การศึกษาเปรียบเทียบการฉีดยาชาเข้ากระบอกตาและการฉีดยาชาใต้เยื่อบุตา ต่อผลการระงับปวดระหว่างการผ่าตัดต้อกระจก

นางวสี ตุลวรรธนะ

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาการพัฒนาสุขภาพ
คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2546
ISBN 974-17-4163-4
ลิขสิทธิ์ของจุฬาลงกรณ์มหาวิทยาลัย

RETROBULBAR VERSUS CIRCUMFERENTIAL SUBCONJUNCTIVAL ANESTHESIA ON THE PAIN CONTROL DURING PLANNED EXTRACAPSULAR CATARACT EXTRACTION WITH INTRAOCULAR LENS IMPLANTATION: A RANDOMIZED EQUIVALENCE TRIAL

Mrs. Wasee Tulvatana

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science in Health Development
Faculty of Medicine
Chulalongkorn University
Academic Year 2003

ISBN 974-17-4163-4

Thesis Title	Retrobulbar versus circumferential subconjunctival anesthesia on the pain control during planned extracapsular cataract extraction with intraocular lens implantation: a randomized equivalence trial
By	Wasee Tulvatana
Field of study	Health Development
Thesis Advisor	Kittisak Kulvichit, M.D., M.Sc.

Accepted by the Faculty of Medicine, Chulalongkorn University in Partial Fulfillment of the Requirements for the Master's Degree

..... Dean of the Faculty of Medicine
(Professor Pirom Kamol-ratanakul, M.D., M.Sc.)

THESIS COMMITTEE

..... Chairman
(Associate Professor Somjai Wangsuphachart, M.D., M.Sc.)

.....Thesis Advisor
(Kittisak Kulvichit, M.D., M.Sc.)

..... Member
(Prasart Laksanaphuk, M.D.)

..... Member
(Mrs. Piyalamporn Havanond, B.Sc., M.Sc.)

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

458 54318 30 : หลักสูตร การพัฒนาสุขภาพ
คำสำคัญ : RETROBULBAR BLOCK / CIRCUMFERENTIAL SUBCONJUNCTIVAL BLOCK / CATARACT / EQUIVALENCE TRIAL

วสี ตุลวรรธนะ : การศึกษาเปรียบเทียบการฉีดยาชาเข้ากระบอกตาและการฉีดยาชาใต้เยื่อบุตาต่อผลการระงับปวดระหว่างการผ่าตัดต้อกระจก. (RETROBULBAR VERSUS CIRCUMFERENTIAL SUBCONJUNCTIVAL ANESTHESIA ON THE PAIN CONTROL DURING PLANNED EXTRACAPSULAR CATARACT EXTRACTION WITH INTRAOCULAR LENS IMPLANTATION: A RANDOMIZED EQUIVALENCE TRIAL) อาจารย์ที่ปรึกษา: อาจารย์ นายแพทย์ กิตติศักดิ์ กุลวิชิต พบ., วท.ม.
40 หน้า, ISBN 974-17-4163-4.

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบการฉีดยาชาเข้ากระบอกตา และการฉีดยาชาใต้เยื่อบุตา ต่อผลการระงับปวดระหว่างการผ่าตัดต้อกระจกและใส่เลนส์แก้วตาเทียม
วิธีการศึกษา: ประชากรตัวอย่างได้จาก ผู้ป่วยที่เข้ารับการผ่าตัดต้อกระจกและใส่เลนส์แก้วตาเทียม ณ สถานีกาชาดที่ 6 อรัญประเทศ ตั้งแต่เดือน พฤษภาคมถึงธันวาคม 2543 แบ่งผู้ป่วยเป็น 2 กลุ่มด้วยวิธีสุ่ม โดยซ่อนรหัสของผู้ป่วยแต่ละคนแยกไว้ในแผ่นกระดาษทึบปิดผนึก กลุ่มที่หนึ่งได้รับการฉีดยาชาเข้ากระบอกตา กลุ่มที่สองได้รับยาชาใต้เยื่อบุตา ผู้ป่วย แพทย์ผ่าตัด พยาบาล และผู้ลงบันทึกข้อมูล ไม่ทราบถึงวิธีการให้ยาชา วัดผลโดยผู้ป่วยให้คะแนนความเจ็บปวดโดยการบันทึกลงบนเส้นที่มีความยาว 100 มม. ทั้งความเจ็บปวดระหว่างฉีดยาชา และ ระหว่างผ่าตัด แพทย์ผู้ฉีดยาบันทึกผลข้างเคียงของการฉีดยาชา แพทย์ผ่าตัดให้คะแนนความพึงพอใจ และบันทึกผลข้างเคียงของการผ่าตัด พยาบาลห้องผ่าตัดบันทึกการใช้ยาช่วยระงับปวดเพิ่มเติม การศึกษานี้ได้กำหนดขอบเขตของการยอมรับว่าคะแนนความปวดของ 2 วิธีเท่ากัน โดยใช้ค่า -10 ถึง +10 มม.
ผลการศึกษา: ผู้ป่วยทั้งสิ้น 145 ราย แบ่งเป็น กลุ่มแรก 81 ราย และ กลุ่มที่สอง 64 ราย มีผู้ป่วย 3 รายที่ไม่สามารถเก็บข้อมูลได้จนครบ เนื่องจากมีการเปลี่ยนวิธีผ่าตัดภายหลัง ผู้ป่วย 1 รายชักก่อนผ่าตัดจึงไม่ได้รับการผ่าตัดต้อกระจก ผลการศึกษาพบว่าเมื่อวิเคราะห์ด้วยวิธี As-treated แล้วนั้น ช่วงความเชื่อมั่นร้อยละ 95 ของมัธยฐานความแตกต่าง ของคะแนนความปวดระหว่างการผ่าตัด และความปวดขณะถูกฉีดยาชา เป็น -8 ถึง 5 และ -1 ถึง 3 ตามลำดับ ส่วนความพึงพอใจของแพทย์ผ่าตัด พบว่าความเชื่อมั่นร้อยละ 95 ของค่าเฉลี่ยความแตกต่าง เป็น 8.4 ถึง 14.4 คือ พอใจกลุ่มแรกมากกว่า การวิเคราะห์ผลด้วยวิธี Intention-to-treat โดยสมมุติกรณีแย่ที่สุด และ กรณีดีที่สุดพบว่าผลที่ได้เป็นไปทำนองเดียวกัน ผลข้างเคียงที่รุนแรงและไม่พึงประสงค์ ทั้งขณะฉีดยาชา และขณะผ่าตัด พบได้น้อย การใช้ยาระงับปวดเพิ่มเติมในกลุ่มแรกมากกว่ากลุ่มที่สอง (ร้อยละ 18 ต่อ 3, ค่าพี = 0.007 โดยการทดสอบฟิชเชอร์เอกแซกท์)
สรุป: การฉีดยาชาทั้ง 2 วิธีสามารถระงับปวดระหว่างการผ่าตัดต้อกระจกได้เท่ากัน ความปวดขณะถูกฉีดยาชาไม่แตกต่างกัน แพทย์ผ่าตัดพึงพอใจวิธีฉีดยาเข้ากระบอกตามากกว่า แต่ผู้ป่วยกลุ่มนี้ต้องใช้ยาระงับปวดเพิ่มเติมมากกว่า การศึกษาครั้งนี้ไม่พบผลข้างเคียงที่รุนแรง ทั้งจากการฉีดยาชาและการผ่าตัด

หลักสูตร การพัฒนาสุขภาพ ลายมือชื่อนิสิต.....
สาขาวิชา การพัฒนาสุขภาพ ลายมือชื่ออาจารย์ที่ปรึกษา.....
ปีการศึกษา 2546

458 54318 30 : MAJOR HEALTH DEVELOPMENT

KEY WORD: RETROBULBAR BLOCK / CIRCUMFERENTIAL SUBCONJUNCTIVAL BLOCK / CATARACT / EQUIVALENCE TRIAL

WASEE TULVATANA : RETROBULBAR VERSUS CIRCUMFERENTIAL SUBCONJUNCTIVAL ANESTHESIA ON THE PAIN CONTROL DURING PLANNED EXTRACAPSULAR CATARACT EXTRACTION WITH INTRAOCULAR LENS IMPLANTATION: A RANDOMIZED EQUIVALENCE TRIAL.

