European Journal of Ophthalmology / Vol. 18 no. 3, 2008 / pp. 361-367

Patient comfort and surgeon satisfaction during cataract surgery using topical anesthesia with or without dexmedetomidine sedation

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PURPOSE. *To determine the safety and efficacy of perioperative dexmedetomidine (Dex) sedation on patient comfort and surgeon satisfaction during cataract surgery under topical anesthesia.*
METHODS. *Forty-four patients having routine clear corneal phacoemulsification surgery under topical anesthesia were included in the study. Patients were randomly divided into two groups: Dex group (n=22) and control group (n=22). Patients in the Dex group were to receive intravenous Dex using an infusion pump and those in the control group were to receive 0.9% saline infusion. Primary outcome measures were patient comfort, surgeon satisfaction, and patient pain perception.*
RESULTS. *There was no significant difference between the groups in terms of baseline characteristics including age, sex, eye side, pupil diameter, and vital signs (p>0.05 for all). Patient comfort and surgeon satisfaction in Dex group was better than in control group (p=0.042 and p=0.003, respectively). The mean pain perception score was lesser in the Dex group (1.23±1.72) than control group (3.64±1.43), (p<0.001). The mean surgical time and intraoperative complications were similar in both groups (p>0.05). There was no significant effect of the Dex sedation on vital signs perioperatively (p>0.05 for all).*
CONCLUSIONS. *Dex sedation improved patient and surgeon satisfaction and decreased patients' pain perception while undergoing cataract surgery under topical anesthesia. It appears to be a safe and suitable choice of sedation for cataract surgery. (Eur J Ophthalmol 2008; 18: 361-7)*

KEY WORDS. *Cataract surgery, Dexmedetomidine sedation, Patient comfort, Surgeon satisfaction*

Accepted: November 27, 2007

INTRODUCTION

For many years, retrobulbar and peribulbar anesthesia were the standard for cataract surgery; however, many serious adverse effects have been reported (1, 2). With the introduction of modern phacoemulsification cataract surgery, topical anesthesia without retrobulbar or periocular injections has become a well-established, minimally invasive technique (3). The addition of intracameral lidocaine to topical anesthesia has been shown to reduce intraocular sensation during phacoemulsification safely and effectively (4), thus addressing an important perceived disadvantage of the topical anesthetic option. However, ideal anesthesia should allow patients to relax in the hands of a skilled surgeon, give the surgeon the opportunity to concentrate exclusively on the primary goals of cataract surgery, and eliminate surgical discomfort from awareness, pressure, and pain. Nielsen and Allerod (5) found that topical anesthesia without sedation has an incomplete intraocular anesthetic effect. The use of complementary intravenous (IV) sedation is thought to increase patients' comfort and satisfaction during surgery (6).

Presented as a poster at the XXV ESCRS Congress; Stockholm; September 8-12, 2007

1120-6721/361-07$25.00/0

Several techniques of IV sedation have been advocated, with varying success (6, 7). Nowadays, several drugs have been used for sedation during cataract surgery, including propofol, benzodiazepines, and opioids (8-10). However, propofol may cause oversedation and disorientation (8), benzodiazepines may result in confusion, particularly when administered to elderly patients (11), and opioids are associated with increased risk of respiratory depression and oxygen desaturation (10). All of these untoward effects may hamper patients' cooperation during surgery (7), and would make these agents less than ideal for the intraoperative management of sedation. In contrast, dexmedetomidine (Dex) is a highly selective α2-adrenoceptor agonist with both sedative and analgesic properties and is devoid of respiratory depressant effect (12). Dex has been used mainly in the intensive care unit as a sedative agent with some analgesic properties; however, its efficacy outside the critical care environment has also been documented without adverse effects (13, 14), and patients typically remain cooperative while sedated (14, 15).

The aim of this study was to ascertain whether IV sedation using Dex minimizes pain and increases patient and surgeon satisfaction in routine phacoemulsification cataract extraction with foldable intraocular lens (IOL) implantation using topical anesthesia.

METHODS

A prospective randomized double-blind trial was performed after local ethics committee approval. Forty-four patients having routine elective clear corneal phacoemulsification surgery under topical anesthesia were included in the study. All patients received written details of the study and signed an informed consent form before participating. Patients were excluded according to the following criteria: mature cataract, previous ocular surgery, inflammation or injury, pharmacologic mydriasis less than 5 mm, shallow anterior chamber, nystagmus, muscle spasm around the eye, orthopnea, breakdown in communication or cooperation such as deafness, senile dementia, and claustrophobia, sensitivity to study drugs, uncontrolled hypertension, and history of hepatic disease.

