Single versus Two-Site Phacoemulsification and Mitomycin-C Trabeculectomy

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Purpose: To compare the outcomes of single-site versus two-site mitomycin-C (MMC) augmented phacotrabeculectomy.

Methods: This matched randomized clinical trial included 34 eyes of 30 patients with visually significant cataracts and poorly controlled glaucoma. Equal numbers of eyes were randomly assigned to the single-site and two-site groups. In the single-site approach, phacoemulsification was performed under a superior scleral tunnel followed by trabeculectomy. The two-site approach included a temporal clear corneal phacoemulsification combined with a separate superior trabeculectomy. MMC 0.2 mg/ml was similarly applied for one minute in both groups.

Results: Patients were followed for a mean period of 13±1.4 (range, 12 to 15) months. Mean best corrected visual acuity one year after surgery was 0.6±0.4 LogMAR in the single-site group and 0.4±0.28 LogMAR in the two-site group (P=0.12). In the single-site group, mean preoperative intraocular pressure (IOP) was 26.4±6.6 mmHg which was decreased to 14.8±2.5 mmHg, one year after the operation (P<0.001). Corresponding figures for the two-site group were 22.9±3.3 and 13.6±1.7 mmHg respectively (P<0.001). At final follow up no significant difference in IOP existed between the study groups. Mean number of anti-glaucoma medications was 0.06±0.24 in the two-site group vs 0.43±0.5 in the single-site group (P=0.014). The rate of complications was not different between the study groups (P=1).

Conclusions: Both single-site and two-site phacotrabeculectomy improved visual acuity which was slightly, but not significantly, better with two-site surgery. Final IOP was comparable with both techniques; however, the two-site group required fewer anti-glaucoma medications.

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INTRODUCTION

The prevalence of cataract and glaucoma both increase with advancing age, but the association between these two conditions is more than mere co-existence: cataracts seem to be more prevalent in certain forms of glaucoma (such as pseudoexfoliative glaucoma), glaucoma medications have been implicated in the progression of nuclear cataracts, and cataract progression may be accelerated following trabeculectomy.[1,2] The management of coexisting cataracts and glaucoma remains controversial. The basic problem is selecting the most appropriate surgical sequence and approach for each individual.[3] In recent years, there has been a widespread trend

towards employing combined phacotrabecul-ectomy as the preferred surgical approach for treatment of coexisting cataract and glaucoma and this procedure has been shown to be effect-tive in terms of visual improvement and intra-ocular pressure (IOP) reduction.[4] The purpose of this study is to compare the efficacy and safety of two different techniques of mito-mycin-C (MMC) augmented combined cataract and glaucoma surgery: single-site versus two-site phacotrabeculectomy.

METHODS

This prospective matched randomized clinical trial was conducted over a two-year period. Patients with visually significant cataracts (BCVA, best-corrected visual acuity ≤20/50) and poorly controlled glaucoma (IOP>21 mmHg on at least two topical medications) were evaluated for eligibility. Exclusion criteria included previous intraocular surgery; sig-nificant corneal opacity; uveitic, neovascular or phacomorphic glaucoma; any significant posterior segment pathology and history of trauma. Patients were also excluded if ma-ximally dilated pupil diameter was less than 5 mm which could necessitate the use of iris retractors or stretchers or if any complication occurred during surgery. Sample size was calculated 34 eyes based on alpha error of 5%, study power set at 90% and inter-group difference of 25%. The ethics committee of the supervising institute approved the study and informed written consent was obtained from all subjects.

Preoperative evaluations included mea-surement of uncorrected visual acuity (UCVA) and BCVA, slitlamp examination, applanation tonometry, gonioscopy and dilated-pupil fun-duscopy. Eligible patients were categorized to three subtypes of glaucoma; primary open angle glaucoma (POAG), chronic angle closure glaucoma (CACG), and pseudoexfoliation glau-coma (PXG). Eyes within each group were randomly allocated to single-site or two-site phacotrabeculectomy. All procedures were per-formed by two of the authors (ABR and SY).

