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Original Research Article

A clinical study of the incidence and disability caused by mesh neuralgia after inguinal mesh hernioplasty and the effects of prophylactic ilioinguinal neurectomy and its role in preventing chronic groin pain after inguinal hernioplasty

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ABSTRACT

Background: Residual neuralgia, called as Inguinodynia, is an important complication unique to groin hernia repair. The reported incidence ranges between 9-63%. The symptoms are potentially disabling. Symptoms are often more pronounced on axial twisting of body. Methods for prevention include identification and preservation of all nerves, Ilioinguinal Neurectomy and triple Neurectomy during surgery.
Methods: One hundred patients underwent elective unilateral Lichtenstein's tension free hernioplasty. 50 patients were subjected to elective ilioinguinal neurectomy. The remaining underwent standard Liechtenstein's mesh hernioplasty, without ilioinguinal neurectomy. Randomization was achieved by allocating alternate patients to each group - prophylactic neurectomy, or nerve preservation. All patients, during each review were asked to fill out a Pain Disability Questionnaire to assess sensory loss and pain disability objectively.
Results: At completion of 6 monthly follow up pain at rest (none in group 'A' compared with 3 in group 'B'), after coughing 5 times (none in group 'A' compared with 7 in group 'B'), after climbing 4 flights of stairs(3 in group 'A' compared with 16 in group 'B') and after cycling for 20 minutes (11 in group 'A' compared with 22 in group 'B') were all significantly lesser in the neurectomy group as compared with the non neurectomy group. More importantly, exertional chronic pain incidence at 6 months was significantly less in group 'A'.
Conclusions: It was concluded that pain after inguinal mesh hernioplasty is a cause of morbidity, pain was complained of by a significantly larger number of non-neurectomised patients at 6 months of follow-up, prophylactic ilioinguinal neurectomy is associated with reduced exertional chronic groin pain, disability caused by pain after inguinal hernioplasty, is significantly reduced by ilioinguinal neurectomy and an extremely significant reduction in the requirement of medication is brought about by neurectomy compared with controls.

Keywords: Hernioplasty, Ilioinguinal, Lichtenstein's, Neurectomy, Residual neuralgia

INTRODUCTION

Hernias of the abdominal wall are the most common condition requiring major surgery. After the advance made by Marcy and Bassini in 1889, individual surgeons have contributed countless modifications. Shouldice clinic was opened in Ontario in 1945; over 80,000 cases were operated in the next 30 years.

In 1989 Liechtenstein and associates introduced the "tension free repair", with primary repair of the floor of inguinal canal using a polypropylene mesh. The

procedure known as Liechtenstein's tension free prolene mesh hernioplasty has become the gold standard of inguinal hernia repair.

Residual neuralgia, called as Inguinodynia, is an important complication unique to groin hernia repair. It occurs more frequently after anterior groin hernioplasty because nerves and spermatic cord are necessarily dissected and mobilized. Nerve entrapment in mesh is a leading cause. The reported incidence ranges between 9-63%.[1] The symptoms are potentially disabling and include sharp pain, paraesthesia, and hyperesthesia in the groin region, Symptoms are often more pronounced on axial twisting of body.

Methods for prevention include Ilioinguinal Neurectomy and triple Neurectomy during surgery.[1] The current consensus is that routine identification and preservation of nerves is the best method of prevention.[2] Remedial inguinal exploration and mesh removal with or without Neurectomy results in favorable outcomes in 60% of patients with mesh Inguinodynia (neuralgia).[3] Prophylactic Neurectomy may afford better results than mesh removal alone. Our study and the present paper focus on prophylactic Ilioinguinal Neurectomy for prevention of Mesh Neuralgia.

