



Colour Doppler Evaluation of Erectile Dysfunction in Tertiary Care Centre

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ABSTRACT

Background: Erectile dysfunction (ED) is a widespread health issue affecting men across different age groups. Its complexity arises from the interaction of arterial, venous, sinusoidal, and nervous systems, with dysfunctions leading to ED. Various factors, such as cardiovascular diseases, diabetes, and lifestyle habits, influence ED. Penile Doppler sonography, a non-invasive method, is instrumental in evaluating ED, offering insights into penile anatomy and vascular flow patterns.

Objectives: To assess the diverse causes of Erectile Dysfunction using Colour Doppler in a tertiary care center.

Materials and Methods: In a prospective observational study from March 2021 to August 2022, 45 patients clinically diagnosed with ED were referred from various departments to the Department of Radio-Diagnosis, Vydehi Institute of Medical Sciences and Research Centre. Evaluation involved an intracavernosal injection of papaverine, followed by peak systolic and EDV measurements in the right cavernosal artery at 5-minute intervals for 30 minutes.

Results: Colour Doppler ultrasound effectively diagnosed ED by showcasing arterial and venous insufficiencies. Systolic velocities below 25cm/s indicated arterial insufficiency, while an EDV over 5cm/s denoted venous incompetence. The method is likely to undergo further refinement in the diagnostic criteria.

Conclusion: Penile Doppler ultrasound emerges as a secure, minimally invasive, and efficient method for evaluating ED. It offers a fast and straightforward assessment, making it a preferred choice in clinical settings.

Key Words: *Erectile dysfunction, penile colour doppler, papaverine injection*



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INTRODUCTION

Erectile dysfunction is defined as the consistent inability to generate or maintain an erection of sufficient rigidity for sexual intercourse [1]. According to some, the condition should persist for six months, although no specific time period is specified. As men age and co-morbid conditions increase, the prevalence of this disorder rises sharply [2].

There are many underlying pathologies that can cause erectile dysfunction [3]. There are many diseases that can lead to erectile dysfunction, such as those affecting the penile arteries, the nerves, hormone levels, smooth muscle tissue, or the endothelium of the body. Cardiovascular disease, diabetes mellitus, hyperlipidemia, and hypertension are among some of the disorders associated with erectile dysfunction [4].

There is a possibility, especially among younger men, that some patients with ED may have a primarily psychological issue, in addition to an organic disease. When ED has an organic cause, there are usually psychological consequences such as marital problems, conflict in relationships, cultural norms, loss of self-esteem, shame, anxiety, and depression. As it negatively impacts the patient and their partner's quality of life, erectile dysfunction can cause considerable emotional damage to patients.

Often, erectile dysfunction is caused by a combination of factors. A psychological or organic etiology can be distinguished early on when a condition is occurring.

There are also many other causes of erectile dysfunction, including neurological diseases (like multiple sclerosis), hormonal disorders (like hypogonadism, thyroid), traumatic injuries (such as pelvic fractures and spinal cord injuries),

hyperlipidemia, stroke, sleep apnea, COPD, glaucoma, multiple sclerosis, sequelae of priapism, depression, prostatic hyperplasia with lower urinary symptoms (BPH with LUTS), iatrogenic (e.g. post transurethral resection of the prostate) and a variety of medications (antidepressants, antihypertensives, antipsychotics, opioids, and recreational drugs).

The risk of erectile dysfunction is greatly increased by cardiovascular disease. There is a significant erectile dysfunction problem in almost 50% of men who have coronary artery disease as determined by cardiac catheterization [5]. This is partly due to the similar size and shape of the coronary arteries and penile cavernous arteries and their tendency to develop atherosclerosis. Since the cavernosal arteries are smaller, they will develop atherosclerotic plaque blockage earlier, resulting in vasculogenic ED years before coronary artery disease becomes clinically apparent [6].

