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## Original article

# Ultrasound Guided Foam Sclerotherapy for the Treatment of Primary Varicose Vein of Lower Limb

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## ABSTRACT

**Background:** Veins have one-way valves that prevent blood from backing up into the legs when we stand or sit. When the valves become incompetent [or begin to have reflux], blood pools and causes an increase in pressure in the leg veins. Leg veins become enlarged and twisted.

**Aim of the work:** The aim of the current study was to evaluate safety and efficacy of ultrasound guided foam sclerotherapy for the treatment of primary varicose vein.

**Patients and methods:** The current trial is a prospective observational cohort study. It had been carried out at Al-Azhar University Hospital [New Damietta], Egypt. It included Fifty patients who had great saphenous vein [GSV] reflux associated with saphenofemoral junction [SFJ] incompetence. They had been offered foam sclerotherapy as an alternative to standard surgical treatment or conservative management. The duration of the study extended between November 2019 to January 2020.

**Results:** results revealed that post intervention; duplex assessment revealed a radiologic success with complete obliteration of GSV and collaterals in 40 patients [80%]. six patients [12%] underwent direct re-injection for further one or two injection sessions over the following two weeks until complete occlusion of GSV and collaterals was obtained.

**Conclusion:** Foam sclerotherapy is effective & safe in treatment of primary varicose veins.

**Keywords:** Varicose veins; Foam; Sclerotherapy; Ultrasound-guided; Lower limbs.

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\* Main subject and any subcategories have been classified according to research topic.

## INTRODUCTION

Varicose veins [VVs] are a common disease worldwide, with different variations of its prevalence estimates<sup>[1]</sup>. It is defined as a dilatation of subcutaneous venous system to at least 3mm in diameter when patient standing in upright position. Varicose veins represented a part of chronic venous disorders [spider veins or fine telangiectasis [ $<1$ mm in diameter], reticular veins [1-3 mm in diameter], and chronic venous insufficiency]<sup>[2]</sup>.

Varicose veins could be presented by painful symptoms, disability, soft tissue damage or venous ulcer, resulting in marked impairment of quality of life<sup>[3]</sup> with consequent healthcare costs<sup>[4]</sup>. In addition, the unsightly appearance could be the main presentation with other types of pain [e.g, aching, heaviness, and pruritis] and early fatigue of the affected leg, especially with prolonged standing or sittings; the symptoms which could be relieved by leg elevation above the level of the heart. Mild edema is a usual finding in mild to moderate cases; with severe disease, signs include thrombophlebitis, hyperpigmentation, lipodermatosclerosis, ulceration, and bleeding from attenuated vein clusters<sup>[5]</sup>

Until the 1990s, high ligation combined with surgical stripping was the gold standard in the treatment of Great saphenous vein [GSV] insufficiency<sup>[6]</sup>. The introduction of minimally invasive therapies has revolutionized the treatment of varicose veins. Chemical ablation, in which foam or liquid sclerotherapy is administered, is a widely used technique for truncal and reticular veins. Endothermal catheter modalities, including endovenous laser ablation [EVLA] and radio-frequency ablation [RFA], have become preferred techniques due to excellent success rates<sup>[7]</sup>.

Foam sclerotherapy is a minimally invasive technology that provides efficacious treatment of venous reflux with minimal discomfort and “downtime” for patients<sup>[8]</sup>. Under ultrasound

guidance the saphenous vein is percutaneously accessed, and the catheter is advanced cephalic toward the saphenofemoral junction, then foam injected directly along great saphenous vein. Tessari method is mixing 1 ml 2% poliocanadol with 3 ml air via three-way tap. These methods have demonstrated clinical superiority to stripping and surgical ligation as well as significantly less postoperative pain and recovery time<sup>[9]</sup>.

In the present work, we suggested that, the use foam sclerotherapy under ultrasound guidance will increase the safety and efficacy of this treatment in VVs. In addition, this study represented our clinical experience.

## AIM OF THE WORK

To evaluate safety and efficacy of Ultrasound guided foam sclerotherapy for the treatment of primary varicose vein.