Aims and objectives

- The Incidence and Disability Caused By 'Mesh Neuralgia' After Inguinal Mesh Hernioplasty.
- To Study the Clinical Effects of Prophylactic Ilioinguinal Neurectomy and Its Role in Preventing Chronic Groin Pain after Inguinal Hernioplasty

METHODS

A Prospective randomized trial to study the clinical effects of prophylactic Ilioinguinal Neurectomy and its role in preventing chronic groin pain after Lichtenstein's Tension Free Inguinal Hernioplasty was carried out at a reputed Tertiary Care Hospital in Western India from 01 Jan 08-01 Mar 10, after due ethical clearance from intuitional ethical committee. Informed consent was taken from one hundred patients between 18- 80 yrs underwent elective unilateral Lichtenstein's tension free hernioplasty. 50 patients were placed in group 'A' or Neurectomy group and subjected to elective Ilioinguinal Neurectomy. The remaining were placed in group 'B' or Nonneurectomy group and underwent standard Liechtenstein's Mesh hernioplasty, without Ilioinguinal Neurectomy. Randomization was achieved by allocating alternate patients to each group - 'A' prophylactic Neurectomy, and 'B' nerve preservation.

The following categories of patients were excluded from the study:

- Bilateral hernia
- ASA III and above
- Females
- E current hernia
- Impaired comprehension / mobility
- Neuropathy

End points for the study were set as under

Primary outcome

- Chronic groin pain at 6 months (any discomfort or pain elicited on follow up or encountered during normal daily activity)

Secondary outcome

- Groin numbness / sensory loss at 6 months
- QOL/Disability at 06 months

Variables were assessed as under

- Pain was assessed by 'Clinical Pain Assessment score' and QOL / Disability by 'The Pain Disability Index', both well-established questionnaires – ANEXURE 'A' and 'B'.
- Sensory loss was assessed subjectively by the patient as none, mild, moderate and severe by comparing with the contra lateral side.

Preop assessment was carried out as per the following protocol

Detailed history

Name, age, sex, occupation, residence and telephone number, duration of symptoms, site, size, mode of onset of swelling and its progress, irreducibility of swelling and presence of other lumps; aggravating / relieving factors, presence of pain at rest / activity, its site, character, severity, duration, radiation, frequency; history of vomiting, constipation, distension of abdomen, Chronic cough, dysuria, co-morbidities.

Meticulous clinical examination

- General examination
- Local examination of the swelling: Inspectory, palpatory and auscultatory findings.
- Specific clinical tests for differentiating between direct and indirect hernia: Zeiman's technique, deep ring occlusion test, finger invagination test.

Routine hematology and biochemistry investigation, special inv for PAC (pre anesthesia checkup)

Preop baseline objective parameters

- Pain at rest
- Pain after activity
- Groin numbness and pain- disability index

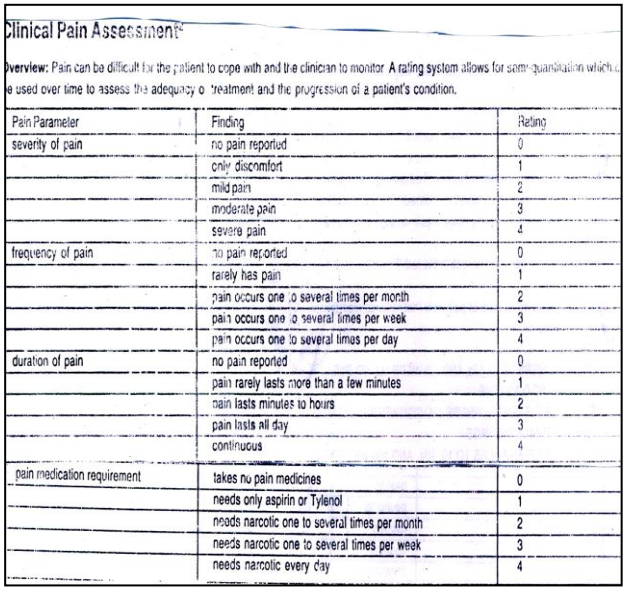
Pre-op prophylactic antibiotics were given to all patients. Standard Lichtenstein's tension free hernioplasty with polypropylene mesh was done under SA. GA was given to patients when SA failed. Medium Weight Polypropylene mesh (density 50-80g/sqcm), with pore size in the range of 600 microns to 2000 microns was the material used in this study. In the "Neurectomy group" Ilioinguinal Neurectomy was done after opening the external oblique aponeurosis. Cremaster was excised only if hindering mesh placement. No drains were placed. Post-op antibiotics were continued till post- operative day -5. Sutures were removed on the 10th post-op day. All patients were discharged only after suture removal, with instruction to report for follow up at 6 months post-op.

