

Research Article



Outcome of C-arm Guided Epidural Steroid Injections in Patients with **Prolapsed Lumbar Intervertebral Disc with Radiculopathy**

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Abstract

Background: Prolapsed Lumbar Intervertebral Disc (PLID) is one of the most common health problems worldwide, as well as in our country, and is one of the potential causes of temporary disability, morbidity, and reasoning of absence at workplaces.

Objective: To find out the outcome of C-arm guided transforaminal and caudal epidural steroid injection for low back pain with radiculopathy due to PLID.

Methodology: This was a randomized clinical trial conducted among purposively selected 54 patients with PLID with radiculopathy as per selection criteria, attending the Department of Physical Medicine & Rehabilitation in BSMMU, Dhaka, from March 2020 to February 2021. Patients (N=54) were randomly allocated into two groups; patients in group A (n=26) were treated with C-arm guided transforaminal and caudal epidural steroid injection with conservative treatment, and patients in group B (n=28) were treated with conservative treatment only. All patients were followed up in 1st week, 1st month, and 3rd month.

Results: The mean age of the participants in group A and group B were $40.88~(\pm~8.70)$ and $43.00~(\pm~11.54)$ years, respectively. In group A, 9 (34.6%) were housewives, 4 (15.4%) were manual workers, while in group B, 10 (35.7%) were housewives, and 8 (28.6%) were manual workers. In group A, 21 (80.8%) had three disc involvement, while in group B, 19 (67.9%) had three discs involvement, where L4-5-disc involvement was most common in both groups. There was no significant statistical difference between the groups regarding VAS scores at baseline (p=0.235), 1st week (p=0.164), and 1st month (p=0.125). The VAS score was significantly reduced in group A compared to group B at 3rd month (p=0.001). The ODI score was significantly reduced in group A compared to group B at 1st week (p=0.034), 1^{st} month (p=0.016), and at 3^{rd} month (p=0.001).

Conclusion: C-arm guided transforaminal and caudal Epidural Steroid Injection significantly improves pain and functional outcomes of patients with radiculopathy due to PLID. Long-term, large scale and multicenter research studies are required to establish the outcome and effectiveness of this procedure.

Keywords: Prolapsed lumbar intervertebral disc; C-arm guided transforaminal and caudal Epidural Steroid Injection; Visual analogue scale; Oswestry Disability Index

Introduction

Lumbar intervertebral discs are complex structures that undergo

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significant axial loading, flexion/extension, lateral bending, and rotational forces. Because of the biomechanical demands placed upon these structures and their inability to remodel due to their avascular nature, lumbar disc prolapse is common [1]. The prolapsed lumbar intervertebral disc (PLID) can lead to substantial radicular symptoms, which, if persistent, may require surgical intervention [2]. More than 95% of lumbar disc herniation occurs at the L4-L5 and L5-S1 levels; the next most common is L3-L4, followed by L2-L3. Consequently, the most common lumbosacral radiculopathies are L5 and S1 [3]. The mean age of patients with a herniated disc was 41 years, with a male preponderance [4].

Al-Hasan et al. [5] reported in the Community Oriented Program for Control of Rheumatic Diseases (COPCORD) study that 174 per thousand Bangladeshi population with non-inflammatory back pain had PLID. Alike Cummins and Coworkers, male predominance (63.3%) was observed among respondents with PLID in Bangladesh [5]. There are some risk factors for PLID development, such as (i) obesity, (ii) individual involved in a physically demanding occupation, and (iii) positive family history for PLID [1].

Lumbar radiculopathy secondary to disc herniation resolved spontaneously in 23 to 48 % of cases. However, about 30 to 70 % of cases had pronounced symptoms after one year, with 5% to 15% of patients undergoing surgery resulting in high economic impact and strain on health services [6].

