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One-site *versus* two-site phacotrabeculectomy in chronic angle-closure glaucoma with cataract

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Abstract

• AIM: To compare one-site *vs* two-site phacotrabeculectomy in chronic angle-closure glaucoma (CACG) coexisting with cataract.

• METHODS: This prospective, randomized study included 41 eyes with CACG. One-site approach was performed in 21 eyes and two-site procedure in 20 eyes. Intraocular pressure (IOP), best-corrected visual acuity (BCVA), the number of antiglaucoma medications and complications were observed. All patients were followed up for 9 months.

• RESULTS: There were no significant differences between the two groups preoperatively. IOP decreased from 22.7 ± 4.9mmHg and 23.7 ± 4.7mmHg preoperatively in one- and two-site groups to 18.0 ± 1.2mmHg and 16.7 ± 1.1mmHg 9 months after operation respectively ($P < 0.05$). There were no significant differences in mean IOP between the two groups at any time ($P > 0.05$). Decrease of the number of antiglaucoma medications and BCVA improvement were similar in both groups 9 months after surgery ($P > 0.05$). There were no significant differences in complications between the two surgical procedures.

• CONCLUSION: There were no significant differences between the two groups in clinical efficacy and complications.

• KEYWORDS: one-site; two-site; phacotrabeculectomy; chronic angle-closure glaucoma; cataract

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INTRODUCTION

The popularity of phacotrabeculectomy has recently been increasing as a combined surgery for chronic angle-closure glaucoma (CACG) coexisting with cataract. Phacotrabeculectomy can be performed either using one-site or two-site incisions[1,2]. The earliest clinical studies of phacotrabeculectomy which were known as a one-site procedure was the same as the scleral tunnel incision for both the phacoemulsification and trabeculectomy[3,4]. The introduction of the temporal incision for phacoemulsification has allowed surgeons to perform two-site procedure, with a prelimbal filtering incision for the trabeculectomy and a separate clear cornea incision for phacoemulsification[5-7]. In this study, we prospectively compared the IOP, best-corrected visual acuity (BCVA), the number of antiglaucoma medications and postoperative complications after one-and two-site phacotrabeculectomy in eyes with CACG and cataract.

MATERIALS AND METHODS

Subjects This prospective, randomized clinical study followed the tenets of the Declaration of Helsinki and was approved by the Review Board/Ethics Committee of Shengjing Hospital, China Medical University. Written informed consent was obtained from all participants before enrollment. Consecutive cases were referred to the investigators for assessment of eligibility. Criteria for inclusion in the study was the presence of visually significant CACG and cataract in the same eye with inadequate control of IOP or requiring 2 or more antiglaucoma medications. IOP of all eyes had more than 21mmHg on at least 1 previous examination. Exclusion criteria included the presence of neovascularization of the iris or angle, a history of uveitis, phacolytic or phacomorphic glaucoma, steroid-induced glaucoma, traumatic glaucoma, or previous incisional surgery in the same eye. Patients older than 89 years were not included. The authors did not enroll patients with known conditions (*e. g.*, macular degeneration) because they would be likely to affect visual acuity. To avoid selection bias, every consecutive patient meeting the inclusion and exclusion criteria was invited to participate in the study throughout the enrollment period. Patients were randomized to one- or two-site phacotrabeculectomy using a random numbers table. Details of the series were unknown to the investigators. Subjects were masked to the treatment method. All preoperative and postoperative examinations were performed by one of the authors, who also was masked to the study group identification. During the study recruitment period from September 2006 to September 2009, 41 CACG eyes with coexisting cataract of 41 patients were recruited.

Methods All surgical procedures were carried out following a standardized surgical procedure. A 7-0 Vicryl corneal traction suture was placed 1mm in a clear cornea at 12:00. A fornix-based conjunctival flap was dissected for one-site approach and a limbus-based conjunctival flap for two-site approach. All cases received subconjunctival mitomycin C 0.4g/L for 2 minutes followed by irrigation with 40mL of balanced salt solution. A 4mm × 4mm triangular scleral flap