Common side effects of intracavernosal injection of papaverine include penile pain, penile ecchymosis, prolonged erection, penile edema and rash many of which are self-limiting. If priapism occurs, the patient must seek emergency medical care, which may involve blood aspiration, surgical shunt creation, or intravenous phenylephrine infusion (ICI) to promote cavernosal vasoconstriction.

USG Doppler of the penile circulation is a minimally invasive tool that can provide insight to organic causes of erectile dysfunction. It can detect arterial/venous insufficiency at the earliest so that adequate treatment can be provided to the patient.

Since many studies have not determined detailed colour doppler evaluation and correlation, this study has been undertaken.

AIMS AND OBJECTIVES

To determine the various causes of erectile dysfunction by colour Doppler in tertiary care center.

MATERIALS AND METHODS

Source of Data

Patients clinically diagnosed with erectile dysfunction and referred from the Departments of Neurology, Endocrinology, Urology, General Surgery and Psychiatry to Department of Radio- Diagnosis, Vydehi Institute of Medical Sciences and Research Centre for penile Doppler.

METHOD OF COLLECTION OF DATA

- **Duration of study** – March 2021 to August 2022.
- **Type of study** – Prospective observational study.
- **Inclusion criteria**- Male patients presenting with symptoms of erectile dysfunction aged 21 years and above.
- **Exclusion criteria**- Patients with heart diseases, known case of Peyronie's Disease and patients with history of drug allergy.
- **Sampling technique**- Consecutive samples will be taken
- **Sample size** – The sample size for the present study was calculated from the reference study [7], using the formula $N = \frac{Z^2 \alpha/2 P(1-P)}{D^2}$ where,

N=number of cases required.

$Z^2 \alpha/2$ =critical value for 95% confidence intervals=1.96.

P= sensitivity/specificity of a given diagnostic aid from reference article= 97%,

D=pre-fixed margin of error=5%.

Substituting the above values in the equation, $N = 1.96^2 * 97^2 / 25 = 45$.

Therefore, a total number of **45** cases with erectile dysfunction were required for the study to have 95% confidence intervals and 80% power.

Methodology

This study employed a structured methodology involving 45 patients who met the inclusion criteria. Once their informed written consent was acquired, the following steps were undertaken:

Initial Examination:

- A greyscale ultrasound of the penis was initially performed to identify and exclude any potential penile pathologies.
- Pre-injection Doppler measurements were taken to note the peak systolic velocity (PSV) and end-diastolic velocity (EDV) for both the left and right cavernosal arteries.

Papaverine Injection:

- Adhering to strict aseptic measures, a 2ml intracavernosal injection of papaverine was administered using a 28G needle. The injection site was under ultrasound guidance and located near the base of the penis. Once the injection was successfully delivered, the area was massaged to ensure even distribution of the medication.

Post-Injection Doppler Measurements:

- Following the injection, Doppler measurements of the cavernosal artery were taken at regular intervals of 5 minutes, lasting up to the 20th minute. During each interval, the diameter of the cavernosal artery, PSV, and EDV were noted for both the left and right arteries. The primary focus of these measurements was to ascertain:
- A systolic velocity below 25cm/s, indicating arterial insufficiency.
- An EDV exceeding 5cm/s, signifying venous incompetence.

Erection Grading:

At the 10-minute mark post-injection, the quality of the erection was assessed and graded based on the following scale:

- No erection.
- Slight tumescence.
- Full volume without rigidity.
- Incomplete rigidity but sufficient for intercourse.
- Full erection with no compromises in rigidity.

This comprehensive methodology ensured a rigorous assessment of erectile dysfunction in the involved participants, leveraging both the diagnostic capabilities of Doppler ultrasound and the pharmacological effects of papaverine.

STATISTICAL ANALYSIS

All the data collected were coded and entered in Microsoft Excel sheet which was re-checked and analysed using SPSS statistical software version 22. Quantitative variables were summarised using mean and standard deviation (SD). Categorical variables were represented using frequency and percentage. The data were represented using the tables, figures, bar diagram and pie chart. Independent sample t-test was used to test statistical significance of difference between means of variables among two independent groups. Pearson Chi-square test and Fisher's exact test were used for comparing categorical variables between groups. A p value of <0.05 was considered statistically significant.