Surgical Technique

In the single-site group, a 7-0 silk traction suture was placed in the cornea. A fornix-based conjunctival flap was prepared superotempo-rally (in right eyes) or superonasally (in left eyes). After scleral shaving and light cautery, cellulose sponges soaked in MMC 0.2 mg/ml were placed between the conjunctiva and sclera for 1 minute. The area was irrigated with 50 ml balanced salt solution (BSS). A half thickness triangular scleral flap 3.5 mm on each side was made and dissected anteriorly into clear cornea. Two stab incisions were made 90 degrees away from the scleral flap to inject intracameral adrenaline 1:100,000 and viscoelastic material hydroxypropyl-methylcellulose (Coatel, Bausch & Lomb, Waterford, Ireland). After performing a 5-5.5 mm continuous curvilinear capsulo-rrhexis, a 3.0 mm keratome was used to enter the anterior chamber beneath the scleral flap. Hydrodissection and hydrodelineation were performed followed by phacoemulsification using the divide and conquer technique; cor-tical material was removed by manual irri-gation and aspiration. A one-piece foldable acrylic lens (AcrySof SA60AT, Alcon Labo-ratories, Fort Worth, Texas, USA) was im-planted in the capsular bag and a 1×1 mm limbal block was excised using a 15° knife afterwards. After viscoelastic removal, acetyl-choline chloride 1% (Alcon Cusí, Barcelona, Spain) was injected for miosis and peripheral iridectomy was performed. The scleral flap was secured using one releasable 10-0 nylon suture at the apex and two permanent 10-0 nylon su-tures placed on both sides. The free end of the releasable suture was buried in the peripheral cornea. The anterior chamber was formed with BSS and releasable suture tension was adjusted to obtain adequate filtration. Conjunctival clo-sure was achieved with two 10-0 nylon wing sutures.

In the two-site group, a limbus-based con-junctival flap was made 8 mm posterior to the limbus superotemporally (in right eyes) or superonasally (in left eyes). MMC was applied as mentioned above. A half-thickness triangu-

lar scleral flap 3.5 mm on each side was dissect-ted. Temporal clear cornea phacoemulsification was performed as mentioned for the one-site group and trabeculectomy was completed in a similar fashion described above except for con-junctival repair which was accomplished using a running 10-0 nylon suture.

Patients were examined on postoperative days 1, 3, 7, 14 and 28, then monthly for six months and every three months thereafter. During the first two weeks, betamethasone 0.1% drops every three hours and chloram-phenicol 0.5% drops every six hours were administered. Chloramphenicol was discon-tinued after two weeks and betamethasone was gradually tapered off over 6 to 12 weeks depending on the degree of inflammation. Releasable suture removal was performed three days to 1.5 months postoperatively according to bleb morphology and level of IOP. Post-operatively BCVA, IOP and the number of re-quired anti-glaucoma medications were eva-luated; intra- or postoperative complications were also recorded.

Compiled data including IOP, BCVA and number of anti-glaucoma medications were analyzed and compared between the two study groups. Chi-square and Fisher's exact tests were used to compare sex distribution and type of glaucoma between groups. Student *t*-test was used to compare age, pre- and post-operative mean IOP, pre- and postoperative mean number of medications and change in visual acuity. Paired t-test was used to evaluate changes in IOP and BCVA within each group.

RESULTS

Thirty-four eyes of 30 patients with visually significant cataracts and poorly controlled glaucoma underwent phacotrabeculectomy. Subgroups included 12 eyes with POAG, 10 eyes with CACG and 12 eyes with PXG. Overall, 17 eyes were randomly allocated to single-site and an equal number underwent two-site surgery. The study arms were compar-able in terms of preoperative characteristics including age, sex, type of glaucoma, baseline IOP, number of preoperative glaucoma medi-cations and preoperative BCVA (table 1). Overall, mean follow up was 13±1.4 (range 12-15) months. Mean follow up was 12.6±1.9 months in the single-site group and 13.4±1.5 months in the two-site group (P=0.86).

