# Lying down looking down test: Evaluating patient suitability for small incision cataract surgery using assisted topical anesthesia

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Purpose: The objective of this study was to evaluate an OPD-based Lying down looking down (LDLD) test for the assessment of patient suitability for assisted topical anesthesia (ATA) during manual small incision cataract surgery (MSICS), and to compare it with assisted local anesthesia (ALA). Methods: The LDLD test was carried out during preoperative assessment of 250 consecutive patients. A standard LED torch was shined in patient's eye after pupil dilation, with the patient in lying down position, while simultaneously elevating the upper eyelid digitally. A positive test was indicated by the ability to maintain downward gaze and the lack of squeezing of eyes or withdrawal. Chi-square and Fisher's exact tests were used to assess the association between LDLD results and suitability for ATA. The positive predictive value and specificity of the test as an indicator of patient suitability for ATA were calculated. Complications (intra- and post-operative) and postoperative inflammation at day 1 and week 6 were compared between the ATA and ALA groups. Results: A total of 250 patients were included in the study, 138 in ALA group and 112 in ATA group. There were 109 males (43.6%) and 141 females (56.4%). Around 7.4% of LDLD- positive patients were converted to ALA during the surgery. Chi-square and Fisher's exact tests demonstrated a significant association of a positive LDLD test with successful ATA (P value 0.002). The positive predictive value and specificity of the test were 92.56% (95% CI86.87-95.9%) and 93.48% (95% CI87.98-96.97%), respectively. Intraoperative complications were similar in both the groups. Congestion and visually significant corneal edema were significantly less in ATA group. Conclusion: The LDLD is a simple, highly specific, OPD-based test to determine patient suitability for MSICS under ATA



Key words: Objective test, LDLD, topical MSICS

Cataract is still the single most common cause of curable blindness in India and worldwide.<sup>[1]</sup> With the objective of eliminating avoidable blindness, VISION 2020 prioritized cataract and recommended performing more cataract surgeries.<sup>[2]</sup> The state-of-the-art technique of cataract extraction is phacoemulsification with the insertion of a foldable intraocular lens (IOL) through a self-sealing incision. However, the associated cost considerations and the steep learning curve makes it a less feasible procedure for high-volume surgery needed in developing countries. Hence, Manual small incision cataract surgery (MSICS) becomes the surgery of choice in such circumstances.<sup>[3]</sup> The most appropriate anesthetic modality should be individualized for every patient. There are three main forms of anesthesia for cataract surgery. General anesthesia (GA) which is rarely used, peribulbar/retrobulbar/ sub tenon's assisted local anesthesia (ALA) and with the introduction of clear corneal phacoemulsification surgery, assisted topical anesthesia (ATA) is becoming more popular.<sup>[4]</sup> With the quest to give experience and results to MSICS patients

Received: 10-Feb-2020 Accepted: 16-Jul-2020 Revision: 18-May-2020 Published: 18-Jan-2021 as similar to phacoemulsification as possible, the use of ATA has seen a rise in MSICS cases. EC Figueira *et al.* have offered Laninder test to determine a patient's suitability for ATA in comparison with ALA in patients undergoing clear corneal phacoemulsification.<sup>[5]</sup> However, no such criteria have been suggested for patients undergoing MSICS under ATA.

ATA may ultimately prove to be the safest mode of anesthesia as it avoids the systemic risks of GA and the risk of trauma to the orbital contents and of orbital swelling, that accompany regional blocks including that of sub tenon.<sup>[6]</sup> For many patients and surgeons, ATA fulfils most of the goals of anesthesia in cataract surgery, disadvantages being increased ocular motility, the requirement for patient cooperation, the possibility of need of intravenous sedation,<sup>[7,8]</sup> and more pain for the patient if the surgery is prolonged or complicated.

In this prospective consecutive study, we describe the use of the LDLD (Lying down looking down) test in evaluating patient suitability for ATA and comparing it with ALA, with respect to complications and postoperative inflammation.

