

Retrospective analysis of the comparison between carbon dioxide laser-assisted deep sclerectomy combined with phacoemulsification and conventional trabeculectomy with phacoemulsification

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Purpose: To compare outcomes of laser assisted deep sclerectomy (LADS) and conventional trabeculectomy both combined with phacoemulsification. **Methods:** We divided 36 eyes into 2 groups, one group with LADS and the other Trabeculectomy. Patients were measured post operatively at 1, 3, 6, 9 months, 1, 2, 3 years for intraocular pressure (IOP), best corrected visual acuity (BCVA) and number of medications. **Results:** In the trabeculectomy group, after 3 year follow up, IOP was 14.67 ± 3.14 , 15.27 ± 4.28 and 17.00 ± 7.79 , BCVA improved to 0.17 ± 0.18 , 0.24 ± 0.20 and 0.24 ± 0.27 and number of medications reduced to 0.6 ± 0.6 , 1.1 ± 1.2 , and 1.5 ± 1.5 . Complete success rate after 3 years was 100%, 80.0% & 80.0% and Qualified success rate was 100%, 88.9% & 88.9%. In the LADS group, after 3 years follow up, IOP was 14.11 ± 3.91 , 16.07 ± 5.51 , 15.80 ± 6.07 , BCVA improved to 0.13 ± 0.11 , 0.10 ± 0.15 , 0.11 ± 0.13 and medications reduced to 1 ± 1.1 , 1.5 ± 1.0 and 1.8 ± 1.0 . Complete success after 3 years was 85.7%, 57.1% & 57.1% whereas qualified success was 92.3%, 84.6% & 84.6%. **Conclusion:** Main limitations of our study were small sample size and lack of prospective comparison. However we were able to perform the surgery comfortably due to the relatively shorter learning curve compared to conventional NPDS.

Key words: Nonpenetrating deep sclerectomy, CO2 laser, primary open angle glaucoma, exfoliative glaucoma

Intraocular pressure (IOP) has always been the only modifiable risk factor in the treatment of glaucoma. Lowering of this risk factor helps to arrest or delay progressive optic neuropathy and prevent irreversible visual field loss.^[1] This is achieved through medical, laser, and surgical modalities. Among surgical modalities, trabeculectomy remains the gold standard. Surgery is indicated when glaucomatous optic neuropathy worsens or visual field damage progresses despite laser trabeculoplasty or maximally tolerated medical therapy.

However, over the decades since its introduction and modification by Cairns (1968) and Watson (1970) respectively, many advancements have been made to minimize the risk of complications and surgical failure. The most common complications include shallow anterior chamber (AC) due to over filtration, hypotony maculopathy, choroidal detachment or hemorrhage, hyphema, aqueous misdirection, cataract, or endophthalmitis.^[2] Others include late sequelae of surgical trauma leading to surgically induced astigmatism and corneal decompensation due to endothelial cell loss.^[3] The occurrence of these complications can be attributed to the fact that surgery is invasive and involves penetration of the AC.

Regardless, with modern strategies called the Moorfields Safer Surgical System,^[4] which includes the use of perioperative antimetabolites, AC maintainer, adjustable and releasable sutures together with secure conjunctival closure technique have shown gradual IOP decrease, reduced risk of complications

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and improved long-term surgical outcomes, trabeculectomy is widely adopted at an early stage of glaucoma surgery.

NPDS was first described by Krasnov^[5] and Walker and Kanagasundaram^[6] in 1964, which involves manual removal of the sclerocorneal tissue and unroofing of Schlemm's canal and exposure of the juxtacanalicular trabeculum thereby relieving local tissue resistance to allow effective fluid percolation, while the AC is not penetrated thereby reducing IOP. Progressive filtration of the aqueous humor from the AC to the surgically created intrascleral space through an intact Trabeculo-Descemet's membrane (TDM) carries a low risk of hyperfiltration.^[7] As this is not an invasive technique, we achieve a higher safety profile as compared with trabeculectomy with almost similar success in controlling IOP.^[8]

Unfortunately, this technique requires high surgical skills and long learning curve, as a result of which only a minority of surgeons adopt this procedure and hence this technique did not gain wide popularity despite its obvious advantages which includes less frequent flattening of the AC, less choroidal detachments, and reduced inflammation.^[9] However, compared to trabeculectomy the IOP reducing potential has also been another factor limiting its popularity.