All Hundred patients completed follow-up at 6 months, during the period between 01 Jan 2015-01 Mar 2016. All patients were interviewed regarding presence or absence of pain at rest and sensory loss/ numbness and presence or absence of pain on being asked to perform the following tasks.

- Coughing 5 times.
- Climbing 4 flights of stair.
- Cycling 10 min (at 6 months)

Following variables were assessed for pain at rest

- Frequency of pain
- Duration of pain
- Severity of pain
- Requirement of pain medication



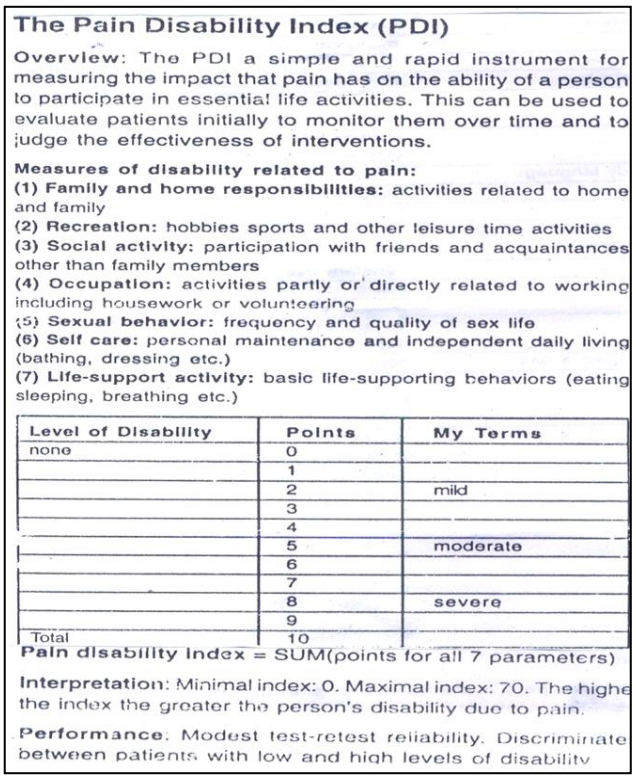
Clinical Pain Assessment

Overview: Pain can be difficult for the patient to cope with and the clinician to monitor. A rating system allows for some quantitation which can be used over time to assess the adequacy of treatment and the progression of a patient's condition.

Pain Parameter	Finding	Rating
severity of pain	no pain reported	0
	only discomfort	1
	mild pain	2
	moderate pain	3
	severe pain	4
frequency of pain	no pain reported	0
	rarely has pain	1
	pain occurs one to several times per month	2
	pain occurs one to several times per week	3
	pain occurs one to several times per day	4
duration of pain	no pain reported	0
	pain rarely lasts more than a few minutes	1
	pain lasts minutes to hours	2
	pain lasts all day	3
	continuous	4
pain medication requirement	takes no pain medicines	0
	needs only aspirin or Tylenol	1
	needs narcotic one to several times per month	2
	needs narcotic one to several times per week	3
	needs narcotic every day	4

Figure 1: Clinical pain assessment.

Linical assessment for complications was carried out scrupulously. All patients, during each review were asked to fill out a Pain Disability Questionnaire to assess sensory loss and pain disability objectively (Figure 1 and Figure 2). Watch was kept on possible complications, namely haemorrhage, retention of urine, urinary infection, surgical site infection, seroma, neuralgia, epididymorchitis, testicular atrophy, deep vein thrombosis, and pulmonary complications.



The Pain Disability Index (PDI)

Overview: The PDI a simple and rapid instrument for measuring the impact that pain has on the ability of a person to participate in essential life activities. This can be used to evaluate patients initially to monitor them over time and to judge the effectiveness of interventions.

Measures of disability related to pain:
(1) Family and home responsibilities: activities related to home and family
(2) Recreation: hobbies sports and other leisure time activities
(3) Social activity: participation with friends and acquaintances other than family members
(4) Occupation: activities partly or directly related to working including housework or volunteering
(5) Sexual behavior: frequency and quality of sex life
(6) Self care: personal maintenance and independent daily living (bathing, dressing etc.)
(7) Life-support activity: basic life-supporting behaviors (eating sleeping, breathing etc.)

