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Non-Toxic Anesthesia for Cataract Surgery

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Abstract: Background: To study the safety and efficacy provided by a minimal and localized anesthesia in cataract surgery. Methods: Randomized controlled trial. A total of 100 patients undergoing cataract surgery were randomly divided into two groups of 50, which respecitvely received conventional topical anesthesia consisting of preservative-free Oxibuprocaine hydrochloride 0.4% drops or minimal localized anesthesia, administered with a cotton bud soaked in preservative-free Oxibuprocaine hydrochloride 0.4% applied to clear cornea on the access sites for 10 s immediately before surgery. The mean outcome measures were intraoperative pain and the incidence of postoperative ocular discomfort. Results: All patients tolerated well the procedure, giving patin scores between 1–3. Fifteen patients (30%) of group 1 and ten of group 2 (25%) required supplemental anesthesia. No intraoperative complications were recorded. No eyes had epithelial defects at the end of the surgery or at postoperative check-ups. Conclusions: Minimal anesthesia in cataract surgery resulted quick, safe and non-invasive.

Keywords: cataract surgery; topical anesthesia; pain score

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1. Introduction

Over the years, many less invasive techniques have been developed to perform anesthesia for cataract surgery. Starting from general anesthesia to retrobulbar or peribulbar block, sub-Tenon block, until topical anesthetic drops, the very first goal was minimizing patients' discomfort and anesthesia-related complication [1–4]. Nevertheless, topical anesthesia may result in complications too. In fact, since multiple eye drops are used for analgesia, these topical anesthetics might have toxic effects on the corneal epithelium. This can reduce the visibility for the surgeon, lead to discomfort in thepostoperative period, reduce tearing and rarely cause severe keratopathy [5,6]. Many alternative techniques of surface anesthesia have been proposed to avoid multiple administrations of anesthetics and possible toxic effects on the cornea [7]. The purpose of our study is to evaluate the efficacy and safety of a minimal localized anesthesia administered with a cotton bud soaked in preservative-free Oxybuprocaine hydrochloride 0.4% applied to clear cornea at incision sites for 10 s immediately before surgery.

2. Materials and Methods

The study involved 100 eyes of 100 patients (50 males, 50 females) who underwent

elective cataract surgery. The study was approved by the Institutional Review Board of the University of Messina and was conducted in accordance with the tenets of the Declaration of Helsinki. All surgeries were performed at the Ophthalmology Department of the University of Messina by the same surgeon (AM). Moderate grades of cataracts (Locs Classification system III) were included in this study. Patients uncooperative due to dementia, hearing impairment, or with previous eye injury, hard cataract, shallow anterior chamber or small pupils were excluded. Informed consent to the surgery were obtained from all patients. All patients preoperatively received povidone iodine 0.6% eyedrops, ofloxacine 0.3% and diclofenac 0.1% bid for 3 days, and tropicamide 1% the morning of surgery. Before starting the procedure, group 1 received conventional topical anesthesia with preservative-free Oxybuprocaine hydrochloride 0.4% eyedrop, while in group 2 minimal localized anesthesia was performed, administered with a cotton bud soaked in preservative-free Oxybuprocaine hydrochloride 0.4% and applied to clear cornea only at the incision sites for 10 s immediately before surgery (Figures 1and 2).

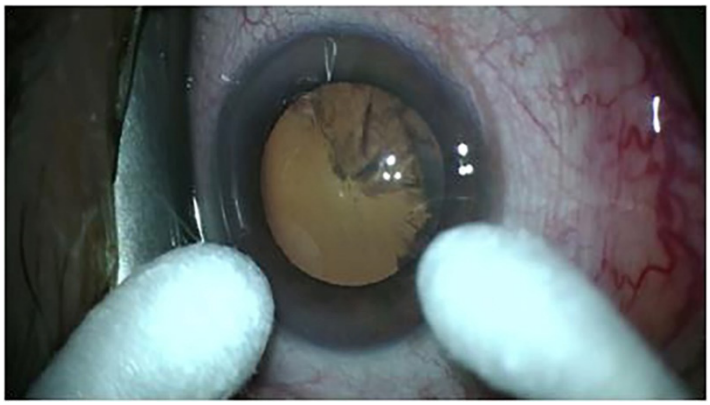

Figure 1. Application of soaked Oxibuprocaine hydrochloride 0.4% cotton buds on the access sites.

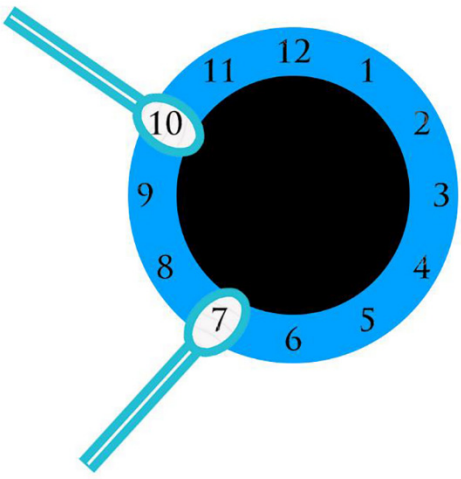

Figure 2. Illustration of the application of cotton buds on the access sites.