Table 1 Patient with phacotrabeculectomy demographics

Demographics	One-site	Two-site	*P* value
No. of eyes	21	20	
Age (yr, mean ± SD)	55.5 ± 15.6	54.8 ± 15.5	0.90
Gender (male/female)	8/13	11/9	0.28
Eye (right/left)	6/15	10/10	0.16
Preoperative IOP (mmHg, mean ± SD)	22.7 ± 4.9	23.7 ± 4.7	0.31
No. of preoperative antiglaucoma medications (mean ± SD)	3.1 ± 0.5	3.4 ± 0.6	0.75
Preoperative BCVA (LogMAR, mean ± SD)	0.7 ± 0.4	0.8 ± 0.6	0.62
Extent of synechial angle closure (degree, mean ± SD)	255 ± 65	268 ± 73	0.27
Postoperative			
Hypotony	3	3	0.99
Shallow anterior chamber	2	3	0.70
Choroidal detachment	1	1	0.99
Hyphema	4	2	0.44
Encapsulated bleb	3	1	0.33

BCVA: Best-corrected visual acuity; LogMAR: Logarithm of the minimum angle of resolution.

was dissected. A 3.2mm keratome was used to enter the anterior chamber beneath the scleral flap for one-site approach and a clear corneal temporal incision for two-site approach. In cases of inadequate pupil dilation, a bimanual stretching technique employing two Kuglen hooks, one through the incision with the keratome and the second through the second port incision, was employed. Phacoemulsification was performed, followed by insertion of a foldable intraocular lens. The scleral flap was closed with two 10-0 nylon sutures in one-site surgery and three 10-0 nylon sutures in two-site surgery. One 10-0 nylon suture was placed through the temporal clear cornea incision in two-site surgery. Postoperatively, all eyes received topical eye drops containing 3g/L tobramycin and 1g/L dexamethasone (TobraDex; Alcon Laboratories Inc., Fort Worth, TX) 4 times a day for 1 week and then tapered off within 1 month. For IOP control, argon laser suture lysis was performed or antiglaucoma medications were added if necessary. The primary outcome measure was postoperative IOP. Secondary outcome measures included mean change in BCVA, the number of antiglaucoma medications postoperatively.

With a power of 80%, significant level set at 0.05, to detect a 2 mmHg IOP difference, a sample size of 41 eyes for each arm was calculated. The median follow-up time was 9 months (ranged from 7 to 14 months). Of these 41 eyes, 21 eyes were randomized into the one-site group, whereas 20 eyes were randomized into the two-site group. The treatment allocation was balanced. Patient demographics and baseline data were summarized in Table 1. Preoperatively there were no differences between the two groups.

Statistical Analysis Statistical analysis was performed using SPSS software version 16.0 (SPSS Inc, Chicago, IL). Continuous variables were analyzed using the paired *t* test for values within a group, and the independent-sample *t* test was used to compare the values between the two groups. Fisher exact test was used to compare the categorical data between the two groups. $P<0.05$ was considered statistically significant.

RESULTS

IOP Mean preoperative IOP were similar in both groups ($P=0.31$). Postoperatively, there was a statistically significant reduction in IOP from baseline at all time points in both groups ($P<0.05$, Figure 1); however, there was no significant difference in IOP between the groups ($P>0.05$).

Antiglaucoma Medications Secondary Outcome Measures There was a statistically significant reduction in number of antiglaucoma medications from baseline at all postoperative time points. In one-site group, the number of antiglaucoma medications dropped from preoperative 3.1 ± 0.5 to 0.3 ± 0.4 at 9 months postoperatively ($P=0.00$). In two-site group, this number decreased from 3.4 ± 0.6 preoperatively to 0.4 ± 0.4 at 9 months postoperatively ($P=0.00$). There was no statistically significant difference between the two groups in terms of the mean number of antiglaucoma medications at 9 months after operation ($P=0.22$).

BCVA The postoperative BCVA was 0.42 ± 0.27 in the one-site and 0.38 ± 0.23 in the two-site group (Figure 2). Postoperative BCVA did not differ significantly between the groups ($P=0.26$).

Complications No significant differences between one-site and two-site phacotrabeculectomy were found in the incidence of hypotony, shallow anterior chamber, choroidal detachment, hyphema, encapsulated bleb.

