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COMPLICATIONS AND PATIENT SATISFACTION AFTER 14- AND 30-DAY WATER CONTACT RESTRICTIONS FOLLOWING CATARACT SURGERY: A RANDOMIZED, CONTROLLED TRIAL.

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ABSTRACT

AIM: To examine and compare post-cataract surgery complications and patient satisfaction after 14 and 30 days of water contact restriction.

METHODS: A total of 250 patients that had undergone standard-of-care cataract extraction were included in this prospective study. Subjects were randomized into either the control group (124 subjects), which followed a 30-day postoperative water contact restriction, or the experimental group (126 subjects), which followed a 14-day postoperative water contact restriction. Postoperative complications and patient satisfaction were examined. The visual analog scale (VAS) was used to evaluate patient satisfaction (10 = highest level of satisfaction).

RESULTS: The VAS score was 7.14 ± 1.1 in the control group and 8.12 ± 1.0 in the experimental group ($P < 0.001$). The vast majority of subjects in the control (121 of 124 subjects [97.6%]) and experimental (118 of 126 subjects [93.7%]) groups had no sign of postoperative infection. However, 3 subjects (2.4%) in the control group and 8 subjects (6.3%) in the experimental group had mild conjunctival injection ($P = 0.274$). No subject in either study group experienced any serious complications, including endophthalmitis.

CONCLUSION: Subjects who adhered to a 14-day postoperative water contact restriction had a higher patient satisfaction score than those adhering to a 30-day postoperative water contact restriction. Additionally, there were no statistically significant differences between groups in visual outcomes or postoperative complication rates.

KEYWORDS : cataract surgery; postoperative eye care; postoperative complications; endophthalmitis

INTRODUCTION

Complications following cataract extraction are a major problem in some Asian and African countries and often result in blindness [1-3]. Current phacoemulsification procedures, small incisions, and standard operative methods generally work well and most patients have excellent visual outcomes following surgery with a low incidence of severe postoperative infection [4-6].

Postoperative care after cataract surgery has not yet been standardized and management methods depend on the surgeon's discretion. Physicians generally recommend abstaining from ocular water contact (eg, during showering or face washing) for 3–4 weeks after surgery to reduce the risk of postoperative infection. This long recovery period often results in significant economic losses because of interference with a patient's ability to work. This forces some patients to take a long period of time off work and patients may become a burden to their caregiver, both of which can result in significant financial losses. A Fourier-domain optical coherence tomography study on surgical incision recovery revealed that surgical wounds had completely healed in 49 of 50 eyes (98.0%) 3 days after cataract surgery [7]. All 50 eyes had completely healed incisions on postoperative Day 10. Therefore, it is reasonable to assume that, after 10 days, patients have fully recovered from cataract surgery and that operative eye contact with water carries little risk of infection.

To the best of our knowledge, no prior studies have compared a shorter postoperative care period to the 30-day standard-of-care period or examined the effect of postoperative care regimens on patient satisfaction. Here, we directly compare patient satisfaction and postoperative complication rates in subjects who have undergone cataract surgery followed by a 14- and 30-day postoperative water contact restriction. This study specifically investigated the satisfaction levels of cataract patients allowed to be in contact with water earlier than 30 days after cataract surgery. Postoperative complication rates (eg, ocular infection) following surgery were also examined to elucidate possible changes in postoperative care recommendations.

SUBJECTS AND METHODS

Study subjects

The prospective study protocol was reviewed and approved by the Prapokklao Hospital Ethics Committee (Chanthaburi, Thailand, CTIREC040/59). All study conduct adhered to the tenets of the Declaration of Helsinki and all subjects provided written informed consent to participate in the study.

This study included 250 subjects who had undergone standard-of-care cataract surgery at Prapokklao Hospital between March and October 2016. Subjects were considered for inclusion if their surgery had taken place within 7 days of study enrollment. All subjects also had to be willing and able to complete the 6-month study follow-up period. Subjects were excluded from the study if any of the following were true: experienced intraoperative complications, received an intravitreal antimicrobial injection to prevent infection, only had one eye, or had a history of severe eye disease.

Subjects were randomly assigned to follow either a 14-day (experimental group) or 30-day (control group) water contact restriction period at the time of study enrollment. All other postoperative care was identical in all subjects, with both groups using the same topical antibiotic/steroid eye drops for 1 month after surgery. Subjects were evenly assigned to the two study groups by a physician's assistant who used a random number generator to determine group allocation. Both the evaluating physician and the staff member who assessed subject postoperative satisfaction were masked to study group assignment (single-masked study).

