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Safety and prognosis of phacoemulsification using active sentry and active fluidics with different IOP settings - a randomized, controlled study

Shouyan Wang[1], Jianjian Tao[1], Xiao Yu[2], Weilin Diao[1], Haiqing Bai[3*] and Lin Yao[4*]

Abstract

Purpose To explore the impact of different intraoperative intraocular pressure (IOP) settings on the safety and prognosis in phacoemulsification.

Methods Age related cataract patients who met the inclusion criteria and underwent phacoemulsification by using active sentry handpiece and active fluidics system. According to different intraoperative IOP settings during surgery, they were randomly divided into two groups: the 20mmHg group and the 60mmHg group. The best corrected visual acuity (BCVA), cumulative dissipated energy (CDE), total U/S time, active surge mitigation (ASM), estimated fluid usage (EFU) as well as the changes in corneal thickness (CT), corneal epithelial layer thickness (CELT) and endothelial cell density (ECD) were collected. The post-operative follow-up was only 1 day.

Results A total of 110 cases (110 eyes) were included in the study. There were 55 eyes in each group. There was no statistically significant difference in postoperative BCVA ($p=0.839$). The CDE, total U/S time and EFU during surgery were (5.22 ± 3.31), (30.60 ± 15.06), (45.07 ± 12.68) and (4.70 ± 2.83), (27.39 ± 13.75), (42.38 ± 11.93) in the 20mmHg group and 60mmHg group ($p=0.381$, 0.246, 0.254). The ASM during surgery in the 20mmHg group and 60mmHg group were (0.95 ± 2.77) and (7.24 ± 6.34), respectively. The 20mmHg group showed a significant decrease in ASM ($p<0.001$). There was no statistically significant difference in the changes in CT, CELT and ECD before and after surgery between the two groups ($p=0.913$, 0.825, 0.624). Both groups did not experience any intraoperative complications, such as posterior capsule rupture.

Conclusion A lower IOP setting of 20 mmHg can significantly reduce the occurrence of intraoperative surges during phacoemulsification. And there was no increase in rate of complications.

Trial Registration The trial registration number is ChiCTR2100050240. The registered date is August 24th, 2021.

Keywords Phacoemulsification, Active sentry, Active fluidics, Intraocular pressure, Active surge mitigation

*Correspondence:
Haiqing Bai
haiqing_bai@126.com; haiqingbai@qdu.edu.cn
Lin Yao
lynyao@126.com
[1]Yantai Aier Eye Hospital, Yantai, China
[2]Department of Ophthalmology, Affiliated Qingdao Third People's Hospital, Qingdao University, Qingdao, China
[3]Department of Ophthalmology, The Affiliated Hospital of Qingdao University, 16th, Jiangsu Road, Qingdao 266003, China
[4]Qingdao Aier Eye Hospital, 519th, Zhujiang Road, Qingdao 266400, China

Introduction

The fluidics system is an indispensable and primary component of phacoemulsification. Currently, both the gravity fluidics system (GFS) and active fluidics system (AFS) are commonly used in practice [1]. The irrigation pressure of the GFS is determined by the bottle height, which is usually set at 80 to 100 mm [2, 3]. The irrigation pressure is approximately 59 to 74 mmHg. The AFS allows surgeons to preset a target intraoperative IOP, which is usually set to be 50 to 60 mmHg [4, 5].

In order to avoid the harm caused by high intraoperative IOP, we gradually reduced the preset target intraoperative IOP in practice. In our study, we found phacoemulsification can also be performed safely even when the preset target intraoperative IOP was 20mmHg by using active sentry handpiece accompany with AFS. Active sentry handpiece is a new kind handpiece with an integrated sensor for dynamic measurement of IOP very close to the patient's eye, which enabled precise and timely IOP measurement [6].

In this study, we compared safety and prognosis of phacoemulsification by using active sentry handpiece and AFS with high and low intraoperative IOP settings.

Methods

Study design and patients

This study was approved by the Ethics Committee of the Yantai Aier Eye Hospital (approval ID: YTAE2021001). The protocol was registered at Chictr.org.cn (ChiCTR2100050240). This was a single center prospective randomized controlled clinical study. Both patients and examiners masked. However, the surgeon was not masked to the settings of intraoperative IOP.

The inclusion criteria for these patients were: 50–80 years of age, 22.0–25.0 mm axial lengths, more than 2000 endothelial cells/mm^2, anterior chamber depth beyond 2.5 mm, dilated pupil diameter beyond 6 mm, cataract nucleus grade 3 (according to Emery-Little classification [7]), without any other oculopathy. Only one eye of each patient was included in this study.

All the included patients were randomly assigned to 20mmHg group and 60mmHg group in a 1:1 ratio according to the different settings of the intraoperative IOP during the surgery by using a random number table method.

