Anterior Subconjunctival Anesthesia for Manual Small Incision Cataract Surgery: A Randomized Controlled Trial

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Abstract

Purpose: To compare the effectiveness of anterior subconjunctival anesthesia (ASCA) with sub-tenon's anesthesia (STA) for manual small incision cataract surgery (MSICS), regarding pain, akinesia, surgeon comfort, and complications.

Methods: This trial randomized 164 patients into two groups. Group 1 received ASCA, and Group 2 received STA. MSICS was performed on all patients. Any complications of anesthesia were noted before starting surgery. Patient ocular motility during surgery was scored between 0 and 4 based on the number of directions of gaze in which movement persisted. Following surgery, patients scored pain felt during surgery on a visual pain-score analog, and the surgeon graded for "discomfort" felt during surgery from 0 (Nil) to 4 (additional anesthesia needed).

Results: Chemosis due to anesthesia and persistence of ocular motility in all four gaze directions were seen in all 82 patients of Group 1, but these did not prevent the surgeon from performing MSICS. Seventy-seven patients (94%) in Group 1 and 79 (96.4%) in Group 2 had no or mild pain during surgery. The surgeon had moderate-to-severe discomfort in 14 (17.2%) Group 1 patients and 3 (3.6%) Group 2 patients, most of whom had deep-set eyes or exhibited excessive eye movements. Two patients in Group 1 and one patient in Group 2 were converted to peribulbar block.

Conclusion: ASCA is a safe and effective alternative for performing MSICS. It does not induce akinesia but provides adequate anesthesia for the surgery in most patients, except those with deep-set eyes, especially if displaying increased anxiety.

Keywords: Anesthesia, Cataract, Clinical trial

Introduction

Topical anesthesia is the most common method of anesthesia for phacoemulsification cataract surgery.[1-3] For manual small incision cataract surgery (MSICS), which is a worthy alternative to phacoemulsification and has been endorsed not just as the most appropriate technique in developing countries[4-7] but also advocated for inclusion in the surgical curriculum in the Western world,[8] peribulbar anesthesia remains the norm in the majority of cases.[5,9,10] Peribulbar anesthesia is a relatively blind and invasive technique with potentially dangerous side effects such as globe perforation, orbital hemorrhage, and brainstem anesthesia.[11-13] Sub-tenon's anesthesia (STA), less invasive than peribulbar, has been found to be as safe and effective as peribulbar anesthesia and is more comfortable to the patient at the time of administration.[9,14-16] Subconjunctival anesthesia is further less invasive than sub-tenon's and is simpler to administer,[17] but has not been studied extensively for its efficacy and safety for performing MSICS.

This study aims to evaluate subconjunctival anesthesia in MSICS by comparing it with STA with regard to pain during surgery, akinesia, surgeon comfort, and complications.

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METHODS

This study was conducted at a Medical College Hospital in South India, between April 2019 and July 2020, in accordance with international agreements and the Declaration of Helsinki (revised 2013). Institute Ethics Committee approval (IHEC/32/2018, dated 24-12-2018) was obtained before the commencement of the study. The study was designed as a prospective, randomized comparative controlled trial and registered with Clinical Trials Registry– India (CTRI/2019/03/018043). Patients scheduled for elective MSICS were screened for exclusion criteria and were recruited for the study after obtaining informed consent. The consent form and patient information sheet had been designed as per the Helsinki protocol guidelines and were available both in English and the local language.

Exclusion criteria were age <18 years, complicated cataract (cataract secondary to other primary ocular disease such as chronic anterior uveitis or acute congestive angle-closure), presence of corneal opacities, any eye not dilating to at least 6 mm preoperatively, and patients with known hypersensitivity to any of the component medications used for anesthesia.

All patients underwent a thorough preoperative examination, including vision, refraction, anterior segment evaluation, and dilated fundus examination. Cataract nucleus grading was done by observing the color of the nucleus on slit-lamp examination and was graded as 1 for white to pale yellow, 2 for yellow, 3 for brownish yellow, and 4 for brown, including reddish and black-brown.[18] Although not as comprehensive as the LOCS III classification system,[19] this system of classification was chosen as it was the grading method routinely performed in the hospital and was deemed to be feasible and adequate for the limited purpose of this study.

Patients were randomized by block randomization method into two groups, using a computer-generated randomization program, by an ophthalmologist not involved in the operating room procedure. The nurse in charge of the operation theatre assigned participants into respective groups. Each patient received two drops of 0.5% proparacaine hydrochloride (Paracain, Sunways, India) within 5 min before surgery.