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## Methods

This was a prospective camp based study conducted on patients from different camps under a district in Maharashtra over a period of 6 months (July 2018 to December 2018). Approval for the study was obtained from the institutional review board, and the study was conducted within the Declaration of Helsinki. A written informed consent was taken from the patients. Patients with uncomplicated cataracts who gave consent for the study were included. Those with complicated cataract, small pupil (size less than 5 mm), congenital cataract, developmental cataract and cataract associated with other diseases or those who didn't complete a month of follow-up were excluded from this study.

Sample size was calculated by using confidence level of 95%, confidence interval of 10 and population size as 2500 (number of cataract surgeries at the hospital). This gave us a sample size of 110 in each group. All patients were screened at different camp sites but operated at a common operation theatre at a district hospital. All patients underwent slit lamp examination to assess the anterior segment, with special consideration to pupillary dilatation and grade of cataract; and indirect ophthalmoscopy for evaluation of posterior segment, wherever possible.

As part of the routine preoperative assessment, 'Lying down looking down' test was performed on each patient in the ward. The test evaluates patient tolerance to the bright light of LED torch, tolerance to the examiner's digital pressure on elevating the eyelid of the eye to be operated on and the ability to maintain eye position in downward gaze. With the patient's pupil dilated and patient in lying down position, the light was held at 25 centimeters from the patient's face. The eyelids were manually separated and the patient was asked to look at the light and down towards his/her feet for 5-7 seconds. The test was considered to be negative when the response was manifested by involuntary eyelid closure/blepharospastic-like closure of the eyelids, withdrawal of head and eyes from the light source or inability to maintain downward gaze on command. But if the patient generally demonstrated indifference to the light stimulus and could maintain the eye in downward gaze on command, it was regarded as a positive response and was considered as predicting suitability for ATA [Fig. 1]. Prospective descriptive data, in particular, patient age, gender, grade of cataract, pupil size, systemic diseases, type of response to lying down looking down test, and type of anesthesia used (ALA, or ATA) were recorded. The cataracts were graded as soft (Nuclear sclerosis 1-2, Posterior subcapsular cataract, Cortical cataract), hard (Nuclear sclerosis 3-4) and mature cataract. No sedation or anxiolytic was given prior to surgery. The patients then underwent MSICS using visco-expression method.

All patients were operated by a single surgeon. Pupillary dilatation was achieved with Tropicamide and Phenylephrine eye drops. A peribulbar injection was given in lying down position by ophthalmic assistants for ALA group. Lidocaine jelly 2% was put in the conjunctival sac 5 minutes prior to surgery for ATA group. The surgical steps were routine in ALA group. Surgical steps in ATA group are as follows: after disinfecting the periocular skin with 10% povidone iodine and draping the eye, the conjunctival sac was copiously flushed with ringer lactate solution. A fornix based conjunctival flap was made and the bleeding vessels were gently cauterized.

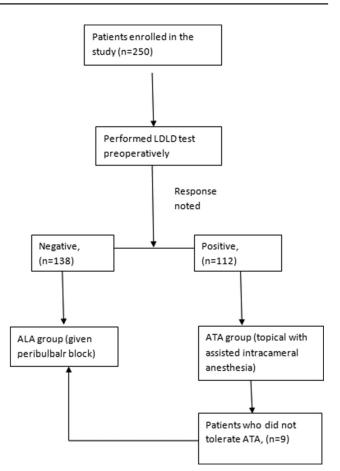


Figure 1: Summary of methodology -Flow Diagram

Side port entry was made with 3 mm keratome. 2% lidocaine with ringer lactate solution in 1:1 dilution was injected for intracameral anesthesia. With the help of trypan blue and viscoelastic, a continuous curvilinear capsulorrhexis (CCC) was performed. In cases CCC was smaller than desired; few nicks were given in it. Sclero-corneal tunnel was made superiorly using a crescent knife and a keratome. The nucleus was brought out in the anterior chamber using hydro procedures and prolapsed with viscoexpression in all cases. With a Simcoe cannula, the remaining cortex was aspirated. PMMA posterior chamber intraocular lens was implanted and anterior chamber was filled with ringer lactate solution. After instilling a drop of 0.5% proparacaine eye drop, subconjunctival injection of gentamycin and dexamethasone was given in the conjunctival flap so that it covers the bare sclera and the case closed.

