Patient-controlled sedation vs. anaesthetic nurse-controlled sedation for cataract surgery in elderly patients

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INTRODUCTION

Cataract surgery is one of the most common elective procedures and is mostly performed in elderly patients. Although reports have suggested that the local anaesthesia alone, such as sub-Tenon’s anaesthesia, could provide sufficient analgesia during cataract surgery (1–3), use of sedation in addition to local anaesthesia might help to allay anxiety. It increases not only the patients’ satisfaction but also patients’ safety by minimising undesirable cardiovascular reaction to stress (4). However, it has also been reported that PCS in elderly patients for cataract surgery may be unacceptable because of head movement that took place in some patients (5). We could also find some elderly patients unwilling to use the PCS device who preferred to be managed by a medical person. Morley et al. (9) also mentioned that older patients have a tendency to prefer anaesthetist-administered sedation to PCS. About postoperative patient-controlled analgesia (PCA), there are reports showing that the nurse-controlled analgesia (PCA) can be as effective as PCA and can be used as an alternative to PCA in several situations (10,11) but we could find no report about intra-operative nurse-controlled sedation using PCA device.

In the present study, we compared the PCS with anaesthetic nurse-controlled sedation (ACS) using the same device and drug in elderly patients undergoing cataract surgery under sub-Tenon’s infiltration.

SUMMARY

Background: Patient-controlled sedation (PCS) with propofol has been used successfully in various conditions, but controversies exist about its use in sedation of elderly patients for cataract surgery. This study evaluates the efficacy of anaesthetic nurse-controlled sedation (ACS) compared with PCS using the same device and the drug. Methods: All of the 153 elderly patients (aged 51–88 years) undergoing cataract surgery with a sub-Tenon’s infiltration were assigned to receive ACS (n = 51) or PCS (n = 51) with propofol or no intra-operative sedation (control, n = 51). Propofol was administered with a bolus dose of 10 mg and a lockout interval of 1 min. Cognitive function, sedation, pain, anxiety, side effects and satisfaction of patients were evaluated. Results: The mean ± SD doses of propofol administered were 34.9 ± 8.8 mg and 30.1 ± 30.4 mg in the groups ACS and PCS, respectively. The anxiety score was lower in both ACS and PCS groups compared with control group but was not different between the two groups. Patient’s satisfaction was highest in ACS group, ACS group was the next, compared with non-sedated group. Other parameters were not different among the three groups. Conclusions: Both ACS and PCS using propofol provided reduced anxiety compared with control, but patient’s satisfaction was higher in the PCS group compared with ACS group.

What’s known
Propofol patient-controlled sedation (PCS) had been attempted in elderly patients undergoing cataract surgery under local anaesthesia but accompanied with controversies about its efficacy.

What’s new
While using propofol with a bolus demand dose of 10 mg and a lockout interval of 1 min, both ACS and PCS reduced anxiety of patients compared with non-sedated patients without significant complications in elderly patients undergoing cataract surgery under sub-Tenon’s anaesthesia. However, patient’s satisfaction was higher in patients who had PCS compared with ACS.
Methods

One hundred and fifty-three American Society of Anesthesiologists (ASA) physical status I–III patients, between 51 and 88 years of age scheduled for cataract surgery from August 2006 to December 2006 in the University hospital were enrolled in this study. The study protocol was approved by our institutional review board, and informed consent was obtained from all patients prior to enrollment. Exclusion criteria included clinical evidence of heart failure, severe pulmonary disease, sedative medication during the month prior to operation, difficulty with language or communication and poor vision in the non-operated eye.

Using computer-generated random numbers (Random Allocation Software, version 1.0, http://www.msaghaei.com), patients were assigned to one or other of three groups: no sedation (control, \( n = 51 \)); ACS with propofol (\( n = 51 \)) or PCS with propofol (\( n = 51 \)). The sequence was concealed until the anaesthesia technique was assigned. Generation of random numbers and the enrollment of participants into the study were carried out by M. J. Yun and the assignment of participants to their groups was carried out by A. Y. Oh.

Premedication was not used. In both sedation groups, the sedation pump (Auto Med\textsuperscript{®} 3200, Acomedical Co., Seoul, Korea) was prepared to contain 18 ml (10 mg/ml) of propofol and to deliver a bolus dose of 10 mg on demand with lockout interval of 1 min. Lidocaine 30 mg was injected intravenously for prevention of pain on injection of propofol before start of the sedation. In the group ACS, anaesthetic nurse activated the demand dose of propofol with her discretion. In the group PCS, patients were encouraged to administer first bolus dose 1–2 min before the sub-Tenon’s infiltration and thereafter whenever they needed. At the end of surgery, total dose of propofol having been administered, the ratio of number of successful attempts (delivery) to the number of total attempts (demand) of self-administration were recorded.