DISCUSSION

This randomized controlled clinical study is conducted to compare the efficacy in IOP control of one-site *versus* two-site phacotrabeculectomy in CACG eyes coexisting with cataract. Previous studies have prospectively evaluated the efficacy and tolerability of one-site phacotrabeculectomy compared with two-site procedure. However, they included more than two types of glaucoma[8-10]. The results of this study imply that the efficacy of two-site phacotrabeculectomy appears to be similar to one-site for the management of CACG and coexisting cataract, and there is nonsignificant difference in complications between two surgical procedures. IOP and BCVA

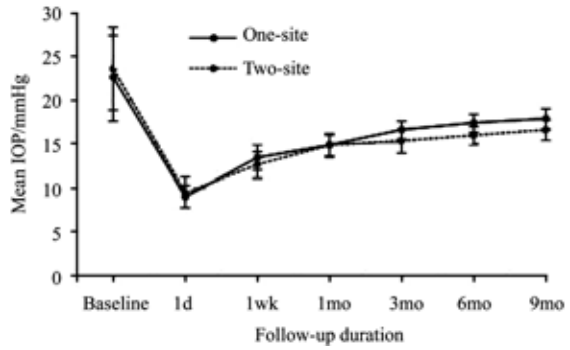

Figure 1 Pre- and postoperative IOP of one-site *versus* two-site phacotrabeculectomy.

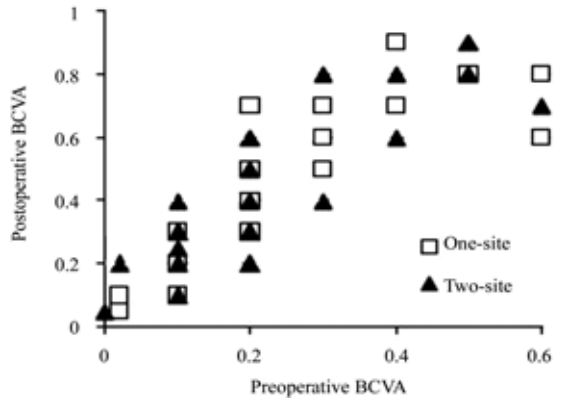

Figure 2 Pre- and postoperative BCVA values of all patients.

merely are surrogate measures for phacotrabeculectomy, and the two surgical procedures may act through pathways independent of this mechanism. There are many preoperative and postoperative key factors to determine which surgical approach is carried out. Factors that may favor a one-site procedure are faster surgical time, less corneal endothelial cell loss, and surgeon experience with a superior approach. Factors that may favor a two-site approach are surgeon familiarity with temporal phacoemulsification, orbital physiognomy, reduced the surgically-induced astigmatism, conjunctival scar, limited superior access, ergonomic comfort for the surgeon, and absence of irrigation outflow underneath the conjunctival flap during phacoemulsification that may potentially affect intraoperative anti-metabolite effect.

In summary, based on the findings of this study, we conclude that both one-site and two-site procedure are efficacious and well tolerated. Pragmatic multicenter, long-term, large sample size, randomized, controlled trials need to further evaluate the efficacy and tolerability of one- *versus* two-site phacotrabeculectomy in the treatment of patients coexisting with cataract and glaucoma.

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不同切口超声乳化吸除术联合小梁切除术治疗白内障合并 CACG

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摘要

目的:评价并比较一切口和二切口超声乳化白内障吸除术联合小梁切除术治疗慢性闭角型青光眼合并白内障的疗效。

方法:采用前瞻性随机对照临床试验研究,包括 41 例 41 眼具有慢性闭角型青光眼合并白内障的患者。21 例行一切口超声乳化白内障吸除术联合小梁切除术,20 例行二切口手术。术后观察的指标包括:术后眼内压(IOP)、抗青光眼药物使用数量、最佳矫正视力(BCVA)以及术后并发症。所有研究对象随访 9mo。

结果:两组研究对象术前各项指标没有差别。术后 9mo,一切口组和二切口组 IOP 分别从术前 22.7±4.9mmHg,23.7±4.7mmHg 降至 18.0±1.2mmHg,16.7±1.1mmHg($P<0.05$)。各随访时间点两组 IOP 差别没有统计学意义($P>0.05$)。术后 9mo,两组抗青光眼药物减少和 BCVA 提高差异均无统计学意义($P>0.05$)。两种手术方式在术后并发症方面无差异。

结论:两种超声乳化白内障吸除术联合小梁切除手术方式治疗的临床疗效和术后并发症没有明显差异。

关键词:一切口;二切口;超声乳化吸除术;慢性闭角型青光眼;白内障