General objective

➤ To find out the outcome of C-arm guided transforaminal and caudal epidural steroid injection for low back pain with radiculopathy due to PLID

Specific objective

- > To find out the effect on the severity and intensity of pain after C-arm guided transforaminal and caudal epidural steroid injection in patients with PLID with radiculopathy
- ➤ To determine the functional outcome of patients with PLID with radiculopathy after C-arm guided Transforaminal Epidural Steroid Injection (TFESI) and Caudal Epidural Steroid Injection (CESI)
- ➤ To compare the pain and functional outcome of radiculopathy due to PLID between the patients treated with C-arm guided Transforaminal Epidural Steroid Injection (TFESI) and Caudal Epidural Steroid Injection (CESI) along with standard conservative treatment and the patients who received only standard conservative treatment

Materials and Methods

This Randomized clinical trial study was conducted in the Department of Physical Medicine and Rehabilitation, BSMMU, in collaboration with the Department of Orthopaedic Surgery, BSMMU, and Dr. Sirajul Islam Medical College Hospital, Dhaka. from March 2020 to February 2021.

Inclusion criteria

- Patients with clinically diagnosed and MRI confirmed PLID with radiculopathy refractory to adequate standard conservative treatment
- Patients willing to participate and give informed written consent

Exclusion criteria

- Herniated disc with motor involvement
- Sensory involvement (Saddle anesthesia)
- Autonomic involvement (Incontinence of bowel and bladder)
- Sequestrated disc
- Patients with inflammatory back pain
- Spondylolisthesis
- Uncontrolled diabetes mellitus and hypertension
- History of receiving C-arm guided TFESI and CESI within the last six months

Data collection method

Data was collected through face-to-face interviews and a semi-structured questionnaire using assessment scales. All efforts were made to collect data accurately. For open questions, the respondents were asked in such a manner so that they could speak freely and explain their opinion in a normal and neutral way. No leading questions were asked.

Ethical consideration

From the ethical point of view, keeping compliance with Helsinki Declaration for Medical Research Involving Human Subjects 1964, a written consent was taken from all patients for inclusion in the study. The process of the treatment was simplified and explained to the patients. Voluntary participations were encouraged. When the researcher was assured that the patient completely understood the study protocol and became aware of his/her rights during the study, the written consent form was signed or fingerprinted by the patient. Before starting this study ethical clearance was taken from Institutional Review Board (IRB) of BSMMU. Permission was also taken from department of Orthopedic Surgery and Dr. Sirajul Islam Medical College and Hospital. The process of treatment had no harm for their health, and they had authority to stop the process of treatment. They were assured of protection of patients' autonomy, privacy, confidentiality. Data taken from the participants were regarded as confidential and kept locked under investigator for purposeful use only.



Results

A total 65 respondents were enrolled in the study. In group A, 26 participants completed 3 months follow-ups, whereas in group B 28 participants completed follow up (Figure 1-7). However, 11 (17%) participants (Group-A=6 and Group-B=5) were dropped out and could not complete pre-scheduled follow-up due to the COVID-19 pandemic situation and its consequences, such as a lockdown. Therefore, 54 samples were considered in the final statistical analysis.

Table 1 shows that in group A, 23 (88.5%) were from the <50 years' age group, while in group B, 20 (71.4%) were from the <50 years' age group. No significant statistical difference was found between the groups regarding age as p=0.179 (obtained by Chi-square test). The mean age of the participants in group A and group B were $40.88 \, (\pm \, 8.70)$ and $43.00 \, (\pm \, 11.54)$ years, respectively.

Table 2 shows that in group A, 14 (57.7%) were male, while 12 (42.9%) were male in group B. No significant statistical difference was found between the groups regarding gender as p=0.586 (obtained by Chi-square test).

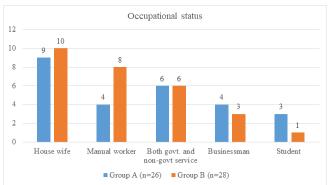


Figure 1: Shows that in group A, 9 (34.6%) were housewives, 4 (15.4%) were manual workers, while in group B, 10 (35.7%) were housewives and 8 (28.6%) were manual workers. No significant statistical difference was found between the groups regarding occupational status as p=0.685 (obtained by Fisher's Exact test).

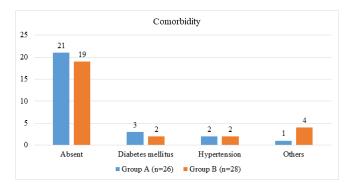


Figure 2: shows that in group A, 21 (80.8%) had no comorbidity and 3 (11.5%) had diabetes mellitus while in group B, 19 (67.9%) had no comorbidity and 2 (7.1%) had diabetes mellitus.

