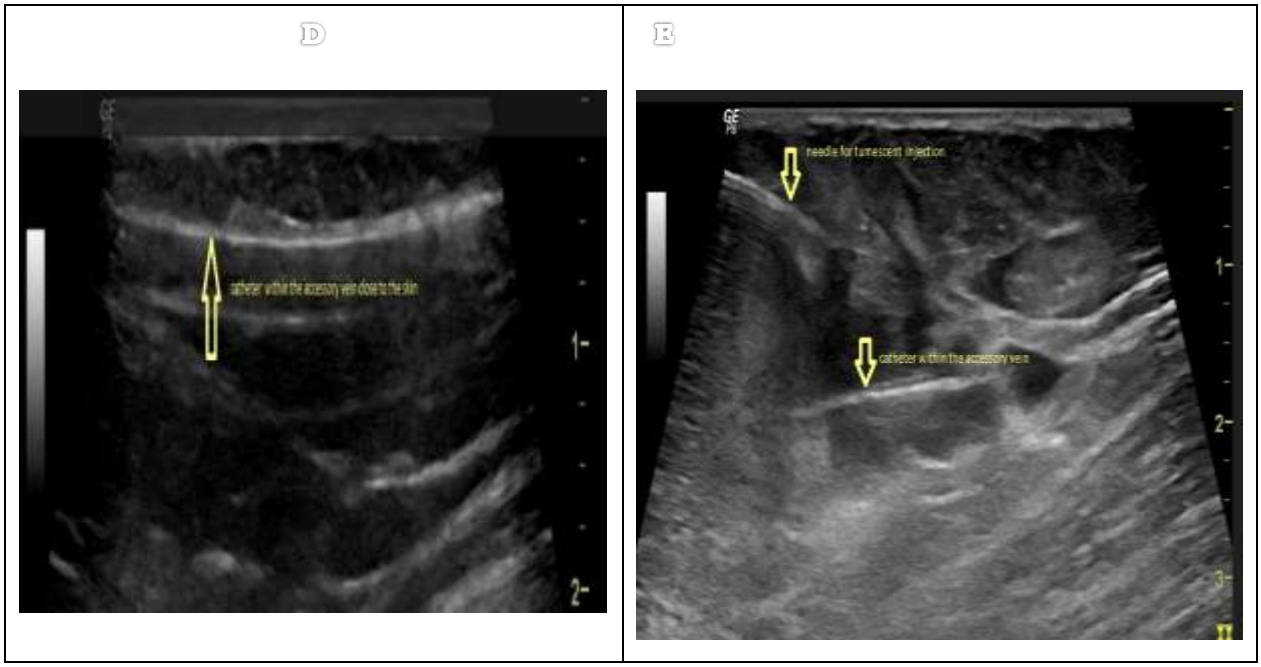


Case 5: A&B: Color Doppler image showing venous reflux, C: showing adequate distance from the SFJ and catheter tip, D&E: showing adequate venous ablation post procedure.

Case 6:



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Case 6: Pre and post for incompetent anterior accessory connected to the GSV at the midthigh with incompetent SFJ. A: color image with prominent incompetent SFJ. B&C: catheter within the accessory vein at its junction with GSV. D: very superficial accessory vein with large tumescent injection to separate the skin away from the catheter. E: Post operative image of obliterated junction between the accessory vein and the GSV

DISCUSSION

Our trial demonstrates that a systematic, algorithmic approach to ten common EVRFA challenges markedly improves procedural safety, efficiency, and technical success. Misleading pre-operative duplex imaging, particularly in settings with operator variability, can misdirect therapy; on-table rescanning by a dedicated vascular sonographer is indispensable **[12].**

Venous spasm and vasovagal reactions, frequent in non-sedated patients, responded uniformly to anesthesia, warming, and positional strategies, underscoring the value of sedation even in minimally invasive procedures.

Sheath-insertion failures in tortuous or sclerotic veins were nearly eliminated through wire-assisted techniques and localized vasodilators, echoing findings by **Vulakh et al. [13].**

Dual-sheath puncture prior to tumescent injection preserved access to adjacent refluxing veins, avoiding staged abortions or blind foam sclerotherapy. For tortuous or partially thrombosed segments, phased ablation via dual punctures achieved 100% occlusion without resorting to surgical bail-outs.

Preventing thermal skin injury in superficial veins through high-volume, multi-stage tumescent infiltration aligns with best practices in endothermal procedures **[14].**

Similarly, proactive management of acute thrombus at the saphenofemoral junction by cranial sheath placement and craniocaudal ablation averts potentially catastrophic pulmonary embolism. Finally, simple maneuvers focused manual compression of high-flow tributaries and standardized ultrasound probe positioning significantly reduced the need for repeat energy cycles and expedited catheter tracking.

CONCLUSION

Implementing standardized corrective algorithms for ten predictable EVRFA challenges in a cohort of 480 patients and 680 saphenous veins yielded a 99.4% six-month occlusion rate, with negligible conversion, abortion, or complication rates. Our protocols—centering on pre-procedure duplex validation, sedation and positional management, advanced sheath techniques,

phased ablation for complex anatomy, and optimized imaging—offer a reproducible framework to elevate the safety and efficacy of endovenous thermal ablation.

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