All anesthesia injections were performed by a single ophthalmic surgeon after exposing the operating eye using a Barraquer universal wire speculum.

Group 1 patients received anterior subconjunctival anesthesia (ASCA). 0.2 mL of lignocaine 2% with adrenaline 1:200,000 (Lox 2%, Neon Laboratories, India) was injected under the temporal anterior bulbar conjunctiva 2 mm behind the limbus, and after a gap of 10–15 s, a further 0.2 mL of the solution was injected, taking care to avoid hitting a blood vessel to the extent possible. This method of 0.4 mL given in two deferred doses was done to ensure minimal pain perception for the patient. The anesthesia was administered with a 26 G needle mounted on a 2 ml syringe similar to the subconjunctival injection of antibiotic steroid combination routinely given after MSICS.

Group 2 received STA. 3 ml of the same anesthetic mixture as in the subconjunctival group was deposited posterior to the equator through a small inferonasal nick in the conjunctiva and Tenon's capsule, around 5 mm away from the limbus, using a sub-tenon's cannula.

In both groups, the patient was instructed to inform the doctor administering the anesthesia if any pain or discomfort felt during injection was not bearable and needed to be stopped.

Major and minor complications of the anesthesia injection, including chemosis, subconjunctival hemorrhage, and retrobulbar hemorrhage were noted before starting the surgery.

The patient was counseled that if s/he felt that the anesthesia administered was not providing adequate painlessness, s/he could request additional anesthesia including peribulbar anesthesia.

All surgeries were done by a single experienced surgeon using a surgical technique designed to minimize instrument pressure on the eyeball. Bridle's suture was not taken. Capsulorrhexis through a side-port and 6 mm temporal scleral tunnel were fashioned without holding the conjunctiva with forceps. Stabilization of the globe was achieved by placing a closed forceps against the globe opposite to the direction of push. After nucleus hydroprolapse into anterior chamber and extraction by sandwich method (vectis and dialer), cortical aspiration was done manually with a Simcoe cannula, and a rigid polymethyl methacrylate intraocular lens was placed in the capsular bag. 0.4 ml subconjunctival injection of equal proportion of gentamicin and dexamethasone was administered, and the eye was patched. Any intraoperative complications in both groups were recorded.

If at any point of time during surgery in either group the operating surgeon himself felt that the effect of anesthesia was inadequate to complete the surgery, he was free to choose any alternate method of anesthesia, with the understanding and prior informed consent of the patient.

Patient ocular motility during surgery (confirmed by the surgeon at the end of surgery) was scored as 0 - no movement/twitch only; 1 - movement in one direction of gaze; 2 - movement in two directions of gaze; 3 - movement in three or more directions with some restriction; 4 - full eye movements.

Following the completion of the surgery, the operating surgeon graded for "Discomfort" felt during surgery as 0 - No discomfort; 1 - mild discomfort; 2 - moderate discomfort; 3 - severe discomfort; 4 - surgery not possible to continue without additional anesthesia administration. Discomfort referred to the surgeon perception of difficulty in performing surgery for whatsoever reason, including excess movements of patient's eye, increased pain perception by the patient, or undue inconvenience perceived by the surgeon. If the surgeon

graded discomfort as 3 or 4, he was asked to give possible details regarding why he felt the increased discomfort.

In the recovery room, the patient was asked to grade the pain felt during surgery on a 10-point Faces Pain Rating (Visual Analog) Scale from 0 (no pain) to 10 (worst pain).[20] An independent observer performed the pain score recording in all patients.

On the 1ˢᵗ postoperative day, uncorrected visual acuity was determined in all patients, and each patient underwent a slit-lamp examination of anterior and posterior segments.

Statistical analysis

Sample size calculation, N, was based on the study by Wu and Tang,[21] in which 97% of patients were reported to be pain-free following subconjunctival anesthesia for cataract surgery. N was calculated as 82 for each of the two groups, by applying the formula $\left(Z^2_{1-\alpha/2}\right) \times P\left(1-P\right) / D^2$ with precision level "4" at 95% confidence interval. The data were entered into Microsoft Excel 2010 version and further analyzed using IBM SPSS Statistics for Windows, Version 23.0. Armonk, New York: IBM Corp; 2015. Descriptive statistics were analyzed using percentages for categorical data and mean and standard deviation for continuous data. For inferential statistics, the Chi-square test (for categorical variables) and *t*-test (for numerical variables, if normally distributed) were used. Mann–Whitney *U* test was used for numerical variables if parameters were not following normal distribution.