All patients received diclofenac sodium 0.1%, two drops every 20 minutes two times; phenylephrine hydrochloride 2.5%, one drop every 5 minutes two times; and cyclopentolate 1%, one drop every 5 minutes three times beginning 45 minutes before the procedure for pharmacologic mydriasis. On arrival to the anesthesia room, patients were randomized to one of two groups. All patients had an IV cannula inserted by an experienced anesthetist.

Anesthesia and sedation techniques

Patients arrived in the operating room un-premedicated. Baseline vital signs including heart rate, systolic and diastolic blood pressure, and O_2 saturation were taken. A 20 gauge cannula was inserted into one of the two nasal prongs of an oxygen nasal cannula. Other standard monitors including electrocardiogram, noninvasive arterial pressure, and pulse oximeter were also applied, and oxygen was administered at 2 liter/min in all patients. Patients in the sedation group were to receive IV dexmedetomidine 1 µg/kg over 10 min using an infusion pump and this was followed by a continuous infusion of Dex 0.1–0.7 µg/kg titrated to Ramsey sedation score of 3 (16). The control group received 0.9% saline infusion. Both surgeon and patient were masked as to whether IV sedation was administered perioperatively. The nurse assessing the patients' pain score, patient satisfaction, surgeon satisfaction, and other outcome measures was also masked to the randomization schedule. This schedule was kept by the anesthetist until the end of the study. The anesthetist was not involved in outcomes evaluation or data analysis.

Topical anesthesia comprised proparacaine 0.5% drops administered into the conjunctival sac three or four times in the 10 minutes preceding surgery. A protocol was established for supplemental anesthesia for breakthrough pain during the surgery. If a patient reported pain, two additional drops of topical anesthetic were placed in the eye. If pain persisted, the anterior chamber was irrigated with lidocaine 1% solution.

Surgical technique

All surgical procedures began 10 to 15 minutes after randomization. After standard aseptic preparation, a wire speculum was inserted and the operating microscope was swung into position and turned on. Phacoemulsification was performed with a Sovereign phacoemulsifier through a superior temporal or nasal, two-plane, 3.2 mm clear corneal incision, two side-port paracentesis; a 5.0–5.5 mm continuous curvilinear capsulorhexis; hydrodissection with balanced salt solution (BSS); and

cataract extraction by the stop and chop technique in all patients. The clear corneal incision was enlarged to a maximum of 3.5 to 4.0 mm. Sodium hyaluronate was injected into the capsular bag in all patients and a single-piece foldable hydrophilic acrylic IOL was implanted. After the ophthalmic viscoelastic substance was removed, the wound was sealed by corneal stromal hydration. All surgical procedures were performed by one experienced ophthalmic surgeon (M.E.).

Primary outcome measures

Patient satisfaction. The patients were asked to rate their satisfaction with the operative experience on a five-point satisfaction scale: 0 = extremely dissatisfied; 1 = dissatisfied; 2 = neither satisfied nor dissatisfied; 3 = satisfied; 4 = extremely satisfied. Patients were also asked whether they would choose the same anesthesia method if they had surgery in the fellow eye.

Surgeon satisfaction. The surgeon was asked to rate satisfaction and patient cooperation during surgery (4 = excellent; 3 = good; 2 = fair; 1 = poor; 0 = extremely poor).

Patient's pain perception. Immediately after the conclusion of surgery, patients were asked to assess pain they experienced during surgery using the Visual Analogue Scale (VAS) (17): 0 = none, 1 = slight discomfort, 2 = slight to light 3 = light, 4 = light to moderate, 5 = moderate, 6 = moderate to severe, 7 = severe, 8 = very severe, 9 = excruciating, 10 = worst pain imaginable.

Secondary outcome measures

Pupil diameter. Because of the inhibitory effects of Dex on pupilloconstrictor nucleus, we measured the effect of this agent on the duration of pupil size during surgery (18). The horizontal pupil diameter was measured using Castroviejo surgical caliper at the beginning of surgery, after nucleus delivery, and after IOL implantation. All measurements were obtained after the viscoelastic material was removed.