Before starting surgery, the povidone-iodine 5% was applied to the conjunctival sac for 2 min. None of the patients received systemic sedatives. After surgery, a masked specialist asked the patients to grade the level of pain felt during surgery, using a scale of pain from 1 to 5 (5 was considered the worst pain felt). Corneal esthesiometry was assessed pre-operatively and post-operatively using the Cochet Bonnet esthesiometer. Each patient filled the ocular surface disease index (OSDI) questionnaire for the diagnosis of dry eye syndrome on day 0 (baseline), 1- and 3-months following phacoemulsification. Tear break-up time (TBUT) for the evaluation of the tear film was also performed to-

gether with corneal fluoresceine staining with Oxford schema for assessing the health of the corneal epithelium.

Statistical Analysis

The numerical data are reported as mean and standard deviation whereas the categorical variables as absolute frequency and percentage. The Kolmogorov-Smirnov test was used to evaluate the fitting of the data to a normal distribution. For each parameter, a statistical evaluation between groups was assessed using the Student's *t*-test for parametric data, the Mann-Whitney U test for non-parametric data, and the Chi-Square test for categorical variables. A p-value < 0.05 was considered to be statistically significant. Statistics were performed using SPSS software V22.0 (SPSS, Inc., Chicago, IL, USA) for Windows.

3. Results

The percentage of patients who reported not having felt the slightest pain during surgery was 20%, the same in both groups. In group 1, 40 patients (80%) graded their pain between 2 and 3, while none graded pain 4 or above; in group 2, 40 patients (80%) graded their pain between 2 and 3, while none graded pain 4 or above. Fifteen patients (30 %) in group 1 and ten in group 2 (25%) required supplemental anesthesia, to reinforce the anesthesia in group 1 another drop of Oxybuprocaine hydrochloride 0.4% was instilled, while in group 2 a focal application through a cotton bud for 10 s was applied on the incision site. No intraoperative complications were recorded in either group. The mean surgery time was 8.5 ± 1.9 min in group 1 and 8.7 ± 1.5 min in group 2. No epithelial defects were detected at the end of the surgery.

No significant changes of corneal esthesiometry were observed after surgery in both groups (Table 1).

The levels of pain sensed by the patients and reported at the end of the operation were low in both groups, without any significant differences ($p=0.8$). Moreover, only a few patients (20%) required additional anesthesia in order to complete surgery safely. OSDI score and T-BUT were assessed at baseline and 1and 3months post-op. Pre-operative OSDI was overlapping in both groups (p $=0.9$), while 1month post-operative group 2 showed healthier values (p=0.04), and 3 months after surgery the values returned similar in both groups, with no statistical differences (p=0.87) Table 1.

Table 1. Changes of ocular surface disease index (OSDI) and tear break up time (T-BUT) from baseline to 3-months post-op.

		OSDI	
	Pre-operative	1 month	3 months
Group 1	10.4 ± 1.3	18.2 ± 3.8	10.8 ± 6.6
Group 2	10.5 ± 1.3	15.9 ± 3.5	10.3 ± 7.2
p-value	0.64	0.003	0.87
		T-BUT	
	Pre-operative	1 month	3 months
Group 1	14.3 ± 3.4	6.1 ± 2.2	13.8 ± 3.2
Group 2	15.1 ± 4.6	11.9 ± 1.9	13.9 ± 3.9
p-value	0.88	0.048	0.98
		Corneal Esthesiometry	
	Pre-operative	1 month	3 months
Group 1	57 ± 25.9	58.3 ± 25.7	57.9 ± 24.8
Group 2	56.1 ± 30.7	57.8 ± 27.7	57.8 ± 26.5
p-value	0.75	0.84	0.94

Additionally, T-BUT showed a statistical difference 1-monthpost-op (p=*0.048*) Table 1. Only two patients suffered from dry eye syndrome in group 1 one-month post-op, while none of the patients in group 2 complained of dry eye symptoms or showed signs of corneal epithelium impairment.

4. Discussion

Several techniques to provide anesthesia in cataract surgery have been developed over the years, in order to reduce patient discomfort and the risk of complications. Nowadays, topical anesthesia, being safe and effective, is the gold standard in cataract surgery [8]. It works blocking the afferent nerves of the cornea and the conjunctiva (long and short ciliary nerves, nasociliary nerves). Today different agents are available for topical anesthesia, like Procaine (1–2–10%), Proparacaine (0.5%), Oxybuprocaine (0.4%), Tetracaine (0.5–1%), Bupivacaine (0.25–0.5%), Lidocaine (0.5–1%), Prilocaine (4%), and Ropivacaine (0.2%/1%). All these agents have different time of onset and duration of anesthesia. Although topical anesthetics are widely used for ocular diagnostic and ophthalmic surgery, these are not completely safe as epithelial and endothelial toxicities are reported, even following a single use [9]. Indeed, several studies reported corneal epithelial cells damage after repeated and prolonged usage, demonstrating cytotoxicity and apoptosis-inducing effects of topical anesthetics [10,11].