Table 1: Distribution of age of the study participants (N=54).

| Age group (in years) | Group A (n =26) | Group B (n=28) | p value |
|---|-----------------|----------------|---------|
| <50 | 23 (88.5%) | 20 (71.4%) | 0.179 |
| 51-60 | 3 (11.5%) | 8 (28.6%) | 0.179 |
| Total | 26 (100.0%) | 28 (100.0%) | |
| Mean ± SD | 40.88 ± 8.70 | 43.00 ± 11.54 | |
| N=Total study participants, n=Participants in group | | | |

Table 2: Distribution of gender of the study participants (N=54).

| Gender | Group A (n =26) | Group B (n=28) | p value |
|---|-----------------|----------------|---------|
| Male | 14 (57.7%) | 12 (42.9%) | 0.506 |
| Female | 12 (46.2%) | 16 (57.1%) | 0.586 |
| Total | 26 (100.0%) | 28 (100.0%) | |
| N=Total study participants, n=Participants in group | | | |

Distribution of occupational status of study participants (N=54)

Table 3 shows that in group A, 7 (26.9%) were from the lower class and 16 (61.5%) were from the lower middle class; while in group B, 13 (46.4%) were from the lower class and 14 (50.0%) were from the lower middle class. No significant statistical difference was found between the groups regarding socio-economic status as p=0.407 (obtained by Fisher's Exact test).

Table 4 shows that in group A, 17 (65.4%) had normal weight while 19 (67.9%) had normal weight in group B. No significant statistical difference was found between the groups regarding BMI as p=1.000 (obtained by Chi-square test). The mean BMI of the participants in group A and group B was 23.98 (\pm 2.87) and 24.11 (\pm 2.52) kg/m², respectively.

Distribution of study participants by comorbidity (N=54)

Table 5 shows that in group A, 23 (88.5%) had a duration of a symptom of>90 days, while in group B, 24 (85.7%) had a duration of a symptom of>90 days. No significant statistical difference was found between the groups regarding the duration of symptoms as p=0.945 (obtained by Chi-square test).

Distribution of disc involvement among groups (N=54)

Distribution of disc involvement (N=54)

Distribution by root involvement (N=54)

Distribution of study participants by VAS score (N=54)

Table 6 shows that there was no significant statistical difference between the groups regarding VAS scores at baseline, 1st week, and 1st month as p>0.05. Significant statistical difference was found between the groups regarding



VAS scores in the 3rd month (p=0.001) (obtained by Independent sample t-test).

Distribution of study participants by ODI score (N=54)

Table 7 shows that the VAS scores significantly reduced after treatment from 6.3 (\pm 0.6) to 3.5 (\pm 0.9) in group A (p<0.001). The VAS scores significantly reduced after treatment from 6.5 (\pm 0.7) to 4.4 (\pm 0.9) in group B (p<0.001) (obtained by paired t-test).

Table 8 shows that there was no significant statistical difference between the groups regarding ODI scores at baseline as p=0.957. At 1st week, 1st month, and 3rd month there was a significant statistical difference between the groups regarding ODI scores as p<0.05 (obtained by independent sample t-test).

Table 3: Distribution of socio-economic status of study participants (N=54).

| Socio-economic status | Group A (n =26) | Group B (n=28) | p value |
|-----------------------|--------------------|-------------------|---------|
| Lower class | 7 (26.9%) | 13 (46.4%) | |
| Lower middle class | 16 (61.5%) | 14 (50.0%) | 0.407 |
| Upper middle class | 2 (7.7%) | 1 (3.6%) | |
| Higher class | 1 (3.8%) | 0 (0.0%) | |
| Total | 26 (100.0%) | 28 (100.0%) | |

Table 4: Distribution of Body Mass Index (BMI) of study participants (N= 54).

| Body Mass Index (BMI) | Group A (n =26) | Group B (n=28) | p value | |
|---|--------------------|-------------------|------------|--|
| Normal weight | 17 (65.4%) | 19 (67.9%) | 1 | |
| Over weight | 9 (34.6%) | 9 (32.1%) | ' | |
| Total 26 (100.0%) 28 (100.0%) | | | | |
| N=Total study participants, n=Participants in group | | | | |

