

A Randomized Controlled Trial on the Impact of an Educational Video on Satisfaction After Glaucoma Surgery in Urban and Rural China

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STUDY PROTOCOL

Principal Investigator (Wenzhou) – Prof Liang Yuanbo MD PHD¹

Principal Investigator (Orbis, QUB) – Prof Nathan Congdon MD MPH^{2, 3, 4}

Co-Investigators

Alice Liu¹

Lin Hao¹

1 ¹The Eye Hospital, School of Ophthalmology and Optometry, Wenzhou Medical University, Wenzhou, Zhejiang, China

2 Queen's University, Belfast, UK

3 Orbis International, NY, USA

4 Zhongshan Ophthalmic Centre, Guangzhou, China

Executive Summary

Glaucoma is the leading cause of irreversible blindness in China, as elsewhere in the world. In Chinese rural settings, where topical glaucoma medication is unlikely to be a practical and sustainable option, surgery is the primary treatment modality for glaucoma. However, it is known that vision is quite likely to decline in the short to medium term after glaucoma surgery, and there are concerns that dis-satisfaction resulting from such vision changes might lead to negative social marketing, affecting uptake not only of glaucoma surgical care but other eye operations (principally cataract) as well.

We propose to test the impact of a multi-media educational intervention on post-operative satisfaction. This educational consultation is designed to give patients a realistic expectation of their post-operative course: glaucoma surgery is being performed NOT to improve vision, but to protect it from future harm, and vision may in fact decline for several weeks post operatively.

A randomized controlled design will be used, and subjects undergoing glaucoma surgery will be enrolled from two centers – one urban hospital at Wenzhou Eye Hospital and 4 rural county hospitals in rural Guangdong province – and randomized to receive the intervention or usual care. The principal outcome will be subjective satisfaction on a questionnaire instrument, administered pre-operatively and post-operatively on two occasions in the first month following surgery. Patients not returning post-operatively to the surgical facility will be contacted by telephone for administration of the questionnaire. Other facility- and patient-related clinical and personal factors expected to influence satisfaction will also be recorded and adjusted for in all analyses.

Background Literature Review

Glaucoma is the leading cause of irreversible blindness worldwide, with Asia accounting for 60% of the estimated number of people with glaucoma (64.3 million) in 2013.¹ In China alone, there are nearly 10 million cases, suggesting a strong need for public health strategies to alleviate this important health issue.^{2,3}

Current glaucoma treatment strategies involve reducing or lowering a patient's elevated intraocular pressure, with the most effective approaches employing either eye drops, laser therapy, or surgery. Additionally, glaucoma treatment requires long-term follow-up care, making patient compliance central to a successful regimen.⁴ However, the treatment of glaucoma in low-resource settings presents significant issues, as the disease is typically asymptomatic until substantial, irreversible vision loss has already occurred.⁵ Poor adherence to follow-up^{6,7} and misconceptions in rural China about glaucoma as a symptomatic disease makes topical medicine an unlikely sustainable option for treatment.⁵

Yet, surgery as the primary treatment modality for glaucoma in rural China come with its own set of challenges. It has been well documented that vision after glaucoma surgery declines initially, with the majority of cases resolving over 1-6 weeks.⁸ Concerns about dis-satisfaction with vision may lead to negative attitudes towards surgery in the community, and affect uptake of not only glaucoma surgery, but also other eye operations, particularly cataract, the leading cause of global blindness, and which can only be treated surgically. Rural community acceptance of surgery is of particular importance because sources of knowledge about glaucoma primarily come from friends, relatives and the news, but not physicians.⁵

Traditionally, the preoperative procedure for glaucoma surgery entails a comprehensive discussion between the physician and patient about the role of surgery, but it is unclear how effective these sessions are at disseminating information.^{9,10} Of primary concern is the extent to which patients comprehend the purpose of glaucoma surgery as a mechanism to prevent future vision loss, rather than recover lost vision. This problem is particularly acute in rural Chinese settings, where patient loads are heavy, and time for detailed discussions may be limited. The situation is further complicated by limited knowledge among caregivers in many cases, and well-documented lack of trust between physicians and patients in rural China.¹¹

Educational interventions employing videos to assist in the preoperative informed consent process have shown visual aids to be a promising tool for increasing patient comprehension and satisfaction.^{12,13,14} Even more essential is the repetition of information in improving patient understanding.¹²

For this study, we will evaluate the effectiveness of repeated showings of an educational video has in raising patient satisfaction with glaucoma surgery.

