

Severe adverse events associated with local anaesthesia in cataract surgery: one year national survey of practice and complications in the United Kingdom.

Richard M H Lee ¹, John R Thompson ², Tom Eke ³

1 Department of Ocular Biology and Therapeutics, Institute of Ophthalmology, London

2 Department of Health Sciences, University of Leicester, Leicester

3 Department of Ophthalmology, Norfolk & Norwich University Hospital, Norwich

Correspondence

Richard M H Lee

Department of Ocular Biology and Therapeutics, Institute of Ophthalmology, 11-43 Bath Street,
London, EC1V 9EL, United Kingdom

Tel (+44) 207 608 6800

e-mail rmh.lee@ucl.ac.uk

Keywords: cataract, anaesthesia, complications, phacoemulsification

Word Count: 2102

Subtitle

Severe adverse events associated with local anaesthesia in cataract surgery

Abstract

Background: Recent years have seen a major change in practice of local anaesthesia (LA) for cataract surgery.

Aims: (i) To estimate current usage of LA techniques for cataract surgery, (ii) to estimate the incidence of severe adverse events associated with each LA technique, (iii) to compare with our previous 2003 study.

Methods: This was a prospective, observational study of routine practice. For 13 months in 2012-3, the British Ophthalmological Surveillance Unit sent monthly mailings to all senior British ophthalmologists, asking for reports of "potentially sight-threatening or life-threatening complications of LA for cataract surgery". Current practice was assessed by questionnaire.

Results: Cataract surgery comprised 3.4% general anaesthesia, 92.5% LA alone, 4.1% LA with sedation. Techniques for the estimated 357 000 LA cataracts were: 8.8% peribulbar, 1.3% retrobulbar, 50.5% sub-Tenon's, 1.4% sub-conjunctival, 13.8% topical, 24.2% topical-intracameral LA. Severe sight-threatening complications included 7 globe perforations, 1 cilioretinal artery occlusion and 1 severe corneal oedema. Severe life-threatening complications included 1 profound vasovagal episode, 1 silent myocardial infarction, 1 anaphylactic reaction and 1 supraventricular tachycardia. Under-reporting means that more complications probably occurred.

Conclusions: There has been a large swing toward 'non-injection' LA in recent years. Serious adverse events were reported with all techniques except topical-intracameral and subconjunctival LA, though the incidence appears lower for 'non-injection' LA.

INTRODUCTION

The small, self-sealing incision in modern phacoemulsification surgery has greatly improved control of the wound and anterior chamber, reducing the need for total akinesia during cataract surgery. The introduction of small-incision phacoemulsification in the 1990's was accompanied by a change in the way that eyes are anaesthetised for cataract surgery. Many surgeons now consider that globe akinesia is no longer mandatory, and some perceive that a 'mobile' eye can actually assist with safe and efficient surgery. Serial studies have documented a major change in anaesthesia for cataract surgery over the last two decades, with a decrease in usage of general anaesthesia (GA) and increasing use of local anaesthesia (LA), and a reduction in the usage of sharp-needle LA techniques. [1-5]

The ideal LA technique would be risk free, and guarantee total comfort throughout the procedure. [1] Traditional needle blocks such as retrobulbar and peribulbar LA provide good analgesia and akinesia, but they can cause serious sight threatening complications including globe or optic nerve perforation, which can result in blindness. They can also cause life-threatening complications: inadvertent injection of anaesthetic through the optic nerve sheath can cause brainstem anaesthesia, unconsciousness, severe cardio-respiratory collapse, and even death. [6-8] With a drive towards safer surgery, newer 'non-needle' techniques were developed. Sub-Tenon's LA utilises a blunt-ended cannula instead of a needle, and should reduce the risk of globe perforation. However, the technique requires tissue dissection, and complications can still occur. [9] Topical and topical-intracameral LA techniques should have fewer anaesthetic related complications, but there is no akinesia, and there may be a lower level of patient comfort. [10, 11] Some clinicians have voiced concerns about possible increased rates of surgical complications with topical LA, though recent reviews have been reassuring regarding this issue. [12, 13]

The recent swing towards 'non-needle' LA is due in part to a perception that these techniques are safer. We last surveyed the complications of LA for cataract surgery in 2003, relying on reports from ophthalmic surgeons. [1] Due to increased awareness of potential complications, and increasing use of sub-Tenon's and topical LA techniques, we felt that this important topic should be re-visited.