Table 1 Demographics and baseline characteristics

Characteristic	20mmHg group ($n=55$)	60mmHg group ($n=55$)	*P* Value
Age (y)	68.73 ± 5.94	67.93 ± 6.75	0.511*
Sex, n (%)			
Male	25 (45.5%)	26 (47.3%)	0.848†
Female	30 (54.5%)	29 (52.7%)	
Right eye, n (%)	29 (52.7%)	27 (49.0%)	0.703†
Left eye, n (%)	26 (47.3%)	28 (51.0%)	
Preoperative BCVA (LogMar)	0.54 ± 0.32	0.55 ± 0.35	0.879*
CT (μm)	531.75 ± 26.36	533.27 ± 37.50	0.805
CELT (μm)	56.20 ± 3.80	56.89 ± 5.28	0.433
ECD (/mm^2)	2676.62 ± 325.24	2719.65 ± 51.66	0.527

Mean ± SD; *Independent-samples *t*-test; †Chi-square test

CT, corneal thickness; CELT, corneal epithelial layer thickness; ECD, endothelial cell density

Surgical procedure and follow-up

All surgeries were performed by the same surgeon (Wang S), who is experienced in phacoemulsification, using the Alcon Centurion Vision system under active sentry handpiece with AFS (Alcon Laboratories, Inc.). The phaco-chop technique was employed to emulsify the nucleus (torsional power: 0-100%, vacuum, 500mmHg, and aspiration flow: 40 cc/min). IA was then used to clear the cortex (vacuum, 500mmHg, and aspiration flow: 38 cc/min). In both phaco and IA procedures, the settings of IOP were 20mmHg and 60mmHg in the 20mmHg group and 60mmHg group respectively. The post-operative follow-up was only 1 day.

Outcome measures and data analysis

Before and 1 day after surgery, the following clinical data of each case were collected: best corrected visual acuity (BCVA), corneal thickness (CT), corneal epithelial layer thickness (CELT) and endothelial cell density (ECD). CT and CELT were measured by Cirrus HD-OCT 5000 (Carl Zeiss Meditec, Inc.). ECD was measured by SP-1P Specular microscope (Topcon, Inc).

During the surgery, cumulative dissipated energy (CDE), total U/S time, estimated fluid usage (EFU) and active surge mitigation (ASM) the occurrence of posterior capsular rupture (PCR) were collected.

The independent-samples t-test was used to compare continuous variables between two groups. The assumption of equal variance was used. The Chi-square tests was used to evaluate differences in categorical variables. Data were analyzed using Statistical Package for Social Sciences software (version 27, International Business Machines Corp.). The level of significance was set to a *P*-value of 0.05.

Results

Clinical

Fifty-five patients were evaluated in each group. The characteristics of the patients in both groups are shown in Table 1. There were no statistically significant differences in any characteristics between two groups.

Primary outcomes

The CDE, total U/S time and EFU during surgery in the 20mmHg group and 60mmHg group were (5.22 ± 3.31),

(30.60±15.06), (45.07±12.68) and (4.70±2.83), (27.39±13.75), (42.38±11.93), respectively. There was no significant difference in CDE, total U/S time and EFU between two groups (p=0.381, 0.246, 0.254) (Table 2). The ASM during surgery in the 20mmHg group and 60mmHg group were (0.95±2.77) and (7.24±6.34), respectively. Compared with the 60mmHg group, the occurrence of ASM was decreased significantly in the 20mmHg group (p<0.001) (Table 2). There was no occurrence of PCR in both groups.

Secondary outcomes

Postoperative BCVA was 0.16±0.15 and 0.17±0.14 in the 20mmHg group and 60mmHg group, respectively. There was no difference between two groups (p=0.839). Changes in CT and CELT were 29.58±25.48 μm, 3.51±3.08 μm in the 20mmHg group and 30.16±30.29 μm, 3.36±3.77 μm in the 60mmHg group. There was no difference between two groups (p=0.913, 0.825) (Table 2). Changes in ECD were 114.31±242.85/mm^2 in the 20mmHg and 136.24±224.34/mm^2 in the 60mmHg group. There was no difference between two groups (p=0.624) (Table 2).

Discussion

Active sentry handpiece can automatically detect patient's eye level, estimate incision leakage and ASM, which is expected to improve anterior chamber stability [6]. In addition, active sentry handpiece can detect the occlusion break instantaneously by the integrated sensor. While, the traditional handpiece is without sensor, and the sensor is on the cartridge, which led to a longer time delay upon stabilization of the anterior chamber [6]. The integrated sensor in the active sentry handpiece can signal the quick valve technology to release fluid into the aspiration tubing so that an occlusion break surge event is prevented [8]. Therefore, active sentry handpiece offers additional advantages for maintaining the anterior chamber depth even during occlusion breaks [9, 10].

