Randomized double-blind clinical trial comparing topical and sub-Tenon’s anaesthesia in routine cataract surgery

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Background. Several local anaesthetic techniques are available for cataract surgery. Recently, topical anaesthesia has gained in popularity. A randomized trial was designed to compare patient discomfort and intraoperative complications following routine cataract surgery under topical or sub-Tenon’s anaesthesia.

Methods. A randomized double-blinded placebo-controlled clinical trial of 210 patients assigned to either a sub-Tenon’s group (sub-Tenon’s anaesthesia with placebo topical balanced salt solution, n=140) or a topical anaesthesia group (topical anaesthesia with placebo sub-Tenon’s injection of balanced salt solution, n=70) was carried out. All patients underwent phacoemulsification with intraocular lens implantation. Patients in the sub-Tenon’s group received a single injection (3 ml) of a combination of lidocaine 2% (2 ml) and bupivacaine 0.75% (1 ml), and four doses of topical placebo (balanced salt solution). Patients in the topical anaesthesia group received four doses of topical proxymethocaine 0.5% and a placebo sub-Tenon’s injection (3 ml) of balanced salt solution. No intracameral injection of local anaesthetic was given. A 10-point visual analogue pain scale was used preoperatively and for postoperative pain assessment immediately after the operation and 30 min postoperatively. The intraoperative complications in the two groups were recorded.

Results. The mean pain score immediately after surgery was 2.42 (SD 2.2) in the sub-Tenon’s group and 3.44 (2.3) in the topical anaesthesia group (P=0.0043). The mean pain score 30 min after surgery was 1.24 (1.7) in the sub-Tenon’s group and 2.25 (2.2) in the topical anaesthesia group (P=0.0009).

Conclusions. Patients undergoing cataract surgery under topical anaesthesia experience more postoperative discomfort than patients receiving sub-Tenon’s anaesthesia. Surgery-related complications were similar in both groups.

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Cataract and glaucoma surgery are the most common elective procedures in the United Kingdom, with about 200 000 performed annually. A survey conducted by the Royal College of Ophthalmologists has shown that local anaesthesia is the preferred anaesthetic technique for intraocular surgery in the United Kingdom. Desai and colleagues have shown that day-care intraocular surgery under local anaesthesia is safe and is also preferred by patients and staff.

Several local anaesthetic techniques for cataract surgery are currently available. These include retrobulbar (intraconal), peribulbar (extraconal), sub-Tenon’s, subconjunctival and topical anaesthesia. Posterior sub-Tenon’s delivery of the anaesthetic, as described by Stevens, has the advantage of using a blunt sub-Tenon’s cannula. This avoids placement of sharp needles into the retro orbital or periorbital spaces, and has been shown to be an efficient and safe technique.

Topical anaesthesia alone for cataract removal and intraocular lens implantation was first described by Fichman. Since then there have been several reports of its safety and efficacy. However, Fukasaku and Marror, comparing...
topical and peribulbar anaesthesia, and Patel and colleagues,\textsuperscript{14} comparing topical and retrobulbar anaesthesia, reported more intraoperative pain in patients receiving topical anaesthesia for cataract surgery.

To our knowledge there has been no randomized placebo-controlled clinical trial comparing sub-Tenon’s and topical anaesthesia in routine cataract surgery. Therefore we designed a prospective double-blinded randomized placebo-controlled clinical trial comparing topical anaesthesia with sub-Tenon’s anaesthesia. We measured the patient’s pain score immediately after the operation and 30 min postoperatively. We also recorded the intraoperative complications.

**Methods**

**Patient selection**

From August 2000 to May 2002, in a continuous cohort of 225 patients on the National Health Service waiting list for cataract surgery, 210 patients were eligible for cataract surgery. From August 2000 to May 2002, 210 patients were eligible for cataract surgery (phacoemulsification with intraocular lens implantation) using either topical or sub-Tenon’s anaesthesia. All patients underwent sutureless cataract surgery through a temporal corneal wound. Approval for the study was obtained from the Lanarkshire Research Ethics Committee and the Lanarkshire Health Board. All surgical procedures complied with the tenets of the Declaration of Helsinki. Inclusion criteria were a cataract listed for surgery at the hands of a single experienced senior surgeon (AIF) and willingness to participate in the trial. Exclusion criteria were dementia, deafness, eye-movement disorder, combination surgery, excessive anxiety, English not the first language or an adverse reaction to lidocaine, bupivacaine or proxymethocaine. All patients gave written informed consent to participate in the study.