METHOD

This was a prospective, observational study of routine practice in the United Kingdom (UK). We repeated our 2003 survey of all senior ophthalmologists in the United Kingdom (UK), using an identical methodology. The 2003 survey has already been described in detail. [1]

Case ascertainment was through the British Ophthalmic Surveillance Unit (BOSU), which exists to facilitate case ascertainment for studies of rare conditions in ophthalmology. [14] Each month, BOSU sends a postcard to all senior ophthalmologists in the UK, asking if they have seen any cases (or none) from a small list of conditions. ~~For 13 months between September 2012 to October 2013,~~ BOSU cards included 'potentially sight-threatening or life-threatening complication of LA for cataract surgery'. Those who reported cases were sent a case report questionnaire for further details regarding the case the ophthalmologist had reported. At the mid-point of the survey, all

ophthalmologists on the BOSU mailing list were sent a ~~different current practice~~ questionnaire, in order to ascertain ~~current practice usage~~ of LA for cataract surgery. This questionnaire was unmarked, in order to encourage full and frank reporting, but this did mean that we could not send reminders to non-responders. The study design and questionnaires were identical to our 2003 survey. The 2013 study was approved by the BOSU steering committee and by the Research and Development Directorate at Norfolk and Norwich University Hospitals NHS Trust via the Integrated Research Application System.

The aims of our study were (i) to estimate the frequency of use of the various LA techniques used in cataract surgery in the UK, (ii) to estimate the incidence of severe adverse events associated with each LA technique, (iii) to document the types of severe adverse events associated with each LA technique, and (iv) to compare practice with the previously reported 2003 BOSU study. [1]

We were unable to obtain exact figures for the total number of cataract operations performed in the entire UK during the 13-month survey period. However, the government does publish these data for England, where the majority of the UK population reside. The Hospital Episode Statistics section of the Department of Health website (www.hscic.gov.uk, accessed 4 March 2014) provides data for National Health Service (NHS) patients in England only, and carries a warning that the figures may not be accurate. We looked at reports for the fiscal years 2012–3, with a primary procedure of ‘Phacoemulsification of lens’ (C71.2). Totals were used to estimate the number of NHS cataract operations done in England during the survey period, and a proportionate correction was made for the number of UK ophthalmologists on the BOSU database whose address was not in England.

The proportion of operations carried out using GA, and the different LA techniques, was calculated using ophthalmologists’ responses to the ‘current practice’ questionnaire. In calculating complication rates, the numerator for each LA technique was the actual number of complications reported. For the denominator, we used the estimated totals, derived from Department of Health figures and our questionnaire, as described above.

RESULTS

The ‘current practice’ questionnaire was returned by 570 of 1163 UK ophthalmologists (49%). Two questionnaires were excluded, because one respondent had retired and another questionnaire was incomplete. Table 1 summarises the responses of the remaining 568 respondents who performed cataract surgery in the UK.

We estimated the actual number of NHS cataract operations done in the survey period was in the order of 357 000. For cataract surgery performed under the National Health Service (NHS), respondents estimated that 3.4% was done using GA, 92.5% using LA without sedation and 4.1% using LA with sedation (Table 1A). For those NHS cataract operations done using LA, the reported usage of the different LA techniques can be summarised as 8.8% peribulbar, 1.3% retrobulbar, 1.4% sub-conjunctival, 50.5% sub-Tenon’s, 13.8% topical and 24.2% topical-intracameral LA (Table 1B, Figure 1). Similar usage was seen for Private practice operations, although there was a greater use of sedation (11.2 vs. 4.1% in NHS LA patients)

Reported complications are summarised in Table 2. There were 20 responses to the BOSU postcards, resulting in 13 reports that were analysed (11 NHS and 2 Private). The 13 eligible cases were all phacoemulsification procedures. Seven potential cases were excluded from the study, the reasons were as follows: 1 LA complication occurred with an operation other than cataract surgery, 2 respondents could not find the case notes and 4 respondents failed to return the case questionnaire, despite reminders.