## PATIENTS AND METHOD

The current work is a prospective, single-center, observational cohort study, designed to estimate the results of ultrasound guided catheter directed foam sclerotherapy in management of primary truncal varicose veins. It had been carried out at department of vascular surgery, Al-Azhar University hospital [New Damietta, Egypt]. The study included fifty patients, who had great saphenous vein [GSV] reflux associated with saphenofemoral junction [SFJ] incompetence. All had been treatment by foam sclerotherapy as an alternative to standard surgical treatment or conservative management. The study duration extended between December 1<sup>st</sup>, 2019 to May 31<sup>st</sup>, 2020. Patients aged 20 to 60 years old, of both sexes, who presented with uni- or bi-lateral primary varicose veins of the lower limb and complained of one or more of the following [leg pain, varicosities, cosmetic disfigurement, leg u ulcer, itching, pigmentation and incompetent SFJ. On the other side, exclusion criteria were:

secondary lower limb varicose vein, lower limb lymphedema, recurrent varicose vein of lower limb, acute superficial thrombophlebitis of lower limb, lower limb Arterio-venous fistula [congenital or acquired], congenital anomalies of venous system of lower limb, general comorbidities, thrombosis of great saphenous vein [acute or chronic], lower limb skin infection, lower limb ischemia, lower limb malignancy, and drug hypersensitivity.

All eligible participants submitted to full history taking, general and local clinical examination, laboratory investigations and radiological examination [Duplex ultrasound of venous system of one or both lower limbs]. The decision to interfere had been made initially in the outpatient clinic on clinical data. The severity of the venous disease had been determined according to venous severity score [VSS] clinical classification<sup>[10]</sup>.

Patients who were selected foam sclerotherapy underwent an initial venous duplex scan using an ATL HDI 5000 [LOGIQ 7 PRO; GE Yokogawa Medical Systems, Tokyo, Japan] with a 5- to 10-MHz transducer, the lower frequencies had been used for deeper placed subcutaneous veins [ $>3$  cm below the skin] and higher frequencies for more superficial veins.

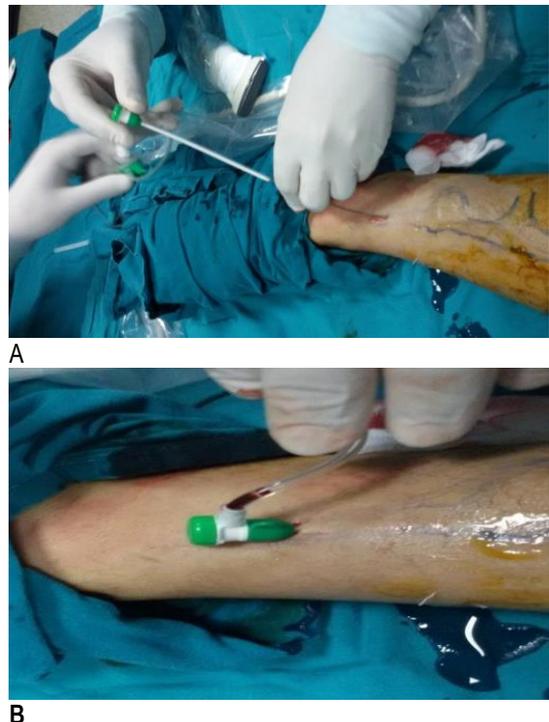
Transducer has an indicator line or LED that indicates the alignment of the sagittal plane of the transducer commonly a 10 MHz transducer was used for its ability to image most subcutaneous veins adequately. They had been examined in the standing position.

Reflux had been defined as a retrograde flow lasting for more than 0.5 sec in the target vein after manual calf compression release. The scan assessed all deep and superficial veins with marking of all perforating veins.

**The Technique:** The maneuver had been completed in operating room with local anesthesia. The limb had been scrubbed by Betadine

[povidone iodine 7.5 %]. The long saphenous vein had been cannulated under ultrasound vision with Seldinger Needle [18g]. The GSV had been routinely cannulated between the ankle and the knee, venous cut down had been performed at the lower level with difficult cannulation. The needle had been inserted close to the transducer tip and along the sagittal plane of the transducer.

When the needle pierced the skin, the tip had been visualized by the ultrasound. The transducer had been moved in small increments to be aligned with the needle, when injection carried out in transverse section, or altered in small increments to be aligned with the sagittal plane of transducer when injection carried out in the longitudinal section. Wire [0.035] had been introduced through the needle then sheath 6 fr. had been introduced over the wire which removed later [figure 1].