**Randomization**

An independent researcher provided the hospital pharmacy with an individual randomization schedule of 250 allocations. A customized pack was prepared from this schedule for each patient. The pack comprised a syringe containing either 3 ml of local anaesthetic lidocaine 2% (2 ml) and bupivacaine 0.75% (1 ml) or placebo, a minims dropper containing either placebo or proxymethocaine 0.5%, and a separate minims dropper containing proxymethocaine 0.5%. These packs were sequentially labelled 1 to 210. The randomization schedule was retained in the hospital pharmacy and was not seen by the investigators until the trial was completed. All patients received a sub-Tenon’s injection and topical eyedrops. They were randomized such that the patients receiving the sub-Tenon’s anaesthesia received a topical placebo, and patients receiving topical anaesthetic had a placebo sub-Tenon’s injection. Each patient entering the trial was allocated a unique trial number from 1 to 210 and received the contents of the pack matching the number. In this way the patients, the ophthalmologist administering the anaesthetic, the surgeon and the nurse measuring the pain score were fully masked from the identity of the contents of the pack.

**Pain evaluation**

Each patient was shown a visual analogue pain scale with numerical and descriptive ratings from 0 (no pain) to 10 (severe pain), as described by Stevens,\textsuperscript{7} to rate their pain. Patients were encouraged to use this pain scale to rate the level of pain felt pre- and postoperatively. If patients were unable to read the printed numbers and descriptive text on the pain scale, a trained ophthalmic nurse read them to the patient.

Following administration of the local anaesthetic (prior to commencement of surgery), baseline pain scores were obtained in both groups (Table 1). This pain was probably caused by the sub-Tenon’s injection. Any verbal expression of pain that patients made during the operation (e.g. on manipulation of the iris) was recorded. These pain scores were repeated immediately and 30 min postoperatively. A blinded independent observer (ophthalmic trained nurse) performed the pain score recording in all the patients.

**Technique for sub-Tenon’s anaesthesia**

All the 210 patients received a single drop of proxymethocaine 0.5%, placed locally in the inferonasal quadrant of the conjunctiva at the site of the sub-Tenon’s injection. A lid speculum was placed and a small ‘nick’ incision was made simultaneously in the conjunctiva and Tenon’s capsule, about 5 mm from the limbus in the inferonasal quadrant, using curved Westcott scissors. Depending on the group to which they were randomized, patients then received either a mixture of 2 ml of lidocaine 2% and 1 ml of 0.75% bupivacaine, or 3 ml of balanced salt solution through a 19-gauge sub-Tenon’s cannula in to the posterior sub-Tenon’s space. Hyaluronidase was not used in this study. No device was used to induce ocular compression.

**Technique of topical anaesthesia**

Depending on the group to which they were randomized, the patients received either topical proxymethocaine 0.5% or a placebo of topical balanced salt solution. Four doses (approximately 40 μl per dose) of unpreserved proxymethocaine 0.5% or placebo were used. They were installed on the ocular surface (two doses on the cornea, and one each in the superior and inferior conjunctival cul de sac) 10 min before surgery. Five minutes before surgery two further doses were installed on the cornea. An additional two doses of proxymethocaine 0.5% on the cornea were allowed in the event of breakthrough pain, which was treated in the same way in both groups.
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Statistical methods
N-Query software was used to calculate the sample size based on the assumptions that the main outcome measure (the pain score) is continuous in nature and normally distributed. The sample size was calculated so that the trial had an 85% power to detect a 10% difference between the two groups with an estimated standard deviation of 2.2. This required 198 subjects, 132 in the sub-Tenon’s group and 66 in the topical anaesthesia group.

The data were entered into Microsoft Excel (Microsoft Inc., Redmond, WA, USA) and was analysed using Stata 8.0. We used the unpaired Student t-test for normally distributed continuous variables (patient’s age and baseline pain score following administration of the anaesthetic before surgery), and the Wilcoxon rank-sum (Mann–Whitney) test for non-normally distributed variables (pain score immediately after surgery and 30 min postoperatively). The χ²-test was used to compare the sex distribution between the two groups. P-values <0.05 were considered to be statistically significant.

Results
From a total of 225 patients assessed, 210 met the inclusion criteria and agreed to participate. The mean age of this cohort was 74.3 (38–92) yr and 62.7% were female (Table 1). Seventy patients were randomized to the topical anaesthesia group and 140 to the sub-Tenon’s group. There were no differences in baseline characteristics between the two groups.