The statistical calculations of visual acuity were performed after converting Snellen visual acuity to logMAR visual acuity, based on the methods explained by Jack Holladay[22] in his guest editorial on visual acuity measurements. Median visual acuity was used to estimate the central tendency of visual acuity data, as the data were not normally distributed. A *P* < 0.05 was considered statistically significant.

RESULTS

A total of 164 patients (74 males, 90 females) were recruited for the study (82 in each group). All 164 patients were admitted and operated as in-patients as per institute policy and were discharged after evaluation on the 1ˢᵗ postoperative day. There was hence no attrition, and statistics from all recruited patients were evaluated.

Tables 1 and 2 present the demography, cataract surgical profile, and visual acuity of the patients analyzed in the study. There was no statistically significant difference between the two groups with respect to age, sex, nuclear grading, and preoperative and postoperative visual acuity.

All patients in both groups allowed the anesthesia to be administered, with none saying pain or discomfort felt during administration is unbearable or that the injection has to be stopped.

Major complications of anesthesia such as globe perforation and retrobulbar hemorrhage were not seen in either group. Among minor complications, chemosis was universal in the ASCA group (100% of patients), compared to 14 (17.1%) in the STA group (*P* < 0.001).

Table 1: Demography of patients

	Group 1 (anterior subconjunctival anesthesia) 82 eyes, *n* (%)	Group 2 (Sub-tenon's anesthesia) 82 eyes, *n* (%)	*P*
Males	34 (41.4)	40 (48.8)	0.346
Females	48 (58.6)	42 (51.2)	
Mean age±SD in years (range in brackets)	60.7±9.1 (33-81)	60.8±11.0 (29-87)	0.963
Right eye	38 (46.3)	41 (50)	0.639
Left eye	44 (53.7)	41 (50)	

SD: Standard deviation

Table 2: Cataract surgical profile and visual acuity

	Group 1 (anterior subconjunctival anesthesia) 82 eyes, *n* (%)	Group 2 (sub-tenon's anesthesia) 82 eyes, *n* (%)	*P*
Nucleus, *n* (%)			
Grade 1	5 (6.1)	4 (4.9)	0.922
Grade 2	35 (42.7)	38 (46.3)	
Grade 3	33 (40.2)	33 (40.2)	
Grade 4	9 (11.0)	7 (8.6)	
Median logMAR vision			
Preoperative	1.48 (in 67 eyes) (6/180 or able to count fingers from 2 m only)	1.48 (in 66 eyes) (6/180 or able to count fingers from 2 m only)	0.697
	Perception of light present and projection of rays accurate (15 eyes)	Perception of light present and projection of rays accurate (16 eyes)	
First postoperative day	0.30 (6/12)	0.30 (6/12)	0.837

Subconjunctival hemorrhage was seen in 20 patients (24.4%) of the ASCA group and in 9 patients (10.9%) of the STA group (P = 0.005).

Capsulorrhexis was completed in all patients, and no tunnel complications such as premature entry or buttonholing were encountered. Posterior capsular rent or vitreous loss was not seen in all 164 patients.

The primary outcomes of this study are presented in Table 3.

Every single eye in Group 1 had a motility score of 4, i.e. ocular movements persisted in all four directions of gaze. In Group 2, nearly half the patients (39, 47.6%) displayed a motility score of zero, and 7.3% (6 patients) exhibited a motility score of one. The numbers of Group 2 patients exhibiting motility scores 2, 3, and 4 were 10 (12.2%), 7 (8.6%), and 20 (24.4%), respectively. The difference in motility scores between the two groups was highly significant (P = 0.0001).

A statistically significant difference was also seen in surgeon discomfort scores between the two groups (P = 0.001). The surgeon graded no or mild discomfort in 66 (80.4%) patients, moderate discomfort in 7 (8.6%) patients, and severe discomfort in 7 (8.6%) patients of Group 1. In Group 2, the surgeon graded no or mild discomfort in 78 (95.2%) patients, moderate discomfort in 3 (3.6%) patients, and severe discomfort in 0 (nil) patients. The surgeon was able to complete the surgery without giving additional anesthesia in 80 of 82 ASCA patients and 81 of 82 STA patients.

In two patients in the ASCA group, the surgeon graded discomfort score as four and converted it to peribulbar block with patient consent. In the STA group, the surgeon graded discomfort as four in one patient and converted to peribulbar block. Each of these patients was indicated by the surgeon as having deep-set eyes and appearing to be anxious while exhibiting excessive eye movements and persistent squeezing of eyelids.