**Figure [1A and B]:** Sheath 6 Fr insertion over guidewire in great saphenous vein below left knee

We had been introduced straight catheter through the sheath under ultrasound vision till saphenofemoral junction [figure 2].



**Figure [2]:** Straight catheter inside great saphenous vein in the thigh

Two 20 ml Luer-lock siliconized syringes and three-way tap was prepared and Foam was generated mixing 3 ml 3% polidocanol in one syringe with 9 ml room air in another syringe by the *Tessari* method. The leg had been elevated to around 30 degrees before injection. The foam had been injected under ultrasound vision when tip of the catheter was away from SFJ > 5 cm and SFJ had been compressed by the US probe to prevent passage of foam to the common femoral vein [CFV] and the catheter had been released out with foam injection. Between injections the patient had been encouraged to plantar and dorsiflex the ankle to increase deep vein blood flow and speed neutralization of any foam that reached the deep vein. The treated limb had been wrapped by a layer of cotton padding followed by crepe bandage while leg had been elevated<sup>[11]</sup>.



**Figure [3]:** Catheter kit for catheter-directed foam sclerotherapy

After one week: the crepe bandage had been removed in out-patient clinic and the elastic stocking [class II] alone had been worn for one month. Immediate ambulation and return to normal activity had been encouraged with elastic stocking.

**Follow up:** The following duplex criteria were used to evaluate the therapeutic effects of foam sclerotherapy in the treated veins: 1] Occlusion/patency; 2] Length of occlusion; 3] Flow/ no flow, ante-grade flow / reflux [ $>$  or  $<$ 1sec]; 4] Compressibility of the vein; 5] Diameter of the vein; 6] Morphologic changes [fibrosis/ thickening of the vein wall]; and 7] Absence of the vein<sup>[12]</sup>. Patients had been assessed routinely one week after treatment where target vein patency had been assessed by duplex.

Patients with remaining visible varicosities or an obviously patent truncal vein had been offered further direct foam sclerotherapy under ultrasound guidance. Further assessment had been offered after one and six months, which included a clinical review and repeat duplex imaging. The treated truncal vein had been classified at ultrasound examination as occluded, partially occluded or patent and incompetent. An occluded vein had no identifiable patent lumen and no detectable blood flow along a significant proportion of its length. A partially occluded vein had a small remaining lumen with detectable flow only in an antegrade direction. A patent vein had remaining reflux flow throughout its length. Any residual segment of vein had been managed by direct foam sclerotherapy, as described above. Re-banding the leg in the region of further sclerotherapy had been usually appropriate.

**The primary outcome is the success rate:** a successful outcome was defined as complete occlusion of the target vein on duplex analysis at follow-up. Patients who underwent direct re-injection or had partial occlusion during the follow up period considered as successful. The secondary outcome included any complications,

venous severity score and varicose veins score at different intervals. The values at the end of follow up period [6 months] are the end points of the current study.

**Ethical considerations:** The study had been conducted according to declaration of Helsinki ethical code of conduct. All patients provided an informed consent after full explanation of the study protocol. In addition, the study protocol had been approved by the local Institutional Review Board [IRP] of Damietta Medical School, Al-Azhar University.

**Data analysis:** data had been collected prospectively and stored into an Excel sheet. Central tendency and dispersion measures had been computed for quantitative data, while qualitative data had been presented in frequency and percent distributions. Appropriate statistical tests of significance had been used. Repeated ANOVA test had been used to compare values across the time of the follow up visits. The value of significance had been set to < 0.05.

## RESULTS

In the current work, the majority of patients [80.0%] were males, their age ranged between 38 to 60 years [the mean age was 42.15 years]. the mean disease duration was 3.0±0.2 years; all patients had primary varicose veins, with 50% of VVs on the leg and 50% on the thigh; the median baseline anatomical extent was 5 [Table 1]. Clinical presentation of the patients showed the classic clinical presentation of the varicose veins. However, Pain, lower extremity edema, and visible varicosities were the most common presentations.

Some of the patients in addition to this were also bothered from the cosmetic appearance.

