DOI: 10.7860/JCDR/2025/78332.21959

Research Protocol

Ophthalmology Section

Comparative Evaluation between Topical versus Sub-Tenon's Anaesthesia in Manual Small Incision Cataract Surgery: A Research Protocol

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ABSTRACT

Introduction: Intraocular lens implantation combined with cataract extraction is arguably the most successful surgical technique in the history of medicine. Cataracts are one of the major causes of preventable blindness worldwide. Cataract surgery is by far the most frequently performed procedure under local anaesthesia. Therefore, it is imperative to develop anaesthetic techniques that are safe, efficient, and financially viable, particularly in India.

Need of the study: The study aims to provide significant insights into enhancing cataract surgical procedures in rural regions by comparing Sub-Tenon's anaesthesia, which may offer improved akinesia and patient comfort, with topical anaesthesia, which is less invasive and easier to administer.

Aim: To compare and evaluate patients' outcomes after topical and Sub-Tenon's anaesthesia in Manual Small Incision Cataract Surgery (MSICS).

Materials and Methods: A two-arm parallel randomised controlled trial will be conducted at Acharya Vinoba Bhave Rural Hospital, Sawangi, Wardha, Maharashtra, India, from June 2024 to June 2026, including 56 patients in total (allocated to topical anaesthesia or Sub-Tenon's anaesthesia). Before the intervention, demographic data will be collected on a pro forma, and after the surgery the Visual Analogue Scale (VAS) score and postoperative outcomes will be recorded. Statistical analysis will be performed using the Mann-Whitney U test. A p-value<0.05 will be considered statistically significant.

Keywords: Implantation, Instruments, Pain, Visual acuity

INTRODUCTION

As cataract surgery has advanced, the conventional need for complete akinetic anaesthesia declined, while analgesia and safety remained essential. Because General Anaesthesia (GA) carries hazards of its own, it is no longer used during cataract surgery except in certain situations. GA remains the preferred method of anaesthesia for young children and infants, for patients who have difficulty understanding or cooperating, and for patients who refuse local anaesthesia. Until the last decade, peribulbar anaesthesia was widely used [1]. The orbit's divided, multicompartmental architecture can cause local anaesthetic to distribute unevenly and incompletely [2]. Ophthalmic surgeons frequently utilise local anaesthetics due to their broad safety profile, high success rate, and rapid patient recovery. Under local anaesthesia, patients with several comorbidities can undergo surgery in the safest possible setting with improved comfort [3]. Concerns about the safety of sharp needles led to the development of a novel approach: the use of blunt needles. This technique, known as Sub-Tenon's anaesthesia and popularised by Hansen and Stevens, has proven to be both safe and equally effective. Other common names for Sub-Tenon's anaesthesia are episcleral block, parabulbar block, and pinpoint anaesthesia [4]. Sub-Tenon's anaesthesia can be used for a variety of cataract surgeries. Sub-Tenon's anaesthesia, or parabulbar or episcleral anaesthesia, involves injecting three to five millilitres of local anaesthetic into the episcleral region. A blunt cannula is used to administer the local anaesthetic after creating a small buttonhole in the conjunctiva and Tenon's capsule with blunt Wescott scissors, while the conjunctiva is held with small forceps [5]. The method is safer than retrobulbar or peribulbar blocks, as it does not blindly inject through a needle. It reduces patient anxiety and the unpleasant sensation associated with using syringes in the peribulbar block [6]. With this method, less medication is needed, and neither the vasculature nor the optic nerve is harmed. Since its introduction in the 1990s, topical anaesthesia has emerged as the most commonly used anaesthetic technique for cataract surgery [7]. Local anaesthetic drops or gel are applied to the surface of the eye. This can be augmented intraoperatively by injecting a local anaesthetic (intracameral) via a blunt needle into the anterior chamber of the eye [8]. Most cataract procedures about twenty years ago used large incision extracapsular techniques and were performed under GA [9]. Currently, MSICS is recommended as the preferred surgical approach to efficiently address the substantial and rising backlog of cataract blindness in low- and middle-income countries through high-volume procedures [10]. Thus far, studies have shown that it produces results comparable to phacoemulsification. Moreover, it is more cost-effective, faster, and requires less technology, making it a better option for developing nations [11].