Level of Disability	Points	My Terms
none	0	
	1	
	2	mild
	3	
	4	
	5	moderate
	6	
	7	
	8	severe
	9	
Total	10	

Pain disability index = SUM(points for all 7 parameters)

Interpretation: Minimal index: 0. Maximal index: 70. The higher the index the greater the person's disability due to pain.

Performance: Modest test-retest reliability. Discriminate between patients with low and high levels of disability

Figure 2: The pain disability index.

The parameters collected were subjected to statistical analysis to assess the utility of Ilioinguinal Neurectomy and disability caused by it.

RESULTS

Table 1: Base line objective parameters-neurectomy group.

Neurectomy group		
Age	**Total**	**%**
15-30	4	8
31-45	8	16
46-60	16	32
61-75	17	34
76and above	5	10
Total	50	100%
Education		
Primary	7	14
Secondary	43	86
Total	50	100%
Comorbidities	Total	%
Diabetes	14	28
Hypertension	15	30

Both the groups were matched in terms of age, education, Co morbidities, and laterality of hernia, pre-op pain and reducibility (Table 1 and 2).

Table 2: Base line objective parameters- non neurectomy group.

Nonneurectomy group		
Age	**Total**	**%**
15-30	1	2
31-45	10	20
46-60	18	36
61-75	14	28
76and above	7	14
Total	50	100%
Education		
Primary	10	20
Secondary	40	80
Total	50	100%
Co morbidities	Total	%
Diabetes	10	20
Hypertension	13	26

Comparison at 6 months

Comparison at 6 months between neurectomy and non neurectomy groups.

Table 3: Pain at rest.

Neurectomy group		Nonneurectomy group	
At 6 months follow up			
Pain at rest	**%**	**Pain at rest**	**%**
Yes	0	Yes	6
No	100	No	94
Total	100%	Total	100%

Statistical significance: Fisher exact test p value = 0.0289: significantly lesser number of patients in the Neurectomy group had pain at rest at 6 months as compared with the Nonneurectomy group

Table 4: Pain on coughing 5 times.

Neurectomy group		Non neurectomy group	
At 6 months follow up			
Pain on coughing 5 times	**%**	**Pain on coughing 5 times**	**%**
Yes	0	Yes	14
No	100	No	86
Total	100%	Total	100%

Statistical significance: Fisher exact test p value <0.0001: significantly fewer patients had pain after coughing 5 times at 6 months, in the Neurectomy group as compared with the non Neurectomy group

Comparison at 6 months between neuroectomy and non neurectomy group for pain at rest, pain on coughing 5 times, pain on climbing 4 flights of stairs, pain on cycling for 20 min, pain characteristics, requirement of medication for pain relief at rest or on sedentary activity at 6 months and Disability index is shown in Table 3,4,5,6,7,8 and 9.

Table 5: Pain on climbing 4 flights of stairs.

Neurectomy group		Nonneurectomy group	
At 6 months follow up			
Pain on climbing 4 flights of stairs	**%**	**Pain on climbing 4 flights of stairs**	**%**
Yes	6	Yes	32
No	94	No	68
Total	100%	Total	100%

Statistical significance: Fisher exact test p value <0.0001: significantly fewer patients had pain after coughing 5 times at 6 months, in the Neurectomy group as compared with the non Neurectomy group

Table 6: Pain on cycling for 20 min.

Pain on cycling 20 min	%	Pain on cycling 20 min	%
Yes	22	Yes	44
No	78	No	56
Total	100%	Total	100%

Statistical significance: Fisher exact test p value = 0.0015: significantly lesser number of patients had pain after cycling for 20 minutes at 6 months in the Neurectomy group as compared with the non Neurectomy group

Table 7: Pain characteristics.

Neurectomy group		Nonneurectomy group	
At 6 months follow up			
Severity	**%**	**Severity**	**%**
0	100	0	94
1	0	1	4
2	0	2	2
3	0	3	0
Total	100%	Total	100%
Frequency	%	Frequency	%
0	100	0	94
1	0	1	0
2	0	2	4
3	0	3	2
4	0	4	0
Total	100%	Total	100%
Duration	%	Duration	%
0	100	0	94
1	0	1	0
2	0	2	6
Total	100%	Total	100%

Groin numbness compared at 1 and 6 months in Neurectomy group is shown in Table 10. Whereas, statistical analysis for sensory loss between neuroectomy and non neurectomy group is shown in Table 11.