THESIS ADVISOR: KITTISAK KULVICHIT, M.D., M.Sc.

40 PAGES, ISBN 974-17-4163-4.

Purpose: To compare the effectiveness on the pain control during extracapsular cataract extraction (ECCE) between retrobulbar anesthesia and circumferential subconjunctival anesthesia.

Methods: Samples were from consecutive cataract cases undergoing ECCE with intraocular lens implantation at the 6th station of the relief unit, the Thai Red Cross Society from May to December 2003. Patients were randomized into two groups by simple randomization. Allocation sequence was concealed in separate sealed opaque paper packets. Group A received retrobulbar anesthesia, and Group B for circumferential subconjunctival anesthesia. The patients, the surgeon, and nurses were masked. Pain scales were recorded at the time of injection and during surgery using visual analogue score (VAS) from 0-100 mm. An equivalence limit of -10 to 10 was defined. Surgeon satisfaction scales using VAS, complication rate, operation time, rescue medication use were recorded.

Results: A total of 145 cases were studied. There were 81 patients in group A and 64 in group B. Three cases did not complete the study due to procedural change. One patient did not undergo the operation due to preoperative seizure. As-treated analysis showed that the 95% CI of median difference of pain score during operation, and pain score at time of injection were -8 to 5 and -1 to 3, respectively. The 95% CI of mean difference of the surgeon satisfaction score was 8.4 to 14.4, favoring group A. With the intention-to-treat analysis assuming worst-case and best-case scenarios, the results were similar. Unexpected and severe complications of the anesthetic injection and the operative complications were rare. Rescue medications were used more frequently in group A than group B (18% VS 3%, p = 0.007, Fisher's exact test)

Conclusion: The pain score during operation is equivalent in both groups. The pain at time of injection between both groups are not different. The surgeon prefer retrobulbar anesthesia, but a higher rate of rescue medications are used in retrobulbar group. Severe complications are uncommon.

Field of study HEALTH DEVELOPMENT Student's signature……

Academic year 2003 Advisor's signature……..

ACKNOWLEDGEMENT

I would like to express my sincerest gratitude to Dr. Uraiwan Tinnungwattana, Dr. Varangkana Tongkhamsai, Miss Bubpha Puangmalee, Miss Chulee Pootong and all of the staff members of the Relief Unit of the Thai Red Cross Society, who were always effective and helpful. Without their keenness, encouragement and support, the study would not be possible.

Constructive comments were continually received from all ThaiCERTC members to refine the thesis up to its maximal level. I am thankful to all of them.

The staff and residents of the Department of Ophthalmology, Faculty of Medicine, Chulalongkorn University, were appreciated for giving me the great opportunity to study in this course.

The thesis will not be complete without mentioning these three fundamental structures. I am fortunate to have them with me always and forever.

First of all, my parents: their perseverance, wisdom, sensibility and modesty have been deeply admired. Following their paths, I find myself sufficient and contented. Together with their unconditional love and care, everything is possible. Secondly, my husband and sons: their love, patience and understandings were simply infinite. Lastly, my thesis advisor who has always been attentive, caring and devoting. The belief in me and in my capability to succeed has guided me through the very best things. Thanks to them all.

The study was financially supported by the Ratchadapiseksompotch Fund of the Faculty of Medicine, Chulalongkorn University (Grant number RA 92).

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CONTENTS

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

LIST OF TABLES

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

LIST OF TABLES

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

LIST OF FIGURES

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER I
RATIONALE AND BACKGROUND

Cataract is the leading cause of blindness worldwide.[1-7] WHO regards the disease as one of the five major concerns in the 'prevention of blindness' global program. To date, there is no proven preventive measure for the disease. The only form of treatment is surgery. Results of successful cataract extraction are excellent. Visual recovery after cataract removal proved to have high impact in the elderly.[8]

Different techniques of cataract extraction have been developed in the last century. The first technique, intracapsular cataract extraction, is now preserved for subluxated lens since intraocular lens implantation is hardly possible unless followed by a relatively lengthy and risky operation. Nowadays, a recently introduced surgical technique, phacoemulsification,[9] is used in most cases. Faster visual recovery, lower incidence of post-operative inflammation, earlier ambulation of the patients are its benefits. The limitations occur in some technically difficult cases such as hard lens nucleus, and weakness or incompleteness of lens capsular support.

Extracapsular cataract extraction (ECCE) is used for mature lens removal and in the settings where phacoemulsification is not possible. While topical anesthesia is widely and almost routinely used in phacoemulsification, it is not appropriate in ECCE due to longer operation time and larger wound size. Ideal anesthesia for extracapsular cataract extractions should provide analgesia for the

patients, akinesia of the extraocular muscles, an optimal time the effects last, optimal intraocular pressure, high patient tolerability, and provoking least complications.

Local anesthetic for cataract surgery may be administered through either injection or the use of topical anesthetic eye drops. Currently there is no consensus as to the optimal approach to regional anesthesia. Choice of local anesthetic technique is largely determined by the surgeon preference.

Routinely used regional anesthesia for extracapsular cataract extraction are retrobulbar and peribulbar blocks. The results from a systematic review on the effectiveness of local anesthesia for the patients undergoing cataract surgery showed good evidence supporting that retrobulbar and peribulbar blocks provide good and equivalent akinesia and pain control during cataract surgery.[10]

Both techniques obtain acceptable akinesia and analgesia. However, blind needle retrobulbar and peribulbar anesthesia are associated with retrobulbar hemorrhage, retinal vascular occlusion,[11-13] globe perforation,[14-16] optic-nerve injury,[17] extraocular muscle injury,[18] brain stem anesthesia,[19] temporary loss of vision in the other eye,[20] and cardiopulmonary arrest.[21-23] The patient's quality of life, the numbers of admissions, the numbers of visits, and the cost of transportation are inevitably affected. If there was another feasible anesthesia technique that showed similar pain control with fewer complications, the practice of extracapsular cataract extraction will substantially be more refined.

Topical anesthesia, in contrary, is associated with minimal risks, although, theoretically, they cannot block the sensory and motor nerves in the iris and ciliary body as complete as retrobulbar

or peribulbar blocks due to insufficient absorption or dilution by tears. Therefore, patients may be intolerant of the operating microscope light and have less satisfaction during lens and iris manipulation in cataract surgery.