RESULTS

General Demographic Variables

Table 1: Presentation of continuous variables in the study

Variable	Minimum	Maximum	Mean	Standard deviation
Age	20	71	37.27	12.590
BMI	16.50	33.00	22.95	2.97

Table 2: Age distribution

Age distribution	N	Percentage
≤25 yrs	9	20.0%
26 – 35 yrs	16	35.6%
36 – 45 yrs	10	22.2%
46 – 55 yrs	5	11.1%
56 – 65 yrs	4	8.9%
>65 yrs	1	2.2%
Total	45	100%

In our study, majority of the patients belonged to the age group of 26-35 years (16/45 patients (35.60%)), followed by 36-45 years (10/45 patients) (22.20%), followed by <25 years (9/45 patients) (20.00%) followed by 46-55 years (5/45 patients) (11.10%) followed by 56-66 years (4/45 patients) (8.90%), and least seen in >65 years (1/45 patients) (2.20%).

Table 3: Presentation of comorbidities in the study

Comorbidity	N=45	%
Nil	29	64.4
Hypertension	4	8.9
Type 2 diabetes	3	6.7
Dyslipidemia	6	13.3
Type 2 diabetes and Hypertension	2	4.4
Dyslipidemia and Hypertension	1	2.2

Majority of the patients had no comorbidities. Out of 45 patients include in our study, 6 patients (13.3%) had history of dyslipidemia 4 patients (8.9%) had history of hypertension, 3 patients (6.7%) had history of type 2 diabetes mellitus, 2 patients (4.4%) had both diabetes and hypertension and 1 patient (2.3%) had history of both dyslipidemia and hypertension.

Table 4: Presentation of habits in the study

Habit	N	%
Nil	33	73.3
Chronic smoker	9	20.0
Chronic alcoholic	2	4.4
Chronic smoker and alcoholic	1	2.2

Majority of the patients had no associated habits. Out of 45 patients enrolled in our study, 9 patients (20.0%) were chronic smoker, 2 patients (4.4%) were chronic alcoholic and 1 patient (2.2%) was both chronic alcoholic and smoker.

Table 5: Distribution of erectile grading within the sample

Erectile grading	N	%
2	17	37.8
3	2	4.4
4	1	2.2
5	25	55.6

Out of 45 patients, 25 (55.6%) had Grade 5 penile erection post 10 mins of injection papaverine during the procedure, 17 patients (37.8%) had Grade 2, 2 patients (4.4%) had Grade 3 while 1 patient (2.2%) had Grade 4.

VENOUS INSUFFICIENCY

Table 6: Comparison of continuous demographic details between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Age (in years)	No	35	38.03	12.37	.454
	Yes	10	34.60	13.66	
BMI (kg/m ²)	No	35	23.15	3.04	.426
	Yes	10	22.29	2.73	
Testosterone (ng/ml)	No	35	371.99	120.68	.621
	Yes	10	351.00	104.91	

None of the variables - age, BMI and testosterone varied between those with and without venous insufficiency.

Table 7: Comparison of comorbidities between those with and without venous insufficiency

Venous insufficiency	Comorbidities						Chi square
	Nil	Hypertension	Type 2 DM	Dyslipidemia	Hypertension + DM	Hypertension + dyslipidemia	P value
No	22	3	3	4	2	1	2.22 (.818)
	62.9%	8.6%	8.6%	11.4%	5.7%	2.9%	
Yes	7	1	0	2	0	0	
	70.0%	10.0%	0.0%	20.0%	0.0%	0.0%	

Distribution of comorbidities did not vary between those with and without venous insufficiency.