Table 5: Distribution of duration of symptom of study participants (N=54).

| Duration (in days) | Group A (n =26) | Group B (n=28) | P value |
|---|-----------------|----------------|----------|
| 42-90 | 3 (11.5%) | 4 (14.3%) | 1 |
| >90 | 23 (88.5%) | 24 (85.7%) | |
| Total | 26 (100.0%) | 28 (100.0%) | |
| N=Total study participants, n=Participants in group | | | |

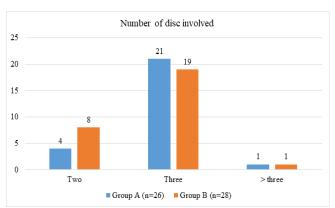


Figure 3: shows that in group A, 21 (80.8%) had three discs' involvement, while in group B, 19 (67.9%) had three discs' involvement. No significant statistical difference was found between the groups regarding disc involvement as p=0.659 (obtained by Fisher's Exact test).

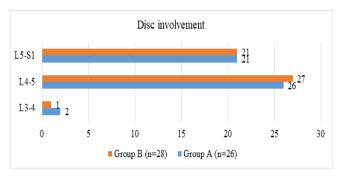


Figure 4: shows that in group A, 21 (80.8%) had L5-S1 disc involvement and 27 (87.1%) had L4-5 disc involvement. In group B, 21 (75.0%) had L5-S1 disc involvement, and 26 (92.8%) had L4-5 disc involvement.

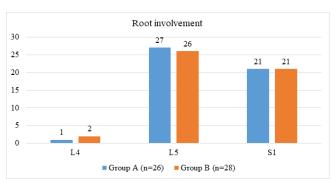


Figure 5: shows that in group A, 27 (87.1%) had L5 root involvement, and 21 (80.8%) had S1 root involvement. In group B, 26 (92.8%) had L5 root involvement, and 21 (75.0%) had S1 root involvement.

Table 9 shows that the ODI scores significantly reduced after treatment from 57.4 (\pm 7.3) to 25.7 (\pm 9.4) in group A where (p<0.001). The ODI scores significantly reduced after treatment from 57.9 (\pm 7.1) to 34.4 (\pm 8.9) in group B where (p<0.001) (obtained by paired t-test).

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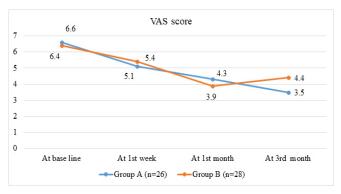


Figure 6: Shows that in group A, at the beginning of treatment, the mean VAS score of the respondents was 6.6. The VAS score gradually decreased in 1st week, 1st month, and in 3rd month, it was 3.5. In group B, at the beginning of treatment, the mean VAS score of the respondents was 6.4. The VAS score decreased in 1st week to 5.4 and in 1st month to 3.9; in 3rd month, it increased to 4.4.

Table 6: Comparison of study participants by Visual Analog Scale (VAS) score (N=54).

| Group A (Mean ± SD) | Group B (Mean ± SD) | p value |
|------------------------|---|---|
| 6.6 ± 0.5 (n=32) | 6.4 ± 0.8 (n=33) | 0.235 |
| 5.1 ± 0.6 (n=32) | 5.4 ± 0.6 (n=33) | 0.164 |
| 4.3 ± 0.9 (n=30) | 3.9 ± 0.9 (n=30) | 0.125 |
| 3.5 ± 0.9 (n=26) | 4.4 ± 0.9 (n=28) | 0.001 |
| | (Mean ± SD) 6.6 ± 0.5 (n=32) 5.1 ± 0.6 (n=32) 4.3 ± 0.9 (n=30) | (Mean ± SD) (Mean ± SD) 6.6 ± 0.5 (n=32) 6.4 ± 0.8 (n=33) 5.1 ± 0.6 (n=32) 5.4 ± 0.6 (n=33) 4.3 ± 0.9 (n=30) 3.9 ± 0.9 (n=30) |

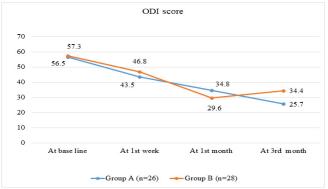


Figure 7: Shows that in group A, at the beginning of treatment, the mean ODI score of the respondents was 56.5. The ODI score gradually decreased in 1st week, 1st month, and in 3rd month, 25.7. In group B, at the beginning of treatment, the mean ODI score of the respondents was 57.3. The ODI score decreased in the 1st week to 46.8 and the 1st month to 29.6; in the 3rd month, it increased to 34.4.