Table 1 Preoperative patient characteristics

	Single-site	Two-site	P-value
Age (years)			
Mean±SD (range)	68.9±7.4 (60-85)	66.6±8.6 (53-83)	0.40
Sex			
Male	12	6	0.16
Female	5	7	
Type of glaucoma			
Primary open angle glaucoma	7	5	0.71
Chronic angle closure glaucoma	5	5	
Pseudoexfoliation glaucoma	5	7	
Preoperative IOP (mmHg)			
Primary open angle glaucoma	23.7±5.1	24.4±2.6	0.79
Chronic angle closure glaucoma	26.8±5.4	22.2±5.0	0.20
Pseudoexfoliation glaucoma	29.8±8.9	22.4±2.0	0.14
Overall	26.4±6.6	22.9±3.3	0.06
Number of glaucoma medications			
Mean±SD	2.4±0.8	2.2±0.7	0.48
2 medications	9 eyes	11 eyes	
≥3 medications	8 eyes	6 eyes	
Visual acuity (LogMAR)			
Mean ± SD (Snellen notation)	0.98±0.54 (20/200)	0.90±0.50 (20/160)	0.65

SD, standard deviation; IOP, intraocular pressure

Twelve months after surgery, BCVA was ≥20/40 in three (18%) and six (36%) eyes in the single-site and two-site groups, respectively. BCVA was 20/200 to 20/50 in 14 (76%) eyes in the single-site and in 10 (58%) eyes in the two-site groups and was less than 20/200 in one (6%) eye of each group. Improvement in visual acuity was statistically significant within both groups (P<0.001) but no significant difference existed between the groups (P=0.54). At final follow up there was no difference between the two groups: mean postoperative BCVA was 0.60±0.40 LogMAR (20/80) and 0.41±0.30 LogMAR (20/50) in the single-site and two-site groups, respectively (P=0.12) (Table 2).

In the single-site group, mean preoperative IOP was 26.4±6.6 mmHg which was reduced to 14.8±2.5 mmHg, one year after the operation (P<0.001). In the two-site group, mean preoperative IOP was 22.9±3.3 mmHg which was

also significantly decreased to 13.6±1.7 mmHg postoperatively (P<0.001). Both surgical techniques followed similar postoperative IOP curves (Fig. 1).

Overall, the percentage of IOP reduction from baseline values was not significantly different between the two study groups at any follow up interval except in eyes with POAG: the two-site approach yielded consistently greater IOP reduction which was statistically significant at one month only; after 12 months, the inter-group difference was of borderline significance (table 3). In contrast, the percentage of IOP reduction from baseline values was consistently greater or comparable to the other approach with two-site surgery in eyes with CACG and PXG (figures 2-4). Overall comparison between groups showed no significant superiority of either technique at any time after surgery (Fig. 5).

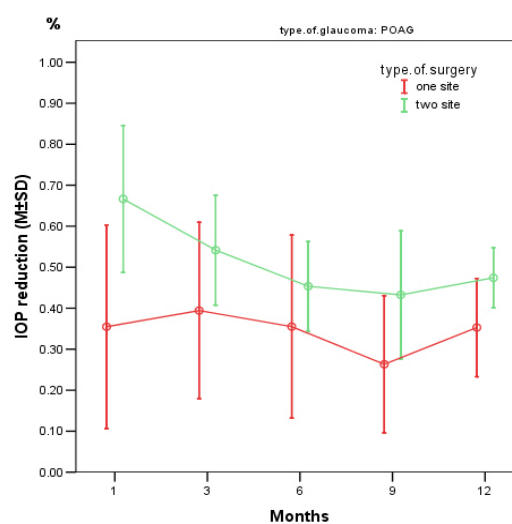**Table 2** Best-corrected visual acuity in the study groups

	Mean±SD (Snellen notation)		P-value
	Single-site	Two-site	
Preoperative	0.98±0.54 (20/200)	0.90±0.50 (20/160)	0.65
Final	0.60±0.40 (20/80)	0.41±0.30 (20/50)	0.12
P- value	<0.001	<0.001	

M, mean; SD, standard deviation
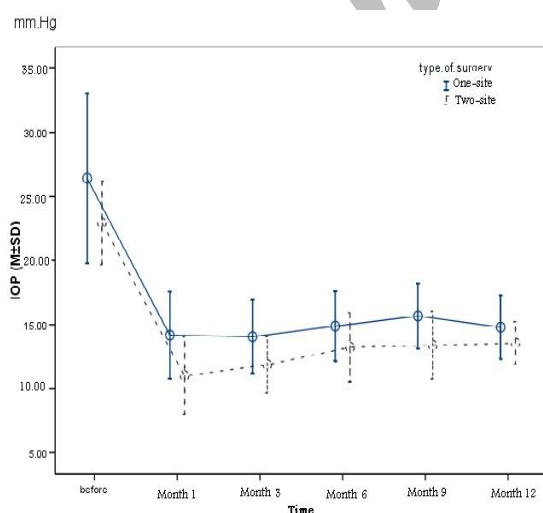
M, mean; SD, standard deviation