Table 8: Comparison of habits between those with and without venous insufficiency

Venous insufficiency	Habits				Chi square
	Nil	Smoker	Alcoholic	Smoker + alcoholic	P value
No	24	9	2	0	7.13 (.068)
	68.6%	25.7%	5.7%	0.0%	
Yes	9	0	0	1	
	90.0%	0.0%	0.0%	10.0%	

Distribution of habits did not vary between those with and without venous insufficiency.

Table 9: Comparison of genital examination findings between those with and without venous insufficiency

Venous insufficiency	Genital examination	Chi square
	Normal	P value
No	35	-
	100.0%	
Yes	10	
	100.0%	

Genital examination findings did not vary between those with and without venous insufficiency.

Table 10: Comparison of grey scale USG findings between those with and without venous insufficiency

Venous insufficiency	Grey scale USG findings	Chi square
	Normal	P value
No	35	-
	100.0%	
Yes	10	
	100.0%	

Grey scale USG findings were normal in all patients.

Table 11: Comparison of pre-injection cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	.99	1.75	.470
	Yes	10	.58	.074	
PSV (cm/sec)	No	35	11.88	4.84	.002
	Yes	10	17.74	5.19	
EDV (cm/sec)	No	35	1.64	.90	.106
	Yes	10	2.16	.69	

Only the pre-injection PSV values were significantly greater in those with venous insufficiency.

Table 12: Comparison of 0th minute cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	1.25	1.95	.435
	Yes	10	.76	.05	
PSV (cm/sec)	No	35	28.38	12.37	.004
	Yes	10	41.92	11.84	
EDV (cm/sec)	No	35	4.70	3.14	.016
	Yes	10	7.56	3.30	

The 0th minute PSV and EDV values were significantly greater in those with venous insufficiency.

Table 13: Comparison of 5th minute cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	1.42	2.64	.515
	Yes	10	.87	.117	
PSV (cm/sec)	No	35	33.55	13.463	.054
	Yes	10	42.47	8.03	
EDV (cm/sec)	No	35	3.72	2.23	.000
	Yes	10	7.76	2.97	

The 5th minute EDV values were significantly greater in those with venous insufficiency.

Table 14: Comparison of 10th minute cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	1.44	2.41	.492
	Yes	10	.91	.119	
PSV (cm/sec)	No	35	33.90	14.76	.046
	Yes	10	44.05	9.09	
EDV (cm/sec)	No	35	2.90	.67	.000
	Yes	10	7.12	2.04	

The 10th minute EDV values were significantly greater in those with venous insufficiency.

Table 15: Comparison of 15th minute cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	1.41	2.40	.497
	Yes	10	.89	.087	
PSV (cm/sec)	No	35	28.94	11.38	.005
	Yes	10	40.00	6.39	
EDV (cm/sec)	No	35	2.62	.988	.000
	Yes	10	6.20	2.35	

The 15th minute PSV and EDV values were significantly greater in those with venous insufficiency.

Table 16: Comparison of 20th minute cavernous artery findings between those with and without venous insufficiency

Variable	Venous insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	35	1.36	2.16	.489
	Yes	10	.88	.15	
PSV (cm/sec)	No	35	26.68	10.15	.001
	Yes	10	39.30	10.84	
EDV (cm/sec)	No	35	2.60	1.05	.000
	Yes	10	6.49	1.98	

The 20th minute PSV and EDV values were significantly greater in those with venous insufficiency.

ARTERIAL INSUFFICIENCY

Table 17: Comparison of continuous demographic details between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Age (in years)	No	37	36.81	13.33	.607
	Yes	8	39.38	8.70	
BMI (kg/m ²)	No	37	22.87	2.98	.696
	Yes	8	23.33	3.07	
Testosterone (ng/ml)	No	37	373.87	123.84	.424
	Yes	8	337.04	72.35	

None of the variables-age, BMI and testosterone varied between those with and without arterial insufficiency.