This study was originally planned to include a third group of patients with a postoperative water contact restriction period of 10 days because clear corneal incisions completely heal within 10 days [7]. However, patients were apprehensive over such a short period and would not consent to participate in that study group. As a result, we did not include a 10-day group.

Study data

A thorough medical and ocular history was taken in all subjects at enrollment. Data collected included age, sex, occupational diseases, visual acuity, and surgical history. The primary outcome was patient satisfaction and secondary outcomes included postoperative infection (eg, conjunctivitis and endophthalmitis) and visual acuity. Postoperative care safety was evaluated using lid/conjunctival infection and endophthalmitis incidences. Symptoms suspicious of endophthalmitis included an injected conjunctiva, conjunctival discharge in the presence of anterior chamber cells, and/or decreased visual acuity. All serious adverse events were reported via standard office telephone or e-mail.

Study assessments

All subjects were assessed at 1 day, 7 days, 1 month, 3 months, and 6 months following cataract surgery. At each visit, all subjects underwent a comprehensive ophthalmological examination, which included slit-lamp biomicroscopy, visual acuity assessment, and intraocular pressure measurement. Patient satisfaction was also evaluated using the visual analog scale (VAS), which has a 0–10 score range, with 10 being the highest level of satisfaction.

Statistical analyses

Study size calculation was determined using the results of observational data, which found that postoperative complications or conjunctivitis occurred in 4 of 15 subjects in a 14-day water contact restriction group and 0 of 15 subjects in a 30-day water contact restriction group. Using a statistical significance level of 0.05 (two-way) and a statistical power of 90%, our study required a sample size of 89 subjects in each group. Therefore, we received approval to enroll 277 subjects (with a target sample size of 250 subjects) to allow for screening failures and subject dropout.

Categorical variables (eg, gender, visual acuity, disease, and surgical methods) were compared between groups using Fisher's exact tests. Continuous variables (eg, age and satisfaction level) were compared between groups using unpaired t-tests. Statistical analyses were performed using STATA (version 12.1, StataCorp LP, Tx77845, USA) and statistical significance was defined as $P < 0.05$.

RESULTS

A total of 277 subjects were screened. Twenty-seven subjects were excluded during the screening process and were not randomized into a study group. The remaining 250 patients (95 male, 155 female; 68.3 ± 11.1 years [range: 40–68 years]) were randomized, with 124 and 126 subjects ultimately included in the control (30-day) and experimental (14-day) groups, respectively (Figure 1). One hundred and thirty-five subjects (50.8%) underwent phacoemulsification and 115 subjects underwent manual small-incision cataract surgery. Preoperative visual acuity was worse than 6/60 in 109 of 124 control subjects (87.9%) and 115 of 126 experimental subjects (92.7%). Systemic disease (eg, diabetes) was present in 46 of 124 control subjects (37.1%) and 50 of 126 experimental subjects (39.7%). Preoperative subject and ocular characteristics were similar between groups, as shown in Table 1.

All subjects had an improvement in visual acuity following surgery and 113 of 126 experimental subjects (89.7%) and 105 of 124 control subjects (84.7%) had better than 6/18 vision, respectively. This slight difference between groups was not statistically significant ($P = 0.199$). Patient satisfaction was 8.1 ± 1.0 in the experimental group and 7.1 ± 1.2 in the control group ($p < 0.001$, Table 2).

Postoperative complications did not occur in 118 of 126 subjects (93.7%) in the experimental group and in 121 of 124 subjects (97.5%) in the control group. This small difference was not statistically significant ($P = 0.216$). However, 7 subjects (5.6%) in the experimental group and 3 subjects (2.4%) in the control group had a small amount of conjunctival injection without discharge 2 days following their first postoperative water contact ($P = 0.274$). Additionally, 1 subject in the experimental group had conjunctival injection with discharge after his eyes had been in contact with water. Fortunately, the symptoms spontaneously resolved after 3 days. No subject in either study group developed endophthalmitis (Table 2). Additionally, there was no significant difference in postoperative complication rates between patients who underwent manual small-incision cataract surgery and phacoemulsification.

DISCUSSION

This study examined the effect of shortening the postoperative water contact restriction period from 30 to 14 days in subjects who had undergone cataract surgery. This issue was examined because not showering or washing the face for 30 days interferes with patients' daily lives, decreasing patient satisfaction after surgery. We found that the rates of infection did not increase by shortening the water contact restriction period from the usual 30 days to 14 days. Furthermore, allowing subjects to shower normally (without shielding the head from water) 14 days earlier significantly increased patient satisfaction. Additionally, postoperative visual outcomes were satisfactory in both groups, with 89.7% of 14-day subjects and 84.7% of 30-day subjects having a visual acuity of 6/18 or better. Additionally, a very small proportion of subjects (30-day: 2.4%, 14-day: 4.0%) had poor visual outcomes (visual acuity worse than 6/60) in both groups. These visual outcome rates are consistent with current standards for cataract surgery [8].