Intraoperative complications. Complications such as squeezing of eyelids, inadvertent eye or head movement, posterior capsule rupture, and vitreous loss were reported immediately after the surgery.

Mean surgical time. Immediately after the conclusion of surgery, the total time spent between creating corneal incisions and corneal stromal hydration was documented.

Vital signs. Heart rate, systolic and diastolic blood pressures, and arterial oxygen saturation were taken before the drug infusion, at the beginning of the surgery and every 10 minutes during surgery, and at the end of the surgery.

Statistical analysis

Data analysis was performed by using SPSS statistical software (SPSS Inc., Chicago, IL, USA) version 11.5 for Windows. Data were shown as mean ± standard deviation for continuous variables, median (minimum – maximum) for ordinal ones, and frequency with percent for categorical ones. Means were compared using Student *t* or Mann-Whitney *U* test, where appropriate. Difference among vital signs and pupil diameters were evaluated by repeated measures analysis of variance (ANOVA) or Friedman test. When the p value from the ANOVA and Friedman test statistics are statistically significant, Bonferroni and Friedman multiple comparison tests were used to know which measurements differ from which others. Categorical comparisons were made by using chi-square or Fisher exact test, where appropriate. A p value less than 0.05 was considered statistically significant.

RESULTS

This study comprised 44 eyes of 44 patients, with 22 eyes having topical anesthesia under Dex sedation and 22 having topical anesthesia only for surgery. Table I shows the baseline characteristics of the patients in both groups. There was no difference between the groups in terms of baseline characteristics ($p>0.05$ for all).

The mean pain perception score was less in the Dex group than control group, 1.23±1.72 (range 0 to 5) and 3.64±1.43 (range 0 to 6), respectively. Patients in Dex group reported better satisfaction scores and this was statistically significant ($p=0.042$). The mean surgeon satisfaction score was higher in the Dex group than control group, 3.41±0.80 (range 2 to 4) and 2.36±1.26 (range 0 to 4), respectively. Surgeon satisfaction in Dex group was also better than in control group ($p=0.003$).

Patients' pain perception scores according to the VAS

TABLE I - BASELINE PATIENT CHARACTERISTICS

	Dex group	Control group
Number of patients	22	22
Age, yr	67.41±9.83 (44–80)	69.46±9.99 (52–85)
Sex (male/female)	7/15	8/14
Eye (right/left)	12/10	11/11
Preoperative		
Systolic arterial pressure (mmHg)	144.41±28.07 (109–218)	150.18±17.64 (107–182)
Diastolic arterial pressure (mmHg)	85.45±13.57 (61–118)	91.13±14.70 (60–123)
Heart rate (beats per min)	76.46±11.67 (54–107)	78.55±12.74 (57–100)
Oxygen saturation (%)	97.45±1.65 (92–100)	96.82±2.28 (90–99)
Pupil diameter (mm)	8.31±0.55 (7.40–9.50)	7.91±0.97 (6.00–9.50)

Data presented as mean ± standard deviation (range) or absolute numbers.
Dex = Dexmedetomidine

TABLE II - PATIENTS' PAIN PERCEPTION SCORES ACCORDING TO THE 10-POINT SCALE DURING CATARACT SURGERY IN THE GROUPS

Pain perception score	Dex	Control
None (0)	13 (59.1)	1 (4.5)
Slight discomfort (1)	2 (9.1)	1 (4.5)
Slight to light (2)	–	1 (4.5)
Light (3)	4 (18.2)	6 (27.3)
Light to moderate (4)	2 (9.1)	8 (36.4)
Moderate (5)	1 (4.5)	3 (13.6)
Moderate to severe (6)	–	2 (9.1)
Severe (7)	–	–
Very severe (8)	–	–
Excruciating (9)	–	–
Worst pain imaginable (10)	–	–

Values are n (%) of eyes. The mean pain perception score was less in the Dex group tahn control group, 1.23±1.72 (range 0 to 5) and 3.64±1.43 (range 0 to 6), respectively.
Dex = Dexmedetomidine

during cataract surgery in Dex and control groups are summarized in Table II.