Comparing topical approaches with retrobulbar and peribulbar methods, there has been a documented decrease in significant complications such as retrobulbar bleeding, globe perforation, and traumatic optic nerve injury [12]. Additionally, these approaches have been shown to shorten the time required to administer local anaesthetics, reducing the overall duration of surgery [13].

Surgeons are becoming more interested in less invasive anaesthetic techniques and ways to minimise surgical times. Turnbull published the first account of Sub-Tenon's anaesthesia in 1884 [14]. Effective substitute techniques for achieving adequate analgesia, patient-friendly delivery, and shorter induction periods include topical and Sub-Tenon's methods [15]. Topical and Sub-Tenon's anaesthetics have become more common. Topical anaesthesia does not provide akinesia. The absence of akinesia can be a major problem when managing uncooperative patients. For cataract surgery, topical and Sub-Tenon's anaesthetics are more recent techniques compared with the peribulbar block. According to reports, cataract-related

complications account for about 29.9% [5]. Pain during and after cataract surgery has been linked to decreased patient satisfaction with anaesthesia [12].

The complications that might arise from an ophthalmic block are classified as sight-threatening or life-threatening. These complications include globe penetration, perforation, chemosis, subconjunctival haemorrhage, vitreous haemorrhage, retrobulbar haemorrhage, and corneal abrasion. Additional risks include brainstem anaesthesia, local anaesthetic agent toxicity, extraocular muscle injury, accidental intravenous or intrathecal injection, and cardiorespiratory arrest [16]. Subconjunctival haemorrhage and chemosis occur frequently after Sub-Tenon's block, with reported frequencies ranging from 7% to 100% [17].

The study aims to provide significant insights into improving cataract surgical procedures in rural regions by comparing Sub-Tenon's anaesthesia, which may offer improved akinesia and patient comfort, with topical anaesthesia, which is less invasive and easier to administer. By understanding the relative levels of discomfort and surgical outcomes associated with these two anaesthetic methods, healthcare professionals can make better decisions and improve the standard and availability of cataract surgery in rural areas. Furthermore, this research may offer insight into the viability and flexibility of various anaesthetic techniques in environments with limited resources, potentially enhancing surgical efficiency and patient care. Therefore, the study aims to compare and evaluate patients' outcomes after topical and Sub-Tenon's anaesthesia in MSICS.

REVIEW OF LITERATURE

The literature review examines various studies on cataract surgery, with particular emphasis on the MSICS technique. It encompasses findings regarding the efficacy of MSICS in conjunction with different forms of anaesthesia, such as topical anaesthesia (including drops or gels) and alternative methods like Sub-Tenon's anaesthesia, which entails the injection of anaesthetic agents. These investigations illuminate the safety and effectiveness of MSICS, particularly in settings where resources may be limited, thereby underscoring its practicality and favourable outcomes.

According to research conducted by Tumbadi KL et al., MSICS demonstrated a high level of patient comfort while mitigating the potential complications associated with injectable anaesthesia when used with topical proparacaine anaesthesia, as opposed to intracameral or periocular anaesthesia. This approach also contributed to a reduction in the time and financial burden of anaesthetic administration, rendering it suitable for widespread cataract surgeries [18].

In a separate study by Nwosu SN et al., it was observed that the two anaesthetic techniques did not significantly affect the duration of the surgery. In contrast to the subconjunctival group, a higher percentage of patients in the Sub-Tenon's group reported experiencing little to no pain. When determining the appropriate surgical approach, the research advocated considering various factors, including the duration of the procedure, the patient's comfort level, and their pain threshold [19].

In another scenario, research has indicated that while phacoemulsification is the preferred method for cataract surgery, MSICS remains essential, particularly for complex cataracts. The exceptional visual and safety outcomes achieved by MSICS under topical anaesthesia, when performed with appropriate techniques and precautions, affirm its significance in cataract surgery [20]. According to a study by Apil A et al., 81% of participants were unaware that topical anaesthesia without an injection might be used during cataract surgery. Despite this, patients had a positive surgical experience, and their average comfort and cooperation scores were good. The procedure took 8.33 minutes on average. The study's findings indicate that both surgeons and patients found topical anaesthetics highly acceptable for cataract surgery [21].