Objectives

Overall Objective: This study will assess whether an educational video is effective in increasing patient satisfaction with glaucoma surgery.

1. Investigate the impact of educational interventions on glaucoma patients' surgical satisfaction.
2. Investigate the post-operative satisfaction of rural glaucoma patients in county hospitals
3. Investigate the difference in postoperative satisfaction between urban and rural glaucoma patients in urban hospitals
4. Investigate other factors that influence postoperative glaucoma satisfaction.

Methodology

Study Design: Randomized controlled trial of an educational intervention.

Study Population: Patients scheduled to undergo glaucoma surgery at either the Wenzhou Eye Hospital or at four rural county-level hospitals in Guangdong province.

Since there may be existing differences in baseline glaucoma surgery satisfaction levels due to patients' place of residence and choice of hospital, we will divide our study population into the following three groups:

- **Group 1:** Urban patients seeking glaucoma surgical treatment at an urban hospital.
- **Group 2:** Rural patients seeking glaucoma surgical treatment at an urban hospital.
- **Group 3:** Rural patients seeking glaucoma surgical treatment at a rural or county-level hospital.

Recruited patients from Wenzhou Eye Hospital will be separated into Groups 1 and 2 based off place of residence. Recruited patients from the Guangdong CREST county-level hospitals will be enrolled into Group 3. Each of these groups will be randomized separately (stratified randomisation) to ensure a balance across study groups with regard to this characteristic.

Sample Size Calculations: 264 total patients

Patient Enrolment Criteria:

- Glaucoma patients ≥ 18 years of age undergoing trabeculotomy or iridotomy

Patient Exclusion Criteria:

- VA < 20/400 (0.05)
- Patients who had previously undergone trabeculotomy
- Severe mental disabilities preventing participants from completing a self-administered questionnaire

Intervention: Subjects will be asked to watch a 5-10 min education film two times (pre-op one day and post-op one day).

Control: Standard patient procedure that includes a pre-operative discussion with an ophthalmologist about glaucoma surgery, during which the surgeon gains the patient's informed consent. Subjects will not be asked to watch education film.

Outcomes

Main outcome: The mean satisfaction outcome over two follow-up visits (1 day and 1 week).

Composite outcome, in which multiple end points are combined, are frequently used as primary outcome measures in randomized trials and are often associated with increased statistical efficiency. (Freemantle N, Calvert M, Wood J, Eastaugh J, Griffin C. Composite outcomes in randomized trials: greater precision but with greater uncertainty? JAMA. 2003; 289: 2554-2559)

While our satisfaction questionnaire has not been previously validated, it contains several items from the Glaust questionnaire, a validated questionnaire measuring patient satisfaction with glaucoma treatment. (Ruiz, M. A., Pardo, A., Martinez de la Casa, J. M., Polo, V., Esquiro, J., & Soto, J. (2010). Development of a specific questionnaire measuring patient satisfaction with glaucoma treatment: Glausat. *Ophthalmic epidemiology*, 17(3), 131-143.)