Figure 1 Intraocular pressure (IOP) changes during the course of the study

M, mean; SD, standard deviation

Figure 2 Percentage of intraocular pressure (IOP) reduction in eyes with primary open angle glaucoma
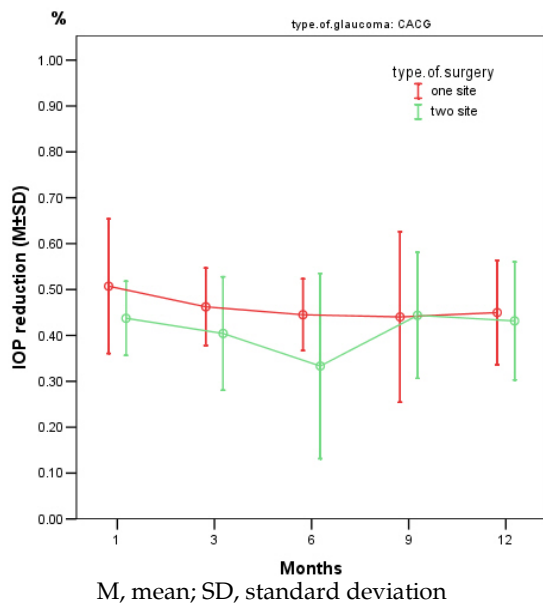
%

type.of.glaucoma: CACG

type.of.surgery
one site
two site

M, mean; SD, standard deviation

Figure 3 Percentage of intraocular pressure (IOP) reduction in eyes with chronic angle closure glaucoma

%

type.of.glaucoma: PXF

type.of.surgery
one site
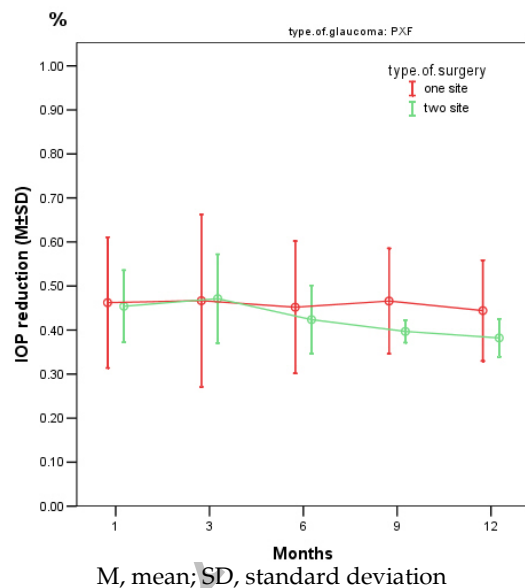two site

M, mean; SD, standard deviation

Figure 4 Percentage of intraocular pressure (IOP) reduction in eyes with pseudoexfoliation glaucoma

In both groups, the number of glaucoma medications was significantly reduced from preoperative values (P<0.001). After 12 months, eyes in the two-site group required significantly fewer medications than the single-site group (P=0.014) (Table 4).

Table 3 Postoperative percentage of intraocular pressure reduction in different study subgroups

	M± SD (mmHg)		P-value
	One-site	Two-site	
Month 1			
POAG	35±24	66±17	0.04
CACG	50±14	43±8	0.38
PXG	46±14	45±8	0.90
Overall	43±19	51±15	0.19
Month 3			
POAG	39±21	54±13	0.21
CACG	46±8	40±12	0.41
PXG	46±19	47±10	0.96
Overall	43±17	47±12	0.47
Month 6			
POAG	35±22	45±10	0.39
CACG	44±7	33±20	0.30
PXG	45±15	42±7	0.69
Overall	41±16	42±10	0.83
Month 9			
POAG	26±16	43±15	0.14
CACG	44±18	44±13	0.98
PXG	46±11	39±2	0.30
Overall	37±17	42±11	0.40
Month 12			
POAG	35±11	47±7	0.07
CACG	44±11	43±12	0.82
PXG	44±11	38±4	0.21
Overall	40±11	42±8	0.67