Circumferential subconjunctival (also termed circumcorneal, perilimbal, or limbal) anesthesia for cataract surgery is a method in which a subconjunctival anesthetic agent is spread 360 degrees around the limbus. This technique or its minor modifications has been shown to be successful in case series of phaco-emulsification,[24,25] combined phacotrabeculectomy,[26] and in several non-comparative trials in extracapsular cataract extraction.[27-31] A controlled trial on the efficacy of subconjunctival anaesthesia versus peribulbar anaesthesia in cataract surgery showed that in terms of anesthesia, both techniques were not different.[32]

To date, there is no randomized controlled trial to compare the efficacy of retrobulbar anesthesia with circumferential subconjunctival block in terms of pain control during ECCE.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER II

LITERATURE REVIEW

The systematic review by Friedman DS et al on the effectiveness of local anesthesia for the patients undergoing cataract surgery showed good evidence supporting that retrobulbar and peribulbar blocks provide equivalent akinesia and pain control during cataract surgery. There was strong evidence that retrobulbar block provides better pain control during surgery than topical anesthesia, but there was fair evidence that peribulbar block provides better pain control than topical anesthesia. On administration of the anesthesia, retrobulbar and peribulbar blocks were more painful than sub-Tenon's and topical anesthesia.[10] However, this review did not differentiate pain control between various surgical techniques.

In phacoemulsification, topical anesthesia has been used to control pain but still offers less pain relief than retrobulbar and peribulbar blocks.[10] Additional anesthesia to topical anesthetics includes intracameral lidocaine and subconjunctival block.[10, 24-26]

In 1995, Anderson CJ reported a combined technique of topical and subconjunctival anesthesia used in 73 consecutive patients undergoing scleral tunnel phacoemulsification cataract surgery. Ninety-five percent of the patients reported no pain. No patients required additional retrobulbar or peribulbar anesthesia.[24,25] In 1999, he also successfully used subconjunctival block in phacotrabeculectomy.[26]

Hatt M[28] and Smith R[29] in 1990 separately reported satisfactory analgesic results of subconjunctival anesthesia in ECCE. However, both studies were not controlled trials. Another prospective non-comparative study to evaluate the effectiveness and the complications related to the use of subconjunctival anesthesia in conventional ECCE with IOL implantation was performed by Makuloluwa CA in 2000.[27] Complications from the subconjunctival anesthesia technique were few. Patients did not report intraoperative pain severe enough to cause the procedure to be abandoned or the anesthesia reinforced; surgery was successfully performed in all cases. They concluded that circumcorneal perilimbal anesthesia was effective for ECCE with IOL implantation.

Redmond RM in 1990 reported a retrospective study comparing two groups of patients that underwent extracapsular cataract surgery. Retrobulbar group had uncomplicated retrobulbar injection with bupivicaine and hyaluronidase. The other group (non-retrobulbar) had superior bulbar, subconjunctival infiltration with bupivicaine and hyaluronidase. The operative complications and postoperative visual outcomes were similar in both groups.[30]

In 1990, Furuta M presented the technique of subconjunctival anesthesia in extracapsular cataract extraction with and without posterior chamber intraocular lens implantation or secondary posterior chamber intraocular lens implantation consists of injecting 0.5 ml of locally-acting anesthetic subconjunctivally (or sub-Tenon's) along the superior limbal border. They performed the operation on 176 cataract patients. Anesthesia was successfully induced in the majority of these patients and all surgeries were carried out successfully with no major complications.[31]

Khurana AK in 1994 conducted a comparative study to evaluate peribulbar anesthesia versus subconjunctival anesthesia. The results showed that peribulbar anesthesia was more effective than subconjunctival anesthesia regarding orbicularis akinesia ($p<0.05$) and ocular akinesia ($p<0.05$). Interestingly, there was no significant difference in the sensory anesthesia, analgesia and intraocular pressure changes in the two groups ($p>0.05$).[32]

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER III
RESEARCH OBJECTIVES

Primary objective

To compare the pain perceived by the patients during the operation in the two anesthetic techniques: retrobulbar anesthesia and circumferential subconjunctival anesthesia.

Secondary objectives

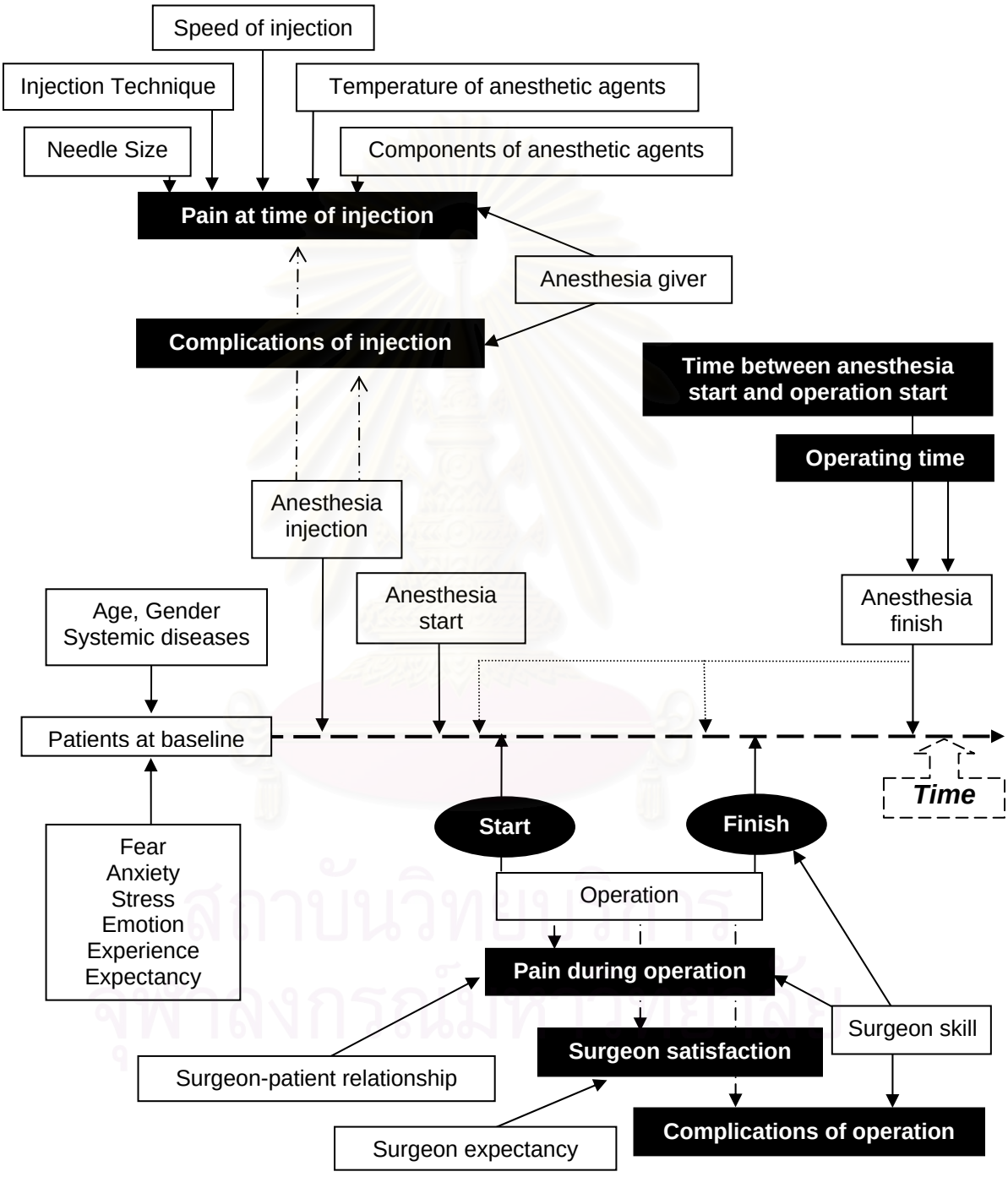
To compare the pain perceived by the patients at the time of anesthetic agent administration between the two anesthetic techniques.