Secondary outcomes:

2. The rate of willingness to recommend surgery to a friend or relative with glaucoma
Measurement method: Satisfaction questionnaire
3. Personality in both groups using Eysenck Personality Questionnaire-Revised Short Scale for Chinese (EPQ-RSC) to assess glaucoma patients' personality. This test measures four aspects of an individual's personality traits: extraversion, neuroticism, presence of psychoticism (aggressiveness or hostility), and lie (tendency to conform).
4. Knowledge scores about glaucoma.
5. Intraocular pressure in both groups. Unit of Intraocular pressure is mmHg.
6. Visual acuity in both groups
Visual acuity testing use Snellen-based letter charts, such as a Snellen score of 6/12 (20/40), indicating an observer can resolve details as small 2 minutes of visual angle, corresponds to a LogMAR of 0.3 (since the base-10 logarithm of 2 is 0.3)

Informed Consent

Informed consent to participate in an educational intervention will be obtained. A standard consent form will be employed and will indicate that, as part of an educational randomized control trial, some of the participants will receive free consultations with a health professional. If they are unable to read it, the form will be read to them in Chinese. Afterwards, they will be invited to sign.

Participant Withdrawal

Patients in either the intervention or control group are free to leave the study at any time. Data collected up to the point of withdrawal of consent will be anonymized, securely stored, and be included in data analysis.

Randomisation

Pre-randomization baseline assessment

Following consent, baseline patient satisfaction levels with previous glaucoma treatment and medical care will be evaluated. Patients will be categorized as “urban” or “rural” based off their place of residence and separated into their designated groups based off place of residence and hospital.

Randomization: Patients will be randomized based off clinic week. For example, all patients having surgery one week will watch the video and be placed in the intervention group. The following week, all patients will be placed in the control week.

Baseline data:

- Patient
 - Age/Sex
 - Profession
 - Martial Status
 - Long-term Residence
 - Distance from home to hospital
 - Time from home to hospital
 - Current glaucoma treatment
 - Baseline uncorrected and best-corrected visual acuity in operative eye
 - Intraocular pressure in operative eye

The Intervention

Subjects will be asked to watch a 5-10 min education film. These sessions will occur during their pre-operative and post-operative 1 day visit.

The film follows the journey of an elderly patient scheduled to undergo glaucoma surgery, beginning with a face-to-face Q&A health session with an eye doctor. After surgery, the patient talks about his post-operative eyesight and discusses the benefits of early diagnosis and glaucoma surgery for treatment with his community.

Participant Recruitment Timeline

An administrator will schedule a time for patients to come in for surgery. When patients come for their pre-surgery visitation, they will be approached for study recruitment. After signing the informed consent form denoting their voluntary participation into the study, they will fill out three questionnaires: 1) Personality (EPQ-RSC) 2) Knowledge of glaucoma treatment. Based off their identity as an “urban” or “rural” patient, they will be separated accordingly into the different groups. Randomization will be determined by clinic week.

The timetable displays what questionnaires will be filled out at each visitation for the control and intervention group.

	Control Group	Intervention Group
Pre-Surgery Visitation	<ol style="list-style-type: none"> 1. Informed consent 2. Personality (EPQ-RSC) 3. Knowledge of glaucoma treatment 4. Baseline Satisfaction questionnaire 	<ol style="list-style-type: none"> 5. Informed consent 6. Personality (EPQ-RSC) 7. Knowledge of glaucoma treatment 8. Baseline satisfaction questionnaire 9. Video
Surgery		
Post-surgery Day 1	<ol style="list-style-type: none"> 1. Satisfaction questionnaire 	<ol style="list-style-type: none"> 1. Satisfaction questionnaire 2. Video
Post-surgery Week 1	<ol style="list-style-type: none"> 1. Satisfaction questionnaire 2. Knowledge of glaucoma treatment 	<ol style="list-style-type: none"> 1. Satisfaction questionnaire 2. Knowledge of glaucoma treatment

Analyses

Statistical Analysis

- Mean patient satisfaction grade for cumulative scores from 2 satisfaction questionnaires, comparing intervention and control groups, with and without adjustment for baseline patient factors.

Prevention of Bias

Potential Harms and Benefits of the Study

Potential Harms

There are no clinical harms from the study protocol itself, as the intervention group is solely receiving additional health counseling sessions.

Potential Benefits

The patients in the intervention group will receive additional counseling with a health professional, which may deepen their understanding of glaucoma surgery

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