Care was taken to make a larger sclero-corneal tunnel than usual for a smooth nucleus delivery. Viscoexpression and no handling of iris made sure that the patient did not experience any discomfort intraoperatively. Vocal encouragement was needed for patients to maintain downward gaze while making sclero-corneal tunnel. The surgical time was measured from the time the patient lied down on the table to the end of procedure after patching the eye. The primary outcome measure was suitability of LDLD test. Paracaine eye drops (proparacaine hydrochloride 0.5% ophthalmic solution) were instilled in case the patient was uncomfortable. But in case the patient did not tolerate topical anesthesia, a peribulbar block was administered on table.

Patients were evaluated for signs of inflammation by another surgeon on day 1 and week 6. Intraocular inflammation was graded using the Standardization of Uveitis Nomenclature Working Group grading classification. According to this classification, less than one cell (in a 1 mm2 field illuminating the anterior chamber) is taken as grade 0, 1 to 5 cells as grade 0.5, 6 to 15 cells grade 1, 16 to 25 cells as grade 2, 26 to 50 cells as grade 3, and more than 50 cells as grade 4.<sup>[9]</sup> Conjunctival chemosis was taken as grade 1 if it involved 30% of the conjunctiva, grade 2 if it involved 30-70% of the conjunctiva, and grade 3 if it involved 70-100% of the conjunctiva. Conjunctival hyperemia was graded as grade 0 for no hyperemia, grade 1 for sectoral engorgement of vessels, grade 2 for diffuse engorgement, and grade 3 for significant engorgement.<sup>[9]</sup> Corneal edema was graded as grade 0, if there was no edema, grade 1, if it was none to minimal, and significant if it was grades 2-4. Grade 2 edema was mild to moderate (visible iris details), grade 3 was moderate to severe (obscuring iris details), and grade 4 was marked (obscuring pupil).<sup>[10]</sup> Masking was achieved by assigning a different person for selection of cases and postoperative evaluation.

Data was entered in MS Excel format and descriptive statistics with frequency, mean and standard deviation were computed. The statistical analysis was done with the SPSS version 22 software package (IBM Corporation, SPSS Inc. Chicago, IL, USA). Chi-square was used to find out association between qualitative data and Mann-Whitney U test was used to find the difference between mean. A *P* value less than 0.05 was considered to be significant. Study variables included surgeon's time, intraoperative and postoperative complications and postoperative inflammation on first postoperative day and 6 weeks later.

A contingency 2 x 2 table analysis of the data was evaluated for the following groups using Chi-square and Fisher's exact tests. These comprised the cohort that had a positive LDLD and tolerated ATA; the cohort that had a positive LDLD in OPD but was converted to ALA; the cohort that had a negative LDLD in OPD and required ALA; and the cohort that had a negative LDLD but for whom it was decided to employ ATA (0 patients). A Chi-square test and Fisher's exact test analysis were performed to determine an association between a positive LDLD response and successful MSICS surgery using ATA. Specificity and positive and negative predictive values for the test were also evaluated from the 2 x 2 contingency table.

### Results

A total of 250 entered the study. After performing LDLD test, they were divided into ATA (n = 112) or ALA (n = 138) group depending upon their response [Fig. 2]. The groups were comparable to each other with respect to age of the participants (mean age in ALA (70.5 years, SD = 14.2) and ATA group (70 years, SD = 14.6).