Table 8: Requirement of medication for pain relief at rest or on sedentary activity at 6 months.

Neurectomy group		Nonneurectomy group	
Medication	**%**	**Medication**	**%**
No	100	No	94
Yes	0	Yes	6
Total	100%	Total	100%

Statistical significance: Fisher exact test - 2 tailed p value <0.0289: significantly fewer patients in the Neurectomy group required medication for pain relief at 6 months, when compared with the Nonneurectomy group

Table 9: Pain disability index.

Neurectomy group		Nonneurectomy group	
At 6 months follow up			
Pain disability index	**%**	**Pain disability index**	**%**
0	84	0	52
1	2	3	4
3	2	5	2
4	4	6	4
7	4	7	18
8	4	8	2
9 - 15	0	9 - 15	14
Total	100%	Total	100%

Statistical significance: Fisher exact test-2 tailed p value <0.0001: Statistically significantly less disability caused by pain in the Neurectomy group at 6 months of follow-up

Table 10: Groin numbness compared at 1 and 6 months- Neurectomy group.

Sensory at 1 month		%
Yes	32	64
Total	50	100%
Sensory loss at 6 months		%
Yes	28	56
Total	50	100%

Table 11: statistical analysis at 6 months.

Sensory loss	Neurectomy	Nonneurectomy	Total
Yes	28	18	46
No	22	32	54
Total	50	50	100
Significance			
Test applied		P value	Statistical significance
Statistical significance: fisher's exact test		0.0704	Not significant, p >0.05
Statistical significance: chi square test with yates's correction		0.0710	Not significant, p >0.05

Statistically no significant difference in sensory loss could be demonstrated between the two groups the end of 6 months follow-up

DISCUSSION

At the conclusion of our study we had a total patient population of 100 patients, all of whom had been assigned to Lichtenstein's tension free Inguinal Mesh hernioplasty with or without Prophylactic Ilioinguinal Neurectomy in a ratio of 1:1. All patients recruited in the study had completed 6 months follow- up.

Authors had 50 patients each in Group 'A'- Neurectomy and Group 'B'- Nonneurectomy. Both groups were comparable in terms of age, education, anesthesia, laterality of hernia, baseline pain and disability and complications.

The clinical characteristics of pain were compared using the Clinical pain assessment tool. We dealt with pain characteristics under 4 heads as follows.

- Severity of pain at 6 months: In group 'A' during assessment at 6 months, none of the patients reported any pain. In group 'B' at 6 monthly follow-up, 47 patients had no pain, 2 had only discomfort, 1 had mild pain and none had severe pain.
- Frequency of pain at 6 months: In group 'A' none of the patients reported any pain. In group 'B' 2 patients had pain one to several times per month, and 1 patient had pain one to several times per week.
- Duration of pain at 6 months: In group 'A' none of the patients reported any pain at 6 months. In group 'B' 3 patients had pain lasting minutes to hours.
- Requirement of pain medication at 6 months: None of the patients in Group 'A' had to resort to taking pain medication, while there were 3 patients in group 'B' who needed to do so. None of the 100 patients enrolled in the study needed anything stronger than NSAIDs for pain relief.

Out of 50 patients in group 'A' 42 had no significant disability or none whatever, 4 patients had mild disability, 2 patients had moderate disability and 2 had severe disability. Out of the 50 in group 'B', 28 patients had no significant disability or no disability at all, 2 patients had mild disability, 12 had moderate disability and 8 patients had severe disability

Clinical testing at 6 months

At completion of 6 monthly follow up Pain at rest (none in group 'A' compared with 3 in group 'B'), after coughing 5 times (none in group 'A' compared with 7 in group 'B'), after climbing 4 flights of stairs(3 in group 'A' compared with 16 in group 'B') and after cycling for 20 minutes (11 in group 'A' compared with 22 in group 'B') were all significantly lesser in the Neurectomy group as compared with the Non neurectomy group . More importantly, exertional chronic pain incidence at 6 months was significantly less in group 'A'.