Reported complications for each LA technique are described in Table 2. There were 11 cases reported in NHS patients and 2 cases in private patients (one globe perforation with peribulbar LA, one cilioretinal artery occlusion with sub-Tenon's LA). Outcomes for the 9 "potentially sight threatening" complications were as follows. There were 7 cases of globe penetration/ perforation with peribulbar LA, 4 of which required further surgery for retinal detachment and 3 had a poor visual outcome (with loss of central vision or field). The case of cilioretinal artery occlusion (sub-Tenon's LA without hyaluronidase) resulted in loss of central vision. The one report of severe epithelial and stromal oedema during surgery (topical Tetracaine LA) did not improve following peri-operative removal of the epithelium. The procedure had to be abandoned because a poor view made surgery impossible. The cornea gradually resolved after 12 days and the patient later underwent routine cataract surgery, this time without Tetracaine drops.

The 4 "potentially life-threatening" complications and their outcomes are described in Table 2. One patient experienced a profound vaso-vagal episode with peribulbar anaesthesia, 1 patient developed a silent myocardial infarction with sub-Tenon's, 1 patient developed supraventricular tachycardia with retrobulbar anaesthesia and 1 patient developed anaphylaxis, possibly related to the use of hyaluronidase with sub-Tenon's anaesthesia (this occurred 5 minutes into the procedure and the swelling made it difficult to perform the operation. Because of this, the patient needed a second procedure to reposition the intra-ocular lens, but there was no long term effect on the patient's well-being or visual outcome). There were no reported deaths. We did not ask for, and we did not receive, any reports of complications attributable to the use of sedation.

Complication rates were estimated for each LA technique by dividing the number of reported adverse events by the estimated number of LAs given (Table 2). We looked for statistical evidence as to whether complication rates varied with LA technique. For 'potentially sight threatening complications', Poisson regression gave strong evidence that rates vary with technique ($p=0.0001$), but provided no evidence of rates varying with technique for 'potentially life-threatening complications' ($p=0.158$).

DISCUSSION

There has been a continuing trend towards the use of LA for cataract surgery, as previously reported in the 1990 National Cataract Surgery Survey and in our 1996 and 2003 studies. [1-4] This study confirms the on-going trend towards the use of LA for cataract surgery, with only 3.4% of cases being performed under GA in an NHS setting (Table 1).

The techniques of LA have also changed significantly in recent years. A 1989 survey of UK ophthalmologists indicated that retrobulbar was the preferred LA technique of the majority of respondents. [15] Our 1996 study [2, 3] indicated a shift towards peribulbar techniques, and the introduction of newer non-needle techniques. Our 2003 study [1] demonstrated a move away from needle blocks to the non-needle techniques. The 2003 study was the first large study to look at the safety of the newer LA techniques with any degree of certainty and indicated a low incidence of serious complications. This 2013 study shows a continuing trend toward the use of non-needle techniques (Figure 1). We also report a lower complication rate for all forms of LA, as compared to the 2003 study (Figure 2). ~~— We believe that the ‘current practice’ questionnaire gave a reasonable reflection of actual LA practice, despite a response rate of 49%. This is because the figures agree with other surveys ^{medisoft LA paper}, [5] and indicate trends which we had already observed ^{1,2,3}. [1-3]~~

Formatted: Superscript

Our results should be interpreted with caution, due to the method of case ascertainment used. Complications reported in this survey may not all be complications of the LA technique itself. The reporter of the cilioretinal artery occlusion with a sub-Tenon’s LA believed that it may not have been related to the LA technique, though this is a recognised complication of the technique. [9] Life-threatening adverse events such as brainstem depression may also occur for other reasons, and therefore it is possible that some of the “complications” reported may have been as a result of chance. Conversely, the complication rates reported by this study are likely to be an under-estimate of the true complication rate.

Under-reporting of adverse events could occur for numerous reasons. ~~Possible reasons for non-reporting include forgetting that a case occurred, non-engagement with the BOSU process, losing the patient details before the case-questionnaire arrives, or refusal to report a case that could potentially have medico-legal implications. -Validation of previous BOSU studies has indicated that around ~~** **%62.5 to 95% of eligible cases do get reported via the BOSU postcard system~~ ^{ref, I think this was referenced in the previous BOSU LA paper}, [1, 14] ~~including under reporting of the BOSU postcard system or the questionnaires we had sent out. The current practice questionnaire was unmarked and meant that we were unable to follow up on non-respondents. It could therefore be argued that the response rate was inadequate to reflect current practice. However we believe that it is more relevant to obtain full and frank responses rather than aim to increase our response rate by identifying non-respondents. Although While it is difficult to ascertain the degree of under-reporting in the current study, we had to exclude 7 of the 20 initial responses to the case report questionnaire.~~~~