Nine of the 121 (7.4%) lying down looking down-positive patients were converted to ALA during the surgery. There were 109 males (43.6%) and 141 females (56.4%). The grade of cataract and systemic associations were similar in both the

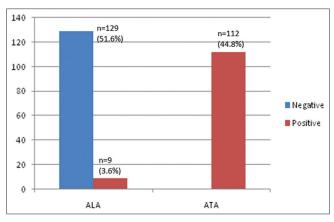


Figure 2: This bar chart describes the results of the LDLD test and the type of anesthesia used for the surgery

groups (P = 0.180 and P = 0.543, respectively). Hence both the groups were similar with respect to the confounding factors [Table 1]. 57 males of the total 109 male cohort (54.1%) and 64 females out of 141 total females (45.4%) were positive for lying down looking down test. The 2 x 2 association of gender with the test results did not reveal a statistically significant value (1.17, P = 0.308), suggesting that the test results are not influenced by gender [Table 1]. No specific pattern was observed for patients who were converted from ATA to ALA.

The 2 x 2 analysis of the contingency table revealed a strong association between a positive Lying down looking down test and a successful ATA procedure (Chi square value 9.953, *P* value 0.002) [Table 2]. To clearly demonstrate an association between the variables, the Fisher's exact test also revealed a strong association (P < 0.00001) between the positive lying down looking down test and successful completion of small incision cataract surgery using ATA.

Specificity values were calculated in a 2 x 2 contingency table analysis as shown in Table 3. The 'Lying down looking down' test used to predict the suitability of patients for ATA has a high specificity of 93.48% (95% CI 87.98–96.97%). The positive predictive value for the test to predict suitability of the patient for ATA is estimated as 92.56% (95% CI 86.87-95.90%).

The mean surgical time was 9.83 minutes in ALA group and 11.60 minutes in ATA group, and the difference was statistically significant (t value = 4.583, P < 0.001).

Intraoperative complications [Table 4] were seen in 14 patients in the entire study group (5.6%); 10 (of 138 patients) in ALA group (7.75%) and 4 (of 112 patients) in ATA group (3.3%). The frequency between the 2 groups was not statistically significant, *P* value = 0.672. The most common complications were tunnel-related (50%, n = 7); tunnel bleed (seen in 2 patients in ATA group) and premature tunnel entry (seen in 5 patients in ALA group). Damage to corneal endothelium occurred in one patient in ATA group while delivering the nucleus. Zonular dialysis was seen in 1 patient and iridodilaysis in 2 patients in ALA group. Posterior capsular tears occurred in 2 patients in ALA group (1.4%) and 1 patient in ATA group (0.9%). They underwent anterior vitrectomy and implantation of intraocular lens in the bag/sulcus, depending on the case. However, one patient in each group had to be kept aphakic.

### Table 1: Comparison of Grade, systemic associations and gender between two groups

	Groups		Total	Chi-square	Р
	ALA	ΑΤΑ		value	
Grade					
Soft	40	51	91 (36.4%)	3.429	0.180
Hard	45	37	82 (32.8%)		
Mature cataract	44	33	77 (30.8%)		
Systemic Associations					
Hypertension	21	19	40 (16%)	1.221	0.543
Diabetes	15	8	23 (9.2%)		
Ischemic heart disease	7	8	15 (6%)		
Gender					
Males	52	57	109 (43.6%)	1.173	0.308
Females	77	64	141 (56.4%)		

\*ALA: Assisted local anesthesia, ATA: Assisted topical anesthesia

### Table 2: 2 x 2 Contingency analysis association of Lying down looking down test results and type of anesthesia

	Type of anesthesia used			<b>Chi-square</b>	Р
	ALA	ΑΤΑ	Total	value	
Lying down looking down test				9.953	0.002**
Negative	129	0	129 (51.6%)		
Positive	9	112	121 (48.4%)		
Total	138 (55.2%)	112 (44.8%)	250		

\*ALA: Assisted local anesthesia, ATA: Assisted topical anesthesia. \*\*P significant