Another study revealed that the outcomes demonstrated the efficacy of anterior subconjunctival anaesthesia in inducing anaesthesia, as all patients exhibited chemosis and sustained ocular movement in all four gaze directions. These factors, however, did not affect the surgeons' ability to perform MSICS. Surgeons in the Anterior Subconjunctival Anaesthesia (ASCA) group observed a greater frequency of moderate to severe discomfort during surgery, especially in patients with excessive eye movements. Most patients in both groups experienced no pain or only mild pain during surgery. The study found that ASCA may be used for MSICS safely, with patient comfort on a par with STA, albeit in some circumstances it might cause somewhat more discomfort for the surgeon [22].

Primary objectives:

- To evaluate the efficacy of Sub-Tenon's anaesthesia in MSICS.
- To evaluate the efficacy of topical anaesthesia in MSICS.

Secondary objectives: To compare the efficacy of Sub-Tenon's anaesthesia and topical anaesthesia in MSICS.

Null Hypothesis: There will be no significant difference in pain scores and surgical outcomes for patients undergoing MSICS with either topical anaesthesia or Sub-Tenon's anaesthesia.

Alternative Hypothesis: There will be a significant difference in pain scores and surgical outcomes between patients undergoing MSICS with topical anaesthesia and those receiving Sub-Tenon's anaesthesia.

MATERIALS AND METHODS

A two-arm, parallel randomised controlled trial will be conducted at Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha, Maharashtra, India, from June 2024 to June 2026. A total of 56 patients with senile cataract will be randomly allocated to two groups of 28 participants each, who meet the inclusion criteria and none of the exclusion criteria, and will be part of the study. Institutional Ethical Clearance (IEC) has been obtained with IEC number DMIHER(DU)/IEC/2024/22. The trial has been registered in the Clinical Trial Registry of India (CTRI) with CTRI reference number 2025/03/082782. Following the Ethical Committee's approval and the participants' informed consent, a thorough history of the study's symptoms, including onset, duration, and aggravating factors, was taken, and a standard physical examination was performed. In compliance with university and international regulations, the authors have obtained and kept the patients' written consent.

Inclusion criteria:

- Age range: 45-70 years;
- Male or female;
- Patients with simple bilateral or unilateral mature or immature senile cataracts;
- Patients who never had ocular surgery in the operative eye;
- Patients who consent to participate in the study.

Exclusion criteria:

- Age <40 or >70 years;
- Patients with complications, such as retinal disorders, and those with complicated, congenital, or traumatic cataracts;
- Individuals with immature cataracts associated with surgery, trauma, or other ocular comorbidities;
- Patients with systemic conditions (diabetes mellitus, hypertension) or intraoperative surgical consequences (nuclear dislocation, Posterior Capsule Rupture [PCR]).

Sample size calculation:

Formula using mean difference

n1=n2=2

Z_{α}=2.58

$$n=\frac{(Z_\sigma+Z_\beta)^2\sigma^2}{(\delta)^2}$$

α=Type I error at 1% at both sides two tailed

$Z\beta$=2.34=Power at 99%

Primary variable: Pain Management Mean difference=0.2 [16]

Considering the estimated standard deviation σ=0.15 Minimum sample size required will be

Sample size $N=n1=n2=2\ \frac{(2.58+2.34)^2(0.15)^2}{(0.2)^2}$=28 per group

Study Procedure

Preoperative evaluation: A thorough ocular examination will be performed on each patient, including external examination of the eyelids, conjunctiva, cornea, iris, pupil, and lens; assessment of visual acuity for both near and distance vision; fundus examination and evaluation of the anterior segment under slit-lamp illumination. Data will be collected on a predesigned proforma that includes sociodemographic information (age, sex, eye site, cause of trauma, etc.), the Visual Analog Scale (VAS), and a postoperative counselling checklist.

