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Original Article

Sevoflurane versus propofol sedation during periocular anesthetic injections in oculoplastic procedures: An open-label randomized comparison

Hatem A. Tawfik [a,*], Mohsen Mostafa [b]

Abstract

Purpose: The purpose of the current investigation was to make an objective controlled comparison of pain tolerance, patient satisfaction and potential complications during the injection of local anesthesia in oculoplastic procedures under short-term sedation using inhalational versus parenteral sedatives.
Methods: This was an open-label, randomized clinical trial where patients were randomized to 3 groups. Group I: Sedation with intravenous propofol. Group II: Sedation with inhaled sevoflurane. Group 3: Control group receiving no sedation.
Results: A total of 396 patients were randomly assigned, and 375 were included in the final analysis. Study groups were similar in age, gender, and distribution of operative procedures performed. There was no statistically significant difference in the adjusted primary composite outcome measure between propofol and sevoflurane (pain scores and patient satisfaction). Significantly more patients in group I required restraining during periocular injections than group II or III ($p < 0.001$). Significantly more patients sneezed in group I than group II ($p < 0.001$) and none in the control group. Three patients in group II suffered severe excitation–disinhibition during emergence from sedation which was rapidly reversible, and 3 more suffered a severe bout of postoperative nausea and vomiting (PONV).
Conclusion: Sevoflurane and propofol during periocular anesthetic injections produce an equally favorable experience. Sevoflurane is introduced painlessly, and offers better patient control with less induction of the sneezing reflex which may provide a higher safety profile, however short-term aggression/disinhibition and PONV may be an issue in some patients.

Keywords: Propofol sedation, Sevoflurane, Periocular anesthesia, Peribulbar anesthesia, Ophthalmic anesthesia

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Introduction

To date the ideal preoperative sedative drug is still elusive. An ideal sedative should be introduced painlessly, should have a rapid onset of action, minimal side effects, and speedy recovery and should not lead to intraoperative behavioral disturbances.[1] The most commonly used sedatives in oculoplastic procedures nowadays are propofol, midazolam, and alfentanil alone or in combination.[2–8]

We hypothesized that volatile anesthetics might fulfill the criteria of the 'ideal sedative' in an oculoplastic setting, and to test our hypothesis we designed a 3-arm randomized study to compare sevoflurane versus propofol with no sedation as the control group. To the best of our knowledge,

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[a] Department of Ophthalmology, Ain-Shams University, Cairo, Egypt
[b] Department of Ophthalmic Anesthesia, Egyptair Hospital, Cairo, Egypt

* Corresponding author at: 5 Ibn Elnafis St., Off Makram Ebeid St., Nasr City, Cairo, Egypt. Tel.: +20 101022513; fax: +20 22749374.
e-mail address: hatem35@gmail.com (HA Tawfik).

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studies evaluating the use of inhalational anesthetics during periocular injections for ophthalmic or oculoplastic procedures have not been previously conducted.

Materials and methods

Participants

All consenting adult patients undergoing elective oculoplastic procedures during the period between September 2010 and May 2012 in 3 Ophthalmology centers were enrolled. After institutional review board certification, all patients were given a written informed consent. Exclusion criteria included patients under 18 years or older than 75, patients refusing to sign the consent, pregnancy, dementia, known psychiatric disorders, hepatic or pancreatic insufficiency, patients with a know history of habitual drug or alcohol abuse, patients who underwent any surgical procedure under local anesthesia in the past 3 years, patients with a known allergy, or sensitivity to volatile anesthetics or to propofol, and patients undergoing any bilateral procedures.

Study design

This was an open-label, multi-center, three-arm parallel group, randomized controlled study comparing 2 different methods of preoperative sedation during the injection of local anesthetics in oculoplastic procedures with a no-treatment (no sedation) concurrent control group as the third arm of the study. Randomization was carried out prior to starting the study with an online computer generated list.

Anesthesia technique

No preoperative medications or antiemetics were given to any patient. Inside the operating room (OR), patients were monitored with an electrocardiograph, non invasive arterial blood pressure and pulse oximetry. In groups I and III, an intravenous (IV) access line was placed in all patients followed in group I by an injection of an IV bolus of 0.5 mg/kg propofol premixed with lidocaine (2 mL, 2% lidocaine is mixed with each 20 mL syringe of propofol).

In group II the patient was asked to firmly hold the face mask herself under close observation from the attending anesthesiologist, breath heavily through the mouth and count till 10. The face mask was connected to a semi-closed anesthetic unit, with sevoflurane 8% mixed with oxygen at a fresh gas flow rate of 6 L/min. Inadequate sedation was managed by maintaining mask application until the desired effect is reached. In group II an IV access line was placed after abolishment of the lash reflex immediately before injection of the local anesthetic.

In arms I and II local anesthetic injections were given immediately after confirmation of abolishment of the eyelash reflex.

Data collection

An independent observer not involved in the study collected data during the induction process and filled the questionnaire with the patients after the surgery in the outpatient recovery room. Inside the OR, vital data were monitored and recorded by the anesthesiologist in charge, the level of sedation was noted by using a simplified sedation score devised by Epstein et al. [9] Additional data included the degree of co-operation of the patient under sedation, presence or absence of sneezing, and his/her behavior during recovery.

In postoperative holding area, patients were asked to rate their pain between 1 and 10 with 0 being the least pain and 10 being severe intolerable pain. To assess the level of recall, patients were asked if they remembered any details while they were sedated, and whether they were satisfied with experience overall or not?

Statistical analysis

Statistical analysis was done with the SPSS software version 21 for Windows (IBM Corporation, New York, United States). Pairwise comparisons were carried out using the Student *t*-test for equality of means (equal variance not assumed) for continuous variables, and Fisher's exact test for categorical variables (age, type of procedure, percentage of sneezers, patient satisfaction, etc.). We integrated average pain scores and overall patient satisfaction as a composite outcome measure. We also set several secondary outcome measures for evaluation including sedation score, recovery behavioral scale, the level of cooperation during anesthetic injections, the rate of induction of the sneezing reflex, and finally patients' recollection of the events. *p* values were calculated as 2-tailed values. A *p* value less than 0.05 was considered statistically significant.

Results

A total of 396 patients were randomly assigned and 375 were included in the final analysis. There were 124 patients in group I, 128 in group II, and 123 in group III. Table 1 summarizes the baseline data. Age, gender, the type of the procedure, and Spo_2 were homogenously distributed and were not statistically different among the 3 groups.

No difference was noted between propofol and sevoflurane in pain scores (p 0.192), sedation scores (p 0.282), or recovery behavior scale (p 0.347). Although sevoflurane patients achieved a lower average recovery behavior scale, 3 patients from this group suffered a brief but severe bout of emergence delirium (ED) during recovery from sedation which was not expected and therefore not accounted for statistically. Two of them had severe hyperexcitability (laughter episode) while the third suffered hysterical crying. All 3 patients had no later recollection of these events.

When we evaluated the adjusted primary outcome measure, both sedation groups fared well (p 0.222) but each fared better than the control group ($p < 0.001$). Significantly more propofol patients were restrained during sedation than sevoflurane and even the control group ($p < 0.001$). There were significantly more sneezers in group I than in group II ($p < 0.001$), but the control group had no sneezers and performed better than the 2 study groups ($p < 0.001$).

In the outpatient recovery room, both treatment modalities impaired memory, but more patients in group I claimed remembering OR events, however this did not reach statistical significance (p 0.0986). Awareness and recall with propofol as well as sevoflurane sedation, and even with the