The mean pain perception score was less in the Dex group than control group, 1.23±1.72 (range 0 to 5) and 3.64±1.43 (range 0 to 8), respectively. The difference of pain perception between the groups was statistically significant ($p<0.001$). The question "Would you choose the same anesthesia method if you had surgery in the fellow eye?" was answered "Yes" by all of the Dex group and 18 patients (81.8%) in the control group. This difference was not statistically significant ($p=0.108$).

The mean horizontal pupil diameter at baseline was 8.31±0.55 mm in Dex group and 7.92±0.97 mm in control group, after nucleus removal was 6.20±1.41 mm in Dex group and 5.82±1.18 mm in control group, and after IOL implantation was 5.25±1.21 mm in Dex group and 4.61±1.07 mm in control group. Although the horizontal pupil was higher in Dex group at all the timepoints, there was no statistically significant difference between the groups ($p>0.05$ for all).

The mean surgical time in Dex group was 25.41±6.05 minutes (median 24.5 minutes, range 15 to 35 minutes) and control group was 23.18±3.97 minutes (median 23.5 minutes, range 15 to 32 minutes). There was no significant difference between the groups in terms of mean surgical time ($p=0.158$). Differences in systolic and diastolic pressures and heart rate during surgery are shown in Figures 1 and 2, respectively. There was no difference in oxygen saturation during surgery in Dex or control groups and between the groups ($p>0.05$ for all).

Table III summarizes the intraoperative surgical complications and additional anesthesia requirement within the groups.

Surgical complications and additional anesthesia requirement were relatively higher in the control group, but it was not statistically significant ($p=0.24$). In three patients, uncontrolled head movements occurred in Dex group. All of these patients were over 75 years of age.

DISCUSSION

This randomized, double-blind study demonstrated that sedation with Dex was more comfortable for patients and

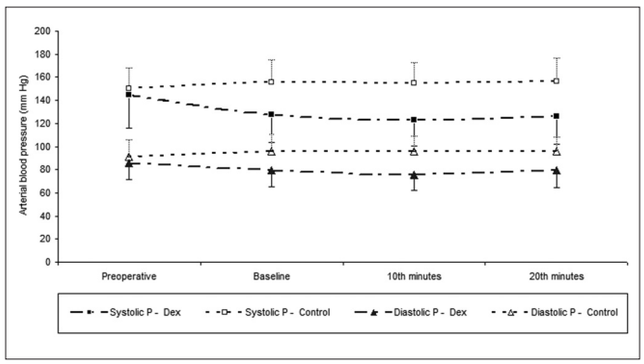

Fig. 1 - *Perioperative systolic and diastolic arterial blood pressure changes in the groups. In control group, there was no difference in systolic and diastolic blood pressures perioperatively (p>0.05 for both). In addition, in Dex group, there was no difference in diastolic blood pressure, perioperatively. However, systolic blood pressure has a tendency to decrease during surgery in this group. But this was not statistically significant. Systolic or diastolic blood pressures in both groups did not differ at all time points (p>0.05 for all). P = Pressure.*

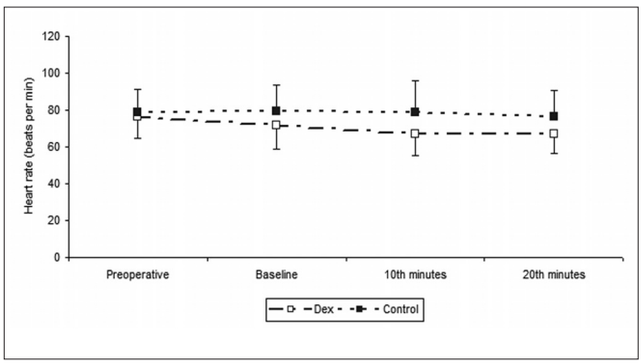

Fig. 2 - *Perioperative heart rate changes in the groups. Initial, baseline, and intraoperative heart rate of the groups were not different (p=0.40). There was a tendency to decreased heart rate in Dex group after initiation of the sedation and this effect lasted at the end of surgery. In control group, heart rate was stable perioperatively.*

the surgeon than without sedation in cataract surgery under topical anesthesia. Dex sedation did not significantly affect the hemodynamic parameters or pupil diameter perioperatively.