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Laser-assisted Deep Sclerectomy (LADS) or CO₂ laser-assisted sclerectomy (CLASS), is considered a modification of nonpenetrating deep sclerectomy (NPDS) which helps to overcome surgical prowess required for NPDS.

First described by Ton Y. *et al.*, this technique involves the use of CO₂ laser for deep tissue ablation especially dry tissues thereby reducing the risk of perforation.^[10] It is to be noted that far-infrared radiation of this laser (wavelength of 10,600) is absorbed in water and thus is ineffective when applied over wet tissues. This allows for localized ablation of the sclera up until the point at which fluid begins to percolate through the thinned wall of the AC. Once percolation occurs, further laser application is ineffective due to wet tissue and thus further tissue ablation is automatically halted.^[11]

The purpose of this study is to evaluate retrospectively the safety and efficacy between CO₂ laser-assisted deep sclerectomy surgery (LADS) combined with phacoemulsification surgery and conventional trabeculectomy with phacoemulsification surgery over a long follow up period.

Methods

Study design

This study was retrospective and conducted after proper consent from the institutional research board. The inclusion criteria included adult patients (aged ≥ 18), medically uncontrolled open angle glaucomas and each should have been operated one eye with Phaco-LADS and other eye Phaco-Trab. Whereas the exclusion criteria consisted of only one eye operated, any previous ocular surgery and followup less than 1 year (Study (RET202000209) has been approved by the Ethics committee on 7 September 2020).

Over 18 patients (36 eyes) were taken in the study after meeting the eligibility criteria and divided into 2 groups. One group consisted of eyes operated with LADS with Phaco and the other group consisted of eyes operated with Trab with Phaco. Follow up periods for both the groups consisted of day 1, month 1, month 3, month 6, month 9, years 1.5, years 2, years 2.5, years 3, years 4, years 5, years 6 and years 7. On every follow up date, BCVA, IOP, CDR, number of AGM, complications and interventions were recorded.

Surgical procedure

All the procedures were performed under subtenons anaesthesia (Lidocaine 2%, mixed with hyaluronidase). LADS was performed in the superior quadrant, using a commercially available OT-135 CO₂ laser system. The procedure involved a corneal traction suture, conjunctival peritomy, opening and dissection of the Tenon's capsule, cauterization of bleeding vessels within the area of exposed sclera and dissection of 50% lamellar scleral flap of dimensions 4 mm × 4 mm at the 12 'o'clock position using a feather blade (initial horizontal incision) and a crescent blade (flap dissection).

After percolation was achieved, scleral flap edges were approximated with two fixed 10.0 nylon intrascleral sutures, applied at the corners of the flap, and conventional conjunctival closure was done with 8.0 vicryl interrupted sutures. Phacoemulsification was done by creating a temporal corneal tunnel at 3 'o'clock, capsulorrhexis with cystitome, removal of lens by Phaco chop technique, PC polishing, IOL implantation by injector and hydration of the wound for a tight closure.

Table 1: Baseline characteristics of PHACO + TRAB and PHACO + LADS

Variables	n (%)
Gender	
Male	14 (77.8)
Female	4 (22.2)
Diabetes	5 (27.8)
Hypertension	7 (38.9)
Asthma	2 (11.1)
Cardiac	3 (16.7)
Hyperlipidaemia	1 (5.6)
Thyroidectomy	1 (5.6)

Table 2: Comparison between groups on subsequent follow ups on the basis of IOP, number of AGMs, best corrected visual acuity (BCVA) and the number of medications