Between these two techniques, also to compare the surgeon satisfaction and complication rates.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER IV

CONCEPTUAL FRAMEWORK



Dark boxes show all variables to be measured in the study
White boxes show all factors concerned

CHAPTER V

OPERATIONAL DEFINITIONS

Pain at time of injection: pain perceived and reported by the patients counting from the beginning of the anesthetic agent injection to end of injection, excluding van Lint facial nerve block

Pain during operation: pain perceived and reported by the patients counting from start to end of operation

Surgeon satisfaction: overall satisfaction to the patient reaction to noxious stimuli during operation e.g. superior Bridle suture, scissors cutting of tissue, knife cutting of the tissue, electric cauterization, lens nucleus expression, IOL implantation, and suturing plus overall performance of the patients during surgery e.g. globe movement to or against the direction of advice

Complications of anesthesia: any detectable, immediate, inadvertent reactions to anesthetic agents and/or the anesthetic techniques e.g. globe perforation, retrobulbar hemorrhage, injection of anesthetic agents into the vitreous, optic nerve, and subarachnoid space

Complications of operation: any undesirable events during the surgery

Range of equivalence: a range within pre-defined tolerance limits, -Δ and +Δ, based on the treatment difference such that any value of pain in this range is clinically unimportant. Delta (Δ) is the smallest value that would represent a clinically meaningful difference. At the same time it is the largest value that would represent a clinically meaningless difference. The range of equivalence in the study is defined as –10 mm to +10 mm of the 100 mm visual analogue scale. This range was set by experts' opinion upon clinical relevance.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER VI

RESEARCH DESIGN AND METHODOLOGY

In an effort to assess the acceptable efficacy of the new circumferential subconjunctival anesthesia technique, which is thought to be less expensive and provoking fewer complications, to an existing standard retrobulbar technique, an equivalence trial is justified.

The study was conducted as a prospective, randomized, positive controlled trial in parallel groups. The patients, surgeons and instrumental nurses, who were the outcome assessors, were masked of the intervention given. However, the caregivers could not be masked.

Population and sample

Target population: cataract patients undergoing ECCE with IOL under local anesthesia.

Study population: cataract patients registered at the 6th Station of the Relief Unit, Thai Red Cross Society, located at the Arunyaprathet district of Sa Kaew Province, Thailand.

Sample population: patients who met the following criteria:

Inclusion Criteria

a. Cataract patients underwent planned ECCE with IOL implantation under local anesthesia
b. Agreed to participate in the study and signed the written informed consent

Exclusion Criteria

a. Patients who could not communicate well including those who were deaf, who had dysphasia, or dementia
b. Patients who had anterior segment diseases other than cataract e.g. glaucoma, anterior uveitis
c. Patients who had already had the first eye participated in the study, the second eye was excluded.

Sample size calculation

The sample size calculation formula for a clinical equivalence trial for normally distributed data when comparing means is different from comparative trials.[33] The allocation ratio was 1:1 and it was assumed that the two methods are likely to be equally effective. According to the following formula, a sample size of 45 per group was required for a two-sided alpha error of 0.025 and a beta error of 0.2.

$$\text{n/ group} = \frac{2\sigma^2 [Z_{(1-\alpha)} + Z_{(1-\beta/2)}]^2}{\Delta^2} = \frac{2\sigma^2 [1.96 + 1.28]^2}{10^2}$$

where σ was the standard deviation of pain score in retrobulbar group, which equaled to 14.61[34] and Δ was the margin of equivalence in the absolute scale. With the anticipated dropout rate of 10%, a sample of 50 eyes per group was planned. However, due to the substantial number of the patients, a rather fast recruitment and the cost-effectiveness of the funding, we extended our research to 8 months (from May 2003 to December 2003) instead of 6 months (May to October) as originally planned. The total sample size reached 145 at the end of the study.

Sampling technique

We employed non-probability sampling by using a convenience method. All consecutive patients who met the inclusion criteria and wished to participate in the study were included.

Randomization

Simple randomization technique using a randomization table was done.

Allocation concealment

Treatment allocation was concealed in separate well-sealed opaque paper packets. The sequence was performed by one of the researchers who was not the outcome assessor in any part of the study. The code was opened by only the anesthetic injector after the recruitment, and just before the intervention was given.

Intervention

The samples were randomized into 2 groups. During preoperative counseling, patients were informed that there would be two techniques to block the pain in the eye during surgery, and the patients would be masked of the techniques given. Anesthesia was performed by a caregiver in an equipped area outside the operating room. There was only one anesthesia giver in this study.

The retrobulbar technique was done in a standard method using a 3.5 cm, 25- gauge disposable needle attached to a syringe containing 2-3 mL of 2% Xylocaine stored at room temperature. Injection was introduced through skin in the inferior temporal margin of the orbit. After piercing the skin, the needle tip was

pointed straight back close to the floor of orbit until beyond the globe and then directed upward and toward the retrobulbar space for a depth of 2.5 - 3.5 cm. When the needle had reached its proper depth, it was aspirated to determine whether the needle had entered a vessel. The anesthetic solution was then slowly injected. (Figure 1)

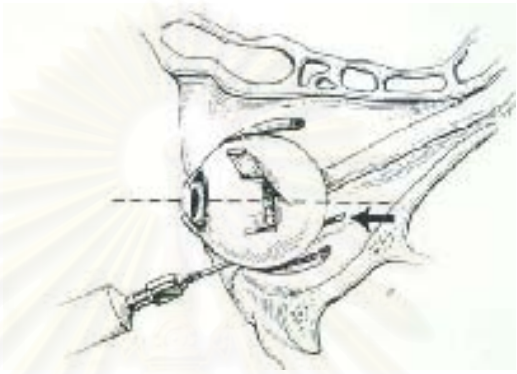


Figure 1. Retrobulbar anesthesia

The circumferential subconjunctival technique was done by the same caregiver, using a 1 cm, 27-gauge disposable needle. Topical anesthesia was instilled in the conjunctival sac. An eyelid speculum was then inserted. After the superior bulbar conjunctiva was elevated with a smooth forceps, 0.5-1 mL of 2% Xylocaine was injected slowly into subconjunctival space blowing the conjunctiva up to a size of an approximate 7-8 mm in diameter. The chemosis was then gently massaged by using a cotton-tipped applicator to ensure spread of anesthetic solution nasally and temporally and then inferiorly. (Figure 2)

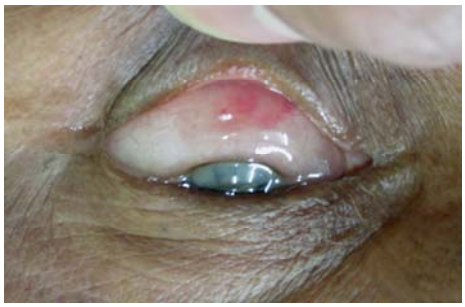


Figure 2. Circumferential subconjunctival anesthesia

All patients received facial nerve block (van Lint technique) in order to paralyse lid squeezing. Immediately prior to the surgery, topical anesthesia (0.4% Tetracaine hydrochloride eye drop) was instilled in the inferior conjunctival fornix to prevent pain during application of eyelid speculum.