**One week follow up:** Post intervention; duplex assessment revealed a radiologic success with complete obliteration of GSV and collaterals in 40 patients [80%]. six patients [12%] underwent direct re-injection for further one or two injection sessions over the following two weeks until complete occlusion of GSV and collaterals was obtained. Four patients had thrombophlebitis [one of them had posterior tibial vein thrombosis] and only one of the patients needed re-intervention but refused reinjection [Table 2].

**After Six months,** 46 out of 50 patients presented for follow-up and were assessed by duplex examination. There was complete occlusion of treated veins in 42 patients [86%] and partial occlusion in 4 patients [8%]. Three of these four patients showed recanalization following complete occlusion obtained after the 1<sup>st</sup> week and one patient had partial occlusion which was present since the 1st week and remained during the follow-up at 6 months because the patient refused reinjection after the first week. Complications of foam sclerotherapy observed during follow-up were: pigmentation [n=11, 22%], superficial thrombophlebitis [n=4, 8%], and post. tibial vein thrombosis [n=2, 4%]. No patients in this study complicated with pulmonary embolism, two patients complained of blurring of vision and migraine which disappeared half an hour post injection [Table 2].

**Table [3]** revealed statistically significant progressive reductions venous severity score, pain score, edema score and varicose vein scores.

**Table [1]:** Patient's and disease characteristics among studied populations

Variable		Statistics
Sex [n,%]	Male	40[80.0%]
	Female	10[20.0%]
Age [years]		42.15 ± 8.45; 38.0 – 60.0
Disease duration [years]		3.0±0.2
Cause [Primary VV]		50[100.0%]
Site	Leg	25[50.0%]
	Thigh	25[50.0%]
Baseline anatomical extent [median, range]		5 [4-9]

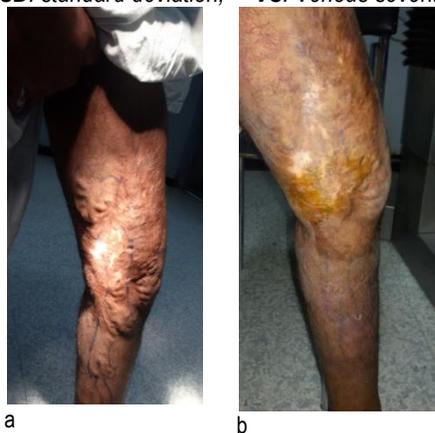
**Table [2]:** The outcome of injection among our patients

		One week		One month		6 months [46]	
		No.	%	No.	%	No.	%
Success	Complete obliteration of GSV and collaterals	40	80.0	49	98.0	42	84.0
	Underwent direct re-injection	6	12				
	Partial occlusion					4	8.0
	Success rate	46	92	49	98		
Complications	Thrombophlebitis	4	8				
	Patients needed re-intervention but refused reinjection.	1	2.5				
	Pigmentation					11	22
	superficial thrombophlebitis					4	2.5
	post. tibial vein thrombosis					2	4
	blurring of vision and migraine					3	6

**Table [3]:** Comparison of mean scores obtained prior to treatment and 1 week and 6 months after the treatment.

Items	Pre-treatment mean [SD]*	1 week mean [SD]	6 months mean [SD]	P value
VS**	5.68 [2.81]	3.40 [1.82]	1.27 [1.01]	<0.001*
Pain	1.86 [0.75]	0.55[0.38]	0.21 [0.32]	<0.001*
Oedema	0.74 [0.83]	0.48 [0.59]	0.07 [0.26]	<0.001*
V V***	2.16 [0.51]	1.26 [0.71]	0.54 [0.46]	<0.001*

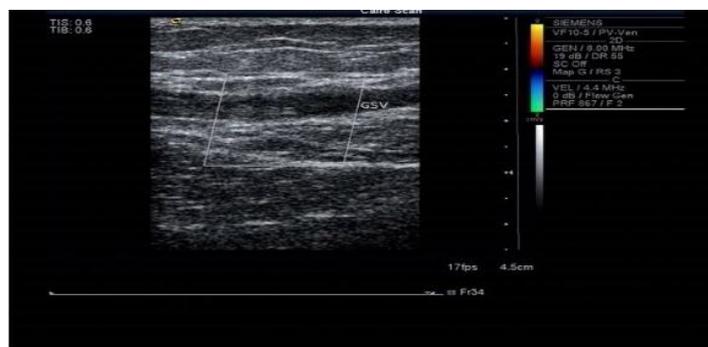
\*SD: standard deviation, \*\* VS: Venous severity, \*\*\*VV: Varicose veins. [p<0.001]