The monitoring consisted of ECG, automatic non-invasive blood pressure and continuous pulse oximetry. All patients received supplemental oxygen via nasal prong (4 l/min).

The sub-Tenon’s infiltration was performed by the surgeon with 1 ml of 2% lidocaine and the quality of anaesthesia was assessed 1–2 min after the infiltration. If the anaesthesia appeared inadequate before the commencement of surgery, the anaesthesia was repeated. At the end of the operation, the surgeon, who was blind to patient group, recorded the satisfaction score (0–10).

Patient assessments were carried out by another anaesthetic nurse who was blinded to the patient group. Cognitive function was evaluated preoperatively and 1 h following arrival in the postanaesthetic care unit (PACU) using a Mini Mental Status Examination (maximum 30) (12). The level of sedation was assessed just before sub-Tenon’s infiltration, immediately at the end of surgery and 1 h following arrival in the PACU using an observer’s assessment of alertness/sedation (OAA/S) scale (13) (modified by reversing the scale, i.e. 1 = awake/alert to 5 = asleep/unarousable) (14). Specific complications such as hypertension, hypotension, tachycardia (change of 30% from baseline values), hyperventilation (ventilatory frequency < 8/min), pulse oximetric desaturation (oxygen saturation ≤ 90%), excessive sedation (OAA/S score of 4 or 5), restlessness, nausea, vomiting and headache were recorded during the operation. Pain measurement on visual analogue scale (VAS) (0–10) was obtained just after sub-Tenon’s infiltration, immediately at the end of surgery, 1-h following arrival in the PACU and 24 h after discharge. The anxiety was assessed using five scales such as 1 = none, 2 = slight, 3 = moderate, 4 = severe and 5 = extreme 1 h following arrival in the PACU.

In a telephone interview performed by an anaesthetic nurse at the 24 h after surgery, patients were asked about pain, nausea, vomiting, headache and other adverse events after their discharge from the day-surgery unit. Patients were also asked to rate their satisfaction with the sedative and analgesic management during the overall surgical experience using a 10-point verbal rating scale.

Sample size was estimated based on a pilot study data of 15 patients in each of the three groups about the satisfaction. The difference of mean satisfaction score for the ACS and the PCS groups was 0.67 and common standard deviation (SD) was 1.03 in pilot data. With a p-value of 0.05 and a power of 0.8, a two-tailed test required at least 51 patients in each group. Statistical analyses were preformed using SPSS Ver. 12 software (Statistical Package for Social Sciences for Windows, SPSS Inc., Chicago, IL, USA). The one-way ANOVA was applied to normally distributed data. The pain VAS and satisfaction score were analysed using a Kruskal–Wallis test. Changes in blood pressures and heart rates among the groups were compared using repeated measures of one-way ANOVA. Parametric summary statistics are presented as mean ± SD. Non-parametric summary statistics are presented as median (interquartile range). Subgroup analysis within the same group was performed with the Pearson chi-squared test or Fisher’s exact test.
Results

One hundred and fifty-three patients who were randomly assigned to one of the other three groups completed the study protocol and the data were analysed for the outcome. No significant differences in patient characteristics or duration of surgery were observed among the three groups (Table 1).

The mean dose of propofol administered was similar between the group ACS (34.9 ± 8.8 mg) and the group PCS (30.1 ± 30.4 mg) (Table 2, p > 0.05). Ten patients of 51 (19.6%) did not use the bolus at all and the mean propofol dose of patients who used PCS was 37.5 ± 29.5 mg in the PCS group. The anxiety score of those patients (1.8 ± 0.42) was not different from that of the patients who used PCS (1.68 ± 0.56) in the PCS group (p > 0.05). All of the patients in the ACS group were administered bolus dose of propofol. The median (range) frequency of delivery was five (2–8) and four (0–18) in groups ACS and PCS, respectively. The delivery/demand ratio was 74% and 54% in the ACS and the PCS groups, respectively.