Outcome measurement

Six variables were measured.

a. The primary outcome was the ‘during operation’ pain score using visual analogue pain rating scale on a 100 millimeters horizontal straight line (where 0 was no pain and 100 was worst possible pain), graded by the patients. Scales were measured by a standardized ruler by the same masked assessor at the end of the study. A masked observer interviewed the patients within an hour after the operation ended. Data was collected as continuous data and analyzed at the end of the study. Patients who were not able to mark on the scale, including one-eyed and illiterate patients, a numerical verbal rating scale was used.[35]
b. The second outcome was the ‘at time of injection’ pain score using the same technique as in (a). A masked observer interviewed the patients within 15 minutes after the injection.
c. The third outcome was the surgeon satisfaction graded by the surgeon who was unaware of the treatment allocation, based on the patient compliance and cooperation. A visual analogue scale on a 100 millimeters horizontal straight line (where 100 was full satisfaction and 0 was a situation

where surgery was impossible due to an uncooperative painful patient) was used. There was only one surgeon in the study and she graded the satisfaction right after each surgery.

d. The fourth one was the length of operation from start (counting from insertion of eyelid speculum) to end (when the eyelid speculum was removed) in the unit of minutes recorded by the instrumental nurse in each case, who was unaware of the given intervention.
e. The fifth one was the type of complication occur at time of injection, e.g. retrobulbar hemorrhage, globe perforation, inadvertent injection of anesthesia to other spaces such as subarachnoid space, optic nerve, vitreous, etc. recorded by the anesthesia giver.
f. The last one was the type of complication occur during cataract surgery, e.g. vitreous loss, posterior capsule tear, uncontrolled iris prolapse, etc. recorded by the surgeon.

Rescue medications

The patients who experienced intractable pain during the operation received intra-operative 2% xylocaine injection subconjunctivally, depending on the surgeon's judgement. Whenever the rescue medications were needed, the pain score was counted as 100.

CHAPTER VII
DATA COLLECTION AND MANAGEMENT

Case record form was generated for each individual patient to keep the patients' data in seven separate sheets (Appendices), which included:

No.	Record sheets	Assessor/ recorder
1	Patient consent form	Research assistant 1
2	Patient's demographic data including age, sex, eye operated (Left/Right, First/Second), anesthetic technique using codes	Research assistant 1
3	a. Time of injection b. Complications of anesthesia administration as a checklist and open-ended questions	Caregiver
4	Pain scale at time of injection	Patient
5	Pain scale during operation	Patient
6	a. Surgeon satisfaction scale b. Complications of operation as a checklist and open-ended questions	Surgeon
7	a. Operating time (time start/time end) b. Use of rescue medications	Research assistant 2

Data were entered separately by two researchers to ensure the accuracy. Case record forms were kept confidential.

CHAPTER VIII

DATA ANALYSES

The study was designed to demonstrate the equivalence of circumferential subconjunctival anesthesia and retrobulbar anesthesia in pain control during cataract surgery. The patient's perception of pain during the operation was the primary end point. Pain rating on a visual analogue scale was treated as continuous data.

Since the primary end point was not normally distributed, it was presented as median difference and the 95% confidence interval of the difference. Using the confidence interval approach, equivalence is concluded if the interval falls entirely within the range of equivalence. Possible results of the comparison of a confidence interval with a pre-defined range of equivalence are shown in Figure 3.

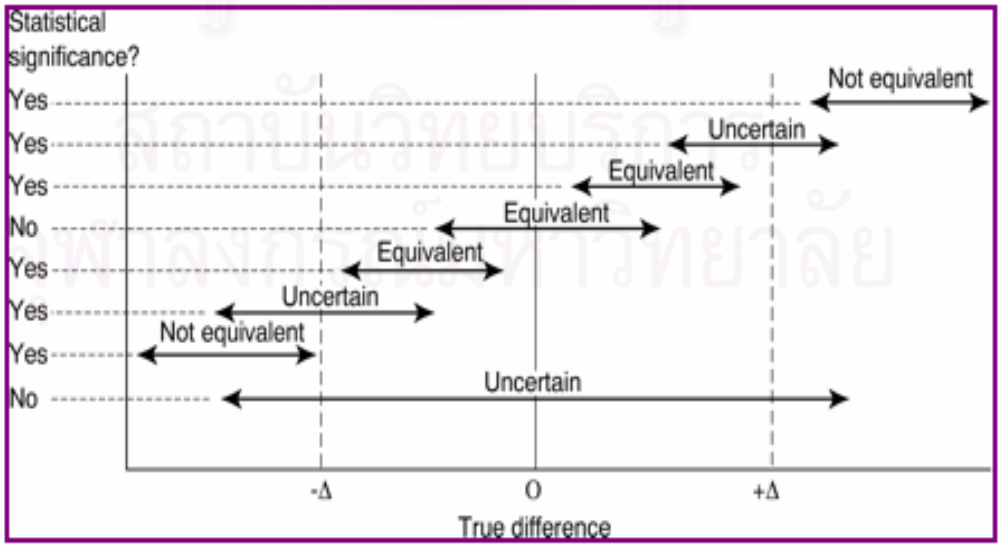


Figure 3. Interpretation of the confidence interval approach in equivalence trials

The patient's demographic data and baseline characteristics, and the duration of the operation was tabulated and presented as descriptive statistics.

Pain scale at time of injection was treated as continuous data. Since the pain scale was extreme in both ends, data transformation could not be done. We therefore presented the data as median difference and the 95% confidence interval of the difference.

Surgeon satisfaction scale was treated as continuous data and presented as mean difference and the 95% confidence interval of the difference.

The complication rates and the use of rescue medications was presented in the form of proportion and compared by using Fisher's exact test.

The analyses were performed under SPSS version 11.0 and MINITAB version 14.

Theoretically, an intention-to-treat analysis will move the estimated treatment difference towards null. As treated analysis (per-protocol analysis) includes only the patients who follow the protocol adequately, which would expect a clearer effect of treatment.[33,36] In this study, both types of analyses were performed.

Missing data was analysed by assuming worst-case scenario (favours retrobulbar block - by assuming retrobulbar block pain as 0 and subconjunctival block pain as 100; surgeon satisfaction in retrobulbar block as 100 and satisfaction in subconjunctival block as 0), and vice versa for best-case scenario. Equivalence can then be more confidently declared if the 95% confidence intervals calculated from every analysis fall within the pre-specified range.

CHAPTER IX
ETHICAL CONSIDERATIONS

The basic principles enunciated in the Declaration of Helsinki were complied with. Patient's informed consent was obtained in all cases. The study protocol and the consent form were reviewed by the Ethical Committee of the Faculty of Medicine, Chulalongkorn University and were approved on March 20, 2003 (Approval No. 153/2003).