M, mean; SD, standard deviation; POAG, primary open angle glaucoma; CACG; chronic angle closure glaucoma; PXG, pseudoexfoliation glaucoma

Complications in the one-site group included corneal edema secondary to Descemet's detachment requiring intracameral expansible gas injection, postoperative uveitis, anterior capsule phimosis and persistent bleb leakage requiring resuturing, each in one eye. Postoperatively, 5-fluorouracil (5-FU) was injected subconjunctivally in 4 (24%) eyes to prevent bleb failure. Complications in the 2-site group included hyphema which improved spontaneously, flat anterior chamber and choroidal effusion that necessitated choroidal tap and anterior chamber reformation, bleb leakage requiring resuturing, postoperative uveitis and choroidal effusion which improved spontaneously, each in one eye. In this group, 5-FU

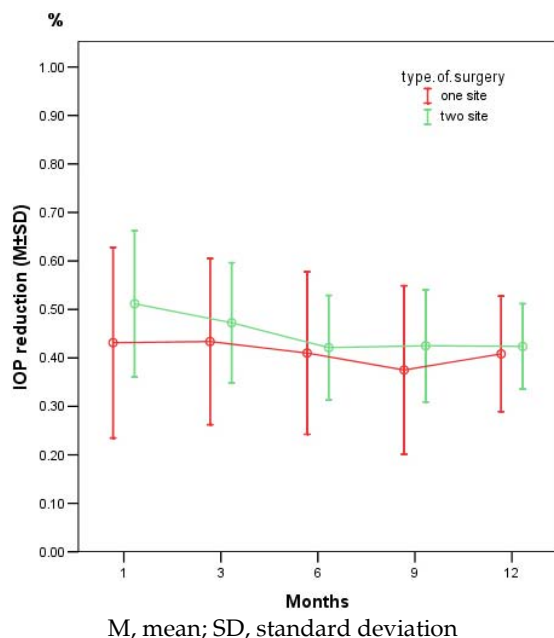was required in 3 (17%) eyes. The rate of complications was not different between the study groups (P=1.0).

M, mean; SD, standard deviation

Figure 5 Overall percentage of intraocular pressure (IOP) reduction

Table 4 Mean number of glaucoma medications

	M±SD		P-value
	One-site	Two-site	
Preoperative	2.41±0.8	2.23±0.7	0.48
Postoperative	0.4±0.5	0.06±0.2	0.014
P-value	<0.001	<0.001	

M, mean; SD, standard deviation

DISCUSSION

The coexistence of glaucoma and cataracts has become more frequent due to improved life expectancy.[5] The first issue in this regard is the decision to perform staged versus combined surgery. Glaucoma surgery may be preceded by cataract surgery when the severity of the glaucoma outweighs visual impairment by cataracts. Drawbacks to this approach include the fact that cataract progression is one of the late complications of trabeculectomy; even after uneventful filtering surgery, cataracts may pro-

gress due to postoperative inflammation and the use of corticosteroids.[6] Another concern with this approach is the possible detrimental effects of phacoemulsification on IOP control in eyes with previous filtering procedures.[7-9]

Although indicated in limited circumstances, cataract surgery may be performed prior to glaucoma surgery in eyes with mild to moderate glaucomatous damage. It is well known that cataract surgery alone results in long-term IOP reduction with values ranging from 1 to 5 mmHg.[10-12] Hayashi et al[10] reported mean IOP reduction of 5 mmHg two years after cataract surgery in patients with POAG. Medications were needed in only 15% of their patients. Patients with pseudoexfoliative glaucoma may experience a slightly more pronounced IOP lowering effect following cataract surgery compared with those with POAG.[13] The greatest benefit in terms of IOP reduction with cataract surgery is in patients with angle closure glaucoma. Hayashi et al[10] reported a reduction of 7 mmHg after two years and 40% of the eyes did not require medications. Other investigators however, have conflicting reports. Verges et al[5] concluded that IOP reduction after cataract surgery is transient and Merkur et al[13] reported that IOP reduction with phacoemulsification in pseudoexfoliative glaucoma was very small after 6 months. One drawback to this approach is the possibility of early postcataract surgery IOP spike in eyes with glaucoma which occurs in 10% to 37%.[11,13]