Endophthalmitis was not observed in any subject and the minimal conjunctival injection rates were not significantly different between groups. These findings are in agreement with prior research on postoperative care after cataract surgery. First, one study found no evidence of complications in cataract patients who did not wear a shield after surgery [9]. Another study allowed patients to remove the shield the day after cataract surgery (if no complications had occurred) and patients were advised to shower, wash their hair, and work as usual. Follow-up examinations did not reveal an increase in infection or other complication rates[10]. Despite these past findings, postoperative care instructions following cataract surgery have not changed.

The current study also examined differences in postoperative complications rates when different cataract surgery methods were used. Manual small incision cataract surgery with a scleral incision was performed on 46% of included subjects and phacoemulsification was performed on 54% of subjects. Postoperative infection was not observed in either surgical method group.

Our study had several limitations. First, our sample size was likely too small to detect changes in endophthalmitis incidence, which is normally very low (0.025-0.43%) [11-15]. Therefore, additional larger studies are needed to confirm our findings that a 14-day water contact restriction period is safe. Second, our study was only single-masked. Clinical evaluators were not aware of the study group assignment, but the subjects were. It may not be possible to overcome this limitation, but this may have affected the satisfaction data.

Forcing patients to avoid washing their face, hair, and eyes for 1 month after cataract surgery greatly impacts daily life, especially for those living in tropical climates. Based on findings from the current and prior studies, we recommended that the postoperative care instructions be changed to allow resumption of water contact and daily activities 14 days after cataract surgery.

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Conflicts of Interest: Kongsap P, None

Table 1 Patients' baseline characteristics

Variable	30 days (n = 124)		14 days (n = 126)		p-value
	N	%	n	%	
Gender					
Male	45	36.3	50	39.7	0.581
Female	79	63.7	76	60.3	
Age (year), Mean ±SD	68.3	±11.1	68.3	±9.9	0.783
Pre-op VA					
<6/60	109	87.9	115	92.7	0.283
6/60-6/18	14	7.3	9	7.3	
>6/18	1	0.8	0	0	
Co-morbidity					
No	78	62.9	76	61.3	0.674
Yes	46	37.1	50	39.7	
Dm	40	87.0	46	92.0	
Anemia	4	8.7	3	6.0	
Renal disease	2	4.3	1	2.0	
Operation					
MSICS	53	42.7	62	49.2	0.305
Phacoemulcification	71	57.3	64	50.8	

Abbreviations: MSICS, manual small incision cataract surgery

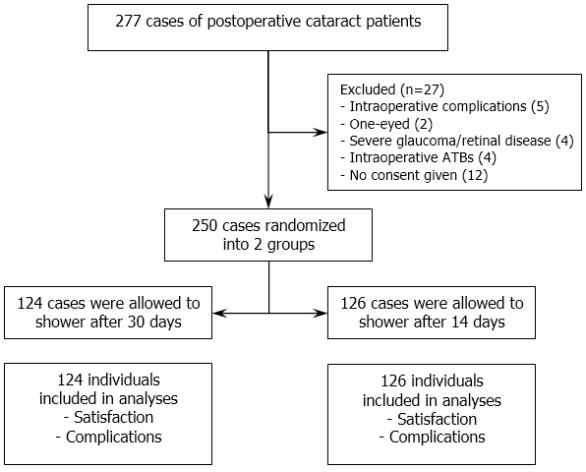
Table 2 Clinical outcomes

Variable	30 days (n = 124)		14 days (n = 126)		p-value
	n	%	n	%	
Post-op VA					
<6/60	3	2.4	5	4.0	0.199
6/60–6/18	16	12.9	8	6.5	
>6/18	105	84.7	113	89.7	
Serious complications					
Endophthalmitis					
No	124	100	126	100	-
yes	0	0	0	0	

Mild complication					
No	121	97.6	118	93.7	0.274
Yes					
Little red eye, no discharge	3	2.4	7	5.6	
Little red eye, discharge	0	0	1	0.8	
Moderate red eye, no discharge, no cells found in anterior chamber	0	0	0	0	
Satisfaction score (0–10), Mean (±SD)	7.1	±1.2	8.1	±1.0	<0.001

Abbreviations: VA, visual acuity; SD, standard deviation

Figure 1: Flow diagram of study design.



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