The study was conducted with an official permission in monthly cataract surgery campaigns, routinely done by the Relief Unit of the Thai Red Cross Society.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER X
RESULTS

A total of 145 cases were recruited in the study, 81 cases in the retrobulbar group and 64 cases in the circumferential subconjunctival group. Three cases (one in retrobulbar group and two in subconjunctival group) did not complete the study due to procedural change intra-operatively. One patient in retrobulbar group developed seizure on the operating table just before the surgery and did not undergo the cataract extraction. The patient demographic data and baseline characteristics are shown in Table 1.

Table 1. Patient baseline characteristics

	Retrobulbar anesthesia	Subconjunctival anesthesia
Number of patients	81	64
Age in years [mean (SD)]	66.2 (11.1)	68.9 (12.9)
Male [number (%)]	41 (50.6)	27 (42.2)
Right eye [number (%)]	37 (45.7)	37 (57.8)
First eye [number (%)]	64 (79.0)	55 (85.9)

The results of each outcome are shown in Table 2. These results are based on 79 patients in retrobulbar group and 62 patients in subconjunctival group, who completed the study.

Table 2. Results in each group: VAS of pain scales and satisfaction scale; Complications; Rescue medication use

	Retrobulbar anesthesia	Subconjunctival anesthesia	*p*-value
Number of patients completed the study	79	62	
Operating time in minutes [mean (SD)]	12.5 (2.9)	13.0 (4.4)	**0.51***
VAS operation pain in mm [median (IQR)]	10 (5, 50)	20 (8.5, 40)	
VAS injection pain in mm [median (IQR)]	7 (3, 20)	10 (1, 15)	
VAS satisfaction score in mm [mean (SD)]	79 (8.4)	68 (9.6)	
Injection complications			**< 0.001****
No complications	78	48	
Subconjunctival hem.	0	14	
Partial retrobulbar hem.	1	0	
Operative complications			**0.44****
No complications	79	61	
Suprachoroidal hem.	0	1	
Rescue medication use [number of patients (%)]	14 (17.7)	2 (3.2)	**0.007****

VAS = visual analog score; IQR = interquartile range; hem. = hemorrhage;
* t-test; ** Fisher's exact test

The median difference and 95% CI of the difference of the pain scales (calculated from as-treated analysis, intention-to-treat analysis assuming worst-case scenario and intention-to-treat analysis assuming best-case scenario) are shown in Table 3. The calculation was based on the pain score of retrobulbar group minus subconjunctival group, therefore, a negative figure favors retrobulbar block and a positive figure favors subconjunctival block.

Table 3. The median difference and 95% CI of the difference of during operation pain and injection pain

	Median difference in mm (95% CI)		
	As-treated	Worst-case	Best-case
Pain during operation	0 (-8, 5)	-1 (-10, 2)	0 (-5, 5)
Pain at time of injection	0 (-1, 3)	0 (-2, 3)	1 (0, 4)

The surgeon satisfaction score was normally distributed. The mean differences and confidence intervals are shown in Table 4.

Table 4. The mean difference and 95% CI of the difference of the surgeon satisfaction scale

	Mean difference in mm (95% CI)		
	As-treated	Worst-case	Best-case
Surgeon satisfaction scale	11.4 (8.4, 14.4)	14.0 (9.8, 18.3)	8.4 (4.2, 16.7)

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER XI

DISCUSSION

The study results were obvious that the confidence interval of the during operation pain scales include zero, therefore it implies that there is no statistical significant difference between groups. With a worst-case scenario assumption, the confidence interval approached the lower equivalence limit but did not cross the line. With the as-treated analysis as well as intention-to-treat analysis assuming best-case scenario, the interval lied entirely within the range. Therefore, we can conclude with confidence that the pain during extracapsular cataract extraction perceived by the patient was equivalent in both techniques.

For the pain at time of injection, there was also no statistical significant difference between groups. Since we did not specify the equivalence limit of this variable beforehand, we would not assess for the equivalence of this outcome. Nevertheless, if the range of equivalence was similar, i.e. from -10 to +10 mm as in the primary outcome, this variable also yielded equivalence of two techniques.

The complications of the injection differed significantly. Circumferential subconjunctival anesthesia gave a higher rate of complications. Subconjunctival hemorrhage was seen in a number of patients. But given the fact that the cataract operation itself always induces subconjunctival hemorrhage and the condition resolves spontaneously without sequel, this side effect is acceptable for most surgeons. The only drawback of this condition in this study is that the anesthesia technique could not be perfectly blinded because the surgeon could guess from the hemorrhage

seen under the conjunctiva, which might explain the difference of the surgeon satisfaction score.

The surgeon preferred retrobulbar block more than subconjunctival block, however, the operations were performed quite well in both groups as the operative time was not different and the complications were rare. Use of rescue medications differed significantly. A higher rate was seen in retrobulbar group.

The operating time in this study is rather short. The results from the study may not generalize well in case of longer surgical time. Theoretically, the subconjunctival anesthesia blocks only at the distal nerves and the anesthetic agents should be absorbed faster than in the retrobulbar technique. If the operation is expected to be longer, the pain scale during operation may not be equivalent. The patient in the subconjunctival group may feel more painful than those in the retrobulbar group.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

CHAPTER XII

CONCLUSION

Circumferential subconjunctival anesthesia gives an equivalent pain control to retrobulbar anesthesia in patients undergoing extracapsular cataract extraction. The pain at time of injection of both techniques does not differ significantly. The surgeon prefers retrobulbar anesthesia, however, a higher rate of rescue medications is used in this group. Subconjunctival hemorrhage was seen in a number of patients in subconjunctival anesthesia. Operative complications were rare.

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

REFERENCES

1. Michon JJ, Lau J, Chan WS, Ellwein LB. Prevalence of visual impairment, blindness, and cataract surgery in the Hong Kong elderly. Br J Ophthalmol 2002; 86(2): 133-9.
2. Singalavanija A, Metheetrairut A, Ruangvaravate N, Tuchinda R, Wanumkarng N. Ocular diseases and blindness in elderly Thais. J Med Assoc Thai 2001; 84(10): 1383-8.
3. Zainal M, Masran L, Ropilah AR. Blindness and visual impairment amongst rural Malays in Kuala Selangor, Selangor. Med J Malaysia 1998; 53(1): 46-50.
4. Jenchitr WT, Tansirikongkol V. Ophthalmology in Thailand 1997. J Med Assoc Thai 2000; 83(2): 107-16.
5. Ho T, Law NM, Goh LG, Yoong T. Eye diseases in the elderly in Singapore. Singapore Med J 1997; 38(4): 149-55.
6. Rahmani B, Tielsch JM, Katz J, Gottsch J, Quigley H, Javitt J, et al. The cause-specific prevalence of visual impairment in an urban population. The Baltimore Eye Survey. Ophthalmology 1996; 103(11): 1721-6.
7. Thomson I. A clinic based survey of blindness and eye disease in Cambodia. Br J Ophthalmol 1997; 81(7): 578-80.
8. Owsley C, McGwin G Jr, Sloane M, Wells J, Stalvey BT, Gauthreaux S. Impact of cataract surgery on motor vehicle crash involvement by older adults. JAMA 2002; 288(7): 841-9.
9. Kelman CD. Phaco-emulsification and aspiration. A new technique of cataract removal. A preliminary report. Am J Ophthalmol 1967; 64(1): 23-35.