Formatted: Superscript

Unrecognised complications would not be identified by the study design. Globe and optic nerve perforation is a well-known complication of needle block techniques but it is not always obvious if such a complication has occurred. One reporter only identified the perforation associated with a peribulbar block at the post-operative visit when trace vitreous haemorrhage was observed on fundal examination. It is therefore likely that the true complication rate of the various LA techniques is higher than this study suggests. ~~—However, overall response rates to the BOSU postcard system were similar in 2003 and 2013, and we used an identical study protocol for the two surveys, therefore we believe that there were indeed a reduced number of serious complications in 2013-~~

We believe that there may indeed have been a genuine reduction in serious complication rates for LA. This could be attributed to improvements in practice, due to increased awareness and improved

LA techniques. Training is available from various sources, including the British Ophthalmic Anaesthesia Society (www.boas.org, formed 1998). The 2001 UK National Guideline on LA for ophthalmic surgery [16] was cited in the 2010 UK Cataract guideline. [17] The LA guideline was revised and updated in 2012, with an expanded section on '*complications and how to avoid them*'. [18] This study confirms one of the main points of the 2012 LA Guideline: "Whatever their cause, serious systemic adverse events in association with ophthalmic surgery do sometimes occur, with all types of local anaesthetic techniques", therefore "All ophthalmic units should have formal policy for dealing with medical emergencies should they occur. Appropriate backup from a cardiac arrest/Medical Emergency Team should always be available." [18]

In conclusion, our study highlights that there is an on-going trend towards non-needle LA techniques, and that the rate of complications appears to have declined for all of the LA techniques. We believe that this is due to increasing awareness of the possible complications of LA, and therefore safer practice both for needle LA and non-needle LA. It is important to highlight that sight-threatening and life-threatening complications may occur whichever LA techniques is used, so practitioners should remain alert to recognise and manage LA complications.

ACKNOWLEDGEMENTS

The authors are grateful to all ophthalmologists who responded to either questionnaire, and to the BOSU steering committee for their advice and support.

The authors would like to acknowledge Antonia Tse and Anita Tse who contributed to checking data entry of the Current Practice questionnaire

REFERENCES

1. Eke T, Thompson JR. Serious complications of local anaesthesia for cataract surgery: a 1 year national survey in the United Kingdom. *Br J Ophthalmol*. 2007;91:470-5.
2. Eke T, Thompson JR. The National Survey of Local Anaesthesia for Ocular Surgery. I. Survey methodology and current practice. *Eye* 1999;13:189-95.
3. Eke T, Thompson JR. The National Survey of Local Anaesthesia for Ocular Surgery. II. Safety profiles of local anaesthesia techniques. *Eye* 1999;13:196-204.
4. Courtney P. The National Cataract Surgery Survey: I. Method and descriptive features. *Eye* 1992;6:487-92.
5. El-Hindy N, Johnston RL, Jaycock P, et al. The Cataract National Dataset Electronic Multi-centre Audit of 55,567 operations: anaesthetic techniques and complications. *Eye* 2009;23:50-5.
6. Hamilton RC. Anesthesia block technique. *Ophthalmol Clin North Am* 1998;11:133-6.
7. Hamilton RC. Retrobulbar block revisited and revised. *J Cataract Refract Surg* 1996;22:1147-50.
8. Davis DB 2nd, Mandel MR. Posterior peribulbar anesthesia: an alternative to retrobulbar anesthesia. *J Cataract Refract Surg* 1986;12:182-4.
9. Kumar CM, Eid H, Dodds C. Sub-Tenon's anaesthesia: complications and their prevention. *Eye* 2011 Jun;25:694-703.
10. Zhao LQ, Zhu H, Zhao PQ, et al. Topical anesthesia versus regional anesthesia for cataract surgery: a meta-analysis of randomized controlled trials. *Ophthalmology* 2012;119:659-67.
11. Davison M, Padroni S, Bunce C, et al. Sub-Tenon's anaesthesia versus topical anaesthesia for cataract surgery. *Cochrane Database Syst Rev* 2007;18:CD006291.
12. Unal M, Yücel I, Sarici A, et al. Phacoemulsification with topical anesthesia: Resident experience. *J Cataract Refract Surg*. 2006;32:1361-5.
13. Lee RM, Foot B, Eke T. Posterior capsule rupture rate with akinetic and kinetic block anesthetic techniques. *J Cataract Refract Surg*. 2013;39:128-31.
14. Foot B, Stanford M, Rahi J, et al. The British Ophthalmological Surveillance Unit: an evaluation of the first 3 years. *Eye* 2003;17:9-15.
15. Campbell DN, Spalton DJ. A national survey of the use of local anesthesia for cataract surgery.