	PHACO + TRAB (n=18)	PHACO + LADS (n=18)	P ^M
Baseline			
IOP (mmHg)	15.72±3.23	17.22±5.25	0.503
No. of AGM	1.8±0.8	2.0±0.8	0.219
BCVA	0.54±0.24	0.57±0.26	0.834
No. of Patients	18	18	
6 months			
IOP (mmHg)	13.61±3.63*	14.76±3.93	0.538
No. of AGM	0.4±0.6*	1±1*	0.255
BCVA	0.22±0.18*	0.18±0.16*	0.571
No. of Patients	18	17	
1 year			
IOP (mmHg)	14.67±3.14	14.11±3.91	0.773
No. of AGM	0.6±0.6*	1±1.1*	0.376
BCVA	0.17±0.18*	0.13±0.11*	0.757
No. of Patients	18	18	
2 years			
IOP (mmHg)	15.27±4.28	16.07±5.51	0.646
No. of AGM	1.1±1.2*	1.5±1.0*	0.154
BCVA	0.24±0.20*	0.10±0.15*	0.034
No. of Patients	15	15	
3 years			
IOP (mmHg)	17.00±7.79	15.80±6.07	0.689
No. of AGM	1.5±1.5	1.8±1.0	0.457
BCVA	0.24±0.27*	0.11±0.13*	0.263
No. of Patients	12	10	
4 years			
IOP (mmHg)	14.40±2.97	19.10±11.67	0.385
No. of AGM	2.2±1.3	1.8±1.3	0.616
BCVA	0.22±0.21*	0.17±0.27*	0.548
No. of Patients	5	10	

Phaco - Phacoemulsification, Trab - Trabeculectomy, LADS - Laser Assisted Deep Sclerectomy, IOP - Intraocular pressure, BCVA - Best corrected visual acuity, AGM - Anti Glaucoma Medication

Trabeculectomy with phacoemulsification was performed in the superior quadrant by constructing a fornix-based flap. The procedure involved a corneal traction suture, conjunctival peritomy, opening and dissection of the Tenon's capsule, cauterization of bleeding vessels within the area of exposed sclera, dissection of 50% lamellar scleral flap of dimensions 4 mm × 4 mm at the 12 'o'clock position using a feather blade (initial horizontal incision) and a