Moreover, in subjects with preexistent ocular surface alterations, such as diabetics and dry eye patients, topical mydriatics and anesthetics can disrupt the corneal epithelium leading to punctate keratitis, impaired corneal wound healing and infections [12,13].

Additionally, high concentrations and prolonged expositions of povidone-iodine during cataract surgery increase the risk of corneal epithelial cells damages [14].

Intracameral techniques have been proposed to reduce the ocular surface damage, improving the anesthetic action on the sensitivity of the iris, the zonule and the ciliary body.

Souki et al. in a clinical trial compared the effects of an intracameral combined mydriatic and anesthetic agent to standard topical mydriatics and anesthetics on the ocular surface after cataract surgery, demonstrating a reduced ocular surface damage with decreased corneal epithelial and conjunctival toxicity, and faster recovery of surface integrity in patients treated with intracameral anesthetic [15].

However, intracameral anesthetics may cause adverse events such as corneal thickening, opacification, and significant corneal endothelial cell loss [16].

Alternative techniques have been proposed such as limbal anesthesia, consisting of applying a cellulose ophthalmic sponge, soaked in preservative-free lidocaine hydrochloride 4%, to the limbal area for 45 s immediately before starting surgery pre-medicating with one drop of benoxinate 0.4% [17].

The analgesia achieved with the application of the sponge can be justified with the block of the peri-corneal and annular plexus, explaining the analgesic effect on the entire circumference of the cornea.

In this study we described an alternative technique of localized topical corneal anesthesia through a soaked Oxybuprocaine hydrochloride 0.4% cotton buds on the corneal access sites.

This approach reduced the time of exposition to anesthetic to 10 s, without use of anesthetic drops, reducing the toxic effects on the ocular surface.This may be responsible for a reduced ocular discomfort after surgery; indeed, our findings demonstrated a significant lower OSDI score in patients underwent minimal localized anesthesia compared to those treated under conventional topical anesthesia.Furthermore, the reduced damages of the epithelial corneal and conjunctival cells, improved the tear film stability and T-BUT after cataract surgery.

In accordance with our study, Scuderi et al. applied ropivacaine-soaked sponges in the inferior fornix for 5 min, demonstrating that deep topical anesthesia appeared to be safe and effective as topical anesthesia [18].

Based on the VAS scores, the patients who underwent deep topical anesthesia reported less pain. This resembles the results by Martini et al. who reported a lower pain score in patients receiving topical ropivacaine with respect to topical lidocaine, although their results did not reach statistical significance [19], whereas Ugur et al. did not report any significant difference in pain score when comparing deep topical anesthesia with ropivacaine to deep topical anesthesia with lidocaine [20].

In topical anesthesia, the drug must generally be administered 20–30 min before surgery, with multiple administrations to allow the drug to penetrate the cornea and ensure that adequate concentrations reach the anterior chamber. Our "minimal anesthesia" technique simplifies the preoperative preparation of the patient, which is reduced to induce mydriasis. This aspect, according with other authors can be very important, especially in a busy outpatient practice or in those affected by dry eye. The advantage of localized anesthesia is the targeted application of the anesthetic, reducing any complication providing the same safety and effectiveness as the topical anesthesia. We also found a reduction of post-operative ocular discomfort and a better objectivity in patient who underwent localized anesthesia one month postoperatively. Several studies reported that dry eye can develop after cataract surgery in about 9.8% of patients [21,22,23]. With a localized anesthesia, the surgeon is confident that the nontoxic dose of anesthetic has been administered at the right time, respecting the corneal epithelium. In conclusion, our experience demonstrates that localized anesthesia can be considered as a valid alternative to the standard multiple preoperative administration of anesthetic eye drops, as it ensures optimum analgesia, permits safe surgery and does not have any toxic effects on the corneal epithelium. This technique might be used for average but selected cataract patients. Nonetheless we need more studies in this regard and a larger number of cases. Our goal is to simplify the surgical practice, to improve the surgical experience for the patients and to look towards a new possible gold standard in topical anesthesia for cataract surgery.

5. Conclusions

Our experience demonstrates that localized anesthesia can be considered as a valid alternative to the standard multiple preoperative administration of anesthetic eye drops, as it ensures optimum analgesia, permits safe surgery and does not have any toxic effects on the corneal epithelium. This technique might be used for average but selected cataract patients. Nonetheless we need more studies in this regard and a larger number of cases. Our goal is to simplify the surgical practice, to improve the surgical experience for the patients and to look towards a new possible gold standard in topical anesthesia for cataract surgery.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approval was obtained from the Ethics Committee of University Hospital of Messina (ID 10/19 31/01/2019).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data are available under request, please contact the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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