Table 7: Comparison of pre-treatment and post-treatment VAS scores between two groups (N=54).

| Group | Pre-treatment score (Mean ± SD) | Post-treatment score (Mean ± SD) | p value |
|---|---------------------------------|----------------------------------|---------|
| Group A (n=26) | 6.3 ± 0.6 | 3.5 ± 0.9 | <0.001 |
| Group B (n=28) | 6.5 ± 0.7 | 4.4 ± 0.9 | <0.001 |
| N=Total study participants, n=Participants in group | | | |

Table 8: Comparison of study participants by Oswestry Disability Index (ODI) score (N=54).

| ODI | Group A (Mean ± SD) | Group B (Mean ± SD) | p-value |
|---|------------------------|------------------------|---------|
| At base line | 56.5 ± 7.1 (n=32) | 57.3 ± 6.9 (n=33) | 0.957 |
| At 1st week | 43.5 ± 4.8 (n=32) | 46.8 ± 6.4 (n=33) | 0.034 |
| At 1st month | 34.8 ± 8.3 (n=30) | 29.6 ± 7.2 (n=30) | 0.016 |
| At 3 rd month | 25.7 ± 9.4 (n=26) | 34.4 ± 8.9 (n=28) | 0.001 |
| N=Total study participants, n=Participants in group | | | |

Table 9: Comparison of pre-treatment and post-treatment ODI scores between two groups (N=54).

| Group | Pre-treatment score (Mean ± SD) | Post-treatment score (Mean ± SD) | p-value |
|---|---------------------------------|----------------------------------|---------|
| Group A (n=26) | 57.4 ± 7.3 | 25.7 ± 9.4 | <0.001 |
| Group B (n=28) | 57.9 ± 7.1 | 34.4 ± 8.9 | <0.001 |
| N=Total study participants, n=Participants in group | | | |

Discussion

The study purposively included 54 patients with clinically diagnosed and MRI-confirmed PLID refractory to adequate standard conservative treatment. Patients were randomly allocated into group A (C-arm guided transforaminal and caudal epidural steroid injection with conservative treatment) and group B (conservative treatment only). Patients with a herniated disc with motor involvement, sensory involvement (saddle anesthesia), autonomic involvement (incontinence of bladder and bowel), sequestrated disc, spondylolisthesis, uncontrolled diabetes mellitus, hypertension and history of receiving C-arm guided TFESI and CESI within last 6 months were excluded from the study.

PLID occurs most commonly in the fourth to fifth decades of life [7]. The mean ages of the study participants were 40.88 and 43.00 years in group A and group B, respectively. These results were consistent with other studies which dealt with epidural steroid injections for PLID [8]. Among the 54 patients in the present study, 51.8% patients were female. PLID is more common in men than women. Examined the rheumatic disease profile of Bangladeshi patients and found that most PLID patients were male (63.3%). Other studies also reported male predominance [9]. The dissimilarity of the result might be due to the small size of the present study. Risk factors for PLID are heavy lifting, especially with torsional stress, strenuous physical activity, and occupational driving. One-fifth of the study participants were manual workers. As most of the study participants of the present study were female, the proportion of housewives was comparatively more compared to other professions. They had to work in the



kitchen room with repeated squatting and a history of using a low commode, which might be the risk factor for PLID.

Participants of the present study were mainly from lower and lower-middle classes. Few were from the upper-middle class. No significant statistical difference was found between the groups regarding socio-economic status. One-third of the study population had overweight. The largest population-based study reported that being overweight and obese significantly increased the likelihood of having lumbar disc herniation [10].