There was no statistically significant difference between both groups regarding the patient perception of pain during surgery.

Seventy-seven patients (94%) in Group 1 indicated no or mild pain during surgery. In Group 2, this number was 79 (96.4%). Three patients (3.6%) in Group 1 and 2 patients (2.4%) in Group 2 graded pain perceived during surgery as moderate. Pain score was not taken from the three patients administered peribulbar block.

Discussion

Anesthesia for cataract surgery can be administered through various modes.[23] Peribulbar and retrobulbar blocks were near-universal a couple of decades ago, but the relatively blind techniques employed and the potential of serious complications such as globe perforation, retrobulbar hemorrhage, and central spread of anesthetic led surgeons to search for better alternatives.[11-13,23,24] The increased popularity of small incision cataract surgery, especially phacoemulsification, allowed for the application and spread of topical anesthesia. This "no-injection" technique appealed to patients and surgeons alike, and the plausibility of safely walking out from the operation theatre without a bandage ensured that topical anesthesia became the norm in the vast majority of phacoemulsification cases.[1,2,24]

In many parts of the world, particularly in developing countries, MSICS forms a significant chunk of cataract surgeries performed.[15,25] It has also been advocated as a valuable skill in developed countries, especially for surgical conversion and to deal with complex and advanced cataract cases, and has been recommended to be a part of resident training programs in the developed world.[26] This is largely due to the ability of MSICS to provide a safe and effective method of cataract removal without having to depend on expensive instrumentation and steep learning curves.[4] Since MSICS involves increased handling of tissues such as conjunctiva and sclera, and potentially increased iris touch in comparison to phacoemulsification, peribulbar anesthesia has remained the most common mode of anesthesia for the procedure.[5,9,10] This is even though multiple authors and reviews have shown the

Table 3: Primary outcomes of the study

	Score/grade	Group 1 (82 eyes), *n* (%)	Group 2 (82 eyes), *n* (%)	*P*
Patient ocular motility score	0 (no movement)	0	39 (47.6)	0.0001
	1 (movement in one gaze)	0	6 (7.3)	
	2 (movement in two gazes)	0	10 (12.2)	
	3 (movement in three gazes)	0	7 (8.6)	
	4 (full movements)	82 (100)	20 (24.4)	
Patient pain grading	0-3 (no or mild pain)	77 (94)	79 (96.4)	0.65
	4-6 (moderate pain)	3 (3.6)	2 (2.4)	
	7-10 (severe pain)	0	0	
	Not taken (converted to block)	2 (2.4)	1 (1.2)	
Surgeon discomfort score	0 (none)	46 (56)	70 (85.4)	0.001
	1 (mild)	20 (24.4)	8 (9.8)	
	2 (moderate)	7 (8.6)	3 (3.6)	
	3 (severe)	7 (8.6)	0	
	4 (additional anesthesia needed)	2 (2.4)	1 (1.2)	

effectiveness and relative painlessness of STA.[9,14-16,27] This could be because STA is still not commonly performed in many training centers and involves the learning of a slightly different and newer method of administering anesthesia. Moreover, the administration of STA involves the deep posterior passage of the cannula for delivery of anesthetic, and there has been a report of perforation associated with STA also.[28] In this context, ASCA can provide a viable and quick mode of anesthesia. It is simpler and quicker than STA while being entirely under visualization of the surgeon. It does away with the risks of deep globe perforation or retrobulbar complications simply because the needle does not need to go behind the globe. Importantly, most MSICS surgeons inject antibiotic-steroid combination solution subconjunctivally at the end of the surgery, and hence, the procedure of subconjunctival anesthesia will not be a new or different technique to learn.

This paper evaluated ASCA as a mode of anesthesia for MSICS and compared the technique in a randomized manner to STA. To the best of our knowledge, a similar comparative study has not yet been reported.

Chemosis was universally present in all patients who received ASCA since 0.4 ml was the standard dose of solution injected. There was also a higher incidence of subconjunctival hemorrhage in Group 1. Both of these complications were significantly more than in the sub-tenon's group, but these complications did not in any way influence the performance of the surgery. The crucial parameter towards evaluating the safety of the anesthesia employed would be the number of dangerous complications and the possibility of having to abort surgery due to a complication of anesthesia. There was no incidence of major complications such as retrobulbar hemorrhage or globe perforation in either group. ASCA proved to be a safe procedure for administering anesthesia in this study.