That surgical injury can lead to chronic pain is now well established.[4-13] From these reviews and studies using a systematic collection of data, the estimated incidences of chronic pain after various procedures are as under:

- Leg amputation about 60%,
- Thoracotomy about 50%,
- Breast surgery about 30%,
- Cholecystectomy 10-20%, and
- Inguinal herniorrhaphy about 10%.

Poobalan and colleagues published a review in 2001 where data on chronic pain after inguinal herniorrhaphy until 2000 were analyzed and found that chronic pain was observed in about 10% of patients undergoing inguinal herniorrhaphy.[14,15] Some of the conclusions are as under:

- Pain reported in 0-53% patients.
- Moderate to severe pain in about 10%
- A special emphasis should be placed on the role of nerve damage in order to outline strategies for prevention and treatment of chronic postoperative pain.

The term 'chronic post-herniorrhaphy pain' has a wide variety of interpretations in the literature. The International Association for the Study of Pain has defined chronic pain as pain lasting more than 3 months.[16] However, with the almost universal use of synthetic mesh for hernia repair, an inflammatory response may last a couple of months as a result of a reaction against the foreign material.[17]In a group of 120 patients, from an earlier study of 4076 patients the following conclusions were drawn.[18,19]

- Severe or very severe pain can occur up to 3 months after the operation.
- 71% still reported pain after 2.5 yrs.
- Only 26% of the 120 patients then described the pain as severe or very severe.
- A 'burn out' effect of the pain complaints was suggested.

A prospective randomized trial in 102 patients comparing Shouldice's procedure to laparoscopy came up with the following results.[20] No patients complained of pain in the laparoscopic group, 46% in the Shouldice group had varying degrees of pain at 1 yr,16% in the Shouldice group still had pain after 6 yr.

Two other studies with more than 1 yr follow up, described declining pain incidences when patients were seen at 6, 12, 24, or 60 months after surgery, but again the specific time-course data on frequency and intensity were not presented from the same group of patients.[21,22] In this study we found a similar trend with fewer patients complaining of chronic pain at 6 months, as compared with the numbers at the 6th month of follow up. We found that in Group 'A' the incidence of pain at rest had decreased from 6 at one month to 0 at six months that of pain on coughing 5 times had decreased from 10 to 0 respectively at 1 and 6 months. Similarly only 6% of patients complained of pain on climbing 4 flights of stairs at 6 months of follow up as compared with 18% who did so at 1 month. In group 'B' 20% patients had pain at rest at 1 month and only 6% at 6 months, 34% patients had pain on coughing 5 times at 1 month while only 14% of them still had pain at 6 months. There was no significant reduction in the number of patients complaining of pain on climbing 4 flights of stairs at 6 month as compared with the numbers at 1 month in the non Neurectomy group. In the same group (non Neurectomy group) 16% of patients required pain medication at 1 month for pain relief at rest or on sedentary activity while only 6% did so at 6 months follow up. This was found to be statistically significant. The difference in prevalence of pain 6 months as measured by the remaining variables in each group was also found to be statistically significant. A significantly higher incidence of pain was found after Lichtenstein's procedure (38%) compared with a Shouldice repair (7%) in a study of 146 patients ($P<0.05$) but follow up was only 60%.[23] The review by Poobalan and colleagues found three articles in which there was less pain after mesh-repair compared with non-mesh.[24-26]

The EU Hernia Trialists review also concluded that mesh repair caused less pain than non-mesh repair.[27] A telephone interview study of patients having elective resection of the iliohypogastric and Ilioinguinal nerves during a tension-free mesh herniorrhaphy (n=191) reported no complaints of postoperative pain.[28,29] No patients reported pain after 1, 6, or 12 months, but 7% of patients complained of numbness or sensory loss after 1 yr. It seems that sensory disturbances are common after inguinal herniorrhaphy and that these patients may be at a higher risk of also having chronic pain[17] Thus, nerve injury after inguinal herniorrhaphy may be a prerequisite for development of chronic pain, although other (unknown) factors must be involved.[17] The total duration of hospital stay is not significantly affected by the addition of this procedure. In light of the above findings, Ilioinguinal Neurectomy can be included as a surgical step in Mesh Hernioplasty to reduce post-op 'Mesh Neuralgia' and significantly reduce morbidity.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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