Cognitive function and pain VAS at each time point were not significantly different among the

| Table 1 Demographic data |
|--------------------------|
|                          | Control (n = 51) | Group ACS (n = 51) | Group PCS (n = 51) |
| Age (years)              | 69.4 ± 8.6 (53–86) | 66.9 ± 7.4 (57–86) | 69.0 ± 9.6 (51–88) |
| Gender (M/F)             | 23/28 | 21/30 | 18/33 |
| ASA (I/II/III)           | 20/29/2 | 24/24/3 | 24/25/2 |
| Weight (kg)              | 61.0 ± 0.5 | 63.3 ± 10.1 | 58.9 ± 10.8 |
| Height (cm)              | 159.6 ± 9.4 | 159.2 ± 10.0 | 159.3 ± 8.7 |
| Previous cataract surgery| 19/51 (37.2%) | 20/51 (39.2%) | 18/51 (35.3%) |
| Duration of operation (minutes) | 34.2 ± 9.5 | 32.4 ± 9.3 | 36.4 ± 12.5 |

Values are means ± SD (range), number of patient (%). Control: cataract surgery without sedation; group ACS: anaesthetic nurse-controlled sedation using a propofol during cataract surgery; group PCS: patient-controlled sedation using a propofol during cataract surgery.

| Table 2 Outcome measures |
|--------------------------|
|                          | Control (n = 51) | Group ACS (n = 51) | Group PCS (n = 51) |
| Propofol dose (mg)       |                  |                   |                  |
| Mean ± SD                | 26.5 ± 1.0       | 26.7 ± 0.8        | 26.4 ± 0.9       |
| Median (range)           | 26.8 ± 1.2       | 27.0 ± 0.8        | 27.2 ± 1.1       |
| MMSE scores (maximum 30) |                  |                   |                  |
| Preoperative             | 0 (0–2)          | 0 (0–2)           | 0 (0–2)          |
| 1 h following arrival in the PACU | 26.8 ± 1.2 | 27.0 ± 0.8 | 27.2 ± 1.1 |
| Pain VAS [0–10, median (range)] |       |                   |                  |
| Just before sub-Tenon’s infiltration | 0 (0–2) | 0 (0–2) | 0 (0–2) |
| At the end of the operation | 1 (0–6) | 1 (0–6) | 1 (0–5) |
| 1 h following arrival in the PACU | 1 (0–3) | 0 (0–5) | 1 (0–5) |
| 24 h after discharge     | 0 (0–3)          | 0 (0–2)           | 0 (0–3)          |
| Anxiety score (1–5, median (range)) | 2 (1–4) | 2 (1–4) | 2 (1–4) |
| No. of patient in 1/2/3/4/5 | 5/24/17/50 | 11/28/9/3/0* | 14/30/6/1/0* |
| Satisfaction of patient  |                  |                   |                  |
| Comfort (0–10)           | 8.4 ± 1.2        | 9.0 ± 0.8*        | 9.4 ± 0.7*       |
| Repeat (1–4)             | 3.5 ± 0.5        | 3.5 ± 0.4         | 3.6 ± 0.4        |
| Satisfaction of surgeon (0–10) | 8.9 ± 0.6 | 9.2 ± 0.7 | 9.1 ± 0.7 |

Values are means ± SD, median (range). Control: cataract surgery without sedation; group ACS: anaesthetic nurse-controlled sedation using a propofol during cataract surgery; group PCS: patient-controlled sedation using a propofol during cataract surgery. Pain VAS; visual analogue scale of pain during operation, PACU, postanaesthetic care unit. *Significantly different from the control group, p < 0.05. †Significantly different from the ACS group, p < 0.05.
three groups (Table 2). The anxiety score measured at 1 h following arrival in the PACU was significantly lower in both ACS and PCS groups compared with control (Table 2, p < 0.01).

The qualities of local anaesthesia were good in all three groups. There were no incidences of patients whose local anaesthetic action wore off during surgery and who had to be supplemented with local anaesthetics in any of the three groups. No patients showed inappropriate movements or restlessness during surgery. Overall, satisfaction of the surgeon in all the three groups were high and not different among the individual groups (Table 2, p > 0.05). Patients in the ACS and PCS group expressed greater satisfaction than patients in control group (p < 0.01) and the satisfaction score of the group PCS was higher than that of the group ACS (Table 2, p < 0.05). Willingness to undergo a repeated procedure using the same sedation technique did not differ among the groups (Table 2, p < 0.05). Satisfaction score was similar in the patients who used PCS device (9.39 ± 0.7) and in those who received but did not use PCS device (9.60 ± 0.51) in the PCS group (p < 0.05).

The degree of sedation checked at the end of operation was higher in the ACS and the PCS groups than the control group but the median OAA/S score was one in all groups (p < 0.01). One patient in the ACS group showed OAA/S three at the end of operation and needed mild physical stimulation to arouse.

The incidence of side effects was low and comparable among the three groups (Table 3). None of the patients experienced ocular complications. One patient in the group ACS complained of moderate degree of dizziness and nausea and was readmitted 6 h after discharge. After getting intravenous hydration and proper symptomatic treatment, she was discharged a day after readmission without side effects.