**Figure [4]:** 45 years male patient with left great saphenous varicosities and SFJ incompetence. [a] pre injection. [b] one week post.injection



**Figure [5]:** 38ys male patient with right great saphenous vein varicosities and SFJ incompetence. [a] Pre injection. [b] 1-week post injection [c] 6 months post injection



**Figure [6]:** 32 years female US picture for great saphenous vein Pre- [A] and 6ms [B] Post.injection

## DISCUSSION

The current work aimed to investigate the safety and efficacy of ultrasound guided foam sclerotherapy for the treatment of primary varicose vein. Males represented the majority of studied subjects [80.0%], with the early fifties as the most common affected age.

**DePopas & Brown**<sup>[13]</sup> reported that, the most relevant risk factors for VV are the patient age and gender. However, **Elshimy *et al.***<sup>[14]</sup> reported that females were predominant in their study [60.0%] with a mean age of 38.8 years. This younger age compared to the current work may be responsible for this inconsistency as contraceptives are one of the known risk factors for VV development.

Regarding clinical presentations, the current work not differ than the study of **Gafar *et al.***<sup>[15]</sup>, who reported that, 50% of patients complained of disfigurement, 60% complained from pain, 60% had heaviness, and 70% had edematous swelling.

**Mohamed *et al.***<sup>[16]</sup> revealed that skin disfigurement represented 45 %, heaviness and pain representing 55%.

Non-thermal, non-tumescent technology such as ultrasound-guided foam sclerotherapy [UGFS] has become a popular treatment modality for primary venous truncal incompetency as it is the least expensive modality, with a high safety profile<sup>[17]</sup>. UGFS employs the use of foamed sclerosant into varicose veins inducing fibrosis. Various methods for the creation of foamed sclerosant, where liquid sclerosant is forcibly mixed with air, oxygen or carbon dioxide, have been described. An ultrasound probe is employed in the technique to scan the veins and guide the intervention. UGFS helps target the non-obvious, non-visible, non-palpable diseased veins.

However, it is accepted that UGFS has lower efficacy with multiple treatments required for complete truncal ablation. Catheter-directed foam sclerotherapy [CDFFS] is a modification of UGFS that involves the use of an intravenous catheter to deliver the sclerosant along the lumen of the

saphenous trunk under duplex ultrasound visualization<sup>[18]</sup>.

The detailed results of the patient outcomes in the current work reflected the high success and safety profiles of UGFS. Our results were supported by study of **Elshimy *et al.***<sup>[14]</sup>, who reported significant improvement of VCSS two weeks after the UGFS in comparison to pre-intervention VCSS [ $P < 0.0001$ ].

In addition, **Figueiredo *et al.***<sup>[19]</sup> found a statistically significant improvement for pain, edema and inflammation in both surgery and sclerotherapy groups. **Guex, *et al.***<sup>[20]</sup> in large multicenter study, reported that, UGFS had been associated with a low rate of significant complications. Stroke, anaphylaxis and pulmonary embolism were extremely rare described complications.

**Morrison *et al.***<sup>[21]</sup> showed that the foam reaches the right ventricle easily with no significant complications. Also, **Figueiredo *et al.***<sup>[19]</sup> reported that foam had been always found in the deep venous system with no complications due to the small amount of foam and to high flow in the deep venous system.

Current results are supported by **Osman *et al.***<sup>[22]</sup> found that 28 patients [93.3%] showed complete clinical improvement of the pre-interventional symptoms two weeks after intervention, 2 patients [6.7%] showed no improvement in symptoms, four patients [13.3%] suffered from complications in the form of thrombophlebitis.

In the study of **Gamal *et al.***<sup>[23]</sup> in foam group, 92% of patient achieve total occlusion, 2% partial recanalization without reflux, 4% partial recanalization with reflux and 2% total recanalization; 3 patients received another session of UGFS and 4<sup>th</sup> one had been satisfied with results and refused to take another session. In

their surgery group, 100% achieve total occlusion at 1 month follow up.