10. Friedman DS, Bass EB, Lubomski LH, Fleisher LA, Kempen JH, Magaziner J, et al. Synthesis of literature on the effectiveness of regional anesthesia for cataract surgery. Ophthalmology 2001; 108(3): 519-29.
11. Coupland SG, Deschenes MC, Hamilton RC. Impairment of ocular blood flow during regional orbital anesthesia. Can J Ophthalmol 2001; 36(3): 140-4.
12. Giuffre G, Vadala M, Manfre L. Retrobulbar anesthesia complicated by combined central retinal vein and artery occlusion and massive vitreoretinal fibrosis. Retina 1995; 15(5): 439-41.
13. Mieler WF, Bennett SR, Platt LW, Koenig SB. Localized retinal detachment with combined central retinal artery and vein occlusion after retrobulbar anesthesia. Retina 1990; 10(4): 278-83.
14. Edge R, Navon S. Scleral perforation during retrobulbar and peribulbar anesthesia: Risk factors and outcome in 50,000 consecutive injections. J Cataract Refract Surg 1999; 25(9): 1237-44.
15. Duker JS, Belmont JB, Benson WE, Brooks HL Jr, Brown GC, Federman JL, et al. Inadvertent globe perforation during retrobulbar and peribulbar anesthesia: patient characteristics, surgical management, and visual outcome. Ophthalmology 1991; 98: 519-26.
16. Ramsay RC, Knobloch WH. Ocular perforation following retrobulbar anesthesia for retinal detachment surgery. Am J Ophthalmol 1978; 86: 61-4.
17. Pautler SE, Grizzard WS, Thompson LN, Wing GL. Blindness from retrobulbar injection into the optic nerve. Ophthalmic Surg

1986; 17: 334-7.

18. Brown SM, Brooks SE, Mazow ML, Avilla CW, Braverman DE, Greenhaw ST, et al. Cluster of diplopia cases after periocular anesthesia without hyaluronidase . J Cataract Refract Surg 1999; 25(9): 1245-9.
19. Javitt JC, Addiego R, Friedberg HL, Libonati MM, Leahy JJ. Brain stem anesthesia after retrobulbar block. Ophthalmology 1987; 94: 718-24.
20. Jovkar S, Connolly WES. Contralateral amaurosis secondary to retrobulbar anesthesia. Ann Ophthalmol - Glaucoma 1999; 31(6): 295-7.
21. Tatum PL, Defalque RJ. Subarachnoid injection during retrobulbar block: a case report. AANA J 1994; 62(1): 49-52.
22. Mayer AS, O'Connor RE. Respiratory arrest after local anesthesia for outpatient cataract surgery: a dramatic but transient complication. Ann Emerg Med 1993; 22(8): 1357-9.
23. Ruusuvaara P, Setala K, Tarkkanen A. Respiratory arrest after retrobulbar block. Acta Ophthalmol (Copenh) 1988; 66(2): 223-5.
24. Anderson CJ. Combined topical and subconjunctival anesthesia in cataract surgery. Ophthalmic Surg 1995; 26(3): 205-8.
25. Anderson CJ. Subconjunctival anesthesia in cataract surgery. J Cataract Refract Surg 1995; 21(1): 103-5.
26. Anderson CJ. Circumferential perilimbal anesthesia for combined cataract glaucoma surgery. Ophthalmic Surg Lasers 1999; 30(3): 205-7.
27. Makuloluwa CA, Dharmarathna L. Circumcorneal perilimbal anesthesia in extracapsular cataract extraction with intraocular

lens implantation. J Cataract Refract Surg 2000; 26(11): 1647-9.

28. Hatt M. Intraocular lens implantation with subconjunctival local anesthesia. Klin Monatsbl Augenheilkd 1990; 196(5): 307-9.
29. Smith R. Cataract extraction without retrobulbar anaesthetic injection. Br J Ophthalmol 1990; 74(4): 205-7.
30. Redmond RM, Dallas NL. Extracapsular cataract extraction under local anaesthesia without retrobulbar injection. Br J Ophthalmol 1990; 74(4): 203-4.
31. Furuta M, Toriumi T, Kashiwagi K, Satoh S. Limbal anesthesia for cataract surgery. Ophthalmic Surg 1990; 21(1): 22-5; discussion 26.
32. Khurana AK, Sachdeva RK, Gombar KK, Ahluwalia BK. Evaluation of subconjunctival anaesthesia vs peribulbar anaesthesia in cataract surgery. Acta Ophthalmol (Copenh) 1994; 72(6): 727-30.
33. Jones B, Jarvis P, Lewis JA, Ebbutt AF. Trials to assess equivalence: the importance of rigorous methods. BMJ 1996; 313(7048): 36-9. Published erratum in BMJ 1996; 313(7056): 550.
34. Kapran Z, Uyar M, Eltutar K, Dincer N. One quadrant sub-Tenon's capsule anesthesia in anterior segment surgery. Eur J Ophthalmol 1996; 6(2):131-6.
35. McDowell I, Newell C. Pain measurements: visual analogue pain rating scales. In: Measuring health. A guide to rating scales and questionnaires, 2nd edition. Oxford: Oxford University Press 1996: 341-6.
36. Ebbutt AF, Frith L. Practical issues in equivalence trials. Stat Med 1998; 17(15-16): 1691-701.

APPENDICES

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

APPENDIX 1
PATIENT INFORMATION AND CONSENT FORM

ข้อมูลสำหรับผู้ป่วยและใบยินยอมอนุญาต
งานวิจัยเพื่อเปรียบเทียบผลการฉีดยาชาเฉพาะที่เพื่อการผ่าตัดต้อกระจก

1. เหตุผลในการศึกษาวิจัย

เนื่องจากการฉีดยาชาเฉพาะที่เพื่อลดอาการปวดในขณะทำผ่าตัดต้อกระจกมีหลายวิธี วิธีฉีดเข้าที่กระบอกตาเป็นวิธีที่ยอมรับกันว่าให้ผลดีมาก ช่วยให้ชาได้ดี แต่อาจมีผลข้างเคียงที่เป็นอันตรายเกิดขึ้นได้ ได้แก่ เข็มฉีดแทงตาทะลุ มีเลือดออกในกระบอกตา เป็นต้น ได้มีวิธีฉีดยาชาอีกวิธีหนึ่งซึ่งน่าจะเป็นวิธีที่ปลอดภัยกว่า โดยฉีดยาชาเข้าที่ใต้เยื่อบุตา ใช้ยาปริมาณน้อยกว่า ฉีดตื้นกว่า ผลระงับอาการปวดน่าจะใกล้เคียงกัน แต่ยังไม่เคยมีการศึกษาที่เทียบการฉีดยาสองวิธีนี้โดยตรง ในงานวิจัยครั้งนี้จึงจะทำการเปรียบเทียบผลการระงับปวดของสองวิธีนี้