Eur J Implant Refract Surg 1992;4:213–17.

16. Astbury N, Bagshaw H, Desai P, et al. Local anaesthesia for intra-ocular surgery (guideline). London: Royal College of Anaesthetists, Royal College of Ophthalmologists, 2001.

17. Benjamin L, Allen B, Desai P, et al. Cataract Surgery Guidelines September 2010. London: Royal College of Ophthalmologists, 2010. <https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2010-SCI-069-Cataract-Surgery-Guidelines-2010-SEPTEMBER-2010.pdf> (accessed 7 March 2015)

18. Kumar CM, Eke T, Dodds C, et al. Local anaesthesia for ophthalmic surgery (guideline). London: Royal College of Anaesthetists, Royal College of Ophthalmologists, 2012. <https://www.rcophth.ac.uk/wp-content/uploads/2014/12/2012-SCI-247-Local-Anaesthesia-in-Ophthalmic-Surgery-2012.pdf> (accessed 7 March 2015)

FIGURE LEGENDS

Figure 1: A comparison of the overall use of local anaesthetic techniques for cataract surgery (phacoemulsification) in the United Kingdom National Health Service, from 1996 to 2013. Data from 1996 and 2003 extracted from previously reported publications by the same authors. [1-3]

Figure 2: A comparison of the reported complication rates of the different LA techniques between the current and 2003 BOSU study. Data from 2003 extracted from previously reported publications by the same authors. [1]

TABLES

Usage (%)			
A: All Cataract Surgery			
	Without Sedation	With Sedation	Total
General Anaesthesia (GA)	-	-	3.4
Local Anaesthesia (LA)	92.5	4.1	96.6
B: Cataract surgery using LA			
	Without Sedation	With Sedation	Total
Peribulbar LA	7.9	0.8	8.8
Retrobulbar LA	1.2	0.1	1.3
Sub-Tenon's LA	47.8	2.7	50.5
Sub-Conjunctival LA	1.3	0.1	1.4
Topical LA	13.1	0.7	13.8
Topical-Intracameral LA	23.8	0.4	24.2

Table 1: Overall use of anaesthetic techniques for cataract surgery in the United Kingdom (National Health Service) in 2013.

Local anaesthesia (LA) Technique	“Potentially sight-threatening” complications	“Potentially life-threatening” complications
Estimated number of LAs given during survey	Number of reports Reported incidence Description of events	Number of reports Reported incidence Description of events
Peribulbar 31, 416	7 Globe perforations 2.23 per 10 000 4 Required further retinal detachment surgery 3 Lost central vision/field	1 “Profound vasovagal episode” 0.32 per 10 000 Occurred 30 minutes after LA administered Duration < 1 minute Was discharged home No effect on general well being
Sub-Tenons 180, 285	1 Cilioretinal artery occlusion 0.06 per 10 000 Patient lost central vision The reporter felt it may or may not be related to the LA technique	1 Silent Myocardial Infarction 0.06 per 10 000 Occurred 20 minutes after LA administered Hypotensive Tachycardic Low pO2 ST Elevation on Electrocardiogram (ECG) Did not affect visual outcome Required a further heart stent 1 Anaphylaxis 0.06 per 10 000 Occurred 5 minutes into procedure “Possibly due to Hyaluronidase”
Retrobulbar 4, 641	No Reports 0 per 10 000	1 Supraventricular Tachycardia 2.15 per 10 000 Occurred 10 minutes after LA administered Transferred to Intensive Therapy Unit (ITU) Did not affect visual outcome Did not affect general well being
Topical 49, 266	1 Intra-operative epithelial and stromal oedema 0.2 per 10 000	No Reports 0 per 10 000

	Topical Tetracaine alone Unable to complete procedure Settled after 12 days Repeat surgery performed without Tetracaine and without complication	
Topical- Intracameral 86,394	No Reports 0 per 10 000	No Reports 0 per 10 000
Sub- conjunctival 4998	No Reports 0 per 10 000	No Reports 0 per 10 000

Table 2: Complications of local anaesthesia (LA) for cataract surgery, as reported to the investigators.