Keratometry: Keratometry will be used to measure K1 and K2; non-contact tonometry will measure Intraocular Pressure (IOP); Amplitude Scan will be used to calculate Intraocular Lens (IOL) power using the SRK II formula.

Method of topical block: One drop of 4% lignocaine will be instilled four to five times at five-minute intervals in the topical anaesthesia (TA) group, before the procedure begins.

Method of Sub-Tenon's anaesthesia [23]: The patient should be in a supine position for monitoring. Clean the anaesthetised conjunctiva with two or three drops of povidone-iodine beneath the lower eyelid, then use the residual solution for the orbital margin. Use aseptic technique to draw the anaesthetic fluid into a syringe. Insert a speculum to prevent blinking and help the patient look up and out for better visibility of the inferonasal quadrant, which can be marked on a wall or ceiling. Lift a small portion of the conjunctiva and Tenon's capsule about 5-10 mm from the inferonasal limbus. Make a small cut in the tissue with ophthalmic scissors to expose the sclera. Pass the blunt-ended sub-Tenon's cannula through this defect and attach a local anaesthetic syringe, advancing the cannula posteriorly until it crosses the equator, ensuring it is placed in the sub-Tenon's space.

Small incision cataract surgery: Small-incision cataract surgery: Create a small, self-sealing sclero-corneal passage using a superior or temporal incision. For deep sockets, a temporal site is preferred over a superior site. The tunnel's length, shape, location, depth, breadth, and point of entry within the anterior chamber define its six dimensions.

Postoperative Follow-up

Postoperative follow-up for ophthalmic procedures includes several key stages. After surgery, patient counselling on eye-drop administration and eye hygiene is crucial. Patients will receive protective eye patches and specific instructions for topical steroids and antibiotics. In Posterior Capsule Rupture (PCR), systemic antibiotics may be given. The first postoperative exam assesses visual acuity, the fundus, the anterior segment, wound healing, corneal clarity, and the position of the IOL. Follow-up typically lasts one month, with a check-up around the second week. Patients should contact their ophthalmologist for any significant symptoms. Discharge times vary based on the type of surgery. Steroid drops are gradually tapered while antibiotics continue as prescribed, and topical Non Steroidal Anti-inflammatory Drugs (NSAIDs) may be used to prevent rebound inflammation in high-risk cases.

Outcomes

Pain assessment will be evaluated using the Visual Analog Scale (VAS). The VAS is a 100 mm horizontal line with 0 indicating no pain and 100 indicating the worst imaginable pain. The patient will mark the line at the point that best reflects their pain. VAS scores will be recorded during the procedure, at 30 minutes, and at 24 hours postoperatively [24]. Best Corrected Visual Acuity (BCVA) will be assessed using a Snellen chart at a distance of six meters and a Jaeger chart at 25 cm for near vision, specifically on postoperative days 1 and 45. Autorefraction, a computer-controlled device, will measure the patient's refractive error objectively and determine the necessary prescription for glasses or contact lenses during an eye exam.

Intraoperative complications, including eye movements and the risk of hemorrhage, will be monitored using a slit lamp examination (Appasamy Associated - AIA-11 3SL) on the first postoperative day and again on the 45th day of follow-up. Postoperative complications such as mild IOP elevation and transient chemosis will also be assessed using slit lamp examination and non-contact tonometry on the first postoperative day and the 45th day.

STATISTICAL ANALYSIS

Statistical Package for the Social Sciences (SPSS) software (version 23) will be used for statistical analysis. VAS scores for intraoperative and postoperative pain will be compared between topical anesthesia and Sub-Tenon's anesthesia using the Mann-Whitney U test or the independent samples t-test, depending on data distribution. Intraoperative and postoperative complications will be assessed with the Chi-square test. A p-value<0.05 will be considered statistically significant.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jan 30, 2025
- Manual Googling: May 03, 2025
- iThenticate Software: May 05, 2025 (6%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Jan 29, 2025**
Date of Peer Review: **Feb 21, 2025**
Date of Acceptance: **May 07, 2025**
Date of Publishing: **Nov 01, 2025**