### Discussion

We have demonstrated that while using propofol with a bolus demand dose of 10 mg and a lockout interval of 1 min, both ACS and PCS reduced the anxiety of patients compared with non-sedated patients without significant complications in elderly patients undergoing cataract surgery under sub-Tenon’s anaesthesia. However, patients’ satisfaction was higher in patients who had PCS compared with ACS.

For postoperative pain management, nurse-controlled analgesia was compared with PCA using a same device and nurse-controlled analgesia was reported to be a good alternative to PCA in special population such as patients in intensive care unit after cardiac surgery (15) or children < 6 years of age (16).

During intra-operative monitored anaesthesia care, PCS is known to be comparable with conventional anaesthesiologist-controlled sedation with continuous infusion of sedative drugs, but with lesser drug administration, a lighter sedation level and a shorter time to meet discharge criteria (17,18). The lighter sedation level is favourable in cataract surgery where full patient cooperation is mandatory and involuntary patient movement could be detrimental. Hence, we could say that the PCS would be more advantageous than anaesthesiologist-controlled conventional continuous intravenous infusion of sedative drugs in monitored anaesthesia care for cataract surgery. However, what if the sedation by a medical person is

| Table 3 Side effects                                      | Control (n = 51) | Group ACS (n = 51) | Group PCS (n = 51) |
|----------------------------------------------------------|-----------------|-------------------|-------------------|
| Hypertension                                             | 6 (11.8%)       | 4 (7.8%)          | 4 (7.8%)          |
| Hypotension                                              | 0 (0%)          | 0 (0%)            | 0 (0%)            |
| Respiratory rate/min < 8                                 | 0 (0%)          | 0 (0%)            | 0 (0%)            |
| Excess sedation (OAA/S 4 or 5)                           | 0               | 0                 | 0                 |
| Headache (PACU/24 h)                                     | 0/3 (5.9%)      | 2/4 (3.9%/7.8%)   | 0/3 (5.9%)        |
| Nausea (PACU/24 h)                                       | 1/4 (2.0%/7.8%) | 1/5 (%/9.8%)      | 1/4 (2.0%/7.8%)   |
| Vomit (PACU/24 h)                                        | 0/2 (0%/3.9%)   | 0/2 (0%/3.9%)     | 0/2 (0%/3.9%)     |
| Pain (PACU/24 h)                                         | 8/11 (15.7%/21.6%) | 10/12 (19.6%/23.5%) | 8/11 (15.7%/21.6%) |
| Dizziness (PACU/24 h)                                    | 0/4 (0%/7.8%)   | 2/4 (4.0%/7.8%)   | 1/4 (2.0%/7.8%)   |

Values are number of patients (%). Control: cataract surgery without sedation; group ACS: anaesthetic nurse-controlled sedation using a propofol during cataract surgery; group PCS: patient-controlled sedation using a propofol during cataract surgery. PACU, postanaesthetic care unit; 24 h, 24 h after discharge.
performed by using the same device and drug with PCS? In our results, the dosage of propofol used was not different between the two groups and all the efficacy and safety profiles of both ACS and PCS methods were the same and the only difference was in patient’s satisfaction who preferred the PCS.

Significant head movements interfering with surgery were reported during monitored anesthesia care with propofol in patients undergoing cataract surgery. Janzen et al. (8) reported that two of their 20 patients using propofol PCS showed significant head movement, probably attributable to disorientation during emergence from sedation. Oei-Lim et al. (19) also reported that the sedation was converted to general anesthesia in four of 100 patients because of their excessive head movements while using bispectral index (BIS)-guided target-controlled infusion of propofol. However, no patient in our study showed significant head movement. The major difference might lie in the dosage of propofol used. We used a bolus demand dose of 10 mg of propofol compared with 0.25 or 0.5 mg/kg in a study of Janzen et al. (8) and the total dose used was about 1 mg/kg/h compared with 2.5–2.9 mg/kg/h in a study of Oei-Lim et al. (19). Pac-Soo et al. (20) also studied the PCS for cataract surgery with a smaller bolus dose (3.3 mg) of propofol but when similar amounts used (about 1 mg/kg/h) as ours, satisfactory decrease of anxiety without significant complications was reported.

In the group PCS, the anxiety score of those who did not use PCS was not different from that of the patients who used PCS. The need for sedation is variable and unpredictable, so the routine infusion of sedative drug is not recommended in cataract surgery. Instead, the use of PCS or ACS, only with a small dose of propofol, can reduce patient anxiety effectively and safely.

In conclusion, both ACS and PCS can be used effectively and safely to reduce anxiety of elderly patients undergoing cataract surgery under sub-Tenon’s infiltration. Patients preferred to control the level of sedation themselves rather than be controlled by anaesthetic nurse, although the ACS can be a good alternative in special situations when needed.

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