A combined surgical approach to address both the cataract and the glaucoma may be appropriate in a sizeable population of patients. The important issue in planning combined surgery is the decision between the single-site versus two-site approach. There is no strong evidence to demonstrate the superiority of either technique, however existing data are more in favor of the two-site technique.[3,14-16] Friedman et al[17] reported slightly better results when the incisions were made separately. They quantified the effect as an additional reduction of 1 to 2 mmHg with two-site surgery. Jampel et al[18] also noted the superiority of the two-site over the one-site technique, reporting an IOP

reduction difference of 1 to 2 mmHg. However, el-Sayyad et al[3] and Wyse et al[15] reported comparable levels of IOP reduction with both techniques but eyes undergoing one-site surgery required more glaucoma medications than those with two-site surgery.

In the current study, significant visual improvement, IOP reduction and less need for glaucoma medications were observed with both surgical techniques. Although BCVA was slightly better with two-site surgery, the observed difference was not great enough to reach statistical significance. This difference may be due to the more stable nature of temporal phacoemulsification incisions and the fact that by separating the surgical sites, the tissue weakening effect of MMC on the larger cataract surgery wound may be avoided. A larger sampled study may reveal the superiority of two-site surgery. Our randomized clinical trial revealed that overall IOP reduction from baseline was comparable in the two groups; except for a borderline greater reduction in eyes with POAG with two-site surgery, the single site technique was equally or slightly better in eyes with CACG and PXG. One definite advantage of the two-site approach was that significantly less anti-glaucoma medications were needed which is similar to Wyse's study.[15] This finding may be attributed to more manipulation of the conjunctiva and sclera at the site of surgery with the one-site approach. Additionally, the phacoemulsification tip may deliver mechanical and thermal energy to the trabeculectomy site, which can theoretically lead to greater postoperative scarring of the filtering bleb.

In the present study a limbus-based conjunctival flap was used for the two-site approach and a fornix-based flap in the one-site technique. There is evidence that both types of conjunctival flaps have similar long-term results. Fornix-based conjunctival flaps provide better visualization during trabeculectomy; however, the risk of leakage is greater especially when antimetabolites are used.[19] Theoretical advantages of the two-site technique include less trauma to the site of filtration and a lower risk of bleb leakage using a limbus-based

peritomy. However, in the current study the rate of bleb leakage was the same in both groups.

The rates of intra- and postoperative complications of cataract surgery seem to be higher in glaucomatous eyes. The corneal endothelium is compromised and corneal edema after cataract surgery is more severe.[20] Very often, pupillary dilation is inadequate and additional manipulations are required to achieve sufficient visualization. Zonular weakness and the higher rate of anterior capsule contraction in PXG prompt delicate maneuvers and consideration for implantation of a capsular tension ring. Glaucomatous eyes demonstrate a higher incidence of postoperative uveitis.[5] Borggrefe et al[14] reported the most frequent postoperative complication in phacotrabeculectomy to be fibrinous exudation (24%). Using small incision cataract surgery for combined procedures, Allan and Barrett[21] found postoperative fibrinous exudation in 33% of eyes in their series. The relatively high incidence of fibrinous exudation in patients with glaucoma and cataract might be explained in part by blood-ocular barrier dysfunction especially in eyes with PXG and those on long-term miotics. Manipulation of the iris such as stretching or synechiolysis also seems to be an important contributing factor. The overall rate of fibrinous exudation in the current study was 6% and the rate was the same in both groups. This is in contrast to Januszewski's study[22] in which breakdown of the blood-aqueous barrier was more common with the two-site approach. We excluded eyes with insufficient pupillary dilation and probable need for iris manipulation, otherwise the rate of postoperative inflammation or other complications could have been different.

The current study was somehow limited in the number of patients and follow up period. Also, the borderline difference in baseline IOP which was higher in the one-site group, especially in the PXG subgroup, makes it difficult to generalize our results. In conclusion, single-site and two-site phacotrabeculectomy led to significant reduction in IOP and improvement

in visual acuity which were comparable one year after surgery. The number of glaucoma medications was also decreased with both surgical approaches but significantly fewer medications were needed with the two-site procedure.

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