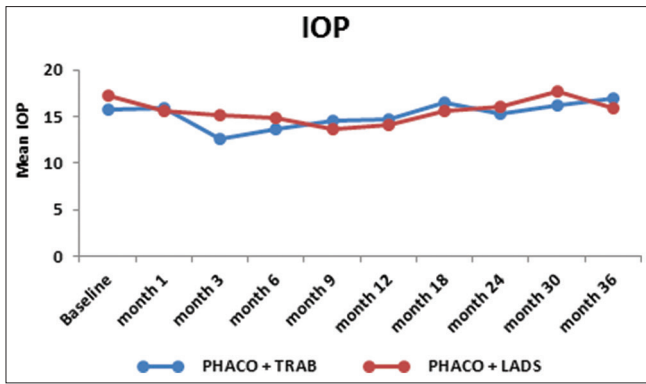


Figure 1: Mean IOP for PHACO + TRAB and PHACO + LADS group

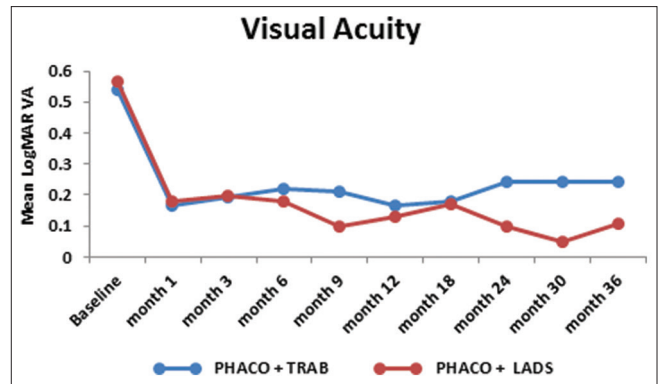


Figure 2: Mean LogMAR VA for PHACO + TRAB and PHACO + LADS group

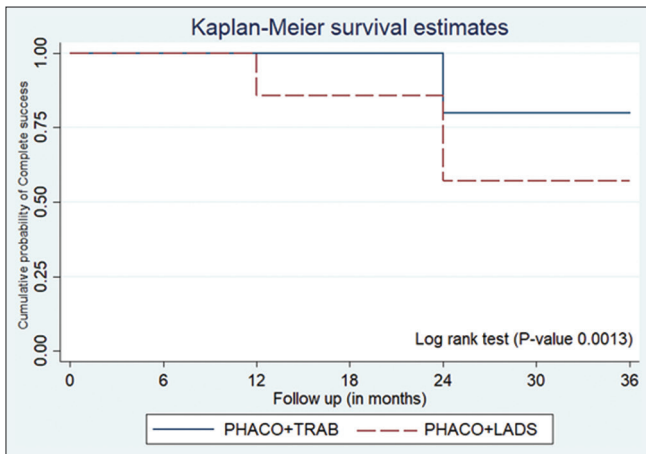


Figure 3: Kaplan Meier Survival estimate for complete success

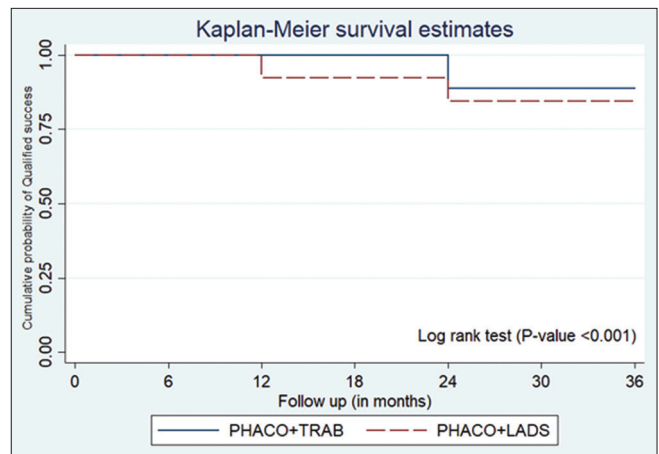


Figure 4: Kaplan Meier Survival estimate for qualified success

Table 3: P comparison of IOP, BCVA, number of AGM between baseline and each follow up visit using Wilcoxon Signed rank test

Baseline vs.	IOP		BCVA		AGM	
	Group 1	Group 2	Group 1	Group 2	Group 1	Group 2
Month 6	0.023	0.226	0.0007	0.0010	0.0007	0.0008
Month 12	0.126	0.076	0.0002	0.0002	0.0010	0.0012
Month 24	0.265	0.377	0.0028	0.0006	0.044	0.032
Month 36	0.782	0.539	0.0026	0.0069	0.215	0.349
Month 48	0.685	0.918	0.042	0.036	0.776	0.435

Group 1 - PHACO + TRAB, Group 2 – PHACO + LADS. IOP - Intraocular pressure, BCVA - Best corrected visual acuity, AGM - Anti Glaucoma Medication

crescent blade (flap dissection), paracentesis, sclerostomy and peripheral iridectomy with Kelly’s puncture. This was followed by constructing a temporal corneal tunnel at 3 o’clock, capsulorrhexis with cystitome, removal of lens by Phaco chop technique, PC polishing, IOL implantation by injector and hydration of the wound for a tight closure. The scleral flap edges were approximated with two fixed 10.0 nylon intrascleral sutures applied at the corners of the flap and conjunctival closure was done with 8.0 vicryl interrupted sutures.

Post operative analysis

Eyes were considered ‘complete success’ when IOP at each follow-up visit ranged between 10 and 18 mmHg and reduced by at least 30% from the baseline without glaucoma medications and considered ‘qualified success’ with IOP within the above criteria with or without glaucoma medications. Intraocular

pressure (IOP) <10 mmHg or >18 mmHg despite medications, reduction of <30% from the baseline, reoperation for glaucoma within 12 months or loss of light perception were classified as failure. Goniopuncture and bleb needling were not considered as failures as both are commonly used as normal postoperative interventions that are required to maintain or augment the operative results of glaucoma surgeries.

Statistical analysis

Descriptive statistics like frequency (percentage) and mean (SD)/Median (IQR) were given for categorical and continuous variable respectively. Shapiro Wilk test was used to check the normality of the data. Wilcoxon Signed Rank test was used to compare the VA between baseline and follow up visits. Mann Whitney U test was used to find out the difference between two independent variables.

Kaplan Meier Survival curve were given for the success rate and log rank test was used to compare the survival curves. A P value < 0.05 was considered as statistical significant. All the analysis were done by using Statistical software STATA (Version 14.0, TEXAS, USA).