Table 2 Intraoperative and postoperative parameters

Parameter	20mmHg group (n=55)	60mmHg group (n=55)	P Value
CDE	5.22±3.31	4.70±2.83	0.381
Total U/S time (s)	30.60±15.06	27.39±13.75	0.246
EFU (ml)	45.07±12.68	42.38±11.93	0.254
ASM	0.95±2.77	7.24±6.34	<0.001
Change in CT(μm)	29.58±25.48	30.16±30.29	0.913
Change in CELT (μm)	3.51±3.08	3.36±3.77	0.825
Change in ECD (/mm^2)	114.31±242.85	136.24±224.34	0.624
Postoperative BCVA (LogMar)	0.16±0.15	0.17±0.14	0.839

CT, corneal thickness; CELT, corneal epithelial layer thickness; ECD, endothelial cell density; BCVA, best corrected visual acuity; EFU, estimated fluid usage

The AFS allows surgeons to preset a target intraoperative IOP, which is usually set to be 50 to 60 mmHg [4, 5]. Due to the advantages of the active sentry handpiece and AFS, lower target intraoperative IOP setting become possible. Previous study also found that lower target intraoperative IOP setting (30-50mmHg) is one benefit of active sentry handpiece [8, 11]. As a high IOP during the surgery may induce ocular perfusion reduction and optic nerve damage, even increasing patients' anxiety and worsening the surgical outcome [12]. In our study, the target intraoperative IOP was set to be 20 mmHg, which is within the range of physiological IOP. And we explored the impact of low target intraoperative IOP setting on the stability of the anterior chamber, prognosis of cornea and postoperative visual acuity.

ASM is a new feature introduced with the active sentry handpiece, which can reduce the vacuum demand from the anterior chamber by partially venting the aspiration line [8]. It dampens the surge volume demand once the onset of an occlusion break is detected by the sensor in the handpiece [6, 13]. Therefore, ASM can represent the stability of the anterior chamber. In our study, compared with the 60mmHg group, the ASM was significantly reduced in the 20mmHg group. This result indicated that the stability of the anterior chamber was better, when the target intraoperative IOP was set to 20mmHg. It was inconsistent with the previous opinion that higher target intraoperative IOP can improve anterior chamber stability [13]. The different conclusion may be due to the pressure gradient, which the irrigation should compensate during an occlusion break, is lower at a low target intraoperative IOP setting [14].

Previous studies had found that the ultrasonic energy in phacoemulsification could be reduced by using the active sentry handpiece compared with other kinds of handpiece [12, 15, 16]. We researched the effect of different target intraoperative IOP settings on CDE and total U/S time when using an active sentry handpiece. There was no statistically significant difference in the CDE and total U/S time between both groups. We also found there was no difference in the change of ECD between both groups. Previous studies had revealed that the loss of endothelial cells is related to the use of ultrasonic energy in phacoemulsification [17, 18]. Therefore, there was no difference in ECD between both groups, possibly because there was no difference in the use of CDE and total U/S time. Visual recovery, EFU, changes in CT and CELT in the immediate postoperative period were satisfied and comparable between both groups. These results may be related to that only simple cataract patients with nucleus grade 3 were enrolled in our study. If patients with hard nucleus or complicated cataract were enrolled, the results may be different. Chen's study found that a low target intraoperative IOP setting (30mmHg) could decrease the

change of central corneal thickness for low pre-operative ECD patients [11]. While in our study, the pre-operative ECD of included patients was normal.

There were also some limitations of the study. The follow-up time was only one day. The influence of difference target intraoperative IOP settings for retina and optic nerve were not researched. As well, the influence of difference target intraoperative IOP settings for complicated cataract cases should be focused on in the future.

Abbreviations

IOP	Intraocular pressure
BCVA	Best corrected visual acuity
CDE	Cumulative dissipated energy
ASM	Active surge mitigation
EFU	Estimated fluid usage
CT	Corneal thickness
CELT	Corneal epithelial layer thickness
ECD	Endothelial cell density
GFS	Gravity fluidics system
AFS	Active fluidics system
PCR	Posterior capsular rupture

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Not applicable.
Our study adheres to CONSORT guidelines and include a completed CONSORT checklist as an additional file.

Author contributions
SW, JT and LY were responsible for data collection and performing the statistical analysis. SW, JY, XY, WD, HB and LY were involved in study conception, data interpretation and the drafting and final approval of the manuscript. All authors reviewed the manuscript.

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Data availability
The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate
This study involves human participants and was approved by the Ethics Committee of the Yantai Aier Eye Hospital (approval ID: YTAE2021001). Informed consent to participate was obtained from all of the participants in the study.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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