Every single patient who received ASCA had extraocular movements persisting in all four directions of gaze. This was in contrast to the effect of STA on eye movements in Group 2 patients; nearly half the patients in this group had nil persisting eye movements, akin to a peribulbar block. Around 25% of these patients displayed movements in all four directions of gaze. In a phacoemulsification surgery done under topical anesthesia, the presence of the thick phacoemulsification hand-piece inside the patient's eye stabilizes the operating eye, and movements are not much of a hindrance to the surgeon. In MSICS, excess movements may be disturbing to the surgeon, especially if the surgeon is not experienced in topical anesthesia. Since the surgeon in this study had considerable experience in topical phacoemulsification surgeries also, the movements faced during surgery were not deemed too troublesome, allowing the surgeon to perform and complete the surgery. However, a surgeon not yet well-versed in operating under topical anesthesia may find patient eye movements under ASCA to be disturbing.

The presence of excessive eye movements in a greater number of ASCA patients was one factor in the higher number of surgeon discomfort scores of 2 (moderate) and 3 (severe) in Group 1. In the immediate postsurgical analysis of such patients, it was seen that in all the seven Group 1 patients where the surgeon discomfort score was 3, either the eye was deep-set (globe deep inside the orbit) and the forehead anatomy interfered in intraocular handling, or excessive eye movements were encountered along with persistent squeezing of the eyelids of the patient. Nevertheless, the point to be noted was that the surgeon could complete the surgery safely in all but two patients in the ASCA group. These two patients were both indicated by the surgeon as having deep-set eyes and appearing to be nervous while exhibiting constant eye movements and persistent squeezing of eyelids. The surgeon felt that both these patients warranted additional anesthesia and elected to administer peribulbar block, with the approval of the patients.

One patient in the STA group, seen as having eyes set deep within the orbital cavity, displayed excessive eye movements along with constant squeezing of eyelids. The surgeon graded discomfort as 4 and administered a peribulbar block and completed the surgery.

Lastly, and probably the most crucial parameter in this study, would be the pain score grading denoted by the patients. The pain scores given by the patients in both groups were not significantly different, with the vast majority in both groups indicating no or mild pain. This is comparable to the nonrandomized case series on "advanced subconjunctival anesthesia" reported in 2018, in which 58 of 60 patients (97%) had no pain during surgery.[21] This leads us to conclude that ASCA is a viable mode of anesthesia for MSICS.

Analyzing the observations gleaned from this study, it can be seen that ASCA is a safe procedure, and most patients have no or mild pain while undergoing MSICS under this method of anesthesia. ASCA does not block eye movements, and surgeons who are comfortable with this aspect only should attempt this anesthesia. It should also be kept in mind that ASCA is invariably accompanied by chemosis, which can be a bother, especially to surgeons in the early learning phase. Patients with deep-set eyes and apparently nervous patients, particularly if displaying excessive eye movements, can induce moderate-to-severe discomfort in surgeons. In such patients, it would seem prudent to administer a peribulbar or retrobulbar block.

It would also be useful to apply some of the surgical techniques employed in this study, such as fashioning scleral tunnel temporally to avoid interference by the brow, no bridle suture, no cautery, and avoidance of holding conjunctiva with toothed forceps.

The role of subconjunctival anesthesia need not be limited to MSICS. We would be inclined to believe that if ASCA can be employed to perform MSICS safely, it can be used as a supplement in topical phacoemulsification procedures where the surgery goes on longer than anticipated or if unexpected complications develop. If the phacoemulsification surgeon

wants to convert to a manual mode of nuclear removal in complicated cases, a quick subconjunctival dose of anesthesia can provide comfort to both patient and surgeon.

For trainee surgeons in the early phase of the learning curve of phacoemulsification surgery, ASCA can be a step in transiting from peribulbar block to topical anesthesia.

This study harbors a few limitations, one being that it is a single-surgeon study and another being the subjective nature of the visual analog pain scale. Orbital measurements were not taken of patients to corroborate the statement of increased discomfort in deep-set eyes. Future studies or surgeons attempting ASCA can attempt intracameral lignocaine before converting to peribulbar anesthesia in grade 4 discomfort cases.

ASCA can be employed as a minimally invasive and simple method to administer anesthesia safely for MSICS. Most patients who undergo MSICS under ASCA perceive no or mild pain, similar to STA. Surgeon discomfort is slightly higher in comparison to STA, particularly if the operating eye is seen as deep-set within the orbital cavity, but this does not prevent successful completion of surgery in almost all patients. Avoiding subconjunctival anesthesia in deep-set eyes or overly nervous patients can alleviate surgeon and patient discomfort.

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