Results

Our study enrolled 18 patients who had underwent LADS with Phaco in one eye and Trab with Phaco in the other eye. This included 14 males (77.8%) and 4 females (22.2%). 15 patients (83.33%) were diagnosed as primary open angle glaucoma (POAG) and the remaining 3 patients (16.66%) were diagnosed as pseudoexfoliation glaucoma (PXF). Other baseline characteristics shown in Table 1.

Table 2 shows comparison between groups on subsequent follow ups on the basis of IOP, number of AGMs, best corrected visual acuity (BCVA) and the number of medications till the fourth year of follow up. The mean IOP (mean \pm SD) for Phaco with Trab group was 15.72 ± 3.23 at preop visit, 13.61 ± 3.63 at 6 months, 14.67 ± 3.14 at 1 year, 15.27 ± 4.28 at 2 years, 17.00 ± 7.79 at 3 years and 14.40 ± 2.97 in the fourth year. Whereas the IOP for the Phaco with LADS group was found to be 17.22 ± 5.25 at pre op visit, 14.76 ± 3.93 at 6 months, 14.11 ± 3.91 at 1 year, 16.07 ± 5.51 at 2 years, 15.80 ± 6.07 at 3 years and 19.10 ± 11.67 at 4 years.

The BCVA (mean \pm SD) for Phaco with Trab group was 0.54 ± 0.24 at pre operative visit, 0.22 ± 0.18 at 6 months, 0.17 ± 0.18 at 1 year, 0.24 ± 0.20 at 2 years, 0.24 ± 0.27 at 3 years and 0.22 ± 0.21 at 4 years. In the Phaco with LADS group, the BCVA was 0.57 ± 0.26 at preop visit, 0.18 ± 0.16 at 6 months, 0.13 ± 0.11 at 1 year, 0.10 ± 0.15 at 2 year, 0.11 ± 0.13 at 3 years and 0.17 ± 0.27 at 4 years.

The number of medication in the Phaco with trab group was reduced from 1.8 ± 0.8 at the preoperative visit to 0.6 ± 0.6 , 1.1 ± 1.2 , and 1.5 ± 1.5 at the end of first, second and third year respectively. Whereas the number of medications in the Phaco with LADS group was reduced from 2.0 ± 0.8 in the pre operative period to 1 ± 1.1 , 1.5 ± 1.0 and 1.8 ± 1.0 at the end of first, second and third year respectively.

Unfortunately many patients were lost to follow up in the fourth year especially in the Phaco with Trab group but has been displayed regardless.

The below table [Table 3] shows the P value for the comparison of IOP, BCVA, number of AGM between baseline and each follow up visit. Wilcoxon Signed rank test was used to compare between and the follow up visit. There was statistically significance between baseline and the corresponding follow up visit.

Mean IOP reduction for both the groups were found to be comparable at the of 36 months as shown in Fig. 1.

The mean LogMAR for BCVA showed better visual outcomes for the Phaco with LADS group compared to the Trab with Phaco group at the end of 36 months as shown in Fig. 2. and it was found to be statistically significant based on the Wilcoxon Signed rank.

Fig. 3 and Table 4 shows the Kaplan–Meier plots of the cumulative probability of complete success in both groups up to 36 months. It was found that the estimated complete success rate in PHACO + TRAB group for 1st, 2nd, 3rd year follow up is 100%, 80.0%, 80.0% and in PHACO + LADS group is 85.7%, 57.1%, 57.1% and the difference between the two groups survival curves is also statistically significant (P value 0.0013).

Table 4: Kaplan-Meier plots of the cumulative probability of complete success

Year	Cumulative probability of Complete success		P^{\dagger}
	PHACO + TRAB	PHACO + LADS	
1 st year	1.000	0.857	0.0013
2 nd year	0.800	0.571	
3 rd year	0.800	0.571	

[†]Log rank test, Phaco - Phacoemulsification, Trab - Trabeculectomy, LADS - Laser Assisted Deep Sclerectomy

Table 5: Kaplan-Meier plots of the cumulative probability of qualified success

Year	Cumulative probability of Qualified success		P^{\dagger}
	PHACO + TRAB	PHACO + LADS	
1 st year	1.000	0.923	< 0.001
2 nd year	0.889	0.846	
3 rd year	0.889	0.846	

[†]Log rank test, Phaco - Phacoemulsification, Trab - Trabeculectomy, LADS - Laser Assisted Deep Sclerectomy

Also, the Kaplan–Meier plots of the cumulative probability of qualified success in both groups for up to 36 months were taken which is shown in Fig. 4 and Table 5. The estimated qualified success rate in PHACO + TRAB group for 1st, 2nd, 3rd year follow up is 100%, 88.9%, 88.9% and in PHACO + LADS group is 92.3%, 84.6%, 84.6% and the difference between the two groups survival curves also statistically significant (P value < 0.001).