Table 18: Comparison of comorbidities between those with and without arterial insufficiency

Arterial insufficiency	Comorbidities						Chi square
	Nil	Hypertension	Type 2 DM	Dyslipidemia	Hypertension + Type 2 DM	Hypertension + dyslipidemia	P value
No (N=37)	25	3	3	3	2	1	6.017 (.305)
	67.6%	8.1%	8.1%	8.1%	5.4%	2.7%	
Yes (N=8)	4	1	0	3	0	0	
	50.0%	12.5%	0.0%	37.5%	0.0%	0.0%	

Distribution of comorbidities did not vary between those with and without arterial insufficiency.

Table 19: Comparison of habits between those with and without arterial insufficiency

Arterial insufficiency	Habits				Chi square
	Nil	Smoker	Alcoholic	Smoker + alcoholic	P value
No (N=37)	28	6	2	1	2.29 (.514)
	75.7%	16.2%	5.4%	2.7%	
Yes (N=8)	5	3	0	0	
	62.5%	37.5%	0.0%	0.0%	

Distribution of habits did not vary between those with and without arterial insufficiency.

Table 20: Comparison of genital examination findings between those with and without arterial insufficiency

Arterial insufficiency	Genital examination	Chi square
	NORMAL	P value
No (N=37)	37	-
	100.0%	
Yes (N=8)	8	
	100.0%	

Genital examination findings did not vary between those with and without arterial insufficiency.

Table 21: Comparison of grey scale USG findings between those with and without arterial insufficiency

Arterial insufficiency	Grey scale USG findings	Chi square
	Normal	P value
No (N=37)	37	-
	100.0%	
Yes (N=8)	8	
	100.0%	

Grey scale USG findings were normal in all patients.

Table 22: Comparison of pre-injection cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	.97	1.70	.497
	Yes	8	.55	.11	
PSV (cm/sec)	No	37	13.73	5.37	.149
	Yes	8	10.65	5.40	
EDV (cm/sec)	No	37	1.76	.93	.928
	Yes	8	1.73	.66	

None of the pre-injection cavernous artery findings varied between the two groups.

Table 23: Comparison of 0th minute cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	1.23	1.89	.452
	Yes	8	.718	.08	
PSV (cm/sec)	No	37	34.05	13.04	.003
	Yes	8	19.10	6.52	
EDV (cm/sec)	No	37	5.45	3.43	.629
	Yes	8	4.81	3.14	

The 0th minute PSV values were significantly greater in those without arterial insufficiency.

Table 24: Comparison of 5th minute cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	1.41	2.57	.498
	Yes	8	.78	.13	
PSV (cm/sec)	No	37	39.62	10.20	.000
	Yes	8	16.66	4.59	
EDV (cm/sec)	No	37	4.89	3.12	.176
	Yes	8	3.34	1.03	

The 5th minute PSV values were significantly greater in those without arterial insufficiency.

Table 25: Comparison of 10th minute cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	1.43	2.33	.455
	Yes	8	.80	.137	
PSV (cm/sec)	No	37	40.41	11.79	.000
	Yes	8	16.48	5.03	
EDV (cm/sec)	No	37	4.06	2.22	.128
	Yes	8	2.81	.57	

The 10th minute PSV values were significantly greater in those without arterial insufficiency.

Table 26: Comparison of 15th minute cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	1.41	2.33	.449
	Yes	8	.77	.148	
PSV (cm/sec)	No	37	34.32	10.02	.000
	Yes	8	17.87	6.87	
EDV (cm/sec)	No	37	3.54	2.19	.371
	Yes	8	2.83	.90	

The 15th minute PSV values were significantly greater in those without arterial insufficiency.

Table 27: Comparison of 20th minute cavernous artery findings between those with and without arterial insufficiency

Variable	Arterial insufficiency	N	Mean	Standard deviation	P value
Cavernous artery diameter (mm)	No	37	1.36	2.10	.429
	Yes	8	.76	.17	
PSV (cm/sec)	No	37	32.23	10.44	.000
	Yes	8	16.76	6.55	
EDV (cm/sec)	No	37	3.64	2.21	.237
	Yes	8	2.67	.99	

The 20th minute PSV values were significantly greater in those without arterial insufficiency.