No patient required a change in the anaesthetic technique for the surgery to be completed. Nine patients (four in the sub-Tenon’s group and five in the topical anaesthesia group) were excluded from the analysis as their pain scores were not recorded. The overall intraoperative complication rate was 2.4% for posterior capsular tear and vitreous loss, and 0.5% for iris prolapse. Three patients (4.3%) in the topical anaesthesia group and two (2.1%) in the sub-Tenon’s group had posterior capsular tear and vitreous loss. One patient (0.5%) in the sub-Tenon’s group had iris prolapse intraoperatively and required a single interrupted stitch to close the corneal wound. The difference between groups was not statistically significant (P=0.391). The pain scores reported by the patients are shown in Table 2. Although patients in the topical anaesthesia group experienced more immediate postoperative pain, none of them required any supplemental analgesia.

Discussion
Ophthalmic surgery in the United Kingdom is dominated by cataract and glaucoma work. There has been a dramatic change in anaesthetic practice for ophthalmic surgery over the past decade, and much of this has occurred since the first guidelines on anaesthesia in ophthalmic surgery were produced by The Royal College of Anaesthetists and College of Ophthalmologists in 1993. The use of local anaesthetic has risen from around 20% of patients in 1991 to over 75% in 1996 and 86% in 1997. The use of sedation with local anaesthesia has fallen from 45% in 1991 to around 6% in 1996.

Although, according to a national survey, the peribulbar technique is used most commonly for intraocular surgery, sub-Tenon’s and topical anaesthesia are gaining popularity. Neither of these techniques requires sharp needles, and they can be performed in the absence of an anaesthetist.

In 1992, Stevens introduced sub-Tenon’s anaesthesia for cataract surgery. He reported no pain or only slight discomfort in 50 patients who underwent both large-incision (extracapsular cataract surgery) and small-incision (phacoemulsification) cataract surgery. Since then there have been several reports confirming the efficacy and safety of sub-Tenon’s anaesthesia during cataract surgery.

To our knowledge, this is the first report of a double-blind randomized placebo controlled trial comparing topical and sub-Tenon’s anaesthesia for routine cataract surgery. In our study, the patients undergoing topical anaesthesia had a higher mean pain score (3.44) immediately and 30 min after surgery (2.25), which was statistically significant when compared with the sub-Tenon’s group. Although the pain score was higher in the topical group, none of the patients in this group required supplemental anaesthesia during surgery.

In their study comparing topical oxybuprocaine with sub-Tenon’s lidocaine 2%, Chittenden and colleagues reported a significantly higher median pain score in the topical group. They concluded that sub-Tenon’s anaesthesia produced less pain in patients undergoing cataract surgery.
surgery through a scleral tunnel, and they recommended topical anaesthesia only if the cataract surgery was performed through a clear corneal incision. Similarly, Manners and Burton\textsuperscript{18} reported a higher pain score in the topical group despite the fact that the patients in this group received an additional subconjunctival injection of lidocaine 2\% to facilitate scleral cautery, as the surgery was performed through a scleral incision.

Zafirakis and colleagues\textsuperscript{19} were the first to compare topical and sub-Tenon’s anaesthesia for phacoemulsification and intraocular lens implantation through a clear corneal incision. They recruited 100 patients in whom the randomization was stratified so that half of the first-eye surgeries and half of the second-eye surgeries were assigned to each anaesthetic group. They concluded that patients having cataract surgery under topical anaesthesia had more intraoperative and postoperative discomfort than patients receiving sub-Tenon’s anaesthesia.

It has been thought that, with topical anaesthesia, phacoemulsification and intraocular lens implantation were less painful when performed through a clear corneal incision than when performed through a scleral tunnel incision, as the former has the advantage of preserving the conjunctiva and avoiding the use of cautery. However, this study shows that even with a clear corneal incision, patients undergoing topical anaesthesia had more pain immediately (3.44) and 30 min postoperatively (2.25) than those with sub-Tenon’s anaesthesia (2.42 and 1.24, respectively).

As this study was designed primarily to detect a difference in the pain score, there was inadequate power to demonstrate a statistically significant difference in the intraoperative complications between the two groups. Also, no provisions were made to compare the degree of operating difficulty encountered by the surgeon that were induced by the anaesthetic technique (e.g. degree of chemosis, subconjunctival haemorrhage). However, we assume that the degree of difficulty would be the same in both groups as both sets of patients received a sub-Tenon’s injection, albeit a placebo in the topical group.

In conclusion, both topical and sub-Tenon’s anaesthesia are safe and effective for routine cataract surgery. Although routine cataract surgery is less painful under sub-Tenon’s anaesthesia, topical anaesthesia is well tolerated by patients. Patients who have a phobia for needles and those who prefer topical anaesthesia should be warned that they may experience discomfort during cataract surgery.

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