Findings of our study on the other hand, contradicts that of **Elshimy et al.**<sup>[14]</sup>, as they reported a non-significant improvement of the VCSS at 6 months after UGFS in comparison to 2 weeks VCSS values. However, their results agree with the current study, when compared values at 6 months to pre-intervention values [ $p < 0.001$ ].

Successful sclerotherapy for the treatment of lower-extremity varicose veins requires detailed planning. In general, sclerotherapy is conducted respecting the order of the reflux points, working from larger caliber varicose veins to those with smaller caliber. Therefore, adequate clinical and anatomic assessments must be performed before treatment. In addition to the clinical assessment, vascular ultrasound plays a crucial role in the assessment of venous reflux in the lower extremities. It is a low-cost, non-invasive examination that is well tolerated by patients. It offers direct visualization, localization, and quantification of venous reflux with 95% sensitivity and 100% specificity<sup>[24]</sup>.

Foam sclerotherapy is preferred method due to less side effects and good contact of the drug with the vessel wall. This benefit is more observed when closing larger veins. Depending upon the size of the vein, appropriate volume of foam should be matched. Excess of foam volume might result in migration of foam to deep veins fostering deep vein thrombosis. Foam sclerotherapy is also known to have significant side effects such as thrombotic complications, visual disturbances, neurological complications, dry cough and other rare occurring side effects<sup>[25]</sup>.

According to **Maurya et al.**<sup>[26]</sup>, none of the patients developed any clinical evidence of any DVT. Only 10 of the 148 legs developed superficial vein thrombosis [6.75%], which was treated with analgesics, limb elevation and compression bandage. For all these complications, no treatment

was required, and they disappeared without any specific treatment. At the end of 6 months and 1-year, no complications and recurrences were found.

**Mohamed et al.**<sup>[27]</sup> revealed that concerning one month follow up, 7 cases out of 12 done via combined injection of the sclerosant via the phlebography and direct in the incompetent perforators revealed total occlusion of the injected veins with perfect outcome of the patient complain, 4 cases out of 12 U/S follow up revealed re-canalized perforators, with total occlusion of the GSV.

**Thomasset et al.**<sup>[28]</sup> reported that, with 3 months as a median time of follow up 79% of cases showed complete occlusion of target veins, 14% showed partial occlusion and the rest 6% showed complete patency. The target veins in this study were the great saphenous vein, small saphenous vein, accessory great saphenous, other unnamed veins or more than a single target vein.

On the other side, **Brittenden et al.**<sup>[29]</sup> reported that, foam sclerotherapy is not superior than traditional or laser surgical interventions. The results even better in surgery group, but with no significant difference. An interesting finding of the **Brittenden et al.** is the worsening of the quality of life after foam sclerotherapy. Unfortunately, the quality of life had not been addressed in the current work. Also, they reported a lower success rate than in the current work. They reported complete successes in 54.6%, partial success without reflux [22.9%] and partial success with reflux [4.4%]. Thus, the overall success rate of foam sclerotherapy is [86.3%].

Finally, **Marsden et al.**<sup>[30]</sup> and **Epstein et al.**<sup>[31]</sup> addressed the cost effectiveness of different treatment modalities of varicose veins, and they concluded that, endothermal ablation, and radiofrequency ablation, respectively, are the most cost-effective treatments. Epstein *et al.* ranked

USGF at the sixth position, while Marsden *et al.* study ranked it in the second position. The heterogeneity of studies, different inclusion criteria and difference samples sizes could explain the variations reported in literature.

In short, USGF represented effective and safe treatment maneuver of saphenous trunk varicose vein. In addition, foam sclerotherapy is simple, safe, effective, and a more satisfactory.

Although our study has some limitations, including the small sample size and relatively short follow-up period, it has demonstrated that foam sclerotherapy effectively eliminated axial reflux in saphenous veins and resulted in a significant reduction in venous diameters. Other limitations of the current work are the absence of a comparative group and the quality of life had not been addressed. Further studies are needed in order to determine whether the reduction of venous diameter truly contributes to the maintenance of the good scores obtained with foam sclerotherapy.

**Financial and Non-financial relationships and Activities of Interest**

None

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