2. ขั้นตอนการศึกษา

1. ผู้ป่วยจะได้รับการฉีดยาชาด้วยวิธีใดวิธีหนึ่งโดยการสุ่ม
2. จักษุแพทย์ผู้ซึ่งมีความชำนาญด้านการฉีดยาชาทั้งสองวิธี จะฉีดยาชาให้กับผู้ป่วย
3. หลังการฉีดยา ภายในเวลา 15 นาที ผู้ป่วยให้คะแนนความปวดโดยกากบาทลงบนกระดาษที่จัดเตรียมไว้ให้
4. ผู้ป่วยเข้ารับการผ่าตัดต้อกระจกโดยจักษุแพทย์อีกท่านหนึ่ง
5. ภายในเวลา 1 ชั่วโมงหลังผ่าตัดต้อกระจก ผู้ป่วยให้คะแนนความปวดโดยกากบาทลงบนกระดาษที่จัดเตรียมไว้ให้
6. ระหว่างผ่าตัด หากผู้ป่วยปวดมากจนทนไม่ไหว สามารถขอยาฉีดระงับปวดเพิ่มเติมได้ตลอดเวลา

3. หากท่านตกลงจะเข้าร่วมในการศึกษาครั้งนี้

1. ท่านไม่ต้องเสียค่าใช้จ่ายเพิ่มเติมจากค่าใช้จ่ายตามปกติของการฉีดยาชาเฉพาะที่
2. ท่านไม่ต้องเสียค่าใช้จ่ายเพิ่มเติมจากค่าใช้จ่ายตามปกติของการผ่าตัดต้อกระจก

4. คำชี้แจงเกี่ยวกับสิทธิของผู้ป่วย

1. การเข้าร่วมการศึกษาครั้งนี้ เป็นไปโดยสมัครใจ ท่านจะปฏิเสธหรือถอนตัวจากการศึกษาได้ทุกเมื่อ โดยไม่มีผลต่อการรักษาของท่าน
2. ข้อมูลของท่านจะถูกเก็บเป็นรหัสลับ และไม่มีการเปิดเผยชื่อของท่านสู่สาธารณะ

5. คำยินยอมของผู้ป่วย

1. ก่อนที่จะลงนามในใบยินยอมให้ทำการวิจัยนี้ ข้าพเจ้าได้รับการอธิบายจากผู้วิจัยถึงวัตถุประสงค์ของการวิจัย วิธีการวิจัย อันตราย หรืออาการที่อาจเกิดขึ้นจากการวิจัย จากการผ่าตัด หรือจากยาที่ใช้ รวมทั้งประโยชน์ที่จะเกิดขึ้นจากการวิจัยอย่างละเอียด และมีความเข้าใจดีแล้ว

2. ผู้วิจัยรับรองว่าจะตอบคำถามต่างๆ ที่ข้าพเจ้าสงสัยด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าพอใจ
3. ข้าพเจ้ามีสิทธิที่จะบอกเลิกการเข้าร่วมในโครงการวิจัยนี้เมื่อใดก็ได้ และเข้าร่วมโครงการวิจัยนี้โดยสมัครใจ และการบอกเลิกการเข้าร่วมการวิจัยนี้ จะไม่มีผลต่อการรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป
4. ผู้วิจัยรับรองว่าจะเก็บข้อมูลเฉพาะเกี่ยวกับตัวข้าพเจ้าเป็นความลับ และจะเปิดเผยได้เฉพาะในรูปที่เป็นสรุปผลการวิจัย การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้องกระทำได้เฉพาะกรณีจำเป็น ด้วยเหตุผลทางวิชาการเท่านั้น

ข้าพเจ้าได้อ่านและทำความเข้าใจในข้อความทั้งหมดของใบยินยอมครบถ้วนดีแล้ว ทั้งนี้ข้าพเจ้ายินยอมที่จะเข้าร่วมในการศึกษาครั้งนี้ด้วยความสมัครใจโดยไม่มีการบังคับหรืออามิสสินจ้างใด ๆ

วันที่.....

ลงนาม.....ผู้ยินยอม
(.....)

ลงนาม.....พยาน
(.....)

ลงนาม.....ผู้ทำวิจัย
(.....)

ข้าพเจ้าไม่สามารถอ่านหนังสือได้ แต่ผู้วิจัยได้อ่านข้อความในใบยินยอมนี้ให้แก่ข้าพเจ้าฟังจนเข้าใจดีแล้ว ข้าพเจ้าจึงลงนาม หรือประทับลายนิ้วหัวแม่มือขวาของข้าพเจ้าในใบยินยอมนี้ด้วยความเต็มใจ

วันที่.....

ลงนาม.....ผู้ยินยอม
(.....)

ลงนาม.....พยาน
(.....)

ลงนาม.....ผู้ทำวิจัย
(.....)

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

APPENDIX 2

CASE RECORD FORM

Patient baseline characteristics

Patient ID……..

Name ……..……..

Address ……..……

……..……

……..……

Date of birth ……/……/……. or Age……Yr

Sex Male Female

Eye Right Left

Eye First Second

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

Anesthesia and complications

Patient ID……..

Anesthetic code A B

Time at injection …….

Complications

- ☐ Subconjunctival hemorrhage
- ☐ Retrobulbar hemorrhage
- ☐ Corneal abrasion
- ☐ Chemosis
- ☐ Globe perforation
- ☐ Others, specify……..

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

Pain at time of injection

Patient ID……..

Pain Scale 1
(At time of injection)

Time……

0 100

ไม่ปวดเลย ปวดมากที่สุด

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

Pain during operation

Patient ID……

Pain Scale 2
(During operation)

Time……

0 ไม่ปวดเลย

100 ปวดมากที่สุด

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

Surgeon satisfaction & surgical complications

Patient ID……..

Satisfaction Scale 1

Time……..

0 100

ไม่พอใจมากที่สุด พอใจมากที่สุด

Complications of surgery

- ☐ Posterior capsule rupture
- ☐ Vitreous loss
- ☐ Uncontrolled iris prolapse
- ☐ Hyphema
- ☐ Others, specify…….

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

Operation time and rescue medications

Patient ID…….

Operation start at ……..
(Insertion of eyelid speculum)

Operation end at…….
(Removal of eyelid speculum)

Rescue medications use

☐ No

☐ Yes: specify…….

สถาบันวิทยบริการ
จุฬาลงกรณ์มหาวิทยาลัย

VITAE

Name: Wasee Tulvatana

Education:

1984-1990	M.D. (honors), Faculty of Medicine, Chulalongkorn University
1993-1996	Residency in Ophthalmology, King Chulalongkorn Memorial Hospital
1997-1998	Clinical Fellowship in Ophthalmology (Ophthalmic pathology service), Massachusetts Eye and Ear Infirmary and Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA
2002-present	Master of Science in Health Development (Clinical Epidemiology), Faculty of Medicine, Chulalongkorn University

Hospital Appointments:

1990-1991	Staff, Royal Thai Air Force Hospital, Bangkok
1991-1992	Staff, Wing 41 Hospital, Chiang Mai
1992-1993	Staff, Royal Thai Air Force Hospital, Bangkok
1996-1997	Staff, Strabismus Clinic and Glaucoma Clinic, King Chulalongkorn Memorial Hospital
1998-present	Staff, Strabismus Clinic, Glaucoma Clinic, and Ophthalmic Pathology Service, King Chulalongkorn Memorial Hospital

Academic Appointments:

1998-2001	Instructor, Department of Ophthalmology, Faculty of Medicine, Chulalongkorn University
2001-present	Assistant Professor, Department of Ophthalmology, Faculty of Medicine, Chulalongkorn University