DISCUSSION

Erectile dysfunction (ED) is a medical condition where an individual is unable to maintain a firm erection for satisfactory sexual activity. Color Doppler sonography, post an intracavernosal injection of a vasodilating agent, is a prominent method to evaluate the cause, particularly in discerning vasogenic causes.

Our study encompassed 45 patients. The majority (35.6%) were aged 26 to 35 years, with the mean age being 37 years. ED's prevalence and its association with age and vascular risk factors are evident, as other studies like that of Tahir Karadeniz et al. and the Massachusetts male aging study have shown [8].

Interestingly, most patients in our study had no co-morbidities or lifestyle risk factors like smoking or alcoholism. Yet, studies, such as those by Jim Z Li et al. [9] and Tsai et al. [10], have shown a significant correlation between ED and various cardiometabolic and psychological conditions. These lifestyle risk factors, like alcohol intake and smoking, are modifiable, indicating that interventions targeting these can potentially reduce ED incidence.

The cavernosal artery diameter was found to be normal in all patients. In our sample, 18 had a vasculogenic cause for their ED. A significant number (10 patients) had venous insufficiency, predominantly younger than 25 years. Most had no significant comorbidities causing the insufficiency. These patients were treated using vacuum erection devices (VED) and deep dorsal vein ligation. Hisham S. Bassiouny's study in 1991 demonstrated the utility of penile duplex scanning in differentiating venogenic from arteriogenic impotence [11, 12].

8 patients were diagnosed with arterial insufficiency, mostly aged 36-45. Studies by Ulas Savas Yavas et al. [13] in 2017 have shown the value of penile color Doppler sonography in diagnosing arteriogenic impotence. These patients were treated with PDE5 inhibitors. PDE5 inhibitors, as observed by Yafi FA et al. [14], have proven effective in treating ED in many individuals. Intracavernosal arterial injection (ICI) of papaverine was seen to have high satisfaction rates in a study by Heaton et al. [15], though it came with potential risks like priapism. Atul Rajpurkar et al. [16] in 2003 found that penile implant surgery had better outcomes in terms of erectile function than sildenafil or ICI.

The ZEN trial by Jason H et al. in presented the effectiveness of drug-eluting stent therapy in increasing arterial inflow and enhancing erectile function in a subset of patients with atherosclerotic ED [17].

Of our study cohort, 27 patients were diagnosed with a psychogenic cause of ED and were advised on behavioral and lifestyle modifications. It's worth noting that while penile Doppler is invaluable in evaluating vasculogenic causes of ED, it can't evaluate pathologies in internal iliac vessels, a limitation of our study. Consequently, for a comprehensive assessment, methods like dynamic cavernosometry, cavernosography, and dual energy CT angiography should accompany penile Doppler ultrasonography.

CONCLUSION

- A color Doppler ultrasound can be used to accurately diagnose erectile dysfunction by demonstrating arterial and venous insufficiencies.
- The peak systolic and EDV measurements are obtained in cavernosal vessels at 5mins interval till 20 mins.
- Systolic velocity of <25cm/s is used as a threshold for arterial insufficiency while an EDV of >5cm/s is used to predict venous insufficiency.
- The diagnostic criteria are likely to evolve further, and it is currently being investigated whether to make significant changes in examination technique.
- It can be concluded from our study that it is safe to perform penile Doppler ultrasound when evaluating ED since it is a minimally invasive procedure and relatively easy to perform and less time consuming.
- However, it is not feasible for ruling out pathologies in internal iliac vessels which is a limitation in our study. Hence, in patients with suspected vaso-occlusive dysfunction, dynamic cavernosometry, cavernosography and dual energy CT angiography should be performed along with penile doppler ultrasonography.

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