A wide variety of local anesthesia options is available for cataract surgery. As cataract removal has become faster, safer, and less traumatic, the need for akinesia and anesthesia has declined significantly. In today's environment, akinesia is not the issue once it was and there is increasing concern to reduce the need for regional anesthesia and the morbidity associated with needle injections. Topical anesthesia effectively eliminates the risk of complications associated with regional blocks. Moreover, phacoemulsification using topical anesthesia has comparable pain levels as with sub-Tenon (19) and peribulbar techniques (20) and offers a safe and effective alternative in the hands of experienced surgeons.

Topical anesthesia without sedation, however, may have some disadvantages in terms of patient and surgeon satisfaction. Kallio et al (21) reported that patients having topical anesthesia needed additional sedation during surgery significantly more often than patients having a retrobulbar or peribulbar block. Still, about 4% of patients having topical anesthesia report being dissatisfied and having some discomfort during surgery in Uusitalo et al's study (22) In the present study, 13.6% (3 of 22) of the patients undergoing cataract surgery under topical anesthesia were dissatisfied while Dex group reported no dissatisfaction related with surgery. In light of our results, we suggest that Dex sedation increases patient satisfaction for routine elective cataract surgery under topical anesthesia. It is previously reported that Dex sedation was equally effective to midazolam in patients undergoing cataract surgery under peribulbar anesthesia (15). In addition, slightly better subjective patient satisfaction was reported compared with the midazolam in this study. These results are in keeping with those reported by Virkkila et al (23), who have demonstrated that a single dose of IM Dex administered 45 min before operation provides sedation comparable with that produced by IM midazolam. Sedative and analgesic properties along with its relatively short elimination half-life of 2 hours make Dex an attractive agent for sedation during monitored

TABLE III - SURGICAL COMPLICATIONS AND ADDITIONAL ANESTHESIA REQUIREMENT

Surgical complication	Dex	Control
Inadvertent eye movement	1 (4.6)	3 (13.6)
Inadvertent head movement	3 (13.6)	–
Posterior capsule rupture	–	–
Squeezing of eyelid	–	2 (9.1)
Suturation	–	1 (4.6)
Additional anesthesia requirement	2 (9.1)	6 (27.3)

Values are n (%) of eyes.
Dex = Dexmedetomidine

anesthesia care for cataract surgery. Dex has several advantages for use as a sedative because it does not cause respiratory depression (12, 24). It is easy to arouse the treated patients and they can be calm and cooperative (25). However, with the need for fiscal responsibility, researchers have begun to question whether IV sedation and monitored anesthesia care during cataract surgery is necessary (26). The prolonged recovery associated with sedation and the costs associated with the presence of an anesthesiologist throughout surgery are disadvantages of IV Dex for clear corneal phacoemulsification surgery.

Surgeon comfort is another important point for cataract surgery under topical anesthesia and it is directly related to patients' cooperation. Communication with the patient is crucial to the success of topical anesthesia. The full range of eye movements under voluntary control may be advantageous to the surgeon during superior cortical cleanup and for better access to IOL implantation by instructing the patient to look up or look down. Most of the common sedatives for cataract surgery unlike Dex provide good sedation but not cooperation. Therefore, voluntary control of the eye movements, which is one of the fundamental aims of the topical anesthesia, may be troublesome. However, Dex provides good patient cooperation along with sedation and analgesia (25).

The dose of Dex we used was chosen for similarities to a previous study (15). In the present study, three patients in Dex group exhibited unwanted head movement because of excessive sedation. We think that this event was the most important disadvantage of the drug. All of these patients were over 75 years of age. Lowering the dose of the drug or head fixation may be helpful for older patients (especially >75 years) before Dex-assisted cataract surgery.

Although the pain induced by phacoemulsification with topical anesthesia is more difficult to characterize qualitatively (27), because of the patient's past cognitive experiences, cultural background and degree of anxiety affect this process (28). Dex sedation decreased the patient's pain perception versus that of control subjects in our study. This could be explained in part by the additional analgesic activity of Dex that could have contributed to improved patient pain perception.

In conclusion, Dex in the studied dose provides satisfactory sedation during cataract surgery under topical anesthesia. Its characteristic conscious sedation enables good cooperation and potentially better operating conditions than that of topical anesthesia alone. However, head fixation seems to be necessary to control unwanted head movements, especially in older patients during cataract surgery with IV Dex sedation.

ACKNOWLEDGEMENTS

The authors thank Salih Ergocen, Ankara, Turkey, for statistical assistance.

None of the authors has any competing financial interests in this study.

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