# Table 3: Sensitivity, specificity, and predictive values of the Lying down looking down test

	ΑΤΑ		ALA		Total	
Test positive	112		9		121 (48.4%)	
Test negative	0		129		129 (51.6%)	
Total	112 (44.8	%) 138 (55.2%)			250	
		Value	Value 9		5% CI	
			Up	per	Lower	
Sensitivity		100%	96.7	76%	100%	
Specificity		93.48%	87.9	98%	96.97%	
Positive likelihood ratio		15.33	8.	15	28.84	
Positive Predictive value		92.56%	86.8	37%	95.90%	
Accuracy		96.4%	93.2	28%	98.34%	

On day 1, postoperative complications were noticed among eleven patients in ALA group (of 138 patients, 8%) and ten patients (of 112 patients, 8.9%) in ATA group [Table 4]. The most common complication in ALA group was significant anterior chamber reaction, seen in 5 out of 11 patients. The most common complication in ATA group was significant corneal edema, seen in 7 out of 10 patients. Postoperative conjunctival congestion was more commonly seen in ALA group with *P* value of 0.045, significant at *P* < 0.05. Grade 3 congestion was seen more in ALA group (10.9% versus 6.3%), though the difference was not statistically significant. On the other hand, subconjunctival hemorrhage was seen more in ATA group (21% versus 21.4%), though the difference was not statistically significant with *P* value of 0.178. Though striate keratopathy was more common in ALA group, 46.4% as compared to ATA group 36.6% (*P* value = 0.33, not significant at P < .05), visually significant corneal edema was more common in ATA group. Similarly, postoperative iritis was more common in ALA group. With *P* value of 0.073, the difference was not statistically significant.

At the end of 6 weeks of follow up, none of the patients (barring surgical aphakia) in either group had any visually significant complications.

### Discussion

In this prospective study, we described the use of the LDLD test in evaluating patient suitability for ATA.

Because the surgical technique is improving, there is a general trend toward smaller incisions and less invasive maneuvers in MSICS. This has been accompanied over the last year by a renewed interest in topical anesthetic techniques, which in many cases enhance the patient's comfort and reduce the inherent risks of retrobulbar and peribulbar injection.<sup>[11-13]</sup> Topical anesthesia has the potential to serve as a safe, economic, and easy technique for MSICS. Patel *et al.*, in a study comparing topical and retrobulbar anesthesia for phacoemulsification surgery, reported that light bothered 10% of cases who were operated under topical anesthesia, mostly occurring during the initial part of the operation.<sup>[14]</sup> They also suggested that, for topical anesthesia, careful selection of the patients was essential for the smooth intraoperative and post-operative course of the surgery. Wang L *et al.* concluded from their study that although

Parameters	Grading/ subdivisions	Groups		Total	<b>Chi-square</b>	Р
		ALA	ΑΤΑ		value	
Intraoperative complications	Tunnel	5 (3.6%)	3 (2.7%)	8	1.546	0.672
	Iris	2 (1.4%)	0	2		
	Lens	1 (0.7%)	0	1		
	Posterior capsule	2 (1.4%)	1 (0.9%)	3		
Congestion	0	0	5 (4.5%)	5	8.154	0.043*
	1	57 (41.3%)	50 (44.5%)	107		
	2	66 (47.8%)	50 (44.5%)	116		
	3	15 (10.9%)	7 (6.3%)	22		
Subconjunctival	No	109 (79%)	88 (78.6%)	197	1.813	0.178
Haemorrhage	Yes	29 (21%)	24 (21.4%)	53		
Chemosis	Absent	138	111	249	1.070	0.301
	Present	0	1	1		
Cornea	Clear	74 (53.6%)	71 (63.4%)	145	0.959	0.327
	Striate keratopathy	64 (46.4%)	41 (36.6%)	105		
Reaction in anterior chamber	2	54 (39.1%)	49 (43.8%)	103	5.237	0.073
	3	74 (53.6%)	61 (54.5%)	135		
	4	10 (7.2%)	2 (1.8%)	12		
Visually significant postoperative complications	Wound	2 (1.4%)	1 (0.9%)	3	11.81	0.019*
	Cornea	1 (0.7%)	7 (6.2%)	8		
	Anterior chamber	5 (3.6%)	0	5		
	Iris	3 (2.2%)	1 (0.9%)	4		
	Intraocular lens	0	1 (0.9%)	1		