Medical comorbidities such as diabetes, hyperlipidemia, and smoking have also been reported as possible risk factors for lumbar disc herniations [11]. The majority of the study participants had no comorbidity, while 5 patients had diabetes mellitus and 4 patients had hypertension. The majority of the study participants had three discs involvement; the most affected disc was L4-L5, followed by L5-S1, which matched other studies. PLID occurs most commonly occurs at L4/5 and L5/S1 disc levels [7]. In 1st month, the reduction of VAS score was more in group B compared to group A. This might be due to the lower adherence of patients of group A to conservative treatment. Patients of group A might believe that they were treated with ESI, which might provide a better outcome than conservative treatment. So, they did not strictly follow physical therapy, exercise programs, lifestyle modifications, and behavioral therapy. On the other hand, patients in group B strictly adhered to the conservative treatment, which provided them with a better outcome in 1st month. In 3rd month, a significant reduction in VAS score was found in group A compared to group B. Inflammatory agents released by the herniation are a significant contributor to the pain and nerve root irritation. Corticosteroids have been shown to reduce inflammation by inhibiting either the synthesis or release of a number of proinflammatory mediators and by causing a reversible local anesthetic effect [12]. prospectively compared the effect of transforaminal ESI injection and conservative treatment among patients with PLID with radiculopathy and observed treatment improvement in both transforaminal ESI injection and conservative treatment group. But the improvement was significantly more in the TFESI group. Another Bangladeshi study compared the effects of epidural steroid injections with conservative management in patients with lumbar radiculopathy. They also found that pain reduction was significantly more in the epidural steroid injection group.

The comprehensive review of [13] reported that in a substantial proportion of patients with lumbar radicular pain caused by contained disc herniations, lumbar transforaminal injection of corticosteroids is effective in reducing pain, restoring function, reducing the need for other health care, and avoiding surgery, stated that caudal epidural injections of local anesthetic with or without steroids might be an effective

therapy for patients with disc herniation or radiculitis. The systematic review demonstrated that trained physicians' epidural injections performed under fluoroscopy improve pain and function in well-selected patients with lumbar disc herniation. Determined the difference in short- and long-term pain improvement between lumbar Epidural Steroid Injections (ESIs) and conservative management in patients with lumbar radiculopathy and observed that ESI is considered to be a better option compared to conservative treatment.

Though there was no significant difference between the groups regarding ODI scores at baseline, significant improvement was observed in the ESI group compared to the conservative group from 1st week. This difference persisted throughout the follow-up period. The result was inconsistent with the study conducted among the Bangladeshi population. They also found that the functional improvement, assessed in ODI, was more compared to conservative treatment, which observed clinically meaningful and significant improvement in all parameters after caudal epidural injections in patients with disc herniation or radiculitis [14]. compared the effectiveness of caudal epidural injection versus nonsteroidal anti-inflammatory drugs (NSAIDs) in the treatment of low back pain accompanied by radicular pain and reported that the caudal epidural injection group's improvement was better and faster than the NSAID groups, and the differences between assessment scores of the groups were statistically significant, except the 3rd month Oswestry scores.

However, the study found no significant difference in functional improvement between ESI and placebo groups. This might be the absence of fluoroscopic guided ESI administration in the patients in the study by Arden et al. [8]. The use of fluoroscopy offers several advantages, including verification of the correct level and side; confirmation, with use of contrast medium, that the injection is accurately placed in the epidural space; and avoidance of intravascular injection [15]. True complications following fluoroscopically guided ESI appear to be rare. In fact, a large cohort of over 1,500 consecutive injections revealed no major complications. No patient in the present study had post injection complications except headache, which subsided by oral paracetamol and adequate hydration.

Conclusion

C-arm guided transforaminal, and caudal Epidural Steroid Injection is effective in pain and functional outcome of patients with radiculopathy due to Prolapsed Lumbar Intervertebral Disc.

Recommendations

1) C-arm guided transforaminal and caudal Epidural Steroid Injections would be an effective treatment for patients with radiculopathy due to PLID



2) Long-term, large scale and multicenter research studies are needed to establish the outcome and effectiveness of this procedure

Limitations of the Study

Some limitations were perceived while planning and conducting the study. The following were the limitation of the study:

- Due to the COVID-19 pandemic, only 65 patients were included in the study, and 54 of them could complete the follow-up schedule, which might not represent the population
- Long-term follow-up could not be done
- The study place and population were selected purposively, which might result in selection bias
- The study was conducted in only one institution (BSMMU), so the results might not represent the entire population

Conflict of Interest:

None.

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