It was found that only 2 patients (11.11%) out of the 18 patients enrolled in the study developed complications which included iris incarceration and fibrin membrane both of which occurred in the Phaco with LADS group.

Discussion

One of the major pitfalls of NPDS and probably main reason for its low popularity among surgeons is its high surgical skill required and the long learning curve needed for the technique. There occurs in 30-50% of cases perforation of the thin trabeculo-Desemet's membrane in this procedure at the learning stage.^[12] Also, if the tissue is not cut deep enough, the filtration may not be effective and the IOP will not decrease to desired target pressures. Though it can be converted to conventional trabeculectomy by goniotomy, the high rates of perforation limit the use of deep sclerectomy as a treatment procedure. LADS offers all the advantages of NPDS without its severe complications namely perforation.

Though there are many studies on NPDS and trabeculectomy we report this comparison on long term follow up of more than 3 years. The complete and qualified success rates were defined based on other literature material.^[13-15] In our study, complete success was reported to be 85.7% in the Phaco + LADS group at the end of 1 year whereas it was 100% in the Phaco + Trab group. A study by Judyta Jankowska-Szmul *et al.*^[16] which reported similar outcomes with a complete success rate as 35% for CLASS versus 60% at the end of 1 year. Subsequent yearly follow up yielded a 57.1% complete success in both years for Phaco + LADS group whereas for Phaco + Trab group it was maintained at 80% for the last 2 years. Our

study also reported qualified success rate to be 92.3% in the Phaco + LADS and that of Phaco + Trab to be 100%.

However, a study by Juan Carlos Izquierdo Villavicencio *et al.*,^[17] however reported success rate of 86.4% in the Phaco + Trab group while it was 97.2% in the Phaco + LADS group and has the added advantage of a larger sample size.

LADS is not without its set of complications which includes microhyphema, choroidal detachment, wound dehiscence and leaks.^[18,19] In our study we report less complications with LADS surgeries in our group of patients and which did not require major surgical interventions. The only complications in our study included fibrin membrane and iris incarceration (11.11%) in the LADS group. The iris incarceration may be due to microperforations of the TDM for which the patient underwent a Nd: YAG laser gonio puncture post operatively. A study by Judyta Jankowska-Szmul *et al.*,^[16] had similar complications, but the patients did not achieve target IOP despite using adjuvants. The Trab group reported no complications. Other studies have shown lesser complications in NPDS compared to trabeculectomy.^[20,21]

The IOP reduction pattern in our study for both the groups was found to be comparable at the end of 36 months. However in the BCVA distribution pattern, it was found that LADS group had better visual outcomes compared to Trab group. A study, Xiaojiao Yu^[22] reported similar outcomes with BCVA improving from 0.77 ± 0.42 preoperatively to 0.33 ± 0.47 postoperatively.

Though a less effective surgery than our traditional trab it has significant effect on moderate glaucomas to maintain on adequate IOP though not on a long term but for a shorter period to prevent progression of glaucomatous optic neuropathy. Experimental models by Assia *et al.*,^[23] have demonstrated reduced coagulative thermal damage to adjacent tissues when using the OT-135 CO₂ laser especially the trabecular meshwork.

The main limitations of our study were a small number of patients as many of them could not afford the procedure and lack of prospective comparison.

Conclusion

Even though LADS showed less IOP lowering effect, our study found it to be comparable to trabeculectomy in terms of visual acuity outcomes and reduction in number of medications. We were able to perform the surgery comfortably with ease due to the relatively shorter learning curve compared to conventional NPDS. We have found this novel technique to be safer and efficacious and can be used as an alternative to trabeculectomy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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