Table 4: Comparison of complications in ALA and ATA group of patients

\*ALA: Assisted local anesthesia, ATA: Assisted topical anesthesia

topical anesthesia alone provides acceptable anesthesia for manual small-incision cataract surgery (MSICS with vectis method or bisection in case of hard cataract), combined topical and intracameral anesthesia decreased patients' discomfort and increased their cooperation during the operation.<sup>[15]</sup> Thus, we used topical anesthesia supplemented with intracameral anesthesia in our study.

Every study performed on topical SICS, nationally<sup>[11,12,16-18]</sup> and internationally,<sup>[13,15,19]</sup> has mentioned uncooperative patients as one of the exclusions criteria. However, they have failed to mention any objective method to determine which patients are unsuitable for topical SICS. Therefore, it would be advantageous to have an objective test in the preoperative evaluation to identify patients who are suitable for ATA. To our knowledge, only EC Figueira et al. have published a study indicating which patients are suitable for ATA as compared to ALA in patients undergoing phacoemulsification surgery by using Lanindar test.<sup>[5]</sup> After dilating the pupil, all patients were adapted to the background illumination of the office for at least 10 min. The light was held 25 cm from the patient's face and the patient's response was noted. Those who demonstrated indifference to the light (considered as a positive test) underwent surgery using ATA. They concluded that the Lanindar test appears to be simple and specific objective method of predicting in the office environment which patients may tolerate phacoemulsification surgery under ATA. No such test has been recommended for MSICS.

In our series, the LDLD test allowed us to decide objectively whether or not to utilize ATA. Nine patients (out of 112) whom we predicted were suitable for ATA, proved intolerant of ATA and were finally operated after giving peribulbar block. Six of these patients were shifted to ALA due to excessive eye movement. In three patients, the pupillary dilatation reduced considerably intraoperatively and it was difficult to operate them under ATA. The specificity of the LDLD test in identifying cases that were not suitable for ATA was 93.48% (95%CI 87.98–96.97%). The specificity of the Lanindar test (EC Figueira *et al.*) for phacoemulsification cases was similar 93.14% (95% CI% 88.23-98.04%).<sup>[5]</sup> To determine the sensitivity of the test reliably, it was required to operate negative LDLD patients under ATA, which was not ethically correct.

It took more time to operate patients under ATA as compared to ALA. This is because patients with ATA required constant vocal encouragement and instructions during the procedure.

The intraoperative complications rate was not significantly different among the two groups. Postoperatively, however, conjunctival congestion was significantly less in ATA group since no injection anesthesia was given to these patients. Because we wanted to keep iris tissue handling to minimum, we used only viscoexpression technique to deliver the nucleus out. With constant low amplitude eye movements of patients ATA group, there are more chances that the nucleus may touch the endothelium, leading to corneal edema in the immediate postoperative period, though not visually significant. Wang L et al. in their series of 300 patients did not found visually significant corneal edema in any of the patients.<sup>[15]</sup> The most common complication they encountered was iris prolapse (2%). Since no other studies have emphasized on intra- and post-operative complications and inflammation, it is not possible to compare all complications head-to-head.

There are some limitations to our study. Since the primary objective was suitability of LDLD test, the comfort of patient was documented as a binary response (yes or no) and not graded. The results could have been generalized better if more than one surgeon, from the same or different center, were involved in the study. It was not a double blinded study in true sense as both the patient and surgeon knew about the method of anesthesia used. However, the observer who evaluated the patients postoperatively was blinded regarding the method of anesthesia.

# Conclusion

The LDLD test is a simple and specific objective method of predicting which patients may tolerate small incision cataract surgery under ATA.

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### **Conflicts of interest**

There are no conflicts of interest.

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